Witness Name: Eddie Gray
Statement No: 1
Exhibits: EG/01-EG/99
Dated:

UK COVID-19 INQUIRY

WITNESS STATEMENT OF EDDIE GRAY

I, Eddie Gray, c/o Department of Health and Social Care ('the Department'), 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 Public Inquiry ('the Inquiry') dated 3 October 2023 made under Rule 9 of The Inquiry Rules 2006 ('the Request'). This seeks a statement concerning the role and involvement of the Antivirals Taskforce ('ATF'), which I chaired between 27 May 2021 and 1 April 2022, in response to the COVID-19 pandemic. At the Inquiry's request, within this statement I have primarily considered events which occurred between 20 January 2020 and 28 June 2022 ('the specified period'). However, much of my involvement within matters of interest to the Inquiry concern the more limited period of time when I chaired the ATF.

2. I am making this statement in my personal capacity and not as a corporate witness on behalf of the Department. This reflects the role I played as an external adviser and Chair of the ATF, as opposed to a politician or an official. I am therefore unable to assist the Inquiry with some of the areas of interest to it, as I was not involved in many of the matters which I am asked to address in the Request. I understand that corporate evidence is being provided to the Inquiry by the Department which will cover such matters. I have been provided with access to some relevant contemporaneous documents from my tenure as

chair of the ATF, and will endeavour to assist the Inquiry in as far as I can in answer to the Request.

3. In terms of my background, I have spent 40 years in the pharmaceutical and biotechnology sector. I was President of European Pharmaceutical Business at GlaxoSmithKline and a member of their corporate executive team, CEO of Dynavax Technologies, and a board member of the Association of the British Pharmaceutical Industry.

SECTION 1: STRUCTURE, ROLE, PEOPLE AND PROCESSES OF THE ATF

Appointment as Chair

4. I first became aware of the potential establishment of the ATF and expressed a willingness to become involved during an informal conversation with Sir Patrick Vallance (then the Chief Scientific Adviser ('CSA')) in approximately March 2021. Shortly thereafter, I recall having a phone conversation with the then Secretary of State for Health and Social Care ('Secretary of State'), Matt Hancock. During this call I again expressed my willingness to become involved in the ATF and explained that I would be available to work on this from early April 2021 onwards. The Secretary of State explained that the goal was for the ATF to obtain antiviral medicines for the winter of 2021. Given that there were only 30 weeks between my proposed start and the first week of November, I noted that this was an ambitious timescale.

5. I first wrote to Matt Hancock and the Department shortly after the telephone call with him because my being willing to take the role was in part dependent upon having a mandate I felt allowed me to be successful. This correspondence continued for some time. I was asked to take part in an interview process which involved submitting a written application and taking part in an interview. The interview was led by Clara Swinson. Following this, I was made aware that I was to be appointed as Chair of the ATF. Throughout this time period, further protracted correspondence took place between me and the Department concerning my letter of appointment. My aim was to ensure that this gave the Chair sufficient and clear authority to deliver the goals, in particular an ability to request/instruct officials, commensurate with the expectations of success of politicians and others. Back and forth correspondence ensued. Each time I felt that the Department attempted to excise or dilute my primary requests concerning the authority of the Chair, which left an impression of wishing to restrict the scope of influence and authority of an external appointee. In late May I received a call to inform me that SoS Matt Hancock was

announcing my appointment at 5pm that afternoon. Expressing concern that we had no agreement on the appointment letter, I was told 'not a problem, we agree to everything you proposed'. I exhibit my letter of appointment **(EG/01 - INQ000410503)**.

6. The speed of this process was disappointing, as it was nearly 2 months after I had been available before I began work on the ATF. In effect, a project with extremely tight timelines had taken 25% of the available time to appoint its Chair. I felt that this was an example of primacy being given to following a process, over urgency and outcome. Interestingly, when meeting the external advisors that the Civil Service had been consulting, they said to me, 'thank heavens you're here, we've been saying for months this was necessary'.

7. Why did a process to appoint a Chair of a time dependent project, a potentially important contributor in a pandemic and already announced by the PM, take 25% of the project's available time, when it was essentially an administrative task? It is not clear why. There are a number of possible reasons, none of which reflect well on decision making.

8. The most simple and least complicated is incompetence: having a standard process to be followed but not expediting it in a timely manner. The second and perhaps most likely was an inability to understand relative risk and to then prioritise the wrong component. This appointment had on one side a need for an experienced, senior individual willing to take the role. Immediate appointment of such an individual maximised the impact of an external appointment that had already been identified as necessary. 0% of the available project time would be lost. The balancing risk was a perceived need to demonstrate that an open recruitment process had taken place. Prioritising this element resulted in 25% of the available project time being utilised in making the appointment. What was the risk? Presumably, that a candidate with equivalent or greater experience may be identified, or at a later date emerge to complain about not being considered. Of course, I cannot say that either of these was impossible, but the key question is whether the likelihood or the benefit of either possibility was worth the loss of 25% of the available project time. In either instance, a confident answer that a Chair appointment in early April rather than June trumped any benefit of either of these alternatives was a convincing and easy answer to communicate, and in addition a much clearer assessment of the relative risk. The third reason is possibly overly influenced by my experience in agreeing a letter of appointment. That the slow process, and prioritising of the process objectives, reflected as reference above a lack of desire for an external appointment, and this was a defendable means of delaying the inevitable.

Role and Structure of the ATF

9. The ATF was established in 2021 to identify two effective oral antiviral treatments for COVID-19, and to provide advice to the UK Government on development and procurement of these medicines by the end of that year. I am unable to comment on the decisions to establish (or dissolve) the ATF, or the timings thereof, as these were decisions taken by the Department in which I played no part.

10. Although I was not involved, the Therapeutics Taskforce ('TTF') had been established by the UK Government at the beginning of the pandemic to investigate and obtain safe and effective treatments to combat COVID-19. I played no role within the TTF and cannot assist the Inquiry with its operations, but I understood that the ATF was spun out of the TTF to consider the single issue of procurement of oral antivirals. At the time of my appointment, the TTF was led by Charlotte Taylor (a Director within the Department), who I believe also held the position of the Senior Responsible Officer ('SRO') for the ATF.

11. My understanding was that the Department intended the ATF to follow a similar path to the Vaccine Taskforce ('VTF'), which had been successful in identifying and supporting the procurement of COVID-19 vaccines during 2020. I was not involved in the VTF but was aware of its excellent work under the leadership of Kate Bingham.

12. My role as the Chair of the ATF was to lead the work set out within my letter of appointment. In this position I reported to the Secretary of State (Matt Hancock, and later Sajid Javid) and Parliamentary Under Secretary of State for Technology, Innovation and Life Sciences (Lord Bethell, and later Lord Kamall). I also worked closely with the CSA Professor Lucy Chappell and the Deputy Chief Medical Officer ('DCMO') Professor Jonathan Van-Tam. I also interacted with the Office of the Chief Medical Officer ('CMO') Professor Sir Chris Whitty, the senior leadership of the NHS and other academics. I was supported in my role by a team of civil servants within the Department.

13. Following my appointment, a Steering Committee for the ATF ('the Steering Committee') was established. Membership of this committee was shared roughly equally between Charlotte Taylor (and her direct reports) and external clinical, scientific and industry advisors. In addition to Charlotte Taylor and myself, the steering committee members were Professor Sir Michael Jacobs who was a physician at Royal Free Hospital, Nick Cammack from the Wellcome Trust, Timothy Hammond, Ruth McKernan, Steve Felstead, Elna van der Ryst and Micheal Westby who were all industry experts in different areas. Jeanette

Howe joined the committee for her pharmacy input. Gordon Muirhead and Jane Stewart agreed to be 'on-call' members who attended as and when their expertise was required. The advisors had been involved and consulted 'ad-hoc' prior to the formation of the ATF. The Steering Committee convened three mornings a week with an agenda of discussion and debate, assessment of reports and progress, decisions and actions. The membership of the steering committee was my way of ensuring that the right balance of scientific and Civil Service skills in addressing the strategic questions was utilised. The primary intent was to focus this combined team on answering the key strategic questions. The diagram at **(EG/02 - INQ000410502)** was produced to identify the relevant questions, summarise our train of thought and identifies the workflow that we adopted early on. To support that strategic agenda and the subsequent workload as represented by the diagram at **(EG/02 - INQ000410502)** Charlotte Taylor proposed the subgroups discussed below. The steering committee then proceeded in addressing the questions and subsequent work items as identified **(EG/03 - INQ000410504)**. The civil service officials were responsible for liaison, records, action and co-ordination across Government for the decisions and actions agreed.

