IN THE MATTER OF THE INQUIRIES ACT 2005

AND IN THE MATTER OF THE INQUIRY RULES 2006

UK COVID-19 INQUIRY

SEVENTH WITNESS STATEMENT OF CLARA SWINSON

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1. I, Clara Swinson, of the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU, will say as follows:

INTRODUCTION

2. I make this statement in response to a request from the UK COVID-19 Public Inquiry (the Inquiry) dated 20 July 2023 made under Rule 9 of the Inquiry Rules 2006 (the Request) asking for a corporate statement on behalf of the Department of Health and Social Care (the Department/DHSC) providing an overview of the structure of the Department and the role it played in the development and deployment of vaccines and therapeutics in the COVID-19 pandemic between 30 January 2020 and 28 June 2022.

3. As this is a corporate statement on behalf of the Department, it necessarily covers matters that are not within my personal knowledge or recollection. This statement is to the best of my knowledge and belief accurate and complete at the time of signing, in line with responding, as far as possible, within the Inquiry's deadlines. Notwithstanding this, it is the case that the Department continues to prepare for its involvement in the Inquiry. As part of these preparations, it is possible that additional material will be discovered. In this eventuality the additional material will of course be provided to the Inquiry and a supplementary statement will be made if need be.

4. I was Director General (DG) for Global Health and Health Protection throughout this period and was responsible for leading teams including emergency preparedness and health protection, international policy and EU and Trade, and a number of COVID-specific teams [as set out in previous statements]. I was the DG-level Senior

Responsible Owner (SRO) for the COVID-19 Battle Plan (the "Battle Plan"). **(CS7/1 - INQ000144792)** Of relevance for this statement, I was responsible for the Therapeutics and Antivirals Taskforces, which were established as a new Directorate in the Department in response to the pandemic.

5. For areas outside of my responsibility, I have relied on departmental records and briefings, and my understanding of the overall approach to the pandemic. While there are elements of our response in all of the Department's work, of particular relevance for this statement is the Science, Research and Evidence Directorate and aspects of the National Institute for Heath and Care Research (NIHR). These are the responsibility of the Department's Chief Scientific Advisor (CSA) (Professor Sir Chris Whitty who was CSA as well as Chief Medical Officer (CMO) for the start of the period, and Professor Lucy Chappell from August 2021 to the present). The work of the NIHR is covered in greater detail in the witness statement of Professor Lucy Chappell. I am grateful to all the departmental officials who have contributed to this statement.

6. This statement is the second of three corporate statements I am making to the Inquiry on Module 4, Vaccines and Therapeutics. This statement covers the Departments role in treatment of COVID-19, using both existing and new medications. In some cases, I will refer to information provided in more detail in one of my other two statements for Module 4 (the first (my Sixth Witness Statement) covers the development and deployment of vaccines and the third (my Eighth Witness Statement) considers issues relating to public messaging, disparities in vaccine coverage and vaccine uptake, tackling misinformation and disinformation, and vaccine safety issues), and to Professor Lucy Chappell's statement on Module 4.

7. This statement is divided into four sections. These are:

    a. **Section 1: Overview of DHSC's Role, Function, Responsibility and Accountability**, which, among other things, provides key information on the Department's role, key decision-makers, relevant governance structures and key organisational relationships.
    b. **Section 2: Background and Impact of the Taskforces**, which describes the three taskforces (Antivirals Taskforce, Vaccines Taskforce and Antivirals and Vaccines Taskforce) that supported governance and delivery of vaccines and therapeutics.

c. **Section 3: Preparedness, Procurement, and Deployment**, describing the actions taken before the pandemic to identify and stockpile relevant treatments and to research potential future treatments in the event of a pandemic.
d. **Section 4: Reflections and Lessons Learned** summarises some of the key lessons learned that may help our ability to respond going forward.

SECTION 1: OVERVIEW OF DHSC'S ROLE, FUNCTION, RESPONSIBILITIES AND ACCOUNTABILITY

8. This section of the statement provides an overview of the role, function and responsibilities of the Department in the development, trials and use of new therapeutics during the pandemic, in addition to the use of existing medications.

Departmental Role

9. As explained at paragraph 153 of Sir Chris Wormald's Third Witness Statement concerning Module 2 dated 29 March 2023, the tools available in most pandemics are testing and isolation, non-pharmaceutical interventions (NPIs), vaccines and therapeutics. **(CS7/1 - INQ000144792)** All pandemics in recent history have been addressed by scientific understanding leading to pharmaceutical countermeasures, such as vaccines and treatments.

10. The Therapeutics Taskforce (TTF) was established in April 2020, with the Deputy Director recruited on 2 April 2020. The Antivirals Taskforce (ATF) was announced by the Prime Minister on 20 April 2021. The two were combined to form the Antivirals and Therapeutics Taskforce (ATTF) from 1 April 2022 until June 2023. The governance of the taskforces is covered in more detail in paragraphs 70 to 84. This statement uses the relevant taskforce names for the periods in which they existed, and ATTF when the taskforces merged in March 2022 and as a collective term for areas such as the overall approach and lessons learnt. **(CS7/2 - INQ000408769; CS7/3 - INQ000257447)**.

Key Decision Makers

11. A list of key decision makers in the Department in respect of the topics outlined in the Provisional Outline of Scope for Module 4 was provided to the Inquiry on 10 November

2023 and an updated list on 22 December 2023 **(CS7/4 - INQ000399472; CS7/5 - INQ000474257)**.

12. For ease, I list the key decision-makers with most involvement in respect of the topics outlined in the Provisional Outline of Scope for Module 4 in relation to antivirals and therapeutics.

13. The ministers in the Department:

    a. Secretary of State for Health and Social Care – Rt Hon Matt Hancock MP from the start of this period considered to 26 June 2021;
    b. Secretary of State for Health and Social Care – Rt Hon Sir Sajid Javid MP from 26 June 2021 to 5 July 2022;
    c. Parliamentary Under Secretary of State (Minister for Technology, Innovation and Life Sciences) – Rt Hon Lord Bethell from the start of this period considered to 17 September 2021;
    d. Parliamentary Under Secretary of State (Minister for Technology, Innovation and Life Sciences) – Rt Hon Lord Kamall from 17 September 2021 to 20 September 2022.

14. Senior officials in the Department:

    a. Sir Chris Wormald the Permanent Secretary from May 2016 to the present;
    b. David Williams the Second Permanent Secretary from March 2020 to April 2021;
    c. Shona Dunn the Second Permanent Secretary from April 2021 to June 2024;
    d. Professor Sir Chris Whitty the Chief Medical Officer (CMO) for England from October 2019 to the present and the Departmental Chief Scientific Advisor (CSA) from January 2016 to August 2021;
    e. The Deputy Chief Medical Officers (DCMO):
        i. Professor Sir Jonathan Van-Tam, DCMO from October 2017 to March 2022. His role covered emergency response and preparedness, infectious diseases, vaccines, and therapeutics;
        ii. Professor Dame Jenny Harries, the DCMO for health improvement from July 2019 to May 2021;
        iii. Professor Thomas Waite, interim DCMO for COVID-19 in July 2021 and was substantively appointed DCMO leading on health protection in April

2022. His responsibilities cover emergency response and preparedness, infectious diseases, vaccines and therapeutics;

f. I (Clara Swinson) have held the role of Director General for Global Health and Health Protection from November 2016 to the present;
g. Professor Lucy Chappell the Departmental Chief Scientific Adviser (CSA) from August 2021 to present;
h. Andy Brittain the Director then Director General for Finance;
i. Dr Louise Wood, the Director of Science, Research and Evidence in the Department between December 2016 and June 2022;
j. Charlotte Taylor Acting Director of the Therapeutics Taskforce, Antivirals Taskforce and thereafter the combined Antivirals and Therapeutics Taskforce from [Spring] 2020 until 30 June 2023.

The Battle Plan

15. Within the Department, the Executive Committee ("ExCo") and COVID-19 Oversight Board oversaw the Department's implementation of the COVID-19 Battle Plan. The Battle Plan was the Department's internal tool to organise the Department's programme to respond to COVID-19. As explained at paragraphs 57 to 58 of Sir Chris Wormald's Third Witness Statement on Module 2 dated 29 March 2023, the initial three-month Battle Plan was commissioned by the Prime Minister at a meeting on 20 March 2020. This drew on work already underway in the Department to identify and organise key workstreams. The Battle Plan was scrutinised by the Health Ministerial Implementation Group (HMIG) and the Prime Minister and agreed on 22 March 2020. **(CS7/1 - INQ000144792).**

16. Work under the Battle Plan was initially split into six workstreams: (1) resilience for the NHS and adult social care; (2) supply of key products and equipment; (3) testing widespread across the population; (4) technology accelerating new interventions; (5) social distancing to slow the rate of transition; and (6) shielding to protect the most vulnerable. Therapeutics was part of workstream four. Under each workstream a number of key performance indicators were identified, and an SRO was assigned to each workstream as shown below at paragraph 17
in respect of therapeutics and antivirals. Progress on the workstreams was reported to the Department's COVID-19 Oversight Board by SROs or their deputies, on a weekly basis. The Oversight Board met weekly until the end of June 2021, after which the

frequency of meetings was agreed by the Board to reflect the level of assurance needed during particular phases of the pandemic. **(CS7/1 - INQ000144792).**

17. The iterations of the Battle Plan below demonstrate the development of the Department's involvement in and planning for the procurement and deployment of antivirals and therapeutics:

    a. In version 1.0 (22 March 2020), antivirals and therapeutics were part of workstream 4 'Technology – accelerating new interventions' in sub-workstream 4.5 'Treatment measures [TBC]' **(CS7/6 - INQ000106286).**

    b. In version 1.2 (27 March 2020) antivirals and therapeutics were part of workstream 4 'Technology – accelerating new interventions' in sub-workstream 4.1 'Identify and research new possible treatments' led by the DCMO (Jonathan Van-Tam) **(CS7/7 - INQ000273560).**

    c. In version 2.0 (04 May 2020), antivirals and therapeutics were part of workstream 5 'Technology – accelerating new interventions' in sub-workstream 5.A 'Identify and research new possible treatments' with the DCMO (Jonathan Van-Tam) named as programme director and Clara Swinson as the Senior Responsible Officer (SRO) **(CS7/8 - INQ000106902).**

    d. In version 3.0 (21 July 2020), workstream 5 was amended to 'Vaccines & Treatments'. Sub-workstream 5.A was amended to 'Identify, research and deploy new treatments' and Charlotte Taylor was appointed programme director with Clara Swinson remaining as SRO **(CS7/9 - INQ000106543)**.

    e. In version 3.1 (1 October 2020), workstream 5 was amended to 'Vaccines & Treatments - Research & Deployment'. Sub-workstream 5.A remained as 'Identify, research and deploy new treatments', Charlotte Taylor and Clara Swinson remained as programme director and SRO respectively **(CS7/10 - INQ000401296).**

    f. In version 4.2 (30 June 2021), workstream 5 'Vaccines & Treatments - Research & Deployment' was amended to have an additional sub-workstream 5.C 'Antivirals Taskforce' with Charlotte Taylor listed as programme director and Clara Swinson as SRO, as well as workstream 5. A which remained as 'Identify, research and

deploy new treatments', with Charlotte Taylor and Clara Swinson remaining as programme director and SRO respectively **(CS7/11 - INQ000502102).**

g. In version 6.0 the sub-workstreams 5. A 'Identify, research and deploy new treatments' and 5.C 'Antivirals Taskforce' moved into workstream 2 to reflect its part in the Living with COVID-19 plan. Workstream 2 was listed as 'Antivirals and Therapeutics' with Clara Swinson listed as SRO. It was comprised of workstream 2.A which was listed as 'Antivirals & Therapeutics Taskforce' and 'NHSEI deployment' with Charlotte Taylor (DHSC) and Gareth Arthur (NHSEI) listed as programme directors respectively **(CS7/12 - INQ000502127).**

Role of the Department in relation to Therapeutics

18. This statement sets out in detail the role of the Department in therapeutics and responds to the detailed questions of the Inquiry. In summary, the Department carried out the following roles:

a. **Research and development**: Commissioned, funded and delivered research, using new and existing NIHR programmes and infrastructure. This was in place pre pandemic and included world-leading trials resulting in speedy advances in patient care and outcomes. This is covered in greater detail in Professor Lucy Chappell's statement.

b. **Procurement, storage and supply**: Negotiated, contracted and procured therapeutics for clinical trials and took on central procurement of novel therapeutics on behalf of the UK. Set up storage arrangement to store and distribute across the whole of the UK. For COVID-19 oral antivirals, established storage and distribution routes for GPs and community pharmacies.

c. **Funding:** Secured new programme budget and budget for procurement, storage and distribution of potential and proven therapeutics, including developing business cases and taking them through appropriate assurance and decision-making processes.

d. **Communications:** Provided an overall coordinating function so information about new therapeutics, including the importance of clinical research, was communicated coherently across the media and the healthcare system.

e. **Holding the health system to account:** Sponsorship of relevant arm's-length bodies (ALBs) including their prioritisation of the antivirals and therapeutics programmes, in particular MHRA, NICE, PHE / UKHSA, NHSE, NHSBT and HRA.

f. **Engagement with the life sciences sector:** Set up expert groups for advice and input and led regular communication with pharmaceutical companies.

g. **Working across the UK:** Developed and agreed a common strategic approach, including in relation to research and clinical access policies. Procured and supplied antivirals and other therapeutics for the whole of the UK.

h. **International collaboration:** Worked with existing international fora and established relationships with international partners to share best practice and intelligence on therapeutics and led on the development of the G7 Therapeutics and Vaccines Clinical Trials Charter, based on the best practice developed in the UK.

i. **Briefing ministers and senior officials:** There were frequent and regular meetings between the Secretary of State, other ministers and the Department and the relevant ALBs to ensure alignment and fast decision making, as well as sharing important information and developments with key senior officials in other departments, including the GCSA. There were also numerous written submissions for decision and information.

19. The Department does not usually take a major role in managing and advising on specific treatments, with MHRA, NICE and the NHS responsible for this in normal times. In the pandemic, the CMO and DCMO Professor Sir Jonathan Van-Tam took a much more active role in directing research, horizon scanning and advising on potential treatments to buy centrally. Some parts of the Department, such as the SRE Directorate and the Medicines Directorate, prioritised its work to respond to the pandemic as early as February 2020. In April 2020, because of the scale and the speed of the task, the Department set up a new team to lead and coordinate the necessary work. In June this team became a new directorate in my Group with Charlotte Taylor

as Director of the Therapeutics Taskforce, and from April 2021 combining this role with the Director of the Antivirals Taskforce (and from April 2022 the ATTF). This new directorate was responsible for delivering the strategic objectives of the TTF/ATF/ATTF, including providing comprehensive, evidence-based advice to Department ministers on therapeutics and providing strategic coordination across responsible bodies to help get effective treatments to patients as fast as possible. This team was approx. 85 FTE at its peak, with three to five Deputy Director led teams with different responsibilities throughout the time period covered by this statement.

20. The size, shape and composition of the team in the Department changed over the period, reflecting the different priorities and requirements, as did the oversight and governance arrangements. These were kept under regular review.

Department's Role & Function and Devolved Administrations

21. There are differences in the Department's role, function and responsibilities in relation to the UK Government and the Devolved Administrations. Paragraph 14 of Sir Christopher Wormald's Third Witness Statement on Module 2 dated 29 March 2023 sets out that, whilst health and social care policy is largely devolved to the Welsh and Scottish Governments and the Northern Ireland Executive, the Department has some reserved policy areas with UK-wide responsibility, including international relations. Public health is a devolved matter, and this meant that certain arrangements to respond to the pandemic could be made separately by the devolved administrations **(CS7/1 - INQ000144792).**

22. Also, in the Third Witness Statement of Sir Christopher Wormald, it notes that the existence of a public health emergency does not change the terms of the existing devolution settlements under which public health, National Health Service (NHS) and care functions are predominantly devolved.

