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UK COVID-19 INQUIRY

CORPORATE WITNESS STATEMENT OF THE DEPARTMENT FOR BUSINESS AND TRADE REPRESENTING THE FORMER DEPARTMENT FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY

FIRST MODULE 5 WITNESS STATEMENT OF SARAH MUNBY

Section 1: Introduction

1.1. I, Sarah Munby, make this statement on behalf of the former Department for Business, Energy and Industrial Strategy (**fBEIS**) (or '**the Department**'). This forms part of the wider Module 5 response of the Department for Business and Trade (DBT).

1.2. I am providing this written statement in response to the Inquiry's Rule 9 request dated 19 March 2024 (the '**Rule 9 request**').

1.3. I was employed by the Department as Permanent Secretary from 20 July 2020 until 7 February 2023. I had overall responsibility for the effective running of the Department, in addition to my responsibilities as Accounting Officer.

1.4. I now hold the position of Permanent Secretary at the Department for Science, Innovation and Technology (**DSIT**). I have held this role since 7 February 2023, following the Machinery of Government (**MoG**) change.[1]

1.5. The Inquiry has asked the Department to respond to a series of requests for information which principally concern government procurement of key healthcare equipment and supplies, and materials relevant to such decisions, insofar as they are held by DBT and its predecessor departments.

1.6. As set out in my previous statements, I recognise the importance of this Inquiry and the serious nature of the impacts of Covid-19 which it seeks to investigate. I am acutely aware from my personal work during the pandemic of the serious consequences which the virus and consequent restrictions had both for individuals and their families in relation to the health impacts, and on businesses and livelihoods across the UK.

1.7. In preparing this statement, I am reliant upon the work of the Department's Inquiry Response Unit. My officials have coordinated and liaised with a number of colleagues with relevant knowledge and experience across the Department. Their contributions have been used for the purposes of preparing this statement, and my statement therefore relies upon those contributions and a review of contemporaneous written material conducted by others. In this statement I have made clear where I have put forward my personal reflections. For the most part, however, this is a 'corporate'

[1] A MoG change is a transfer of functions between Ministers, either between Ministers in charge of departments or other Cabinet Ministers, or between a Minister and a non-departmental public body. It can affect functions carried out by the Minister's department or a public body such as an executive agency under the Minister's control, or by other public bodies. Usually the transfer of a function takes effect immediately.

statement in the sense that – to meet the understandably broad nature of the Inquiry's request – I have drawn and relied upon extensive input from relevant colleagues.

1.8. The documents I have relied upon to prepare this statement and accompanying chronology have been identified from the Department's IT systems (SharePoint) and the Department's email accounts.

1.9. Colleagues and I have done our best to assist the Inquiry on behalf of the Department, drawing upon documents identified as part of the Department's disclosure review. If further relevant material is identified, I would be happy to add to or clarify this statement to take it into account.

Section 2: <u>Structure of this Statement</u>

2.1. In Sections 3 – 6, I provide a summary of the Department's role, functions, and responsibilities prior to and during the pandemic, including the key decision-making bodies and individuals involved in the response.

2.2. In Sections 7 – 10, I set out the role of the Office for Product Safety and Standards (**OPSS**) and address particular topics that the Inquiry has asked the Department to consider. The topics include:

a) OPSS' shared and exclusive responsibilities during the pandemic;

b) An explanation of the regulatory standards and legislative framework governing Personal Protective Equipment (**PPE**);

c) A description of the regulatory easements introduced during the pandemic, the process and rationale for implementation, the effect of the easements and the impact of EU Exit;

d) The role of OPSS in respect to monitoring PPE compliance;

e) A summary of the bespoke compliance advice provided to key potential PPE manufacturers; and

f) A summary of the lessons learned following several review exercises conducted by OPSS to reflect and build on the work it has done since the start of the pandemic.

2.3. In Section 11, I set out a summary of the Department's role in the Ventilator Challenge.

2.4. In Sections 12 and 13, I set out in detail the role of PPE Make between its creation on 27 April 2020 and disbandment in September 2020. This section addresses particular topics that the Inquiry has asked the Department to consider including:

a) The appointment of Tim Jarvis, and his role within PPE Make;

b) Assistance provided to the Department of Health and Social Care (**DHSC**) during the pandemic;

c) An explanation of the 'fast-tracking' process;

d) The role of the PPE Make Team in business identification and stakeholder engagement; and,

e) Regional support and local resilience forums (**LRFs**).

2.5. Section 14 details the lessons learned in respect to PPE Make following a lessons learned exercise as part of the handover of their involvement in the PPE Taskforce.

2.6. Section 15 provides concluding remarks in relation to the content of the statement.

2.7. As there are many acronyms used in this statement, I have included a list of them at Annex 2 for ease of reference.

Section 3: Overview of the Roles and Responsibilities of BEIS Prior to the Pandemic

Overview of the Department and MoG Changes

3.1. To assist the Inquiry, I set out below a summary of the Department and its predecessors' history and key functions.

3.2. The Department of Trade and Industry (**DTI**) was a government department formed on 19 October 1978. DTI was responsible for UK government policy in the following areas: company law, trade, business growth, innovation, employment law, regional economic development, energy, science and consumer law. On 28 June 2007, DTI was replaced with the creation of the Department for Business, Enterprise and Regulatory Reform (**BERR**) and the Department for Innovation, Universities and Skills (**DIUS**).

3.3. BERR was set up to lead work on creating the conditions for business success through competitive and flexible markets that created value for businesses, consumers and employees. On 5 June 2009, BERR merged with DIUS to create the Department for Business, Innovation and Skills (**BIS**). BIS sought, through investment in skills and education, to promote trade, boost innovation and help people to start

and grow businesses. Its remit also included the protection of consumers and the development of government policy in areas of business regulation and support. A MoG change in 2011 moved IT, telecoms and digital portfolios from BIS to the then Department for Culture, Media and Sport (**DCMS**).

3.4. On 14 July 2016, BIS merged with the Department of Energy and Climate Change (**DECC**) in another MoG to form the Department. The universities and skills policy portfolios were transferred to the Department for Education (**DfE**) at this time. The Department had key responsibility for government policy in the following areas: business, science, research and innovation, energy and clean growth and climate change.

3.5. On 7 February 2023, after a further MoG change, the Department was broken up to create three new departments. The changes took place immediately, with each department assigned a new set of policy objectives.

3.6. As part of the MoG, DBT was set up to focus on delivering economic growth opportunities across the economy, to ensure economic security and supply chain resilience, to support free trade and to promote British businesses on the global stage and attract high-value investment. DBT brought parts of the Department together with the Department for International Trade (**DIT**).

3.7. DSIT was set up to focus on research and development investment, promote research and innovation systems, encourage international collaboration on science and technology and lead regulatory reforms to promote innovation. It was formed from the relevant portfolios of former BEIS and includes policy areas previously owned by DCMS, including responsibility for the Online Safety Bill. I now hold the position of Permanent Secretary for DSIT.

3.8. The Department for Energy Security and Net Zero (**DESNZ**) was established to focus on energy supply, energy efficiency and ensuring that the UK meets its Net Zero commitments. DESNZ was created from the energy portfolio of former BEIS. Responsibility for National Security and Investment policy, moved from the Department to sit under the Chancellor of the Duchy of Lancaster (**CDL**) in Cabinet Office.

BEIS Roles and Responsibilities (Prior to the Pandemic)

3.9. The Department held key responsibility for the following policy areas: business, industrial strategy, science, research and innovation, energy and clean growth and

climate change. This is set out in further detail at paragraph 3.5 of the Department's Module 2 corporate witness statement.

3.10. As provided at paragraphs 3.6 – 3.8 of the Module 2 corporate witness statement, the Department was the designated Lead Government Department (**LGD**) for emergencies affecting the Critical National Infrastructure (**CNI**) sectors of Energy, Civil Nuclear, Chemicals, Space, and Postal Services. CNI sectors are critical elements of infrastructure, the loss or compromise of which could result in a major detrimental impact on the availability, integrity or delivery of essential services. If an emergency occurred in these sectors the Department would lead on the cross-government response and Cabinet Office could request that the Department Secretary of State chair Cabinet Office Briefing Rooms (**COBR**). For emergencies where the Department was not the LGD, such as a pandemic, it would provide assistance within the scope of its policy responsibilities.

3.11. The Department also had responsibility for the majority of wider, non CNI business sectors. These included: automotive, manufacturing, construction, steel, hospitality, retail, personal care and professional and business services. Paragraph 4.1 of the Module 2 corporate witness statement sets out that the Department also had an interest in the food retail sector which was sponsored by the Department for Environment, Food and Rural Affairs (**Defra**) as well as supply chain logistics. The Department also held responsibility for employment rights and employer responsibilities.

3.12. As set out at paragraph 3.10 of the Module 2 corporate witness statement, at the time of its creation in July 2016, the Department established an executive committee ('**ExCo**'), to oversee internal governance. The Energy Resilience and Emergency Response ('**ER2**'), team was also created at this time, and was responsible for ensuring teams across the Department were prepared for an emergency. ER2 provided a network of trained staff who could be mobilised in an emergency.

3.13. As set out at paragraphs 3.12 – 3.14 of the Module 2 corporate witness statement, a sub-team of ER2, the Emergency Response - Capabilities and Operations team (**ERCO**) was created in July 2017 to function as a single, central team covering the Department's interests. This followed a July 2017 internal review which recommended that the Department could improve its emergency response through standardisation across the Department.

Project Kingfisher

3.14. The Department has considered the request by the Inquiry to explain Project Kingfisher, and to provide an assessment as to whether it assisted the Department in responding to the demands of the Covid-19 pandemic. Project Kingfisher was established in 2019 to enable the Government to respond quickly, effectively and consistently to economic impacts on business as a result of a potential no deal EU Exit. Project Kingfisher developed a series of prospective options to support companies in distress and guidance on when these could be used. Project Kingfisher was not a policy response itself — it gathered intelligence and offered expert advice on possible intervention options. Background on Project Kingfisher has been provided to the Inquiry at SM/001 INQ000096904.

3.15. Project Kingfisher provided a model for cross government interaction. The Department's Kingfisher Unit's analysis identified vulnerable places, sectors and companies drawing on data from across Whitehall. The project was multi-faceted. It considered sectors, individual companies and regions and provided a holistic view to ensure the right funding went to the right place. A series of email communications from early in the pandemic demonstrate this. These are provided at SM/002 INQ000475313.

3.16. As set out in a Business Impact Assessment paper, circulated on 8 March 2020, SM/003 INQ000066034, as part of Project Kingfisher, the Government developed capacity for translating economic shocks into sectoral and highly local impacts – focussing on firms who played a disproportionate role in the local economy. During the early stages of the pandemic, the lessons from Project Kingfisher allowed the relevant teams to identify potentially at-risk locations primarily in manufacturing sectors and target support.

Section 4: <u>BEIS Roles and Responsibilities During the Pandemic</u>

4.1. As set out at paragraph 4.1 of the Module 2 corporate witness statement, the Department continued to have the responsibilities outlined in paragraphs 3.9 – 3.13 above during the pandemic. Across Government, Department Ministers attended Cabinet and Cabinet Committee meetings. Department Ministers also attended Small Ministerial Groups when required.

4.2. On 13 March 2020, the Prime Minister requested that four new cross departmental implementation committees be established, as set out at paragraph 4.13 of the Module 2 corporate witness statement:

a) **Health and Social Care Ministerial Implementation Group** (**HSCMIG**) – HSCMIG was chaired by the Health Secretary to focus on the preparedness of the National Health Service (**NHS**) and the medical and social package of support;

b) **General Public Sector Ministerial Implementation Group (GPSMIG)** – GPSMIG was chaired by the Chancellor of the Duchy of Lancaster to look at preparedness across the rest of the Public and Critical National Infrastructure, excluding the NHS;

c) **Economic and Business Response Implementation Group (EBRIG)** – EBRIG was chaired by the Chancellor. The Business Secretary was deputy chair. EBRIG was attended by Ministers and officials from across Government. EBRIG reported on the business implications of Covid-19 to the Prime Minister. EBRIG had two functions: 1) to ensure rapid communication and engagement with business; and 2) to monitor and respond to the implications for key sectors and businesses. As part of this work, the Department provided information about strategically important vulnerable businesses and potential support measures in order to support No. 10 and Her Majesty's Treasury (**HM Treasury)** decision-making. EBRIG also coordinated ministerial roundtable meetings with key sectors. On occasion, EBRIG was split into the following groups:

   i. **EBRIG(M) (also referred to as EBRMIG)** – attended only by Ministers; and

   ii. **EBRIG(O)** – attended only by officials.

d) **International Ministerial Implementation Group (IMIG)** – IMIG was chaired by the Foreign Secretary. IMIG considered the international response to the pandemic.

The Department's Roles and Responsibilities During the Pandemic Within the Government, Devolved Administrations and Local Administrations

4.3. The Department was involved in establishing a domestic manufacturing supply chain for PPE through its programme 'PPE Make' as discussed at Section 12 of this statement. The Department also had policy responsibility for the laws relating to the safety of PPE, through OPSS, an organisation within the Department. Further detail regarding OPSS can be found at Section 7 of this statement. As part of the Government's wider economic support package, the Department delivered a number

of grant schemes through funding provided to local authorities responsible for the schemes' administration. In anticipation of sector re-opening the Department, alongside the Department for Levelling Up, Housing and Communities (**DLUHC**), held meetings with local authorities and other interested parties. DBT understands that these schemes will be the subject of more detailed evidence in a later module and propose to provide further details in response to any request received at that time.

4.4. OPSS provided local authorities with regulatory guidance. As set out at paragraph 10.125 of the Module 2 corporate witness statement, OPSS also worked with the PPE Make team, the Health and Safety Executive (**HSE**) and local authorities to fast-track PPE through product safety assessments and implement regulatory easements to the existing regulations. More detail regarding PPE Make has been provided at Section 12 of this statement. More generally, as set out at paragraph 10.120 of the Module 2 corporate witness statement, at the beginning of the pandemic, OPSS provided daily guidance to local authorities regarding PPE regulation.

4.5. The Department's relationship with the Devolved Administrations is set out at Section 15 of the Module 2 corporate witness statement. Key strategic discussions and forums with the Devolved Governments and the business communities in Scotland, Wales and Northern Ireland were convened by the Department's Devolution and the Union team. From March 2020, the team were involved in coordinating senior official and ministerial engagement between the Department and the Devolved Administrations. The Department's Devolution and Union team's role was to facilitate dialogue between the four UK Administrations and ensure their views were being factored into policy within the Department's areas of responsibility. As set out at paragraph 15.6 of the Module 2 corporate witness statement, the Department's Devolution and the Union team delivered a series of meetings between Department Ministers and senior officials and business representatives in each nation. The Economic Directors Forum facilitated a series of meetings, throughout the pandemic, which discussed the impact of pandemic interventions on sectors, operational/delivery channels and business support measures. From October 2020, the Devolution and Union team's Stakeholder and Business Engagement Team directly coordinated business engagement in Scotland, Wales and Northern Ireland. This team worked with Scottish, Welsh and Northen Irish businesses and business organisations in the Department's priority sectors, focussing on sector recovery.

The Department's Roles and Responsibilities During the Pandemic Within the Government, Devolved Administrations and Local Administrations in Relation to Emergency Response

4.6. Regarding emergency response measures, as set out at paragraph 4.2 of the Module 2 corporate witness statement, from the onset and throughout the pandemic, one of ExCo's functions was to oversee the Department's emergency response and ensure that adequate resources were available to the teams involved. ExCo also delegated specific areas of work, such as staff mobilisation and resource management, to the People and Operations Committee.

4.7. As set out at paragraph 4.7 of the Module 2 corporate witness statement, the Department's Covid-19 Coordination Hub was established on 1 April 2020 as a central briefing hub. The Hub, Project Management Office, and the emergency response provided by the Emergency Response Team (**ERT**) operated simultaneously to cover different aspects of the response:

a) ERT and the Department's Covid-19 Coordination Hub were the liaison between the Department and central government; and

b) ERT participated in coordination activity through Cabinet Office Civil Contingencies Secretariat, with a focus on the Department's CNI sectors.[2]

4.8. The Department's Covid-19 Coordination Hub fed into Cabinet Office Secretariat, with responsibility for policy responses to Covid-19, this potentially could have included areas outside of the Department's CNI sectors. Overall, the coordinated policy effort grew out of ERT, which managed the early monitoring stages of the pandemic.

4.9. On 21 September 2020, the Covid-19 Coordination Hub was replaced by the Covid-19 Programme Directorate, which then became the liaison between the Department and central government. The purpose of this was to move the team from a temporary mobilisation of staff to a standing directorate for the duration of the pandemic. This provided stability in resourcing and enabled mobilised staff to return to their home teams. The new Directorate acted as a single centre of expertise and coordination for all matters relating to the pandemic within the Department.

[2] Cabinet Office's Civil Contingencies Secretariat was the executive department of Cabinet Office, responsible for emergency planning.

Areas of Government Policy in which the Department had Exclusive and Shared Responsibility

4.10. As set out at paragraphs 6.1 – 6.4 of the Module 2 corporate witness statement, for the period 1 January 2020 to 28 June 2022 the Department had exclusive responsibility for:

a) **Research and innovation policy** — During the pandemic the Department supported research and innovation institutions. It was the Department's responsibility to ensure that research could continue during the pandemic. This work was directed through the Department funded, non-departmental body UK Research and Innovation (**UKRI**); and

b) **Vaccine Taskforce** — From 1 August 2021, as set out in a Written Ministerial Statement from the Prime Minister, the Vaccine Taskforce (**VTF**) became a joint unit across DHSC. A Memorandum of Understanding (**MoU**) split the accountability for the VTF between the two departments: DHSC became accountable for VTF activities where the primary purpose was vaccine procurement or clinical development; the Department remained accountable for any projects bringing Covid-19 vaccine manufacturing and research and development by the UK Research and Innovation (**UKRI**) onto UK shores. Please refer to correspondence dated 27 April 2023 regarding the agreed approach to questions relating to this area of Covid-19 policy.

4.11. As set out at paragraphs 6.5 – 6.7 of the Module 2 corporate witness statement, the Department shared competencies included:

a) **Delivery of economic support, such as Covid-19 grants and loans schemes** — The Department contributed to discussions regarding the design of economic support policy, though final decisions and policy design were made by HM Treasury and Cabinet Office. The Department Secretary of State was accountable for these Schemes. DBT understands that these Schemes will be the subject of more detailed evidence in a later module and proposes that further details will be provided in response to any request at that time;

b) **Delivery of the 'Covid-secure' or 'Working Safely' guidance** — This guidance was first led from the Department at the request of the Chancellor. Cabinet Office later took on a coordination role and was increasingly responsible for policy direction. Teams within BEIS then reflected this in guidance for the Department sectors. DBT understands that guidance for business will be the subject of more detailed evidence in a later module and

proposes that further details will be provided in response to any request at that time;

c) **'Contain' and 'Test and Trace'** — DHSC led these initiatives with some Department input. DBT understands that Test and Trace will be the subject of more detailed evidence in Module 7 and proposes to provide further details in response to any request received at that time;

d) **Personal Protective Equipment (PPE)** — A team within the Department supported UK Make, a Cross-Whitehall PPE programme. This work is discussed in more detail at Section 12; and

e) **Office for Product Safety and Standards** — OPSS was an organisation within the Department and remains an organisation within DBT. It had policy and delivery responsibilities for the regulation of product safety, legal metrology, and construction products. HSE as the principal enforcement body for workplace PPE safety, OPSS, and the Ministry of Housing Communities and Local Government (**MHCLG**) (later DLUHC) advised on enforcement mechanisms for Business Closure Regulations. DBT understands that guidance for business will be the subject of more detailed evidence in a later module and proposes that further details will be provided in response to any request at that time. Further detail regarding OPSS' PPE regulation responsibilities is provided at Section 7.

4.12. To note, OPSS did not issue guidance or liaise with the NHS in relation to infection control.

Section 5: <u>Key Decision-Making Bodies and Decision-Making Individuals</u>

5.1. The Inquiry has asked the Department to set out the key decision-making bodies and decision-making individuals within the Department, that relate to the outline scope for Module 5. This covers the period of 1 January 2020 to 28 June 2022. Details of this are set out at Annex 1.

The Decision-Making Committee

5.2. The Decision-Making Committee (**DMC**) was created by DHSC, Cabinet Office and NHS England (**NHSE**) in March 2020, to respond to the urgent need to source safe and usable PPE and medical devices to the NHS. The wider DMC membership included other Government and NHS stakeholders, such as policy holders, regulators, buyers, assurers, and users.

5.3. OPSS officials were advisory members to DMC, providing technical and policy advice on the safety of Covid-19 PPE.

5.4. The primary objective of DMC was to provide decisions on whether a specific product would meet stringent Essential Health and Safety Requirements, and whether the product could be used by NHS staff to protect against Covid-19. The official aims of the committee were to bring together key stakeholders in a single forum to consider the criticality of supply across the Treatment and Supplies Cells and therefore make rapid decisions in the following areas:

a) The definition of a "*critical product*" for its inclusion on the critical product list and additions/retractions to this list;

b) Determining product safety and supply chain threats to consumers and businesses. Please see SM/004 INQ000475455;

c) Approval of appropriate alternatives to critical products; and

d) "*Rapid technical assurance approvals on novel PPE manufacturing and new/alternative PPE products*". Please see SM/005 INQ000477715.

5.5. In April 2020, early discussions between OPSS and HSE raised concerns about DMC's processes, emphasising the need to move at pace and make decisions at the right time. OPSS and HSE noted one example of the circumvention of the approval process for PPE being imported into the UK and suggested that a review be conducted to try to improve DMC processes. Please see SM/006 INQ000478738 and SM/007 INQ000477693. As a result of this review, the Regulatory Coordination Cell (**RCC**) was formalised and OPSS became involved in advising DMC on these issues. The RCC is discussed in further detail below at paragraphs 5.7 – 5.14.

5.6. Examples of the role of OPSS during DMC meetings include:

a) Advising on updates to guidance. Please see notes from the PPE Decision-Making meeting on 15 April 2020 at SM/008 INQ000475322;

b) Advising on specific products and types of products for approval by DMC. Please see the following notes from PPE Decision-Making meetings: 17 April 2020 – SM/009 INQ000475329; 21 April 2020 - SM/010 INQ000475335; 23 April 2020 - SM/011 INQ000475338; and 5 May 2020 - SM/012 INQ000475369;

c) Advising on consumer safety and non-PPE masks. Please see notes from the PPE Decision-Making meeting on 24 April 2020 at SM/013 INQ000475340 and

DHSC seeking clarification on Covid and non-Covid PPE from OPSS SM/014 INQ000475487;

d) The identification of untrustworthy companies for the supply of PPE. Please see notes from the PPE Decision-Making meeting on 24 April 2020 at SM/013 INQ000475340; and

e) Advising on testing and liaison with testing bodies. Please see the following notes from PPE Decision-Making meetings: 8 May 2020 - SM/015 INQ000478752; and 14 May 2020 - SM/016 INQ000478756.

5.7. Following a meeting of DMC on 15 June 2020, a gateway for escalating concerns about the quality of PPE in use, including complaints, was created. While OPSS itself did not have a decision-making role in this process, it was party to concerns about PPE that were raised at DMC and contributed to discussions with its technical and regulatory expertise when required. There is evidence of correspondence between OPSS and health and social care organisations seeking technical advice relating to compliance of PPE being sourced or procured with applicable regulations and associated standards.[3] In these cases, the person making the request was made aware of the relevant regulatory requirements and guidance and a provisional view was offered on compliance. This view was subject to the caveat that it was the responsibility of the individual undertaking the assessment to make the final decision, given any potential regulatory obligations that may flow from their role in the supply chain. The responsibility for product compliance rested with the manufacturer and the Notified Body. HSE, as the Market Surveillance Authority, could take a view on adherence to the relevant regulatory requirements. Please see as an example the DMC papers forwarded by the cover email at SM/017 INQ000477729. Examples of OPSS correspondence with NHS England regarding compliance are provided at SM/017a INQ000498073 and SM/017b INQ000508349.

The Regulatory Coordination Cell

5.8. The RCC was established and had its first meeting on 29 April 2020 following earlier meetings in April 2020 between OPSS, HSE and the Medicines & Healthcare products Regulatory Agency (**MHRA**) to set the terms of reference, please see SM/018 INQ000475347. Its regular composition was of officials from OPSS, HSE, MHRA and the Health and Safety Executive for Northern Ireland. The meetings were

[3] There was no central record collating or tracking the requests received, or the response sent in return. They were often received by individual members of OPSS via direct email, and a not central database.

chaired by a representative from OPSS. Membership of the RCC intentionally overlapped with that of DMC to promote a coordinated approach to the advice given by the regulators to DMC and Cabinet Office. Please see SM/018 INQ000475347, and later finalised terms of reference at SM/020 INQ000477767.

5.9. Representatives from the following organisations also attended the RCC on a less regular basis: UK Make (DHSC), PPE Make, NHS Innovate, NHS Supply Chain, the Office for Nuclear Regulation, and DHSC's anti-fraud team.

5.10. The aim of the group was:

"*…to rapidly and efficiently address and overcome regulatory issues resulting from the unprecedented and immediate demand for personal protective equipment (PPE) and medical devices; specifically in regard of the safety and effectiveness of PPE for the NHS supply chain, but also considering safety of non-NHS and public supply issues in respect of advice on standards, specifications, testing and market surveillance activities.*" Please see SM/018 INQ000475347.

5.11. The RCC worked to achieve its aims through the following activities:

a) By providing guidance on the applicable regulations and associated standards and specifications for PPE and medical devices to enable their rapid release;

b) The joint working of OPSS, HSE and MHRA at the Daventry site to ensure efficient regulatory review through an agreed process of technical documentation reviews and investigations;

c) Coordinating with stakeholders to support UK testing capability and capacity by Notified Bodies and facilitate rapid product assessment;

d) Providing specialist regulatory and technical advice and support for wider cross-government procurement processes; and

e) Sharing knowledge and intelligence to improve market surveillance activities.

