Witness Name: Dame June Munro Raine CBE
Statement No.: 4
Exhibits: JR/1 – JR/80
Dated: 31 January 2025

UK COVID-19 INQUIRY

MODULE 5

WITNESS STATEMENT OF DAME JUNE MUNRO RAINE CBE

I, **June Munro Raine**, will say as follows: -

1. I make this statement in response to Rule 9 requests dated 22 May 2024 and 26 September 2024 to address matters of relevance to the role of the Medicines and Healthcare products Regulatory Agency (referred to as the "MHRA" or "Agency") in the Covid-19 pandemic insofar as it relates to matters relevant to Module 5 and where specific information has been requested.

2. On behalf of the MHRA, I would like to express my sincere condolences and sympathy to all those affected by the Covid-19 pandemic.

3. My first three statements of 2 February 2024, 11 September 2024 and 20 December 2024 addressed the topics set out by the Inquiry in respect of Module 3 (Medicines and Medical Devices) and Module 4 (Vaccines and Therapeutics).

4. This statement covers the period relevant to Module 5, i.e. between 1 January 2020 and 28 June 2022, as stated in the Rule 9 request, although I will refer to certain events outside this period in order to answer some of the Inquiry's specific questions. Unless stated otherwise, matters in my statement will refer to England, Wales, Scotland and Northern Ireland as the MHRA is the regulator for the UK nations. In Northern Ireland, the competent authority for EU authorised products is the European Medicines Agency

(EMA). EU versus GB authorised products and their requirements are described further below at paragraph 41.

5. The preparation of this witness statement has required the involvement of specialists and officials within the MHRA and my legal advisers. This statement is to the best of my knowledge and belief accurate and complete at the time of signing. Notwithstanding this, the MHRA continues to prepare for its involvement in the Inquiry. As part of these preparations, it is possible that additional relevant material may be identified. In that eventuality the additional material will be provided to the Inquiry and a supplementary statement will be made if required.

Background

6. I am the Chief Executive of the MHRA; I took up that role as interim in September 2019 and became permanent from 23 February 2021. In this role I am accountable to Health Ministers for ensuring that the MHRA takes all possible steps to ensure that medicines, medical devices and blood products for transfusion meet appropriate standards of safety, quality, effectiveness and performance, thereby protecting the interests of the public, and that the MHRA provides high standards of services to manufacturers, healthcare professionals, patients and the public.

7. I trained in Medicine at the University of Oxford, and in 1978 attained a Bachelor of Medicine and Surgery after undertaking an intercalated MSc in Pharmacology by research. After undertaking various junior hospital jobs and attaining Membership of the Royal College of Physicians, I trained in general practice, attaining Membership of the Royal College of General Practitioners in 1982.

8. In 1985 I joined the Medicines Division of the Department of Health as a Senior Medical Officer working on the Review of Medicines. In 1989 I became a Group Manager in the Medicines Control Agency, an Arms-Length Body of the then Department of Health, overseeing post-authorisation licensing activities. From 1992 to 2005 I was the Principal Assessor to the Medicines Commission.

9. In 1998 I was appointed Director of the Post-Licensing Division of the Medicines Control Agency which, in 2006, became the Vigilance and Risk Management of Medicines Division. In this role, I was responsible for the operation of the Yellow Card scheme

which, as I explain further below, is a mainstay of safety monitoring of medicines in the UK.

10. From 2005 I chaired a European working party on pharmacovigilance and in 2012, I was elected Chair of the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency. In this capacity, I was closely involved in the introduction of the new European Union pharmacovigilance legislation.

11. From 2003 to 2024 I was a member and subsequently Co-Chair of the World Health Organisation Advisory Committee on Safety of Medicinal Products.

The role, functions and aims of the MHRA

12. The MHRA is an executive agency of the Department of Health and Social Care (DHSC). This means that it is legally indistinguishable from the Secretary of State. However, it is operationally independent. Under the Carltona principle[1], the MHRA acts and takes decisions on behalf of the Secretary of State. The MHRA was formed in 2003 following the merger of the Medicines Control Agency and the medical devices Agency. In 2013 the MHRA merged with the National Institute for Biological Standards and Control (NIBSC). The mission of the MHRA is to enhance and improve the health of millions of people in the UK every day through the effective regulation of medicines and medical devices, underpinned by science and research.

13. The MHRA is the United Kingdom's regulator of medicines, medical devices, and blood components for transfusion, responsible for ensuring their safety, quality, and effectiveness. Specifically, the MHRA's primary responsibilities are:
    a. Ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and effectiveness;
    b. Ensuring that the supply chain for medicines, medical devices and blood components is safe and secure;
    c. Promoting international standardisation and harmonisation to assure the safety, quality and effectiveness of all medicines;

[1] The principle was recognised by the Court of Appeal in *Carltona Ltd v Commissioners of Works* [1943] 2 All ER 560.

d. Helping to educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use;
e. Supporting innovation and research and development that are beneficial to public health;
f. Influencing UK and international regulatory frameworks so that they are risk-proportionate and effective at protecting public health; and
g. Designating Approved Bodies (ABs) for third party conformity assessments of medical devices in the UK (as of 1 January 2021).

14. It is not the role of the MHRA to assess medical devices for compliance and assurance marking. This role is carried out by Notified or Approved Bodies, as described below at paragraph 33.

15. I have been asked about the MHRA's role in relation to procurement of healthcare equipment and supplies. The MHRA has no decision-making role in the procurement of either medicines or medical devices for the healthcare system and does not undertake any specific procurement activities in relation to healthcare equipment and supplies. This was the case prior and during the Covid-19 pandemic and continues to be.

16. Further information in relation to the MHRA's functions is set out in the Framework Agreement between the Department of Health and Social Care and the MHRA dated 21 March 2024 [**JR/1 – INQ000507348**].

Key regulations and legislation under which the MHRA operates

17. The MHRA is responsible for regulating medical devices on the UK market, discharging the functions of the Secretary of State under the Medical Devices Regulations 2002. The Medical Devices Regulations 2002 are "safety regulations" within the meaning of section 11 of the Consumer Protection Act 1987. Key regulatory responsibilities in relation to medical devices include pre-market assessments of clinical investigations, setting the regulatory framework for the conditions that devices have to meet before being placed on to the market, assessing all allegations of non-compliance brought to us, using a risk-based system (discussed further at paragraph 202), monitoring the activity of UK Approved Bodies designated by MHRA to assess the compliance of manufacturers (discussed further at paragraphs 34 and 74) and investigating adverse incident

reports or intelligence indicating a potential problem with a medical device (discussed further at paragraphs 198 to 200).

18. As with medicines, as a result of the UK's exit from the EU, different provisions apply to the regulation of medical devices in Great Britain from their regulation in Northern Ireland. In Great Britain, devices are regulated under the Medical Devices Regulations 2002. In Northern Ireland (under the terms of the Windsor Framework), devices continue to be regulated by the EU Medical Devices Regulations (Regulation 2017/745) and the In Vitro Diagnostic Medical Devices Regulations (Regulation 2017/746).

19. It is important to note that the MHRA only regulates products which fall under the definition outlined in Regulation 2 of the Medical Devices Regulations 2002. A medical device under this definition is: any instrument, apparatus, appliance, software, material, or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which:
    a. is intended by the manufacturer to be used for human beings for the purpose of:
        i. diagnosis, prevention, monitoring, treatment or alleviation of disease,
        ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
        iii. investigation, replacement or modification of the anatomy or of a physiological process, or
        iv. control of conception; and
    b. does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means.

20. By Regulation 2 of the Medical Devices Regulations 2002, an 'in vitro diagnostic medical device' means a medical device which:
    a. is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination; and
    b. is intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information—
        i. concerning a physiological or pathological state,
        ii. concerning a congenital abnormality,

iii. to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients, or

iv. to monitor therapeutic measures and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for in vitro diagnostic examination.

21. In the context of Module 5 of the Inquiry, the following are examples of 'medical devices' under the definition of the Medical Devices Regulations 2002:

    a. Medical masks and surgical gloves and gowns for healthcare professionals intended to protect the patient.
    b. Ventilators.
    c. Continuous Positive Airway Pressure ("CPAP") machines.
    d. Lateral flow sample collection kits; and
    e. Polymerase chain reaction ("PCR") sample collection kits.

22. With respect to the definitions provided by the Medical Devices Regulations 2002, the intended purpose of a product plays a crucial role in determining whether it qualifies as a 'medical device'. If a product is not classified as a medical device, it is not within the scope of the Medical Devices Regulations 2002. Details of products which are not classified as medical devices and by whom they are regulated can be found at paragraph 79 to 85.

23. By way of example, personal protective equipment (PPE), face masks, gloves or a gown worn by a healthcare professional may be medical devices if it is intended to protect the patient (as opposed to the wearer), and so must meet the requirements of the Medical Devices Regulations 2002 and be CE, CE UKNI or UKCA marked before it can be sold in the UK. Assurance markings are discussed further at paragraph 41. The intended purpose of the device is stated in the technical documentation the manufacturer holds for the device.

24. By contrast, if a medical face mask is intended to protect the wearer, then it is not considered a medical device and is instead regulated as personal protective equipment (Regulation (EU) 2016/425 of 9 March 2016 on personal protective equipment). Further information can be found within guidance published by the Agency in March 2020 (and updated thereafter) [**JR/2 – INQ000283578**].

25. Therefore, within this statement, protective equipment which meets the above definition of a medical device (and as such is regulated by the MHRA) is referred to as a "protective medical device". Protective equipment that does not meet the above definition of a medical device (and as such is not regulated by the MHRA), is referred to as "PPE".

26. Dual purpose PPE is PPE that can also be used as a medical device as it protects the patient as well as the wearer. As discussed in paragraph 74, it is the responsibility of the manufacturer to define the intended use of their product, and therefore to decide whether it will be marketed as PPE, a protective medical device, or dual use. In the case that the device is dual use, it must meet the requirements of both the PPE Regulation 2016 and the Medical Device Regulations 2002. For example, The UK Medical Device Regulations 2002 contain rules for gloves that are intended to be used both as medical devices and PPE and as such have a 'dual use'. In such cases they will need to meet the relevant requirements of the UK Medical Device Regulations 2002 and the PPE Regulation 2016.

Classification of medical devices

27. Under Regulation 7 of the Medical Devices Regulations 2002 (SI 2002 No 618, as amended), general medical devices are classified into four classes of increasing levels of risk: Class I, IIa, IIb or III in accordance with criteria in the Medical Devices Regulations 2002, Annex IX (as modified by Schedule 2A). These criteria are often called "classification rules". Examples of classification are given below:

    I. Class I – lowest risk e.g. syringes without needles, medicine spoons, spectacle frames, standard adhesive bandages, examination lights.
    II. Class IIa – e.g. short-term corrective contact lenses, suture needles, standard hearing aids, transcutaneous electrical nerve stimulation (TENS) devices.
    III. Class IIb – e.g. apnoea monitors, ventilators, surgical lasers, diagnostic X-ray sources.
    IV. Class III – highest risk e.g. pacemakers, total hip joint replacements, breast implants, contraceptive IUDs, devices containing medicinal substances.

28. The classification of In Vitro Devices ("IVDs") is different to that of General Medical devices. The Medical Devices Regulations 2002 provide for four categories of IVDs, in order of increasing perceived risk to patient safety:

    a. General IVDs, i.e. all IVDs other than those covered below.
    b. IVDs for self-testing (a medical device intended by the manufacturer to be able to be used by lay persons in a home environment) – excluding self-test medical devices covered below.
    c. IVDs in the classifications stated in Part IV of the UK Medical Devices Regulations, Annex II List B [^1]: which, amongst others, includes reagent products for rubella, toxoplasmosis and phenylketonuria as well as medical devices for self-testing for blood sugar.
    d. IVDs in the classifications stated in Part IV of the UK Medical Devices Regulations, Annex II List A [^2]: which includes reagents and products for HIV I and II, Hepatitis B, C and D, and reagent products for determining ABO systems and anti-kell including those used to test donated blood plus tests for screening.

29. Class I medical devices without a sterile or measuring function are self-certified by the manufacturer of the device, which is described at paragraph 75. All other device classifications require assessment and assurance markings by a Notified or Approved Body [**JR/3 – INQ000498483**].

30. Finally, in July 2021 Regulation 2 of the Medical Devices Regulations 2002 was amended to include a definition of 'coronavirus test device' (this includes self-tests) as meaning an "in vitro diagnostic medical device for the detection of the presence of a viral antigen or viral ribonucleic acid (RNA) specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)". This amendment was in order to create a regulatory requirement for the mandatory approval of diagnostic tests for Covid-19 and ensured that tests for sale in the UK meet minimum standards in their sensitivity and specificity. Further detail on the Medical Devices Regulations 2002 and the amendments for Covid-19 tests can be found within the Explanatory Memorandum [**JR/4 – INQ000498480**].

Enforcement powers

31. The Medicines and Medical Devices Act 2021 ("MMD Act") granted the MHRA enhanced enforcement powers, including issuing compliance, suspension, safety, and information notices for non-compliance with the Medical Devices Regulations 2002. Prior to this Act,

the MHRA's authority came from the Medical Devices Regulations 2002 and the General Product Safety Regulations 2005. The MMD Act expanded the MHRA's powers, allowing it to issue enforcement notices requiring a 'person' to take certain action. We can issue such notices not just to manufacturers, but also to others in the marketing and supply chain. Examples of the notices we can issue under the MMD Act include:

I. compliance notices, requiring the person to comply with a specified medical devices provision;
II. suspension notices, restricting the availability of a device in order to protect health and safety;
III. safety notices, imposing prohibitions or requirements on the availability of a device in order to protect health and safety; and
IV. information notices, requiring a person to provide information to MHRA.

32. If we consider it is necessary take action to protect health or safety in relation to a medical device which has already been made available to the public, we can recall that device by taking steps to organise its return. A device may only be recalled if no alternative steps would sufficiently protect health or safety.

Notified Bodies

33. A Notified Body is a third-party body which undertakes assessments of medical devices (outside of Class I) to assess whether manufacturers and their medical devices conform with the regulatory requirements set out in EU legislation. These conformity assessment bodies are responsible for providing assurance markings known as 'CE marks' described further at paragraph 41. An EU Notified Body is designated and monitored by an EU member state. Before the UK's exit from the EU on 1 January 2021, all medical devices intended for market in the EU (outside of Class I) were assessed by Notified Bodies for compliance and assurance markings.

Approved Bodies

34. Prior to the UK's exit from the EU, the MHRA had designated three Notified Bodies: The British Standards Institution (BSI), Underwriter Laboratories (UL) and the General Society of Surveillance (SGS). As of 1 January 2021, with the UK's exit from the EU, the UK introduced Approved Bodies, the UK equivalent of an EU Notified Body. The MHRA is responsible for the designation and monitoring of Approved Bodies. Approved Bodies for medical devices and IVDs are designated in accordance with the provisions of the

Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) and Regulation 920/2013. Organisations applying to be a UK Approved Body for medical devices need to obtain UKAS accreditation under ISO 17021.1:2015 for ISO 13485 before the MHRA can designate them as an Approved Body. Applications to both UKAS and MHRA can be made in parallel.