14. The Steering Committee was supported by sub-groups to consider specific areas of ATF work. Their precise composition and frequency with which these groups met evolved over time. My attendance at the meetings depended on the issues on the agenda. They considered the following areas of ATF work:

    14.1. Trial implementation and deployment. This group met weekly and considered trial design, pharmacy and dispensing, deployment updates, human challenge trials, use case policy, drug-drug interactions, use in pregnant women and others, safety profiles and engagement with collaborators.

    14.2. Future Planning. This group met weekly and considered horizon scanning for phase 2 antivirals, alignment of ATF and TTF activities for winter, ATF programme resilience (adapting to scenarios) and antiviral evolution and resistance.

    14.3. Procurement, supply and manufacture. This group met fortnightly and considered commercial updates, regulation and clinical access, logistic, supply and volumes and manufacturing.

    14.4. Policy and communications. This group met fortnightly and considered communications strategy and updates, international aspects, policy in respect of high risk groups and public announcements.

14.5. Plan on a page. This was an ad hoc group which considered progress reporting and working and learning from other groups.

15. I also attended (and occasionally chaired) the ATF Operations Board. This was the over-arching forum in which decisions were formally discussed and taken regarding the operation of the ATF. This board was attended by a wide range of stakeholders, including representatives of other Government departments.

16. I was aware that a Programme Board, which covered the work of both the ATF and the TTF, was chaired by Charlotte Taylor. This was a forum for the completion of tasks and actions across both taskforces, and I was not involved in this body.

17. I recall that the ATF interacted with several bodies in its work. These included the Medicines Healthcare products Regulatory Agency ('MHRA'), National Institute for Health and Care Excellence ('NICE'), the National Institute for Health and Care Research ('NIHR'), NHS England ('NHSE') These interactions were on an 'as needs' basis. The ATF would contact individuals at these bodies by telephone and either resolve the matter during that conversation or if necessary, a meeting would be arranged.

18. The ATF remained independent of the Department, which I understood was reflected in my appointment as its Chair. I generally attempted to ensure that this independence was maintained during my tenure as Chair when approaching actions and decisions, rather than through the institution of any particular policy or procedure.

19. I am asked to explain the governance framework and processes to ensure accountability and for the management of conflicts of interest which applied to ATF. I recall completing a conflict of interest form upon my appointment, but these were generally matters for the Department. As I was not involved in these procedural aspects of the ATF's operation, unfortunately I cannot assist the Inquiry in this regard.

Strategic Agenda of the ATF

20. I joined the ATF with three questions (see diagram at **EG/02 - INQ000410502)** I felt needed to be answered for us to be successful. Why are we buying these medicines? What are we trying to achieve with them? Do we know how to get the best from them? These three questions became the strategic agenda of the ATF.

21. These questions were informed by different experiences; an understanding that antivirals can be deployed in different ways to different effect, experience from the 2008 'bird-flu' when I had been in industry and the UK Government of the time was interested in purchasing one of our products and fact that the early conversations leading to my appointment heavily focused on a primary goal of 'two antivirals by winter' because that was what the Prime Minister had announced.

22. Shortly after its inception, discussions within the Steering Committee led to agreement that answers to the above questions were best informed by a group composed of clinicians, scientists, epidemiologists, who were close to the current data, evolution of the virus, potential patient populations and current treatment choices. It was also felt that a group 'independent' of the purchasing and negotiation function would aid credibility of recommendations. Steering Committee member Professor Sir Michael Jacobs agreed to convene such a group.

23. Therefore, the Antiviral Use Case Expert Panel ('the Mike Jacobs group', as we called it) was established and met three times in June 2021. It was comprised of experts from the fields of microbiology and resistance, clinical trials and regulation, research and development, and safety and toxicology. I did not sit on this group but was closely aware of its work and contributed to at least one meeting. The following individuals were members of the Mike Jacobs group:

    23.1. Michael Jacobs (UCL)
    23.2. Susan Hopkins (PHE)
    23.3. Nick Cammack (Wellcome)
    23.4. John Edmunds (The London School of Hygiene & Tropical Medicine).
    23.5. William Welfare (PHE)
    23.6. Meera Chand (PHE)
    23.7. David Lalloo (The London School of Hygiene & Tropical Medicine).

    The group was supported by DHSC officials including Charlotte Taylor.

24. As it was already starting to become evident that volumes of antivirals would not be infinite, the Mike Jacobs group was also charged with considering the three questions with a view to determining prioritisation/ hierarchy of patient groups, specific goals, data needs, concerns and issues.

25. There were essentially two simplified approaches to deployment of antivirals in the situation we faced; a) widespread, including possibly prophylactically, to tackle infection and interrupt/disrupt transmission, or b) utilise for confirmed infections with primary goal of reducing both serious and less serious sequala. At the formation of the ATF focus was essentially path a) above, in response to, as I recall, the following brief:

'a treatment for infected individuals particularly the vulnerable, a reduction in transmission of virus and therefore a positive reduction in spread and being aware of the emergence of a virus variant that escaped current vaccines.'

26. In the circumstances this was an understandable position. However, as will be described later, it did not overlay well with the product development path of the leading candidates, and their subsequent price/value proposition, or indeed with evolution of the virus. As such, the detailed work and stratification of need undertaken by the Mike Jacobs group became very important in the work of the ATF.

SECTION 2: KEY DECISIONS, ACTIONS AND DOCUMENTS

27. I am asked to provide a chronology of key events, actions and decisions relevant to the work of the ATF. In preparation of this overview, I have primarily drawn on the documents which have been made available to me by the Department, rather than just my memory of events, and have exhibited these where they are available. As such, there may be omissions from this chronology due to the passage of time and the absence of available documents. This chronology is also limited to events in which I was involved or otherwise had some close knowledge of their detail, as there was work which occurred at more junior levels within the ATF in which I was not involved and am unable to provide evidence.

    27.1. On 1 June 2021 I began my role as Chair of the ATF.

    27.2. On 8 June 2021 the first meeting of the Mike Jacobs group was held, chaired by Sir Mike Jacobs. As explained above, this panel was convened to consider questions around the most effective use of antiviral treatments in order to support the work of the ATF. At this meeting the possible antiviral use cases were discussed for modelling purposes. The Mike Jacobs group was attempting to identify and describe particular patient groups, for example patients with cancer on immunosuppresive drugs, and then attempting to order them in some

recognition of risk and therefore need. I exhibit a summary of the meeting discussion **(EG/04 - INQ000340238; EG/04A - INQ000111333).**

27.3. A further meeting of the Mike Jacobs group was held on 17 June 2021, at which the use cases were refined. I exhibit the meeting slides **(EG/05 - INQ000061110)** and minutes **(EG/06 - INQ000113015).**

27.4. On the 18 June 2021 I was informed that the Treasury had approved a funding envelope for the ATF of £621.5 million in the financial year 2021/22. I exhibit an email which I received on this date explaining the conditions which attached to this funding **(EG/07 - INQ000410506).**

27.5. A third meeting of the Mike Jacobs group was held on 28 June 2021, at which the antiviral use cases were finalised. I exhibit the slides for this meeting **(EG/08 - INQ000408748).**

27.6. The first meeting of the ATF Operations Board was held on 30 June 2021, chaired by Lord Bethell. At this meeting I provided a strategic update. It was agreed that the data to support rollout of any antiviral would be through a large, randomised control trial and the statement of need and the use case model were endorsed. It was also agreed which groups of patients would be prioritised for treatment. I exhibit the meeting minutes and papers from this meeting **(EG/10 - INQ000061222; EG/11 - INQ000061230; EG/12 - INQ000061217; EG/13 - INQ000061228; EG/14 - INQ000061227).**

27.7. On 8 July 2021 I held a meeting with Stephen Powis of NHSE. At this meeting deployment of antivirals were discussed, and we agreed that NHSE would lead on the planning for this work. I exhibit a briefing note prepared for me in advance on this topic **(EG/15 - INQ000340390).**

27.8. On 14 July 2021 a briefing was prepared for the NIHR for a new clinical trial platform. I exhibit this as **(EG/16 - INQ000410509; EG/16A - INQ000410508).**

27.9. On 26 July 2021 I chaired a meeting of the ATF Operations Board, in the absence of Lord Bethell. At this meeting the health system requirements for effective deployment of antivirals within the community were discussed and agreement was reached regarding who would take forward different areas of work in this regard. We also considered the ongoing and proposed clinical trials of antivirals. I exhibit the minutes of this meeting and papers prepared in advance of it **(EG/17 - INQ000111721; EG/18 - INQ000410515; EG/19 - INQ000410510; EG/20 - INQ000061455; EG/21 - INQ000061453; EG/22 - INQ000061456; EG/23 - INQ000061454).**

27.10. On 18 August 2021 I sent a letter to No 10 Downing Street providing an update on the work of the ATF **(EG/23A - INQ000064095).**

27.11. On 25 August 2021 I produced a speaking note relating to the business case for purchase of antivirals. I exhibit this note **(EG/24 - INQ000410517)**.