23. That being said, a number of activities undertaken by the Antivirals & Therapeutics Taskforce (the ATTF) discussed below were on behalf of the whole UK (including the Crown Dependencies and Overseas Territories). This included procurement of treatments that were not readily available through normal channels, particularly novel treatments, where companies wanted to engage at a national government level for supply agreements. Where possible, clinical trials were delivered in all four nations, so

that research was representative of the whole population and to ensure patients across the UK had the opportunity to access potential treatments as early as possible. As also seen below under Section 2, the deployment of treatments, including clinical assessment, dispensing and administration, remained the responsibility of the respective health services in the UK.

24. RAPID C-19, a key collaborative that was set up as part of the pandemic response and described at paragraph 168, included membership from all of the Devolved Nations including the Scottish Medicines Consortium, All Wales Therapeutics and Toxicology Centre, All Wales Medicine Strategy Group, and the Department of Health for Northern Ireland which are discussed at paragraphs 45 to 49.

Departmental Functions

25. My first statement of this Module covers relevant departmental functions, arms-length bodies, committees, and other organisations that played a role in both the development and deployment of vaccines and therapeutics. I outline below further information as it relates to the development and deployment of therapeutics and antivirals. Professor Lucy Chappell's statement to this Module also provides further detail where relevant, in particular in relation to the role of NIHR in clinical trials.

National Institute for Health and Care Research (NIHR)

26. In relation to therapeutics, during the COVID-19 pandemic, SRE, through the NIHR, supported a range of COVID-19 research, including funding and delivering vaccines and therapeutics research studies, including commissioning of new COVID-19 research, a rapid and wide-ranging pivot by research groups to COVID-19 research, and prioritisation of COVID-19 research studies. The existing research infrastructure supported by the NIHR was key to internationally recognised, successful research response to COVID-19, including recruiting patients into COVID-19 trials at pace. Further details of the work of the NIHR are set out in Professor Lucy Chappell's statement.

Arms-Length Bodies (ALBs)

27. There are a number of arms-length bodies that played a role in the development and deployment of therapeutics and I outline their roles in relation to therapeutics and antivirals below.

Public Health England (PHE)/ The UK Health Security Agency (UKHSA)

28. The management of pandemic preparedness stockpiles had been the responsibility of PHE since its establishment in 2013 and became the responsibility of UKHSA from 1 October 2021. During the COVID-19 pandemic, PHE/UKHSA were also responsible for the provision of testing kits to enable the identification of patients with mild COVID-19 who may need to receive treatment, as well as a range of in vitro testing of potential vaccine and therapeutic candidates and approved vaccines and therapeutics against different variants of the SARS-COV-2 virus. Further information has been provided in my First Statement on this Module.

The Medicines and Healthcare products Regulatory Agency (MHRA)

29. The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion in the UK. In relation to therapeutics, the MHRA decides whether medicines should be granted licences (also known as Marketing Authorisations) and whether licences can be varied as information about the medicines develop. These decisions are based on safety, quality and efficacy/effectiveness data submitted to the MHRA **(CS7/13- INQ000408763).**

30. A medicine that is granted a licence does not necessarily become immediately available to patients in the UK. The approval process of new therapeutics in normal times operates as follows:

    a. To be made routinely available to NHS patients in the UK, new medicines must normally receive a marketing authorisation from the MHRA.

    b. To demonstrate safety, efficacy and quality and a positive recommendation from the NICE (for England) or the SMC (for Scotland) or the AWTTG (for Wales) for use in the NHS, they must demonstrate clinical and cost effectiveness.

c. The MHRA will usually provide an opinion on approvability within 150 days of receipt of a valid application **(CS7/14- INQ000399494)**. Applications may be fast tracked if there is compelling evidence of benefit in a public health emergency such as a pandemic or if there is a shortage of supply of an essential medicine that has been verified by the Department. To make a request for fast tracking a marketing authorisation, applicants write to the MHRA outlining the following:

    i. the justification for fast tracking.
    ii. a brief description of the major clinical properties of the product.
    iii. evidence supporting the claimed benefits of the product for the proposed indication(s) **(CS7/15 - INQ000399495)**.

31. MHRA is also responsible for clinical trials approvals in the UK, and inspecting them to ensure they comply with Good Clinical Practice standards **(CS7/13 - INQ000408763).**

32. As set out below under paragraphs 163 to 177, during the COVID-19 pandemic, the MHRA played a pivotal role in the delivery of new COVID-19 treatments by working closely with the Department and other healthcare partners and stakeholders to rapidly identify where flexibilities in the regulation of medicines and medical devices was possible to expedite the approval of COVID-19 treatments. It is important to note that these flexibilities did not displace or diminish any other obligations applicable to the relevant products. Accordingly, any medicinal product which benefited from the regulatory flexibilities remained subject to marketing authorisation **(CS7/16 - INQ000408734).**

33. MHRA was also a member of RAPID C-19 which is discussed at paragraph 168 of this witness statement.

Executive Non-Departmental Public Bodies (ENDPBs)

34. ENDPBs are separate legal entities that are set up in primary legislation and have a greater degree of independence from the Department than SHAs or EAs. My First Statement to this Module gives further information on ENDBPs. NHSE and NICE were the Department's most critical ENDPBs in relation to the development and deployment of therapeutics.

NHS England

35. During the COVID-19 pandemic, the Department took steps to help provide a consistent and sufficient supply of treatments, including entering into supply agreements for novel treatments and making them available to the NHS. The NHS was then responsible for the provision of treatments to patients in England. This statement sets out at a high level how this was done and the interaction with the Department's responsibilities; if further information is needed this would be better addressed by NHSE.

36. NHSE ran expert working groups that developed clinical guidelines on the use of each treatment, to inform decisions by clinicians. These interim clinical access policies were adopted across the UK, to ensure consistency and support equitable access. As effective treatments for mild COVID-19 became available, NHSE also developed COVID-19 Medicine Delivery Units ("CMDUs") which assessed eligibility and arranged treatment, including following GP referrals. CMDUs are covered in more detail in paragraph 179.

National Institute for Health and Care Excellence ("NICE")

37. The National Institute for Health and Care Excellence ("NICE") is an executive non-Departmental public body established by the Health and Social Care Act 2012. NICE drives best practice and value for money in the health and care system through the translation of research into authoritative, evidence-based recommendations and guidance, including on the use of medicines.

38. The relationship with NICE is governed by a Framework Agreement. Formal meetings and accountability take place at senior level, including annual accountability meetings between NICE's Chair and Chief Executive and the responsible minister, and quarterly accountability meetings with the NICE senior team and senior departmental sponsor. These are supported by regular informal communication with the sponsor team to manage day to day operational matters.

39. Under normal arrangements, to be routinely funded by the NHS in England, new medicines normally not only receive a marketing authorisation from the MHRA for the

UK as explained below, but they also normally require a positive recommendation from NICE to demonstrate clinical and cost effectiveness.

40. Wherever possible, NICE aims to issue recommendations on new medicines around the time of licensing. The NHS in England is then legally required to fund new licensed medicines recommended by NICE, normally within three months of the publication of NICE guidance **(CS7/17 - INQ000502149)**. The NHS in Northern Ireland and Wales normally adopt NICE's recommendations on new medicines, whilst decisions on new medicines in Scotland are made by the Scottish Medicines Consortium.

41. During the COVID-19 pandemic, NICE maintained guidance on COVID-19 treatments and supported the RAPID C-19 initiative as described below at paragraph 233 The normal health technology appraisal process for new drugs, or for already licensed drugs to be used for different indications, was not applied prior to making decisions on procurement or patient access in the timeframe covered by this witness statement, as the evidence base needed to do so was not complete and there was, exceptionally, benefit in implementing an interim clinical access policy to enable patient access immediately or very soon after positive clinical trial data was available. Technology appraisals have subsequently been completed, to inform NHS patient access in the longer term, and guidance published to support this.

Special Health Authorities (SHAs)

42. As I explain in my First Statement of this Module, SHAs are separate legal entities that are created by secondary legislation to carry out the functions of the Secretary of State. My First Statement sets out their role in greater detail. NHSBT is the SHA most relevant to the development of therapeutics.

NHSBT

43. The NHS Blood and Transplant ("NHSBT") is responsible for the supply of blood, organs, tissues and stem cells. It is a special health authority, sponsored by the Department. It collects and supplies blood to hospitals in England and is the organ donation organisation for the UK. In 2020-21, it ran a convalescent plasma donation programme, to support research into whether plasma containing antibodies from someone who has recovered from COVID-19 was an effective treatment for COVID-19 **(CS7/18 - INQ000486425**. This is covered in greater detail in Professor Lucy Chappell's statement.

Devolved Nations Arms-Length Bodies

44. We also worked in partnership with ALBs in the devolved nations, key ones of which I set out here.

Scottish Medicines Consortium

45. The Scottish Medicines Consortium (SMC) was established to provide a single point of advice and reduce duplication of work and differences in availability of medicines across NHS Scotland.

46. The SMC is a committee of clinicians, pharmacists, NHS board representatives, the pharmaceutical industry and the public. Members of the committee consider a broad range of evidence in order to decide which medicines should be accepted for use by NHS Scotland. Most of the clinicians have a direct role in patient care, while the SMC's three volunteer public partners ensure the views of the Scottish public are taken into account during decision making. The committee meets once a month.

47. The SMC also carry out horizon scanning to ensure NHS boards are aware of new medicines expected to come to market over the next financial year. This helps NHS boards plan their budgets more effectively **(CS7/19 - INQ000399505).**

All Wales Therapeutics and Toxicology Centre

48. The All Wales Therapeutics and Toxicology Centre (the "AWTTC") is an NHS organisation that delivers a range of services supporting the best use of medicines to help patients in Wales. AWTTC was a member of RAPID C-19 which is discussed at paragraph 168-169

All Wales Medicine Strategy Group

49. The All Wales Medicines Strategy Group (AWMSG) advises Welsh Government about the use, management and prescribing of medicines in Wales. AWTTC supports AWMSG and its subgroups. The role of AWMSG is to:
    a. Develop timely, independent and authoritative advice on new medicines.

b. Advise Welsh Government about future developments in healthcare.
c. Help Welsh Government to develop a medicines prescribing strategy for Wales **(CS7/20 - INQ000408772).**

Department of Health Northern Ireland

50. The Department of Health for Northern Ireland is a devolved Northern Ireland government department in the Northern Ireland Executive.

51. The Department of Health for Northern Ireland has three main business responsibilities:
    a. Health and Social Care, which includes policy and legislation for hospitals, family practitioner services and community health and personal social services;
    b. Public Health, which covers policy, legislation and administrative action to promote and protect the health and well-being of the population;
    c. Public Safety, which covers policy and legislation for fire and rescue services **(CS7/21 - INQ000408773).**

Non-departmental Public Bodies (NDPBs)

52. A non-departmental public body (NDPB) is a body which has a role in the processes of national government. It is not a government department but operates at arm's length from ministers.

UK Research and Innovation (UKRI) / MRC

53. Launched in April 2018, the UK Research and Innovation (UKRI) is a non-departmental public body sponsored by BEIS (now the Department for Science, Innovation and Technology (DSIT)) **(CS7/22 - INQ000399501)**. Operating across the whole of the UK with a combined budget of more than £6 billion, UKRI consists of seven disciplinary research councils, Research England, which is responsible for supporting research and knowledge exchange at higher education institutions in England, and the UK's innovation agency, Innovate UK **(CS7/23 - INQ000399502)**.

54. UKRI allocate funding for collective programmes and to each of its councils: the seven research councils, Research England, and Innovate UK. UKRI's COVID-19 response started in early 2020 and consisted of a variety of investments. As per the UKRI impact analysis, UKRI's COVID-19 response funded 1,194 awards for a value of £501 million (this includes 376 pre-existing UKRI awards worth more than £147 million that were repurposed for the COVID-19 response). Thematically, awards addressed most aspects of the pandemic, from support for vaccines development through to studies to model the effects of policy measures and to understand the social consequences of lockdowns. In particular, the Medical Research Council (MRC) was one of the most active research councils in research for COVID-19 therapeutics, commissioning significant COVID-19 research as well as co-funding research with the NIHR. UKRI made recommendations to the CMO for England on which promising treatments should be prioritised for entry into UK trials through the UK COVID-19 Therapeutics Advisory Panel (UK-CTAP) process covered in paragraph 92 to 94 **(CS7/24 - INQ000408738).**

Committees

55. This section outlines some key committees that supported delivery of the Departments objectives in terms of therapeutics and anti-virals.

Antivirals Expert Group

56. The Antivirals Expert Group was a small task and finish group led by Professor Sir Michael Jacobs. Its objective was to develop a robust needs assessment of the potential uses of potential oral antivirals candidates to inform ATF procurement decisions. The group met three times, in June 2021, prior to the formation of the ATF, and its discussions helped inform the ATF's "statement of need", which was approved by the ATF Operations board in June 2021 **(CS7/25 - INQ000061110; CS7/26 - INQ000113015; CS7/27 - INQ000408748; CS7/28 - INQ000408747; CS7/29 - INQ000111332; CS7/30 - INQ000340240; CS7/31 - INQ000502109)**.

Antivirals Security Board

57. The Antivirals Security Board was established to oversee and direct the security of supply and demand of novel oral antiviral treatments which were to be supplied into

community pharmacies. The Board reviewed and assessed risk and mitigation strategies across all threat parameters and included members from across government and the devolved administrations. **(CS7/32** **INQ000497084**

SECTION 2: BACKGROUND AND IMPACT OF THE TASKFORCES

58. The significant innovation in vaccine and therapeutic progress during this period relied on effective collaboration and governance, which was exercised largely through the taskforces that were set up to focus urgently on ensuring we could respond rapidly and effectively. These taskforces include the Antivirals Taskforce (ATF), the Therapeutics Taskforce (ATT) and the Antivirals and Therapeutics Taskforce (ATTF). This section discussed the governance and impact these structures had on the Department's response.

Key Phases of the Response to COVID-19

59. The Department's response to potential and proven therapeutics varied over the time period of this statement and reflected the changing strategic context and stage of the pandemic. This included our changing understanding of the COVID-19 virus, the nature and progression of the disease, clinical vulnerabilities and the development and roll-out of effective vaccines. As set out in previous statements, significant uncertainties at the start of the pandemic meant that decisions had to be taken on limited information; and this changed over the course of the pandemic as more evidence became available.

60. At the start of the pandemic, there were no known effective treatments for COVID-19, which was a novel pathogen. The focus was therefore on establishing and delivering critical research to test medicines that had been developed for other diseases in the hope that they might reduce the risk of COVID-19 patients progressing to require hospitalisation or further clinical support, or the risk of dying. Data from research in the UK and globally grew rapidly, although not all data was high quality or could be used to inform clinical practice or procurement decisions. Further information on research and clinical trials can be found in Professor Lucy Chappell's statement.

61. As our understanding of the virus and disease progressed, patients began to have access to effective treatments which were already available for other diseases and were then licensed for COVID-19. This included remdesivir (which, initial evidence available at the time indicated, shortened the recovery time for hospital patients with COVID-19) **(CS7/33 - INQ000502111; CS7/34** INQ000398991 and dexamethasone (which reduced the risk of mortality for hospitalised patients receiving supplemental oxygen) **(CS7/35 -** INQ000283566 **CS7/36 - INQ000069699; CS7/37 -** INQ000502078, whilst prior infection and then vaccination began to change the immune profile of patients, adding in further complexity.

62. At the same time, novel treatments were being developed specifically for COVID-19, and these began to be available, initially through clinical research and then more widely following marketing authorisation. Novel monoclonal antibody treatments were the first to go into clinical trials **(CS7/38 - INQ000502145)** and then receive marketing authorisation, **(CS7/39 -** INQ000399489 **CS7/40 - INQ000257005)** though their inherent vulnerability to viral mutations limited their impact, as did their administration through intravenous infusion. Antivirals, and in particular oral antivirals, took longer to develop – though they came to market significantly faster than normal drug development timelines – meaning that patients could be treated at home for mild COVID-19, without needing to access a medical facility.

63. Throughout the first year, the therapeutics work was an important complement to that on vaccines, as it was by no means certain that it would be possible to develop and deploy a safe and effective vaccine, which would have left treatment as our only pharmaceutical intervention. Even with vaccination, therapeutics would be needed to treat those who had not gained immunity. A combination of preventative measures and treatments was the basis of how the country is now Living with Covid.

