Witness Name: Charlotte Taylor
Statement No: 1
Exhibits: CT/1 – CT/41
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UK COVID-19 INQUIRY

WITNESS STATEMENT OF CHARLOTTE TAYLOR

I, Charlotte Taylor, Director at the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU, will say as follows:

INTRODUCTION

1. I make this statement in response to a request from the UK COVID-19 Inquiry dated 11 July 2023 under Rule 9 of the Inquiry Rules 2006, asking for a draft witness statement for Module 4.

2. I understand that a request for a corporate statement has similarly been made to the Department of Health and Social Care ('the Department') in respect of Module 4. My understanding is that, at the time of completing this statement, the corporate response is not yet complete. I have been asked to contribute to that statement as I remain part of the Departmental team and can speak to the matters identified by the Inquiry as relevant to the scope of Module 4.

3. It may be that a degree of overlap is warranted, but I have endeavoured to provide responses in this statement which reflect my personal understanding and experience, whereas I would anticipate the Departmental response will necessarily be wider ranging. In part you have asked me questions which I would anticipate are better answered by the Department and I have identified where I believe that to be the case.

4. This statement is accurate and complete to the best of my knowledge and belief at the time of signing. The Department continues to work on its involvement in the Inquiry. In

the event that additional material is discovered, it will be provided to the Inquiry, and I will be happy to make a supplementary statement if required.

Background

5. I am a career civil servant, having joined the Civil Service Fast Stream in November 2000. I have worked in a number of departments in various roles; immediately prior to moving to the DHSC I was working in the Cabinet Office on EU Exit issues.

6. I was appointed to the Therapeutics Taskforce ('TTF') as part of a government-wide surge resource exercise which took volunteers from other teams and placed them in priority areas to provide additional capacity to the pandemic response. I was allocated a deputy director post in DHSC to work on the TTF, initially for a period of three months from 2 April 2020. This was extended by mutual consent, and I am now a permanent member of DHSC staff. On 1 July 2020 I was temporarily promoted to director of the TTF (and then also the Antivirals Taskforce ('ATF'), then the Antivirals and Therapeutics Taskforce ('ATTF')) from its creation in April 2022 to 30 June 2023.

7. From June 2020 my line manager was Clara Swinson, Director General of Global Health and Health Protection, but with a 'dotted line' to the deputy Chief Medical Officer, Jonathan Van Tam. As the deputy director and then director of the TTF, ATF and ATTF, I was responsible for delivering the agreed objectives of the taskforces, including programme, budget and people management.

8. For a period in April 2020, ministers from the then Department of Business, Energy and Industrial Strategy ('BEIS') were involved in decisions regarding the work of the TTF before reporting lines were clarified so that the Vaccines Taskforce was based in BEIS and the TTF in DHSC, although there remained a number of areas of common interest, particularly in relation to neutralizing antibodies.

9. The Secretary of State – initially Matt Hancock, and latterly Sajid Javid – along with Lord Bethell was particularly involved in the TTF and ATF, holding regular meetings and receiving frequent updates on progress. Lord Bethell also chaired the TTF/ATF Engagement Board, the main formal body for working with external partners.

10. The Engagement Board was part of the overall TTF and ATF governance structures. These were reviewed and amended at regular intervals over the three years, to reflect the changing context, the decisions that needed to be made, and the course of the pandemic. They also provided formal routes of engagement across government, for example through membership of the Executive and Programme Boards, to complement direct working relationships.

ATTF's role, functions and responsibilities

11. In general terms, the ATTF was responsible for the provision of safe and effective therapeutics for the whole UK, including the Devolved Administrations ('DAs'), Crown Dependencies and Overseas Territories where it was not possible through other arrangements for these to be made available.

12. It became apparent very early on in conversations with pharmaceutical companies that they were looking to engage at national levels in respect of potential supply agreements. Accordingly, where the Department procured therapeutics for the treatment of COVID-19 that could not be secured through normal routes, such as with the generic drug dexamethasone, which was in routine use already, the volume was intended for the whole of the UK and was allocated using the Barnett formula (the mechanism used to calculate funding across the DAs). The DAs remained responsible for the identification and treatment of COVID-19 patients. Letters sent from the Secretary of State to the Four Nations in July 2020 and December 2020, confirming UK wide procurement of stockpiles by the Department, can be found at [CT/1 - INQ000279786; CT/2 - INQ000279787; CT/3 - INQ000279788; CT/4 - INQ000279785; CT/5 - INQ000279809; CT/6 - INQ000279810; CT/7 - INQ000279811].

13. It was agreed as an early principle that interim clinical access policies – i.e., policies which determine the cohorts of patients potentially eligible for COVID-19 treatment – would apply across the whole UK, meaning that there would be no difference in eligibility for patients in England versus Scotland versus Northern Ireland versus Wales. The interim clinical access policies were issued by the four Chief Medical Officers. Similarly, clinical research was conducted on a cross-UK basis whenever possible.