27.12. On 27 August 2021 I again chaired a meeting of the ATF Operations Board. At this meeting a paper considering patient pathways for the use of possible antivirals from development of symptoms to taking the medicine was presented and discussed **(EG/25 - INQ000066753)**. The instigation of NIHR medical trail to ascertain how effective antivirals were in treating those who had test positive for COVID-19 was also discussed, which later became the PANORAMIC study. I exhibit the minutes of this meeting **(EG/26 - INQ000410532)**.

27.13. On the same day I received a call from the UK General Manager of the manufacturers for 'Project Tyne' (one of the candidate antivirals) Pfizer. I exhibit an email I sent summarising this call as **(EG/27 - INQ000410519)**.

27.14. On 30 August 2021, I, along with others, provided advice to the Secretary of State on the options available for purchase of antivirals at that stage. I advised that my preferred position was to procure 1.8m courses in relation to 'Project Arrow' (molnupiravir) and 250,000 courses in respect of 'Project Tyne' (Paxlovid) for 2021/22 (in total 2.75m courses), and a further 700,000 additional doses of 'Project Arrow' for 2022/23. This view was supported by the CMO and DCMO, and I exhibit an email recording this as **(EG/28 - INQ000421149)**. I exhibit a note recording this advice as **(EG/29 - INQ000489913).**

27.15. On 31 August 2021 I held another call with the manufactures for 'Project Tyne' Pfizer. I exhibit a readout of this call as **(EG/30 - INQ000410522).**

27.16. On 1 September 2021 I understand that the Secretary of State held a call with the manufactures for 'Project Tyne' Pfizer. I exhibit a brief for this call (which I approved) as **(EG/31 - INQ000421150).**

27.17. On 2 September 2021, I sent an email containing further advice on the viable options for antiviral procurement directly to the Secretary of state. I exhibit this email **(EG/32 - INQ000410523).** I sent a further email on the same subject the following day which I exhibit **(EG/33 - INQ000410524).**

27.18. On 3 September 2021 an updated business case was sent to No 10 Downing Street for approval of purchase of antivirals for 'Project Arrow'. A few days later, a response was received that further work was sought to reach a 'common position' between the Department and the Treasury on optimum volumes to be procured. I exhibit the chain of emails as **(EG/34 - INQ000421152).**

27.19. On the same day I received a call from the manufactures for 'Project Tyne' (Pfizer), offering a possible price for purchase. I exhibit a follow-up email I received and forwarded as **(EG/35 - INQ000421151).**

27.20. Also on 3 September 2021, I attended a meeting regarding antivirals with the SoS and senior officials in the department. In that meeting, I agreed with the SoS that it was for ministers to decide whether to fund antivirals based on the clinical evidence. I exhibit a readout of the meeting as **(EG/35A - INQ000500147).**

27.21. On 8 September 2021 I emailed the Secretary of State directly in an attempt to encourage urgency in decision making on the volumes of antivirals to be purchased. I exhibit this email as **(EG/36 - INQ000410525).**

27.22. On 15 September 2021 I sent an email directly for the attention of the Prime Minister seeking his intervention to decide on the volumes of antivirals to be procured. I exhibit this email as **(EG/37 - INQ000410527).**

27.23. On 26 September 2021 approval was given by No.10 Downing Street to procure 480,000 doses of antiviral medicine in respect of 'Project Arrow'. I exhibit an email recording this as **(EG/38 - INQ000410528).**

27.24. On 1 October 2021 I attended a meeting with Fionn Craig (Deputy Director on the ATF) and others from the Department to provide advice on the approach which was being proposed towards stage 2 antiviral procurement. I expressed broad agreement with the stage two approach adopted thus far, and the draft prioritisation criteria being used to filter the antiviral compounds identified through the horizon scanning process. I suggested that stage two procurement be de-linked from a specific date or deadline to deploy acquired antivirals, as this may necessarily exclude promising candidates. I exhibit the rough minutes of this meeting **(EG/39 - INQ000410565).**

27.25. On 6 October 2021 I chaired a meeting of the ATF Operations Board. At this meeting an update was provided on the published phase 3 trial (known as the MOVe-OUT trial) results in relation to 'Project Arrow' antiviral (molnupiravir). These suggested a 50% reduction in hospitalisation and death. There was further discussion on the possible deployment of antivirals, especially in light of the decision to limit the number of antiviral courses purchased to 730,000 (which I believe had been taken by the Prime Minister) which reduced the scope of possible deployment. In essence this was the output from senior level decision making on volumes vs affordability. Having asked for SoS, Chancellor, PM to decide, they agreed to stay within the budget and limit purchase as described. I exhibit the minutes of this meeting **(EG/40 - INQ000067384)**.

27.26. On 8 October 2021, in line with the decision described above, a decision was taken on 'Project Arrow' and 'Project Tyne'. It was decided to procure 480,000 courses of molnupiravir and 250,000 courses of Paxlovid antiviral totalling the 730,000 figure.

27.27. On 11 October 2021, the Secretary of State agreed to reduce the contractual requirement for shelf life of 'Project Arrow' antiviral (molnupiravir) from 14 to 12 months. This was relevant because as new agents the maximum shelf life that could be offered at this stage was 12 months. The email recording this decision is exhibited **(EG/41 - INQ000410533).**

27.28. On approximately 13 October 2021 the contract for 'Project Arrow' was signed.

27.29. On approximately 18 October 2021 the contract for 'Project Tyne' was signed.

27.30. On 19 October 2021 I sent an email to Charlotte Taylor and the DCMO stating that I felt there needed to be a formal press announcement made concerning the signing of the contract for 'Project Tyne'. I exhibit this email as **(EG/42 - INQ000410535)**.

27.31. On 20 October 2021 the UK Government announced the procurement of the 480,000 courses of molnupiravir and 250,000 courses of Paxlovid antiviral.

27.32. On 21 October 2021 the Treasury requested sight of the ATF's deployment plan for antivirals. I exhibit a copy of this plan **(EG/43 - INQ000410536).**

27.33. On 2 November 2021 I sent an email commissioning a short paper on potential for resistance to molnupiravir. I exhibit this email as **(EG/44 - INQ000410538)** I subsequently reviewed a submission to the DCMO on this subject which I exhibit as **(EG/45 - INQ000410539).**

27.34. On 3 November 2021 I attended a meeting of the ATF Steering Committee, which considered and agreed the proposed criteria for prioritisation of possible stage 2 antivirals within a Public Information Note ('PIN') process. I understand that these criteria were subsequently approved by the DCMO and CSA.

27.35. On 4 November 2021 the MHRA approved the use of molnupiravir for use in those patients who had mild to moderate symptoms of COVID-19 and at least one risk factor for developing severe illness.