35. Once an organisation has submitted its application to the MHRA for Approved Body status, this is reviewed by the MHRA to assess four key areas in relation to the organisation:

    I. Legal and organisational requirements, including issues relating to independence and impartiality, liability and financial viability.

    II. Ensuring that the organisation has an effective and controlled Quality Management System.

    III. Resource requirements to ensure that the organisation has sufficient numbers of appropriately qualified staff to undertake conformity assessment of the devices seeking designation.

    IV. Process requirements to understand whether the processes and procedures that the Approved Body will implement for conformity assessment are effective and are in accordance with the requirements set out in the regulations and associated guidance.

36. The MHRA also conducts an audit of UK Approved Bodies covering organisational and general requirements, quality systems, resource requirements and processes. During the pandemic, the MHRA implemented remote audits via Microsoft Teams to ensure Approved Body applications were not delayed, despite travel restrictions. Following the audit and application review process, a designated MHRA Approved Body panel makes the final decision on designation of the new Approved Body. The designation process should take approximately 12-18 months but is dependent on a number of factors, including the readiness of the applicant to progress through the stages outlined. The MHRA's current fees for designating a new Approved Body can be found here: [**JR/5 – INQ000274040**].

37. After successful designation, the MHRA monitors UK Approved Bodies by regular audits and by witnessing their compliance assessment of manufacturers. Both designation and monitoring are subject to fees.

38. Like Notified Bodies, Approved Bodies assess medical devices intended for market in the UK (other than Class I) for conformity with the Medical Devices Regulations 2002. Approved Bodies provide compliant devices with a UKCA mark which allows for medical devices to be placed on the GB market but not the EU. Under the terms of the Windsor Framework, medical devices on the market in NI must comply with EU regulations. Assurance markings are described below at paragraph 41.

39. After 1 January 2021, the MHRA automatically rolled over the previous designation of the three Notified Bodies and appointed them to act as Approved Bodies. To ensure a smooth transition, CE marked devices were recognised in the UK during and following the pandemic, initially to 30 June 2023. In 2023 the Government introduced measures to extend acceptance of CE marked devices in Great Britain to between 2028 to 2030 depending on which EU legislation the product was certified under. An infographic illustrating these dates can be found here: [**JR/6 – INQ000496588**]. The first new organisation to be designated by the MHRA as an Approved Body was the Deutscher Kraftfahrzeug-Überwachungs-Verein (DEKRA), appointed on 2 October 2022.

40. Currently, all designated UK ABs also have a 'sister' EU Notified Body which can issue UKCA and CE marks respectively.

Assurance Marking

41. As described above, it is the role of the Notified and Approved bodies to assess a medical device for assurance marking against regulatory requirements set by the EU or MHRA respectively. Assurance markings signify that a medical device meets specific safety and quality standards, providing assurance to consumers and facilitating market access. Different assurance marks are required according to where the medical device is intended for use, and the timeframe under which it was approved to be placed on the market. The UK Medical Devices Regulations 2002 (as amended) require, since January 2021, that all medical devices whatever their assurance marking, must be registered with the MHRA before being placed on the GB market. Registration on the MHRA's list of medical devices placed on the GB market is not conditional on an assessment.

42. There are four assurance marks:

    i. **CE Mark**: The CE mark signifies that the medical device complies with EU legislation and can therefore circulate freely within the European

market, as well as the UK market within the transitional agreements discussed in paragraph 38. Any mandatory third-party conformity assessment for CE marks must be carried out by an EU Notified Body.

ii. **UKCA Mark**: The UK Conformity Assessed (UKCA) mark was introduced on 1 January 2021 and is the UK's medical device assurance marking. It covers medical devices that previously required the CE mark and indicates that the medical device meets UK requirements. Any mandatory third-party conformity assessment for the UKCA mark must be carried out by a UK Approved Body. The first medical device UKCA certificate was issued by the Approved Body BSI on 29 January 2021.

iii. **CE UKNI / UKNI Mark**: A UKNI mark approved by a UK Notified Body can be used to place a device in circulation in Northern Ireland. This will not allow circulation in Great Britain or the EU. A CE mark approved by an EU Notified Body can be used to place a device in circulation in both Northern Ireland and the EU. A UKNI mark is required if a medical device is to be placed on the Northern Ireland market only, the medical device requires mandatory third-party conformity assessment, and a UK Notified Body is used to carry out those conformity assessments. To issue a UKNI mark, a conformity assessment body must be designated as a UK Notified Body. To date, no organisations have applied for designation as a UK Notified Body. Medical devices circulating in Northern Ireland are therefore marked with a CE mark approved by an EU Notified Body.

Registration of medical devices

43. Prior to the Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) that came into force from 1 January 2021 with the UK's exit from the EU, only Class I medical devices, IVDs, custom-made devices and system or procedure packs needed to be registered. Registration of a device does not represent any form of accreditation, certification, approval or endorsement, but is a requirement for placing a device on the market. A 'system' is a combination of products, either packaged together or not, which are intended to be interconnected or combined to achieve a specific medical purpose. On the other hand, a procedure pack is a combination of devices packaged and

marketed together for a specific medical purpose. Manufacturers whose products were being produced overseas who wished to market them in the UK would be required to appoint either a UK or an EU authorised representative to bring their product to market. However, since 1 January 2021, the MHRA only accepts registration of devices, including protective medical devices, from manufacturers where the manufacturer is based in the UK. If the manufacturer is based outside the UK, they must appoint a UK Responsible Person. This UK Responsible Person will then assume certain responsibilities on behalf of the manufacturer as described in the guidance for UK Responsible Persons [**JR/7 – INQ000498482**], including registering the device with the MHRA. The UK Responsible Person must provide written evidence that they have the manufacturer's authority to act as their UK Responsible Person.

44. In cases where the Great Britain importer is not the UK Responsible Person, the importer is required to inform the relevant manufacturer or UK Responsible Person of their intention to import a medical device. In such cases, the manufacturer or the manufacturer's UK Responsible Person is required to provide the MHRA with details of device importers.

45. Obligations also apply in relation to storage, transportation and checking device labels for the CE marking or UKCA marking. Further requirements can be found here [**JR/7 – INQ000498482**].

Leadership of the MHRA in relation to M5 during Covid-19

46. As outlined above, I have been the Chief Executive and Accounting Officer of the MHRA (SCS3) since September 2019 (interim until February 2021). I led the design, delivery, and continuity of the MHRA's response to Covid-19. I reported to the then Permanent Secretary of the DHSC, Sir Chris Wormald.

47. In respect of the senior MHRA leaders and experts for devices, ventilators and protective medical devices, none of these individuals procured any devices during Covid-19, but worked on efforts to provide regulatory guidance to individuals and bodies who had a decision-making role in procurement.

    a. Dr Alison Cave: Chief Safety Officer (SCS2) since July 2021, reporting to Dame June Raine. She oversees the benefit risk evaluation teams and the patient

safety monitoring team, which monitor the safety of Covid-19 vaccines, medicines, and devices on the UK market.

b. Dr Laura Squire OBE: Chief Healthcare Quality & Access Officer (SCS2) since November 2021, reporting to Dame June Raine; previously Deputy Director, DHSC, working on Covid-19 vaccine deployment policy. In this role she managed the licensing teams that approve vaccines and therapeutics for Covid-19, as well as the MHRA's inspections programme, ensuring compliance with enforcement of medicines legislation, setting medicines standards including through publishing the British Pharmacopoeia.

c. Graeme Tunbridge: Director of the Devices Division (SCS1), reported to Dame June Raine, and to Dr Alison Cave from July 2021. He managed the Devices division and attended NTAG/VTAG meetings discussed below at paragraph 52 and co-chaired the NHS Test and Trace and MHRA Oversight and Steering Group meetings as discussed below. He left the MHRA on 31 December 2021.

d. Dr Janine Jolly: Devices Safety and Surveillance Group Manager (SCS1) until January 2022 reporting to Graeme Tunbridge. Following the restructuring of the Agency, she was appointed to the role of Deputy Director of Benefit Risk Evaluation II and reports to Dr Alison Cave. She oversaw the safety and surveillance strategy for medical devices, of staff responsible for inspection meetings for protective medical devices and procurement and of deployment meetings with manufacturers. She attended the NHS Test and Trace and MHRA Oversight and Steering Group meetings.

e. Johan Ordish: Devices Software and Apps Group Manager (SCS1), until 10 April 2023. He reported to Graeme Tunbridge and then to Dr Laura Squire until his departure and led on software and applications management for medical devices. He attended meetings with NHS England regarding the NHS app to ensure regulations were met and to provide advice. Johan Ordish left the MHRA on 10 April 2023.

f. Tony Sant: Devices Information and Operations Group Manager (SCS1) until 18 February 2022, reporting to Graeme Tunbridge. He oversaw market surveillance of medical devices, specifically overseeing advice on Yellow Card reports for medical devices.

g. Dr Camilla Fleetcroft: Devices Regulatory Group Manager (SCS1) until May 2022, reported to Graeme Tunbridge and then to Dr Laura Squire until her departure. She oversaw compliance, specifically regarding protective medical devices and whether procured protective medical devices met regulations, as well as the Exception Use Authorisation team.

h. Dr Duncan McPherson: Devices Clinical Team Clinical Director (SCS1) until September 2021, reporting to Graeme Tunbridge. He led on the development of the ventilator specifications and provided clinical expertise to internal MHRA teams as well as manufacturers involved with the Ventilator Challenge. He attended the Technical Design Authority meetings stood up by Cabinet Office as discussed below.

The MHRA's Independent Expert Advisory Committees during Covid-19

48. Decision-making by the MHRA is undertaken in the context of independent expert advice from several expert advisory committees. These committees can also establish expert working groups to address specific issues. In the context of Module 5 of the Inquiry, the most relevant committees and advisory groups are the Device Expert Advisory Committee (DEAC) (stood down March 2022, which I explain below) and the In-Vitro Diagnostic Expert Advisory Group (IVDEAG).

a. The IVDEAG was established in February 2021 to advise the MHRA on the development of guidance, policy, regulations, Target Product Profiles ("TPPs") and priority work areas for IVDs. It also advised on the MHRA's communications with relevant stakeholders and professional bodies in relation to IVDs. The IVDEAG has met on 19 occasions since February 2021 and continues to operate. The IVDEAG reported to and advised the DEAC, then reported to and advised the Interim Devices Working Group (IDWG) set up in April 2023 following the DEAC standing down. Between 18 November 2021 when the DEAC was stood down and April 2023 when the IDWG was established, the IVDEAG provided advice direct to the MHRA acting on behalf of Health Ministers.

b. The DEAC was a non-statutory body made up of clinical and scientific experts responsible for providing independent expert advice on a wide range of

aspects relating to medical devices on request from the MHRA in the execution of its role in ensuring the effectiveness and safe use of medical devices. Meetings were held between 2 July 2015 and 18 November 2021.The IDWG was then set up in April 2023. Terms of reference and meeting minutes can be found here [**JR/8 – INQ000498491**].

The MHRA's cooperation and working with the UK Government during the Covid-19 pandemic

49. In line with normal practice, the MHRA co-operated with government departments, agencies and wider throughout the pandemic, to provide regulatory advice to government organisations procuring medical devices. These co-operations helped to ensure that the products being procured met the necessary standards for safety, quality and effectiveness.

50. For example, in 2020, in collaboration with the DHSC, the Health and Safety Executive (HSE), the Office for Product Safety and Standards (OPSS) and Supply Chain Coordination Limited (SCCL), the MHRA led the review of manufacturers' technical documentation on safety and performance of approximately 1,000 lines of protective medical devices and PPE (e.g. facemasks, gowns and gloves) which had been procured by DHSC and held in storage units in Daventry. This is outside the MHRA's normal role as the MHRA does not assess medical devices or PPE for compliance unless an issue has been reported through one of our reporting channels. However, this process was initiated to support access to essential equipment for the public and healthcare workers. An example of an assessment form used internally by the MHRA assessors to support standardisation of process and robust record-keeping and decision-making can be found here [**JR/9 – INQ000534258**]. The MHRA's recommendations were recorded in the product assurance database (PAD) of Supply Chain Coordination Limited (the organisation which operates the NHS supply chain). The MHRA recommendations included 'release / further information required / do not supply'. A formal handover for decision-making to the DHSC technical and regulatory assurance team took place in December 2020 following comprehensive training and support. The MHRA continued to provide scientific and regulatory advice, support and action where necessary throughout the pandemic.

51. The MHRA maintained regular communication with public health bodies, including NHS England (NHSE), Public Health England (PHE) and its counterparts in Wales, Scotland, and Northern Ireland. The MHRA and NHSE co-chaired the NHS Test and Trace and the MHRA Oversight and Steering Group meetings 'A' and 'B' which started in January 2021 and included representation from a large number of organisations and the devolved governments. Meeting A focused on strategic, tactical and operational issues such as development of the test and trace policy and future TPPs for Covid-19 diagnostics. Meeting B focused on post-market surveillance issues where partnership working between relevant bodies was required, for example in relation to system-wide responses to new Covid-19 variants. At these meetings, the MHRA provided advice on all aspects of the NHS Test and Trace project, specifically on the regulations that govern approval of diagnostic devices. This regulatory advice assisted other organisations in making decisions on procurement during the pandemic.

52. The MHRA attended meetings chaired by PHE to provide advice on compliance with regulations for Covid-19 tests, including at the New Technologies Assessment Group (NTAG) and Virus Detection Technology Assessment Group (VTAG) meetings established in March 2020 by the DHSC, and chaired by PHE. The NTAG focused on assessment of serology tests (for example, coronavirus antibodies) and VTAG focused on assessment of technology for the detection of SARS-CoV-2. Graeme Tunbridge attended these meetings on behalf of the MHRA. In the summer of 2020, the Technology Validation Group (TVG) was formed and incorporated the roles and remit previously performed under VTAG and NTAG. The exception to this was assessment and review of Lateral Flow Devices for detection of SARS-CoV-2 which was maintained under the remit of NHS Test and Trace and PHE overseen by the Lateral Flow Oversight Group.

53. Finally, during the pandemic the MHRA sought independent expert advice from the then DEAC. Additionally, the MHRA holds a register of clinical, scientific and technical subject experts who have undergone and have maintained their conflict-of-interest clearance, and who can be consulted when further scientific expert advice is required.

54. Cross-government meetings which took place in relation to ventilators, or the Ventilator Challenge, are discussed in the 'Ventilators' section of this statement.

Independence and Impartiality of the MHRA

55. As outlined above, the MHRA is an executive agency of the DHSC. Whilst the MHRA is indistinguishable from the Secretary of State, it is operationally independent. It acts and takes decisions on behalf of the Secretary of State. The MHRA is accountable to the DHSC, on behalf of the Secretary of State who is accountable to Parliament. Scrupulous care was taken in the Covid-19 pandemic to separate Licensing Authority decisions on vaccines and medicines from procurement and deployment decisions taken by other organisations.