14. The TTF was established at the start of April 2020, very soon after the establishment of the Vaccines Taskforce ('VTF'), and was intended as a complementary structure, recognising that prior to the development of a vaccine – and even with an effective vaccine – there was an urgent need for safe and effective therapeutics to minimise the risk of death and serious illness as a result of the pandemic. Whilst vaccines were ultimately given more resources and ministerial attention, therapeutics were regarded as important and there were frequent ministerial updates on their development. There was also CMO and DCMO input into the development of therapeutics, as well as engagement from other senior stakeholders such as the NHSE Medical Director and the Chief Executive of MHRA.

15. The initial focus of the TTF was on repurposed drugs (meaning drugs that were already licensed for use for other conditions) as these were available to put into clinical research. As our collective understanding of the disease and the virus developed, pharmaceutical companies were able to take forward the development of novel treatments (meaning drugs that were not already licensed for other conditions) either through the acceleration of existing work on antivirals for coronaviruses or through the development of COVID-19 specific treatments, including those derived from patients who had recovered from COVID-19.

16. The TTF was intended to provide an end-to-end view of the drug identification, development, approval, procurement and administration process, removing barriers to swift progress and reducing the normal time taken for new treatment options to be made available on the NHS. Having a single team with responsibility for making treatments available to patients meant that we were able to run different stages in parallel rather than sequentially. For example, with the monoclonal antibody treatment Ronopreve, because it is administered via an intravenous ('IV') infusion, we identified at an early stage that new out-patient facilities would need to be commissioned by the NHS to administer the treatment in appropriate settings as existing suitable infrastructure was not available. Close liaison with the company developing and trialling the treatments meant that we knew what was required operationally, such as how long the treatment takes to administer plus the observation period afterwards to monitor for an adverse reaction. We were also able to be sighted on when the company was aiming to get marketing authorisation from MHRA to make the product available in the UK. This also supported the procurement process, enabling a supply agreement to be signed that made the product available to UK patients without delay after MHRA approval. Continued close working with the company regarding the impact of new

variants on Ronopreve after it was being used to treat NHS patients meant that we were able to communicate promptly and clearly when the Delta variant undermined its efficacy.

17. The ATF was established in April 2021 to give a specific impetus to the development of novel, oral antivirals. This reflected the developments in research which meant that several companies were starting to make progress in this area. Previous focus had been on treatments to stop those patients who were admitted to hospital from deteriorating, and to stop those in intensive care units ('ICU') from dying. The treatments that were becoming available for the treatment of mild COVID-19 (i.e. in non-hospitalised patients) required outpatient administration, such as through an intravenous infusion, which is an expensive and resource-intensive method of treatment and requires COVID-19 patients to come into healthcare settings to receive treatment.

18. The intention of the ATF programme was to make available a treatment which could be taken orally by patients without requiring specialist medical support, for example tablets or capsules. The Prime Minister's objectives for the ATF were for at least two oral antivirals to be made available by winter 2021/22. These objectives were reflective of the fact that it was anticipated that a patient may need to receive treatment using a combination of drugs, as well as that some patients might be unable to receive a particular treatment due to existing medication or conditions. Having a range of treatments would also mitigate against the risk of the virus developing to evade all available treatment options. The Prime Minister's objectives were met with the introduction of molnupiravir in November 2021, followed by nirmaltrevir and ritonavir in February 2022.

19. Despite the overall success, the development of oral antivirals did face some obstacles. During clinical development, the number of candidates with early promise did not translate into robust phase III trial data to support licensing. For example, the Roche/Atea collaboration on AT-527 ended following the disappointing trial results published in October 2021. There were also challenges with forecasting the appropriate volume of treatment courses to procure, as this relies on robust forecasts of disease prevalence in both the general population and the population expected to have the most clinical benefit from treatment.

20. The ATF was established in parallel with the TTF to provide specific focus, including that provided by the externally appointed chair, Eddie Gray. My Senior Responsible Officer ('SRO') responsibilities were extended to include both the ATF and the TTF. Recognising that the experience of the TTF would be invaluable to achieving the ATF objective, staff worked across both taskforces as required. Additional staff were brought into the programmes to provide further resource.

21. Because the ATF had a time bound objective, it was agreed by ministers that it would be appropriate to bring it to a close once that was achieved [CT/8 - **INQ000257267;** CT/9 - INQ000391269]. Some elements of delivery were still required, however, in both the ATF and TTF space, and it was therefore also agreed by ministers that the two taskforces should be re-amalgamated and renamed the ATTF, and that the ATTF programme should aim to close by the end of March 2023.

22. The rationale behind the re-amalgamation of the taskforces was that further work was still required to embed the treatment options that had already been introduced to the NHS. Further work was also required to continue exploring the options for treatment and for pre-exposure prophylaxis that were still being developed. Important clinical research, notably PANORAMIC, was also still ongoing. In addition to this, work was still needed on how to respond to the changing epidemiology, such as where a new variant meant that an existing treatment became less effective, and to move back towards business-as-usual approaches for procuring and making available novel treatment options, including supporting the eventual NICE technology assessment.