27.36. In early November 2021, a team within the taskforce was tasked with assessment of Future Pandemic Preparedness (FPP). As part of that work, they interviewed me for my thoughts. I provided some advice on future pandemic preparedness in response to specific questions. I encouraged the exploration of the full end-to-end process of drug development to patient access, with a view to understanding where the UK exhibits strengths, where it is weak, and how the expertise of the ATF could best be used to contribute to greater health security for the UK in the event of a future pandemic. Having been shown the note of my meeting with the FPP team, it does appear to capture many of my views on how the FPP should organise and prioritise its thinking and its work. My advice today would remain the same. I have been asked about the 'Questions for Katie

following Eddie Call' part of the document. It appears that in addition to reporting my advice, the team identified further questions/thoughts/ideas/workstreams that arose as a result of the call with me. I exhibit this document as **(EG/46 - INQ000340387).**

27.37. On 10 November 2021 the ATF received an email raising queries from the manufacturers of molnupiravir (Merck) regarding the PANORAMIC study. I exhibit an email chain discussing the response to these concerns as **(EG/47 - INQ000410540).**

27.38. On 11 November 2021 a meeting of the ATF Operations Board, chaired by Clara Swinson, was held. At this meeting I provided an update on the proposed deployment of the two antivirals which had been purchased. It was agreed that in addition to the proposed clinical trial, molnupiravir should be deployed to a limited cohort of 'ultra high risk' patients through an adapted pathway. I exhibit a paper prepared on this topic and circulated in advance **EG/48 - INQ000067387**. It was also confirmed that Paxlovid would not be available for use until spring of 2022. I exhibit the minutes of this meeting **(EG/49 - INQ000410545).**

27.39. I understand that on the same day a decision was taken by the ATF Programme Board members (by email) to approve arrangements for storage and distribution of the two antivirals which had been obtained. I was not involved in this decision.

27.40. On 17 November 2021 a PIN was published which indicated that the UK Government was interested in entering into a negotiation for a stage 2 antiviral. The purpose behind this process was to collate information on applicable antivirals which were in development in the market, so that the ATF could provide suitable advice on possible acquisition. I exhibit a copy of the published PIN **(EG/50 - INQ000410570).**

27.41. On 19 November 2021 clinical prioritisation advice was provided by a group, chaired by Ian McInnis, concerning access to antivirals. This work suggested which groups should receive priority access to antivirals when they became available based on need and likely outcome. As I recall, this was a NHSE initiative, which sought to 'translate' the earlier work into language that would be easier for front line GPs to recognise and apply to individual patients such as people with Downs Syndrome.

27.42. On 23 November 2021 a webinar was held concerning the PIN process, chaired by Charlotte Taylor. This was attended by figures from the pharmaceutical industry and was intended to explain the criteria of interest to the ATF to potential suppliers. I did not attend this webinar. I exhibit a readout and slides from the event **(EG/51 - INQ000410543; EG/52 - INQ000410566).**

27.43. On the 24 November 2021 I chaired a 'roundtable' meeting with experts from the pharmaceutical industry and research fields following the publication of the PIN. This meeting was intended to learn more about the current state of the market and ensure the ATF was aware of all relevant antivirals in development. I exhibit brief prepared in advance of this meeting and the readout from this meeting **(EG/53 - INQ000410567; EG/54 - INQ000408752).**

27.44. On 26 November 2021 the Secretary of State asked the ATF to procure further stocks of the candidate antivirals in light of the emergence of the Omicron variant of COVID-19 **(EG/54A - INQ000309469).**

27.45. On 1 December 2021 a second a webinar was held concerning the PIN process, which I chaired. This meeting was attended by representatives from pharmaceutical industry, and was a further opportunity to ask questions concerning the PIN process and applicability of antivirals in development. I exhibit a briefing I received for this meeting, along with a readout **(EG/55 - INQ000410542; EG/56 - INQ000410544).**

27.46. On the same date I sent an email to the Secretary of State detailing my frustration at the time it was taking to decide to secure further stocks of antivirals. I exhibit the email I sent as **(EG/57 - INQ000309476)** and a readout of the Secretary of State's response as **(EG/58 - INQ000309477).** I exhibit a further email I sent a week later on the same subject, expressing similar concerns, as **(EG/59 - INQ000309488).**

27.47. On 8 December 2021 a public announcement was made by the Secretary of State concerning the launch of the PANORAMIC study.

27.48. On 9 December 2021 a meeting of the ATF Operations Board, chaired by Clara Swinson, was held. At this meeting I provided a strategic update on the imminent deployment of oral antivirals and the ongoing work to consider the effects of the emerging Omicron variant on antiviral efficacy. I exhibit the minutes of this meeting **(EG/60 - INQ000067618)**.

27.49. On 19 December 2021 agreement was reached with the manufacturers of the two oral antivirals for purchase of further courses, which included a 12.5% discount on the quoted price for molnupiravir. I exhibit an email I sent a few days later to the Chancellor and Prime Minister summarising the deals reached **(EG/61 - INQ000421153).**

27.50. On 20 December 2021 I attended a meeting of the ATF Steering Committee. At this meeting I noted my dissatisfaction with how the announcement of the PANORAMIC trial for antivirals was handled, as I felt that the events which took place failed to make clear who was eligible and what could be done to access

this treatment. There was some discussion about how delivery of this trial could be improved and possible international collaboration. I exhibit the notes of this meeting **(EG/62 - INQ000067733).**

27.51. On 22 December 2021 the UK Government announced the procurement of a further 1.75 million further courses of molnupiravir and a further 2.5 million courses of Paxlovid antiviral.

27.52. On 1 January 2022 I attended the ATF Operations Board which was chaired by Clara Swinson. I provided a strategic update and noted that the existing PANORAMIC test programme needed to be expanded. Plans to increase deployment of existing antivirals was also discussed by using a Lateral Flow Device ('LFD') to test, as this was quicker than a polymerase chain reaction ('PCR') test. A paper was prepared on this topic in advance of the meeting **(EG/63 - INQ000113014)**. A deployment plan for antivirals, as requested by HMT, was also agreed. I exhibit the minutes of this meeting **(EG/64 - INQ000410551).** The following day, I understand that the ATF Programme Board approved the use of funds from the existing budget to increase communications concerning the PANORAMIC test programme. I exhibit the minutes from this meeting **(EG/65 - INQ000410534).**

27.53. On 5 January 2022 I understand that a decision was taken by officials not to expand the PANORAMIC trial for antivirals internationally, and instead to explore a meta analysis. I was not involved in this decision.

27.54. On 10 January 2022 I sent a note to the Secretary of State concerning manufacturing capacity of antivirals. I exhibit this note as **(EG/66 - INQ000410547)**. I exhibit a further note I produced on this subject as **(EG/67 - INQ000410550)**. In this note I stated that I had asked my team to begin working up a paper about the role that antivirals and therapeutics would play in the next pandemic. I have been asked to confirm whether such a paper was produced, but I am unable to ascertain whether it was.

27.55. On 12 January 2022 I attended a meeting of the ATF Steering Committee. At this meeting we discussed the next steps for stage 2 antivirals and considered a paper on prioritisation for potential new antivirals **(EG/68 - INQ000410548)**. At this meeting we agreed to deprioritise those compounds which were in drug discovery or pre-clinical stage. I exhibit the notes of this meeting **(EG/69 - INQ000410568; EG/70 - INQ000410549)**.

27.56. On 10 February 2022 I attended a meeting of the ATF Operations Board which was chaired by Clara Swinson. I exhibit the agenda and papers for this meeting **(EG/71 - INQ000410552; EG/72 - INQ000410554; EG/73 - INQ000410555;**

EG/74 - INQ000410556; EG/75 - INQ000410558; EG/76 - INQ000410553; EG/77 - INQ000410557). I have been asked to explain the role of the ATF in the deployment of antivirals in the community, through the COVID Medicine Delivery Units ('CMDUs'). I have little knowledge of the deployment of antivirals through the CMDUs. The Department of Health and Social Care is best placed to provide this information.

27.57. On 21 February 2022 I attended a meeting of the ATF Steering Committee. At this meeting a future plan of work for the remainder of the financial year was agreed **(EG/78 - INQ000340389).** There was some discussion concerning the ongoing PANORAMIC test for antivirals. I exhibit a note of actions and recommendations from this meeting **(EG/79 - INQ000410559).**

27.58. On 2 March 2022 a decision was taken not to proceed with further paid advertising to promote the PANORAMIC trial, as recruitment numbers had increased significantly, meaning that the trial team were at full capacity. I exhibit an email sent a few weeks later providing an update on recruitment to the trials **(EG/80 - INQ000410560).**

27.59. On 9 March 2022 I attended a meeting of the ATF Operations Board which was chaired by Clara Swinson. At this meeting I provided my usual strategic update and there was discussion regarding the wider deployment model for antivirals, including the appropriate scenarios which should be employed for modelling purposes. I exhibit a paper circulated in advance on this subject **(EG/81 - INQ000112336)**. There was also discussion concerning the implication of the publication of the 'living with COVID strategy' on the ongoing PANORAMIC trial. I exhibit a paper circulated in advance on this subject **(EG/82 - INQ000410569)**, along with the minutes of this meeting **(EG/83 - INQ000410563)**.