5.12. Further details of the RCC's core intended activities are set out at SM/018 INQ000475347.

5.13. At the final meeting of RCC on 31 March 2022, the membership of the RCC agreed that its meetings should pause but could reconvene as required. Please see meeting notes reflecting these decisions at SM/021 INQ000475492.

5.14. The RCC was created primarily to deal with regulatory issues resulting from the unprecedented demand for PPE and medical devices within the NHS supply, but it also considered the safety of non-NHS and public product supply, standards, specifications, testing and surveillance. At the RCC, the regulators were able to share information and coordinate their response on issues such as:

a) Technical queries on the categorisation and specification of products and conformity assessment through Notified Body capacity. Please see the relevant RCC meeting notes for 5 May 2020 at SM/022 INQ000477711, 11 June 2020 at SM/023 INQ000475412, 16 June 2020 at SM/024 INQ000475411, 30 June 2020 at SM/025 INQ000477737, 20 August 2020 at SM/026 INQ000477751, 10 September 2020 at SM/027 INQ000477755, 24 September 2020 at SM/028 INQ000475458 and 25 March 2021 - SM/029 INQ000477762;

b) Feedback on regulatory and technical requirements to procurement teams to inform their purchasing decisions. Please see the relevant RCC meeting notes for 15 May 2020 at SM/030 INQ000475378 and 5 November 2020 at SM/031 INQ000478774;

c) Assisting DHSC's anti-fraud team in the identification of fraudulent products. Please see the relevant RCC meeting notes for 21 May 2020 at SM/032 INQ000475401;

d) Contributing to the publication of DHSC guidance. Please see the relevant RCC meeting notes for 28 May 2020 SM/033 INQ000475403 and 10 December 2020 at SM/034 INQ000478775;

e) Work at the NHS distribution centre in Daventry and involvement in the interception of non-complaint PPE. Please see the relevant RCC meeting notes for 21 May 2020 at SM/032 INQ000475401; 11 June 2020 at SM/023 INQ000475412, 23 June 2020 at SM/035 INQ000475416, 30 July 2020 at SM/036 INQ000475438, and 4 August 2020 at SM/037 INQ000475442;

f) Market surveillance, product recalls and product safety. Please see the relevant RCC meeting notes for 7 July 2020 at SM/038 INQ000477739, 9 July 2020 at SM/039 INQ000477740, 14 July 2020 at SM/040 INQ000475430 and 16 July 2020 at SM/041 INQ000475435;

g) Liaison with DHSC on the regulatory easements. Please see the relevant RCC meeting notes for 12 November 2020 at SM/042 INQ000475469 and 22 April 2021 at SM/043 INQ000478776; and

h) The expiration, repurposing and re-use of PPE and medical devices. Please see the relevant RCC meeting notes for 1 July 2021 at SM/044 INQ000477764, 29 July 2021 at SM/045 INQ000475488, 24 September 2020 at SM/028 INQ000475458 INQ000475459 and 18 February 2021 at SM/047 INQ000477761.

Section 6: Key Materials

6.1. The Inquiry has asked DBT to identify and describe any key materials that the Department held relating to its involvement in the response to the Covid-19 pandemic between 1 January 2020 and 28 June 2022. Please refer to Annex 3 for a schedule of the key materials exhibited to this statement.

Section 7: Office for Product Safety and Standards

7.1. This section will set out the roles and responsibilities of OPSS, an organisation within the Department, that was created in January 2018. It will set out OPSS' roles and responsibilities prior to the pandemic and its roles and responsibilities during the pandemic itself, including the governance structure under which it operated. It will also highlight the close working relationship between OPSS and HSE, and the respective responsibilities of each organisation. The section concludes by setting out the regulatory standards and legislative framework for PPE and bespoke regulatory support provided to large-scale manufacturers.

OPSS' Roles and Responsibilities Prior to the Pandemic

7.2. OPSS was created in January 2018. From inception, it has been the national regulator for most consumer products, except for vehicles, medicine and food, with a remit ranging from policy to delivery. OPSS is responsible for advising Ministers on product safety and market surveillance policy and is the government's enforcement authority for various goods and standards-based regulations.

7.3. OPSS also has overall responsibility for UK market surveillance policy and coordination and responsibility for standards and accreditation policy in the UK. Market surveillance refers to the suite of activities that help protect citizens from non-compliant and unsafe non-food products. Please see SM/048 INQ000475490 for an account of national market surveillance programmes.

7.4. Market surveillance is delivered by a range of national and local bodies who are referred to as Market Surveillance Authorities. Market surveillance activity for PPE is undertaken by different organisations depending on the use of the products involved. HSE is responsible for the market surveillance and enforcement of PPE used in the workplace, for example in hospitals, by front line emergency workers and in businesses. Local authorities are responsible for enforcement of PPE products sold to and used by consumers. OPSS, through the Secretary of State, is the Market Surveillance Authority for discrete policy areas outside of the Module 5 Provisional Outline of Scope.

OPSS' Roles and Responsibilities During the Pandemic

7.5. During the pandemic, OPSS' key policy responsibilities were:

a) **Product safety policy: responsibility for PPE safety regulation** — OPSS was responsible to Department Ministers for policy on the safety of PPE. It advised Ministers on the applicability, efficacy and coordination of legislation, guidance or other policy interventions aimed at ensuring the safety and compliance of PPE with applicable Regulations;

b) **Market surveillance coordination** — OPSS was responsible for market surveillance coordination and operated a forum for Market Surveillance Authorities to share information, coordinate operational activities and agree operational leads on products such as hand sanitiser and face coverings where there could be ambiguity as to which regulator would be best placed to lead. Surveillance and enforcement of PPE in the workplace remained the responsibility of HSE as the Market Surveillance Authority;

c) **Policy lead for standards and accreditation policy and sponsorship relationship with British Standards Institution (BSI) and UK Accreditation Service (UKAS)**;

d) **Providing guidance to local authority regulators on business closure legislation** — OPSS was tasked by Cabinet Office to advise on suitable enforcement mechanisms for the Business Closures Regulations in England drawing on its knowledge of local authority regulatory services regulators and

its responsibility for Primary Authority.[4] As this area of policy is outside the scope of Module 5 it will not be discussed further in this statement;

e) **Developing a robust, intelligence led mechanism for targeting unsafe goods as they enter the UK** — OPSS was responsible for the coordination of enforcement activities carried out by local authorities at the UK border. OPSS undertook a strategic intelligence assessment of Covid-19 risks to consumers and established import risk profiles;

f) **Operational and technical support on PPE** — OPSS provided operational, regulatory and technical support drawing on its technical and regulatory expertise; and

g) **Product safety policy: Regulatory and technical advice: Other Products** — OPSS advised on other non-medical PPE products such as air filtration and UV-C devices. Further detail regarding these responsibilities can be found at SM/049 INQ000475253.

OPSS and HSE's Respective Responsibilities for PPE Safety During the Pandemic

7.6. OPSS and HSE worked closely together to meet their respective responsibilities for regulating PPE during the pandemic. OPSS was responsible for product safety policy, including PPE, and was the national regulator for consumer goods, excluding food, medicines and vehicles. It had responsibility for developing policy and guidance in relation to all PPE (including that intended for workplace use) and regulating all other PPE (with local authorities) that was not intended for workplace use. Medical devices and medicines regulation was the responsibility of MHRA. HSE's responsibility, as national regulator for workplace health and safety, was to enforce the health and safety requirements that must be met before PPE products intended for workplace use could be placed on the market. This included not only non-medical workplaces using PPE, but also NHS and private medical employers.

OPSS' Governance Structure During the Pandemic

7.7. OPSS Covid-19 incident response, from 10 March 2020 until 24 February 2021, was managed by its Strategic Coordination Group (**SCG**). Please see OPSS Organogram SM/050 INQ000475500. The SCG was responsible for setting OPSS' strategy for the pandemic and overseeing its response. SCGs were convened by OPSS as high-level working groups to manage a broad range of emergency or significant incidents.

[4] Primary Authority is a means for businesses to receive assured and tailored advice on meeting regulations such as environmental health, trading standards or fire safety through a single point of contact.

Please see, for example, the SCG convened to consider a no-deal EU Exit scenario, provided at SM/051 INQ000475465. The purpose of an SCG was to take overall responsibility for managing an incident, and to establish the framework to guide OPSS' response.

7.8. On 10 March 2020, an SCG was convened to manage OPSS' strategic incident response to the Covid-19 pandemic. A covering paper outlining the establishment of this SCG is available at SM/052 INQ000475251. During the pandemic, OPSS' Chief Executive Officer, Graham Russell, was a member of the SCG and it was chaired by Will Creswell (Deputy Director, National Capability, OPSS).

7.9. The SCG met twice weekly, on Tuesdays and Thursdays. Please see SM/052 INQ000475251 and SM/053 INQ000477651 for a list of attendees and an agenda of the first meeting of a Covid-19 SCG. Please see SM/054 INQ000475310 for an organogram reflecting SCG's position within OPSS' response to Covid-19.

7.10. Part of the role of an SCG was to manage business disruptions to OPSS, including monitoring the risks of staff working from home. Please see for example SM/055 INQ000475254. It also engaged with policy and sector developments relevant to OPSS during the pandemic. Teams within OPSS, analysis teams within the Department, and within Government more broadly, fed into the SCG's decision-making. One example of this was the Ports and Borders team within the Department submitting a proposal for the SCG's consideration on the control of PPE at UK borders. This is available at SM/056 INQ000475333 and SM/057 INQ000475334.

7.11. Underpinning the strategy set by the SCG were several Tactical Coordination Groups (**TCGs**). These were chaired by Deputy Directors and were responsible for managing and coordinating OPSS response at a tactical level:

a) **The Tactical Coordination Group: People** — Focused on staff wellbeing, internal communications and business continuity;

b) **The Tactical Coordination Group: Regulatory** — Focused on regulatory easements and business intelligence; and

c) **The Tactical Coordination Group Local Authorities Engagement** — Focused on coordinating local authorities on business closures within England.

7.12. Reporting to these TCGs, Tactical Working Level Groups were responsible for the delivery of specific workstreams (for example communications, evidence, business

closures, hand sanitisers). For further detail regarding OPSS' leadership and governance, please refer to the organogram at SM/058 INQ000477768.

7.13. As set out above, OPSS was responsible for the policy of the safety regulation of PPE, both prior to and during the pandemic. The principal bodies responsible for enforcement of these regulations were HSE, for workplace PPE, and local authorities for consumer PPE. Workplace PPE regulation was the responsibility of HSE as defined through the Regulations — Personal Protective Equipment (Enforcement) Regulations 2018. Please see a copy of this at SM/059 INQ000477775. Consumer PPE enforcement was the responsibility of local authority Trading Standards.

7.14. In addition, OPSS had access to the Secretary of State's enforcement powers in relation to the enforcement of PPE regulations. The increase in PPE demand generated by the pandemic increased OPSS workload, but its remit did not materially change.

7.15. One of the changes to OPSS' activities during the pandemic was advising on, and implementing, regulatory easements relating to PPE. This is discussed in greater detail at Section 8.

7.16. A further change to OPSS' working practice was through the work of the RCC. The RCC was established to rapidly address and overcome regulatory issues resulting from the unprecedented demand for PPE and medical devices. OPSS also undertook market surveillance activities on consumer PPE imports, working with local authority enforcement teams.

Regulatory Standards and the Legislative Framework for PPE

7.17. At the start of the pandemic, the UK was in the EU Exit transition period and subject to EU law. Under the EU framework, adopted in 2008 to strengthen conditions for placing products on the EU market, PPE was a product that was subject to harmonised rules. 'Harmonisation' in this context refers to common standards implemented across the EU internal market ('**the internal market**').

7.18. Council Directive 19/865 ('**the Directive**') set out the harmonised requirements PPE needed to comply with before it could be placed on the internal market. The Directive, based on 'new approach'[5] principles set out the essential requirements which applied to PPE. Technical details were adopted by the European Committee for

[5] EU technical standards have developed over time. The 'old approach' refers to detailed texts containing standardisation requirements. The 'new approach', developed in 1985, restricted the content of legislation to 'essential requirements' leaving the technical details to European harmonised standard.

Standardisation and the European Committee for Electrotechnical Standardisation, in accordance with Regulation (EU) No 1025/2012 of the European Parliament and Council.

7.19. On 9 March 2016, the Directive was replaced by Regulation 2016/425 to ensure greater consistency of standards across Member States. This is set out in further detail at SM/060 INQ000477706.

7.20. This new Regulation governed the design and manufacturing requirements that PPE had to meet before it was sold in the internal market. The purpose of the legislation was to ensure that safe and effective products were placed on the market by requiring manufacturers to show how their products met the Essential Health and Safety Requirements, as listed at Annex II. Both the Regulation and Annex II are provided at SM/060 INQ000477706. This Regulation was directly applicable in the UK from 21 April 2018 and governed the regulatory framework for PPE prior to the pandemic.

'Top 10' UK Manufacturers

7.21. As part of the wider support package for UK businesses looking to increase the supply of PPE, including face masks, visors and gowns, OPSS provided regulatory support to a number of large-scale manufacturers in procurement discussions with Cabinet Office. Please see SM/061 INQ000475467 and SM/062 INQ000478737. Deloitte were instructed by Cabinet Office to identify the top 10 businesses producing the following products:

a) Kingsmoor – eye protection;

b) Numatic – eye protection and masks;

c) Ineos – hand sanitiser;

d) Rolls Royce – gowns and eye protection;

e) McLaren – eye protection;

f) Survitec – gowns;

g) Bentley – gowns;

h) William Grant & Sons – hand sanitiser;

i) Photocentric – eye protection; and

j) Rapuk – eye protection.

7.22. OPSS provided regulatory advice on various matters including:

a) Interpretation of guidance and easements to advise on which regulations and standards may be relevant. Further information on the easements' guidance is discussed at paragraphs 8.25 to 8.35 and exhibited at SM/063 INQ000475300. The guidance for high volume PPE manufacturers is provided at SM/064 INQ000475337 and discussed at paragraph 8.32;

b) Technical requirements including EU standards, World Health Organisation (**WHO**) guidelines and other regulatory matters; see paragraph 7.17 for further detail on the EU standards;

c) Options for manufacturers on how to arrange testing and conformity assessment of relevant products, including identifying the UK Notified Bodies and the most effective way to access the approvals process within the PPE Make workstream; and

d) Any ad hoc queries on meeting the requirements of Cabinet Office DMC. Please see SM/065 INQ000478741.

7.23. OPSS' advice was consistent with publicly available guidance, but the support was proactive given the scale of production these companies were offering. A summary of the support given is set out in updates sent to the senior OPSS team on 20, 21 and 22 April 2020, exhibited at SM/066 INQ000478740, SM/067 INQ000478742 and SM/068 INQ000478744.

7.24. The support given to these potential manufacturers would continue throughout the initial application process until they received approval from a relevant Notified Body. By the end of April 2020, these companies had the information and guidance they needed to decide how to meet any relevant regulatory obligations and OPSS' focus turned to smaller businesses who needed additional support. If a potential manufacturer had been rejected by DMC, OPSS would have provided further advice on meeting regulatory requirements and how to access conformity assessment through Notified Bodies, but none of the companies requested follow up advice. Some manufacturers chose not to continue with the process due to the complexity of the changing manufacturing processes, however OPSS does not hold records confirming which of these potential manufacturers were ultimately awarded government contracts to supply PPE, as this was managed by Cabinet Office.

7.25. OPSS did not specifically liaise with the Notified Bodies on behalf of any manufacturers but had dialogue with UK Notified Bodies to ensure they were aware of the scale of manufacturing being offered by these companies.

Section 8: <u>Regulatory Easements</u>

Legislative Background

8.1. The term regulatory easement refers to the steps taken by Government to ease regulatory process requirements for a time limited period to potentially increase the rate at which compliant PPE could enter the UK market, in line with the European Commission Recommendation 2020/403 ('**the Recommendation**'). The Recommendation was made on 13 March 2020 and can be found at SM/069 INQ000269669.

8.2. The Recommendation addressed conformity and market surveillance procedures within the context of the pandemic and was directed at all economic operators within the supply chain as well as Notified Bodies and Market Surveillance Authorities. Its objective was to ensure that a greater volume of compliant PPE and medical devices could reach markets quickly, without compromising health and safety. To note, Notified Bodies are independent organisations appointed by EU Member State governments and notified to the European Commission to carry out the procedures for conformity assessment and certification set out in the Regulation.

8.3. The Recommendation enabled the UK Government to potentially speed up the supply of essential PPE for a limited time. Under Article 19 of the Regulation, PPE within scope was subject to a conformity assessment in accordance with its risk categorisation (specified at Annex I of the Regulation). The Recommendation altered, or 'eased', this requirement for a limited time provided the PPE still met all Essential Health and Safety Requirements.

Easement in respect of PPE not Purchased by Government for Frontline Healthcare Workers

8.4. In the case of PPE not purchased by Government for frontline healthcare workers, provided conformity assessment procedures had been started via a Notified Body, the easement permitted PPE to be put on the market before the product had an affixed CE Mark confirming all checks had been completed. The CE marking of PPE was never suspended, only delayed.

8.5. The CE marking was affixed by the manufacturer to confirm their own assessment that a product had met EU requirements and that the appropriate conformity

assessment procedures had been completed. It provided an important indication to buyers that the products met all the legal requirements to be sold throughout the EEA Single Market. However, it was not necessary to ensure product safety provided the conformity assessment was undertaken.

8.6. Conformity assessment is the process where a manufacturer or importer must attest to the safety of the product. In some cases, this requires a third-party organisation, usually a test house, to carry out tests and assess the product and then declare it meets the Essential Health and Safety Requirements of the relevant Regulations. The easements did not alter the obligations on the manufacturer to make sure the items complied with the Essential Health and Safety requirements.

8.7. Manufacturers seeking to use the easements would be expected to demonstrate full compliance with the Essential Health and Safety Standards to the Notified Body, with information on the design, manufacture and testing of the products, but would not need to seek third party certification. Although such certification provided a layer of assurance, responsibility for health and safety always has been with the manufacturer. OPSS was confident legitimate manufacturers would act responsibly and ensure the products they were making were fully compliant. The change was therefore focussed on streamlining the processes in place to get the product onto the market more quickly.

Easement in respect of PPE Purchased by Government for Frontline Healthcare Workers

8.8. In the case of PPE purchased by Government for frontline healthcare workers, PPE could be placed on the market without conformity assessment, provided it was manufactured in line with relevant European, WHO or other technical standards, and had been approved by the Market Surveillance Body, HSE.

8.9. Conformity assessments could be undertaken by HSE. HSE produced technical specifications for PPE and published guidance on the gov.uk website. Please see SM/070 INQ000477778. To ensure maximum supply to the NHS and the best use of resources this route of assessment was only available to large-scale manufacturers. Please see SM/071 INQ000475368.

8.10. The Recommendation also stated regarding:

a) **Conformity assessment procedures** — That Notified Bodies should prioritise conformity assessment activities for Covid-19 specific PPE and conduct these swiftly; and

b) **Market surveillance procedures** —That Market Surveillance Authorities were permitted to allow PPE that had been tested in other jurisdictions with similar safety requirements to be placed on the market without being EU conformity assessed, provided it had been approved in those other markets. It further stated that relevant Market Surveillance Authorities should prioritise action against non-compliant PPE and medical devices.

8.11. OPSS was not responsible for setting the technical specifications for PPE or PPE standards, either prior to, or during the pandemic. Its role was to provide advice and guidance on compliance with the regulatory requirements to manufacturers and others, see for example SM/072 INQ000477763. This is discussed in further detail at paragraph 7.5. For PPE intended for use in healthcare settings, technical guidance was published by Public Health England (**PHE**), in response to NHS clinical requirements.

Regulatory Easements: Implementation in the UK

8.12. Following the EU Recommendation, the easements were given careful consideration by senior officials and Ministers before implementation. Following discussion at the Covid-19 SCG on 19 March 2020, see SM/073 INQ000475256, the Secretary of State gave an initial positive response to the easements on 20 March 2020. Please see SM/074 INQ000475257.

8.13. On 24 March 2020, the Secretary of State met with OPSS' Deputy Director and agreed to proceed with implementing the two easements set out above. The Secretary of State emphasised that the easements should be taken forward in a manner that continued to offer high levels of protection for consumers and workers. He sought reassurance from officials that OPSS' work with HSE and other government departments did not compromise product safety. Please see SM/075 INQ000475266 and SM/076 INQ000477662. Implementing the easements did not necessitate a change to the Regulations as they were delivered through administrative measures.

8.14. The Secretary of State raised the easements at EBRIG meetings on 26 and 27 March 2020 for discussion. The Secretary of State did not require collective agreement to implement them. Please see SM/077 INQ000475277. The paper submitted for discussion by the Department Secretariat is exhibited at SM/078 INQ000475273 and SM/079 INQ000475274. The briefing provided by OPSS to the Secretary of State is available at SM/080 INQ000475261, and the briefing provided by the Cabinet

Secretariat is available at SM/081 INQ000475275. Officials noted at the EBRIG meeting on 26 March 2020 that adopting this approach would allow for consistency with the regulatory stance taken in Spain and Germany and, if implemented, the easements would make it *"easier for the NHS to access PPE for frontline staff, while maintaining appropriate levels of safety and efficacy"* as well as *"facilitate increased production by existing and new manufacturers, and placing on the UK market from overseas suppliers not previously selling to UK market".*

8.15. The risk of allowing non-effective or unsafe products on the market was noted, but Department officials recommended implementing the easements, as it was considered highly unlikely that the risk would manifest itself from legitimate manufacturers using the easements process. In practice, those manufacturers were very likely to comply with all necessary health and safety requirements and worked closely with OPSS. New, fraudulent manufacturers seeking to exploit the increased demand for PPE would realistically not engage with the relevant requirements, and as such, were unlikely to make use of the easements. The risk of unsafe PPE reaching the market was managed through separate enforcement action taken as part of Operation Safeguard — an enforcement operation at UK ports which provided support to local authority Trading Standards teams dealing with non-compliant PPE. Operation Safeguard is discussed in more detail at paragraph 9.3.

8.16. Following the meeting on 27 March 2020, relevant departments were directed that they *"should proceed with measures to increase the supply of PPE".* Please see formal read out and actions from the meeting at SM/082 INQ000475286 and SM/083 INQ000083300.

8.17. As confirmed by Cabinet Office minutes of the EBRIG meeting on 27 March 2020, please see SM/084 INQ000475288, the following points were made and noted, on the use of the two regulatory easements:

"a) simplifying the approvals process for newly produced or imported personal protective equipment and hand sanitiser was sensible, but clinical standards set by PHE, MHRA and HSE must be maintained. Otherwise, there would be a loss of confidence in these products;

b) when these changes were announced the messaging should be clear that regulatory processes had been streamlined, rather than standards being lowered…"

8.18. On 29 March 2020, the Secretary of State wrote to the BEIS Select Committee and Rt Hon Rachel Reeves MP to announce the use of regulatory easements for PPE. Please see SM/085 INQ000475280. The use of the easements was announced in the press on 30 March 2020. Please see SM/086 INQ000475279 and SM/087 INQ000475283.

HSE's Involvement with the Regulatory Easements

8.19. HSE, as the national regulator for workspace health and safety, was responsible for compliance and enforcement of workplace PPE Regulations. During the pandemic, HSE was the Market Surveillance Authority for workplace PPE. This included the PPE used in the NHS, as per Regulation 3 of the Personal Protective Equipment (Enforcement) Regulations 2018. The Health and Safety Executive Northern Ireland was the relevant Market Surveillance Authority in Northern Ireland. For private, consumer or domestic use of PPE, local authorities were the Market Surveillance Authorities. OPSS, through the Secretary of State, had access to enforcement powers alongside local authorities.

8.20. Following the decision by the Secretary of State to implement the easements, OPSS drafted a letter to HSE, Notified Bodies and local authorities. On 25 March 2020, Sarah Smith (Deputy Chief Executive, OPSS) wrote to Rick Brunt (Head of Operational Strategy, HSE) to request that HSE "*prioritise over other market surveillance work, the clearance or otherwise of non-compliant PPE that is necessary for protection against Covid-19, to ensure that it meets Essential Health and Safety Requirements*". This is provided at exhibit SM/088 INQ000269653 with the covering email at SM/089 INQ000475271. Ms Smith also asked HSE to review non-compliant PPE which could meet safety requirements but was non-compliant for another reason. She set out that this PPE would be evaluated to determine whether it could be used to meet demand, even if it was not CE marked and had not undergone conformity assessment. Further, Ms Smith also recommended that if HSE's evaluation of non-compliant PPE deemed it unsafe and a serious risk to users then appropriate enforcement action should be taken, as provided for in the 2018 Regulations.

8.21. On 25 March 2020, Ms Smith also wrote to Local Authority Heads of Service, Regional Coordinators and members of the National Product Safety Group with the same request to prioritise the clearance of otherwise non-compliant PPE over other market surveillance work. This is exhibited at SM/090 INQ000477680. On the same

day Notified Bodies were also provided with guidance, exhibited at SM/091 INQ000477681, which urged them to prioritise conformity assessing all newly submitted PPE deemed necessary for protection in the context of the Covid-19 emergency.

8.22. During this early stage of the pandemic, HSE was limited in its ability to proactively undertake market surveillance and OPSS identified that it required urgent regulatory assistance. On 2 April 2020, OPSS officials advised Paul Scully MP (Minister for Small Business, Consumers and Labour Markets) and me, that there was a specific need to support businesses seeking to import compliant PPE, help new manufacturers understand PPE compliance requirements as well as address the risk of non-compliant products. To address this need, OPSS (as the policy lead for PPE) provided advice to HSE to support it in its role as the Market Surveillance Authority and ensure "*new suppliers or to non-EU technical standards to be assessed and supplied as quickly as possible".* More detail regarding this can be found at SM/092 INQ000475294. OPSS' support of HSE as the Market Surveillance Authority is set out in more detail in the 'PPE at ports' section at paragraph 9.2, and 'Daventry' section at paragraph 9.18 of the statement.