23. The amalgamation happened in April 2022 and was relatively straightforward, as there were limited changes to staffing or reporting lines as a result, although we took the opportunity to refresh Terms of Reference and membership of the boards involved in the delivery and governance of the programmes. The timing of the amalgamation felt appropriate as the primary objective of the ATF had been achieved. Re-amalgamation prior to achieving the goal would have been counterproductive.

24. The ATTF programme was closed as the acute phase of the pandemic had passed and, in addition to the vaccines, a range of therapeutic options had been made available to treat patients at every stage of disease progression. The value of retaining a COVID specific programme in this space was diminishing, and it was time to support

the transition back to business-as-usual approaches to procuring new drugs for the NHS.

25. The Terms of Reference for the ATTF Strategy Board and Programme Board can be found at [CT/10 - INQ000391270; CT/11 - INQ000391272]. I consider that the core aims and objectives set out in the Terms of Reference were met in full.

Relationships, accountability and governance

26. I am asked for details of key bodies and individuals with whom the ATTF and its predecessors co-operated and worked with. I list the main ones as below:
    a. The Medicines and Healthcare Products Regulation Agency ('MHRA')
    b. The National Institute for Health and Care Excellence ('NICE')
    c. UK Research and Innovation /Medical Research Council
    d. Public Health England / UK Health Security Agency
    e. NHS England
    f. National Institute for Health and Care Research ('NIHR')
    g. The Scottish Government
    h. The Welsh Assembly
    i. The Northern Ireland Executive
    j. His Majesty's Treasury ('HMT')
    k. The Cabinet Office
    l. The Foreign Commonwealth and Development Office
    m. The Department for Business, Energy and Industrial Strategy (as was)

27. In practice the relationships between these individuals and organisations worked through a mix of formal and informal interactions. For example, representatives from relevant organisations would sit on boards as part of the formal ATTF governance arrangements as well as having regular calls with me to discuss topical issues on a less formal basis.

28. The ATTF and its predecessor taskforces were directorates within the Department and were not independent as such. However, the ATF in particular benefitted from an externally appointed chair, giving the programme considerable freedom in respect of the strategic approach to tackling the agreed objectives.

29. The ATTF (and the TTF and ATF) were part of the Department's Battleplan process. This involved providing regular oversight and assurance in respect of delivery against the agreed objectives of the taskforces. These objectives related to responding to the pandemic or considering issues, particularly where they impacted more than one area, which were impeding progress.

30. The three taskforces were also reviewed through the DHSC Biannual Assurance process, which is the six-monthly review of delivery against targets chaired by the Permanent Secretary.

31. In respect of potential conflicts of interests, the Department has policies which apply to all staff employed by the Department, including those working in the ATTF. All senior civil servants are required to confirm "nil returns" as well as provide details of potential conflicts. The ATF chair and expert advisers completed Conflict of Interest forms as part of the appointment processes.

32. The Urgent Public Health (UPH) process was run by the National Institute for Health and Care Research (NIHR). NIHR representatives were included in the relevant governance boards of the ATTF (and predecessor taskforces) but decisions on UPH badging – i.e., designating a study as having UPH status – were not the responsibility of ATTF.

33. The ATTF provided advice to ministers on a number of areas, including proposed objectives, strategic approach and individual procurement options, with decisions taken by ministers and delivery delegated to the SRO in the usual way.

34. Clinical eligibility for treatment was (and is) determined by individual clinicians, supported by the interim clinical access policies agreed by the four CMOs on the basis of recommendations by RAPID C-19 (see section 'RAPID C-19' below).

35. Regulatory decisions were taken by MHRA and the Health Research Authority ('HRA'), considering all the available data in relation to safety and effectiveness.

36. Procurement decisions were made by ministers, supported by full business cases and other analysis developed by the ATTF and other Department analysts which considered cost effectiveness so far as possible given the limited data available to support decision-making at pace.

37. The ATTF engaged widely with companies based in the UK and internationally, to explore potential new drugs in development and to expand scientific understanding.

38. Supply agreements for COVID-19 therapeutics outside of normal NHS supply arrangements were as follows:
    a. Gilead supplied remdesivir – initially through EU Joint Procurement Agreement arrangements, then supply agreement for UK;
    b. Roche supplied casirivimab/imdevimab;
    c. Pfizer supplied nirmaltravir+ritonavir;
    d. MSD supplied molnupiravir;
    e. GSK supplied sotrovimab.

39. I cannot speak to vaccine procurement, however in relation to antivirals, the UK did not purchase any therapeutic drugs whilst they were still in development. The supply agreements for the therapeutics provided a contractual basis to procure treatments should they receive marketing authorisation from the MHRA, in line with the regulations on the supply of medicinal products for wide-spread use in the UK. The antivirals were effectively 'ring-fenced' at an agreed price, to be purchased when they were licensed. This would ensure there was a minimal gap between the decision to purchase and the treatments reaching patients.

