Witness Name: Professor Sir Jonathan Nguyen-Van-Tam

Statement No: 3

Exhibits: JVT3/001 - **147**

Dated: 07 October 2024

UK COVID-19 INQUIRY

MODULE 4

THIRD WITNESS STATEMENT OF PROFESSOR SIR JONATHAN NGUYEN-VAN-TAM

Contents

I, PROFESSOR SIR JONATHAN STAFFORD NGUYEN-VAN-TAM will say as follows:

Section 1: Introduction

1.1 I make this statement in response to a Rule 9 request received from the UK COVID-19 Public Inquiry ("the Inquiry") dated 1 December 2023. This is the third witness statement I have provided to the Inquiry. The first, dated 9 June 2023, was submitted for Module 1 and the second, dated 8 September 2023, was submitted for Module 2. I have also contributed to the corporate witness statements made on behalf of the Office of the Chief Medical Officer ("OCMO") by Professor Sir Christopher Whitty, the Chief Medical Officer ("CMO") for Modules 1, 2, 3 and 4.

1.2 The Sixth Witness Statement of Professor Sir Christopher Whitty dated 29 February 2024 ("the OCMO Module 4 Corporate Statement") addresses much of the background that is relevant to this module. I will not repeat here information contained in that statement. I will, where appropriate, refer to particular sections of the OCMO Module 4 Corporate Statement and I recommend that this statement is read alongside it.

My background

1.3 I am an epidemiologist and physician specialising in public health, mainly communicable disease control. I have a medical degree, a Diploma of membership of the Faculty of Public Health of the Royal Colleges of Physicians and a doctorate in medicine (DM) in epidemiology and public health from the University of Nottingham. My doctoral thesis was about influenza vaccine uptake in older people. I am an Hon. Fellow (formerly Fellow) of the Faculty of Public Health, an Hon. Fellow (formerly Fellow) of the Royal Society of Public Health, a Fellow of the Royal College of Pathologists (by publications), an Hon. Fellow of the Royal College of Physicians, and an Hon. Fellow of the Faculty of Pharmaceutical Medicine. In July 2023, I voluntarily relinquished my Licence to Practice, although I remain registered as a doctor with the General Medical Council, UK.

1.4 Until August 2024, I was a part-time Senior Strategy Adviser to the University of Nottingham School of Medicine and a part-time, self-employed consulting Clinical Advisor to pharmaceutical and biotechnology companies (not necessarily in relation to COVID-19). I have now stepped down from my role at the university, but continue to

consult on a self-employed, part-time basis. Since April 2022, and with written DHSC approval, I have consulted at different times for Seqirus (influenza vaccine manufacturer and developing a COVID-19 vaccine), Merck and Co. Inc (MSD) (manufacturer of molnupiravir, an antiviral medicine used to treat COVID-19, which the consultancy work did not relate to) and Moderna and Novavax (COVID-19 vaccine manufacturers). I have given remunerated lectures or talks for AstraZeneca (COVID-19 vaccine manufacturer), Sanofi (COVID-19 vaccine manufacturer), Gilead (manufacturer of remdesivir, an antiviral medicine used to treat COVID-19), and Seqirus. Over the course of a 36-year career I have held a range of positions in both the private and public sectors. Between 2004 and 2007, I was Head of the Pandemic Influenza Office at the Health Protection Agency Centre for Infections ("Colindale"). Between 2005 and 2009, I was a member of the UK national Scientific Pandemic Influenza Committee ("SPI"). I was a member of the UK Scientific Advisory Group for Emergencies ("SAGE") during the 2009-10 A/H1N1 influenza (swine flu) pandemic. I have chaired the European Centre for Disease Prevention and Control ("ECDC") Expert Advisory Group on H5N1 (bird flu) vaccines and acted as a short-term consultant and temporary adviser to the World Health Organisation ("WHO"), ECDC, and the European Commission on multiple occasions from 2005 to 2017. I am the Senior Editor of the textbook, *Introduction to Pandemic Influenza,* and I have published more than 200 peer-reviewed scientific papers. Most of my academic career has been spent engaged scientifically on aspects of the epidemiology, prevention and control of respiratory virus infections, particularly influenza.

1.5 Between 2014 and 2017 I was the Chair of NERVTAG. This is a Department of Health and Social Care ("DHSC") committee advising the Government on the threat posed by new and emerging respiratory viruses. In October 2017, I was appointed as Deputy Chief Medical Officer ("DCMO"), a post I held until March 2022. I did this as a formal secondment from the University of Nottingham and remained a university employee throughout. As DCMO, my portfolio was vaccines, pharmaceuticals, health protection and biosecurity.

Glossary

1.6 In this statement I refer to a number of acronyms, committees and groups. I define and summarise them here to assist the reader.