27.60. On 28 March 2022 I sent a letter to the Secretary of State summarising my concluding thoughts following my tenure as Chair of the ATF **(EG/84 - INQ000410561).** I was not involved in any subsequent papers or work on future pandemic preparedness following the end of my tenure.

27.61. On 30 March 2022 I attended the last meeting of the ATF Operations Board which was chaired by Clara Swinson. This was the final meeting of this board before its merger into the Antivirals and Therapeutics Taskforce Strategy Board. At this meeting a paper on the stage 2 antivirals strategy was considered **(EG/85 - INQ000410562)** and it was decided that there was no immediate need to commence work on a new tendering process for more antivirals. This was because there was sufficient stock for the winter of 2022 and there appeared to

be no suitable candidates within the immediate pipeline. I exhibit the minutes of this meeting **(EG/86 - INQ000410564)**.

27.62. On 1 April 2022 my appointment as Chair of the ATF concluded.

SECTION 3: DEVELOPMENT, TRIALS, USE OF NEW THERAPEUTICS AND EXISTING MEDICATIONS

Development of Antivirals

28. I have been asked to explain the ATFs role and activities in relation to the identification, development, manufacture, procurement, supply and deployment of COVID-19 antivirals. As will be clear from the above, the ATF did not, manufacture or supply these medicines. Rather, at inception we identified three antiviral drug candidates for potential procurement which were in development by different pharmaceutical companies. These were:

    28.1. molnupiravir (Lagevrio), which was being developed by Merck. This drug was given the code name 'Project Arrow';

    28.2. nirmatrelvir/ritonavir (Paxlovid), which was being developed by Pfizer. This drug was given the code name 'Project Tyne'; and

    28.3. AT-527, which was being developed by Roche and Atea Pharmaceuticals. This drug was given the code name 'Project Clyde'.

29. The initial work of the ATF focused on the development of these drugs. It soon became apparent that 'Project Clyde' was not a viable candidate because the early trial readout was not strong enough and work therefore focused on the two remaining candidates.

30. In identifying possible candidate antivirals, the ATF did not differ in approach when considering new or repurposed medicines. When assessing antiviral pharmaceutical candidates, I attempted to ensure that we were driven by the strategy outlined above.

31. The ATFs work included commercial negotiations with the manufacturers, examples of which are included above. At the conclusion of these negotiations, advice was provided by the ATF for purchase of these drugs, subject to market authorisation by the MHRA. The decisions on procurement were ones for Government to make, although I expand below on the problems that we faced in this regard. Contracts for their procurement were signed in October 2021 in which access to 730,000 courses was secured.

32. Following the procurement of the first round of antivirals, we were asked by the Secretary of State to secure further volumes in light of the emergence of the Omicron variant towards the end of 2021. This resulted in the purchase of a further 4.25 million courses of the two candidate antivirals just before the end of that year.

33. At the same time, the ATF was also engaged with industry in order to establish possible candidates for what was known as stage 2 antivirals. This was a 'horizon scanning' exercise in order to identify what was in the pipeline and potentially available for future procurement. I exhibit a note outlining the criteria established by the ATF to apply to these medicines as **(EG/87 - INQ000410529; EG/88 - INQ000410530; EG/89 - INQ000410531).**

34. I have been asked to explain what role the ATF played in considering other drugs such as Evusheld, Ivermectin or Hydroxychloroquine. As the ATF's role was limited to oral antivirals, it did not include consideration of other drugs such as these.

35. From my perspective, ethical standards and transparency were observed during the work of the ATF throughout.

36. I am asked to consider the ATF's role vis-à-vis the Devolved Administrations. There were interactions between the ATF and the DAs. The DAs formally agreed to work with ATF rather than go their own way. There were occasional meetings held on Zoom at which CMOs of devolved administrations were present. They agreed that our approach was acceptable and they wished to be a part of the ATF's process rather than stand up entirely independent processes of their own. They also had the opportunity to customise aspects of the PANORAMIC trial patient identification and communication approach to suit their systems. My recollection is that an issue arose regarding ensuring delivery to Northern Ireland post Brexit however I was not directly involved with this issue. We attempted to ensure that equal access to antivirals was secured for those outside England, and that the needs of the whole of the UK were considered in the work of the ATF. For example, I exhibit an email, sent in response to an early proposal for a clinical trial, which stressed the need to widen the geographic scope to include those within the whole country **(EG/16 - INQ000410509; EG/16A - INQ000410508)**. In addition, the ATF shared the DAs' focus on ensuring that there was equal access to the trials infrastructure despite the challenging locations in remote areas of Scotland, Wales and Northern Ireland. I also exhibit further relevant documents in relation to collaboration with the DAs **(EG/90 - INQ000410507; EG/91 - INQ000410536; EG/92 - INQ000410541).**

Clinical Trials

37. The ATF followed a number of on-going clinical trials for the use of the selected antivirals closely (for example, the MOVe-OUT trial mentioned above). As part of this, the ATF received and considered anonymous data from such trials and factored it into the advice which was provided on the candidate antivirals. As the ATF did not organise or oversee such trials, we had no control over the diversity of the trial participants.

38. However, as 2021 progressed, it was felt that more work was required to understand the 'real-world' impacts of the chosen antivirals within a population. The ATF, working with NIHR, therefore commissioned the PANORAMIC study, which was carried out within the NHS and represented a 'first-of-its-type' study anywhere in the world. The study was open to people above the age of 50 or who had a pre-existing health condition, that had tested positive for COVID-19 within 5 days of enrolling. This was a very large and complex programme which saw considerable work between ATF, NIHR, Senior officials within the NHS and CMO office leadership and a GP-based research organisation in Oxford. I have considered the reasons behind and outcomes of this study in more detail below.

39. I have been asked to explain what role the ATF played in the 'urgent public health badge process'. Public safety was maintained within the ATF's work by maintenance of the integrity of the regulatory approvals process by the MHRA (see below).

Other Bodies

40. As will be clear from the above, the ATF frequently interacted with a range of other bodies. I am specifically asked to consider the ATF's role and interaction with Research to Access Pathway for Investigational Drugs in COVID-19 ('Rapid C-19'). I personally had no role in this as this was carried out by the Civil Service members of the ATF. However, I did have occasional interactions with its leadership on strategic questions regarding PANORAMIC.

41. I am also asked to explain the role the ATF played in the Therapeutics Clinical Review Panel and UK COVID-19 Therapeutics Advisory Panel ('UK-CTAP'). I was aware of the establishment of the Therapeutics Clinical Review Panel in January 2022, but I was not closely involved in the work of either body. I was aware that others within the ATF worked with UK-CTAP in identifying possible candidate antivirals shortly after the ATF was established.

Public Engagement and Communication

42. The ATF did play a role in public engagement and communication, but this was relatively small in comparison to that which was required in respect of vaccines. As it became clear that the primary role of antivirals would be to benefit key high risk groups, the benefits of communication to groups representing such patients became more important. The ATF was in contact with these groups, primarily via the Department, emphasising awareness of patient need and general assurances of progress and confidence in our ability to source products as they became approved. Occasional patient charity group heads and CEOs expressed desire to speak to me as Chair, and I tried to be responsive when this occurred.

43. Given our focus on high risk groups, we did not see significant benefit in proactive wider public communication, as most of the population were unlikely to receive such medicines assuming vaccines continued to be effective. We also did not want to confuse or distract from the vaccine communication of which there was a consistently high-volume concerning boosters and other important messages. As we approached the launch of the PANORAMIC study, which was the vehicle for identification and prescription of antivirals to high-risk patients, we identified a greater need for proactive communication. The goal of this was maximising awareness of the study, why the focus on high risk groups and understanding of the qualification parameters. Primarily we attempted to execute this utilising people like the DCMO, who is both high profile and a physician, also utilising those physicians conducting the study. There were some requests for me as Chair to be interviewed of which we accepted one with BBC Radio. I exhibit a readout of that interview as **(EG/94 - INQ000410546).** This represents a good general summary of the communication objectives for the ATF.