56. In discharging those responsibilities on behalf of the Secretary of State, it is vital that the MHRA demonstrates its independence from any influence over the sectors and activities it regulates. The public understandably expect this of the MHRA, and it is the most fundamental element of our licence to operate, which we take very seriously. It is a topic that requires continual management to evidence the basis for, and maintain, public trust in our independent decision-making. On a practical level, this means the MHRA needs to be aware of the risk of, and put policies in place to manage, potential conflicts of interest in our staff, in our board members, in the members of the independent scientific advisory committees and between different activities of the MHRA, where corporate conflicts of interest may potentially occur.

57. The below paragraphs set out our systems to ensure management of each of those differing types of potential conflict. However, ensuring impartiality and independence of decision-making is an ongoing responsibility of all staff and often features in discussions at the highest level of the MHRA. The MHRA takes legal advice and the judgement of senior leaders, as needed, to ensure we avoid engaging with pharmaceutical and medical devices companies other than in the proper conduct of regulation.

Corporate conflicts of interest

58. During the pandemic, a robust conflict of interest policy was operated by several divisions or groups within the MHRA. For members of advisory bodies, conflicts of interest were overseen by the Operations team; for staff, it was owned by Human Resources; for corporate activities, it was managed by the Policy team; and, for the Board, it sat with the Directorate.

59. When the MHRA's Governance Office was created in June 2021, as a result of the MHRA's transformation programme, the overall responsibility for conflicts of interest was brought together in one place in this new team. The Governance Office is responsible for overall co-ordination of the MHRA's policy on all types of conflicts and for supporting colleagues, such as the Human Resources Group or those supporting expert committees, to implement policies effectively. As part of our ongoing commitment to manage conflicts effectively, the MHRA has worked to update and improve our policies across the board. The MHRA's approach is continually monitored and assessed, with independent and objective assessment by the Government Internal Audit Agency (GIAA), as well as ongoing scrutiny by the Audit and Risk Assurance Committee of the Board.

60. At a corporate level, the MHRA follows its 'Corporate Conflicts of Interest Policy and Procedure'. The policy and procedures for 2020 and 2021 can be found here [**JR/11 – INQ000274043**; **JR/12 – INQ000274037**]. These procedures require the MHRA to continually assess whether any activity that we undertake, or wish to undertake, will cause an actual or a perceived conflict of interest. The policy and procedures are based on the objective of enabling the MHRA to continue its activities and develop new areas of work, in the interests of public health, whilst identifying and taking steps to mitigate and/or avoid potential, actual or perceived conflicts of interest in a transparent way. The policy, and a tracker of our assessment of potential conflicts and the actions we have taken, are published on our website. The latest version of the 'Corporate Conflicts of Interest Policy and Procedure' was published in November 2023 [**JR/13 – INQ000503579**].

Board member conflicts

61. The MHRA's unitary Board is not involved in any regulatory decisions affecting medicines, medical devices or blood products; these are the responsibility of the Chief Executive and the Executive team. The Board's Terms of Reference are here: [**JR/14 – INQ000274034**]. The MHRA's Board members who are not covered by the staff policy (see paragraph 62) are required to declare interests in the pharmaceutical and medical devices industry under the MHRA's 'Policy on Declaring and Managing Interests for Members of the MHRA Unitary Board' (effective from March 2021) [**JR/15 – INQ000274033**]. This policy also provides guidance on holding and declaring other relevant interests, and on how interests that have been declared will be managed.

62. At each Board meeting, as well as annually and as part of the recruitment process, non-executive directors are invited to declare any relevant conflicts of interest. Any conflicts of interest are considered by the Chair, with the support of the Governance Office and noted in the minutes of each meeting (which are published online) and included in the annual list of declarations, which is also published on the MHRA's website [**JR/16 – INQ000274032**]. The policy sets out a range of actions that the Chair may take where a Board member has a relevant interest, including removing the member from the meeting or for a specific discussion.

Staff conflicts

63. As civil servants, all the MHRA's staff are committed to the Civil Service's core values of integrity, honesty, objectivity and impartiality as set out within the Civil Service Code. During the period of the pandemic, the MHRA had a policy 'Dealing with Staff Conflicts of Interest' dated February 2017 [**JR/17 – INQ000274029**]. The policy sets out that staff cannot hold any direct financial interests in the industries the MHRA regulates (the pharmaceutical and healthcare product (medical devices) industries). This policy was updated in 2023 in line with GIAA best practice to provide better technical support for declarations and to improve both declaration rates and line manager action [**JR/18 – INQ000400286**]. However, the underlying principles of avoidance of any conflict of interest remain the same and there were no significant changes to the requirements of staff.

64. Staff are required to declare all relevant interests on appointment, when they arise and annually so that they can be discussed, mitigated and/or disposed of as required. The Human Resources Group produces regular reports on declaration rates. Line managers are required to ensure conflict of interest declarations are completed and, where necessary, mitigations are agreed, implemented and sufficiently address the issue.

Expert members conflicts

65. Decisions relating to the safety, quality and effectiveness of medicines and medical devices are often taken in the face of significant uncertainties and can be complex in form, scope, and potential consequences. These difficult decisions involve making use of the best available scientific evidence to weigh the respective benefits and risks of medicines and medical devices and, sometimes, involve intricate judgements to provide the greatest benefit to the affected populations. Consequently, decisions relating to the

safety, quality and effectiveness of medicines and medical devices can benefit hugely from the advice of independent experts, who are highly skilled professionals with appropriate expertise and are well regarded in their respective fields.

66. As I have outlined above, the MHRA receives advice from a number of independent advisory bodies. On the basis of this advice, the MHRA takes decisions on behalf of Ministers, remaining impartial at all times. Cost is not a factor in the MHRA's decision-making.

67. In July 2020 the report of the Independent Medicines and Medical Devices Safety (IMMDS) Review (a review conducted by Baroness Cumberlege) was published [**JR/19 – INQ000486333**]. The review reflected the continued need for a robust management of committee members' interests. Furthermore, public expectations of public sector transparency and reporting have continued to increase. It was identified that the practice of these advisory committees needs to develop to meet those expectations and demonstrate the best practice expected.

68. The Code of Practice in place before the IMMDS Review report for the MHRA's advisory committees required that committee members declare all interests for all medicines and devices both prior to joining the committee and for every product on the agenda at committee meetings [**JR/20 – INQ000507338**].

69. In the context of the Code, a "personal interest" involved the payment, in any form, to an individual personally, by a pharmaceutical company whose business may be directly affected by the advice of the advisory body. At a meeting, personal interests must be declared as specific (that is, payment relates to a particular product under consideration), or as non-specific (that is, not related to the particular product under discussion). A "non-personal interest" in the context of the Code, involved payment that benefits a department for which an individual is responsible, but is not received by the member personally. As with personal interests, non-personal interests at a meeting must be specific or non-specific. However, it is not only financial interests in the pharmaceutical industry that are relevant. Both the old and new codes of conduct capture a wide range of other matters which may also be considered relevant, depending on the circumstances and matters under consideration by a committee on which an individual serves, and could include non-financial interests.

70. There are no standard guidelines dictating whether "other" interests must be declared. In considering whether an interest is relevant and therefore should be declared, the guiding principle must be whether the matter might reasonably be perceived as affecting a member's impartiality. This relates to a recommendation of the IMMDS Review, which suggested that there should be a clear and transparent governance process to cover potential conflict of interests. The current Code provides that the processes to manage conflicts of interest are robust and clear to all, the role of patients and the contribution they make to committee advice is clearly defined and that they are properly supported to contribute effectively, and that experts remain independent and impartial.

The MHRA's Funding

71. In 2021-2022, the MHRA's activities were funded as set out below:
    a. Medicines regulation is funded from fees charged to the regulated industry. In setting its fees the MHRA takes account of full cost recovery rules as set out in HM Treasury's Managing Public Money document.
    b. Devices regulation is funded by the DHSC with approximately 10% of its revenue from fees charged for services.
    c. The MHRA laboratories, formerly the NIBSC, derive approximately half of their revenue from fees charged for services, including the sale of biological standards, and from research funding. The DHSC provides the remaining funding to finance the MHRA laboratories' important public health functions.
    d. The Clinical Practice Research Datalink (CPRD) is the MHRA's real-world data research service supporting retrospective and prospective public health and clinical studies. The CPRD collects de-identified patient data from a network of GP practices across the UK. Primary care data are linked to a range of other health related data to provide a longitudinal, representative UK population health dataset. The data during 2021-2022 encompassed over 60 million patient records, including 16 million currently registered patients. CPRD recovers its costs via research service fees. Most of its revenue is through Multi-Study Licences to commercial clients. The balance is made up through the sale of a number of other service lines.

72. The MHRA provides bespoke scientific advice and guidance to manufacturers, for example on the development of a medicine. Under normal circumstances, the MHRA encourages manufacturers to contact the MHRA as early in the process as possible to seek regulatory advice. The MHRA charges fees to manufacturers for its regulatory,

licensing and advice activities. Fees and the activities chargeable are published online [**JR/21 – INQ000274040**]. These reflect the charges provided for by regulations, such as The Medicines (Products for Human Use) (Fees) Regulations 2016 (as amended). The standard principle is to set charges to recover full costs. This in practice means that the regulated sector (rather than the taxpayer) bears the cost of regulation. Another principle is to ensure that the MHRA does not profit from fees or make a loss which must then be subsidised by the DHSC or wider government.

73. For certain projects, the MHRA receives grant funding which will set conditions of the funding as to the scope and the delivery of the work. The MHRA is accountable to the grant funding bodies for undertaking the work within the scope of the grant. In respect of Covid-19, the MHRA received such funding from the DHSC, the Coalition for Epidemic Preparedness Innovations and the World Health Organisation. Further information about the Agency's funding arrangements can be found within its 'Annual Report and Accounts for 2020/21' [**JR/22 – INQ000274032**].

Manufacturer and external responsibilities in medical devices

Responsibility of the manufacturer in medical device certification and relationship with MHRA

74. Manufacturers must consider if their product is a medical device before placing it on the market. If their product claims meet the definition of a medical device as outlined at paragraph 19, they must seek appropriate assurance marking. The MHRA has produced extensive guidance on this, and readily provides advice to manufacturers about whether their product is a medical device and if so, which class it may fall into [**JR/23 – INQ000498482**].

75. Under the EU Medical Devices Regulation (2017/745) low risk devices such as Class I medical devices (defined at paragraphs 27 to 29), are self-certified by the manufacturers of the device. To self-certify their device, manufacturers are required to check products meet relevant essential requirements, carry out clinical evaluations and notify the MHRA of any proposals to carry out a clinical investigation to demonstrate safety and performance, register with the MHRA and implement and maintain corrective action and vigilance procedures including a systematic procedure to review experience gained in the post-production phase. Further details on requirements can be found here [**JR/24 – INQ000498490**]. During the pandemic, due to urgent clinical need, there was an

increase in registration of Covid-19 devices for supply to the UK market, which included self-certification by manufacturers. The MHRA did not change requirements for self-certification or registration during the pandemic.

76. If a Class I medical device has a measuring function or is sterile, then it cannot be self-certified and requires a third-party conformity assessment by a Notified or Approved Body. Medium and high-risk devices, classified as Class IIa, IIb and III medical devices, such as hip joint implants or cardiac pacemakers, always need to be certified by a Notified or Approved Body.

77. Finally, manufacturers need to demonstrate that their medical device meets the relevant requirements in the UK Medical Devices Regulations 2002 by carrying out an assessment, known as a conformity assessment. The key requirements of a conformity assessment for medical devices include: essential requirements, ensuring devices are designed and manufactured to be safe; clinical evaluation, where manufacturers must evaluate relevant data, often from clinical studies; a quality management system (QMS), which ensures controlled and documented processes for design, manufacturing, and distribution; comprehensive technical documentation providing evidence of the device's compliance; and a post-market surveillance (PMS) system to monitor device performance and safety after-market release, addressing any adverse events. Depending on the device's classification, the assessment can be done by the manufacturer to self-certify a device or must be done by an Approved, or by a Notified Body. This is discussed in detail above at paragraph 27 to 29.

78. Once a medical device has been placed on the UK market, the manufacturer is required to submit vigilance reports to the MHRA when serious incidents occur in the UK that involve their device, and take the appropriate safety action. The criteria for incident reporting are provided on the MHRA website. The manufacturer must ensure that their device meets appropriate standards of safety and performance for as long as it is in use. Further information about this process can be found at [**JR/25 – INQ000283579**].

The Office for Product Safety and Standards (OPSS)

79. If a manufacturer is not intending to market their product as a medical device, then it may be regulated under the Office for Product Safety and Standards (OPSS). This would have been the case for many PPE products during the pandemic which did not meet the definition of a medical device (e.g. facemasks which are intended to protect the wearer).

80. The OPSS, part of the Department for Business and Trade (DBT), serves as the UK's national product regulator. It is responsible for ensuring the safety of PPE that falls outside the classification of a medical device, using a combination of policy development, legislation, guidance, and market surveillance. The OPSS also leads the coordination of market surveillance across the UK, chairing the Market Surveillance Network, which all Market Surveillance Authorities (MSAs), including the Health and Safety Executive (HSE), attend.

81. During the pandemic, the OPSS provided technical and policy support to the HSE and the MHRA through the Regulatory Coordination Cell, to inform regulatory decisions. This cell was chaired by OPSS and shared intelligence between the groups, as well as technical and policy support. This technical support included providing opinions on whether PPE should be considered as a medical device, and on its compliance. Should the PPE be considered a medical device (therefore considered a protective medical device), compliance would be assessed against the UK Medical Devices Regulations 2002. The MHRA's Devices Compliance Unit (DCU) also worked with the OPSS to share compliance and enforcement documentation to assist with seizures being made at the ports.

82. The Joint Regulatory PPE/Medical Device Clearance Team, also formed during the pandemic, was a temporary group including representatives from the OPSS, the HSE, and the MHRA, which aimed to address the immediate demand for PPE and medical devices by rapidly assessing products arriving from non-standard routes for the NHS supply chain. Decisions were based on available evidence of scientific, technical and regulatory data to support the safety and performance requested by the MHRA from the legal manufacturer and/or its legal representative of the protective medical device. Certificates and test reports were carefully checked for validity to reduce risk posed by counterfeiting. This team was particularly useful for sharing intelligence, advice and decision-making for dual purpose products (i.e. PPE and medical devices).

The Health and Safety Executive (HSE)

83. The HSE is responsible for the enforcement of the Health and Safety at Work Act 1974 throughout Great Britain. Its work includes ensuring that risks to people's health and safety from work activities are properly controlled. The collaboration between the HSE and the MHRA is outlined in agreements such as the Memorandum of Understanding

(MoU) between the HSE, the Department of Health, and the Association of Chief Police Officers (ACPO).

84. The HSE is responsible for investigating accidents in the workplace relating to medical devices, that are not a direct result of shortcomings in the device or instructions for use, but may involve shortcomings by staff, carers, managers or work practices. This includes processing reports from healthcare professionals, medical device manufacturers, and the public to ensure that any safety issues are promptly addressed. The HSE will inform the MHRA, as soon as practicable, when it becomes clear that information, or emerging evidence from an incident or a complaint, is relevant to the MHRA, and vice versa.

85. The MHRA worked in collaboration with the HSE where devices had dual use, to review supporting documentation for protective medical devices and verify compliance with the relevant standards.