40. ATTF also procured generic drugs from various wholesalers, for example high dose ascorbic acid not normally available within the UK to provide supply for clinical trial.

41. The commercial team within the Department agreed and signed all supply agreements.

Timeline

42. In respect of the key events relevant to the work of the ATTF I would expect these to be covered within the Department's corporate statement and chronologies. Similarly, I would expect key documents to be provided by the Department directly.

UK & International Research

43. The ATTF supported a number of trials and research projects in various different ways, according to what was required to enable the trial to deliver its objectives. This ranged

from communications support (such as the "Ask JVT" video to support PANORAMIC); messaging to the research community (such as the letter from the four CMOs [CT/12 **INQ000069095];** provision of trial supply where it was not otherwise available in the UK; and supporting the trial leads as a community to learn from each other and provide peer support. The ATTF also liaised with companies conducting research in the UK to help them overcome barriers to set-up and completion.

44. I was involved in all aspects of this work throughout the period in question, but my exact role varied at different points in time. For example, I led early engagement with companies who were able to provide supplies to support a clinical trial in the UK to test potential COVID-19 treatments, but as the ATTF grew, other members of the team took the lead on this.

45. The key trials were:

a) RECOVERY: a large-scale trial of possible treatments for patients hospitalised with severe COVID-19 infection. The results can be found at [CT/13 - INQ000391250; CT/14 - INQ000391244; CT/15 - **INQ000472233;** CT/16 - INQ000391248; CT/17 - INQ000391245; CT/18 - INQ000391246; CT/19 - INQ000069699; CT/20 - INQ000391259; CT/21 - INQ000391258; CT/22 - **INQ000069584;** CT/23 - INQ000391243; CT/24 - INQ000391251; CT/25 - INQ000391247].
b) REMAP-CAP: an international adaptive platform trial in community acquired pneumonia, that was specifically designed to be employed in a pandemic to evaluate multiple interventions simultaneously in critically ill patients. The results can be found at [CT/26 - INQ000391262].
c) PRINCIPLE: the world's largest clinical trial of COVID-19 treatments for recovery at home, focusing on those most at risk of serious illness from COVID-19. The results can be found at [CT/27 - INQ000391263].
d) AGILE: a phase I/II study to help determine the optimal dose, safety and efficacy of various potential treatments.
e) PANORAMIC: set up to identify which groups of higher risk people were most likely to benefit from new antiviral treatments for COVID-19. The study allows multiple antiviral drugs to be tested in parallel. The results can be found at [CT/28 - INQ000391271].

f) HEAL-COVID: testing potential treatments to determine whether they can improve the longer-term outcomes for patients who have been discharged from hospital after recovering from COVID-19. The results can be found at [CT/29 - INQ000391256].

g) PROTECT-V: testing prophylactic interventions for COVID-19 in vulnerable renal and immunocompromised patients. It aims to test their effectiveness at reducing infections at events such as regular hospital check-ups or dialysis appointments.

h) PROTECT-CH: testing prophylactic treatments for COVID-19 in care home residents. The study was stopped after 10 months due to no longer being feasible.

i) STIMULATE-ICP: testing the effectiveness of repurposed drugs to treat long COVID by measuring the effects of three months' treatment, including on people's symptoms, mental health and outcomes such as returning to work.

46. By working closely with the trial leads, ATTF was able to prepare effectively for the outcome of testing specific drugs to reduce the time needed to make treatment available to NHS patients (where the results for the drug were positive) and to ensure that the findings were understood in the UK and globally, including negative results. For example, when the RECOVERY trial announced their findings in relation to dexamethasone on 16 June 2020, including at the televised press conference led by the Prime Minister that day, the interim clinical access policy was published within hours, making this drug standard of care for all eligible patients. As discussed in paragraph 43 of this statement, the ATTF worked with trial leads by ensuring there was a space for them to share their knowledge and provide each other with peer support. A specific example of how this was beneficial would be the protocol agreed between the RECOVERY and REMAP-CAP clinical trial leads regarding the enrolment of hospitalised patients who could be eligible for either trial, to ensure that both were able to operate successfully in the same locations.

47. It should be noted that the ATTF did not hold personal data from participants in clinical trials.

48. Significant effort and attention were paid to health inequalities and inequities, particularly as evidence began to emerge regarding higher risk cohorts of patients in relation to certain protected characteristics and vulnerabilities.

49. For example, trial leads were supported to increase recruitment from ethnic minority patients through the NIHR Equality Diversity and Inclusion work [CT/30 - INQ000391273]. Where appropriate, trials have added paediatric arms and to enable pregnant women to be added to the inclusion criteria, on the basis of available safety data and following approval by MHRA and HRA and in consultation with patient groups and experts [CT/31 - INQ000391255].

50. Some trial drugs were or are not appropriate for these patients; for example, molnupiravir may have teratogenic properties (meaning it can interfere with embryonic development) and so is unsuitable for pregnant women.