64. As vaccinations began providing protection to most of the population in 2021, the focus of the therapeutics work was predominantly targeted at those patients for whom the vaccine did not provide adequate protection and who were at higher risk of developing severe or critical COVID-19 if exposed to the virus. This expanded beyond treatments into potential prophylactics as well, which are covered in further detail in paragraph 191 and paragraphs 205 to 207.

65. When the Omicron variant was detected, there was concern that it could both evade the current vaccines and also cause more severe disease among moderate and lower

risk groups than previously experienced, so an additional procurement of oral antivirals was completed in order to continue to provide population level protection to prevent the health service from being overwhelmed and enable the continued removal of non-pharmaceutical interventions as part of the Government's strategy of "Living with COVID".

66. The deployment of effective treatments was a key activity, led by NHSE and their devolved equivalents but supported and overseen by the Department. By the end of March 2023, over 125,000 of the most vulnerable patients in the UK had been treated for mild disease with novel antiviral or monoclonal antibody medicines to minimise the risk of hospitalisation from COVID-19, **(CS7/41 - INQ000399496)** and over 120,000 patients in England had been treated in hospital for severe disease with novel or repurposed treatments secured and / or funded by the ATTF **(CS7/42 - INQ000408766).**

67. The ATTF and its predecessors (the TTF and the ATF) were responsible for the end-to-end provision of treatments for COVID-19 in the UK from April 2020 to March 2023. They were responsible for identifying potential COVID-19 therapeutics; trialling these as part of an advanced programme of clinical trials; and procuring and deploying effective treatments to patients across the whole of the UK.

68. Achievements of the ATTF and its predecessors from April 2020 to March 2023 include:

    a. Over 125,000 of the most vulnerable patients in the UK were treated for mild disease with novel antiviral or monoclonal antibody medicines to minimise the risk of hospitalisation from COVID-19 **(CS7/42 - INQ000408766).**

    b. 100,000 doses of GSK's Xevudy (sotrovimab) and nearly 5 million courses of Pfizer's Paxlovid (nirmatrelvir + ritonavir) and MSD's Lagevrio (molnupiravir) were secured, providing reassurance that lockdown measures could be relaxed as part of the Government strategy of "Living with COVID" **(CS7/43 - INQ000497101 CS7/41 - INQ000399496).**

    c. Over 120,000 patients in England were treated in hospital for severe disease with novel or repurposed treatments secured and / or funded by ATTF **(CS7/42 - INQ000408766).**

d. The UK made a significant contribution to the global understanding of COVID-19, including through the biggest clinical trial for treating COVID-19 in the world (RECOVERY) and the biggest and fastest recruiting clinical trial for mild disease in the world (PANORAMIC) **(CS7/44 - INQ000068589).** As outlined above, these clinical trials are covered in more detail in Professor Lucy Chappell's statement.

e. The ATTF promoted international co-operation, with G7 Health Ministers signing the Therapeutics and Vaccines Clinical Trials Charter in 2021, along with regular WHO and Five Eyes engagement. **(CS7/45 - INQ000101061).**

Therapeutics Governance

69. Key bodies relevant to governance and decision making on Therapeutics are set out in this section.

The Therapeutics Taskforce, April 2020- March 2021

70. To co-ordinate and oversee the process for identifying, procuring, and deploying treatments for COVID-19, senior members in the Department agreed a government team should be established. This followed the plan outlined by Patrick Vallance, Government Chief Scientific Advisor, to set up both a Vaccines Taskforce (VTF) and a Therapeutics Taskforce on 26 March 2020, which was discussed with the Secretary of State for Business, Energy and Industrial Strategy. The Therapeutics Taskforce (TTF) was established in April 2020 to fulfil this role **(CS7/2 - INQ000408769)**.

71. As covered in paragraph 19 above, the TTF was a Directorate of the Department. Antibodies were initially considered by the VTF during the early pandemic because of their potential for use in prophylaxis in the event that no effective vaccine candidates were developed. However, at the end of 2020 as promising vaccines were coming through, this responsibility was subsequently transferred to the TTF. This is outlined again later in this statement, under the heading Pre-exposure Prophylaxis (from paragraph 189).

72. The 'Therapeutics Executive Board' was chaired by the DCMO Professor Sir Jonathan Van-Tam. Initially this included industry representatives, but quickly focused down to key decision-makers within the Department and key partners, with members evolving over time. The Board made strategic decisions on procurement of therapeutics in advance of the normal process for making new medicines available to NHS patients. These decisions were supported by reviewing evidence from trial outcomes and input from advisory groups. The Executive Board met 16 times between June 2020 and March 2021. We are sending the minutes of the Board to the Inquiry as general disclosure.

73. As the work and size of the Taskforce grew a 'Therapeutics Taskforce Programme Board' was established chaired by the Programme Director Charlotte Taylor. This board first met in October 2020 and continued to meet fortnightly until March 2022, when it was combined into the 'Antivirals and Therapeutics Taskforce Programme Board', which met until the Taskforce closed at the end of March 2023. The Board oversaw progress of the programme milestones, reviewed and assessed risk and mitigations, and approved spending decisions in relation to the supply, storage and distribution of oral antivirals (subject to normal Departmental Accounting Officer processes and extraordinary approval processes established to consider larger procurements).

74. The impact of the TTF is set out below, at paragraphs 75 to 125.

The Therapeutics Taskforce and the Antivirals Taskforce, April 2021 – March 2022

75. The Executive Board evolved into the 'Therapeutics Taskforce Oversight Board' chaired by Lord Bethell from May 2021 to September 2021 and then by me (Clara Swinson), from December 2021 to February 2022.

76. The 'Therapeutics Taskforce Programme Board' continued to function as before, reporting to the COVID-19 Oversight Board.

77. Consistent with the phase of the response and the potential of emerging novel oral medicines for early treatment interventions, separate funding for oral antiviral treatments was sought. A separate programme was established in the form of an Antivirals Taskforce (the ATF) in April 2021.

78. Strategic direction, programme oversight and leadership of the ATF was kept separate from the TTF in order to:

    a. maintain a distinct and 'taskforce' focus on early interventions: oral treatments for a mass population in community settings;
    b. maintain a clear and separate reporting of the funding of oral antiviral treatments; and
    c. model on the VTF in making use of external expertise where necessary.

79. Mirroring the TTF, strategic decision and oversight was provided by an 'Antiviral Taskforce Operations Board', which was chaired by Lord Bethell from May 2021 to June 2021, Eddie Gray from July 2021 to October 2021, and I (Clara Swinson) chaired from November 2021 to February 2022.

80. Programme review, and oversight was performed by the 'Antivirals Taskforce Programme Board' chaired by the Programme Director Charlotte Taylor. This board was established in June 2021 and continued to meet until March 2022, when it was combined into the 'Antivirals and Therapeutics Taskforce Programme Board', as described above. The Board oversaw progress of the Programme milestones, reviewed and assess risk and mitigations, approved spending decisions in relation to the supply, storage and distribution of oral antivirals (subject to normal Departmental Accounting Officer processes).

81. Taking lessons learnt from the VTF and the involvement of external expertise and leadership from industry, the Department sought external commercial and technical expertise for the ATF. Accordingly, an external ATF chair was advertised, and ministers appointed Eddie Gray to this role. In addition, an external panel of strategic advisers, covering clinical, pharmaceutical manufacturing, commercial and pharmacy skills appointed to the 'Antiviral Taskforce Steering Group' which was chaired by Eddie Gray and met thrice weekly from June 2021 to March 2022, covering the phase during which antiviral candidate medicines were identified, deployment and patient access planned and agreed, and decisions made ahead of operational delivery.

The Antivirals and Therapeutics Taskforce, April 2022 – April 2023

82. Reflecting the changing context again, including the completed procurement of significant volumes of oral antivirals and deployment arrangements, and the success of the vaccine roll-out programme, it was decided to combine the ATF and TTF into the 'Antivirals and Therapeutics Taskforce' (ATTF) from April 2022. The decision to amalgamate governance rather than continue separately reflected changing context as priorities evolved.

83. The ATF was originally governed separately due to the need for specific, rapid clinical and industry advice on novel antivirals, and for reasons set out in paragraph 80 above. By April 2022, however, antiviral procurement was agreed and funding secured, making closer collaboration more practicable. The ATF and TTF programmes were already working closely together before April 2022, with shared staff, common budgetary management processes and board secretariats. At this point joint governance arrangements was the logical next step, and a joint programme board were established. The ATF and TTF programmes were, however, already working closely together before April 2022 sharing staff, common budgetary management processes and board secretariats. Combining programme governance formally, including membership of component boards, happened in April 2022 at the start of the financial year, as antiviral procurement transitioned to a steady state, and when Eddie Gray's tenure as Chair of the ATF came to an end.

84. The 'Antivirals and Therapeutics Strategy Board' replaced the TTF and ATF Operational Boards and was chaired by me (Clara Swinson), from April 2022 to March 2023. The 'Antivirals & Therapeutics Taskforce Programme Board' was formed in April 2022 to March 2023 and was chaired by the ATTF Director, Charlotte Taylor. These boards also oversaw the closure of the ATTF, when the elements of work were either completed, transferred to business as usual functions, or moved to contingency arrangements. This is not part of the time period of this Module so is not covered in any detail; board papers set out the closure approach and agreements.

ATF, TTF and ATTF Governance Boards

85. The taskforces were key to bringing the relevant people together to support decision-making, and their governance reflects the senior levels needed to facilitate this.

86. The Governance of the three taskforces as summarised above is set out in the table below:

Name	**When it was set up**	**Closed**	**Chair**	**Frequency**
Therapeutics Executive Board	Early, informal meetings from April 2020 with first board meeting in June 2020	March 2021	Professor Sir Jonathan Van Tam	Fortnightly Met 16 Times
Engagement Board	October 2020	March 2023	Lord Bethell then Lord Kamall	Quarterly Met 8 times. Once in 2020, 7 times in 2021.
TTF Programme Board	October 2020	March 2022	Charlotte Taylor	Twice per month
TTF Operations Board	May 2021	Feb 2022	Lord Bethell (May 2021, June 2021) Clara Swinson (December 2021 and Feb 2022)	Met 4 times
ATF Operations Board	June 2021	March 2022	Lord Bethell (June 2021) Eddie Gray (July, August, and Oct 2021) Clara Swinson (Nov 2021 to March 2022)	10 times in total Six times in 2021 and four in 2022
ATF Programme Board	June 2021	March 2022	Charlotte Taylor	Twice monthly
ATF Steering Group	June 2021	March 2022	Eddie Gray	Meet three times a week- Met 70 times

Antiviral Security Board	March 2022		Alex Churchill, Deputy Director, Antivirals & Therapeutics Taskforce	Met 3 times
Antivirals and Therapeutics Strategy Board	April 2022	March 2023	Clara Swinson, Director General, Global Health, DHSC	Monthly – met 9 times [seven times in 2022 and twice in 2023]
ATTF Programme Board	April 2022	March 2023	Charlotte Taylor, Antivirals and Therapeutics Taskforce Director	Monthly – met 9 times [met 7 times in 2022 (Aug update was via email) and met twice in 2023)]

Table 1: Governance Boards of the ATF, TTF and ATTF

The Therapeutics Clinical Review Panel (TCR)

87. The Therapeutics Clinical Review ("TCR") panel was formed of senior clinicians from all four nations and provided advice to the four UK Chief Medical Officers on the definition and revision of eligible patient cohorts for new COVID-19 therapeutics. This included a process to provide advice on questions from patient and clinician stakeholders, through a nominated clinician representing a group or individual.

88. The initial work on cohorts started in December 2021 and was led by Professor Iain McInnes and the Independent Advisory Group (IAG), prior to the formation of the TCR panel, which was chaired by Professor McInnes. This was established in February 2022 to provide more oversight and transparency around the evidence base for decisions on patient cohorts until it closed in March 2023

89. The TCR panel reviewed the evidence on COVID-19 risk, and identified cohorts that should be prioritised for treatments for prophylaxis. The panel's work directly informed eligibility for oral antivirals and monoclonal antibodies, and the provision of lateral flow testing necessary to support deployment, from February 2022 to March 2023. The work of the TCR panel was also shared with NICE to inform appraisals of COVID treatments and prophylaxis **(CS7/46 - INQ000399506; CS7/47 - INQ000391266; CS7/48 - INQ000112375; CS7/49 - INQ000112376).**

90. On 27 April 2022 at the ATTF Strategy Board the Deputy Director for Policy Engagement and International presented a paper produced by the ATTF on the future strategy of neutralising monoclonal antibodies (nMABs). The paper set the context and outlined issues, explained the use of neutralising monoclonal antibodies as part of the portfolio of antibodies and antivirals, the impact of variants of concern on efficacy. It further set out the stock position at that time and the future pipeline of supply and demand for both the upcoming financial year and longer term. It set out options and questions for the Board to provide steers on the ATTFs work on nMABs relating to procurement, management and ownership of this work. The Board agreed for the ATTF to complete further work to agree the details of a potential procurement of nMABs to address the potential treatment gap, if sotrovimab was removed from clinical policy due to inefficacy, subject to a full business case process, with a decision in May/June.

91. At the same meeting on the 27 April, the Deputy Director for Policy Engagement and International also presented a paper on pre-exposure prophylaxis (PrEP) treatments, where the board agreed that the ATTF continue to work on PrEP, noting that significant issues around AZD7442 (known as Astronaut) remain to be resolved, and agreed that the Department's Commercial team commence formal negotiations with AstraZeneca, offering favourable terms for the Department which take into account the uncertainty over future variants **(CS7/49 - INQ000112376; CS7/50 - INQ000502128).**

UK COVID Therapeutics Advisory Panel (UK-CTAP)

92. The TTF Executive Board, discussed above, decided that an independent panel should be established to make recommendations on the most promising therapeutics that should be prioritised for testing through the UK clinical trial platforms. On this basis, the TTF, in collaboration with NIHR and UK Research and Innovation, set up the UK COVID Therapeutics Advisory Panel (UK-CTAP) **(CS7/24 - INQ000408738)**, with the first UK-CTAP meeting taking place at the end of July 2020. Prior to the establishment of UK-CTAP, this function was delivered by UKRI. Details of the processes performed by UKRI, which is a non-departmental body of the Department of Science and Technology (DSIT), before UK-CTAP was established would need to be provided by UKRI or DSIT.

93. UK-CTAP made recommendations on which therapeutic compounds should be studied through the ongoing national publicly funded clinical trials, based on submissions from industry and academia **(CS7/51 - INQ000391265; CS7/52 - INQ000497099 CS7/53 - INQ000497098 CS7/54 - INQ000497071 CS7/55 - INQ000497074** Professor Patrick Chinnery, MRC clinical director, was the chair of UK-CTAP **(CS7/46 - INQ000399506)**. The panel reviewed available scientific evidence and made recommendations to the principal investigators of each trial and Professor Chris Whitty, the CMO and also the Chief Scientific Adviser for the Department for [most of] the period of this statement. Please see Professor Lucy Chappell's statement for further information on the recruitment and outcomes of these platform trials. The panel reviewed available scientific evidence and made recommendations to the principal investigators of each trial and Professor Chris Whitty, the CMO and also the Chief Scientific Adviser for the Department for [most of] the period of this statement.

94. UK-CTAP ceased operations in September 2021, having recommended drugs to seven national publicly funded platform trials which recruited over 50,000 patients across the UK **(CS7/56 - INQ000399508)**, before being stood up again temporarily as part of the response to the emergence of the Omicron variant in the autumn / winter of 2021.

The Therapeutics Taskforce (TTF)

95. The TTF provided input into Government strategies for managing COVID-19. Decision making at the time was guided by scientific evidence supplied by the NIHR, NERVTAG, SAGE, PHE (now UKHSA), the ONS infection survey, the MRC and clinical trial data. To ensure a joined-up approach across all four nations, the TTF worked very closely with the devolved administrations on a range of aspects of the TTF's responsibilities.

96. The collective focus of the TTF and the other parts of the healthcare system involved in this work, including NHSE&I, MHRA, PHE (now UKHSA) and NIHR, was to make available to NHS patients safe and effective treatments for COVID-19 at each stage of the disease progression as quickly as possible. The TTF's provided end-to-end oversight of the process for doing this, including bringing together key clinical, research and industry stakeholders and to help drive forward this shared ambition and expedite decision making. The TTF worked with a wide range of external partners, including through close collaboration with the Wellcome Trust and Syncona in the initial weeks

after the inception of the TTF, to ensure these functions and objectives represented a shared vision of what the TTF should deliver.