- ATF: The Antivirals Taskforce. The ATF was established within DHSC in April 2021 with the aim of ensuring that the UK had access to at least two effective antiviral treatments by the winter of 2021 that could be used in the community.

- ATTF: The Antivirals and Therapeutics Taskforce. The ATTF was established in April 2022, amalgamating the TTF and the ATF.

- CEPI: The Coalition for Epidemic Preparedness Innovations. CEPI is a global partnership that aims to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats. It was formed in 2017 in response to the 2014-2016 Ebola outbreak.

- CHM: The Commission on Human Medicines. The CHM is an advisory non-departmental public body sponsored by DHSC. It advises ministers on the safety, efficacy and quality of medicinal products. It worked in collaboration with the MHRA to monitor and advise on the safety of the COVID-19 vaccines. It is chaired by Professor Sir Munir Pirmohamed.

- GCSA: Government Chief Scientific Adviser. The GCSA is responsible for providing scientific advice to the Prime Minister and members of the Cabinet, advising the government on aspects of science for policy and ensuring and improving the quality and use of scientific evidence and advice in government. The GCSA is a permanent secretary level post, reporting to the Cabinet Secretary. Sir Patrick Vallance held the position between April 2018 and April 2023.

- JCVI: The Joint Committee on Vaccination and Immunisation. JCVI is an independent Departmental Expert Committee ("DEC") and Scientific Advisory Committee ("SAC") and, unlike most other DECs/SACs, has a statutory basis in England and Wales. It is formed of a main committee with subject specific sub committees. It was originally an advisory board for polio immunisation that became JCVI in 1963. It was put on a statutory footing when it became a SAC, established in England and Wales under the NHS Act 1977. The NHS (Standing Advisory Committees) Order 1981[1] established JCVI in its current form. That order specifies that it is constituted for the purpose of advising on *"The provision of vaccination and immunisation services being facilities for the prevention of illness"*. JCVI, when

[1] SI 1981/597

providing advice on COVID-19, was chaired by Professor Wei Shen Lim, standing in for Professor Sir Andrew Pollard who had a perceived conflict of interest arising from involvement with what became the Oxford/AstraZeneca vaccine.

- MHRA: The Medicines and Healthcare Products Regulatory Agency. The MHRA is an executive department of DHSC and is the body that regulates medicines, medical devices and blood components for transfusion in the UK. It was responsible for approving COVID-19 vaccines for use in the UK and continually monitoring their safety once the rollout was underway. The MHRA is led by Chief Executive Officer, Dame June Raine.

- MRC: The Medical Research Council. MRC is part of UK Research and Innovation ("UKRI"). It is responsible for coordinating and funding medical research to prevent illness, develop therapies and improve human health. It concentrates on basic research through to translational and complements the work of NIHR.

- NERVTAG: The New and Emerging Respiratory Virus Threats Advisory Group. NERVTAG is a standing committee of DHSC. It advises the CMO and DHSC on the threat posed by new and emerging respiratory viruses. The NERVTAG COVID-19 Therapeutics Sub-Committee was established early in 2020 to provide initial advice on therapeutics.

- NHSE: NHS England. NHSE leads the NHS in England.

- NHSEI: NHS England and NHS Improvement. NHS Improvement and NHS England worked together as a single organisation since 1 April 2019, to help improve care for patients, and provide leadership and support to the wider NHS. NHS Improvement merged with NHS England in July 2022.

- NIHR: The National Institute for Health Research (the National Institute for Health and Social Care Research since April 2022). NIHR is the main Government funder of applied research in health and social care, and one of the largest government funders of medical, public health and care research in Europe. It supports a major network of research in the NHS as well as in universities. It concentrates on translational and applied research and complements the work of MRC. As CSA in DHSC I was the head (CEO equivalent) of NIHR for the early part of the pandemic until August 2021.

- nMABs IAG: COVID-19 Neutralising Monoclonal Antibodies and Antivirals Access Independent Advisory Group. The group was established in late 2021 to identify a set of patient cohorts that were deemed to be at the very highest risk of adverse COVID-19 outcome.

- PHE: Public Health England. PHE was the forerunner to UKHSA on health protection. It also had responsibility for health improvement (primarily non-communicable diseases). The functions of PHE were separated in 2021, when UKHSA and the Office for Health Improvement and Disparities ("OHID") were established.

- POG: Prophylaxis Oversight Group. The POG was established in July 2020, as a group of independent experts, with the remit of deciding which candidates were suitable for COVID-19 prophylaxis trials (working with the UK COVID-19 Therapeutics Advisory Panel), considering prophylaxis research challenges and determining how prophylactic trials fitted into the wider COVID-19 trial landscape.

- SAGE: The Scientific Advisory Group for Emergencies. SAGE is an independent advisory group, convened to provide scientific advice to support decision-making in COBR in the event of a national emergency.