44. I am asked to explain our understanding of any public concerns relating to antivirals. Given that antivirals were not yet available, concerns from the public were not specific or frequent. However, as time passed, we could assume that general concerns regarding safety would arise and, given some of the discussions in relation to vaccines, concerns about rapid regulatory review were also likely. We were also conscious that the 2009 purchases of, in particular, Tamiflu had led to considerable press coverage subsequently regarding trial data and effectiveness. Given the focus of antiviral candidates upon high value endpoints, we saw this latter issue re-emerging as lower risk. Overall, the major concern expressed seemed to be whether any particular high risk group would or would not be eligible to receive these products.

45. I was very conscious of the need for antiviral communication to be consistent with their overall role in responding to COVID-19. Vaccines were the primary public health response, quite rightly, and overcommunication regarding antivirals had a risk of causing confusion. It was also important people did not think they could be casual in adoption of vaccines because they thought a tablet was easily available should they catch COVID-19. As such, ATF did not make overt attempts to communicate or publicise its work for most of its lifetime. We did recognise this would change if a COVID-19 variant emerged which rendered vaccines ineffective. In that instance antivirals would be more prominent in public consciousness, and we would of course have need to be more proactive in explaining their role, availability and priorities for deployment. Thankfully, this never came to pass.

46. As indicated above, the only tangible proactive communication we engaged in surrounded the PANORAMIC study. Generally, I found this a frustrating exercise. Government communications were closely guarded, nothing was allowed until approved at the highest level, and timings were governed by a 'grid' which controlled timing of all communications across Government. Communications regarding PANORAMIC were low risk with no crossover to other Government business, and timeliness was important to ensure high risk people knew what action to take. From where we sat, it was not obvious why something like PANORAMIC needed such tight management. We did have conversations with Science Media Centre (at the Wellcome Trust) regarding journalist briefings, which they had organised for vaccines, but ultimately these failed. As we already had well-established channels to brief patient interest groups, we emphasised that channel of communication instead. The Government communications function did find an additional budget for this campaign which was very welcome.

SECTION 4: LESSON LEARNING

47. In response to the Request, I have considered what went well and what did not and the challenges and barriers which the ATF faced in its work.

48. In this regard the context when the ATF was established is relevant. The ATF which was established in 2021 faced a different world than it would have earlier in the pandemic. The scientific challenge was evolving, given the availability and success of vaccines, and the economic and financial challenges were more acute because of the lost economic production and the financial costs of earlier adopted policies like lockdowns. As such, the public perception of Government performance, of individuals, and of specific policies was now the subject of fierce debate. When the ATF was established, within politics

particularly, there were now groups more openly questioning continued expenditure and emphasising a need for a greater focus upon controlling finances and regenerating economic activity. Other voices challenged these assertions, and loss of life resulting from COVID-19 infection and/or policy decisions remained a high concern amongst the public generally. Against a backdrop of a rapidly evolving picture and a seemingly worsening understanding and/or use of data, the debate about the cost of COVID-19 was becoming more prominent.

ATF Membership and Support

49. The formulation and operation of the Steering Committee worked well. When I joined the ATF, recruitment for participants from the civil service was already well advanced. The external experts who had been identified and were consulted were of high quality and were informed because of earlier consultations. Their experiences covered the full spectrum we required. In discussion, those whose skills and experience were most directly relevant to the task were asked to form part of the Steering Committee. Others who would be needed on occasion, e.g. Manufacturing expertise, agreed to be available as needed. A negotiation team of two was also in place. They were balanced (Kevin Bates and Stuart Carroll one was a commercial negotiator and one a health economist). Both had been part of the VTF operation and were quickly able to demonstrate they had control of their brief. In short, the civil service had done a good job of identifying external contributors, although perhaps underutilising some of them.

50. More general staff support from the civil service took longer to assess. Experience showed the junior members to be an extremely bright cohort, not necessarily with the most appropriate backgrounds or qualifications (see below), but hard working and demonstrating a strong desire to 'get it right', even if not always clear what right was. There were periods of intense work including one particular Bank Holiday weekend. The commitment and energy of that period was no less than I would have hoped to see in any large private sector setting.

51. I felt that staff from the civil service perhaps suffered the most from a lack of relevant experience. All were generalists, and prior posts did not always read across to the responsibilities held on the ATF. Where Charlotte Taylor was concerned this did not impact us, her determination and resilience in realising our agenda across Government was the most important thing and she performed this well. Below her, there was some sense on occasion of 'square pegs in round holes', which made it harder for them to influence across

Government and to manage their teams. Given these observations, I should say I thought hard about requesting some changes of significant personnel. On balance, the short time frame of the ATF's work made this too high a risk.

52. Considerable interaction with other areas and offices was a feature of the ATF's operations. The scientific interactions were, as you might expect, considerably better informed, but I was also on the whole favourably impressed by the understanding of risk and need for commitment across the board. Despite challenging timelines, the senior leadership of NHS in particular were impressive, helped by good contacts and relationships with the civil service members of the Steering Committee with responsibility for this area.

53. My initial view of the organisational structure for ATF reporting was one of some mystification. It seemed there were multiple committees with little obvious recognition of what they contributed to the decision making, approval process or how they would further any proposed actions. I could see that it was useful for knowledge of ATF activities and progress to known, so that other areas of Government knew what was potentially impacting them. However, my experience of attendance at these meetings led me to conclude that they were too frequent. There was repetition and redundancy as we knew which other groups we needed help from and had regular dialogue with the people actually doing the work. I also felt that some people at the meetings were often not well informed and/or it was the same voices that were heard.

54. It should be noted that sponsorship of the ATF by Ministers from the Department in these meetings was consistent and appreciated. As discussed elsewhere, contribution was limited by scientific or industry understanding but enthusiasm was high and a genuine desire to see delivery of goals was always evident.

Budget

55. A budget of £621.5 million was set during the establishment of the ATF which was modelled on the purchases of oseltamvir (Tamiflu) and zanamivir (Relenza) for the H1N1 infections of 2008/9. However, there were some important differences between these medicines and those under consideration for COVID-19. At the time of their purchase, these medicines were approved and in public use. This meant that they had an established manufacturing process, significant capacity or access thereto, and an established history of production under high regulatory scrutiny. The data which supported the effectiveness

of these products also showed some impact on symptomatic relief but no information on more serious health impacts of infection, such as serious illness (requiring hospitalisation) or death. The price of these medicines therefore reflected this, and they were relatively inexpensive compared to other antiviral medications.

56. In contrast, the candidate antiviral medicines in response to COVID-19 were still in development, and so required assessment by regulatory bodies before they could be made available. Little product volume had been manufactured meaning that robust manufacturing processes/supply chains of significant volumes under regulatory scrutiny were yet to be established. These candidate medicines were also being trialled with a Primary Endpoint in studies of 'reduction in hospitalisation and death'. The price expectations of manufacturers were consistent with these uncertainties and an expectation that the Primary Endpoint would be met (this was confirmed by an announcement by the US government in June 2021 of an agreement to purchase molnupiravir at a price of $700 per course).

57. Whilst some information (e.g. Primary Endpoint of studies) should have provided an indication, or warning, that assumptions in setting the budget were likely to be significantly wrong, it is hard to be too critical given how early in the process this exercise was completed. However, it is less easy to be generous when considering subsequent commitment to this budget when initial assumptions were clearly so awry.

58. At different phases in the process the allocated budget became a focus of internal debate. The first assessment and recommendation was an 'eye-watering' £11.5 billion. This was not a huge surprise as it effectively answered the demands of the original brief for widespread use and the 'insurance policy' of available volume if the virus 'escaped' vaccine coverage. However, it did so at the price levels manufacturers were demanding, even after heavy discounting, because of the significant clinical impacts they expected to deliver.

59. This initiated a sensible review of the original budget brief within an environment where better assessment of the virus and its possible development reduced the perceived risk/need for, in particular, insurance against complete vaccine escape. This resulted in further recommendations which focused upon use for high-risk individuals only. They utilised the hierarchy developed by the Mike Jacobs group and also recognised the emerging realisation of likely available volumes and timing of deliveries being significantly less than assumed in the early budget brief.

