Witness Name: Dame June Munro Raine CBE
Statement No.: 6
Exhibits: JR/1a-JR/60
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UK COVID-19 INQUIRY

MODULE 7

WITNESS STATEMENT OF DAME JUNE MUNRO RAINE CBE

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

1. I make this statement in response to a Rule 9 request dated 26 June 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 7 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. This statement covers the period relevant to Module 7, i.e. between 1 January 2020 and 28 June 2022, 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).

4. 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, it is the case that 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

5. I was the Chief Executive of the MHRA until 31 March 2025. I took up that role as interim CEO in September 2019 and became permanent from 23 February 2021. In this role I was 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. This protected the interests of the public, and ensured that the MHRA provided high standards of services to manufacturers, healthcare professionals, patients and the public.

6. 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.

7. 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.

8. 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.

9. 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.

10. From 2003 until 2023, I have been a member and subsequently Co-Chair of the World Health Organisation (WHO) Advisory Committee on Safety of Medicinal Products.

The role, functions and aims of the MHRA

11. 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.

12. 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;
    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 for third party conformity assessments of medical devices in the UK as of 1 January 2021.

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

13. With regard to the provisional outline of scope of Module 7, the MHRA was not involved in devising the strategy for the national Covid-19 testing initiative but contributed to ensuring the availability and compliance of testing devices. For example, as discussed in paragraph 181 below, the MHRA's issuance of Exceptional Use Authorisations (EUA) for testing devices contributed to the achievement of the Government's testing target, and as discussed in paragraphs 142 to 155 below, the MHRA engaged in regulatory action to ensure the compliance of testing devices with the regulatory requirements. The MHRA did not play a role in the decision-making, the structure, or the maintenance of the infrastructure, of the test, trace and isolate system. The MHRA's role was to ensure safe access to innovative products and provide regulatory oversight of the Covid-19 testing kits and their components.

14. Furthermore, it is not the role of the MHRA to assess medical devices, including testing kits, for compliance and assurance marking. This role is carried out by Notified or Approved Bodies, as described below at paragraphs 32 to 39.

15. 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. The Framework Agreement defines the working relationship between the MHRA and the DHSC. During the Covid-19 pandemic, the 2016 Framework Agreement was in place **(JR/1a – INQ000283506** On 21 March 2024, an updated Framework Agreement was published **(JR/1 – INQ000507348)**. This version did not fundamentally alter the responsibilities or accountabilities within which the MHRA operates but rather conformed to new HM Treasury framework templates and aligned with any new government operating best practices.

Key regulations and legislation under which the MHRA operates

16. The MHRA is responsible for regulating medical devices, including testing kits on the UK market, discharging the functions of the Secretary of State under the Medical Devices Regulations 2002 ("MDR 2002"). The MDR 2002 are "safety regulations" within the meaning of section 11 of the Consumer Protection Act 1987. The MHRA is the authority responsible for determining the policy enacted into law by these regulations, subject to parliamentary processes. Key regulatory responsibilities in relation to medical devices include:

a) Assessment of applications to perform clinical investigations of devices that have not yet been marketed;
b) Setting the regulatory framework for the conditions that devices have to meet before being placed on to the market;
c) Assessing all allegations of non-compliance brought to us, using a risk-based system (discussed further at paragraphs 142 to 143);
d) Monitoring the activity of UK Approved Bodies designated by MHRA to assess the compliance of manufacturers (discussed further at paragraphs 33 to 39) and investigating adverse incident reports or intelligence indicating a potential problem with a medical device that is on the UK market (discussed further at paragraphs 128 to 141).

These regulatory responsibilities, in addition to those set out below, relate to the availability of and ensure the compliance with test, trace and isolate technologies, as within the provisional scope of Module 7.

17. Therefore, it is important to re-emphasise that the MHRA does not approve medical devices, including testing kits, but rather regulates medical devices according to the responsibilities described above. The process of approving a medical device via a Notified or Approved Body and assurance marking prior to being placed on the UK market is described below at paragraphs 32 to 42. In exceptional circumstances, the MHRA may temporarily authorise manufacturers to supply a device, where doing so is in the interests of public health and where there is no UKCA/CE marked device available to meet the clinical need. This is discussed in detail below at paragraphs 108 to 127.

18. As a result of the UK's exit from the EU, different provisions apply to the regulation of medical devices, including testing kits, in Great Britain from their regulation in Northern Ireland. In Great Britain, devices are regulated under the MDR 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 MDR 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 MDR 2002, an 'in vitro diagnostic medical device' (IVD) 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 for the examination of specimens, including blood and tissue donations, derived from the human body, in vitro 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. On 28 July 2021, the DHSC introduced an amendment to Regulation 2 of the MDR 2002 via the Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021. This included 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)". A key part of the government's approach to managing Covid-19 was to support the private sector market for Covid-19 detection tests to

supplement and support the testing led by NHS Test and Trace. This Coronavirus Test Device Approvals (CTDA) amendment was therefore made in order to introduce additional requirements for diagnostic tests for Covid-19 and was designed to ensure that Covid-19 tests for sale in the UK met minimum standards in their sensitivity and specificity. This ensured that test kits sold privately in the UK were of the same high quality as those used by the NHS. Further detail on the aims of the CTDA amendments can be found within the Explanatory Memorandum to the 2021 Regulations (**JR/2 – INQ000498480**). Until May 2023, the CTDA scheme was operated by UK Health Security Agency (UKHSA), following which responsibility for its operation moved to the MHRA. Applicants are required to provide the same data for all CTDA submissions.

22. In the context of Module 7 of the Inquiry, the following are examples of Covid-19 testing devices which fell within the scope of the CTDA amendment of the MDR 2002:
    a. Lateral flow sample collection kits; and
    b. Polymerase chain reaction ("PCR") sample collection kits.

23. Lateral flow sample collection kits are used for rapid antigen tests that can process Covid-19 samples on site without the need for laboratory equipment. These tests produce easy-to-understand results in under half an hour. The sample collection typically involves a swab from the nose and/or throat, or sometimes a saliva sample. These samples can be collected at home or by a healthcare professional and are then tested for presence of the SARS-CoV-2 virus.

24. PCR sample collection kits are used for highly sensitive and specific tests to detect genetic material from pathogens. The sample collection usually involves taking a swab from the nose and throat. The collected sample is then sent to a laboratory where the PCR technique amplifies small segments of DNA or RNA, allowing for the detection of even trace amounts of the target genetic material from the SARS-CoV-2 virus.

25. A sample collection kit is the name given to the different parts of a Covid-19 test that help obtain a sample. It consists of several devices, which can include sample collection devices, assays and cassettes. A sample collection device is a tool used to obtain a biological sample from the human body for testing, such as a swab used to obtain a sample of secretion from the inside of the nose, or a syringe used to obtain a blood sample. Assays are tests that can detect the presence of, or provide evidence of the risk of, a certain disease or infection. A cassette is a lightproof container used to hold, protect from light exposure, or process biological samples (such as blood, urine, or tissue) for

analysis. Each device within the sample collection kit (sample collection device, assay and cassette) is classified as an in vitro diagnostic medical device (IVD).

26. Each individual IVD that makes up a sample test kit is required to conform with the requirements of MDR 2002. Depending on the class of device, this may require assessment by a Notified or Approved Body, which are described at paragraphs 32 to 39. However, during the Covid-19 pandemic, we also allowed for entire sample test kits to be approval-marked as a single entity. Test kits deemed to have met the requirements were also issued EUAs. This is discussed further at paragraph 108.

Enforcement powers

27. 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 MDR 2002. Prior to this Act, the MHRA's authority came from the MDR 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 device 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.

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

29. Enforcement action taken by the MHRA during the pandemic is discussed in paragraphs 142 to 155 below.

Classification of medical devices

30. Under regulation 7 of the MDR 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 MDR 2002, Annex IX (as modified by Schedule 2A).

31. However, the classification of IVDs is different from that of general medical devices. All products and devices for testing kits are IVDs and are therefore regulated as such. The MDR 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 MDR 2002, 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 MDR 2002, 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.

Notified Bodies

32. A Notified Body is a third-party body which undertakes assessments of medical devices (outside of Class 1) 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 paragraphs 40 to 42. 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 1) were assessed by Notified Bodies for compliance and assurance markings.

Approved Bodies

33. 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. 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 MDR 2002 and Regulation 920/2013. Organisations applying to be a UK Approved Body for medical devices need to obtain United Kingdom Accreditation Service (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.

34. 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.

35. 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 this 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/3 – INQ000274040).**

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

37. Like Notified Bodies, Approved Bodies assess medical devices intended for market in the UK (other than Class 1) for conformity with the MDR 2002. Approved Bodies provide compliant devices with a UKCA mark which allows for medical devices to be placed on the Great Britain market but not the EU. Under the terms of the Windsor Framework, medical devices on the market in Northern Ireland must comply with EU regulations. Assurance markings are described below at paragraphs 40 to 42.

38. 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 the EU legislation under which the product was certified. An infographic illustrating these dates can be found here: **(JR/4 – 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.

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

Assurance Marking

40. As described above, it is the role of the Notified and Approved Bodies to assess a medical device or IVD for assurance marking against regulatory requirements set by the EU or MHRA, respectively. Assurance markings signify that a medical device or IVD meets specific safety and quality standards set by the Notified or Approved bodies, providing assurance to consumers and facilitating market access. Different assurance marks are required according to where the medical device or IVD is intended for use, and the timeframe under which it was approved to be placed on the market. The MDR

2002 require, since January 2021, that all medical devices or IVDs, 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 by the MHRA.

41. It is the responsibility of the manufacturer to demonstrate that their medical device meets the relevant requirements of the MDR 2002. This is discussed in further detail at paragraphs 90 to 93. Further, as discussed below at paragraph 91, manufacturers of testing devices for Covid-19 were required to apply for approval from UKHSA, in line with the CTDA amendment to MDR 2002.

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 below. 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 an 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 or IVDs circulating in Northern Ireland are therefore marked with a CE mark approved by an EU Notified Body.

Independence and impartiality of the MHRA

43. 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, acting on behalf of the Secretary of State who is accountable to Parliament. Scrupulous care was taken throughout the Covid-19 pandemic to separate regulatory decisions from procurement and deployment decisions taken by other departments or teams within Government.

44. In discharging those responsibilities on behalf of the Secretary of State, it is vital that the MHRA demonstrates its independence from any influence of the sectors and activities it regulates. The public understandably expects 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.