- TTF: The Therapeutics Taskforce. The TTF was established within DHSC in April 2020 with the remit of coordinating the Government's efforts to deliver safe and effective treatments for COVID-19 as quickly as possible.

- UKHSA: The UK Health Security Agency. Established in name in April 2021 and formally operational from October 2021, UKHSA is responsible for protecting the public from the impact of infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats.

- UKRI: UK Research and Innovation. UKRI is the umbrella body of the seven research councils, including the MRC.

- UKVN: The UK Vaccine Network. The UKVN was established in 2015 to support the development of vaccines and vaccine technology for infectious disease with the potential to cause an epidemic in low and low-middle income countries ("LMICs"). It brings together expertise from across industry, academia and relevant

funding bodies to advise DHSC on research and development investment. It has been chaired by the CMO since its inception.

- VTF: The Vaccines Taskforce. The VTF was set up in March 2020 and formally established in April to coordinate and drive forward the UK's efforts to develop and procure an effective vaccine against COVID-19. It brought together expertise from across government and the private sector in pursuit of that objective. Dame Kate Bingham was appointed as Chair in May 2020, reporting directly to the Prime Minister and working within the Department for Business, Energy and Industrial Strategy ("BEIS").

Summary of my role in respect of vaccines and therapeutics

1.7 My role during the pandemic was primarily to work on behalf of the CMO on the acquisition of vaccines and therapeutics, at the interface between policy (led by policy officials), procurement (led by the VTF, TTF, ATF and ATTF) and clinical trials and studies of the same (led by the NIHR). I was therefore involved, to a greater or lesser extent, across the breadth of processes that culminated in the rollout of COVID-19 vaccines in the UK and in the exploratory work to find safe and effective medications for the treatment of COVID-19. I had no decision-making powers in relation to any matters within the remit of the MHRA (for example, decisions on medicines licensure and safety monitoring). I was particularly careful to protect the MHRA's full independence on such matters.

1.8 As the DCMO leading on vaccines and therapeutics during the pandemic, I had a prominent role in advising and updating Ministers on the development, procurement, approval and delivery of these pharmaceutical interventions. The approval of vaccines and medicines was, and remained throughout, for the MHRA as the independent regulator. This was not a process in which the CMO, DCMOs, nor the OCMO had any involvement as a decision-maker; nor did we have any ability to influence the MHRA's decisions. With DHSC, we did write to the MHRA asking it to begin the process of considering vaccines for Emergency Use Authorisation under Regulation 174 of the Human Medicines Regulations 2012 (see paragraph 2.22 below). Whether a vaccine should receive temporary authorisation was for the MHRA to consider and approve. We maintained contact with the MHRA to track the progress of potential approvals so that we could update Ministers as necessary. I regularly briefed the Secretary of State

for Health and Social Care ("the Health Secretary") and the Prime Minister (in writing and in person) on the progress that was being made in relation to vaccines and therapeutics. I also regularly liaised with and advised officials and scientists across Government and within NHSE and PHE/UKHSA. In addition, I also occupied the following relevant roles during the pandemic:

1.8.1. JCVI observer (main committee and COVID-19 sub-committee) – JCVI is an independent committee with a statutory role to advise the Health Secretary on the provision of vaccination and immunisation. I was not a member of JCVI, but I did regularly attend meetings as an observer so that I could keep the CMO and the Health Secretary (and the PM when asked) apprised of its deliberations. I was able to contribute to JCVI discussions since the Chair always allowed me to raise points for members to consider, and to ask questions of members, insofar as these were relevant to policy or implementation issues.

1.8.2. NERVTAG observer – NERVTAG is a standing committee of DHSC that advises the CMO and DHSC on the threat posed by new and emerging respiratory viruses. During the pandemic, it had a broad remit that included advising on matters pertinent to this Module. It provided early advice on existing medications that might be suitable for repurposing (via the NERVTAG COVID-19 Therapeutics Sub-Committee, which I assisted in setting up). As with JCVI, I was not a member of NERVTAG, but I did attend meetings as an observer when I could. Again, as with JCVI, I was not a silent observer. The NERVTAG chair also allowed me to raise points for the committee to consider and to ask questions (insofar as these were relevant to policy or implementation issues). NERVTAG has no role whatsoever in setting vaccine recommendations, which is solely the territory of JCVI.