60. The success of the UK vaccine effort securing volumes early had also sensitised manufacturers to how they allocated volumes across different countries. At this point the Treasury position included a view that the original budget limit must be held. I was perfectly comfortable with the idea that government had a responsibility to consider affordability alongside the public health need (the decision-making process for such an assessment will be considered below). An additional debate regarding the budget year, when products would be used/paid for and why not all the budget could in fact be used for purchase was farcical, and little more than mischief-making by Treasury as far as I could see.

61. Overall, the budget process is a lesson for the future. I recognise some benefit for the organisation of a placeholder in the budget. I also understand at some point it may be necessary to balance need with affordability, so long as this is achieved involving appropriate seniority and accountability. Less understandable is an inability to address what were clearly incorrect assumptions and to challenge the basis of flawed assumptions. On balance, I think we can say for purchase of antivirals in this pandemic the UK did not suffer as a consequence, but that was good fortune resulting from the eventual viral strain evolution that occurred and cannot be considered as a model of good practice.

Decision Making – Understanding of Science and Industry

62. My time as Chair of the ATF left me strongly of the view that Government lacked the necessary skills and experience to make informed decisions in this area. I encountered a lack of understanding and experience in science, business and industry. Some of these elements were present and strong in a number of key points e.g. Office of the CMO, but the 'rank and file' of civil service and politics showed much less facility. Within the civil service this was evident at all levels. The ATF members were hard working and keen to deliver, as said above, but in a group of 80/90 people dealing with a pandemic, I found 1 PHD, and a small handful of science degrees.

63. There also appeared to be a view by officials that they could consult (in this case with academia, the NHS etc) and that was sufficient. Sadly, science in particular requires knowledge to interpret, challenge or foresee the consequences of advice. This was clearly not present in sufficient depth.

64. If anything, understanding of industry, its operations, its strengths and weaknesses and in this case the extent and reach of its regulatory environment was equally low. Real experience of manufacturing environments seemed non-existent. Sadly, a suspicion of

industry and its motives remained common. In one virtual meeting I joined, involving members of No 10 Downing Street Office of the Chief of Staff, I observed some of the most simplistic and ill-informed comments I had heard in some time.

Decision Making – Understanding Risk

65. Equally, I found that the nature of and understanding of how to manage risk was widely lacking. I acknowledge that finding the appropriate balance between the potential costs of a decision and the range of possible outcomes is a complex matter to comment upon. Partially, explanation for an inability to understand this balance adequately is contained within the comments above and follows directly from lack of specific knowledge or experience.

66. However, I experienced what I can only describe as a cultural fear of making a decision that might be wrong. Not making a decision seemed eminently 'safer' than a wrong decision. Within the Department this seemed most obvious within the Legal and Commercial groups, who appeared to be strongly influenced by experience purchasing Personal Protective Equipment ('PPE') earlier in the pandemic.

67. This seemed to impact the ATF in two ways. Firstly, there was a desire for a belt and braces approach to contract management. Despite my assurances and supportive explanation (patents, scientific publications, viable timelines for clinical trials etc) that we knew no other antivirals existed which could be considered for winter 2021 and/or winter 2022, there was still a fear that lawsuits might ensue from people who had not been given a chance to bid for supply. Although I understood there were a plethora of such issues associated with PPE, there was a lack of willingness or knowledge to recognise the obvious differences in purchasing these two different categories. Secondly, and closely associated, was concern about where and how blame might fall for any mistakes which led to a conservative approach.

Decision Making – Process

68. Within and between Government departments what I experienced was an almost wholly written iterative process. I found it a complicated, time-consuming method that was extremely hard to keep pace with. The sense I had was that a need for a written record at all stages was deemed paramount. As ideas developed or proposals/decisions were being formed, the basis for communication between departments was a submission, updating

prior versions. Feedback on these were sometimes verbal and sometimes in writing. This interaction led to further updates in writing and so on. It was my experience that the demands of a pandemic; ever changing challenge as the virus changed, need for speed etc., delivered a system that generated huge workload on junior members of staff, and where it was easy for earlier thoughts and ideas/threads to be lost.

69. As a result of this system, I received multi page new submissions for immediate review, with no simple way to compare with earlier versions. This led to an environment where my overriding feeling was that the process and its deadlines inevitably came to take precedence over whether the core message was now correct. It felt like the final report was continually trying to be written, even when we were a long way from knowing what would be in it. As a result, I subsequently abandoned this process and elected to write directly to the Secretary of State on a number of key occasions with advice and even the Prime Minister (see above). Although this was primarily an issue of clarity - I suspected that the 'official advice' they would be receiving needed supplement by independent comment - I also found myself unable to ensure those messages did not simply get lost in the machine.

70. Within the ATF itself we had lots of communication with sections of the NHS. This process was more consistent with my experience in the private sector; briefing documents, a higher proportion of verbal interaction, agreements and decisions captured, with development of full documentation as the finishing line could be at least understood, if not seen. I found this was a more efficient way to operate.

Decision Making – Authority

71. As mentioned above, the financial challenges for the Government as a consequence of COVID-19 were growing when the ATF was established. The Treasury expressed concern regularly, both within Government and externally about absolute spending. Not without merit, a need to balance expenditure with affordability was becoming a more vocal issue. As Chair of the ATF, I acknowledged the legitimacy of this concern, recognising public health is a core Government responsibility, and as such, cannot and should not be easily laid aside.

72. In my view, the appropriate response to this obvious tension was a decision making process that ensured all information is available, and that 'balancing decisions' between public health and affordability were made by appropriately senior and accountable

individuals. The most significant problem I encountered as Chair of the ATF was a loss of belief that such a decision-making process would deliver that goal. The iterative process described above combined with an unequal and flawed balance of power between Treasury and other departments. As a result, I observed a slow journey away from the Department advocating what it felt was the appropriate public health response towards a position of finding a proposal that 'the Treasury would accept'. In our case this was essentially a debate regarding the volume of antivirals to be purchased. Internal discussion started to accept a reduction in the volume that ATF firmly felt to be the optimal that could be achieved, balancing need, available volume, time and cost. The iterative process above went into overdrive as the back and forth with Treasury continued, and I was extremely concerned that the rational for our proposal, and the supportive arguments, were being lost or obfuscated. By way of illustration, I exhibit emails I sent on 28 August 2021 **(EG/95 - INQ000410520),** 30 August 2021 **(EG/96 - INQ000410521; EG/29 - INQ000421148), 2 September 2021 (EG/32 - INQ000410523)** and 8 September 2021 **(EG/97 - INQ000410526)** expressing some of these frustrations.

73. If this had been allowed to continue, and the Department and Treasury simply found agreement for a consensus position, in effect the balancing decision between public health and affordability would have been made by relatively junior civil servants. Therefore, it was at this point I decided to step back from the iterative system and, as Chair, summarise my own conclusions and recommendations in a direct communication to the Secretary of State. There are multiple examples of this exhibited above. As time passed, and I saw similar patterns of behaviour emerging in different places, I felt it necessary to repeat this direct approach **(EG/37 - INQ000410527; EG/57 - INQ000309476).**

74. More generally, a firm impression from my time as Chair of the ATF was that given the imbalance in power between departments, a well-honed effective approach of forcing consensus up each branch of Government (as described above), is very useful if you are Treasury!

75. Furthermore, the taskforce role was to advise and execute upon agreed actions through the iterative submission process described above. Occasions arose where disagreement across government departments was evident, and delays ensued. In those instances, we reached out to SoS to provide guidance and advice directly, to seek a steer and understand objectives/preferences and on occasion, take the decision to the triumvirate of himself, Chancellor, and PM for arbitration/decision.

76. The request for decisions to be made by the SoS, Chancellor and PM arose on three occasions. It was not clear to me whether their interaction was in person or written; nor was it always clear whether the PM engaged with the others separately and then delivered his own ruling; or if it was a ruling agreed whilst all three were together. Feedback on decisions to my memory usually emanated from No 10.

