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IN VITRO DIAGNOSTIC TEST PROCUREMENT DURING THE COVID-19 PANDEMIC

Lessons Learnt and Recommendations

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CONTENTS

LIST OF TABLES AND FIGURES

EXECUTIVE SUMMARY

1. The COVID-19 pandemic ("the pandemic") precipitated a globally unprecedented public health crisis. To address it, governments used lockdowns and other social restrictions. Public procurement also played a fundamental role. There was an immediate demand within the public sector for medical supplies and services. This included Personal Protective Equipment ("PPE"), ventilators, and test kits to determine who had contracted the virus.

2. In the UK, the Government quickly mobilised a Test and Trace strategy. This, in turn, necessitated the procurement of vast quantities of test kits and related raw materials and technology as well as the establishment of testing capacity within laboratories and other settings to facilitate mass testing. In doing so, the Department of Health and Social Care ("DHSC"), also acting through its executive agencies, had to act as purchaser, manufacturer, regulator and tester, buying technologies, products and services, validating these for use, and placing them on the market.

3. This White Paper examines the procurement of *in vitro* diagnostics ("IVDs"), specifically, commonly used test kits during the pandemic. It is intended to fill an important gap in academic research, public policy debate and oversight. The research has been commissioned by the British In Vitro Diagnostic Association ("BIVDA") in academic partnership with the University of Nottingham Public Procurement Research Group ("PPRG") under a Sponsored Research Agreement. The aims are to better understand:

   (1) How test kits were procured, including their validation and regulatory approval for placement on the market;
   (2) What lessons can be learnt from this experience; and
   (3) What recommendations can be made in light of those lessons to improve future emergency preparedness and diagnostics procurement generally, supported by a sustainable domestic diagnostics industry.

4. The White Paper comprises the following Parts. Part I provides an introduction to the White Paper's aims and objectives and outlines key events. Part II examines the national technical validation process for evaluating tests. The analysis has found that a centralised validation process provided an important means of ensuring that products met basic performance requirements for use. However, it also identified a number of issues, lessons learnt and recommendations. These include a need to:

   ✓ Clarify roles and responsibilities – there has been a degree of uncertainty as to who is responsible for validation as distinct from procurement decisions and what those responsibilities involve.

   ✓ Develop clear Target Product Profiles as early as possible to ensure effective "demand signalling" in line with Government strategy – it was not clear from the outset what the Government required and how industry could meet requirements.

   ✓ Improve the clarity and quality of validation process guidance – the guidance is largely *ad hoc* published on gov.uk websites, requiring information but not always clearly identifying how it will be assessed.

   ✓ Improve communication and transparency by publishing reviews and interim reports of the conduct of the validation process – a high proportion of test kits failed the validation stage such that it is necessary to know how submissions can be improved and how issues arising in the process are being addressed.

- ✓ Demonstrate better awareness of the cumulative impact of Government decisions on the market – key validation decisions may have affected procurement decisions which, in turn, affected regulatory approvals, all of which impact market access for suppliers.

5. Part III examines contracting, specifically processes for non-competitive or "direct" and competitive contract awards and the corresponding processes for identifying and selecting suppliers. This includes some aspects of contract management. The analysis has found that there was a high incidence of direct awards made without any formal competition. Legally, there are at least arguable justifications for many of these awards on grounds of extreme urgency. Further, competitive procurement mechanisms such as framework agreements and dynamic purchasing systems were introduced and which have been used to meet requirements. However, again, the White Paper identifies a number of issues, lessons learnt and recommendations. These include a need to:

   - ✓ Consider ways to more effectively centralise and/or coordinate the procurement model to the extent possible – there were a number of executive agencies operating under the auspices of DHSC with potential to complicate roles and responsibilities, an issue magnified when procurement within the NHS is factored in.

   - ✓ Improve identification and understanding of the supply base – use of private consultancies, internet searches, and known lists of existing suppliers on framework agreements exposed limitations in the Government's understanding of diagnostics industry and supply chain capacities and capabilities.

   - ✓ Deploy advance purchasing arrangements earlier – even accepting the circumstances of extreme urgency necessitating direct awards, it took some time to set up and operationalise key framework agreements and dynamic purchasing systems.

   - ✓ Develop more agile procurement responses where the market takes the lead – the UK Rapid Test Consortium presented an opportunity to develop an antibody test where the Government's needs and specifications could not be fully known in advance and where there was no or limited existing capacity. However, analysis has revealed some uncertainty as to how to address proposals from industry and who should approve research contracts. There was also apparent uncertainty as to the role of advisors in the procurement process and as between executive agencies as to validation requirements. Some of these issues have also come to light in the contractual fall out of Government disputes with industry consortia members.

   - ✓ Improve procurement to deliver better outcomes, reduce risk of legal challenge and increase transparency through:

     - ➢ Clearer Target Product Profile and specification design;
     - ➢ Driving more competition into diagnostics procurement;
     - ➢ Applying more principled controls on use of direct awards (e.g. on pricing);
     - ➢ Clarifying the boundaries between scientific and commercial decision-making; and
     - ➢ Publish more procurement guidance which addresses the procurement process end-to-end.

6. This Part also examines some of the issues that may arise in respect of contract management. It draws on a range of illustrative examples of contract awards to highlight problems in planning vehicles for delivery of contracts, allocating and managing risk and addressing contractual disputes. As there are ongoing legal proceedings in respect of contract performance, this White Paper does not address these issues in detail nor identify recommendations but this area must be a point of focus going forward.

7. Part IV examines associated regulatory approvals for placing tests on the market with a particular focus on exceptional use authorisation exempting devices from full approval and the introduction of The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 ("CTDAR 2021"). The analysis has found that certain key test kits were exempt from approval and which resulted in their quick entry to the market to facilitate mass testing. However, a US Food and Drug Administration review of approvals in one case has raised broader questions about the current process for granting exceptional use authorisation for IVDs. The White Paper identifies a number of issues, lessons learnt and recommendations. These include a need to:

   - ✓ Consider legislative reform of reg.39 (the statutory basis for exemption) of the Medical Devices Regulations 2002 to place clearer controls on the granting and review of exemptions subject to conditions – the legislation provides for a very broad authorisation to exempt medical devices from full regulatory requirements but subject to relatively few legal and policy constraints.

   - ✓ Publish a more detailed process for exceptional use authorisations and their review – in contrast to guidance on validation, there is little published guidance on the process for exemption of medical devices from regulatory approvals.

   - ✓ Publish the outcome of exceptional use authorisation decisions including any associated conditions – in contrast to the publication of test evaluation reports, there is presently limited information published in respect of decisions taken to exempt devices from regulatory approval.

   - ✓ Consider the use of independent notified bodies for exceptional use authorisation in cases of emergency – there may be a need to increase the ability of executive agencies to independently verify information provided in support of applications.

8. As indicated, this Part also examines the CTDAR 2021 which was introduced to impose further regulatory approvals for COVID-19 devices entering the market. As the CTDAR 2021 regime has been the subject of a statutory review, this White Paper does not provide its own lessons learnt and recommendations. However, drawing on questionnaires, interviews and a review of the statutory reviews findings, this White Paper does call into question whether this was the appropriate choice of regulatory model, the timing of its introduction relatively late on in a declining market for COVID-19 testing, and whether the aims and objectives as stated have been met in light of users' experiences.

9. Part V concludes by identifying key cross-cutting themes which emerge from the analysis and which provide a frame of reference for developing a Government-industry stakeholder UK diagnostics dialogue on procurement issues. These themes comprise the following:

   - ✓ **The need to clearly articulate and integrate the role of public procurement within a national strategy for diagnostics**. Creditably, the recently published MedTech Strategy has identified the significant role of diagnostics in the health and social care system. The instrumental role of public procurement is also acknowledged. However, the Government should focus more attention on the role

of public procurement as a strategic tool for achieving UK diagnostics policy aims and the processes needed in support.

- ✓ **The need to put "procurement preparedness" at the heart of the UK's policy on diagnostics.** Whilst related and often inter-dependent, "procurement" and "supply chain" considerations are often conflated. When thinking about future "pandemic preparedness", there is a risk of focusing too much on addressing supply chain resilience which, in large part, is about levels of investment in domestic capability, onshoring, and logistics of supply and not enough on how the Government defines what it needs and how it goes about buying it. There needs to be an expert focus on who is doing the buying (i.e. the key institutions and their organisation) and how. A cross-Government department expert procurement group should be convened to better understand how procurement fits within a wider diagnostics policy strategy and the institutional and organisational architecture, what are the challenges of responding in an emergency and what practical reforms can be introduced to ensure emergency procurement preparedness. This should inform but also be distinct from wider thinking about supply chains, logistics and other supporting infrastructure (e.g. laboratory capacity).

- ✓ **The need to better "triangulate" procurement, validation and approvals processes.** The White Paper has identified a number of instances in which it was not clear how these processes operated distinctly and interacted. For instance, the national technical validation process was described as the "national procurement process" but it was a technical validation exercise to determine test use viability; it provides no guidance on the actual process of buying test kits. Further, it is clear that decisions in respect of validation and regulatory approval impacted procurement in terms of which suppliers to select and timescales for products getting to market. There was also a degree of uncertainty between executive agencies as to validation requirements and how they would be applied in individual cases. These aspects require more careful coordination.

- ✓ **The need to drive more competition into emergency procurement.** Whilst legally justified on grounds of extreme urgency, there was a high incidence of direct awards which led to questions about transparency and value for money. The Government needs to carefully consider what are the challenges which prevent competition, how it can be facilitated even in emergencies, and how it plans for the use of competitive procurement mechanisms earlier e.g. use of framework agreements and dynamic purchasing systems.

- ✓ **The need for effective communication by Government and between Government and industry.** The MedTech strategy recognises the need for clearer "demand signalling" so that industry has a clearer indication of what the Government wants. However, more fundamentally, communications could be handled better. One area concerns how processes are communicated to industry and how it is informed at interim stages about how processes are operating. There is also a degree of market sensitivity that must be carefully considered when making statements about contract awards. This is necessary to avoid risks of perceptions that industry, or certain parts of it, is being "shut out" of awards, or that there is "favourable treatment" which may not necessarily be justified.

- ✓ **The need for the Government to draw on international experiences as comparators.** A number of countries experienced the same difficulties and which should be a point of comparison in planning the UK's future response.

- ✓ **The need for a more formal Government-industry supplier forum for UK diagnostics.** Industry associations such as BIVDA and the Association of British Health Tech Industries (ABHI) have provided a vital point of communication between Government and industry. There is scope to establish more formal lines of communication in which such actors can play a prominent role alongside suppliers individually. This, in turn, will help the Government in its efforts to improve “demand signalling” to industry, make industry more aware of its policy priorities and possible market opportunities and to develop potential partnerships of the kind found in other sectors.

PART I:
AIMS AND OBJECTIVES IN CONTEXT

1. INTRODUCTION

Context

1.1. The COVID-19 pandemic precipitated a globally unprecedented public health crisis. Governments used a range of strategies to address it. Lockdowns and other social distancing measures were imposed. It was also necessary to put in place measures to protect against exposure and to track the spread of the virus.

1.2. Public procurement also played a fundamental role. There was an immediate demand within the public sector for medical supplies and services. This included PPE such as face masks, gowns and hand sanitizer to limit exposure, ventilators to treat those who had fallen seriously ill following exposure, and test kits to determine who had contracted the virus. Ordinarily, Governments advertise contract opportunities which identify required goods and services and suppliers compete against each other to meet and deliver them through government contracts. Extraordinarily, in the pandemic, governments and public sector bodies competed against each other to secure goods and services from whoever was available to supply to time and cost.

1.3. In the UK, the Government quickly mobilised a Test and Trace strategy. This, in turn, necessitated the procurement of vast quantities of test kits, raw materials and related technology as well as the establishment of testing capacity within laboratories and other settings to facilitate quick and reliable mass testing. In doing so, DHSC, also acting through its executive agencies, had to act as purchaser, manufacturer, regulator and tester, buying technologies, products and services, validating these for use, and placing them on the market. This also extended to relying on consultants from the private sector offering services in mapping supply chains and providing public messaging. The Government and public bodies had to adapt existing procurement policies, processes and practices and create new ones in response. Further, they had to comply with existing legal requirements concerning the award of public contracts and regulatory approvals for placement of medical devices on the market and even created new legislation in view of an apparent market failure.

1.4. The UK has an established diagnostics industry comprising suppliers of domestic origin and multi-nationals with UK subsidiaries. This industry may have had actual or potential capacity to ramp up manufacturing and related support to scale for certain requirements. However, in the early stages of the pandemic, it was necessary to manufacture test kits quickly for mass use which, in reality, meant relying primarily on suppliers from countries with established capacities to deliver on a massive scale (e.g. China and the US). Further, where the international market could not supply in areas requiring research and development, such as antibody testing, Governmental support was required to develop domestic capacity.

1.5. The Government and diagnostics industry had to coordinate and negotiate a complex response without the benefit of foresight in changeable circumstances. At the onset, there was inevitably much uncertainty from a procurement perspective. There was no prescribed specification for tests. Therefore, it was necessary to quickly translate emerging needs into technical requirements and performance characteristics for tests (e.g. user setting, specificity and sensitivity, and samples); however, this was, in part, a reactive rather than proactive process in responding to what the market could actually offer and with some requirements contrived to introduce controls on what could be supplied and how in light of industry responses. It was also necessary to understand the wider supply base and logistics (e.g. who could supply from which locations using what materials in terms of plastics, ethanol, and reagents) and what other customs and export restrictions could create supply chain bottlenecks or reliability of supply issues; however, again, certain of these supply risks and

issues could only have been known once goods were being supplied. These issues were compounded by other extraneous variables pertaining to the virus itself such as uncertainty about transmissibility, how the virus might evolve, the possibility of new variants, whether contracting the virus would lead to immunity, and whether and when a vaccine could be developed that would reduce the need for testing. Unsurprisingly, these factors also necessitated spot or speculative buying. A prime example was the procurement of antibody tests which, it transpired, were not required on the scale initially anticipated once it was determined that contraction of the virus did not provide total immunity and in view of the rapid development of a vaccine.

1.6. In terms of organisation, it was necessary to identify who should be tasked to undertake validation, procurement, manufacture or licencing for production and approval for placement of test kits on the market. This principally involved DHSC within central government (supported by the Cabinet Office in coordinating a procurement response generally) and its executive agencies such as Public Health England ("PHE") (being replaced by the UK Health Security Agency ("UKHSA")) responsible *inter alia* for validation and testing as well as the Medicines and Healthcare products Regulatory Agency ("MHRA") responsible for approving products for placement on the market. It also included individual responses by National Health Service ("NHS") Trusts and Foundation Trusts purchasing at the local level.

1.7. As indicated, to be procured, test kits first had to undergo scientific validation to ensure that they were suitable for use. This involved identifying the most appropriate technologies or processes (e.g. assays – a means of laboratory testing to determine the measure of a substance) and products, evaluating them (e.g. in a lab and in-service) on the basis of factors such as sensitivity and specificity, and approving them for procurement. Procurement itself involved identifying suppliers and soliciting offers by various means (e.g. through an open "call to arms" and requests for information ("RFIs")) on the supply market. Procurement processes were applied such as direct awards on grounds of extreme urgency involving negotiations with single suppliers and, in the later stages, through competitive procurement mechanisms such as framework agreements and dynamic purchasing systems. Suppliers were then selected based on their offers (e.g. according to supplier qualifications, price, quality and other factors such as ability to supply to scale and reliability of supply). Products that had been validated and procured also needed to meet regulatory approval requirements (or exemption therefrom) (e.g. being Conformitè Europëenne ("CE") CE marked or met other requirements) for placement on the market.

1.8. The Government then had to address contract management issues such as the contractual vehicle for delivery (e.g. grant or procurement contract through a single supplier or consortium), how the contract would be structured (e.g. through licencing and manufacturing agreements and "back to back" contracts with a lead supplier and sub-contractors), and the allocation and transfer of risk (e.g. in respect of intellectual property retention and (re)payment terms). It also had to address the reality of performance issues such as ensuring raw materials would be delivered in sufficient quantities, reliability of supply in light of customs and export restrictions, reduced supply due to suppliers meeting other demand and how to dispose of or repurpose unusable products. This is quite apart from the need to then operationalise testing across the UK through laboratories and on-site testing facilities at various locations.

1.9. At the outset, it must be acknowledged that the pandemic presented many unforeseeable challenges as well as foreseeable challenges for which little could have been done with better planning in any event. In certain instances the Government and industry might well have acted similarly if similar events occurred again. It is also easy to assess issues with the benefit of hindsight. Indeed, ultimately, whilst there is scope for debate on the extent to which the Test & Trace programme achieved its objectives, it must be considered a qualified success to the extent that testing capacity was ramped up to meet demand and largely met demand. Tests

which were validated for use, procured and placed on the market were generally reliable and people could access testing in healthcare and home settings.

1.10. Nevertheless, issues have arisen of sufficient public interest to attract widespread media attention and investigation by audit bodies such as the National Audit Office, Parliamentary Committees, courts and other forthcoming inquiries.[1] The reality is that billions of pounds were spent on contracts for which there must be proper scrutiny and accountability. In the context of public procurement, there are legitimate concerns to ensure that suppliers are not discriminated against, are treated equally, that processes are transparent and that contracts achieve value for money even in cases of emergency where the main priority (to the subordination of others) may simply be to secure goods and services which respond to the crisis. Whatever the findings or outcomes, legal challenges and high-profile contractual disputes at least raise important questions about how public procurement has been conducted.

1.11. Similarly, in respect of validation of products and their placement on the market, issues have arisen which merit closer analysis. Products need to be subject to exacting but proportionate controls to ensure that they do not pose a risk to public health. However, many products offered by suppliers failed to meet validation requirements; both Government and industry must soberly reflect on the underlying reasons as to why this was the case. Further, on one hand, regulatory controls were applied to exempt some products from medical devices regulations when placing them on the market whilst, on the other, entirely new legislation was introduced to subject other products to substantial regulatory controls before placement on the market. These regulatory exemptions and interventions had important implications for market access for suppliers and for consumers. This must be considered against an apparent wider background of concern about standards applied to in vitro diagnostic testing and that "the SARS-CoV-2 pandemic has provided a microcosmic insight into the inadequate state of current processes for evaluating and regulating medical tests".[2]

1.12. A perception has grown that there were "winners" and "losers" in the race to supply COVID-19 test kits, that regulatory rules, policies and processes kept changing, and, in particular, that foreign suppliers did well and domestic industry less so. This must be considered against the backdrop of the Government's stated ambition during the pandemic to build the UK diagnostics industry but which is yet to materialise. Analysis may go some way towards addressing the accuracy of these perceptions but, ultimately, what matters is that the Government and industry acknowledge the issues which have arisen. Most importantly, both must draw from lessons and recommendations which translate into meaningful reform of diagnostics procurement for future emergencies and generally.

White Paper Aims and Objectives

1.13. This White Paper examines the procurement of *in* IVD test kits. These are tests which rely on bodily samples of fluids or tissue and can test a range of conditions and diseases from pregnancy to HIV/AIDs and coronaviruses. The focus here is on the procurement of "lateral flow" and polymerase chain reaction or so-called "PCR" test kits to detect COVID-19.

1.14. It is intended to fill an important gap in academic research, public policy debate and oversight. To date, the main focus of attention in all quarters has been on the procurement of

[1] One early example is National Audit Office, Report by the Comptroller and Auditor General Cabinet Office, Investigation into government procurement during the COVID-19 pandemic, HC 959 Session 2019-2021, 26 November 2020. Others are cited throughout this White Paper.

[2] Royal Statistical Society, Diagnostic Tests Working Group Report, June 2021, p.7.

PPE[3] or other types of requirement and the wider Test & Trace strategy.[4] This risks overlooking the role and significance of IVD test kits specifically. The Government's response has been highlighted in Parliament as requiring further analysis with general calls for lessons learnt and recommendations to improve the use of diagnostics capability in emergencies.[5] This White Paper should provide a more focused analysis of the specific issues arising.

1.15. The research has been commissioned by the British In Vitro Diagnostic Association ("BIVDA") in academic partnership[6] with the University of Nottingham Public Procurement Research Group ("PPRG").[7] To confirm, to the extent possible (given the acknowledged source of funding), the research was commissioned to be independent and is independent, BIVDA having previously made its own recommendations for reform in this area.[8] It does not advocate or represent the interests of any individual supplier or industry association.

1.16. The Terms of Reference included the following aims and objectives. The aims are to better understand:

(1) How IVD test kits were procured, including the validation and approval for placement on the market;
(2) What lessons can be learnt from this experience; and
(3) What recommendations can be made in light of those lessons to improve future emergency preparedness and diagnostics procurement generally, supported by a sustainable domestic diagnostics industry.

1.17. The objectives in support of these overall aims are to:

(1) Provide a desk-based academic analysis of relevant legislation, available policy guidance, practice and published data on contract awards and approvals;

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[3] National Audit Office, Initial learning from the government's response to the COVID-19 pandemic Cross-government, Report by the Comptroller and Auditor General, session 2021-22 19 May 2021 HC 66; and House of Commons Committee of Public Accounts, Initial lessons from the government's response to the COVID-19 pandemic Thirteenth Report of Session 2021–22, together with formal minutes relating to the report, HC 175, 25 July 2021. Procurement of PPE is mentioned extensively but not in relation to diagnostics. The Government's response is available at: https://committees.parliament.uk/work/1225/initial-lessons-from-the-governments-response-to-the-covid19-pandemic/publications/.

[4] National Audit Office, The government's approach to test and trace in England – interim report, Report by the Comptroller and Auditor General, HC 1010 Session 2019-2021 11 December 2020; National Audit Office, Test and trace in England – progress update, Department of Health & Social Care, Report by the Comptroller and Auditor General, Session 2021-22, 25 June 2021, HC 295; House of Commons Public Accounts Committee COVID-19: Test, track and trace (part 1) Forty-Seventh Report of Session 2019–21 Report, together with formal minutes relating to the report, HC 932, 10 March 2021; House of Commons Committee of Public Accounts Test and Trace update Twenty-Third Report of Session 2021–22 Report, together with formal minutes relating to the report, HC 182, 27 October 2021.

[5] UK Diagnostics Industry and Covid-19 Recovery, Volume 714: debated on Tuesday 10 May 2022: https://hansard.parliament.uk/commons/2022-05-10/debates/72B27D55-3B21-49B2-941A-BB358BFA2B45/UKDiagnosticsIndustryAndCovid-19Recovery.

[6] BIVDA is a partner under the Economic and Social Research Council (ESRC)-University of Nottingham funded Impact Leaders Programme which aims to build and embed knowledge exchange capacity across the social sciences.

[7] For earlier PPRG-led research in this area, see: S Arrowsmith, L R A Butler, A La Chimia, and C R Yukins (eds), *Public Procurement in (A) Crisis: Global Lessons from the COVID-19 Pandemic* (Hart, 2021). That research was part-funded under AHRC AH/V012657/1, An Urgent Review of Single Source Procurement During the Pandemic: Recommendations for Best Practice and Reform.

[8] Written evidence submitted by British In-Vitro Diagnostics Association (CLL0019) October 2020 as cited in House of Commons Health and Social Care and Science and Technology Committee, Coronavirus: lessons learned to date, Sixth Report of the Health and Social Care Committee and Third Report of the Science and Technology Committee of Session 2021–22, together with formal minutes relating to the report, HC 92, 12 October 2021.

(2) Conduct questionnaires and interviews with a range of expert stakeholders to obtain an anecdotal or impressionistic understanding of practice during key phases of the pandemic which will inform the findings and recommendations.

1.18. The research methodology can be found in Appendix A.

1.19. This research is published in a White Paper format in preference to traditional academic journal articles. This is to ensure that the research is available "open access" for download without cost for public use and to establish a foundation for further policy dialogue between Government, industry and other key stakeholders on the issues raised. Specifically, this White Paper could assist as follows:

- For posterity, this purposely lengthy account will serve as a "snapshot" of some aspects of diagnostics procurement during the pandemic. It is important to ensure that these matters are documented so that any insight and experience gained is not simply lost to history or discounted on the basis that the world has moved on.

- It will provide an analysis and evidence base which could inform forthcoming national or Parliamentary Committee inquiries, for example, the COVID-19 inquiry. Relevant "modules" have been identified as including "Government procurement and PPE" and "Testing and tracing".[9]

- It should provide a springboard for further dialogue and knowledge exchange between the Government (and within it civil servants such as commercial officers and public health professionals), industry, the scientific community and academic community on ways to improve procurement, validation and approvals processes in respect of IVDs. It should be viewed as a starting point not an end point with many of the lessons learnt and recommendations designed to provoke a wider discussion and other more concrete recommendations from those on the frontline. This should lead to reform of policies, processes, practices and, if necessary, legislative reform.

Scope and Qualifications

1.20. This White Paper mainly examines "procurement" broadly construed, that is, the main elements of regulation (law and policy) and practice implicated in the buying of test kits. Procurement professionals know that "procurement" is often narrowly conceived as the advertisement (through publication of contract opportunities) and award (procedures involving stages of supplier selection and evaluation of the offer) of contracts and excludes how procured contracts are commercially structured and performed. Indeed, much public procurement legislation only focuses on the advertisement and award aspects.

1.21. By contrast, this White Paper is necessarily broader in its ambit in two respects. First, it also examines processes for the technical validation of products; contract award procedures will involve an assessment of whether a product meets a technical specification which means that the product must have been validated. It also examines medical devices regulations which must be complied with to ensure that a procured product is safe for placement on the market. As will become apparent, the procurement of test kits involves more than the typical buying of a product "off the shelf" as it also includes significant scientific and medical input. It is not possible to properly examine the processes for awarding test kit contracts without a fuller understanding of the relevance and impact of these wider validation and regulatory approvals processes on procurement itself. Second, more briefly, it examines some aspects of contract

[9] Information on the COVID-19 Inquiry and the designated modules can be found at: https://covid19.public-inquiry.uk/modules/.

management. At the time of writing, there are ongoing disputes relating to contractual terms and performance in respect of awarded contracts which may also be relevant to procurement decision-making particularly in planning procurement exercises. However, the fact that these disputes are ongoing means that it would not be appropriate to comment or speculate on "live" issues (even if widely publicised) let alone examine them in detail pending their resolution. For this reason, contract management issues are not explored in detail. Notwithstanding, it is important to at least include contract management as an aspect of coverage in principle as it should be a point of focus in any wider dialogue about diagnostics procurement and industrial strategy going forward.

1.22. Several further qualifications must be entered. First, the focus is on procurement of IVD test kits given their prominent role in the pandemic. Of course, a whole range of other goods and services were procured in connection with diagnostics e.g. from software scanning and reader equipment to personnel administering testing services at various facilities. The National Audit Office has already published its investigation into the procurement of certain test services.[10] The scope of this White Paper excludes a much broader analysis of procurement of diagnostics-related contracts during the pandemic. There have also been a number of issues regarding the operation of diagnostics laboratories with potential regulatory implications which are not considered here. For example, there are reported incidents of errors in laboratory testing which led to the public being given the wrong information as to their viral status, prompting questions about how such facilities and test centres are accredited and regulated.[11] Again, these sorts of operational issues are not explored here.

1.23. Second, this White Paper is written by a public procurement lawyer with expertise in evaluating legal and policy documents and who was not directly involved in procurement during the pandemic. Expertise does not extend to analysis of how acute scientific judgements are made (e.g. how validation criteria are devised and applied or, similarly, medical device approvals determined). In any event, other disciplines are already contributing to debate on reform diagnostic testing following the pandemic.[12] This is an important limitation because it means that many of the lessons learnt and recommendations made are necessarily regulatory or process-oriented to ensure legal compliance and more accountable and transparent decision-making. This could leave the White Paper exposed to charges that its findings will only "tinker at the edges" when, in reality, it is necessary to penetrate the heart of what drives key strategic, commercial and scientific decision-making if meaningful reform is to be achieved. Moreover, it is those decision-makers rather than lawyers who devised key policies and processes, being best placed to make decisions. Those at the frontline must be consulted before any credible proposals for process-related reform can be offered e.g. including scientists in discussions about regulatory and process issues rather than simply commercial or legal specialists.

1.24. Nevertheless, there is also merit in ensuring that rules, policies and processes are well designed from the perspective of legal certainty, ensuring non-discrimination, equal treatment of suppliers and transparency (where applicable), and value for money and accountability to the taxpayer. As indicated, this White Paper promises no more and no less than to provide a springboard for a much wider engagement of all key stakeholders in discussion on reform.

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[10] National Audit Office, Investigation into the government's contracts with Randox Laboratories Ltd, Department of Health & Social Care, Report by the Comptroller and Auditor General, Session 2021-22, 24 March 2022 HC 1018.

[11] See, for example, the IBMS Council's position statement on the need for registered staff and accreditation in laboratories undertaking COVID-19 testing, 13 August 2020: https://www.ibms.org/resources/news/high-quality-staff-deliver-high-quality-services/.

[12] See, for example, the contribution of the Royal Statistical Society's COVID-19 Task Force which has examined the role of statistical input in modelling the virus and made various recommendations relevant to this White Paper: Royal Statistical Society Diagnostic Tests Working Group Report, June 2021.

1.25. Third, the form and limitations of the research methods and methodology must be acknowledged. As explained in Appendix A, the research has comprised mainly desk-based analysis but informed by questionnaires and semi-structured interviews. Time, budget and other resource constraints necessarily limited the scope for investigations on the scale of a public inquiry; however, the research has been careful to acknowledge the limitations of any data and information provided. Further, the research has been institutionally ethically approved.

1.26. Fourth, there are temporal and geographical limitations. This White Paper does not examine procurement in the context of the latest developments e.g. the procurement of new or adapted tests to address the Omicron variant. It also focuses to a greater extent on the response by the UK central Government. It considers some aspects of procurement at the local level e.g. through NHS Trusts but not to a significant extent and various laboratories across the UK will no doubt have their own experiences to relay. Further, it focuses mainly on procurement within the national Test & Trace strategy within England. Similar arrangements were in place in Wales, Scotland and Northern Ireland but these jurisdictions will have their own distinct experiences. All of these limitations must be acknowledged but the focus on key aspects ensures an early provisional analysis of the response to inform change as soon as possible.

1.27. Fifth, there was a temptation to provide extensive citations of the many media and other online sources which have reported or speculated on contract awards, exemptions from regulatory requirements and ongoing contractual disputes. Many of these have usefully brought matters to public attention for further scrutiny but some have, on occasion, led to claims which are at best conjectural or, at worst, sensationalist. This includes various claims which go beyond alleged "favouritism" to "cronyism" and "corruption" which have not been conclusively established (at least at the time of writing), or, indeed, cannot be established (e.g. there is no criminal law offence of, or civil law liability for, "cronyism"). As a result, perception (which may or may not be the reality) appears to have played a significant role in fuelling litigation and market reaction during the pandemic. To ensure impartiality as far as possible, the analysis in this White Paper is based mainly on publicly available information on government websites and reported judgments in legal challenges where matters of fact and evidence have been determined by a court of law. In a limited number of instances, it has been necessary to rely on media sources where these provide quotations (and which it must be assumed have been verified by those sources).

1.28. Finally, this White Paper cannot be construed as constituting a comprehensive legal analysis or the provision of legal advice.[13] It cannot investigate whether or not there have been instances of non-compliance with legal requirements in individual cases. As indicated, there is ongoing litigation or the possibility of litigation in respect of contract awards, certain of which are briefly referenced in this White Paper and it would not be appropriate to comment further.

1.29. In light of the above, this White Paper should be received in the spirit intended. It is not designed to single out individual conduct within Government or industry or to disparage the work of the many tasked with finding solutions to an unprecedented crisis. Indeed, the White Paper's findings and recommendations have been assisted by the positive willingness of officials and industry to volunteer their time for discussion and are deserving of many thanks.

[13] Any contracting authority, supplier or other stakeholder is advised to obtain independent legal advice on any matter raised in this White Paper.

1.30. Provisional findings from the research for this White Paper were presented at the BIVDA MGM on 12 October 2022.[14] This White Paper is accurate as at the date of writing.[15]

Structure

1.31. The remainder of this Part I provides a chronology of key events as context for the analysis (Chapter 2). Part II examines the national technical validation process (also referred to as the "national procurement process") for evaluating products for procurement (Chapter 3). Part III examines approaches to contracting, namely, the processes for awarding contracts (Chapter 4) and contract management (Chapter 5). Part IV examines regulatory approvals under the Medical Devices Regulations 2002 with a particular focus on the exceptional use authorisation process (Chapter 6) and the Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 (Chapter 7). Part V goes beyond lessons learnt and recommendations made to identify key cross-cutting themes or threads arising from the analysis which could help frame debate going forward (Chapter 8). Appendices outline the research methods and methodology and provide a select list of abbreviations and acronyms.

[14] The presentation slides are available on request.

[15] All views expressed by the author are solely attributable to the author and do not represent the views of any Government Department, public body, industry association or other organisation, or individual who responded to a questionnaire or interview (and who remain anonymous). Any errors or omissions in statements of fact in the compilation and presentation of data or analysis for this White Paper remain those of the author. Any required corrections will be duly noted, made and published, if necessary.

2. KEY EVENTS

Introduction

2.1. The NHS carries out over 1.5 billion diagnostic tests every year and more than 85% of clinical pathways involve a diagnostic test. Diagnostics are a significant part of the UK Life Sciences sector, with £2.9 billion in turnover and employing more than 15,000 people in the UK.[16] Diagnostics played a prominent role in the fight against COVID-19.

2.2. On 11 March 2020, the World Health Organisation announced that the spread of a new Severe Acute Respiratory Syndrome Coronavirus 2 ("SARS-CoV-2") constituted a global pandemic.[17] On 23 March 2020, the first mandatory UK lockdown was announced.[18] On 25 March 2020, the Coronavirus Act 2020 came into effect including powers to restrict movement. Between June and July 2020, restrictions were replaced with social distancing rules.

2.3. It is well documented that there were major challenges facing the state generally.[19] One aspect concerned the need for quick and effective public procurement of key items such as PPE, sanitiser, ventilators, and test kits within the framework of UK public procurement law and policy.[20] Global demand for PPE inverted the competitive paradigm. Instead of suppliers competing against each other to supply to Government, contracting authorities were effectively competing against each other in a buyer's competition to source PPE in vast quantities. These were bought at whatever price could be afforded as suppliers sold to the highest bidder. Suppliers even violated existing supply commitments to sell to those who could offer a higher price. Legal challenges[21] and National Audit Office reports and other inquiries[22] have shed light on issues that have arisen in respect of procuring PPE. Similarly, there was a need for ventilators which were developed, in part, through the so-called ventilator challenge.[23] Other contracts were awarded to ensure effective communication on

[16] Department of Health & Social Care, Medical Technology Strategy 2023, p.34 and citation at fn22 of NHS England and NHS Improvement Board meetings held in common, Date: 201001 Ref: BM/20/25(Pu): https://www.england.nhs.uk/wp-content/uploads/2020/10/BM2025Pu-item-5-diagnostics-capacity.pdf.
[17] Information on the WHO's tracking of COVID-19 related developments since this date can be found at: https://www.who.int/europe/emergencies/situations/covid-19.
[18] The then Prime Minister's announcement in this regard can be found at: https://www.gov.uk/government/speeches/pm-address-to-the-nation-on-coronavirus-23-march-2020.
[19] J Calvert and G Arbuthnot , *Failures of State: The Inside Story of Britain 's Battle with Coronavirus* (HarperCollins, 2021).
[20] See generally, S Arrowsmith and LRA Butler, 'Emergence Procurement and Regulatory Responses to COVID-19: The Case of the United Kingdom' in S Arrowsmith, L R A Butler, A La Chimia, and C R Yukins (eds), *Public Procurement in (A) Crisis: Global Lessons from the COVID-19 Pandemic* (Hart, 2021).
[21] See, for example, *The Queen On The Application Of The Good Law Project v Secretary Of State For Health And Social Care* [2020] EWHC 3609 (TCC); *The Queen On The Application Of The Good Law Project Limited (and Others) v Secretary of State for Health and Social Care* [2022] EWHC 46; *The Queen On The Application Of The Good Law Project v Secretary of State for Health and Social Care (and Others)* [2021] EWHC 346 (Admin).
[22] National Audit Office, Report by the Comptroller and Auditor General, The supply of personal protective equipment (PPE) during the COVID-19 pandemic, HC 961 Session 2019 – 2021, 25 November 2020; House of Commons Public Accounts Committee, COVID-19: Government procurement and supply of Personal Protective Equipment, Forty-Second Report of Session 2019 – 21 Report, together with formal minutes relating to the report, HC 928, 4 February 2021.
[23] National Audit Office, Report by the Comptroller and Auditor General, Cabinet Office and Department of Health & Social Care, Investigation into how government increased the number of ventilators available to the NHS in response to COVID-19, HC 731 Session 2019–21 (30 September 2020) 36; House of Commons Public Accounts Committee, Covid-19: Supply of ventilators Twenty-Seventh Report of Session 2019 – 21 Report, together with formal minutes relating to the report, HC 685, 16 November 2020.

Government strategy and which have also been the subject of legal challenge.[24] As indicated, there was also a pressing need for diagnostics and related services in the form of test kits and the provision of testing which was critical to tracking the spread of the virus.

2.4. This Chapter provides a brief overview of just some of the key events as they relate to diagnostics procurement at certain stages of the pandemic. It is not intended to be a comprehensive factual account and does not detail every initiative within every central and local government institution. Rather, it provides the broad context for understanding the timeline of validation, procurement and regulatory approvals processes discussed in the remaining Parts.

Pre-Pandemic Preparedness

2.5. The UK had undertaken some planning for emergencies before the pandemic. Examples include the UK Influenza Preparedness Strategy 2011 and the National Risk register of Civil Emergencies.[25] It is more difficult to discern to what extent the Government had developed specific strategies for procurement in emergencies, in particular, in respect of diagnostics. Certain Government Departments which ended up playing a key role in the pandemic had devised policies to procure requirements at a time of war or armed conflict (e.g. the Ministry of Defence's urgent capability requirements policy).[26] There is also some indication that the Government had considered procurement issues in respect of outbreaks of certain diseases (e.g. Ebola).[27] However, ultimately, the Government could not have predicted the nature and scale of procurement needed in a global pandemic, including the prevalent role that diagnostics would play. Indeed, the courts have rejected arguments that there was no extreme urgency to justify direct awards of contracts during the pandemic because earlier planning exercises could have anticipated the nature and extent of the need in advance.[28]

2.6. Similarly, suppliers within the UK diagnostics industry may have had relevant experience of manufacturing or supplying tests for diseases such as AIDS or Ebola and even other coronaviruses but COVID-19 was a novel coronavirus requiring new diagnostics. Further, as discussed in Part II, Chapter 3, the understanding is that many suppliers were geared to design tests for use in laboratories on a smaller scale not for mass testing in a range of settings.

2.7. As it stood, the Government and industry simply had to work within existing constraints of capacity, capability, and processes and adapt accordingly.

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[24] *The Queen on the application of The Good Law Project v Minister for the Cabinet Office (Public First Limited as Interested party)* [2021] EWHC 1569 (TCC); *The Queen on the application of The Good Law Project v Minister for the Cabinet Office* [2022] EWCA Civ 21. See also Cabinet Office, Boardman Report on Cabinet Office Communications Procurement (8 December 2020) available at www.gov.uk/government/publications/findings-of-the-boardman-review.

[25] Information is available at: https://www.gov.uk/government/publications/uk-pandemic-preparedness/uk-pandemic-preparedness.

[26] Information is available at: https://www.gov.uk/government/publications/the-european-union-defence-and-security-public-contracts-regulations-dspcr-2011/chapter-9-procuring-urgent-capability-requirements.

[27] Information is available at: https://www.gov.uk/government/news/ebola-virus-pm-calls-on-european-council-for-action.

[28] *The Queen On The Application Of The Good Law Project v Secretary Of State For Health And Social Care* [2020] EWHC 3609 (TCC), at [53]; see also *The Queen On The Application Of The Good Law Project v Secretary of State for Health and Social Care* [2021] EWHC 844 (TCC) at [33].

Establishing Test & Trace and Building the British Diagnostics Industry

2.8. It is understood that there was not sufficient testing capacity and infrastructure within the NHS, PHE and the private sector to cope with the demands of a global pandemic for a novel virus. In any event, the imposition of lockdowns reduced the amount of routine testing being undertaken for other diseases such that existing diagnostics capacity was not being fully utilised or ready for use. From March 2020, DHSC, supported by other Government bodies, began to significantly scale up testing capacity and launched a new NHS Test and Trace ("T&T") service.

2.9. The need for accurate test kits was an important foundation for the T&T strategy. Two main types were required, namely, tests to detect the virus (antigen[29] and molecular tests) and tests to detect immunological reaction to the infection (antibody tests). These mainly took the form of lateral flow tests ("LFTs")[30] and polymerase ("PCR") tests,[31] although there are other forms e.g. Loop-mediated isothermal amplification ("LAMP") tests. Three key measures of the effectiveness of the tests are: (1) the "limit of detection";[32] (2) "sensitivity";[33] and (3) "specificity"[34].[35] Any number of variables must be taken into account to ensure that test kits are of sufficient quality, accuracy and volume. Just some examples in respect of the "raw" components include: the nature and origin of the sample used (e.g. antibody levels might be higher in someone recently infected than historically), the strength of the infection present, the type of antigen used, and the materials used in manufacture especially if these have to be sourced from outside the UK. Other variables which impact testing include the range of different methods used to assess tests themselves e.g. sample sizes, comparator assays, etc.

2.10. Before launching a formal strategy to secure test kits on a mass scale, there was an attempt to procure antigen and antibody test kits *ad hoc* with offers predominantly from outside the UK. It has been recorded in legal judgments that this is because the UK and, in particular the NHS, had very little testing capacity and that there was not a well-developed UK

[29] An antigen is a protein that causes the immune system to produce antibodies and trigger an immune response, determining the presence of the pathogen. In the case of COVID-19, spike proteins are found on the surface of the SARS-CoV-2 virus. An antigen test detects these proteins.

[30] LFTs can test for antigen and antibodies. These rapid tests involve applying a sample of bodily fluid or other material to an absorbent material that is allowed to flow down, coming into contact with a sample of the antigen protein and, following a reaction, identifies an outcome.

[31] PCR tests seek genetic material in the form of Ribonucleic acid ("RNA") which instructs the virus to make the proteins. PCR tests are sent to a laboratory; reagents are used to convert the RNA into Deoxyribonucleic acid ("DNA"). The nucleic acid sample is amplified or replicated to identify the organism.

[32] The limit of detection (LOD) is defined as a measure of the lowest concentration (smallest amount) of the viral target (protein or RNA) which can be reliably identified in a sample and with a high degree of confidence. Usually, the LOD refers to the amount detected at least 95 times out of 100 attempts (95% probability of obtaining a correct result).

[33] The sensitivity is a measure of how well the test correctly identifies individuals with the coronavirus. The sensitivity can be used to understand the chance that a test will incorrectly give a negative result for someone who actually has coronavirus (that is, someone who would have tested positive if the test was completely accurate). This is called a 'false negative'. Tests that are less sensitive are likely to lead to more 'false negatives'. This means an increased risk of individuals entering certain settings believing they do not have the virus when they in fact do, for example.

[34] Specificity is a measure of how well the test correctly identifies individuals without coronavirus. It can be used to understand the chance that a test will incorrectly give a positive result (a 'false positive') for someone who does not have coronavirus and would have tested negative if the test was completely accurate. Tests that are less specific are likely to lead to a greater number of false positives. This means an increased possibility of individuals unnecessarily self-isolating, for example.

[35] For useful explanations of key terms, see generally, UK Health Security Agency, Technologies Validation Group: using tests to detect COVID-19, 17 June 2021 (last updated 19 October 2021): https://www.gov.uk/guidance/technologies-validation-group-using-tests-to-detect-covid-19.

diagnostics industry.[36] However, it cannot necessarily be discounted that there might have also been strategic reasons for the Government to only source tests from one or two suppliers rather than from a wider supply base whatever the capacity available or which could otherwise be developed in the UK. For example, limiting sourcing to one or two suppliers rather than several or many might have mitigated the risk of logistical challenges procuring from multiple sources as well as ensuring a certain degree of certainty or security given the need to protect public health. Ultimately, it is not clear whether UK suppliers working collectively could have met a high proportion of demand even if they could not have done so individually.

2.11. By March 2020, a pressing issue was whether an infected person could generate antibodies the presence of which would establish levels of immunity. If high levels of immunity on infection were possible, this would necessarily increase the importance of test kits for antibody detection pending the development of a vaccine. Laboratory tests for detecting antibodies were already in place but were expensive, took time and were not widely available for mass testing.[37] This led to proposals to use LFTs instead. It is understood that, at this time, Oxford University had developed an antigen needed for effective antibody testing in laboratory and other settings.[38] Of course, with hindsight, it is now known that infection and vaccination is no guarantee of immunity, thereby limiting (although not negating) the utility of antibody testing.

2.12. Around mid-March 2020, the Government began to receive offers of antibody tests. A special Scientific Advisory Panel ("SAP") alongside other support (e.g. from MHRA) was to be convened to assess serological tests and LFTs before any commitments were made to purchase them in large quantities. This also included setting up a laboratory designed to evaluate the tests being submitted.[39] At this point, Oxford University had developed its lab-based enzyme-linked immunosorbent assay ("ELISA") test. To explain its relevance, at the onset of the pandemic, a number of antibody tests (including those developed by Roche and Abbott) used a protein which could detect antibodies and thus presence of COVID-19 infection but not antibodies which could produce immunity; the ELISA test used a spike protein which could identify such antibodies.[40]

2.13. However, most prototype sample LFT kits sent for evaluation did not work at all or sufficiently well. DHSC purchased many antibody LFTs from companies from the UK and abroad who had made LFTs for other purposes and claimed to be able to produce antibody LFTs "off the shelf" but that these were not, in fact, sufficiently reliable.[41] Many were not sufficiently accurate or were only accurate when testing hospital based samples where there tended to be more powerful antibody responses in view of the severity of the infection. Further, the antigen used was often not of high quality or the right kind. The physical build of some of the LFT test kits was also described as "flimsy".[42] The ability to secure suitable tests from outside the UK was also limited given that the USA had imposed export bans on antibody LFTs, China had halted consignments of tests to the UK, and there were other demands on global supply chains.[43] In addition, whilst the ELISA test proved successful, an appropriate LFT platform still needed to be designed and manufactured which was beyond SAP or Oxford University's capability.[44] It is understood that at the same time, in parallel, DHSC began

[36] *The King (on the application of the Good Law Project Limited) v The Secretary of State for Health and Social Care v Abingdon Health Plc* [2022] EWHC 24688 at [87].
[37] *Abingdon Health plc* [8].
[38] *Abingdon Health plc* [86].
[39] *Abingdon Health plc* [89].
[40] *Abingdon Health plc* [96]-[97].
[41] *Abingdon Health plc* [13].
[42] *Abingdon Health plc* [100].
[43] *Abingdon Health plc* [99]-[100].
[44] *Abingdon Health plc* [101].

purchasing large quantities of LFTs without waiting to see if these would ultimately be validated and were also said to have fared little better than the prototype sample kits.[45] On 31 March 2020, what became the New Test Advisory Group ("NTAG") communicated the results of evaluations of 19 LFT kits from around the world, confirming that none had been approved, and a test provided by a UK supplier (Surescreen Diagnostics Ltd) also failed.[46]

2.14. This early experience evidenced a need to develop a "home grown" antibody LFT test. An important award was a contract directly awarded to Abingdon Health plc which, as discussed in Part III, Chapter 4, has been the subject of a legal challenge. Following the setting up of a testing triage inbox, Abingdon Health plc emailed the inbox proposing a coordinated effort between suppliers to provide tests manufactured to scale.[47] This was not actioned at the time, however, on 29 March 2020, the Secretary of State for Health and Social Care (then Matt Hancock) announced that "we are going to build the British diagnostics industry".[48] In April 2020, meetings were held with key industry partners to develop a strategy to rapidly scale up the UK's diagnostics industry to support COVID-19 testing. Proposals were put forward for a "manageable consortium" including Abingdon Health plc, Omega Diagnostics (Scotland), BBI (Wales), and CIGA (Northern Ireland).[49] This resulted in the launch of a business consortium, the UK Rapid Test Consortium ("UK-RTC"), to design and develop a new antibody test.

2.15. DHSC entered into three contracts with Abingdon Health plc as the contracting party, apparently on behalf of the UK-RTC. The first made on 11 April 2020 was a research contract for the development of a test. The second was made on 2 June 2020 to fund the purchase of LFT components to enable Abingdon Health plc to make 10 million tests (title to the components remaining with DHSC until incorporated into the manufactured tests); this also contemplated the making of a third contract for actual supply of LFTs and was conditional on Abingdon Health plc producing an LFT that was validated and approved by MHRA. The third contract made on 14 August 2020 was for purchase of 1 million LFTs but with the right to purchase a further 9 million; although by the time it was made, Abingdon Health plc had not obtained a satisfactory evaluation from PHE nor MHRA approval.[50]

2.16. At the same time, DHSC called for the scaling up of COVID-19 testing programmes, outlining a five pillar strategy.[51] The first pillar was testing for those with a medical need in PHE labs and NHS hospitals. This comprised PCR tests involving a swab sample taken and analysed in a laboratory. On 18 March 2020, the Government announced that it would aim to increase testing capacity from 5,000 tests a day to 10,000 and then 25,000. In the second pillar, the Government launched a partnership with universities, research institutes and companies to begin rollout of a network of new laboratories and testing sites UK-wide, to provide PCR swab tests for critical key workers (NHS frontline staff and social care workers) to ensure a return to work as soon as possible. This involved setting up a new network of testing sites to collect samples and new "super labs" (at Milton Keynes, Alderley Park and Glasgow) to analyse results. The third pillar was antibody testing to detect immunity, initiatives in respect of which were being developed, as indicated above. The fourth pillar was surveillance, namely, to conduct large-scale surveys to find out what proportion of the population had already contracted the virus using a high-accuracy antibody test operated by PHE at their Porton Down science campus. This was seen as a means of informing key choices about

[45] *Abingdon Health plc* [102].
[46] *Abingdon Health plc* [108].
[47] *Abingdon Health plc* [103].
[48] *Abingdon Health plc* [104].
[49] *Abingdon Health plc* [123]-[125].
[50] *Abingdon Health plc* [17].
[51] Coronavirus (COVID-19) Scaling up our testing programmes, Department of Health and Social Care, Published 04 April 2020.

social distancing measures and exit from them. The fifth and "most ambitious" pillar was to build, in a short space of time, a large-scale diagnostics industry. It was stated that UK pharmaceutical giants, which do not have a tradition of diagnostics, would work with the UK's world-leading but smaller diagnostics companies to build a large-scale British diagnostics industry at scale.[52]

2.17. Several other initiatives had also been announced which had been developed drawing on partnerships with industry. Those identified included: (1) a new testing laboratory to be set up by AstraZeneca, GSK and Cambridge University which was to be used for screening, with the aim of carrying out 30,000 tests a day by the start of May with companies exploring the use of alternative chemical reagents for test kits in order to help overcome supply shortages; (2) AstraZeneca and GSK provision of scientific and technical expertise in automation and robotics to support the Government's new national testing centres; (3) Thermo Fisher's commitment to continuing to supply the UK with testing kits and to scale up manufacturing at its existing UK sites; and (4) use of Oxford Nanopore's sequencing technology in multiple laboratories to rapidly sequence the virus and other pathogens that may also be present in a sample, supporting epidemiology and scientific understanding of coronavirus. It was also reported that its R&D team was exploring advanced test options using its Dexoyribonucleic Acid ("DNA")/Ribonucleic Acid ("RNA") sequencing technology.[53]

2.18. The Government also committed to setting up a testing taskforce with over 100 companies. The then Health Secretary set out four challenges to industry to help scale up testing capability in a way that was also resilient and scientifically robust. These were: (1) to provide additional testing consumables in short supply, such as swabs, tubes and components for test kits; (2) for universities, research institutes and private companies to donate additional laboratory testing capacity for tests, supported by best practice guidance on specific requirements; (3) to develop new technology to diagnose quicker and new methods of delivering tests widely across the UK safely; and (4) put forward proposals in support of reliable and accurate antibody testing. As indicated, the fourth challenge was to be the culmination of proposals for a UK-RTC.[54]

National Procurement of In Vitro Diagnostic Test Kits

2.19. As indicated, it appears that, in the early stages, a number of test kits were procured before they had been validated for use and before a standardised national validation process and national procurement process had been established. The Government had procured a number of test kits from around the world, although it is not clear how suppliers were identified in the very early stages. It became clear that the Government began to seek expressions of interest or offers from companies who could manufacture and supply new or existing types of coronavirus tests for antigens and antibodies, requiring that these met MHRA requirements. The Government then set up an online portal providing companies with specifications for its most urgent requirements and an opportunity to submit offers of test kits. This was necessary to ensure that the Government could identify suppliers from the widest possible pool to meet demand and to ensure an early filter to solicit only those tests which were suitable. The Government further stated that suppliers were also able to access a range of support from Government, including accelerated regulatory approval, centralised procurement support if appropriate and, in some cases, development grants;[55] although it is difficult to find consolidated information in one place on the forms of support available.

[52] Press release, Industry responds to call to arms to build British diagnostics industry at scale, 8 April 2020: https://www.gov.uk/government/news/industry-responds-to-call-to-arms-to-build-british-diagnostics-industry-at-scale.
[53] Ibid.
[54] Ibid.
[55] Ibid.

Designated online submission forms were set up to solicit offers through a portal, effectively, a national "call to arms" similar to the national portal for soliciting PPE, for example. There was also a call for direct offers of laboratory capacity and the provision of consumables, reagents and equipment (the latter has since closed).[56]

2.20. As discussed in more detail in Parts II and III, the Government did not appear to publish any specific or detailed guidance on how to procure IVD test kits. The Cabinet Office did publish general Procurement Policy Notes[57] indicating in basic terms the existing lawful procurement routes available and emphasised the limits on, and need for, explicit justification for direct awards without competition due to extreme urgency in accordance with the Public Contracts Regulations 2015 (SI 2015 No.102) ("PCR 2015"). This preceded even briefer European Commission guidance to similar effect.[58]

2.21. As also discussed in more detail in Part IV, Chapter 6, it appears that the next set of guidance to be published concerned the processes for regulatory approvals for placement of products on the market. On 25 March 2020, the MHRA published what it referred to as "Guidance on Exemptions from Devices regulations during the coronavirus (COVID-19) outbreak" which purported to identify "how to get fast-track approval of medical devices during COVID-19".[59]

2.22. Before contracts for test kits were awarded, they would need to undergo some form of validation to determine whether they met basic technical requirements. As indicated above, in the very early stages, it is possible that contracts were already awarded subject to validation or that offers of test kits were being assessed for award alongside being subjected to a process of validation. By April 2020, the Government had established a centrally coordinated national validation process. On 8 April 2020, the MHRA published its specification criteria for serology point of care ("POC") tests and self-tests against which certain tests would be validated. For self-tests, this included a required acceptable sensitivity of more than 95% and specificity of more than 98% and desirable sensitivity and specificity at 98%. These criteria made up the Target Product Profile ("TPP").[60]

2.23. In May 2020, the MHRA issued three guidance documents on COVID-19 test kits. The first was for industry and manufacturers which explained how to seek approval of testing kits. It noted that the science underlying the specifications was rapidly evolving; that where manufacturers considered that they meet TPP requirements, they should contact DHSC through the COVID-19 portal; and that it would be possible to derogate from regulatory requirements with guidance on how manufacturers could apply for derogation (as indicated above). The second set out TPPs for POC/near patient tests kits (e.g. for use in hospitals/by healthcare professionals in healthcare settings) and self-test kits (e.g. for use in private residences). The third was for patients, the public and professional users which provided general advice on how test kits work (e.g. different methods of sampling tests, home-testing

[56] UK Health and Security Agency, Guidance, Help the government increase coronavirus (COVID-19) testing capacity (published 8 April 2020 and withdrawn on 29 June 2022): https://www.gov.uk/guidance/help-the-government-increase-coronavirus-covid-19-testing-capacity#how-to-help%5C.

[57] Cabinet Office, Procurement Policy Note - Responding to COVID-19 Information Note PPN 01/20, March 2020.

[58] Communication from the Commission, Guidance from the European Commission on using the public procurement framework in the emergency situation related to the COVID-19 crisis (2020/C 108 I/01) OJ C 108 I/1

[59] Medicines & Healthcare products Regulatory Agency, Guidance, Exemptions from Devices regulations during the coronavirus (COVID-19) outbreak, 25 March 2020: https://www.gov.uk/guidance/exemptions-from-devices-regulations-during-the-coronavirus-covid-19-outbreak.