97. The TTF's access to leaders in central government and the life sciences sector enabled it to expedite decision making and secure treatments rapidly and in some instances at risk, based on an initial cost-benefit analysis. To support the procurement of potential treatments, the TTF commissioned Oliver Wyman Services Limited, an external consulting company, to develop a recommendation model to support decisions to procure existing drugs in advance of robust COVID-19 clinical trial data **(CS7/57 - INQ000502080; CS7/58 - INQ000497075 CS7/59 - INQ000502135).** This was a framework which used available trial data to assess the clinical evidence, quality of research, mortality end point and signal of harm of each drug, along with its wider use in non-COVID-19 clinical practice and cost. The assessment indicated what procurement decisions should be considered, including whether to consider securing an additional supply of potential COVID-19 treatments.

98. The triage assessment tool was initially designed to support decisions on securing supply of a range of treatments that had the potential to reduce the health and economic burden of COVID-19 – focussing particularly on treatments aimed at primary care likely to reduce infections and hospitalisations. The triage assessment was intended to indicate whether investment may be required when evidence was at a very early stage and before any decisions made by experts in RAPID C-19 on access. This was so that action could be taken to investigate further including looking at potential costs if supply was needed. The triage tool was utilised to assess treatments including, tofacitinib, regdanvimab, bamlanivimab, and baricitinib.

99. From summer 2020, the Taskforce used the Procurement Tool, developed by Oliver Wyman, to look at repurposed medicines and whether they should be considered for procurement. However, this did not work for novel products coming through to treat COVID-19. As a result, the Taskforce created a simple RAG rating system to understand products of potential interest, using information on key clinical trials from RAPID C-19, information from desk-based research and conversations with companies, where relevant, to understand potential costs and where the product was most likely to be used (e.g., primary or secondary care). The triage tool also acted as a tracker to help the Taskforce understand the latest updates for each product.

100. At the start of April 2020, the TTF set up a public facing mailbox to ensure companies and individuals could contact the TTF with suggestions for promising compounds to enter the nationally prioritised clinical trial platforms (e.g. RECOVERY). In the early stages of the pandemic, re-purposed treatments were the only options available, and also represented more easily scalable treatments that already had a clear safety profile in humans; over time novel treatments started to emerge.

101. Alongside drug candidates highlighted through the TTF mailbox, the TTF also worked with partners across government and in the life sciences sector to consider other promising treatment candidates. For example, in April 2020, the Department announced the convalescent plasma collection programme in collaboration with NHS Blood and Transplant (NHSBT) on the advice of the CMO and DCMO **(CS7/60 - INQ000502075).** Convalescent plasma was trialled in RECOVERY and REMAP-CAP. The collection programme aimed to build up a sufficient supply of convalescent plasma that could be made available promptly if it showed efficacy as a treatment.

102. On 29 April 2020 the UK Government announced a new Urgent Public Health (UPH) -badged Phase 2 clinical trial platform called ACCORD-2, led by the University of Southampton, which aimed to rapidly test promising compounds in early phase trials and fast-track successful candidates into Phase 3 studies (e.g. RECOVERY). Six compounds were initially selected for this trial platform based on a longlist of possible candidates collected by the TTF[1] **(CS7/61 - INQ000502076).** The six compounds were as follows:

Codename	**Company**	**Antibodies**
Apollo	GSK + Vir	VIR7831 and VIR7832
Astronaut	AZ	AZD7442
Ganymede	Tychan	TY027
Mercury	Regeneron	REGN10933 and REGN10987*
Olympus	Lilly	LY3819253 (LY-CoV555)
Sirius	Brii	BRII-198 and BRII-196

*combination of these two later named REGN-COV2

1 Provided by UKHSA based off due diligence summaries dated 7 August 2020. These are the product names as they were known at that time, rather than any subsequent/brand names they were later given

Table 2: List of the codenames, company names and antibodies selected for trials.

103. In June 2020, all four Phase 2 platforms agreed to work as an alliance to ensure efficiency in patient recruitment and data sharing across the platforms. The TTF maintained a lighter-touch oversight of these platforms but continued to provide information on promising compounds that could be suitable for these candidates when appropriate.

104. In September 2020, the NIHR, MRC and the ATTF agreed to support two additional early-phase trial platforms – RECOVERY+ and AGILE.

105. RECOVERY+ was a Phase 2 extension of the existing larger Phase 3 trial platform RECOVERY.

106. AGILE was funded by the MRC, with strategic input from the NIHR and ATTF as a multicentre, multi-arm, multi-dose, multi-stage open-label, adaptive, seamless Phase 1/2 Bayesian randomised platform trial to determine the optimal dose, activity and safety of multiple candidate agents for the treatment of COVID-19. Further details of the input of NIHR in this work is provided in Lucy Chappell's statement.

Collaboration with VTF on Antibodies

107. By August 2020, the TTF had started to collaborate with the VTF in BEIS on a COVID-19 antibodies workstream. The VTF had been investigating the use of antibodies as prophylactic treatments as potential alternative preventative interventions should vaccines prove ineffective. The VTF had identified six neutralising antibody candidates that showed potential to be used for treatment, as well as prophylaxis, which they shared with the TTF **(CS7/62 - INQ000408739)**. The candidates are listed above in paragraph 102.

108. One of these treatments identified, casirivimab/imdevimab (also known as REGEN-COV2 or Ronapreve), was entered into the RECOVERY trial. On 16 June 2021, the RECOVERY trial announced that the novel monoclonal antibody casirivimab/imdevimab (REGEN-COV, or Ronapreve) marketed by Roche was effective in treating hospitalised patients who have not mounted their own immune

response (seronegative patients) **(CS7/63 - INQ000391251)**. Upon the advice of the Vaccines Taskforce and with input from the Therapeutics Taskforce, ministers agreed to procure 50,000 doses of casirivimab/imdevimab pending a Conditional Marketing Authorisation (CMA); this is when authorisation is given by the MHRA on less comprehensive clinical data than normally required, where the benefit of immediate availability of the medicine outweighs the risk inherent in the fact that additional data are still required.

109. In the summer of 2020, as the TTF increased in resource it began to transition to a more proactive management of the therapeutic response. This transition was supported by:

a. A COVID-S commission in July 2020 to develop an operational delivery plan built around Cabinet Office planning scenarios. The plan was based on Scenario 2 where the infection rate rose substantially in November 2020 and peaked in January 2021. The plan confirmed the TTF's objective to identify and research possible new treatments to support the NHS in treating patients with COVID-19, ensuring effective treatments get to patients rapidly and at scale. **(CS7/64 - INQ000497061**

b. A period of recruitment in August 2020 allowing the TTF to divide its portfolio between three Deputy Director-led teams. This allowed greater focus on clinical trials, manufacturing and supply and therapeutics strategy as well as internal functions like governance and finance.

c. Board agreement for an independent panel to be established to make recommendations on the most promising therapeutics that should be progressed to the prioritised UK clinical trials platforms. This led the TTF, in collaboration with NIHR, to set up UK C-TAP **(CS7/65 INQ000502084).** The C-TAP Podio system opened on 17 September 2020. As a larger operation, the panel was able to look at a much broader scope of compounds across a wider range of mechanisms of actions, including novel therapeutics as these began to complete pre-clinical studies. The TTF worked closely with UK C-TAP to set the therapeutics trial strategy until it closed in September 2021 (and when it was briefly stood up again in response to the emergence of Omicron in winter 2021).

110. The VTF ministerial panel that discussed decisions regarding antivirals and therapeutics was run by the Vaccines Taskforce (VTF). On 22 February the VTF ministerial panel agreed with a recommendation to not procure a monoclonal antibody for prophylactic use at that time **(CS7/66 INQ000066717 CS7/67 - INQ000497076** On 14 July the VTF ministerial panel approved the Windermere Business Case **(CS7/68 – INQ000408749)**. The Vaccines Taskforce, which is now part of UKHSA, holds all of the VTF ministerial panel papers.

111. On 16 December 2021 Roche announced that REGEN-COV has diminished potency versus Omicron **(CS7/69- INQ000502120)**. Stocks of REGEN-COV were retained in the event that a variant against which it does have neutralising activity may have emerged, and were destroyed on expiry. **(CS7/70 - INQ000497083 CS7/71 - INQ000497094**

The Antivirals Taskforce (ATF)

112. Antivirals are a type of therapeutic medication used specifically to treat a specific viral infection (e.g., influenza, COVID-19, HIV etc). They aim to minimise the symptoms of an infection and shorten its duration. They also can help reduce transmission of a virus. Rather than killing the virus directly, antivirals usually suppress the virus's ability to infect and multiply in cells and so are most effective when used early on in infections. The ATF was tasked with the objective of having at least two oral antiviral treatments available for UK patients by the winter 2021 that could be used as a community treatment – that is, one that does not require administration in a secondary care setting **(CS7/3 - INQ000257447)**.

Initial work of the ATF

113. Alongside recommendations from the Government Office for Science and UK C-TAP, the newly established ATF undertook comprehensive horizon scanning at pace to identify and monitor antiviral compounds which were being developed globally and which demonstrated efficacy against coronaviruses and were available within a year. The ATF began to build the offer of a single-entry point into the UK system for companies with potentially viable/deliverable drugs. A shortlist of three priority candidates was agreed by the Antivirals Expert Group (an ad hoc advisory group of industry and clinical experts), the Government Chief Scientific Advisor, Sir Patrick

Vallance, and the DCMO, Professor Sir Jonathan Van-Tam, based on the criteria of being orally administered, being a direct acting antiviral and having potential to be available to deploy in winter 2021/22.

114. The ATF's strategy was to secure treatments with different mechanisms of action (known as a 'portfolio' approach), with a sharp focus on those that would be available to procure for the UK the soonest. This portfolio approach was adopted to minimise the likelihood of resistance emerging from just one antiviral, therefore improving effectiveness of antivirals against the disease. Additionally, if a single antiviral was procured that produced drug-drug interactions this could limit its use in some target populations, particularly for those taking a combination of drugs to manage pre-existing conditions. Having two oral antivirals would mitigate this risk and ensure broader protection. The approach of more than one antiviral was also due to potential for antivirals to be taken in combination, which would minimise emergence of resistance to antivirals (**CS7/72 - INQ000408752)**.

Paxlovid and Lagevrio

115. Following extensive commercial discussions, the ATF agreed deals to procure two of the shortlisted candidates for the whole of the UK in October 2021. These were molnupiravir (also known as *Lagevrio)* from Merck, Sharp and Dohme (MSD) and Ridgeback Biotherapeutics, and nirmatrelvir + *ritonavir (also known as Paxlovid)* from Pfizer.

116. At the time of commercial engagement, molnupiravir had demonstrated around a 30% relative reduction in the rate of hospitalisation in unvaccinated patients and was demonstrating positive effects in Phase 3 trials in India **(CS7/73 - INQ000086652)**. Additionally, MSD was trialling molnupiravir MOVe-OUT, which was expected to complete in Autumn 2021.

117. Nirmatrelvir + ritonavir was undergoing Phase 2/3 trials in the United States which were expected to readout in winter 2021/22 and had demonstrated a reduced relative risk of COVID-19 associated hospitalisation or death by 88% in unvaccinated patients who received treatment within 5 days of symptoms appearing **(CS7/73 - INQ000086652)**.

118. A third candidate was deprioritised following an announcement that its Phase 2 trial had not met the primary endpoint and that Phase 3 data would not be available until the second half of 2022. This meant it no longer fulfilled the eligibility criteria. Throughout negotiations with the antiviral suppliers, the ATTF stressed the importance of global equitable access and encouraged companies to take steps to ensure this, including through voluntary licensing.

119. The initial ambition was for antivirals to be deployed to a large percentage of the population both for treatment and for post-exposure prophylaxis (PEP), however due to the cost of procuring the antivirals, an alternative deployment strategy was devised. The ATF worked closely with NHSE and the devolved administrations to develop deployment mechanisms. The Antivirals Expert Group made recommendations on the optimal clinical use patient cohorts for antivirals. This group recommended that, as the UK already had a mostly vaccinated adult population, more data should be gathered from a large-scale Phase 3 UK trial first to identify who would benefit most from these treatments before moving to widescale deployment, given that trial data was largely based on an unvaccinated population. This data would also help decision-making on future clinical access and cost-effectiveness of these treatments. This group also recommended that patients for whom vaccination would not provide adequate protection and were at high risk of disease progression from COVID-19 should be given direct access to COVID-19 oral antiviral treatments, as the available trial data provided evidence of capacity to benefit. This recommendation was endorsed by the Antivirals Taskforce Operations Board, the ATF determination that more data was needed to inform how best to use oral antivirals in a largely vaccinated population because the trial data available to date had been generated prior to wide-spread vaccination led to the creation of the PANORAMIC trial. The PANORAMIC trial is further discussed in Professor Lucy Chappell's statement.

Antivirals and Therapeutics Taskforce (ATTF)

120. When the ATF closed in March 2022, its responsibilities were combined with the Therapeutics Taskforce to form the Antivirals and Therapeutics Taskforce. As explained under Section 1, the ATTF's primary objective was to identify and deploy effective treatments for COVID-19. The ATTF also aimed to transfer ongoing responsibilities to other parts of the health care system, by the end of March 2023, so

that it would no longer need to exist in its then format. Some of the Taskforce's other key objectives included to:

a. Continue oversight of existing COVID-19 trial platforms to identify potential effective treatments until transition to BAU processes occurred. Provide contingency planning for future taskforce support in rapidly assessing the effectiveness of therapeutics against new Variants of Concern;

b. Establish and implement a deployment pathway for antivirals and monoclonal antibodies procured in 2021/22;

c. Ensure appropriate procurement, supply and contract management of current and potential future COVID-19 antivirals and therapeutics;

d. Develop policy to support the deployment of existing and future COVID-19 treatments;

e. Engage with stakeholders and communicate internally and externally (including internationally) the work of the Taskforce;

f. Assess the impact of the Taskforces and use learnings to inform future government activity as appropriate, including preparation for future pandemics;

g. Provide effective Taskforce management and transition Taskforce responsibilities to other parts of government and the health system by March 2023 **(CS7/74 - INQ000391270)**.

121. The ATTF Strategy Board objectives were to make decisions on taskforce strategy and policy in areas including:

a. Deployment of antivirals and other therapeutics;

b. Clinical trials including PANORAMIC;

c. Stock management and supply for antivirals and other therapeutics;

d. Strategic direction of the ATTF.

122. Throughout the COVID-19 pandemic, the ATTF took a UK-wide approach to securing and deploying therapeutics and antivirals, working closely with the Devolved Administrations to ensure all UK patients received treatments as soon as possible and under a consistent clinical access policy. This was evident in:

a. Clinical decision making – Devolved Administrations' representatives were part of RAPID – C-19, the multi-agency initiative discussed further below, which was tasked with getting COVID-19 treatments to patients as quickly and safely as possible as part of temporary emergency arrangements put in place during COVID-19;

b. Clinical trials – national platform trials recruited participants across the UK, providing access to COVID-19 treatments with potential benefit to patients as soon as possible;

c. Procurement decisions – The Department led on UK-wide procurement to enable effective commercial engagement with pharmaceutical companies, with supply allocated to each nation according to the well-established Barnett formula **(CS7/2 - INQ000408769)**;

d. Deployment - England, Scotland, Wales, NI were responsible for deployment in each UK nation, through the NHS and devolved healthcare systems. However, there was regular engagement to ensure a similar approach in each part of the UK, even if implementation was local.