8.23. As a stipulation of the easement's introduction, OPSS requested data from all regulatory actors in the PPE easement process. This included HSE and any UK Conformity Assessment Bodies that had granted products quicker passage through conformity assessment process using the easement. OPSS periodically collated the data and presented it internally and to HSE. HSE expressed concern that the data collection and collation exercise did not cater for the complexity of their part in the easement implementation and commenced their own data gathering exercise. OPSS did not receive further updates from HSE on this separate exercise, and OPSS ultimately ceased its own data collation and assessment exercise once the easement ceased to have effect. Please see SM/093 INQ000475497 for an account of this process.

8.24. Data were collected on a quarterly basis by OPSS on both regulatory easements. Data on the first easement, that is the easement related to use by non-frontline healthcare workers, were collected from the BSI. Other Notified Bodies were contacted but did not have any further data that they could provide. Data on the second easement, the PPE easement for Government purchased PPE for use by frontline healthcare workers, were collected from HSE. The data collection ran for the

entirety of the easement period. Both data sets were split down by PPE product type. Please see SM/094 INQ000477765. A more detailed account of these data is provided at the 'Regulatory Easements: Use in Practice and Wind Down' at paragraph 8.50 and 'Lessons Learned' starting at paragraph 10.1 of this statement.

Regulatory Easements: Guidance

8.25. OPSS, as the organisation responsible for the policy and regulation of PPE safety, ensured that the easements introduced did not downgrade or compromise the efficacy of PPE through the provision of guidance. Manufacturers and importers were responsible for conducting technical assessments for PPE. The successive versions of guidance provided below pointed to the BSI and WHO standards to ensure the UK was implementing rigorous and globally recognised standards.

8.26. Sector business guidance for PPE was published by OPSS as part of its role as regulator. OPSS provided guidance on the Regulation, as well as the easements introduced under the Recommendation. This guidance, published on 4 April 2020, and exhibited at SM/063 INQ000475300, provided advice on:

a) **PPE's regulatory scope** — The guidance defined PPE as equipment, its essential components, or connection systems, designed and manufactured to be worn or held by a person for protection against risks to their safety;

b) **The Regulation's requirements** — The guidance set out that the Essential Health and Safety Requirements applied to all PPE within the scope of that Regulation. Under Article 19, all PPE within scope had to undergo a conformity assessment procedure in accordance with its risk categorisation to demonstrate compliance. Under the easements, PPE specified as necessary for protection in the context of the Covid-19 outbreak had to continue to meet the Essential Health and Safety Requirements;

c) **Obligations** — The guidance set out that, under the easement, manufacturers still had to ensure that PPE had been designed and manufactured in accordance with Essential Health and Safety Requirements, but that a conformity assessment, technical documentation and affixed CE marking were no longer required;

d) **Authorised representatives' obligations** — The guidance set out that manufacturers could appoint authorised representatives to retain the declaration of conformity and technical documentation at the Market

Surveillance Authority's disposal for 10 years after it was placed on the EU market. Further, they were obligated to assist and co-operate with them in any request they may have;

e) **Importers and distributers' obligations** — The guidance set out that Covid-19 related PPE purchased by Government for use by frontline health workers did not have to undergo conformity assessment procedures but could be imported and purchased without the CE marking or Declaration of Conformity, provided it met the Essential Health and Safety Requirements. The guidance further set out that other Covid-19 related PPE could be imported and sold, provided conformity assessment procedures had commenced, but were not necessarily completed;

f) **Notified Bodies** — The guidance provided details of Notified Bodies and notified to the European Commission to carry out the procedures for conformity assessment and certification; and

g) **Enforcement** — The guidance set out that the enforcement regulations gave powers to enforcement authorities to act against economic operators for PPE that did not conform with the Regulation. They also set out that manufacturers, distributors, and importers had to co-operate with the enforcement authority on request. The guidance further stipulated that the Secretary of State had powers to enforce the EU PPE Regulation on Accreditation and Market Surveillance (765/2008) and that UK Market Surveillance Authorities would take all appropriate measures to withdraw products or to prohibit and restrict their supply.

Guidance for High Volume Manufacturers

8.27. After publishing the guidance above, OPSS produced specific guidance for new manufacturers seeking to produce Covid-19 PPE. OPSS published its guidance for high-volume PPE manufactures on 4 April 2020. This guidance is exhibited at SM/095 INQ000475302. This guidance provided advice to those who wanted to switch their manufacturing process to make high volumes of PPE. It also advised that the extent to which conformity assessment procedures had been eased depended on the eventual customer for the PPE, either:

a) **Healthcare workers** — Where the manufacturer only intended to sell or donate the PPE to the NHS via the Government. In these instances, before it was

purchased or donated to the Government for use in the NHS it was required to meet all the criteria listed at 8.28 below; or

b) **The key workers in public and private healthcare companies** — Where manufacturers intended to sell PPE to distributors, retailers or directly.

8.28. PPE intended for use by healthcare workers was required to meet all the following criteria:

a) That the products were manufactured according to either:

i. A relevant harmonised EU standard;

ii. Any of the standards referred to in the WHO guidelines; or

iii. Any other non-EU standard or technical solution, provided that the chosen standard or technical solution ensured an adequate level of safety in respect to the Essential Health and Safety Requirements.

b) That the products:

i. Had been assessed against the standard(s) or technical solution chosen by the cross-government DMC, which comprised HSE, DHSC, MHRA and OPSS. More information regarding DMC can be found at paragraph 5.2 to 5.7;

ii. Were part of a purchase organised, or donation agreed, by the Government or the NHS;

iii. Were only to be made available for healthcare workers;

iv. Were only to be made available for the duration of the current outbreak of Covid-19; and

v. Were not to enter regular distribution channels and were not to be made available to other users.

8.29. The guidance set out that prospective manufacturers were required to register their interest online and send the relevant compliance documentation to DMC. The guidance also stipulated that PPE intended for use by non-healthcare workers was required to meet the Essential Health and Safety Requirements at Annex II of the Regulation, and to be assessed in line with the Recommendation's regulatory easements. This meant that any PPE produced did not need to complete conformity assessment requirements, but the product had to be in the conformity assessment

process with a Notified Body; and the Notified Body had to attest that the product would have passed the conformity assessment process, had it been in place.

8.30. The guidance set out that products would then be subject to simplified product testing whereby it was the Notified Body's responsibility to specify what evidence it required to determine if the Essential Health and Safety Standards had been met.

8.31. PPE manufactures were advised that, following approval, they must:

a) Keep the technical documentation for 10 years after the PPE had been purchased;

b) Ensure that processes were put in place for series production to remain approved by DMC or Notified Body;

c) Perform sample testing and keep a register of complaints regarding products which do not meet the Essential Health and Safety Requirements;

d) Ensure that the product bore a type, serial or batch number, or any other element allowing for its identification; and

e) Ensure that the product was accompanied by clear, legible instructions and safety information in English, as provided at Section 1.4 of Annex II of the Regulation.

8.32. The guidance for high volume manufacturers was updated multiple times. A list of these updates and a summary of the substantive amendments in each version is set out below.

a) **Version 2 — April 2020** exhibited at SM/064 INQ000475337. The guidance was updated to incorporate information on donated PPE.

b) **Version 3 — May 2020** is exhibited at SM/096 INQ000475358; The guidance was updated to:

i. Confirm the easement allowed PPE to be placed on the market once assessment had commenced, but prior to its completion, and provided the Essential Health and Safety Requirements had been met;

ii. Clarify that the easements were applicable to all Covid-19 PPE for all workers, not just healthcare workers; and

iii. Clarify that, before placement on the market, manufacturers had to contact Notified Bodies via an application (an email was insufficient) and

receive confirmation they had been accepted into the assessment process as well as provide confirmation of their accepted application.

c) **Version 4 — May 2020** is exhibited at SM/097 INQ000475388. The guidance was updated to:

i. Include a link to the simplified specifications issued by HSE;

ii. Update the centralised PPE acquisition process by the Government; and

iii. Include a section setting out importers' duties under the easements.

d) **Version 5 — July 2020** is exhibited at SM/098 INQ000475426. The guidance was updated to:

i. Reflect the closure of the Government PPE Offers Portal and move to a competitive tendering process;

ii. Remove the requirement for the Notified Body number to be placed on each individual piece of PPE; and

iii. Align the traceability requirements for both large-scale and small-scale manufacturers.

e) **Version 6 — September 2020** is exhibited at SM/099 INQ000475451. The guidance was updated to:

i. Incorporate the European Commission guidance on Recommendation 2020/403; and

ii. Set out the role of the Market Surveillance Authority in approving Covid-19 related PPE before it could be placed on the UK market. The guidance also clarified that non-CE marked PPE could not be placed on the EU market.

f) **Version 7 — September 2020** is exhibited at SM/100 INQ000146526. The guidance was updated with simplified text in respect to Transitional Arrangements for PPE on the market under previous arrangements.

8.33. OPSS published detailed guidance for small-scale manufacturers on 6 May 2020. This is exhibited at SM/071 INQ000475368. The guidance set out the steps small scale manufacturers were expected to follow to ensure their PPE provided effective protection against Covid-19. These were:

a) **Step 1** — Ensuring that the PPE made could protect against Covid-19. This was split into two methods. If small scale manufacturers followed a relevant 'BS'[6] or 'EU' standard their PPE would be presumed to comply with Essential Health and Safety Requirements. Otherwise, manufacturers should follow another technical solution such as a US standard or a standard referenced in the WHO PPE guidelines, provided at SM/101 INQ000478109; and

b) **Step 2** — Arranging for a third party to assess whether the PPE was safe. This set out that, whichever of the above approaches was chosen PPE would need to be assessed by a Notified Body.

8.34. To assist small scale manufacturers, the guidance provided a simplified version of HSE produced technical specifications exhibited at SM/102 INQ000269668. It noted that whilst the guidance was for PPE being supplied through a specified high volume channel for use in the NHS, it should still provide a useful guide.

8.35. The guidance documents for small scale manufacturers were also updated multiple times. A summary of the updated versions and any substantive amendments are set out below:

a) **Version 2 — 2 July 2020** update at SM/103 INQ000475428. This version was updated to:

i. Reflect the closure of the Government PPE Offers Portal and move to competitive tendering;

ii. Remove the requirement for the Notified Body number to be placed on each individual piece of PPE;

iii. Align the traceability requirements for both large-scale and small-scale manufacturers;

b) **Version 3 — 3 September 2020** is exhibited at SM/104 INQ000475450. This version was updated to incorporate the updated European Commission guidance Recommendation 2020/403. The principal amendment set out the role of the Market Surveillance Authority in approving Covid-19 related PPE before it could be placed on the UK market and clarified that non-CE marked PPE could not be placed on the EU market; and

[6] BS standards refers to the standards produced by the British Standards Institution.

c) **Version 4 — September 2020** is exhibited at SM/105 INQ000146527. This version was updated with simplified text in the Transitional Arrangements section.

Regulatory Easements: EU Commission Guidance Updates and Implementation

8.36. OPSS continued to update their guidance on the easements based on new guidance from the European Commission. On 10 July 2020, the Commission updated their guidance on implementing the Recommendation. The revised guidance applied to the first easement, for PPE which was not procured by the government for frontline healthcare workers. It clarified the Commission's view that the relevant Market Surveillance Authority should be responsible for clearing PPE which met Essential Health and Safety requirements in advance of normal conformity assessment being completed. The guidance set out the following:

a) **The role of the Market Surveillance Authority** — In the case of Covid-19 related PPE intended for the workplace, HSE was primarily responsible for confirming PPE met the essential safety requirements and allowing its placement on the market to be fast-tracked;

b) **Conformity assessment completion required** — The new guidance defined the 'limited period of time' between placing of non-CE marked batches and CE marked batches on the EU market as *"normally only a few days";*

c) **Traceability** — Market Surveillance Authorities were guided to ensure that all economic operators had set up an efficient and functioning tracing system. In the instances where the conformity assessment later identified serious risks, there had to be a means of recalling the product from the market;

d) **PPE end users** — The new guidance made it clear that PPE under the easement could be made available to industrial users and consumers, not just to healthcare workers, provided there was adequate training and the Market Surveillance Authority was able to specify the requirements for labelling/marking of pre-CE marked products; and

e) **No free movement for non-CE marked products** — Finally, the guidance set out that there was to be no free movement of non-CE marked products across the EU, and the relevant Market Surveillance Authority could only approve movement across its own Member State. The conformity assessment guidance for manufactures is provided at SM/106 INQ000475281.

8.37. To summarise, the guidance resulted in four main changes:

a) Market Surveillance Authority approval would be required before placing PPE on the market where conformity assessment had not yet been completed;

b) Only a limited period of a few days would be permitted between the placing on the market of such PPE and the completion of conformity assessment and CE marking;

c) The easement was not limited to healthcare workers but applied to PPE which could be made available to industrial users and to consumers; and

d) The Market Surveillance Authority approval only applied to the UK Market and could not be transferred to another Member State. That is, if a PPE manufacturer had obtained HSE approval this could not then be used to place PPE on, for example, the German market, without approval by that Member State's relevant Market Surveillance Authority.

8.38. In an email dated 27 July 2020 HSE officials confirmed they, as the relevant Market Surveillance Authority, had sufficient capacity to take on this role going forward. OPSS agreed to work with HSE so that they could operate alongside the relevant Notified Body and clear PPE where it had not yet completed a conformity assessment. Please see SM/107 INQ000477746.

8.39. At the time of the update, OPSS considered the effect of the change to be limited due to the low adoption rate for the non-healthcare easement outside of both the public and private healthcare sector.

8.40. OPSS considered that the impact of the change would be further limited by the fact that any PPE already approved under this easement had to be in the process of conformity assessment with a Notified Body, so in effect the easement itself was time limited if all PPE completed the normal process in time. A summary of these changes and their implications can be found at SM/107 INQ000477746.

8.41. There were no significant changes to the second easement, which allowed UK authorities to procure PPE for frontline healthcare without conformity assessment. This second easement had been used extensively by DHSC and NHS Procurement to supply the NHS since being adopted in March 2020. OPSS updated its guidance accordingly, so manufacturers were aware of the change and endeavoured to work with Notified Bodies to implement the change. This guidance is exhibited at SM/108 INQ000475433.

Regulatory Easements: Issues Raised

8.42. OPSS operated a Business Reference Panel (**BRF**). This panel provided an opportunity for businesses, and representative groups to discuss emerging issues, explore business thinking and identify potential solutions. During the pandemic, it provided a forum to engage businesses in OPSS' work, and share concerns. OPSS held regular meetings with PPE trade associations to discuss best practice and consistency of application of PPE regulation. Please see SM/109 INQ000475432.

8.43. The British Safety Industry Federation (**BSIF**), the UK's main PPE trade association, raised concerns at a BRF held on 4 June 2020. The BSIF highlighted that, despite the number of PPE items intercepted at UK ports of entry, the market was still "*awash*" with non-compliant respiratory protective equipment. Please see SM/110 INQ000478761. BSIF's Chief Executive Officer followed up these concerns with HSE on the same day, setting out that they were *"living under real threat of losing members because we have told them that they should not sell non-compliant PPE (unless under the conditions of easement 2020/403) while they see many, many others selling KN95 (as FFP2) and other non - compliant RPE without sanction"*. They also noted that this stance was causing them to lose market share to other businesses.

8.44. This communication was forwarded onto OPSS who acknowledged that a *"real challenge"* for OPSS was how they could communicate the *"enforcement/bad PPE story"*. Concerns regarding highlighting non-compliant PPE issues had to be weighed against concerns from BEIS' Communications team, as well as Cabinet Office, regarding the media and public perception of PPE being blocked due to 'red tape'. Despite this challenge, OPSS agreed that this was a serious concern and BSIF required swift support. A follow up call was organised with Sarah Smith who spoke with BSIF CEO, Alan Murray, to hear directly about members' concerns and provide details of how intelligence about non-compliant products and bad actors in the supply chain could be fed into the regulatory system. This communication can be found at SM/111 INQ000477723. OPSS responded to these concerns through its intelligence work on 'Operation Safeguard' and Daventry. OPSS' Intelligence Team sourced referrals and aided local and central authorities in implementing product control efforts. These referrals provided intelligence to staff undertaking the checks at the Daventry site. These are discussed in further detail at Section 9.

8.45. On 18 June 2020, BSIF contacted OPSS and HSE and set out that, following their 4 June 2020 email, they were now at the stage of expelling a member who had been

selling KN95 masks and resisted BSIF attempts to communicate and encourage compliance. BSIF did not identify the member, and OPSS therefore do not have a record of this supplier. The email highlighted that BSIF felt isolated as other Market Surveillance Authorities had not acted on non-conforming products in the domestic supply chain and sought advice on how to manage the appearance that rules without enforcement were not adhered to. OPSS were not the Market Surveillance Authority, and therefore did not retain a central record of suppliers reported to be non-compliant. BSIF highlighted that they had reported over 200 suppliers of non-compliant PPE. HSE advised that it was not for the regulator to comment, and that HSE PPE unit was a dedicated resource regulating the supply of PPE to the UK healthcare system. HSE explained it had a remit for technical assessment and regulatory activities to prevent PPE which did not reach the required standards from entering UK supply, but assured BSIF they were acting to ensure that PPE supplied on the GB Market protected the workers that used it. Please see SM/112 INQ000477734. BSIF reported suppliers to the OPSS intelligence team, HSE, and Trading Standards. A record of the suppliers reported is provided at SM/112a INQ000498075. The OPSS intelligence team collated the reports and uploaded them to a central database, the IDB system, which was used to notify trading standards authorities. The respective Market Surveillance Authority progressed the reports, and OPSS are not aware of what was action was taken as it fell outside their remit.

Regulatory Easements Case Study: Chief Medical Officer (CMO) Objections and the Eventual Adoption of N95 Masks into the UK Market

8.46. In March 2020, there was uncertainty within OPSS about whether N95 masks, the clinical standard of respirator masks in the US, could be placed on the UK and EU markets through the newly established regulatory easements. On 24 March 2020, internal OPSS emails reflected uncertainty regarding whether HSE was planning to authorise USA-standard N95 masks for emergency use in the UK. The emails refer to HSE's *"initial, unpublished, assessment*" that:

"an N95 mask approved for use in the US will meet EU essential safety requirements and therefore could be placed on the EU market subject to the EU's Recommendations on relaxed conformity assessment/market surveillance i.e. a CE mark is not necessarily required."

8.47. Further emails demonstrate that OPSS was planning to include this announcement in the letters they were drafting to PPE Market Surveillance Authorities. Please see SM/113 INQ000475265. However, following a call between OPSS' Sarah Smith and

Rick Brunt at HSE, this assessment was not included in OPSS' letters to PPE Market Surveillance Authorities as the CMO wanted to consider a broader position on USA PPE. Please see SM/114 INQ000475268. In response, OPSS redrafted the press release intended to accompany letters to Market Surveillance Authorities and Notified Bodies, provided at SM/115 INQ000475270 This redraft removed reference to N95 masks meeting the EU Essential Health and Safety Requirements and a statement that they could be placed on the UK market immediately, and replaced it with a statement that OPSS was also working with HSE who were "*urgently considering whether masks approved for markets outside the UK/EU will meet essential safety requirements and so can be supplied immediately*". The subsequently published version is provided at SM/116 INQ000475272.

8.48. Following this, HSE and OPSS considered the position on N95 compliance. On 30 March 2020, OPSS and HSE colleagues held a call regarding N95 and EN149 masks. Please see SM/117 INQ000477674. Key outcomes from that call, noted in an email between attendees, set out that HSE would provide clear guidance on EU equivalence of standards with international standards e.g. equivalence of FFP2 and NIOSH N95 masks. These are provided at SM/118 INQ000475295.

8.49. On 19 April 2020, an internal document was produced by an OPSS member of staff regarding potential specification for public-use face masks. This document considered N95 masks' technical suitability and suitability in other contexts for use by the general public as well as the suitability of a range of other types of masks including FFP2 masks. The official did not conduct technical experiments and considered information publicly available at the time. The paper stated that PPE masks rated at FFP2/N95 or higher provided a significant level of protection to the wearer if they fit well and were used correctly. Please see SM/119 INQ000475328. HSE published a Rapid Evidence Review on 22 April 2020, which was led by the Government's Chief Scientific Adviser. The Review outlined why the N95 mask was a suitable product for UK markets, and that it was comparable to the preferred EU standard of the FFP2 mask. It drew upon the input of several other market standards, including Germany, the USA, and the WHO to support its conclusion as to the safety of the N95 mask. Please see SM/120 INQ000477684. By 23 April 2020, PPE purchasing guides included N95 masks. However, in a guide jointly produced by the OPSS and HSE in April 2020 to support procurement, N95 were deemed to be third in the hierarchy of purchasing priorities after the EU-approved FFP3 and FFP2 masks. Please see SM/121 INQ000478745. By 14 July 2020, N95 and N99 masks were deemed as

equivalent to the FFP2 and FFP3 masks respectively and were identified by the Department as the relevant standard when purchasing PPE in the Department's guidance for Economic Operators. Please see SM/122 INQ000475429.

Regulatory Easements: Use in Practice and Wind Down

8.50. In November 2020, OPSS at Cabinet Office's request prepared an evaluation on the use of the regulatory easements. OPSS noted that the data was incomplete, limited and that it was not possible to compare the two easements. Please see covering email at SM/123 INQ000475466 and presentation at SM/124 INQ000477756. An account of that report is provided below. The data used in the presentation was provided to the OPSS by HSE and anecdotal evidence from BSI and test houses. A collation of the data is provided at SM/124a INQ000508357.

8.51. Between April and September 2020, 257 PPE products, not for NHS use, made use of regulatory easements. This included 156 mask products. More products were making use of the easements than not, by an average of 53%. OPSS analysis saw this as a correlation to the need to quickly get products to market because of demand rapidly increasing.

8.52. OPSS reported that, according to the BSI, the average approval time for a product not making use of the easements would be estimated at 12 weeks for masks, two to three weeks for screens and 15 weeks for clothing. The average time for products under the easements was significantly less at approximately two weeks at the beginning of the pandemic, and approximately five weeks by November 2020. The BSI estimated that amongst those products using the easements, there was an 85% fail rate on masks, 26% on face screens and 60% on clothing during the conformity assessment process. These figures were not unexpected as there were a number of new manufacturers entering the market, and the easement effectively moved forward the conformity assessment to an earlier stage. Although these products did not ultimately reach the market, there was a high level of confidence that the products which did pass approval under the easement were safe for consumers.

8.53. Between April and September 2020, 94 PPE products for the NHS made use of regulatory easements and received approval. This included 37 mask products. 59% of PPE easement applications were successful. The peak of PPE easement use for NHS PPE was in April – July 2020, correlating with a need to get PPE to NHS facilities as patient numbers increased. The fail rate for NHS PPE was also high: for masks the fail rate was 60%, for face screens it was 31%, and for clothing it was 55%. In

total, between April and September 2020, 351 different PPE products used regulatory easements across both NHS and non-NHS settings. 81% of these were face masks/shields.

8.54. A further 'light touch' easement evaluation, spanning March 2020 to June 2021, was presented to the RCC for discussion on 28 October 2021 to provide an overview of OPSS' data collection on easements. Please see SM/094 INQ00077765 and covering email SM/125 INQ000475489. The findings, drawn from HSE and BSI Data, were that:

a) From April 2020 – June 2021, 497 different PPE products made use of regulatory easements across the NHS and the general market;

b) More products successfully used easements in the general market (non-NHS PPE);

c) The majority of products using easements across both markets were face masks and shields, at 83%;

d) For both easements there was particularly high use in May, June and July 2020 making up 50% of total use up to the time of the presentation; and

e) At the height of the pandemic, April to July 2020, manufacturers chose to make use of regulatory easements to expedite the process of getting PPE products to market. The presentation noted that, on the NHS side, this rapidly dwindled to effectively no use of easements in the beginning of 2021 as the NHS had increased their stock to a sufficient level. The easement and its successor domestic legislation enabled the internal distribution of some of that PPE from central stocks to the frontline. For PPE which was not procured by the Government for frontline healthcare workers, there was still some use of easements, particularly in January 2021, but there were still far more products not making use of them.

8.55. Further detail regarding these findings and their implications can be found at the Lessons Learned section of this statement, starting at paragraph 10.1.

8.56. Regarding Government purchased PPE used by frontline healthcare workers, one of the clinical leads at the Cabinet Office stated that the NHS easements had been of "*essential importance*" and that the vast majority of PPE products required an easement, especially non-CE marked products which came from Asia. Please see SM/094 INQ00077765. This was attributed to the conformity assessment by a

Notified Body requiring a two to three month turnaround time. The easement process crucially reduced decision-making time by half.

8.57. On 16 November 2020, OPSS met with HSE and Dr Darren Mann from PPE Make to discuss the status of the easements as the UK approached EU Exit. It was agreed that the easements were still needed. They discussed whether easements had led to more poor-quality PPE being imported, with HSE reporting that rejections under the easements had been higher than normal, and more non-compliant products had reached the market. It was noted that, prior to the pandemic, HSE considered PPE to be a low-risk, mature product and that, from this low base, HSE was seeing more non-compliant products. Please see SM/126 INQ000475470. Further information regarding the transition to EU Exit and its impact on the easements is set out below.

Transition to EU Exit

8.58. Prior to the UK's departure from the EU, legislation was passed to continue these easements and facilitate the production and supply of PPE during the pandemic. The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (England) Regulations 2020 came into force at the end of the implementation period. These Regulations provided that up to 31 March 2021, PPE that usually required a conformity assessment by a Notified Body could instead be placed on the market without having completed the conformity assessment process. HSE was still required to certify the PPE as compliant with all relevant health and safety requirements. The easement was extended to 30 June 2021 for PPE purchased by or on behalf of the NHS for use by healthcare or specified frontline health and care sector workers. Please see the Personal Protective Equipment (Temporary Arrangements (Coronavirus) (England) Regulations 2020 provided at SM/127 INQ000477759.