[60] Medicines & Healthcare products Regulatory Agency, Guidance, Target Product Profile: antibody tests to help determine if people have recent infection to SARS-CoV-2 (currently Version 2.0, updated 7 October 2022): https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/target-product-profile-antibody-tests-to-help-determine-if-people-have-recent-infection-to-sars-cov-2-version-2#target-product-profile.

kits and laboratory tests), the type of tests (e.g. PCR tests), limitations, and how they are regulated (e.g. must be CE marked prior to being placed on the market etc).[61]

2.24. It appears that it was not until June 2020 that DHSC published guidance on the actual validation process itself, which it described as the process for how the Government assesses offers of COVID-19 tests from developers for procurement and use in the UK.[62] As discussed in more detail in Part II, the guidance purports to set out how the government will triage, review and evaluate offers of viral detection, antigen and antibody tests in support of the national T&T programme.[63]

2.25. As will also be discussed in more detail in Part III, Chapter 4, at these relatively early stages in the pandemic, perhaps unsurprisingly, it was not considered possible or viable to conduct formal openly competitive procedures for award as this would involve having to assess the individual qualifications and offers of every single supplier. Rather, given the sheer volume and diversity of offers, it was necessary to collate all of those received and to hone in on those which appeared to be most promising. Further, given the need to procure quickly (i.e. within days or weeks not months), it was not even viable to conduct accelerated competitive procedures with reduced timescales. As there were no obvious mechanisms set up pre-pandemic to specifically provide for emergency contracting (e.g. through large-scale framework agreements or dynamics purchasing systems), there was extensive recourse to direct awards on grounds of extreme urgency. Offers had been identified through processes such as the national portal and DHSC and other contracting authorities entered into direct negotiations with suppliers without any tendering leading to the award of contracts. Alternatively, suppliers registered on existing framework agreements for non-COVID-19 diagnostics related goods were able to provide range extensions to their existing product lines to meet COVID-19 requirements. It appears that circumstances were such that DHSC directly awarded contracts for imported test kits and even undertook responsibility as manufacturer to repurpose their use (e.g. a professional use test repurposed as a self-test).[64] Of course, direct awards offered a degree of procedural flexibility in their award but were nevertheless required to comply with other applicable public procurement law requirements.

2.26. By the end of 2020, the first rollout of the vaccination programme commenced. As discussed in more detail in Part III, Chapter 4, this inevitably impacted decision-making around the need for, and role of, testing, in particular, antibody testing.

Increased Use of Competitive Purchasing Mechanisms

2.27. In 2021, the Government's attempts to introduce competition into procurement of COVID-19 contracts became more apparent through a number of policy interventions. First, in February 2021, the Cabinet Office published a new version of its Procurement Policy Note which

[61] Medical Devices & Healthcare Regulatory Agency, Guidance, How tests and testing kits for coronavirus (COVID-19) work (13 May 2020). Last updated 7 October 2022: https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work.

[62] UK Health Security Agency, Guidance, Assessment and procurement of coronavirus (COVID-19) tests (3 June 2020). Last updated 22 November 2022: https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests.

[63] UK Health Security Agency, Guidance, National technical validation process for manufacturers of SARS-CoV-2 (COVID-19) tests, Updated 22 November 2022: https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/coronavirus-covid-19-serology-and-viral-detection-testing-uk-procurement-overview.

[64] See, for example, a contract award to Innova Medical Group Inc: https://www.contractsfinder.service.gov.uk/notice/ca07d68e-8f93-4864-9c4b-f24f1e117162?origin=SearchResults&p=2.

addressed some matters raised by audits, investigations, and reviews of certain contracts[65] as well as post-Brexit proposals for reform of public procurement regulation generally, as discussed in more detail in Part III, Chapter 4. This included identification of certain risks of conflicts of interest and risks to value for money which may arise when using direct awards and a reminder to contracting authorities of the possibility of using competition even in direct awards.

2.28. Second, as also further discussed in Part III, Chapter 4, in April 2021,the Government sought to make more and better use of competitive purchasing arrangements. Earlier in November 2020, PHE established a multi-lot national microbiology framework agreement valued at £22 billion but this took time to operationalise with the first contracts being awarded in 2021. Further a lateral flow Dynamic Purchasing System for LFT test kits was established, among others. However, as in the nature of an ongoing emergency, it was not simply a case of discontinuing a practice of direct awards of short-term contracts in favour of competitive awards of longer-term contracts. Direct awards which had been made to cover a period of initial uncertainty were also extended to prevent gaps in provision pending other suppliers coming on stream to meet demand. This included extending direct awards to deal with the new Omicron variant.

2.29. It was also considered whether the Government might orient away from particular reliance on select international suppliers towards increased use of domestic suppliers. By 2021, only a small number of UK based suppliers had been awarded contracts but it appears with relatively limited success, as discussed in more detail in Part III, Chapter 5. For example, Mologic Ltd received a grant to develop a rapid antigen test. The test was accredited with a CE mark for professional use but did not receive approval for use by the public.[66] The Government also announced that it had awarded contracts for the domestic manufacture and supply of LFTs to Omega Diagnostics, according to which DHSC would provide it with equipment and working capital to scale up whilst DHSC selected and licensed the chosen test to it.[67] However, DHSC did not give Omega Diagnostics a licence to manufacture an approved test, manufacture was not undertaken, no orders were placed and the contract simply expired. However, certain UK tests (e.g. by Avacta)[68] have been approved for professional use.

Increasing the Role of Validation for Public and Private Testing

2.30. The national T&T programme focused on tests for use in public settings. In April 2021, the Universal Testing Offer ("UTO") was launched, providing free LFTs via gov.uk, Pharmacy Collect, and some community test sites. Further, in order to continue to meet demand for mass testing, the Government announced the introduction of three new "lighthouse" labs (understood to refer to PCR technology using fluorescent light in virus detection) to process COVID-19 tests, based in Brants Bridge, Gateshead and Plymouth.[69]

2.31. However, by the Autumn, in the COVID-19 Response Autumn and Winter plan 2021, the Government committed to ending universal free provision of LFTs for asymptomatic testing.

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[65] Cabinet Office, Procurement Policy Note – Procurement in an Emergency Information Note PPN 01/21, February 2021.

[66] These events have been reported by various sources although this White Paper does not guarantee their accuracy. For example, information is available at: https://www.360dx.com/business-news/mologic-sues-uk-government-over-sars-cov-2-antigen-test-validation#.ZAXgk3b7TIU.

[67] Information is available on Contracts Finder at: https://www.contractsfinder.service.gov.uk/notice/a3a41480-1751-4b5b-b975-ea52c821cd71?origin=SearchResults&p=1.

[68] Information is available at: https://www.voxmarkets.co.uk/articles/avacta-group-receives-uk-approval-for-affidx-covid-19-test-0fa651e/.

[69] The majority of these mass testing facilities have since been closed given that access to free COVID-19 testing has ended. https://www.gov.uk/government/news/three-lighthouse-laboratories-begin-testing-for-covid-19.

As the UTO was scaled down, the Government expected the private sector to scale up so that individuals who wished to test on a discretionary basis to manage personal risk could purchase tests.[70] It was considered that a strong private market for testing was necessary to ensure international travel and testing by businesses of employees etc. This required tests on the private market to be subject to the same minimum standards for validation so that consumers could be assured of the quality of tests and compare them for use. The need for such tests to undergo validation rather than a self-declaration of conformity was reinforced by the Government's experience that many tests had failed to meet the requirements for validation under the national procurement process outlined above. As discussed in more detail in Part IV, Chapter 7, on 27 July 2021, the Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 (SI 2021 No.910) ("CTDAR 2021") were adopted to require antigen and molecular COVID-19 tests to be subjected to mandatory desktop review to assess their performance before placement for sale on the UK market.

2.32. Testing itself has been carried out by a number of means and has been tracked.[71]

2.33. The Government has stated that it has been difficult to accurately assess the number of COVID-19 diagnostics products on the UK market as there is no requirement for pre-market registration. However, it has reported a reduction in the number of CTDAR 2021 validation applications which could suggest reduced demand and interest in the COVID-19 testing market generally. It has further stated that whilst testing has been an important tool in the response to COVID-19, the public now has stronger protection against the virus through vaccinations, natural immunity, antivirals, and increased knowledge; as a result, COVID-19 testing is likely to play a less important role moving forward with data on the number of reported COVID-19 virus tests indicating a decline in testing.[72]

Other Relevant Regulatory Developments

2.34. As this White Paper has a substantial regulatory focus, for the sake of completeness, it is also necessary to highlight two regulatory developments which, whilst not directly related to the Government and industry's response to COVID-19, may nevertheless be relevant in general terms to IVD procurement in future.

2.35. First, the legal framework governing public procurement in the UK is currently undergoing substantial reform. Until Brexit, public procurement in the UK was mainly regulated by EU Directives, in particular, Directive 2014/24/EU[73] as implemented in the PCR 2015 which largely copy out the Directive. The PCR 2015 apply to contracts exceeding prescribed contract value thresholds. As contracts for IVD test kits were valued at millions of pounds, all or most IVD contracts will have exceeded the contract value thresholds and were therefore subject to the PCR 2015, as discussed in Part III, Chapter 4. Following Brexit, in accordance with the Public Procurement (Amendment etc.) (EU Exit) Regulations 2020 (SI

[70] UK Health Security Agency, Information for providers interested in entering the domestic LFD market: https://www.acs.org.uk/sites/default/files/information_sheet_for_retailers_considering_entering_the_domestic_private_testing_market.pdf.

[71] Information is available at: https://www.gov.uk/government/publications/coronavirus-covid-19-testing-data-methodology/covid-19-testing-data-methodology-note#:~:text=pillar%201%3A%20swab%20testing%20in,from%20having%20had%20COVID%2D19 (this guidance was withdrawn on 12 April 2022). There is now a COVID-19 dashboard which provides relevant information: https://coronavirus.data.gov.uk/?_ga=2.175332583.45913583.1678009598-1272169883.1669301542.

[72] UK Health Security Agency, Research and analysis Statutory review of the Coronavirus Test Device Approvals (CTDA) process, 29 December 2022, p.6. Available at: https://www.gov.uk/government/publications/coronavirus-test-device-approvals-ctda-statutory-review-of-process/statutory-review-of-the-coronavirus-test-device-approvals-ctda-process.

[73] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC OJ L 94/65.

2020/1319), the PCR 2015 continue to apply as "retained EU" law with modifications. Therefore, contracts which were awarded during the pandemic were effectively subject to the same rules as applied under EU law. However, in 2020, the Cabinet Office published the *Transforming Public Procurement* Green Paper ("Green Paper") proposing reform of UK procurement regulation, including changes informed by experience of the pandemic.[74] Many of these proposals feature in a Procurement Bill which is currently proceeding through Parliament and which is likely to enter into force as an Act in Spring 2023.[75] This is likely to result in changes which are at least a general improvement on EU rules regarding procurement during emergencies. Certain reforms could help to address some of the issues which arose in respect of procurement of IVDs during the pandemic. It should nevertheless be observed that the reform proposals address procurement across sectors generally and do not target diagnostics procurement specifically and the potential impact of these reforms on diagnostics procurement should not be overstated. This is one reason why the lessons learnt and recommendations identified in this White Paper do not propose introducing substantial reform of UK public procurement law generally to address specific issues in respect of diagnostics. Another reason is that caution must be exercised against simply proposing new legislation or reform of existing legislation where issues could be more appropriately addressed through policy and process oriented reforms.

2.36. Second, as discussed in more detail in Part IV, both the EU and UK are in the process of reforming medical devices regulation generally, including for IVDs. Again, Brexit did not appear to immediately impact on how medical devices regulation applied in respect of COVID-19 related IVD test kits and transitional measures have further lessoned the impact. However, as indicated, the UK has introduced the CTDAR 2021 which imposes new domestic regulatory controls on approval of COVID-19 test kits which are not related to EU regulation specifically. It will need to be determined if, and how, this regime will be developed in light of changes to wider IVD regulation. It is beyond the focus of this White Paper on procurement to assess the broader reform of medical devices regulation more generally but any future Government and industry dialogue on procurement, validation and approval of IVDs should be cognisant of the potential relevance of the wider medical devices regulatory landscape.

[74] Cabinet Office, "Transforming public procurement" Green Paper CP 353 (15 December 2020). The Government response is available at: https://www.gov.uk/government/consultations/green-paper-transforming-public-procurement/outcome/transforming-public-procurement-government-response-to-consultation.
[75] Information is available at: https://bills.parliament.uk/bills/3159.

PART II:
TECHNICAL VALIDATION

3. NATIONAL TECHNICAL VALIDATION

Introduction

3.1. Validation, that is, the technical process of scientific evaluation of products and the determination of their suitability *for* procurement has been a significant feature of the Government's response to the pandemic.

3.2. Validation appears to have been part of a "rolled up" or "all in one" process by which offers of test kits are both validated and procured together. To explain, ordinarily, a contracting authority might set out in its tender documents a technical specification prescribing that the required product must meet certain technical requirements and performance characteristics; this may be evidenced, for example, by demonstrating that the product has, or will be, validated as suitable by an independent body in a separate process. Therefore, a product will have already been validated or will be before it is ultimately procured. By contrast, in the pandemic, the Government had to procure products which were new or repurposed to meet a novel virus, had not previously been validated, and, in fact, required the establishment of a new validation process. Therefore, in the very early stages, at least, in order to secure test kits and associated technology quickly, it was necessary to procure them *before* they had been validated or for validation and procurement to run concurrently as offers were received. This could even include the possibility of cancelling a provisionally awarded or concluded contract if the product did not ultimately subsequently meet validation requirements.

3.3. As will be discussed, as the COVID-19 pandemic progressed, a national centralised approach was introduced by which suppliers would offer products both for validation and their procurement together in a "one stop shop". The Government does not appear to have published two distinct processes i.e. one for submitting a test for technical validation followed by a separate process for submitting and considering offers of products which have been validated or are in the process of validation (at least under the central nationally administered portal). This combined validation and procurement process has been described as the "national procurement process" even though, as will be discussed, the guidance on this process is, in fact, principally focused on validation not procurement.

3.4. This Part mainly examines this national technical validation process which supports viral detection, antigen and antibody tests pursuant to the national T&T programme. As qualified in Chapter 1, it does not examine any separate validation or verification processes adopted e.g. within the NHS at the local levels, although the effectiveness of any processes for local evaluation should also be a point of further consideration in response to this White Paper. It begins by assessing the six-step process for validation. It then considers published validation process data before examining a range of issues which appear to have arisen in applications.

Six-Step Process

3.5. Before examining the six-step process itself, certain preliminary observations can be made. First, it is difficult to determine how validation was undertaken before the national technical validation process was introduced. As indicated, it is understood that tests were procured and subject to validation processes before a national centralised process was established but there is no reliable published information on procurement and validation in these early stages.

3.6. Second, it appears to have taken some months to formalise a national validation process as it was not until 3 June 2020 that DHSC published the first iteration of its guidance titled *Coronavirus (COVID-19) serology and viral detection testing: UK procurement overview.*[76]

3.7. Third, as indicated, whilst procurement featured in the title to the guidance, the national validation process mainly concerns validation not procurement. As discussed below, the guidance identifies procurement as the final step but does not actually explain the procurement process. Assuming a test meets technical specifications as a result of validation, it does not go on to explain how offers are assessed according to commercial factors e.g. supplier suitability, price and quality. There appears to be no or limited information on the commercial assessment of offers. As indicated, in the absence of a clear identification of validation and procurement as distinct processes, it appears that the process set out for receiving, evaluating and validating products is also a means of soliciting offers and selecting suitable suppliers. Indeed, as discussed below, the guidance has referred to not only triaging offers to determine which products should be given priority for technical validation (e.g. based on likely scientific or technical merit) but also "shortlisting" which could imply a commercial assessment of the most promising offers based on other factors unrelated to scientific or technical merit.

3.8. Fourth, the national validation process actually comprises several routes and processes published on different gov.uk website pages. It can be difficult to discern which is the appropriate route or process in the absence of clear process maps for prospective suppliers or other interested stakeholders keen to understand how validation works. For example, there is a Lateral Flow Device Route and a route for all other technology (on which see below). There is a standard process and an alternative process for non-machine based LFT and home testing kits.[77] Further, antibody test manufacturers are invited to seek independent evaluation of their tests under a national standardised test performance process for SARS-CoV-2 serology antibody tests.[78]

3.9. Importantly, this national validation process has not precluded test developers or suppliers from also supplying tests with relevant regulatory authorisation to UK customers by means other than this national portal.

3.10. The UKHSA is currently responsible for the suite of applicable documents[79] including the validation guidance[80] which was last updated on 22 November 2022 (at the time of writing).

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[76] The earliest versions of the guidance do not appear to be publicly available on the gov.uk website but are available from other sources. The earliest version is available at: https://allcatsrgrey.org.uk/wp/download/public_health/pathology/Coronavirus-COVID-19-serology-and-viral-detection-testing_-UK-procurement-overview-GOV.UK_.pdf.

[77] UK Health Security Agency, Guidance, Protocol for evaluation of rapid diagnostic assays for specific SARS-CoV-2 antigens (lateral flow devices), updated 22 November 2022: https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/protocol-for-evaluation-of-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens-lateral-flow-devices.

[78] UK Health Security Agency Guidance, National standardised test performance process for manufacturers of SARS-CoV-2 virus antibody tests, Updated 22 November 2022: https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/national-standardised-test-performance-process-for-manufacturers-of-sars-cov-2-virus-antibody-tests.

[79] The full list of validation related documents is available at: https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests.

[80] UK Health Security Agency, Guidance, National technical validation process for manufacturers of SARS-CoV-2 (COVID-19) tests, Updated 22 November 2022: https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/coronavirus-covid-19-serology-and-viral-detection-testing-uk-procurement-overview.

Step 1: Registering Interest

3.11. Antigen test manufacturers are invited to complete an online form (still live at the time of writing) for each type of test that they want to supply.[81] However, if the manufacturer has been contacted "proactively" by another Government Department who is already reviewing the offer, the form is not to be filled out unless there is a specific request to do so. This does raise a wider question as to how the Government has solicited offers from manufacturers who have not otherwise made themselves known by registering online, an issue discussed in more detail in Part III, Chapter 4.

3.12. To supply through this route, the test must meet (or be intended to meet where under development), the requirements of one of the relevant MHRA TPPs, although failure does not necessarily mean that a test does not have wider applications for use in the UK.[82] TPPs state preferred and minimally accepted profiles based on intended use(r), target populations and other desired product attributes, including safety and performance and operational characteristics. It is acknowledged that TPPs may require further review and revision as new scientific evidence is generated. The guidance also states that TPPs assist procurement decisions but, as indicated, the guidance does not appear to explain how as a procurement process is not prescribed.

3.13. It should be observed that TPPs were not introduced at the outset. It is understood from interviews that TPPs became necessary as a means of establishing minimum requirements given that a significant number of offers of tests and related technology were received which were not necessarily required at all, not clearly suitable for use, or were not required for particular types of user. Some respondents to the questionnaire expressed concern about the clarity of the initial requirements against which suppliers would be assessed and the need for these to be fixed as far as possible at the outset without the need for updating. According to one respondent, the acceptance requirements initially were not available and when some were published, they were not achievable due to availability or access of samples etc (a matter discussed below). Another commented that the TPP and submission methods need to be fixed early. It was stated that there is ample industry guidance to set a TPP with adequate performance requirements without having to update it regularly, and sample types need not be so stringent if the performance data are adequately defined. This could suggest that, whilst TPPs were an important intervention to help clarify requirements that may only become clear once there has been an initial response from the market, it would be useful if indicative TPPs could be established from the outset or as quickly as possible and then firmly set. Setting clear specifications at the start limits the risk of procuring tests which do not meet a particular use case or, in the worst case, are unusable. Of course, it must be acknowledged that this may be easier said than done in an emergency but consideration might be given in future to ways in which to improve forward planning on specification setting.

3.14. It is also understood from interviews that MHRA played a significant role in developing TPPs. There is no suggestion that MHRA were not the appropriate executive agency to do so and, in the circumstances, the priority would have been on trying to refine the products required to avoid clearly unsuitable offers. However, it might be considered whether or not MHRA should be the appropriate body for setting TPPs. For example, MHRA appears to be primarily responsible for undertaking regulatory approvals and post-market surveillance activity. Its function is not pre-market product specification and validation *for* procurement. Of course, a

[81] This is available at: https://support-covid-19-testing.dhsc.gov.uk/Full-Test-Kit-Covid19.

[82] Medicines & Healthcare products Regulatory Agency, Guidance,
How tests and testing kits for coronavirus (COVID-19) work, 13 May 2020, last updated 7 October 2022: https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work.

body can exercise more than one function at different stages and which may be good for consistency or continuity of decision-making across a process. However, where one body is simultaneously involved in discharging several functions at once in the same process e.g. setting product specifications on the one hand and deciding whether a product should receive regulatory approval for placement on the market on the other, there may be an increased risk of conflicts of interest arising or objectivity or independence being compromised. There are other risks of this kind, one being DHSC acting as manufacturer of a test kit who then relies on its own executive agencies (e.g. the MHRA) to approve placement of its products.

3.15. The online form itself includes mandatory questions which must be completed for an offer to be triaged from among the large volume received. It is stated that these questions capture the main clinical *and* commercial information required although, as indicated, there is little guidance on how commercial information is assessed from a procurement perspective. Failure to complete the questions results in rejection of the submission and a request to resubmit. The submission also requires upload of supporting documents e.g. Instructions for Use ("IFUs"), clinical studies and performance data. Information should be provided directly from the test manufacturers to ensure that the technical information can be confirmed directly with them. Interviews have suggested that there were instances in which suppliers (particularly those new to diagnostics testing without significant knowledge of the industry) simply relied on information provided by manufacturers assuming it to be reliable without undertaking their own assessment. However, interviews have not confirmed whether or not these mandatory questions have provided an effective means of filtering out unsuitable offers early on without the need for further assessment. Further, the guidance does not indicate how responses to mandatory questions are then assessed (e.g. what, if any, criteria guide the assessment) to reach a determination as to whether or not to triage the offer.

3.16. The current guidance also mentions that manufacturers are invited to join the Dynamic Purchasing System which requires registration prior to access. As discussed in more detail in Part III, Chapter 4, this DPS was not set up immediately and did not therefore feature in the initial June 2020 guidance on validation. It is understood that the DPS was introduced to maintain an ongoing supply for targeted testing after the end of universal free testing.[83] This evidences an attempt to rely on more competitive procurement processes having mainly awarded contracts directly without competition in the early phases. In the nature of a DPS, the guidance states that joining it does not guarantee that any orders will be placed with a supplier and it does not constitute a contract to provide goods; only once an invitation is issued and a contract awarded will a contract be formed and will only cover the specific requirement needed by that invitation. It is understood that DHSC internal guidance sets out (in a process diagram) the DPS route by which lateral flow devices are assessed through a Lateral Flow Group ("LFG") separate to TVG.[84] Antibody test manufacturers are also invited to seek independent evaluation of their tests under the national standardised test performance process.[85]

3.17. Finally, it is not necessarily clear if the national validation process was always open for use by everyone in the market. Anecdotally, it has been suggested (but not verified) that, at one point, the triage process for suppliers was closed from around August 2020 (if not before) with no further requirement for applications and that this was indicated in Government

[83] UK Health Security Agency, Research and analysis Statutory review of the Coronavirus Test Device Approvals (CTDA) process, 29 December 2022, p.6.

[84] The accompany process diagram was disclosed to BIVDA but is not reproduced here.

[85] UK Health Security Agency, Guidance, National standardised test performance process for manufacturers of SARS-CoV-2 virus antibody tests, Updated 22 November 2022: https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/national-standardised-test-performance-process-for-manufacturers-of-sars-cov-2-virus-antibody-tests.

guidance at the time.[86] Therefore, it is not clear whether this may have limited opportunities for suppliers to submit tests for validation. Relatedly, as indicated above, if a supplier has not registered through the portal for the national T&T programme, they are not otherwise precluded from supplying tests to UK customers. Therefore, products validated by other means could be sold to other customers provided they had obtained MHRA regulatory approval. This would not appear to preclude those suppliers from submitting through the national portal subsequently. However, the guidance was not necessarily unequivocal as to whether, if the decision was taken not to register on the national portal early on, suppliers would be precluded from registering at a subsequent date. Again, anecdotally, it is understood (but not verified) that there was a perception that if a supplier did not register on the national portal at the outset, they would not be able to supply through the national portal in future.

Step 2: Triage

3.18. A scientific advisor then reviews the online submission and any supporting documents to categorise the type of test and refer it through the appropriate validation and evaluation route. For any viral detection and antigen tests, steps 3-6 below apply. Non-machine based LFT and home testing kits are excluded being subject to an alternative protocol. As indicated, the triage process does not appear to be fully explained in the guidance in terms of the criteria and assessment applied.

Step 3: Initial Review by the Scientific Expert Group

3.19. A member of the Scientific Expert Group ("SEG"), a sub-group of the Technologies Validation Group ("TVG"), initially reviews the online form and supporting documents. This comprises a detailed assessment of the clinical and technical information provided by the manufacturer against the MHRA TPPs. Following the review, tests are deemed to be one of the following: (1) aligned to the current national testing priority needs and progressed for national validation and evaluation; (2) not aligned and held on file for review in case of any future changes to testing needs; or (3) not to currently have the performance and clinical data required to pass triage but where it is recommended that the organisation generates this data. Companies should expect to receive any outcome from the SEG within two weeks but which may be longer subject to the volume of offers being reviewed.

3.20. Again, certain observations can be made about the initial review. As a "detailed" assessment is to be undertaken, there is likely to be a prescribed internal SEG review process to follow. If so, this does not appear to have been published or made widely available. Further, there is no general indication as to how the information received is reviewed (e.g. whether there are any general criteria to be applied beyond those described in the appropriate MHRA TPP).

3.21. In addition, it appears from certain validation protocols that there may be a further process of "shortlisting" but it is unclear what, if any, criteria apply to down-select offers. For example, the non-machine based LFT and home testing kit guidance acknowledges that there are an increasingly large number of commercial lateral flow antigen devices available but that "it is not feasible to conduct large scale evaluations on all of them; current sample resources only allow a limited number of devices for full evaluation."[87] It continues that: "there is therefore a

[86] It is difficult to verify changes made to the guidance over time as it does not appear that all changes are clearly registered on the gov.uk website pages through version control and older versions of guidance do not appear to be publicly available against which to cross-reference those changes.

[87] UK Health Security Agency, Guidance, Protocol for evaluation of rapid diagnostic assays for specific SARS-CoV-2 antigens (lateral flow devices), Updated 22 November 2022: https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/protocol-for-evaluation-of-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens-lateral-flow-devices.

need to shortlist this limited number from many candidates as quickly as possible." However, there are only general statements to the effect that only products deemed by DHSC to have "potential" will be referred. Whilst it is conceivable that suppliers will be informed as part of the initial review process what criteria are applied, it is not immediately apparent to an outside observer (e.g. a prospective supplier) whether the initial review involves an assessment of the "potential" in scientific terms or in commercial terms or both and who makes this decision (e.g. scientific advisors or commercial procurement teams or both collectively).

3.22. It must be acknowledged that in February 2021, UKHSA published that it had concluded a review of the most likely future requirements and use cases for rapid diagnostic assays for antigen LFDs, identifying that the review had enabled UKHSA to develop selection criteria for priority assessment of tests.[88] Whilst helpfully demonstrating how the Government has learnt from its experience in planning for future requirements, this raises the question of what, if any, selection criteria applied before, that there might have been problems experienced in respect of tests submitted previously such as to necessitate additional criteria, and how any criteria might be applied. Further, there may be explicable reasons but it is not clear why it took until 2021 to conduct a review and publish these.

Step 4: Technical Validation and In-service Evaluation

3.23. Offers deemed by the SEG to have met the relevant TPP will be progressed for technical validation and in-service evaluation. Manufacturers will be matched with a validation laboratory and be expected to: (1) provide product samples and all required consumables and reagents free of charge; (2) provide the laboratories with additional relevant technical information; (3) provide the relevant supporting legal documents and non-disclosure agreements, where needed; (4) agree to the results of the process to be made public; and (5) confirm that they have immediate availability of sufficient testing kits to allow further in-service evaluation and can provide sufficient product volumes, including consumables and reagents, with a lead time less than one month from order.

3.24. Technical validation includes, but is not limited to, a bio-safety assessment, lower dynamic range analysis and an initial test accuracy assessment. The information generated at this stage will be compared to the TPP. Products that meet the technical validation criteria may progress to an in-service evaluation. Initially, in June 2020, the guidance indicated that there was no standardised evaluation protocol, but which was to be developed by the National Measurement Laboratory. Standardised protocols have since been developed.[89] In-service evaluation (e.g. in hospitals and care homes) involves tests being performed by the intended user in the relevant setting to develop real-world evidence. This evaluation is tailored to the setting and type of test. It typically includes consideration of whether the equipment requires specialist installation or calibration and usability factors (e.g. does the result require any interpretation and, if yes, how skilled does the user need to be to interpret the result?).

3.25. One observation in respect of the above is that the legal status of validation or evaluation protocols is not clear. This could potentially be relevant were decision-making pursuant to those protocols to be the subject of legal challenge (e.g. if decision-making is exercised outside the scope of any statutory authority conferred by legislation or irrationally etc). As discussed in Part IV, Chapter 6, the Medical Devices Regulations 2002 (as amended) refer

[88] UK Health Security Agency, Guidance, Lateral flow evaluation prioritisation criteria for rapid diagnostic assays for specific SARS-CoV-2 antigens, 8 February 2021. Last updated 2 December 2022: https://www.gov.uk/guidance/lateral-flow-validation-prioritisation-criteria-for-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens#full-publication-update-history.

[89] UK Health Security Agency, Guidance, Technical validation protocol for SARS-CoV-2 nucleic acid detection, Updated 22 November 2022: https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/technical-validation-protocol-for-sars-cov-2-nucleic-acid-detection.

to the Secretary of State's power to issue "protocols" in respect of decisions taken to exempt products from regulatory approvals for placement onto the market. By contrast, there does not appear to be a clearly prescribed legal basis for validation or evaluation protocols.

3.26. Further, it is not clear whether technical validation only appears to require confirmation of the availability of sufficient product for evaluation purposes only or to also confirm that demand can be met for actual use from the date products are ordered. The latter might appear to be a procurement decision based on commercial factors such as capacity to supply in the required volumes to scale following contract award rather than a technical validation decision. Reinforcing the earlier observation, again, it is not necessarily clear who is making what decisions in this regard.

3.27. As discussed in Part III, Chapter 4, contract awards to Abingdon Health plc have been challenged on grounds of irrationality on the basis that the Government undertook an evaluation which was not published and there was not a sufficient assessment of tests before entering into contracts. The challenge failed but the risk remains of legal challenge by suppliers on the basis that unclear or undisclosed criteria are being applied in evaluations. As a matter of good procurement practice, it should be explicitly clear to prospective suppliers whether they are being expected to submit a case for validation, a commercial bid for procurement or both and how those submissions will be assessed in both respects. It may be insufficient for whatever processes and criteria that are applied to only become known (if these are made known) to those who have actually submitted offers and gone through the triage process.

Step 5: Review by the Technical Validation Group

3.28. The TVG reviews the technical validation and in-service outcomes. The TVG comprises a range of experts in technologies, viral testing and infectious disease, including representatives from: (1) the central validation labs (including what is now UKHSA, Frimley, Cumbria); (2) the COVID-19 National DiagnOstic Research and Evaluation Platform ("CONDOR") which tests new COVID-19 diagnostics in various settings (e.g. GP surgeries, care homes, hospitals and laboratories); (3) Innovate UK; (4) academic professional bodies (Royal College of Pathology); and (5) MHRA. The TVG reviews the outcome of all of the validations and evaluations and makes recommendations on the suitability of the solutions and technologies.

3.29. The TVG was preceded by other validation bodies with details emerging from the recent legal challenge concerning contract awards to Abingdon Health plc. It is understood that around mid-March 2020, the Government started to receive offers of antibody tests. A Scientific Advisory Panel ("SAP") was established (comprising Professor Sir John Bell, University of Oxford and members of the MHRA and a DHSC senior civil servant) to assess serological tests and LFTs before any commitments were made to purchase them in large quantities.[90] The SAP was described in evidence "a loose assemblage of scientists" who "did not need to make decisions via any kind of majority or quorum" and who were "simply providing advice to Government".[91] This also included setting up a laboratory designed to evaluate submitted tests. Draft Terms of Reference for the SAP were produced but it is not clear that any final terms of reference were ever approved.[92] A triage box was also set up to receive information about test kits being offered or proposed by interested manufacturers

[90] *Abingdon Health plc* [89].

[91] *Abingdon Health plc* [170].

[92] *Abingdon Health plc* [91]. Further, it is understood that when NTAG's terms of reference were subsequently established, they expressly stated that NTAG provides rapid assessment and "procurement" of new testing technologies. See *Abingdon Health plc* [93].

and suppliers. Sample kits would then be ordered and evaluated if they looked promising.[93] This process appeared to involve a review by the SAP of new and complete testing solutions and new specifications or designs for suppliers for both antigen and antibody testing which had passed initial triage. Recommendations would then be made by the SAP and any new test recommended would be sent to PHE and the MHRA for evaluation and approval. If the products were assessed as high priority, the SAP had the authority to authorise procurement of tests and materials as they saw fit prior to PHE and MHRA evaluation and approval being done.[94]

3.30. It has been acknowledged that at the point that the SAP was involved in proposals for a UK-RTC, it did not have "formal processes in place yet" but that, as time went on it became more organised.[95] At some early stage, whilst technically distinct, the SAP became the New Test Advisory Group ("NTAG") with a larger membership than the SAP and which did include proposed terms of reference.[96] Online form submissions were reviewed by the clinical and diagnostics experts at either NTAG for serology tests or the Viral Detection Tests Approval Group ("VTAG"). The NTAG consisted of representatives from the central evaluation labs (PHE Oxford), Innovate UK, the Government's Serology Taskforce and MHRA, as well as independent scientific advisers and was chaired by Professor Sir John Bell. The VTAG consisted of representatives from the central evaluation labs (including PHE Frimley, Cumbria), Innovate UK and MHRA, as well as independent scientific advisers and was chaired by PHE. It is understood from interviews that the TVG was introduced to provide more rigorous validation than could be provided by PHE for various reasons (e.g. resource, the fact that PHE was not directly involved in establishing the TPPs which became the standard point of reference etc).

3.31. Observations on the nature of TVG validation assessments and data are reserved for discussion below. A number of more general observations about the process may be made here. First, whilst it is acknowledged that the extreme urgency of the pandemic meant that establishing formal bodies with clearly defined roles and responsibilities might not have been possible at the outset and which needed to adapt to the circumstances as they arose, it should be clear who is responsible for making key decisions. Evidence in the legal challenge against contract awards to Abingdon Health plc was that decisions were not always minuted or recorded.[97] The court indicated that a lack of records in this context was not surprising but the fact remains that evidence had to be called to understand what happened at meetings and therefore that lack of records rendered it difficult to verify key decisions.

3.32. Further, as discussed in Part III, Chapter 4, the evidence in the Abingdon Health plc challenge could be interpreted to suggest that it was not necessarily always clear what civil servants were asking scientific advisors to advise on e.g. whether they were to make purely scientific judgements which might inform decisions about procurement or procurement decisions (which could conceivably involve assessments of commercial factors). Whilst it is important to emphasise that there was no finding that any decision-making was unlawful, even in an emergency it would perhaps be a reasonable expectation for the terms of reference for a group to be clear especially where external advisers are being asked to input

[93] *Abingdon Health plc* [90].

[94] *Abingdon Health plc* [91].

[95] *Abingdon Health plc* [140].

[96] Its scope was said to be: "[p]rovides rapid assessment and procurement of new testing technologies for immunity and surveillance. Operating at risk with trusted manufacturers where appropriate. Provides a decision (where required) on the prioritisation of validation (by reviewing the validation master log) and reviews results from validation testing across all UK Testing Labs, agreeing clear next steps. Will also consider novel RNA/DNA tests where they have applicability to key worker rapid testing requirement (non-lab based testing). Where required, this group should consult the Expert Panel to consult on recommendations": *Abingdon Health plc* [93].

[97] *The King (on the application of the Good Law Project Limited) v The Secretary of State for Health and Social Care v Abingdon Health Plc* [2022] EWHC 2468 at [141].

into a procurement process or even make procurement decisions themselves; as indicated the SAP, for example, was given authority to authorise procurement. There also remains relatively limited published information about the TVG in its current constitution. Clear roles and responsibilities which are well-defined and with published terms of reference could mitigate the risk of legal challenges or general complaints about the transparency and accountability of key decision-making.

3.33. Second, the experience of the pandemic might indicate a need for clearer coordination on who should ultimately be responsible for undertaking evaluation. It is understood that testing in the early stages was largely able to be done through PHE but that it became clear that PHE was not set up for a mass scale operation.[98] There was also assignment of different types of testing to different sites which is likely to have posed challenges for coordination e.g. Colindale for PCR assays and Porton Down for antibody assays, in addition to other testing facilities. It is further understood that products required more thorough and quicker validation than PHE could offer. Early organisational challenges may indicate the need for clearer pre-planning and coordination on evaluation in the event of an emergency.

3.34. Third, there may have also been other issues that could have arisen in respect of scientific decision-making underpinning evaluation and validation decisions which could have potentially impacted on market access, competition and treatment of suppliers. It is beyond the scope and competence of this analysis to examine these, although these should be a point of consideration going forward. For example, it would need to be considered what decision-making underpinned the selection of samples and comparators and whether there was a risk of preferences for certain types of assay or other requirement developing which might have pre-determined or favoured certain tests etc.

Step 6: Procurement

3.35. As indicated, the guidance does not address in any detail the procurement routes available to procure test kits (or diagnostics-related contracts generally). In respect of the limited guidance that is provided, there has been an apparent change of emphasis. The June 2020 guidance initially stated that, for technologies performing at the required level against the TPP, a recommendation would be considered to procure the technology at scale for UK-wide roll-out and that "at this point, DHSC's procurement and commercial teams will contact the developer or supplier to discuss the terms under which such a roll-out may occur." There was no specific reference to the use of a competitive procurement process and likely reflects the prevalence of direct awards without competition in the early phases as corroborated in Part III, Chapter 4. Reference to "the terms under which such a roll-out may occur" suggests that additional criteria (beyond meeting the scientific or technical TPP criteria) would be used as part of any "discussion" (in effect, negotiation) to determine whether a supplier should be awarded a contract and the terms of any contract. By contrast, as indicated above, the latest guidance mentions use of the lateral flow DPS in the context of registering interest and appears to be an attempt to introduce coordinated competition into the process. In this regard, it further states that, for those technologies recommended by the TVG that suit use cases with unmet demand, "the DHSC commercial team will invite those developers or suppliers to take part in a competitive procurement either via "mini-competition or via appropriate frameworks". However, the guidance does not provide any further steer as to how any competitive or non-competitive procurement process might generally proceed.

3.36. Finally, the guidance states that commercial and supply chain conversations will commence earlier in the process and happen "in parallel". Whilst not unequivocal, this likely recognises

[98] House of Commons Science and Technology Committee, The UK response to covid-19: use of scientific advice, First Report of Session 2019–21 Report, together with formal minutes relating to the report, HC 136, 8 January 2021.

the reality that validation will happen at the same time that commercial decisions are being made in respect of the supplier and its supply chain. As indicated above, it is sometimes difficult to discern whether commercial and supply chain conversations have featured in decision-making about technical validation as there is no clear separation of the validation process and procurement process nor any detailed explanations of the commercial considerations that may be made.

TVG Validation Data

3.37. It has been observed that accurate, comprehensive information about the evaluation and performance of diagnostic tests is essential to allow the public and clinicians to make informed decisions, to enable policy makers to decide on testing strategies and the procurement and deployment of tests.[99] The Government has creditably published information on validation conducted to date, providing a degree of transparency in this regard and which is considered below.

Products in the TVG Pipeline

3.38. The Government has published a Table indicating the number of products currently in the TVG pipeline. Whilst the national technical validation process guidance in force at the time of writing was updated on 22 November 2022, the list of products in the TVG pipeline is listed as at 11 January 2022.[100] It is unclear whether there is an updated list.

Table 1: Products in the TVG pipeline (as at 11 January 2022)

Status	Number of Tests
In early stages of validation	0
Currently being validated or evaluated	8
Validation concluded or paused	129
Validated technology	24
Total	**161**

3.39. The above would appear to indicate that most products submitted for validation have now undergone validation as none are in the early stages. Importantly, only 24 have been validated which would appear to be low in real terms. As discussed below, there may be any number of reasons why, although it must also be acknowledged that it might be difficult to actually estimate the number of COVID-19 tests expected to be validated in relative terms (e.g. as against other types of test) given that these were new tests responding to a novel virus. Further, the clear majority (129 tests) have resulted in validation being concluded or paused, the possible reasons for which are also explored below.

3.40. There appear to be few other published statistics and no published reports explaining trends in respect of the national technical validation process and the key challenges faced. However, the above findings appear to be corroborated by other sources. For example, it has been recorded that, in the early stages (as at 31 March 2020), all antibody tests submitted for validation from the UK and globally failed.[101] Further, in the Government's

[99] Royal Statistical Society Diagnostic Tests Working Group Report, June 2021, p.58.
[100] The list is available at: https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/coronavirus-covid-19-serology-and-viral-detection-testing-uk-procurement-overview#products-in-the-pipeline-tvg.
[101] *Abingdon Health plc* [108].

consultations on proposals to introduce the CTDAR 2021 for private testing discussed in Part IV, Chapter 7, it reported that some COVID-19 tests did not perform as expected and as disclosed in their IFUs stating that only 25% passed through all stages of DHSC lateral flow validation.[102] It also stated that 277 molecular and antigen tests have been reviewed by DHSC, of which only 58 have passed to the point where they could be considered of sufficient quality for procurement.[103] The fact that only a low number of tests for public use passed the national validation process was considered to be a strong argument against the suggested option of introducing a voluntary validation approach for tests on the private market.[104]

3.41. The Government has also published a Table of products in the TVG pipeline for which validation has concluded or paused. These are listed by TVG reference number, primary use location (e.g. POC, laboratory etc), product type (e.g. lateral flow, PCR etc) and a "high-level justification" for concluding or pausing validation. This lengthy Table is not reproduced here but is available on the gov.uk website.[105] Rather, below, a Table based on this information has been compiled by the author which further breaks down the "high-level" justifications provided into categories and the number of times each justification is cited to gauge a better sense of the main reasons given for concluding or pausing validation. It should be qualified that the justifications are essentially brief explanations. It follows from their generality that some justifications could also possibly mean the same thing e.g. "scaleability" and "resilience" may also cover instances where the product is inadequate "to support DHSC surge capacity" etc. Note that more than one justification may be given in respect of an individual product.

Table 2: High-Level Justifications for Concluding or Pausing TVG Validation

High-level Justification	Number of Times Cited
Supplier non-engagement, difficulty obtaining technical data	18
Processing through alternative route	14
Assay does not provide additional capacity to meet DHSC need	12
Assay does not meet Target Product Profile standards	7
Not ready for market due to stage of development (e.g. at research stage)	6
Supplier withdrew product from validation	5
Multiplex assay and validation sits outside DHSC	3
Biosafety concerns	3
Scaleability	2
Reliability	2
Resilience	1
Commercial reasons	1
Protocol being updated by company to improve clinical performance	1
Little differentiation between negative reaction and presumes positive result, and low throughput	1

[102] UK Health Security Agency, Consultation outcome, Private COVID-19 testing validation, updated 14 February 2022, p.6: https://www.gov.uk/government/consultations/private-coronavirus-covid-19-testing-validation/private-covid-19-testing-validation. Similarly, see UK Health Security Agency, Validating COVID-19 tests in the private market 19 October 2021 (Impact Assessment) which stated at p.6, para.1, fn2 that approximately 114 products have been through TVG the validation process and only 14 have been validated. This is similar for LFD validation, where 101 have gone through the validation process and only 20 validated.

[103] Impact Assessment, p.11, para.28.

[104] Impact Assessment, pp.18-19, paras.55-63.

[105] The Table can be found at: https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/products-in-the-pipeline-tvg-validation-concluded-or-paused.

Product already being supplied by another distributor	1
Manufacturing concerns	1
Significant transportation concerns	1
Use cases restricted and not adding any additional testing capacity	1
Limited use case due to clinical performance and assay being laboratory	1
Solution not viable within timelines required to support DHSC surge capacity	1
Validation paused to clarify assay performance	1
Contradictory statements in the IFU on the assay	1
Concerns of throughput	1
Concerns over the amount of equipment required	1
Requires CE mark	1
Concerns over extensive manual pipetting requirement being prone to error	1
Inconsistencies between sensitivity and specificity	1
Product irregularities (turnaround time, too complex, high error probability and associated costs)	1

3.42. Building on earlier observations, some of the above justifications may look less like the outcomes of scientific decision-making and more like commercial or procurement specific justifications e.g. “scaleability”, “capacity”, “manufacturing concerns” and “commercial reasons”. It is possible to put forward the argument that decisions about the validation of a product can go hand in hand with decisions about procuring it and some decisions may involve a degree of overlap. However, the above does not provide a clear indication of who has made such determinations. If it is not the TVG, an alternative possibility is that someone other than TVG (i.e. a member of a procurement team) has made an assessment that the product cannot be procured on the basis of a commercial justification (of the kinds above) which results in pausing or concluding a concurrent validation process. Whatever the position, the above are not exclusively validation-based justifications, it is not clear from the guidance the process by which certain of these justifications are made, and the justifications themselves are somewhat vague. The upshot is that it is difficult to know whether prospective suppliers should be submitting a scientific case for validation or a commercial bid or both at the same time and there is little insight from these justifications as to the precise reasons why validation has been concluded or paused.

Other Published Validation Outcomes

3.43. The Government has also published a range of other data. One example is publication of the results of certain product reviews, the first being in respect of the ELISA test.[106]

3.44. Another example is published information in respect of the first wave of non-machine based LFTs. It is understood that since its establishment in August 2020, UKHSA Porton Down and the University of Oxford antigen test validation cell has evaluated over 160 lateral flow devices referred by DHSC. Approximately 30% met the standards for phase 2 validation set out in the protocol for evaluation of rapid diagnostic assays for specific SARS-CoV-2 antigens. The Government has published a Table summary of lateral flow devices that have passed phase 3a validation from 11 September 2020 (being the earliest) to 30 June 2022 and which is not reproduced here.[107] The Table only identifies the pass status (not whether

[106] This provides a link to an article titled Antibody testing for COVID-19: A report from the National COVID Scientific Advisory Panel. Available at https://www.medrxiv.org/content/10.1101/2020.04.15.20066407v2.

[107] UK Health Security Agency, Guidance, Outcome of the evaluation of rapid diagnostic assays for specific SARS-CoV-2 antigens (lateral flow devices), updated 22 November 2022, Table 1: summary of lateral flow devices that

any have failed) and the date the evaluation was completed. In summary, at the time of writing, 50 evaluations have been completed in total. The earliest to receive completed evaluations were Innova / Xiamen Biotime (11 September 2020), Orient Gene / Healgen (2 October 2020), Fortress Diagnostics (12 November 2020), Roche SD Bisensor (2 December 2020) and Surecreen (2 December 2020). As discussed in Part III, Chapter 4, a number of these tests were directly awarded contracts without formal competition.

3.45. The Government has also published the first wave of PHE laboratory assessments of molecular tests from 4 June 2020 to 22 February 2021.[108] A summary report for each laboratory assessment is published alongside a series of individual assay assessments.

3.46. Finally, the Government has published a list of validated technologies including validation reports which can also be accessed through the national archive.[109] As indicated, it is beyond the scope of this White Paper to examine the scientific decision-making and determinations underpinning evaluation and validation reports.

Issues in Respect of Validation, Evaluation and Process Application

3.47. Whilst, as indicated, certain data and evaluation report information has been published, the Government has not published any form of interim or other reviews of the national or other validation processes which "take stock" of how these have been applied. It is therefore difficult to gain better insight into the challenges facing validation design, what a good or bad submission for validation looks like, the specific reasons why so many applications may fail, and what could be done by the Government and industry to improve the process. As discussed below, some independent working group studies have provided brief insight into evaluation processes but it has also been necessary to obtain further information through interviews and questionnaires. At the outset, it must be cautioned that views expressed may not be representative of all experiences and what follows only identifies an illustrative list of the issues.

3.48. To put the following analysis in context, it should be acknowledged that neither the Government (and its executive agencies) nor industry had extensive experience of undertaking validation of the kind required in the pandemic and it was a learning process for both. The validation models adopted by Government are necessarily experimental; as will become evident in Part IV, Chapter 7, the CTDAR 2021 regime builds on the experience of the national validation process but even this regime is not necessarily settled on the best model for undertaking validations. Further, whilst industry might argue that it does have relevant experience of validation, many within industry would also probably readily acknowledge that experience has mainly been in the area of professional use tests for laboratories not self-tests for use at home and so suppliers have been used to validating products for a different kind of market. In which case, Governmental processes and industry responses may not have been adequately geared for validation and which may have affected expectations of, and approaches to, the exercise.

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have passed phase 3a validation: https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/outcome-of-the-evaluation-of-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens-lateral-flow-devices.

[108] Public Health England, Research and analysis, COVID-19: PHE laboratory assessments of molecular tests, 4 June 2020, updated 22 February 2021: https://www.gov.uk/government/publications/covid-19-phe-laboratory-assessments-of-molecular-tests.

[109] UK Health Security Agency, Guidance, Coronavirus (COVID-19) serology and viral detection tests: technical validation reports, 7 December 2020, updated 18 February 2022: https://www.gov.uk/government/publications/coronavirus-covid-19-serology-and-viral-detection-tests-technical-validation-reports.

3.49. Turning to the questionnaire and interview responses, the questionnaire asked: "to what extent do you believe the TVG validation process has been a success in response to COVID-19?" There was a low response rate and results appear to be mixed. 50% considered it to be completely or relatively unsuccessful (2 completely; 5 relatively). 5 were neutral and 2 indicated it was moderately successful. Participants were also asked to provide any comments on ways to improve validation processes. Ultimately, the questionnaire did not reveal any significant criticism of the TVG validation process (in contrast to the CTDAR regime discussed in Part IV, Chapter 7). For instance, one questionnaire participant stated that the TVG process was fit for purpose. They noted, in particular, that there was communication between the TVG and suppliers which led to a better understanding of the rationale underpinning the requirements and that the chance to have discussions with TVG members helped both sides understand the issues and proposed solution. Another said there was good communication and that TVG felt closer to the reality of the laboratories so there was open discussion and collaboration. This analysis now turns to consider interview responses which comprise a mix of views from the perspective of those undertaking validation and those within industry submitting products for validation.

3.50. From the perspective of validation bodies, it is first important to acknowledge that interviewees working within validation bodies emphasised that the process did work: there were suppliers who did meet validation requirements and validation did prevent poor performing tests from being procured which could have created public health risks. Therefore, industry will need to acknowledge that whatever responsibility the Government might bear for any process-related issues impacting suppliers' ability to meet validation requirements, industry also bears a degree of responsibility for failure to meet validation requirements. As indicated, the main justification given for pausing or concluding validation was that industry failed to sufficiently engage with Government and the Government were unable to obtain technical data. This is corroborated by the Impact Assessment for the CTDAR 2021 which states that the desktop review stage of the validation process already in place had:

> shown that a significant number of manufacturers have undertaken minimal work to collect evidence on the performance of their device. The evidence initially provided in their applications has often fallen short of the requirements set out in the TPPs both in terms of quality of the evidence and the number of samples used to evidence that the device can detect the sample.[110]

3.51. Therefore, in the first instance, tests appear to have failed because of human rather than scientific factors, namely lack of engagement with the process or providing inadequate information. Obviously, these factors should not be a principal reason for failure. It is unclear the underlying reasons for a lack of engagement not only at the outset (which might be explained by a period of mutual adjustment to a new process) but which persisted. This should be a point of reflection within Government and industry.

3.52. Interviews have suggested that one possible factor to consider may be the diversity of applicants for validation. It has been identified that there were essentially two camps: established diagnostics companies (albeit that these had to transition from supplying mainly professional use tests to self-tests) and suppliers who had no or limited previous experience with diagnostics. For example, a review of the CTDAR 2021 regime discussed in Part IV, Chapter 7, has stated that anecdotal evidence provided by CTDA officials and industry stakeholders suggested that, during the early stages, a number of manufacturers pivoted to the diagnostics industry to capitalise on the sudden peak in demand for COVID-19 testing devices; based on the number and quality of initial applications, there was a view that a lot of applicants were new to the sector and struggled with submitting either the correct evidence

[110] Impact Assessment, p.19, para.61.

to support applications, or devices of suitable quality.[111] Further interviews have suggested that there was possibly a degree of naivety on the part of new suppliers, in particular, regarding their knowledge of requirements and what validation processes involve. It was also observed that a number of suppliers may have found tests from manufacturers or other suppliers based in other countries which they proposed but did not have their own internal scientific personnel or processes to undertake their own checks with an overreliance on information provided by the manufacturer or other third parties at face value. This may have complicated the ability to clearly communicate with such companies and assess tests. It has been observed that if validation bodies only had to deal with established suppliers, processes would likely have been more straightforward and there may not have been any need to introduce the more heavily regulated CTDAR 2021 regime.

3.53. Notwithstanding issues experienced with new suppliers, the fact that a majority of tests failed validation suggests that established suppliers also encountered difficulties for various reasons. Again, interviews have indicated that a number of general problems were encountered, the following being illustrative not exhaustive.

3.54. According to interviews, one apparent difficulty was the transition from offering professional use tests to self-tests. It is understood that a number of companies were geared to test their own tests in professional use settings. However, one interviewee stated that evidence may suggest that the performance of tests reduces when not done by a professional user. Therefore, whilst it is possible to claim that a test has a certain percentage sensitivity or specificity when used by a professional user, it may not when used by a lay person. This may render it difficult to verify whether the level claimed (in a professional use setting) will be the case in a self-test setting. This may impact whether the test meets requirements.

3.55. Another apparent problem was the low sample numbers offered by suppliers e.g. providing a low sample range among a limited group selected by the supplier bearing in mind the need for tests to be used on thousands of people. To be clear, it is understood that the ability to produce sufficient sample numbers was not necessarily or always a fault of industry. Interviewees reported that there was an issue of sourcing samples for everyone (e.g. TVG, manufacturers and researchers experienced similar difficulties) given that so many were attempting to get tests validated. It is also understood that there was a shortage because of the focus on sourcing samples for vaccination studies given that this would be the optimal solution to the pandemic.

3.56. Yet another issue appears to have been the difficulty of judging the limit of detection ("LOD"). The LOD is defined as a measure of the lowest concentration (smallest amount) of the viral target (protein or RNA) which can be reliably identified in a sample and with a high degree of confidence. Usually, the LOD refers to the amount detected at least 95 times out of 100 attempts (95% probability of obtaining a correct result).[112] Interviews have suggested that one problem was a lack of available materials required to dilute down to find the lowest concentration. This meant that sometimes the wrong materials were used. Further, it is understood that there was a risk that different methods for assessing LOD were being used across tests which could potentially distort results. For example, an extractive molecular assay takes DNA from a sample which is concentrated down and amplified up to make it as easy as possible for the test to detect whereas in the case of a direct molecular assay, the concentration process is not applied rendering the process easier. However, if, in assessing LOD for a direct assay, the direct assay uses extractive materials (which involve concentration), it could make the direct assay look better than it is in detection terms because the sample has been concentrated down before being put in the direct assay. This is

[111] Statutory review of the Coronavirus Test Device Approvals (CTDA) process, p.18.

[112] UK Health Security Agency, Technologies Validation Group: using tests to detect COVID-19, 17 June 2021 (last updated 19 October 2021).

problematic when it comes to applying the test in practice where the concentration step is not used leading to unclear LOD results.

3.57. Another issue concerns analytical specificity, that is, a test should only detect what it is required to test. A number of tests will potentially detect SARS Cov-1 in addition to SARS Cov-2. Interviews have indicated that this was permissible given that SARS Cov-1 was in limited circulation. However, there was a risk that tests could also detect other viruses e.g. flu which could lead to giving false positive results for COVID-19. Interviews indicated that a number of companies were not able to provide clear information on what tests should not detect.

3.58. A final example of an issue identified in interviews is the distribution of viral loads. To explain, viral loads may differ across symptomatic and asymptomatic people. It cannot be assumed that a symptomatic person would necessarily have a higher viral load than an asymptomatic person. A symptomatic person may have a low viral load and an asymptomatic person may have a high viral load or *vice versa*. In clinical settings, for example, there would be symptomatic and asymptomatic people presenting themselves to medical professionals whose viral loads could not be known in advance. However, it is understood that some suppliers apparently indicated that their test could only be used on those with high viral loads. If a test to demonstrate sensitivity is based on a sample of 100 people but they all have high viral loads, the test may be more accurate more of the time. The difficulty is that, as indicated, different people have different viral loads which cannot be known in advance and a test would need to be used for both symptomatic and asymptomatic people. Therefore, there was a need for samples to represent a distribution of viral loads as would be the case in practice but these were not provided.