45. Ensuring impartiality and independence of decision-making is an ongoing responsibility of all staff and features regularly in discussions at the highest level of the MHRA. The MHRA follows its 'Corporate Conflicts of Interest Policy and Procedure' (**JR/4a – INQ000503579**), taking legal advice and the judgement of senior leaders, as needed, to ensure MHRA staff avoid engaging with pharmaceutical and medical devices companies other than in the proper conduct of regulation. The policy, and a tracker of our assessment of potential conflicts and the actions we have taken, are published on our website. The policy and procedures for 2020 and 2021 can be found here (**JR/4b – INQ000274043**) and (**JR/4c – INQ000274037**).

Funding of MHRA

46. In 2021-2022, the MHRA's activities were funded as set out below:

a) Medicines regulation is funded from revenue 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. Over time the importance and demand of fast changing technology, component parts and scrutiny of devices regulation has increased. In response, investment and resource spent on devices have increased, and therefore proposals have been put forward in a public consultation for fees uplifts in 2025 to support cost recovery and post market surveillance costs **(JR/5 – INQ000533197)**. Following the consultation, on 6 March 2025, the MHRA published its fees uplifts for ongoing cost recovery, and these will be implemented in April 2025 **(JR/5a – INQ000591752**

c) The MHRA laboratories, formerly known as the National Institute for Biological Standards and Control (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. The 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.

47. Further information about the Agency's funding arrangements can be found within its 'Annual Report and Accounts for 2020/21' (**JR/6 – INQ000274032**). 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/3 – 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. An important principle is that the MHRA does not profit from the fees it charges or make a loss which must then be subsidised by the DHSC or wider Government.

48. For certain projects, the MHRA receives grant funding which will set conditions 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.

Leadership of the MHRA in relation to Module 7 during the Covid-19 pandemic

49. 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 DHSC Permanent Secretary, Sir Chris Wormald.

50. In respect to senior leaders who worked within the scope of Module 7: the following individuals worked on efforts to provide regulatory guidance to individuals and bodies to support the approach to testing and tracing adopted during the pandemic in England, Wales, Scotland and Northern Ireland.

    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 MHRA's inspections programme, ensuring compliance with enforcement of medicines and devices legislation.

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 60 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) Dr Nicola Rose: Deputy Director, Research and Development (SCS1) since March 2022, reporting to Dr Marc Bailey. Dr Rose oversees research and development programmes related to biological medicines. Previously Head of Vaccines, NIBSC, from January to March 2022, Dr Rose was responsible for the independent batch testing of Covid-19 vaccines. Previously Head of Virology, NIBSC, from February 2020 to end 2021, Dr Rose reported to Dr Christian Schneider and subsequently Dr Marc Bailey. In that role she was responsible for coordinating the control testing of vaccines and produced a number of biological reference materials to support Covid-19 vaccines and diagnostics test development and evaluation.

The MHRA's Independent Expert Advisory Committees during Covid pandemic

51. 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 7 of the Inquiry, the most relevant committees and advisory groups were the Devices Expert Advisory Committee (DEAC) (stood down in March 2022, which I explain below) and the In-Vitro Diagnostic Expert Advisory Group (IVDEAG).

    a) 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 17 March 2022, when the DEAC was stood down to allow the Government to plan the establishment of a statutory expert advisory committee on medical devices. The DEAC meeting minutes are published on GOV.UK. The Interim Devices Working Group (IDWG) was then set up in April 2023. Terms of reference and meeting minutes can be found here **(JR/7 – INQ000498491)**. The DEAC had no involvement with advising on the Test and Trace scheme or in relation to specific IVDs. Instead, the MHRA staff would regularly update the group on activity relating to the wider pandemic response.

    b) 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 and its chair reported to and advised the DEAC, then reported to and advised the IDWG, set up in April 2023 after the DEAC was stood 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 in its role acting on behalf of Health Ministers.

MHRA's cooperation with relevant Government groups

52. The MHRA co-operated with wider Government departments and agencies throughout the pandemic to provide regulatory advice, in line with normal practice. To assist the DHSC's procurement efforts during the pandemic, the MHRA provided regulatory training to staff of NHS England, Devolved Governments and the DHSC. The MHRA routinely holds quarterly cross-UK Partnership meetings with representatives from the Devolved Governments and NHS England. These meetings are primarily to update the Devolved Governments on Agency work and priorities, including Covid-19 work. During the pandemic, these meetings also included updates on regulatory flexibilities.

53. The MHRA and NHSE co-chaired the NHS Test and Trace, and the MHRA Oversight and Steering Group meetings A and B. Meeting A focused on strategic, tactical and operational items such as development of the test and trace policy and future target product profiles ("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 viral variants. These meetings started in January 2021 and included representation from a large number of organisations and the Devolved Governments. At these meetings, the MHRA's role was to provide 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.

Department of Health and Social Care and Covid-19 tests

54. During the pandemic, in the context of the public health need, the DHSC procured Covid-19 tests at scale. The MHRA provided extensive regulatory advice and assistance to the DHSC and to NHS Test and Trace to mitigate potential risks around deployment of tests, including recommendations on appropriate use of test devices in accordance with their performance.

55. For example, due to the urgent clinical need to test the general public for Covid-19, the MHRA supported the DHSC in becoming a legal manufacturer, meaning they were responsible for ensuring compliance with the MDR 2002, for a Covid-19 test device. Innova was a manufacturer of the tests for professional use only ("Innova test"). In the UK, these tests were repurposed as self-tests (the "DHSC self-test"), to meet the

increasing need to be able to identify positive Covid-19 cases and then isolate, to reduce transmission rates.

56. At the time, there were no CE marked tests available in sufficient numbers to deploy to the UK general public. To enable deployment of these tests for this purpose at scale, the DHSC took on the responsibility as the legal manufacturer of these tests and applied for an EUA. Although the DHSC were the legal manufacturer under the regulations, the DHSC subcontracted the provision for the supply of the kits to Innova.

57. The MHRA provided extensive regulatory guidance to support the DHSC in becoming a legal manufacturer and provided support on the EUA application process. This included introducing regular meetings, and formalising engagement between the MHRA and the DHSC / NHS Test and Trace to ensure effective coordination of activities. Further, an MHRA member of staff was loaned for a short time to DHSC to support these extraordinary efforts. The MHRA secondee provided support to the DHSC in ensuring that the instructions for use for the self-tests were fit for purpose and compliant with regulations.

58. Throughout this period, the MHRA and the DHSC / NHS Test and Trace developed an effective working relationship that found an appropriate balance to allow the MHRA to continue to offer comprehensive regulatory support to the national testing programme, whilst respecting MHRA's role to apply independent scrutiny and oversight in line with our statutory responsibilities. The MHRA actively managed such potential conflicts of interests. For example, staff providing advice and support were not part of the final decision-making and did not work on the final EUA approval. The DHSC was subject to the regulatory requirements and processes as applicable to any other legal device manufacturer, including the enhanced safety monitoring of products granted an EUA which is discussed at paragraph 110.

59. The DHSC EUA application is exhibited as **(JR/32 – INQ000283520)** and the EUA granted on 22 December 2020 as **(JR/7a – INQ000283521).** Other EUAs, issued as detailed in the table at paragraph 118 below, followed for similar reasons, as demand for tests outstripped supply of CE marked products.

Public Health England

60. The MHRA attended meetings chaired by Public Health England (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, Covid-19 antibodies) and VTAG focused on assessment of technology for the detection of Covid-19. Graeme Tunbridge attended these meetings on behalf of the MHRA. In the summer of 2020, the Technology Validation Group (TVG) was formed, and this incorporated the roles and responsibilities previously performed under VTAG and NTAG. The exception to this was assessment and review of Lateral Flow Devices (LFDs) for detection of Covid-19, which was maintained under the remit of NHS Test and Trace and PHE and overseen by the Lateral Flow Oversight Group.

Variants of Concern Assurance Group

61. The MHRA was also a member of the Variants of Concern (VoC) Assurance Group established in collaboration between the MHRA, the Technologies Validation Group (a dedicated group within DHSC Test and Trace), PHE, NHSE, and partners in the Devolved Governments, in January 2021. The VoC Assurance Group established robust processes for in silico and wet testing of IVDs for circulating Covid-19 variants, and risk-mitigating actions were required to be implemented to ensure public and patient health. The VoC Assurance Group was replaced by the Pathogen Diagnostic Assurance Group, which produced guidance for manufacturers on diagnostic efficacy assurance with the Covid-19 variants in circulation. The guidance can be found here: **(JR/8 – INQ000533187).**

NHS Test and Trace

62. From approximately January 2021, the MHRA participated in weekly meetings with NHS Test and Trace to provide regulatory advice on lateral flow tests and ensure safe and effective components of test kits. The MHRA also attended these meetings to provide regulatory advice on sample collection devices to ensure that they were safe and

compliant. Prior to January 2021, there had been regular, informal meetings with PHE designed to promote mutual understanding and collaboration.

NHS Digital

63. The MHRA's software team worked with NHS Digital on the Covid-19 app in relation to the development of contact tracing and the lateral flow device reader.

MHRA's International collaboration

64. Throughout the pandemic, the MHRA collaborated with other regulators internationally. On 10 June 2021, the US Food and Drug Administration (FDA) issued a safety notice to the public, and a Class 1 recall letter relating to Innova SARS-COV-2 Antigen Tests, as Innova-manufactured tests had been made available for sale in the US without FDA approval. The FDA raised concerns about the Innova tests in 3 key areas: unauthorised sale; inadequately documented test performance; and failures in quality management. These concerns around test performance characteristics may have resulted in false-negative results or false-positive results, leading to further spread of the virus in the US. The MHRA had no prior knowledge of this investigation or recall and treated this FDA safety notice as a 'signal', raising concerns with the UK manufacturers of Innova tests: Innova, manufacturer of the professional use only Innova test, and the DHSC, legal manufacturer of the DHSC self-test.

65. The MHRA contacted the US FDA on 11 June 2021 for a complete picture of their concerns and contacted Innova to assess any wider risks. Furthermore, in the days prior to the publication of the FDA safety notice, the MHRA had issued an extension to the existing EUA for the DHSC self-tests. In view of the concerns raised by the FDA we placed this extension on hold pending receipt of a satisfactory Incident Corrective and Preventative Action Plan (CAPA) from the DHSC, which was submitted on 14 June 2021 **(JR/8a –** **INQ000496261**

66. Some of the concerns raised by the FDA were not applicable in the UK. For example, Innova-manufactured tests had been legally placed on the market in the UK, there were therefore no concerns of unauthorised sale. Furthermore, Innova confirmed that they had no direct supply of their Covid-19 test to the UK market outside of the national testing

programme. Regarding the DHSC self-tests, the MHRA was reassured by the DHSC's role as legal manufacturer of the DHSC self-tests supplied in the UK under the EUA, which meant that separate quality management systems had been set up and independent verification of batches of products had taken place by Intertek, a third-party testing house. Intertek provided assurance that the tests performed accurately and that nasopharyngeal swabs provided in test kits were sterile as per ISO 11737-1. The DHSC's intended purpose of the self-tests focused on the asymptomatic population, which was different to the indication for use in the US. As such, substantial mitigations were already in place in the UK context and the risks to UK users were not as presented by the US FDA recall letter.