8.59. Regulation 2016/425 provided the regulatory requirements for PPE in the UK. The Personal Protective Equipment (Enforcement) Regulations 2018 provided the domestic system for enforcing compliance with Regulation 2016/425. These Regulations were preserved by the EU Withdrawal Act 2018 and the safety and technical requirements for PPE compliance did not change upon the UK's exit from the EU. Following EU Exit, the relevant domestic regulation was then amended by the Product Safety and Metrology etc (Amendment etc) (EU Exit) Regulations 2019.

8.60. On 31 December 2020, at the end of the transition period, UK businesses that used to act as a 'distributer' legally became an 'importer' if they placed products from the European Economic Area (**EEA**) country onto the UK market. In this instance, the

businesses had adopted importer obligations for EEA-supplied goods. The November 2020 guidance OPSS produced for equipment being sold in Northern Ireland is exhibited at SM/128 INQ000477757.

8.61. The Government also announced that it intended to implement a new 'Fast-Track' provision which would allow manufacturers to place products on the UK market where they met the EU essential requirements and, where required, they had been conformity assessed by a Notified Body. To benefit from this provision, manufacturers would be required to affix the UKCA marking and draw up the UK declaration of conformity, listing compliance with the relevant EU legislation. If products were to fall within multiple regulations, a mixture of both UKCA and CE conformity assessment procedures would be able to be used. This proposed regulatory scheme was designed to provide longer-term certainty and flexibility for businesses should the UK mandate UKCA affixture for certain regulations in the future. Please see SM/129 INQ000477776 and SM/130 INQ000477777.

Section 9: <u>PPE Compliance and Monitoring</u>

9.1. OPSS responded to the demands of monitoring the quality and compliance of PPE in the UK during the pandemic in a number of ways. As discussed at paragraphs 5.7 to 5.14, the RCC and its interaction with other regulators, bodies and DMC were a key part of OPSS' response to the demands during this period. Not only did RCC attendees note the usefulness of the meetings at the time, please see SM/131 INQ000475486, the RCC was later identified in OPSS Covid Lessons Learned reflections as a useful forum and comprised one of its recommendations for further coordination between regulators. It was subsequently included in the 18 January 2021 iteration of the Incident Management Plan, please see SM/132 INQ000477760. In addition to this ongoing engagement, OPSS undertook the following steps:

a) **Initiated 'Operation Safeguard'** — Operation Safeguard monitored PPE compliance at ports of entry and aimed to prevent potentially unsafe and/or non-compliant PPE entering the UK (discussed further at paragraphs 9.2 to 9.7);

b) **Monitored online suppliers of face masks and hand sanitisers** — OPSS addressed non-compliant products with referrals to the appropriate Market Surveillance Authority and requests to the online selling platforms to remove the products from those platforms;

c) **Provided advice and training for Cabinet Office buyers in China** — OPSS, alongside MHRA, PPE Make and HSE, provided advice and training to help buyers identify compliant PPE. The training was provided in May and June 2020 through the auspices of DMC. Please see SM/133 INQ000478771, SM/134 INQ000478753, SM/135 INQ000475318, and SM/136 INQ000478755. Further discussion of OPSS' efforts to prevent the flow of non-compliant PPE into the UK are set out in the 'Daventry' and 'PPE at Ports' sections below; and

d) **Daventry** — OPSS provided operational support and advice via the joint Regulatory PPE/Medical Devices Clearance team to speed up supply at point of entry.

Operation Safeguard / Ports and Borders

9.2. On 1 April 2020, OPSS took over responsibility from National Trading Standards for the Product Safety at Ports and Borders Programme. This change was the result of an ongoing programme to transfer responsibilities to OPSS following its creation in 2018. Sixteen local authorities were funded to undertake market surveillance checks at significant border import points around the UK. Local authority Trading Standards teams delivered this programme, by undertaking documentary and physical checks of goods before they entered the UK market. Please see SM/137 INQ000475484. The purpose of the programme was to target high risk products and traders. Given the intelligence that PPE was in short supply it was highly likely that bad actors would seek to import potentially unsafe and/or non-compliant PPE into the UK. As a result, resources were directed towards PPE checks and Operation Safeguard was established to coordinate these efforts.

9.3. Operation Safeguard was an enforcement operation at UK ports established in May 2020 to provide additional support to local authority Trading Standards teams to deal with the significant influx of non-compliant PPE arriving at UK points of entry. It aimed to prevent potentially unsafe and/or non-compliant PPE entering the consumer market. The objectives of the operation were:

a) **Deterrence** — Reduce the quantity of potentially unsafe and/or non-compliant products being imported, by deterring businesses from taking a careless or criminal approach to safety compliance;

b) **Intercept more potentially unsafe and/or non-compliant products** — Increase the capacity and capability for robust product safety enforcement at

UK ports and borders to enable more potentially unsafe and/or non-compliant products to be identified and intercepted before they were placed on the market;

c) **Robust enforcement action** — Ensuring appropriate enforcement action was taken against businesses that had disregarded their legal obligations by supporting those entities with enforcement responsibility such as HSE and Border Force; and

d) **Demand** — Educating buyers on what to look for to purchase safe PPE and other high-risk products during the Covid-19 crisis. Please see SM/138 INQ000475404.

9.4. On receiving a consignment of PPE in the UK, the UK Border Force would review whether the goods were in scope and, where those goods were referred to the Ports and Borders Specific Point of Contact, details of the consignment would be referred to a Market Surveillance Authority (in the case of workplace and commercial PPE, this was HSE). The relevant Market Surveillance Authority then considered if an assessment was required. The assessment by the Market Surveillance Authority was case specific, but generally would determine whether a product had been through an appropriate conformity assessment procedure, was labelled appropriately, and was supported by the necessary documentation. OPSS provided operational and post-operational support, utilising technical expertise, project management experience, and legal and strategic support. Please see SM/139 INQ000475359.

9.5. Operation Safeguard also reinforced OPSS' intelligence function, which became a key part of OPSS' enforcement response. In the period 24 March 2020 to 15 October 2021, over 1000 points of information were referred to OPSS' Intelligence Team from sources including the Intellectual Property Office (**IPO**), BSIF, market participants, National Trading Standards, local authority Trading Standards teams, and other law enforcement agencies.[7] These referrals aided local and central authorities in implementing further product control efforts, and enabled an enhanced understanding of business entities active in the supply chain. The referrals provided intelligence to staff undertaking the checks at the Daventry site. Specific intelligence led, in April 2020, to an alert being placed on 'UV wands', 12 of which were shared with National and Local Trading Standards Authorities and the IPO.

[7] The Intellectual Property Office is the UK Government body responsible for intellectual property rights. This includes copyright, trademarks, designs and patents.

9.6. By way of an example, as part of Operation Safeguard, OPSS Enforcement Officers attended East Midlands Airport supporting Border Force and HSE on different occasions and took possession of consignments. OPSS targeted its checks by building 'risk-based' importer profiles based on intelligence received from Border Force and Her Majesty's Revenue and Customs. All were found to be non-compliant with the PPE regulations. All of these non-compliant products were destroyed. Other inspections included checks at Manchester and Heathrow airports between April – July 2020. These inspections consisted of market surveillance checks in conjunction with Border Force. OPSS inspection visits to Heathrow Airport were captured in a tracker document, available at SM/140 INQ000475491. In June 2020, Border Force invited OPSS to take a more hands on role at Heathrow Airport, to support with training to help them identify non-compliant goods. See SM/141 INQ000475406.

9.7. As noted in its Covid-19 Lessons Identified Report of May 2021, whilst productive relationships were established with its operational partners (e.g. Border Force, local authority Trading Standards etc.) at Heathrow Airport during Operation Safeguard, engagement at other airports was less developed. Please see SM/139 INQ000475359 for the OPSS airport resourcing model. However, these limitations should be placed in the context of the scale of the project which included the inspection of 40.1 million items of PPE for product safety compliance and the removal of 4 tonnes of unsafe products from the supply chain. As noted in the report, provided at SM/142 INQ000475485, the operation also led to the creation of a Rapid Response team for deployment to ports in accordance with agreed criteria. This is now an established team in OPSS. In addition, OPSS now operates a Border Programme at various locations to deliver a coherent UK approach. Examples of the work OPSS did to intercept consignments and faulty PPE can be found here at SM/143 INQ000475501 in the OPSS Operation Safeguard Resolution Report. The Report notes that checks were conducted at the following ports of entry: Heathrow Airport, East Midlands Airport and Manchester Airport. It also provides information about the number and types of items that were subject to checks.[8] See also SM/144 INQ000478777 and SM/145 INQ000478779.

Monitoring Compliance of Products Sold Online

[8] In this regard, 59 consignments were checked by OPSS, and 86% of those were non-compliant. All consignments checked were for face masks or shields, in quantities ranging from 840 to 2 million.

9.8. Between April to July 2020, OPSS conducted a Covid-19 Consumer Survey, focused on the purchase and use of Covid-19 related consumer products. The survey took place in three waves, using the services of Kantar Research. In total it received 5,093 responses. The survey's findings informed OPSS' response to the pandemic, including through the investigations into UV-C products detailed below. Information about the survey can be found in SM/146 INQ000477754.

9.9. During the pandemic, OPSS sought to ensure that only compliant and safe face masks were available to buy online for UK consumers. Between April and July 2020, OPSS officials conducted a specific Online Selling Project which involved a series of online enforcement activities to intervene in the selling of hand sanitisers and face masks online. A report about the project is available at SM/147 INQ000475476. This work included surveys being sent to online selling platforms. In addition, OPSS employed the skills of the National Trading Standards' Crime Team to conduct searches on social media platforms and Google, and to facilitate taking down websites when necessary. OPSS' Online Markets Working Group, along with HSE and MHRA, met monthly from April to July 2020 with the online retailers Amazon, eBay and Ali Express, to share intelligence about online selling platforms. See for example, SM/148 INQ000478747.

9.10. Various methodologies were employed to investigate hand sanitisers and face masks being sold online, and further information is available at SM/147 INQ000475476. OPSS officers created a series of spreadsheets for each retailer to capture sales information about the products in question, enabling OPSS officers to follow up on points of concern. Where appropriate, in respect to face masks, OPSS involved the National Crime Agency to deconflict intelligence about the sellers before OPSS would intervene. OPSS also involved HSE as the Market Surveillance Authority for workplace PPE. As a result of this work, OPSS focused their face mask surveillance on masks claiming compliance to KN95 masks as they presented the most serious risk to users if they did not meet the KN95 specification.

9.11. After investigating the hand sanitisers and face masks, OPSS uploaded information about all non-compliant products on the EU's ICSMS and Rapex databases.[9]

[9] The EUs ICSMS is an IT platform used for pan-European market surveillance. Rapex is a rapid information exchange system used by the EU to flag products (except food, pharmaceutical and medical devices) that are found to pose a serious health and/or safety risk.

9.12. When defective or unsafe products were identified, OPSS worked to have the products removed from online platforms. Online platform operators identified as listing such products were also encouraged to inform buyers and invite recalls. There were varying levels of cooperation and compliance from different online platforms, more information about this is available at SM/147 INQ000475476.

9.13. OPSS was made aware by local authority trading standards teams about the increased demand for and online sale of UV-C products. OPSS' intelligence teams identified a range of issues around these sales, including false marketing claims about the value of the products in treating Covid-19 and over-inflated claims about the products' safety. Results of OPSS Covid-19 Consumer Survey suggested that between one-third to one-fifth of consumers who bought UV-C products online during the pandemic were using them unsafely. OPSS worked with PHE to conduct testing of various UV-C products available online, after which OPSS then contacted sellers to remove the products or amend the online marketing. Information about retailers contacted, and their responses, as well as a report on this piece of work, is available at SM/149 INQ000475481. Further, whilst local authority Trading Standards teams were responsible for enforcement in their local area, OPSS, in its role as the national regulator, supported trading standards colleagues by providing: advice and guidance, access to technical expertise, provision of training and a product safety testing protocol that enabled them to have products tested at no cost to the local authority. This enabled local authorities to prioritise this area of work knowing they had the competency and resources to work effectively.

The China Team

9.14. The below discussion of the 'China Team' refers to the team staffed by Cabinet Office, the Foreign and Commonwealth Office (**FCO**) and the Former Department for International Trade (**fDIT**) and DHSC to coordinate PPE procurement from China during the Covid-19 pandemic. In this section I provide a brief overview of the training and regulatory support provided by OPSS to support the China Team. International procurement in general, and the formation of the China Team in particular, will be discussed in more detail in the statement provided by fDIT.

9.15. As set out at paragraph 9.1, in an effort to ensure compliance with UK regulatory requirements OPPS, in conjunction with HSE, MHRA and PPE Make, delivered training to the China Team through the auspices of DMC. DMC is discussed in more detail at paragraphs 5.2 to 5.6.

9.16. OPSS was copied into discussions on 23 April 2020 regarding DIT's China focussed procurement work. OPSS' focus in relation to this discussion was to provide a regulatory understanding to those involved in the wider procurement process and ensure efficient expedited product approval upon arrival at the UK border. To this end, OPSS advised that documentation which was required for entry into UK ports should be obtained from the manufacturers in China prior to shipping. Please see SM/150 INQ000475344 and attachment SM/151 INQ000477701.

9.17. OPSS was also kept informed of nascent quality assurance developments produced jointly by the FCO and Cabinet Office. OPSS noted the importance of ensuring regulators were confident that the overseas process complied with UK regulatory requirements. OPSS officials attended a meeting with the China Team on 28 April 2020 to discuss this "*upstream process*" and the medium to long term strategy for purchasing. OPSS was conscious that the advice it provided on these issues respected HSE and MHRA's role as the Market Surveillance Authority. OPSS sought to use its regulatory experience and expertise to assist other government departments and bodies to identify and resolve issues. Please see SM/152 INQ000475345.

Daventry

9.18. Daventry was a temporary distribution centre, managed by Supply Chain Coordination Limited (**SCCL**), where PPE and medical devices were screened before being released to the NHS. OPSS and HSE provided operational support and advice via the joint Regulatory PPE/Medical Devices Clearance team at Daventry to speed up supply at point of entry. The joint Regulatory PPE/Medical Devices Clearance team was made up of OPSS, HSE, MHRA, Cabinet Office China Buying Team, the Ministry of Defence (**MoD)**, Hatmill Limited and SCCL. To note, SCCL is the legal entity through which the NHS Supply Chain undertakes its procurement services and transacts with customers and suppliers. At the time of the pandemic, SCCL was a limited company owned by the Secretary of State for Health and Social Care. Ownership of SCCL transferred to NHSE/I on 1 October 2021. The company provided oversight and operational management for the NHS Supply Chain and its service providers. Hatmill Limited is a supply chain and logistics consulting firm which handled routine operations at the Daventry site.

9.19. Prior to the pandemic, PPE was sourced for NHS trusts though SCCL. As the Covid-19 crisis escalated in early 2020, this body struggled to deal with the unprecedented demand.

9.20. PPE purchasing was transferred to Cabinet Office's PPE Sourcing Cell. This Cell, which housed specialists from the MoD, Cabinet Office and NHS organisations, established a parallel logistics process responsible for the four routes though which PPE could enter the NHS supply stream:

a) Stock purchased through the existing SCCL supply chain, from trusted suppliers;

b) PPE purchased from new UK suppliers which was generally CE marked and compliant, and donations either from within the UK or overseas;

c) New suppliers from overseas, primarily in Beijing and Shanghai, with purchases facilitated through the FCO and DIT; and

d) From novel manufacturers who were switching production facilities towards PPE.

9.21. All the stock was routed through the Daventry hub. Please see SM/153 INQ000475317 for further detail regarding this.

9.22. The Clearance Team was the operating arm of the RCC, established in April 2020 and disbanded in March 2022. The Clearance Team was comprised of representatives from HSE, MHRA, SCCL and OPSS. It was set up to rapidly assess products arriving by non-standard routes into the NHS supply chain and address the immediate demand for PPE and medical devices. The joint working of the regulators was intended to enable more efficient technical assurance review. The team's draft Terms of Reference are provided at SM/154 INQ000475421.

9.23. During early April 2020 stock began to flow into the Daventry site. By 9 April 2020, OPSS had received reports that there were 4.5 million units of PPE stock awaiting clearance. Please see SM/155 INQ000475314. During this early period, OPSS worked consistently with HSE and MHRA, providing them with the administrative support and tools to enable HSE and MHRA to assess and clear this PPE backlog and distribute it to the NHS as quickly as possible.

9.24. One such example of cooperation during this period was the clearance of a shipment of 200,000 cleanroom gowns. OPSS liaised with Satra, a Notified Body, and then

requested and received HSE approval for these gowns to be released into the NHS distribution supply stream. See email chain exhibited at SM/156 INQ000477690. This collaborative work was captured in the form of a master tracking document used by staff from OPSS, MHRA, HSE, the MoD, Hatmill Limited, NHS, SCCL and others. The document captured all incoming PPE that required testing, and tracked supplier information, the findings of any testing, and any regulator comments. A version of the master document is available at SM/157 INQ000478782 and a process map for using the document is available at SM/158 INQ000475402.

9.25. At this stage of the pandemic, OPSS and HSE were working to agree a position on the compliance requirements for products coming though Daventry and the processes that would deliver confidence at pace. OPSS was of the view that the speed with which protection could be provided was imperative, and there needed to be credible, resilient approaches to approval decisions which could withstand real time demand. Please see SM/159 INQ000477687, SM/160 INQ000477688, SM/161 INQ000475305, and SM/162 INQ000475309 for an account of the discussions.

9.26. An agreed position was reached on 11 April 2020 when HSE, as the Market Surveillance Authority, confirmed that if items clearly displayed a genuine CE mark, then they could be released into the supply chain without further reference to HSE. Please see SM/163 INQ000475316 and SM/164 INQ000477691.

9.27. OPSS assisted by liaising between HSE and Notified Bodies to speed up their inspection and approval process. An example of this was OPSS' liaison with Satra, to expedite their review of thousands of donated gowns that were being held at the Daventry site. OPSS also requested BSI's assistance on documentation, sample size and timelines for testing. Email communication regarding this is exhibited at SM/165 INQ000475303 and SM/166 INQ000475304.

9.28. On 16 April 2020, OPSS' Head of Risk visited Daventry to perform an initial triage and risk assessment to better understand its logistics and consider what assistance OPSS could provide. More detail regarding the findings of that exercise can be seen at SM/167 INQ000475327 and SM/168 INQ000477692. The team at Daventry logged and processed items, with HSE leading on PPE and MHRA leading on medical devices. HSE employed a team on the ground at Daventry which assessed consignments. Please see SM/169 INQ000475326.

9.29. Products intended for use in the NHS were only subject to assessment at Daventry if they had come from non-standard supply chains. Usual NHS suppliers of PPE such

as SCCL did not need to be re-assessed. Please see a process map which is exhibited at SM/170 INQ000477714. The process at Daventry included a visual inspection by HSE and MHRA to check for discrepancies in the documentation and consideration as to whether further testing would be needed. Please see SM/171 INQ000475323 and its attachment SM/172 INQ000475324 for an account of the approvals process for products intended for NHS use at this time.

9.30. On the same day, 16 April 2020, at a meeting between OPSS and HSE, it was agreed that HSE would take the regulatory lead at Daventry, with OPSS providing support as required. HSE had staff working on site seven days a week and had direct contacts within OPSS and MHRA to verify technical details, documents and medical devices. Please see SM/173 INQ000475325. During this critical period, OPSS, HSE and MHRA were conducting daily meetings. Please see examples at SM/174 INQ000475336 and SM/175 INQ000475331.

9.31. In May 2020, OPSS was receiving approximately ten requests a day to gather documentation to help HSE and MHRA to make assessments on site at Daventry. Please see SM/176 INQ000475377. OPSS also provided support for documentation review and translation. At an RCC meeting on 15 May 2020, it was reinforced that intelligence needed to be fed back to procurement teams to inform purchasing decisions. Please see SM/030 INQ000475378. By this time the inbound assurance process for incoming PPE had solidified. This set out that Clipper Logistics, a company contracted by DHSC, would capture photos of inbound PPE which would then be emailed to OPSS' Operational Support Unit, who would upload these to a SharePoint site and notify HSE and MHRA. These bodies would then determine whether further OPSS advice was required, or if further testing was needed, which would be arranged by OPSS. This process assurance map is exhibited at SM/177 INQ000475349. Please see SM/178 INQ000475348 for OPSS' internal inbound technical assurance process.

9.32. On 4 June 2020, OPSS' Intelligence Unit drafted a proposed model for risk assessment. This set out the relevant risk parameters required to help identify actionable intelligence that could be developed and disseminated for enforcement action. Please see SM/179 INQ000475408. Please note that although this version is referred to as a draft, it then became the risk assessment model used by OPSS.

9.33. In June 2020, OPSS began to hand over its responsibilities at Daventry to the MoD and SCCL, as Quality Assurance leads at the site. By this stage, OPSS was satisfied

the processes it had advised on were well developed and it was appropriate for the MoD and SCCL to take them forward and for OPSS to step back into an advisory role. Please see SM/180 INQ000475409. For this purpose, it created the Joint Regulatory Clearance Team, a temporary group that represented the operational level of the RCC. The group was comprised of representatives from HSE, MHRA, OPSS and SCCL and the MoD. HSE would remain at Daventry as the primary regulator, until it left at the end of September 2020. Please see SM/181 INQ000475454. Once commenced, the handover was intended for completion by the end of the June 2020. Please see SM/023 INQ000475412. The IT systems set up by OPSS were handed over to SCCL in mid-June 2020, and MHRA began working directly with the NHS through this IT system. Please see SM/182 INQ000475413. At the time of handover to SCCL, OPSS roles at Daventry consisted of:

a) Hosting and collating compliance documentation;

b) Reporting metrics;

c) Translation of Chinese language documents; and

d) OPSS staff attending the Daventry site two days a week to support the regulatory clearance team. This is outlined in OPSS' handover plan provided at SM/183 INQ000475410.

9.34. OPSS finalised the handover and produced a completion report in August 2020. This is provided at SM/184 INQ000475443.

9.35. During OPSS' involvement with the Daventry project, spanning from April 2020 until final winddown in September 2020, 2.2 billion items were subjected to coordinated checks and 1,300,477,091 of these were rejected from the site. The number intercepted is provided at SM/185 INQ000475493 and corresponding total number checked is provided at SM/186 INQ000477769.

Section 10: <u>Lessons Learned</u>

10.1. Throughout the Covid-19 pandemic, OPSS conducted several lessons learned exercises to reflect and build on the work it had done since the start of the pandemic. Many of the lessons within the various exercises and reports are not relevant to the Module 5 Provisional Outline of Scope and as such have not been summarised within this statement.

10.2. The Incident Management Team (**IMT**) provided a *"facility to submit issues and lessons to be learned."* Please see SM/187 INQ000478773.

10.3. From August 2020, IMT led an exercise to de-escalate the response to Covid-19 within OPSS. The exercise to restore previously established business activity involved three phases:

a) The first phase included collating information about lessons learned through the Covid-19 Lessons Identified Log. A link to this Log was circulated weekly with the Covid-19 Birdtable Minute[10] to ensure that members of OPSS were completing the log throughout the incident response, see for example SM/188 INQ000475424. A Covid-19 Lessons Identified Feedback document was sent to individuals to provide feedback and Covid-19 workshops were held on key themes. See template provided at SM/189 INQ000475456. In December 2020, senior staff in OPSS held a PPE Lessons Workshop. The workshop reflected on keys areas of OPSS' work in relation to PPE during the first wave of the pandemic and outlined lessons learned. The notes and findings from the workshop are available at SM/190 INQ000475473;

b) The second phase consolidated and identified next steps in relation to the information collated. Please see SM/191 INQ000475445 and SM/192 INQ000475457; and

c) In the final phase IMT formally closed the incident and produced a Covid-19 Lessons Identified Report. Please see SM/142 INQ000475485. This report also incorporated lessons learned from No Deal EU Exit planning and Whirlpool incidents that OPSS was also involved in.

May 2021 — Covid-19 Lessons Identified Report

10.4. Many issues that arose throughout the response were addressed and resolved during the incident. This resulted in continuous improvements to the processes. Lessons that were not resolved were captured and included in the Covid-19 Lessons Identified Report which was published in May 2021. These lessons are set out in further detail below. Please see SM/142 INQ000475485

10.5. **Communication between OPSS staff and external partners** — At various points, OPSS found it difficult to obtain suitable contact details for staff in partner organisations (including other regulators/government departments). This made

[10] A Birdtable refers to an informal meeting, conducted frequently, to discuss routine issues.

coordination difficult. The report found that this was a particular challenge when answering enquiries from businesses, and that this may have caused a reputational risk because it could have appeared that OPSS could not identify the right contact points to provide answers. The lesson drawn from this was that OPSS should maintain a central list of key contact details in partner organisations.

10.6. **Covid-19 Business Reference Panels** — During the response to Covid-19, businesses were contacting OPSS regarding issues that were not covered by OPSS' policy areas. To manage the queries, OPSS facilitated Business Reference Panel events. The Panel events brought together policy leads across Government, as well as from stakeholders and local authorities. The Panels provided a forum for queries from businesses and trade associations to be answered. These were well-received, and the report recommended that OPSS further develop incident specific versions of these panels.

10.7. **OPSS within BEIS** — Engagement with teams within the Department identified that there was a lack of understanding about where OPSS fit, and for which policy areas it had responsibility. There was also a need for OPSS to foster a closer relationship with the Department's Sector Teams. The report recommended that OPSS improve engagement with relevant Department teams.

10.8. **OPSS taking the lead in cross-government workstreams** — OPSS, on more than one occasion, took the lead coordinating the cross-governmental response where there was no obvious owner. The Leadership Team recognised that OPSS had both the capability and the capacity to provide direction and governance. In future similar situations the paper recommended that a 'scope of mission' and terms of reference should be drawn up and signed off at a senior level at an early stage, with an exit strategy in place before substantive work commenced. It further set out that OPSS should continue taking the lead amongst Market Surveillance Authorities and ensure the activity is tracked and auditable.