123. The ATTF carried out extensive lessons learned activity, for both future taskforces and pandemic preparedness. This included engaging external stakeholders with a survey and carrying out 20 internal interviews, leading to production of several lessons learned documents, for both future taskforces and future pandemic preparedness **(CS7/75 - INQ000502141; CS7/76 - INQ000502142; CS7/77 - INQ000502129; CS7/78 - INQ000497096**

124. Utilising the lessons learned activity, the ATTF produced a paper entitled "Future Pandemic Preparedness: Recommendations to enable the use of antivirals in the UK in a future respiratory pandemic". On 8 November 2022 this paper was then

presented to the Pandemic Influenza Preparedness Programme (PIPP) Board, (which later became the Pandemic Preparedness Portfolio, PPP). This programme was focused on the management of pandemic influenza preparedness within the health and social care system in England. Its board comprised officials from the Department of Health, the Cabinet Office, NHS England and Public Health England. It was agreed by the PIPP board for the report recommendations to be considered by the Clinical Countermeasures Team as part of the Clinical Countermeasures Review Prioritisation exercise. The exercise would inform policy decision about which future pandemic measures are to be taken forward across the board, and if so, how. The board also agreed for the report and recommendations to go into the Centre of Pandemic Preparedness (CPP) Evidence repository at UKHSA, to be considered alongside other evidence in future pandemic planning, including if there is resource for future analytical work. UKHSA can provide more information on the CPP Evidence repository **(CS7/79 - INQ000502138; CS7/80 - INQ000502139; CS7/81 - INQ000502140)**.

125. Having achieved its overall programme objective of identifying, developing and making available safe and effective treatments for COVID-19, the ATTF taskforce closed on 31 March 2023 **(CS7/41 - INQ000399496)**.

The VTF and the Ministerial Panel

126. Some decisions on antibodies were taken by the relevant government ministers through the Vaccine Taskforce Ministerial Panel VTF, covered in more detail in Section 1 of Statement A (further detail on the panel and its composition may be available through UKHSA). The Panel agreed to provide commercial and financial approvals for the ATF and TTF business cases relating to COVID-19 at its meeting on the 14 July 2021 **(CS7/68 - INQ000408749).** This consisted of the following members:

a. Rt Hon Sir Sajid Javid MP, Secretary of State for Health and Social Care;

b. Rt Hon Nadim Zahawi MP, Parliamentary Under Secretary of State for Business, Energy and Industrial Strategy;

c. Rt Hon Stephen Barclay MP, Chief Secretary to the Treasury;

d. Rt Hon Wendy Morton MP, Parliamentary Under Secretary of State for the Foreign, Commonwealth and Development Office.

Apologies were received from:

a. Rt Hom Kwasi Kwarteng, Secretary of State for BEIS;

b. The Minister of State in the Cabinet Office, Lord Agnew, who submitted approval and comments to the Panel in advance **(CS7/82 - INQ000128474).**

127. Some medicines were utilised as soon as clinical effectiveness and market authorisation allowed for example, remdesivir was used extensively for hospitalised patients as soon as MHRA approved from 26 May 2020, tocilizumab had been used as part of REMAP CAP and RECOVERY trials and from January 2021 in treatments; this was taken from hospital stock with the Department reimbursing costs. Decisions to reimburse costs, procure additional remdesivir as NHS trusts required (modelling against likely future demand) was approved by Departmental ministers outside the Vaccine Taskforce Ministerial Panel. Other procurements included potential treatments should clinical trials prove successful e.g. inhaled budesonide, colchicine. Decisions were made through ministerial submissions to the relevant minister based on advice from the Therapeutics Taskforce.

128. The work of the VTF on monoclonal antibody treatments as part of its collaboration with the Therapeutics Taskforce (TTF) on a COVID-19 antibodies workstream is discussed further under Section 2 at paragraphs 107-111 and in more detail in Witness Statement A of this module, at paragraphs 23 to 31.

Living with COVID

129. The Government's "Living with Covid" strategy was published in February 2022, and remains in place today to manage COVID-19 **(CS7/73 - INQ000086652).** The approach set out in that document shows that therapeutic development and deployment, alongside vaccine development and roll out, meant that the country could move to manage it as an endemic disease. It set out that:

*"The Government is able to take this step now because of the success of the vaccination programme, and the suite of pharmaceutical tools the NHS can deploy to treat people who are most vulnerable to COVID-19 and the most severely ill (see chapter 4)."***(CS7/73 - INQ000086652)**

130. It also stated:

*"As a result of the success of the Government's strategy to invest in scientific and medical innovation, the Government has been able to rely more on vaccines and medical treatments, and gradually remove restrictive guidance for those at an increased risk of COVID-19."***(CS7/73 - INQ000086652)**

131. The "Living with Covid" plan also set out the progress made in therapeutics from the start of the pandemic to that point. Given the timeframe of this module, it gives a helpful summary of the position at that point, and the impact it had already made on patient care. It sets out:

"In April 2021, the Prime Minister launched the Antivirals Taskforce (ATF), in order to identify, procure and deploy novel antiviral treatments for UK patients with COVID-19. Antivirals can be used at the earliest stage of infection to help reduce the development of severe COVID-19 by blocking virus replication.

The ATF has secured a supply of almost 5 million courses of antivirals - more per head than any other country in Europe. These antivirals are the first medicines which can be given at home to treat people whose immune systems mean they are at higher risk from COVID-19.

In company trials, Paxlovid (nirmatrelvir + ritonavir) reduced the relative risk of COVID-19-associated hospitalisation or death by 88% in unvaccinated patients who received treatment within 5 days of symptoms appearing. Results from Lagevrio (molnupiravir) company trials show around 30% relative reduction in the rate of hospitalisation in unvaccinated patients. Both antivirals have now received conditional marketing authorisation from MHRA, making the UK the first country in the world to approve an oral antiviral that can be taken at home for COVID-19.

People at highest risk of developing severe COVID-19 can now access antivirals should they test positive for COVID-19. UKHSA has sent priority PCR tests to around 1.3 million people to support rapid turnaround of results so they can access the treatments as soon as possible after symptoms begin. In England, around 14,000 people with weakened immune systems have already been treated with the new antivirals, Lagevrio (molnupiravir) and Paxlovid (nirmatrelvir + ritonavir), and the new monoclonal antibody treatment, Xevudy (sotrovimab).

The Therapeutics Taskforce was quickly established in April 2020 to ensure that COVID-19 patients in the UK had access to safe and effective treatments as soon as possible. Effective therapeutics have played a vital role in lessening the severity and impact of COVID-19.

The UK has led the way in the testing and deployment of life-saving treatments, which have been made available to patients in the UK and across the world. World-leading clinical trials such as RECOVERY - the world's largest randomised controlled clinical trial for COVID-19 treatments have helped to discover new effective treatments for COVID-19.

In June 2020, the UK was the first in the world to discover that dexamethasone - a low-cost corticosteroid - reduced the risk of mortality in hospitalised COVID-19 patients requiring oxygen or ventilation by up to 35%. UK Government-funded trials demonstrated tocilizumab and sarilumab - monoclonal immunomodulatory antibody treatments - reduced the relative risk of mortality by up to 24% when administered to patients within 24 hours of entering intensive care.

New therapeutics like Xevudy (sotrovimab), a monoclonal antibody, have been authorised for use in people who have mild to moderate COVID-19 infection and at least one risk factor for developing severe illness. In a clinical trial, a single dose of the monoclonal antibody was found to reduce the risk of hospitalisation and death by 79% in high-risk adults with symptomatic COVID-19 infection." **(CS7/73 - INQ000086652)**

SECTION 3: PREPAREDNESS, PROCUREMENT AND DEPLOYMENT

132. This section provides further details on therapeutics prior to COVID-19, stockpiled therapeutics, procurement, patient access to treatment and deployment, barriers and international collaboration and use of new therapeutics during the pandemic.

Therapeutics pre-COVID-19

133. Prior to the COVID-19 pandemic, the types and volumes of therapeutics which had been stockpiled as part of the UK's pandemic influenza preparedness programme (PIPP) were as follows:

a. Antivirals stockpiled for treatment of pandemic influenza, in quantities sufficient to treat 50% of the UK's population (the proportion expected to develop symptomatic infections in the reasonable worst-case scenario for an influenza pandemic) **(CS7/83 - INQ000022884)**.

b. Antibiotics stockpiled for treatment of secondary bacterial infections, in quantities sufficient to meet the reasonable worst-case scenario in an influenza pandemic. Secondary bacterial infections have been a significant cause of mortality in previous influenza pandemics.

134. At a meeting of the Pandemic Influenza Preparedness Programme (PIPP) Clinical Countermeasures Board (CCMB) on 9 October 2019 (the final meeting before COVID-19 pandemic), the levels of pandemic stockpiles were reviewed and the official stock levels were calculated at that point to contain approximately 43 million pharmaceutical items including antivirals and antibiotics **(CS7/84 - INQ000131499).**

135. Decisions about the volume and type of products stockpiled were derived from modelling based on the reasonable worst-case scenario for an influenza pandemic. These products were held in stockpiles on a 'just in case' (JIC) basis to facilitate rapid distribution in times of need and because of potential risks to supply chains in the event of a global pandemic. Paragraph 138 to 142 below set out why the therapeutics stockpiled for an influenza pandemic were not utilised in response to COVID-19.

Research in the early phase of the pandemic – early 2020

136. On 11 March 2020, the day the World Health Organization (WHO) declared COVID-19 a global pandemic, there were no approved treatments for COVID-19 **(CS7/85 - INQ000106182)** or evidence-based vaccines. There was therefore uncertainty in the early stages of the pandemic about which existing medicines licensed for other indications should be prioritised for clinical trials and where research efforts should be focused to develop novel therapeutics and vaccines.

137. As already mentioned, the strong existing research infrastructure (including NIHR, UK Research and Innovation/ Medical Research Council) contributed to the UK's ability to respond quickly to the research needs of the early pandemic. The NIHR prioritised COVID-19 research above other research. Further details of research and clinical trials are provided in Professor Lucy Chappell's statement on this module.

Stockpiled therapeutics

138. I am asked about whether any of the stockpiled therapeutics were of use in responding to the COVID-19 pandemic and why or why not they were used.

139. As discussed at paragraphs 132-135, the medicines that had been stockpiled prior to COVID-19 as part of our preparedness for an influenza pandemic were either specific antivirals for flu, or generic antibiotics to mitigate the impact of any secondary bacterial infections in an influenza pandemic. In relation to the antibiotics, these proved not to be needed in response to COVID-19 as we did not see COVID-19 patients with secondary bacterial infections in the way that is typically seen with influenza.

140. As discussed at paragraphs 132-135, other components of the Pandemic Influenza Preparedness Programme (PIPP) stockpile were released to support the response to COVID-19. These components included the PPE and hygiene consumables that were released early in the pandemic response, and the combined needles and syringes and sharps bins that were released to support delivery of the COVID-19 vaccination programme (see statement 4A paragraph 121).

141. In relation to other therapeutics, it is not possible, by definition, to stockpile specific therapeutics for novel diseases in advance. Once a novel disease has

emerged, it is possible to trial whether existing therapeutics are effective and to commission research, development and clinical trials into potential new treatments. The UK had already identified that effective and safe treatments would be a critical part of the response, alongside vaccines, to help mitigate the clinical impact of the disease and trials into COVID-19 treatments began to be funded from March 2020. Further detail is provided in Professor Lucy Chappell's statement.

142. As a result of the clinical trials that were undertaken, none of the therapeutics discussed above that had been stockpiled prior to the onset of the pandemic were used, as the trials did not satisfactorily establish that any of the stockpiled drugs would be effective treatment against COVID-19. However, as a result of the clinical trials that were undertaken, including the ones funded by NIHR and UKRI, it was discovered that dexamethasone significantly reduced the risk of mortality among critically ill patients hospitalised with COVID-19 and receiving supplementary oxygen. This drug is already held in large quantities across the NHS as it is used in routine treatment of other conditions. A Central Alerting System (CAS) alert was issued which introduced a UK wide interim clinical access policy for dexamethasone within hours of results being released so that NHS patients were able to receive treatment immediately **(CS7/86 - INQ000497060**

Trials

143. A platform trial is a type of prospective, disease-focused, adaptive, randomised clinical trial (RCT) that compares multiple, simultaneous and possibly differently timed interventions against a control group. Platform trials differ from traditional clinical trials in that they are open ended, meaning new interventions can be added, assessed, and removed as time goes on, without having to specify what they might be at the start. Compared to a more traditional intervention focussed trial design (for example, is this drug better than usual care / placebo), a platform trial can be better thought of as disease focussed (what is the best drug for this disease?) **(CS7/87 - INQ000399510)**.

144. When considering trial 'Phase', the most common phases in clinical trials are Phase 2 trials (efficacy) and Phase 3 trials (effectiveness). Feasibility and/ or pilot studies may be used in the run-in to Phase 2 or Phase 3 trials to determine processes or the size of trial needed. C.

a. I = first in human
b. II = proof of concept/efficacy

c. III-V = effectiveness

145. The three key national platform trials, as named at the time in 2020 by the CMO, were RECOVERY, PRINCIPLE and REMAP-CAP **(CS7/44 - INQ000068589)**.

146. The TTF worked to accelerate the development of new drugs and reduce the time taken to set up clinical studies for new therapies from months to weeks. The establishment of the Accelerating Covid-19 Research and Development (ACCORD) programme aimed to get an early indication of effectiveness in treating COVID-19, with the initial intention that treatments with positive data would be moved swiftly into later phase trials. Ministers took a close interest in the progress in setting up the trial and enrolling the first patients, with the Secretary of State for BEIS, Sir Alok Sharma, taking a particular lead at this stage. **(CS7/88** **INQ000478977**

147. The Inquiry askes for views on issues about relationships brought up in Kate Bingham's book. The work on vaccines and therapeutics required deep collaboration between government, researchers, industry, regulators and the NHS at unprecedented pace. Overall this worked well and relationships were strong, focussed on the end goal of developing effective pharmaceutical interventions to minimise the impact of the pandemic as soon as possible. Different individuals will have different perspectives from their involvement; the departmental view is that these innovative arrangements helped ensure that the UK could provide access to effective treatments to our patients with COVID-19 among the fastest in the world.

148. Therapeutics trials for COVID-19 including how the Devolved Governments were involved in commissioning and delivering research is covered by Professor Lucy Chappell's statement.

Procurement

149. During the start of the COVID-19 pandemic, procurement of potential treatments was challenging, with rapidly changing and competitive global markets and a need to act fast with very limited data; there was worldwide demand for potential therapeutics such as dexamethasone, colchicine, lopinavir/ritonavir, hydroxychloroquine. Cognisant of these challenges, the Department acted quickly through collaboration with the NHS, funders, academia, the pharmaceutical industry

and the general public **(CS7/89 - INQ000399139).** In doing so, it identified a group of drugs as targets for procurement for use in trials in anticipation of a positive read-out leading to supply availability concerns **(CS7/90 - INQ000109126; CS7/91 - INQ000049372; CS7/92 - INQ000109096; CS7/93 - INQ000408767)**. These included: hydroxychloroquine, azithromycin, lopinavir/ritonavir and dexamethasone **(CS7/94 - INQ000399485)**. Data snapshots were produced to inform senior members of the Department of progress in procuring these products **(CS7/93 - INQ000408767)**, and final volumes were determined by market availability as well as subsequent revisions of modelling assumptions.

150. As the pandemic situation developed over time, other therapeutics were identified as being of potential use (such as colchicine, ascorbic acid and favipiravir, interferon-beta) and at various times approval was sought for further procurement, either for use in sponsored trials or prospectively for wider population deployment in the event that a decision would be made to do so. The final position on procurement of all products is set out in the table at paragraph 161.

151. Given the circumstances of the COVID-19 pandemic and the need to roll out new and repurposed medicines rapidly without disrupting other budgets and services, therapeutics were funded centrally by Government through funding specifically allocated by HMT, with the exception of dexamethasone. The UK Government centrally purchased a stockpile of dexamethasone in April 2020 as a precautionary measure, with the bulk of stock used being purchased by the NHS through their usual routes. **(CS7/95 - INQ000486299) CS7/95 - INQ000486299; CS7/96 - INQ000486303)** The Devolved Governments reimbursed the Department for therapeutics procured centrally. Other treatments were either expensive (e.g., novel medicines, monoclonal antibodies) or if proved effective would be potentially used in significantly above normal BAU levels, e.g., azithromycin, colchicine, inhaled budesonide, remdesivir, tocilizumab, sotrovimab, remdesivir. The Taskforce took steps to procure a buffer stock and/or reimburse NHSE over and above normal BAU supply chains (or in the case of tocilizumab, which could not be stockpiled, worked with the manufacture on likely volumes needed, so that its licensed clinical use would not be unduly affected).