67. The assessment conducted by the MHRA was informed by an audit undertaken by the MHRA of DHSC as the legal manufacturer in May 2021, as part of the enhanced monitoring of all products given EUAs **(JR/8b – INQ000594562**

68. The MHRA's assessment also took into account the CAPA submitted by the DHSC on the 14 June 2021. The MHRA was satisfied with the analysis of the issues and the limited applicability of the FDA findings. This demonstrated that the DHSC self-test could be used for its intended purpose of finding positive Covid-19 cases in asymptomatic people testing themselves at home, that the DHSC self-tests did not need to be recalled in the UK, and that the EUA extension could be granted. On 17 June 2021, a submission for information was sent to the then Secretary of State, informing him of these actions **(JR/9 – INQ000566492).**

69. On 29 June 2021, the MHRA sought advice from the IVDEAG regarding this signal and the assessments conducted by the MHRA, which raised concerns regarding data provided by the company to support the EUA extension granted on 17 June 2021 for the DHSC self-tests, and the intended purpose of the tests. The IVDEAG advised in support of the MHRA raising these concerns and provided advice on the type of data required from the DHSC for MHRA's assessment **(JR/9a - INQ000594559**. With this advice, the MHRA re-evaluated the performance claims and evidence base for the DHSC self-test, continuing to provide regulatory advice and guidance to DHSC/NHS Test and Trace, including via principles of best practice regarding assessment of the performance of tests in use.

MHRA Laboratories

70. The MHRA's laboratories (formerly the single entity known as the National Institute for Biological Standards and Control or 'NIBSC') play a major role, nationally and internationally in assuring the quality of biological medicines and vaccines through the development of standards and reference materials, product control testing and carrying out applied research. The MHRA has a laboratory complex comprising of a range of specialist facilities at its Science Campus in South Mimms. The MHRA is responsible for developing and producing over 90% of the biological international standards in use around the world, is designated the UK's Official Medicines Control Laboratory ("OMCL") and delivers the mission-critical regulatory research and development to support the above.

71. The MHRA laboratories are also responsible for independent regulatory testing of biological medicines under Regulations 60A and 60B of the Human Medicines Regulations 2012 (as amended). The MHRA's laboratories also host the UK Stem Cell Bank and are a key UK research centre in the field of pandemic flu.

Development of research reagents for Covid-19 test development

72. Throughout the pandemic the MHRA laboratory scientists were responsible for developing more than 150 research reagents, all sourced, produced, characterised and made available globally to the scientific community through the NIBSC Centre for AIDS Reagents repository (CFAR). For context, research reagents are biological materials that have been made to support the scientific work of academic and commercial researchers. Research reagents are an important part of our biological reference reagent provision. These reagents included plasmids (small, circular DNA) molecules, nucleic acid extracts (molecules like DNA that make up genetic material), recombinant proteins (artificially produced proteins), antibodies (proteins produced by the body to target a specific foreign microorganism's antigen), cell lines (permanently established cell cultures), live and inactivated viruses.

73. These key reagents were instrumental for the development of diagnostic tests, as well as to support a variety of more fundamental research projects on Covid-19. Most notably, these reagents were used as positive controls for the evaluation and comparison of the molecular (PCR-based) testing performed by diagnostics laboratories

in the United Kingdom such as Public Health England and the Lighthouse Laboratories, to ensure the performance of both in-house and / or commercial kits. For example, to support the development of molecular tests designed to detect Covid-19 RNA (PCR tests), MHRA laboratory scientists developed research reagents for the scientific community, making them available as early as March 2020.

74. One of the research reagents developed by MHRA scientists was a safe, synthetic reagent created by packaging overlapping fragments of the Covid-19 genome into defective, non-replicative HIV particles. Four of these particles, covering the whole Covid-19 genome, were combined to create the reagent known as 19/304. This reagent was provided free of charge to UK laboratories conducting the molecular testing for Covid-19 to allow them to compare performance of their PCR testing methods and optimise them against standardised Covid-19 RNA.

75. To provide some context, each SARS-CoV-2 particle contains the information to replicate itself in the form of a string of nucleic acids called viral RNA. In the development of the standard, the viral RNA was modified to prevent replication of SARS-CoV-2 proteins so that no further virus could be formed, but in a manner that it could still be recognised by the PCR tests. Then, to make it similar to a clinical sample (i.e. a sample which might be collected from a patient with Covid-19) so that it mirrored a sample that should be detected by a PCR test for Covid-19, the SARS-CoV-2 modified viral RNA was incorporated into HIV-like virus particles. These particles are only the outer shell of an HIV particle, but do not contain any of the information to make more of those particles and therefore are non-replicative.

76. In April 2020, a separate research reagent was made available by MHRA scientists to assist with quality assurance of antibody testing performed in studies, and to aid in the evaluation of vaccines and therapeutics. This reagent was developed in partnership with the Coalition for Epidemic Preparedness Innovations (CEPI) and NHS Blood and Transplant (NHSBT). A reference panel, which is a group of reference materials established to collectively aid the evaluation of the performance of diagnostic tests, was made available at the same time.

77. These reagents were complemented with additional reference materials designed to assure the performance of sero-diagnostics assays. Sero-diagnostics assays are tests to detect antibodies against a pathogen of interest in a blood sample and can be used,

for instance, to understand how many individuals have been infected and whether a vaccine has generated a response which will protect the patient, or to evaluate new treatments. To evaluate the performance of sero-diagnostics tests, it is important to have positive and negative controls which reflect the samples from the patient. This is usually plasma or serum, essentially, those components of the blood containing the antibodies. The reagents or 'standards' were prepared from plasma samples that would not contain antibodies to SARS-CoV-2 (negative control), as they were available from before the pandemic, as well as convalescent plasma (positive control) from individuals who had recovered from Covid-19.

78. Selected pre-pandemic and convalescent plasma samples (antibody-rich plasma from someone who has recovered from a Covid-19 infection) obtained from NHSBT were used to prepare verification and validation panels, the latter containing 200 separate pre-pandemic plasma samples to establish specificity and 200 convalescent plasma samples to assess sensitivity of assays. Sensitivity and specificity, described further as follows, are measures of how well a diagnostic test can correctly identify a person as having or not having a disease:
    a) Sensitivity is the ability of a test to correctly identify people with a disease. A test with high sensitivity has few false negatives, meaning it misses fewer cases of disease.
    b) Specificity is the ability of a test to correctly identify people without a disease. A test with high specificity has few false positives.

79. As a WHO Collaborating Centre for Biological Standardization, the Expert Committee on Biological Standardization (ECBS) endorsed the development by the MHRA of certain International Standards for Covid-19 RNA and antibodies, which is essential to eliminate variability in the measurement of pathogens in diagnostic assays (**JR/10 – INQ000533178).** The average timeframe for the production of an International Standard is usually 2-3 years, which was clearly not commensurate with the urgency imposed by the pandemic.

80. Identifying the most appropriate source of antigen (recombinant or inactivated virus) and establishing the optimal method of inactivation at pace was critically important. Creating international standards involved evaluation across multiple international laboratories, analyses from expert statisticians who have expertise and training in development of biological metrology standards, and compilations of reports which have to be considered by the ECBS global experts, all of which would normally take years to develop. However,

through close work with our established partnerships (including WHO, CEPI, NHSBT, and UKHSA) and our network of collaborators worldwide, the MHRA laboratory scientists were able to produce these important international standards within 9 months of the Covid-19 pandemic being declared.

81. The uptake of these standards was unprecedented. The widespread demonstration of the value of antigen tests led the WHO, on 19 November 2020, to task the MHRA laboratory science teams to develop an antigen standard to support the evaluation of rapid tests, such as lateral flow tests. For the antibody standard 20/136, which was developed and supported by CEPI, the MHRA laboratories shipped over 2,400 units to over 580 end users globally, primarily companies that were developing and manufacturing Covid-19 diagnostic devices. This caused a depletion of the stock by August 2021 and a new study was launched to prepare the second WHO International Standard, which was then completed in 2022.

Detection of Covid-19 and variants of concern in wastewater

82. An important responsibility of the MHRA laboratories, which are designated as a WHO Collaborating Centre on Polio, is routine environmental surveillance of poliovirus. The MHRA laboratories have been conducting this surveillance since 2016 by testing wastewater samples from a North London sewage site serving 4 million people. As a consequence, MHRA laboratories were able to analyse samples collected and archived from before the pandemic and follow up samples for the presence of SARS-CoV-2. During retrospective analysis undertaken in July 2020, published in September 2020, it was determined that low levels of SARS-Cov-2 viral RNA had been present in a sample collected on 11 February 2020, three days before the first case of Covid-19 was reported in the sewage plant catchment area **(JR/11 – INQ000533183).**

83. To bolster the wastewater detection sensitivity of the assay used by MHRA scientists, a novel semiquantitative molecular assay based on next generation sequencing analysis of spike-gene DNA amplicons (small fragments of DNA that have been artificially duplicated via polymerase chain reaction (PCR) was designed to specifically detect and quantify the presence of key mutations that discriminate SARS-CoV-2 variants of concern (VoCs). Intensive testing using this assay was conducted between February 2020 and December 2022 at a single site in Beckton, London. The testing method involved quantifying sequence variation at nucleotide positions known to specifically

identify variants of concern by deep sequencing of short amplicon or PCR products from two different regions of the spike protein gene. This allowed us to detect changes in variant dominance.

84. This capability meant that the MHRA laboratories were able to detect changes in VoC predominance throughout the Covid-19 pandemic at an early stage, preceding results from clinical samples, making it a useful surveillance tool for detecting the presence of pathogens in a community. The results of this testing underscored that early detection of new variants requires access to a diverse array of data sources in community surveillance such as passive case detection PCR data, cross-sectional community infection surveys, genomic surveillance, and wastewater monitoring.

85. In response to the emergence of Covid-19 VoC, the WHO's Technical Advisory Group on Virus Evolution (TAG-VE) established a working group in 2022 intended to monitor the immune evasion by the new variants from the protection conferred by infection from early isolates or from vaccines. The working group set up a study to evaluate the comparability of the results from the neutralisation assays used within this network, comprised of 15 laboratories in all WHO regions. The MHRA joined this working group in January 2023 with the aim of setting up a surveillance system for SARS-CoV-2 VoC. Since the start of the pandemic, the MHRA Laboratories' Centre for AIDS Reagents had amplified and characterised 75 variants, including all VoC, allowing the MHRA to contribute to the project by identifying suitable control reagents and distributing those to the international community of participating laboratories as infectious and/or inactivated materials or nucleic acid extracts.