British Standards Institution

86. The British Standards Institution (BSI) is appointed by the Government to develop British standards and represent the UK's interests in standards development at a European and global level. During the pandemic, the BSI produced guidance on safe working practices which included recommendations on suitable PPE and protective medical devices for first aiders. The BSI is also a Notified and Approved Body providing conformity assessments for medical devices.

Border Force

87. The Border Force is a law enforcement command within the Home Office. The Border Force secures the UK border by carrying out immigration and customs controls for people and goods entering the UK. The Border Force, as part of its normal activities, may control medical devices entering the UK. However, during the pandemic, the Border Force increased its awareness and prioritised the control of medical products.

88. During the pandemic the Border Force was physically present and active at the ports, stopping and seizing suspected non-compliant medical devices and medicines. The MHRA's DCU worked with Border Force to support this work in producing a pocket size guide which Border Force staff could carry on their person to help assist them in identifying non-compliant devices [**JR/26 – INQ000534255**].

National Crime Agency

89. The National Crime Agency (NCA) leads the UK's fight to cut serious and organised crime, protecting the public by targeting and pursuing those criminals who pose the greatest risk to the UK.

90. For a limited time, the NCA had a dedicated team created to investigate any crime in connection with the Covid-19 pandemic. This resulted in the NCA investigating non-compliant medical devices, and the MHRA's DCU worked alongside the NCA on numerous investigations.

91. For the most part, criminal investigations into medical devices are led by the Border Force, NCA and Home Office police forces, with the MHRA playing a supporting role where necessary. For example, the NCA prosecuted the selling of unauthorised test kits in the UK, Europe and USA which had been refused authorisation by the MHRA but claimed they were 'currently in for approval within the UK health authority' [**JR/27 – INQ000498487**].

Collaborative working

92. I am asked to discuss whether the division of responsibilities between the MHRA and the HSE and BSI may have caused confusion and difficulties in regulation of healthcare equipment. There were clearly defined roles between the respective organisations during the pandemic in line with normal working practices, as described above. In the very early stages of the pandemic, the MHRA's DCU received queries from authorities which investigate medical devices, including local authorities, police, the NCA and the Border Force, enquiring if the products they had encountered were medical devices or not. In some cases, the MHRA received queries that were relevant to healthcare equipment not regulated by the MHRA. For example, the MHRA received queries regarding facemasks which were not medical devices, and these should have been addressed to the HSE. In these cases, the MHRA was able to signpost organisations to guidance available on GOV.UK setting out the differing regulatory responsibilities between the HSE, OPSS, MHRA and Trading Standards [**JR/28 – INQ000498484**].

93. The MHRA published guidance on the regulatory status of equipment being used to prevent Covid-19, detailing the different regulations that applied to medical devices,

protective medical devices and PPE. This assisted the public and health and social care sector agencies in understanding which regulations applied to which equipment [**JR/28 – INQ000498484**].

MHRA's role in supply and technical specifications during Covid-19

Guidance and technical specifications

94. I have been asked about the MHRA's role in relation to technical specifications for medical devices during the pandemic. It is not part of the MHRA's usual role to produce technical specifications for healthcare products. The BSI is the organisation that develops and publishes technical standards.

95. However, to assist UK-based companies in producing protective medical devices, PPE and other key healthcare equipment, the MHRA published specifications for certain medical devices (including ventilators, protective medical devices, PPE, and tests) which set out the clinical requirements based on the consensus of 'minimally acceptable' performance in the opinion of the relevant professionals and the MHRA specialists. The purpose of publishing these documents was to assist manufacturers in ensuring that the medical devices they produced met the 'minimally acceptable' threshold applied by the MHRA, reflecting the minimal requirements where a medical device can be considered to be effective and acceptably safe.

Protective medical devices

96. The MHRA provided proactive regulatory and technical scrutiny for protective medical devices and PPE, that were being considered for procurement by the DHSC. The DHSC requested consideration by the MHRA of a number of protective medical devices and PPE products between 2020 and 2022. The MHRA developed guidance to support this process [**JR/29 – INQ000283573**]. The MHRA would advise the DHSC of their findings on regulatory compliance under the Medical Devices Regulations 2002.

97. The MHRA also worked with NHS England and NHS Improvement to provide advice during the production of a transparent face mask technical specification [**JR/30 – INQ000498481**].

Reusable protective medical devices and PPE

98. The majority of re-usable PPE does not fall under the definition of a medical device (as outlined in paragraph 19 of this statement) and is therefore regulated by the HSE. However, the MHRA did produce a small number of technical specifications for manufacturers for re-usable protective healthcare equipment considered to be a medical device. For example, a manufacturing specification for reusable isolation gowns was produced by the HSE in collaboration with the MHRA as these gowns are dual use (PPE and medical devices), thus falling under the remit of the MHRA [**JR/31 – INQ000498479**].

Target Product Profiles

99. The MHRA also produced Target Product Profiles, specifically in response to the Covid-19 pandemic, for manufacturers of In Vitro Diagnostic (IVD) self-tests for Covid-19 [**JR/32 – INQ000498488**]. The TPPs were guidance documents intended to support and accelerate the development and evaluation of new in vitro diagnostic technologies to address specific unmet clinical or public health needs of high strategic priority to the UK population.

100. The TPPs summarise the key features and anticipated performance specifications of a new device in advance, to enable innovators to design and develop high quality products that are fit for purpose and meet specific health-related aims. They are intended to be used to support product design, research and development planning and to facilitate discussions with regulators.

101. The TPPs do not represent UK Government policy and are not regulatory requirements, therefore devices that do not meet the terms of TPPs can still be approved if they meet applicable regulatory standards.

102. The TPPs are based on the best information available to the MHRA at the time, but the science was (and continues to be) rapidly evolving and so the TPPs are subject to review and could be updated at short notice. By way of example: on 5 June 2020 the MHRA published a Target Product Profile for Enzyme Immunoassay Antibody tests to help determine if people had antibodies to SARS-CoV-2 [**JR/33 – INQ000283516**]. On 15 June 2020 a new Target Product Profile for Point of Care SARS-CoV-2 detection tests

was published [**JR/34 – INQ000283517**]. Further TPPs can be found at [**JR/35 – INQ000283574**]. The TPPs were regularly updated by MHRA experts throughout the pandemic, and we understand that they were found to be of value in many countries.

Ventilators and Continuous Positive Airway Pressure ("CPAP") Devices

103. In response to exceptional circumstances where hospitals were facing ventilator shortages, the Ventilator Challenge was initiated by the then Prime Minister, and the MHRA assisted the DHSC with their regulatory expertise, in creating technical specifications for manufacturers making ventilators and CPAP machines. Further information on the Ventilator Challenge and technical specifications can be found from paragraph 121.

104. The technical specifications created by the MHRA outlined working and safety parameters for ventilators and CPAP machines, but also included specifications on materials, and contained detailed technical instructions [**JR/36 – INQ000498485; JR/37 – INQ000498486**]. On 29 March 2020 a specification for rapidly manufactured CPAP systems to be used during the coronavirus outbreak was published online [**JR/38 – INQ000283523**]. The BSI contributed to some of the more technical guidelines for production, which were essential to help companies, especially those that did not normally produce medical devices, design safe and effective devices. Importantly during the pandemic, the BSI shared their standards free of charge, which allowed the MHRA to include them in their technical specifications.

105. This work enabled companies to ensure that their products met minimum safety standards before applying to put their products on the market and was vital in the success of the Ventilator Challenge, which will be discussed in the 'Ventilators' section of this statement. During the pandemic, and since, the MHRA's technical standards for ventilators and CPAP machines have been used by other countries, the WHO, and companies for the manufacture of ventilators and CPAP machines.

106. I have been asked whether the MHRA and BSI discussed sharing their standards free of charge. To date there has been no discussion or formal agreement between the MHRA and the BSI regarding this matter. However, it is the view of the MHRA that formalisation of an agreement with BSI will ensure the timely availability of standards free of charge in the event of a future pandemic.

Regulatory easement

107. I am asked whether there was any regulatory easement during the relevant period in respect of key healthcare equipment and supplies, and specifically regulatory 'fast-tracking' of PPE and its safety testing. The MHRA did not ease the regulatory requirements for medical devices, however the Agency did operate flexibly using existing regulatory processes to assist in the UK response to the pandemic. For example, under the Medical Devices Regulations 2002 the MHRA can issue an Exceptional Use Authorisation and provided guidance on other routes to fast-tracked approvals.

108. Whilst the MHRA adopted a flexible approach to operational processes involved in the regulation of medical devices, this did not impact on the standards of safety and performance expected to be met which remained aligned with international standards.

Exceptional Use Authorisation

109. An Exceptional Use Authorisation ("EUA") enables the MHRA (acting on behalf of the Secretary of State), to authorise the placing on the market, or putting into service, non-UKCA or CE marked devices in the interests of protection of public health and where there is no legitimate alternative. The MHRA would only consider an EUA application if there is an immediate clinical need for the device, if there are no alternative UKCA/CE marked devices and if there are immediate supply demands, where alternative UKCA/CE marked devices are available but not sufficient to fulfil an immediate need. Following approval of any EUA application, it is a mandatory condition of the manufacturer to report monthly to the MHRA to ensure that any adverse incidents are addressed and to inform the MHRA of the numbers of products supplied and where they were supplied to, to allow traceability. As part of the standard conditions set in an EUA approval, manufacturers must continue to work towards an appropriate assurance marking.

110. The power was used more frequently during the Covid-19 pandemic due to supply shortages of CE marked devices and because new devices needed to be developed and put into use within a short timeframe, for example tests for SARS-CoV-2 or CPAP machines.

111. Applications for exceptional use of medical devices are reviewed by the MHRA's medical devices specialists who consider a number of matters when assessing the suitability of the EUA application. For example:

    a. Review the reasons why the device is not UKCA/CE marked.
    b. Ensure there is certificate evidence of testing to relevant standards. Where no certificate of testing to standards exists, the MHRA will review the data to ensure it meets the appropriate standards.
    c. Conduct a risk assessment of any deviations from the standards based on safety concerns and requirements.
    d. Identify if there is an immediate clinical need for the device, and that there are no alternative UKCA/CE marked devices.
    e. Ensure considerations have been made for the cohort of users, evaluating whether the device is suitable and safe for the intended users, considering factors such as age, health conditions, and any other relevant demographic or clinical characteristic.
    f. Where relevant, ascertain if a Quality Management System for the manufacturing facility is available.

112. A template for the approval of a successful EUA application can be found here: [**JR/39 – INQ000534262**]. Standard conditions could be added to or amended by the assessor as required.

113. During the Covid-19 pandemic, the MHRA did not alter the criteria for assessing EUA applications for medical devices, although they were rare before the pandemic. To illustrate: 56 EUAs were issued during the period March 2020 September 2020, as compared to 3 approvals in the period March to September 2019. In order to meet the urgent demand, the MHRA scaled up the number of assessors and support staff. This scaling up was essential as the team received 131 applications in April and May 2020 alone. From April 2020, to meet demand within short timescales, applications for EUAs were considered within one week. This was achieved through the creation of a new team of re-allocated assessors and support staff from other devices teams, who worked to streamline systems and processes, and reprioritise tasks to facilitate agility and responsiveness.

114. In cases where protective medical devices without a CE mark that were not originally intended to be placed on the market in the EU or UK were to be purchased and

distributed through the parallel supply chain, the MHRA would review the documentation and issue an EUA where appropriate.

115. Recognising the importance of transparency of regulatory decision-making for public trust and confidence, the MHRA published on its website a list of the medical devices which were given EUAs during the pandemic [**JR/40 – INQ000283557**].

Fast track approvals

116. To further ensure that essential and safe medical devices were rapidly available, on 25 March 2020 the MHRA published guidance online on how manufacturers may obtain an EUA for medical devices during the pandemic [**JR/41 – INQ000283571**]. Reflecting the devices that were most in need during the early stages of the pandemic, the online guidance specifically identified ventilators, PPE (including protective medical devices such as gloves, gowns and medical face masks) and Covid-19 diagnostic testing kits.

Procurement and supply of ventilators and related medical equipment

Ventilators

117. I am asked to provide evidence about the MHRA's role, functions and responsibilities in relation to the procurement and supply of ventilators and related medical equipment and supplies. For the purposes of this statement, I understand 'ventilators and related medical equipment and supplies' to include:
    a. Continuous Positive Airway Pressure ("CPAP") machines.
    b. Bilevel Positive Airway Pressure ("BiPAP") machines.
    c. Ventilator machines.
    d. Anaesthetic machines.

118. At paragraphs 17-25 above, I have set out the key regulations under which the MHRA operates with a focus on medical devices; the classification of medical devices; enforcement powers; and assurance marking. As was the case during the pandemic, most ventilators and related medical equipment and supplies are classified as Class IIa or Class IIb medical devices. As such, the MHRA is the responsible regulatory authority. The MHRA's statutory functions do not include either the procurement or supply of ventilators and the MHRA's regulatory role for ventilators was the same as that described in paragraph 15 for other medical devices.

119. In the context of the procurement and supply of ventilators and related medical equipment and supplies, I am asked to provide the names of the key individuals, or groups of individuals, within the MHRA who undertook the preparatory work, decision-making, or who helped implement those decisions once made, including their respective roles, what their roles involved and the chain of command. The leadership of the MHRA, their roles and the chain of command can be found at paragraph 47.

120. Importantly, Dr Duncan McPherson who was the Devices Clinical Team Clinical Director (SCS1) until September 2021, reporting to Graeme Tunbridge, led on the development of the ventilator specifications and provided clinical expertise to internal MHRA teams as well as manufacturers involved with the Ventilator Challenge (see below). Dr McPherson attended the Technical Design Authority meetings in support of the Ventilator Challenge which were stood up by the Cabinet Office, as discussed below.

The Ventilator Challenge

121. On 16 March 2020, the Prime Minister asked companies to help manufacture, design and build thousands of NHS ventilators in the fight against Covid-19, in an initiative called the Ventilator Challenge [**JR/42 – INQ000514108**]. The MHRA's Devices Division supported the Ventilator Challenge. In the initial stages specialist MHRA staff assisted the procurement team in the DHSC by contacting known ventilator manufacturers and asking if they had stock available. A list of those with available stock was passed to the DHSC and can be found here [**JR/43 – INQ000534263**].

122. As above, pursuant to the Medical Devices Regulations 2002, ventilators and related medical equipment and supplies are required to be assessed by a Notified or Approved Body as described at paragraphs 33 to 40. Once a ventilator meets the essential requirements, it will receive a certificate from the Notified or Approved Body. This enables the manufacturer to mark the device with a UKCA, CE or a CE UKNI mark and place the device on the UK market. Assurance marking is described in detail at paragraphs 41 and 42. The depth and rigour of the assessment process means that it can take a significant amount of time for a Notified or Approved Body to issue a certificate (approximately 12 months, though this varies depending on individual circumstances) and for the device to be marked and reach the market. At the time, there was also a backlog in applications to Notified Bodies for new medical devices including ventilators due to the transition to updated regulations following the UK's exit from the

EU. Indeed in 2021, the average time to certification was 6-12 months for 43% of devices and 13-24 months for 53% of devices.