10.9. **The RCC** — OPSS established the RCC to bring together UK regulators involved with PPE. It was a productive forum to advise and support PPE procurement, and the report identified it as a format that should be used for future cross-government groups, and reconvened if the need arises again in relation to PPE procurement. The recommendation from the report, to include the RCC in the next iteration of the Incident Management Plan was followed through as the report was being finalised.

From 18 January 2021 the RCC was included in version three of OPSS Incident Management Plan, please see SM/132 INQ000477760.

10.10. **Operation Safeguard and Border Inspections of PPE** — This project was successful in ensuring that 40.1 million items of PPE were inspected for product safety compliance (and removed 4 tonnes of unsafe products from the supply chain). However, there was an opportunity for OPSS Legal Team to be involved at an earlier stage. As a bespoke legal team providing advice at an operational level, would have provided reassurance to decision makers who could rely on their knowledge and expertise. OPSS also created a Rapid Response Team and the report recommended that the capability of the team be further developed. OPSS has since established a team to work at UK ports and borders.

November 2021 — Light-touch Evaluation on the Use of Regulatory Easements

10.11. OPSS prepared a presentation to evaluate the use of the regulatory easements. This was presented at an RCC on 24 February 2022 provided at SM/193 INQ000477766. The presentation considered the aims of the project and provided an overview of OPSS' data collection over the course of the Covid-19 pandemic. It also included OPSS' reflections on the use of the regulatory easements to procure PPE. This would then go on to aid the review of Covid-19 from 2022 onwards.

10.12. The presentation noted that the easements were widely used by the NHS and manufacturers. To inform the review, stakeholders provided reflections on their experience using the regulatory easements. Feedback was collated and recommendations included:

a) That the Government provide consolidated guidance for products that fall under dual/multiple regulators (e.g. OPSS and MHRA);

b) Stronger enforcement from regulators to ensure that new entrants were placing safe PPE on the market; and

c) Adapting the process to be more like the MHRA derogation process or otherwise providing a fast-track process for conformity assessment.

10.13. The presentation noted that, at the time, the use of the regulatory easements seemed the best approach in the circumstances. However, on reflection, OPSS would have recommended a different approach of a derogation system that was more tightly controlled (similar to that of MHRA). MHRA's derogation process allows manufactures of medical devices to temporarily derogate from usual conformity

assessment procedures. This process, unlike the easements, is set out in the regulatory framework in advance and is more tightly controlled.

10.14. The data collected by OPSS was not able to provide an overall market perspective, and the evidence gaps were acknowledged in the presentation. OPSS had no data on the outcomes for businesses that did not use the easements, and struggled to get data on how long it took for the easements to be granted.

10.15. The regulatory easements created a system to identify and allow safe, non-CE marked or non-conformity assessed products on to the market to deal with the immediate and unprecedented demand for PPE presented by Covid-19. Both purchasers and manufacturers did not have the understanding that PPE was a product that was highly regulated and required specialist knowledge and manufacturing capability. This lack of understanding increased the risks in the sector, and the demand for advice from regulators. Future solutions identified in the lessons learned review, were to:

a) Ensure that NHS purchasers were provided with appropriate advice and training to enable them to procure and purchase safe PPE only; and

b) Ensure future easements were more tightly controlled (and regulators were better resourced and informed), draw more on the newly created domestic PPE manufacturing base; and have clear guidelines about PPE use.

Lessons Learned: Reflections and Implementation

10.16. OPSS has carefully considered the lessons learned reports discussed above and the recommendations relating to PPE safety policy, market surveillance coordination and those relevant to its own ways of working. A key example of these reflections being put into practice to better prepare OPSS and the UK in the event of a future pandemic, is the *"Smarter Regulation UK: Product Safety Review consultation*", provided at SM/194 INQ000477770. This review seeks to reform the UK's product safety legislative system and the way easements would operate in the future.

10.17. The consultation specifically discusses "*supporting supply of critical products in emergencies*". This sets out the proposals for an emergency derogation with the aim of ensuring that "*essential products go through a swifter regulatory process that allows them to reach the market more quickly, whilst maintaining high, but proportionate, safety standards*". The proposal builds on the emergency measures introduced as part of the Covid-19 response to support the faster supply of PPE. The

proposal is supported by views from the Call for Evidence, held from 11 March 2021 until 17 June 2021, and feedback from PPE Make, which urged OPSS to establish a derogation process similar to MHRA.

10.18. OPSS took on responsibility for the product safety at borders programme in early 2020 for the reasons set out at 9.2. The work on Operation Safeguard highlighted the need for better coordination and co-operation between OPSS and the local authorities working at UK ports and borders. Since 2020, OPSS has: increased the funding to local authority partners, expanded the number of border locations that are part of the programme and provided enhanced intelligence, profiling and coordination support to local authorities. In addition, it has established a team within OPSS to work alongside local authorities at ports and borders and through the import supply chain.

10.19. At the onset of the pandemic, OPSS had only existed for two years, and had a relatively small number of staff to respond to its unprecedented demands. Since then, OPSS has further developed its capacity and capability. This development is, in part, to enable it to implement the robust changes to product safety legislation outlined above. This growth has seen key teams expanded including: the IMT, Policy, Enforcement, Science and Technical, and Legal to deliver its functions. In respect of the latter, the Chief Legal Officer attends SCG level discussions with legal support also provided at TCG and operational levels throughout OPSS, ensuring swifter and more consistent decision making and implementation.

Section 11: <u>Procurement of Ventilators</u>

11.1. UKRI is a non-departmental body which invests in innovation and research projects across the UK funded by grant-in-aid by the Department. Please see SM/195 INQ000477774 which sets out UKRI's funding model. The Government established a network of seven Catapult Centres, through Innovate UK, to commercialise new and emerging technologies in areas with large global market opportunities, please see SM/196 INQ000475250.

11.2. The Advanced Manufacturing Research Centre (**AMRC**) at the University of Sheffield led on the Ventilator Challenge. It was asked to coordinate and bring together all the suppliers to coordinate skills, logistics, innovation and delivery. Please see SM/197 INQ000478760. The AMRC is one of seven High Value Manufacturing Catapult (**HVMC**) centres in the UK. AMRC shortlisted 20 consortium partners, working with existing manufacturers of ventilators to increase their production and assisting other

major manufacturers to reconfigure their production lines to produce ventilators. Please see SM/198 INQ000475374.

11.3. On 13 March 2020, the WHO issued guidance for the clinical management of severe acute respiratory infection. Following this, the Government issued a 'call to arms' asking that UK manufacturers switch to producing ventilators. On 16 March 2020, the Department requested, through its gov.uk webpage, that UK businesses make contact if they could support the production and supply of ventilators and ventilator components. The request included manufacturers, design and specification, rapid prototyping, contract and product assembly, certification, testing, logistics, and medical training. During this time, officials contributed to cross departmental policy discussions regarding the utility of placing export restrictions on UK companies producing ventilators and their components. Please see SM/199 INQ000475260.

11.4. Business offers were triaged through the business support helpline and the Ventilator.Support@beis.gov.uk email address (**VC Inbox**). Please see SM/200 INQ000477773. Cabinet Office directly accessed, and actioned, offers through a shared database. Nearly 3000 responses via email and phone had been tallied by 19 March 2020. Please see SM/201 INQ000064750. By 20 March 2020, Cabinet Office withdrew its request for further offers of support.

11.5. Following this initial engagement, from the end of March 2020 the Department provided some limited assistance to the wider ventilator procurement effort, which was led by Cabinet Office. Please see SM/202 INQ000477664.

11.6. On 20 March 2020, Minister Zahawi's office was made aware of Ventilator Challenge UK (**VCUK**) — a consortium which included UK-based aerospace and automotive companies. The VCUK was developed under the chairmanship of Dick Elsy who was the Chief Executive Officer of the HVMC established through Innovate UK (for further information see paragraphs 11.1 and 12.76). Please see SM/203 INQ000475258. A briefing was later prepared for Minister Zahawi prior to a call with Mr Elsy scheduled for 23 March 2020, where Mr Elsy sought confirmation that financial compensation would be available for the work involved (both that already completed, and the work still to come). Please see SM/204 INQ000475262.

11.7. The consortium was scaling up a ventilator design from Smiths Group (a UK-based FTSE 100 engineering and manufacturing business) and had already presented their proposal to the Chief Commercial Officer in Cabinet Office. A number of actions arose out of the meeting, including that Minister Zahawi had agreed to explore whether the

Department could handle media queries relating to the project, to look into whether the MoD could provide some security personnel, and for the Government to provide the consortium with a written assurance of support. Please see SM/205 INQ000475264. A Ministerial letter of comfort was issued the next day to Mr Elsy confirming support. Please see SM/206 INQ000475267 and SM/207 INQ000477663.

11.8. On 26 March 2020, correspondence confirmed that the Smiths 'ParaPAC' ventilator model had received the required CE mark, and efforts to rapidly increase production were underway. Further Government support was requested for PPE for staff on manufacturing lines, logistics/supply chain support, and assistance with its existing customers (though it is unclear what support was requested to be offered). Please see SM/208 INQ000477666.

11.9. On 27 March 2020, Cabinet Office requested that the VC Inbox be stood down, and that instead the Support for Business online process be promoted, which involved offers of support from businesses (including offers of medical equipment) being fed into Cabinet Office, who then forwarded them onto the appropriate teams for action including within DHSC. Please see SM/209 INQ000475312. The VC Inbox was updated to provide an automatic 'out of office' response, that asked that those who wished to get in touch redirect their email to "existing.ventilators@dhsc.gov.uk," as the inbox would no longer be monitored daily. Please see SM/210 INQ000475311.

11.10. As part of his role as Under Secretary of State for the Department, Minister Zahawi regularly engaged with members of the automotive sector who were also members of the VCUK. However, meetings held with such members in April 2020 were for the purposes of discussing other matters, such as possible Government financial support where those members had been impacted by the Covid crisis. Please see SM/211 INQ000478743 and SM/212 INQ000477696.

11.11. Because the Department and Minister Zahawi were asked to cease involvement with the VCUK from 27 March 2020 onwards, our ability to comment on the challenges of the procurement of ventilators and the subsequent lessons learned is limited.

Section 12: PPE Make

12.1. This section will set out the role and function of PPE Make during the pandemic, including working with DHSC and the MoU that was in place. It will also set out the assistance given by PPE Make to NHS Trusts and local authorities. For clarity, it does

not set out those issues and arrangements that PPE Make was not involved in nor responsible for.

12.2. A comprehensive overview of the role of the Department is set out at paragraph 4.1 for the period 1 January 2020 to 28 June 2022. The domestic manufacture and supply of Lateral Flow Tests (**LFTs**) and Polymerase Chain Reaction (**PCRs**) test kits fell outside the role, function and responsibilities of the Department as they pertained to the regulation of medical devices. Between 27 April and September 2020, the BEIS PPE Make team had no role, function or responsibilities in relation to the domestic manufacture of LFT and PCR tests. The BEIS PPE Make team did not have any involvement by way of a 'call to arms' to existing/emerging diagnostic businesses.

12.3. The role of PPE Make was to identify businesses who were able to assist in the manufacturing of PPE and thereafter facilitating them in this process. Prior to the commencement of the process on 28 April 2020, Deloitte had identified UK manufacturers with the potential for domestic PPE production. Deloitte were assisting Cabinet Office and working directly into that Department. At this time, BEIS were not yet involved in identifying manufacturers, and were not aware of the remit Deloitte had been given and the criteria they were using to identify potential manufacturers. The process from this time and the role of PPE Make in identifying businesses and engaging with them is set out in detail later in this section.

Overview of PPE Make

12.4. On 10 April 2020 DHSC released a UK-wide plan for the national effort for PPE. An element of this UK-wide plan was pursuing a new 'Make' strategy, which focused on UK manufacturing capability as a new source of producing PPE. The plan stated that DHSC would, *"welcome support from other manufacturers who wish to offer their production facilities where they can meet the required specifications for use by the NHS and care sector."*

12.5. On 17 April 2020, a document from the NHS provided an update on the Make workstream, which set out eight steps in the Make supplier pipeline: Please see SM/213 INQ000513154.

a) Manufacturers identified;

b) Manufacturers contacted;

c) Manufacturers ready for technical review;

d) Technical review completed;

e) Supplier on boarding;

f) Manufacturers ready for contracting;

g) Contracting complete/purchase order raised; and

h) Orders placed.

12.6. This update stated that the Make team had insufficient people and capability and that manufacturing capacity was such that the identified eight steps could not be completed quickly enough to meet demand. As such, the paper identified that there was an increasing number of companies stuck at step three of the eight step process as manufacturers did not have the capacity to perform the technical review and the Make team did not have enough capacity to assist manufacturers in this. The document proposed the following overhaul: *"We recommend putting in place option 'C(i)', a rapid expansion of size, capability and remit of the Make team to increase UK manufacture of* PPE *by an order of magnitude"*.

12.7. This would amend the current Make workstream to focus on technical support for suppliers during set up.

12.8. On 19 April 2020, Lord Deighton was appointed by Rt Hon Matt Hancock MP, the Secretary of State for Health and Social Care, to lead the national effort to produce essential PPE equipment for frontline health and social care staff. Lord Deighton *"was to coordinate the end-to-end process of design through to manufacture, including streamlining the approvals and procurement process to ensure new domestic PPE supplies are rapidly approved and get to where they are needed"*. Please see SM/214 INQ000064907. This team became known as UK Make and focused on scaling up domestic production of PPE. This UK Make Team formed part of the wider cross-Whitehall PPE programme.

12.9. On 21 April 2020, a Covid-19 Deep Dive Meeting on PPE took place. The Department's objective was to demonstrate its willingness and ability to support the national PPE effort. Please see SM/215 INQ000475332. In this meeting the ways in which the Department could support this work were noted as follows:

a) Building on the work of OPSS to facilitate the approval of PPE and support the Market Surveillance Authorities to clear products quickly for release to the NHS;

b) Look across sectors to understand which companies may be able to provide raw materials or support manufacturing of PPE products identified by NHSE, particularly where demand in their own sectors has fallen;

c) Work with manufacturers to avoid bottlenecks at the approval stage and assess how to support new suppliers;

d) Work with the HVMC to provide support across sectors;

e) Use relationships with sectors to obtain support for manufacturing PPE and help companies navigate regulatory requirements to start production; and

f) Work with DHSC, NHSE, HSE and other partners to ensure targeted, coordinated communications to the sector, clarifying products required, product specifications and associated standards.

Launch of the UK PPE Make Team, the BEIS-DHSC Unit and the Appointment of Tim Jarvis

12.10. The UK Make Team, led by Lord Deighton, was launched on 27 April 2020, please see SM/216 INQ000475350. The Department and DHSC initially worked together to resource Lord Deighton's PPE Make team through the Office for Life Sciences (**OLS**) a joint BEIS-DHSC unit. Please see SM/217 INQ000146513. The rationale for this was that OLS was an existing body which shared staff and resources between DHSC and the Department and, as such, it had the relevant infrastructure in place and new ways of joint working would not need to be developed. However, as the BEIS PPE Make team acted as an advisory and support team to the DHSC PPE functions, the joint team envisaged to support Lord Deighton's PPE Make team did not work in practice as the terms of the OLS did not permit for other organisations to be established underneath it. The overall mission of BEIS PPE Make and DHSC remained akin to that of the joint team, namely to: *"Instigate and support British industry to retool to manufacture critical items of PPE that we do not have enough of, so that health care professionals and carers can still work."*

12.11. The focus of UK Make was to:

a) Identify UK manufacturers who could produce PPE and support them through the process to manufacture;

b) Re-tool manufacturing facilities in the UK that made similar products to convert them to making PPE; and

c) Focus on the critical items of PPE needed. Please see SM/218 INQ000475352.

12.12. Tim Jarvis was appointed on 27 April 2020 as Director to lead a BEIS PPE Make team which would assist and support Lord Deighton with UK Make. Prior to his formal appointment, Tim Jarvis was approached by Sam Beckett, the then Permanent Secretary, in relation to the role, following contact with the Permanent Secretary of DHSC who requested a Department team to assist the UK Make team. The intention was that the Department would assist DHSC with a focus on manufacturers. OPSS worked alongside the PPE Make team in the Department which included the work of Lord Deighton and Tim Jarvis. The Department agreed to provide 15 – 20 personnel.

12.13. The BEIS PPE Make team was established on 28 April 2020 with a Director and supporting staff member. By early May 2020 the team had expanded to eight, including an OPSS secondee. The purpose of the OPSS secondee was to ensure smooth, close working relations between PPE Make and OPSS. Please see SM/219 INQ000477721.

12.14. The team provided policy expertise and sector contacts for Lord Deighton and the central procurement team's use, and this is discussed in more detail in paragraph 12.49. They assisted in setting up governance systems and mechanisms and provided insights into sectors such as medical equipment and textile manufacturing where companies could support PPE production, particularly where demand in their own sectors had fallen. The team contributed to facilitating the approval of PPE for NHS use — this work built on the work of OPSS and coordinated with other regulators and is discussed further in paragraph 12.56.

12.15. The BEIS PPE Make team also worked with manufacturers to assist them in navigating the regulatory landscape to produce PPE. This included the 'easing' of regulations, namely making the regulatory process easier without lowering regulation standards, to assist in decision-making to fast-track supplies of PPE. These easements are discussed at Section 8 above.

12.16. On 28 April 2020 Tim Jarvis wrote to Lord Deighton by email, please see SM/220 INQ000477771, setting out areas where there was potential for the Department to add value, notwithstanding the need for a triaging process, namely:

a) Business identification;

b) Business engagement;

c) Supporting technical design; and

d) Making the regulatory approval process more agile.

12.17. In an update provided on 30 April 2020, it was noted that the Department would provide policy expert focus and sector contacts as well as support in setting up governance mechanisms. Please see SM/221 INQ000475343.

12.18. In early May 2020, Lord Deighton was asked to expand the remit of his role and to lead the overarching PPE Taskforce. This meant alongside leading PPE Make, he would oversee other aspects of the PPE Programme, in particular buying and distribution. Following the expansion of Lord Deighton's role, the BEIS PPE Make team remained linked to the UK Make strand of the Taskforce. From 8 May 2020, DHSC took on responsibility for UK Make, with Department officials providing input and support to ensure the Department perspective was represented. This was confirmed in the MoU (see paragraphs 12.31 to 12.37 for more information).

BEIS, DHSC and the Initial Contracts

12.19. Whilst the remit of the Department was to provide policy expert focus and sector contacts, as well as support setting up governance mechanisms, please see SM/217 INQ000146513, there was an exception to this. Prior to the creation of the BEIS PPE Make Team and the appointment of Tim Jarvis, Lord Deighton directed Chanzo Limited, a consultancy firm, to commence work on the PPE Make Project. The scope of this work included recruitment, project management and consultancy services. Please see SM/222 INQ000477712.

12.20. The initial intention was for BEIS HR to put in place any contracts with Chanzo required for services and resources to prevent undue delay and account for the lack of capacity within DHSC. Work on this was commenced by BEIS HR ahead of the 27 April 2020 launch date for PPE Make.

12.21. On 28 April 2020 Emma Ferguson-Gould (Director, BEIS Commercial & Operations) wrote to Tim Jarvis regarding the lack of a contract with Chanzo. It was agreed between BEIS HR, Commercial and Tim Jarvis, that BEIS HR would engage with Chanzo to ensure the appropriate commercial arrangements were put in place, please see SM/223 INQ000475351. At this point, it was still envisaged that Chanzo and the related resources would be contracted out of the joint DHSC and BEIS unit, OLS. Please see SM/224 INQ000477703.

12.22. Following the expansion of Lord Deighton's role in May 2020, the work to be undertaken by Chanzo also increased to provide continued support to him in his new role as head of the PPE Taskforce. On 6 May 2020, a submission for decision was drafted for Sam Beckett, the then Department Permanent Secretary and the Department Director Generals regarding the contracting situation of UK Make. The submission recommended that the contract with Chanzo should not be signed by the Department and on the basis that Chanzo would be reporting into Lord Deighton, DHSC should be the contracting authority. The submission raised several concerns about contracting with Chanzo, including the long-standing relationship between Lord Deighton and Jean Tomlin (Chanzo Founder and CEO).

12.23. Tim Jarvis saw the role of the Department as onboarding Chanzo so that the PPE Make Project could commence as DHSC did not have capacity to put a process in place for this.

12.24. It was agreed at a meeting between DHSC, BEIS officials and Jean Tomlin on 8 May 2020 that DHSC would lead on contractual arrangements with Chanzo. The previous arrangements through OLS were no longer deemed appropriate with the expanding role Lord Deighton, and by extension Chanzo, were fulfilling. Barry Hooper (Programme Director Covid-19 DHSC & NHSE&I Supply Cell) confirmed this in writing to the Department on 8 May 2020. From this point, UK Make was not considered a joint BEIS and DHSC unit.

12.25. Following Barry Hooper's email of 8 May 2020, Tim Jarvis also sought written confirmation from Jonathan Marron (Director General of PPE and Public Health, DHSC) that DHSC would hold the contracts.

12.26. BEIS Corporate Services began onboarding 18 contractors identified by Chanzo. This process was paused in mid-May pending confirmation of the contracting arrangements as outlined above. On 19 May 2020, it was confirmed by Tim Jarvis that the contracts would be transferred to DHSC and the 18 contractors should therefore be offboarded by the Department and moved to DHSC. Any new contractors would be onboarded by DHSC. Please see SM/225 INQ000477719.

12.27. However, despite the agreed arrangements outlined above, the contractors were not offboarded and transferred to DHSC. On 22 May 2020 Alice Hurrell (HR Director, BEIS) emailed Tim Jarvis setting out the next step options for the contractors. Her email recommended that the Department continue to onboard contractors including those mid-process, with DHSC paying for the contractors via charge-back. This

option was suggested as it reduced the risk of delays for future onboarding. Tim Jarvis replied on 27 May 2020 and stated that the decision had already been made to offboard and transfer to DHSC. This was in line with reassurances he had provided to Sam Beckett, the then Permanent Secretary, in an email dated 21 May 2020 regarding her Accounting Officer duties. Please see SM/226 INQ000475398.

12.28. It is unclear what occurred between 19 May and 22 May 2020 to reverse this decision; however, in his email of 27 May 2020, Tim Jarvis stated he would agree to 'ring-fence' the 18 contractors who were mid-process and continue to onboard them through the Department. Any future contractors would be onboarded by DHSC.

12.29. Though the 18 contractors remained funded through the Department, BEIS PPE Make had no decision-making role regarding extending their contracts or increasing their rate of pay. These decisions would be approved by DHSC and communicated to the PPE Make Team for action. The contractors reported directly to Lord Deighton.

12.30. The BEIS Finance team sent an invoice for the agreed charge back on 28 July 2021. This covered the costs of the 18 contractors for three months from April to July 2020. DHSC and Chanzo entered into a contract on 25 August 2020 for the provision of services between April and September 2020.

The Memorandum of Understanding

12.31. As a consequence of the 18 initial contracts, an MoU was put in place to formalise the arrangements between the Department and DHSC, and to set out the Department's involvement in UK Make. The MoU was agreed and signed by the Department on 20 July 2020 and by DHSC on 21 August 2020. Please see SM/214 INQ000064907. Although the MoU was not signed until July and August 2020 the goals it placed upon the BEIS PPE Make team were in place by June 2020. Michael Ring, a Deputy Director from UKRI, a partner organisation of the Department, worked part time for the BEIS PPE Make team from 4 May 2020 completing this task. Please see SM/227 INQ000477732; SM/228 INQ000477730 and SM/229 INQ000475397.

12.32. The MoU set out the four goals for the BEIS PPE Make team:

a) Produce a long term 'proactive' strategy to ensure a robust supply of PPE produced domestically;

b) Streamline the online technical guidance available to companies seeking to produce PPE for the first time, to help them to get their PPE to the frontline more quickly;

c) Expedite the technical approval process for PPE products by exploring the ways to expand test house capacity in the UK; and

d) Explore regional manufacturing and innovation, pending strategic resilience decisions.

12.33. Under the terms of the MoU, Tim Jarvis was to report directly to Lord Deighton and engage regularly with the programme senior responsible officers, Jonathan Marron (DHSC) and Emily Lawson (NHSE). Further, the BEIS PPE Make team was to report to the PPE Programme Delivery Board and PPE Leadership Team meetings weekly and twice-weekly respectively.

12.34. BEIS PPE Make's role was to provide policy expert focus and sector contacts, as well as support in setting up governance mechanisms. Please see SM/217 INQ000146513. BEIS PPE Make supported this work by:

a) Looking across sectors to understand where companies may be able to support PPE production, particularly where demand in their own sector has fallen;

b) Looking to build on the work of OPSS to facilitate the approval of PPE and support the Market Surveillance Authority to clear products quickly for release to the NHS; and

c) Leading on temporary regulatory easement measures to fast-track supplies of PPE.

12.35. An internal BEIS PPE plan dated 4 May 2020 set out five workstreams for the Department to support. Please see SM/230 INQ000475420. The five workstreams were:

a) Business engagement and manufacturer identification;

b) BEIS support for sprints;

c) Regulatory landscape;

d) Regional 'hub and spokes' model; and

e) Industrial strategy for PPE.

12.36. A PPE Oversight Board was created shortly after the commencement of UK Make. Lord Deighton chaired the board, and its members included Jenny Harries (Deputy CMO) Dido Harding (Chair of NHS Improvement) Gareth Rhys-Williams, (Government Chief Commercial Officer) and representatives from DHSC, Cabinet

Office, No 10, HM Treasury, DIT and the Department. Sam Beckett was the Department representative. A PPE Executive Team brought together the senior responsible officers for each PPE 'cell'. Tim Jarvis was a member of this team as the Department Liaison (Make).