1.8.3. Vaccine Taskforce member and Clinical and Public Health Adviser – The VTF is discussed in more detail below (paragraphs 2.10 - 2.11 and 2.15 - 2.18) as well as in the OCMO Module 4 Corporate Statement. I was deeply involved in the work of the VTF. This was a natural transition, given that I had already been involved in very early vaccine discussions with GCSA, that included the need for the VTF to come into being. The VTF's work focused on the procurement and, following approval, supply of vaccines. As the

Clinical and Public Health Adviser to the VTF Steering Group, my role was to consider the available clinical data, for example neutralisation studies undertaken by PHE Porton Down, readouts from clinical trials and observational studies, and to provide clinical advice. That included anticipating future JCVI decisions (which might impact the supply of a particular vaccine). For the sake of clarity on this point, in a highly competitive international market for limited supplies, the UK could not wait for a JCVI recommendation before it planned the potential volumes of vaccines we would need to procure. The latter had to take place in Spring 2020, whereas JCVI was not in a position to finalise clinical recommendations until it had assessed the results of clinical trials and until it knew, broadly speaking, which vaccines seemed likely to make it over the threshold to licensure. My role was essential to advise the VTF so it could 'cover the likely bases'. When I relinquished my role as DCMO in March 2022, I was asked to continue as an Adviser to the VTF on a consultancy basis. I continued in that role until October 2022, when the VTF's functions were transferred to the UKHSA, DHSC and Office for Life Sciences.

1.8.4. Member of the Oxford/AstraZeneca vaccine steering group – I was one of two Government members of this steering group (the other being Dame Kate Bingham, the first chair of the VTF). In that role, the focus of the steering group was on clinical efficacy and I offered an opinion on the emerging clinical trials data from a public health and policy-related perspective. It was not commercial in any way, and regulatory submissions to the MHRA were a matter entirely for the company, AstraZeneca. Such submissions did not fall within the remit of the steering group. My involvement in the steering group is also discussed at paragraph 6.20 of the OCMO Module 4 Corporate Statement.

1.8.5. Therapeutics Taskforce, Chair of the Executive Board – As explained above, the TTF was set up to coordinate the Government's efforts to deliver safe and effective treatments for COVID-19 as quickly as possible. I chaired its decision-making Executive Board.

1.8.6. Antivirals Taskforce member – As explained above, the ATF was established in April 2021 with the aim of ensuring that the UK had access to

at least two antiviral treatments by the Autumn of 2021. I assisted in its establishment and was a member.

1.9 As I hope the Chair will recognise, I was involved in a number of different bodies during the period with which this module is concerned. Given the intensity of the work I was undertaking during that period, it is difficult for me now to recall with clarity the detail of the many matters on which I worked. For example, I find it difficult to now separate the work I was involved in as part of the TTF and that as part of the ATF, and although I am sure I chaired TTF meetings, I cannot in all honesty say that at the time I recognised these to be Executive Board meetings as such. In seeking to provide as much information as possible to the Inquiry, I have of course refreshed my recollection where possible by reviewing the relevant contemporaneous documents. However, I have made every effort to avoid describing matters with the benefit of hindsight.

Section 2: Vaccines

Pre-January 2020

2.1 Pandemic influenza has been at the top of national emergency planning in the UK since the first National Risk Register in 2008. It will therefore come as no surprise that, in the period preceding the COVID-19 pandemic, the majority of Government efforts and resources when it came to vaccine development and procurement were focussed on pandemic flu. From my time chairing NERVTAG (2014-2017), I was cognisant of those efforts. In particular, the establishment of the NERVTAG Subcommittee on Pandemic Influenza Vaccines and the negotiation of 'sleeping contracts' for the provision of influenza vaccines. However, I was only involved in supporting the strategic principle of sleeping contracts, rather than the detail of volume consideration or commercial matters.

2.2 When I became DCMO in October 2017, I continued to advise on vaccine procurement and at the same time, advocated for greater investment in novel vaccine technologies and onshoring of such manufacturing capabilities. I had previously been struck by the fact that during the 2009 'swine flu' pandemic, the UK and all other countries battled the virus without vaccines from May 2009 until October 2009. A chapter in the textbook I co-edited (*Introduction to Pandemic Influenza*, 2009) deals at length with delays in access to pandemic influenza vaccines. I was in favour of investing in technology being

developed by the Canadian pharmaceutical company, Medicago Inc, that used tobacco plants as bioreactors to create vaccines and therapeutic antibodies, much quicker than standard egg-based technologies. My support for this technology and the company was primarily based on what I perceived to be the UK's influenza needs at the time and in the future. My view at the time (and it remains my view now) was that pandemic influenza represented the most significant public health threat to the UK. I was therefore looking to secure rapid access to pandemic flu vaccines. However, at the same time, I also recognised the broader potential of the technology. For example, Medicago had already used it to develop a Rotavirus vaccine and constructs for Norovirus and Ebola. So, while the emphasis was, rightly in my view, on influenza; investing in Medicago and incentivising it to bring its manufacturing to the UK would, I believe, have had wider benefits. As it happened, I considered that the necessary investment would have been (at that time) in the region of £200m (based on matched private sector funding). I raised the matter with the Permanent Secretary in DHSC, but although he was personally very supportive, the response was that, in a climate where there was pressure to reduce public spending, my proposal would need a lot more 'flesh on the bones' and multi-departmental support (for example, from BEIS) in order to generate sufficient political enthusiasm for an investment of the magnitude necessary. In the circumstances, and given my limited remit as DCMO, I was not able to drive this further alone.