86. In addition to this, in December 2020 a CEPI funded collaborative project between the MHRA and UKHSA known as 'Agility' was initiated, with the objective to perform in vitro and in vivo evaluation of VoC. The immune escape potential of more than 35 viruses was assessed with several panels of sera from vaccinated, convalescent individuals and NIBSC reference reagents (20/136, 21/234, 21/338), using a validated authentic virus neutralising assay. Data generated were published on 25 February 2023 **(JR/12 – INQ000533184).** This project is still ongoing with evaluation of recent variants. The current planned end date for this work is May 2025, but the MHRA is in discussion with CEPI and hopes to extend the project and expand its scope to other coronaviruses and priority pathogens.

87. The MHRA laboratory scientists also collaborated with CEPI to initiate the sourcing of reference materials to generate a Reference Panel constituting convalescent plasma or serum from recovered Covid-19 patients infected with one of the known VoC, as of December 2021. The MHRA scientists evaluated and established the first WHO International reference panel for VoC to facilitate the evaluation of the impact of VoCs on serological assay performance.

88. Also, the potency of the WHO International Standards for anti-SARS-CoV-2 antibodies was found not to be suitable against the Omicron lineages. This was because the antibodies against SARS-CoV-2 are mainly directed to interact with a particular region of the virus, which changed considerably with the Omicron lineages. The plasma used to make the WHO International Standards was collected at the time prior to the Omicron variant and contained antibodies directed against a version of the virus that was no longer circulating, making the standard unsuitable to act as a comparator.

89. In response, we developed a new antibody standard for Covid-19 VoC which was fit for purpose, as demonstrated during a collaborative study run in 2022 by the MHRA, CEPI, NHSBT, the University of Liverpool and the hospital Sirio-Libanes in Brazil. This standard was established in October 2022 by the WHO ECBS **(JR/13 – INQ000533182).**

Responsibilities in relation to Covid-19 testing kits

Responsibility of the manufacturer for medical device certification

90. Manufacturers need to demonstrate that their medical device meets the relevant requirements of the MDR 2002 by carrying out an assessment, known as a conformity assessment. The key requirements of a conformity assessment for a medical device 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, manufacture, 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.

91. Depending on the device's classification, the assessment can be done by the manufacturer to self-certify a device or it must be done by an Approved or a Notified Body. This is discussed in detail above at paragraphs 30 to 39. In addition, following approval in line with the MDR 2002 as explained above, manufacturers of testing devices for Covid-19 were required to apply, in line with the CTDA amendment to MDR 2002 as described in paragraph 21, for approval from UKHSA. This was implemented to ensure that Covid-19 tests for sale in the UK met minimum standards in their sensitivity and specificity, ensuring that test kits sold privately in the UK were of the same high quality as those used by the NHS.

92. The MHRA has produced extensive guidance on these requirements and readily provides advice to manufacturers about whether their product is a medical device and if so, in which class it falls **(JR/14 – INQ000498482).**

93. Once a medical device or IVD 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 to take the appropriate safety action. This is described below in the Post Market Surveillance section at paragraph 128.

Health and Safety Executive

94. The Health and Safety Executive (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 DHSC, and the Association of Chief Police Officers (ACPO).

95. The HSE is responsible for investigating incidents in the workplace relating to medical devices that are not a direct result of shortcomings in the device or instructions for its 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's responsibilities, and vice versa.

96. The MHRA and HSE both hold regulatory responsibility for products whose status as personal protective equipment (PPE) or a medical device could fall within the responsibility either of the HSE or the MHRA, for example, a face mask.

97. In regard to Covid-19 testing devices, the HSE had to provide advice to manufacturers and workplaces on their testing devices. The HSE met with the MHRA to agree on the advice and recommendations which they provided to manufacturers, and the MHRA produced a scoping paper for a testing regulatory framework to give clarity to manufacturers on specific requirements and responsibilities **(JR/37 – INQ000566497).**

98. The MHRA is unlikely to have received referrals from HSE specifically concerning testing kits for Covid-19 as their status as a medical device is not in doubt. Rather, a typical HSE referral would include details about a face mask being marketed as a medical device and therefore likely to fall within the scope of the MDR 2002.

National Crime Agency

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

100. For a limited time, the NCA had a dedicated team which was created to investigate any crime committed in connection with the Covid-19 pandemic. This resulted in the NCA investigating certain non-compliant medical devices. The MHRA's Device Compliance Unit (DCU) worked alongside the NCA on numerous investigations.

101. The MHRA, Trading Standards, UK Border Force, NCA and Police forces can all play a role in criminal investigations into medical devices. In circumstances where the MHRA is not leading the investigation, the Agency typically works in support of any criminal investigation into medical devices.

102. For example, the NCA, in conjunction with the Crown Prosecution Service, prosecuted the sale of some 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/15 – INQ000498487).** Prompt regulatory action was taken in relation to the distribution of the non-compliant devices.

MHRA's role in standardisation of medical devices for detecting Covid-19

Target Product Profiles

103. In response to the Covid-19 pandemic, the MHRA produced six Target Product Profiles (TPPs) for manufacturers of In Vitro Diagnostic self-tests for Covid-19. All TPPs were published on GOV.UK, including the six TPPs published with regard to products, devices and/or kits produced for detecting SARS-CoV-2: **(JR/19 – INQ000566494, JR/22 – INQ000566493, JR/20 – INQ000283516, JR/21 – INQ000283517, JR/23 – INQ000533179, JR/24 – INQ000533180).**

104. These TPPs were guidance documents intended to support and accelerate the development and evaluation of new medical technologies to address specific unmet clinical or public health needs of high strategic priority to the UK population.

105. The TPPs, first published on 13 May 2020, summarise the key features and anticipated performance specifications of a new medical device in advance, to enable innovators to design and develop high quality products that are fit for purpose and meet specific health-related goals. They are intended to be used to support product design, research and development planning, and to facilitate discussions with regulators. The TPPs also helped to promote international standardisation and harmonisation across testing kits. This was an innovative practice. The World Health Organization also published their own TPPs **(JR/17 – INQ000283575) (JR/18 – INQ000283518),** and we understand that TPPs were found to be of value in many countries.

106. The TPPs were developed by lead devices specialists in the MHRA's medical devices safety and surveillance team, with input from external stakeholders. Towards the end of 2020, a role was established at the MHRA to lead on the development of TPPs, due to their public health importance and wide use. Sensitivity and specificity requirements were determined through engagement with stakeholders, and values can be found listed in the TPP for IVD self-tests for the detection of Covid-19. This outlines the desirable and acceptable sensitivity (≥95% with 95% confidence interval and ≥80% with 95%

confidence interval respectively) and specificity (≥99.9% with 95% confidence interval and ≥99.5% with 95% confidence interval respectively) **(JR/19 – INQ000566494).**

107. It is important to note that TPPs are not regulatory requirements. Devices that do not meet the terms of TPPs can still be approved if they meet applicable regulatory standards. Instances where the MHRA was made aware of devices not meeting regulatory standards and any regulatory enforcement action taken by the MHRA are discussed at paragraphs 142 to 154 below. The TPPs were based on the best scientific information available to the MHRA at the time, but the science was (and continues to be) rapidly evolving, 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 TPP for Enzyme Immunoassay Antibody tests to help determine if people had antibodies to Covid-19 **(JR/20 – INQ000283516).** On 15 June 2020, a new TPP for Point of Care Covid-19 detection tests was published **(JR/21 – INQ000283517).** The TPPs were regularly updated by MHRA experts throughout the pandemic, with independent advice from the IVDEAG.

Regulatory Flexibilities

Exceptional Use Authorisations

108. I am asked what flexibilities were applied to Covid-19 testing kits and the impact this had. The MHRA did not ease the regulatory requirements for Covid-19 testing kits, however we did operate adaptably and flexibly using existing regulatory processes to assist in the UK response to the pandemic, through the use of Exceptional Use Authorisations (EUAs) described below. The MHRA also provided guidance on other routes to fast-track approvals and for some In Vitro Diagnostics, the MHRA published TPPs as discussed above at paragraphs 103 to 107.

109. The EUA route enables the MHRA (acting on behalf of the Secretary of State), to give temporary authorisation to 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 (UKCA or CE marked, compliant, suitable, and available) alternative, under Regulation 12(5) of the MDR 2002 (SI 2002 No 618, as amended). This also applies for active implantable medical devices in Regulation 26 and for in vitro diagnostic medical devices under Regulation 39(2). The MHRA generally only considers an EUA application

if there is an immediate clinical need for the medical device, if there are no alternative UKCA/CE marked devices and if there are immediate demands for supply, where alternative UKCA/CE marked devices are available but not sufficient to fulfil an immediate need.

110. Following approval by MHRA of an EUA application, it is a mandatory condition of the manufacturer to report monthly to the MHRA to ensure that any adverse incidents are managed, and to inform MHRA of the numbers of products supplied and where they were supplied, to allow traceability. As part of the standard conditions set in an EUA approval, manufacturers must continue to work towards an appropriate assurance marking. Applying for and being granted an EUA did not have any impact on whether a medical device could or would gain full approval.

111. The EUA route 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, as was the case for Covid-19 tests and Continuous Positive Airway Pressure (CPAP) devices.

112. All EUA applications for medical devices are reviewed by the MHRA's medical devices specialists who consider a number of factors when assessing the evidence provided for the application. For example:
    a. Identify if there is an immediate clinical need for the device, and that there are no alternative UKCA/CE marked devices.
    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. Review the reasons why the device has not obtained a UKCA/CE mark.
    e. Ensure relevant considerations have been made for the cohort of users.
    f. Where relevant, ascertain if a Quality Management System for the manufacturing facility is available.

113. An EUA application template can be found here: **(JR/25 – INQ000534262**). Standard conditions could be added to or amended by the assessor as required.

114. During the Covid-19 pandemic, the MHRA did not alter the criteria for assessing EUA applications for medical devices, although such applications were infrequent before the pandemic. To illustrate, 56 EUAs were issued during the period March 2020 to September 2020, as compared to 3 approvals in the period March 2019 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.

115. 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 medical devices teams, who worked to streamline systems and processes to facilitate agility and responsiveness, and reprioritised tasks. Not all applications were granted EUAs; for devices relevant to Module 7, companies making applications that were not granted were referred to the MHRA's testing guidance page for further advice and information on TPPs **(JR/26 – INQ000533185)**.