123. As well as EUA applications, the Ventilator Challenge required review of both technical documentation and supporting evidence for the proposed designs, and audit of quality management systems at proposed build sites. The MHRA therefore developed an expedited assessment process, which could be completed within days to weeks depending on the application, to ensure that medical devices could be accessible to patients in the shortest possible time and met the relevant essential requirements and an assessment of the manufacturer's Quality Management System to ensure ISO 13485 critical requirements were covered. The ISO 13485 is an internationally agreed standard that specifies the requirements for quality management systems in the medical device industry. Given the context of the pandemic and the need to act at speed, MHRA requested assistance from Approved Bodies to review applications received as part of the Ventilator Challenge. This process involving Approved Bodies was specifically developed for the Ventilator Challenge and is not the standard process for EUA review.

124. Whilst this expedited assessment process was specific to ventilators, the MHRA implemented accelerated review processes for other medical devices and technologies during the pandemic. Reviews for all EUAs received during the pandemic were accelerated. This included, for example, desktop reviews for EUAs of testing devices, as I discuss at paragraphs 187 and 188. More generally, MHRA processes were adapted as needed to ensure rapid assessment and deployment of critical medical devices. These processes relied on the dedication and exceptional hard work of MHRA staff, who worked in the shortest possible time to ensure thorough and timely assessments.

125. The MHRA remains committed to retaining the scientific and regulatory expertise necessary to enable expedited review processes without compromising its high standards of safety, efficacy and quality. Furthermore, effective strategies for surge resourcing in all main regulatory activities during a pandemic will be vital. In future pandemics, the MHRA would use similar redeployment strategies to those utilised during the Covid-19 pandemic.

126. On 18 March 2020 the MHRA published a technical specification for rapidly manufactured ventilator systems to assist manufacturers in their development [**JR/44 – INQ000283511**]. The specification set out the clinical requirements based on the

consensus of what was 'minimally acceptable' safe performance according to the opinion of specialists in anaesthesia and intensive care medicine from the Health Services Research Centre at the Royal College of Anaesthetists, and experts from the MHRA. It was proposed that:

> "…these ventilators would be for short-term stabilisation for a few hours, but this may be extended up to 1 day of use for a patient in extremis as the bare minimum function. Ideally it would also be able to function as a broader function ventilator which could support a patient through a number of days, when more advanced ventilatory support becomes necessary."

127. I have been asked whether these ventilators were only used for short-term use, and how this was regulated or monitored. The MHRA's responsibility is to ensure that medical devices are acceptably safe and meet the regulatory requirements. We can provide guidance on the safest way to use a device based on the manufacturer's instructions. However, we do not have the ability to monitor how the devices are deployed in clinical practice. It is the responsibility of health trusts to ensure that all employees are familiar with the equipment that they use and any limitations. Healthcare professionals are subject to their own regulatory bodies to ensure that their members meet professional standards, including following the instructions for use for the equipment they use.

128. On 10 April 2020, the specification was updated to adapt to the clinical experience in the UK of the care of patients with Covid-19 and the way this impacted on the requirements for ventilators. For example, clinical advice was that respiratory secretions are more copious in Covid-19 infection than in 'normal' critical care pneumonia, necessitating more frequent suction of secretions, therefore more weight was put in the specification to the closed suctioning test covered in Appendix B [**JR/44 – INQ000283511**]. Further updates are found under the heading "Update on recent clinical experience 10th April 2020" of the exhibited updated specification.

129. As clinical understanding of Covid-19 developed and experience from other countries was gained, Continuous Positive Airway Pressure ("CPAP") therapy was found to be effective for treating patients with respiratory compromise. To meet the increased demand for this device type, the design and building of CPAP devices was included in the Ventilator Challenge. On 29 March 2020, a Specification for Rapidly Manufactured CPAP Systems to be used during the coronavirus pandemic was published online [**JR/38 – INQ000283523**] by the MHRA.

130. The MHRA issued two EUAs for ventilators that met the appropriate requirements. On 15 April 2020 the MHRA authorised the first newly adapted ventilator design. Penlon Ltd was given exceptional use temporary authorisation to supply non-CE marked ESO2 ventilators to UK hospitals, subject to specific conditions [**JR/45 – INQ000283512**]. On 28 May 2020, Penlon was given an EUA to supply ESO2 ventilators manufactured at an additional site to expand production capacity [**JR/46 – INQ000283515**].

131. On 27 May 2020 the MHRA authorised Smiths Medical to supply the Parapac Plus P300 ventilator manufactured at sites not on the CE certificate subject to specific conditions [**JR/47 – INQ000283514**]. The device was already CE marked, but the MHRA granted an EUA to cover the expansion of the production of the ventilator at two additional sites so that demand could be met.

132. The MHRA also issued one EUA for a CPAP device which met the appropriate requirements. On 2 April 2020, the MHRA issued an EUA for a CPAP device developed by University College London (UCL-Ventura) [**JR/48 – INQ000283572**]. This EUA was issued to the developers 36 hours after the MHRA received the test device and technical documentation, with the developers having first contacted the Agency on 18 March 2020. The UCL team commended the MHRA on our effort to support the device from idea to manufacture in such a quick time frame [**JR/49 – INQ000534256**].

133. The EUA for the Ventura CPAP device was extended several times due to ongoing clinical need [**JR/50 – INQ000283550**] and [**JR/50a – INQ000283551**]. The story of how the UCL Ventura CPAP devices was developed and approved was published on 21 September 2020 in the Lancet Journal [**JR/51 – INQ000534257**] and demonstrated the extraordinary efforts of the collaboration between the MHRA, clinicians, bioengineers, UCL, government and industry, including Mercedes Benz Formula One teams. The UCL Ventura CPAP device went on to be approved across 105 countries world-wide, to support other nations, especially low-income and middle-income countries.

134. I have been asked whether the MHRA is aware of UCL Ventura CPAP devices provided to NHS trusts with labels advising that these 'should not be used for clinical use'. To my knowledge, the MHRA was not aware of these labels. We understand that devices were not supplied by the device manufacturer with these labels, and the MHRA had no involvement in the application of such labels.

135. The Ventura CPAP devices remained in service in the UK until 7 December 2022 when they were no longer needed by the clinical community. At that time the MHRA removed

the EUA. The remaining devices were placed into storage by the DHSC in preparation for any future surge in clinical demand for this type of device.

136. These regulatory actions by MHRA contributed to the success of the Ventilator Challenge which enabled 14,000 ventilators to be produced during the pandemic [**JR/52 – INQ000283586**]. Although the initial target of 18,000 by the end of April 2020 was not achieved, by then demand for ventilators was not as high as worst-case scenarios had predicted, modelled on the experiences of other countries. Due to the healthcare system demand having been met, the application route for new submissions to the Ventilator Challenge was closed on 28 April 2020.

137. All ventilators that successfully completed the medical device assessment were required to have specific labels attached to them informing users that these devices were only for use during the Covid-19 pandemic. The labels also contained details of how to report incidents to the MHRA's enhanced post market surveillance mailbox. For ventilators granted an EUA as part of the Ventilator Challenge, increased vigilance of the products was required to ensure any safety issues could be identified and resolved quickly to minimise any risk to patients. Therefore, ventilator manufacturers were given new reporting requirements to report adverse incidents to MHRA in addition to standard reporting requirements [**JR/53 – INQ000283509**]. These additional reporting systems were on top of standard reporting requirements for manufacturers with shorter timescales to report incidents (5 days) and more stringent reportability guidelines.

138. Following the closure of applications to the Ventilator Challenge, the specification was kept on the MHRA website for reference only, and no changes were made to it as it was no longer in use for the development of ventilator designs. The decision to stop accepting applications for the Ventilator Challenge was taken once the Penlon Ltd and Smiths Medical devices had completed the assessment process and production had begun.

Regulatory teams

139. The MHRA set up "Team Vent" on 13 March 2020 and daily meetings were held between 16 March and 20 April 2020. The team's purpose was to manage and prioritise the MHRA's activities relating to supporting the Ventilator Challenge including further clarifying the device specification developed by the UK Government, contacting existing ventilator manufacturers for information on their current ventilator supply, assessing

prospective devices, issuing EUAs, and monitoring the safety and performance of approved medical devices once they were in clinical use.

140. In March 2020, the Cabinet Office convened a Technical Design Authority ("TDA") to assess ventilator designs submitted as part of the Ventilator Challenge and inform decisions. The MHRA participated in meetings of the TDA held between March and May 2020, reporting on the progress of the manufacturers who participated in the Ventilator Challenge. New prospective medical devices were initially screened for viability at the TDA meetings before undergoing MHRA assessment. The MHRA received situational updates from the DHSC about the programme, for information.

141. Further, representatives from the MHRA's internal Team Vent met with manufacturers and designers of potential ventilators to discuss regulatory requirements, including the progress of the designs, the safety and performance requirements of the specification and the assessment process. These meetings were arranged at the request of the manufacturer as they felt they were needed via PA Consulting, or via direct contact with the MHRA assessor leading on the assessment of the device. They were then organised and scheduled by the MHRA, to ensure that the MHRA was up to date with issues, could provide assistance and could update overseas governments on availability as required. In addition, the Government engaged PA Consulting to help with the project management and coordination between government and manufacturers. Any non-regulatory questions were forwarded to the team of independent advisors who were retained for this purpose. Members of the MHRA Team Vent led by Dr Duncan McPherson met as required with members of the PA Consulting team, who were assigned to each manufacturer to monitor progress and discuss potential barriers, such as difficulty in setting up a manufacturing facility to the standard required for meeting the assessment criteria.

Regulatory Costs

142. The MHRA's financial relationship with manufacturers and other bodies is outlined in paragraphs 71 to 73. These principles were not changed for manufacturers of ventilators or as part of the Ventilator Challenge. The MHRA was not paid fees by manufacturers for the Ventilator Challenge.

Patient Safety and incident management

143. I am asked about the MHRA's role in assessing ventilators procured from overseas. Ventilators procured from overseas were all CE marked at the time of purchase as required at the time by the Medical Device Regulations 2002. This meant that the MHRA had no role in assessing the safety or performance of these ventilators unless an incident with the device was reported through our surveillance channels.

144. Between 1 February 2020 and 30 June 2021, the MHRA received 1,261 incident reports concerning all ventilators, anaesthesia machines and CPAP/BiPAP devices on the market at the time. These reports included medical devices sourced both from the UK and from abroad. The manufacturer was required to investigate each of these incidents under the supervision of the MHRA. All reports that led to issuance of safety notices are described at paragraphs 148 to 158.

145. During this time manufacturers also carried out 19 Field Safety Corrective Actions (FSCAs) for ventilators and ventilator equipment. These are actions where the manufacturer has noted a systematic issue with a device that could cause patient injury and is taking action to address this. These actions could range from the manufacturer visiting the site where the device is being used to replace a component, to issuing advice to users on how to address an issue.

146. An FSCA is always accompanied by a Field Safety Notice (FSN) that alerts the users to the issue and informs them of actions to take to ensure patient safety. All these notices are posted on the MHRA website for information and the MHRA monitors the progress of all FSCAs occurring in the UK. The most common FSCA issued during this time was to inform users of the safest way to use an anaesthetic machine as a long-term ventilator. The actions included, for example, regularly checking for condensate build-up and monitoring carbon dioxide levels in the breathing systems since anaesthesia machines have carbon dioxide absorbers which need to be regularly replaced or replenished unlike a ventilator for use in intensive care; and monitoring for drops in pressure when suctioning because ventilators for use in intensive care have auto-compensation systems for suctioning whereas anaesthesia machines do not. This off-label use of an anaesthetic machine is further discussed at paragraphs 152 and 153.

147. When the MHRA considers that a medical device safety issue needs to be communicated to device users, or that additional risk management action is required

other than the manufacturer's, we issue a Device Safety Information (DSI) notice. For higher risk patient safety issues, we issue a National Patient Safety Alert (formerly a Medical Device Alert). National Patient Safety Alerts are disseminated to Medical Device Safety Officers and Medicines Safety Officers in NHS organisations via the MHRA's Central Alerting System (CAS). These alerts were also posted on the MHRA website, and more recently, on the gov.uk website. Alerts can also be sent directly to anyone who has signed up to receive them via the MHRA website. Publication of Medical Device Alerts ceased on 17 September 2020, having been replaced by the National Patient Safety Alert, which is recognised throughout the healthcare system as the most important form of safety alert [**JR/54 – INQ000514109**].

148. The MHRA issued several safety alerts relating to ventilators and CPAP devices during the pandemic. No safety alerts were issued for ventilators or CPAP devices developed as part of the Ventilator Challenge. On 23 September 2020 a National Patient Safety Alert was issued by the MHRA regarding the Philips Respironics V60 ventilator [**JR/55 – INQ000514110**]. The Philips Respironics V60 ventilator had been in use since 2012. The alert was issued following identification of a technical fault with a small number of specific V60 devices that could result in their unexpected shutdown, with or without an alarm, leading to loss of ventilation. The MHRA had received 213 reports to the MHRA between 2012 and 2020 regarding the V60 devices. It is important to note that not all of these reports received related to this specific technical fault as earlier information systems cannot match the report to this specific fault. However, all reports are analysed by assessors, and action is taken when a safety signal is identified. The National Patient Safety Alert advised V60 ventilators be removed from use until the manufacturer had repaired the device and users to seek alternative devices.

149. Given that the alert on the Philips Respironics V60 ventilator was issued during the pandemic when there was a high clinical need for ventilators, the MHRA was mindful to consider risk mitigation strategies to avoid leaving trusts without vital ventilation equipment to meet the increased need brought about by the pandemic. By working closely with DHSC, the MHRA were able to offer suitable alternative CE marked ventilators from stock purchased by the DHSC from various manufacturers to ensure no trust was without equipment.

150. Following the first National Patient Safety Alert, the manufacturer of the Philips Respironics V60 ventilator proposed a corrective action that addressed the problem with the ventilator alarm, however the potential for loss of ventilation was not fully addressed.

The MHRA received a further 8 reports between September 2020 and 29 March 2022, including 2 resulting in patient harm. The MHRA therefore issued an updated National Patient Safety Alert on 29 March 2022 to inform users to seek alternative devices and remove V60 ventilators from use until the manufacturer had repaired the device [**JR/56 – INQ000283583**].

151. Following this alert, the MHRA received 1 report between 29 March 2022 and 18 May 2023 of a fatality suspected to be due to ventilator alarm failure. Despite thorough investigation by the MHRA into this issue, it was not possible to determine the root cause of this failure. The MHRA carried out further extensive safety and technical review, and in line with the recommendations of the Interim Devices Working Group on the 19 April 2023 [**JR/57 – INQ000514107**], concluded that all V60 devices were affected by this issue and did not meet General Requirements set out in Medical Devices Regulations 2002. As such on 18 May 2023, the MHRA issued a National Patient Safety Alert advising all users to permanently remove these ventilators from use [**JR/58 – INQ000514111**].