2.3 The Inquiry has asked about the UK's preparedness for the rapid development of a 'Disease X' vaccine in early 2020. My understanding is that the UK's large-scale and industrial preparedness was limited to the influenza manufacturing facilities in Speke, Liverpool, owned by Seqirus, who at the time also held the UK's Advanced Purchase Arrangement (APA) contract for pandemic influenza vaccines. I was aware that UKVN were funding research work, but this seemed to be mainly targeted at scientific support for early development of vaccines for eventual use in resource poor nations to control epidemics (e.g. malaria and viral haemorrhagic fevers), and where a lack of the normal commercial incentives of a 'western market' would blunt the enthusiasm of established manufacturers to get involved.

January-March 2020

2.4 When news of the novel coronavirus emerged in January 2020, we (the OCMO, the GCSA, DHSC and the scientific research community) recognised early on that

research and the development of clinical interventions (vaccines, therapeutics and diagnostics) were going to be essential to the global response. We therefore initiated discussions and began the necessary work from mid-late January onwards, before a pandemic was declared.

2.5 On 23 January 2020, I attended a meeting convened by the DHSC Permanent Secretary at which I was tasked with producing a note for Ministers on treatments and vaccines for the novel coronavirus. Submitted on 24 January, that note summarised as follows:

"There are no vaccines for WN-CoV and a vaccine is unlikely to be available, even in experimental or unlicensed form (as per Ebola) for at least 12 months (best case scenario) and probably far longer.

The leading agency for accelerated development of a vaccine is CEPI (Coalition for Epidemic Preparedness Innovations). CEPI was already acting in funding research to develop a vaccine against MERS-CoV and has been well placed to provide immediate funding of three new research initiatives directed towards development of vaccines against WN-CoV. A fourth partnership may be announced soon.

The approximate timelines that these partners are working towards are to begin phase 1 trials (first use in humans) in June/July 2020, but this [is] subject to the unknown rate of scientific progress in the interim." **(JVT3/001 & 002 – INQ000047553 & INQ000047554)**.

2.6 On 25 January 2020, the then Health Secretary, the Rt Hon Matt Hancock MP[2], asked the OCMO for advice on how we could *"accelerate vaccine discovery"* **(JVT3/003 – INQ000047560)**. In response to this request, I prepared a more detailed note with input from the GCSA, Sir Jeremy Farrar, then Director of the Wellcome Trust, and others within DHSC. That document set out *"the latest information on the current state of research into coronaviruses and the likely costs and timelines to develop a vaccine ready for large scale testing in an outbreak setting"* **(JVT3/004 – INQ000047660)**.

2.7 The Inquiry has asked what, if any, response there was to the advice in that note that "*Though not the focus of this paper, there are many areas of non-vaccine research*

[2] References hereafter to "Health Secretary" are to the Rt Hon Matt Hancock MP.

that could warrant further investment. For example… assessing the feasibility of developing monoclonal antibody treatments using blood taken from recovering patients…". I do not recall any response to that specific piece of advice at that time. However, the prospect of developing monoclonal antibody treatments remained live throughout much of the pandemic and there was specific interest in treatments developed from convalescent plasma. In mid-April 2020, I contributed to a submission to the Health Secretary that outlined a proposal for trialling convalescent plasma within the REMAP-CAP and RECOVERY trials. That submission noted as follows:

"Convalescent plasma is plasma collected from donors who have recovered from COVID-19 (and have developed antibodies), which is processed and then used as a treatment for COVID-19 patients. There is emerging but still inconclusive evidence from China of some effectiveness of such a treatment. The Government's Therapeutics Taskforce has recommended to Professor Jonathan Van Tam that convalescent plasma is a priority for testing as a treatment in COVID-19 patients. This recommendation has been accepted by Professor Van Tam, who is a firm advocate of the use of convalescent plasma based on an evidence review he performed in 2014-15 for WHO in relation to mainly SARS-CoV data, which showed a dramatic mortality reduction, albeit on low quality evidence." **(JVT3/005 – INQ000421490)**.

2.8 Ministers agreed with the recommendations contained in that submission. Ultimately, results from the REMAP-CAP and RECOVERY trials showed no clinical benefit from treatment with convalescent plasma, but the scientific rationale for pursuing this at a time when it was uncertain if a vaccine could ever be found was, in my opinion, extremely sound.

2.9 On 27 January 2020, the GCSA convened a 'WN-CoV UK Science Teleconference' that I attended alongside the CMO and my fellow DCMO, Professor Jenny Harries **(JVT3/006 – INQ000063572).** At that meeting, it was noted that a joint rapid research call between MRC, The Wellcome Trust and DHSC/NIHR was to be set up and that the first part of the call would address vaccines so that the process of developing a vaccine could be got underway at speed.