116. On 25 March 2020, to further support rapid availability of essential medical devices meeting acceptable standards of safety, the MHRA published online guidance on how manufacturers could apply for an EUA for a medical device during the pandemic **(JR/27 – INQ000283571).** Reflecting the types of medical devices that were most in need during the early stages of the pandemic, the online guidance specifically identified Covid-19 diagnostic testing kits, ventilators, and PPE (including protective medical devices such as gloves and gowns and medical face masks).

117. Recognising the importance of transparency of regulatory decision-making for public trust and confidence, the MHRA published a list of the medical devices which were given EUAs during the pandemic on GOV.UK **(JR/28 – INQ000283557).** In relation to Module 7, the MHRA issued 17 EUAs for medical devices for Covid-19 testing, all of which can be found on the website. These include EUAs for full test kits, for test kit items such as swabs or assays, and for aids to using devices that detected Covid-19 such as an artificial intelligence reader to support reading the results of lateral flow Covid-19 tests and sending these to the national reporting system.

118. The 17 EUAs related to devices for testing Covid-19 issued by MHRA are listed in the table below. These EUAs have now expired (as EUAs only last a maximum of six months unless renewed) or been cancelled:

Product Name and Manufacturer	Date EUA Issued
Covid-19 Assay by Public Health England	5 March 2020
Xpert Xpress SARS-CoV-2 Rapid Test Kit by Cepheid	27 March 2020
DNA Nudge by Imperial College - Translation and Innovation Hub	9 April 2020
BioFire Test by BioMérieux	21 April 2020
Covid-19 Contact Tracing App by NHSX	30 April 2020
Home Test Kit by Public Health England	30 April 2020
Wuxi Nest Oropharyngeal swab	1 May 2020
King's College saline tubes for test kits	11 June 2020
IVD SARSCOV2 Serological Assay Test by Attomarker Ltd	29 June 2020
Sterilab Services – Sample Collection Tube VirNA tube for SARSCOV2 RNA testing	9 July 2020
Department of Health Northern Ireland – Symptom Checker App – COVIDCARE NI	18 September 2020
Vivostat – VIRNA TUBE FOR SARS COV2 RNA TESTING	9 November 2020
DHSC Covid-19 Self-Test Kit by Innova	22 December 2020
Sensus Group – Zhejiang Orient Gene Biotech Co., Ltd – Test Kits	28 May 2021
SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab – Gold) by SureScreen Diagnostics Ltd	10 November 2021
MagnifEye by Sensyne Health Group Limited (used with Surescreen LFTs)	27 January 2022
UnifAI Reader by UnifAI	21 April 2022

119. In relation to Module 7, regulatory flexibilities focused on the issuance of EUAs and expediting clinical investigations for products that might provide significant clinical benefit in the pandemic. Part of the Exceptional Use work also focused on supporting repurposed Covid-19 tests through usability studies, performance evaluation studies and seroprevalence (the level of pathogen in a population, as measured by antibodies present in blood) research. Usability studies evaluate the user's experience and the functionality of a product. Seroprevalence studies aim to determine risk factors for infection by comparing the exposure of infected versus that of non-infected individuals. This was outside the MHRA's usual regulatory role for in vitro diagnostic medical

devices, but it was undertaken to support the National Testing Strategy and to expand the UK testing capacity by providing EUAs for suitable tests. This enabled regulatory oversight of tests which were intended to be used in the home setting where users would be able to see and interpret their own results. The MHRA applied regulatory flexibilities in a time where Notified Bodies were understood to have had long delays in assessments for such tests.

120. 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.

121. In respect of testing kits, the MHRA did take steps to assist with supply chain issues. On 5 March 2020, the MHRA issued an EUA to PHE to expand PCR testing to NHS laboratories. This in turn increased the capacity for diagnostic testing for the SARS-CoV-2 virus throughout the country. Additionally, documentary evidence provided by the manufacturers of the 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 process. In March 2020 and throughout Spring 2020, PCR testing was the only mass testing option available as lateral flow tests had not yet been developed.

122. Testing by PCR detects the presence of ribonucleic acid, the genetic material of the virus, and provides an accurate measure of the presence of the virus. However, its use was limited by laboratory capacity, and it had other disadvantages, notably the time it took to get results, and the cost. Rapid antigen tests, better known as lateral flow tests, potentially offered some crucial advantages. These tests did not involve a laboratory, results were produced within minutes and tests were much cheaper, enabling people to test themselves much more frequently than was possible with PCR tests.

123. On 4 April 2020, the DHSC issued its 'Coronavirus (Covid-19) Scaling up our testing programmes' policy to increase PCR testing **(JR/29 – INQ000283547)**. This required an EUA application in order to put large numbers of non-CE marked swabs into use in sample collection kits and increase access to testing, in the context of rapidly rising cases. In the face of significant demand for PCR testing capacity and the associated consumables and the intense global competition for supplies, the MHRA participated in a DHSC-led specialist team called the 'Testing Consumables Group'.

124. This group was chaired by the DHSC and was established to assist both the DHSC and the Department for Business, Energy and Industrial Strategy (BEIS) with sourcing suitable products for testing kits. The team conducted desktop reviews of regulatory documentation to ensure that only appropriately regulated devices were purchased for use in the national testing programme.

125. At the beginning of May 2020, the MHRA assessed and granted applications for EUAs for certain products which were critical to the Covid-19 testing programme, such as sample collection swabs, which enabled the government to deliver on its target of 500,000 PCR tests by 31 October 2020. Once initial lateral flow tests were made available for use by healthcare professionals, a policy initiative was announced by the then Secretary of State that would result in these professional Covid-19 tests (i.e. to be used by trained clinicians) being repurposed and deployed to healthcare staff to test themselves. This repurposing was deemed necessary to maintain access to testing 2-3 times per week, as was required to enable them to continue to attend work and provide continuity of care to patients. Normally this circumstance would require a specifically designed device for "self-testing", but such a device only became available later in sufficient numbers for deployment to the general public.

126. Following this announcement, the MHRA mobilised a team to work with the NHS to mitigate residual risks associated with this repurposing initiative. For example, many of these professional kits required measurement of buffer solution, unlike the self-testing kits available later in the pandemic that included pre-measured sachets of buffer solution. As such, the MHRA recommended the development of a revised instruction leaflet to be included with repurposed kits to ensure safe and proper use. The MHRA provided feedback on draft instructions provided by the NHS and this leaflet was included in test kits intended for self-testing use **(JR/30 – INQ000566495, JR/31 – INQ000566496).**

127. Throughout 2020 and 2021 the PCR testing programme expanded and the MHRA supported the DHSC procurement teams with desktop reviews of the scientific evidence supporting PCR tests. The MHRA also assisted with formalised procurement procedures to help 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. 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 its usual regulatory role. These devices were part of the DHSC-led procurement tenders, to ensure that there was an ongoing supply of devices that were critical to deliver PCR testing in all settings. As there were only limited suppliers, and no further assessment was required on these devices considered by the MHRA, this work was completed from December 2020 to January 2021.

Post Market Surveillance

128. The MHRA operates a post market surveillance system for the safety monitoring of medical devices once these are in clinical use. This is the function by which the MHRA identifies new risks and cases of non-compliance with legislation, regulations or guidance which may require regulatory or enforcement actions, as discussed at paragraphs 27 to 29 above. All testing kits classified as medical devices are subject to this surveillance system.

129. It is a mandatory regulatory requirement that once any medical device (including testing kits) is placed on the UK market, the manufacturer submits a report to the MHRA detailing any serious safety incidents or efficacy problems which occur that involve its device, as discussed below in paragraph 138. Reports made to the MHRA regarding safety incidents or efficacy problems relating to testing for Covid-19 are discussed below in paragraphs 146 to 155. Further information and guidance for manufacturers on medical device vigilance requirements can be found at **(JR/33 – INQ000283579).** Voluntary reporting routes are also available for healthcare professionals, patients, and the general public through the Yellow Card scheme, as discussed below.

Yellow Card Scheme

130. The MHRA's Yellow Card scheme, established in 1964, collects and monitors information on suspected safety concerns or adverse incidents involving vaccines, medicines, medical devices (including testing kits) and e-cigarettes. The scheme also collects suspected safety concerns involving defective (not of an acceptable quality), falsified or fake healthcare products.

131. As with any medical device, if an individual identifies a fault or concern, or experiences an incident with a testing kit, they can report this to the MHRA through the Yellow Card website. The Yellow Card reporting system asks the reporter to detail if they are a patient, carer or relation of a patient or a healthcare professional. Further details are then requested of the incident or issue, alongside other relevant details including age, ethnicity, pregnancy, past medical history, and any co-morbidities.

132. 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. The MHRA therefore took immediate steps to establish a dedicated Coronavirus web portal for healthcare professionals and the public to report via Yellow Card any suspected side effects associated with Covid-19 treatments and adverse events related to medical devices. The MHRA ensured rapid establishment of the portal through an expedited internal process.

133. The expedited process enabled the delivery of this external-facing reporting facility at pace. A cross-agency team worked to deliver the project, from initial documentation, project planning, and user journeys to development and testing in parallel workstreams to facilitate the rapid deployment of core functionality. The Coronavirus web portal was deployed on 28 April 2020 for medicinal products with an associated press release **(JR/34 - INQ000593241)**. On 28 May 2020, medical devices reporting was added, with vaccine ADR reporting via the web-portal available by the time of approval of the first Covid-19 vaccine.

134. Covid-19 testing kits, alongside medical devices specific to Covid-19, were given new device identification codes to enable reports submitted through this new web portal that related to these devices to be separated from those associated with other similar devices. This assisted with signal detection and trend monitoring activity for test kits through the surveillance systems detailed above.

135. I have been asked if earlier establishment of the Coronavirus Yellow Card portal would have affected the MHRA's safety actions. The Coronavirus Yellow Card portal was established promptly at the start of the pandemic and, before its creation, healthcare professionals, patients, and the public could report suspected adverse events associated with medicines and devices for Covid-19 via the well-established Yellow Card scheme which already incorporated web-based reporting. Earlier implementation

of the Coronavirus Yellow Card portal would not have been likely to have had a particular impact on the MHRA's safety actions.

136. Between 3 March 2020 and 30 June 2022, the MHRA received 3,430 adverse incident reports through the Yellow Card Scheme in association with devices used in testing for Covid-19, in the context of millions of tests undertaken in the UK. This included reports of missing or defective components of the testing kit, and incidents relating to incorrect results. It should be noted that the submission of a Yellow Card report does not necessarily mean that the device was defective or produced an incorrect result, but that the reporter suspected the device may have been at fault. All Yellow Card reports were triaged, assessed and investigated according to normal safety surveillance processes.