152. Additionally, in late March 2020 the MHRA identified that as a result of a well-publicised shortage of ventilators in Intensive Care Units, anaesthetic machines were being used as an alternative. Some of the manufacturers published their own warnings about the off-label use of their devices. The MHRA recognised that there were inherent safety concerns with respect to using these machines as an alternative to a ventilator because although both machines are designed to provide suitable respiratory gases to the patient, anaesthetic machines are only designed to do this for relatively short periods of time corresponding to the durations or operations for patients under anaesthesia. There will also be differences in the training and experience of clinical staff.

153. The MHRA recognised that although such off-label use of anaesthetic machines in this way introduced risks (such as the risk of clinicians not having sufficient training to operate anaesthetic machines, and the risk of anaesthetic machine failure due to being used for longer durations than normal), there may have been no other option available in view of the lack of suitable Intensive Care Unit ventilators. Therefore, on 8 April 2020 the MHRA published a Medical Device Alert to draw attention to the risks involved with off-label use of anaesthetic machines [**JR/59 – INQ000283584**].

154. The Medical Device Alert advised that if it was essential to use an anaesthetic machine in this way, the healthcare professionals involved needed to carry out and document a

risk assessment for the patient, familiarise themselves with how the chosen device worked, and follow the specific guidance from individual manufacturers referenced in the alert on the risk mitigating steps that should be taken. The MHRA received 5 reports of incidents resulting from the off-label use of the anaesthetic machines during the pandemic, one of which resulted in patient harm where the patient's blood oxygen levels temporarily dropped below a normal amount, then recovered.

155. Finally, on 23 June 2021, the MHRA issued a National Patient Safety Alert informing patients and users about a component degradation issue affecting most Philips CPAP and BiPAP devices. As above, these devices had been on the market since before the pandemic and were not part of the Ventilator Challenge. The alert was issued following a small number of reports received by the MHRA from outside of the UK in hot and humid environments. Reports detailed degradation of the foam component of the devices causing short-term effects such as irritation to the skin, eyes and respiratory tract, an inflammatory response, headaches, and asthma. However, no confirmed incidents of patient harm had been reported in the UK.

156. An alert was initially issued in the United States on 14 June 2021 by the FDA which recommended stopping the use of the device. Philips issued a notification that they were recalling devices in the United States only [**JR/60 – INQ000514112**]. The MHRA in response carried out an analysis of the known risks of patients suddenly stopping treatment with the theoretical risks posed by the continued use of the device. The analysis concluded that the risk of harm to the patient was higher when treatment was stopped. Details of this assessment can be found in the "Risks involved in stopping treatment" section of our alert on this issue published on our website [**JR/61 – INQ000514113**].

157. Therefore, on 23 June 2021, the MHRA issued a National Patient Safety Alert advising that patients should not stop using the device unless a risk assessment had concluded that the risks outweighed the benefits. It also advised on actions to be taken which included implementing and documenting a risk assessment to determine the suitability of the continued use of the device, to source alternative devices where clinically appropriate, and to train staff and patients in using the alternative devices [**JR/61 – INQ000514113**].

158. Following the MHRA review, the advice to continue use unless a risk assessment indicated otherwise was adopted by other countries. This included the United States

where the FDA published updated advice on their website on the 30 June 2021, a few days after the MHRA's alert [**JR/62 – INQ000514114**]. Following the National Patient Safety Alert, the MHRA received 70 reports associated with claims of degradation of the polyester-based polyurethane sound abatement foam, which is used to reduce sound and vibration in these affected devices. Of these, 34 reported suspected injury resulting from the foam degradation. The devices were inspected by the manufacturer; only one device was confirmed to show signs of foam degradation, and no report indicated that the patient involved had suffered any negative health consequences.

Reflections on the Ventilator Challenge

159. Finally, I am asked to consider an article published on 4 May 2020 in the Guardian newspaper: 'The inside story of the UK's NHS coronavirus Ventilator Challenge':

> *"According to one source, the firms that opted to design and build new machines had to lean heavily on support from the medical device regulator, the Medicines and Healthcare products Regulatory Agency (MHRA)."*
>
> *"Without the independent regulatory teams, most of these projects would have gone nowhere," the source said. "It's easy to say you can just design a ventilator, but the safety isn't just in the design, it's about how you make them, the quality management, servicing them. It's not an innovation programme, it was there to meet a clinical need. And that need was always most likely to be met by scaling up manufacture of existing devices."*

160. I have set out above the support which the MHRA provided in the designing and building of new ventilators with regards to regulatory guidance and technical specifications. With the announcement of the Ventilator Challenge, the MHRA received a large influx of interest from manufacturers of different sectors to start making ventilators. This initial correspondence was triaged in TDA meetings, which are discussed above at paragraph 140.

161. The MHRA Team Vent, via the PA Consulting firm as discussed at paragraph 141, met with manufacturers to advise on their designs and quality management systems. Of the 12 viable ventilator designs that were reviewed in full by the MHRA, 9 designs were rejected, and 3 were deemed to meet safety standards and requirements (outlined in

paragraphs 130 and 131). Two of the designs came from companies that were already medical device manufacturers, one of which only required quality management system advice as it was using new manufacturing sites to upscale the manufacture of their device, and one which redesigned anaesthetic machines it was already producing.

162. Of the rejected ventilator designs, many were rejected where they did not meet safety standards and requirements. Medical devices have rigorous safety standards and requirements which need to be met, due to the intended use of the product and associated risks. These standards would have been difficult to achieve by companies that did not already produce medical devices, especially in the short timescale required by the Ventilator Challenge.

Protective Medical Devices and Personal Protective Equipment

163. As is explained with an example from paragraphs 23 to 25 within this statement, protective equipment which meets the definition of a medical device (and as such is regulated by the MHRA) is referred to as a "protective medical device". Protective equipment that does not meet the above definition of a medical device (and as such is not regulated by the MHRA), is referred to as "PPE", unless it can be used as both PPE and a protective medical device, in which case it will be referred to as 'dual use'. Dual use legislative requirements are also discussed in paragraph 26.

164. In the context of Module 5 of the Inquiry, the following are examples of 'protective medical devices' under the definition of the Medical Devices Regulations 2002:
    a. Medical masks intended to protect the patient
    b. Surgical gloves intended to protect the patient
    c. Gowns for healthcare professionals intended to protect the patient.

165. The key legislation, regulations and guidelines which set out the standards and specifications for protective medical devices, prior to and during the relevant period, are described in detail at paragraphs 17 to 25. There were no amendments to the Medical Device Regulations 2002 in relation to PPE or personal medical devices.

Co-operation with organisations concerned with PPE

166. In line with normal practice, the MHRA co-operated with government departments, agencies and more widely within the National Health Service throughout the pandemic, to provide regulatory advice to government organisations procuring medical devices. These co-operations helped to ensure that the products being procured met the necessary standards for safety, quality and effectiveness.

167. Committees, workstreams, working groups and liaisons in which the MHRA was involved with regard to decision-making on protective medical devices and PPE are described from paragraph 49. In summary this includes:

a. Collaboration with the DHSC, the Health and Safety Executive (HSE), the Office for Product Safety and Standards (OPSS) and Supply Chain Coordination Limited (SCCL); the MHRA led the review of manufacturers' technical documentation on safety and performance of approximately 1,000 lines of protective medical devices and PPE which had been procured by DHSC prior to a formal handover to DHSC in December 2020 (see paragraph 50).

b. The Regulatory Coordination Cell, where the OPSS provided technical and policy support to the HSE and the MHRA, and shared intelligence between the groups, as well as technical and policy support. The terms of reference of the Regulatory Coordination Cell can be found here: [**JR/63 – INQ000534254**]. This technical support included providing advice on whether PPE should be considered as a medical device and if so, its compliance with legislative requirements i.e. the UK Medical Device Regulations 2002.

c. Ad hoc collaboration between the MHRA's Devices Compliance Unit (DCU) and the OPSS to share compliance and enforcement documentation to assist with seizures of non-compliant products being made at the ports.

d. The Joint Regulatory PPE/Medical Device Clearance Team, which aimed to address the immediate demand for PPE and personal medical devices by rapidly assessing evidence and documentation of product safety and performance. This related to all stock held by the DHSC in storage units in Daventry including those medical devices granted an EUA by the MHRA and supplies from recognised medical device organisations (such as established

medical device manufacturers or distributors) and non-medical 'non-standard' routes of supply (such as retail store). Regardless of source, such stock was subjected to the same level of MHRA scrutiny of the evidence available and robust decision-making to either allow release of stock, or that it should not be supplied (see paragraph 96).

e. Ad hoc collaboration with the HSE where devices had dual use, to review supporting documentation for protective medical devices and verify compliance with the relevant standards.

f. Ad hoc collaboration with the Health and Safety Executive to develop guidance as described in paragraph 98.

g. Ad hoc work with the British Standards Institution which produced guidance on safe working practices which included recommendations on suitable PPE and protective medical devices for first aiders.

h. The MHRA's DCU collaboration with the Border Force to identify non-compliant devices and prevent sale and supply.

168. Furthermore, with regard to protective medical devices and PPE, the MHRA participated in the DHSC Decision-making Committee. This was a multi-disciplinary group involving DHSC, OPSS, HSE, PHE (now replaced by UKHSA), and infection prevention and control (IPC) cells of the devolved governments [**JR/64 – INQ000534261**], which aimed to enable regulatory technical and clinical decision-making on product concerns that were escalated from PPE buying cells, regulators, as well as issues from reuse and innovation. The group also agreed essential specification standards and took informed decisions on whether product specifications met the requirements of use.

169. The MHRA also attended adverse incident review meetings with NHSE and DHSC to discuss emerging safety trends and appropriate actions. Throughout the pandemic the group used a range of data sources including Yellow Card reporting information.

User considerations for personal medical devices and expiry dates

170. In terms of providing guidance for the end users of PPE during the relevant period, it is outside of the MHRA's regulatory remit to recommend devices or alternative devices for use by end users. The MHRA's role lies in regulating whether devices meet essential requirements of safety and performance when used as intended by the manufacturer and does not extend to making comparisons of products for use by end users. Further, I have been asked whether the use of the respiratory hood was recommended as an alternative to other protective medical devices or PPE during the pandemic. Respiratory hoods are PPE, protecting the user, and therefore do not fall under the MHRA's regulatory remit.

171. Manufacturers are responsible for setting and monitoring expiry dates as per the regulations set out in paragraphs 74-78. In setting expiry dates, manufacturers will undertake real-time or accelerated 'ageing testing' which examines a medical device's longevity and ensures that the device meets the relevant essential requirements of safety and performance during its shelf life and clinical use. The MHRA is not responsible for checking expiry dates. However, if protective medical devices are found to be in circulation without expiry dates or there is an issue reported with expiry dates, this might be reported to the MHRA through one of our surveillance channels as a labelling issue and the MHRA would require the manufacturer to ensure that a validated expiry date was included on the device or ensure there is a valid scientific rationale for not including one.

172. Where there is a need to extend an expiry date, accelerated ageing tests can be performed on products to replicate the effect of, for example, 3 years of ageing over a period of 3 months, as per BSI standards ISO BS EN 11607 for stability testing [**JR/65 – INQ000534253**]. Evidence would need to be gathered to ensure that the safety and performance of the medical device and all relevant requirements within the regulations are still met before placing on the market or putting it into use.

173. There were occasions during the Covid-19 pandemic where protective medical devices in circulation were being used outside of their original expiry dates set by the manufacturer. This was following the extension of expiry date testing project coordinated by PHE and DHSC as part of Pandemic Influenza Preparedness Programme (PIPP) stockpiling prior to the pandemic and where a new expiry date label was applied. The MHRA had limited input into this project. The PIPP medical face masks were, however, brought into Daventry stock from the PIPP stockpile.

174. When put into use, one brand of polyurethane medical face masks was reported, via channels discussed in paragraph 192, including the Yellow Card scheme, to cause respiratory irritation from degradation of the polyurethane foam being inhaled by the wearer [**JR/66 – INQ000534260**]. Therefore, the DHSC requested the MHRA protective medical device team to provide regulatory and technical guidance and to assess the evidence obtained by PHE and DHSC and the device company involved.

175. The MHRA recommended further testing by the company, and asked for evidence that the testing had been performed and results of the tests to confirm that the material(s) in the protective medical device did not increase the risk of producing particles or other degradation factors when used past its original expiry date, and that the device met certain performance criteria against a recognised standard (BS EN 14683). The investigation concluded that the stock should be disposed of. Following an in-depth investigation and review of the evidence, the MHRA recommended to DHSC that no further PIPP stock should be supplied, where needs could be met by other means.

176. Additionally, the DHSC formed a working group to explore the feasibility of extending the original expiry date of certain protective medical devices held in Daventry following procurement. Whilst the MHRA was not part of this group, it provided technical and regulatory advice. The MHRA advised that new scientific evidence and repackaging and relabelling would be required to demonstrate compliance with relevant essential requirements of safety and performance of the protective medical devices. The MHRA advised that undertaking this would be the role of the manufacturer or the DHSC. In the latter case, the DHSC would effectively become the legal manufacturer. It would then take on its responsibilities to meet all relevant requirements set out in Medical Devices Regulations 2002 to apply the UKCA (or CE) mark, in order to protect patients.

Manufacture, importation and distribution

177. The applicable legislation, regulations and guidance that the manufacturer must consider when placing a protective medical device on the market are outlined in paragraphs 74 to 78. The MHRA does not provide regulatory oversight for importers, distributors or those who sell or supply medical devices, however the MHRA may be made aware of issues at the point of importation, distribution or selling of a product through its surveillance systems. For example, during the pandemic, the Border Force would regularly report to the MHRA protective medical devices they considered might be non-compliant.

The MHRA would respond by assessing these items at the border, prior to any distribution or sale in the UK. If found non-compliant, the Border Force would seize the medical devices, and these would not enter the UK market. Between March 2020 and March 2023, the MHRA's records show that DCU prevented 20,619,501 medical devices related to Covid-19 from entering the UK market. These represent individual devices (such as a mask, a gown, gloves etc.).

178. I am asked what approvals, authorisations, certifications or declarations, prior to and during the relevant period, were required for the importation and use of protective medical devices manufactured abroad for use in the UK health and social care systems. Prior to and following the pandemic, protective medical devices to be used in the UK (regardless of where they are manufactured) require an assurance marking, either by self-certification or via conformity assessment by a Notified or Approved Body as described in paragraphs 33 to 42.

179. Protective medical devices are generally Class I devices, and unless they are marked as sterile they can generally be self-certified by the manufacturer without the involvement of a Notified or Approved Body, as described in paragraph 75. However, since the pandemic created an immediate clinical need for protective medical devices and an immediate supply demand, where available UKCA/CE marked devices were not sufficient to fulfil the need, the MHRA responded by issuing EUAs for non-CE marked or UKCA marked devices, including protective medical devices, following an appropriate assessment.

Exceptional Use Authorisations for protective medical devices

180. During the pandemic between January 2020 and June 2022, the MHRA issued 12 EUAs related to protective medical devices which can be found in the table below. These EUAs have now expired or been cancelled.