3.59. Other bodies involved in validation have also identified problems that arose early on in respect of tests meeting requirements in particular settings. For example, a presentation given by CONDOR identified a survey which revealed that in the first six months, the settings with the greatest unmet need for diagnostics were healthcare and hospitals. It observed that data was limited in terms of: (a) lack of descriptive information on the patient population sources of samples used for evaluation; (b) use of samples from patient populations which were likely to magnify spectrum effects (i.e. hospitalised patients vs health controls); and (c) absence of evaluation across a range of viral loads, or lack of this descriptive information (e.g. CT values or comparator assays). It also identified what would be beneficial, namely: (1) a need for better safety demonstration i.e. for manufacturers to include evidence of viral inactivation in the IFU and to assess the safe use of their tests and equipment (e.g. robustness of tube sealing, and if open tubes are used, what has been put in place to prevent spills); (2) user designation – manufacturers should consider that in some settings, CE marking for professional use only may be very restrictive; (3) training for non-healthcare professionals regarding use (e.g. in care homes); and (4) sampling – some required large amounts of sputum collection which was difficult to produce if unwell and the need to rationalise the volume required to improve usability etc.[113]

3.60. From the perspective of industry, there may be unfavourable perceptions of the quality, consistency and transparency of validation decisions. To give an example, it has emerged from the legal challenge against contract awards to Abingdon Health plc that Abingdon challenged *inter alia* PHE's evaluation methodology in respect of antibody tests. More specifically, the Chairman of Abingdon stated that PHE compared the performance of Abingdon's LFTs against one produced by Roche but which was incomparable on the basis that the Roche assay was for total antibodies to the nucleocapsid protein and not the spike

[113] COVID-19 Task Force Meeting, CONDOR identification of clinical needs and observations of reviewed diagnostic tests for SARS-CoV-2, presentation 06/11/20 (disclosed to BIVDA and retained on file).

protein and had a smaller number of serum samples as well as a lower sensitivity.[114] As discussed in more detail in Part III, Chapter 4, there was similar uncertainty in respect of MHRA's evaluation of Abingdon's antibody test. The court was not able to comment, observing that the Government and supplier blamed each other in respect of the process and outcomes and that there were disputed accounts.[115] Further, Mologic's application for validation was rejected by Porton Down on the basis of a 60% failure rate. It is understood that Mologic requested Porton Down to evaluate their test with an independent third party observer which was refused. A Freedom of Information request was also submitted to determine details regarding when it first failed validation but it is understood that UKHSA could not disclose this information.[116] Mologic issued a pre-action letter with a view to commencing legal action alleging that there was a "potentially misleading laboratory-based evaluation for assessing rapid tests.[117]

3.61. This White Paper cannot verify or substantiate any claims about the conduct of evaluation processes. However, an interview with an industry supplier suggested that known challenges made by suppliers to evaluations and a perceived lack of open communication in respect of validation outcomes may have impacted industry confidence in the quality and transparency of validation processes generally. It is not clear what, if any, adverse impact this may have had on industry engagement when submitting applications for validation.

3.62. Respondents to the questionnaire also identified some issues which, again, are illustrative only and may not be wholly representative. In general terms, several perceived a general lack of transparency of the validation and evaluation process necessary to ensure a fair and consistent approach which corroborates the observations above. One stated that processes appeared to be guided by the larger manufacturers. Another stated their perception that "favourites" were selected by the TVG although no explanation was provided to support this perception.

3.63. Some also expressed concern with the requirements for evaluation. For example, it was stated that sensitivity and specificity requirements were "way too high" and "not necessarily appropriate for clinical decisions". It was suggested that the number of samples required was unnecessarily high considering the difficulty of sourcing samples for evaluation at short notice. It was also stated that diagnostics criteria for comparator assays were too restrictive. Further, performance characteristic templates were not considered suitable for non-PCR assays. As indicated, it is beyond the scope of this White Paper to examine what is and is not appropriate in scientific terms.

3.64. Concerns were also raised about repeated updating of the process. One respondent stated that regularly updating and changing the submission process causes confusion and frustration and that it should be fixed; the fact that it was different each time they tried to submit and no guidance given as to the precise requirements meant each time the process halted as they came across an unexpected change. It is not clear whether this was a reference to the TVG or other validation processes given that the TVG process has remained fairly consistent and it must also be acknowledged that processes will necessarily have to be revised as experience develops and requirements evolve.

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[114] *Abingdon Health plc* [243].

[115] *Abingdon Health plc* [245].

[116] Request by Stefan Garrett, ref: 29/11/21/kl/1843, 2 February 2022. Available at: https://www.whatdotheyknow.com/request/812795/response/1965802/attach/4/1843%20FOI%20Date%20of%20failed%20validation%20of%20specific%20LFD.pdf?cookie_passthrough=1.

[117] J Lubbock, 'UK COVID Testing Dependent on Imports Despite British Companies Being Available To Do the Same Work', *Byeline Times*, 20 August 2021: https://bylinetimes.com/2021/08/20/uk-covid-testing-dependent-on-imports-despite-british-companies-being-available-to-do-the-same-work/. The contents of this article have not been verified by the author of this White Paper with the quotation extract as reported.

3.65. Another respondent indicated that the process was overly bureaucratic and slow. Some considered that more resource and funding was necessary to fully complete the required validations in an appropriate time period. Similarly, one indicated that a way to improve would be to engage more laboratory medicine and MHRA professionals with the relevant expertise. However, there appeared to be fewer comments on resource in respect of TVG review than the CTDAR 2021 regime which is discussed in more detail in Part IV, Chapter 7.

3.66. A final issue concerns a perception that informal preferences might have developed for certain types of validation which could have influenced procurement choices. To explain, BIVDA, for example, submitted a Freedom of Information request to better understand whether certain test kits were identified as "preferred" for use because they had undergone a particular validation.[118] It was its understanding that there had been instances in which NHS laboratory customers had been told that they may not buy products from certain suppliers because they had not been validated by PHE and that products which had been sent for evaluation at PHE Colindale had not been completed or were still awaiting a response. BIVDA therefore asked *inter alia*: (1) Why has PHE "recommended/imposed" particular kits without evaluating others? and (2) What criteria was set and how were they evaluated? In response, DHSC confirmed that it is not PHE policy to block use of particular products by the NHS, that PHE does not have any authority over NHS purchasing decisions and PHE has not issued any such guidance to the NHS. It reiterated that PHE's assessments of commercial assays are conducted primarily for its own purposes as set in a prescribed process.[119] PHE was not aware of any supplier who had not received feedback. Therefore, there was no indication that there was any particular "preference" for products to have undergone a particular validation in order for them to be procured. Notwithstanding, it is important to safeguard against any "predetermination" that certain assays or tests validated by particular bodies should be used given that this can effectively impact on the market and buyers and customers should be wary of expressing any such preference.

3.67. Ultimately, the Government introduced a functional process which led to the validation of key tests and technologies and the rejection of tests which did not meet technical requirements. This White Paper cannot make assessments about the scientific decision-making underpinning validation decisions nor speculate as to whether validation processes resulted in preferential treatment of certain suppliers. Nevertheless, the above has identified a range of illustrative issues which should prompt further policy discussion around how validation processes operate in an emergency and should operate generally going forward.

Lessons Learnt and Recommendations

3.68. As indicated, it is beyond the scope of this White Paper to examine the scientific decision-making which underpins validation and approvals processes. In any event, other scientific studies have already examined approaches to evaluation of COVID-19 IVD tests, an example being the Royal Statistical Society's analysis which has identified lessons learnt based on considerations of good study design for evaluation of diagnostics tests.[120] It is interesting to further observe that the Royal Statistical Society also identified a number of "regulation matters" and recommendations for regulatory reform.[121] This is an important indication of the value of cross-disciplinary engagement in developing diagnostics procurement policy going forward.

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[118] BIVDA, Request for Information relating to awards for contracts without a call for competition, sent to Department of Health and Social Care, 6 August 2020. Provided by BIVDA and retained on file.

[119] Department of Health & Social Care, Contract Award Notices – Request for Information response, 17 August 2020. Provided by BIVDA and retained on file.

[120] See, in particular, Royal Statistical Society Diagnostic Tests Working Group Report, June 2021, Section 5.

[121] Royal Statistical Society Diagnostic Tests Working Group Report, June 2021, Section 6.

3.69. This Section identifies just some possible recommendations for improving validation processes as these relate to IVD procurement. As indicated, it is no more than a starting point for triggering a wider debate and more specific recommendations from those on the frontline.

✓ Review the centralised validation model and formalisation of roles and responsibilities

3.70. Before the pandemic, there was no national centralised system for medical device validation, in particular, for infectious diseases. From a user perspective, the national technical validation process is an innovation, providing a uniform means of evaluating products for use by others. For example, the NHS may rely on it as an authoritative source of validation which can then be supplemented with local verification. This model has also provided important learning for the establishment of other centralised models, a prime example being the CTDAR 2021.

3.71. However, it is recommended that the Government **conduct a comprehensive review of the set up, mobilisation and performance of the national technical validation process** to better understand the challenges and opportunities for this sort of centralised model being introduced for future emergencies. As the CTDAR 2021 regime has already been the subject of a statutory review, it would seem appropriate to undertake the same in respect of the national technical validation regime.

3.72. From a design perspective, as discussed in Part IV, Chapter 7, as the CTDAR 2021 regime was set up by legislation, there is a statutory requirement to undertake a review of the regime's operation. By contrast, the national technical validation process was set up ad hoc and does not have an express statutory underpinning. It follows that the Secretary of State's powers and the ability to adopt protocols in respect of validation are not explicitly prescribed although the exercise of powers pursuant to any protocols or other guidance are nevertheless subject to general legal constraints e.g. under public law (such that decision-making might be determined to be unreasonable or irrational) or possible public law duties (such as to comply with prescribed policies unless there is a good reason to depart from them). Therefore, going forward, **it may be considered whether the national validation process or something of its kind should be put on a basic statutory footing**. At present, it may now seem inconsistent that there is a statutory CTDAR 2021 regime which, whilst technically a regime on regulatory approvals for placement on the market (being an amendment to the Medical Devices Regulations 2002), is, in part, a derivative of the national validation process but the national validation process remains largely legally unregulated. There may be arguments for and against but which ought to be considered. It is suggested that this could be done as part of the wider-ranging review of UK IVD regulation. In any event, it would be useful to **clarify the legal status of different documents which are titled "protocols"** as well as the intended legal effect or not of the ad hoc process related guidance relating to validation which has been published.

3.73. From an operational perspective, as indicated, it appears that the national technical validation process was not stood up until at least August 2020. Before this time, it is a matter of record that products were being procured before they had been validated, it is possible that products may have been procured without proper validation at all, and that it was necessary to formalise validation centrally. There is a risk of products being procured which then fail to meet requirements for the relevant use(r). Therefore, it is recommended that a review of the national central validation model should **identify ways in which centralised validation can be introduced more quickly as a targeted response to an emergency**.

3.74. Relatedly, there is the issue of establishing and coordinating the right bodies to undertake validation and evaluation of tests. The TVG was the product of earlier iterations but the roles and responsibilities of validation bodies were not formally defined and allocated at the outset. In terms of who was responsible, it appears that PHE were initially assigned a major role but it was necessary to reassign certain functions. Further, the TVG was preceded by earlier iterations without any formal terms of reference. Moreover, MHRA had to assume a role beyond market surveillance. There is a risk of organisational issues arising in respect of validation which may impact procurement itself. As soon as those bodies become involved in procurement decision-making either in advising those making procurement decisions or making procurement decisions themselves, there is a risk of decision-making being subject to legal challenge under UK public procurement law and related public law. It is therefore important to have absolute **clarity on who is exercising what decisions under clear terms of reference with clearly defined and delimited responsibilities**.

3.75. From a mobilisation perspective, again, there may be any number of issues that could arise. For example, anecdotally, it has been suggested (but not verified) that it was not always clear how the national technical validation process operated alongside other validation and verification processes. Further, it has been suggested that it was not necessarily always clearly communicated which validation processes were open or not and/or remain open and whether there were any implications if a choice was made by a supplier to enter the national validation process or not at particular stages e.g. being precluded from offering tests elsewhere. Therefore, **it should be considered how validation processes are communicated and opened up for access by suppliers**. In addition, as indicated, and as discussed in more detail below, there has also been uncertainty regarding the nature and form of policy guidance published in respect of the national technical validation process which could affect how effectively the national technical validation process is implemented.

3.76. As discussed below, recommendations for interim or other reviews of the national technical validation process could reflect not only on practical issues of implementation (i.e. how validation submissions have been processed and assessed to improve the process) but also on how the entire system is designed.

✓ Develop clear Target Product Profiles as early as possible

3.77. As indicated, this White Paper does not assess the scientific judgements which underpin validation policies and processes. However, for the sake of completeness, it should be acknowledged that it has been recommended that TPPs should be reformed. For example, the Royal Statistical Society has stated that **the role of the MHRA in defining suitable TPP "reference standards" (i.e. the test(s) used to classify individuals according to whether they have the target condition) is an issue for consideration**. It recommends that scientific methods should be reviewed and developed to help regulators create TPPs that describe the characteristics and required performance of an IVD for a particular intended use. [122]

3.78. This White Paper adds further recommendations. Perhaps more fundamentally, **it should be considered whether MHRA is the appropriate body to take the lead on setting TPPs**. Ordinarily, the MHRA has a market approval and post-market surveillance role. However, during the pandemic, it was involved both in establishing the pre-procurement parameters for tests through TPPs (effectively product specifications and performance characteristics) but also in regulatory approvals or exemptions for their placement on the market. There is no evidence or suggestion that MHRA was conflicted in these roles but a multi-faceted role does create the risk of institutions "wearing too many hats", being overburdened with

[122] Ibid, pp.56-57.

responsibility and the implications for resourcing. Consideration might be given as to whether an independent or at least specifically designated body should be set up to establish TPPs.

3.79. Further, whilst easier said than done with the benefit of hindsight, **there could be earlier planning and introduction of TPPs in an emergency**. TPPs appeared to have been a reaction to test kits being offered without clear use cases, intended users and performance. Consistent with the above recommendation, **a designated body could be tasked with establishing standing or working TPPs for a range of diagnostics tests and services** so that characteristics and required performance for a specific intended use are clear. As has been observed elsewhere, it can be challenging to ascertain the performance for a test that will make it fit for intended use such that research methods to support this task are required.[123] A designated body with a dedicated research team could develop TPPs for certain at-risk diseases and viruses.

✓ Improve the Clarity and Quality of Validation Process Guidance

3.80. First, it is recommended that, as a matter of form, **the Government should publish a consolidated user guide on validation as a single point of reference** where all key information can be found. As indicated, the national technical validation process guidance currently comprises individual gov.uk websites which suppliers and other interested stakeholders are expected to navigate to determine the appropriate route (and associated protocols) and then the various phases and stages within a route. As a result, it is necessary to piece together information. This can impact on the visibility, transparency and accessibility of a process, especially in an emergency where ease of reference is critical.

3.81. Relatedly, it is recommended that **guidance should include more process mapping diagrams and documents**. At present, the guidance is narrative and linear in its explanation of key processes. As indicated, it is understood that the Government has developed internal process diagrams for key validation routes within the national validation process (e.g. TVG and LFG). It is not clear whether there is any good reason for not publishing these as standard as part of the guidance as they do not appear to contain confidential or other sensitive information (for public health or commercial reasons). Further, process diagrams for phases and stages within each of these routes could be developed which would break processes down. These might also help clarify how prioritisation, triaging and shortlisting is undertaken including any indicative criteria. Other commissioned reviews of procurement during the pandemic (e.g. the Boardman Review) have made recommendations to similar effect in respect of public procurement in an emergency generally.[124]

3.82. Second, it is recommended that **certain aspects of the validation guidance could also be improved in substance**. A non-exhaustive list may be provided here. One aspect is clarification of roles and responsibilities in respect of validation and procurement and how the validation and procurement processes relate and are distinct. As indicated, it is often difficult to discern who is making technical validation decisions and who is making commercial decisions. This is necessary for suppliers to better understand the nature of the application being submitted i.e. an application for technical validation or a commercial bid for a contract or both. Similarly, officials and advisors who are not procurement specialists may nevertheless have potentially important roles to play in respect of procurement (e.g. being best placed to advise on the Government's scientific requirements and how these can be met) such that guidance could better clarify their roles in the procurement process itself, if any. More generally, this would increase transparency and accountability. In addition, it could also mitigate some of the adverse risks of legal challenge where the role of key decision-makers and decision-making is not clearly spelled out.

[123] Ibid, p.55.
[124] Boardman Report on Cabinet Office Communications Procurement, 8 December 2020, p.1, para.6.

3.83. Another aspect concerns the criteria used for assessment and, more generally, an indication of how information is assessed. Inevitably, there may be ways to improve the guidance in terms of the nature and type of information that should be provided. Perhaps more importantly, one possible issue with the current guidance is that it requests a lot of information but does not always clearly explain why it is required and how the information is to be assessed not only according to TPPs but any other criteria. It is likely the case that validators and procurers will have internal process guidance including criteria on how information received should be assessed. It is not necessarily recommended that all internal guidance or the full criteria or factors used for assessment should be published. It is important to ensure that the Government's discretion is not unduly fettered or exposed to unnecessary legal risk on the basis that it could be held to criteria which may need to be applied flexibly or modified, a consideration which is especially relevant in cases of emergency where decisions must be made quickly and decisively. Moreover, there may not be any legal obligation to disclose such criteria in advance. However, there may be a risk of legal challenge in cases where there are undisclosed criteria or that offers have been prioritised for assessment which could result in preferential treatment. Therefore, **guidance could at least identify an illustrative and non-exhaustive list of indicative factors which inform decisions about how submissions or offers are assessed and what a shortlisting process (for example) might entail**. Realistically, this might only marginally improve decision-making but is also a simple and effective means of providing greater certainty and transparency.

3.84. Finally, as recommended in Part III, Chapter 4, there is **a need for more and clearer guidance on the procurement process** itself. As indicated, the national validation guidance purports to address a procurement process but does not actually provide any guidance on how contract award processes are conducted, an observation that is also made in respect of how contracts for PPE were awarded. At present, the very short section on procurement in the national validation guidance looks anomalous when it has been titled a procurement process and otherwise sets out fairly detailed protocols for validation but not procurement. At the very least, given that later guidance includes express reference to the LFD DPS arrangements, there could be expanded guidance on how this particular process works.

✓ **Improve communication and transparency by publishing reviews and interim reports**

3.85. As indicated above, it is recommended that the Government should undertake a formal Departmental review of how the centralised national technical validation model has operated; this should focus on the appropriateness the model and key design elements. It is further recommended that, in future, either as a matter of general practice or at least in times of emergency, **the Government should publish at least one interim or provisional "stock take" review of the practical operation of validation processes**. A key theme which predominates throughout this White Paper is a need for improved communication. As indicated, the main reason why validations have been concluded or paused and not progressed is industry failure to engage with the process and provide the required information. Engagement might be improved at least in part by better communication on the Government-side. Whilst it is possible that the Government may have communicated fully with individual suppliers in respect of their individual submissions, it would be useful to identify for the benefit of all key factors which have affected supplier submissions and what could be done to improve as well as any issues in respect of the process which the Government will address (i.e. "you said, we did"). This would not be an admission of failure but an acknowledgment that, in an emergency, processes are "trial and error" and will necessarily be adapted. As discussed in Part IV, Chapter 7, the CTDA team have usefully provided industry webinars offering a general assessment of commonly recurring issues in submissions and the process reforms introduced. Interim reviews of this kind would provide at least some measure of reassurance and even confidence to stakeholders relatively early on that concerns are being heard and acted on, particularly, for prospective suppliers who

have not yet submitted to the process. If this could be a means of genuinely improving submissions, it might also reduce the need to make more drastic regulatory interventions to address validation failures. In an emergency, it may be difficult to open up interim reviews to a period of further stakeholder consultation by which suppliers can raise issues for reform but an informal consultation mechanism e.g. coordinated through key industry associations might also be useful.

3.86. Of course, it is acknowledged that it may be difficult to publish interim reviews in an emergency when the focus is on getting products to meet a public health crisis; however, the Government has published TVG data and conducted internal reviews of validation processes (e.g. through the CTDAR 2021 regime and MHRA exceptional use authorisation approvals as discussed in Part IV). It would be relatively easy to compile this data and experience into an interim review for publication.

3.87. Moreover, as indicated, various scientific data is published in the form of evaluation reports. Whilst welcomed, there is a risk of a morass of scientific information being published which not even suppliers within the diagnostics industry (let alone the public) will understand. Rendering some of this information intelligible through interim reviews could provide further transparency. This should be considered in the context of other studies which have recommended the need to publish systematic reviews of study reports on evaluations.[125]

✓ **Consider comparative experiences of validation and procurement in other jurisdictions**

3.88. It is also recommended that **the Government should explore how validation is done in other countries** to learn any lessons from comparative experience during the pandemic. Of course, it will need to be mindful of any similarities and differences in terms of how healthcare systems are organised and delivered and how procurement systems operate etc. As briefly mentioned in Part IV Chapter 7, the Statutory Review of the CTDAR 2021 has drawn on the experience of other jurisdictions to better understand how regulatory approvals are applied for placement of medical devices on the market.

✓ **General mindfulness or foresight of the impact of validation on the market**

3.89. Finally, less a concrete recommendation and more a consideration going forward, there may be **a need for clearer foresight (as far as possible) or pre-emption of how validation-related decisions may directly or indirectly impact the market**. There are a number of possible examples in which Government decision-making could impact market access for suppliers. For instance, as indicated, there appears to have been some uncertainty on the part of industry as to what, if any, consequences there might be if suppliers did not immediately opt for the national procurement process but wished to do so subsequently. Obviously, it is for industry not for the government to determine their market strategy. However, it would be useful to better understand how any division or partition of markets which might result (along national and local lines) might ultimately impact supply. If, at any point, a national process is closed off or demand elsewhere reduces, issues then arise as to how access to the national process or not is managed and communicated. **The Government could also better communicate whether there is a backlog in applications for validation** so that industry can better plan their business activities and marketing strategies, including communications in respect of them.

3.90. Further, as discussed in more detail in Part III, Chapter 4, there appeared to have been some uncertainty as regards the impact of validation on procurement which resulted in direct awards being made before contracts were validated, contracts being made subject to

[125] Royal Statistical Society Diagnostic Tests Working Group Report, June 2021, p.60.

validation outcomes (which necessitated options to cancel contracts if suppliers did not meet validation requirements) and continuation of direct awards to certain suppliers because other suppliers were still going through validation which had not yet been achieved. The Government has justified direct awards on the basis *inter alia* that the timing of LFTs meeting UK technical requirements was a factor that was unforeseeable which could possibly suggest that the Government itself was not fully prepared for the impact validation would have on procurement.

3.91. In addition, as indicated, whilst there is no evidence to this effect and which has been firmly rejected by DHSC, there is a possible risk of various actors within Government or its civil service expressing informal preferences for certain types of test or aspects thereof (e.g. assays) or method of validation (e.g. PHE) which, may, in turn, have the effect of limiting market access for certain suppliers who could otherwise provide viable offers.

3.92. As discussed in Part IV, Chapter 7, in its statutory review of the CTDAR 2021, the Government has recognised and consulted on the impact of regulatory interventions on the market. Therefore, it would be useful to consider more strategically the cumulative impact of these types of decisions on market access and treatment.

PART III:
CONTRACTING –
CONTRACT AWARDS AND MANAGEMENT

4. CONTRACT AWARDS

Introduction

4.1 As indicated in Part II, the national technical validation process appears to be a "rolled up" validation and procurement process. This national call to arms was one means of soliciting offers which could lead to direct negotiations with each individual supplier or, as indicated, registration on a DPS leading to a contract awarded in competition. Of course, there are other ways in which contracts may have been procured e.g. through the Government proactively contacting suppliers leading to negotiations and award and the use of competitive purchasing arrangements other than a DPS such as framework agreements leading to "call-off" contracts. This Chapter examines how contracts have been awarded within the legal framework which regulates public procurement in the UK.

4.2 It begins by putting the number and value of diagnostics-related contracts awarded during the pandemic in context based on published information. It is then sub-divided into three sections: the first examines direct awards which were particularly prevalent in the early stages; the second examines competitive awards which increased in the later stages; and, finally, lessons learnt and recommendations are offered.

4.3 At the outset, it must be qualified that what follows is not a comprehensive legal analysis of the compatibility of all contract award processes with UK law. There have been a number of high-profile and widely reported legal challenges by the Good Law Project to COVID-19 contract awards e.g. in respect of PPE, communications and antibody tests developed by Abingdon Health plc which is considered in some detail.[126] It should, however, be noted that the antibody test challenge was rejected. Moreover, it should not be taken to be representative of all test kit contract awards. It concerned the award of consecutive contracts for the development and manufacture of antibody tests whereas most test kit contracts were, in fact, "off the shelf" or repurposed test kits. Importantly, at the time of writing, there does not appear to have been any other legal challenges made to IVD test kit contract awards. The Abingdon Health plc judgment nevertheless highlights some of the typical legal issues and risks which have arisen and could arise in any future emergency and is useful for illustrative purposes.

4.4 Further, whilst the following analysis could be charged with being too "legalistic", this focus is justifiable. The widely reported legal challenges to government contracts during the pandemic appear to have heightened public consciousness around the legal aspects of government contracting which should be reflected accordingly in any analysis. Further, the absence of a clear understanding in a number of quarters as to what is lawful or legal, permitted and not, has led to certain misperceptions or inaccuracies in the critique of the Government's response. For example, claims have been made that legal judgments have confirmed or evidenced "corruption" and "cronyism" which is simply not the case. Independent reviews have also identified that there are certain factors which have encouraged a suspicion of favouritism in contract awards, one being a lack of understanding of the legal basis for direct awards in reg.32 PCR 2015.[127] A legal analysis of key rules by reference to what the judgments actually say helps to clarify what is legally required or permitted including areas of genuine legal uncertainty.

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[126] Information on the application for permission for judicial review is available at: https://goodlawproject.org/case/abingdon-health/. For the reported hearing, see *R (Good Law Project Limited) v Secretary of State for Health and Social Care* [2021] EWHC 844 (TCC). The grounds of resistance are available at https://www.abingdonhealth.com/app/uploads/2021/08/2021.07.12-DGR-Abingdon-final.pdf.

[127] Boardman Review of Government Procurement in the COVID-19 pandemic, p.3.

4.5 From the Government's perspective, it is clear that it will need to plan to mitigate legal risks in procurement processes during emergencies in future and which is being done, in part, through ongoing reform of UK public procurement law. From an industry perspective, it is important to understand that what may be perceived to be unfair treatment and lack of transparency does not necessarily equate to a breach of legal obligations owed by the Government and which may help to manage expectations as regards the conduct of procurement processes in future.

4.6 It should also be noted that questionnaires asked for bidders' experiences of applying or tendering for diagnostics-related contracts during the pandemic and to what extent, if at all, procurement regulation and procurement routes could be improved to enable better market access and treatment. In contrast to more detailed responses in respect of validation processes (discussed in Part II) and regulatory approvals for placement of devices on the market (discussed in Part IV), responses on procurement specifically were very limited and of little use as means of verifying practice. Interviews have provided some further insight.

Contract Awards by Value and Number

4.7 In the UK, public procurement has been regulated primarily by EU Directives, in particular, Directive 2014/24/EU, as transposed in the PCR 2015. Generally, these rules require contract opportunities to be formally advertised and contracts awarded following a competitive process involving submission of tenders.[128] The PCR 2015 prescribe rules *inter alia* on publication of contract and contract award notices and different types of competitive procedure. Examples include the open procedure (the process is open to any supplier to submit a tender), restricted (only pre-qualified suppliers can tender) and competitive negotiation (qualified suppliers selected to tender can enter into successive rounds of negotiation resulting in a final tender). There are also certain advance purchasing arrangements which can be set up pursuant to one of these procedures e.g. a framework agreement or DPS for commonly used purchases.[129]

4.8 The above procedures do also accommodate the need to procure in emergencies. In open and restricted procedures, where urgency duly substantiated renders the time limit impracticable, the time limit between publication of a contract notice and receipt of tenders may be reduced.[130] Further, reg.32 PCR 2015 permits a contracting authority to use a negotiated procedure without prior publication of a contract notice in specific circumstances.[131] One ground is where the time limits for more competitive procedures, including accelerated forms, cannot be complied with because of extreme urgency brought about by events unforeseeable by the contracting authority and use is only insofar as is strictly necessary; the circumstances must not be attributable to the contracting authority.[132] Another ground is where the requirement can be supplied only by a particular supplier because competition is absent for technical reasons or for the protection of exclusive rights (including intellectual property rights).[133] The fact that reg.32 does not require formal advertising does not preclude procuring entities from choosing to conduct an informal competition between select suppliers if they wish; although, as will be discussed, the tendency has been to negotiate with a single supplier leading to an award and the term "direct award" is used. There is no requirement to publish a notice in advance of relying on reg.32 but a contract award notice must be published which includes the justification for

[128] Reg.26.
[129] Reg.34.
[130] Reg.27(5); Reg.28(10).
[131] Reg.32(1).
[132] Reg.32(2)(c).
[133] Reg.32(2)(b).

recourse to reg.32.[134] It is also possible to modify contracts which have been awarded without requiring a new procedure in prescribed circumstances.[135]

4.9 According to the National Audit Office, by the end of October 2020, for activity related to the T&T programme, DHSC had signed 407 contracts with 217 suppliers.[136] The total value was £7 billion (£8 billion including contract extensions). Testing accounted for 198 (49%) of the contracts with a value of £6.2 billion. Just ten of the largest suppliers accounted for more than half (£3.9 billion) of the total value.[137] Between November 2020 and March 2021, DHSC estimated that it would award a further 154 contracts (£16.2 billion). In total, it was reported that the T&T programme had 325 contracts in the pipeline with a total value of £21.4 billion.[138] By the end of March 2021, DHSC had signed 964 contracts with 454 suppliers.[139] The total value was £14.1 billion. There were 549 contracts relating to testing, although not all would have exclusively concerned tests as distinct from related services.[140] Test contracts represented 57% of the total number of contracts and 90.4% of the total value of contracts (£12,695 million). Ten of the largest suppliers accounted for more than half (£7.3 billion, 52%) of the total contract value, Innova Medical Group Inc being the supplier with the highest value contract for LFT kits (£3,196 million) and Tanner Pharma UK Ltd with a contract for the same (ranked eighth, £348 million).[141]

4.10 Of the £14.1 billion total contract value, £7.5 billion (or 53% of the total contract value) was awarded directly under what the National Audit Office referred to as "emergency regulations without competition", while £3.4 billion was awarded directly under existing frameworks and £3.1 billion through "other routes". [142] From January to March 2021, DHSC let, extended or varied fewer contracts using emergency regulations in the period (27 contracts or 6% of contracts) than in April to June 2020 (51 contracts, or 46% of contracts). Over the same timeframe, the value of those contracts also decreased as a proportion of all contracts (from 76% down to 52%) but the absolute value more than doubled (from £1.1 billion to £2.6 billion). This increase was mainly due to a £1.9 billion contract for LFT test kits awarded to Innova Medical Group Inc in the period January to March 2021. The Figure below was compiled by the National Audit Office and is reproduced here with kind permission.

[134] Reg.50.

[135] Reg.72.

[136] National Audit Office, Report by the Comptroller and Auditor General, Department of Health & Social Care, The government's approach to test and trace in England – interim report, HC 1070, Session 2019–2021, 11 December 2020, p.38 and Figure 9, Number and value of signed NHS Test and Trace contracts by service category, as of the end of October 2020.

[137] Ibid., p.39, Figure 10, The 10 suppliers with the total highest contract values signed by the end of October 2020.

[138] Ibid., p.38.

[139] National Audit Office, Test and trace in England – progress update Department of Health & Social Care, Report by the Comptroller and Auditor General, Session 2021-22, 25 June 2021, HC 295, p.36.

[140] Test contracts were identified as including: contracts for testing infrastructure, laboratories, new testing technology, for example, lateral flow device testing, and testing related consumables, reagents and equipment. See Figure 8, Number and value of contracts signed by the NHS Test and Trace Service by programme areas, as of the end of March 2021. Source: National Audit Office analysis of contracts data provided by the NHS Test and Trace Service.

[141] National Audit Office, Test and trace in England – progress update (supra), Figure 9, The 10 suppliers with the total highest contract values signed by the end of March 2021. Source: National Audit Office analysis of contracts data provided by the NHS Test and Trace Service.

[142] Ibid., Figure 10, Value and number of new contracts, contract extensions and variations, by award route and date of contract signature up to March 2021.

Figure 1: Value and Number of New Contracts, Contract Extensions and Variations, by Award Route and Date of Contract Signature up to March 2021

The NHS Test and Trace Service has reduced the number of contracts it awarded under emergency regulations since April to June 2020, but the reduction in the value of these contracts is much smaller

Value of new contracts, contract extensions, and variations (£m)						
	2019-20	2020-21				
	Before April 2020	April to June 2020	July to September 2020	October to December 2020	January to March 2021	Total value of contracts
Call off from framework	6	244	747	1,104	1,337	**3,445**
Direct award under emergency regulation	216	1,051	1,905	1,768	2,565	**7,504**
Other	0	81	680	1,349	992	**3,102**
Total	**222**	**1,376**	**3,332**	**4,221**	**4,893**	**14,051**
Proportion under emergency regulation	97%	76%	57%	42%	52%	53%

Number of new contracts, contract extensions and variations						
	2019-20	2020-21				
	Before April 2020	April to June 2020	July to September 2020	October to December 2020	January to March 2021	Total value of contracts
Call off from framework	9	36	94	235	327	**703**
Direct award under emergency regulations	8	51	45	58	28	**190**
Other	2	24	32	116	148	**322**
Total	**19**	**111**	**171**	**409**	**503**	**1,215**
Proportion under emergency regulation	42%	46%	26%	14%	6%	16%

Notes

1 The NHS Test and Trace Service can award its contracts through several different routes, including through framework agreements in place with the Government with or without bidding, direct awards to firms and partners under the power of emergency Regulation 32, or variations to existing contracts under Regulation 72. It also contracts with other Government or public bodies under arrangements such as memoranda of understanding and grants.

2 The award route can differ for the initial contract and any subsequent extensions or variations. Because of this, the table breaks down value and number of contracts separately for initial contracts, contract extensions and variations. The number of contracts total to more than the number of initial contracts, as shown in Figure 8.

3 Other includes grants, memoranda of understanding with other public bodies such as Office for National Statistics and universities, single-source contracts, public to public collaboration under Regulation 12 and contracts awarded under Regulation 14 as well as variations under regulation 72. It also includes directly awarded contracts with small (subthreshold) values awarded directly without competition.

4 Two contracts let off framework without commencing and signatory dates with a total value of (£6 million) are not included in the table.

5 Two contracts with an associated value of £6 million could not be allocated to a financial quarter, but are included in the overall totals. The quarterly figures in the 'call off from framework' and 'total' rows therefore do not sum to the total.

Source: National Audit Office analysis of contracts data provided by the NHS Test and Trace Service

Direct Awards

4.11 As indicated, it appears that a majority of contract awards by number and value were direct awards, principally, pursuant to reg.32 PCR 2015.[143] This Section examines direct awards in more detail. To focus the analysis, it begins by identifying key examples of LFT and PCR

[143] For an academic discussion of direct awards and their legal regulation in the context of emergencies, see S Arrowsmith, 'The Approach to Emergency Procurement in the UNCITRAL Model Law: A Critical Appraisal in Light of the COVID-19 Pandemic', pp.36-54; S Arrowsmith, 'Recommendations for Urgent Procurement in the EU Directives and GPA: COVID-19 and Beyond', pp.75-92; and L R A Butler, 'Regulating Single-Source Procurement in Emergency Situations in Light of the COVID-19 Pandemic: Issues in Policy and Practice' in S Arrowsmith, L R A Butler, A La Chimia and C R Yukins (eds), *Public Procurement in (a) Crisis: Global Lessons from the COVID-19 Pandemic* (2021 Hart).

supply contracts awarded under reg.32 PCR 2015. This gives a sense of the chronology of typical awards at certain stages. It will then hone in on certain examples of contract awards to explore some of the key legal and practical issues arising.

Examples of Direct Awards for LFT and PCR Tests

4.12 The following Tables (compiled by the author) provide examples of directly awarded LFT and PCR test contracts awarded under reg.32 PCR 2015 by supplier, requirement, contract value and contract start and end date.

Table 3: Sample of LFT diagnostic supplies (CPV 33124130), diagnostic kit (CPV 33141625), and diagnostic and radiodiagnostic devices and supplies (CPV 33124000) contracts awarded

Contracts Finder Reference and contractor	Requirement	Contract Value (GBP)	Contract Start/End
CF-0023800D Abingdon Health Ltd	Components/materials for LFT kits	£10,272,590	02/06/20 14/08/20
CF-0046900D Innova Medical Group Inc	LFT kits and consumables	£103,600,000	17/09/20 31/10/20
CF-0048700D Tanner Pharma	LFT kits and consumables	£10,000,000	05/10/20 31/10/20
CF-0066100D Innova Medical Group	LFT kits and consumables	£496,080,000	06/10/20 31/12/20
CF-0066000D Abbott Rapid Diagnostics Limited	LFT kits and consumables	£120,000,000	07/10/20 31/10/20
CF-0047100D Tanner Pharma	LFT kits and consumables	£148,500,000	09/10/20 31/12/20
CF-0102900D Tanner Pharma	Variation agreement for LFT kits and consumables	£64,125,000	16/11/20 31/12/20
CF-0102800D Innova Medical Group Inc	Variation agreement for LFT kits and consumables	£225,971,003.41	20/11/20 31/12/20
CF-0096700D Ecam Diagnostics Limited	LFT to be sent to Porton Down for validation	£162,500	25/11/20 31/03/21
CF-0096800D Aptamer Group Ltd	LFT to be sent to Porton Down for validation	£250,000	30/11/20 31/03/21
CF-0103800D SureScreen Diagnostics Ltd	LF antigen tests for Sars-Covid-2, with the option to purchase further tests	£6,000,000	01/12/20 30/09/21
CF-0095800D Global Access Diagnostics Ltd	LF antigen tests for Sars-Covid-2	£3,160,000	08/12/20 30/09/21
CF-0147300D SureScreen Diagnostics Ltd	Supply of raw materials for manufacture of LFTs	£5,300,000	24/12/20 31/03/21
CF-0115500D Una Health Limited	LF devices for Covid-19 testing	750,000	11/01/21 28/02/21
CF-0155700D Innova Medical Group Inc	LFT kits and consumables	727,614,408.90	15/01/21 28/02/21
CF-0116100D SureScreen Diagnostics Ltd	LF antigen tests for SARS-Cov-2	503,430,000	15/01/21 15/01/23
CF-0134700D Omega Diagnostics Limited	Manufacture of LFTs	374,000,000	12/02/21 11/02/23
CF-0134800D Global Access Diagnostic Ltd	Manufacture of LFTs	1,152,000,000	16/02/21 15/02/23
CF-0027700D Abingdon Health Limited	LFT kits	75,000,000	02/06/21 14/02/22

CF-0569500D Innova Medical Group Inc	LFTs pending implementation of a Dynamic Purchasing System	215,000,000	29/12/21 31/02/22
CF-0576000D Tanner Pharma UK Ltd	LFTs pending implementation of a Dynamic Purchasing System	169,000,000	29/12/21 31/01/22
CF-0575900D Medco Solutions Ltd	LFTs pending implementation of a Dynamic Purchasing System	59,500,000	31/12/21 31/01/22
CF-0576300D Innova Medical Group Inc	LFTs pending implementation of a Dynamic Purchasing System	215,000,000 – 430,000,000	31/12/21 31/01/22

Table 4: Sample of PCR diagnostics contracts awarded

Contracts Finder Reference and contractor	Requirements	Contract Value (GBP)	Contract Start/End
tender_238968/920364 Primerdesign Ltd	Provision of Geneseo® Real-Time PCR Coronavirus CE IVD Kit and other reagents	£983,456	13/03/20 31/07/20
CF-0024400D0O000000rwimUAA1 VWR International Limited	Provision of PCR equipment and consumables in support of Pillar 1	£2,119,113.60	3/04/20 31/03/21
CF-0022600D0O000000rwimUAA1 Primer Design Limited	Provision of assay test kits in support of Pillar 1	£63,335,240	26/04/20 4/11/20
CF-0056300D0O000000rwimUAA1 Abbott Laboratories Ltd	Supply of goods (test kits) for use in Pillar 1	£8,963,711.99	27/04/20 31/05/20
CF-0017800D0O000000rwimUAA4 Eurofin	REACT 1 - Round 2, 2b and 3 Lab testing from Eurofins (Swabs, viles, biohazard bags and PCL analysis)	£28,000,000	4/05/20 18/09/20
CF-0018400D0O000000rwimUAA5 Eurofins Bionmis UK Limited	Supply of Laboratory Services for provision of Testing requirements related to COVID-19.	£8,800,000	18/05/20 18/11/20
CF-0025500D0O000000rwimUAA1 Eurofins Biomnis UK Limited	Provision of Lab Testing in support of Covid-19 PCR tests	£37,300,000	18/05/20 18/07/20
MEDDISC001-DN487692-79287368 Hamilton	Purchase of COVID 384 PCR System instruments and accessories related to the establishment of a Lighthouse laboratory	£121,500	19/05/20 31/05/21
CF-0100600D0O000000rwimUAA1 Eurofins Biomnis UK Limited	Collection, Identification, Packing and Transporting to the Laboratories for Wet Swab PCR Testing and analysis for Covid-19	£58,800,000	24/08/20 31/01/21
CF-0026000D0O000000rwimUAA1 Immensa Health Clinic LTD	Urgent requirement to develop volume for PCR testing for COVID in line with test and trace requirements	£119,035,000	07/09/20 04/03/21
700979368	3 x PCR COVID Testing Machines and all the	£767,204.94	11/09/20 26/2/21

LIFE TECHNOLOGIES LIMITED	necessary equipment and consumables to carry out 60,000 tests.		
BIP578878541 University of Exeter	Sequencing services for 100-200 SARS-CoV-2 RNA samples per week.	£50,000	01/11/20 01/03/21
CF-0060900D0O000000rwimUAA1 University of Birmingham	Provide diagnostic (RT-PCR) testing for COVID-19 under Laboratory Testing Services Agreement	£11,300,000	12/10/20 31/03/21
CF-0061100D0O000000rwimUAA1 Accora Limited	Provision of laboratory testing services	£18,729,060	24/10/20 08/12/20
CF-0077800D0O000000rwimUAA1 Queen Mary University of London	provide diagnostic (RT-PCR) testing	£6,944,285	12/11/20 31/03/21
tender_255624/900433 Qiagen Ltd	provision of a digital PCR instrument urgently needed to support COVID-19 work.	£177,399.68	17/11/20 16/11/24
tender_257840/910859 Fisher Scientific Ltd	Urgent requirement for laboratory equipment for covid wastewater testing.	£1,397,182	02/12/20 01/07/21
tender_257840/910882 Thermo Fisher	Urgent requirement for laboratory equipment for covid wastewater testing.	£279,567.90	01/12/20 01/07/21
tender_259360/917172 Altona Diagnostics UK Ltd	Test kits	£2,700,000	04/12/20 31/03/21
CF-0098000D0O000000rwimUAA2 HSL Pathology LLP	Provision of diagnostic (RT-PCR) testing for COVID-19	£38,000,000	01/09/20 01/06/21
CF-0097900D0O000000rwimUAA1 Imperial College Projects Limited	Provision of testing services	£7,526,279	15/12/20 31/03/21
CF-0115000D0O000000rwimUAA1 King's College London	Provision of diagnostic (RT-PCR) testing	£12,500,000	08/01/21 31/03/21
CF-0108400D0O000000rwimUAA1 Source Bioscience Limited	Urgent requirement to develop volume for PCR testing for COVID in line with test and trace requirements.	£7,610,000	19/12/20 06/02/21
Procurement reference CF-0139600D0O000000rwimUAA1 Qnostics Ltd	Provision of additional ancillary services to evaluate the efficacy of cohort pooling nasopharyngeal swabs in the detection of SARS-CoV2 by qRT-PCR workflows at selected laboratories	£13,025	10/02/21 31/03/21
RQ304204 A MENARINI DIAGNOSTICS LTD	Rapid Covid test kits for Vita PCR platform	£82,943.36	18/06/21 17/09/21
MEDDISC001-DN565086-64610750 Life Technologies Limited	Supply and installation of equipment for COVID-PCR testing via the Accredited assay: Thermo Kingfisher flex Quant	£500,000	23/07/21 23/08/21

RQ304235 A. MENARINI DIAGNOSTICS LIMITED	Rapid Covid test kits for Vita PCR platform - 16 week supply	£189,265.76	24/07/21 23/11/21
CQC RCCO 029 PRENETIC EMEA	To provide latex free PCR testing kits and a specialist testing facility	£31,600 to £316,000	01/11/21 01/11/22

4.13 Before considering the legal aspects, it is useful for context to set out some of the general concerns which have been expressed in respect of direct awards for IVD test kit contracts during the pandemic.

4.14 From an industry perspective, in August 2020, BIVDA submitted a Freedom of Information request to DHSC for details regarding certain of these direct awards.[144] BIVDA was concerned about significant awards being made to suppliers for diagnostic testing without a call for competition when, in its view, there is a highly active and competitive UK IVD sector with products and equipment available and robust supply chains and capacity to supply in the volumes required. BIVDA members expressed "serious concern" that the procurement activity (particularly procurement from DHSC and PHE) was not competitive, transparent or fair and was "stretching the criteria required for Regulation 32(2)(c) beyond its reasonable use". BIVDA requested DHSC *inter alia* to : (1) set out the issues relating to the published award notices and to receive a response detailing the process followed to determine the use of this procurement route, including the criteria and selection of suppliers; and (2) to be assured that this procedure will no longer be used for COVID-19 testing procurement requirements. It also wanted to understand the process that the NHS laboratories would follow to procure from the wider supplier base and from what date. DHSC issued a response to the effect that that it did not accept that its reliance on reg.32(2)(c) was "in any way" unlawful and that it had not been applied "beyond its reasonable use", confirming that legal advice was obtained in respect of its use.[145]

4.15 Whatever the legal position to be discussed in the remainder of this Section, there seems to have been a perception within industry of a lack of clarity and transparency in the procurement process. For instance, in response to the BIVDA questionnaire, one member stated:

> The way in which contracts were published / awarded should have been more transparent and all BIVDA members should have had the same chance to offer and apply for these procurement exercises – as far as we were concerned, there was no procedure – it was all in favour of those large companies who had the budget to make a noise about their product, even though it may not have been superior.

Others stated that: "overall the process appeared to favour large multinational companies"; "this appeared to be a closed shop, once we had expressed our limits of production/supply we were no longer invited/involved in further discussions of supply"; and "[w]e understand things had to move quickly but [*sic*] very little visibility of contracts or testing requirements that were needed [*sic*] this seemed to be directly through certain large diagnostic companies". Another requested "greater transparency of process and award criteria".

[144] BIVDA, Request for Information relating to awards for contracts without a call for competition, sent to Department of Health and Social Care, 6 August 2020.

[145] Department of Health & Social Care, Contract Award Notices – Request for Information response, 17 August 2020.

4.16 To date, DHSC has only been required to put forward legal justifications for particular direct awards in individual cases in response to legal challenges e.g. that extreme urgency justified an award to a single supplier. It has not published wider unexpressed public policy reasons which may have also informed its sourcing strategy and which are not necessarily grounded in a legal justification but might have other defensible objectives (e.g. to protect public health and guarantee logistics of supply). For instance, there is no explicit legal ground permitting a direct award to a single supplier to mitigate public health risks which could result from relying on more than one supplier. In practice, relying on one or a few select suppliers means that the public is exposed to as few testing options as possible; public health might otherwise be compromised by the availability of a diversity of tests whose accuracy and performance could vary (even if those tests have passed validation and approval given their testing in limited settings). Further, if the Government were to rely on a greater number of suppliers, the risk of distribution and supply problems might be magnified whereas reliance on one or two may limit this risk and simplify logistics. Therefore, whilst the PCR 2015 do not prescribe explicit "security of supply" grounds for awards, it is possible to envisage that these might be additional reasons (beyond extreme urgency) for relying on a limited number of suppliers.

4.17 Of course, the decision to make a direct award is a calculated one, is not risk-free and involves inevitable trade-offs. For example, reliance on one or two suppliers may not only invite legal challenge from other potential suppliers but may also increase the risk of dependency on those sources where diversification of supply would provide alternatives. Further, reliance on one or two suppliers to deliver under a mass testing programme does limit the range of other available markets for the rest of industry to supply and who then end up having to sell to the NHS or others directly (including in the private market), for example. This risk of closing off the market is further exacerbated if the Government then imposes further measures on supply into those other markets e.g. by imposing additional evaluation requirements for those markets (as has been the case with the CTDAR 2021 regime discussed in Part IV, Chapter 7).

4.18 Ultimately, these are fine judgements as is the balance of various interests which industry and other stakeholders are keen to protect e.g. fairness, transparency and value for money. Whether the Government got its IVD procurement strategy right or wrong to whatever degree should be a point of reflection going forward. However, particular policy choices which underpin it and which contributed to a high incidence of direct awards do not necessarily render the *processes* by which contracts were awarded unlawful, particularly, if a lawful ground can be relied on and respecting (as the courts do) that key decision-makers are best placed to weigh up policy choices in exercising their discretion (within legal bounds).

4.19 The remainder of this Section examines the extent to which UK law actually requires use of competition, disclosure of selection and award criteria and transparency, drawing on examples of IVD test kit contract awards during the pandemic.

Clarifying Legal Requirements in Direct Award Cases

4.20 To put the legal analysis which follows in context, it is first necessary to begin by clarifying common misconceptions or misunderstandings about the purposes of the PCR 2015 and various rules and what is actually legally required. This may help focus in on areas where there is genuine legal uncertainty that must be acknowledged.

4.21 First, the PCR 2015 derive from EU Directives on public procurement. The EU Directives' objectives are to prohibit discrimination on grounds of nationality and remove market access barriers to trade within the EU internal market when awarding public contracts. It follows that the PCR 2015 have the same objectives. They are not designed to provide a comprehensive legal code geared to ensuring value for money or full transparency and certainly not to

address the idiosyncrasies of diagnostics procurement. Therefore, any purported impact of recourse to reg.32 (lawful or otherwise) on value for money should be treated with caution. Breach of the Directives as implemented in the PCR 2015 may result in unequal treatment or lack of transparency which may compromise value for money but ensuring value for money is not a focus of the rules.

4.22 Second, it is suggested that there has been a tendency to intimate that direct awards are generally prohibited unless justified and which, in turn, means that there must be very strict scrutiny in cases where direct awards are made. Quite apart from the media, even lawyers sometimes refer to the use of reg.32 as a "derogation" or an "exception" from the "normal" rules on competition. In the Abingdon Health plc judgment, Waksman J observed that it is not useful to use the word "exception" because that automatically implies some, perhaps, higher level of scrutiny that applies to reg.32 to justify its use when, in reality, it is an alternative or different "much truncated procedure" which does not involve "critically, advertisement or the usual competitive tendering". [146] Thus, viewing reg.32 as authorising a legitimate alternative to a formal competitive procedure may alter perceptions that its use should be viewed with some undue circumspection or even suspicion as perhaps appears to have been the case. Of course, it does not follow that no scrutiny applies at all. The contracting authority bears the burden of proving that the circumstances justifying recourse to reg.32 apply and recourse to it must be strictly interpreted.[147]

4.23 Third, whilst reg.32 is identified as a "procedure", in reality, it primarily sets out grounds for use and does not, in fact, set out a procedure in the way that is the case for other competitive procedures. This means that there are no explicit procedural rules which apply to any process conducted pursuant to reg.32. As the case law has demonstrated, general principles as opposed to specific procedural rules may apply e.g. reg.18 prescribes "principles of procurement", namely, that contracting authorities must treat suppliers equally and without discrimination and act in a transparent and proportionate manner; and the design of the procurement must not be made with the intention of excluding it under the rules or of "artificially narrowing competition" (favouring or disadvantaging certain suppliers). This may be in addition to any more general rules applicable to all awards e.g. the publication of contract award notices and keeping records and producing reports etc. However, there are no detailed requirements to publish all forms of selection criteria in advance or the process applied for section or to explain every decision in order to ensure fair treatment of all bidders.

4.24 Further, there is no PCR 2015 rule which creates some explicit anti-corruption or anti-cronyism obligation. The PCR 2015 provide remedies for breach of statutory duty; they do not establish criminal offences of "corruption". The PCR 2015 do provide rules to ensure the possibility of excluding suppliers from a procurement procedure for certain violations and a basic obligation to identify and prevent conflicts of interest. Similarly, other areas of law may provide for misfeasance in public office and public law provides for rules against actual or apparent bias. All of these may loosely approximate to conduct which might be associated with corruption, bribery or other criminal conduct but they are not corruption. It is partly for this reason that claimants seeking to challenge COVID-19 contract awards may have had to found claims outside the PCR 2015 on much broader domestic public law grounds of this kind e.g. apparent bias to challenge the way contracts have been awarded although, again, case law has demonstrated that it is at least arguable whether notions of apparent bias apply at all in the context of public procurement.

4.25 Fourth, it is important to observe the nature and scope of judicial review. As the courts have acknowledged, the court's role is to assess the lawfulness of the process not to carry out its own assessment on the merits of what alternative course the contracting authority might

[146] *R (Good Law Project Limited) v Secretary of State for Health and Social Care* [2021] EWHC 844 (TCC) at [10].
[147] C-394/02 *Commission v Greece* ECR I-4732, [33].

have taken.[148] Therefore, the court respects that the contracting authority is best placed to determine its needs and how to meet them e.g. whether through an open competition or direct award; it is only in view of that choice that the court then undertakes judicial review to determine whether the conditions for recourse to reg.32 are met. It follows that the courts will not lightly engage in counterfactuals or hypotheticals of what alternative courses could have been undertaken at various phases of any emergency. In a similar vein, the courts have signalled caution against challenging recourse to reg.32 because of an objection to the identity of a particular supplier who has been awarded the contract. For example, on occasion, the media and other commentary have made statements about the nature of a particular supplier's finances, their experience etc which, in turn, calls into question whether the process for awarding the contract to them was lawful. As the courts have stated, the focus is on whether the time limits for a competitive procedure cannot be complied with for reasons of extreme urgency due to unforeseen events and that the procedure is strictly necessary, not scrutinising the suitability of suppliers in general.[149]

4.26 The upshot of the above is that, whilst there may be a perception that reg.32 is some rare derogation to be invoked exceptionally, is subject to detailed constraints, and breach of which confirms corruption or cronyism, the legal reality is more nuanced, as will be discussed in more detail below. Further, it is important to acknowledge that the applicable legal requirements in respect of reg.32 and direct awards generally have been uncertain. It was not the case that contracting authorities were procuring in light of clearly established legal requirements which had been "tried and tested" before the courts. It is only following recent legal challenges to contract awards made during the pandemic that a clearer understanding has emerged of the nature and extent of these legal requirements but there still is still a degree of legal uncertainty. Moreover, it is also not the case that contracting authorities did not appreciate the legal risk of making direct awards and always proceeded regardless. For example, in the Abingdon Health plc judgment it was confirmed in evidence that the legal risk of proceeding with a direct award was acknowledged.[150]

4.27 To confirm the current position, emerging case law suggests an increasing acceptance that recourse to reg.32 (i.e. whether the grounds for use are established) at various stages in the pandemic (not simply at the start) was lawful at least in the range of circumstances that were the subject of legal proceedings. The main issue has concerned the much narrower question of whether any rules apply to the conduct of any procedure where reg.32 has been lawfully relied on. Ultimately, perhaps contrary to what is sometimes reported, whilst the courts have found instances where the process for selecting suppliers has been unlawful, those findings have been limited. Moreover, no breaches were found in the Abingdon Health plc judgment, which appears to be the only major case on the award of IVD test kit contracts to date.

4.28 Notwithstanding, the above should not detract from the importance of identifying continuing areas of uncertainty which could be addressed by either legislative reform or through additional policy guidance. Further, the fact that a process is not found to be unlawful does not necessarily mean that it represents good procurement practice, a matter which is not within the court's jurisdiction to assess. This Section now turns to consider various aspects of direct awards.

Identification of Diagnostics Suppliers to Solicit Offers

4.29 Interviews have suggested that there was a perception within industry that not all suppliers who existed were identified by Government and not all suppliers who were known were

[148] *Public First Limited*, [93].
[149] *R (Good Law Project Limited) v Secretary of State for Health and Social Care* [2021] EWHC 844 (TCC), [30] and [37].
[150] *Abingdon Health plc*, [231].

contacted. Of course, suppliers could make themselves known through the national portal for technical validation once it was set up but this would not necessarily have been the case before, raising the question of how suppliers contacted Government and *vice versa*. Further, there are ways other than a national portal to identify suppliers. This raises the legal question of whether there are any legal obligations to widely search the market to identify suppliers, to contact known suppliers and to conduct some form of competition. The starting point must be that the reg.32 negotiated procedure without prior publication of a contract notice does not expressly require any form of competition. This does not preclude contracting authorities from conducting an informal competition (i.e. one that is not advertised but does involve tendering). However, the reality is that negotiations will have been undertaken directly with each single supplier resulting in a contract.

4.30 It is also likely that the Government will have not simply entered into separate contracts consecutively (i.e. one after the other) with different suppliers but will have entered into direct negotiations separately and simultaneously with a number of different suppliers resulting in contract awards with each single supplier on similar terms. In which case, a further legal question is whether there are wider PCR 2015 obligations to conduct market searches and award processes in ways that ensure *inter alia* non-discrimination, equal treatment, transparency and proportionality (principles under reg.18 PCR 2015 as discussed below) across all of those suppliers (i.e. that all suppliers are subject to the same processes in terms of the supplier qualification and selection criteria applied or information given).