12.37. On 11 May 2020, Lord Deighton set up a Programme Integration Delivery Unit (**PIDU**). An induction held by Lord Deighton was attended by Emily Lawson, Jonathan Marron, Tim Jarvis, Barry Hooper, and consultants from McKinsey, Chanzo and Arup. In Tim Jarvis' notes of the induction, Lord Deighton said that *"...the role of the PIDU was to bring it all together as a single source of truth and inform and command and control model to those responsible at the top – [Lord Deighton], Emily Lawson and Jonathan Marron."*

Restructuring PPE Make and the Role of BEIS After 8 June 2020

12.38. On 8 June 2020, the PPE Taskforce structure merged into a combined DHSC and NHS organisation run by Lord Deighton, Jonathan Marron and Emily Lawson. The 'Buy' and 'Make' components of the programme were integrated into a category-based structure. Two PPE co-directors reported to the senior leadership of Lord Deighton, DHSC and NHS; Andy Wood and Gil Steyaert (Co-Director PPE Taskforce). Andy Wood previously worked for DHSC, and Gil Steyaert was one of the 18 consultants onboarded in April 2020 by the PPE Make Team.

12.39. Each category of PPE had its own management team led by a Category Lead. The Category Lead reported to the PPE co-directors. Each category management team would be responsible for all procurement, including Make, Buy, and Re-use. These elements were previously separated into different 'cells' working across all categories. The categories were split as follows: gloves, chemicals, eye protection, face masks, gowns, and films.

12.40. Lord Deighton set out in an email to all PPE team members on 5 June 2020 that "*this category-based approach will enable integrated, cross-functional teams to work with a common category purpose and clearly defined goal – sourcing and buying agreed PPE products to meet the demand plan ensuring optimum stock, optimum price, and product compliance, for delivery to the front line.*" Please see SM/231 INQ000475495. This marked the operational end of the UK Make team as a distinct entity working solely on domestic production.

12.41. A number of 'enabling teams' also reported to the PPE co-directors including Strategy & Operations, Technical Assurance & Regulatory, Transaction Guidance, and Change Management teams.

12.42. The BEIS PPE Make team continued to support the PPE Taskforce. Their work expanded to include working on the UK Make policy strategy, and an economist joined the team. Please see SM/232 INQ000475407 and SM/233 INQ000475494. Tim Jarvis was part of the interim leadership team as the UK Make Policy Lead. Please see SM/231 INQ000475495. In this role, as set out in the MoU, BEIS PPE Make would produce a long term 'proactive' strategy to ensure a robust supply of PPE produced domestically. The long term strategy is discussed more at Section 13. This would "*confirm the priority products and the volumes we should seek to produce in the UK in the long term, the raw material requirements, and the productive capacity of the UK*".

12.43. In an update to Sam Beckett on 12 June 2020, the upcoming priorities for the BEIS PPE Make team included "*clarifying roles and responsibilities in the context of the new structure of Lord Deighton's team*" and "*assessing the extent to which BEIS will need to be involved in PPE work in future and in what form*". Please see SM/234 INQ000064865.

12.44. On 24 June 2020, it was reported to Tim Jarvis that the Secretary of State had been "*under-selling*" the Department's contributions to the PPE Taskforce, please see SM/235 INQ000477736. This caused some concern to the BEIS PPE Make team as it was felt that other Ministers were of the opinion that the Department was not pulling its weight on the PPE effort. To address this, Tim Jarvis updated the Permanent Secretary and stated he had a team of 10, including a Deputy Director, and set out the work BEIS PPE Make had undertaken to date to support the PPE effort. Please see SM/236 INQ000475417.

12.45. By 1 July 2020, the BEIS PPE Make team was listed on an organogram as being an "*enabling team*" that sat outside the PPE cell. Please see SM/237 INQ000475415.

UK Make Scoping and Risk Assessments

12.46. To undertake scoping exercises, Lord Deighton brought in supply chain specialists to consider the processes involved in making PPE and whether there were businesses and manufacturers making similar products, or that had the capability to start manufacturing such products. Risk assessments of these products were undertaken as part of the procurement process. The BEIS PPE Make team was not directly

involved in the scoping exercises or risk assessments. Their role was more nuanced and involved trying to obtain a holistic understanding of the UK manufacturing industry and which existing teams within the Department may be best placed to assist in this process. The BEIS PPE Make team then facilitated contact between the manufacturer and the correct part of UK Make.

Role of BEIS PPE Make: Business Identification and Stakeholder Engagement

12.47. The key role of the BEIS PPE Make team was identifying businesses who could assist in the manufacturing of PPE and assisting them in navigating the process of doing so — it was a facilitating role. As mentioned above, BEIS PPE Make was a small team supporting the wider UK Make team which was led by Lord Deighton. DHSC were the lead Department for the PPE Taskforce and therefore led on strategic and procurement decisions alongside Lord Deighton and NHS England. The assistance provided by BEIS PPE Make to businesses was largely in supporting and facilitating the relationship and contact with the right parts of Government and those making procurement decisions and assisting with navigating technical processes. This is discussed below in further detail at paragraph 12.62.

12.48. BEIS sector teams reviewed the businesses identified and suggested further potential manufacturers based on their experience and knowledge of the sectors. UK Make was set up to assist in triaging these offers, however, the Department thought the engagement process needed streamlining. Prior to BEIS PPE Make commencing work on 28 April 2020, Deloitte was triaging the offers of assistance and identifying UK manufacturers with the potential to produce PPE domestically.

12.49. Tim Jarvis met with Deloitte on his first day as BEIS PPE Make Director to understand the current businesses engaged. The Department sector teams reviewed the businesses identified and suggested further potential manufacturers based on their experience and knowledge of the sectors. Prior to the pandemic, and within its usual remit, BEIS was the Department that regularly engaged with business representative organisations (**BROs**) and trade unions. As set out in my statement to the Inquiry in Module 1, the Department had a number of dedicated sector teams that specialised in engagement with business sectors to inform government policy making. As a result of this, BEIS had the expertise and knowledge of the sectors required to identify manufacturers that may have the ability to assist in increasing PPE supply. In a 'Go Live' call the preceding day, it was stated that 175 manufacturers had been identified

and triaged. BEIS PPE Make requested this list but never received it. The Department is not aware of why it was not provided.

12.50. Following the 'call to arms' in April, the Government received thousands of offers of assistance. The Department's engagement team proposed, on 24 April 2020, that a 'PPE Manufacturers Challenge Group' be set up to create a regular engagement channel with the largest domestic UK manufacturers and relevant BROs. This would emulate the Ventilator Challenge Group that BEIS Ministers attended. The proposal suggested regular meetings be held and chaired by Lord Deighton. Tim Jarvis reiterated this proposal to Lord Deighton once the UK Make team launched a few days later. Lord Deighton suggested a call the following day to specifically discuss business engagement. Lord Deighton wanted to be certain of what UK Make would ask of the businesses before meeting with them.

12.51. The UK Make team worked in 'sprints', initiated by Lord Deighton. Sprints are a project management system, where there is a dedicated time frame in which a set amount of work is to be completed. Each sprint would last for a week and focus on a specific priority product. The objective of the sprints was to find the right suppliers and complete a high-level supply chain design. This would then allow the PPE Taskforce to execute deals and begin implementation and ongoing supply chain management. A BEIS PPE Make team member was allocated to each sprint. Their role was to provide a point of contact between the sprint team and key sector contacts. BEIS PPE Make would identify potential businesses who had manufacturing capacity and assist in unblocking process issues. In practice, the BEIS PPE Make team member allocated to a sprint did not have a specific role but adopted different roles depending on the product and the main issues being faced by that sprint. The BEIS PPE Make team member also acted as a link and point of contact between the procurement and supply chain specialists involved in the sprints and Government.

12.52. On 4 May 2020, Tim Jarvis suggested to Lord Deighton that he arrange calls with the Confederation of British Industry (**CBI**), Make UK and the British Chamber of Commerce, in the first instance. Lord Deighton agreed to meeting these three organisations.

12.53. Tim Jarvis and Lord Deighton continued to meet regularly with BROs to identify additional manufacturers. The BEIS PPE Make team remained a key point of contact for trade associations, answering questions and feeding back issues that were raised.

12.54. The BEIS sector engagement team also provided feedback to the BEIS PPE Make team on PPE specific issues. The CBI said that businesses were "*in limbo*" after responding to the Government's call for assistance with PPE. The CBI said that this was disrupting the supply of PPE to other parts of the economy. The feedback is provided at SM/237a INQ000477713.

12.55. Towards the end of May 2020, 14,300 companies had offered PPE. Due to finite resources within UK Make, and a need to develop a long term strategy, there was a move away from processing ad hoc offers of support. UK Make instead focussed on key manufacturers who could produce PPE on a large scale and at pace with a view to closing the 90-day PPE forecast gap, as set out in an update to the Secretary of State on 15 May 2020, provided at SM/237b INQ000475379. DHSC were responsible for determining and updating the criteria in accordance with what products were required at the time. DHSC produced and circulated a process map playbook that included the criteria for 'high priority' opportunities. A version dated 20 May 2020 is provided at SM/170 INQ000477714. By way of example, in this version, FFP3 masks opportunities were considered high priority if the company size was larger than 250 employees, and the manufacturer could produce more than 1 million masks. By 12 June 2020, the overall PPE Make team was reporting to the Department's Secretary of State that the routes of help via the Government website would be closed down, and all companies contacted.

Regulatory Easements and BEIS PPE Make Input to Assist Manufacturers

12.56. A key issue facing the PPE Taskforce when they formed in April 2020 was the bottleneck of businesses at the technical design stage. Please see SM/238 INQ000477702; SM/213 INQ000153154. The BEIS PPE Make team worked to accelerate the regulatory approval process. Please see SM/239 INQ000475370.

12.57. On 28 April 2020, Tim Jarvis met with Graham Russell. Three main actions were agreed in the meeting: *"1. advice on vires for simplified specifications and approved patterns, 2. test houses and capability, 3. contact points"*. Pease see SM/240 INQ000475346.

12.58. Following the meeting, OPSS provided the BEIS PPE Make team with a list of testing houses and an assessment of the UK's current testing capacity for both PPE and medical devices. Testing houses were responsible for testing and certifying PPE and medical device products. They provided evidence for the products to attain the CE marking required at the time for products being traded on the Single Market in the

EEA. Testing houses can be owned by private businesses, Notified Bodies, or be government laboratories. Only two Notified Bodies had their testing houses in the UK.

12.59. An OPSS official was seconded to the BEIS PPE Make team from 4 May 2020 to assist the work on regulatory processes. Tim Jarvis also agreed a model with Graham Russell, whereby the BEIS PPE Make team could *"call on them for specific things",* namely, support on technical questions regarding regulations and standards.

12.60. On 5 May 2020, the BEIS PPE Make team reviewed recommendations on the role of the regulators (OPSS, MHRA and HSE) in bringing new PPE products to the market. Please see SM/241 INQ000477710. Recommendation 3a was *"improving prioritisation of work through testing houses".* The BEIS PPE Make team stated that it was working with OPSS and Deloitte on this and exploring if there were other options to improve manufacturer access to testing houses. Delays were also being caused by new manufacturers not understanding the testing and evidence required. To address this, the BEIS PPE Make team worked with HSE and MHRA to develop additional guidance or training to prospective manufacturers about the process. This guidance is discussed at paragraphs 8.27 – 8.35.

12.61. By 14 May 2020, the technical approval process had become a key priority of the PPE Taskforce. The BEIS PPE Make team focussed on the process for obtaining technical approvals for products with a CE marking and for which the regulators had issued minimum specification. Testing house capability and capacity was identified as a blocker and was slowing down procurement deals being finalised. Testing houses are a highly specialised service, requiring certification from the UK Accreditation Service, and specialised equipment for each product type. Prior to the pandemic, there was limited demand for testing houses in the UK. As such, when demand increased as UK manufacturers required products to be tested, testing houses in the UK were limited in their ability to increase capacity. This, combined with the time it would take for other institutions to obtain accreditation, affected procurement deals. By way of example, in an update to Cabinet Office from PPE Make on 14 May 2020, it was noted that for testing of surgical masks there was a 3 to 6 week wait time, and therefore, UK Make were looking to utilise testing houses based outside of the UK to ensure contracts were progressing. The update is provided at SM/241a INQ000508352.

12.62. The BEIS PPE Make team supported UK Make, and the regulators, with technical approval for manufacturers in the following two areas:

a) By assisting the regulators to increase testing house capability and capacity; and

b) By assisting the regulators to guide manufacturers through the approvals process.

12.63. On 22 May 2020, Tim Jarvis updated Lord Deighton on his team's progress in these areas. Please see SM/242 INQ000475400. The original intention was for BEIS PPE Make to create process maps for each product setting out: what tests were required, where to get products tested, and lead times for testing. However, as the work of Lord Deighton's UK Make team developed into the 'sprint' approach mentioned above in paragraph 12.51, the need for process maps of this kind changed. Instead, the approach adopted by the UK Make team was to focus on specific suppliers and therefore generic advice for all manufacturers on testing options was no longer required. HSE and MHRA continued to jointly develop guidance regarding the technical specifications for PPE. BEIS PPE Make assisted with developing this simplified guidance, which also set out the tests and evidence manufacturers were required to produce. The technical guidance was published online By HSE and MHRA. The guidance published on 28 August 2020 is provided at SM/242a INQ000475498.

12.64. In May 2020, the National Physical Laboratory (**NPL**), a company wholly owned by the Department, was put forward as an option to fill the gap in testing capability for IIR surgical face masks. The BEIS PPE Make team was *"working with MHRA to establish exactly what they will need to be comfortable with for NPL approval"*. The BEIS PPE Make team was in discussions with universities, laboratories and certification bodies investigating whether their facilities could be used for testing and therefore expediate the approvals process.

12.65. An OPSS case worker was also being assigned to every deal that was signed off by "*Gil's team*" (referring to Gil Steyaert, a member of the PPE Make Team). The role of the case worker was to proactively guide and push the manufacturer through the approvals process. In this update, Tim Jarvis also provided feedback on the current process to Lord Deighton:

"…my own view is that we need a more radical overhaul of the whole process and a wider discussion which I would welcome the opportunity to be part of. We can keep pushing the regulators and refine the process to get us over the line on the immediate challenges but the system does not work and is not set up to deliver

pragmatic decisions which appropriately balance the need to ensure the safety of the front line staff with an efficient process which gets suitable kit to where it is needed at pace".

12.66. On 3 June 2020, the BEIS PPE Make team drafted a letter to Jonathan Marron and Emily Lawson regarding testing and guidance of PPE. It had previously been suggested that government laboratories such as the Defence Science and Technology Laboratory (**DSTL**), an MoD body, and NPL could begin to test items to ease delays caused by demand. However, neither laboratory was accredited by the UKAS for the specific tests required for clinical PPE. The laboratories had access to 'suitable experts' instead. The BEIS PPE Make team was to meet with MHRA to ascertain if these laboratories could be used for the urgent testing required. The letter sought the NHS' views on whether the substitute tests would be acceptable.

12.67. The BEIS PPE Make team undertook scoping work to ascertain if there was a shortage of testing and whether this shortage could be reduced through additional UK based testing. This included surveying existing testing capacity. The assistance of the DSTL and NPL was not required as existing testing houses brought on board provided additional capacity. This was also the case in regards to the conversations with universities, laboratories, and certification bodies mentioned above in paragraph 12.64, that is that the pace of accreditation was overtaken by the existing testing houses increasing capacity.

12.68. On 29 June 2020, Tim Jarvis provided an update to Lord Deighton on the progress that had been made by the BEIS PPE Make team, please see SM/243 INQ000475422. He noted that the team were currently evaluating the economic viability and broader desirability of UK Manufacture. Aspects of this work included:

a) Product strategies and analysis of the costs and benefits of UK manufacture;

b) What form Government support should take, including any necessary support for UK involvement in upstream and downstream parts of the supply chain (e.g. polymers);

c) The role that regional supply to local/regional markets would have, including existing regional structures and different regional approaches. This was with input from Local Enterprise Partnerships (**LEPs**), Growth Hubs and MHCLG; and

d) Innovation - including new designs of PPE that were more readily re-used and/or recycled, as well as ensuring the UK framework kept pace with emerging technology developments and supported their entry into the NHS.

12.69. On 20 July 2020, the BEIS PPE Make team produced a paper setting out the required tests for clinical PPE and testing capability within the UK ahead of a potential second wave of Covid-19. Please see SM/244 INQ000475452. The paper stated that by this time, all UK manufacturers supplying central Government procurement had completed their testing.

12.70. This paper also identified the move from the crisis response period to the lessons learned period, in preparation for a second wave. It recommended that ahead of any potential second wave, the DHSC procurement teams concentrate their efforts on purchasing products that had already passed the appropriate tests and regulatory approvals. When purchasing equipment that still required regulatory approval, the BEIS PPE Make team recommended taking into account the lead in times. Surgical gowns and FFP3 respirators were key items of concern in the immediate future due to long lead in times for testing. The paper set out the ways this could be addressed which included providing direct funding for new facilities. The BEIS PPE Make team had engaged with a testing house with regard to costing the construction of new facilities and concluded that the State Aid Rules would allow for direct government support.

12.71. As the BEIS PPE Make team's involvement in the PPE Taskforce wound down from July, they provided recommendations on the future of testing in a lessons learned exercise undertaken in August.

12.72. The PPE Make Team helped to develop clearer guidance for manufacturers on tests and the evidence needed to meet standards to sit alongside the more detailed technical specifications owned by the regulators.

Fast-Tracking

12.73. As part of the fast-track work, the team worked with HSE and local authorities to fast-track PPE through the product safety assessment process. The team also worked with manufacturers to avoid the bottlenecks at the approval stage of their product and to assess how else to support new suppliers to start successful production quickly, including scaling up the activities of HSE to provide safety sign off and, via OPSS, producing online guidance for businesses wanting to manufacture PPE. This included

guidance for both small scale and high-volume manufacturers, discussed at paragraphs 8.27 to 8.35.

12.74. In late April, it was envisaged that the Department would work closely with Cabinet Office, Lord Deighton and DHSC to rapidly clarify the volume requirements for PPE and associated equipment and launch a focused effort to increase production of materials to support industry without disrupting work to secure additional supplies to health. Please see SM/217 INQ000146513.

BEIS PPE Make Team: Regional Engagement

12.75. On 28 April 2020, in his first day summary email to Lord Deighton, Tim Jarvis stated that the current bottleneck was technical design. He stated that *"we need to understand more about what the problem is"* and suggested investigating if there was potential for the HVMCs to get involved. Please see SM/239 INQ000475370.

12.76. The HVMCs are a group of manufacturing research centres. They were set up by Innovate UK, a former BEIS partner organisation, in 2011. There remain seven centres located throughout the UK. The HVMCs were set up to strengthen the UK's manufacturing capability by providing a bridge between academia and industry. The HVMCs assist companies in transforming innovation into usable product. They do this by providing expertise and insight into the manufacturing industry and its key players. The HVMCs can also provide access to specialist equipment to assist with production.

12.77. In an update to Lord Deighton on 4 May 2020, the BEIS PPE Make team was *"co-ordinating and mobilising manufacturing expertise at a regional level through the Catapult network…"* to support technical design issues. Sue Pritchard (NHS) was developing a 'hub and spoke' model with Deloitte to reach potential regional and local suppliers. Please see SM/245 INQ000477708. Central government was the 'hub' with regional 'spokes' of supply meeting regional demand. Please see SM/230 INQ000475420. The purpose of this model was to manage and reduce the current PPE challenge and mitigate future PPE challenges for the NHS through a model which encouraged collaboration between regional and national levels as well as supporting regions to become enablers of their supply and demand for PPE. Please see SM/246 INQ000477704. Three regional pilots were to be established in the North East.

12.78. At a meeting with Lord Deighton on 27 May 2020, Tim Jarvis reported that the BEIS PPE Make team was engaging specialist support for companies. BEIS PPE Make did

not have a budget to provide financial support to manufacturers but provided practical assistance by connecting them to organisations such as the HVMC.[11] The HVMCs provided manufactural help, such as reviewing and improving their processes. One such example is set out below. The BEIS PPE Make team linked the company Ramfoam with an HMVC to assist with the repurposing and regulatory approvals for its reusable masks.

12.79. On 2 June 2020, BEIS PPE Make met with a representative from the AMRC. The purpose of the meeting was to ascertain how HVMCs could support companies who were producing PPE for the UK Make team. The meeting notes the HVMCs may also be used if regional 'Make' programmes developed. Please see SM/197 INQ000478760.

12.80. At the meeting, HVMCs spoke of the request it had received to assist Ramfoam with its production of face visors. Ramfoam had secured a contract to produce three million visors a week. They needed to significantly increase their capability to fulfil this and intended to recruit a further 220 employees. Ramfoam faced several manual bottlenecks and sought the assistance of the HVMC from the University of Warwick. However, as the HVMC was brought on after the contract was secured, their costs were not included in Ramfoam quotes to UK Make. HVMC sought funding from the BEIS PPE Make team to complete this work. They also sought clarification as to whether their services would be required in an ad hoc or consistent way and noted that if companies approached them earlier in the process, their fees could be included in the quotes to UK Make and bottlenecks could be addressed sooner.

12.81. By 22 June 2020, Ramfoam had secured practical support from the HVMC, and were contracted to supply 71.1 million eye protectors. In an email dated 30 June 2020, Ramfoam confirmed that they no longer required additional support from BEIS PPE Make and that they would secure the additional monies themselves for HMVC support. Please see SM/247 INQ000478764. As mentioned above, BEIS PPE Make did not have a budget to provide the financial support requested and assisted by connecting manufacturers such as Ramfoam with organisations who could provide the manufacturing expertise required. In their email dated 30 June 2020, feedback from Ramfoam confirmed that HMVC support had made a difference as supply chains

[11] The BEIS PPE Make team did not have the manufactural expertise, but rather, sector contacts. As the Department that managed HMG's involvement with industry contacts, business representative organisations, and innovations such as the HVMCs, BEIS PPE Make linked manufacturers with services that could be provided across Whitehall and industry.

had been secured, production numbers had increased, and the large-scale factory was progressing well.

Assistance Provided to NHS Trusts Procuring PPE

12.82. The role and focus of the BEIS PPE Make team was to help identify businesses who could assist in the manufacture of PPE to meet the demand caused by the pandemic. BEIS PPE Make did not provide assistance, guidance or advice to NHS Trusts on their procurement of key healthcare equipment and supplies during the pandemic. The procurement of PPE for NHS Trusts was done through the central distribution team. BEIS PPE Make provided support to the businesses identified for the manufacturing of PPE and assisted them to navigate the regulatory systems in place. This included working with OPSS, HSE, and MHRA on helping businesses understand the technical approvals process required. Further, BEIS PPE Make used their sector contacts to link manufacturers and organisations that could assist, such as the case of Ramfoam explored above in paragraph 12.78.

12.83. Whilst procurement and the related assistance and guidance to NHS Trusts was outside the role of BEIS PPE Make, there was one exception to this in relation to Agua Fabrics. Please see SM/248 INQ000477735. The BEIS PPE Make team and Tim Jarvis became involved in this matter to act as a mediator between Agua Fabrics, Cabinet Office and DHSC (this is set out further at paragraph 12.93). Tim Jarvis provided advice and offered his opinion in relation to the Agua Fabrics matter but neither he, nor the BEIS PPE Make team, made any decision in relation to the contract and next steps. Whilst Cabinet Office and DHSC may have received other complaints on contract matters, this was the only matter in which the BEIS PPE Make team and Tim Jarvis were involved.

12.84. Agua Fabrics is a performance upholstery fabrics contracting company with a partner network for worldwide warehousing and distribution. It has been a long-time supplier of fabrics to the NHS, typically for customer areas such as table covers. In April 2020, Agua Fabrics were contacted by a consultant at Whittington Hospital who was *"desperate for gowns"*. It designed a gown and began discussing orders with NHS Trusts directly. Agua Fabrics ordered substantial amounts of fabric to accommodate the orders it was receiving directly from NHS Trusts.

12.85. By 29 April 2020, there were orders for 2 million gowns sitting with Agua Fabrics. The fabric and design had been tested and accepted at Royal Free Hospital and St Georges' Hospital. Orders had been received from five NHS Trusts. The Trusts were

in the process of supplying purchase order numbers when they were advised on 28 April 2020 that Cabinet Office had to approve the orders. This coincided with the beginning of the PPE Taskforce led by Lord Deighton and when procurement was centralised. The NHS Trusts were informed they could not purchase the PPE themselves and it had to go through central procurement.

12.86. Agua Fabrics attempted to make contact with Cabinet Office between 29 April 2020 and 19 May 2020. They continued to receive orders from other NHS Trusts during this time.

12.87. On 2 May 2020, Cabinet Office's PPE Procurement team contacted Agua Fabrics and asked for its certificates of conformity. HSE initially rejected the gowns as they did not have the correct certifications. Agua Fabrics resubmitted the certificates and on 15 May 2020 received notice from the regulators that it was approved to make and supply gowns. Agua Fabrics was told it would receive a contract form and agreement of terms from the "*Make Team*". An internal email from Darren Blackburn (Cabinet Office) to Deloitte and NHS said: "*Agua Fabrics – approved to make Gowns!! Can we get the next stages done quite quickly please…they could have easily given up and caused a fuss with the papers*".

12.88. Agua Fabrics were then subject to financial due diligence through Cabinet Office. Dawn Chamberlain (Director, Clinical Improvement, Temporary NHS Lead PPE Support, NHSE and NHS Improvement) became involved on 19 May 2020 and asked Cabinet Office to liaise with Agua Fabrics as "*we have struggled to get traction from the Make team*".

12.89. On 27 May 2020, Cabinet Office called Agua Fabrics and informed the company it had not passed Cabinet Office's financial due diligence as it did not meet the criteria. Agua Fabrics was told that it could supply individual NHS trusts and that Cabinet Office would put it in touch with the Liverpool University Hospitals NHS Foundation Trust ('**Liverpool Trust**') to arrange supply to that trust. Agua Fabrics asserted that it was never told what the criteria were before they it was subjected to the checks.