51. NHSE data on treatment was analysed at the NHSE Antivirals Steering Group meetings attended by ATTF, for example to consider apparent differences in diagnosis and uptake, with integrated care boards ('ICBs') responsible for ensuring equality and equity in access.

52. Patient groups were represented on the ATTF Engagement Board and provided invaluable advice on matters such as hard to reach groups.

53. We were very conscious that multiple treatments were needed to provide options to meet patient needs. For example, some renal patients are unable to take nirmatrelvir+ritonavir so may be prescribed sotrovimab instead, whereas older or frail patients or patients with a learning disability may struggle with an IV infusion and an oral treatment may be preferable.

The role of new and repurposed medicines

54. As set out above, the initial focus was on repurposed medicines because novel medicines were not yet available. Early in vitro research suggested that certain repurposed medicines might be useful to either counter the virus or treat the symptoms of COVID-19. The UK approach was to put these into clinical trials to understand whether this theoretical promise was borne out in clinical practice. Because of the wider issues being experienced with supply chains, even before the TTF was established it was decided to stockpile certain medicines with potential utility in anticipation of use in COVID-19 where to do so would not adversely impact their

availability to treat patients for other conditions. This included dexamethasone, hydroxychloroquine and ritonavir/lopinavir.

55. Even when licensed, novel treatments were not available for stockpiling, as – at least initially – companies were trying to meet global demand for products in short supply.

56. Early in the pandemic in particular, there was strong pressure to put certain drugs straight into clinical practice if there was potential for them to have patient benefit. The UK determined that robust evidence was required to support the use of any therapeutics and set up the RECOVERY and PRINCIPLE clinical trials to evaluate the use of therapeutics in hospitalised and non-hospitalised patients respectively and supported the pivot of REMAP-CAP from its original purpose of studying Community Acquired Pneumonia in ICU to COVID-19 in ICU patients. Each of these platform trials generated important data regarding treatments that worked but also treatments that did not.

57. The ATTF amplified the publication of clinical trial results for both positive and negative outcomes. It also ensured that key international partners, such as the other countries in the Five Eyes alliance (the United States, Canada, Australia, New Zealand) were aware of developments in our understanding of how best to treat the disease.

RAPID C-19

58. The RAPID C-19 collective was established in April 2020 to provide an alternative method of considering the available data on safe and effective treatments to consider whether they should be made available to NHS patients ahead of the formal assessment of cost and clinical effectiveness undertaken by NICE under standard arrangements. Details of the group and its processes can be found at [CT/32 - INQ000391264; CT/33 - **INQ000315554;** CT/34 - INQ000330922].

59. The work of RAPID C-19 was innovative and agile, significantly expediting patient access whilst ensuring that the decisions made by the four CMOs on whether to make a drug available to NHS patients or not (and to which specific cohorts of patients) were rooted in robust evidence and analysis.

60. Representatives from ATTF attended RAPID C-19 meetings. This helped, for example, to ensure that decisions on access were supported by relevant information on supply availability of specific drugs, or to provide policy context for issues under consideration by RAPID C-19. The ATTF was not a decision-maker for the RAPID C-19 process. The ATTF made a small amount of funding available to support the operation of RAPID C-19 in the financial year 2022/23, including the completion of a lessons learnt exercise [CT/34A - INQ000469758]. The decision-makers for the ATTF were the RAPID C-19 Oversight Group.

61. The chair of RAPID C-19, Carla Deakin (programme director for commercial and managed access at NICE), was a member of the ATTF Programme Board, to help ensure clear lines of sight of programme objectives and delivery.

62. The role of the UK COVID-19 Therapeutics Advisory Panel (UK-CTAP), chaired by Patrick Chinnery, was to consider potential treatments, including those submitted through an open nominations' portal. The UK-CTAP website records details of treatments considered and recommended by it for national publicly funded trials.

63. UK-CTAP was part of the Clinical Trials Infrastructure National Core Study formed to accelerate delivery of large-scale trials for COVID-19 treatments. I, or another member of the team, attended UK-CTAP meetings. We actively participated at these meetings but were not the decision makers. We provided useful context for the decisions that were being made, for example regarding supply limitations.

64. The Panel reviewed available scientific evidence and made recommendations to the principal investigators of each trial and Professor Chris Whitty, the Chief Medical Officer for England (CMO England) and Chief Scientific Adviser for the Department.

65. Further information on this panel can be found at [CT/35 – INQ000391265].

Pre-Exposure Prophylaxis (PrEP)

66. Monoclonal antibodies ('MAbs') – laboratory made proteins that act like human antibodies in the immune system – were originally a VTF lead, given their potential role in pre-exposure prophylaxis (PrEP) as an alternative to vaccination should the vaccine development programmes be unsuccessful.