Product Name and Manufacturer	**Date EUA Issued**
Kesslers Model 1 Face Shield manufactured by Kesslers International	16 April 2020
Dual use Visor manufactured by Macpac	7 April 2020

Product Name and Manufacturer	Date EUA Issued
Versoshield manufactured by Agentdraw Ltd	7 April 2020
Sempermed Supreme Latex powder-free medical gloves manufactured by Semperit Group	7 April 2020
OptiPro 3ply Disposable Protective Face Mask manufactured by Optimum Medical / Optimum Medical Solutions Ltd	23 April 2020
Non-woven Isolation Gown manufactured by VHMED and distributed by Bio-spectrum	17 April 2020
Type IIR masks manufactured by Naton Biotechnology Co., Ltd.	20 April 2020
Type II masks manufactured by 365 Healthcare	27 April 2020
Type IIR masks manufactured by 365 Healthcare	16 May 2020
Type IIR masks manufactured by Xiantao Zhongyi	14 May 2020
NPF2001-2005 Hong Xin Disposable Nitrile Examination Gloves manufactured by Shijiazhuang Hongray Group Co Ltd	22 April 2021
Type IIR masks manufactured by Full Support Healthcare Ltd	5 May 2021

181. Full details on the provision of EUAs during the relevant period can be found within the 'Easements' section, paragraphs 107 to 116.

182. As described in the 'Easements' section, EUAs were a necessary measure during the pandemic which allowed protective medical devices onto the market without assurance marking but following review of available evidence by the MHRA. However, a clause was included within EUA provisions that manufacturers must pursue full assurance marking in parallel.

183. Where EUAs or other flexibilities were granted for protective medical devices, these were based on risk-proportionate decision-making and where there was a clinical need. Other flexibilities (not EUA invoked) were allowed in cases of minor labelling issues that did not impact on safety and performance. These are justified in the MHRA checklist (see paragraph 50 and 167(d). Such flexibilities were supported by NHSSC/NHSE. Important Customer Notices or other communications were issued to end users to explain the flexibility that had been used by MHRA, and to provide assurance on safety.

184. The MHRA did not issue EUAs unless review of available data demonstrated adequate evidence of performance and safety. For example, during the relevant period, the Chinese government announced that from 26 April 2020, they would be stepping up supervision on exports of medical face masks, which are required to meet the quality standards of either China or their respective export destination, leading to its announcement of export control measures. This led to some manufacturers who wished to export from China but were unable to meet the new requirements having to remove the valid CE mark from packaging for exports.

185. The MHRA considered the EUAs route was the pragmatic solution to ensure such imported protective medical devices met standards of safety and performance. Protective medical devices that were held in Daventry (further detailed at paragraph 50) were cross-checked against the MHRA EUA authorisations. Where these protective medical devices met the criteria, the MHRA issued an approval to release stock. This stock was subject to an Important Customer Notice or direct communication on supply to provide end users with assurance that the protective medical device met standards of safety and performance and to explain the absence of a CE mark on the packaging or label.

Lateral flow tests and PCR tests

186. During the pandemic, the MHRA provided regulatory guidance to responsible government groups to support their procurement decision making, and provided guidance to support the development of Covid-19 diagnostics in the form of Target Product Profiles (TPPs) as discussed in paragraphs 99 to 102. As with other medical devices, the MHRA does not and did not have a direct role in the procurement and distribution of testing equipment during the Covid-19 pandemic.

187. Furthermore, the MHRA took steps in its regulatory capacity to assist with advice regarding issues with the supply chain for testing kits. For example, in March 2020, the MHRA issued an Exceptional Use Authorisation to Public Health England to expand PCR testing to NHS laboratories, to increase the capacity for diagnostic testing for the virus throughout the country. Additionally, documents provided by the manufacturers of the lateral low test kit components were assessed by the MHRA in desktop reviews to check regulatory compliance. This supported NHS Test and Trace and the DHSC in

understanding the regulatory status of the kit components and, as such, supported their procurement processes.

188. Throughout 2020 and 2021 the PCR testing programme expanded and the MHRA supported the DHSC procurement teams with desktop reviews of PCR test kits and issuing EUAs. The first EUA was issued to Public Health England to support the roll out of PCR (polymerase chain reaction) testing in March 2020 [**JR/67 – INQ000283508**]. The first EUA for self-test antigen tests for asymptomatic members of the public was issued in December 2020, together with details of the conditions which the manufacturer must adhere to before deploying the tests [**JR/68 – INQ000283521**].

189. The MHRA also provided advice in relation to procurement procedures to secure supplies of critical consumables such as swabs and sample collection tubes, by providing expert comment on the quality and the compliance status of the devices proposed for procurement.

190. Further, the MHRA conducted reviews of regulatory documents submitted by manufacturers of test consumable devices (i.e. the assay or cassette and the swabs or sample collection devices) in line with our usual regulatory role. These devices were part of the DHSC-led procurement tenders, to ensure that there was an ongoing supply of medical devices that were critical to delivering PCR testing in all settings. As there was only a limited number of suppliers, and no further assessment was required on the devices considered by the MHRA, this work was completed over a short period from December 2020 to January 2021.

191. The MHRA operates a surveillance system for the safety monitoring of medical devices once these are in clinical use. This is also the function by which the MHRA identifies cases of non-compliance with legislation, regulations or guidance. All SARS-Cov-2 detection kits classified as medical devices are therefore subject to this surveillance system.

192. It is a mandatory requirement that once a medical device (including test kits) is placed on the UK market, the manufacturer submits a report to the MHRA detailing any serious incident which occurs that involves its device. Voluntary reporting routes are also available through the Yellow Card scheme for healthcare professionals and the general

public. If cases of non-compliance are recognised through reports of this nature, the MHRA will investigate these.

193. The Medicines and Medical Devices Act 2021 (MMD Act) provided the MHRA with enhanced enforcement powers, including issuing compliance, suspension, safety, and information notices for non-compliance with the Medical Devices Regulations 2002. Prior to this Act, the MHRA's authority came from various regulations such as the Medical Devices Regulations 2002 and the General Product Safety Regulations 2005. The MMD Act expanded the MHRA's powers, allowing it to issue enforcement notices requiring a 'person' to take certain action.

194. The MHRA can issue these notices not only to manufacturers, but also to others in the marketing and supply chain. Examples of the notices that can be issued under the MMD Act include:

    I. Compliance notices, requiring the person to comply with a specified medical devices provision;
    II. Suspension notices, restricting the availability of a medical device in order to protect health and safety;
    III. Safety notices, imposing prohibitions or requirements on the availability of a medical device in order to protect health and safety;
    IV. Information notices, requiring a person to provide information to MHRA.

195. As discussed above at paragraph 32, if the MHRA considers it is necessary to restrict the availability of a medical device to protect health or safety, and the device has already been made available to the national health service or to patients and the public, the MHRA can require the device to be recalled from the market. This was done during the pandemic for home test kits supplied by Randox discussed in the paragraph below.

196. I am asked about regulatory action the MHRA may have taken regarding testing kits in relation to compliance. In July 2020, the MHRA conducted a regulatory review of home test kits supplied by Randox after they were flagged by the National Testing Programme which was supplying these to the social care sector. In early August 2020, the MHRA instructed Randox to recall some of its home testing kits as their swabs were incorrectly labelled with a CE mark as there had been no Notified Body assessment of aspects of manufacture relating to sterility, which is a regulatory requirement for Class I medical devices which have a sterile component. This causes a risk of contamination of nasal

swabs. However, there were no reports of patient harm. No other enforcement action was taken for Covid-19 testing kits by the MHRA.

Infection prevention and control guidance

197. I have been asked about the MHRA's role in drafting infection prevention and control guidance for use in the NHS across the UK, and whether there were any concerns and subsequent amendments made to the guidance. I have also been asked to consider whether the guidance was fit for purpose, and whether it differed from that in place in other countries. I am unable to comment on these questions or any questions relating to the infection prevention and control guidance because the MHRA had no role in its drafting or decision-making regarding it.

Market Surveillance

Compliance

198. The MHRA does not approve medical devices and as such addresses non-compliance of medical devices reactively when reported through our surveillance and monitoring systems. The MHRA's safety surveillance and monitoring systems for medical devices operate largely though the role of the DCU which is notified of issues of potential non-compliance with medical devices on the market and takes regulatory action as appropriate. The role of the DCU is described in detail below at paragraph 201.

199. I am asked how many healthcare items procured by DHSC during the pandemic were found to be non-compliant and whether the MHRA has undertaken an analysis of the proportion of key healthcare equipment and supplies imported and sold during the pandemic that were considered to have been non-compliant in each of the constituent countries in the UK. I am also asked how many non-compliant items the MHRA successfully prevented from being circulated in the UK market.

200. Although, as discussed above at paragraph 50, the MHRA did aid in the monitoring of protective medical devices during the pandemic, the MHRA does not monitor the importation or supply of healthcare equipment, including protective medical devices. Therefore, the MHRA cannot comment on exactly how many items procured by the

DHSC were non-compliant or the proportion of these procured by NHS Trusts or DHSC across the UK that were considered to be non-compliant. Non-compliant medical devices being imported into the UK were most commonly identified by Border Force agencies (as described at paragraph 87) and seized by the MHRA following assessment for compliance.

The Devices Compliance Unit

201. The MHRA's DCU receives complaints or allegations of non-compliance for medical devices and investigates these. These allegations of non-compliance come to the MHRA from a variety of sources. Typical sources include HSE (paragraph 83), OPSS (paragraph 79), Border Force (paragraph 87), manufacturers (paragraph 74), as well as trade associations, the NHS, charities, health care professionals, patients, the public, and whistle-blowers. These were largely received directly by the DCU via the Devices.Compliance@mhra.gov.uk mailbox. However, the DCU also investigated potential non-compliance reports that came through the MHRA's Yellow Card scheme. This represented only a small number of cases and is discussed below at paragraph 204.

202. Following identification of non-compliance, the DCU will take regulatory action (also known as enforcement action). Enforcement powers are detailed at paragraph 31.

203. Between March 2020 and March 2021, the DCU investigated or made interventions in relation to 188 potential cases of non-compliance for Covid-19 medical devices. The outcomes of investigations varied, however they often resulted in devices being prohibited from marketing and/or those seized by the MHRA were found to be non-compliant. Further information on MHRA's regulatory powers can be found at paragraph 13 to 19.

Safety Monitoring

Yellow Card Scheme

204. Voluntary reporting routes are available through the MHRA's Yellow Card scheme for healthcare professionals and the general public. If a healthcare professional identifies a fault or concern or experiences an incident with a medical device, they can report this

through the Yellow Card website. The Yellow Card reporting system asks the reporter to detail if they are a patient, relation of a patient or a healthcare professional. Further details are then requested, including age, weight, height, ethnicity, pregnancy, past medical history and co-morbidities alongside details of the medical device and the incident or issue.

205. The Yellow Card scheme collects and monitors this information on suspected safety concerns or incidents involving vaccines, medicines, medical devices, and e-cigarettes. The scheme also collects suspected safety concerns involving defective (not of an acceptable quality), falsified or fake healthcare products.

206. The Coronavirus Yellow Card site offered a dedicated route through which individuals including health and care staff, and organisations could report suspected side effects associated with medicines, and vaccines, and incidents associated with medical devices and test kits used in coronavirus testing and treatment. Those reports were then expedited for scientific review. The Coronavirus Yellow Card site formed the first pillar of the Agency's Covid-19 surveillance strategy (the remaining three pillars are only relevant to vaccines). The portal went live in May 2020 and was continually enhanced throughout the pandemic.

207. During the pandemic, the MHRA quickly recognised the need for additional routes to aid healthcare professionals and the public to report their safety concerns rapidly. Medical devices which were specific to Covid-19 were therefore given new device identification type codes to enable reports to the MHRA relating to these devices to be separated from those associated with other similar devices. This assisted with signal detection and trend monitoring activity through the surveillance systems detailed above.

208. In addition to the Yellow Card scheme, manufacturers are required to report incidents with their medical device that meet the criteria, which can be found in section 5.1.1 of the European Commission guidelines for reporting to the MHRA including any safety issue or adverse event [**JR/69 – INQ000498478**]. Manufacturers also could issue Field Safety Notices ("FSNs") to inform their customers about corrective actions needed to address safety issues with medical devices. Any FSN would be posted on the MHRA website [**JR/70 – INQ000498489**].

209. Between March 2020 to January 2022, the MHRA received 370 incident reports relating to protective medical devices via the Yellow Card scheme and from manufacturers.

Subsequent to these reports, investigations were carried out by the manufacturers as required by the regulations under the supervision of the MHRA. All Yellow Card reports were entered into a specialised database and analysed rapidly allowing safety issues or 'signals' to be detected. Potential signals were triaged and evaluated to identify previously unidentified potential hazards and any new information including in relation to recognised effects or safety issues. Any incidents or concerns with any CE marked medical devices reported to the MHRA during the pandemic were investigated and would have been subject to enforcement powers and relevant safety communications as necessary. The MHRA Devices team led a proactive adverse incident trend review group which met with representatives of NHSE and DHSC to discuss emerging trends and appropriate risk mitigation actions. Throughout the pandemic, the group used a range of data sources including Yellow Card data to identify trends for investigation and action which would be taken into account in any decision by the team.

210. For example, a trend in Yellow Card reports was observed for Type IIR (fluid resistant) medical face masks. It was reported that the foam strip on the nose bridge of the mask was flaking, posing a risk of the degraded products entering the user's airway. Additionally, ties and/or stitching were coming away from the mask. The MHRA requested the manufacturer conduct additional visual and product testing, and based on the evidence, issued an alert recommending all affected lots of these masks be recalled and destroyed to reduce the risk of user harm. Consequently, a Medical Device Alert was issued [**JR/71 – INQ000498492**]. Further examples of actions taken following safety issues are discussed in the 'Protective Medical Devices and PPE' and 'Ventilators' sections of this statement.

211. As a general principle, there were a small number of medical devices safety alerts compared with safety alerts for medicines. This is expected, as protective medical devices are generally low risk devices. Furthermore, the root cause for issues with protective medical devices during the pandemic was usually related to the prolonged conditions of use.

212. A specific healthcare professional reporting route was implemented for lateral flow tests via the Yellow Card scheme with more detailed information requested than normal Yellow Card reporting, to allow for greater information gathering and speedy identification of safety signals. Manufacturers had a legal requirement to assess promptly the performance of their test when new Covid-19 virus variants were identified. An email mailbox was set up for manufacturers to submit their data to the MHRA for

rapid review. As new variants arise, this work is ongoing, and the MHRA continues to regularly update guidance for manufacturers on the impact of new variants of concern on post-market surveillance processes [**JR/72 – INQ000283580**].

213. In addition to the Yellow Card scheme and manufacturer reporting systems, specialist MHRA staff analyse data from a range of sources including pre-existing reports, the scientific literature, media outlets, enquiries from healthcare professionals and the public, scanning of publications and surveillance activities in other countries.

Safety Information Alerts

214. For higher risk safety issues, the MHRA will issue alerts in the form of Medical Device Alerts or National Patient Safety Alerts and develop or update guidance for stakeholders. In line with standard practice, draft safety communications are sent to devolved governments for comment or information in advance of publication.