12.90. On 27 May 2020, Dawn Chamberlain emailed Tim Jarvis confirming the orders would not be taken forward and that *"lessons need to be learnt".* On 29 May 2020, Cabinet Office emailed Lord Deighton's private secretary confirming that Agua Fabrics did not meet the criteria as:

a) **Financial** — The total contract value proposed was far in excess of the company's turnover;

b) **Manufacturing capability** — It did not have manufacturing capability and was proposing to outsource this; and

c) **No security in their ongoing raw materials supply**.

12.91. On 29 May 2020, Agua Fabrics was contacted by the Liverpool Trust and told that as it had not passed the financial due diligence required by Cabinet Office, the opportunity would not be pursued. Dawn Chamberlain emailed Tim Jarvis with Agua Fabrics copied in asking him to speak with them.

12.92. At this stage, Tim Jarvis stepped in to mediate the situation, even though it was outside the proposed scope of his team. Agua Fabrics emailed Tim Jarvis its formal complaint, seeking a reversal of Cabinet Office decision. Agua Fabrics began to escalate its complaint, copying in Members of Parliament, and Lord Deighton's House of Lords inbox. The complaint was forwarded from the office of Rt Hon Penny Mordaunt MP, Paymaster General, to the office of Jane Hunt MP.

12.93. Tim Jarvis spoke with Agua Fabrics on 29 May 2020 and said he would respond to Agua Fabrics by 'close of play' 2 June 2020 once he had investigated further. He emailed Cabinet Office seeking clarification on why the company was rejected and who was formally replying to its complaint. Cabinet Office replied stating that no one was going to respond officially as there were many suppliers who had not passed due diligence. Cabinet Office asserted that Agua Fabrics was told repeatedly by the Buy and Make teams that Agua Fabrics would have to pass due diligence.

12.94. Jane Hunt MP forwarded the Agua Fabrics email to Lord Agnew, Minister of State for Efficiency and Transformation, and asked him to respond to the complaint. At this stage, it was flagged that legal teams should become involved, and that a full email trail should be put together, as well as a briefing for Lord Agnew.

12.95. Tim Jarvis compiled a briefing for Ministers as Agua Fabrics continued to pursue its complaint via ministerial offices. Tim Jarvis suggested to Gil Steyaert, that a letter be sent. The decision not to progress with the Agua Fabrics contract was not being questioned. He stated that "*this would not prevent them agreeing a deal with an individual trust as they had appeared to have done, subject to sample testing, before they were directed to the portal*".

12.96. On 2 June 2020, Tim Jarvis spoke with Agua Fabrics. He stated that a central block had not been placed on Agua Fabrics and local trusts and authorities were free to contract with Agua Fabrics if they wished. Agua Fabrics acknowledged it had sold a total of 50,000 gowns to various NHS trusts but had additional fabric for 80-90,000 units. It fed back that there was confusion about manufacturing specification for gowns.

12.97. Following the call, Tim Jarvis wrote to Gil Steyaert stating:

"…this doesn't seem a fair way to treat a UK company. One part of government (an individual NHS Trust) effectively places an order with them and then another part of government (Cabinet Office) tells them a few weeks later that they have failed a financial due diligence test. Yet they have fabric and an acceptable gown design which they now can't sell because the trust that originally ordered them can get alternatives from central procurement."

12.98. Tim Jarvis suggested that the PPE Taskforce re-look at the decision not to proceed. Gil Steyaert agreed with this approach pending assurance of the source and manufacture of the material.

12.99. On 3 June 2020, Agua Fabrics provided further certifications to Tim Jarvis as well as text messages from Whittington Hospital. Of particular note was a message from Kevin Curnow, Financial Director at Whittington Hospital who says he was *"nervous without CO [Cabinet Office] authority"*.

12.100. Tim Jarvis continued to liaise between Agua Fabrics and the PPE Taskforce and NHS Trusts. Other members of the BEIS PPE Make team became involved at this point. They checked the invoices and orders placed by the NHS Trusts and met with some of the Trusts directly. Tim Jarvis undertook further work on the Agua Fabrics matter. In an email dated 11 June 2020, please see SM/249 INQ000477726. He stated that it was a finely balanced matter but noted that Cabinet Office's "*decision not to proceed based on the central criteria for orders has not been in question".* Based on the further work he had undertaken, Tim Jarvis advised that:

"there is insufficient basis to recommend to Jonathan or Emily that they should revisit the decisions that have been made. It is difficult to see how we could justify an order with Agua given St George's position and [Cabinet Office's] assessment of the Agua proposal. Revisiting that decision risk setting a precedent for other companies who may have been in a similar position. That said, it is not a great story."

12.101. On 11 June 2020, Tim Jarvis proposed that Cabinet Office due diligence checks should not be revisited and that the Agua Fabrics case should be closed. Cabinet Office suggested that the fabric from Agua Fabrics be purchased, rather than the gowns. In response to this Tim Jarvis noted *"this might change the letter!"*. Please see SM/250 INQ000477727. Further correspondence between Tim Jarvis, DHSC, and Cabinet Office then ensued throughout June 2020. Further work in relation to Agua Fabrics also took place, for example the providence of the test certificate was investigated.

12.102. However, during a meeting with Agua Fabrics on 17 June 2020 it was stated that the material had already been cut into gowns and therefore purchasing the fabric was not an option.

12.103. In a follow up email on 17 June 2020, Tim Jarvis emailed Cabinet Office and Gil Steyaert and suggested buying the outstanding 96,000 gowns that Agua Fabrics could not sell. Cabinet Office then responded that they could not be procured by direct award as there was surplus of stock in the warehouse. She suggested directing them to NHS Trusts to sell at the local level, and it would be up to those Trusts to ensure the necessary certification was in place.

12.104. Tim Jarvis sent an email to Lord Deighton, Emily Lawson and Jonathan Marron on 30 June 2020. Please see SM/251 INQ000477743. In this email Tim Jarvis set out the background and conclusions in relation to Agua Fabrics. He stated that he did not see a case for revisiting the decision not to proceed with an order and that Agua Fabrics should be advised accordingly. A discussion about whether Agua Fabrics should be paid for the 96,000 gowns then ensued – Tim Jarvis and Emily Lawson supported this plan. On 23 July 2020 legal advice was received from lawyers within DHSC. Based on this legal advice Cabinet Office was content to close this matter. In response to this, Tim Jarvis stated that he would prefer to go through with the order as this is *"an exceptional case"*. Please see SM/252 INQ000477744. The Cabinet Office decision to raise an order and purchase the gowns was then communicated to Emily Lawson and Jonathan Marron. Please see SM/253 INQ000477745.

12.105. Further discussions then took place between Cabinet Office, DHSC and PPE Make, but on 10 August 2020 it was confirmed to Agua Fabrics that a DHSC Request for Approval of Spend documentation had been submitted for finance and legal review. BEIS PPE Make was not involved in this communication or in the subsequent email

which confirmed that an NHS representative would provide intermediary support from 13 August onwards. Please see SM/254 INQ000478770.

12.106. On 20 August 2020 BEIS PPE Make was again included in correspondence in relation to this matter. In this email it was confirmed that following further legal advice the gowns would not be purchased and that Agua Fabrics would be informed that they had failed the due diligence process. Tim Jarvis responded to this email noting that he was surprised by the decision and that to inform Agua Fabrics *"at the end of August that they have 'failed the due diligence process' seems very unfair if not disingenuous*", please see SM/255 INQ000477749. Although, it was accepted that the final decision was not for the BEIS PPE Makes team. However, on 21 August 2020 Tim Jarvis emailed DHSC and NHSE stating that the:

"legal advice is unequivocal and it is difficult to see how any decision to proceed with this contract can now be taken. Having explored other options with [Cabinet Office], it is also clear that none is viable. I therefore agree with [Cabinet Office's] advice... that we should not proceed and should advise Agua accordingly", please see SM/256 INQ000477750. This concluded the involvement of Tim Jarvis and the BEIS PPE Make team in the Agua Fabrics issue.

12.107. DHSC decided it would not pursue a contract with Agua Fabrics and that it would communicate this decision to the company. On 8 September 2020 Dr JJ Van de Meer (Category Director PPE, DHSC) wrote to Agua Fabrics. Please see SM/257 INQ000478772. In this letter it was stated:

"As set out in our email dated 3 July 2020 and discussed in our meeting on 8 July 2020, [DHSC] could only contract with [Agua] for the supply of non-sterile isolation gowns subject to confirmation of necessary approvals. It is regrettable that, following the necessary technical and legal assessments, the DHSC cannot offer a contract to Agua at this time.

It is, of course, not disputed those pre-contractual negotiations with Agua in relation to a potential order for equipment reached a relatively advanced stage. At all times, however, those negotiations remained subject to contract and did not reflect any legal commitment on the part of either the DHSC or Agua to purchase or supply equipment respectively..."

12.108. The letter set out that DHSC's position was final and that it would not be engaging in further correspondence on the subject.

Assistance Provided to DHSC During the Pandemic

12.109. The BEIS PPE Make team, between its creation on 27 April 2020 and disbandment in September 2020 were not involved in the procurement of key healthcare equipment and supplies and did not support DHSC in this regard.

12.110. The Department has considered the question "*please describe what checks and monitoring were carried out in respect of…*". This question may be better asked of DHSC who were involved in the procurement of key healthcare equipment and supplies. Further, the BEIS PPE Make team was not involved in:

a) Advising DHSC teams on regulatory and technical specifications for key healthcare equipment and supplies; or

b) Assisting DHSC in testing for compliance and quality of healthcare equipment or supplies.

12.111. The role of the BEIS PPE Make team between 27 April 2020 and September 2020 was to assist DHSC and Lord Deighton's PPE Make team in a facilitating capacity. The BEIS PPE Make team engaged with businesses to assist them in navigating the regulatory process and to put them in contact with the right part of Lord Deighton's PPE Make team. The BEIS PPE Make team also contacted testing facilities to try to secure locations for testing but did not assist DHSC in testing for compliance and quality. The BEIS PPE Make Team engaged with DSTL and NPL to explore their capacity to assist. BEIS PPE Make's work in relation to identifying testing facilities is set out at paragraph 14.6.

12.112. The BEIS PPE Make Team had limited to no involvement in the decisions relating to and the disposal of PPE that failed compliance or quality testing. However, the PPE Make Team within BEIS was kept abreast of developments in relation to the decisions relating to the disposal of PPE. The following provides non-exhaustive examples of this.

12.113. On 19 June 2020 Tim Jarvis received an email from Selvin Brown MBE (Director, PPE Policy & Engagement, DHSC) recounting a conversation between them the previous day, 18 June 2020, in which they discussed the list of PPE that DHSC would dispose of and that which they would re-test to see if they could meet a lower standard. This email chain demonstrates that decisions and discussions in relation to such were undertaken by DHSC and not BEIS.

12.114. Tim Jarvis and NHSE/NHS Improvement, were provided with updates in relation to PPE, including the fact that other groups, such as the Royal Academy of Engineering, were drawing on their extensive academic and engineering base (nationally and internationally) to work on a range of PPE related issues. This included longer term issues such as the recycling and/or disposal of PPE and the re-use of new and existing PPE.

12.115. The possibility of the repurpose or resale of items of PPE was further raised by Tim Jarvis in his handover email. Please see SM/258 INQ000477753 to DHSC. This was raised in the context of supplies purchased for use in the NHS in Daventry which had been identified as unsuitable or no longer required by the NHS to deal with the Covid-19 crisis. Tim Jarvis stated that DHSC may wish to consider whether it was appropriate to repurpose or resell these items, noting that the products would need to be safe and compliant with the relevant legal requirements before being placed on the market or used for other purposes. He raised that DHSC would want to consider the legal responsibility in making decisions around repurposing and onward sale and that OPSS could provide advice on this matter.

Assistance Provided to Local Authorities in Procuring and/or Distributing PPE and LRFs

12.116. As set out at paragraph 12.109, the BEIS PPE Make team was not involved in the procurement and distribution of key healthcare equipment and supplies, as such assistance was not provided in this regard between 27 April 2020 and September 2020 when the BEIS PPE Make team was disbanded.

Regional Support and LRFs

12.117. On 20 May 2020, the BEIS PPE Make team produced a document promoting regional manufacturing of clinical PPE. Please see SM/259 INQ000475396. The BEIS PPE Make team proposed using the existing regional networks to support small and medium enterprises (**SMEs**) to scale up their manufacture of clinical PPE. Support would be provided by the HVMC and Innovate UK. BEIS PPE Make also suggested working with OPSS to ensure companies have accurate information regarding the requirements for testing and certification. Regional manufacturing would focus on SMEs that were likely to be too small to be considered for central Government contracts. The BEIS PPE Make team would coordinate this work. The proposal was sent to Lord Deighton, Emily Lawson and Jonathan Marron.

12.118. On 27 May 2020, Lord Deighton and Tim Jarvis met and spoke about the work the BEIS PPE Make was undertaking. Regarding regional manufacturing opportunities,

BEIS PPE Make had provided Lord Deighton with a proposal earlier in the week. Lord Deighton was said to be *"tentatively ok"* with the proposal but noted that the primary focus of the project should be to engage with business rather than assessing demand and how it was being met.

12.119. BEIS PPE Make team spoke with colleagues in the commercial section of MHCLG, specifically, Georgina Aplin (Deputy Director, Commercial) to obtain a better understanding of the real supply and demand of PPE. In addition, OPSS supported a wide range of companies manufacturing at a regional level with advice on standards testing to assist new manufacturers through the process.

12.120. In late June 2020, the BEIS PPE Make team sent out questionnaires to LEPs seeking information about how they had secured PPE. Please see SM/260 INQ000475447. The questionnaire stated, *"we want to build a picture of the capacity the UK has to produce PPE at a regional level and to find out which responses and initiatives have worked well in the different regions of the UK."*

12.121. It was accepted that whilst the survey did not provide a complete picture of local manufacturing, it did highlight the importance of local supply chains and LRFs in ensuring continued supply when the central system was struggling in the early pandemic, please see SM/261 INQ000477752. It should be noted the BEIS PPE Make team did not work directly with the LRFs. The scope of the activity undertaken by LRFs varied widely across the UK, with the overall role of the LRF broadly fitting into one of three categories:

a) Procuring PPE elsewhere and then ensuring distribution across all sectors that required PPE;

b) Another group of LRFs worked in partnership with local authorities, but would cease to do so once the 'emergency drops' stopped; and

c) Acting as an intermediary.

12.122. The survey illustrated that the highest number of manufacturing companies were in the Greater Manchester region and the North West with:

a) 15 companies producing masks (including surgical masks and face coverings for the public);

b) 9 companies producing hand sanitiser;

c) 5 companies producing gowns;

d) 3 companies producing scrubs; and

e) 3 companies producing visors.

12.123. The BEIS PPE Make team regularly engaged with the coordinating team in the Manchester region and, by September 2020, this responsibility had been handed to the relevant DHSC team and the Cities and Local Growth team in the Department.

12.124. In addition to the innovation taking place within local supply chains supported by LEPs, by September 2020 the Department, via Innovate UK, had supported 56 projects related to the innovation of PPE across the UK. This included funding (£50,000), regulatory advice and support and funds for testing where required. The funded projects fell into 3 categories:

a) Novel devices;

b) Improvements to existing devices; and

c) Improvements to manufacturing processes.

12.125. BEIS PPE Make fully endorsed the proposal from the NHS Re-use team to embed a team in the PPE Buying Cell to ensure such support continued, especially as one area of difficulty raised by stakeholders was obtaining a clear pathway into the NHS supply chain.

12.126. On 12 August 2020, BEIS PPE Make produced a Regional Make summary paper. This paper, provided at SM/260 INQ000475447, summarised the fact-finding efforts to coordinate the sourcing, manufacture, and delivery of PPE to healthcare and business sectors at a local level. This was sent to DHSC to contribute to the development of its long term resilience strategy. The paper set out the contributions of local authorities, LRFs and LEPs across the country in procuring and supplying PPE. The paper was informed by the questionnaire results, and discussions BEIS PPE Make held with the former MHCLG PPE Cell.

Assistance to the Care Sector

12.127. Thirty-eight LRFs were set up at the start of the pandemic by the Government to supply PPE and other vital supplies to the health and social care sectors. Local services would request PPE via the LRF, who would report these requests centrally. However, most services used this as an emergency route to PPE. Local authorities also took on the responsibility for procuring PPE, and in many instances, this was not a role they were fulfilling before the pandemic.

12.128. Each LRF and local authority worked in a different way. While some procured PPE and ensured distribution, others would act as an intermediary for distribution. Meanwhile, some LEPs were procuring and running their own triage, safety assessment and due diligence of potential suppliers.

12.129. The BEIS PPE Make team, between 27 April 2020 and September 2020, did not provide assistance to the care sector in relation to the procurement of key healthcare supplies and equipment as this fell outside of the role and responsibilities of the team.

Work with Devolved Administrations

12.130. BEIS PPE Make did not assist any authorities in the Devolved Administrations, or those connected to central government, in the detection and seizure of fraudulent or non-compliant healthcare equipment and supplies. The role of BEIS PPE Make was to help identify and assist manufacturers who could produce PPE.

12.131. On 22 July 2020 the 'Personal Protective Equipment (PPE) Strategic Four Nations Meeting' took place. This meeting was attended by representatives from the Devolved Administrations, DHSC, the PPE Team and Cabinet Office. Please see SM/262 INQ000477748. Tim Jarvis provided an update on PPE Industrial Strategy in which he set out the work being undertaken by DHSC and that "*he was keen to hear about DA's work on this area too*". The key points were:

"It was estimated that initially less than 1% of PPE being supplied to health and social care settings was coming from UK manufacturers, this has since increased to around 20% for current orders placed. This is not spread evenly across products with some items easier to shift to UK production than others.

The current focus is looking at how domestic manufacture is supported and how to ensure resilience going forward. There are a range of policy interventions being looked at, from longer term contracts to allow companies to invest, to looking at contracts and how we tender them to give a nod to UK manufacturers, e.g. length of time to get to the frontline or major capital investment to encourage manufacturers in the UK. There is awareness that there is less visibility of the smaller manufacturers including those that supply social care and local trusts. Conversations are ongoing with business representatives about what businesses need and their experience of the system.

Keen to share BEIS's early thinking on this and to hear what DAs are doing to support UK manufacturing and reduce reliance on overseas supply."

Section 13: Longer Term and the De-mobilisation of the BEIS PPE Make Team

13.1. In May 2020, the BEIS PPE Make team began working on an industrial strategy for PPE — a long term resilience strategy to consider all potential sources of products and the resilience of local supply chains. One aspect of the long term resilience strategy was the domestic manufacture of particular products, however, the extent to which this domestic manufacture was cost effective and efficient depended on the risk and mitigations of alternative sources of supply. By the end of June 2020, Tim Jarvis described the BEIS PPE Make team as doing *"a lot of the heavy lifting"* on developing a resilience strategy. Please see SM/263 INQ000475418. This reflected the feeling within the BEIS PPE Make team that DHSC and DIT, who had the requisite expertise and specialisms, had not begun to develop a proper resilience strategy. The BEIS PPE Make team worked to develop a sufficient strategy through their own research and analysis. The team worked with DIT to set the analytical framework and analyse product markets to develop product strategies.

13.2. On 21 July 2020, BEIS PPE Make met with BROs and trade unions to discuss longer-term strategy. In the meeting, BEIS PPE Make officials indicated they wanted to help UK manufacturers and were working on what proportion of supply should come from UK manufacturing in the longer term. Feedback from the attendees was that there needed to be long term security and certainty for manufacturers, with clear guidance and demarcation between the various types of PPE. Further, there was confusion and concern regarding the product marking and the use of CE and UKCA in the UK. When asked if PPE manufacture in the UK had longevity, BEIS PPE Make officials advised that no final decision had been made.

13.3. At a meeting of the cross-Whitehall Oversight Committee on 29 July 2020, Emily Lawson announced that the supply gap had closed and the PPE Taskforce was *"confident in the procurement of critical PPE items"*. Please see SM/264 INQ000475434.

13.4. On 29 July 2020, Tim Jarvis and Jonathan Hoare presented at a meeting of the BEIS Covid-19 Programme Board. They stated that as the supply gap was closed, the BEIS PPE Make team could begin to exit their involvement from the wider PPE Taskforce. Please see SM/264 INQ000475434.

13.5. On 29 July Tim Jarvis provided an update on the work of BEIS PPE Make to Lord Deighton. Please see SM/265 INQ000477747. This update noted that he had turned his attention to how the Department could support PPE Make in the long term. He

noted that the Department should be sighted on DHSC procurement strategy going forward and that he was focussing on regulation and enforcement, which would involve further discussion between OPSS and HSE. In this email Tim Jarvis also took the opportunity to note that:

"there is a pressure for my team to return to their day jobs as business as usual ramps up again in the Department. This is going to leave a skeleton team during August but sufficient to wrap up the work that we are doing and ensure there are ongoing contracts and support within BEIS for the buying organisation".

13.6. It was confirmed that the Department would support a DHSC long term procurement strategy.

13.7. On 30 July 2020, Julian Critchlow (Director General, BEIS) emailed Jonathan Marron, and set out the contributions the BEIS PPE Make team had made to the PPE Taskforce, please see SM/266 INQ000478768. He said the team had "*developed an analytical framework for the PPE buying organisation's category strategies, working closely with DIT colleagues and drawing on the analysis in Project Defend and Project Moat."* On 28 September 2020, DHSC published its strategy to prepare for a second wave of Covid-19.

13.8. Julian Critchlow outlined the role of the Department going forward. He wrote that the Department support would be mainstreamed and that the BEIS PPE Make team would return to their previous roles with the team being officially disbanded by the beginning of September. He also set out the internal Department teams which would continue to assist the PPE Taskforce as required. Please see SM/266 INQ000478768. This included the Chemicals and Plastics Sector Team which could assist with engaging manufacturers and BROs in those sectors and the BEIS Industrial Strategy team which could provide overall strategy support. Contacts for the Innovation team to assist with UKRI funding, and HVMCs were also provided.

13.9. The BEIS PPE Make Director and Deputy Director would remain as the first points of contact throughout September 2020.

13.10. On 4 September 2020 Tim Jarvis met Peter Howitt (Director of PPE Policy, DHSC) and Gary Horsfield (Chief Operations Officer, National PPE Cell, DHSC). On 8 September 2020 Tim Jarvis sent a follow up handover email. Please see SM/258 INQ000477753, which provided:

a) A summary of the main issues the BEIS PPE Make team had worked on, namely: Strategy and Stakeholder, Local Manufacturing, Innovation, Template Designs, Testing, OPSS Support in Daventry, and Regulation.

b) Contacts for the relevant Department teams going forwards ahead of the demobilisation of the standing Department team;

c) That he was satisfied that there were no fundamental barriers to entry to the PPE and medical devices market for UK manufacturers; and

d) That standing Department teams would be able to assist DHSC around the role of UK manufacturing in an overall resilience model for PPE.

13.11. The work of the BEIS PPE Make team was summarised as follows:

"My teams focus was to support the PPE Make cell to help to ensure that UK companies could manufacture PPE and medical devices as early as possible. Our work looked at a range of issues including strategic questions for resilience management with local manufacturing and supply, innovation and template designs, testing and the regulatory environment. BEIS also provided support through the Office for Product and Safety Standards (OPSS) who provided on the ground support in Daventry and ongoing support through the Decision-Making Committee".

13.12. On 11 September 2020 the BEIS PPE Make team was formally disbanded.

Section 14: <u>Lessons Learned</u>

Achievements

14.1. By 24 July 2020, the supply gap in clinical PPE had been closed. A strategy was being formed for short and medium term resilience in the face of a secondary wave in winter 2020/2021.

14.2. Prior to the Covid-19 pandemic, UK manufacturers supplied less than 1% of the clinical PPE used by the health and social care sectors. Following the establishment and efforts of the PPE Taskforce, this was expected to hit 20% by the end of 2020. Pease see SM/267 INQ000478766. Most of these manufacturers were making PPE for the first time and had benefitted from a range of Government support including the Coronavirus Business Interruption Loan Scheme, support with sourcing raw

materials and machinery to convert processes and specialist advice from the manufacturing catapults.[12]

Lessons Learned

14.3. On 12 August 2020, the BEIS PPE Make team, with input from OPSS, undertook a lessons learned exercise as part of the handover of their involvement in the PPE Taskforce. Please see SM/268 INQ000066032.

14.4. The lessons learned paper made a number of recommendations in light of the BEIS PPE Make team's experience since April 2020. It is broken down into three periods of time:

a) Emergency response phase: April to August 2020 (including a discussion of the regulatory framework paper);

b) Winter strategy (until spring 2021); and

c) Long term future.

Lessons Learned: Emergency Response Phase - April to August 2020

14.5. In order to improve the regulatory approvals process, it was recommended that for any future regulatory approvals, the regulators (OPSS, MHRA and HSE) develop accompanying guidance on the tests and evidence needed to sit alongside the specifications.

14.6. A key issue that the BEIS PPE Make team dealt with was a lack of testing house capability and capacity. To resolve this, many UK laboratories expanded their capacity and brought facilities online to test items. However, the paper noted that some of the measures undertaken to meet demand were not considered sustainable in the long term, such as extensive shift work for staff members. Further, at the time of the review, the UK still did not have capacity for two key tests required for surgical gowns and international wait times remained long.

14.7. The BEIS PPE Make team collated feedback from LEPs and NHS Trusts regarding local manufacturing and supply chains. The paper noted that the Cities and Local Growth Unit in the Department would continue to support any LEPs and seek input on how to assist local manufacturers.

Regulatory Framework Paper

[12] The Coronavirus Business Interruption Loan Scheme was designed to provide financial support to smaller businesses across the UK that were losing revenue, and seeing their cashflow disrupted, as a result of the Covid-19 outbreak.