67. The TTF worked closely with the VTF in respect of monoclonal antibodies that showed potential for use as a treatment. For example, the decision to put casirivimab/imdevimab into the RECOVERY trial in September 2020 was led by the VTF with input from the TTF, amongst others. As the vaccine programmes developed, responsibility for PrEP was moved to the TTF. RAPID C-19's role was similarly expanded to encompass PrEP, as well as treatment.

68. The change in responsibility for PrEP was implemented as it became clearer that there would be at least one effective vaccine and because the MAbs being developed still had potential for both PrEP and treatment use. If responsibility had remained with the VTF, the position may have arisen where VTF and TTF were both negotiating with the same company for the same product, but for different uses. I agreed with this shift in responsibility, though it did change the remit of the TTF in a fundamental way that was perhaps not fully anticipated initially. This includes the different stakeholder groups that were now within scope of the TTF.

69. Within the TTF, PrEP was an important strand of the programme and increasing amounts of resources were put onto key policy issues such as understanding the cohorts of patients who might benefit from PrEP.

70. The TTF work in relation to PrEP encompassed significant engagement with companies developing potential treatments, as well as supporting clinical research in this area. PROTECT-CH was intended to research the use of PrEP in care homes but was unable to recruit sufficiently to be able to undertake this work. PROTECT-V was established to research the use of PrEP in vulnerable patients who were unlikely to be protected by vaccination. This started with renal patients but was expanded to include other categories of vulnerable patients as well. PROTECT-V opened to patient recruitment in February 2022 and (at the time of writing) is researching inhaled niclosamide, an anthelminthic drug normally used to treat parasitic infection, and sotrovimab, a novel monoclonal antibody made by GSK and licensed for the treatment of COVID-19 in the UK as Xevudy.

71. Other potential prophylactics considered by the ATTF include SNG001, a novel inhaled interferon beta developed by the company Synairgen, as well as the nitric oxide nasal spray now marketed as Sanotize and monoclonal antibodies, including Evusheld, which is discussed in more detail in paragraph 75 below.

72. In anticipation of an effective PrEP being developed, the CMO commissioned work to be taken forward under the auspices of a Prophylaxis Oversight Group, chaired by David Lalloo and supported by the ATTF. This included consideration of the cohort of patients who would be both unlikely to benefit from vaccination and also be at higher risk of adverse complications from COVID-19. More detail on the work of the Therapeutics Clinical Review Panel is available at [CT/36 - INQ000391266].

73. One of the downsides of monoclonal antibodies is that they can be more vulnerable to becoming less effective when the virus mutates, depending on the changes seen in the virus and the mechanism of action of the MAb. A MAb may need to be withdrawn from use if it is not believed to be effective, either following confirmed infection genotyping or on the basis that community prevalence means that the patient is most likely to be infected by the variant that is not susceptible to the MAb. For example, casirivimab/imdevimab was withdrawn from use in the UK when the Omicron variant became dominant, as in vitro testing demonstrated that it was not effective against that variant.

74. The downside becomes more pronounced in respect of PrEP, as it is hoped that administration of a PrEP would provide longer lasting protection to enable vulnerable individuals to resume a more normal lifestyle. If there is uncertainty about the likely level of protection, vulnerable individuals either run the risk of contracting COVID-19 or deciding to adopt habits and behaviours which curtail their life. In both cases, the purpose of a PrEP programme has been undermined.

75. Evusheld is a PrEP treatment composed of the two MAbs tixagevimab and Cilgavimab and manufactured by AstraZeneca. The decision to be made by ministers in respect of Evusheld hinged around whether the UK should enter into an advance purchase agreement to secure supply in advance of the normal regulatory assessments, and cost and clinical effectiveness appraisals undertaken by MHRA and NICE respectively. Examples of where ATTF advised ministers to seek to secure supply in this way included sotrovimab, casirivimab/imdevimab, nirmatrelvir, ritonavir and molnupiravir. Despite significant consideration of the data available at different points in time, and preparatory work completed to ensure readiness for deployment should procurement be taken forward, the ATTF concluded that there was a lack of robust evidence to support a recommendation for procurement of Evusheld outside of the normal processes and ministers decided not to proceed down this route. The ministers

responsible for taking this decision were the Secretaries of State, at this time, Sir Sajid Javid and then Steve Barclay. Details on the evaluation process have been published and are exhibited at [CT/37 - INQ000391257]

76. Prior to becoming the responsibility of the ATTF, Evusheld was originally the responsibility of the VTF, being seen as an alternative line of defence if vaccines were not successful. The ATTF had collaborated with the VTF in regard to Evusheld and when it became clear that the vaccines were successful, the VTF began to pull away. As the ATTF was still interested in MAbs for treatment purposes going forward, responsibility of Evusheld shifted to the ATTF. In hindsight, if the VTF had sat within DHSC, Evusheld probably would have remained the responsibility of the VTF and would have been better sat there. There is also the possibility that pre-exposure prophylaxis could have been the responsibility of a specific team, but I believe the outcome would have remained the same in any case. In relation to Evusheld, as with all procurements that did not follow the usual process of NICE appraisal prior to patient access, the ATTF considered the available data and information and made recommendations. Similarly, RAPID C-19 were making clinical recommendations to CMOs to inform advice to ministers as the decision-makers.