215. The MHRA issued several device safety information alerts relating to medical device safety in use during the pandemic: for example, with respect to haemofiltration systems [**JR/73 – INQ000283604**]. Furthermore, in July 2020 the MHRA conducted a regulatory review of home test kits supplied by Randox which is discussed at paragraph 196. I have discussed further specific safety information and alerts relating to protective medical devices and ventilators in the 'Protective Medical Devices and PPE' and 'Ventilators' sections of this statement.

Reflections

Introduction

216. The Covid-19 pandemic was a profoundly challenging time for everyone, not least those public servants who were at the forefront of the national response effort. The MHRA and those who worked for the Agency were among those at the vanguard of the UK's response to the pandemic. The scale and urgency of the pandemic brought out many of the Agency's strengths: a willingness to innovate and utilise regulatory flexibilities to reach robust decisions in the shortest possible time; a commitment to science-based decision making in the shortest time possible as soon as evidence was available; and a workforce which demonstrated its determination and commitment to protect public health.

217. Whilst I do not believe it adversely effected the MHRA's pandemic response in any way, it should be noted that we were dealing with Covid-19 at the same time as preparing for and transitioning from the UK's exit from the EU. This presented opportunities but also challenges as we began to work within a new regulatory regime as a standalone regulator. The Agency was also responding to the recommendations of the Independent Medicines and Medical Devices Safety Review (a review chaired by Baroness Cumberlege) which was published on 8 July 2020, and as a result was commencing the overhaul of our safety systems to better listen to and respond to the concerns of patients and the public.

218. The pandemic highlighted opportunities for the Agency to strengthen its response and improve its readiness for future emergencies. In 2020-2021 the Agency conducted an internal review [**JR/74 – INQ000283532**]. That report followed a report by the Government Internal Audit Agency [**JR/75 – INQ000283531**]. The Agency has also undertaken a more detailed review of its approach to diagnostics [**JR/76 – INQ000283548**].

219. In the summer of 2020, the then MHRA Devices Division undertook an informal, internal review of lessons learnt from the Covid-19 pandemic [**JR/77 – INQ000534259**] This review covered: ventilators, medical devices and PPE, IVDs and regulatory flexibilities.

Collaboration with other healthcare organisations

220. The MHRA would not have been able to adeptly navigate the challenges of providing guidance regarding the development, approval and surveillance of new medical devices had it not been for effective collaborations across the healthcare ecosystem, with industry and across government. For example, as set out in paragraph 132 above, I would highlight the development and approval of the UCL Ventura CPAP device, which was only possible through the extraordinary collaborative efforts between the MHRA, clinicians, bioengineers, UCL, government and industry, including Mercedes Benz Formula One teams. Vitally important to the success of these collaborations was the flexibility with which the MHRA could operate and share our regulatory and scientific expertise.

221. I have been asked by the Inquiry whether the creation of a single body focussed on the regulation of products used in hospital and care settings for infection prevention and

control may assist in the regulation of such items. As is discussed at paragraphs 92 and 93, there were clearly defined roles between the respective organisations of OPSS, HSE, BSI, Border Force and NCA, as well as clear mechanisms of collaboration with UK Government agencies as described in paragraphs 49 to 54. The existing relationships between organisations and the agreed roles allowed the MHRA to act flexibly as required, provide expert regulatory guidance when needed and defer quickly to the expertise of other organisations.

222. Whilst I do not believe there is an obvious need for a separate single body to focus on these items, the MHRA did receive some queries which should have been directed to other organisations. Therefore, the MHRA published guidance on the regulatory status of equipment being used to prevent Covid-19, detailing the different regulations that applied to medical devices, protective medical devices and PPE. This assisted the public and health and social care agencies in understanding which regulations applied to which equipment [**JR/28 – INQ000498484**]. Therefore, when considering lessons learnt, continued education and communication for relevant stakeholders regarding the roles and responsibilities of various bodies will help remind and explain how various devices are regulated.

Regulatory support for specific categories of medical devices

223. The MHRA's core expertise in regulation and regulatory frameworks allowed us to act as a proactive and enabling regulator during an unprecedented public health crisis. This is evident in the MHRA's work providing advice during the production of a transparent technical specification for a face mask [**JR/30 – INQ000498481**] (as discussed at paragraph 97); providing guidance to support the development of Covid-19 diagnostics, in the form of Target Product Profiles (TPP) (as discussed in paragraphs 99 to 102); and in developing the technical specification for rapidly manufactured ventilator systems to assist manufacturers in their development [**JR/44 – INQ000283511**], (as discussed at paragraph 126). Furthermore, the UCL team commended the MHRA on its effort to support the UCL Ventura CPAP device from idea to manufacture in such a short time frame [**JR/49 – INQ000534256**], a device which went on to be approved across 105 countries world-wide and to support other nations, especially low-income and middle-income countries.

Ventilators

224. I am asked to consider an article in the Guardian newspaper published on 4 May 2020, which describes the MHRA's role in helping firms design and build new medical devices for the Ventilator Challenge. The article states:

> *"According to one source, the firms that opted to design and build new machines had to lean heavily on support from the medical device regulator, the Medicines and Healthcare products Regulatory Agency (MHRA)."*
>
> *"Without the independent regulatory teams, most of these projects would have gone nowhere," the source said.*

225. I discuss in detail the MHRA's reflections on the Ventilator Challenge at paragraphs 121 to 142 above. In regard to lessons for future pandemics, it would have been useful for guidance on the development of ventilators to have been targeted according to the kind of manufacturers i.e. for those with experience in developing ventilators versus new manufacturers without experience. This may have resulted in more manufacturers being able to meet guidance requirements and more ventilators meeting the necessary regulatory criteria for the Ventilator Challenge in addition to the three that were successful.

Protective Medical Devices and PPE

226. As discussed at paragraph 50 above, the MHRA was able to play a vital role in reviewing technical documentation on the safety and performance of the protective medical devices and PPE stored in Daventry in 2020, providing a team of experienced experts in the relevant medical device standards to help review and (where appropriate) suggest the release of compliant medical devices into the UK supply chain. In this context the MHRA was also able to provide training for DHSC and Cabinet Office technical assurance and procurement teams on the regulatory requirements for the procured devices, further supporting the UK supply chain.

227. The MHRA also played an active role in ensuring that manufacturers were aware of the relevant UK safety standards. The Agency worked to create and publish specifications and associated documentation outlining the essential requirements and regulatory standards for protective medical device and PPE manufacturers. For example, the

MHRA produced a manufacturing specification for reusable isolation gowns in collaboration with HSE, as the gowns are classed as dual use (PPE and medical devices), thus falling under the remit of both organisations [**JR/31 – INQ000498479**]. Such publications were intended to support manufacturers in meeting the relevant standards of safety in the pre-market phase, ensuring that industry was producing compliant devices to bolster supply.

228. When considering improvements which could be made for future pandemics, earlier consultation during the procurement process to enable proactive development of technical specifications would likely reduce the need for retroactive regulatory review and foster a better-informed industry to ensure that UK-compliant devices were available in sufficient quantities to meet the exceptional demand. Therefore, in a future pandemic the MHRA will engage at the earliest stages with government procurement teams to ensure an up to date understanding of regulatory considerations and provide proactive regulatory advice.

Covid-19 Tests

229. On 2 April 2020, the Government set a target of achieving 100,000 tests a day by the end of April 2021. The MHRA's approval of the EUA for Medline swabs contributed to the achievement of the Government's testing target. Unlike other response areas such as the Ventilator Challenge, Covid-19 testing continued to feature highly on the Government's agenda throughout the pandemic, with ever increasing targets, changes in strategic approach and changes to strategic partners and external colleagues. Therefore, the MHRA's critical work on TPPs and continued partnerships within the Government healthcare organisation matrix were key enablers to product development, testing validation and DHSC procurement. However, the procurement of tests at scale started before MHRA involvement and resulted in the procurement of non-compliant testing kits which resulted in some devices having to be recalled, for example the Randox test kit in July 2020 as is discussed at paragraph 196 above. For future pandemics, national testing strategies would benefit from early regulatory advice to ensure tests considered for procurement were compliant.

Strengthening market surveillance

230. I have been asked whether there are any changes or reforms which the MHRA would welcome in light of our experience of regulating items used to prevent the spread of

Covid-19 during the pandemic. The MHRA continuously evaluates how we may best operate as a regulator and had already considered its position on the regulation of medical devices, in particular our role in market surveillance. The Covid-19 pandemic further contributed to the learning and steps taken by the MHRA to review its regulatory role. As described within this statement, the MHRA's role in taking action on non-compliant medical devices is largely reactive, and it was recognised that the legislative framework could be strengthened to better support the availability of safe and performing testing devices.

231. Following the UK's exit from the EU, there was an opportunity to improve how medical devices and IVDs are regulated in the UK. The Medicines and Medical Devices Act (2021) allows for amendments to the Medical Devices Regulations 2002 which govern medical devices in Great Britain. In 2021, the MHRA launched a consultation to strengthen medical devices legislation [**JR/78 – INQ000527710**]. Following an analysis of the consultation responses, five 'pillars' or headline objectives emerged, which include strengthening the MHRA's ability to act on medical device safety issues, focussing on access to innovation, addressing health inequalities, building international access routes and contributing to global standards.

232. As a result, legislative reform began through an amendment of the Medical Devices Regulations in relation to post-market surveillance requirements (the Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024). These amending regulations were introduced into Parliament on 21 October 2024 and seek to provide the MHRA with enhanced powers to better monitor the safety and effectiveness of medical devices, in particular by imposing more stringent requirements on manufacturers to conduct periodic reviews of their post-market surveillance data and enhanced serious incident reporting obligations for manufacturers to support the prompt detection of safety issues. The amendments were agreed in both Houses following debates on the 26 and 28 November 2024 and written into law on 16 December 2024.

233. The MHRA plans to propose legislative changes to the regulatory requirements that a medical device must meet before it is placed on the market in Great Britain. This will better align the UK 2002 medical device regulations with those in other jurisdictions. For instance, the MHRA's proposed classification of IVD tests is based on the framework of the International Medical Device Regulators Forum, an association of global regulatory authorities working towards harmonisation.

234. The proposed legislative amendment will also: improve traceability of medical devices by introducing unique device identifiers and implant cards for patients receiving implanted medical devices; ensure that the claims manufacturers can make about devices are consistent with the evidence used to gain approval; and adjust the classification of some general medical devices so that this better reflects their risk. I have been asked whether the further legislative amendments referenced above in paragraph 233 will deal with regulation of medical devices used in emergency situations and I can confirm that this is the case.

235. The policy proposals on the UK Medical Devices legislation have evolved significantly since the MHRA's initial 2021 consultation. In November 2024, the MHRA launched a further consultation on four areas: improved patient and public safety; greater transparency of regulatory decision making and medical device information; close alignment with international best practice; and more flexible, responsive and proportionate regulation of medical devices [**JR/79 – INQ000527711**]. This consultation includes proposals for a new International Reliance pathway, which aims to speed up the approval process for new medicines in the UK by leveraging the expertise and decision-making of trusted regulatory partners. Recognising the regulatory decisions of other trusted regulators in determining whether a product can go on the market in the UK will be an important part of protecting supply to the NHS, which is especially crucial during pandemics. During the Covid-19 pandemic we were still in the transition period of our exit from the EU which meant CE marked products could enter the UK without friction. The revised proposals on which MHRA is consulting seek to enable reliance on the decisions of trusted international regulators whilst ensuring the MHRA has the controls it needs to keep patients and the public safe.

Facilitating access to innovative medical devices

236. In recognition of the great public health need for innovative medical devices during the pandemic, the MHRA operated flexibly using existing regulatory processes to assist in the UK response. Under the Medical Devices Regulations 2002 as described above at paragraphs 109 to 116, EUAs enable the MHRA to authorise the placing on the market, or putting into service, of non-UKCA or non-CE marked devices in the interests of protection of public health and where there is no legitimate alternative.

237. The EUA route was used more frequently during the pandemic, and successfully ensured that patients and the public could access innovative devices in the shortest time

possible. EUA approvals were granted to the UCL Ventura CPAP device, the adapted ESO2 Penlon ventilator, the Parapac Plus P300 ventilator, a number of types of masks, gloves, and face shields (as discussed at paragraph 180), and PCR and self-antigen tests, for example. This was an essential contribution to the pandemic response. Following approval of any EUA application, the medical devices were closely monitored by the MHRA. When a product is approved via the EUA route, it is a mandatory condition for the manufacturer to report monthly to the MHRA to ensure that any adverse incidents are addressed and to inform MHRA of the numbers of products supplied and where they were supplied to, to allow traceability. Furthermore, as part of the standard conditions set in an EUA approval, manufacturers must continue to work towards an appropriate assurance marking.

238. The demand for EUAs has remained above pre-pandemic levels, possibly due to the higher profile of the EUA route during the pandemic. As well as applications from innovators seeking early market access, the MHRA is receiving applications which, whilst meeting the EUA criteria (an immediate clinical need, no approved alternative and a public health need), also arise from root causes connected with compliance failings such as misclassification of a device, failure to renew a certificate, or supply disruptions.

239. In response to the post pandemic demand increase for EUAs, the MHRA is revisiting its operating procedures with a view to clarifying in guidance what the exceptional use power can be used for. A triage process is now used to consider whether there is a more appropriate route for some of these products, such as through a clinical investigation. The Innovative Devices Access Pathway, launched in 2023, is a pilot pathway designed to accelerate the development of innovative medical devices that meet an unmet clinical need in the NHS and support their integration into the UK market [**JR/80 – INQ000527712**]. In the pathway, the use of an EUA as an early access route for innovative products meeting an unmet clinical need is also being piloted. The results of this pilot will be studied along with the experiences of international partners, and the MHRA will consider how such a pathway could enable innovation outside of a public health emergency.

Conclusion

240. On behalf of the MHRA, I would like to express my sincere condolences and sympathy to all those adversely affected by the Covid-19 vaccines, and our determination to continue to strengthen our safety systems.

241. The Covid-19 pandemic highlighted the critical importance of effective collaboration by the MHRA with other healthcare bodies and stakeholders. This collaboration was essential for navigating the challenges of developing, approving, and monitoring new medical devices. The MHRA's regulatory expertise for the rapid development of technical specifications and TPPs, and our continued partnerships within the Government healthcare organisation matrix, were key enablers to product development. The MHRA's approvals of EUAs for testing devices, protective medical devices, and ventilators all contributed to the achievement of the Government's testing target, the Ventilator Challenge, and the supply of vital protective medical devices to healthcare and the public. In future pandemics, providing more specific guidance for manufacturers and involving the MHRA early in the procurement process to proactively develop technical specifications could minimise the need for retroactive regulatory reviews. The MHRA will therefore aim to strengthen early engagement with government procurement teams to ensure a current understanding of regulatory considerations and to offer proactive regulatory advice.

242. The regulatory routes for medical devices in place during the pandemic proved to be effective, demonstrating the need for regulatory flexibilities that enable responsiveness in future pandemics. The MHRA is working to strengthen market surveillance of medical devices, including by recognising the regulatory decisions of other trusted regulators to determine whether a product can be marketed in the UK. This approach is crucial for protecting the supply of medical devices to the NHS, especially during pandemics.

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: 31 January 2025