152. With regard to antivirals, an initial procurement was announced on 20 October 2021 of 730,000 patient courses of oral antivirals – 480,000 of molnupiravir from MSD and 250,000 courses of nirmatrelvir + ritonavir from Pfizer. This volume was based on the anticipated need for these treatments, in addition to existing vaccines and other

treatment options, in the UK in winter 2021/22. Contracts were subject to MHRA issuing a Conditional Marketing Authorisation. Molnupiravir received authorisation on 4 November 2021 and nirmatrelvir + ritonavir received authorisation on 31 December 2021.

153. In terms of therapeutics or prophylactics considered by the Panel, a summary of all therapeutics and antivirals procured by the Department in the period between March 2020 and March 2023 is set out in the table below.

154. The procurements by the TTF/ATF/ATTF were supported by business cases which were approved by ministers. The Ministerial Panel was used, as for vaccines, for some procurements (e.g., sotrovimab), which provided a streamlined single meeting or correspondence rather than consecutive clearances from DHSC, CO and HMT. Business cases (which followed Green Book Guidance) for other procurements (e.g., remdesivir) were put to Ministers and HMT, after various financial checks. Paragraphs 171- 176 of Statement A for Module 4 provides further clarity on the process of putting procurements to ministers and HMT. Procurements led by PHE are also covered in the table below for completeness. Pre pandemic, PHE normally led procurements for countermeasures that had been agreed by ministers, and in the early stage of the pandemic some procurements continued in that way. The Department and the additional ATTF resource then took on the task for future procurements.

155. The Ministerial Investment Panel was established by the VTF to provide commercial and financial approvals for vaccine procurement contracts over £150 million. It brought together ministers from relevant departments to support responsive, robust decision-making on investments made by the programme, at the pace required for the ongoing commercial negotiations. **(CS7/97 INQ000497070**

156. The terms of reference for the Ministerial Panel were updated in July 2021 to include therapeutics, the first therapeutic to be considered was the procurement of Xevudy (sotrovimab) from GSK. **(CS7/98 - INQ000420973**

157. Central procurement of COVID-19 therapeutics, including oral Antivirals and storage and distribution services followed the main principles and guidance, set out in Managing Public Money and the Green Book. This included developed outline and full business cases setting out options, identifying uncertainties and risks covering all strategic, economic, management and commercial aspects. A commercial strategy

was developed, and in all cases, ministers were kept appraised of the strategy and process steps prior to business cases being developed.

158. For novel medicines, in particular where there was only one supplier, and where urgency was needed in order to secure supply limited by global demand and capacity, it was necessary to use single tender action. In these cases, Accounting Officer Assessments were developed to test regularity, propriety, value for money, feasibility and programme risks, including legal advice on compliance with the Public Contract Regulations (PCR 2015). To minimise commercial risk, a Prior Information Notice exercise was also carried out in parallel to provide additional market engagement for monoclonal Antibody manufacturers and oral antiviral manufacturers.

159. Having satisfied internal Taskforce controls, business cases setting out full options were then presented to the ministers for approval. Given this size of procurements, approval was also sought from Cabinet Office and HMT prior to ministerial approval. Supply agreements and commercial arrangements were finalised using normal commercial practice **(CS7/99 - INQ000236651).**

160. For example, the Ministerial Panel discussed at paragraph 126 met on 14 July 2021 to consider the proposal from the TTF to procure sotrovimab, a novel antibody. The Ministerial panel stood down at the end of September 2021 following the VTF's review of the role of the Panel. **(CS7/68 - INQ000408749)** We have provided some further information (including minutes) on the Ministerial panel in the section on the VTF in Statement A for this module. More detailed information may be available from UKHSA.

161. The table below outlines the medicines procured by the Taskforces during March 2020 to March 2023.

Medicine Generic	Brand/version Brand name if relevant	Rationale POTENTIAL TREATMENT USED AS TREATMENT TRIAL / investigational medicinal product (IMP)	Procurement Route	Total Procured (units/patient courses) Some medicines used multiple units per course/ dose refer to clinical access policy	Date (when contracts became valid i.e., from MHRA approval or supply)	Outcome
ascorbic acid	Alliance	Trial IMP stock	Single tender from two viable suppliers by the Therapeutics Taskforce **(CS7/100 - INQ000497067**	4,621	Jan 2021 onwards	Stock procured for REMAP-CAP trial which concluded treatment was not effective.
	Clinagen			77,214		
azithromycin	Generic supplied by wholesalers	Potential treatment	Procured by PHE	4,387,134	Spring 2020	Procured as a potential treatment as a contingency in case of supply shortage ahead of PRINCIPLE and RECOVERY trial results, both trials concluded treatment was not effective and therefore the stock was not used.
casirivimab + imdevimab	Ronapreve produced by Roche	Treatment	Single tender action from Roche UK by the Vaccine Taskforce **(CS7/101 - INQ000497079**	50,000	Aug 2021	Procured as treatment ahead of positive results from the RECOVERY trial. Treatment became ineffective due to the Omicron variant

colchicine	Generic supplied by Accord UK	Potential treatment	Variety of single tender actions across the UK wholesalers by the Therapeutics Taskforce **(CS7/102 - INQ000497068**	36,000	Spring 2021	Procured as a potential treatment as contingency in case of supply shortage ahead of PRINCIPLE and RECOVERY trial results, both trials concluded treatment was not effective and therefore the stock was not used.
	Generic supplied by HFA			27,500	Spring 2021	
	Generic supplied by Morningside			25,000	Spring 2021	
	Generic supplied by Sigma			2,000	Spring 2021	
	Generic supplied by Vertical			5,300	Spring 2021	
corticosteroid	Dexamethasone sourced from wholesalers	Treatment buffer stock	Procured by PHE **(CS7/103 - INQ000497065**	376,026	Spring 2020	Procured as treatment as contingency in case of supply shortage ahead of RECOVERY trial results and further significant waves of infections. Not used as business as usual supply routes into hospitals were maintain despite increase worldwide use.
	Hydrocortisone source from wholesalers			45,000	Autumn 2020	
favipiravir	Avigan supplied by Toyama Chemical	Trial IMP stock	Single tender from only importer by the Therapeutic Taskforce **(CS7/104 - INQ000479897)**	700		Stock procured for PRINCIPLE trial which concluded treatment was not effective. This was to supplement supply donated by Avigan.
Hydroxychloroquine	generic	Potential treatment	Procured by PHE	238,438	Spring 2020	Procured as a potential treatment as contingency in case of supply shortage ahead of RECOVERY trial results, The trial concluded treatment was not effective and therefore the stock was not used.

	Zentiva Hydroxychloroquine			217,766	Spring 2020	
	Avloclor Chloroquine			196,440	Spring 2020	
	Malarivon			29,355	Spring 2020	
Interferon Beta 1A		Trial IMP stock	**(CS7/104 - INQ000479897)**	108		Stock procured for trial.
Inhaled budesonide	Pulmicort Turbohaler 200 made by AstraZenica	Potential treatment	Single tender action from AstraZeneca UK Limited **(CS7/105 - INQ000497069**	0	Mar 2021	Procured as a potential treatment as contingency in case of supply shortage and to protect business as usual use in UK, ahead of PRINCIPLE trial results, The trial concluded treatment was not effective and therefore the stock was not used, Contract reduced to zero value by agreement.
lopinavir + ritonavir	Aluvia	Potential treatment	Donation from Abbvie	2,000	Spring 2020	Procured as a potential treatment as contingency in case of supply shortage ahead of RECOVERY trial results, The trial concluded treatment was not effective and therefore the stock was not used.
	Kaletra		Donation from Abbvie	711	Spring 2020	
	Generic		Procured by PHE **(CS7/106 - INQ000486299**	85,986	Spring 2020	
molnupiravir	Lagevrio made by MSD	Treatment	Procured as single tender action from MSD by the Antivirals Taskforce **(CS7/107 - INQ000497080**	2,079,000	Nov 2021 onwards phased delivery	Procured and used as treatment
nimatrelvir + ritonavir	Paxlovid made by Pfizer	Treatment	Procured as single tender action from Pfizer by the Antivirals Taskforce **(CS7/108 - INQ000497082**	2,449,000	Dec 2021 onwards phased delivery	Procured and used as treatment

remdesivir	Veklury made by Gilead Sciences.	Treatment	Procured by PHE (through EU Joint Procurement Action) and direct by DHSC – single tender action from Gilead Sciences UK, by the Antivirals & Therapeutics Taskforce **(CS7/109 - INQ000497062**	372,352 vials	From May 2020 through to Dec 2022, as needed	Procured and used as treatment
sotrovimab	Xevudy made by GSK	Treatment	Single tender action from GSK by the Therapeutics Taskforce **(CS7/110 - INQ000497081**	100,008	Dec 2021 onwards phased delivery	Procured and used as treatment
tocilizumab	Actemra made by Roche	Trial IMP stock	Donation from Roche **(CS7/111 - INQ000497063**	85	Mid-2020	Procured for RECOVERY trial. All treatment stock was taken from business as usual supplies with the Therapeutics Taskforce working with Roche to ensure continued access.

Table 3: Therapeutics procured by the Therapeutics Taskforce (TTF), the Antivirals Taskforce (ATF) and the Antiviral & Therapeutics Taskforce (ATTF) (or on behalf of the Department) during Mar 2020 – Mar 2023

Access to Treatment and Deployment

162. The Department moved quickly at the outset of the COVID-19 pandemic to ensure that those at risk of and suffering from COVID-19 had early access to safe and effective treatments. It began to consider deployment in advance of approved drugs so that, once they were available, they could be deployed as quickly as possible. The Department considered options ranging from business as usual, e.g., for repurposed drugs that were in good supply in the NHS, to tailored approaches for access to therapeutics in the community (alongside tests), in primary care and in hospitals.

163. As discussed above at paragraph 32 of this statement, during the COVID-19 pandemic the MHRA worked closely with the Department and other healthcare partners and stakeholders to rapidly identify where flexibilities in the regulation of medicines and medical devices was possible, to accelerate the approval of COVID-19 treatments. For instance, it approved new trials to test potential therapeutics, such as the PRINCIPLE trial, and amendments to existing trials to enable them to pivot to COVID-19 research such as the REMAP-CAP trial, or to expand their ambit to include additional potential treatments or different patient groups. In addition, the Health Research Authority (HRA) introduced a fast-track service for COVID-19 research applications that needed a rapid research ethics review. This was a key contribution from the HRA to ensure that it expedited the parts of the regulatory journey for approving COVID-19 studies that were within its control **(CS7/112 - INQ000502074).**

164. The MHRA also reviewed applications from pharmaceutical companies seeking marketing authorisation for new COVID-19 treatments and prophylactics, including issuing conditional marketing authorisations at pace for two monoclonal antibodies (Ronapreve (casirivimab/imdevimab)) approved on 20 August 2021 **(CS7/40 - INQ000257005)** and Xevudy (sotrovimab) approved on 2 December 2021 **(CS7/113 - INQ000399489)** and two antivirals (Lagevrio (molnupiravir) approved on 4 November 2021 **(CS7/114 - INQ000257098)** and Paxlovid PF-07321332 (which was later given the approved generic name nirmatrelvir) and ritonavir approved on 31 December 2021**(CS7/115 - INQ000257234)**. The approval of Lagevrio (molnupiravir) was particularly ground-breaking making the UK the first country in the world to approve an antiviral for COVID-19 that could be taken at home **(CS7/114 - INQ000257098)**.

165. On 26 May 2020, the MHRA published the first positive scientific opinions for use of Gilead's remdesivir **(CS7/116 - INQ000399479)**. Remdesivir, sold under the brand name Veklury, is an antiviral indicated for the treatment of COVID-19 in adults and paediatric patients (≥28 days old and weighing ≥3 kg) with positive results of SARS-CoV-2 viral testing, who were hospitalised or had mild to moderate COVID-19 and were at high risk for progression to severe COVID-19 including hospitalisation or death **(CS7/117 - INQ000399497)**. Remdesivir was the first COVID-19 treatment that

received a positive opinion from the Early MHRA Access to Medicines Scheme (EAMS) **(CS7/116 - INQ000399479)**.

166. Launched in April 2014, the EAMS aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need. At its point of establishment, it was anticipated that medicines with a positive EAMS opinion could be made available to patients 12-18 months ahead of formal marketing authorisation **(CS7/118 - INQ000408770).**

167. Regulation 174 of the Human Medicines Regulations 2012 operates to disapply on a temporary basis the typical authorisation procedures and regulations where that is in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation, which may cause harm to human beings. The COVID-19 pandemic met this definition and therefore new COVID-19 medicines could be considered under regulation 174. It should be noted that a regulation 174 approval is not the same as a Marketing Authorisation. The Human Medicines (Coronavirus and Influenza)(Amendment) Regulations 2020 inserted a new regulation 174A setting out the action to be taken in the event of a breach of the conditions, the MHRA was able to define safeguards for the supply and use of unlicensed products which mirrored the conditions of a licence **(CS7/119 - INQ000067190; CS7/120 - INQ000111690; CS7/121 - INQ000067797; CS7/122 - INQ000067444)**.

168. During the COVID-19 pandemic, clinical access policies for therapeutics were not developed through the standard MHRA and NICE processes as outlined at paragraphs 36-38, but decisions on their use were instead taken through a bespoke, rapid clinically led arrangement specifically put in place to assess their clinical benefits and the groups of patients who would benefit the most. The group that managed this process was the NICE-chaired Research to Access Pathway for Investigational Drugs for COVID-19 ("RAPID C-19"). The RAPID C-19 group was set up in May 2020 and was tasked with monitoring emerging trial evidence on the clinical effectiveness of potential COVID-19 treatments during the pandemic. This meant that evidence could be assessed rapidly, and COVID-19 therapeutics made available to patients if there was strong evidence of benefits without waiting for the full, more usual cost benefit appraisal process to complete. **(CS7/123 - INQ000399509)**

169. RAPID C-19 was a collaboration between the following organisations, along with representation from the appropriate bodies from the four nations:

a. NICE;

b. NIHR;

c. NHS England;

d. MHRA;

e. Scottish Medicines Consortium (Healthcare Improvement Scotland);

f. All Wales Therapeutics and Toxicology Centre;

g. All Wales Medicines Strategy Group;

h. Department of Health in Northern Ireland;

i. ATTF **(CS7/123 - INQ000399509).**

170. RAPID C-19 used the NIHR Innovation Observatory (NIHRIO) to provide a horizon scanning function to review later stage clinical trial data in detail to see if it should change UK clinical policy. Established in 2017, the Innovation Observatory is the NIHR-funded horizon scanning facility. Their role was to provide the group with up-to-date intelligence on all national and international trials for COVID-19 treatments, including all antivirals, cell-based therapies and other therapeutics. They extracted and collated trial data, which was then shared with the group and used by colleagues in NICE. As the trial landscape began to expand, NIHRIO worked with NICE and others to develop a set of criteria to enable prioritisation of the most promising treatments. **(CS7/124 - INQ000315554**

171. RAPID C-19 became an important partner for the ATTF who collaborated with them to streamline the process of making new treatments available for use for NHS COVID-19 patients **(CS7/125 - INQ000330922).**

172. RAPID C-19 advice and evidence reviews were presented to CMO, including recommendations to introduce or change an Interim Clinical Policy.