14.8. As set above in Section 10, OPSS conducted a number of lessons learned exercises to reflect and build on the work it had done during the pandemic. In addition, in August and September 2020, PPE Make conducted an analysis of the regulatory frameworks governing PPE and medical device product safety. A paper was prepared to accompany Tim Jarvis' handover note to DHSC on 8 September 2020, provided at SM/269 INQ000477772. The paper provided an overview of the regulatory frameworks, operation of those frameworks during the pandemic, lessons learned, and proposals for future consideration. Whilst the paper was not prepared by OPSS it did provide a number of lessons for the organisation. Please see SM/270 INQ000475453.

14.9. The lessons from this paper are set out below, as well as several proposals that were made for future consideration by OPSS. These lessons fall into the following categories:

a) Organisations operating within the regulatory framework;

b) Guidance produced for manufacturers;

c) Continued use of the regulatory easements; and

d) The operation of the regulatory framework.

14.10. Lessons related to the organisations within the Regulatory Framework:

a) **Organisational responsibilities** — Both the operation of the easements and the approval process that manufacturers had to undergo were more difficult because of the regulatory framework. Two different bodies, HSE and MHRA, were responsible for setting policy and regulations, and three different bodies, HSE (as market surveillance authority) MHRA and OPSS (as PPE product safety policy holder), were responsible for enforcing those regulations because certain PPE was being worn for the dual purpose of protecting the worker and the patients. Having two organisations as leads created issues that were exacerbated by the difference in governance and departmental responsibilities. The paper recommended that OPSS review the policy and regulatory framework and, working with HSE and MHRA, OPSS should determine a single enforcement and market surveillance authority;

b) **Clarity regarding roles and responsibilities** — It was not clear what the role of organisations were in the operation of the easements (discussed above at Section 8). The paper determined that OPSS, HSE and MHRA should prepare

a short guide to explain what their roles and responsibilities were in relation to the operation of the easements. Additionally, when a new procurement organisation was formed, they should provide a briefing note and organogram to OPSS, HSE and MHRA in order to ensure clarity on roles and responsibilities across the board;

c) **Continuity of staff** — The issues related to the regulatory framework were exacerbated by a "*changing cast list of staff*" as short term appointments of consultants were made to key posts;

d) **Authority to oversight committee** — DMC chaired by NHSE was set up as an escalation route for clinical technical and quality questions raised. However, committee members were not always empowered to make decisions and had to revert to senior members of their organisation. Additionally, DMC itself did not have sufficient authority vested in it to drive forward cross-departmental regulator work in relation to essential technical specifications for PPE; and

e) **Sustainability and Innovation Unit** — The report also recommended that a Sustainability and Innovation Unit be established within the new PPE procurement organisation.

14.11. Lessons related to guidance for manufacturers and product approvals:

a) **Guidance** — Initially, the guidance produced by HSE and MHRA to manufacturers and suppliers on the essential technical specifications for PPE was not fit for purpose. As issues arose, they were rectified through subsequent revisions to the guidance, but the following examples were identified in the lessons learned process:

i. The specifications assumed knowledge that was lacking where manufacturers were responding to the Government's call to support the NHS and producing PPE for the first time;

ii. The specifications were not clear about the evidence that needed to be submitted to HSE/MHRA; and

iii. The specifications were focussed on ensuring compliance with relevant regulations, however they needed to also include NHS user specifications (e.g. be linked with the 4 Nations PPE Infection Control Guidance).

b) **CE mark for manufacturers** — Manufacturers that had a contract to supply the NHS for longer than one year should apply for their CE Mark. This would mean that they would not be required to perform additional tests on the product. OPSS, alongside MHRA, was to ensure as far as possible, that this was communicated to manufacturers. OPSS would also investigate providing better support for organisations that were obtaining a CE Mark by potentially issuing guidance to simplify and speed up the CE marking process;

c) **Marketing prior to CE mark** — OPSS would consider whether to allow manufacturers and distributers to market their product for use in a health care setting before the CE marking process is complete. This would have the effect of making the regulatory easement in the document permanent; and

d) **Uncertainty in demand** — Due to the uncertainty around demand forecasts, manufacturers should apply for approval to HSE/MHRA in the first instance. Following approval from HSE/MHRA, they should apply for a CE mark.

14.12. Lessons related to continued use of the regulatory easements:

a) **Easements under review** — OPSS should keep the need for regulatory easements under review and retain the existing easements until there was certainty that sufficient fit for purpose PPE was in the UK to withstand subsequent waves of the pandemic; and

b) **Derogation process** — OPSS should consider a derogation process like the one used under the Medical Devices Regulations 2002, which would remove the need to introduce and operationalise easements in a future event.

14.13. Lessons related to the operation of the regulatory framework:

a) **Faulty products** — It was not clear whether the system was effective at identifying and reporting faulty products. MHRA and HSE, who were responsible for regulatory and policy aspects of PPE and medical devices, had various ways to discover if a product was faulty. MHRA had an online system for reporting faulty medical devices. HSE carried out market surveillance through a virtual product safety team and published information online about how to alert it to a faulty workplace product. It was not clear whether these were well known within the NHS;

b) **Products that are neither PPE or medical devices** — There were some non-PPE products, such as boots and helmets for construction workers, for which

regulatory approval was sought, that were neither PPE nor medical devices and, as such, were regulated under general health and safety legislation and did not require a CE mark. The paper recommended that these products should be brought under product safety legislation.

c) **The process of CE marking is a potential barrier to market entry** — Not all testing that was usually carried out to meet the Essential Health and Safety Requirements for CE marking was necessary in the context of Covid-19. For example, respiratory masks did not need to be tested for prolonged exposure to dust (such as would be necessary for use in a construction context);

d) **Testing rigidity** —The regulatory framework allowed for other innovative solutions to meet the Essential Health and Safety Requirements. Notified Bodies had discretion within the regulatory framework regarding the application of test procedures, but this was being applied in different ways and led to a general lack of consistency of approach across Notified Bodies[13]. OPSS should consider options to ensure the Notified Bodies were flexible and exercised discretion in the tests required for PPE (for example, through guidance or regulation); and

e) **Hazardous PPE** — The paper recommended that OPSS conduct further work to examine how to avoid products being placed on the market that were able to obtain a CE mark but may contain materials that were potentially hazardous or were manufactured in unsanitary conditions. HSE was undertaking some work with the European Committee for Standardisation that set the standards for PPE however scope for further action was identified.

Lessons Learned: Winter Strategy (Until Spring 2021)

14.14. The paper set out that a major problem with the emergency response phase was a lack of clarity around roles and responsibilities for addressing issues that arose during the operation of the regulatory easements. Knowledge on easements' operation was lost due to the constant changing of staff and heavy reliance on consultants. This

[13] An example of such inconsistency was the application of a test for 3D printed face visors. The EN 166 eye protection standard stated that eye protection intended to provide protection against high-speed particles must be tested at extreme temperatures of 55 degrees Celsius and above. The EN 166 standard was for all eye protection, and not specifically PPE for Covid-19. A meeting of the PPE Decision Making Committee on 22 May 2020 noted that this test was being applied by some Notified Bodies but not others in relation to face visors being produced as PPE. The minutes are provided at SM/271 INQ000509486. HSE confirmed on the same day that *"the testing to 55C is not necessary"* for face visors being placed on the market for Covid-19 protection in healthcare. This email is provided at SM/272 INQ000509478.

resulted in delays and mixed messages. Further, it meant that inappropriate demands were made of the regulators.

14.15. Long testing times could delay future delivery of PPE to the frontline. However, the paper noted that there should be reduced demand in future due to the steps taken to increase capacity. OPSS was also working to develop approved designs that could be used by companies and reduce demand for testing. Finally, NHSE were working to increase the use of re-usable PPE.

14.16. To address the lack of testing facilities in the UK for key items, the recommendations set out that the NHS should stockpile certain products, and that the Government should consider supporting the development of new facilities for testing surgical gowns. The paper also recommended the expansion of capacity testing for FFP3 respirators as well as laundry facilities for pre-treatment of reusable isolation gowns.

Lessons Learned: Long Term Future

14.17. The BEIS PPE Make Team recommended that any long term resilience strategy should consider UK manufacturing and ways to encourage manufacturers to enter the market. The paper set out the financial options that could be deployed and suggested that grants would be the most effective tool as they lacked the associated costs and administrative burdens of other financial options. The Regional Growth Fund and Exceptional Regional Growth Fund were put forward as two potential mechanisms to facilitate this.

14.18. The paper also set out that the nature of the emergency phase meant that there was insufficient input from frontline NHS staff into designs. Specifically, that there was a gulf between technical specifications and frontline comfort fit that should be addressed in future. The PPE Re-use Cell found that when manufacturers sought early and repeated input from frontline NHS staff, user comfort and acceptance was increased significantly.

Section 15: <u>Concluding Remarks</u>

15.1. As indicated at the outset I have sought within this corporate statement to set out a summary of the Department's role, the role of OPSS and the role of PPE Make. I have also sought to summarise the lessons learned following review exercises conducted by OPSS (Section 10) and the lessons learned in respect of PPE Make (Section 14).

15.2. As I emphasised at the outset of this statement, and in my previous statements, I recognise the importance and seriousness of this Inquiry and the far-reaching impact of Covid-19 and wish to highlight these lessons learned in concluding this statement.

15.3. As outlined at Section 10, throughout the pandemic OPSS conducted several exercises to learn from and build on the work it had done during the pandemic. Since the pandemic, OPSS has increased significantly in size, which is, in part, to enable it to implement the changes outlined in these reviews.

15.4. As set out at Section 14, PPE Make was a time-limited exercise focused on UK manufacturing capability as a new source of producing PPE. The lessons learned have facilitated input into a long term resilience strategy, supporting DHSC to consider the UK manufacturing base in future work.

15.5. Whilst I have endeavoured to produce a comprehensive and detailed statement on behalf of the Department to best assist the Inquiry with the matters which it seeks to investigate, I would be pleased to assist with any matters which require clarification.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data

Dated: 11 October 2024

Annex One – Key Individuals

Where an individual is listed as still in post, their role transitioned from BEIS to DBT in February 2023

NAME	ROLE	PERIOD IN POST
Ministers		
Johnson Government		
Rt Hon Andrea Leadsom MP	Secretary of State	July 2019 – February 2020
Rt Hon Alok Sharma KCMG MP	Secretary of State	February 2020 – January 2021
Rt Hon Kwasi Kwarteng MP	Secretary of State	January 2021 – September 2022
	Minister of State for Business, Energy & Clean Growth	July 2019 – January 2021
Rt Hon Anne-Marie Trevelyan MP	Minister of State for Business, Energy & Clean Growth	January 2021 – September 2021
Rt Hon Greg Hands MP	Minister of State for Business, Energy & Clean Growth	September 2021 – September 2022
Rt Hon the Lord Jo Johnson of Marylebone	Minister of State for Universities, Science, Research & Innovation	July 2019 – September 2019
Rt Hon Chris Skidmore MP	Minister of State for Universities, Science, Research & Innovation	September 2019 – December 2019
Amanda Solloway MP	Minister for Science, Research & Innovation	February 2020 – July 2021
George Freeman MP	Minister for Science, Research & Innovation	September 2021 – July 2022

NAME	ROLE	PERIOD IN POST
Rt Hon Kelly Tolhurst MP	Minister for Small Business, Consumers & Corporate Responsibility	July 2018 – December 2019
	Minister responsible for OPSS	July 2018 – February 2020
Paul Scully MP	Minister for Small Business, Consumers & Labour Markets	February 2020 – February 2022
	Minister responsible for OPSS	February 2020 – July 2022
Jane Hunt MP	Minister for Small Business, Consumers & Labour Markets	July 2022 – September 2022
	Minister responsible for OPSS	July 2022 – September 2022
Rt Hon Nadhim Zahawi MP	Minister for Business & Industry	July 2019 – December 2019
Lee Rowley MP	Minister for Business & Industry	September 2021 – July 2022
Lord Grimstone of Boscobel Kt	Minister of State for Investment	March 2020 – July 2022
Lord Callanan	Parliamentary Under-Secretary of State for Business, Energy & Corporate Responsibility	February 2020 – September 2022
Truss Government		
Rt Hon Jacob Rees-Mogg MP	Secretary of State	September 2022 – October 2022

NAME	ROLE	PERIOD IN POST
Rt Hon Graham Stuart MP	Minister of State for Climate	September 2022 – October 2022
Jackie Doyle-Price MP	Minister of State for Science & Investment Security	September 2022 – October 2022
Nus Ghani MP	Minister of State for Science & Investment Security	September 2022 – October 2022
Dean Russell MP	Parliamentary Under-Secretary for Enterprise & Markets	September 2022 – October 2022
	Minister responsible for OPSS	September 2022 – October 2022
Lord Callanan	Parliamentary Under-Secretary of State for Business, Energy & Corporate Responsibility	September 2022 – October 2022
Sunak Government		
Rt Hon Grant Shapps MP	Secretary of State	October 2022 – February 2023
Rt Hon Graham Stuart MP	Minister of State for Energy & Climate	October 2022 – February 2023
Nus Ghani MP	Minister of State for Industry	October 2022 – February 2023
George Freeman MP	Minister of State for Science & Investment Security	October 2022 – February 2023
Kevin Hollinrake MP	Parliamentary Under-Secretary of State for Enterprise & Markets	October 2022 – February 2023

NAME	ROLE	PERIOD IN POST
	Minister responsible for OPSS	October 2022 – July 2024
Lord Callanan	Parliamentary Under-Secretary of State for Business, Energy & Corporate Responsibility	October 2022 – February 2023
Permanent Secretaries		
Alex Chisholm		July 2016 – April 2020
Sam Beckett		April 2020 – July 2020
Sarah Munby		July 2020 – February 2023
Directors General		
Julian Critchlow	Energy Transformation & Clean Growth	May 2018 – March 2021
Joanna Whittington	Energy & Security, Emergency Response	February 2020 - Present
Jo Shanmugalingam	Industrial Strategy, Science and Innovation	July 2019 – February 2023
David Bickerton	Business Sectors	August 2021 - Present
Mike Keoghan	Business Sectors	September 2020 – July 2021
Sarah Munby	Business Sectors	July 2019 – July 2020
Directors		
Tim Jarvis	PPE Make	April 2020 – September 2020

NAME	ROLE	PERIOD IN POST
Alice Hurrell	HR	July 2016 - Present
Paul Monks	Chief Scientific Adviser	July 2020 - present
Emma Floyd	C19 Programme Directorate	July 2020 – July 2021
Jess Skillbeck	C19 Programme Directorate	July 2020 – August 2021
Emily Bourne	C19 Coordination Hub	March 2020 – July 2020
Catherine Bremner	C19 Coordination Hub	March 2020 – July 2020
Ben Golding	C19 Coordination Hub	March 2020 – July 2020
Helen Shirley-Quirk	C19 Coordination Hub	May 2020 – July 2020
Deputy Directors		
Jonathan Hoare	PPE Make	May 2020 – September 2020
Mike Ring	PPE Make	May 2020 – June 2020
OPSS		
Graham Russell	Chief Executive	February 2020 – present
Rebecca Bradfield	Deputy Director, Trade, International and Policy	February 2020 – February 2022
	Deputy CEO, Policy and Partnerships	March 2022 - present

NAME	ROLE	PERIOD IN POST
Sarah Smith	Deputy Chief Executive, Policy and Engagement	February 2020 – Feb 2022
	Deputy Chief Executive, Regulation & Market Surveillance	March 2022 - present
Will Cresswell	Deputy Director, National Capability	February 2020 – February 2022
	Deputy Chief Executive, Testing & Targeting	March 2022 - present
Kate Alderney	Deputy Director, Strategy & Transformation	February 2020 – February 2022
	Deputy Chief Executive, Strategy	March 2022 - present
Duncan Johnson	Deputy Director, Construction Products and Delivery	February 2020 – present
Wendy Middleton	Deputy Director, Science, Engineering and Analysis	February 2020 – present
Caroline North	Deputy Director, Energy and Product Enforcement	April 2021 – present
Special Advisers		
Alex Hitchcock		April 2020 – March 2021
Natasha Adkins		February 2020 – October 2022
Celia McSwain		June 2020 – September 2022

NAME	ROLE	PERIOD IN POST
Marcus Natale		August 2021 – September 2022
Cameron Brown		July 2020 – September 2022

Annex Two – Key Terms and Abbreviations

British Safety Industry Federation (BSIF) - BSIF is the Trade Association for the safety industry. Set up in 1994 the Federation has 400 members representing the complete supply chain including manufacturers, importers, and distributors of personal protective equipment and safety products, through to test houses, certification bodies and specialist safety service providers.

British Standards Institution (BSI) - BSI is the national standards body of the United Kingdom. BSI produces technical standards on a wide range of products and services and also supplies certification and standards-related services to businesses.

Cabinet Office - Cabinet Office is a ministerial department responsible for supporting the Cabinet and the Prime Minister.

Cabinet Office Briefing Rooms (COBR) - COBR is shorthand for the Civil Contingencies Committee that is convened to handle matters of national emergency or major disruption.

Cabinet Office Secretariat - The Cabinet Secretariat provided assistance to the Prime Minister, the Cabinet and its Committees, and worked to ensure coordination across government departments. Meetings would normally be attended by the Permanent Secretary, but over time were delegated to Directors General and Directors with expertise in the topic under discussion.

CE Mark -This marking indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health, and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU.

Decision-Making Committee (DMC) - DMC was a cross-government group to assist with the procurement of PPE. It was comprised of HSE, the Department for Health and Social Care, the Medicines and Healthcare Products Regulatory Agency and the Office for Product Safety and Standards, and other experts as required.

Department for Business, Energy and Industrial Strategy (BEIS) - BEIS was a ministerial government department which was created on 14 July 2016. The Department was created through a MoG change and following the merger of the former Department for Business, Innovation and Skills and Department of Energy and Climate Change. The Department was responsible for government policy in the following areas: business; industrial strategy; science, research and innovation; energy and clean growth; and climate change.

Department for Business and Trade (DBT) - DBT is a ministerial government department, which was created on 7 February 2023. It was formed following a MoG change, and now incorporates the functions of the former Department for International Trade (DIT) and some of the functions of the former Department for Business, Energy, and Industrial Strategy (BEIS). It is the department for economic growth and looks to support businesses to invest, grow and export to create jobs and opportunities in the UK.

Department for Education (DfE) - DfE is a ministerial department responsible for children's services and education within the UK.

Department for Energy Security and Net Zero (DESNZ) - DESNZ is a ministerial department established to focus on energy supply, energy efficiency and ensuring that the UK meets its Net Zero commitments.

Department for Health and Social Care (DHSC) - DHSC is a ministerial department which supports Ministers in leading the nation's health and social care to help people live more independent, healthier lives.

Department for International Trade (DIT) - DIT was a ministerial government department responsible for striking and extending trade agreements between the United Kingdom and foreign countries, as well as for encouraging foreign investment and export trade. The department existed between 2016 and 2023.

Department for Trade and Industry (DTI) - DTI was a ministerial department that existed between 1970 and 2007, focussed on UK government's trade, industry and investment activities. It was replaced by the Department for Business, Enterprise and Regulatory Reform and the Department for Innovation, Universities and Skills.

Department for Levelling Up, Housing and Communities (formerly the Ministry of Housing, Communities & Local Government) (DLUHC) - DLUHC is a ministerial department which supports communities across the UK to thrive, with the aim of making them great places to live and work.

Department for Science, Innovation and Technology (DSIT) - DSIT is a ministerial department which focuses on scientific and technological research and development and promoting innovation.

Economic and Business Response Implementation Group (EBRIG) - EBRIG is an MIG which reported on the business implications of Covid-19 to the Prime Minister. EBRMIG had two functions: 1) to ensure rapid communication and engagement with business; and 2) to monitor and respond to the implications of key sectors and businesses.

Emergency Response Team (ERT) - ERT is the generic term for a team, or structure put in place to deal with an emergency. It follows the gold, silver, bronze command structures. Team structures, can change depending on the emergency, will adjust according to issues faced and as part of the transition from response to recovery.

Energy Resilience and Emergency Response (ER2) - ER2 was formed from the expansion of the Energy Resilience team in 2017. It is responsible for working with teams across the Department to ensure they are well prepared for an emergency.

European Economic Area (EEA) - The EEA unites the EU Member States and the three EEA EFTA States Iceland, Liechtenstein, and Norway into an Internal Market governed by the same basic rules.

Executive Committee (ExCo) - ExCo is the senior executive leadership of Cabinet Office which monitors departmental delivery and performance, communicates decisions taken by the Permanent Secretary and takes collective decisions on corporate issues affecting the Department.

Foreign, Commonwealth Office (FCO) - FCO was the UK's ministerial department for foreign affairs. It existed from October 1968 to September 2020. It then merged with the

Department for International Development to create the Foreign, Commonwealth and Development Office (FCDO).

Health and Safety Executive (HSE) - HSE is an executive non-departmental public body, sponsored by the Department for Work and Pensions. HSE is Britain's national regulator for workplace health and safety and seeks to prevent work-related death, injury and ill health.

High Value Manufacturing Catapult (HVMC) - HVMCs are a network of seven Catapult Centres established through Innovate UK, to commercialise new and emerging technologies in areas with large global market opportunities and a critical mass of UK capability. The Catapult programme is a network of technology and innovation centres aimed at bridging the gap between research findings and their development into commercial propositions. The network provides technology and expertise and encourages greater collaboration between research and business.

HM Treasury (HM Treasury) - HM Treasury is a ministerial department and is the Government's economic and finance ministry, maintaining control over public spending, setting the direction of the UK's economic policy and working to achieve strong and sustainable economic growth.

Incident Management Team (IMT) - IMT were an OPSS team who were responsible for implementing OPSS' Covid-19 response plans.

Local Resilience Forums (LRFs) - LRFs are multi-agency partnerships made up of representatives from local public services, including the emergency services, local authorities, the NHS, the Environment Agency and others. These agencies are known as Category 1 Responders, as defined by the Civil Contingencies Act.

Market Surveillance Authority - Market Surveillance Authorities monitor and enforce the requirements of product safety law, using the powers and enforcement tools provided by UK law. Different authorities enforce different aspects of product safety legislation.

Medicines and Healthcare products Regulatory Agency (MHRA) - MHRA is an executive agency of the Department of Health and Social Care in the United Kingdom which is responsible for ensuring that medicines and medical devices work and are acceptably safe.

Ministry of Defence (MoD) - The MoD is a ministerial department in the UK Government responsible for implementing its defence policy.

National Crime Agency (NCA) - The NCA is a UK law enforcement agency. It works to combat many types of crime, including organised crime; human, weapon and drug trafficking; cybercrime; and economic crime.

National Health Service (NHS) - The National Health Service is the publicly funded healthcare system in the UK.

National Trading Standards - the National Trading Standards is a body that is responsible for collecting intelligence to combat rogue traders. It works closely with local trading standards services and the Chartered Trading Standards Institute.

Notified Body - A Notified Body is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market. These bodies carry out

tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required. The relevant Notified Bodies are: SGS United Kingdom Limited, BSI Assurance Limited, SGS United Kingdom Limited, CCQS UK Ltd, Shirley Technologies Limited, trading as BTTG, INSPEC International LTD, SIRA CERTIFICATION SERVICE, ITS Testing Services (UK) Ltd, UL INTERNATIONAL (UK) LTD and SATRA.

The Office for Product Standards and Safety (OPSS) - OPSS is the UK's national product regulator, within the Department. Its purpose is to protect people and places from product-related harm, enabling trade and growth by ensuring consumers and businesses can buy and sell products with confidence.

Personal Protective Equipment (PPE) - PPE is equipment used to prevent or minimize exposure to hazards including biological and chemical hazards.

PPE Make - The PPE Make Taskforce was created jointly by the Department and DHSC in April 2020 with a focus on supporting and facilitating PPE production and procurement.

Public Health England (PHE) - PHE is a former executive agency of DHSC which operated to protect and improve health and wellbeing. This was disbanded in March 2021 and replaced by UK Health Security Agency and Office for Health Improvements and Disparities.

Regulatory Coordination Cell (RCC) - The RCC was established by OPSS to address and find solutions to regulatory issues, which had arisen because of the pandemic.

Strategic Coordination Group (SCG) - SCGs were strategic working groups convened by OPSS to oversee its incident response.

Supply Chain Coordination Limited (SCCL) - SCCL provides oversight and operational management for NHS Supply Chain and its service providers. SCCL is the legal entity through which NHS Supply Chain undertakes its procurement services and transacts with customers and suppliers.

Tactical Coordination Group (TCG) - TCGs were groups designed by the SCG to focus on specific areas of OPSS response to the pandemic at a tactical level. TCGs developed and implemented specific workstreams.

Tactical Working Level Groups - These groups were responsible for delivering specific workstreams such as 'business closures' under the report of a TCG.

UK Accreditation Service (UKAS) - UKAS is the UK's national accreditation body which assesses the competency of organisations to provide certification, testing, inspection, and calibration services.

UK Border Force - UK Border Force is an enforcement command unit sitting within the Home Office, which is responsible for frontline border control operations at UK air, sea and rail ports.

UK Make - UK Make was a joint team, initially set up by DHSC and the Department and run by Lord Deighton. The team aimed to support British industry to produce PPE, allowing healthcare professionals and carers to continue their work. The team would identify and support potential and existing manufacturers who could either scale up production of clinical PPE or retool their existing manufacturing capabilities to start making clinical PPE.

UK Research and Innovation (UKRI) - UKRI is a non-departmental public body sponsored by the Department. UKRI supports research and knowledge exchange at higher education individuals in England and Innovate UK, the UK's innovation agency. UKRI's objective in relation to Covid-19 was to fund research relevant to the stated, emerging and potential needs of government and other actors (e.g. public services, private enterprise) dealing with all aspects of Covid-19 and its wider implications, and to produce impact or useable/actionable knowledge within the lifetime of short-to-medium term awards.

Vaccine Taskforce (VTF) - VTF was a taskforce set up in 2020 to meet the challenge posed by Covid-19 with the objective of securing effective vaccines for the UK as quickly as possible.

World Health Organisation (WHO) - WHO is a United Nations agency responsible for international public health.

Annex Three – Exhibit Table

Please see attached.