77. The ATTF were in frequent contact with AstraZeneca, the developer of Evusheld, over many months AstraZeneca were keen for a purchase to be made and were actively engaging in discussions regarding different purchase agreements. These discussions were taking place at ministerial level, including when Steve Barclay replaced Sir Sajid Javid in July 2022. However, the clinical evidence did not justify the purchase of Evusheld outside the usual processes for making treatments available on the NHS and an agreement was never reached with AstraZeneca.

78. For the purchase of Evusheld to be a good clinical decision, it had to be able to prevent people contracting COVID-19 or lessen the severity of the disease significantly. If this was not the case, those who were shielding would not have the reassurance needed to feel confident to begin going out again. The clinical evidence that Evusheld would be effective at preventing COVID-19 infections or lessening the severity of the disease significantly was limited, with a high “number needed to treat” - that is, the number of people who would need to receive treatment in order for one person to benefit. Further to this, as with all MAbs, Evusheld was vulnerable to being compromised by new variants of the COVID-19 virus both in theory and in practice. As the Omicron (BA) variants emerged, the data to support the use of Evusheld was limited further. Initially

countries such as the USA who previously purchased and used Evusheld issued guidance to increase the recommended dose of Evusheld, but in time they withdrew it from use and recommended against its use as PrEP for COVID-19.

79. It is worth noting that the logistics of a PrEP programme were relatively complicated, with Evusheld needing to be administered in a clinical setting (unlike the vaccines), and the need to ensure that patients who were more vulnerable to the effects of COVID-19 would be appropriately protected from the risk of catching COVID-19 during their visit to receive PrEP treatment. Detailed planning and preparation work was undertaken in case a decision was taken to deploy Evusheld or another PrEP product.

80. Whilst the whole cost of standing up a PrEP programme was, of course, considered, it was not the determining factor in the decision not to procure Evusheld outside of the normal processes.

81. I have been asked to provide an estimate of when Evusheld would have been available had it been purchased. Without a great deal of speculation, it is impossible for me to say what would have happened had we decided to go ahead with the purchase of Evusheld.

82. I am familiar with the work of Kate Bingham, but I am unaware of the suggestion as quoted that prophylactics should not be purchased because of the availability of treatments.

83. As detailed above, a range of effective treatments were available to treat patients at all stages of disease progression. Support for immunocompromised patients in general did not come under the remit of the ATTF and therefore was not my direct responsibility. However, the ATTF continued to ensure that there was a good supply of treatment drugs so that patients, including the most vulnerable, who became unwell with COVID-19 were able to recover.

Public Safety, ethical standards and transparency

84. The MHRA retained its existing responsibility for determining the safety of therapeutics as part of the regulatory process. ATTF supply agreements were contingent upon products successfully receiving marketing authorisation from the MHRA to enable them to be sold in the UK.

85. The MHRA also retained responsibility for the "yellow card" system, which allows clinicians and patients to report adverse events.

86. The chair of the ATF made a specific request for a toxicology expert to be part of his steering group, to ensure that safety was considered as a key part of the ATF approach.

87. The ATTF and predecessor taskforces had pages on GOV.UK, setting out the objectives of each programme. The ATTF was covered by the Freedom of Information Act 2000 and responded to requests for information in line with departmental policy and legal requirements. Latterly, information relating to the decisions regarding prophylaxis (including Evusheld) was published and is exhibited at [CT/37 - INQ000391257].

88. The Engagement Board, supplemented by bilateral engagement with key stakeholders, provided a forum to present progress and an opportunity to discuss and challenge the strategic approach and delivery plans, particularly during the first two years of the TTF/ATF.

89. The ATTF used public "talking heads" on a small number of occasions where it was particularly important to reach a wider audience than clinical experts, the science media or patient groups. For example, the deputy Chief Medical Officer, Professor Jonathan Van Tam, recorded a short video that was released by the Department in January 2022 to explain how antivirals work to promote enrolment into the PANORAMIC trial [CT/38 - INQ000391260], whilst in 2020 public figures such as Kate Garraway and Lord Darzi spoke about the importance of clinical research, encouraging patients to enrol if they had the opportunity to do so [CT/39 - INQ000391261].

90. The NHS Blood and Transfusion Service were responsible for public engagement and communication in support of the programme to collect convalescent plasma.

91. In my opinion external communication to the public was effective and, I hope, sufficiently addressed any concerns that may have arisen.