173. In practice, the EWG developed or amended draft clinical policy as soon as RAPID C-19 had identified a clear signal of effectiveness. The NHSE EWG produced a 'Rapid Policy Statement' which set out the relevant new or amended UK interim clinical commissioning policies. The clinical policies were developed with four nation input and on behalf of the four CMOs to ensure a consistent clinical policy across the UK. The draft Interim Clinical Commission Policies together with a covering 'COVID-19 Therapeutic Alert' were sent to CMO. COVID-19 Therapeutic Alert and Interim Clinical Commissioning Policies were published utilising the MHRA Central Alert System **(CS7/126 - INQ000107091)**. A specific page alerting clinicians across the UK was established to collate all interim and updated interim clinical policies for COVID-19 therapeutics **(CS7/127 - INQ000502152).**

174. The ATTF also utilised existing access schemes to make treatments available to patients when the evidence supported this. As explained above, the EAMS and the positive scientific opinion from MHRA supported the use of remdesivir on certain NHS patients **(CS7/128 - INQ000399480).** The MHRA opinion was based on the assessment of quality, safety and efficacy data from clinical trials data, notably from the ACTT-1 study in the United States **(CS7/116 - INQ000399479)**. The early data from these clinical trials showed that remdesivir could shorten recovery time in patients by about 4 days **(CS7/128 - INQ000399480).** This enabled the NHS and the Department to provide access to remdesivir for selected hospitalised patients across the UK on the basis of a positive COVID-19 result before remdesivir obtained full regulatory approval. Similar arrangements were made with other countries, including an emergency use authorisation of remdesivir by the FDA in the US and MHLW/PMDA in Japan **(CS7/128 - INQ000399480).**

175. The Department worked very closely with NHSE throughout in order to gain their clinical and delivery input into the design of the end-to-end process, and to ensure that any potential implementation issues were identified early and could be addressed. The ATTF built this perspective into their advice to ministers alongside the industry, scientific and commercial aspects. The ATTF worked closely with the NHSE Specialised Commissioning team and the Chief Pharmacist in the first phases, including the commissioning of CMDUs, before a dedicated team was set up for the deployment of oral antivirals for outpatient and community use (Gareth Arthur was

SRO in NHSE). NHSE were involved in the formal governance, including the NHS Medical Director Sir Steven Powis. Dr Powis also of course worked closely with the CMO, DCMO and CSA with the common objective of being able to research, procure and supply effective treatments to NHS patients as quickly as possible.

176. In deployment planning, how to get drugs to the most vulnerable was an integral part of consideration and planning. Those who were eligible for the therapeutics were by definition those with the greatest clinical risk of developing severe or critical COVID-19, and consideration was also given to those who were house-bound, or would have other difficulties in accessing the services. This included bespoke arrangements for collection and home delivery in some locations. Testing kits were made available by post or collection, first to the whole population, and continued in later phases to be made available free of charge for those who were most vulnerable.

177. The pandemic-specific approach meant that treatments were available to patients within days of trial results, rather than what would have been months had the normal process for new treatments been followed. NICE have since conducted technology appraisals on the treatments procured by the ATTF, to support the return to usual commissioning and funding arrangements.

Antivirals

178. As explained above, the Prime Minister launched the ATF to identify, procure and deploy novel antiviral treatments for UK patients with COVID-19 **(CS7/73 - INQ000086652).** The ATF, TTF, NHS England and counterparts in the devolved administrations collectively set up deployment mechanisms to administer these antivirals to eligible patients at the highest risk from COVID-19.

179. For instance, as part of the government's COVID-19 Enhanced Protection Programme, an independent advisory group (the "IAG") **(CS7/129 - INQ000399492)**, led by Professor Iain McInnes, was established at the request of the DCMO and supported by NHS England and RAPID C-19, to identify a set of patient conditions (cohorts) deemed at the very highest risk of an adverse COVID-19 outcome and an estimated population size of these cohorts. Individuals within these defined cohorts were eligible to receive new COVID-19 treatments, such as neutralising monoclonal

antibodies (nMABs) outlined below and antivirals, if they tested positive for COVID-19 via a lateral flow test or PCR and had not been admitted to hospital **(CS7/130 - INQ000408756)**. The cohorts identified were agreed by the CMOs for all four nations and formed the basis of the clinical access policy for treatment from Covid Medicine Delivery Units (CMDUs) and equivalents in the devolved administrations. One or more CMDU was established by each integrated care system (ICS). The CMDU model ensured that treatments were delivered quickly following symptom onset since GP practices did not need to confirm eligibility or discuss treatment options. The CMDUs treated around 114,830 patients in England from the week ending 19 December 2021 and the week ending 2 July 2023 **(CS7/129A - INQ000399490; CS7/131 - INQ000408766)**.

180. The work of the ATF and its delivery partners, including the NHS and counterparts in the Devolved Administrations, ensured the UK was the first country in the world to administer oral antivirals to patients in the community in December 2021 **(CS7/132 - INQ000257154).**

Neutralising monoclonal antibodies (nMABs)

181. A number of nMABs to treat SARS-CoV-2 had been developed by the summer of 2021 and were under evaluation in clinical trials. There was an urgent need to evaluate the broader potential of these novel therapies and to develop strategies to deploy them as quickly and as effectively in clinical practice to manage the impact of the 2021 summer and winter waves, given their ability to potentially withstand variations of concern, and limited initial availability **(CS7/133 - INQ000421850)**.

182. A major barrier to the use of nMABs was the rapid mutation of COVID-19 which meant their effectiveness significantly diminished with the advent of new variants. The potential loss of a previously effective drug necessitated a change in a focus of therapeutic strategy away from neutralising monoclonal antibodies to emerging small molecule directly acting antivirals.

183. I am asked about improving the evidence to evaluate the effectiveness of nMABs against variants. Since December 2020, MHRA was made aware of increasing concerns relating to the performance of diagnostic tests for SARS-CoV-2 virus variants, the MHRA began monitoring and collaborating with external partners including the UK Health and Security Agency (UKHSA) and regularly engages with

suppliers and manufacturers of test products in the UK to review their post-market assurance processes for the most recently published variants in circulation in the UK.

184. I am specifically asked, once the ATF was established, to what extent were pre-exposure prophylactics part of the therapeutic strategy, this is covered above at paragraphs 71, 89 to 91 and 107 above and below at paragraphs 189 to 207.

Access to Testing

185. Testing patients to diagnose infection and therefore provide treatment was a vital use of testing, and for many months, testing was available to the whole population. In April 2022, free lateral flow testing ended for the general population. However, access to free testing was retained for the identified cohorts to enable them to continue to access the treatments via the CMDUs following a positive test **(CS7/73 - INQ000086652).** Further, the identified cohorts' treatments were exempt from prescription charges; this exemption was first introduced in December 2021 and renewed for a year in April 2022 **(CS7/134 - INQ000408759).**

186. In May 2022, the IAG and the Therapeutics Clinical Review Panel completed a review of the of the cohorts and identified additional conditions that should be included. This was approved by the UK CMOs. The IAG published the 'Higher-risk patients eligible for COVID-19 treatments: independent advisory group report' on 30 May 2022 **(CS7/130 - INQ000408756).** An updated version of this report was published on 31 March 2023 and updated in September 2023 **(CS7/135 - INQ000408765; CS7/130 - INQ000408756).**

187. The clinical additions were implemented by the NHS and in Scotland, Wales and Northern Ireland on 13 June 2022 **(CS7/136 - INQ000408758).** It took into account several improvements to coding and other processes, which enabled the NHS to better identify patients **(CS7/130 - INQ000408756).** As a result of the clinical additions and technological improvements, the cohort size increased from around a million patients UK wide in December 2021 to around 1.5 million in June 2022. By March 2023, the cohort size was close to 3 million patients UK wide.

188. The bespoke arrangements established for the pandemic were beginning to close, moving back into normal channels. The ATTF Strategy Board considered a

range of options for the deployment of antivirals along with the arrangements for accessing testing, the provision of treatment via primary care and the closure of CDMU's. The Department worked closely with NHSE and UKHSA to agree the roles and the transition arrangements. **(CS7/137 - INQ000497089**

Pre-exposure prophylaxis

189. The concept of 'pre-exposure prophylaxis' (PrEP) for COVID-19 involves treatments that can be given *before* someone is exposed to COVID-19 and that could increase their protection against the virus. This could be particularly important for patients who do not respond well to vaccination, such as those who are immunocompromised in either the short-term (e.g., transplant patients) or longer term, enabling them to live, work and study more normally than when "shielding" because of the protection offered by a PrEP. If the PrEP is not effective, or there is significant uncertainty about its effectiveness, the benefits are reduced, as vulnerable patients may choose to not engage in activity outside of their home in order to manage the risk of contracting an infection.

190. The VTF, and subsequently TTF / ATTF, sought to identify effective prophylactic treatments, engaged with companies, supported clinical trials research and worked to identify target cohorts.

191. Prophylactics were initially considered by the VTF during the early pandemic, in the event of no suitable vaccine candidates. Following the successful development and deployment of multiple vaccines, the TTF took on this responsibility, but with the intention of using them for the smaller population for whom the vaccines may not have offered sufficient protection **(CS7/50 - INQ000502128**

192. At the TTF Executive Board on 18 September 2020 was provided with an update on neutralising antibodies. The Board noted that the VTF had the overall lead on antibodies, but further discussion was needed to ensure clear lines of accountability and ownership of specific strands, including whether it was appropriate that antibodies for therapeutics use should be wholly owned by the TTF. Charlotte Taylor, Director of the TTF, took an action to discuss ownership of Neutralising Antibodies with Clive Dix, Deputy Chair of the UK's Vaccine Taskforce, with a view to transferring this to the TTF.

The action was subsequently completed by 11 December 2020 **(CS7/138 - INQ000502088; CS7/139 - INQ000502096; CS7/140 - INQ000502133).**

193. The most high-profile treatment was tixagevimab plus cilgavimab manufactured by AstraZeneca (known during its development as AZD7442 and then branded as Evusheld). Like other COVID-19 therapeutics, Evusheld was reviewed by RAPID C-19 on a regular basis.

194. In late 2020, the VTF negotiated an advance order of 50,000 courses of prophylaxis to be made available in late 2021 into 2022. This was a VTF lead but they discussed with the Departmental vaccines and therapeutics teams how the courses could be used in the context of plans for vaccine deployment, for example what demand would be in specific months.

195. In February 2021, HMG decided not to procure AZD7442 outside of the normal process for making medicines available to NHS patients. The Department also provided input from DCMO (Jonathan Van Tam) with an advisory decision not to procure **(CS7/141 - INQ000066714).** The reason for this is that trial data on efficacy was not yet available, the level of need for prophylaxis was unclear, and the UK could still procure product once it reached the market in 2022 if desired. This decision was made via the IMG following a write round via the VTF.

196. Throughout 2021, TTF worked to identify potential cohorts for prophylaxis to understand potential demand and deployment requirements. This focussed on patients with medical conditions that mean they do not respond as well to COVID-19 vaccines and have lower levels of protection (for example patients with certain immune disorders).

197. TTF officials provided advice to ministers on 17 March 2022 following the MHRA granting conditional marketing authorisation **(CS7/142 - INQ000502126)**. The advice outlined that procurement had not been progressed as clinical experts required further information on its proven efficacy against Omicron. Further activity would also be ongoing to understand data on efficacy, potential cohorts who would benefit, value for money and options for deployment in the NHS.

198. Officials met with Minister for Technology, Innovation and Life Sciences and the Secretary of State during May 2022 to explain the background and potential options around Evusheld, given the high levels of public and parliamentary interest **(CS7/143** **INQ000497087** Advice summarising the clinical opinion and options around Evusheld was provided to ministers on 21 June 2022 **(CS7/144 -** **INQ000497090**, via a submission dated 20 June 2022. This took account of advice from RAPID C-19 and the CMO. The advice asked ministers to agree that the Department should not seek to deploy Evusheld in a PrEP programme at that time, and that Evusheld should be considered through NICE's topic selection process for potential formal referral to NICE's technology appraisal programme. Secretary of State, Minister for Technology, Innovation and Life Sciences and the Minister for Vaccines and Public Health agreed with this advice on 28 June 2022. This was fed back to AstraZeneca in a meeting on 4 July 2022. **(CS7/145 -** **INQ000497092** **CS7/146 -** **INQ000497091**

199. AstraZeneca also wrote to the Department on 13 July, proposing the UK procure and deploy Evusheld and evaluate outcomes via observational data. AstraZeneca referred to observational studies in other countries that they said showed Evusheld was effective against Omicron variants. **(CS7/147 -** **INQ000497085**

200. The ATTF contacted the Expert Working Group (EWG), which had been established by NHSE to provide the detailed proposed Interim Clinical Policy, on 15 July to look at literature on double dosing **(CS7/148 -** **INQ000497093** A submission dated 18 July 2022 recommended not to proceed with the AstraZeneca counter proposal. ATTF followed up on 1 August with 'real-world evidence' (RWE) and dose info submitted by AstraZeneca. AstraZeneca, ATTF, NICE and the CSA met on 26 August to discuss the RWE counter proposal AstraZeneca had submitted. RAPID C-19 sent a report on RWE to the CMO on 1 September and the decision not to procure remained in place. **(CS7/149 -** **INQ000479901**

201. Evusheld was withdrawn in many countries in late 2022 or in 2023, as evidence emerged to indicate it had reduced effectiveness against newer COVID-19 variants. In June 2023, NICE concluded its appraisal of Evusheld and did not recommend it as a treatment. **(CS7/150 -** **INQ000339319**

202. Other potential prophylactic treatments of note were sotrovimab and niclosamide which were part of the Prophylaxis for Patients at risk of COVID-19

Infection ("PROTECT-V") trial. PROTECT-V was an international, multicentre study aiming to identify medications which protected vulnerable patients from COVID-19. The trial enrolled participants who were at particularly high risk of COVID-19 and its complications. It recruited individuals who were immunocompromised for any reason, be that primary or secondary immunodeficiency. These included vulnerable populations who were underrepresented in other clinical trials. **(CS7/151 - INQ000399513)** The study began recruitment in February 2021 and was designed to evaluate several different drugs at the same time including intravenous Sotrovimab and intranasal Niclosamide:

a. Sotrovimab is a fully human IgG1κ monoclonal antibody (mAb) derived from the parental mAb S309, a potent neutralising mAb directed against the spike protein of SARS-CoV-2. Sotrovimab is delivered as a single, one-off, intravenous infusion. It was used for the early treatment of those with COVID-19 in routine clinical practice, it was not known yet whether it could prevent infection. PROTECT-V actively recruited to this arm of the trial; participants were randomly assigned to either receive treatment with sotrovimab or placebo and neither the patient nor the trial investigators knew which treatment a patient had been assigned to.

b. Niclosamide is a medication routinely used to treat tapeworm infections, which had demonstrated in vitro action against SARS-CoV2. It was hypothesised that this would disrupt SARS-CoV2 replication and penetration into cells. Niclosamide is typically taken as an oral tablet, but PROTECT-V used a stable liquid formulation (UNI911) via a nasal spray in order to maximise the effect in the nasal lining where SARS-CoV2 initially predominantly replicated. The niclosamide arm of the trial recruited 1653 patients. On the 16 June 2023 the study announced that niclosamide nasal spray does not prevent infection in vulnerable kidney patients.

203. The ATTF requested that NIHR contract with the host organisation in order to fund one arm of this study looking at an agent called ciclesonide. However, due to issues with supply of the agent, this contract was terminated by the Department and NIHR and closed in June 2023 with no spend.

204. Ultimately, the Department did not procure products to be used for prophylaxis as limited options and limited clinical trial evidence were available and those that were,

had unclear evidence or noted / compromised efficacy against the dominant COVID-19 variants circulating in the UK.

205. Decisions on prophylactics were based on considerations of clinical vulnerability. The potential for prophylaxis to support vulnerable groups who were immunocompromised, for example, was consistently recognised, but in respect of AZD7442 there was a lack of clinical data to understand efficacy (in early 2021 clinical trial data was not available, and there was not yet an understanding of the target populations and level of need, and in 2022 the concern was that AZD7442 was not sufficiently effective against Omicron). The advice also included considerations of cost / value, and with the context that the cost-effectiveness of the intervention was not clear given the uncertainties mentioned including the event of a reduction of efficacy against dominant circulating variants. **(CS7/152 - INQ000067807)**

206. The Department were continually advised by clinical experts from the Prophylaxis Oversight Group, UKHSA, RAPID C-19 and CMO, which provided consideration of clinically vulnerable groups. **(CS7/153 - INQ000503287 CS7/154 - INQ000502125)**

207. Prophylactics were initially considered by the VTF during the early pandemic, in the event of no suitable vaccine candidates. However, as VTF were considering prophylactics for wider population protection, the price point was very different. The TTF continued to monitor potential prophylactics throughout the pandemic but considering for a smaller population **(CS7/50 - INQ000502128**

Barriers of Newly Developed Therapeutics

208. I am asked whether there were any barriers, imposed by pharmaceutical companies or others, to using the UK's stores of newly developed therapeutics in independent comparative clinical trials, and this section sets this out. I am not aware of barriers imposed by pharmaceutical companies or others to using the UK's stores of newly developed therapeutics in clinical trials.