2.10 In late January and into February 2020, I recall having conversations with the GCSA that touched on the work that would be needed to develop a COVID-19 vaccine. To the best of my recollection, these conversations were largely outside of formal channels. They happened via telephone or possibly at the margins of other meetings

that we had both been attending. They tended to be very early in the morning or into the evening when we caught up, because we were both in back-to-back meetings every day. The GCSA and I shared the view that we were not going to navigate a way out of the pandemic quickly without developing a vaccine. It was also clear to us both that we were not going to achieve that unless we could mount a concerted effort via a dedicated workforce, whose time was protected to work solely on vaccines. The GCSA said he was going to discuss this with the Prime Minister and towards the end of March, the VTF was established. To the best of my recollection, the delay between a decision being taken by the GCSA to raise this with the Prime Minister and full approval to proceed being given was 1-3 weeks. It was definitely not months.

2.11 An initial Specification for the VTF (signed off by me and the GCSA), dated 30 March 2020, set out its purpose in the following terms:

"Objective: The UK must be in a position to vaccinate the right proportion of the population as soon as possible after a vaccine is available. To the extent it is complementary to that primary objective, we must ensure longer-term UK vaccine capability and capacity for clinical and industrial benefit.

…

Currently there is work going on across government but it is not sufficiently coordinated. The taskforce will bring together government, industry, academics, funding agencies, regulators, logistics and finance to make rapid decisions to put the UK in a position to accelerate vaccine development and vaccinate the right proportion of the population as soon as possible after a vaccine is available" **(JVT3/007 – INQ000151747).**

2.12 On 7 February 2020, the CMO, the GCSA and I briefed the Health Secretary on vaccine development **(JVT3/008 & 009 – INQ000421477 & INQ000421478)**.

2.13 On 27 March 2020, I attended a COVID-S meeting, chaired by the Prime Minister, and briefed the committee alongside the GCSA on vaccines, therapeutics and the establishment of the VTF **(JVT3/010 – INQ000088602)**.

April-December 2020

2.14 In the period April to December 2020, work on vaccines (via the VTF) and on therapeutics (via the TTF) came to dominate my entire life. The pace was frenetic and unrelenting. I was prepared to, and did, prioritise this above all of my other work and indeed my domestic commitments as a husband and a father. It was literally the most important thing in my life. I was prepared to work as many hours as it took to obtain safe vaccines that could be delivered to the population as quickly as possible. I publicly thank my family for making this sacrifice and for supporting me.

2.15 The VTF met for the first time on 1 April 2020. That meeting was chaired by Alex Jones (Director of Science, Research and Innovation, BEIS) and attended by representatives from across Government and the research community. The minutes of that meeting record an introduction to the VTF from the GCSA and me as follows:

"PV [Patrick Vallance] emphasised the importance of the Taskforce and noted vaccines action already being made across government. Through accelerating vaccine development and ensuring supply, the taskforce had a central role to play in both UK recovery and supporting international efforts (for example through CEPI – The Coalition for Epidemic Preparedness Innovations). A key aim was to work together at pace, to identify and address bottlenecks, barriers and gaps. JVT [Jonathan Van-Tam] echoed these points, noting that the Taskforce was about end-to-end oversight" **(JVT3/011 – INQ000421486)**.

2.16 An updated VTF Specification dated 6 April 2020 set out the following five aims/workstreams **(JVT3/012 & 013 – INQ000151746 & INQ000151747)**:

- Support the discovery, scale up and clinical testing in the UK
- Prepare the UK to offer itself as a possible manufacturing site
- Review regulations: to facilitate rapid, well supervised trials
- Develop funding and operational plan for procurement and delivery of vaccines
- Build on the UK's R&D expertise to support the international effort

2.17 In May 2020, Dame Kate Bingham was appointed as Chair of the VTF, reporting directly to the Prime Minister and working within BEIS.

2.18 Between April and December 2020, the VTF met more than 80 times. I attended the majority of those meetings. In my capacity as an expert adviser to the VTF, I had a role to play in some of the practical aspects of vaccine procurement. For example, the VTF might have asked for advice on the number of doses of a particular vaccine that they should seek to procure and by what date. Those were difficult questions to answer because they depended on decisions that were yet to be made by JCVI. It would have been inappropriate for those questions to have been put to JCVI because it would not have had the requisite data to address them, and we would not have wanted a situation in which JCVI was pressured into recommendations that were based on decisions that had already been made about procurement. It therefore sometimes fell to me to make informed predictions, based on my expertise and experience, about the volumes of vaccine that might be required once JCVI had made its recommendations. In effect, I had to second guess what JCVI might reasonably conclude further down the tracks. This was in the context of a highly competitive marketplace for products that didn't even exist yet. It was vital that we acted with speed and procured at risk, as otherwise we faced the very real possibility of losing out to other countries that were all also trying to acquire a finite number of vaccine doses.