137. A specific healthcare professional reporting route was also implemented for lateral flow tests via the Yellow Card scheme with more detailed information requested than is usual for Yellow Card reporting, to allow for greater information gathering and prompt identification of safety signals. In line with the MDR 2002, the MHRA considers reports relating to circulating variants to potentially be serious public health threats, therefore significant safety issues (for example, decrease in performance) should be reported within 48 hours. As new variants emerged, the MHRA added conditions for authorisation of an IVD under EUA to require fortnightly monitoring for variants. As such manufacturers had a legal requirement to promptly assess the performance of their test when new Covid-19 virus variants were identified **(JR/8 – INQ000533187)**. An email mailbox was set up for manufacturers to submit their data to the MHRA for rapid review. This work is ongoing as new Covid-19 variants arise, and the MHRA continues to regularly update guidance for manufacturers on the impact of new VoC on post-market surveillance requirements **(JR/35 – INQ000283580).**

138. Furthermore, in addition to the Yellow Card scheme, manufacturers are required to report to the MHRA any incidents with their test kits that meet the requirements found in section 5.1.1 of the European Commission guidelines for reporting including any safety issue or adverse event **(JR/36 – INQ000498478)**. Manufacturers could also issue Field Safety Notices (FSNs) to inform their customers about corrective actions needed to address safety issues with the testing kits they market. An FSN is a way of the manufacturer communicating an action to mitigate a risk with a device. Producing FSNs is a regulatory requirement. The MHRA publish FSNs on GOV.UK to ensure full transparency.

139. A total of 16 FSNs were issued by manufacturers regarding Covid-19 testing devices **(JR36a – INQ000575534, JR/36b – INQ000575535, JR/36c – INQ000575536, JR/36d – INQ000575537, JR/36e – INQ000575538, JR/36f – INQ000575539, JR/36g – INQ000575540, JR36h – INQ000575541, JR/36i – INQ000575542, JR/36j – INQ000575543, JR/36k – INQ000575544, JR/36l – INQ000575545, JR/36m – INQ000575546, JR/36n – INQ000575547, JR/36o – INQ000575548, JR/36p – INQ000575549).**

140. As an example, on 14 September 2021 a FSN was issued by RT Diagnostics regarding a Covid-19 PCR sampling kit that it produced which included components that had not been subject to UK conformity assessment procedures and therefore may not have been suitable for the intended use. The other FSNs were issued for a wide variety of reasons, including software upgrades, incorrect labelling of Covid-19 testing kit items, and updates to instructions for use.

141. All FSNs issued for Covid-19 testing kits during the Covid-19 pandemic were published on GOV.UK **(JR/38 – INQ000498489).**

Medical Device Compliance

142. As previously stated, since the MHRA does not directly approve testing kits (or any medical devices) unless they have been temporarily authorised under the EUA route, cases of non-compliance with regulatory requirements are addressed when reported through our post market surveillance and monitoring systems. The Devices Compliance Unit (DCU) receives reports about suspected non-compliant medical devices on the market and takes regulatory action as appropriate. The DCU is a key component of the MHRA's safety monitoring system for medical devices.

143. The DCU receives reports of complaints or allegations of non-compliance for medical devices, including IVDs, and investigates these. Concerns of non-compliance come to the DCU from a variety of sources. Typical sources include HSE (see paragraph 94), manufacturers (see paragraph 90), as well as trade associations, the NHS, charities, healthcare professionals, patients, the public, police departments, trading standards, the National Crime Association, and whistle-blowers. These are largely received directly by the DCU via the Devices.Compliance@mhra.gov.uk mailbox.

144. The DCU also investigated potential non-compliance reports that came through the MHRA's Yellow Card scheme. Throughout the pandemic, the DCU received a number of allegations of non-compliance for a range of Covid-19 related medical devices, including Covid-19 test kits. Following identification of non-compliance, the DCU takes regulatory action (also known as compliance and or enforcement action), as discussed at paragraphs 27 to 29 above.

145. An example of compliance action undertaken by the DCU during the early stages of the pandemic included working with the General Pharmaceutical Council to ensure UK pharmacists understood the legal requirements for selling Covid-19 test kits to members of the public.

146. In July 2020, the MHRA conducted a regulatory review of home test kits supplied by the company Randox after they were flagged on 3 July 2020 by the National Testing Programme, which was supplying these test kits to the social care sector. The National Testing Programme was looking to verify whether the home test kits supplied by Randox met the requirements to establish CE mark status. The review highlighted that there had been no Notified Body assessment of aspects of manufacture relating to sterility, a regulatory requirement for Class I medical devices which have a sterile component. This failure would therefore have been associated with a risk of contamination of nasal swabs.

147. On 6 August 2020, while awaiting test results of the swabs' sterility, the MHRA instructed Randox to recall some of its home testing kits as a precautionary measure to prevent any further use of these tests. The risk to public safety was low, there was no evidence that Covid-19 test results from Randox kits were affected, and there were no reports of patient harm. On 7 August 2020, the DHSC released a news story notifying the public of the issue relating to test kits produced by Randox laboratories **(JR/38a – INQ000575553).** The DHSC supported the issuance of replacement kits to affected testing settings.

148. On 30 September 2021, SureScreen Diagnostics applied for an EUA for their Antigen Rapid Test Casette (Nasal Swab – Gold). The MHRA refused this application following regulatory assessment, which found that the device did not meet acceptable sensitivity levels in relation to CTDA requirements. SureScreen provided additional information to the MHRA to appeal this decision, such as clinical benefits of the test in comparison to

other available Covid-19 tests, in conjunction with further information from UKHSA relating to the critical need of the device.

149. Upon further consideration of facts presented in the appeal, and in light of the urgent clinical need for Covid-19 tests, on 10 November 2021 the MHRA granted an EUA. The EUA noted that the test performance was not superior to alternatives already on the market, in particular for asymptomatic testing, however with the lack of available alternatives to meet any supply gaps in a reasonable timeframe, it was accepted that it was in the interests of the protection of public health to authorise the supply of the device **(JR/38b –** **INQ000594557**

150. Furthermore, during the pandemic, new Covid-19 variants had the potential to impact on the effectiveness of existing Covid-19 test devices. The Variants of Concern Assurance Group, as discussed in paragraph 61 above, monitored the performance of assays. The MHRA engaged with suppliers and manufacturers of test products to review their post-market assurance processes for the most recently published VoC in circulation.

151. As such, the MHRA was made aware that the DHSC self-test device that had fallen below desirable and acceptable specificity and sensitivity levels. The MHRA followed its usual regulatory processes, including seeking advice from the IVDEAG regarding these devices, and ensuring mitigations were in place, as is described in the paragraph below.

152. On 6 January 2022, the DHSC requested an extension to the EUA granted on **22** December 2020 for the DHSC self-test. As part of post-market surveillance requirements for IVDs, the latest Post-Market Performance follow up study showed that the test specificity was high, however there had been a decrease in the clinical sensitivity in studies on Delta variant samples. This was discussed at the IVDEAG on 25 January 2022 **(JR/38c –** **INQ000594560** where the MHRA explained that there appeared to be decreased clinical sensitivity in the Adult Social Care context. Further, the MHRA was cautious regarding the interpretation of transmission data and claims that subjects with lower viral concentration would have little infectious virus, as there was little evidence on how viral concentration correlated with infectiousness.

153. The MHRA granted an EUA extension for the DHSC self-test until 28 February 2022, with agreed conditions of approval including that daily testing of contacts was not covered by the authorisation, scope of use of the authorisation, and submission of a

detailed plan for UKCA/CE marking of the device **(JR/38d - INQ000594558** The MHRA also requested further information from the manufacturer which included, but was not limited to, a full risk analysis report concerning the observed decrease in clinical sensitivity in line with procedures for risk management, a breakdown of UK adult social care sensitivity data, and real-world sensitivity data of other devices in deployment at the time.

154. In addition to receiving this requested information through regular meetings with DHSC, the MHRA regularly interacted with the manufacturer to help mitigate any risks. Improvements to safe use were generally made via iterative steps under MHRA scrutiny. This included, for example, updates to the instructions for use, or requests to conduct in silico testing against variants, and to submit periodic safety reports to the MHRA for review.

155. As part of its ongoing post market surveillance, if the MHRA identifies a safety issue which poses a significant risk to patients or the public it will issue communications in the form of National Patient Safety Alerts (formerly known as Medical Device Alerts) and develop or update guidance for stakeholders. This will be discussed in detail in the Messaging section of this statement at paragraphs 161 to 174 below.

Impact of the mass Covid-19 testing programme

156. Whilst the MHRA did provide regulatory guidance for testing devices as described above, it is important to reiterate that the MHRA was not responsible for, nor involved in, the strategy of the mass testing programme.

157. As to the impact of the mass testing programme, the MHRA found it to be a useful source of data to support its post-market surveillance of the Covid-19 vaccines including whether their benefits continued to be observed in widescale use. Modelling data using the effectiveness analyses was used to understand the potential impact of different forms of regulatory action on incidence of Covid-19 infection, hospitalisation, and death rates. It was also useful as new viral variants emerged, with the mass testing program generating evidence on the evolving effectiveness of the vaccines.

158. Data on the incidence of infection are critical in order to accurately estimate the risks associated with Covid-19 infection and not only in those who have progressed to more

severe disease. The data collated by the mass testing programme was used in epidemiological studies to directly compare the risk of specific rare but serious adverse events following vaccination with the risk of similar events associated with severe Covid-19 disease.

159. By way of example, a 2022 paper **(JR/39 – INQ000533181)** found increased risks of myocarditis associated with a positive Covid-19 test compared to the risk of myocarditis associated with the AstraZeneca (Vaxzevria), Pfizer/BioNTech (Comirnaty) and Moderna (Spikevax) Covid-19 vaccines. It estimated that there were an additional 40 reports of myocarditis per 1 million patients in the 28 days following a Covid-19 positive test compared to 2, 1, and 6 reports per million people vaccinated with a first dose of the AstraZeneca, Pfizer, and Moderna vaccines respectively and 10 per million people vaccinated with a second dose of the Moderna vaccine.

160. Finally, the epidemiological studies that utilised data from the mass testing programme supported the MHRA's evaluation of the benefit risk balance of the vaccine in under-represented populations, for example pregnant women and other groups that were not included in clinical trials **(JR/40 – INQ000533186).** In a future pandemic, the MHRA safety surveillance activities would benefit from similar access to data generated from a mass testing scheme.