4.31 For reasons discussed below, in the Abingdon Health plc judgment, the court expressed the view that where reg.32 is lawfully relied on, reg.18 procurement principles may not apply at all; in which case, it will be difficult to argue that that DHSC should have taken proactive steps to identify whether any other possible suppliers existed or were capable of meeting requirements, that some form of competition should be held, and some process applied to ensure non-discrimination, equal treatment and transparency. Put simply, then, it should not be assumed that there is any extensive legal obligation to undertake market searches and engage with known suppliers, at least in cases of extreme urgency. This must moderate any claims that industry were unlawfully "shut out" of contract awards on the basis that they were not contacted, because no competitions were held, and that there was unfair treatment.

4.32 Whilst there may be no express legal obligations to conduct extensive market searches and competition, there remains industry's concern that whatever market searches that were conducted were not particularly systematic. This raises the practical issue of how suppliers were actually identified and how this could be improved in future. Of course, on the one hand, the more suppliers who are known to Government, the greater the chance that it will fulfil its need (either from sourcing from suppliers who can supply or working with them to develop capacity) and will enable better understanding of supply chains and associated risks e.g. with manufacturing and logistics. On the other hand, it must be acknowledged that in an emergency, it may be counterproductive to spend more time searching the market for every conceivable supplier than procuring to meet an immediate need where one or two suppliers are known or become known and could meet a significant proportion of the demand for a particular requirement. Whatever the view, the point remains that the more that can be known in advance of an emergency about the supply market, the less resource is then required at the onset of the emergency to identify potentially suitable suppliers from scratch. This requires upfront investment to understand the market and develop systems for quick identification.

4.33 There is a possible indication that no (or few) systematic mechanisms were in place for identifying suppliers and that there was not sufficient information on the diagnostics market. In the Abingdon Health plc judgment, it was confirmed that some initial research was done to map UK LFT manufacturers in cooperation with McKinsey, a private company, alongside

identification of suppliers through the national portal and other searches.[151] As this research does not appear to have been published, it is not possible to comment on the extent to which this mapping exercise was effective or ways in which it could be improved. More generally, it is difficult to discern precisely how suppliers were identified before initiatives such as the national portal were established. For example, in evidence, a civil servant made reference to the "buy any test you can find" phase[152]. In this phase, a number of suppliers came forward and claimed to be able to produce kits but were determined not to be sufficiently reliable. Anecdotal evidence suggests (but which has not been verified) that other means used in these early months included identifying suppliers registered on existing framework agreements, which is discussed in more detail below.

4.34 As indicated, a national portal was then set up as a means of dealing with submissions and referrals. A Freedom of Information request by the Good Law Project has identified that offers of assistance were received through a variety of channels. The main routes were a purpose built gov.uk portal and four dedicated DHSC mailboxes. Some offers of help were also routed through Ministers' offices, parliamentarians or senior officials. The four shared mailboxes used were for 'COVID testing priority contacts', 'COVID19 innovation', 'COVID testing triage' and 'COVID19 offer triage'. These inboxes were used at different points between March 2020 and October 2021. It is understood that some suppliers emailed their offer directly to a mailbox (self-referring); offers from others were forwarded into a mailbox, or to relevant officials working on the response by Ministers, parliamentarians and other parts of government.[153]

4.35 Further, it has been identified that all offers of support were assessed and triaged by civil servants working on testing procurement. It has been stated that "a large volume of emails and offers" were received every day and officials looked for offers that would support the scaling up of the UK's testing network as quickly as possible. As discussed in more detail below, the Good Law Project has alleged that there was a "VIP lane" for test contracts. In response to a Freedom of Information request by the Good Law Project, UKHSA explained the triage process including use of "VIP". It stated that where emails related to specific, urgent offers or to services or products that were high priority (e.g. in an area of shortage or an innovative technology) or were from a supplier with an established reputation in diagnostics, or wider health services, the email could be tagged as "VIP", "Fast Track" or "Priority". These tags helped the DHSC team to identify which offers and emails should be prioritised to ensure viable offers progressed quickly and also helped officials to provide progress reports to Ministers and senior officials. It has been stated that the tags did not relate to the status of the referrer and suppliers were not aware of the tagging system. There was no separate VIP route or channel for testing suppliers and Ministers were not involved in the evaluation or procurement process for contracts.[154]

4.36 In the Abingdon Health plc judgment, it was identified that suppliers contacted the triage team and emails were also received from Ministers and commercial supply teams.[155] In this regard, it is important to clarify that it was not necessarily the case that recipients of major contract awards were contacted by Government. For example, it is understood that suppliers such as Innova submitted offers through the national portal. Further, contrary to suggestions that the Government contacted Abingdon Health plc, it was found that Abingdon Health plc submitted its expression of interest through the call to arms triage mailbox.[156] There is no

[151] *Abingdon Health plc*, [133].
[152] *Abingdon Health plc,* [127].
[153] UK Health Security Agency, Freedom of Information request, ref: 03/11/22/KMG/1000, ICO ref: IC-150101-Z2Z4, 21 December 2022: https://drive.google.com/file/d/1i1DhMGaIvuQlfqn2tTUiBC0TcNy5rYll/view.
[154] ibid.
[155] *Abingdon Health plc*, [139].
[156] *Abingdon Health plc*, [103].

indication that these suppliers were given prior instruction to submit to the mailbox based on any initial preliminary contact made by the Government. Nevertheless, there is a broader question about how these national call to arms triaging processes operate alongside other means of identifying suppliers. As explained in Part II, the national technical validation process guidance refers to the fact that a manufacturer may have been contacted "proactively" by another government department rather than through the portal. This is relevant because there is a possible risk that where the Government contacts suppliers of its own initiative rather than through established mechanisms, there is likely, at least, to be a perception that such suppliers might get priority or preferential treatment which, in turn, could lead to a legal challenge.

4.37 The Government has also used a number of other means of contacting suppliers. For example, in respect of the early development of antibody tests, the Government convened a "kick-off" meeting involving various companies invited to develop the UK-RTC.[157] It is understood that civil servants were conscious of the need to ensure that this was not perceived as selective and that a number of suppliers should be invited albeit that it was considered that there were good reasons for proceeding with a limited number.[158] In the Abingdon Health plc legal challenge, it was claimed that a national preference had been expressed for Abingdon Health plc in the efforts to develop a UK-based "home-grown" test contrary to EU rules of non-discrimination but the court dismissed this argument citing in support that the kick-off meeting was not limited to companies incorporated in the UK.[159] Moreover, DHSC continued to use the national portal and other means of identifying suppliers at the same time as engaging with the UK-RTC. Further, industry associations were also contacted who could then make referrals. For example, DHSC contacted BIVDA to identify suppliers which included a referral for Una Health Ltd/Fortress Diagnostics.[160] In addition, evidence in the Abingdon Health plc judgment revealed that a Director of NTAG also undertook a quick "google" search of possible LFT providers.[161] It is also understood that at various stages, Requests for Information ("RFIs") were advertised by way of notice to get a better understanding of who could supply. An example is a September 2020 RFI to "build an understanding of suppliers in the market" who could scale up for procurement of sample collection consumables for COVID-19 antigen testing.[162]

4.38 In its Freedom of Information request, BIVDA asked for evidence as to the lack of other suppliers available to meet demand. BIVDA's view was that neither it, as the trade association, nor suppliers of similar products had been consulted or approached relating to capacity in the UK or the potential to fulfil demand as distinct from those who could fulfil immediate requirements for specific test kits and assays and that there was significant manufacturing and distribution capacity that was not considered.[163] In response, DHSC stated that it had been made aware of exceptionally high demand for rapid POC COVID-19 test kits. DHSC was not at liberty to share the detail with BIVDA but stated its assurance that DHSC's own due diligence confirmed that the demand was real and urgent. DHSC stated that it did contact the Chief Executive of BIVDA in March 2020 seeking information in respect of details of suppliers who DHSC anticipated may be able to assist and would have been happy to receive details of other interested suppliers or for the email to be forwarded to BIVDA members. It further indicated that it was, therefore, reaching out to relevant trade bodies and did in fact purchase a Fortress Diagnostics product through a contract with Una

[157] *Abingdon Health plc*, [116].
[158] *Abingdon Health plc*, [130].
[159] *Abingdon Health plc*, [360].
[160] *Abingdon Health plc*, [160].
[161] *Abingdon Health plc*, [129].
[162] Information is available at: https://www.contractsfinder.service.gov.uk/Notice/9d0ee7bb-e549-445c-832f-961375e50139.
[163] BIVDA, Request for Information relating to awards for contracts without a call for competition, sent to Department of Health and Social Care, 6 August 2020.

Health having been provided with contact details by BIVDA's Chief Executive.[164] However, it is not clear to what extent DHSC's request went beyond simply asking for names rather than a more systematic enquiry as to capacity within industry or whether DHSC sought to follow-up where further information and support was volunteered by industry associations or individual suppliers.

4.39 Lessons learnt and recommendations in respect of identifying suppliers can be identified below.

Grounds for a Direct Award

4.40 The most often used ground for direct awards under reg.32 PCR 2015 during the pandemic appears to have been "extreme urgency". The constituent elements of this ground require some unpacking to better understand its application in the context of procuring IVD test kits.

Extreme urgency

4.41 Reg.32 requires that there must be "reasons of extreme urgency". It is possible to argue that contracts should not have been awarded under reg.32 on the basis that there was no extreme urgency and events were foreseeable at the onset of the pandemic; further, that even if there was extreme urgency that was unforeseeable at the onset, this was not the case some months in.

4.42 The EU Directives and PCR 2015 do not define or expand on the concept of "extreme urgency". Therefore, it is ultimately a question of fact for the court as to whether circumstances of extreme urgency existed at the time of award.[165]

4.43 In the case of antibody tests, in the Abingdon Health plc legal challenge, it was claimed that there was no basis for a direct award in March or April 2020 because: (i) the need for rapid tests was not unforeseeable: DHSC was aware of the need to acquire tests for many months and inaction was due to DHSC's own lack of planning and appropriate action; and (ii) DHSC had sufficient time to call off a contract under an existing framework agreement or DPS. At the stage of giving permission for judicial review, Waksman J determined that there was extreme urgency in March and April 2020. He stated that it is easy to look back with hindsight but at the time: (1) there was a lockdown; (2) at that stage it was unclear whether there would be a reliable antibody test; (3) the relationship between possessing antibodies and immunity was not clear; (4) it was not clear at that point whether there would be a successful vaccine; and (5) in March and April 2020, no existing test had passed validation.[166] Ultimately, he considered that it was difficult to think of a greater situation of urgency so far as the obtaining of tests was concerned given that this would be the key test in determining immunity and the possibility of easing social restrictions. He stated that it was first necessary to find someone who could at least develop the test and which had to be done as a matter of extreme urgency and which explained the very sharp timescale for the awarding of a contract to somebody in April to undertake research.[167] It was considered that as this was a case of science in a fairly undeveloped state (not manufacturing widgets) where things could not simply be done in a couple of weeks, on the face of it, a contracting authority was entitled to wait to see what the results of the research were and to proceed to a further contract for manufacture, if necessary.[168]

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[164] Department of Health & Social Care, Contract Award Notices – Request for Information response, 17 August 2020.
[165] *Public First Limited*, [90].
[166] *The Queen On The Application Of The Good Law Project v Secretary of State for Health and Social Care* [2021] EWHC 844 (TCC), [31] and [32].
[167] Ibid., [34].
[168] Ibid., [35].

4.44 It was also determined that there was extreme urgency in June and August 2020 to get the components which were understood to be in short supply and make the first tests such that it was not necessary to wait even fifteen days under an accelerated competitive procedure.[169] There was at least sufficient confidence that someone should be awarded a contract to develop the test so as to make it available in the sort of numbers which would provide real assistance going forward.[170]. By the time of the full hearing, it was accepted as common ground by all parties that there was extreme urgency.[171]

4.45 The courts have not considered in detail whether there was extreme urgency during the same periods (March to August 2020) in respect of other types of diagnostic test. The likely indication is that extreme urgency would also be found in these early stages. To the extent analogous, in challenges to PPE and communications contracts, the courts have accepted that there was extreme urgency.

Events unforeseeable

4.46 Reg.32 also requires that extreme urgency must be brought about by "events unforeseeable by the contracting authority". In respect of antibody tests, in the Abingdon Health plc legal challenge it was also claimed that the need for rapid tests was not unforeseeable from April 2020 onwards. For the reasons given above, Waksman J stated that, of course, everybody knew they needed tests but this did not mean that "you could throw a contractual switch" and contract with someone to produce tests immediately. As no sufficiently accurate test had passed validation, there had to be a staged process which first involved research which, if promising, would necessitate a further contractual framework including for supply.[172]

4.47 Concerning antigen tests, BIVDA submitted a Freedom of Information request to DHSC in respect of various awards expressing its view that since March 2020, there was no longer a state of extreme urgency with events unforeseeable.[173] It identified that by this point, Government conducted bi-weekly industry webinars, developed its Pillar 1 and Pillar 2 strategy, worked with suppliers and trade associations to launch the Open Innovation Platform, extended existing frameworks from PHE and NHS Supply Chain and invited suppliers to add their COVID-19 products to them as range extensions. In response, in mid-August 2020, DHSC stated that the demand for POC tests was (and remained at that time) exceptionally high and, in the absence of the contracts in question, there was a real risk that the products would be sold elsewhere. There was an extreme urgency to protect available and future stock from being acquired by other purchasers. Also, experience in other countries (the EU for example) demonstrated that there was little or no incentive for suppliers to participate in competitive procedures as they were able to supply to numerous purchasers throughout the World without the time and cost involved in a competitive award. On the issue of unforeseen events, DHSC stated that, whilst COVID-19 was known to DHSC in April 2020, neither the full extent of its impact and measures required to control it nor the change in market dynamics in the form of the buyer's competition was foreseeable.[174]

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[169] Ibid.

[170] Ibid., [36] and [37].

[171] *Abingdon Health plc* [24] and [295] repeating O'Farrell J's original decision. On an oral renewal hearing, Waksman J refused permission for largely the same reasons – see paras [28]-[37] of that judgment: *Abingdon Health plc* [296].

[172] *The Queen On The Application Of The Good Law Project v Secretary of State for Health and Social Care* [2021] EWHC 844 (TCC), [32].

[173] BIVDA, Request for Information relating to awards for contracts without a call for competition, sent to Department of Health and Social Care, 6 August 2020.

[174] Department of Health & Social Care, Contract Award Notices – Request for Information response, 17 August 2020.

4.48 This response is fairly general and does not appear to directly address the suggestion that the Government's actions in engaging with the rest of industry indicated that there was no extreme urgency and that it could open contracts to competition so as to negate any possible justifications for future direct awards. However, it might be argued that whether extreme urgency existed is not negated by further engagement with industry. Ultimately, direct awards had already been made to cover a period of six to twelve months to meet what appeared to be the bulk of its requirements. Further engagement with industry in the intervening period might simply be a means of informally communicating to the market that industry could potentially meet other or additional demand in this period and in future by other means. As discussed below, it actually subsequently transpired that direct awards continued to be made following earlier direct awards which further delayed the introduction of competitive procurement but, again, a legal justification was provided. Moreover, as indicated, if extreme urgency is established, there may be no legal obligation to conduct extensive searches of the market or to conduct competitions in any event. There may be a theoretical possibility of competition or alternative suppliers available on the market but this does not necessarily mean that there is a legal obligation to try to facilitate competition and identify other suppliers at all costs, especially in cases of ongoing extreme urgency.

4.49 Similarly, to the extent comparable or analogous, the courts have also rejected claims that urgency was foreseeable and attributable in other COVID-19 contract award cases e.g. due to lack of proper planning. [175] The courts have considered that whilst a need might be established as foreseeable, the extent to which a need may increase and the market may radically change may not be foreseeable.[176]

4.50 Whatever the legal position, Government engagement with industry referencing or signalling future opportunities might have given the impression that there would be sizeable opportunity for competition when, in reality, the opportunity was more limited and would not actually be introduced as early as anticipated through framework agreements and DPS. Rather than being a legal issue, the issue may be one of effective market signalling and expectation or impression management i.e. avoiding the suggestion that competitive procurement was on its way shortly when this was by no means certain and was ultimately not the case. This is a delicate balancing exercise given that the Government also needed to indicate that it was, at least, engaging with industry at a time when sizeable direct awards had been made to certain suppliers.

4.51 From September 2020 onwards, direct awards continued to be made for kits such as that provided by Innova Medical Group Inc/Biotime. The DHSC published its reg.32 justification for the award as well as a redacted copy of the contract.[177] On extreme urgency, it stated that there were genuine reasons in the form of a surge in global demand for LFTs and that DHSC was responding immediately because of public health risks. On unforeseeability, it stated that the timing of availability of new COVID-19 LFT technology meeting the relevant UK technical requirements coupled with high international demand and limited global capacity was not foreseeable. Again, these justifications may appear brief and somewhat generic but, as discussed in more detail below, the PCR 2015 do not require extensive

[175] Notification of the Judge's decision on the application for permission to apply for judicial review (CPR 54.11, 54.12) HT-2020-000226, 17 November 2020 and *Public First* [124].
[176] Notification of the Judge's decision on the application for permission to apply for judicial review (CPR 54.11, 54.12) HT-2020-000226, 17 November 2020.
[177] Information is available on the Contracts Finder website at: https://www.contractsfinder.service.gov.uk/notice/ca07d68e-8f93-4864-9c4b-f24f1e117162?origin=SearchResults&p=1.

information to be provided in respect of the reasons for the award and the process followed.[178]

4.52 Notwithstanding, the justification referring to the timing of new LFT technology meeting relevant UK technical requirements is not entirely clear, for example, whether it refers to the introduction of the national technical validation process (which seems more likely) or MHRA regulatory approval for placement of test kits on the market; as will be discussed in Part IV, Chapter 6, the Innova/Biotime test kit received an exceptional use authorisation for placement on the market which meant that it did not have to undergo full regulatory approval. On one hand, it might be argued that it could not necessarily be foreseen that validation processes of the kind introduced would be required, take as long (e.g. due to the number of submissions made), or that so many suppliers would fail validation. On the other hand, it could be argued that the Government has sought to rely on the timing of the introduction of one of its own processes as a reason for a direct award such that extreme urgency and the circumstances are attributable to it.

4.53 However, it might be difficult to argue that an award to a particular supplier was not justified where it had been able to obtain validation before other suppliers. Ultimately, a supplier may simply have first mover advantage with a ready for use test and may be able to supply to scale whereas other suppliers may not meet validation or approval requirements and cannot supply to scale. Indeed, it could even be argued that, in addition to the ground of extreme urgency, it might be possible to rely on the technical reasons or exclusive rights ground for recourse to reg.32 on the basis that only one or a select number of suppliers could meet validation and regulatory approval requirements and were, therefore, the only suppliers capable of supply but this is not clear. The upshot is that there could, at least, be a *prima facie* legal justification for such contract awards in the early stages.

4.54 Whilst there appears to be general acceptance that there was extreme urgency with circumstances unforeseeable in the earlier stages, one potential outstanding issue is at what point can it be said that there is no longer extreme urgency? On one hand, even many months into the pandemic, there were still a number of "unknowns" e.g. how COVID-19 might mutate with new variants of concern, the extent of immunity, the potential for success of the vaccine, risks in respect of other public health contingencies e.g. winter flus, quite apart from how the continuation of COVID-19 might affect economics e.g. of demand and supply and public finances. On the other hand, months and now even years on, there is more certainty on many of these issues and there is scope to plan for contingencies which leaves contracting authorities better placed to determine the nature and extent of their need. Indeed, the Cabinet Office revisions to its guidance in February 2021 appeared to indicate an understanding of a risk that recourse to reg.32 might not be justified in all cases as time passed, emphasising the need to continue to provide sufficient information to justify decisions taken and to consider some form of informal competition as well as due diligence on the supplier market before making a direct award.[179]

4.55 Any conceivable assessment of extreme urgency and foreseeability as time passes is fraught with difficulty. As discussed below, as evident in contract award notices, the Government has claimed that the new Omicron variant has led to increased demand. Of course, it might be argued that the Government could plan for such new variants of concern and probably did plan for such risks. However, there may be scope for all manner of

[178] For a discussion of this issue in more detail, see L R A Butler, 'Regulating Single-Source Procurement in Emergency Situations in Light of the COVID-19 Pandemic: Issues in Policy and Practice' in S Arrowsmith, L R A Butler, A La Chimia, and C R Yukins (eds), *Public Procurement in (A) Crisis: Global Lessons from the COVID-19 Pandemic* (Hart, 2021), pp.126-128.

[179] Procurement Policy Note – Procurement in an Emergency Information Note PPN 01/21, February 2021, paras.9 and 10.

arguments about the timing of new variants which could not be anticipated, the pool of new potential users of test kits being expanded in ways not envisaged etc, and a range of other contingencies and variables which create further extreme urgency and unforeseeability. For example, a year into a pandemic, a competitive framework agreement or DPS may be set up to competitively procure large volumes of test kits which pass validation and approval as a means of providing a "standing" or reserve stock to guarantee supply or distribution from a range of sources. However, if a new, more rapidly transmissible variant is discovered, requiring even larger volumes on a mass scale, there may be a risk that if further competitive call-off awards are made under the framework agreement or DPS to try and meet this demand, the existing stock available under them may be quickly exhausted. This might necessitate a direct award to a single supplier (who may have received direct awards previously and is even registered on the framework agreement or DPS) to meet the surge demand and which avoids impacting reserve supply. It might be open to argue that call-offs should be made under the framework or DPS first before considering direct awards but this may not fully meet demand in any event and exhaustion of stocks would end arrangements whose purpose is to provide a reserve thereby leaving no reserve. Similarly, it might be argued that, as time passes and a number of products pass validation or regulatory approval for placement on the market, a technical rights/reasons justification for a direct award to a single supplier who has been licensed to supply might become less tenable. Again, there may be any number of conceivable technical or exclusive rights reasons for continuing with direct awards to the same supplier.

4.56 The upshot of the above is that whilst it is easy to assert that as time passes there is no longer a state of extreme urgency or unforeseeability, much will depend on the circumstances and there is certainly scope for legitimate justifications for continuing direct awards to be put forward many months into a pandemic. This does not mean to say that the Government cannot better plan in future to try to minimise the expected use of direct awards e.g. through effective planning of advance purchasing arrangements which involve a degree of competition and anticipate risks to avoid "stop gap" direct awards, where possible.

Time limits for more competitive procedures cannot be complied with

4.57 Reg.32 also requires that "the time limits for the open or restricted procedures or competitive procedures with negotiation cannot be complied with". It might also be argued that at various points in the pandemic, it would have been possible to conduct accelerated competitive procedures. In a contract award notice for a contract to Abingdon Health plc, DHSC stated that it was impossible to comply with the usual PCR 2015 timescales in a way that would allow DHSC to manufacture or secure delivery of products and that delay would have led to a significant and real risk that a competing purchaser would have secured them, leaving the Department without provision and severely undermining its ability to offer immediate POC testing and protect frontline workers and the public. Demand for POC test kits was said to be high and there was little or no incentive for suppliers to participate in competitive procurement procedures.[180] The contract award notices for the Innova direct awards were more brief in simply stating that it was not possible to comply with the timescales due to the urgent requirement to ensure delivery of LFTs for distribution across the UK.[181]

4.58 In a Freedom of Information request in respect of certain test kit contracts, BIVDA stated that the contracting authority would have no way of knowing the impact of running an accelerated

[180] Contract award notice 2020/S197-478551: https://ted.europa.eu/udl?uri=TED:NOTICE:478551-2020:TEXT:EN:HTML&src=0. See the similar justification provided in respect of an award to Diagnostics for the Real World Ltd: Contract award notice 2020/S 150-369085: https://ted.europa.eu/udl?uri=TED:NOTICE:369085-2020:TEXT:EN:HTML.

[181] Contract award notice 2020/S 217-533961: https://ted.europa.eu/udl?uri=TED:NOTICE:533961-2020:TEXT:EN:HTML&src=0.

procedure within the compressed timescales and asked for information on how long was the time between approaching single suppliers with no competition and awarding and concluding a contract.[182] In response, DHSC maintained that there was no time to run an accelerated procurement restating the kinds of reasons provided in contract award notices above. DHSC stated that it very much hoped that going forward there would be an appetite for suppliers to engage with the new National Microbiological Framework (which is considered in below).[183]

4.59 In the Abingdon Health plc judgment, the court considered that competitive procurement within short timescales would not be possible.[184] In another challenge by the Good Law Project to the award of a Cabinet Office communications contract, it was argued in similar terms that an accelerated competitive procedure could have been used.[185] In that case, an existing Research Marketplace DPS allowed procuring entities to buy research services by running competitions among a list of registered suppliers. However, evidence confirmed that the possibility of its use within a period of two weeks would only have been suitable for the simplest requirements, assumed available staff resource, presumed that documents would be in place by commencement, and would leave limited time for bidder responses.[186] O'Farrell J earlier observed that case law supported the relevance of these factors in the assessment. In considering whether an accelerated procedure was possible, the court must consider the minimum time needed in practice for other steps such as allowing for preparing tender documentation, evaluating tenders, and communicating awards.[187]

4.60 In light of the above, it is conceivable that in the time taken to make direct awards, it might have been theoretically possible to use accelerated competitive procedures. Indeed, it cannot be assumed that direct awards were always made more quickly than could otherwise be the case under an accelerated competitive procedure, particularly if there were protracted negotiations with suppliers. However, there is no express legal requirement to test or trial whether an accelerated competitive procedure could be undertaken more quickly before deciding whether to make a direct award. Further, as indicated, the case law suggests that there are other factors which might make it impractical in the case of more complex requirements, of which IVD test kits are likely to be an example (e.g. in terms of documentation required, evaluation etc). If there are ways to practicably facilitate accelerated competitive procedures for procuring diagnostics in certain cases, these should be considered going forward.

Use is only insofar as is strictly necessary

4.61 Reg.32 must also be used "only insofar as is strictly necessary". In the Abingdon Health plc legal challenge, it was argued that whatever contract is awarded must be proportionate or strictly necessary such that contracts for vast sums of money must not be awarded where a smaller "stop-gap" contract will do pending such time as an open transparent competition could be conducted.[188] Waksman J determined that, on the facts, these were relatively limited contracts. One contract for securing components with a view to developing the test

[182] BIVDA, Request for Information relating to awards for contracts without a call for competition, sent to Department of Health and Social Care, 6 August 2020.
[183] Department of Health & Social Care, Contract Award Notices – Request for Information response, 17 August 2020.
[184] It was acknowledged that there is an accelerated procedure allowing for 15 days but that even this would not need to be used provided that reg.32 is complied with: *Good Law Project Ltd v Secretary of State for Health and Social Care* [2021] EWHC 844, [29].
[185] *Public First*, [72].
[186] Ibid., [102]; [103]; [104]; [105]; [106].
[187] Ibid., [91] citing *Salt International Ltd v Scottish Ministers* [2015] CSIH 85 at [46], [106], [107] and Court of Appeal, [39].
[188] *The Queen On The Application Of The Good Law Project v Secretary of State for Health and Social Care* [2021] EWHC 844 (TCC) [38].

was of modest duration (June to July 2020) and a subsequent contract to purchase only one million tests (with an option to purchase nine million) was also limited.[189] In other COVID-19 contract award cases, the courts have also accepted that recourse to reg.32 was strictly necessary.[190]

4.62 In a number of contract award notices, the explanation given has simply been that test kits were strictly necessary to meet the demand to scale up the testing programme. There are further references made to evidence of exceptionally high demand (for instance, foreign governments, private healthcare organisations, corporations and airports) which far exceeded limited supply. The contract award notice for the October 2020 Innova contract added a further explanation, referring to a "constrained supply of validated products". More specifically, it states that some raw materials required to manufacture LFDs are only globally available in a limited number and can suffer supply chain disruptions; further, while many potential LFD suppliers exist, PHE Porton Down validation had revealed that many of these suppliers did not have viable products. On this basis, it stated that there was only a very small number of global developers of validated products and many of these were small companies attempting to scale manufacture at the time.[191] The issue of justification based on validation requirements has already been considered above.

Technical Reasons or Exclusive Rights

4.63 For the sake of completeness, it should be observed that there are also examples of contract awards relating to diagnostics made on other grounds such as technical reasons or exclusive rights. For example, contracts were awarded to Ortho Clinical Diagnostics and Abbott Laboratories in respect of test kits for use as part of pre-existing testing capacity.[192] In the case of Ortho Clinical Diagnostics, in the contract award notice, the reg.32 justification stated that DHSC procurement strategy required efficient use of the capacity of test instruments already installed at UK laboratories; as a test had been developed using Ortho test instruments installed in UK laboratories, this justified the continuing use of Ortho testing. It was also stated that DHSC understood from enquiries made from its own technical experts that the test instruments in both cases were a 'closed' platform, meaning that only goods manufactured by them would be interoperable. Further, the supplies could only be supplied by a particular economic operator: Ortho and Abbott had exclusive intellectual property rights over the testing laboratory systems and were the only suppliers who could provide testing kits that would work on the instruments already in use in the relevant labs. No reasonable alternative or substitute existed for these reasons and the absence of competition was not the result of an artificial narrowing down of the parameters of the procurement but was rather part of the UK Government strategy to increase testing capacity exponentially to meet demand.

4.64 Again, whilst it could be claimed that such instances might risk creating certain informal preferences for certain tests used by certain laboratories based on existing testing infrastructure, ultimately, in the instances identified a technical reason was provided based on a policy of ensuring that existing capacity was used as efficiently as possible. This is an important consideration given that existing capacity was likely to be stretched.

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189 Ibid., [39].

190 *The Queen On The Application Of The Good Law Project v Secretary Of State For Health And Social Care* [2020] EWHC 3609, [329] - [331]; *Public First*, [4]; [74]; [144]; [116-117].

191 Contract award notice 2020/S 217-533961.

192 See, for example, contract award notice 2020/S 135-331346: https://ted.europa.eu/udl?uri=TED:NOTICE:331346-2020:TEXT:EN:HTML.

Exercise of Options and Modifications to Existing Contracts

4.65 It is also important to acknowledge that, as indicated in the National Audit Office figures, a number of existing contracts were extended or varied, although it is not necessarily clear whether this concerned contracts that were awarded pre-pandemic and extended to respond to COVID-19 or contracts awarded during the pandemic and then extended to respond to further developments in the pandemic. As indicated, Reg.72 PCR 2015 permits the lawful modification of contracts without the need for a new contract award procedure in prescribed circumstances.

4.66 There are examples of short contracts awarded (e.g. for six months) which simply included contract options to extend contracts for a short time limited duration.[193] Provided the exercise of such options is simply the result of contractual terms under the contract and which does not alter the contract beyond those terms so as to effectively constitute a different contract (which might trigger the need for a new award process), these are lawful.

4.67 There are also examples where contracts did not expressly contemplate the exercise of lawful options but circumstances have arisen which were unforeseeable and require modification of the contract (or, indeed, lawful options were included but the circumstances which have arisen exceed even the permissible limits of those options).[194] One circumstance that has been cited during the pandemic is Reg.72(1)(c) where the need for modification has been brought about by circumstances which a diligent authority could not have foreseen, the modification does not alter the overall nature of the contract and any increase in price does not exceed 50% of the value of the original contract. There are examples of certain high-profile contract awards (e.g. the Innova awards) being modified more than once. In practical terms, such "stop-gap" modifications (a description used in a modification notice for Innova test kits)[195] may be desirable to ensure continuity of supply; this may be a better alternative to undertaking multiple new and successive procurement exercises. Further, as discussed below, the Government published modification notices indicating that such extensions have been justified to cover new developments such as the impact of the Omicron variant.

4.68 As modifications in this context are most likely involve the procurement of additional quantities (even substantial) of the same product at the same specification, such modifications are likely to be lawful. To date, to the author's knowledge, there does not appear to have been any legal challenges to contract modifications specifically.[196] Notwithstanding, there is, nevertheless, a risk that these could become convenient tools to avoid competition. Therefore, practice in respect of how contract modifications are planned for and implemented even in emergencies (where their flexibility may be most needed to cover unexpected changes) must be carefully monitored going forward.

Processes for Selecting Suppliers in Direct Awards

4.69 Even if recourse to reg.32 grounds are lawful, there remains the question of what, if any, rules or principles apply to any process for selecting suppliers pursuant to these grounds. A contracting authority may have lawful grounds for making a direct award but may still act

[193] This was the case in *Public First* [2021] EWHC 1569 and where it was determined that the award of shorter stop-gap contracts of this kind was not disproportionate.

[194] For a useful discussion of contract modifications in the context of emergencies, see S Arrowsmith, 'The Approach to Emergency Procurement in the UNCITRAL Model Law: A Critical Appraisal in Light of the COVID-19 Pandemic', pp.59-60 and S Arrowsmith, 'Recommendations for Urgent Procurement in the EU Directives and GPA: COVID-19 and Beyond', pp.73-74 in S Arrowsmith, L R A Butler, A La Chimia and C R Yukins (eds), *Public Procurement in (a) Crisis: Global Lessons from the COVID-19 Pandemic* (2021 Hart).

[195] See e.g. Contract award notice 2020/S 247-615579 Modification notice https://ted.europa.eu/udl?uri=TED:NOTICE:615579-2020:HTML:EN:HTML&tabId=1&tabLang=en.

[196] These were considered in *Public First* [2022] EWCA Civ 21, [58].

unlawfully if the process they follow in making the award breaches other legal requirements. For instance, whilst in the Abingdon Health plc legal challenge it was common ground that there was extreme urgency, what was not common ground was what other obligations under the PCR 2015 apply where reg.32 is relied on.[197] Recent legal challenges suggest that there is no obligation to hold a competition, reg.18 principles do not apply and, even if they do, there are unlikely to have been breaches. However, as indicated above, this does not mean that guidance and processes for making direct awards pursuant to emergency grounds cannot be improved in practice. This Section considers what, if any, legal requirements under the PCR 2015 could apply in the context of IVD test contract awards.

Competition

4.70 As already indicated, it is questionable whether an obligation to hold a competition or consider other suppliers may ever arise in the sorts of circumstances experienced in procuring diagnostics during the pandemic. For instance, PPE involved multiple suppliers making offers on a rolling basis through an open source process where no single supplier could meet total demand. This is not wholly dissimilar to the national validation and procurement process for COVID-19 tests discussed in Part II, Chapter 3. In a legal challenge to PPE awards, the court simply considered the holding of a competition or tendering exercise to be unrealistic given constantly changing demand.[198] Conversely, there have been contract awards for more limited services in which a few suppliers exist and a single supplier could meet demand. One example is a legal challenge to a contract awarded for communications services. However, even here, the court stated that whilst the general requirement for a call for competition is the heart of the PCR 2015 which "triggers" procedures and processes on which their application depend, as reg.32 does not require a call for competition, none of these other rules on procedures and processes therefore apply. Further, it was stated that if negotiation with just one supplier is strictly necessary, there was no requirement for a comparative tender exercise.[199] In the Abingdon Health plc judgment, Waksman J stated his agreement that when, on the face of it, a particular procedure which consists of a direct award to one supplier qualifies under reg.32, it is difficult to see how any other regulation which presupposes an open or some other competition between a number of suppliers can apply.[200]

4.71 It is further recalled from above that it was also not the case in respect of contract awards to Abingdon Health plc that DHSC did not give consideration to the issue of whether there should be a general competition of some kind; the risk of proceeding under reg.32 and making a direct contract award without any competition was acknowledged.[201]

Equal Treatment

4.72 Another issue is whether any other more general legal principles of public procurement apply where a direct award is made pursuant to reg.32 such as those contained in reg.18 PCR 2015, in particular, any principle of equal treatment. In the Abingdon Health plc judgment, Waksman J stated that reg.18 seems to presuppose that there is in fact a competition (i.e. involving a number of suppliers), in which case, a procurement should be conducted fairly as between competitors.[202] As explained above, he was actually of the view that where there

[197] *Abingdon Health plc* [25].

[198] It was not a case where only one supplier could source required PPE (which could be justified under Reg.32(2)(b) on exclusive rights or technical reasons grounds) or within the required timescale. Multiple suppliers could provide but not a single one could meet total demand: *The Queen On The Application Of The Good Law Project Limited (and Others) v Secretary of State for Health and Social Care* [2022] EWHC 46, [347].

[199] *Public First* [2022] EWCA Civ 21 [42] citing that this is what happened in *Salt International.*

[200] *Abingdon Health plc* [301].

[201] Ibid., [165].

[202] Ibid., [302].

was a single award to a supplier (as was the case on the facts) which did not require a competition, reg.18 did not apply. Notwithstanding, he was prepared to determine the case on the basis that reg.18 did apply given that this was a central feature of the Good Law Project's challenge.[203] In this regard, he acknowledged that the "overall position" on the applicability of reg.18 where reg.32 applies seems to be unclear in view of dicta in other COVID-19 contract award cases. Considering those other cases, Waksman J stated that reg.18 did not apply where there was only a single award as was the case on the facts.[204] In real terms, this could mean, for example, that consistent with the absence of any requirement to publish a call for competition and run a competitive tender process, there is no requirement to publish exclusion, supplier selection (e.g. qualification) or award criteria or other minimum requirements. That said, nor did it follow that if reg.18 does not apply, there is some kind of "procurement free-for-all". Some regulations will still apply e.g. the obligation to publish a contract award notice under reg.50. Moreover, it was observed that if there are grounds to suppose that the contract is nonetheless tainted by unlawfulness in any other way, such as irrationality of decision-making (which can be challenged on public law judicial review grounds), those types of challenge remain available.[205] Inevitably, it was acknowledged that everything depends on the circumstances of each case.[206]

4.73 Ultimately, the legal challenge in Abingdon Health plc failed. As indicated in Part I, Chapter 2, three contracts were made for research, component supply and manufacture. Concerning the supply contract, it was not claimed that there should have been a competition to arrive at a single source but rather that DHSC should have contracted with a group of suppliers instead of just Abingdon Health plc. This was rejected by the court because the Good Law Project did not challenge the earlier research contract entered into solely with Abingdon Health plc on the basis of a breach of reg.18 and could not therefore do so in respect of the subsequent contract for components.[207] Further, it was very difficult to see which other supplier had been "unequally treated" unless it was the entire group of suppliers who might have been able to develop at short notice, who had already started developing a test, and who were now ready to commence production.[208] If DHSC should have advertised so as to draw them out, that was tantamount to requiring a competition which was not required here.[209] Moreover, it was wrong to suggest that only Abingdon Health plc had access to DHSC as there was a readiness to deal with anyone.[210] Finally, even if reg.18 were violated, it was objectively justified.[211]

4.74 Concerning the LFT supply contract, by that point in the pandemic, the question of whether COVID-19 infection resulted in immunity remained unclear; therefore, so was the extent of the role that antibody testing could usefully play if it transpired that there was no or limited immunity. It was not about whether other suppliers might have been available to develop a test and supply but rather about how many units were ultimately needed for manufacture in light of this uncertainty. It was hard to see why there should have been more than one supplier at this stage where it was looking increasingly less likely that millions of units for antibody tests would now be needed if no immunity was provided and contractual protections were built into the contract to mitigate the risk of needing less (and in reality it was less than 10 million).[212]

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[203] Ibid., [306].
[204] Ibid., [306].
[205] Ibid., [303].
[206] Ibid., [304].
[207] Ibid., [381].
[208] Ibid., [382].
[209] Ibid., [384].
[210] Ibid., [383] - [386].
[211] Ibid., [387]-[390].
[212] Ibid., [392].

4.75 Concerning the choice of Abingdon Health plc as the sole contractor, the court also noted the following. First, the Good Law Project did not show that there was any contractor prepared to contract on the same terms given to Abingdon Health plc and which actually gave DHSC a very good deal because of all of the options and protections it felt it had to obtain.[213] Second, at the same time, there was still thought to be a use for the tests.[214] Third, no unlawful assistance was given to Abingdon Health plc (e.g. in the form of State aid or subsidy).[215] Fourth, any uncertainty as to test performance or need (which it was claimed included poor test results) did not mean that the selection of Abingdon Health plc as the supplier was unjustified, especially given its terms. Initial test performance results were disappointing but this was explained and test results improved.[216] It was not possible to conclude that, at all material times, there was a host of readily available relevant LFTs from other manufacturers which could have done the job without needing to do other development first, and in the same timescale or were comparable or would have met TPPs.[217] Finally, the fact that DHSC indicated that it would buy from other suppliers if Abingdon Health plc would only take a price above a certain level did not indicate that there were other relevant tests already available prior to making the supply contract.[218]

4.76 In the absence of other legal challenges to the award of test kits resulting in published judgments, it is not possible to comment on the risks of breaching equal treatment obligations in a more straightforward purchase of tests. However, the indications from the COVID-19 cases generally suggest that it may be difficult to establish that reg.18 applies and, if it does, that there will be categorical (as distinct from merely arguable) breaches of equal treatment and other obligations on the basis that there were other potential suppliers who should have been considered or that particular suppliers were given favourable treatment.

4.77 It should be added that, at the time of writing, the Good Law Project is investigating what it describes as the "latest VIP scandal" in respect of test kit contracts, although no legal challenges appear to have yet been made.[219] To put this issue in context, there had been a high-profile Good Law Project challenge to the award of contracts for PPE on the basis of an alleged "VIP" lane. In that case, the court confirmed that a high-priority lane did breach equal treatment and transparency obligations.[220] However, it must be qualified that it was a limited finding because the court determined that the awards were justifiable. Whether offers were assessed through the designated portal or a high-priority lane, it was very likely that the same suppliers would have received the awards.[221] Further, it should be observed that in the Abingdon Health plc challenge, the evidence indicated that this was something DHSC was cognisant of when undertaking due diligence. For example, civil servants requested "more detail on VIP" which was considered critical as "they would face significant legal challenges" if they have affected the market by offering one company a competitive advantage and how were they protecting against this risk.[222]

4.78 In June 2021, the Good Law Project published emails in which it alleged the existence of a "fast track" for testing contracts where leads originated from a Minister or private office

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[213] Ibid., [394].
[214] Ibid., [395].
[215] Ibid., [396].
[216] Ibid., [397] – [399].
[217] Ibid., [409]-[402].
[218] Ibid., [403].
[219] Information is available here: https://goodlawproject.org/revealed-for-the-first-time-full-list-of-vip-test-and-trace-firms-given-priority-treatment/ and here: https://goodlawproject.org/revealed-the-names-of-those-who-referred-covid-testing-firms-into-the-vip-lane/.
[220] *The Queen On The Application Of The Good Law Project Limited (and Others) v Secretary of State for Health and Social Care* [2022] EWHC 46, [398]-[399].
[221] Ibid., [401], [403] and [518].
[222] *Abingdon Health plc*, [152] and [199].

alongside the ordinary portal and triage route.[223] It obtained via a Freedom of Information request correspondence which it said indicated that SureScreen Diagnostics Ltd was awarded a contract after "heavy prompting" from Dr. Liam Fox MP who allegedly sent an email to the then Health Secretary in June 2020 in which he pushed for PHE to contact SureScreen.[224] It further reported that in January 2021, DHSC announced that SureScreen's tests had been approved and, without competition, it had been awarded a two year £503 million contract. The Good Law Project also submitted a Freedom of Information request for further information in respect of an alleged VIP lane for the T&T and trace programme. This included a request for publication of both the names of suppliers who it claimed received priority treatment and the names of those who referred them. In response, UKHSA published a list of fifty suppliers and which is reproduced below.[225] In November 2022, the Information Commissioner's Office then determined that the UKHSA had failed to demonstrate why further information could not be published on the basis that the costs of compliance were excessive.[226] The UKHSA has since published the names of ministers or senior officials who referred suppliers; however, this list is not reproduced here and does not address comments which have been made regarding the basis for referral by the relevant individual to avoid any further speculation.[227]

Table 5: List of Suppliers provided in response to the Good Law Project request

Supplier Name	
Innova Medical Inc	HSL
Thermo Fisher (including Life Technologies – acquired by Thermo Fisher in 2014	King's College London
Hologic Ltd	University of Birmingham
SureScreen Diagnostics Ltd	Sterilab Services
DNANudge Ltd	Queen Mary University of London
LGC Ltd	University of York
University of Southampton	Bigneat Ltd
Origin Ltd	Tecan UK Ltd
Roche Diagnostics Limited	UNA Health
Eurofins UK Limited	Diasorin Ltd
Ecolog International (UK) Ltd	Qnostics Ltd
LumiraDx UK Ltd	Charnwood Campus Management Ltd
Accora Ltd	The University of Manchester
IQVIA Services Ltd	Pro-Lab Diagnostics
Aptamer Group Ltd	University of Oxford
Hotel Logistics Ltd	Wolf Laboratories Limited
Thriva Ltd	Pal International
Omega Diagnostics Limited	Newcastle University
The Native Antigen Company Ltd	University College London
Bio-Rad Laboratories Limited	University of Liverpool
Otigene Limited	University of Warwick
Primerdesign Ltd	Detact Diagnostics
Abbott Laboratories Ltd (including Abbott Rapid Diagnostics Limited)	Waters Limited

[223] Information is available at: https://goodlawproject.org/news/vip-lane-for-testing-contracts/.
[224] Information is available at: https://goodlawproject.org/news/vip-test-and-trace-surescreen/.
[225] Information is available at: https://goodlawproject.org/news/revealed-for-the-first-time-full-list-of-vip-test-and-trace-firms-given-priority-treatment/.
[226] Information Commissioner's Office, Reference: IC-150101-Z2Z4, Freedom of Information Act 2000 (FOIA) Decision notice, 3 November 2022: https://ico.org.uk/media/action-weve-taken/decision-notices/2022/4022669/ic-150101-z2z4.pdf.
[227] UK Health Security Agency, 03/11/22/KMG/1000, IC-150101-Z2Z4, 21 December 2022: https://drive.google.com/file/d/1i1DhMGaIvuQlfqn2tTUiBC0TcNy5rYll/view.

Dante Labs (Immensa)	Humasis Co Ltd
Berkshire And Surrey Pathology Services	CAS Ltd

4.79 It appears that the nature and status of this list cannot be discerned from the UKHSA response e.g. whether it is a standing list of known suppliers, a list of referred suppliers, a list of TVG approved suppliers or other. The list does contain suppliers such as universities but there is no indication on the information available that these have been given priority treatment, also bearing in mind that these are not private sector companies. It is possible (but which does not appear to have been verified) that this looks more like a list of suppliers for validation.

4.80 The UKHSA Freedom of Information response also outlined the procurement evaluation process in respect of these contract awards. It was stated that all offers were evaluated by commercial professionals against the same criteria, assessing value for money and their ability to meet the government's rigorous standards and deliver the service required. It further stated that the testing services provided by suppliers were often for complex or innovative scientific products or services such that, where necessary, an expert technical evaluation process was also carried out. As recalled from Part II, Chapter 3, the relationship between the technical validation and evaluation and procurement processes is unclear in terms of which criteria have been applied and how. The UKHSA does not shed much further light on the details of how procurement of test kits was conducted in terms of the selection and award criteria applied. This request is a further indication that there may be ways to improve the transparency of the processes for making such awards in practice to mitigate the risk of possible legal challenges. Ultimately, at the time of writing, it is not clear whether the Good Law Project intends to proceed with a legal challenge to any alleged priority treatment of test kits.

4.81 As a postscript, it may be added that the VIP lane issue has been raised in debate on the Procurement Bill. An amendment was proposed to require that any Minister, peer or senior civil servant involved in recommending a supplier for a contract must make a public declaration of any private interest but this was voted down.[228]

Irrationality and Apparent Bias

4.82 In addition to challenges to COVID-19 contract awards under the PCR 2015, there have also been attempts to challenge the legality of contract award processes on domestic public law grounds. Claims include that the Government has acted "irrationally" or with "apparent bias". However, again, in reality, these have had, and are likely to have, limited success. In the Abingdon Health plc judgment, the Good Law Project claimed that contract awards were irrational for various reasons which the court rejected. These included the approach to considering approval of decisions by the SAP, failure to properly enquire into suppliers' capability, suitability, supply chain or financial position, an unlawful preference for Abingdon Health plc on grounds of nationality, and the fact that contracts had been entered into before they had received validation or approval by MHRA.[229] Further, it was argued that there was apparent bias as a result of the alleged interest in, and assistance given by, scientists in respect of certain companies as well as apparent bias of others involved in decision-making. Waksman J was of the view that the doctrine of apparent bias was not applicable at all in this context.[230] Moreover, even if it were, this claim was rejected.[231]

[228] Parliamentary Debates, House of Commons Official Report, General Committees, Public Bill Committee, Tuesday 7 February 2023, Procurement Bill [Lords] Clause 41, at 139.
[229] *Abingdon Health plc* [314]-[322]; [323]-[326]; and [330].
[230] Ibid., [339] following an earlier ruling by the Court of Appeal in *Public First* at [71].
[231] *Abingdon Health plc* [263]-[283]; [345] and [348].

4.83 As discussed in Part II, Chapter 3, whilst it is important to emphasise that there has been no finding of any unlawful conduct in respect of approaches to validation, legal challenges of this kind brought in respect of contract awards to Abingdon Health plc are nevertheless an important reminder that uncertainty in validation processes and the role of key decision-makers is a legal risk which can be mitigated through clearer and more transparent validation processes.

Transparency

4.84 A final issue is whether there are any applicable legal obligations to ensure transparent procurement processes. At the outset, it should be acknowledged that there are increasing calls for greater transparency of public procurement and which tends to assume or expect that the Government is legally required to publish all manner of information. However, it must also be qualified that, in reality, the Government only has certain legal obligations in respect of transparency in the conduct of public procurement and there are also legitimate reasons for not providing full transparency. For example, as indicated, in the case of direct awards, there is no legal requirement to publish contract notices advertising a contract opportunity. This necessarily increases the importance of publishing contract award notices of the kind discussed in this analysis. Further, characteristic of international regulatory regimes on public procurement, information obligations are relatively piecemeal in terms of what information is required at different stages of a procurement process and the detail to be provided. For example, there are no general legal obligations to publish the processes for awarding contracts in terms of publishing the selection and award criteria and there are fairly limited record keeping and reporting obligations. This Section considers some of the main legal obligations which do apply and the levels of transparency which appear to have been provided in respect of the procurement of IVD test kits during the pandemic.

4.85 First, reg.18 PCR 2015 provides for a generally expressed principle that contracting authorities must act in a transparent manner. In the Abingdon Health plc judgment, the court considered this general transparency principle. It is recalled that the court questioned whether reg.18 applied at all and, even if it did, it did not find any specific breaches.

4.86 Second, reg.50 PCR 2015 requires the publication of contract award notices. For context, there has been a high-profile Good Law Project challenge to the Government's failure to publish contract award related information and which the Government has acknowledged.[232] The Government has committed to publishing outstanding information although it does not appear to have been confirmed that this has, in fact, been done for all relevant contracts. It is possible that not all contract award notices in respect of contracts awarded under the T&T programme have been published and which should be done as a matter of priority. Nevertheless, it has been possible to identify key contract award notices published in respect of diagnostics contracts. This has even included the separate publication of reg.32 justifications on the gov.uk website. (i.e. not simply contained in, or appended to, a notice). As indicated, some of these contract award notices have been referenced earlier in this analysis. The justifications often take the form of generic descriptions or explanations and it is not uncommon to find the same information repeated in a number of different contract award notices for different awards. This is perhaps unsurprising given that the PCR 2015 (and EU Directive 2014/24/EU on which these rules are based) do not prescribe detailed rules regarding the information which must be provided to justify direct awards and the provision of similar information across notices may, on balance, mitigate legal risk. Perhaps contrary to some expectations, there is no express legal requirement to provide detailed explanations of why contracts were awarded to a particular supplier as against other suppliers.

[232] *The Queen On The Application Of The Good Law Project v Secretary of State for Health and Social Care (and Others)* [2021] EWHC 346 (Admin).

4.87 Third, reg.84 PCR 2015 requires contracting authorities to draw up a written report which includes reference to the circumstances justifying recourse to reg.32 and to document the progress of the procurement procedure. The National Audit Office has identified generally that there have been issues in respect of keeping records documenting aspects of the process for awarding COVID-19 contracts.[233] In the Abingdon Health plc judgment, the court appeared to acknowledge that the circumstances may have prevented detailed record keeping. For example, in evidence, it was revealed that advice given through conversations with the SAP was not recorded in written form. This was explained on the basis that it was a highly pressured situation and that work would not have been done had every conversation been recorded.[234] The court considered that this explanation for the absence of a record of deliberations with SAP was plausible and that there were, in any event, some records of NTAG meetings insofar (at least) as they concerned specific results of its evaluations.[235] The SAP also confirmed that there appeared to be no formal record of the SAP being consulted in relation to Abingdon Health plc being selected nor a formal record of a recommendation to proceed with Abingdon Health plc. More generally, it was stated that there was no formal record of any decision taken by SAP at this stage of the pandemic as it was entirely advisory and made no procurement decision on lateral flow serological tests but that there were active discussions amongst members of the group about the possibility of improving the LFT with innovations that Abingdon Health plc agreed to test.[236] Again, ultimately, reg.84 does not prescribe detailed informational and documentary requirements.

4.88 As indicated in Part II, Chapter 3, whether or not there is a breach of any legal obligation in respect of transparency concerning decisions taken, an important lesson in practice is to ensure that there are clear processes for minuting or at least keeping a basic record of key material decisions (howsoever determined). It is suggested that it would be a reasonable expectation to do so even in emergencies. Industry associations have kept minutes and recordings of their meetings when mobilising a response to the pandemic so the same expectation should apply to Government. This would also contribute, at least in part, to mitigating the risk of legal challenge.

4.89 Fourth, Government policy requires the publication of contract documents and information.[237] A number of contracts published on UK government portals (Contracts Finder/Find A Tender) do provide redacted versions of contracts including terms and conditions and supply schedules alongside contract notices.

4.90 Finally, as this White Paper has referenced throughout, information can also be requested under the Freedom of Information Act 2000 and information can be withheld under exemptions to protect commercial and confidential information. A number of such requests have been made in respect of validation, procurement and regulatory approvals for placement on the market. As discussed in more detail in Part IV, Chapter 6, there are instances where information which has only been revealed following a Freedom of Information request could simply be published as a matter of course to increase transparency with little risk of prejudicing confidentiality or other legitimate interests.

4.91 In light of the above analysis, it is suggested that a number of key direct awards of IVD test kit contracts are likely to have been legally justifiable on grounds of extreme urgency or other

[233] National Audit Office, Report by the Comptroller and Auditor General Cabinet Office, Investigation into government procurement during the COVID-19 pandemic, pp.12, 27 and 31.
[234] *Abingdon Health plc* [140-141].
[235] Ibid., [141].
[236] Ibid., [170].
[237] Publication of Central Government Tenders and Contracts, Central Government transparency Guidance Note, updated November 2017 (withdrawn on 24/06/2021) and Procurement Policy Note – Update to Transparency Principles Action Note PPN 01/17, February 2017.

in reg.32 PCR 2015, although no definitive assessment can be made of any individual contract award as not all facts are knowns. Case law has, at least, indicated that there are no extensive legal obligations regarding the procedure or processes for awarding contracts pursuant to reg.32 and it is questionable which obligations do apply in respect of direct awards. Therefore, any claims about a categorical failure to open contracts to competition, that there was a lack of equal or fair treatment and transparency must be considered in this light. In the only major legal challenge to IVD contract awards resulting in a judgment to date, the court found no breaches. Notwithstanding, the legal issues which have arisen expose areas where lessons may be learnt and recommendations made to improve procurement practice, just some of which are considered in more detail below.

Competitive Awards

4.92 Whilst a majority of contract awards at key phases in the pandemic were direct awards, it is important to acknowledge examples of competitive procurement. Unsurprisingly, it was not the case that many open, restricted or competitive negotiation procedures were used. There is evidence from contract notices that, initially, the Government stated that it intended to run accelerated open procedures.[238] Further, contract modifications to existing direct awards were made as a purported "stop-gap" pending conduct of an accelerated procedure for future requirements.[239] However, it appears that, instead, further direct awards and contract modifications of existing awards continued to be made.

4.93 To the extent that competitive awards were made, these typically took the form of awards through existing framework agreements or DPS as these could be used to source large volumes of similar products from a number of suppliers. Even then, it should be qualified that, at least regarding framework agreements, the extent of competition may have been limited; the framework agreement may have been established via a competitive process but many individual contracts are likely to have been direct call-offs rather than being subject to any further re-opening to competition.

4.94 This Section examines the use of these more competitive purchasing arrangements. At the outset, it should be observed that there does not appear to be a published consolidated list of all framework agreements and DPS applicable in respect of diagnostics and, in particular, for use in response to the pandemic. It has therefore been necessary to focus on select examples which have been repeatedly publicised and referenced in interviews.

Framework Agreements

4.95 The PCR 2015 provide that framework agreements must be procured in compliance with one of the prescribed competitive procedures.[240] Framework agreements offer a flexible means of procurement where a contracting authority can identify the nature of the products to be procured but its individual requirements cannot be identified in advance of purchase. It can put in place an arrangement to procure from suppliers without creating any obligation to purchase exclusively from a single supplier and then "call-off" contracts as and when necessary. Framework agreements can take the form of a single supplier or multi-supplier

[238] Contract Notice 2020/S 218-536544: https://ted.europa.eu/udl?uri=TED:NOTICE:536544-2020:TEXT:EN:HTML.