77. The reputation of the Department across Government was also not high. Cabinet Office officials, in particular, were scathing. The primary challenge of this was a lack of credibility leading to outright suspicion of any ideas emerging from the Department, and consequent 'double guessing'. That said, to an outsider like me, it was not always clear what contribution the Cabinet Office made; themes I might have expected to be their responsibility appeared to be assumed by the Treasury. For example, my expectation was that CO would be a central driver of policy and be consistent and continual in delivery of outcomes. In short, be the primary drivers of the agenda. In reality, much of that energy seemed to be emanating from the Treasury, and certainly DHSC staff seemed more aware and responsive to the Treasury than CO.

Relationships with Potential Suppliers

78. By the time I joined the ATF, significant scientific and commercial interaction was already established. Overall, this worked well in my view. There were the normal frustrations on both sides (most frequently timeliness in making and communicating decisions, or differences in opinion regarding developing clinical data), but nothing out of the ordinary for a situation such as this. Negotiators on both sides appeared to remain professional.

Regulatory Approvals Process

79. As the body responsible for procurement of antivirals, it was accepted by all that interaction between ATF and MHRA was sensitive and could not be interpreted as influencing in any way. As such, contact was regular, and at the most senior levels, with a goal of helping MHRA understand timelines and strategy. I recall one key strategy for managing risk in negotiations was the intent for all negotiated contracts to contain a clause 'subject to regulatory approval'. All communication of a product nature was strictly between MHRA and individual companies - the ATF played no part in this aspect. I would say on reflection, as someone experienced in the normal processes and timelines of regulatory approval, that the emergency management of MHRA processes to respond to a pandemic situation were extremely impressive.

PANORAMIC Study

80. Whilst ATF pursued its goal of identification and procurement of antivirals the world did not stand still. A key change was the apparent success of vaccination and the consequent recognition that the UK population was increasingly divergent from the populations in the key antiviral clinical trials.

81. In short, as the companies were recruiting for clinical trials the pandemic was in its early phases, the most prevalent strains in circulation were causing significant serious sequala, and in nearly all countries the winter of 2020 saw a rising number of hospitalisations and deaths. This was the population being recruited into antiviral trials. The good performance in this group in these trials and the high value impact produced, meant the companies were seeking a price commensurate with this value.

82. However, looking forward to winter 2021 - when approved antivirals would be first available for use - a significant majority of the UK population would have received some vaccination. Omicron was to become the dominant strain (which ultimately would inflect a less serious pattern of sequala although this was not known at the time), and the work of the Mike Jacobs group and NHS colleagues meant we could identify groups of patients we would wish to prioritise for antiviral use. In addition, we could now see available volumes of antivirals were not without limit, and a realisation that we could not have significant use in patients who were relatively low risk without compromising availability and protection for high risk groups. Similarly, the lower hospitalisation and deaths now being seen in the population meant it would be more difficult to deliver the value assumed in the price.

83. Some excellent work had been done at this point (particularly in the UK) in determining 'real world' impact of potential COVID-19 interventions. However, given the changing picture outlined above, it was felt that UK infrastructure and clinical expertise could extend this approach to General Practice and provide a means of both achieving our goal of targeted distribution whilst also generating data to help assess impact and some sense of value in what now represented the 'real world population'. This view led us to commission the PANORAMIC study.

84. The PANORAMIC study showed antivirals to have contributed a reduction in symptoms and time to recovery but not in hospitalisation and death. Although this was not really surprising, given how the impact pattern of Omicron unfolded, the study demonstrated a consistent pattern of value being delivered to individual patients regardless of the

challenge, but greater benefit and greater value being delivered (across the population) the more challenging the circumstances. I therefore consider that it was a valuable and worthwhile study to have conducted.

Innovations

85. There were a number of innovative approaches employed during the pandemic which will have utility in future pandemics. I identify them below.

86. Identification of potential candidates: the ATF used Industry personnel allied to external experts and assessment via pandemic enabled bodies such as C-TAP and Rapid C-19 to identify potential antivirals. This was a similar process to that adapted by the VTF and will definitely be necessary in a future pandemic.

87. Direct Purchase of agents not yet approved: the pandemic and the speed of response which it required necessitated government agencies such as MHRA and NICE adopting new procedures. Medicines, unlike many vaccines, are not normally purchased directly or centrally. Negotiations therefore had to incorporate elements not normally addressed in medicine purchasing for example. assessments for volume, understanding and incorporation of evolving clinical evidence into negotiation, direct competition for limited volume from other countries, short decision-making windows and physical distribution options. In a future pandemic this experience will definitely need to be reproduced.

88. Deployment: deployment through the PANORAMIC study was innovative not only in the UK but internationally. The primary driver was the difference between the study populations and the majority of the UK population by the time of availability. As such, deployment in this way in a future pandemic may or may not be valuable depending upon the circumstances at the time. The primary drawback was the link, or absence thereof, between this evolving process and the funding.

Recommendations for the Future

89. I have now had some time to consider the work of the ATF and the lessons which can be drawn from its work in order to prepare for and tackle a future health crisis or pandemic. In my view the most significant lesson to be taken from this work is exploring whether antivirals might offer some positive impact before the vaccines arrive. The experience of COVID-19 demonstrated the value of effective vaccines. Prior to their availability, we can

all recall the hospitalisation, the death rates, the non-pharmaceutical interventions and their financial and societal impact. It does not require much to consider the potential impact antivirals could have had in that pre-vaccine period in high-risk individuals or environments (such as care homes), or the value they may have delivered if vaccines had taken longer to arrive. In my view we should not simply accept that the first year (or first 100 days if the vaccine plans are successful) of the next pandemic will look like 2020.

90. Although we cannot know exactly what the next pandemic will be, but we do know that classes of antivirals will 'stretch' across different virus threats (because of the way they work inside the cell) so can be a 'transferable skill' across different pathogens. As such, antivirals that are not necessarily specific to the emerging pandemic may not be optimal, but may have some utility and offer some reduction in risk and burden in high-risk situations. We were aware of this fact when responding to COVID-19 in recognising that emerging virus strains had the possibility of evading the vaccine if the 'strike protein' changed too extensively. Therefore, antivirals, as the only therapeutic option not subject to changes in the strike protein, would at that point have been the primary defence until new vaccines came through. Can they perform a similar role before the next pandemic?

91. Another lesson I consider we can learn is to maintain flexibility of focus when formulating a strategy to achieve objectives. For instance, the focus on my joining the ATF was primarily driven by the Prime Minister's announcement of 'two antivirals by winter'. This is a very useful rallying call and communication device; it is not a strategy or a thoughtful response. This focus, perhaps exacerbated by the timelines, led to some unhelpful, seemingly 'absolute' positions being adopted early. These included implicit assumption of product profile and consequent budget. This scoping should not just be an 'internal' exercise for the civil service, but should include external experienced industry help. Creating a fluid, responsive strategy which recognises that the virus will inevitably do things you don't expect should be the goal. That also means that the consequences of exercising that fluidity and changing plans may be necessary. All players across Government need to understand and accept that possibility.

92. I have been shown a document entitled *"Future Pandemic Preparedness: Recommendations to enable the use of antivirals in the UK in a future respiratory pandemic"* **(EG/98 - INQ000087218)**. After I left, I had no further involvement in the work on FPP, although it clearly continued. I can see consistency between this document and numerous points that I have made, and I would therefore support it. Furthermore, the inquiry has directed me to a report entitled *"100 Days Mission to Respond to Future*

Pandemic Threats" **(EG/99 - INQ000101061)**. I would be strongly supportive of recommendation 3 in this report regarding antivirals, as the outcome of the thought processes described in paragraphs 14a, 37, 38, 41 and 47 of the report.

93. Finally, I consider we should maintain a focus on those who are the most vulnerable to any future pandemic. We know who these are in advance and should certainly be able to identify venues, such as care homes. However, we can we go further than this (as the Mike Jacobs group did) and identify conditions/situations of known immune status compromise. Such features could be identified in advance and if possible, given antivirals immediately upon declaration of pandemic for use in case of infection.

94. I am asked to consider in what circumstances should bodies similar to the ATF be established in the future and the threshold for their instigation. I suggest that this should occur where there is a significant risk to the population posed by a health emergency and where skills, experience or knowledge, which is not commonly drawn upon in the public sector, is required. Equally, this should occur where specialist scientific, technical or industrial expertise is required in order to provide advice or inform decision makers. I also consider it would be beneficial to establish such a group if potential responses to a health crisis are not yet available and/or where timelines are short.

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

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Dated: _____20/Aug/2024_____