Safety Messaging

161. During the pandemic, the MHRA worked alongside wider government to produce a range of safety communications to convey key public health messages to the public regarding Covid-19 vaccines, therapeutics, and devices. I am asked about the MHRA's safety messaging in relation to Covid-19 testing kits. In the context of this statement, I understand the term 'safety messaging' to encompass any communication produced and distributed by the MHRA with the purpose of ensuring that patients and the public, healthcare providers, test service providers and industry manufacturers were informed of the latest safety, performance and instructions for use information regarding Covid-19 testing kits available on the UK market.

Guidance on Covid-19 Testing Kits

162. To support the UK mass testing programme, on 13 May 2020 the MHRA published guidance developed by its highly specialised technical experts and scientists aimed at educating different audiences on the purpose and safe use of Covid-19 tests and testing kits. These audiences included patients and the public, testing service providers and industry manufacturers **(JR/41 – INQ000283600, JR/42 – INQ000283601, JR/43 – INQ000283602).** In addition to encouraging safe and proper use of Covid-19 testing kits, this guidance also signposted to the MHRA's Yellow Card reporting site where patients and healthcare providers can report any adverse incidents they may have experienced whilst using one of these devices.

163. Further, the MHRA established an easily accessible hub on GOV.UK that hosted this guidance in a single place, making efforts to ensure that the webpage was highly visible on search engine outcomes so that the public could easily access accurate information on Covid-19 test kits from a trusted source **(JR/44 – INQ000533190).**

Drug and Medical Device Safety Updates

164. For safety updates regarding a medicine or medical device, the MHRA (in conjunction with the independent scientific advisory body, the Commission on Human Medicines) publishes a monthly electronic bulletin for UK healthcare professionals on GOV.UK, the Drug Safety Update (DSU). The DSU is also disseminated by a trusted third-party provider on a monthly basis by email to a wide list of health care professionals. This provider uses their own database of contacts, totalling approximately 150,000 addressees.

165. The DSU provides current advice and information about the safe use of medicines or medical devices. Whilst no DSU articles specific to Covid-19 testing kits were distributed during the Covid-19 pandemic, monthly DSUs published during this time would signpost the public to report adverse incidents with any medicine or medical device (including testing kits) via the MHRA's Yellow Card reporting site. For example, the May 2020 monthly DSU included information regarding the recently launched dedicated Coronavirus Yellow Card web portal **(JR/45 – INQ000533191).**

166. On 25 March 2025, the MHRA launched a new monthly safety bulletin, the 'MHRA Safety Roundup', as part of a three-year 'Strategy for Improving Safety Communications' to make medicines and medical device information clearer and more accessible for healthcare professionals. The bulletin, which is sent to subscribers and published online, provides a summary of all the MHRA safety alerts for the past month including DSU, device safety information (DSI), national patient safety alerts, recalls and medicines notifications, and letters sent to healthcare professionals **(JR/45a – INQ000591753**

Central Alerting System

167. As part of its ongoing surveillance, if the MHRA identifies a safety issue likely to pose a significant risk, it will issue an alert in the form of a National Patient Safety Alert (NatPSA) and develop or update guidance for stakeholders. In 2020 the MHRA was accredited by the National Patient Safety Committee to issue NatPSAs for both medical devices and medicines, and this was implemented in September 2020. Before then, Medical Device Alerts (MDAs) were used to communicate safety issues with higher-risk devices. Publication of MDAs ceased in 2020, having been replaced by the NatPSAs, which are recognised throughout the healthcare system as the most important form of safety alert requiring action.

168. In line with standard practice, draft safety alerts are sent to NHS organisations and Devolved Governments for information or comment in advance of publication. The NatPSAs are disseminated to NHS organisations via the Central Alerting System (CAS), where a designated CAS liaison officer is required to ensure the alert rapidly reaches the designated executive and relevant senior leader who will be coordinating delivery of any required actions. In addition to the CAS system, NatPSAs are discussed at monthly meetings of the Medical Devices Safety Officer network, where safety alerts from the MHRA are a standing item on the agenda. The NatPSAs are also posted on the GOV.UK website to view, where anyone is given the option to sign up to receive NatPSAs directly.

169. On 8 June 2020, the MHRA issued an alert regarding Covid-19 testing via CAS in the form of a Medical Device Alert **(JR/46 – INQ000533188)**. This alert related to safety issues arising from Covid-19 antibody test providers supplying at-home sample collection kits. The alert requested that laboratories offering Covid-19 testing services for the public, private healthcare or the NHS should pause the service immediately if accepting capillary blood samples. This followed the MHRA becoming aware that some

laboratories were providing a Covid-19 testing service whereby the sample type had not yet been validated or verified by the manufacturer of the assay. This meant that the performance of the test could not be confirmed and was not covered by the CE mark. The laboratories affected were known by the antibody test providers. This alert was accompanied by a news story published on GOV.UK **(JR/47 – INQ000533189).**

170. Due to the emergence of PCR testing, followed by antigen virus tests provided through national testing programmes, Covid-19 antibody testing use rapidly declined during this period. This significantly reduced the impact and therefore subsequent analysis became unnecessary. Within three months of issuing the Medical Device Alert, a Covid-19 antibody test manufacturer successfully completed validation and updated the instructions for use. The MHRA additionally provided guidance for Covid-19 home sampling kits. By September 2020 this issue was resolved. No further safety messaging specific to Covid-19 test kits was distributed via CAS.

Media Enquiries

171. The MHRA published a range of press releases throughout the pandemic regarding medical devices intended to test for Covid-19, addressing the following:

a) On 4 April 2020, the MHRA announced that an increasing number of bogus medical products were being sold through unauthorised websites claiming to treat or prevent Covid-19 and were being investigated. This provided advice on how to safely source medicines and medical devices (**JR/49 – INQ000533192**).

b) On 6 May 2020, the MHRA announced the availability of a new reagent to support global diagnostic testing of Covid-19. This reagent was used in tests to confirm whether an individual was infected with Covid-19 and supported the Government's national testing strategy (**JR/51 – INQ000533194**).

c) On 3 July 2020, the MHRA announced a warning that thermal cameras and temperature screening products, some of which made direct claims to screen for Covid-19, were not a reliable way to detect the virus. This warning discussed the lack of scientific evidence around this method and provided advice on safe working during the Covid-19 pandemic. (**JR/48 – INQ000533195**)

d) On 23 December 2020, the MHRA announced issuing an exceptional use authorisation for the NHS test and trace Covid-19 self-test device to be used by members of the public. This provided information on when and how the device could be used, as well as how to interpret the results (**JR/50 – INQ000533193**).

172. In addition to these press releases, the MHRA engaged more widely in reactive media and enquiry handling regarding Covid-19 test kits. This included weekly direct emails sent to subscribing healthcare professionals and interested registrants regarding MHRA guidance on Covid-19-related medicines and medical devices **(JR/52 – INQ000283539)**. In this email, the MHRA updated on new medical devices given EUAs, safety reporting systems, any new guidance for industry, and safety updates relating to Covid-19. The MHRA also regularly posted through our social media channels and proactive outreach through our public health campaigns, to inform the public of new guidance, or regulatory safety action.

173. The MHRA makes provision to ensure that all its communications made through digital channels are accessible, for example, by ensuring that content is compatible with assistive technologies such as screen readers, and that lay summaries are used wherever possible. Google Translate is also embedded as a standard function within our GOV.UK and other public-facing sites to help ensure language requirements from the public are met.

Misleading Advertising of Covid-19 Testing Kits

174. The MHRA took action with regards to false and misleading advertising of Covid-19 test devices. In addition to the press release published on 3 July 2020 **(JR/48 – INQ000533195),** warning against thermal cameras falsely advertised as being capable of screening for Covid-19 (referenced in paragraph 171 above) in April 2020 the MHRA took action to disable 9 web domain names and social media accounts selling fake or unauthorised Covid-19 products, some of which included self-test kits. This action came following a National Crime Agency (NCA) investigation in collaboration with the MHRA into a number of reports of the sale of counterfeit healthcare products relating to Covid-19.

175. The MHRA runs the #FakeMeds campaign, which aims to provide quick and easy tools to the public to help inform and educate on how to avoid fake medical products when

shopping online. This campaign was signposted in a press release in March 2020 regarding the MHRA's crackdown on other unlicensed medical products related to Covid-19, including unlicensed Covid-19 test kits **(JR/53 – INQ000533196).**

Reflections and Lessons Learnt

176. 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 as soon as sufficient evidence was available; and a workforce which demonstrated its unwavering determination and commitment to protect public health.

177. The MHRA's focus was at all times maintaining access to safe and effective IVD products through effective collaboration, however it would be appropriate to draw attention here to the need for absolute clarity of accountability at all times, alongside maintenance of regulatory independence.

178. The pandemic has 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/54 – INQ000283532).** That review followed a report by the Government Internal Audit Agency **(JR/55 – INQ000283531).** The Agency has also undertaken a more detailed review of its approach to diagnostics **(JR/56 – INQ000283548).** Some of the learnings from these reviews are discussed below. For example, collaboration with other healthcare organisation is discussed at paragraph 193.

179. In the summer of 2020, the then MHRA Devices Division undertook an informal, internal review of lessons learnt from the Covid-19 pandemic **(JR/57 – INQ000534259**). This review covered: ventilators, medical devices, and PPE, IVDs and regulatory flexibilities. The lessons learnt identified in this review contributed to the broader lessons learnt relating to this module, which are found below. As an example, the early involvement of MHRA in the provision of regulatory support is discussed at paragraphs 180 to 184.

Enabling innovation

180. 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 guidance to support the development of Covid-19 diagnostics, in the form of Target Product Profiles (TPP) (as discussed in paragraphs 103 to 107 above).

181. 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, a type of oropharyngeal swab, contributed to the achievement of the Government 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.

182. Indeed, in the context of the public health need to identify positive Covid-19 cases to reduce transmission rates, the MHRA provided extensive regulatory guidance and support to the DHSC in becoming a legal manufacturer for the Innova DHSC self-tests. These tests were an important part of the national testing programme, with no other tests CE marked tests available in sufficient numbers to deploy to the UK general public at the time. This is discussed at paragraphs 54 to 59 above and exemplifies the extraordinary efforts and working relationships that enabled the appropriate use of procured testing devices according to their performance, ensuring tests deployed at scale were fit for purpose and compliant with legislation. These excellent working relationships which allow innovation are always appropriately balanced against the MHRA maintaining its role as an independent regulator.