[239] See for example, the modification of the contract award to Innova Medical Group Inc – Contract award notice 2020/S 247-615579: https://ted.europa.eu/udl?uri=TED:NOTICE:615579-2020:HTML:EN:HTML&tabId=1&tabLang=en.

[240] Reg.33. For a useful discussion of framework agreements in the context of emergencies, see S Arrowsmith, 'The Approach to Emergency Procurement in the UNCITRAL Model Law: A Critical Appraisal in Light of the COVID-19 Pandemic', pp.30-34 and S Arrowsmith, 'Recommendations for Urgent Procurement in the EU Directives and GPA: COVID-19 and Beyond', pp.68-71 in S Arrowsmith, L R A Butler, A La Chimia and C R Yukins, *Public Procurement in (a) Crisis: Global Lessons from the COVID-19 Pandemic* (2021 Hart).

agreement. Multi-supplier agreements may include a direct call-off or a "mini-competition" among framework suppliers resulting in a call-off contract. There is no obligation to publish an award notice in respect of a call-off. The term of a framework agreement must not exceed four years, save in exceptional cases duly justified.

4.96 To put their use for diagnostics in context, in 2016, an initial PHE Microbiology Framework was launched. This appeared to be the first framework agreement of its kind (or one of the first) to coordinate procurement of diagnostics across the sector in the UK. It was established to run for two years with an option to extend for another two, had a value of between £80 million and £120 million, and could be accessed by a number of UK public sector bodies but not NHS Trusts or NHS Foundation Trusts which used their own purchasing arrangements. PHE reserved the right to purchase the same or similar supplies and/or services from suppliers not appointed to the framework agreement at its sole discretion e.g. for economic or technical reasons.

4.97 Whilst the framework agreement could not have anticipated the pandemic, it was used in response. It therefore provides an example of the utility of advance purchasing arrangements for emergencies not least in providing a means of identifying a list of potential suppliers. Certain substantial awards were made relatively early on in the pandemic using this framework agreement. For example, PHE made a direct award to Roche Diagnostics Ltd under Lot 1 of the framework to run from March to September 2020 with an option to extend for six further periods of three months each.[241] The contract was valued at £21 million for supply of certain assays and related consumables, instruments and services. It is also understood that the Government resorted to so-called "range extensions", that is, enabling suppliers to provide new, modified or updated products or services within the same category of those already supplied under the framework agreement to meet additional demand for COVID-19. There does not appear to have been any significant publicised concerns or legal challenges regarding the use of range extensions exceeding the legitimate scope of framework agreements.

4.98 However, throughout much of 2020, there appeared to be no other dedicated or substantial framework agreements established to respond to the pandemic. The National Audit Office has reported that there had been some concern within Government about the lack of competitive procurement in certain direct awards which provided impetus for introducing another PHE microbiology framework. For example, a number of direct awards were made to Randox, including further variation of a contract on the basis that Randox was considered fundamental to meeting testing targets. This prompted the Permanent Secretary of the Cabinet Office to express disappointment at another direct award for the contract variation, given its view that there was time to organise a competitive process. According to the National Audit Office, the Cabinet Office insisted on a written commitment from DHSC that it would initiate a competitive process in time for new contracts to be let from March 2021. This took the form of PHE's National Microbiology Framework.[242]

4.99 In November 2020, PHE established another multi-lot national microbiology framework valued at £22 billion.[243] This comprised four lots: (1) the supply of diagnostics goods or services for the qualitative and quantitative examination of specimens and samples; (2) the supply of R&D goods or services for the same; (3) the development, manufacturing and commercialisation of assays/kits/medical or other therapeutic products; and (4) the supply

[241] Information is available at: https://www.contractsfinder.service.gov.uk/notice/3d248282-eabf-4992-9579-6ecb58a40e6e?origin=SearchResults&p=1.
[242] National Audit Office, Report by the Comptroller and Auditor General Cabinet Office, Investigation into government procurement during the COVID-19 pandemic, p.42, 3.5.
[243] Information is available at: https://www.contractsfinder.service.gov.uk/Notice/04e4b020-b4da-46c8-9600-fdf5509ee3ef.

of clinical laboratory testing services. Lot 1, for example, principally concerned supply of IVDs and associated services. All reagents and consumables had to comply with current CE regulations and/or UKCA regulations as applicable (on which see Part IV, Chapter 6). Notably, this framework agreement appeared to envisage more than just procurement of goods for immediate use with a more substantial engagement of the diagnostics industry envisaged through R&D, manufacture and commercialisation albeit within the permitted time-bound limitations of a framework agreement. [244] The framework agreement was also intended to be accessed by a wider range of public sector bodies, this time including NHS Trusts and NHS Foundation Trusts. The term of the framework agreement was for an initial two years with options to extend by up to two more. DHSC indicated at the time that it could not rule out the possibility that it would be necessary to rely upon reg.32 in the future given the evolving nature and impact of COVID-19, but it hoped that this new framework agreement would significantly reduce the need to do so.[245] As discussed below, it reduced the need for recourse to direct awards to some extent but it is questionable whether there was a significant reduction given that direct awards of high value and volume continued to be made.

4.100 By way of illustration of certain lots, Lot 1 had a contract start date of 8 March 2021 and end date of 8 April 2023 with a total value of £3 billion.[246] It is understood from published information that contracts have been awarded to 112 suppliers, of which it appears 100 were UK registered companies with only 2 from China and 2 from the USA, for example.[247] The author has compiled a Table below indicating a sample of call-off contracts under the framework agreement.

Table 6: Sample of Call-off Contract Awards under the National PHE Microbiology Framework

Supplier and reference	Requirement	Contract Value (GBP)	Contract Start/End
tender_126843/859459 Roche Diagnostic Limited	Contract for supply of cobas® SARS-CoV-2 COVID-19 assays and related consumables, instruments and service to Roche Diagnostics Limited	£21,000,000	16 March 2020 30 September 2020
tender_126843/854825 Pro-Lab Diagnostics	Contract for the supply of Viasure SARS-CoV-2 RT-PCR for COVID-19 testing	£5,181,750	16 April 2020 15 July 2020
tender_126843/861578 Biomerieux UK Ltd	Purchase of Torch 4 PCR platforms and panels to ramp up testing for Covid 19	£9,000,000	22 April 2020 21 April 2021

[244] Information is available at: https://www.gov.uk/government/news/microbiology-framework-created-to-speed-up-access-to-supplies-and-build-threat-resilience.

[245] Department of Health & Social Care, Contract Award Notices – Request for Information response, 17 August 2020. Provided by BIVDA and retained on file.

[246] Information is available at: https://www.contractsfinder.service.gov.uk/Notice/c87ea5c3-e23f-4432-9bc1-996a39f1cc48.

[247] 2 from China; 1 from the Czech Republic; 1 from France; 2 from Germany; 2 from Ireland; 1 from Slovak Republic, 1 from Turkey, 2 from the USA. This information was compiled by the author from the published list of providers under the framework agreement at the date of writing.

CF-0022200D0O000000rwimUAA1 Life Technologies Limited	Purchase of RNA extraction and PCR testing robots for automation from Thermo Fisher to ramp up testing	£7,217,700	16 July 2020 31 March 2021
CF-0022300D0O000000rwimUAA1 Life Technologies Limited	Purchase of consumables for PCR from Thermo Fisher	£331,791,068	29 July 2020 31 January 2021
CF-0022100D0O000000rwimUAA1 Tecan Uk Ltd	Purchase of liquid handling robots for automation from Tecan UK to ramp up testing	£896,202.58	12 August 2020 24 December 2020
tender_126843/911326 Abbott Laboratories Ltd	Contract for the provision of Abbott Alinity m SARS-CoV-2 assays and associated consumables (with the option to extend for a further six months)	£18,000,000	27 November 2020 31 March 2021

4.101 A brief survey of contract awards suggests a tendency towards direct call-offs under framework agreements during the pandemic. Further, justifications have been published which are similar to those provided in respect of technical reasons or exclusive rights under reg.32. To give just one example, in continuing the work of the Lighthouse laboratories (which performed approved and accredited PCR testing using Thermo Fisher Scientific instruments), DHSC purchased under Lot 1 RNA extraction and testing robots for automation for Thermo Fisher Scientific (Life Technologies) to ramp up testing. Continued use of the Thermo Fisher assay was considered necessary to ensure interchangeability and interoperability with existing equipment (i.e. this was the only possible provider).[248] However, it is not the case that there were no call-offs awarded via mini competition, of which examples have been found.[249]

4.102 It should be added that it was also possible to procure diagnostics through existing NHS Supply Chain framework agreements.[250] NHS Supply Chain also set up related framework agreements e.g. on Pathology and Point of Care Testing, Associated Equipment, Instruments, Consumables and Accessories and Managed Services.[251] Whilst beyond the scope of this White Paper (given its focus mainly on procurement of test kits), for the sake of completeness, it should also be mentioned that framework agreements to provide testing services have also been established. For example, in April 2021, DHSC set up its Assisted Testing Framework.[252] This is a four-year framework for the provision of Assisted Testing

[248] Information is available at: https://www.contractsfinder.service.gov.uk/notice/b01d57f7-14a9-49ea-9a44-5fdce97dc282?origin=SearchResults&p=1.

[249] See, for example, awards to AlphaBiolaboraties Analytical https://www.contractsfinder.service.gov.uk/notice/ef3fc64a-258b-4433-b68e-5e331249e620?origin=SearchResults&p=1; and BGI Genomics UK Ltd: https://www.contractsfinder.service.gov.uk/notice/2c5d877f-0378-489a-974a-faf07fcaa75b?origin=SearchResults&p=1.

[250] Information is available at: https://www.supplychain.nhs.uk/categories/diagnostic-equipment/.

[251] Information is available at: https://www.supplychain.nhs.uk/product-information/contract-launch-brief/pathology-and-point-of-care-testing/.

[252] Information is available at: https://www.contractsfinder.service.gov.uk/Notice/682908d9-378d-402e-bdc4-780c7b4d63a4.

services to support DHSC and other procuring entities with outbreaks of viruses or diseases that may be present now or in future and require a testing programme. It will cover but is not limited to the COVID-19 T&T programme, comprises seven regional lots and is valued at £383.3 million.

4.103 In contrast to high-profile publicity and legal challenges to direct awards which have revealed details of how contracts were awarded, it appears that there have been no widely publicised accounts of how framework agreements were actually administered during the pandemic in the UK. However, a number of general observations might be made in this regard based on interviews and other inferences.

4.104 First, the time it took to set up the PHE microbiology framework agreement may suggest that there are possible lessons to learn. There was clearly a concern expressed about the number of direct awards that were being made in the early phases. Various Government communications sought to provide assurance that industry would be able to bid for contracts through such framework agreements. However, the PHE microbiology framework agreement was not established until November 2020 with actual call-offs not being made until 2021 i.e. almost a year after which many direct awards had been made. Whilst there will have inevitably been a number of factors that could have slowed progress, it is open to question whether the process could have been established quicker. One issue could be ownership i.e. who (in terms of executive agency or other body) should take responsibility for setting framework agreements up centrally and how these might relate to other existing initiatives by other public bodies as well as resource issues. For example, PHE did not only set up the microbiology framework but was also tasked with a number of other functions in responding to the pandemic which it also had to coordinate. Further, it is clear that other framework agreements were either set up or continued to operate alongside e.g. NHS Supply Chain. These factors could impact coordination and set up.

4.105 Second, framework agreements may have been preferable to direct awards but may have also limited market access. Anecdotally, it has been suggested (but not verified) that the qualification criteria to get on large framework agreements were problematic e.g. in requesting detailed account information and bank guarantees of suppliers who had already been involved in the response to the pandemic elsewhere. Further, contracts were made by way of direct call-offs i.e. without mini-competitions. This raises the issue of whether the absence of further competition may have impacted the way individual user procuring entities then administered framework agreements to meet their individual requirements and which it has not been possible to discern from interviews. For instance, in the absence of further competition, there are inevitable risks that specifications may be changed to suit certain suppliers, new requirements added, or other changes which may have impacted market access. In response to the BIVDA questionnaire, one supplier stated that they did not get a chance to make an application for the framework agreements because the standards required kept changing.

4.106 Third, another issue is that framework agreements are necessarily confined to suppliers registered on them. In an emergency, this leaves the question of access of suppliers who are not registered but consider themselves capable of delivering requirements. This may result in call-offs being made to registered suppliers who, in fact, enter into separate arrangements with non-registered suppliers who then ultimately provide the products or services. Whilst these partnerships might be a way around the framework membership limitation, they could give rise to “agent”, facilitator or “middlemen” problems, brokering relationships which could cause issues in respect of legal liability and practical issues of who pays and when under contracts e.g. contracting authorities reimbursing suppliers for costs incurred in paying other suppliers etc. This is quite apart from the implications for transparency and accountability in the contracting process.

4.107 The above are just some illustrative issues which indicate the need for a more comprehensive analysis of the effectiveness of diagnostics framework agreements in responding to emergencies and generally.

Dynamic Purchasing Systems

4.108 The PCR 2015 also provide for use of a DPS.[253] A DPS is used for goods, services and works which are commonly available on the market. It must be operated as a completely electronic process. A DPS follows the rules of the restricted procedure and is essentially a two-stage process. At the first stage, all suppliers meeting the selection criteria (and not otherwise excluded) must be admitted to the DPS. They are permitted to apply to join at any time during the life of the DPS (unlike under a framework agreement). At the second stage, individual contracts are awarded in which all suppliers on the DPS (or the category within the DPS, as appropriate) are invited to tender for a specific contract. Therefore, there is no general basis for direct or "single tender" awards under a DPS (unless only one eligible tenderer has applied). Again, DPSs were used alongside framework agreements in response to the pandemic, certain forms of which are explained here.

4.109 On 5 March 2021, DHSC established a Lateral Flow DPS to operate through the UKHSA to help fulfil the requirement for ongoing supply of additional LFT kits.[254] This aligned with the Government's objective for increased asymptomatic testing with 75% of tests being capable of use as a self-test. As a procurement mechanism, it was intended to provide a more flexible route to market and be "future-proof" i.e. capable of covering new providers and innovations (e.g. new specimen collection) to meet evolving DHSC needs. It had an estimated total value (excluding VAT) of over £8 billion. The start date was 7 April 2021 for initial responses with an end date of 6 April 2022. DHSC controlled purchasing under the DPS but could issue tests to other authorities. All legal, economic, financial and technical information regarding conditions for participation were to be provided on the designated eSourcing platform (Atamis). Phase 3A validation was a key gateway criterion. PHE's Protocol for evaluation of rapid diagnostic assays explains the process for achieving this validation. More information on validation is provided in Part II, Chapter 3.

4.110 Whilst the Government does not appear to have published detailed guidance on procurement processes, it did publish a helpful webinar explaining the lateral flow DPS.[255] It explained that the DPS involved an application phase (comprising an application stage and lot admission stage) and a call-off phase. The DPS lots were said to be structured based on two key criteria. The first was the number of tests contained in a box (e.g. 1-2, 7-12, 19-25 etc). The second was the administration method (e.g. self-test, professional test requiring only a trained operator or other professional test). The use of a DPS was said to have several benefits: (1) the qualification window remained open for the duration of the DPS; (2) providers could work to get the right levels of credentials over time; (3) if a provider failed to meet the admission requirements, they could re-apply; (4) lot applications could be updated as and when bidders for lots chose; and (5) new products may be developed and entered at a later date.

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[253] Reg.34. For a useful discussion of dynamic purchasing systems in the context of emergencies, see S Arrowsmith, 'Recommendations for Urgent Procurement in the EU Directives and GPA: COVID-19 and Beyond', pp.68-71 in S Arrowsmith, L R A Butler, A La Chimia and C R Yukins, *Public Procurement in (a) Crisis: Global Lessons from the COVID-19 Pandemic* (2021 Hart).

[254] Information is available at: https://www.find-tender.service.gov.uk/Notice/004511-2021.

[255] This was published under a contract notice on Contracts Finder on 19 March 2021 as CF-0145700D0O000000rwimUAA1. Information is available at: https://www.contractsfinder.service.gov.uk/Notice/be2a436e-b4f9-472b-a3f2-966156389a77.

4.111 The author has compiled a Table providing an illustrative sample of DPS call-offs.

Table 7: Sample of Call-off Contract Awards under the Lateral Flow Dynamic Purchasing System

Notice reference and supplier	Estimated/Total Value (GBP)	Award criteria + weighting (%)	Tenders received	Contract Date
2021/S 000-016593 Innova Medical Group Inc	£143,750,000 2021/S 000-023641 modified to 518,750,000	Price	1	16/06/21
2021/S 000-016597 Medco Solutions Ltd	£62,475,000 2021/S 000-023643 modified to 240,975,000	Price	1	17/06/21
2021/S 000-016599 Tanner Pharma UK Limited	£103,600,000	Price	1	17/06/21
2021/S 000-023103 Medco Solutions	£325,220,000	Price	9 (2 non-EU)	02/09/21
2021/S 000-023111 Tanner Pharma UK Limited	£243,360,000	Price	9 (2 non-EU)	03/09/21
2021.S 000-023112 Sterilab Services	£271,560,000	Price	9 (2 non-EU)	06/09/21
2022/S 000-001383 Innova Medical Group Inc	£322,500,000	Quality/Social Value: 30 Price: 70	9 (2 non-EU)	17/12/21
2022/S 000-007559 Medco Solutions Ltd	£237,800,000	Quality: 30 Social Value: 10 Price: 60	17	23/02/22
2022/S 000-007560 Tanner Pharma UK Limited	£595,000,000	Social Value: 10 Quality: 30 Price: 60	17	23/02/22
2022/S 000-007561 Pharmaceuticals Direct Limited	£85,100,000	Quality: 30 Social Value: 10 Price: 60	17	23/02/22

4.112 Again, in the absence of detailed published information on the operation of DPSs during the pandemic, several more general observations can be made.

4.113 First, similar to the time taken to operationalise the PHE microbiology framework, it took a relatively long time to operationalise the Lateral Flow DPS. It was not advertised until March 2021 and the first awards not made until mid-2021 by which point a majority of direct awards had already been made. This may have been a strategic policy response to increase availability of LFTs which were not necessary to meet an immediate need but it might be questioned whether the DPS could have been introduced earlier.

4.114 Second, as indicated by the Table, early recipients of contracts under the DPS were already the major recipients of earlier direct awards e.g. Innova Medical Group Inc and Tanner Pharma UK Limited. Indeed, it appears that call-offs made under the DPS to these suppliers were also expanded in their scope. For instance, the contracts awarded to Innova Medical Group Inc and Medco Solutions Ltd were initially for one value specified in a notice but then corrected with a significant increase. UKHSA also published an invitation to tender ("ITT") on 27 July 2021 for the supply of up to 600 million LTFs in packs of seven.[256] This tender concluded and contracts were awarded in September 2021. However, as a result of the Omicron outbreak and its high transmissibility, which UKHSA stated was not foreseeable, there was an apparent significant and urgent surge in demand for LFTs. It was therefore considered necessary to increase the volume of LFTs available under that tender to 713,500,000 so as to avoid exhausting the current stock. The total value was £322,500,000. No further tender process was considered required to implement this modification (for which there was an allocation mechanism in the ITT) because the view was that it met the requirements set out in reg.72(1)(c) PCR 2015. The modification was not considered to alter the overall nature of the contracts let under the tender process and the increase in price did not exceed 50% of the value of the original contracts.

4.115 The same suppliers also continued to receive direct awards outside the DPS. As indicated in Table 7, in December 2021 i.e. 6 months into the DPS's operation, Innova, Tanner Pharma and Medco received direct awards. The reg.32 PCR 2015 justification was that, whilst UKHSA had ensured supply of LFTs by procuring them competitively through the DPS, the Omicron outbreak led to an urgent and unforeseeable surge in demand. As a result, UKHSA was unable to comply with the time periods required for a further competitive tender under the DPS or otherwise because any delay would risk the current stock of competitively procured LFTs being exhausted, thereby introducing significant risk to public health.[257]

4.116 Therefore, on the one hand, the Lateral Flow DPS is to be credited for introducing a competitive process. It might well have been that the same suppliers who had received direct awards were also the most competitive in terms of their offering to scale through the DPS; although, as indicated in the Table, it is understood that in respect of the Innova, Medco and Tanner awards, only one tender was actually received. On the other hand, the fact that the DPS required a competition but that DPS call-offs were expanded and direct awards continued to be made may have limited the overall purpose and effectiveness of the DPS.

4.117 Notwithstanding the continuing prevalence of direct awards, the above sample indicates that the DPS did, at least, achieve a degree of competition. For instance, as indicated by the above Table, it is apparent that early on price was clearly the main criterion but, over time, quality and social value were given greater weighting (social value possibly coinciding with the Government's policy drive for contracting authorities to apply a 10% social value weighting). Further, whilst there was a limited number of tenders received at the outset, the number clearly increased with an indication that there was more EU wide competition in the later stages.

[256] Information is available at: https://www.contractsfinder.service.gov.uk/Notice/b7dd9231-126c-4496-b737-5139271e0106.

[257] This justification appears to have been provided more than once. Information is available at: https://www.find-tender.service.gov.uk/Notice/002064-2022.

4.118 It should be observed that other relevant DPS were also established. Examples include the Consumables Reagents and Equipment DPS [258] and a Testing Solutions DPS set up to help fulfil the requirement for the ongoing supply of additional LFT and PCR kits. UKHSA has sought applications from potential providers to be admitted to the latter. It is intended to have a value (excluding VAT) of £2 Billion with a start date of 13 June 2022 and end date of 12 June 2024. In addition, it appears that an antibody testing DPS has been established.[259] Outside these designated DPSs, other contracts which support diagnostics functions have been awarded via other DPSs e.g. information technology services to provide digital readers for interpreting COVID-19 self-report LFD test kit results with contracts being procured under the Crown Commercial Service Spark DPS.[260]

4.119 The Government has recently reported that its use of the DPS for LFDs and PCR test kits has reduced, consistent with the overall decline in testing in the UK.[261]

4.120 Similar to the findings in respect of framework agreements, it would be useful for the Government to undertake a more systematic analysis of the effectiveness of diagnostics DPSs in responding to emergencies and generally.

Lessons Learnt and Recommendations

4.121 This Section now turns to identify lessons learnt and recommendations as a starting point for improving public procurement of diagnostics and which must be further developed by those on the frontline going forward. Before doing so, it should be acknowledged that various Parliamentary inquiries, National Audit Office reports, independent reviews of contract awards[262] and academic works have already identified various recommendations for improving public procurement and its regulation in the context of emergencies in light of the pandemic experience.[263] These general recommendations should also be carefully considered given that these could also improve procurement of diagnostics but these are not rehearsed here.

✓ Ensure compliance with new legal requirements under the forthcoming UK Procurement Act

4.122 The above analysis is somewhat legalistic but it does not follow that a major focus should be on legislative reform of public procurement. It is important to emphasise this point because of an apparent tendency (seen in political discourse and Parliamentary debate) to assert that public procurement legislation should be a tool to address all manner of issues whether it be

[258] Information is available at: https://health-family-contract-search.secure.force.com/ProSpend_CS_ContractPage?SearchType=Projects&uid=a074J000007Fr3oQAC&searchStr=&sortStr=Recently+Published&page=1&filters=.

[259] Information is available at: https://www.gov.uk/guidance/ukhsa-commercial-and-partnerships.

[260] Information is available at: https://www.crowncommercial.gov.uk/agreements/RM6094.

[261] UK Health Security Agency, Research and analysis Statutory review of the Coronavirus Test Device Approvals (CTDA) process, p.6.

[262] See the Boardman Review on Cabinet Office Communications Procurement and the Boardman Review of Government Procurement in the COVID-19 pandemic. Both are available at: https://www.gov.uk/government/publications/findings-of-the-boardman-review. See also the Government's Statement regarding the Boardman review of COVID-19 Procurement, updated 7 May 2021: https://www.gov.uk/government/publications/findings-of-the-boardman-review/government-statement-regarding-the-boardman-review-of-covid-19-procurement.

[263] S Arrowsmith and L R A Butler, 'Emergency Procurement and Regulatory Responses to COVID-19: The Case of the United Kingdom' and S Arrowsmith and L R A Butler, 'The Experiences and Lessons of the COVID-19 Pandemic: Public Procurement Regulation in (a) Crisis?' in S Arrowsmith, L R A Butler, A La Chimia and C R Yukins (eds), *Public Procurement in (a) Crisis: Global Lessons from the COVID-19 Pandemic* (2021 Hart).

alleged corruption, cronyism, or other. To be clear, it is important to not lose sight of the fact that public procurement legislation is principally about the processes for buying goods, services and works i.e. how to award contracts. Moreover, whilst it notionally distinguishes between civil, utilities and defence procurement, it does not regulate the particularities of specific sectors e.g. diagnostics. Therefore, it is simply not feasible on the current regulatory model to recommend that general legislation on public procurement should be reformed to accommodate the particularities of diagnostics procurement.

4.123 This does not mean to say that legislative reform of public procurement law generally cannot address some of the issues raised in this analysis to a limited extent. In May 2022, the Government introduced the Procurement Bill in Parliament which is designed to provide a new model of public procurement regulation which replaces that under the EU Directives as implemented in UK regulations. As will be briefly considered below, the Bill includes certain provisions which draw on the pandemic experience, including facilitating better use of advance purchasing arrangements (framework agreements and DPS), clarification of grounds for use of direct awards in emergencies, and improved transparency, all of which touch on aspects considered in the preceding analysis.

4.124 Importantly, however, at the time of writing, the Bill is not yet law and may be subject to amendment. At this point, it can only be stated that the Government will obviously need to comply with these new legal requirements when procuring in emergencies and generally and the diagnostics industry will need to understand how the rules may be applied. Of course, policy guidance on diagnostics procurement should be developed in full compliance with these legal requirements.

4.125 As the remainder of this Section considers, **there must be compliance with the law but the main emphasis should be on reform of procurement policies, processes and practice in the diagnostics sector**.

✓ Consider greater centralisation of the procurement model

4.126 It is recommended that **the Government should consider the (de)merits of adopting a more centralised procurement model for diagnostics in emergencies and generally**. As indicated in Part II, Chapter 3, the national technical validation process provided a useful means of centralising or at least a nation-wide means of validating products for use. This simultaneously provided a means of soliciting offers for procurement. However, within DHSC, there were also a number of executive agencies undertaking and managing procurement alongside the NHS. Therefore, needs and requirements differed with each working to their own processes and timelines. By contrast, suppliers only have one set of resources to respond across the board. Further, only a fairly limited range of centralised procurement techniques (e.g. framework agreements and DPS) were used.

4.127 At an organisational level, it is therefore possible to conceive of a more centralised procurement model. Whilst not necessarily put forward as a preferred model (there could be any number), by way of example, UKHSA or another executive agency could be assigned primary responsibility for undertaking all evaluation and procurement with other institutions operating “business as usual” or acting only in reserve. If other institutions or organisations require supplies, it might be possible to allocate from the centre following arrangements such as the NHSE central stock allocation model. Of course, this would require much greater resource allocated to a single institution which would be able to enter into contracts and service provider arrangements as well as draw on contacts to secure the expertise of the scientific community and industry associations (and lessen the *ad hoc* use of consultancy companies, for example).

4.128 Of course, this would be a substantial undertaking and require fundamental re-organisation. The relative advantages and disadvantages of greater centralisation in procurement would also have to be weighed up. For example, there may well be good reasons for an element of decentralisation to meet local needs (e.g. within the NHS). Nevertheless, at the very least, undertaking a planning exercise to assess the viability of greater centralisation would identify areas where there could be better coordination centrally within the existing model, even if a fully centralised model were not adopted.

4.129 As further recommended below, beyond organisation, centralised coordination could also be better achieved through more effective use of central advance purchasing arrangements e.g. framework agreements and DPS.

✓ Improve Identification of Suppliers

4.130 It is recommended that t**he Government could improve its means of identifying suppliers**. Industry should also reassess its supply chains to better understand its supply and distribution networks and risks given the premium on quick and reliable supply from trusted sources in an emergencies.

4.131 As indicated, there could have been more systematic means of identifying and soliciting offers than using consultancy companies to map LFT test kit providers or conducting basic internet searches. Fundamentally, this requires a much deeper understanding of the diagnostics industry in the UK and its domestic and global supply chains to know what capacity there is, where and how capacity could be developed, the supplier and supply chain risks, and where there is (inter)dependence on foreign sources. Of course, this is a matter of wider emergency planning but can have specific implications for procurement. This needs to be granular including specific details about corporate structure, financing and previous experience on government contracts and in supplying diagnostics, all of which may expose all sorts of issues or risks which may specifically impact procurement planning and execution. Corporate structure assessment can reveal foreign ownership which may have political implications as well as identify manufacturer and distributor networks which can be important in identifying who is best able to supply relevant information. General understanding of company finance may pre-empt due diligence exercises and inform choices about risks in respect of pre-payment of suppliers. Understanding past experience and performance will be an indicator of whether suppliers are able to bear the risk and likely deliver. Supply chain locations may also identify potential logistics vulnerabilities in terms of manufacture and supply of raw materials, export risks or supply chain bottlenecks. Target areas could then be the subject of strategic investment or monitoring. Therefore, systematic mapping of the UK diagnostics industry across a range of diagnostics capabilities is important, especially given the Government's stated ambitions to build the UK diagnostics industry and to better understand the impact of regulatory interventions on the diagnostics sector.

4.132 A better understanding of the market is also a precursor to improving market engagement. The Boardman Review, as part of its recommendations for improving procurement preparedness, identified the need for more extensive market engagement to understand the capabilities and capacity of the private sector.[264] This should go further than hosting industry showcase events to include **the establishment of a more permanent Government-supplier forum**. There are other Departmental examples of formal models for such engagement, a prime example being the Ministry of Defence and industry Defence Suppliers Forum.[265] This could be used to help generate "standing lists" of suppliers and offer an

[264] Boardman Review of Government Procurement in the COVID-19 pandemic, p.8.

[265] Information is available at: https://www.gov.uk/government/groups/defence-suppliers-forum.

opportunity to undertake preliminary consultations with industry on forthcoming contract opportunities, of course, within the constraints of UK public procurement law (which ensures that preliminary market consultations on a contract opportunity with certain suppliers do not confer an advantage in the subsequent award of any contract).

4.133 Any number of these and other measures in combination, alongside the formalisation of more and better advance purchasing arrangements (discussed below), could lead to the better identification of diagnostics suppliers which is critical in an emergency.

✓ Increase Effective Deployment of Advance Purchasing Arrangements

4.134 It is recommended that **the Government should examine more closely the effectiveness of advance purchasing arrangements as a response to emergencies**, consistent with recommendations made in academic research.[266]

4.135 As indicated, framework agreements and DPSs were important means of facilitating a degree of competitive procurement of diagnostics during the pandemic. Academic research into various countries' procurement responses during the pandemic generally has identified that these purchasing arrangements are increasingly being used to facilitate advance planning even for emergencies of unknown timing and extent.[267] This research has proposed certain "tweaks" to legal rules within international legal frameworks to render these more flexible e.g. allowing framework agreements to be used by contracting authorities and suppliers not originally party to the framework among other reforms.[268] Further, there is a need for more systematic analysis of how these have been set up and operated in practice and how their use can be improved as an emergency response.

4.136 There are inevitable trade-offs in deciding whether to invest time and resource in setting up standing framework agreements for supply in emergencies which may not eventuate and which, in any event, will be time-limited in accordance with requirements of public procurement law. However, it is clear from the pandemic that mechanisms such as the PHE microbiology framework agreement could anticipate emergency use.

4.137 The following areas are identified as just some potential points of focus:

(1) Consistent with the recommendations above, **it should be considered whether framework agreements and DPSs could be more effectively centralised for use**. As indicated, a number of framework agreements were set up and operated by different actors with a range of user contracting authorities relying on them. This creates potential for organisational and coordination issues which could be addressed at least in part by a rationalisation of the portfolio of framework agreements offered. Again, there are inevitable arguments for and against, not least that framework agreements can become too big and unwieldy, for example, and may not respond effectively to local needs (a problem of centralisation more widely, as indicated above).

(2) Another aspect is the time taken to mobilise framework agreements and DPSs. Whilst there may be good reasons as to why it took some time to set these up in the pandemic, **it should be considered whether there are ways in which to speed up their set up and mobilisation** e.g. in establishing terms and conditions for competitions and call-offs and

[266] See generally, S Arrowsmith and L R A Butler, 'Emergency Procurement and Regulatory Responses to COVID-19: The Case of the United Kingdom' and S Arrowsmith and L R A Butler, 'The Experiences and Lessons of the COVID-19 Pandemic: Public Procurement Regulation in (a) Crisis?' in S Arrowsmith, L R A Butler, A La Chimia and C R Yukins (eds), *Public Procurement in (a) Crisis: Global Lessons from the COVID-19 Pandemic* (2021 Hart).
[267] Ibid., pp.592-3.
[268] Ibid.

identifying product lines etc. Indeed, a concern about speed has been raised in other Government Departments. For example, the Boardman Review observed that purchasing teams within the Cabinet Office were "frustrated" with the length of time a procurement process can take in ordinary circumstances, even when using platforms such as DPSs.[269] Boardman questioned whether these are sufficiently responsive to meet demands in urgent situations where priorities can shift very quickly and recommended a closer examination of the adequacy of these tools in addition to whatever improvements are introduced to these advance purchasing mechanisms through legislative reform (considered below).

(3) In addition to organisation and mobilisation, **another key aspect to be addressed concerns the administration or use of framework agreements**. As indicated, it was not possible to obtain detailed information on how central framework agreements were used by individual procuring entities to call off contracts. The Boardman Review similarly identified gaps in process and guidance where individual procuring entities were accessing central framework agreements and recommended the need for additional contract check sheets and training to ensure legal and other compliance by users.[270]

(4) A final aspect concerns supply arrangements e.g. regarding supply arrangements between registered framework agreement or DPS suppliers and non-registered suppliers, including sub-contracting. Again, this appears to have been experienced more generally. According to the Boardman Review, there was concern about the practice of awarding work to sub-contractors of suppliers on an existing purchasing tool such as a DPS. It was stated that while it may be legitimate for suppliers to use sub-contractors to deliver aspects of services, this must not be used as a method of bypassing the proper process in order to award work to a specific sub-contractor. Boardman recommended that such processes are "tightened" through improving understanding of the use of sub-contracting under advance purchasing tools and ensuring principles such as that subcontractors must be appointed by the primary contractor, not at the direction of the department (although Government must still undertake appropriate due diligence on sub-contractors to ensure they meet relevant legal and policy requirements); and that all subcontracted work must be ancillary to the primary contractor's work and should never be standalone.[271]

4.138 More generally, **it should be considered whether framework agreements could be less "transactional" (i.e. in facilitating one off or regular purchases) and become more effective means of developing the diagnostics industry (i.e. becoming a better industrial development tool)**. For instance, the PHE microbiology framework was an example where opportunities for research and development were built in, offering more scope for developing partnerships between Government and industry beyond simply offering "off-the-shelf" product, albeit within the time-bound constraints of a framework agreement's duration.

4.139 As indicated, the expectation is that legislative reform will generally improve the use of advance purchasing arrangements.[272] The Procurement Bill intends to provide greater flexibility in this regard. For example, it provides the possibility for "open frameworks", allowing contracting authorities the option to admit new suppliers to the framework during its term. For open frameworks over three years, suppliers will have the opportunity to join the framework agreement at least once during its term and these cannot be closed to market access for longer than five years. The maximum duration of an open framework can be up to eight years. These sorts of flexibilities could help better facilitate advance planning of framework agreements for emergencies as well as mitigate some of the risks of framework

[269] Boardman Review on Cabinet Office Communications Procurement, p.8.
[270] Boardman Review on Cabinet Office Communications Procurement, pp.9-10.
[271] Ibid, p.9.
[272] See generally, clauses 34-40 (on dynamic markets) and 45-49 (on framework agreements).

agreements being closed off with other practices developing to facilitate market access for those who are not registered. Similarly, the Procurement Bill has extended the concept of a DPS to "Dynamic Markets" which can be used for all types of procurements rather than goods commonly available on the market. It is beyond the scope of this White Paper to examine these possibilities but their potential impact on the diagnostics industry specifically should also be considered.

✓ Develop More Agile Procurement Response to Approaches by the Market

4.140 It is recommended that **the Government should consider ways to better address scenarios in which it relies on the market to determine its needs**. Governments are used to identifying their need, advertising it and inviting tenders from the market. Governments are less used to not knowing what they want and relying on the market to provide solutions either unsolicited or following a general "call to arms" to assist. This issue arose in a number of areas of procurement during the pandemic e.g. the call for PPE and the so-called "ventilator challenge". The procurement of diagnostics was no exception.

4.141 There are a number of examples where the Government's approach may have raised issues. Before the Government established the national portal, it had to address offers which were solicited and unsolicited *ad hoc* which may create risks of legal challenge as well as the need to establish more formal processes. The national portal for offers of IVD test kits also meant that the Government had to develop systems for "finding the diamond in the rough", by responding to Ministerial and other referrals from reputable sources and prioritising the assessment of offers through triaging and shortlisting. This does raise the general question of how effective these general calls to arms are as a means of processing offers leading to their procurement and whether they can be improved.

4.142 For instance, the Boardman Review (which only referred to the calls for arms for PPE and ventilators but not expressly diagnostics) has recommended that any future call to arms should be managed and streamlined to ensure it is as focussed as possible. It identified that the call to arms for PPE, for example, was admirable in its ambition but the scale and complexity of managing the huge public response to this appeal was underestimated with too many enthusiastic offers causing a bottleneck which slowed down the process of finding the most appropriate offers.[273] In the case of IVD test kits, there may not have been the same volume of offers as for PPE given that they are a more specialist requirement but the fact that triaging and TPPs had to be introduced indicated that the scale of demand was still high and likely posed similar issues. Therefore, it should be considered whether this sort of "call to arms" response is appropriate for diagnostics and, if so, how it could be improved. Consistent with the above recommendations, if more effective means of identifying suppliers are identified, this should correspondingly reduce the prevalence of referrals, for example.

4.143 Further, as indicated, recently it has been questioned whether there was a "VIP lane" for test kit contracts. Again, the Boardman review identified that the use of a 'high priority lane' for PPE as a triaging mechanism to manage the volume of offers and referrals alongside the ordinary portal created perceptions and allegations of apparent bias and that these should be avoided in future if appropriate resourcing is found and other changes to process are made.[274] **A simple way of increasing transparency and mitigating the risk of legal challenge would be to publish guidance or process on how offers may be triaged or prioritised including indicative shortlisting criteria or factors for assessment**.

4.144 In addition, there is also the issue of how to undertake procurement where the Government has an identified requirement but it is necessary for industry to develop a solution rather than

[273] Boardman Review of Government Procurement in the COVID-19 pandemic, p.23.
[274] Ibid.

simply provide an "off the shelf" product. As indicated, in respect of antibody test kits, Abingdon Health plc approached the Government through the triage inbox but with a view to meeting the requirement through an industry consortium. As further discussed in Chapter 5, this resulted in the conclusion of a research contract which bypassed the established National Institute for Health and Care Research ("NIHR") funding route initially without NIHR knowing. Further, when the RTC was established, DHSC officials raised the possible need to formalise a process for R&D proposals which are put forward by industry going forward, although it provided no indication as to how this might be done.

4.145 Elsewhere, existing research has identified that legal frameworks are not necessarily suitably adapted to instances where the market proactively approaches government with offers to provide a solution and for this issue to be explored in more depth in the context of emergencies, in particular.[275]

✓ Improve Procurement Processes to Improve Outcomes, Reduce Legal Risk and Increase Transparency

4.146 It is recommended that **the Government should reform procurement processes to improve procurement outcomes, mitigate risk of legal challenge and increase general transparency and accountability**. To qualify, as indicated, to date, there have been no findings of illegality in the procurement of IVD test kits but legal challenges have exposed areas where procurement could be improved. This White Paper does not consider all potential aspects but an illustration of some may prompt a more systematic examination of procurement practice during the pandemic and how it could be improved in future.

Specifications

4.147 As already considered in Part II, Chapter 3, the Government faced the difficult task of having to try and identify its needs and the technical and performance characteristics of tests as quickly as possible. This necessitated the drafting of TPPs in respect of which recommendations have been made above. More generally, **the Government could consider whether its approach to revising specifications and its communications on revising specifications during the pandemic was satisfactory**. Interviews and other anecdotal remarks (which have not been verified) suggested a perception that sometimes specifications were changed without a clear understanding as to why this was the case. This risks perceptions that certain tests are being favoured for procurement, which may not necessarily be the case.

4.148 More generally, the DHSC Medical Technology Strategy published in 2023 refers to the procurement of lateral flow tests against nationally provided TPPs and the need to learn from this experience in providing industry with "a clearer, more granular demand signal for it to respond to across all products, and the confidence of intent to buy through a clear procurement and commitment-based process to reduce commercial risk."[276]

Driving more competition into procurement

4.149 **The Government should also consider ways to drive more competition into the procurement process earlier**. It is acknowledged that this may be easier said than done and any number of factors may have prevented and could continue to prevent attempts to

[275] L R A Butler, 'Regulating Single-Source Procurement in Emergency Situations in the Light of the COVID-19 Pandemic: Issues in Policy and Practice' in S Arrowsmith, L R A Butler, A La Chimia and C R Yukins (eds), *Public Procurement in (a) Crisis: Global Lessons from the COVID-19 Pandemic* (2021 Hart), pp.110-114.

[276] Department of Health & Social Care, Medical Technology Strategy 2023, 3 February 2023, p.25: https://www.gov.uk/government/publications/medical-technology-strategy/medical-technology-strategy.

inject more competition. However, the fact that there was a high incidence of direct awards throughout (not simply at the onset of the pandemic) will inevitably raise the question as to whether there are any reforms to processes which could result in marginal gains in opening up procurement to competition.

4.150 As the Boardman Review has observed, emergency provisions should not be used indefinitely or inappropriately and that, whilst direct awards have a place in a crisis, appropriate longer-term arrangements should be competitively tendered as soon as possible.[277] It is important to emphasise in the first instance that, perhaps contrary to perceptions, recourse to reg.32 does not in fact preclude a competition. This need not involve extensive advertisement but it is possible to undertake an informal competition among a select number of suppliers through inviting tenders. For example, MOD policy on procuring urgent operational requirements emphasises the possibility of a "closed competition" among chosen tenderers which will typically involve an invitation of three tenderers and providing them with "sufficient time" to prepare a proper tender.[278]

4.151 It is important to candidly understand and periodically assess whether there are any real constraints on undertaking a very short competitive procurement exercise with a limited number of suppliers and, if not, to encourage competition accordingly where this is possible. As the Boardman Review has further observed, monitoring the continued use of direct awards necessarily involves considering when to undertake competitive tendering (as and when appropriate) with a need for procurement teams to plan for an early transition to competitive procurement wherever possible.[279] The analysis in this White Paper has provided indications in contract notices of the Government's intention to transition to openly competitive processes but direct awards were necessitated in the interim. It is less clear what measures were in place to periodically review whether competitive procurement was possible. For example, there is always a risk of continuing to specify use of the same product specifications or adapting them only slightly with the effect that the same suppliers continue to receive the same sorts of contracts when there may be scope to change requirements to widen the possible supply market or introduce new competitive approaches (e.g. framework agreements or DPSs).

More principled controls on use of direct awards

4.152 It is recommended that **procurement policy should introduce further controls on the use of direct awards**. Academic research has identified a number of issues that have arisen in respect of the use of non-competitive contract awards during the pandemic which could be addressed through better regulation and policy guidance.[280] Examples include: improving the quality of reg.32 PCR 2015 justifications for direct awards stated in contract award notices which, it is recalled, are often fairly generic; introducing policy guidance on principles of negotiation with single suppliers; and the application of pricing controls to ensure that costs are reasonable and can be verified.[281]

4.153 Concerning grounds for use of direct awards, before publication of the Procurement Bill, research had already recommended the need for a special crisis ground to avoid having to rely on "extreme urgency" grounds which might deter effective action because of concerns

[277] Boardman Review of Government Procurement in the COVID-19 pandemic, p.31.

[278] Guidance, DSPCR Chapter 9: procuring Urgent Capability Requirements (UCRs), Updated 28 November 2022, paras.40-45: https://www.gov.uk/government/publications/the-european-union-defence-and-security-public-contracts-regulations-dspcr-2011/chapter-9-procuring-urgent-capability-requirements.

[279] Boardman Review of Government Procurement in the COVID-19 pandemic, p.2 and p.25.

[280] See generally, L R A Butler, 'Regulating Single-Source Procurement in Emergency Situations in the Light of the COVID-19 Pandemic: Issues in Policy and Practice' in S Arrowsmith, L R A Butler, A La Chimia and C R Yukins (eds), *Public Procurement in (a) Crisis: Global Lessons from the COVID-19 Pandemic* (2021 Hart), , pp.110-114.

[281] Ibid. pp.124-6.

about how decisions made in difficult circumstances under extreme pressure might be judged with hindsight.[282] It would also be justified by improving legal certainty (i.e. defining more clearly grounds for use) and to limit other procedural burdens (e.g. reporting) to secure a better balance of interests. The Boardman Review similarly recommended such a ground as well as the need for more guidance (although not necessarily in the public domain) on what constitutes "extreme urgency".[283]

4.154 The Procurement Bill has acted on the pandemic experience in this regard. It permits a direct award if a direct award justification applies.[284] A direct award justification for urgency is provided, namely, where: (1) the goods, services or works to be supplied are strictly necessary for reasons of extreme urgency and unavoidable urgency and (2) as a result, the public contract cannot be awarded on the basis of a competitive tendering procedure.[285] An urgency is unavoidable if it is: (a) not attributable to any act or omission of the contracting authority and (b) could not have been foreseen by the contracting authority.[286] The Procurement Bill also goes further by providing a separate direct award ground for the protection of life or health.[287] This could avoid the need to engage in protracted argument about urgency and foreseeability. Further, the Procurement Bill provides that a contracting authority may modify a public contract if the modification is on similar grounds.[288]

4.155 In addition, the Procurement Bill also seeks to improve *ex ante* transparency. It provides that, before making a direct award in special cases, a contracting authority must publish a transparency notice setting out that a contracting authority intends to award a contract directly, and any other information specified.[289] More generally, the reforms are intended to introduce a form of open contracting which should enable a more systematic identification of suppliers, awards, conflicts of interest and contract management information.

4.156 It is hoped that these new provisions in the Procurement Bill will spur the creation of more targeted supplementary policy guidance on direct awards which will address issues such as how to undertake informal competitions, principles of negotiation, pricing and other factors.

Clarifying boundaries between scientific and commercial decision-making

4.157 It is recommended that **the procurement process should more clearly distinguish between technical validation, procurement and regulatory approvals processes in order to clarify who is making scientific decisions or commercial procurement decisions and how**. As indicated in Part II, Chapter 3, this issue has arisen in respect of the "national procurement process" (the national technical validation process).

4.158 On one hand, it, may not only be useful but vital to have scientists involved in informing the procurement process. Scientists and other healthcare professionals are perhaps best placed to determine what the Government needs to procure in terms of technology, to help set

[282] S Arrowsmith and L R A Butler, 'The Experiences and Lessons of the COVID-19 Pandemic: Public Procurement Regulation in (a) Crisis?' in S Arrowsmith, L R A Butler, A La Chimia and C R Yukins (eds), *Public Procurement in (a) Crisis: Global Lessons from the COVID-19 Pandemic* (2021 Hart), p.368 citing at fn 117 S Arrowsmith, 'Reimagining public procurement law after Brexit: seven core principles for reform and their practical implementation' Part 2 (2020) Working Paper, para 5.3.2.2.

[283] S Arrowsmith and L R A Butler, 'Emergency Procurement and Regulatory Responses to COVID-19: The Case of the United Kingdom' in S Arrowsmith, L R A Butler, A La Chimia and C R Yukins (eds), *Public Procurement in (a) Crisis: Global Lessons from the COVID-19 Pandemic* (2021 Hart), pp.366-9 citing the Boardman Review, Part II.

[284] Clause 40. The direct award justifications are set out in Sch.5.

[285] Sch.5, para.13.

[286] Sch.5, para.14.

[287] Clause 41 and Sch.5, para.15.

[288] Clause 69. Permitted modifications are contained in Sch.8.

[289] Clause 43.

technical specifications and determine user settings, and even to assist in deciding which test from a range of validated tests is best in terms of technical performance. On the other hand, there is a risk of blurring boundaries between scientific and commercial decision-making where decisions are made by both scientists in an advisory capacity and civil servants. For example, it is possible to conceive of instances in which civil servants might ask scientists not only to advise on the scientific merits of a test or technology but whether to procure a test all things considered (technical and commercial aspects). This requires a clear understanding of respective roles and responsibilities e.g. what civil servants are asking scientists to advise on and how. If it is not clear who is making what decisions, there is a risk that the rationality of procurement decision-making being questioned. In extreme cases, it can lead to unsubstantiated claims of bias or conflict of interest.

4.159 As indicated, in the Abingdon Health plc judgment, the court categorically rejected any claim that decisions were irrational or suffered from any form of bias in the process where scientists were involved. To be clear, this important finding confirms the integrity of the scientific community's vital role in the process. Nevertheless, it was necessary to call evidence to clarify the role of scientific advisors in the procurement process. The evidence also indicated the absence of clearly constituted and defined terms of reference at points and a lack of record keeping. It might be suggested that **even in emergencies, clear terms of reference should be established to clarify roles and responsibilities and key decisions recorded from the outset**. As the Boardman Review has observed in respect of COVID-19 contract awards generally, incomplete record keeping is one potential factor among others which may have encouraged suspicion of favouritism and that even when individuals are working at pace under considerable pressure in challenging circumstances, records should be kept.[290] This expectation is even greater in cases where procurement professionals are not simply relying on their own judgements but their decision-making is informed by other experts.

4.160 This could even extend to developing internal guidance on the role of external scientific advisors in procurement processes.

✓ Publish More Procurement Guidance

4.161 It is recommended that **the Government should publish more detailed guidance on the process for awarding diagnostics contracts**.

4.162 Unsurprisingly, the Government did not and could not have realistically published a comprehensive "buyer's manual" on how to procure during emergencies in anticipation of, or immediately in response to, the pandemic. Each Department is buying different goods, services and works and will have their own procurement guidance and processes tailored accordingly; indeed, there may not even be uniformity within a large Department with executive agencies adopting different approaches. The procurement of ventilators, PPE and IVDs all require distinct approaches even if there is a commonality in respect of some aspects (e.g. use of national portals) and that all are generally procured within a common legal framework (e.g. under the PCR 2015). Moreover, any such "end to end" guidance covering everything from sourcing strategy and routes to market through to contract award and management risks being too generic or too detailed to be usable in a specific context, especially in an emergency. Nevertheless, the preceding analysis has found that there appears to have been limited published guidance.

4.163 As indicated, the guidance on the national technical validation process refers to a "national procurement process" but is ultimately a set of processes for validation for procurement, not processes for procurement *per se*. It is understood that Departmental procurement guidance

[290] Boardman Review of Government Procurement in the COVID-19 pandemic, p.3 and p.12.

was developed for use internally even if only at a high-level of process. For example, it is known that by 2021, DHSC had started to issue standard guidance in the form of a T&T End-to-End Commercial Process and Toolkit to achieve a degree of uniformity in application. Further, there was internal guidance on the various routes to market e.g. through direct awards, framework agreements, NHS Supply Chain etc. However, it is not clear that there was any detailed internal guidance specifically on procurement of diagnostics.

4.164 Even if there is internal Departmental guidance on the procurement of diagnostics, the difficulty for suppliers and the general public is that guidance does not appear to be publicly available. Publicly available guidance can serve a number of functions. It can usefully assist prospective suppliers keen to understand which routes to market are available and an indication of the process by which their offers may be assessed (as distinct from how their product offerings may be technically validated). Existing suppliers may use published guidance to determine if there might be a basis for legal challenge where they feel aggrieved. More generally, it can provide a means of transparency and accountability for the concerned taxpayer keen to understand how public money is being spent. There appears to be at least some civil society demand for such guidance. For example, the Tony Blair Institute for Global Change has published a COVID-19 Guide to Procuring Antibody Tests which is basic and brief but a model for identifying at least some key procurement policy and process-oriented considerations in procuring test kits.[291]

4.165 Therefore, **the Government should develop and/or revise its existing suite of internal procurement guidance and process documentation on the procurement of diagnostics**. If this guidance already exists, it should be revised in consideration of the findings in this White Paper. In addition, some version of basic procurement guidance should also be made publicly available for the reasons indicated above.

4.166 In terms of form, **it is necessary for guidance to be rendered more "user-friendly" e.g. comprising more flow charts and process diagrams**. This will not only aid comprehension but also more clearly set out some of the interstitial aspects of a process e.g. how different stages of triage and shortlisting operate. It is understood that there are internal Departmental process diagrams in circulation (including as disclosed to industry during presentations) but these do not appear to have been published. This is a simple recommendation but is consistent with the Boardman Review of Cabinet Office contract awards which identified a need for a single, clear, user-centred process to be properly delineated in the form of flowcharts with links to relevant guidance and that the process must be practical, manageable, easy to use and with roles and responsibilities clearly understood.[292]

4.167 Of course, in addition to this "outward facing" guidance for public consumption, **there may also need to be more focus within Government on improving the format of guidance internally which might even extend to creating an "end-to-end" "buying manual" for diagnostics** of suitable length which could be used as a toolkit for procurement. Again, if this already exists, the findings of this White Paper should be used to inform revisions of this guidance. Again, this would be consistent with the Boardman Review which recommended (albeit not specifically referring to diagnostics but rather PPE) that there should be detailed "buying manuals" kept by buyers in NHS procurement teams covering not only the specification of the item, but also packaging, length of use, sources of supply and scalability

[291] Tony Blair Institute for Global Change, COVID-19: Guide to Procuring Antibody Tests, June 2020: https://institute.global/sites/default/files/inline-files/Tony%20Blair%20Institute%2C%20Guide%20to%20Procuring%20Antibody%20Tests.pdf.
[292] Boardman Review on Cabinet Office Communications Procurement, p.1.

of the contract.[293] It is ultimately for Departmental commercial policy managers to determine the scope and content of internal guidance learning lessons of the pandemic.

4.168 In terms of substance, this White Paper has already identified a number of areas which could be the subject of revised guidance. A checklist of possibilities might include the following and which is not exhaustive:

- ✓ **Identification of the various routes to market and advance purchasing arrangements available** (e.g. framework agreements, DPS, accelerated competitive procedures, direct awards with or without competition etc).
- ✓ **Processes for identifying suppliers** to contact [see recommendations above].
- ✓ **Processes and guidance for soliciting offers** including a careful focus on any process for prioritisation in the assessment of offers.
- ✓ **Dedicated guidance on the setting up and administration of advance purchasing arrangements**.
- ✓ **Dedicated guidance on how direct awards processes may be conducted**. One aspect would concern grounds for use (particularly extreme urgency and technical reasons and exclusive rights given the significance of licensing in the context of IVDs). This would be consistent with the Boardman Review which recommended that when guidance on reliance on extreme urgency grounds (including the definition of 'extreme urgency and the use of different purchasing tools in urgent situations) is issued to departments, this guidance should be circulated by departmental commercial teams to each business unit as soon as it is received.[294] Another aspect would concern the actual contract award stages and related considerations e.g. means of undertaking limited advertising if possible; conduct of closed or informal competitions and tendering exercises; principles for negotiating with individual or select suppliers including on matters such as pricing (and any potential pricing controls to assess the reasonableness of prices).
- ✓ **Guidance on general principles for undertaking qualification and evaluation assessments** (providing indicative or illustrative criteria, although there is no legal requirement to publish these in advance in cases of direct awards, for example).
- ✓ **Guidance on ways to identify, manage and prevent conflicts of interest** including the role of external expert advisors in procurement processes [see recommendations above];
- ✓ **Guidance on how the procurement process relates to the timing and operation of other key processes** which are integral to the procurement process or on which the procurement process is contingent e.g. validation and regulatory approvals for placement on the market.
- ✓ **Guidance on the use of options in emergency contracts and on contract modifications** to ensure these remain lawful.
- ✓ **Guidance on transparency** e.g. record-keeping, reporting, information and justifications to be provided in contract award and other notices as well as processes for dealing with Freedom of Information requests and redactions of contract documents (the latter could be the subject of separate guidance).
- ✓ **Guidance on contract management** considerations (e.g. intellectual property management and supplier payment etc).
- ✓ **Examples of any identifiable good or best practice** in respect of all of the above.

4.169 Decisions would need to be made as to how such guidance could be coordinated and adapted. If driven by central Government, it will need to be considered how it may be adapted for use locally within the NHS, for example.