Achievements and Closure

92. I am immensely proud of the achievements of the ATTF, which are wide ranging and significant. These include:
    - ensuring that the decisions made were supported by rigorous evidence and data.
    - supporting the completion of clinical research to generate data, used for decisions on access in the UK but also globally, including the REMAP-CAP trial's positive finding on tocilizumab and identification of a class effect (that is, the type of drug has an effect rather than this being limited to the specific drug) with its findings on sarilumab for critically ill patients, and the confirmation by the RECOVERY trial of positive findings on tocilizumab in patients hospitalised for COVID-19 treatment.
    - ensuring supply was available as soon as possible, and without interruption, to NHS patients. We were the first in the world on a number of occasions to secure supply or to treat patients with safe and effective therapeutics. Examples included the change to the standard of care for COVID-19 patients in hospital receiving supplementary oxygen within hours of the publication of positive RECOVERY findings on dexamethasone; and patient access outside of a clinical trial to the novel treatments molnupiravir, nirmaltrevir+lopinavir and sotrovimab.
    - establishing and maintaining a consistent four nations approach, and also making supply available to Crown Dependencies and Overseas Territories which may not have otherwise had a local supply. We secured arrangements with FCDO and MoD to provide access to crown servants and their families overseas without local access to treatments.
    - contributing to the saving of many lives by feeding into the development of effective treatment following the success of the various clinical trials as discussed above. Research published by NHSE in 2021 estimated that the

dexamethasone data from the RECOVERY trial was responsible for saving over 1 million lives globally [CT/40 - INQ000391249].

Lessons Learned

93. I have given considerable thought to the lessons that can be learnt from my experience of the work I have detailed above. These observations are my own and should not be taken to represent the Department's corporate position, which may differ.

94. My experience has made me reflect on the importance of research and making decisions on clinical access based on reliable data. I consider it extremely important for taskforces such as these to have a coordinating function to oversee the end-to-end approach. This ensures someone has sight of all the different parts, in order to speed up handovers between different parts of the process and to be able to look ahead to the likely challenges and anticipate, as far as possible, how best to respond to these.

95. I consider it extremely important that clear signals are sent to industry by the government, indicating the strategic priorities and intention to procure products that meet requirements, in order to give companies confidence to invest in developing novel products and to, for example, manufacture at risk.

96. It is of course important to retain key elements of process, for example regulatory approval, but also to agree where these can be expedited or where bespoke arrangements are required in order to move at pace, for example for procurement to take place ahead of full NICE appraisal.

97. I understand that the treatment landscape is more complicated than the vaccines and prevention landscape. This is due to, for example, the different stages of disease, different patient needs, the need for testing and diagnosis and the potentially short window to treat for best effect. These issues require different and innovative ways of thinking and solutions to ensure impact can be made at the right time. I also appreciate that there are literally thousands of potentially effective compounds, even before novel compounds emerge.

98. I can see that the first effective treatments to come through may have their roots in other diseases, therefore investing in research and development in these areas - even

where not directly benefitting the UK in the first instance - may have significant benefits in a crisis. I also see that treatments that are susceptible to variants are of limited utility: as the virus mutates they can become potentially less effective or even totally ineffective.

99. I consider it a necessity to have excellent structures and facilities that can be pivoted and focused onto new priority areas. One upside to having high rates of disease means that it is possible to enrol trial participants more quickly and complete research more quickly. The importance of cooperation and timely information sharing cannot be emphasised enough. The letter from the four CMOs and NHSE Medical Director [CT/41 - INQ000391240] reinforcing the importance of clinical research as part of clinical care was a vital early message to health care professionals in the UK, and similar communication may be helpful or necessary in a future pandemic.

100. For pandemics, there is likely to always be an element of "chasing the wave", where research needs to be primed to take advantage of an increase in numbers and where different parts of the world are impacted at different times and being impacted by different variants.

101. Successful clinical trials require patients to consent to participate in research, and the thousands of patients who agreed to take part in vital research each made a very valuable contribution. Retaining patient confidence in high standards of research in the UK, particularly across a broad cross-section of the population, is likely to be critical in a future pandemic.

102. It would have been helpful at certain points to have had a more regularly updated, centrally agreed projection of our best understanding of the likely number of future cases, in order to underpin decisions for example on the volumes of treatments to procure. These were made available by the Cabinet Office at various points, but not updated as frequently as would have been ideal. I am not able to speak to the reasons for this.

103. Not having access to frequently updated information resulted in the use of RWCS projections which were widely acknowledged to be out of date. The alternative to this was to use our own models, which ran the risk of not being consistent with planning assumptions made by other parts of the COVID-19 response. This introduced a level of uncertainty to our analysis of certain data, for example optimal volumes to procure.

104. In the event of a future pandemic, having more frequent updates to the RWCS projections would help the teams who need to plan on the basis of projected case numbers, even if the conclusion of the update was that it was not possible to update the projections due to factors such as uncertainty and a lack of data.

105. A cross-UK position is likely to be the most appropriate to adopt in relation to treatment procurement and access policies.

106. Experts across the UK and beyond gave their time, knowledge and expertise generously and often without payment: their contributions to the successes of the ATTF are gratefully acknowledged and are likely to be required in a future pandemic.

107. Vaccines, diagnostics and therapeutics are all equally important elements of a pharmaceutical response to a pandemic, and all depend on each other to some degree.

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: 1 August 2024