International Collaboration

209. Throughout the pandemic, international collaboration was important to ensure effective management of the virus, including treatments such as therapeutics and anti-virals. This section sets out some key international collaboration.

Bilateral Discussions

210. In the period between 30 January 2020 and 28 June 2022, the Department held many bilateral and multilateral meetings with other countries and international partners to discuss cooperation, share the latest scientific information, provide medical assistance, and support global access to safe and effective vaccines and therapeutics in the COVID-19 pandemic. The ATTF in particular engaged, both bi-laterally and multi-laterally, to share strategies and learning on the use, deployment and evaluation of COVID-19 therapeutics and antivirals. This engagement informed government policy as evaluating the similarities and differences in approaches helped to strengthen the UK's approach, particularly when new variants emerged.

211. Dialogue between the Department's Ministers and their foreign counterparts also supported the UK's approach by providing insights into the experiences of other countries grappling with similar issues. During the time period covered by this witness statement, there were many ministerial and senior official level bilateral meetings including Secretary of State calls with international partners such as the US, China, Germany and The Netherlands. A list of 29 bilateral meetings which took place between the Department's Ministers or Permanent Secretary and other foreign officials during the early stages of the pandemic is set out at paragraph 7 of the Third Witness Statement of Clara Swinson, Module 2 **(CS7/155 - INQ000273636)**.

WHO Collaboration

212. COVID-19 demonstrated that pandemics are a global challenge and that the mechanisms at the time, related to vaccines and therapeutics, were not sufficient alone to prepare for or respond to pandemics. A truly global vaccine and therapeutics solution was needed to allow member states and organisations to address the threat of future pandemics.

213. At the World Health Assembly in May 2021, the Member States of the WHO adopted the decision to discuss a new international treaty on pandemics at a special session starting on 29 November 2021. On 1 December 2021, the WHO Member States reached consensus to start the process to draft and negotiate a convention,

agreement or other international instrument under the Constitution of the WHO to strengthen pandemic prevention, preparedness and response **(CS7/156 - INQ000257143).** An intergovernmental negotiating body (INB) made up of Member States was established to take forward the negotiations. **(CS7/157 - INQ000497086** The UK government, as a member of the INB, has been supporting the development of the Pandemic Accord, as part of a comprehensive approach to pandemic preparedness and response. In May 2022, the 75th World Health Assembly directed Member States to work on a package of targeted International Health Regulations (2005) amendments through the Working Group on amendments to the International Health Regulations (WGIHR) it was agreed that a package of amendments should be sent for consideration by the 77th World Health Assembly in May 2024. **(CS7/158 - INQ000497088**

The G7 Summit

214. In June 2021, the UK hosted the G7 summit as part of its 2021 G7 Presidency. International cooperation and capacity for Clinical Trials was a key theme for the UK's G7 Presidency in 2021. Work continued internationally through G20 and through the development, negotiation and adoption of a WHA Resolution on strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination. The TTF continued its contributions to this work by feeding in lessons learned from COVID-19 clinical trials.

215. COVID-19 highlighted failings in the global clinical trials infrastructure and ways of working between countries, international organisations, and industry. The Department made significant progress in leading collaborative international action on clinical trials. As part of the UK's Presidency of the G7 in 2021, G7 Health Ministers agreed a package of action to strengthen cooperation on clinical trials, including a Therapeutics and Vaccines Clinical Trials Charter (the "Charter") **(CS7/159 - INQ000234915).**

Therapeutics and Vaccines Clinical Trials Charter

216. The Charter set out principles to support better cooperation and coordination between countries to ensure well designed clinical trials that meet key public health and clinical needs and to avoid unnecessary duplication, whilst enabling quicker and easier sharing of results from clinical trials. The agreed Charter formed the basis of the

World Health Assembly resolution on clinical trials, which agreed mechanisms to strengthen international clinical trial practice **(CS7/159 - INQ000234915)**.

The 100 Days Mission

217. Another initiative agreed at G7 Health Ministers and Leaders Communiques was the 100 Days Mission, which aims to reduce the impact of future pandemics by making diagnostics, therapeutics and vaccines available within 100 days of WHO declaring a Public Health Emergency of International Concern **(CS7/45 - INQ000101061)**. The 100 Days Mission was also highlighted in the 2022 G7 Health Ministers and Leaders Communiques. The 100 Days Mission at G20 in 2021, with a reference on supporting science to shorten the cycle for the development of safe and effective vaccines, treatments and tests from 300 to 100 days in the Health Ministers and Leaders Declarations.

SECTION 4: REFLECTIONS AND LESSONS LEARNED

218. In this final section, I will outline the lessons which the Department has learned in relation to therapeutics. I will also give further reflections on the Four Nations approach, obstacles that the Department encountered in relation to rapid development and improvements and stockpiling for future diseases.

219. Section 2 of this Statement outlines how the Department's position before the pandemic facilitated a robust response to development vaccines and therapeutics that were a world leading success. While the Department's response changed as we learned more about the nature of the virus and the therapeutics that might respond to it, the resilience of our structures and the range of potential responses at our disposal were key to responding at pace.

220. The Department continues to affirm that the single most important source of its reflections on lessons learned is set out in the "Technical report on the COVID-19 pandemic in the UK, A technical report for future UK CMOs, Government Chief Scientific Advisers, National Medical Directors and public health leaders in a pandemic", ("the technical report") published on 1 December 2022 **(CS7/160 - INQ000203933** This report includes chapters on research, on vaccines and therapeutics, and corresponding reflections and advice on at pages 117-119 and 334-336 respectively. It sets out a number of concluding points on therapeutics including:

- *"Speed of decision-making was crucial, particularly at the outset of the pandemic. Decisions regarding research and procurement needed to be made early, and often ahead of complete information.*
- *An adequately powered trial with a faster result will prevent more deaths than an apparently perfect trial with later results. On the other hand, too many trials would have led to few or none reporting.*
- *Some nations internationally experienced an explosion of trials, but with few getting to robust endpoints. Prioritisation of trial infrastructure based on realistic power calculations and patient flow and uptake were essential.*
- *The pressure to 'just do something' was intense on individual clinicians especially early in the pandemic. High-profile senior support of research and pharmaceutical development (including CMOs) was needed for united and oriented cross-agency work and to ensure that the NHS prioritised enrolment of patients in trials.*
- *Existing research infrastructure (such as NIHR and MRC) and relationships (such as NHS and the academic community) were built on rather than setting up new organisations wherever possible. This meant that the structures were functional and built on established relationships, resulting in rapid and more flexible work and, ultimately, better results.*
- *CMOs and GCSA are not responsible for procurement, but the rapid procurement of potentially useful drugs and vaccines at risk was essential and cannot wait for the final published trial results in an emergency."* **CS7/160** **INQ000203933**

221. The Department continues to believe that five lessons articulated in the Module 1 closing statement stand out, and our reflections are set out under these headings below. Therapeutics in the UK was a world-leading success, building on the strong underlying capabilities in the UK and the ability to scale them at speed.

Lesson 1: A toolkit of capabilities is more important than plans

222. The UK's response to the pandemic was strongest where there were already robust capabilities. This included the UK's science base, research development, trial infrastructure, and NHS provision of services. These underlying strengths were turned to the national mission very effectively, without the need for a detailed plan. Broad-

based expertise in these sectors was able to turn itself to the novel challenge presented by the emergency of COVID-19.

223. The technical report notes:

> *"Strong existing research infrastructure (especially NIHR, MRC and UKRI) was important for the rapid start-up of research, as were linked data systems, which built on learning from the 2009 H1N1 influenza or 'swine flu' pandemic and subsequent independent review of governmental response.'*
>
> *'Trial recruitment at speed and scale was crucial, and existing organisations rapidly pivoted to focus on COVID-19 in advance of the UK's first wave.'*
>
> **CS7/160** | **INQ000203933**

Lesson 2: The underlying resilience of the system matters

224. Industry, academia and public bodies, including the Department and the broader 'health family' worked together resiliently and coherently to facilitate development and deployment of COVID-19 therapeutics. The clinical trials process, supported by Departmental civil servants, proved both agile and robust. As a consequence, UK clinical trials informed decision-making not just in the UK, but also around the world. Clinical practice was able to benefit from the results, leading directly to reduced mortality and morbidity. This is covered in greater detail in Professor Lucy Chappell's statement. As covered in paragraphs 32 and 163, the regulatory system for therapeutics worked rapidly to identify flexibilities to accelerate the approvals process, without diminishing the scrutiny and obligations of approvals, to prepare therapeutics for swift deployment when approved. The NHS routinely enables newly-approved therapeutics to be prescribed to patients who will benefit, so was able to put in place deployment routes quickly and effectively.

Lesson 3: The ability to scale up in the first few months is essential

225. After identifying finding a safe and effective vaccine or therapeutic as a priority from of the start of the pandemic, the Department took action to help the research

infrastructure scale up at pace. This included early calls for research, which led to some of the largest ever trials.

226. The Department and NIHR worked together to prioritise the most important and impactful studies, which was critical to establishing effective treatments and provided key lessons on scaling up at pace. The success the scaling up of research and its impact is covered in more detail in Professor Lucy Chappell's statement.

227. The Department set up the TTF and ATTF to scale up multi-disciplinary teams including science, commercial, finance, analytical and policy expertise, and worked with other health bodies such as MHRA to increase its capacity. The taskforce structure brought different teams together in pursuit of a common goal with clear objectives. This also gave a clear sign of its importance across Whitehall, industry, the NHS and patient groups. High levels of resourcing and funding were also essential elements of the success. **CS7/161 - INQ000354469)**

228. The technical report notes:

> *"The TTF was established in April 2020 followed by a specific antiviral taskforce (ATF) one year later. As well as working with NIHR to support therapeutics trials, the TTF and ATF worked with industry and academia to identify and procure therapeutics and novel antivirals at pace and scale. They took strategic decisions on procurement and stockpiling of drugs at an early stage based on scientifically informed best guesses, working closely with the Deputy CMO for England on behalf of all the CMOs to ensure access to drugs for UK patients in the case of a successful trial outcome. Generally, sufficient confidence to put a repurposed drug into one of the key national clinical trials was taken as a strong enough signal that it should be purchased in bulk in advance at risk. This initial 'no regrets policy' has meant that where a NHS patient was eligible for treatment with a proven therapeutic, it was available."* ***(CS7/160 –*** **INQ000203933**

Lesson 4: Diagnostics and data are crucial in a pandemic response

229. Diagnostics and data are an essential capability to help enable both research and patient care. Understanding the attributes of SARS-CoV-2 and its impact on

humans and the healthcare service at pace was important for development of vaccines and therapeutics.

230. A key lesson was learning how to access data that could be used in decision-making faster. The Department and the NIHR, for example, worked together to prioritise funding for studies to support the effort to develop effective therapeutics; this facilitated output that could benefit public health faster. Details of this work are covered in further detail in Professor Lucy Chappell's statement.

Lesson 5: Prepare for future threats, not just for COVID-19

231. The fifth lesson that the Department has flagged is about the importance of preparing for all routes of disease transmission. Rapid vaccine development worked very effectively in this pandemic, but we cannot guarantee that the same approach will apply to future pandemics. Factors that may impact on future capability to respond at pace and develop an effective response include the type of pathogen and the range of potential responses (including whether or not a vaccine is possible), scientific understanding, ease of design of effective therapeutics and vaccines to respond to specific pathogens, and similarities to other therapeutics and vaccines already being used. As I, Clara Swinson highlighted in my Statement on Vaccines, it is essential that research and development is focused on therapeutics and diagnostics in addition to vaccines. The 100 Days Mission covered in paragraph 217, covers all three elements.

Further Reflections

232. As set out in Sir Christopher Wormald's second Witness Statement to the Inquiry, much of the Department's lessons learned activity was done in 'real time' and applied to its COVID-19 response. This was also the case for therapeutics. **(CS7/162 - INQ000185190)**

233. MHRA and NICE have also both drawn on their experiences of the COVID-19 pandemic in considering how their standard, business as usual approval processes of new therapeutics can be improved. For example, the Innovative Licensing and Access Pathway (ILAP) is a partnership between NICE, MHRA, NHSE and the devolved administrations (the All-Wales Therapeutics and Toxicology Centre and the Scottish Medicines Consortium, part of Healthcare Improvement Scotland) that draws on the

RAPID C-19 model and aims to streamline patient access to safe, financially sustainable and innovative medicines **(CS7/163 - INQ000399500)**.

Reflections on The Four Nations Approach

234. Throughout this statement I have set out how the Department worked with the Devolved Administrations to maximise the impact and shared learning on the development and deployment of therapeutics and vaccines. Sections 1 and 2 of this Statement set out how the different structures within the Department worked closely with the Devolved Administrations and with their respective Arm's Length Bodies. Sections 2 and 3 set out how the Department worked closely with the Devolved Administrations to research, develop, procure and deploy therapeutics and vaccines, collaborating closely with representatives at all stages.

235. At official and technical level there was regular detailed engagement throughout the pandemic to discuss plans for research, ongoing findings and any Four Nations elements of the research response to the pandemic. This collaborative approach, which was outlined in Section 3 of this Statement, describes these relationships in more detail. The success of these relationships and the importance of recruiting participants on a UK-wide basis for research studies is a key lesson.

236. The Technical Report notes:

> *'From the outset a 4-nation joint approach was taken to leadership, research, governmental delivery and procurement in therapeutics and vaccines. This combined resource facilitated faster and more diverse trial recruitment, supported equity of access for therapeutics, and strengthened the UK's negotiating position in a globally competitive market.'* **CS7/161** **INQ000354469**

Obstacles encountered in relation to rapid development and improvements

237. The Inquiry has asked about obstacles in this area. Obstacles mainly arose due to the inevitable lack of data and uncertainty from a novel pathogen. As mentioned in Sir Christopher Wormald's Third Witness Statement, at paragraph 34, highly impactful decisions had to be considered and taken based on the scientific understanding and the data available at the time. The Department's and the

Government's understanding at any point in time should be understood by reference to the published studies and documents that were then available **(CS7/1 - INQ000144792)**.

238. As set out in the 'Technical report on the COVID-19 pandemic in the UK', one of the main obstacles to the rapid development of pharmaceutical interventions was that:

> *"In the first weeks and months of the COVID-19 pandemic no evidence-based therapeutic options (drugs) or vaccines were available, and there was uncertainty about which existing treatments should be prioritised for clinical trials and where research efforts should be focused to develop novel therapeutics and vaccines. Procurement of potential treatments was challenging, with rapidly changing and competitive global markets and a need to act fast with very limited data. These needs were addressed through collaboration between the NHS, funders, academia, the pharmaceutical industry and the general public."* **(CS7/160 - INQ000203933**

Stockpiling for a future 'disease x' pandemic

239. I am asked about the Department current position on therapeutics stockpiling as a preparedness strategy in relation to a future 'disease x' pandemic, and this section sets this out.

240. In line with key learnings from the COVID-19 pandemic, the Department is expanding its approach to clinical countermeasures to cover the five main routes of transmission: respiratory (e.g. COVID, flu), touch (e.g. Ebola, Lassa), sexual/blood (e.g. HIV, Mpox), oral (e.g. cholera, BSE/nvCJD) and vector (e.g. plague, zika). As part of this expanded approach, the Department convened a review of Emergency Preparedness Countermeasures to inform policy on countermeasures and ensure that its approach is applicable to a broader range of pathogens with pandemic potential and other emerging infectious disease risks. Building on the lessons of COVID-19 and the latest clinical and scientific evidence, the review sought advice on materials that should be held, or otherwise contracted for, to expand UK preparedness to this wider range of risks. Policy development on vaccines, therapeutics and PPE as part of our Pandemic Preparedness Portfolio is ongoing based on the advice from the review.

Relevant governance papers regarding the clinical countermeasures review are exhibited at **(CS7/164 - INQ000184088)**.

241. In addition, it is important to note that not all drugs which could be stockpiled as part of our pandemic preparedness are "therapeutics" and that many are, for example, intensive care unit supportive drugs to sedate people and to allow ventilation, etc. In a global pandemic scenario, there is a need to stockpile against supply and demand shocks in relation to these drugs as well as "therapeutics", as pandemic impacts overseas can impact drug supply.

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: 6 September 2024