4.170 It must be acknowledged that the more policy and process developed and published in respect of diagnostics procurement, the greater the risk of potentially fettering contracting authority discretion in areas where flexibility may be needed, particularly in an emergency. Further, whilst the publication of clearer procurement policies and processes may mitigate

[293] Boardman Review of Government Procurement in the COVID-19 pandemic, p.11.
[294] Boardman Review of Cabinet Office Communications Procurement, p.8.

the risk of legal challenge, it cannot be excluded that it creates other legal risks e.g. challenges on the basis that a contracting authority is departing from a stated policy in breach of public law principles.

4.171 On balance, the publication of at least some guidance which explains processes more clearly and provides more substantial indications of how information is assessed and by who(m) is better than a lack of information which only leads to Freedom of Information requests and legal challenges in any event. Even better, some of this procurement guidance could be developed in closer consultation with industry so that both the buyer and supplier perspectives are adequately reflected to instil trust and confidence in scientifically robust, commercially sound and transparent processes.

5. CONTRACT MANAGEMENT

Introduction

5.1. As indicated in the Introduction, this White Paper's principal focus on public procurement of IVD test kits necessarily excludes detailed analysis of aspects of contract management which operate either side of the process of awarding contracts, namely, planning contractual vehicles for delivery and performance. Further, as there are a number of ongoing legal disputes concerning contractual matters (as opposed to challenges to the award of contracts), it is cautious to avoid pre-empting or otherwise seeking to influence any decision-making pending their outcome. In any event, as relevant information will remain confidential and privileged, it is not possible to provide detailed analysis and it would be inappropriate to speculate. For the same reasons, this Chapter does not make specific recommendations on contract management. Notwithstanding, it is necessary to at least acknowledge the importance of contract management issues given that these have informed procurement decisions and which are integral to understanding public contracting for diagnostics as a whole.

5.2. There is a long list of possible contract management issues that could be considered. These include: the selection of contractual vehicle (grant or procurement contract); the allocation and management of various contractual risks; pricing and how transparency of costs are ensured (such as through "open book" accounting methods);[295] payment and repayment issues where sums have been advanced; and how to address unusable and surplus equipment. This relatively short Chapter provides a brief overview of just some of the issues which are reported to have arisen using as an illustration the selection of contractual vehicles and risk allocation and management.

5.3. It is hoped that once any legal disputes are resolved, this important area will be revisited to derive lessons learnt and recommendations for the future.

Planning Vehicles for Delivery

5.4. The analysis in this White Paper has primarily concerned the Government's use of procurement processes to award contracts e.g. direct awards pursuant to reg.32 PCR 2015. However, the Government used a range of purchasing options other than awarding contracts through conventional procurement e.g. grants for research and development ("R&D").

5.5. One issue concerns certainty around the choice of vehicle for delivering a requirement. To explain, in the Abingdon Health plc legal challenge, for example, the facts appeared to indicate that the provision of R&D by Abingdon Health plc to develop a test would be by way of grant to a single supplier rather than some form of competition. However, a DHSC accounts officer queried this approach. It was then explained that it was necessary to work with one company not several as it "wouldn't be agile and rapid to design in this way" and that, in any event, the result could be an open source specification which would therefore enable other suppliers to get involved later on.[296] In response, it was accepted that time was of the essence but it was questioned whether it would be possible to "do a quick call to industry challenge fund – pick the three most promising?".[297] What seemed to drive the

[295] In the legal challenge to contract awards to *Abingdon Health plc*, in evidence it became apparent that the Government insisted on the use of open book with Abingdon but did not require the same of Abbott and Roche, raising the issue of whether this was fair: *Abingdon Health plc* [223]-[224] ad [448].
[296] This seemed, in part, to corroborate statements by Professor Bell to limit the number involved: *Abingdon Health plc*, [122]; [130].
[297] *Abingdon Health plc* [127].

accounting officer's query was that it was not clear what would be the basis for selecting Abingdon Health plc above other suppliers, the need to be clear on the criteria for choosing the supplier, and that it was unclear how you could say "yes" to one supplier but "no" to the next five who came up with a similar proposition; it would be a different calculation if *only* Abingdon Health plc could do it.[298] In further response, it was stated that there was a time constraint which precluded running an industry challenge type fund. Ultimately, the accounts officer appeared to be reassured in stating that if there was a strong case for a sole source - no competition approach based partly on timescales and partly on Abingdon Health plc's track record and recommendations, this would be appropriate.[299] For the court, this was a sufficient indication that whilst there were initial concerns, there was reassurance on how to proceed.[300]

5.6. Notwithstanding, this line of questioning perhaps reveals a degree of uncertainty as to the most appropriate contracting vehicle for several reasons. Fundamentally, it does not appear to be immediately clear whether or not the initial R&D contract was subject to the PCR 2015 and thus a formal procurement process and whether there were any criteria for award (other that Abingdon Health plc was considered to be the best). Further, as a matter of practicality, the time constraints were accepted but it is unclear whether another model e.g. an R&D challenge could have been set up very quickly given that it appeared to be assumed that no formal procurement process should otherwise apply. On the evidence, there was some apparent concern about how the proposed model of delivery (an industry consortium with one lead contractor) would be received. In response to concerns raised that industry would be annoyed with the Abingdon Health plc partnership, it was stated that any set of companies would be encouraged to form partnerships and that the Government "need to maybe formalise this for other proposals that come out [sic] way".[301] It was also stated that "I expect quite a lot of the IVD companies to say that we have to help them do everything but I think we should take an industrial strategy stance to this akin to the Sector deal process which was you (industry) come up with the proposal and we will review it".[302]

5.7. Whilst mindful that this is just one example of a development contract for diagnostics entered into during the pandemic, it provides a useful illustration of aspects which may require clarification going forward. One issue is how the Government addresses potential vehicles for delivering requirements which do not involve direct contracting with a single supplier through a conventional procurement process as regulated by the PCR 2015. A prime example as mentioned is an "industry challenge fund". It has already been acknowledged that there is a possible need to formalise approaches to development proposals which rely on a partnership model. Research into the responses of a number of countries in respect of procurement during the pandemic has found that there does not appear to have been much consideration of the use of "alternative market-led methods" in procurement in emergencies, that is, where industry itself puts forward proposals on how to address a Government need. It has been recommended that more thinking should be done on how to facilitate these more "agile" responses.[303] Recently, it has been recommended that the UK should develop more strategic partnerships comprising similar consortia to the UK RTC with its apparent "effectiveness" demonstrating that it is possible to allow domestic innovative technology to respond to unmet needs and that this will require further investment and scaling of the

[298] Ibid.

[299] Ibid., [131].

[300] Ibid., [132].

[301] *Abingdon Health plc* [162].

[302] Ibid.

[303] L R A Butler, 'Regulating Single-Source Procurement in Emergency Situations in Light of the COVID-19 Pandemic: Issues in Policy and Practice' in S Arrowsmith and L R A Butler, in S Arrowsmith, L R A Butler, A La Chimia and C R Yukins (eds), *Public Procurement in (a) Crisis: Global Lessons from the COVID-19 Pandemic* (2021 Hart), pp.110-114.

domestic industry.[304] Going forward, it has been suggested that there is great potential for collaboration between Innovate UK and industry, for example, to create national projects that focus on key unmet needs, an approach which is currently said to be fragmented.[305]

5.8. In addition, there seemed to be some uncertainty regarding the process for establishing the R&D contract. On the evidence, it appeared that NIHR was said to provide funding although DHSC would be the contracting party. To provide some context, NIHR had a number of functions during the pandemic. It has helped develop CONDOR and initiatives such as Medtech and In Vitro diagnostics Co-operatives ("MICs"), which have assisted in expediting testing of new COVID-19 tests in various settings; it has also undertaken horizon scanning of tests currently in development through the NIHR Innovation Observatory ("NIHRIO").[306] More relevant for present purposes, its functions also included developing an urgent health prioritisation system to identify a relatively small number of studies proposed to it for funding testing initiatives. This process for assessing eligible funded projects involved setting up new panels and assessment processes, and truncating and speeding up its own triage and assessment procedure, with decisions being made in a week or less.[307] On the facts in the Abingdon Health plc legal challenge, it appears that NIHR ultimately considered that the Abingdon Health plc proposal met its criteria but felt that it had been "by-passed" by the Government entering into an arrangement directly with Abingdon Health plc since the funding decision had effectively been made for them; it stated that this is "no way to do business but we are in exceptional times".[308] This raises the issue of how the Government coordinates grant making and procurement processes in this context.

5.9. Relatedly, the use of funding schemes in the form of grants and contracts during emergencies also gives rise to potential State aid considerations. In the UK, EU law has provided the main legal framework for addressing State aid and subsidy issues. Article 107(1) TFEU provides that: "[s]ave as otherwise provided in the Treaties, any aid granted by a Member State or through state resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the internal market." In the Abingdon Health plc judgment, claims of State aid were argued but rejected by the court. The Good Law Project argued that, in reality, the development contract for £2.5 million was nothing more than a grant or subsidy. Waksman J rejected this for three reasons: (1) the fact that it was awarded as a research contract was not surprising as this is what NIHR did (as discussed above) and it expressly contemplated that it might be classed as State aid, having included provisions to deal with that eventuality; (2) there was an earlier suggestion that the £2.5 million might be a straight grant but this is not what eventuated; and (3) there was clear value given to DHSC for the £2.5 million, namely foreground intellectual property and the research data that would enable it to licence the specification to other potential suppliers and it was sent out for potential manufacture.[309] Abingdon Health plc did obtain an irrevocable worldwide licence of potential great value to it but the research contract also contemplated the making of a revenue-sharing agreement in the second component contract and likely DHSC recoupment of both the £2.5 million and additional £0.5 million return in line with private equity fund returns.[310] In addition, the £2.5 million sought was not excessive (companies abroad being paid far in excess to develop tests and the profit margin

[304] BD, UK Diagnostics Industrial Strategy, The route to a world-leading diagnostics sector, March 29 2021: https://www.bd.com/en-uk/company/news-and-media/bd-articles/industry-leaders-gather-to-discuss-how-to-take-forward-the-bd-uk-diagnostics-industrial-strategy-.
[305] Ibid.
[306] Information is available at: https://www.nihr.ac.uk/covid-19/tests-and-diagnostics.htm.
[307] *Abingdon Health plc* [175].
[308] Ibid., [176]-[178].
[309] Ibid., [434] – [436].
[310] Ibid., [438].

was less than what it would usually have been for Abingdon Health plc).[311] In addition, the research contract was not being postulated by reference to illegitimate policy considerations.[312] The Good Law Project also made similar arguments in respect of the second contract e.g. that it was an interest free loan of £10 million (so as to pay for components for the first 10 million tests) which was again rejected.[313] The court also rejected arguments in respect of the manufacturing contract to the effect that there was no proper price benchmarking exercise and the agreed price was excessive.[314]

5.10. At the very least, therefore, it is clear that the Government properly considered State aid risks in planning for the contract and managed these risks accordingly. It may also be useful to aid industry's understanding that whilst it may be easy to plead State aid, it is not especially easy to prove, especially in cases where contracts are actually entered into on the basis of a clear identification of principles for price negotiation and determination (e.g. benchmarking) and issues of intellectual property ownership and commercial exploitation are resolved in advance. It is beyond the scope of this White Paper to consider State aid implications of Government decision-making in the diagnostics sector more generally; however, suffice to state that if the Government seeks to deliver on its firm commitment to developing the domestic diagnostics industry and were it to develop funding schemes to boost investment, it will need to carefully consider the risk of claims of "Buy British" policies that could have implications for international trade and might be the subject of legal challenge with State aid often being identified as a relevant legal basis for claims.

Risk Allocation and Management

5.11. Another aspect of contract management which requires consideration is risk allocation in procurement contracts, an area which is generally under-researched and the impact of which on COVID-19 diagnostics contracts during the pandemic is unknown.[315] Risk may be relevant in a number of respects e.g. who should retain intellectual property in the case of development, who should retain ownership of components where these are to be manufactured, who should bear risk in respect of any scaling up of manufacturing capability in anticipation of manufacture, how risks in delivery should be allocated (logistics and supply chain and sub-contracting issues), how any ancillary arrangements for further commercial exploitation should be addressed, how surplus or unused equipment should be addressed, and how force majeure and related (e.g. frustration) type events should be addressed contractually.

5.12. It is possible to identify examples of good practice and potential issues arising in this regard during the pandemic. In terms of instances where risk was considered, again, the contract awards in Abingdon Health plc may be used as an illustration given that it was necessary to manage a range of contingencies. These included: whether to manufacture millions of antibody tests where the effects of the virus on immunity were as yet not fully known; where it was becoming clear that less tests would be required; where it was unclear whether products would actually receive validation and approval for use; and where manufacture by other suppliers were catching up and presented potentially viable alternative procurement options. It was necessary to factor in all of these variables in the make-up of successive and

[311] Ibid., [439].
[312] Ibid., [440].
[313] Ibid., [442] – [445].
[314] Ibid., [448].
[315] See generally, L R A Butler, 'Regulating Single-Source Procurement in Emergency Situations in Light of the COVID-19 Pandemic: Issues in Policy and Practice' in S Arrowsmith and L R A Butler, in S Arrowsmith, L R A Butler, A La Chimia and C R Yukins (eds), *Public Procurement in (a) Crisis: Global Lessons from the COVID-19 Pandemic* (2021 Hart), pp.135-149.

contingent contracts. To explain, as indicated, following the development contract, a second contract was entered into to fund the costs of the purchase of LFT components for Abingdon Health plc to make 10 million tests and in contemplation of a contract for supply of actual LFTs. DHSC would retain title of the components until incorporated into manufactured tests with the anticipated supply agreement conditional on Abingdon Health plc's LFT being validated and approved by MHRA. A third contract was for the purchase 1 million LFTs but with the right under an option to purchase a further 9 million. In this regard, the contracts were clearly structured to manage risk. For instance, it was originally considered whether DHSC should procure components directly but it was ultimately decided to permit Abingdon Health plc to source them and reimburse it for the costs incurred, subject to State aid and commercial rules.[316] Further, DHSC's retention of title meant that if Abingdon Health plc failed to develop a suitable LFT itself, DHSC could, as owner of the components, sell them elsewhere.[317] Nevertheless, there had been concerns about the commercial risks in respect of these arrangements.[318]

5.13. By contrast, as discussed below, whilst full details have not been released regarding ongoing contractual disputes, the very fact that there are disputes on issues such as whether there is a breach of contract and whether pre-payments should be repaid or outstanding payments made may indicate that there may have been instances where it was potentially unclear between the parties as to who bore contractual risks where it was necessary for a contract to be terminated or permitted to expire for various reasons e.g. because the Government no longer needed the requirement or it was not possible for the contract to continue for some other reason e.g. a product did not receive validation or approval.

5.14. As indicated, no specific recommendations are made in this White Paper in respect of risk allocation in the context of contract management. Nevertheless the Boardman Review recommended that risk management should be prioritised as a proper cross-government profession to enable Government to respond to rising risk levels.[319] It was considered that a separate profession could acknowledge a wider definition of risk and risk management, such as risk related to legal, policy, reputation, procurement, use of resources, supply chain etc.[320] The Boardman Review has also recommended that better forecasting of demand (e.g. through data modelling) could improve understanding of what capacity will be needed and when which may aid risk management.[321] It would, therefore, be consistent with those recommendations for this to also be a point of focus in respect of diagnostics contracting. Ultimately, there have been a number of legal disputes which have necessarily increased legal risk which requires careful assessment going forward.

5.15. In the interests of balance, it might be added that this should also cause industry to carefully consider its appetite for risk when seeking to enter into contracts in an emergency given the possible implications that non- or partially executed contracts may have on their business models.

Unused or Surplus Equipment

5.16. An aspect which is attracting increasing attention is the management of unused or surplus stock that was procured during the pandemic.[322] It may be difficult to argue that the fact that

[316] *Abingdon Health plc* [200].
[317] Ibid., [194].
[318] Ibid., [196] – [198].
[319] Boardman Review of Government Procurement in the COVID-19 pandemic, p.2, p.31-32.
[320] Ibid., p.8.
[321] Ibid., p.2.
[322] There are processes in place for dealing with unused COVID-19 tests as waste: https://www.gov.uk/government/publications/managing-waste-unused-coronavirus-covid-19-test-kits-rps-c29/managing-waste-unused-coronavirus-covid-19-test-kits-rps-c29.

surplus or unusued stock remains calls into question the legality of a prior procurement process i.e. that left-over stock confirms that there was no urgent need for it initially. This is so not least because it will have been difficult to have anticipated the extent of the need at the outset and the contracting authority is best placed to determine its needs at the time.

5.17. However, a host of issues arise. One issue concerns contractual protections for Government. For example, a contracting authority may procure a test which turns out to be unusable or inaccurate. This raises the question of whether there is any effective contractual stipulation that payment is only to be made if the test is usable and sufficiently accurate. There is a risk of procuring tests and paying for them, either not knowing the risk that they would not be usable or sufficiently accurate or accepting the risk and paying in advance regardless. There may be reasons for doing so i.e. to secure those tests for validation; otherwise, tests may simply not have been developed. However, this then creates the problem of whether it is possible to recoup payments that have been made and which may lead to disputes.

5.18. Another issue is that contracting authorities may go on to sell or make available (e.g. free of charge) stock procured for use elsewhere. It is conceivable that contracts may specify at the outset that products which are procured may be put to alternative use to cover this contingency. However, there is a risk that suppliers who sell in the market where these products are now being used might argue that, had this been the initial purpose for which these products were to be used, they may have bid for a contract on that basis and, thus, that there has been an unlawful contract modification.

5.19. It is understood that there are ongoing legal proceedings in respect of unused or write-off stock procured during the pandemic and is not therefore the subject of further analysis here. It is, nevertheless, another indication of some of the challenges of effectively planning for and managing risks that arise during an emergency and the need for awareness of the wider market implications such decisions may have.

Contractual Disputes

5.20. Finally, the importance of addressing contract management and performance issues is further confirmed by the number of high-profile and, in some cases, ongoing legal disputes between the Government and suppliers. Examples which could easily constitute "case studies" of various issues arising may be provided. One example is contracts concluded with Abingdon Health plc (as distinct from the legal challenge to the procurement process for award of those contracts). It is a matter of record that there was a dispute between the DHSC and Abingdon Health plc in relation to whether Abingdon Health plc still had a contractual obligation to manufacture 10 million units even when DHSC was not going to take them itself.[323] There also arose a dispute about how much DHSC did or did not owe Abingdon Health plc.[324] It should be observed that the nature of this dispute has been such that the Government requested a firm to conduct an audit of its dealings with Abingdon Health plc as a result of a number of concerns it expressed which included that Abingdon Health plc was benefitting excessively.[325] Ankura Consulting Europe Limited was engaged by DHSC to audit aspects of Abingdon Health plc's operation, which included its purchase of components for the tests and its procurement processes and to determine the margin it made.[326] This report does not appear to be publicly available. Its findings provided the basis for DHSC's position taken in relation to how much it said it owed Abingdon Health plc. It transpires that a settlement agreement has since been reached which has included the payment of

[323] *Abingdon Health plc* [251].
[324] Ibid., [253].
[325] Ibid., [457].
[326] Ibid., [458].

"substantial sums" by DHSC to Abingdon Health plc.[327] This settlement was only reached on 22 June 2022. To put this in context, legal proceedings challenging the process for awarding the contracts commenced in November 2020.

5.21. Another example concerns contracts entered into with Omega Diagnostics. For context, Omega Diagnostics was part of the UK RTC alongside Abingdon Health plc. The Government awarded a contract for the domestic manufacture of LFTs to Omega Diagnostics in two phases. First, DHSC would provide it with equipment and working capital to scale up to manufacture. Second, DHSC would select the chosen test and then licence it to Omega Diagnostics for manufacture. Omega Diagnostics made public announcements to investors regarding certain arrangements.[328] A £2.5 million pre-payment was to be made under a contract alongside £11 million raised by investors to increase manufacturing capacity in advance of licensing of the test and Government-funded equipment was installed. However, DHSC did not licence Omega Diagnostics to manufacture an approved test; phase 2 manufacture was not undertaken with no orders placed and the contract expired in phase 1, Omega having already expended money and resource in preparation. Instead, LFTs were purchased from Zhejiang Orient Gene Biotech. Omega received confirmation from DHSC acknowledging that the contract expired on 1 October 2021 and requested that Omega submit a proposal for the repayment of the pre-production payment of £2.5 million (net of VAT). The Board of Omega, having taken initial legal advice, did not believe that the company was required to repay the pre-production payment.[329] Omega has also sold its manufacturing business to a subsidiary of the Chinese group Orient Gene. Omega attributed sale of part of its business to the loss of COVID-19 test related revenue and has since effectively exited the UK diagnostics market. At the time of writing, it is understood that Omega Diagnostics is still pursuing recovery of its costs from the DHSC. In addition, as Omega was part of the UK RTC for developing the antibody test, it is understood that it has also been involved in other proceedings in respect of the contracts between the Government and Abingdon Health plc. Similarly, Global Access Diagnostics (a sister company of Mologic) was awarded a contract to manufacture tests but this similarly failed to proceed.

5.22. A final example to illustrate is ongoing litigation between the Government and Primerdesign Ltd and Novacyt S.A. in respect of a supply contract initially for £134.6 million.[330] It is understood that Novacyt signed a contract with DHSC for provision of a PCR test in April 2020, under which Novacyt would supply the test for six months. A second supply arrangement was concluded according to which Primerdesign (Novacyt's molecule diagnostics division) would supply to DHSC for a further six months. Whilst there has been speculation about the basis of the legal dispute, there have been few published details and which are not the subject of discussion here.

5.23. Reflecting on the above, one the one hand, the Government should be able to terminate or not proceed with further contracts where there is no longer a need or where certain conditions are not met e.g. failure to secure validation as well as to initiate actions against suppliers in respect of contract performance or to recover or refuse to pay sums of money

[327] Ibid., [20]. The exact figures are not disclosed: [255].

[328] Qualified information is available here: https://sharebuyers.co.uk/shares/omega-diagnostics-qa-colin-king-dhsc-contract/.

[329] See Omega Diagnostics Gp, DHSC contract update, RNS Number: 2678V, Omega Diagnostics Group PLC, 10 December 2021 stating: "[a]cting in good faith we used these pre-production payments, along with our own funds, to upgrade our manufacturing facilities to be able to integrate the Government-furnished equipment and bringing on the additional staff required to be able to supply the DHSC using our UK-based volume manufacturing services. We therefore are confident that, having sought legal advice, we will not be required to make this repayment." This information can be found at: https://www.investegate.co.uk/omega-diagnostics-gp/rns/dhsc-contract-update/20211210093001267 8V/.

[330] Information is available at: https://novacyt.com/wp-content/uploads/2022/04/Novacyt-DHSC-dispute-update-1.pdf.

where contractually required. Ultimately, the Government has a responsibility to secure value for money for the taxpayer. On the other hand, by effectively encouraging a space for industry to develop consortia (in the case of antibodies) or giving or being perceived to give certain assurances (if not contractual, then political), companies were committing to a venture with expectations of future business and choosing not to sell into other markets. What is apparent is that some of the above examples may call into question whether it was necessarily clear to all parties at the outset what the contractual expectations were and how these should be communicated, whether there was a clear understanding of risk and how it was allocated and reflected in contractual provisions, including where there were "back-to-back" agreements between suppliers or successive follow on contracts. If these were all clear, it is less clear why a number of contracts have resulted in contractual disputes and which should be a point of careful reflection for Government and industry.

5.24. More broadly, disputes of this kind raise the issue of trust and confidence between the Government and the diagnostics industry. It is difficult to refute that the "optics" of these disputes do not look particularly encouraging whatever the legal outcomes. Ultimately, the Abingdon Health plc judgment has shown that external auditors were appointed to verify costs, settlements have been reached after protracted disputes of which there have been a number, and it has even been claimed that the sale of a domestic UK diagnostics manufacturing capability to a Chinese company is partly attributable to the fallout of contracting with the Government. It is perhaps unsurprising that suppliers might be reluctant to come forward and assist the Government in an emergency in future given the risks and uncertain exposure to protracted legal disputes and liability, whatever any rights and wrongs of actions by parties on either side.

5.25. The upshot is that Government and industry need to be very clear about how they set and manage expectations before entering into contracts and throughout. For example, if a company comes forward to help in a national effort, of course, they will also have a profit motive (it is a commercial opportunity) but in any event must also assume commercial risk. That said, if the Government enters into a contract with them, there is an element of "good faith" (whether construed in legal terms or not) and goodwill (in the non legal sense) invested in that relationship. If, for whatever reason, contracts are procured but not executed e.g. because the Government's need changes, the contract expires, or there are other problems, there needs to be an effective means of planning for those contingencies at the start i.e. in the contracts and by other means to regulate the consequences, and effective processes of resolution between the parties.

5.26. The above reinforces the need to carefully review contract planning and management practices going forward.

PART IV:
REGULATORY APPROVALS FOR MEDICAL DEVICE USE ON THE MARKET

6. EXCEPTIONAL USE AUTHORISATRION UNDER THE MEDICAL DEVICES REGULATIONS 2002

Introduction

6.1. The preceding Parts have examined the validation and procurement of IVD tests. In addition, products which have been validated for procurement must also receive regulatory approval for their placement on the market in accordance with Medical Devices Regulations 2002 ("MDR 2002"). This Chapter focuses principally on exemptions from approvals rather than the approvals process itself given the prominence of exemption in respect of key contracts.

6.2. Whilst not strictly an aspect of public procurement *per se*, it is necessary to consider regulatory approvals for at least three reasons. First, a number of key suppliers under public contracts for IVD tests received so-called "exceptional use authorisations" ("EUAs") to exempt test kits from being subject to the normal requirements for regulatory approval. This provides an important indication of the cumulative effect of regulatory controls across the contracting process (validation, procurement and approvals), in particular, where these are reduced through exceptions (as under reg.32 PCR 2015 for direct awards) or exemptions (through EUAs). Indeed, various sources tend to treat "evaluation" of products as an "all in one" comprising validation (e.g. under the national technical validation process), regulatory approvals for placement on the market (e.g. MHRA regulator approval for market placement) and award (e.g. as part of the contract award process). Second, there have been instances where the MHRA has not granted regulatory approval for IVD test contracts to be procured; a prime example is denial of approval to Abingdon Health plc in respect of antibody tests with details about validation and regulatory approvals issues emerging from the legal challenge to the contract awards. Third, the regulatory approvals regime provides context for understanding the CTDAR 2021 which amend the MDR 2002 to introduce an entirely new legal regime for placing COVID-19 tests on the market, as discussed in Chapter 7.

6.3. At the outset, it should be observed that the regulatory landscape for approvals of medical devices has been described as confusing and difficult to navigate.[331] EU law, which has been the principal source of legal regulation in this area, is currently undergoing reform. Further, the future of UK medical devices regulation (particularly following Brexit) has been the subject of consultation.[332] It is beyond the scope of this White Paper to explain in detail and evaluate the current state of the regulatory framework for medical devices more generally and which also partly explains the limited focus on exemptions from regulatory approvals. Notwithstanding, it is necessary to provide a brief explanation of key features as context for this and the following chapters. Going forward, the findings in this Chapter should be considered in the context of ongoing regulatory reform and other studies have made similar recommendations to this effect.[333]

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[331] UK Health Security Agency, Consultation outcome Private coronavirus (COVID-19) testing validation:government response, Updated 14 February 2022, p.20.

[332] Information is available at: https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom/medicines-and-medical-devices-act-2021-assessment.

[333] Royal Statistical Society, Diagnostic Tests Working Group Report, June 2021, pp.54-57.

Medical Devices Regulations

6.4. The UK regulatory framework for medical devices derives principally from EU Directives. Before Brexit, these comprised Directive 98/79/EC on in vitro diagnostic medical devices ("EU IVD"),[334] Directive 93/42/EEC on medical devices ("EU MDD"),[335] and Directive 90/385/EEC on active implantable medical devices ("EU AIMDD").[336] In the UK, these were implemented in the MDR 2002 issued under the Consumer Protection Act 1987.

General Regulatory Framework

6.5. In respect of tests used by trained medical professionals, manufacturers must demonstrate that the device meets the MDR 2002 requirements by carrying out a conformity assessment.[337] The assessment route depends on how the device is classified. Manufacturers of Class I medical devices and general IVDs can self-declare the conformity of their devices against the UK MDR 2002 before affixing a CE marking on the product to show that it has met the requirements (e.g. on safety, health, or environmental requirements), complies with other EU requirements, and can move freely within the EU market.[338] Manufacturers of tests with a measurement component and for self-use by an individual must make an application for examination of the device in order to obtain a CE mark, unless it is possible to obtain an exemption. Therefore, professionally administered and self-use tests must obtain a CE mark; as discussed below, there are instances where professional tests were re-purposed for self-use and tests were approved for professional use but applications for self-use were denied. As discussed in Chapter 7, this may be contrasted with tests to be sold within the private market purely for use by consumers in respect of which it is possible to self-declare conformity without any third party assessment at all.

6.6. Following Brexit, EU law which has been retained took effect as UK domestic law on 31 December 2020. As discussed below, UK law has provided for a transitional period to address the continuing regulation of IVDs pending wider reform.[339] As a matter of international legal obligation, the EU-UK Trade and Cooperation Agreement does not expressly address aspects such as recognition of CE marks. Thus, manufacturers and suppliers must comply with UK and EU law, as applicable. In practice, this means that the EU will no longer recognise UK Notified Bodies responsible for issuing CE certifications where required. Further, the UK has introduced its own "UK Conformity Assessed" ("UKCA") mark and UK Notified Bodies. In addition, as indicated, the EU regulatory framework is also undergoing reform, the Directives being replaced by Regulation 2017/745 Medical Devices Regulation ("EU MDR") fully applicable from 26 May 2021 and Regulation 2017/746 In Vitro Diagnostic Medical Devices Regulation ("EU IVDR") fully applicable from 26 May 2022.

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[334] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices OJ L 331.

[335] Council Directive 93/42/EEC of 14June1993 concerning medical devices OJ L 169/1.

[336] Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices OJ L 189/17.

[337] Information in this regard is available at: https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk. See specifically, MHRA Guidance on legislation, Guidance on the regulation of In Vitro Diagnostic medical devices in Great Britain, January 2021.

[338] See generally, Department for Business and Trade and Department for Business, Energy & Industrial Strategy, Guidance, CE marking, 8 October 2012, last updated 14 November 2022: https://www.gov.uk/guidance/ce-marking.

[339] The Medical Devices (Amendment etc) (EU Exit) Regulations 2019 (UK MDR 2019), SI 2019/791; The Human Medicines and Medical Devices (Amendment etc) (EU Exit) Regulations 2019, SI 2019/1385; The Medical Devices (Amendment etc) (EU Exit) Regulations 2020, SI 2020/1478; The Medical Devices (Amendment) (EU Exit) Regulations 2021, SI 2021/873; The Medical Devices (Northern Ireland Protocol) Regulations 2021, SI 2021/905.

6.7. To manage this transition, the UK the Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 which came into force in December 2020 introduced changes to how medical devices are placed on the market in Great Britain. All medical devices, including IVDs need to be registered with the MHRA before placing them on the market.[340] A manufacturer based outside the UK wishing to place a device on the Great Britain market must appoint a single UK Responsible Person who will act on their behalf to carry out registration.[341] In Great Britain, devices must conform to the MDR 2002, the EU MDR until 30 June 2023, or the EU IVDR until 30 June 2023 in order to be registered with the MHRA. Thus, CE marking will continue to be recognised in Great Britain until June 2023.[342] In addition, devices that have been CE marked under the EU MDD, EU AIMDD or EU IVDD will continue to be accepted on the Great Britain market until 30 June 2023 if their certificates remain valid for the EU market under the transitional arrangements in the EU MDR and EU IVDR. Thus, certificates issued by EU-recognised Notified Bodies will continue to be valid for the Great Britain market until 30 June 2023.

6.8. These transitional changes are still ongoing[343] and have coincided with the pandemic, although as key changes were not introduced until at least the end of 2020, a number of early significant contracts approved in 2020 would not have been subject to these changes in any event. Further, there do not appear to be any major reports that these anticipated changes had any specific impacts on how regulatory approvals were applied within the UK in respect of COVID-19 tests. It follows that it was simply the case that IVD test kits used in healthcare settings continued to require a CE marking unless exempt and MHRA had oversight over the placement of products on the market.

6.9. The MHRA is primarily responsible for regulating the UK medical devices market and ensuring compliance with the above requirements. It also performs market surveillance and is able to take decisions on marketing and supply in the UK.[344] As discussed in Part II, Chapter 3, it also played an instrumental role in validation through its oversight of TPPs. Whilst it is beyond the scope of this White Paper to examine all of the wider issues it faced regarding entry of tests onto the market, it should be acknowledged as a matter of context that it played an key role in ensuring that test services which could be a risk to public health were removed. Just one example was an attempt by commercial suppliers to sell antibody test services to the public. As there were no lateral flow assays licensed for use in the home, suppliers provided a means of collecting blood from a finger prick provided by the individual directly which was then processed on laboratory machines. The MHRA suspended sales given that capillary blood was not an approved specimen for laboratory machines pending further evaluation studies to determine their performance.[345]

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[340] Medicines and Healthcare products Regulatory Agency, Guidance, Register medical devices to place on the market, 31 December 2020, last updated 6 December 2022: https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market.

[341] MDR 2002, regs 12, 21C, 44A.

[342] MDR 2002, regs 10, 19B, 24, 30A, 36, 44ZA.

[343] Information is available at: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period.

[344] Medicines & Healthcare products Regulatory Agency, Guidance
Medical devices: the regulations and how we enforce them, Updated 26 February 2019: https://www.gov.uk/government/publications/report-a-non-compliant-medical-device-enforcement-process/how-mhra-ensures-the-safety-and-quality-of-medical-devices.

[345] Information is available at: https://www.gov.uk/government/news/action-taken-to-halt-sales-of-fingerprick-coronavirus-covid-19-antibody-testing-kits.

Exemption through the Exceptional Use Authorisation

6.10. Importantly, most relevant for present purposes, the MDR 2002 authorise exemptions from regulatory requirements.[346] In the case of IVDs, reg.39(2) provides for exemption from the essential requirements for authorisation and for a CE marking where there is "a duly justified request" and it is in the interests of protection of health. In these circumstances, the Secretary of State is authorised where appropriate for a specified period, to place on the market or put into service a particular device of a particular class or description without a CE marking, where appropriate subject to conditions (which are to be complied with). Before the pandemic, this so-called "exceptional use authorisation" or EUA was used for a range of medical devices although it is understood not to the extent experienced in the pandemic. As discussed below, exemptions or derogations became important in respect of a number of contract awards. For example, in the Abingdon Health plc judgment, it was confirmed that it was not possible to obtain a CE mark for an LFT self-test which is why it was necessary for the MHRA to provide a derogation, and thereby approve it without a CE mark.[347] Further, an EUA was granted in respect of the Innova test kit.

6.11. A general observation which has perhaps been brought into sharper relief in the pandemic is that reg.39 is a broad authorisation subject to few apparent constraints. For example, it does not prescribe any statutory protocol or process regarding the grant of an EUA which, in practice, is undertaken by the MHRA not the Secretary of State directly. As discussed in Chapter 7, this may be contrasted with the CTDAR 2021 exemption which expressly refers to such a protocol.

6.12. Before the pandemic, the MHRA did not appear to publish any detailed guidance or other substantial information on the EUA process. By contrast, on 25 March 2020, the MHRA published what it referred to as *Guidance on Exemptions from Devices regulations during the coronavirus (COVID-19) outbreak* which purported to identify "how to get fast-track approval of medical devices during COVID-19".[348] The guidance was last updated on 17 December 2021 but does not appear to have been further updated. Again, similar to observations made in respect of the national technical validation process guidance, the guidance does not actually reflect the title. To explain, whilst it states that it may be possible to get exemptions from certain regulations for medical devices (which will depend on what is being manufactured), it only goes on to list the routes for validation or approval of various products (e.g. ventilators, PPE etc). It does not provide any detailed guidance or process for exemption. For instance, in respect of tests and testing kits, it simply refers to TPP specifications which, again, does not concern exemption. At the end of the webpage under the title "Exemptions for all other kind of medical device", it gives examples such as medical face masks, gloves etc and states that an application must be made directly to the MHRA and to include listed information in the application to be sent to a dedicated email address. In the absence of any further information provided on exemption for test kits specifically, it might have to be assumed that the same information is to be submitted as for other devices. The gov.uk website then simply lists medical devices granted EUAs during the pandemic.[349] Similarly, it is observed that the MHRA general guidance on regulation of IVD medical devices does not address this important exemption in any detail.

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[346] Reg.12(5) and 26(3) for GMD and AIMD.

[347] *Abingdon Health plc* [58].

[348] Medicines and Healthcare products Regulatory Agency, Guidance, Exemptions from Devices regulations during the coronavirus (COVID-19) outbreak, 25 March 2020, last updated 17 December 2021: https://www.gov.uk/guidance/exemptions-from-devices-regulations-during-the-coronavirus-covid-19-outbreak.

[349] Information is available at: https://www.gov.uk/government/publications/medical-devices-given-exceptional-use-authorisations-during-the-covid-19-pandemic.

Fast Track Approval

6.13. A closer analysis of the guidance and process reveals certain issues. It appears that the application process is simply an email to a designated email address. It is not clear from the guidance how the application should be originated e.g. whether it must be at DHSC's prior initiative (i.e. recommending that the supplier apply for exemption) or at the supplier's initiative. It is not suggested here that an application following a Departmental request necessarily results in a favourable assessment but this is a risk. For example, in respect of the Innova test kit exemption, it was a case of the DHSC being identified as the manufacturer and effectively making an application to one of its own executive agencies, the MHRA, for exemption. It is also not clear when the application should generally be made i.e. at what point in time relative to the validation and procurement processes.

6.14. As reg.39 prescribes a broad power, the general information which the MHRA lists as required for an exemption (as referred to above) does not appear to be statutorily required. This is not unusual given that legislation is unlikely to exhaustively prescribe such information and which will vary depending on the medical device and circumstances in question. As explained above, according to the gov.uk website, the information to be provided appears to be that which is applicable to all medical devices not simply IVDs. The listed information is reproduced here as follows:

(1) Confirmation of the role of the applicant: (i) whether the applicant is the legal manufacturer for the medical device; (ii) if the manufacturer is outside of the UK, provide the details of the UK Responsible Person or Northern Ireland-based Authorised Representative;
(2) Confirmation that the product is intended for the Great Britain market, Northern Ireland market, or both;
(3) Details of the product(s) (including model name, description and intended purpose of use);
(4) Impact in the context of the COVID-19 pandemic: (i) clinical justification for requesting an exemption from the regulations; (ii) evidence of demand for the device e.g. evidence of a purchase order/enquiries from NHS or government for you to supply;
(5) Reasons why the product does not have a valid CE, CE UKNI or UKCA mark;
(6) An essential requirements checklist demonstrating how the device meets appropriate standards. Where standards are not met a rationale/plan should be provided;
(7) Evidence of ISO 13485 certification or equivalent;
(8) Evidence of regulatory approval of the product within other jurisdictions e.g. U.S. Food and Drug Administration etc;
(9) Explanation of any alternative CE, CE UKNI or UKCA marked products on the UK market and reasons why using these products would not be appropriate;
(10) Numbers of product likely to be supplied under the exemption, plus an indication of how widely used the product is;
(11) Expected time to gain/re-gain CE, CE UKNI or UKCA certification;
(12) Instructions for use/labelling plus relevant marketing material;
(13) The clinical evidence base - clinical studies, literature etc;
(14) A detailed plan on how the manufacturer will demonstrate compliance or withdrawal of the device from the market after the temporary derogation expires.

6.15. The applicant is also expected to have evidence that the device performs as intended. In this regard, the guidance identifies as examples performance data such as bench testing, including any that comply with a relevant standard (although this only links to PPE) including European standards or other and any study data. The MHRA states that it might ask for more information once the application has been received, that it expects to receive a high volume of applications for derogations, and will prioritise applications based on the needs of the

healthcare providers to increase the supply of critical devices and tests. Similar to the observations in Part II, Chapter 3, the MHRA does not appear to identify any criteria applied for prioritisation of assessment based on need. EUAs will be issued directly to the manufacturer of the medical device and normally do not allow for distributor sales.

6.16. Again, several general observations can be made in respect of these information requirements. As the statutory requirement to demonstrate protection of health is relatively easy to establish, presumably, the emphasis should be on providing a substantial and particularised justification as to why the EUA should be granted which, in turn, necessitates the provision of fairly detailed reasons. However, there is no apparent steer as to what sorts of information and explanations would be useful. There is reference to "a clinical justification" but it does not specify what this actually requires. Similarly, it is not clear how, if at all, this is related to what appears to be a separate requirement to provide the "clinical evidence base" which is, presumably, the evidence in support of the clinical justification. Further, there is a requirement to give "reasons", a "rationale" and "explanations" but the level of detail required is not specified. More fundamentally, these requirements are not couched in unequivocal terms that there has to be a clear justification as to why the exemption should be temporary. Presumably, if there is any indication from the manufacturer that there will be no attempt to seek CE marking or otherwise ensure conformity, there should be additional strict requirements applicable to justify the extent of the exemption and additional conditions attached.

6.17. In respect of the remainder of the process once information has been received, the MHRA does not appear to have published a high-level process (e.g. based on any internal process guidance) on how to assess the listed information required or the basis or criteria for prioritising certain applications above others. It is also not necessarily clear to what extent the MHRA relies primarily on determinations made by other DHSC bodies or agencies as to the need and clinical justification in the first instance and grants approval on this basis or undertakes its own completely independent assessment.

6.18. Ultimately, the MHRA has issued exemptions, thereby facilitating the successful placement of much needed test kits. However, there are some indications that issues have arisen in respect of the approvals process. One concerns the nature of interactions between DHSC, MHRA and suppliers. In the legal challenge to contract awards to Abingdon Health plc (which may not necessarily be indicative of the experience of others), MHRA did not provide approval for mass home testing in relation to its LFT. Waksman J observed that DHSC and Abingdon Health plc to some extent blamed each other for problems in the evaluation process. It was common ground that Abingdon Health plc submitted a Clinical Performance Study Protocol document to MHRA which involved a trial of over 1500 individuals sitting in their cars which was supervised by Ulster University and yielded excellent results but MHRA wanted trials conducted by people at home. Abingdon Health plc then submitted results from home-testing trials but at that point MHRA had stopped the process. The reason was said to be the absence of a "critical clinical need" for antibody LFTs on a mass basis which the MHRA said the Government should have provided by that stage but did not.[350] A DHSC civil servant agreed that MHRA did need a confirmation of clinical need but that DHSC never got to the stage where it was required to produce it. DHSC claimed that, firstly, Abingdon Health plc should not have used its previously obtained data through Ulster University and needed to do a "raw performance" test without which the MHRA would not proceed to consider the case for clinical need. Moreover, it was said that Abingdon Health plc did not accept the help that DHSC was trying to give it in relation to its engagement with the MHRA. In addition, DHSC claimed that Abingdon Health plc had not advanced another proposal for a limited home use derogation which it could have done.[351] The court stated that it was not going to

[350] *Abingdon Health plc* [245].
[351] Ibid., [246].

attempt to resolve these disputed accounts of the difficulties with the MHRA which, for all it knew, "might involve an element of fault on the part of MHRA itself".[352]

6.19. Of course, it may be that there was no such fault but it does evidence that there were difficulties. The above account appears to suggest that there may have been issues in respect of engagement between Abingdon Health plc and MHRA given that DHSC considered that Abingdon needed help. If this were the case, it is not clear why. As indicated in Part II, Chapter 3 in the context of validation, if supplier engagement has been an issue, the reasons why must be addressed. It also raises the wider issue of the extent to which DHSC is involved in applications made by a supplier and the impacts it may or may not have on regulatory approval decisions, as indicated above. It also appears to suggest that there may have been some uncertainty regarding what evidence was expected in terms of the performance data. It is not clear why Abingdon Health plc proceeded to offer evidence which DHSC and MHRA appeared to consider was not sufficient. Presumably, it would be known to all parties what evidence would be needed if all processes were clear. There also seemed to be some uncertainty between DHSC and its own executive agency as to when and why a critical need justification would not be provided. Collectively, this indicates another example of issues arising in respect of the triangulation of the buyer, supplier and regulator in procuring, validating and approving products and the need for clearly defined expectations and lines of communication.

6.20. Another study has also raised issues regarding the evaluation studies which have been relied on in granting exemption from approval. According to the Royal Statistical Society, there has been an apparent over-emphasis on laboratory testing and, thus, insufficient focus on field testing. To explain, it has been acknowledged that the Government has undertaken a standard process of performing laboratory studies of key analytical properties of new COVID-19 tests prior to assessing their accuracy in real world field settings. However, it has also found that for many applications for "Emergency Use Authorization (EUA) marketing approval", for example, evidence from analytical studies (i.e. studies in controlled laboratory settings) has been the main evidence considered; evaluations of the clinical performance of tests in the real world in accordance with their intended use has often followed later or not at all.[353] It has concluded that robust studies of analytical performance provide necessary but insufficient evidence to implement IVDs and recommended that field or clinical evaluation studies are needed to evaluate the performance of an IVD for each intended use case.[354]

List of Exempt Manufacturers

6.21. The guidance has stated that, to ensure transparency around the supply of medical devices, MHRA provides a list of manufacturers and their devices which have been granted exemption. The list also includes manufacturers whose exemption expired or was cancelled and who remain listed for two months after expiry or cancellation. The list does not include any manufacturers who applied for exemption but were refused. Publication of the lists appears to have begun on 29 June 2020 with lists updated weekly. Lists which have previously been published do not appear to remain publicly available but it is understood that, initially, in the region of fifteen suppliers were granted EUAs.[355] The current list of

[352] Ibid., [247].

[353] It is not clear from the report whether this refers to EUA processes applied in the UK or in the USA or other countries where EUAs are applied (e.g. Canada).

[354] Royal Statistical Society Diagnostic Tests Working Group Report, June 2021, p.52.

[355] These companies included: Vygon; Becton Dickinson, Numed Cardiac Diagnostics, Department of Health, UCLH NHS Foundation Trust, Mercedes-Benz, Sensyne Health, Survitec, Zhekiang Orient Gene Biotech, Christoph Miethke and Co. These are identified in Building Better Healthcare, '15 medtech companies given green light to sell to NHS in effort to address COVID-19 pressures'12 January 2022: https://www.buildingbetterhealthcare.com/news/article_page/15_medtech_companies_given_green_light_to_sell_to_NHS_in_effort_to_address_COVID-19_pressures/198005.

exempted[356] and no longer exempt[357] manufacturers is available. There appear to be only two major listed exempt manufacturers for COVID-19 tests remaining at the time of writing. The first is DHSC in respect of the repurposed Innova/Biotime test kit. The exemption was initially issued on 22 December 2020 but has been extended with a current expiration date of 30 June 2023. The second is the SureScreen Diagnostics antigen rapid LFT. The exemption was initially issued on 10 November 2021 but has been extended to 31 December 2023.

6.22. As discussed in Part III, Chapter 5, a number of direct awards and call-off contracts were made in respect of the Innova test kits. The first contract award was made in September 2020. However, an EUA for exemption was not granted until December 2020. The exemption was actually granted to DHSC as the legal manufacturer although the MHRA does not appear to have publicly stated why this is the case on the gov.uk website. As indicated above, this does, in effect, also mean that a Government Department applied to one of its own executive agencies for exemption. No necessary implication or inference can be drawn that this would affect how the application was assessed, although there is always a possible risk of perceptions arising regarding the independence of the regulatory approvals process in instances where the Government is acting as buyer, manufacturer, and regulator. To clarify, the Innova professional use test is legally placed on the market as it carries the CE mark and is registered with MHRA by the legal manufacturer Xiamen Biotime. An exemption was required in this instance because this professional use test was repurposed as a self-test throughout the UK to detect infection in asymptomatic individuals. As will be discussed below, the exemption was subject to a further MHRA review with an extension granted following that review.

6.23. As indicated, there are now few manufacturers subject to an exemption but these have had seemingly long expiration dates given the relative duration of the pandemic. It may therefore become increasingly difficult to maintain that EUAs were only ever intended to be, and are, temporary.

6.24. It should be added that, unlike the TVG validation process which, as discussed in Part II, Chapter 3, publishes a list of suppliers including justifications for pausing and concluding validations, the MHRA does not appear to routinely publish justifications for exemption or refusal. A Freedom of Information request was submitted (not by the author) for the initial EUA application for the Innova/Biotime test kit and associated information and documentation. This was refused on the basis of the burden required to assess whether it could be released.[358] However, MHRA did provide a letter from MHRA to DHSC dated 22 December 2020 in response to the request for the EUA.[359] The letter confirms the grant of the authorisation and states that it meets the requirements of reg.39(2). This does not identify in any particular detail the specific reasons why the authorisation was granted but does list twenty conditions which the DHSC would be required to fulfil and which are restated here:

1. The date EUA would end: the EUA would end on whichever of the following dates occurred first: (1) 22 June 2021; (2) the date when the device is CE marked; or (3) the

[356] Information is available at: https://www.gov.uk/government/publications/medical-devices-given-exceptional-use-authorisations-during-the-covid-19-pandemic/list-of-medical-devices-given-exceptional-use-authorisations.
[357] Information is available at: https://www.gov.uk/government/publications/medical-devices-given-exceptional-use-authorisations-during-the-covid-19-pandemic/list-of-medical-devices-that-are-no-longer-covered-by-an-exceptional-use-authorisation.
[358] Freedom of Information Request Reference FOI-1293961, 14 April 2021: https://www.whatdotheyknow.com/request/719170/response/1768848/attach/html/3/FOI%201293961%20Liddell.pdf.html.
[359] Medicines & Healthcare Regulatory Agency, Ref: DEU/012/2020/003, 22 December 2020: https://www.whatdotheyknow.com/request/719170/response/1768848/attach/html/4/MHRA%20Letter%20DHSC%20COVID%2019%20Self%20Test%2022122020%20Redacted.pdf.html.

date when sufficient quantities of CE marked alternative product is available on the market.
2. The scope of use only within the terms of use reviewed by the MHRA.
3. Requirement for DHSC to inform MHRA before changing any of the components of the devices.
4. That the devices are fit for purpose in line with the assessed performance.
5. Sharing of the plan for distribution and roll-out with MHRA.
6. Securing MHRA agreement of the content of the IFU before the devices are rolled out.
7. That recipients of devices are given necessary IFUs.
8. DHSC agreement to authorisation being listed on the MHRA website to confirm the manufacturer and products authorised under the EUA including the issue date and duration.
9. DHSC submits to the MHRA a detailed time plan for CE marking of the device, or explanation as to why it will not be seeking CE marking.
10. A bi-weekly report to the MHRA detailing a summary of "adverse incidents" whilst under the authorisation, the number of devices supplied and to whom and tracking of every device down to the end user.
11. That the manufacturer has in place or puts into place mechanisms for monitoring performance of devices.
12. That they will cease to supply the devices when CE marked stocks become available.
13. That at the end of the period or when CE marked alternatives become available, the devices supplied will be returned or destroyed unless a further derogation is granted.
14. That the DHSC shall conduct suitable verification prior to deployment of tests.
15. That within 3 weeks plans for post market performance study are submitted to collect further evidence of clinical and analytical performance.
16. DHSC must have a post market surveillance plan and quality management system to collect and evaluate any complaint received in relation to compromised safety, quality or performance and to undertake the necessary corrective and preventive actions.
17. Within three weeks, submit a detailed performance surveillance plan for monthly reports to MHRA to include listed information.
18. Implement a proactive post market surveillance plan to survey user experience to include listed information.
19. To provide full details of any adverse incidents that occur.
20. To provide details to users of any adverse incidents.

6.25. This is an extensive list of conditions which would not otherwise be publicly known had a Freedom of Information request not been submitted. It appears that the most important condition is the time limitation on the exemption and a clear expectation that the product would become CE marked or CE marked alternatives would become available. As indicated above, this emphasis is not as explicit in the published information which is listed as required for an application for exemption. The other conditions suggest a heavy focus on planning and monitoring use. However, it remains unclear to what extent these conditions were enforced and compliance monitored. For example, it is difficult to discern whether sufficient numbers of CE marked products are now in fact available such that the EUAs should be terminated and at what point this could have been the case. Moreover, as indicated above, elsewhere it has been questioned whether there has been sufficient focus on evaluating clinical performance as distinct from analytical performance and collection of relevant data.

Review of Exemptions

6.26. Reg.39(2) does not identify any particular safeguards to ensure its proper use. This may be less important in cases where an exemption is temporary but could become more so in cases where there is a repeated extension of an exemption. Further, the initial policy on granting an exemption contains no detailed reference to review of an exemption and any internal

MHRA policy on review of exemptions does not appear to have been published. However, a letter from the MHRA to DHSC in respect of the Innova/Biotime test kit states that if, following expiry of the authorisation, "there continues to be a need for a further authorisation, the position will be reviewed by the MHRA and a decision taken on whether it remains in the interests of the protection of health for a further authorisation or an amendment to this authorisation to be made". It does not indicate how a review will be conducted.

6.27. It did become necessary for the MHRA to review EUAs granted. On 17 June 2021, the MHRA issued a statement that it had extended the EUA for T&T LFDs used as part of the Government's asymptomatic testing programme to 28 August 2021 i.e. the Innova test kit.[360] This was stated to have followed a satisfactory outcome of a review undertaken as a result of a recently issued US FDA warning about LFDs manufactured by Innova Medical Group Inc in the US. In a press release, the MHRA stated in relevant part:

> Following our normal process to investigate any product concern, the MHRA immediately began reviewing all available information. A full risk assessment was undertaken by DHSC as legal manufacturer of the LFDs in the UK and the MHRA has undertaken a thorough review to ensure that we were satisfied with the assessment and any action proposed. We have now concluded our review of the risk assessment and are satisfied that no further action is necessary or advisable at this time. This has allowed us to extend the EUA to allow ongoing supply of these LFDs over the coming months. People can be assured of the MHRA's work to continuously monitor the tests in use; as is our standard process […] In exceptional circumstances the MHRA can issue EUAs allowing medical devices to be used that have not followed the standard approval process. The EUA process has been used during the pandemic to ensure that the health system has access to critical products. Once an EUA is issued following an assessment by the MHRA, the products given approval through this process are closely monitored by the MHRA.[361]

6.28. Whilst publication of a statement on the review outcome evidences welcome transparency, the fact that further Freedom of Information requests were made may suggest that this information was not sufficient. The Innova test kit exemption is not the only one to have been the subject of further requests for information. For example, it has been asked in Parliament when the EUA was given to SureScreen,[362] although the reason for the request does not appear to have been stated.

6.29. MHRA did actually provide further useful information in response to certain of these Freedom of Information requests which, perhaps, could have been published at the outset. For instance, on 2 July 2021 and 30 July 2021, a Freedom of Information request was made (not by the author) for information about what information led to the review of the EUA, the rationale and data in respect of the "satisfactory review" and its outcome.[363] MHRA responded to the effect that DHSC/NHS T&T published data on 7 July 2021 on LFT

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[360] Medicines and Healthcare Regulatory Agency, Government response, Following a satisfactory review, MHRA extends authorisation of NHS Test and Trace lateral flow devices, 17 June 2021: https://www.gov.uk/government/news/following-a-satisfactory-review-mhra-extends-authorisation-of-nhs-test-and-trace-lateral-flow-devices.

[361] Ibid.

[362] Question for Department of Health and Social Care UIN 103542, tabled on 13 January 2022 by Jonathan Reynolds MP: https://questions-statements.parliament.uk/written-questions/detail/2022-01-13/103542.

[363] Medicines & Healthcare products Regulatory Agency, FOI release, Freedom of Information request on basis of the extended authorisation of the Innova LFT antigen test (FOI 21-765)), 27 April 2022: https://www.gov.uk/government/publications/freedom-of-information-responses-from-the-mhra-week-commencing-2-august-2021/freedom-of-information-request-on-basis-of-the-extended-authorisation-of-the-innova-lft-antigen-test-foi-21-765.

performance and recommended contacting DHSC as the legal manufacturer who may be able to offer more information. The information in respect of data requested was determined to be exempt from release under s.44 Freedom of Information Act 2000. MHRA reiterated that the December 2020 list of exempt medical devices was published, that the EUA extension for the Innova test was granted subject to a number of conditions, including a requirement to re-evaluate the performance of the test, the burden of proof being on the legal manufacturer to provide sufficiently robust data to be able to demonstrate that the test performs as intended, and that a copy of the EUA conditions could be requested from the legal manufacturer. It also stated that, should there be an application for a further extension, it would follow its usual processes which involves requirements for further data, a "robust internal review" and "input from external experts where required". It also directs to the gov.uk site on the EUA process. It concluded that based upon the evidence it reviewed to date, it believed that there was a "satisfactory likelihood" that when used in combination with other measures the self-tests would have the potential to moderately reduce transmission through identification of positive cases but that this is "heavily reliant" on the compliance and behaviour of participants "and evidence of impact is yet to be demonstrated". It would "continue to press DHSC/NHS T&T to generate and demonstrate this evidence and to make it publicly available. It also reiterated that it is the role of DHSC and T&T to determine how the tests are deployed in the UK and to ensure that they are fit for purpose.