2.19 The Inquiry has asked about the "NHS Vaccine Registry" ("the Registry"). The Registry, the full title of which was the "NHS COVID-19 vaccine research registry", was launched on 20 July 2020. It was an online registry set up by the Government that allowed members of the public to register their interest in participating in COVID-19 vaccine studies. The work to establish the Registry was coordinated through the VTF. I was therefore aware of it but did not have a role in its establishment. The VTF issued a press release on 20 July announcing agreements it had reached with various pharmaceutical companies. The release also noted as follows:

"The government has also today launched the NHS COVID-19 vaccine research registry. This new website will enable people in the UK to play their part by volunteering for future vaccine studies.

The new online service will allow members of the public to register their interest and be contacted to participate in clinical studies. To enable large-scale vaccine studies to take place across the UK, the aim is to get 500,000 people signed up by October,

which is considered vital in the fight against coronavirus." **(JVT3/014 – INQ000421520)**.

2.20 On 21 July 2020, in an article published in the Daily Express, I encouraged the public to sign up for trials via the Registry **(JVT3/015 – INQ000421524)**.

2.21 November 2020 saw the announcement of Phase 3 vaccine trial data from Pfizer/BioNTech (9 November), followed by Moderna (16 November), and then Oxford/AstraZeneca (23 November). The interim results from each of these trials showed high efficacy rates against symptomatic infection. I undertook various public messaging engagements in response to these results. For example, on 9 November, I appeared alongside the Prime Minister and Brigadier Joe Fossey at a No.10 press conference and spoke about the Pfizer/BioNTech announcement **(JVT3/016 & 017 – INQ000071543 & INQ000071551)**. On 11 November, I chaired a vaccine press conference alongside Dr June Raine (CEO of the MHRA) and Professor Wei Shen Lim (Chair of the JCVI sub-committee on COVID-19), at which we laid out the traditional path of vaccine development, the regulatory process, the role of JCVI and vaccine prioritisation, and then fielded questions from members of the press **(JVT3/018 & 019 – INQ000071584 & INQ000071585)**. On 23 November, I had an article published in the Sun newspaper that discussed the results of each of the three trials **(JVT3/020 – INQ000421523)**.

2.22 In light of these encouraging data, I wrote (jointly with Emma Reed, the Director of Emergency Preparedness and Health Protection in DHSC) to Dr Raine regarding the regulatory approvals process for the Pfizer/BioNTech vaccine (by letter of 17 November 2020) and the Oxford/AstraZeneca vaccine (by letter of 24 November 2020). We acknowledged that full trial data were yet to be published and peer reviewed, but nevertheless asked for MHRA views on the suitability of these vaccines for temporary authorisation under Regulation 174 of The Human Medicines Regulations 2012 **(JVT3/021 & 022 – INQ000071697 &** **INQ000059052).** A similar letter was sent in respect of the Moderna vaccine on 24 December **(JVT3/023 –** **INQ000401310).**

2.23 On 2 December 2020, the MHRA, having taken advice from the CHM, approved the Pfizer/BioNTech vaccine for use in the UK. On 8 December, Margaret Keenan became the first person in the world to receive the vaccine at University Hospital in Coventry.

The Oxford/AstraZeneca vaccine and the Moderna vaccine were authorised for use on 30 December 2020 and 8 January 2021 respectively.

Eligibility and prioritisation

2.24 Decisions around eligibility and prioritisation were for Ministers to take based on the advice of JCVI, which they had agreed in advance they would follow. As explained in the OCMO Module 4 Corporate Statement (paragraphs 6.39 - 6.42), there were some limited occasions on which the OCMO was asked to advise on such matters. For example, in relation to who should be considered a 'frontline health and social care worker'. I contributed to that advice. It is set out in more detail in the OCMO Module 4 Corporate Statement, and I do not repeat it here.

2.25 In April 2021, questions arose around whether elite athletes should be prioritised for vaccination in order to allow sporting events that were scheduled for early spring and summer to go ahead. In mid-May 2021, the Health Secretary sought advice from the OCMO on the matter. On 12 May, my view was conveyed to DHSC as follows: *"It is a political decision and possibly important for national sporting pride. There are no direct clinical grounds"* **(JVT3/024 – INQ000073290)**. Ultimately, Ministers decided not to prioritise the vaccination of elite athletes and they were called for vaccination in line with JCVI's priority groups alongside the rest of the population.