183. During the Covid-19 pandemic, the procurement of tests at scale started before MHRA involvement. The legislation that underpinned the regulatory requirements for IVDs meant that most tests for Covid-19, where they were intended for professional use, were classed as low risk IVDs and could therefore be self-certified and legally placed on the UK market. However, there can be a mismatch between the envisaged use of a device and the way the test is destined to be used once on the market. This resulted in the procurement, in some cases, of non-compliant testing kits which resulted in some

devices having to be recalled, for example, the Randox test kit in July 2020 (discussed at paragraph 146 above). This limitation in the framework has brought about the strengthening of the legislative framework, which is discussed in the 'Regulatory reform and strengthening market surveillance' section below.

184. For future pandemics, national testing strategies would benefit from early regulatory advice to ensure tests considered for procurement were compliant, and to consider appropriate use of test devices in accordance with their performance. Furthermore, we would wish to continue to operate flexibly and provide extensive support to essential programmes, all the while respecting the MHRA's role to apply independent scrutiny and oversight within its statutory responsibilities.

Application of scientific expertise

185. The pandemic highlighted the MHRA's ability to enable innovation through its scientific capability and preparedness in relation to technologically complex issues. This was key to making rapid progress on essential deliverables such as Target Product Profiles for diagnostics. The timely production of biological physical standards was also possible because of a critical mass of expert scientific staff and existing long-standing research in this area which meant the MHRA laboratory functions could rapidly progress the development of Covid-19 standards.

186. For example, the timeframe to produce an international standard is usually 2-3 years, but as a result of co-operation between the MHRA and other international laboratories and the WHO Expert Committee on Biological Standardization (ECBS), this was accelerated to a matter of months. Following the announcement of the pandemic in March 2020, the MHRA laboratories were able to rapidly research reagents that would go on to become the international standards. These international standards were made available by December 2020. As the leading WHO Collaborative Centre on biological standardisation, the MHRA laboratories are well positioned to prepare and respond in a similar manner for future pandemics.

187. The early development of reference methods, materials and controls is essential. Scientific validation of variable-disease associations alongside clinical reference standards is needed to thoroughly understand the disease and diagnostic in order to develop effective testing strategies that protect patients and the public.

188. While some surge resource was made available to meet the demands placed upon the MHRA and its laboratories in these regards, this was largely achieved through preparing and training staff to effectively perform their roles. This work was of both national and international importance, and it is therefore critical that the MHRA maintains sufficient expertise and ongoing training to enable staff to undertake similar work in the event of a future pandemic.

189. The overall lesson learnt on preparedness in the area of MHRA's scientific expertise is that it is vitally important that there is continued investment in MHRA's capability for pandemic preparedness if the government's '100 Days Mission' aim of accessing diagnostics, vaccines and therapeutics within 100 days of a pandemic being declared is to be achieved.

Horizon scanning and early detection

190. As discussed at paragraphs 82 to 89 above, the MHRA's laboratory scientists were able to apply the scientific expertise gained from wastewater testing projects commenced in 2016 to monitor the spread of Covid-19 by analysing samples collected and archived from before the pandemic and assessing samples for the presence of SARS-CoV-2. Our laboratories were able to detect low levels of viral RNA in a sample collected on 11 February 2020, which was a few days before the first case was reported in the sewage plant catchment area. Whilst this was a retrospective study, it demonstrated a proof of concept that variants of the pathogen can be detected before clinical cases become apparent arising from infection with that variant. In addition, a novel test was designed to specifically detect and quantify the presence of key mutations of SARS-CoV-2 variants of concern. Hence, we were able to detect changes in the predominance of different variants of concern throughout the Covid-19 pandemic, before the results from clinical samples.

191. This method of horizon scanning proved to be extremely effective when testing for emerging variants during the Covid-19 pandemic, and as such should be utilised prior to and during any future pandemic scenarios. As such, plans are ongoing to continue wastewater testing work in close collaboration with UKHSA and in the context of expansion of current environmental surveillance for poliovirus. Currently, whilst SARS-

CoV-2 waste water testing has ceased, such testing is ongoing for polio and related viruses.

192. The ultimate aim is to set up surveillance systems for multi-pathogen detection targeting bacteria and viruses associated with the human diseases with the greatest public health impact. This could also assist with the early detection of future pandemics. In fact, the system would be able to detect any pathogen for which we have a sequence to provide the useful surveillance data described at paragraph 83. Whilst an estimate for completion is not possible at this time, work with UKHSA on establishing this system fully is currently under way.

193. The MHRA will continue to invest in its scientific preparedness, capability and strategic relationship with the WHO to maintain its leading contribution to the UK's preparation and response to future pandemics. The MHRA has also developed comprehensive standard operating procedures, cross-agency and inter-agency ways of working to support the early development of reference methods, materials, and controls. To continue excellence in its scientific preparedness, the MHRA is continuing to work on a pandemic preparedness plan, which will cover scientific preparedness, business continuity and use of Agency estates.

Collaboration and Data sharing

194. The MHRA's collaboration with government healthcare organisations such as PHE, UKHSA, NHSE and NHS Test and Trace enabled the use of data from the mass testing programme, such as the incidence of Covid-19 infection, to support post-market surveillance of the Covid-19 vaccines. The epidemiological studies that utilised data from the mass testing programme supported the MHRA's evaluation of the benefit risk of the vaccine in under-represented populations, for example pregnant women and other groups that were not included in clinical trials **(JR/40 – INQ000533186).** In a future pandemic, the MHRA would benefit from similar access to data generated from a mass testing scheme, with timeliness, scale and accuracy of testing being important factors. Ensuring test results are swiftly integrated into GP systems would aid epidemiological studies of potential safety issues.

195. Further useful data were obtained and shared through UKHSA and other partners from the mass testing scheme on circulating SARS-CoV-2 variants of concern, which allowed

the MHRA to assess the impact of these viral strains on the performance of IVDs by advising manufacturers to carry out specific testing. The use of robust post-market surveillance methods, such as in the Variant of Concern Assurance Working Group, and post-market-performance follow up studies by manufacturers and government, can help to mitigate risks and ensure that the evidence supports safe and effective use of IVDs.

196. Access to clinical samples, data, reference laboratories and trial participants for in-context performance evaluation studies could expedite IVD validation and verification. Global collaboration on surveillance of new variants and co-operation around clinical samples, evidence, regulatory intelligence and data-sharing early on in a pandemic would be beneficial.

Regulatory reform, and strengthening post market surveillance

197. I have been asked whether there are any changes or reforms which the MHRA would welcome in light of our experience of regulating healthcare products used to prevent the spread of Covid-19 during the pandemic. The MHRA continuously evaluates how we may best operate as a regulator and has 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 support greater proactivity to better support the availability of safe and performing testing devices.

198. Following the UK's exit from the EU, there was an opportunity to improve how medical devices and IVDs, such as the Covid-19 tests, are regulated in the UK. The Medicines and Medical Devices Act 2021 allows for amendments to the MDR 2002 which govern medical devices in Great Britain. In 2021, the MHRA launched a consultation to strengthen medical devices legislation **(JR/58 – 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.

199. As a result, legislative reform began through an amendment of the MDR 2002 in relation to post-market surveillance requirements (the Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2023). 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. These new regulations will come into force on 16 June 2025.

200. A suite of guidance was published on 15 January 2025 and is designed to help medical device manufacturers understand and prepare for the new post-market surveillance regulation for medical devices **(JR/58a – INQ000575552**. Key new requirements are enhanced data collection, shorter timelines for reporting serious incidents and summary reporting to enable the MHRA and manufacturers to identify safety issues earlier, as well as clearer obligations for risk mitigation and communication to protect patients and users. The post-market surveillance requirements vary based on the risk level posed by the device to patients. The guidance will provide additional detail on these requirements to support manufacturers with their post-market surveillance activities and help to ensure their devices continue to meet appropriate standards of safety and performance.

201. The MHRA plans to put a further legislative amendment before Parliament in 2025 to propose 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's MDR 2002 with those in other jurisdictions, for instance the 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. The legislative amendment will also improve traceability of medical devices by mandating unique device identifiers and implant cards for patients receiving implants; ensure the claims manufacturers can make about devices align to the evidence on which approval was gained; and adjust the classification of some general medical devices so that the classification better reflects their risk.

202. 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/59 – INQ000527711, JR/59a – INQ000575550**

203. This consultation includes proposals for an International Reliance route. International Reliance will allow the MHRA to utilise the expertise and decision-making of other regulatory partners for the benefit of patients. The MHRA will retain the authority to reject applications if the evidence provided is considered insufficiently robust. Recognising the regulatory decisions of other trusted regulators in determining whether a medical device can be marketed 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 UK without friction. The revised proposals on which MHRA has consulted seek to enable reliance on the decisions of other international comparator regulators, including the EU whilst ensuring the MHRA has the controls it needs to keep patients and the public safe.

Expediting approval of innovative medical devices

204. During the pandemic, recognising the great public health need for innovative medical devices, the MHRA operated flexibly using existing regulatory processes to assist in the UK response. As described above at paragraphs 108 to 117, Exceptional Use Authorisations (EUAs) enable the MHRA to authorise the placing on the market, or putting into service, non-UKCA or non-CE marked devices in the interests of protection of public health and where there is no authorised alternative.

205. The EUA route was used more frequently during the pandemic and successfully ensured that patients and the public could access testing devices in the shortest time possible. This was an essential contribution to the pandemic response. As discussed above in paragraph 110, following approval of any EUA application whether during the pandemic of during business as usual, the medical devices are closely monitored by the MHRA. Under this provision 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.

206. 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.

207. 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.

208. The Innovative Devices Access Pathway (IDAP), 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/60 – INQ000527712).** In the IDAP 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

209. The Covid-19 pandemic highlighted the critical importance of effective collaboration with other healthcare bodies and stakeholders, while maintaining clarity of accountability. This collaboration was essential for navigating the challenges of developing, approving, and monitoring new medical devices. The MHRA's scientific preparedness and regulatory expertise for the rapid development of international standards, TPPs, and our continued partnerships within Government and the wider healthcare matrix were key enablers for product development and innovation. The MHRA's approvals of EUAs for testing devices contributed to the achievement of the Government's testing target, enabling the national testing strategy for healthcare and the public.

210. In future pandemics, involving the MHRA early in the procurement process to proactively develop technical specifications or TPPs could minimise the need for retroactive regulatory reviews. The MHRA will therefore aim to strengthen early engagement with Government procurement teams to ensure understanding of regulatory considerations and to offer proactive regulatory advice.

211. The MHRA aims to enhance its scientific readiness and strategic relationships with international partners to ensure the UK is prepared for future pandemics and is establishing a pandemic preparedness plan covering scientific preparedness, business continuity, and estates.

212. 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 post market surveillance of medical devices, including recognising the regulatory decisions of other trusted regulators globally, to determine whether a product can be marketed in the UK. This approach will be 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: 2 April 2025