6.30. Concerning the US FDA warning, in the Freedom of Information request response the MHRA did state that it carefully considered the areas of non-compliance identified. It observed that the FDA safety action focused on three areas of non-compliance with their regulations: (1) that tests were being sold without the appropriate FDA approvals; (2) that there were discrepancies around the documented test performance; and (3) that Innova did not have an appropriate Quality Management System in place.[364] It stated that, on becoming aware of the FDA safety notice, in line with its normal processes, MHRA immediately asked DHSC/NHS T&T as legal manufacturer of the test in the UK to investigate whether the UK could be affected by any of the FDA concerns. MHRA stated that it undertook a rapid assessment of the information submitted by DHSC/NHS T&T in addition to its regular analysis of post-market surveillance data provided to it as part of the EUA conditions. It further stated that the EUA terms require DHSC to re-evaluate test performance and report regularly to MHRA and that DHSC operate their own quality management system independent of that of Innova Medical Group. Taking all of the above into account, MHRA were satisfied that there was limited applicability of the FDA's actions to the products supplied in the UK and was satisfied by NHS T&T's proposed actions to mitigate any risks.

6.31. On 23 November 2021, a further Freedom of Information request was made (not by the author) for information as to whether Innova LFTs were still being used and issued past the original agreed EUA date of 28 August 2021, what other makes of LFTs were in circulation in the UK, how many, and the accuracy data for them.[365] MHRA confirmed that an extension to the EUA had been granted, that manufacturers of marked devices could be found on the Public Access Database for Medical Device Registration,[366] that MHRA does not undertake performance testing of CE marked devices or hold manufacturer sales figures with a recommendation to contact the manufacturer for this information.

[364] The actual warning letter (to which the MHRA does not refer) is publicly available. See Innova Medical Group, Inc. 614819 – 06/10/21 FDA: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/innova-medical-group-inc-614819-06102021.

[365] Medicines & Healthcare products Regulatory Agency, FOI release, Freedom of Information request on the if Innova Lateral Flow Tests are still being used and issued past the original agreed EUA date of the 28th August 2021 (FOI 21/1282), 31 May 2022: https://www.gov.uk/government/publications/freedom-of-information-responses-from-the-mhra-week-commencing-20-december-2021/freedom-of-information-request-on-the-if-innova-lateral-flow-tests-are-still-being-used-and-issued-past-the-original-agreed-eua-date-of-the-28th-augus.

[366] Information is available at: https://aic.mhra.gov.uk/era/pdr.nsf/name?openpage&start=1&count=200.

6.32. Again, there remain some outstanding issues in light of these responses. For instance, it is not clear why MHRA could not provide a copy of the EUA conditions and which instead had to be requested from the legal manufacturer. As indicated, it published the conditions attached to the initial grant of the exemption pursuant to a Freedom of Information request. Further, the response perhaps suggests that there might have been issues in ensuring compliance, not least because it acknowledges that it pressed the manufacturer for evidence and wanted evidence to be made publicly available. Most importantly, it does not actually state how the review process was conducted and why it was satisfied as to the limited applicability of the FDA's actions and of the proposed actions to be taken to mitigate any risks. It is not known, for example, why the outcome of the FDA findings did not constitute a breach of any number of the conditions pertaining to the initial grant of exemption.

Lessons Learnt and Recommendations

6.33. The Royal Statistical Society has already recommended *inter alia* that the MHRA should review and revise the national licensing process for IVDs to ensure public safety is protected, particularly in a pandemic, and states that this review needs independent expert input from the relevant disciplines.[367] Therefore, the following identifies just some lessons learnt and recommendations which could feed into a more systematic independent expert review.

✓ Institutional roles, responsibilities and expectations in respect of regulatory approval need to be clarified and clearly communicated

6.34. It is recommended that **there needs to be a clearer understanding of the roles, responsibilities and expectations of key stakeholders in the regulatory approvals process**. As indicated, there appear to have been certain instances which have raised questions about the relationship between DHSC, the MHRA as its executive agency and applicants. Examples include: DHSC acting as manufacturer seeking approval from its own executive agency; a perceived need for DHSC to manage engagement between applicants and the MHRA; and uncertainty as to what information or data is required to be provided to obtain approval or exemption. This should form part of a wider discussion on the different roles of executive agencies and where functions should be allocated in the context of diagnostics. As indicated below, clearer guidance on process could also help to clarify and better delimit or delineate roles, responsibilities and relationships.

✓ Amend the Reg.39 MDR 2002 exemption

6.35. As indicated in the Introduction, this White Paper does not make extensive recommendations for legislative reform, not least because it is possible to achieve incremental improvements through reform of policy guidance and practice. However, perhaps one exception in this regard is reg.39(2) MDR 2002 which provides a broad discretion to exempt products from the essential requirements for authorisation and CE marking. At present, there are no explicit conditions for use or other requirements to ensure that the justification is robust. Further, there appears to be no or limited guidance on what is likely to constitute a duly justified request and no reference to any protocol which may be followed. By contrast, the more recent CTDAR 2021 have amended reg.39 to make explicit reference to a protocol in respect of coronavirus tests. Therefore, **it should at least be considered whether reg.39 should be amended to place further regulatory controls on its use**. For example, it could be considered whether to introduce more explicit limitations on the grounds for use and even time limited conditions for exemption subject to possible renewal e.g. a period of months, subject to review. Further, as indicated in Part II, Chapter 3, it would be useful to clarify the legal status of protocols in this area generally.

[367] Royal Statistical Society Diagnostic Tests Working Group Report, June 2021, p.57 with other recommendations listed.

✓ Publish a process for exceptional use authorisation and review

6.36. It is recommended that **the MHRA should publish a process for EUAs and review of EUA use**. First, the information required for submitting an application could be improved and made clearer. Second, as the MHRA is likely to have an internal process for assessing EUA applications in place, the guidance should set out a "high-level" process identifying general criteria that may be applied and how information provided is to be assessed. This could extend to setting out principles on how the MHRA assesses information and data provided by DHSC and other executive agencies, how it assesses whether conditions for exemption continue to be met, and the circumstances in which authorisations may be extended (bearing in mind that authorisation should be exceptional and presumably temporary in any event). The guidance could also include general considerations which will apply in respect of a review of the exemption (including whether the criteria for assessing whether the exemption should be renewed are the same as those for considering the initial application). This would be preferable to general press releases stating that a process has been followed but which is likely to raise more questions than answers. It would also be more consistent with the Government's approach to validation given that the national technical validation process is specified in guidance.

✓ Publish the outcome of an EUA decision

6.37. It is also recommended that rather than simply publishing a list of exempt suppliers, **MHRA should also publish the reasons for the grant of an exemption as well as the general conditions to which an exemption might be subject** (subject to any commercial in-confidence redactions). As indicated, this sort of information can already be obtained by Freedom of Information request. In addition, it should be clarified who is responsible for publishing what information in respect of EUAs given the apparent uncertainty as to whether information must be provided by the manufacturer or MHRA.

✓ Consider use of independent notified bodies for EUAs in cases of emergency

6.38. It is recommended that **it should be considered whether MHRA be given more capacity to assess information and data when determining exemption applications, including the ability to have recourse to independent notified bodies**. As indicated, whilst MHRA sought to make formally independent assessments of the data and information provided, to an extent, it needed to rely on what was provided by the DHSC and applicant as a "given". Exemption routes will not formally involve consultation or independent verification by other approved bodies as may be the case in respect of other applications e.g. commercial organisations such as the British Standards Institute. To aid the MHRA in cases of emergency, it might be possible to put such arrangements in place. This may avoid any overreliance or deference to decisions made by others (e.g. during validation) on exemption approval albeit adding additional process. This should be considered in the wider context of findings of other reports which have recommended that the EUA process should involve greater consideration of clinical evaluation studies.

7. CORONAVIRUS TEST DEVICE APPROVALS

Introduction

7.1 As indicated in Part I, Chapter 2, from April 2021, the Government sought to scale back its UTO of universal free provision of LFDs. The expectation was that going forward individuals could purchase tests privately for own use e.g. for international travel and in the workplace with the private sector scaled up to meet market demand. This, in turn, would further reduce restrictions and aid economic recovery. Whilst the Government considered that free-to-use COVID-19 tests had been subject to rigorous clinical evaluation to assess their quality in the procurement process, tests on the private market needed to be subject to the same minimum standards not least given an apparent "influx of poor quality tests coming onto the market".[368] Therefore, the Government introduced The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 ("CTDAR 2021") to require antigen and molecular COVID-19 tests to undergo mandatory review by UKHSA to assess their performance before being placed on the market. The CTDAR 2021 came into force in July 2021.

7.2 This Chapter examines this regulatory framework. Technically, this could be omitted given the White Paper's principal focus on public procurement. However, its consideration is merited because its adoption is informed by the national technical validation and procurement process, it amends the MDR 2002 raising issues relating to exemptions from regulatory approvals (an issue relevant to procurement for the reasons indicated in Chapter 6), and the regime is a significant example of regulatory intervention on which questionnaire participants and interviewees were keen to comment.

7.3 Analysis is timely because on 29 December 2022 UKHSA published its statutory review of the regime's implementation. UKHSA has claimed that there is "strong evidence" that the regime has met its overall objective of addressing market failure "that saw poor quality, inaccurate tests made available for sale" by removing them from the market and that a large number of tests have now successfully passed through the process, indicating a robust market that gives consumers genuine choices.[369] However, as will be discussed, it is questionable whether other specific objectives have been met. Further, the statutory review has indicated that further minor reforms could be introduced. This Chapter begins by explaining the policy drivers before examining the approvals process and exemptions and concludes with the statutory review's broader findings.

7.4 At the outset, it should be qualified that the following is not a comprehensive evaluation of the CTDAR 2021 as against other legislative and non-legislative options that were initially considered (e.g. third party conformity assessments) nor possible future regulatory models. This is because the statutory review has intimated that there is some uncertainty about future regulation in this area, stating that whilst options such as third party conformity assessment could have utility in non-emergency situations and be a proportional approach to regulation, there are still questions as to whether these are stringent or prescriptive enough to prevent the type of market failure experienced with COVID-19 tests.[370] Further, this would require more detailed comparative research on regulatory models in other jurisdictions and

[368] UK Health Security Agency, Research and analysis, Statutory review of the Coronavirus Test Device Approvals (CTDA) process, published 29 December 2022, p.3. https://www.gov.uk/government/publications/coronavirus-test-device-approvals-ctda-statutory-review-of-process.
[369] Statutory Review, p.3 and pp.23-24.
[370] Statutory Review, pp.24-25.

considered in the wider context of IVD regulation which is beyond this White Paper's scope.[371]

7.5 As the statutory review already provides lessons learnt and recommendations, this Chapter does not add to these but the analysis of the regime presented here may help inform ongoing reform efforts.

Policy Drivers for Regulatory Approvals of Private Test Kits

7.6 It is understood that LFG and TVG validation of test devices for use in the national mass testing programme and parts of the NHS (discussed in Part II, Chapter 3) established consistent disparities between manufacturers' claims (including field outcomes for selected products) and actual performance, even for well-performing devices.[372] This has been the case despite nine out of ten suppliers having the CE mark, with three-quarters meeting the ISO 13485 standard in relation to post market surveillance.[373] In light of this reality, the desired outcome of the CTDAR 2021 was to ensure that all mature (antigen and molecular detection) COVID-19 testing technologies sold on the UK market and used meet a minimum standard of performance, achieved through independent validation of those devices.

7.7 The difficulty for the private market is that, as the Government has observed, the European framework for IVDs is weak in relation to "low risk" technologies because it allows a manufacturer to independently self-certify that it meets requirements for bearing a CE mark.[374] Consumers have had to rely on a self-declaration by manufacturers of the performance and functionality of their test kits. As the data used by each to achieve its CE marking is unique, they have been able to tailor their use cases or "game the CE marking system" by creating a testing environment for their product which is conducive for demonstrating high product performance and which risks tests not performing as well in real-world scenarios. This performance declaration has not been required to be independently verified before sale. Therefore, there has been no audit or conformity assessment from a Notified Body. Further, there was no legally binding or consistent process for establishing the minimum threshold performance of COVID-19 tests. Moreover, enforcement has necessarily been reactive rather than proactive as tests are placed on the market and only removed subsequently if problems come to light.[375] In addition, consumers as individuals have not been able to conduct the same level of scientific validation as is the Government not least because it could be prohibitively expensive.[376]

7.8 These circumstances resulted in market failure because it limited consumer choice in having to rely on selecting kits based on manufacturer-claimed performance and consumers could not compare performance against others. This was also said to act as a barrier to effective competition and risked public health in potentially creating false results limiting the ability to track the virus or resulting in unknowing transmission.[377] The Government has stated that whilst, normally, self-declaration is adequate regulation, the influx of new COVID-19 tests

[371] For a useful exercise in this regard, see the Statutory Review, Annex A: international examples of COVID-19 test validation.
[372] Impact Assessment, p.6, fn2; p.11; p.19, para.61.
[373] Department of Health and Social Care and UK Health Security Agency, Consultation outcome, Private COVID-19 testing validation, updated 14 February 2022, p.6. https://www.gov.uk/government/consultations/private-coronavirus-covid-19-testing-validation/private-covid-19-testing-validation#the-proposals.
[374] reg.40(1) of the Medical Devices Regulations 2002. Impact Assessment, p.17 citing at fn10: Cruciani, Mario, 'COVID-19 Impact on Diagnostic Innovations: Emerging Trends and Implications' Diagnostics 2021, volume 11, page 182 (viewed 5 October 2021).
[375] Impact Assessment, p.6.
[376] Ibid.
[377] Ibid., p.6 and p.39.

during the pandemic exposed weaknesses in this process and made it clear that more regulation was needed.[378]

7.9 The Government also identified five other objectives for introducing more regulation, namely to: (1) reduce false negative and positive test rates which will help to manage spread of the disease, reduce incidence of unnecessary self-isolation and contact tracing; (2) correct information asymmetry between consumers and sellers; (3) establish a well-regulated minimum bar in COVID-19 devices; (4) increase reliability of test products and easier comparability of their performance should drive increased take up of testing by employers and institutions; and (5) increase consumer confidence in tests and subsequently, increase volumes of private tests being reported.[379]

7.10 The Government also claimed wider policy objectives with some grand ambitions, namely to grow a "thriving private sector market" for COVID-19 testing that will enable "domestic innovation" to become a "world leader" in development and manufacture.[380] The Government identified a longer-term need for considerable expansion of domestic protection of COVID-19 testing and thus strong private sector capability in testing to meet expected demand from businesses and consumers.[381] It observed that whilst the US is the world's leading exporter of tests with China quickly increasing production creating a strong global supply chain, there are bottlenecks e.g. in demand for raw materials. By forcing companies to focus on developing high quality tests in order to enter the market, it can expect this to mean raw material and other resources are more efficiently allocated further down the supply chain towards those companies producing higher quality tests. The government has stated that it is keen to develop a resilient UK based supply chain to safeguard test supply particularly as the UK strives for improved quality and that, as imports continue, it will be important that these regulations apply equally and fairly to overseas manufacturers and wholesalers as they do to UK manufacturers and retailers.[382] Thus, the CTDAR 2021 for private tests was intended to set the "gold standard" for a UK government-run validation process that could potentially provide recognition in export markets, giving UK tests a competitive advantage against unvalidated tests, rendering the UK a key market due to the high regulatory quality.[383]

7.11 The Government initially considered a range of delivery models but ultimately proposed the introduction of two stages, namely desktop verification and lab-based validation. These were to be given effect in two separate and successive Statutory Instruments adopted under the Medicines and Medical Devices Act 2021. The Government launched a public consultation[384] which ran from 8 April 2021 to 5 May 2021. The consultation and the stakeholder feedback, including the Government response to it, were published.[385] Whilst the number of consultation responses was fairly low,[386] there was broad support for introducing the regime. However, notably, one industry association stated that: "[t]he proposal is not a suitable template for future regulation and feels punitive and reactive. It may be viewed as a

[378] Statutory Review, p.4.
[379] Impact Assessment, p.2.
[380] Consultation outcome, Private COVID-19 testing validation, p.5.
[381] Ibid., p.10.
[382] Ibid.
[383] Ibid., p.12.
[384] A public consultation must be carried out before regulations are made under the Medicines and Medical Devices Act, s.15.
[385] Department of Health and Social Care and UK Health Security Agency, Consultation outcome, Private COVID-19 testing validation, updated 14 February 2022. On the Government response, see: Department of Health and Social Care and UK Health Security Agency, Consultation outcome, Private coronavirus (COVID-19) testing validation: government response, Updated 14 February 2022: https://www.gov.uk/government/consultations/private-coronavirus-covid-19-testing-validation/outcome/private-coronavirus-covid-19-testing-validation-government-response.
[386] 43 responses were received: 27/43 were from organisations and 16/43 were from individuals.

disincentive for innovation, particularly by smaller companies."[387] Some respondents also offered alternative suggestions to the proposed approach. Some felt that the stated aims of the proposed mandatory validation process could all be achieved within the existing regulatory framework.[388] More broadly, it is observed that the Regulatory Policy Committee questioned the original Impact Assessment for the CDTAR 2021 on the basis that it was lacking an evidence base and explanation as to the impacts.[389]

7.12 As indicated, the regulatory model as initially conceived was to involve a verification stage comprising a "desktop review" followed by a laboratory validation stage. The mandatory desktop review validation stage has been put on a statutory footing under the CTDAR 2021 (SI 2021 No.910) made on 27 July 2021 and which came into force on 28 July 2021.[390] The CTDAR 2021 amend the MDR 2002.[391] An accompanying Impact Assessment explains the policy at a "high level" of generality but not the detail of specific legal provisions such as the role of exemptions. The CTDAR 2021 approvals process applies to tests already on the market and those being developed and newly introduced once CE/UKCA marking has been obtained and to both domestically manufactured and imported tests. This was considered necessary to ensure that there are enough competitors in the market to guarantee supply, and, through competition, drive up quality and drive down prices.[392]

7.13 The second stage of mandatory laboratory validation was intended to build on desktop review. A second Statutory Instrument to cover this stage was intended to be laid in Winter 2021.[393] However, the Government decided not to proceed with this second stage. The reason given was that laboratory validation was not deliverable in time to address the immediate market failure swiftly but it was the apparent intention to introduce the second stage at some point to provide the greatest assurance.[394] This has not happened.

7.14 To facilitate implementation, the Government indicated that it would stagger introduction of the requirements, ensure that the validation process was "clear and transparent", facilitated by "extensive guidance" for manufacturers and consumers, easier to navigate in view of concerns expressed that the existing regulatory framework is "confusing", and ensure an efficient process, avoiding unnecessary barriers to strong performing tests getting on the UK market .[395] These matters had been "carefully considered in the design of the policy" e.g. by ensuring the "right level of capacity" required to process applications in a timely manner.[396] In support of the legal requirements, on 28 July 2021, the Government issued its guidance for manufacturers and distributors on how to apply for COVID-19 test approval in accordance with the CTDAR 2021.[397]

7.15 It should be observed that the approval requirements do not apply in respect of any period before 1 September 2021. A person could place on the market, put into service or supply a

[387] Private coronavirus (COVID-19) testing validation: government response, p.29.
[388] Ibid., p.20.
[389] Research and analysis, Medical Devices (Coronavirus Test) Regulations 2021: RPC Opinion, Regulatory Policy Committee opinion on DHSC's Draft Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021, 21 July 2021 providing reference to Regulatory Policy Committee, Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021, RPC-DHSC-5073(1): https://www.gov.uk/government/publications/medical-devices-coronavirus-test-regulations-2021-rpc-opinion.
[390] Reg.1(1).
[391] Reg.2.
[392] Consultation outcome, Private COVID-19 testing validation, p.9.
[393] Impact Assessment, p.24.
[394] Government response, p.21.
[395] Government response, p.9 and p.21.
[396] Ibid., p.21.
[397] UK Health Security Agency, Guidance, COVID-19 test approval: how to apply, 28 July 2021, last updated 19 April 2022: https://www.gov.uk/guidance/covid-19-test-approval-how-to-apply.

coronavirus test device from 1 September 2021 to 31 October 2021 if they had made an application for approval.[398]

Coronavirus Test and Device Approvals Process

Approval

7.16 The CTDAR 2021 provide that no person may place a coronavirus test device[399] on the market, put it into service, or supply it unless the Secretary of State has approved it and the approval remains valid.[400] In practice, at the time of writing, this process is administered by UKHSA. This approval requirement does not apply where there is public sector use of coronavirus test devices i.e. where it is placed on the market, put into service, or supplied only for use by the Secretary of State, devolved public health body or health service body pursuant to an existing contract.[401] Therefore, the Secretary of State can themselves still place on the market and supply COVID-19 devices whether or not they have a CTDA approval, although they would still require a CE mark or a derogation under reg.39(2) MDR 2002 as discussed in Chapter 6. This does raise the question of the potential market impact of DHSC being permitted to place tests (in reality produced by private sector companies) on the market without having to undergo full regulatory approval and whether additional regulatory safeguards are necessary as a result.

7.17 A person may make an application for approval.[402] It must include such information as the Secretary of State may require. The Secretary of State must approve a device if they are satisfied on the basis of the information contained in the application that it meets the prescribed performance requirements.[403] An approval is valid for five years, although it is not clear what is the process thereafter (e.g. a simple renewal or new application etc). An application must be made through a designated portal on the gov.uk website.[404] According to the published policy guidance, there are essentially two main steps: (1) Step 1: submit the application and (2) Step 2: desktop review which is subject to additional guidance that is updated.[405] After submission, UKHSA will do a basic check of: (1) manufacturer and product information; (2) regulatory status; (3) product performance; (4) biosafety; and (5) supplementary documents (e.g. current version of the IFU, biosafety documents, and evidence of performance characteristics). This must be submitted to the Coronavirus (COVID-19) test device approvals service for which an account must be registered.

7.18 The desktop review is a systematic assessment of the evidence submitted by a supplier against a minimum required data set. The information submitted will be subjected to three stages: (1) a scientific advisor undertakes the initial assessment which will be peer-reviewed and presented to a Desktop Review Assurance Group meeting; (2) the Desktop Review Assurance Group will assess the submission and make a recommendation for pass or fail; and (3) all decisions will then be ratified by the Regulatory Approvals Committee. The main areas of assessment are as follows: (1) Manufacturer and test information; (2) Regulatory status; (3) Intended use case; (4) Product performance - in this regard, the CTDAR 2021

[398] Reg.34C.
[399] As defined in reg.2(3).
[400] Reg.34A.
[401] Reg.34B.
[402] Reg.38A.
[403] Reg.38B.
[404] Reg.38A.
[405] UK Health Security Agency, Guidance, COVID-19 test approval – step 2: process for desktop review, Updated 22 November 2022: https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/covid-19-test-approval-step-2-process-for-desktop-review.

provides that antigen tests, direct molecular tests, and extracted molecular tests, must meet the prescribed levels of sensitivity and specificity; and (5) Biosafety.

7.19 UKHSA aims to provide an initial response or acknowledgment of receipt within 20 days, but this may take longer if there is a high volume of applications. UKHSA will prioritise certain applications where necessary, for example, if it is in the interests of public health. Of course, assessing all applications will be in the interests of public health and no further guidance is provided on prioritising applications. If UKHSA needs more information, the manufacturer/distributor must respond within 20 working days. If not, the application might be rejected.

7.20 Applicants receive a report following the desktop review which details whether they have or have not met the application guidance and the threshold performance of their type of technology.[406] These reports do not appear to be published.

Payment

7.21 Applicants must pay a fee of £14,000 or £6,200 if a Small or Medium Sized-Enterprise ("SME") (i.e. the company has no more than 250 individuals in total). If the person withdraws from the process after payment is made, payment will not be refunded.[407]

Complaints and Reconsideration

7.22 Applicants who want to complain about the process should email their complaint using the webform service with a full summary of the complaint and any relevant supporting information. If the application is unsuccessful, a request can be made to UKHSA to reconsider its decision by using the webform service.

Number of Applications

7.23 As discussed below, UKHSA appears to only formally publish details of approved products not statistics on the number of applications made and trends. According to the statutory review, there was a large number of applications in the initial stages which appeared to correspond to the anticipated winter peak of a high number of COVID-19 cases and death between January and June 2021.[408] However, as indicated in Chapter 2, it appears that the market for COVID-19 testing is in decline as reflected in the number of applications made. As of 28 November 2022, there have been 286 applications, 99 (34%) of which were made since 1 January 2022: 107 applications have been successful; 101 applications have been unsuccessful; and 22 applications have been withdrawn. The remaining 56 are in progress. According to UKHSA, this highlights the regime's balance between allowing quality tests onto the market while removing a significant number of poor quality ones. The number of applications per month has been on a general downward trend from a peak of 88 in August 2021 to a low of 4 in September 2022. This trend aligns with perceptions that there is limited long term growth in the COVID-19 diagnostics market and that manufacturers are pivoting into other IVD markets or leaving the sector altogether.[409]

[406] Statutory Review, p.11.
[407] Reg.56A.
[408] Statutory Review, p.8 and p.15.
[409] Statutory Review, p.7.

Register of Approved Coronavirus Test Devices

7.24 It is recalled that one of the policy drivers for the CTDAR 2021 is the lack of comparable information on each test's performance which could inform consumer choice. Acknowledging the asymmetry between buyers and sellers, it was proposed to introduce a publicly available register to address apparent consumer confusion when purchasing.[410]

7.25 The CTDAR 2021 provide that the Secretary of State must establish a register of approved devices and publish it on the gov.uk website.[411] The format is an online spreadsheet. Only basic prescribed information is required, namely:

(a) the name and address of the registered place of business of the applicant;
(b) if the applicant was not the manufacturer, the name and address of the registered place of business of the manufacturer;
(c) the country in which the manufacturer is established;
(d) the name and address of the registered place of business of the UK responsible person or the manufacturer's authorised representative having a registered place of business in Northern Ireland, if there is one in respect of the device;
(e) the name and description of the coronavirus test device;
(f) the date and version number of the IFU included in the application;
(g) whether the coronavirus test device is an antigen test, a direct molecular test, or an extracted molecular test;
(h) the date on which the coronavirus test device was approved and the date on which that approval ceases to be valid.

In addition to the above, the COVID-19 test approval application site also requires the CE certification number and sample type for outcome reporting. The CTDAR 2021 provides that the Secretary of State may publish additional information relating to the test device and its intended use which they consider appropriate.[412] It is not apparent what, if any, additional information beyond that listed has been published in accordance with this statutory power.

7.26 According to the statutory review, there are no plans to publish a register of tests that have failed validation, a reason for which is not given.[413]

7.27 As of 1 December 2022, the register had been viewed around 3,100 times in 2022. This was up from around 1,800 views in 2021, comprising a total of around 4,900 unique views. The Government has stated that this demonstrates that the register is in use and has increased as the regime has matured over time.[414]

7.28 An open question is whether the register has, in fact, achieved the major objective of correcting market failure, particularly the apparent information asymmetry that prevented consumers from understanding or being able to compare test devices. According to the statutory review, respondents were split.[415] One issue appears to concern publicity of the register. The consensus has been that the register was not well publicised, potentially limiting the impact it could have in informing the public and businesses when making purchasing decisions and that, in future, wider promotion of such registers, both to industry

[410] Impact Assessment, p.9.
[411] Reg.38C. See UK Health Security Agency, Guidance, COVID-19 test validation approved products,18 October 2021, last updated 28 February 2023: https://www.gov.uk/government/publications/covid-19-test-validation-approved-products.
[412] Section 38C(4).
[413] Statutory Review, p.15.
[414] Ibid., p.16.
[415] Ibid., p.21.

and the public, would better inform consumer knowledge of tests.[416] A second issue was the format of the register which was said to be too technical for a lay user to interpret. The statutory review reported that the register was set up at pace to allow the results of validation to be viewed publicly but that the format could be improved and promoted to a wider audience to ensure greater accessibility.[417] A third issue is that the Government acknowledges that data on usage of the register did not enable it to determine how many users are repeat users or what the experience of the register has been.

7.29 A fourth issue concerns the quality of the information on the register necessary for consumers to make informed decisions. On the information provided, whilst some respondents to the call for evidence cited how the regime's uniformed performance requirements meant that all tests were approved based on the same minimum criteria, allowing users to be confident that tests were of a prescribed quality, others indicated that it was not clear how the policy provided greater understanding to consumers. While the register shows which tests have successfully passed validation, some thought the information could be confusing for some as no specific performance data was published. On comparability, a majority of respondents (57%) disagreed that the regime had made it easier to compare the performance of test products.[418] The salient point raised was that the lack of published performance data for approved tests and testing services made it difficult for users to compare between devices. The statutory review acknowledges that the register does not allow for "meaningful comparison of test performance between those devices that meet the minimum standards, so its utility as a comparative tool is limited."[419] Nevertheless, it states that it does provide an assurance that these devices have met defined performance levels, providing greater clarity on the quality of available tests compared to that before the regime was implemented. It also observed that comparisons between products can also be made on other criteria, such as technology type or sampling method, although it does not identify to what extent this is really possible or useful for consumers. Further, the statutory review stated that the figures for successful and unsuccessful outcomes suggests that the regulatory process is delivering on the objective of increasing reliability through requiring satisfactory evidence of performance to access the market noting that it is just as important to remove or prevent unsuccessful tests from entering the market as it is to ensure high quality tests can continue to be supplied to patients and consumers.[420]

7.30 Notwithstanding, the statutory review acknowledged that in accordance with reg.38C(4), further improvements could potentially be made to the content and data held within the register to allow better comparison between tests based on use or performance and to indicate the frequency of register updates.[421] More generally, it suggests that improvements to the promotion, design and content of the approved devices register would likely make it easier to achieve the objective of increasing comparability, allowing purchasers to make informed decisions and possibly increase its utility as a marketing tool as more users become cognisant of test device performance and product quality. It further stated that publishing confirmed test performance may also lead to competition and further innovation to increase test accuracy, but such changes to the register's content would require the consideration of the Secretary of State.[422]

7.31 A number of broader reflections may be made in respect of these findings. It is suggested that, fundamentally, it remains unclear what problem the Government is trying to address in

[416] Ibid., p.16.
[417] Ibid., p.21.
[418] Ibid., p.22.
[419] Ibid.,, p.4.
[420] Ibid., pp.22-23.
[421] Ibid., p.16 and p.21.
[422] Ibid., p.24.

respect of information asymmetry for consumers. In theory, consumers might wish to compare the performance of different test devices but it is at least questionable to what extent this is something that consumers actually want in practice as distinct from simply knowing that the test is approved for use. As indicated, the register has only been viewed around 4,000 times and the users are unknown. This is not necessarily a compelling indication that there are highly discriminating consumers and that there is extensive consumer demand to be able to make informed choices through accessing a register. Further, whilst the Government indicates that the information has proven to be inadequate to make such choices, it perhaps should have been obvious at the outset that this information was never going to be sufficient for this purpose. Moreover, it is not clear why it has been necessary to wait for a statutory review to make changes to the register given that these could have been instituted earlier; after all, it makes *ad hoc* amendments to the guidance in light of experience. Finally, by its own logic, if there is a reduced need for COVID-19 tests on the private market, it is not clear why these changes will now be necessary or particularly useful at this stage in the pandemic.

Exemptions

7.32 It is recalled that Chapter 6 examined EUAs under reg.39 MDR 2002. The CTDAR 2021 provide for a similar exemption. Reg.39A provides that the approval requirement does not apply where the Secretary of State has decided to permit, where appropriate for a specified period, the placing on the market or putting into service of coronavirus test devices that have not been approved following an application. This is only possible in circumstances which give rise to a need to protect the public from a risk of serious harm to health. Permission may be given subject to such conditions as are set out in a protocol established by the Secretary of State and who may withdraw or amend the protocol. Further, permission may be withdrawn.

7.33 The Impact Assessment and Explanatory Notes and other documents do not address the issue of exemption in any detail; similarly, the statutory review only mentions the basis for exemption but does not review its use to date. [423] This is perhaps surprising given the prior prevalence and profile of EUAs.

7.34 In terms of the rationale for permitting exemption, according to the statutory review, some manufacturers struggled to provide the necessary evidence to be validated through the CTDAR 2021 in time and that failure to meet the requirements would have meant temporary removal from the market whilst they completed validation, potentially leading to a contraction in supply at a time when testing was expected to ramp up. In order to safeguard supply, the Secretary of State exercised powers under reg.39A to publish a protocol list of certain tests that have both passed public sector validation and have lodged an application for validation through the CTDAR 2021. Tests on this list would be able to remain on the market until 28 February 2022 or until the outcome of their validation application had been determined.[424]

7.35 The protocol appears to have been first published on 13 October 2021.[425] Two further protocols were published by the Secretary of State. One was introduced to allow a specific list of tests to remain on the market pending the outcome of an application (1 November 2021 to 28 February 2022). A second protocol was introduced with a list for professional use tests exempt for three months (1 March 2022 to 31 May 2022) and self-test devices exempt for six months (1 March to 31 August 2022). The Government has stated that these were

[423] Statutory Review, pp.10-11.
[424] Ibid.
[425] The earliest version of the Protocol does not appear to be publicly available on the current gov.uk website. A version is available at: http://data.parliament.uk/DepositedPapers/Files/DEP2021-0789/Coronavirus_Test_Device_Protocol.pdf.

created to extend the time devices could remain on the market while manufacturers gathered the necessary data to satisfy the approval process.[426] The protocols were designed to be temporary measures to strike a balance between supply and ensuring devices on the market were properly evaluated against the more stringent requirements of CTDAR 2021.[427] It is understood that tests included in the protocol had previously been through public sector evaluation or verification such that the CTDA team had some assurance over performance.

7.36 The protocols have now expired. It appears that the gov.uk website was updated on 1 September 2022 to confirm expiration.[428] The protocol annexes listing applicants exempt under the protocols also appear to have been removed but the original texts are retained on file and reproduced below. In terms of content, the protocol confirms that a reg.38A application for approval has been made in respect of each of the listed devices and that the application has not yet been determined or withdrawn. The Protocol specifies that if the reg.38A application is withdrawn or not approved, the protocol ceases to apply to the device after the expiry of the "relevant period" which is 10 days of notification (which can be by means of email) of withdrawal or no approval.

Table 8: Protocol annexe: list of exempted COVID-19 IVDs [13 October 2021]

DEVICES Manufacturer	Device name	CE Marking reference	IFU reference Number
Abbott	Alinity m - SARS-Cov2 09N78-090	Declaration of Conformity (Self-Declared)	53-608209/R2
Abbott	Alinity m - 4 plex 09N79-090	Declaration of Conformity (Self-Declared)	53-608193/R3
Abbott	IDNOW Covid 19	Declaration of Conformity (Self-Declared) 82-2021-02	IN191000 v1.0
Abbott	m2000	Declaration of Conformity (Self-Declared)	51-608442/R2
Abbott	Panbio Covid-19 Antigen Self Test	CE V1 106240 0002 Rev.O1	41FK-ST-01-EN-A1
Acon Biotech (Hangzhou) Co., Ltd.	Hughes SARS-CoV-2 Antigen Rapid Test(Self-Testing)	CE V9 0420740032	1151297001
Acon Biotech (Hangzhou) Co., Ltd	Flowflex SARS-CoV-2 Antigen Rapid Test	Declaration of Conformity (Self-Declared)	1151301501
Acon Biotech (Hangzhou) Co., Ltd	Flowflex SARS-CoV-2 Antigen Rapid Test(Self-Testing);	CE V9 0420740032	151327403
Altona Diagnostics	Real Star Altona PCR kit	Declaration of Conformity (Self-Declared)	821015 01 2021
ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.	COVID-19 (SARS-CoV-2) Antigen Test Kit(Colloidal Gold)	EC 1434-IVDD-445/2021	No.IFU-COVID-19Ag-NST-01,Ver.A/3

[426] Statutory Review, p.10.
[427] Ibid., p.11.
[428] This information is provided in the listed history of updates to versions of the register. This is available at: https://www.gov.uk/government/publications/covid-19-test-validation-approved-products.

Assure Tech. (Hangzhou) Co., Ltd	COVID-19 Antigen Rapid Test Device	EC NL-CA002-2021-59221	REV 1.0Effective date: 2021-05-12
Ausdiagnostics	SARS-COV-2 Flu and RSV kit	EC V1 0034960006 Rev 00	20081-r02.2
Biomerieux	Biofire products: BIOFIRE® Respiratory 2.1 plus Panel	CE 667639	BFR0000-8307-01 July 2020
Biopanda Reagents Ltd	COVID-19 Rapid Antigen Test	Declaration of Conformity (Self-Declared)	PI-RAPG-CVA-019
Cepheid	Xpert Xpress SARS-CoV-2	CE Declaration of Conformity (Self-Declared)	302-5159, Rev. C
Cepheid	Xpert XpressSARS-CoV-2 Flu RSV	CE Declaration of Conformity (Self-Declared)	302-3787, Rev. B
CerTest Biotec	VIASURE SARS-CoV-2 Real Time PCR Detection Kit	Declaration of Conformity (Self-Declared)	IU-NCO212Eenes1120 rev.02
Diagnostics for the Real World Ltd	SAMBA II SARS CoV-2 Test	Declaration of Conformity (Self-Declared)	C19-0084-EN V8
DnaNudge Limited	DnaNudge CovidNudge	Data Inaccessible	DN-ENG-IFU-001 Rev 6
Dynamiker	DenScreen SAS CoV2 Antigen Test	EC Declaration of Conformity (Self-Declared)	No version control
Excalibur Healthcare Services Ltd	RAPID SARS-COV-2 ANTIGEN SCREENING TEST CARD	V9 0613170006 Rev 00	1N40C6 v2.01
Genereach Biotechnologies, Taiwan	Pockit iiPCR Analyser and Reagents	EC Declaration of Conformity (Self-Declared)	2020/04
Guangzhou Wondfo Biotech Co., Ltd.	Wondfo 2019-nCoV Antigen Test	V9 0580080037 Rev 00	2021/05/28 Rev. A2
Hangzhou Laihe Biotech Co.; Ltd.	Lyher Novel Cornavirus (COVID-19) Antigen Test Kit	EC HL2069313-1	Version 2.0/EN
Healgen Scientific Limited Liability Company	Rapid COVID-19 Antigen Self-Test	V90923780008 Rev 00	Revision date: 2021-05-06 B22170-01
Hologic	Aptima™ SARS-CoV-2 Assay (Panther™ System)	Declaration of Conformity (Self-Declared)	AW-22752-001_002_01
Life Technologies Corporation	TaqPath(TM) COVID-19 CE-IVD RT-PCR Kit	EC Declaration of Conformity (Self-Declared)	MAN0019215
LumiraDx UK Ltd	LumiraDx SARS-CoV-2 Ag Test Strip Kit	Declaration of Conformity (Self-Declared) S-RA-REP-00127	SPEC-32312 R7 ART-00571 R13
Nonacus Ltd	VirPath SARS-CoV-2, Multiplex 1 Step qRT-PCR	Declaration of Conformity (Self-Declared)	C3COV187 C3COV188 (IFU) v1.0.3
OptiGene Limited	COVID-19_Direct Plus RT-LAMP KIT	EC Declaration of Conformity (Self-Declared)	IFU V1.4 07/07/2021

OptiGene Limited	COVID-19_RNA RT-LAMP KIT	EC Declaration of Conformity (Self-Declared)	IFU V1.4 09/06/2021
Oxford Nanopore Diagnostics Ltd	LamPORE Covid-19 Test Kit	CE Declaration of Conformity (Self-Declared)	ONT-08-00669-00 Rev3
Perkin Elmer	SARS-CoV-2 RT-qPCR Reagent Kit (96 tests per kit) 3501-0010	CE-marked	13909197-10
Primer Design Ltd	PROmate COVID-19	Declaration of conformity	IFU Issue 10.00 Published Date: 23rd July2021
Qiagen	NeuMoDx™ Flu A-B/RSV/SARS-CoV-2 Vantage Test Strip	Data Inaccessible	Data Inaccessible
Qiagen	300800 NeuMoDx™ SARS-CoV-2 Test Strip	EC Declaration of Conformity (Self-Declared)	40600425_G 2020-11
Qiagen	QIAstat-Dx Respiratory SARS-CoV-2 Panel	EC Declaration of Conformity (Self-Declared)	Instructions for Use (Handbook) Version 1
QuantuMDx Group Ltd	Q-POC SARS-CoV-2 Assay	Declaration of Conformity (Self-Declared)	Q27001
QuantuMDx Group Ltd	SARS-CoV-2 RT-PCR Detection Assay	CE-marked	Q22301
Roche	cobas SARS-COV-2 & Influenza A/B test for use with the cobas LIAT system	EC Declaration of Conformity (Self-Declared)	09343784001-04EN Ver 4
Roche	cobas SARS-COV-2 for use with cobas 6800/8800 systems	Declaration of Conformity (Self-Declared)-2020-47	09323236190-02EN Ver 2
Roche	cobas SARS-COV-2 + Flu A + Flu B for use with the cobas 6800/8800 Systems	Declaration of Conformity (Self-Declared)-2020-80	09233652001-03EN Ver 3
SD Biosensor	SARS COV 2 Antigen Self Test Nasal	CE-marked; C-BE100-TF65-O1-Declaration of Conformity (Self-Declared) (Rev.0)	09441476001 V2.
SD Biosensor	SARS-CoV-2 Rapid Antigen Test Nasal	CE-marked; C-BE100-TF56-O1-Declaration of Conformity (Self-Declared) (Rev.0)	09327789001 V2.
SD Biosensor	SARS-CoV-2 Rapid Antigen Test	CE-marked; C-BE100-TF56-O2-Declaration of Conformity (Self-Declared) (Rev.0)	09368230001 V2.

SureScreen Diagnostics Ltd.	SARS-CoV-2 Antigen Rapid Test Cassette	EC Declaration of Conformity (Self-Declared)	SSDCOVID19AGVC QR240621001
Zhejiang Orient Gene Biotech Co.Ltd	Rapid COVID-19 (Antigen) Self-Test	EC No. V9 092305 0003 Rev. 00	Version B22088-01 Effective date 2021/06/2

Table 9: Protocol annexe: list of exempted COVID-19 IVDs [Updated 3 August 2022]

Manufacturer	Device name	IFU number	CE Mark
Acon Biotech(Hangzhou) Co., Ltd	Flowflex SARS-CoV-2 Antigen Rapid Test(Self-Testing); Flowflex SARS-CoV-2 Antigen Rapid Test	1151327403 Effective Date: 2021-06-29	CE Certificate Number No. V9 042074 0032 Rev. 00
SD Biosensor	SARS COV 2 Antigen Self Test Nasal	09441476001, V 2, 2021-06	CE cert number No. V1 075369 0058 Rev. 01
Acon Biotech (Hangzhou) Co., Ltd.	Hughes SARS-CoV-2 Antigen Rapid Test(Self-Testing)	1151297001 Effective Date: 2021-06-18	CE Certificate Number No. V9 042074 0032 Rev. 00
Guangzhou Wondfo Biotech Co., Ltd.	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	P/N W634P0024 W634P0025, W634P0026, W634P0027, W634P0028 W634P0029) Rev. A2 Rel.:2021/05/28	CE Cert No: V9 0580080037 Rev.00
Healgen Scientific Limited Liability Company	Rapid COVID-19 Antigen Self-Test	P/N GCCOV-502a-H1 GCCOV-502a-H2, H3, H5, H7, H10, H15, H20 Revision date: 2021-12-28	CE Cert No No. V9 092378 0008 Rev. 00
Zhejiang Orient Gene Biotech Co.Ltd	Rapid COVID-19 (Antigen) Self-Test	Revision 11-11-2021	CE Certificate Number: V9 092305 0003 Rev. 00
Hangzhou Laihe Biotech Co.; Ltd.	Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) for self testing	(Cat No.: 3030) V2.0/EN Effective Date: May 15,2021	CE Number-HL206 9313-1
Beijing Beier Bioengineering Co Ltd	COVID-19 Antigen Rapid Test Kit	IFU revision date: 12.01.2021 Ref: COVID 19AG20-1.1	CE Cert Number 1434-IVDD-472/2021
Healgen Scientific Limited Liability Company	CLINITEST Rapid COVID-19 Antigen Self Test Two IFUs containing product numbers but no IFU number or version number	11556327 (GCCOV-502-H5)	CE Cert No. V9 092378 0008 Rev. 01

	1155633 (GCCOV-502-H1)		

7.37 Several observations can be made about exemption certain of which are similar to those raised in Chapter 6 regarding the reg.39(2) MDR 2002 EUA. First, reg.39A includes a requirement to publish a protocol specifying a period of time for which it has effect whereas reg.39(2) contains no such reference. This creates a degree of uncertainty regarding the legal status and effect of protocols. As discussed in Part II, Chapter 3, protocols have been published for the validation of products (as opposed to exemption from validation). Second, the Secretary of State has very broad discretion to authorise exemption. They may (not must) give permission subject to such conditions as are set out in the protocol. Therefore, conditions may not be imposed at all. Third, there is some uncertainty regarding any applicable conditions. As indicated in Chapter 6, whilst the general conditions to which an EUA may be subject have not been published, Freedom of Information requests have determined that EUAs may be subject to a number of conditions. The CTDAR 2021 does not appear to indicate which conditions apply in respect of the grant of an exemption, save reference to the fact that the protocol will cease to apply after expiry of a relevant period if a reg.38A application for approval is withdrawn or not approved. Fourth, despite prescribing a protocol, there does not appear to be policy guidance in respect of applying for exemption e.g. in terms of the information and justification required. Similarly, there does not appear to be any indication of whether, and if so how, reviews of exemptions are conducted.

7.38 In the call for evidence for the statutory review, respondents made a number of references to the impact of the exemption process. Respondents stated that it was unclear which tests were included in the protocol and that they were uncertain on the rationale for inclusion.[429] Further, respondents claimed that the presence of Government-provided free testing in parallel with the strict CTDAR 2021 criteria created a two-tiered approach to regulatory approval and a resulting market imbalance, distorting market dynamics. A trade association cited this as giving a small number of suppliers a significant competitive advantage in this space. The exemptions in place for tests procured directly by DHSC was also the principal reason given as to why it was felt that the CTDAR 2021 regime does not meet the objective of ensuring that all tests on the UK market were of the same standards as those used in the NHS on the basis that the exemptions produced a "fundamentally flawed system for ensuring equitable standards in quality".[430] Respondents even went as far as stating that the temporary protocol was a "confounding factor" that impacted relative cost and profit across the sector.[431] Some of the general concerns appear to be corroborated to an extent in the questionnaire responses obtained for the purposes of the White Paper before the statutory review was published. One respondent stated that there needed to be "less unwarranted exemptions". Another noted that the DHSC were exempt from the CTDAR 2021 process and continued to supply lateral flow tests that had not completed the process, which does not seem to present a level playing field.

7.39 In response, the statutory review states that it should be noted that the use of EUAs to approve tests early in the pandemic was vital as part of the Government's asymptomatic testing programme, and the MHRA only grant such exemptions in exceptional circumstances to ensure the health system has access to critical products. [432] It further stated that tests procured and used by the Government have already undergone rigorous clinical evaluation to ensure performance is accurate. It continued that tests supplied to health service bodies, including NHS trusts, could continue until the supply contract ended, provided that the

[429] Statutory Review, p.17.
[430] Ibid., p.22.
[431] Ibid., p.17.
[432] Ibid., pp.17-18.

relevant contract was entered into before CTDAR 2021 was launched on 28 July 2021. Any new contracts entered into after 28 July 2021 would not benefit from this exemption and would be subject to validation through the CTDAR 2021. It was observed that, while this may have resulted in parallel requirements, a transitionary period was required to ensure vulnerable settings were able to continue to supply users with tests during the pandemic.[433] In addition, it stated that while UKHSA acknowledges a period during which some tests were temporarily exempt from the CTDAR 2021, these tests were still required to eventually undergo and pass CTDAR 2021 approval to continue to be procured and used. This approach allowed UKHSA to eventually apply the same stringency to all available tests, while ensuring security of supply.[434]

7.40 However, as indicated in Chapter 6, it is not necessarily the case that the EUA process conducted by MHRA was clear and there does not appear to be any significant indication of any attempt to introduce improved controls on the use of exemption under the CTDAR 2021 based on the experience of the MDR 2002 EUAs. It might have been perceived that there was no need for such further controls on exemption but the fact the EUAs attracted attention including a review of an EUA might have cautioned the need for such controls. Moreover, the UKHSA states that tests would "eventually" undergo and pass under the CTDAR 2021 regime. Again, it is not clear how long this process would take. Concerning the above list, it appears that a number of those manufacturers and devices that were initially exempt appear to have remained on the exempt list (if determined e.g by IFU number) until nearing the end of the protocol's validity. Examples include Acon Biotech (Hangzhou) Co Ltd for two devices, Zhejiang Orient Gene Biotech Co Ltd and Hangzhou Laithe Biotech Co. Ltd. Similar to observations in respect of the reg.39(2) EUA process, it is open to question to what extent these can really be said to be temporary exemptions; the entirety of the period up to expiry of the protocols would have to constitute a temporary period.

Review of CTDAR 2021 Performance

7.41 The Government's initially stated goal was to ensure a process that was "clear, transparent, quick and efficient"[435] ,"as light touch and flexible as possible to minimise restrictions on tests making it to market," and "clear, straightforward and accessible to maximise participation from producers around the globe on an equal footing."[436] As indicated, there has been an opportunity to review whether this has, in fact, been the case. On 1 September 2022, the Government issued a call for evidence on the regime's operation for the purposes of compiling the statutory review.[437] In anticipation, a questionnaire was issued for the purpose of this White Paper which asked the following question: "In your view, to what extent has the CTDA approvals process been a successful response to COVID-19?" Answers were graded according to "completely unsuccessful", "relatively unsuccessful", "neutral", "moderately successful", and "very successful". The provisional view from a relatively small sample of responses is that the regime has been unsuccessful. 7 said it was completely unsuccessful, 4 said it was relatively unsuccessful, 2 were neutral and 1 said it was moderately successful. None said it was very successful. Participants were also offered an opportunity to provide additional comments on their own experiences in respect of the process which are included in the analysis below.

[433] Ibid., p.22.
[434] Ibid., p.25.
[435] Impact Assessment, p.3.
[436] Consultation outcome, Private COVID-19 testing validation, p.4 and p.9.
[437] UK Health Security Agency, Coronavirus Test Device Approvals (CTDA): call for evidence, 6 September 2022: https://www.gov.uk/government/consultations/coronavirus-test-device-approvals-ctda-call-for-evidence.

7.42 As indicated, on 29 December 2022, the Government published a statutory review, as required by the CTDAR 2021.[438] This is creditable as it provides useful further insight into the policy drivers, implementation and future prospects and reinforces the recommendations in Part II, Chapter 3 on the importance of providing interim reviews on validation and approval processes to aid communication and transparency. In total, UKHSA received 24 written responses to the exercise. 95% of responses were from organisations and a majority of these (62%) were manufacturers. 16 respondents (66%) had or were applying to have their test device approved.[439]

7.43 At the outset, it is submitted that the statutory review is not a particularly extensive review and is fairly brief on substance. It makes some suggestions for reform but these are not concrete recommendations. Moreover, it does not clearly explain the future of the regime, simply stating that the review forms the basis for "subsequent work on the future of the legislation" and that the general experience of introducing legislation to respond to a specific market failure will inform "longer decisions about the future of the policy and potential systems that may be required for other pathogens as part of infection risk management in future significant outbreaks or pandemics".[440] Certain key findings in the statutory review have already been discussed above. This White Paper now turns to consider a range of other general issues that have been identified in the statutory review and further informed by responses from the questionnaire and interviews conducted for this analysis.

Policy Rationale and Need for Legislation

7.44 Whilst the questionnaire and interview responses acknowledged that there was a legitimate concern about the quality of tests for the private market, it was not clearly understood why a process additional to MHRA regulation and other requirements was necessary; it was described as a "bureaucratic response" to a problem which had not been fully explained. A more sceptical view which is difficult to substantiate is that the regime was an attempt to reduce the number of suppliers providing tests as opposed to improving the quality of tests, as well as constituting a new revenue stream. Some questionnaire and interview responses also suggested that it was a "redundant" and costly process, the TVG process being considered more efficient and it not being clear why both TVG validation and this regime were necessary.

7.45 Ultimately, an objective assessment of the published materials and an evaluation of the experience of TVG validation in Part II, Chapter 3 indicates that there was a genuine problem. Not only new but also existing suppliers within the diagnostics sector were not passing validation, thereby indicating an increased risk in the private market subject to fewer controls. However, it remains difficult to discern from the preparatory materials (e.g. Impact Assessment and Explanatory Notes) precisely why an entire regulatory framework needed to be created through legislation. Even if legislation were necessary (e.g. because a voluntary regime might not have been taken up), it is not clear why it could not have been more carefully aligned with the existing framework. There may be good reasons but these do not appear to have been clearly explained.

7.46 As discussed below, the statutory review also accepts that certain policy objectives are no longer appropriate or cannot be achieved e.g. as self-isolation and contact tracing has ended, the CTDAR 2021 has no role in reducing unnecessary self-isolation and contact tracing and it cannot contribute to increasing volumes of private tests being reported.

[438] Reg.10.
[439] Statutory Review, p.16.
[440] Ibid.

Timing of Introduction

7.47 Concerns have also been raised about the relatively short transitional period in which to submit applications for approval. In response to the questionnaire for this analysis, one respondent stated that there should have been more notice at the start. It is understood that transitional arrangements would be put in place to ensure that there was no sudden contraction in supply and those already with tests on the market would be able to continue to sell them while undergoing validation in the transitional period. However, it is questionable whether the transitional arrangements were realistic. For instance, suppliers were to be given four weeks before the requirements were introduced to allow sufficient time to submit data. The CTDAR 2021 came into effect on 28 July 2021 with a deadline for applications for products to remain on the market of 31 August 2021 and a deadline for approvals for products to remain on the market of 31 October 2021. A CTDA team webinar given to industry helpfully acknowledged some of the early challenges of implementation, one being the short timeframe for manufacturers to prepare applications.[441] It appeared to be encouraged that products should be submitted for desktop review early to stay on the market past the transitional period. However, this relies on a clearly communicated process at the outset and quick desktop review (which, as discussed below, was not the case) and would also need to safeguard against the risk of submitting poor applications in haste. To assist, the Government stated that "extensive guidance" would be developed to provide clarity, including on transitional arrangements and the proposed verification process for tests where robust performance evidence already exists. [442] However, it is not clear that such measures were actually introduced (the guidance was arguably not extensive) and, if they were, these proved not to be sufficient given the problems encountered during the process in terms of delay and approval outcomes. This may be further evidenced by the fact that, as indicated above, the protocols for exemption had to be extended to enable manufacturers to gather the required data.

Institutional Resource

7.48 A related issue concerns institutional resource. According to the statutory review, the division of labour between MHRA, DHSC and UKHSA played to their strengths during the pandemic; MHRA continues to ensure the function of the wider medicines and medical devices market, whilst T&T (now UKHSA) had the capacity and technical capability to quickly stand up the CTDAR 2021 regime to address the market failure and move at pace to bring in legislative powers and a delivery team.[443] It further states that the unique circumstances that existed at the height of the pandemic no longer apply and that, going forward, the location of the assessment team for approving applications will be considered with a view to transferring functions to MHRA when appropriate.[444]

7.49 If institutional organisation and coordination between the DHSC and executive agencies has not been an issue (which is difficult to verify), at the very least, resourcing has been an issue. In the responses to the questionnaire for this analysis, one respondent indicated that the programme itself is "vastly under-resourced". Another indicated that more resources were needed to cover the backlog of applications. Yet another stated that the programme is expensive to run. In terms of institutional costs, the statutory review states that the delivery costs are broadly cost-neutral, with a projected small (less than 10%) surplus at year end. However, it does acknowledge that it has been affected by difficulties recruiting civil servants thereby forcing a reliance on contractors, the slow on-boarding of staff into UKHSA, and the

[441] Professor Dame Sue Hill, CTDA webinar to industry, 21 March 2022; slides were provided by kind permission of BIVDA and retained on file.
[442] Government response, p.21.
[443] Statutory Review, p.7.
[444] Ibid.

front-loaded nature of demand. Further, depending on the ultimate outcome of CTDAR 2021 regime, there may be a requirement for some UKHSA funding, particularly if the regulatory ownership transitions to the MHRA.[445]

7.50 In light of these findings, it is at least questionable whether some of these problems should have been anticipated before promising a regime that would be quick and efficient to administer, especially given that some of these issues were not a unique consequence of the pandemic (e.g. difficulties in civil service recruitment). Resourcing has been identified as a major contributor to delay in the approvals process, to which this White Paper now turns.

Delays

7.51 A significant issue that has arisen is delays in approvals. In response to the questionnaire for this analysis, one respondent attributed delays to a lack of preparation for the number of submissions. Their view was that delay prevented companies from being able to supply kits that were already approved by many other recognised bodies in the world. Another stated that there was a perceived lack of urgency which was very frustrating especially for suppliers who had passed the TVG process and were supplying quality tests to the NHS to help with the pandemic. Some respondents provided more specific comments on timeframes. One respondent stated that the CTDA team have taken beyond what might be considered a reasonable period of time to process applications. The main issue was the timeline for approval. According to one respondent, the four-week indication was vastly underachieved with the application taking five months. Another stated that the duration of the approval process was six months in their case and had a negative impact on commercial decisions, potentially compromising future investment in the UK market. One reported that it successfully provided a test kit for many months that was then blocked from the market for six months and by the time they received approval, the winter season was over. More broadly, it was stated that the timeframe to achieve the approval was unacceptable and raises significant concerns if this type of process is going to be implemented across all tests currently performed in the market.

7.52 This appears to be corroborated in the statutory review findings. Approximately 71% of respondents who answered questions relating to their experience of the process referenced how the regime has been unable to deliver on the timescales specified within the legislation, including an outcome decision within 20 days. There are certain trends that can be observed in decision outcomes from the period between August 2021 and November 2022: (1) approximately 30% of all decision outcomes took 5 months or less; (2) the most common value calculated within the dataset was an outcome decision at 5 months (12%); (3) of applications received since January 2022, most outcome decisions have been made at 4 months; (4) of the 286 applications received, only 58 (20%) are still awaiting an outcome; and (5) approximately 20% of all approvals have been made in the last 3 months (between August and November 2022). The Government acknowledges the challenges and long wait times for approval in the earlier stages of the regime and accepts that the time taken on applications exceeded the anticipated timelines. This delay has been explained on the basis that it was linked to a number of factors, including an initial influx of applications in the first month coupled with challenges in recruiting qualified staff, which created a backlog. This is reflected in collected data which shows that in the first month of the regime (August 2021), 88 applications were received. This was the highest number of applications in a single month since the regime began.[446] Anecdotally, it has been suggested (but which has not been verified) that this influx was, in part, because there had not been clear communication as to which tests would be subject to the regime and that, once clarified, there was a rush of applications. Indeed, the statutory review does indicate that from November 2021 to October

[445] Statutory Review, p.20.

[446] Statutory Review, p.11. See also Figure 1: Received applications each month (August 2021 to October 2022).

2022, the number of applications was subsequently between only 10 to 20 and mainly at the lower end constituting a "consistent but more manageable amount".[447] The statutory review has also attributed delay to its assessment that a large number of the applications received in August 2021 were poor quality and UKHSA's commitment to ensure each applicant was fully supported during their application would have slowed the process overall.[448]

7.53 The statutory review states that the expected turnaround time was later changed on the gov.uk website to reflect that an initial review of the application, rather than outcome, would be made within 20 days. Respondents have noted that the process has evolved and improved in its handling of applications and engagement with applicants over time without compromising the focus on safety and quality products, and expertise and knowledge of the process has improved. The UKHSA states that once the backlog of applications has been cleared, it expects that far less resource will need to be allocated to the process. Processing times will remain the same or improve with further streamlining of the validation process and governance, and fewer staff would be required to carry out the work.[449]

7.54 Whilst the statutory review explains why resourcing and other issues have caused delays, it does not acknowledge that it perhaps should have anticipated that there would be a high number of applications, including poor quality applications. The reality of poor quality applications was a principal reason for introducing the regime in the first place. It is suggested that the resourcing issue should have been a much more significant factor in deciding on whether the regime was viable. Improvements must be creditably recognised but the statutory review continues to acknowledge a backlog and even in 2022 it has taken 4 months to reach outcome decisions. In retrospect, it is certainly questionable whether the Government's claims to be able to provide a well-resourced and efficient process were ever credible.

Reasons for Application Failures and Other Application Issues

7.55 As indicated in Part II, Chapter 3, it is important for industry to acknowledge that not all issues can be attributed to problems with the design and execution of validation and approvals processes. Applications may simply not have met requirements also bearing in mind the legitimate public health imperative of the CTDAR 2021 to prevent poor quality tests from entering the market. Further, industry will need to reflect on the reasons for lack of engagement and its approach to engagement.

7.56 Importantly, the statutory review has not collected data on the exact reasons for applications failing on the basis that "failure points varied from application to application".[450] This may be contrasted with the TVG validation process which, it is recalled, at least published high level justifications for the conclusion or pausing of validations. It is suggested that there could perhaps have been a more systematic way of recording the general reasons for failure.

7.57 The CTDA team has usefully provided some examples of reasons for applications failing. In a CTDA webinar delivered to industry, it was stated that a general issue has been that the availability of the 'Declaration of Conformity' route to CE-marking meant that most manufacturers had not previously submitted evidence of performance for independent review and that submission of evidence for independent review will become the norm for regulatory approvals of IVDs in the future under third party conformity assessment requirements for UKCA marking and IVDR. [451]

[447] Ibid., p.12.
[448] Ibid.
[449] Statutory Review, p.12.
[450] Ibid.
[451] Professor Dame Sue Hill, CTDA webinar to industry, 21 March 2022.

7.58 From an industry perspective, the responses to the questionnaire for this analysis identified a range of issues. Some referred to the basis for scientific determinations which, as indicated, are not the subject of comment in this White Paper. Therefore, the findings of the questionnaire are simply reproduced here without comment and which scientific decision-makers may wish to reflect on or address in future dialogue with industry.

7.59 In response to the questionnaire, one participant stated that the process was relatively straightforward and the requirements for performance data and supporting information for the device itself were clearly stated; this allowed them to be confident that the application would be successful which was identified as “good given the non-refundable cost associated with the process”. However, other respondents raised a number of concerns. Before considering specific aspects of the process, a general concern identified was a lack of transparency in the process and criteria and one respondent stated that no example documents were provided.

7.60 Similar to observations in respect of the TVG process, some respondents stated that the requirements were set too high, that the diagnostics criteria for comparator assays were too restrictive, and that the number of samples required was unnecessarily high considering the difficulty of sourcing samples for evaluation at short notice. One stated that there needed to be a better understanding of the technologies involved so that almost impossible requirements were not requested giving, as an example, 10% of positive samples with QT >35, when a comparator assay was deemed negative at 37 cycles. One also simply stated that the levels set are higher than those set by the US FDA whilst another indicated in broader terms that the “rigid criteria” limits access to the market for new innovative solutions, limiting competition in the market for both new entrants and established suppliers.

7.61 Some respondents also indicated that the process was not able to effectively manage changes in assays which came onto the market whilst approval was ongoing. One stated that there was a lack of process for improved versions of approved assays which was slowing down access to newer technology in the NHS. Another stated that they selected a well-known high performing assay that was already being used in the market and fully CE marked only to find out after submission that, as the assay no longer met the current CTDA requirement and was going through the same review process, it caused their approval to be delayed until the assay was finally approved. It stated that the apparent response was “just repeat the process with an assay that was now approved which is time consuming and expensive if performed correctly”.

7.62 There were also issues regarding the format of required information. One respondent stated that the excel file which has been created for PCR tests does not align with requirements for rapid tests and, therefore, several sections are marked as “Not Applicable”. It was stated that there is not enough space to provide comments which means it is not possible to add more information and give context to studies performed and the results. This has then led to several emails between the reviewer and customer thus extending approval lead times unnecessarily. Another stated that the performance characteristic template was not suitable for non-PCR assays.

7.63 One respondent identified the need for better triaging of issues that should have been spotted early on but only raised later. They identified that eight months following submission, the CTDA team informed them that one comparator assay was not appropriate and that this should have been identified in some form of triage process at the beginning.

7.64 Some also questioned the quality of expertise and decision-making in respect of approval. One stated that basic questions concerning their application were asked many months after submission; on occasion, the data already provided had been asked to be provided again.

Another stated that, at certain points, there were technical questions raised by the CTDA team that made no sense technically.

7.65 A final issue was consistency of decision-making. One participant perceived that there was an issue in respect of the consistency in requirements that were applied by different reviewers. Another expressed frustration that one assay was approved in weeks but a second assay with identical documents took six months for approval when both were submitted on the same day. Finally, another commented that changes introduced to the process mid-study created additional work.

7.66 According to the statutory review, unsuccessful applications were due to unmet guidance or minimum performance thresholds, with a majority being the former.[452] This appeared to be the case notwithstanding that the statutory review reports that officials worked with applicants and supported them through the application, providing clarification on why applications risked failure and giving applicants the opportunity to ensure their application met guidance and minimum standards where appropriate. It states that this commitment to supporting applications has undoubtedly affected the timeliness of approvals overall but ensured that good quality tests were not unduly rejected. However, the statutory review does not appear to consider to what extent, if at all, the guidance itself (e.g. any areas of uncertainty) may have contributed to unsuccessful applications or why it was the case that applications continued to fail despite substantial support ostensibly being given by the CTDA team. It is understood that aspects of the guidance on the approvals process have been revised at points in light of experience. Therefore, issues in respect of the guidance could also be a contributing factor alongside others.

7.67 The statutory review usefully identifies that some of the factors cited in poor quality applications included: (1) the comparator assay (which is used to calculate device performance) did not meet guidance; (2) incomplete datasets were provided for each sample type; (3) clinical data had a high proportion of high viral sample or a lack of evidence that the test had been evaluated across a full range of viral loads; (4) no new data had been generated since test inception; and (5) clarification questions were required.[453] In addition, many manufacturers of self-test LFDs have provided only professional-use data to support their applications, and no self-test data (which will typically observe a reduction in performance in comparison). It was stated that, in many cases, such data is repeatedly requested from applicants as the assessing team is unable to progress an application until this has been provided. This is supported by data that shows a majority of unsuccessful applications have been antigen LFDs (67% of all applications) as of 28 November 2022.[454] Some of these reasons appear to corroborate interview findings in respect of applications for validation under the national technical validation process discussed in Part II, Chapter 3..

7.68 As indicated, it is understood that the guidance has been revised in response to feedback and experience from initial reviews. This includes: (1) relaxing the requirement for low viral load samples – allowing no less than 20% of positive samples with CT>30 rather that no less than 10% with CT 30-35 and >35; (2) highlighting the requirements for comparator assays – as many applicants used comparators that were not CE-marked or which did not meet the CDTA team's requirements for sensitivity and specificity; (3) clarification that the performance data sample types must match those in the IFU – self-test/professional use, nasal/nasopharyngeal etc; (4) clarification that positive samples can be drawn from pre-identified COVID-19 cases (a prospective study is not required), that the data set can combine data from different studies but that discordant samples should not be excluded; and (5) clarification that antigen tests can be any technology that detects viral component(s) such

[452] Statutory Review, p.12.
[453] Ibid., p.13.
[454] Ibid., pp.12-13.

as proteins, lipids, or whole virus and include those that require an analyser or reader and those that do not. Examples include lateral flow tests, immunofluorescence, mass spectrometry and microscopy.[455]

Communication, Complaints and Queries

7.69 A repeated issue raised in questionnaires and interviews for this analysis concerned the quality of communication with suppliers. It was stated that communication needs to improve greatly. One respondent compared communication to that provided in other countries. The US FDA was taken as a "well-established example" noting that the FDA arrange pre-submission meetings to understand the process, expectations in respect of it and to help clarify areas where tests may be different. It was identified that the absence of someone to communicate by means other than email submission was "frustrating", a "major failing", and would be a significant improvement. It was stated that lack of engagement except to email suppliers informing them that a decision had been made was an "obvious error" and that communication and verbal dialogue would have improved the efficiency of the process. This was said to also create a lack of transparency as to what exactly would be acceptable. Further, communications were perceived as dismissive and unhelpful. However, as indicated in Part II, Chapter 3 in respect of the national technical validation process, there also appeared to be issues regarding industry approaches to engagement which may have impacted the ability to undertake effective communication.

7.70 There were also a number of references in questionnaire responses to a lack of effective feedback. One respondent stated that no feedback was provided. Another reported that feedback was poor and not provided in a timely manner. Further, responses were identified as repetitive and not constructive. By contrast, one respondent stated that CTDA team did always answer questions in a timely fashion but they were not conclusive as to when approval would be granted such that "it was a waiting game" and that it would be more helpful to be given an indication of approximate timelines for responses.

7.71 According to the statutory review, the Government has aimed to provide a high level of transparency and communication with applicants throughout the process. These steps include dedicated communication, review and complaint channels, which are live with acknowledgments within 48 hours and responses issued within 20 days across a three stage process. Applicants receive a report following the desktop review that details where they have or have not met the application guidance and the threshold performance for their type of technology.[456]

7.72 Further, the statutory review states that complaints and queries data was collected by the CTDA team to track the number and nature of complaints received. To note, complaints data also encompassed general queries and did not exclusively represent only negative engagement or complaints related to the process, policy or operation. The statutory review has identified a number of reasons behind the complaints and queries. Some were due to poor applications submitted, including examples where CTDA officials have chased applicants for missing or better quality data. Also, while some applicants were content with guidance and were able to follow the process to successfully submit their application, some applicants were less able to do this and asked a number of questions related to the application process. The quantity of queries represents the ongoing engagement needed to support some manufacturers through the process.[457]

[455] Professor Dame Sue Hill, CTDA webinar to industry, 21 March 2022.
[456] Statutory Review, p.11.
[457] Statutory Review, p.15.

7.73 The number of complaints and queries was highest during the initial transition period after the launch of the CTDAR 2021 in July 2021, with a high of 35 in November 2021. The statutory review states that, considering the speed at which the regime was set up and the anticipated influx of applications given the coming winter peak, a large number of complaints and queries at the beginning of the process could be expected and that the number and nature of complaints changed as the process matured into the new year. Initial queries during the transition period were focused on the protocol and policy surrounding the regime, whereas a greater proportion of queries in the new year were concerned with chasing applications, which aligns with stakeholder feedback on longer than expected waiting times. To address feedback on a lack of communication and long wait times, CTDA officials introduced face-to-face engagement with applicants leading to more timely, comprehensive responses to questions which began in July 2022. The statutory review does not indicate why it took so long to introduce face to face engagement but this is, perhaps unsurprising given the possible resource issues. It states that applicants have become more content with the level of engagement, complaints handling and feedback as time has progressed, and resourcing and experience has begun to match demand. This is reflected in a sharp decrease in complaints observed from May 2022 onwards, as part of a general downward trend in monthly complaints.[458]

Fees

7.74 One issue concerning administration of the regime was the fee for processing applications. Some respondents to the questionnaire for this analysis stated that there was little or no transparency or justification as to why the fee was set so high and why multiple devices of the same type could not be included on a single application. It was stated that, even with the discounted fee, it costs tens of thousands of pounds for a collection of similar COVID-19 test devices to be approved. Other administrative problems were identified. For example, one respondent stated that the payment system was very poor taking weeks to confirm payment such that an application should not get stalled on this basis. Further, it was observed that the guidance omitted to mention that in order to apply for the discounted fee offered for SMEs, the applicant must provide a statement of company size from the CEO as well as a payroll statement confirming the number of staff which caused additional delay.

7.75 In contrast, the statutory review stated that the application fee was relatively cheap in comparison to other costs involved in bringing a test to market, and therefore pricing is somewhat elastic. It stated that industry feedback indicated that applicants would prefer to pay more and receive a faster response, rather than pay less and have to wait longer for approval outcomes. However, as indicated, response times have not been fast.

Impact on Business

7.76 A number of more general impacts of the regime were also identified. It has already been noted from the responses to the questionnaire for this analysis the general impact of delays. This included not only delayed sales for suppliers; it was also reported that this caused inconvenience for customers. One respondent also indicated that, as an SME, the process had a significant impact on its plans which has been difficult in an already challenging industry. More broadly, it was also stated that the process is damaging to both British business and the healthcare system, by preventing the fast adoption of cutting-edge technology. It was commented that the process limits access to the UK market due to costly and timely premarket assessment. One respondent fully recognised the need and rationale behind the process to prevent sub-standard kits being on the market, however, perfectly suitable kits with comprehensive support data were blocked from the market during this

[458] Ibid.

lengthy process. In some cases, exporting kits from the UK was a more favourable route for UK businesses.

7.77 The call for evidence for the statutory review looked to gather views on the direct impacts of the regime on businesses. Approximately 66% of respondents who answered the call for evidence section relating to CTDA costs stated that the overall costs of applying have been significant. Some multinational manufacturers and distributors provided a number of comments on perceived CTDAR 2021 related factors impacting profitability within the UK COVID-19 test market. There were three main types of costs incurred due to the regime: (1) costs leading up to submission; (2) costs between submission and before outcome; and (3) costs incurred to generate additional data. While these respondents commented on ostensibly high costs, most did not provide further detail or evidence on gross profit margins or average unit of production costs, citing confidentiality concerns. The statutory review reported that, using the costs that were provided shows that costs varied greatly between manufacturers, although most were aligned in stating it has been significant. From the range of estimated total costs received, on the lower-end, one distributor estimated their total costs to be around £47,000, although they acknowledged that for manufacturers, it is likely to be more. At the higher-end, numerous manufacturers stated their costs had been in excess of £100,000 and another had estimated total costs of £260,000 across seven products.

7.78 Respondents to the statutory review were also asked for their views on their future investment plans for COVID-19 diagnostic devices. Consensus among respondents was that manufacturers were pivoting their focus and technology away from COVID-19 for use elsewhere as demand has decreased, with some manufacturers leaving the sector altogether. Some respondents expected the demand for COVID-19 related devices to be tied to routine winter respiratory testing. 45% of respondents were looking at creating multiplex tests and consolidating their existing medical devices portfolio to take advantage of this.[459]

7.79 Concerning impacts on the market more widely, the Government has recognised that the UTO was a "major intervention in the market and it distorted demand and supply of tests into the market" and is, therefore, keen to better understand the impact of market interventions such as free testing and the CTDAR 2021 on the wider market.[460] According to the statutory review, the majority (71%) of respondents who considered this issue felt that provision of free public testing had a broadly negative impact on the private market. One manufacturer stated they had decided not to apply through the CTDAR 2021 regime as LFDs were already being universally offered by the Government. As discussed above in respect of exemptions, respondents suggested that government free testing in parallel with the strict CTDAR 2021 criteria created a two-tiered approach to regulatory approval resulting in market imbalance e.g. where manufacturers also benefitted from EUA exemption.

7.80 Of those respondents who submitted written responses in the call for evidence relating to levels of growth they expect to see in COVID-19 testing, almost 60% envisaged limited growth in the future COVID-19 testing market, tied to a decrease in demand as the pandemic progressed, public attitude changes and increased vaccination rates. This may also explain why some manufacturers were less inclined to put in revised applications, considering the diminishing returns of securing a successful application. Respondents also felt the end to free testing had a profound impact on the COVID-19 testing market by reducing public demand for tests overall.[461]

[459] Statutory Review, p.17.
[460] Coronavirus Test Device Approvals (CTDA): call for evidence, p.11.
[461] Statutory Review, p.18.

7.81 More widely, the statutory review observed in respect of the regime's impact on innovation that, early and ongoing criticisms of the regime suggested it would stifle innovation and potentially hamper the supply of COVID-19 testing products on the market. However, operational data shows that only 2.7% of total registered applications were identified as duplicate products, providing strong evidence that a consistent stream of unique products was being put forward for approval and a diverse private market was being cultivated. All respondents who answered questions related to trends in consumer confidence and consumer behaviour asserted that there has been increased confidence and acceptability of private testing as the pandemic progressed.[462] However, it is suggested that findings that not many products submitted were duplicates is not particularly strong evidence either way.

Impact on International Regulation and Trade Flows

7.82 According to Government commissioned research, UK based firms represented 33% of the total volume of tests on the UK COVID-19 diagnostic market, with the remaining 67% taken up by non-UK based firms. Further, the UK COVID-19 diagnostics market share by UK and non-UK based firms is 33% and 67% respectively.[463] Given non-UK supplier presence in the diagnostics market and the issue of ensuring international competitiveness of the domestic diagnostics industry, the statutory review considered views on international regulation compared to the CTDAR 2021, trade flows and the country origin of applications. Respondents to the call for evidence were broadly aligned in comparing the regime unfavourably with international equivalents. It was stated that principal themes included the perception that the CTDAR 2021 was an unnecessary additional step on top of existing regulatory requirements.[464] However, it is not clear from the statutory review to what extent those respondents had extensive experience in selling in other countries such as to be able to make any meaningful comparison of systems in other countries.

7.83 As of 7 November 2022, manufacturers of 284 test devices had applied for CTDAR 2021 approval. These 284 applications break down by country of manufacture as follows: UK – 162; China – 65; Korea – 17; USA – 9. Countries with 3 applications or fewer (total of 31 combined) included: Australia; Belgium; Canada; Denmark; France; Germany; Italy; Luxembourg; Netherlands; Singapore; Spain; Turkey; UAE. This data showed that 43% of applications were from non-UK based companies. According to the statutory review, this suggests that the CTDAR 2021 did not make the UK unattractive to the global market. Nevertheless, it was acknowledged that, based on some of the applications and interactions with applicants in different countries, there may have been difficulty interpreting the regulations; language barriers may have been a factor, and which was something to consider in future when rapidly stepping up a regulatory initiative and working seamlessly across borders will be necessary.[465]

7.84 The statutory review also stated that alignment with other regulatory approaches on diagnostic device validation would likely make the validation process easier and cheaper for industry, and allow a greater number of products to enter the market. In this regard, it identified that some frameworks, such as the Therapeutic Goods Administration (the medicine and therapeutic regulatory agency of the Australian government), use third-party conformity assessment as part of the pre-market assessment of COVID-19 devices. Some respondents highlighted this as a possible alternative to the CTDAR 2021. By contrast, as indicated above, third party conformity was considered as a possible model but rejected as a basis for the CTDAR 2021 regime. The statutory review maintains that this was justified on the basis that the CTDAR 2021 was able to quickly and more effectively address the

[462] Ibid., pp.17-18.
[463] Impact Assessment, pp.14-15 based on Orion Market Research.
[464] Statutory Review, p.18.
[465] Ibid., pp.18-19.

urgent issues presented by poor quality tests, and the lack of minimum performance standards in this approach could have kept the UK open to influxes of poor quality tests.[466] As indicated, this White Paper does not evaluate the appropriateness of the regulatory model chosen against other options but, suffice to state, the CTDAR 2021 regime has not been quick. The question would therefore be whether third party conformity assessment or another approach would have been even slower.

7.85 Notwithstanding all of the above, the clear expectation in the preparatory documentation for the CTDAR 2021 was that approval would confirm products as high quality and thus render them internationally competitive. In reality, it has not been possible to verify to what extent suppliers who have received approval have experienced this as a benefit in domestic and international export markets as against any possible competitive disadvantage of having to meet an additional regulatory approval to which foreign suppliers (not submitting CTDAR 2021 applications) are not subject. Further, the statutory review does not examine UK trade flows in foreign markets i.e. the impact which the CTDAR 2021 has had on suppliers' ability to export to foreign markets. Nor does it undertake any assessment of the CTDAR 2021 regime against approvals processes in other countries to determine whether it represents an international "gold standard", as claimed.

Meeting Broader Objectives

7.86 As indicated, the CTDAR 2021 Impact Assessment identified five objectives. The extent to which four out of five have been met has been discussed above. Despite mixed views on the regime's ability to meet the above objectives, stakeholders mostly agreed that the objectives and rationale remained appropriate, especially when considering the protection of public health.[467] However, the statutory review has acknowledged that certain objectives are no longer appropriate or cannot be achieved. One is the objective of reducing false negatives and positives. According to the statutory review, respondents were generally positive about the regime's role in this regard albeit acknowledging that this reduction could be linked to a number of factors. Further, it noted that there was insufficient data to demonstrate the regime's impact on self-isolation and contact tracing. UKHSA has acknowledged it is no longer an appropriate objective to assess the impact on self-isolation and contact tracing as both of these policies were retired after the initial objectives were devised in early 2022 and resultantly are no longer current policy objectives.[468]

7.87 It is recalled that another objective was increased consumer confidence in tests and, subsequently, increased volumes of private tests being reported. Although respondents for the statutory review generally agreed that consumers have increased confidence in tests, they were unconvinced this resulted from the CTDAR 2021. Some cited how consumers are unlikely to refer to the approved list in deciding what test to use, which is also complicated by the ongoing exemption for tests procured by DHSC. It was acknowledged that consumer confidence is inherently subjective and that there was limited data on which to base further analysis albeit that anecdotal engagement with manufacturers reported improved consumer confidence in testing.[469] Further, as there is currently no requirement or provision to report private tests, there is no data to produce an analysis of the effect the regime may have had on reporting rates. The statutory review acknowledged that the reporting of private tests is not currently possible making this aspect of the objective unachievable and simply states that the Government is planning to introduce the ability for individuals taking private tests to voluntarily report their results into the NHSCOVID-19 app.[470]

[466] Ibid., p.19.
[467] Statutory Review, p.23.
[468] Ibid.
[469] Ibid.
[470] Ibid.

7.88 The statutory review states that the remaining objectives are still considered to be appropriate given the current stage of the pandemic and the possibility of future variants of concern.[471]

7.89 The statutory review does not appear to commit to a definite planned future for the CTDAR 2021 and does not explain how it will develop. The overriding impression from the above analysis, questionnaires, interviews and the statutory review is that some form of validation model was necessary for tests on the private market and that the regime has prevented poor performing tests which could have otherwise impacted public health. Indeed, it is clear that the CTDA team have worked hard to build engagement and render the approvals process functional. However, the sense is that the Government overstated the likely success of this regime. Certain claimed objectives either lacked a clear rationale and/or were not clearly communicated. The regime was introduced relatively late on in the pandemic, has been far too slow and under-resourced, and now lacks a clear purpose sufficient to justify the current state of regulatory intervention in the market. The regime will be an important case study on how to regulate (or not) the diagnostics sector in future.

[471] Ibid., p.24.

PART V:
KEY THEMES FOR DIAGNOSTICS PROCUREMENT POLICY DISCOURSE

8. CONCLUSIONS

Introduction

8.1 This White Paper has examined certain key aspects of the procurement of IVD test kits during the pandemic, covering contract award processes and associated validation and regulatory approvals for their placement on the market. It has identified lessons learnt and recommendations which are illustrative not exhaustive and should be considered alongside those made in other inquiries, reviews and research alluded to throughout. These are all intended to provide a springboard for an important next step, that is, to establish a more sustained dialogue between the Government and UK diagnostics industry on procurement issues. This will be necessary to ensure that both are ready not only for a future emergency but generally given the projected role of diagnostics in the med-tech space.

8.2 This concluding Chapter will not rehearse these lessons learnt and recommendations. Rather, it situates them within a wider frame of reference, namely, overarching and cross-cutting policy themes which have emerged from analysis and which should underpin or drive stakeholder discussions about reform. Taking up the mantle, those on the frontline may well identify other priority themes which should also inform future dialogue.

Public Procurement as a Strategic Tool in UK Diagnostics Policy

8.3 This White Paper has focused exclusively on the procurement of diagnostics within the framework of existing legislation and policy guidance. It does not address UK diagnostics policy more generally. However, how diagnostics are procured and the effectiveness of related processes necessarily depends on the various policies which underpin diagnostics policy generally. It is submitted that a clear UK diagnostics policy must first be articulated by the Government in order to begin to understand how public procurement should be used as a strategic tool to leverage better public health outcomes and industrial development.

8.4 There have been some recent attempts by industry to call for this policy.[472] The DHSC's "high level" Medical Technology Strategy published in February 2023 is a welcome first step in identifying diagnostics as one of two main med tech areas (the other being med tech in the community) that would benefit from an increased focus.[473] It has acknowledged that over the last two years, the pandemic has demonstrated the importance of fast and accurate diagnostic testing, genome sequencing, and the existence of robust diagnostic infrastructure to process and share results; further, the wide adoption of home lateral flow testing has demonstrated the potential for increased use of diagnostics outside of formal clinical settings to support earlier diagnosis. Importantly, it observes that demand for diagnostics is continuing to rise as waiting lists have increased following the reduction in availability of services during the pandemic, necessitating an improved and expanded diagnostic capacity.[474] Certain features of this strategy are directly relevant to the findings in this White Paper. One is industry engagement, in particular, the need for clear "demand signalling" to industry. Another is an NHS led review of diagnostics commissioning to ensure "benefits

[472] BD, UK Diagnostics Industrial Strategy, The route to a world-leading diagnostics sector, March 29 2021: https://www.bd.com/en-uk/company/news-and-media/bd-articles/industry-leaders-gather-to-discuss-how-to-take-forward-the-bd-uk-diagnostics-industrial-strategy-.
[473] Department of Health & Social Care, Medical Technology Strategy 2023, 3 February 2023: https://www.gov.uk/government/publications/medical-technology-strategy/medical-technology-strategy.
[474] Medical Technology Strategy 2023, p.34.

across the pathway are recognised, and that regulatory and evaluation processes are simplified and clarified."[475]

8.5 Whilst encouraging, the Medical Technology strategy only contains five brief references to procurement mainly focused on ensuring continuity of supply and resilience and better "demand signalling". On the former, there is reference to working with NHSE "on the development of procurement policy to promote the proportionate application of requirements for resilience". On the latter, there is reference to the need to provide industry with "a clearer, more granular demand signal for it to respond to across all products, and the confidence of intent to buy through a clear procurement and commitment-based process to reduce commercial risk" and for priorities for innovation to be reflected "within established processes, including regulatory, research, evaluation and procurement processes".[476]

8.6 It is suggested that the Government must now articulate a clear vision for the discrete role of public procurement in achieving UK diagnostics policy and how all of the above will be specifically addressed. There are many procurement aspects which could be affected by a broader diagnostics strategy. To give just one example bearing in mind Brexit and regulatory changes within the EU in this area, any domestic strategy seeking to improve domestic capability and resilience through key investment and procurement decisions which could be construed as a "Buy British" diagnostics policy may have implications in international trade, both legally and politically. For instance, the Boardman Review has indicated a need for a sovereign manufacturing capability for antibodies, noting that steps had been taken to establish "some capacity" for the manufacture of COVID-19 tests and that the "potential growth and maintenance of this 'emergency' base should be considered within a longer term strategy for national resilience.[477] This is easier said than done when the UK (and its industry) operates within an international rules based order for trade. A key challenge is to find ways to strengthen investment and procurement in a way that supports growth of the UK diagnostics industry domestically whilst acknowledging the global nature of supply. In other areas of Government policy, there are post-pandemic references to increasing "onshoring" and building the domestic supply base. As the Medical Technology Strategy identifies, procurement policy will need to ensure "proportionate" application of requirements for resilience.

8.7 Further, it would need to be considered how procurement policy can be better coordinated institutionally and organisationally within central Government, across its executive agencies, and across the wider NHS. A recurring theme throughout this White Paper is to what extent is centralisation useful.

8.8 The substance of procurement policy will also need to be considered. As indicated above, it is not clear what form "requirements for resilience" will take *qua* procurement requirements, how commercial risks will be addressed within procurement policies, and how procurement processes will be rendered clearer.

8.9 In addition, it would need to be considered how procurement policy is then operationalised. As indicated throughout this White Paper, internal procurement policy documents are not necessarily comprehensive, which may vary across organisations, and published procurement policy guidance is presently *ad hoc* with much information simply posted onto gov.uk websites leaving the user to navigate various pages.

8.10 Therefore, it is submitted that the Government should now commit more specifically to honing in on procurement, its aims and objectives in the context of UK diagnostics, how it

[475] Ibid., p.35.
[476] Ibid., pp.22, 23, 25, 27 and 28.
[477] Boardman Review of Government Procurement in the COVID-19 pandemic, pp.9-10.

should be organised, and how it should be operationalised. This requires more than "roundtables" for consultation. It requires the convening expert groups who are invested in procurement and who will map procurement priorities and coordinate action.

Procurement Preparedness

8.11 The Medical Technology Strategy 2023 importantly acknowledges the need for better "pandemic preparedness" and that DHSC will use the legacy of investment during COVID-19 to ensure it. It states that UKHSA, through the Centre for pandemic Preparedness, will work in conjunction with NHSE and the Pathology Networks to ensure that diagnostic facilities are ready for future pandemics and that existing infrastructure and latent capacity is capable of being mobilised.[478]

8.12 This is to be welcomed but it is not clear to what extent it will focus primarily on "infrastructure", that is, ensuring that the organisation and operation of laboratories and other facilities for testing are capable of meeting needs in an emergency. It is submitted that there also needs to be a specific focus on "procurement pandemic preparedness" more specifically for a range of possible diseases. This may be implicit but the focus on effective procurement needs to be explicit.

8.13 For example, it is important to separate procurement from supply chain planning and resilience issues when addressing future "pandemic preparedness". Some reviews have tended to state that procurement can be improved by addressing what are, in reality, supply chain considerations e.g. whether suppliers have capacity to meet surge requirements, the availability of raw materials, problems with bottlenecks due to export and other controls which might be addressed through better supply chain mapping. Whilst these variables may impact procurement in terms of timing of delivery and reliability of products, to be clear, these are not procurement issues. These aspects concern much broader questions about the nature of supply and demand in the diagnostics sector in the UK and globally, the extent of investment in domestic manufacturing and other capability and the reality of global supply chains. There is a risk of lumping these together indiscriminately but, in doing so, failing to focus on how products are actually purchased i.e. suppliers identified, specifications set, contracts awarded and managed.

8.14 Becton Dickinson, in calling for a national diagnostics strategy, has recommended in respect of commissioning and procurement that the Government set up a pandemic or public health taskforce which focuses on future planning for diagnostics.[479] Consistent with recommendations in other reviews (e.g. the Boardman Review), planning should, of course, look at current UK dependence on raw materials in foreign countries, current UK capability gaps, the state of domestic manufacturing etc to build up resilience, planning to better understand export restrictions and supply chain bottlenecks including mapping supply chains in advance and managing stockpiles etc. However, there is a need to go further. Within any planning taskforce, it would be useful to convene a group of procurement experts from within central Government and across the NHS who have experience of making key policy and commercial decisions about procurement in the context of diagnostics (including scientists involved in processes integral such as validation or approval) as well as industry who supply through government procurement processes. Procurement must be a focus not solely supply chain issues.

8.15 A cross-Government expert procurement group could easily devise a "long list" of issues that arise in respect of procurement end-to-end from planning a procurement, through to

[478] Medical Technology Strategy 2023, p.36.
[479] BD, UK Diagnostics Industrial Strategy, The route to a world-leading diagnostics sector, p.35.

conducting a procurement process and managing performance, drawing on experience of the pandemic and generally. At the very least, it could easily identify a number of "quick wins" in terms of ways to improve procurement.

8.16 There could be any number of areas of focus in this regard. One would be to examine challenges and opportunities for institutional organisation *within* central government (e.g. roles and responsibilities within DHSC and its executive agencies) and *across* Government (e.g. DHSC and its agencies vis-à-vis NHS Trusts and among NHS Trusts). This is particularly important at a time when the Government was simultaneously having to act as purchaser, manufacturer, validator/evaluator and regulator and central government had to liaise not only with executive agencies but also with individual NHS Trusts. It raises all sorts of policy issues about the chain of command, the extent to which responsibility should be centralised or decentralised or devolved, how inter-executive agency relationships are conducted, and how these all interact in turn with industry. It is necessary to ensure that organisations are agile and adaptable as the emergency evolves as lack of clear roles and lines of responsibility at the outset and problems of communication during an emergency can affect clarity and consistency of decision-making. Getting this right from the outset is easier said than done, especially when roles and competences develop in response to institutional learning and where issues may be cross-cutting e.g. a validation issue can become a procurement issue which can become a regulatory approvals issue and *vice versa*. However, clear roles and responsibilities will avoid or at least mitigate potential concerns about who is exercising what decision-making powers (e.g. where these are not clearly set out in legislation under a broad exercise of Secretary of State power), who has the requisite competence to make those decisions (e.g. scientific versus commercial), the potential for roles to change or new bodies set up in the course of an emergency (e.g. there is a transfer of responsibility in respect of validation or approval), and to safeguard against the risks of conflicts of interest. This also ties to other themes such as ensuring an effective triangulation of validation, procurement and approvals decisions (considered below).

8.17 Another area of focus would be to look at challenges and opportunities for actually procuring diagnostics e.g. in knowing the market and identifying suppliers, soliciting offers, using procurement routes, developing vehicles for procurement and conducting award procedures. Again, this also ties to other themes such as improving the quality of guidance and processes (considered below).

8.18 Whilst contract management could be treated as an area of focus in its own right, this would also need to be considered as part of procurement in terms of how contractual vehicles for delivery are developed, risk is allocated, models of contract terms and conditions are formulated, how supplier management is undertaken in respect of performance and payment issues etc.

8.19 Thus, rather than making generic recommendations which purport to concern procurement but, in fact, concern wider issues of industrial strategy and supply chains, there should be a more systematic focus on procurement itself. Again, to give just one illustration, Becton Dickinson has made the following procurement-specific recommendations. These include: (1) The Government should assess international suppliers of diagnostics and develop a value-based list of preferred suppliers; (2) Central guidance should be issued to NHS and other relevant buyers in the public sector to apply a greater score/weighting to reliability and resilience in purchasing decisions; (3) The UK should develop similar consortia to the UK-RTC for diagnostics; and (4) NHSEI ("NHS England and NHS Improvement") and the Office for Life Sciences ("OLS") should state their intention to move more diagnostic commercial awards onto longer term strategic partnerships based on genuine risk-share, value and

population health.[480] Any number of such similar proposals could be put forward or rejected but ultimately based on a better understanding of procurement-specific issues.

Triangulating Procurement, Validation and Approvals

8.20 Another theme which has recurred throughout the analysis in this White Paper is the close interaction with, or even interdependence of, validation, the process of award, and regulatory approvals. It has been observed, for example, that, in procurement terms, the UK vaccination project was a "success of systems approach" rather than "centralised command and control" in the interplay between independent bodies and between the different elements such as procurement and regulatory approvals.[481] It is open to question whether the same was the case in respect of the procurement of IVD test kits.

8.21 There did appear to be some issues in respect of the coordination of procurement, validation and regulatory approvals with any decision in respect of one aspect potentially affecting the other. As indicated in Part II, Chapter 3, the national technical validation process which is intended to lead to procurement involves the solicitation, prioritisation of assessment and shortlisting of offers. This raises questions about whether validation related processes are a feature of procurement which may then be subject to assessment for compliance with UK procurement law. Further, the Government continued to make direct awards on grounds of extreme urgency for reasons which included the fact that suppliers had not met the validation requirements or that the validation of products was ongoing. Therefore, there is the issue of ensuring that validation processes and procurement processes align to the extent possible. In addition, as discussed in Part IV, questions have arisen as to the effect of exemptions from regulatory approval on procurement.

8.22 At a policy level, the Government needs to carefully consider how these aspects are "triangulated" and, similarly, industry needs to ensure that it can effectively anticipate how each phase or stage in these processes may impact each other. As repeatedly stated throughout this White Paper, this is all easier said than done but it is important to avoid instances in which procurement is undertaken without a clear understanding of validation and what is required and the likely outcomes and to better understand ways to mitigate the effects of one part of the process on the other. For example, the issues experienced in respect of the UK-RTC indicated that even though the Government planned in the procurement process for the contingency that validation would not be achieved, it is a matter of judicial record that there were problems for DHSC, suppliers and MHRA in working through the validation process. There were also not inconsiderable knock on consequences for other suppliers in the UK-RTC too. There are also indications that processes needed to be changed to accommodate the fact that validations were still pending e.g. the number of direct awards, contract modifications, and EUAs for regulatory approval. No doubt, there are likely to be a number of areas which could be identified where these phases could be better coordinated.

8.23 The nature of diagnostics which necessarily involve additional processes for validation and regulatory approval complicate their procurement such that there is a need to think more holistically about these wider aspects and their impacts when designing procurement policy and processes. This may improve the delimitation of roles and responsibilities of the various actors, improve procurement and validation processes in clarifying the type and timing of decisions at each stage, and overall accountability and transparency. This would mitigate or

[480] Ibid.

[481] House of Commons Health and Social Care and Science and Technology Committees, Coronavirus: lessons learned to date Sixth Report of the Health and Social Care Committee and Third Report of the Science and Technology Committee of Session 2021–22 Report, together with formal minutes relating to the report, HC 92, 12 October 2021, p.107.

avoid altogether any impression that different processes are applied or disapplied or introduced at various times to effectively favour certain suppliers to the detriment of others and which can lead to legal challenges.

Driving More Competition into Emergency Procurement

8.24 Another theme which has predominated is the lack of, and need for, more competition in emergency procurement. Of course, whilst not verified, it may well be that competition in the diagnostics sector may naturally be more limited than in others in any event. Like other high-tech sectors, the demand is for niche products, there will be fewer specialist suppliers, and the R&D and technological components will mean that suppliers have exclusive rights through intellectual property. All of these factors are conducive to more single source non-competitive contract awards. Further, it is important not to be too dogmatic about the virtues of competition in an emergency. There may simply be a need to get supplies from whoever is available at whatever price, including at the risk of reduced value for money. Moreover, in practical terms, even accelerated competitive procedures can take too much time where time is of the essence.

8.25 Nevertheless, it is possible that even where competition is limited, there may be scope to increase access to the procurement market for diagnostics through opening contracts to competition where feasible. Key concerns about the choice of select suppliers and transparency would have been lessened had there been more competition even if the participation of more suppliers in competitions may have increased the potential for legal challenges (simply because more parties are involved). More competition would have meant There would be more publicised market engagement. Competition may have also reduced price and/or improved quality. Industry would be less concerned about being shut out of awards if suppliers were selected from a wider pool.

8.26 As this White Paper has shown, there is scope for more effective advance planning and operationalisation of advance purchasing arrangements. The Government does not appear to have publicly explained why it took some time to establish competitive mechanisms for procuring IVD test kits, even accepting that it takes time to set up and run large scale open or restricted procedures, as well as mechanisms such as DPS and framework agreements. There may well be good reasons. If these exist, knowing them would provide useful lessons regarding the obstacles to mobilising competition more quickly in future emergencies and may assuage industry concerns that market access is being closed off. Further, at the point at which the Government was consulting industry and providing reassurance to it that competitive procurement was to be introduced, it was still making direct awards on grounds of urgency months into the pandemic. Again, there might be a justifiable rationale for these “stop gap” or transitional measures, in which case, it is important to better plan to minimise the impact of these stop gap awards.

8.27 In any event, the Government needs to address a perception that direct awards are an easy option. There may be scope to accelerate competitive procedures at least in some cases. There may be an opportunity to undertake informal competitions where a decision is taken not to advertise but negotiate directly with one or a select number of suppliers. Further, there may be ways to expedite the transition to competitive awards.

Quality of Guidance and Processes

8.28 As indicated throughout this White Paper, many observations have been made about the general nature and content of policy guidance. In the pandemic, the Government had to not

only revise existing guidance but also develop entirely new guidance on aspects such as validation and regulatory approvals. However, this analysis has shown that whilst there may be internal Departmental guidance, this has not been published. There are likely to be areas which have not been addressed by that guidance. Further, there is a need to publish more and better quality guidance in certain areas. In particular, in contrast to more detailed guidance on validation (and to a lesser extent regulatory approvals), there appears to be very little published process or guidance on procurement of diagnostics itself both in emergencies and generally.

8.29 The Government as procurer, validator and regulator must be able to exercise discretion in an emergency subject to as few constraints as are necessary. Therefore, caution must be exercised against publishing excessively detailed guidance which could limit or bind the exercise of discretion in ways which could be detrimental. There are also legitimate confidential and commercial considerations which should prevent the publication of certain information. However, there is a risk that a lack of published process or guidance can affect suppliers' ability to understand requirements and thus access or participate in the market. It can also lead to legal challenges or general perceptions that processes are not transparent or accountable.

8.30 Freedom of Information requests have revealed that certain criteria and conditions are applied, that further process stages such as reviews may be involved, and that outcomes are communicated to suppliers e.g. through reports. Whilst this White Paper has not recommended full publication of internal guidance and process, it is difficult to see a reason, in principle, why processes could not be explained in more detail and in a clearer format, whether through flow diagrams or illustrative or indicative lists of key considerations to be made. This could mitigate perceptions about a lack of transparency and a potential risk of legal challenge. This also reinforces another theme, namely, improving transparency through communication (considered below).

8.31 These processes are also likely to involve acute scientific judgements which will inevitably determine the content and structure of policy guidance and processes. Therefore, it should not be a case, for example, that validation, procurement and regulatory approval policy guidance be developed in isolation by civil servants working in the commercial function. It should incorporate key members of the scientific community and industry who are other key users of such guidance.

Transparency, Communication and Signals to the Market

8.32 Another major theme which has emerged throughout the analysis is the need for better transparency, communication and signalling to the market.

8.33 The pandemic has increased the spotlight on public procurement and heightened calls for transparency. However, it is important to understand that the Government is not legally required to provide full transparency and there are also lawful limitations on transparency e.g. for reasons of confidentiality or commercially sensitive information which is protected. Creditably, the Government has actually usefully published information in respect of matters such as validation reports for tests, reasons for concluding or pausing validations and lists of those exempt and similarly public registers have been published in respect of CTDAR 2021 applications. Further, there has been a degree of transparency in the procurement process as far as is legally required. For example, contract notices and contract award notices including justifications for direct awards have been published. Whilst it is the case across a range of procurement undertaken during the pandemic (e.g. for PPE, ventilators and test kits) that not all notices have been published and/or some have been identified as

outstanding, it has been possible in this White Paper to piece together a general picture of IVD test contract awards. Further, contractual and other information has been disclosed.

8.34 Notwithstanding, putting aside compliance with legal requirements, there are areas where transparency could be improved in various ways even where there is no express legal requirement to do so. For example, more could be published in respect of processes for validation, regulatory approvals and associated exemptions to better understand how key decisions are made. Further, whilst there have been no findings of illegality in respect of the keeping of records in contract award processes, there is a need for better record keeping and reporting of contract awards. Increased visibility of processes may go some way to providing reassurance to industry and civil society about how decisions are made generally and mitigate potential legal challenges in respect of the rationality of decisions.

8.35 Again, caution must be exercised as there are legitimate, commercial, and other practical reasons for not providing total transparency. For example, there is the administrative burden of doing so in an emergency when the priority is likely to be on delivering services. Further, there is a risk of suppliers and others engaging in disproportionate fishing expeditions for information or bringing legal challenges simply because there is a published policy position or process in respect of which to bring a claim. However, more careful release of useful information could reduce speculation and improve accountability. For example, this analysis has found that certain information which has been obtained through Freedom of Information requests could have simply been published.

8.36 In addition to the issue of what information is published, there is the issue of how it is communicated and when. As indicated in the Medical Technology Strategy, DHSC has identified the need to improve how it undertakes “demand signalling” to the market. Further, as indicated, much information about validation and regulatory approvals was only published relatively late on or where reviews have taken place *ex post*. The Government could publish information much earlier not only to deter legal challenges or other speculation but to improve industry responses which, in turn, improve the functioning of Government processes. A prime example is in the area of validation and approval. It would have been useful to publicly engage with industry much earlier on problems encountered with undertaking validation and why suppliers were unable to meet requirements and how they could improve. This might have improved the quality of applications and reduced the case for a new statutory regime under the CTDAR 2021. Again, it must be acknowledged that there have been some attempts to provide updates to industry but these have not been regular or systematic. Even accepting that there are resource constraints and the priority to actually get products to market, the Government should consider ways to conduct interim reviews. By taking stock and showing industry that there is reflection on how processes are working provides a degree of confidence and assurance to suppliers that concerns are being addressed.

8.37 More widely, there may be some strategic thinking to be done about communications between Government and industry generally. It is suggested that the Government and industry have perhaps made statements which, on reflection, might have required moderation. Examples include the Government expressing its firm commitment to building a UK diagnostics industry but without necessarily clearly indicating how this would be achieved beyond identifying an immediate set of priorities for addressing the pandemic. Even years into the pandemic, as indicated, it is difficult to discern from the Medical Technology Strategy how this is going to be done. Other examples by Government and industry include making announcements about awards before contracts have been formalised, a matter which may also be affected by regulatory reporting to the market.

8.38 What information and how much information to release and hold back is obviously a delicate balance. As this analysis has shown, at points the Government has not been insensitive to

this; an example is an awareness of how communications in respect of the Abingdon Health plc contract awards might be perceived. Nevertheless, communications may have been improved all round especially where these will have impacts in the market e.g. on investor decisions.

8.39 Ultimately, whatever the issues that have arisen, some of the "optics" do not look particularly good. A number of perceptions have grown which are not necessarily accurate. One is that the Government favoured cheaper foreign (in particular Chinese) imports at the expense of the domestic diagnostics industry and has shut domestic industry out of awards. Another is that the Government has no intention of following through on a commitment to build a UK diagnostics industry. Yet another is that industry is now less trusting of Government and would be unlikely to assist in future emergencies given instances where it has pursued suppliers for repayment and imposed new regulatory requirements that did not apply to all. Obviously, perceptions can become entrenched but better communication and transparency early on might have provided more assurances and allayed fears.

8.40 It should be observed that this is not a problem specific to diagnostics in the pandemic but a wider issue. For example, the Boardman Review has identified as a resourcing issue that there is a need for the Government to be able to respond and provide information quickly and accurately to maintain public confidence in a crisis. It stated that an agile communications function could assist with this, including communications specialists trained to manage queries including from suppliers and that communications functions must include sufficient technical knowledge to keep the public properly informed of the work being done, ideally including members from a science background.[482] It has been suggested that the Government could have expanded its communication strategy at an appropriate point during the pandemic to focus not only on the important public health messages but also to proactively explain to the public what it was doing and why.[483] Whilst a general issue, this may have a particular resonance in the context of diagnostic procurement in light of the analysis presented in this White Paper.

Compare International Experiences

8.41 Another theme which emerges from the analysis is a need to determine the international implications of UK diagnostics policy. Firstly, Brexit means that the UK will now adopt its own approach to public procurement generally and will introduce new regulation of medical devices. Both areas have historically been heavily conditioned by EU law and policy in the field. Any future reform of diagnostics policy, including procurement must be acutely aware of this EU-derived history and its potential implications. Secondly, as indicated, concerns have been expressed about the impact of applying detailed additional regulatory controls for COVID-19 devices under the CTDAR 2021 on suppliers who are not subject to similar requirements in other countries. The Government has suggested that higher quality validation will render UK suppliers more globally competitive whereas some industry suppliers may question continuing investment in a market where they can supply to larger markets subject to fewer regulatory constraints. On either view, in assessing the international competitiveness of the UK diagnostics industry, understanding the comparative experiences of procurement and its associated regulation in other countries will be essential. As the CTDAR 2021 statutory review has indicated, any regime must be adaptable and learn from best practice as it emerges in other regulatory regimes around the world.[484]

[482] Boardman Review of Government Procurement in the COVID-19 pandemic, p.17.
[483] Ibid., p.3.
[484] Consultation outcome, Private COVID-19 testing validation, p.10.

8.42 There is already academic research on how public procurement and its regulation operated during the pandemic which should be consulted for general lessons learnt on this aspect[485] but which should extend to associated areas of regulation in the context of diagnostics such as validation and regulatory approvals. For example, it is understood that other countries experienced issues with the time taken for notified bodies to provide approvals where these apply and the US FDA reviews are a clear example of how such decisions may affect UK regulatory approval practice e.g. prompting a MHRA review of the Innova test kits.

Government-Industry Stakeholder Forum for UK Diagnostics

8.43 Finally, if nothing else, this White Paper has shown the need for a more formal and sustained dialogue between the Government and industry in the area of diagnostics. There have been roundtables and engagement with industry associations but there is scope for a more substantial Government-supplier forum for diagnostics. This would provide a means of better "demand signalling", identification of, and engagement with, key suppliers and supply chains, and of co-developing a UK diagnostics policy and industrial strategy.

8.44 As a final remark, the author reiterates thanks to all of those dedicated Government, industry and other stakeholders who have given their time to the national effort in an unprecedented global crisis. To honour that commitment, we must learn from those experiences and achieve meaningful reform. Modestly, it is hoped that this White Paper will be a conversation starter.

[485] A starting point is S Arrowsmith, L R A Butler, A La Chimia, and C R Yukins (eds), *Public Procurement in (A) Crisis: Global Lessons from the COVID-19 Pandemic* (Hart, 2021).

APPENDICES

Appendix A: Research Methods and Methodology

1. This research principally comprises a desk-based analysis of key legislation, cases, published Government policy documents, and published data and information regarding contract awards and approvals. The research is not intended to be a comprehensive data analysis of contract awards. This would require the services of a private sector company specialising in the collation of bid statistics, use of CPV code tracking, and other statistical measures which would exceed the budget and time constraints for the project. It is nevertheless possible to derive useful indicative data from desk-based searches. In this regard, searches were undertaken of Tenders Electronic Daily ("TED"), the Find a Tender Service, Contracts Finder and portals in the devolved administrations (e.g. Sell2Wales). To give an example of a typical search, the terms "LFD" and "COVID-19" or variations thereof could be entered in Contracts Finder within a date search (1/1/20-1/07/22) to cover the onset of the pandemic to the present (time of writing). This could be further refined by referring to industry CPV codes of all diagnostics related items. This yielded a large search return from which it was possible to derive key dates in award, which types of supplier received more than one award, pursuant to which type of procedure, contract start and end date, contract values, etc. It was then possible to further refine searches e.g. by individual company or by purchasing methods e.g. a particular framework agreement or dynamic purchasing system with refined search returns cross-checked against the large search return to confirm or identify gaps in searches.

2. Further, a questionnaire was issued to BIVDA members as the largest representative industry association in the UK diagnostics sector by membership. Ideally, this would have been sent to a range of other stakeholders within Government, industry and civil society but this was considered disproportionate in view of the time and budget constraints. Of course, a more widespread stakeholder survey would be useful in future to increase the reliability and generalisability of any findings. Respondents were given four weeks to respond with two prompted reminders. Only 14 responses were received but it is understood that this was typical with interviews and informal discussions being the preferred mode of engagement. Moreover, the response rate was not so low as to merit exclusion of all questionnaire responses and useful narrative responses are included in the findings where these corroborate or support data and information obtained by other means. The fact that BIVDA has commissioned the research and is a source of questionnaire data has been treated with appropriate caution in assessing and presenting the findings. For example, the author had direct input into the questions asked to ensure that these were sufficiently general and objective and analytically rigorous. The views solicited are of individual BIVDA members and do not necessarily represent the views of BIVDA itself. A copy of the questionnaire is available on request.

3. In addition, semi-structured interviews were conducted with 17 individuals drawn from within DHSC, its executive agencies and industry. The interview component of this research has been approved by the University of Nottingham Law School Research Ethics Committee in accordance with the University's Research Ethics Code of Conduct. All interviews were provided by consent and no individual can be identified by name, affiliation or attribution in this White Paper. The responses can only be treated as anecdotal evidence and not necessarily representative of all views among stakeholders.

Appendix B: Abbreviations and Acronyms

CE – Conformitè Europëenne
CONDOR – COVID-19 National DiagnOstic Research and Evaluation Platform
CTDAR 2021 – The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021
DHSC – Department of Health & Social Care
DNA – Deoxyribonucleic Acid
DPS – Dynamic Purchasing System
ELISA – Enzyme-linked immunosorbent assay
EUA – Exceptional Use Authorisation
EU MDR – Regulation 2017/745 Medical Devices Regulation
EU IVDR – Regulation 2017/746 In Vitro Diagnostic Medical Devices Regulation
FDA – U.S. Food and Drug Administration
IFU – Instructions for Use
ITT – Invitation to Tender
IVDs – In Vitro Diagnostics
LAMP – Loop-mediated isothermal amplification
LFG – Lateral Flow Group
LFT/D – Lateral Flow Test/Device
LOD – Limit of Detection
MHRA – Medicines and Healthcare products Regulatory Agency
NHS – National Health Service
NHSEI – NHS England and NHS Improvement
NIHR – National Institute for Health and Care Research
NIHRIO – NIHR Innovation Observatory
NTAG – New Test Advisory Group
OLS – Office for Life Sciences
PCR – Polymerase Chain Reaction
PCR 2015 – UK Public Contracts Regulations 2015
PHE – Public Health England
POC – Point of Care
PPE – Personal Protective Equipment
R&D – Research and Development
RFI – Request for Information
RNA – Ribonucleic Acid
SAP – Scientific Advisory Panel
SEG – Scientific Expert Group
SME – Small or Medium Sized-Enterprise
T&T – Test and Trace
TPP – Target Product Profiles
TVG – Technical Validation Group
UKCA – UK Conformity Assessed
UKHSA – UK Health Security Agency
UK-RTC – UK Rapid Test Consortium
UTO – Universal Testing Offer
VTAG – Viral Detection Tests Approval Group

Appendix C: About the Author

Dr. Luke R.A. Butler, LLB(Hons), LLM (European Law), Pg.Dip., PhD, SFHEA, Barrister at Law (currently non-practising) is an Associate Professor in Law, Head of the UK Public Procurement Unit within the Public Procurement Research Group and Director of the Postgraduate Executive Programme in Public Procurement Law and Policy at the University of Nottingham. He is also joint General Editor of the Public Procurement Law Review (alongside its founder, Professor Emerita Sue Arrowsmith KC (Hons)), a member of the UK Procurement Lawyers' Association, and a Senior Fellow of Advance HE. Luke is the author and co-editor of a number of books and articles which most recently includes S Arrowsmith, L R A Butler, A La Chimia and C R Yukins, *Public Procurement in (a) Crisis: Global Lessons from the COVID-19 Pandemic* (2021 Hart). Luke is also the recipient of a number of grants relating to public procurement during the pandemic including AHRC Grant AH/V012657/1, *An Urgent Review of Single Source Procurement During the Pandemic: Recommendations for Best Practice and Reform*. Luke regularly provides consultancy on public procurement law, regulation and reform for governments, international organisations and industries, and is available to assist in inquiries and other reviews. He can be contacted at Luke.Butler@nottingham.ac.uk.