2.26 The Inquiry has asked, more broadly, about my awareness of *"any politically motivated decisions or proposed strategies for prioritisation of vaccines"*. I am not aware of any such decisions or proposed strategies. The closest I came to being aware of anything of that nature was when the Health Secretary put a proposal to me in mid-December 2020 (I do not recall and do not have a record of the exact date). Approximately one week after the first vaccination had been administered in the UK (8 December 2020), the Health Secretary rang me to suggest that he and I be vaccinated on live television, the next day, in order to demonstrate the high confidence that we had in the safety and efficacy of the vaccine. It was a short call, and I did not respond substantively to the suggestion. Reflecting on the proposal, I was firmly of the view that it would not be morally right for me to effectively jump the queue and receive the vaccine before I was due (in accordance with JCVI's order of priority). For example, I would then have been vaccinated before my elderly mother and this would have happened on the grounds of my status as DCMO. This did not feel right when public acceptance of the vaccine was

extremely high, and the public, especially the elderly, did not seem to require additional convincing of the merits of vaccination. I simply did not feel convinced that there was any public health rationale for the idea. If we had been faced with significant vaccine hesitancy in the early priority groups, there might have been some justification for a proposal such as this (equally, it could have been seen by others as a desperate stunt reminiscent of the Agriculture Minister, John Gummer, eating a beefburger with his daughter during the BSE crisis). However, that was not the case and there was no particular need to galvanise public confidence at that time. I therefore called the DHSC Permanent Secretary, Sir Chris Wormald, within minutes and expressed my concerns about the idea. His response was that the proposal was not being taken forward, but that he would call me back to confirm shortly. He did so. Nothing therefore came of this suggestion and the Health Secretary never mentioned it again.

2.27 For the record, I began my course of COVID-19 vaccinations soon after the time that I began volunteering for frontline vaccinator duties in mid-January 2021. At the end of a vaccination session there were unused doses in an already opened vial. The clinician in charge therefore chose to offer the vaccine to me in my capacity as a HCW along with several others staffing the clinic, in order to reduce wastage. I accepted this.

Delivery

2.28 The NHS and PHE (and then UKHSA) had primary responsibility for the practical side of the vaccine rollout. My involvement was five-fold:

i. to advise those leading the rollout on clinical and operational matters;

ii. to drive forward the pace of the rollout by providing constructive and persistent challenge to those leading it;

iii. to act as a conduit between different parts of the health system to ensure that any potential blockages or issues were addressed in a timely manner;

iv. to encourage uptake through public messaging (discussed in more detail in the section below); and

v. to administer vaccines to members of the public in my free time as one of thousands of frontline vaccinators.

2.29 My advisory role in respect of vaccine delivery began long before we even had access to a viable vaccine. I provided advice and guidance to the DHSC team (led by Steve Oldfield, DHSC Chief Commercial Officer) on practical matters that might not have been immediately obvious to someone without a vaccinology background. For example, I was adamant that a future rollout should not be disrupted by any problems with the consumables that would be required for a vaccine programme. I was conscious that, as with the vaccine itself, there would be strong market competition for the procurement of items such as needles and syringes. I was therefore very front-footed in advising early procurement of these items. For example, on 18 April 2020, I attended a vaccines meeting with the Health Secretary and others. A note of that meeting records my advice in the following terms, *"whatever vaccine we get will come in 10ml vials (enough for 10 people) and for Moderna you need two doses. Need syringe and two needles per patient (x2 for two doses) so need to think early on supplies"* **(JVT3/025 – INQ000492028)**. I reiterated the point in late-July / early-August 2020 when the potential issue was raised by the EU Health Security Committee[3]. A note for discussion in the Health Security Committee on 21 July 2020 explained as follows:

"due [to] the high volume of population to be vaccinated and the expected two doses required, the estimation of the demand of syringes and needles for COVID vaccination in the EU amounts to close to 1 billion units. There might not be enough capacity to supply all this demand unless EU Member States commit to the supply of needles and syringes for vaccination as soon as possible to avoid a bottleneck in production and supply, as seen previously with PPE during the pandemic, with vaccines available but no medical devices to deliver [them].

They also consider that the selection of the device for vaccination is another key decision to minimise losses of vaccine from multi-dose vials."

I forwarded this note to colleagues within DHSC, PHE and the VTF and said, *"Mission critical we do not miss a beat on this and have zero delay if moves needed to shore up UK position; now clearly EU waking up to this. Things will only get worse from here"*

[3] The EU Health Security Committee was set up in 2001 at the request of EU Health Ministers as an informal advisory group on health security at European level. It was formalised in 2013 and is mandated to reinforce the coordination and sharing of best practice and information on national preparedness activities. Member States also consult each other within the Committee with a view to coordinating national responses to serious cross border threats to health.

and *"This is what I am banging on about…"* **(JVT3/026 & 027 – INQ000152635 & INQ000152627).**

2.30 I also recall having a conversation with Steve Oldfield in which I advised that we should buy as many -70ºC freezers as we could, because I knew they would be necessary for storing the mRNA vaccines and that every country would be trying to acquire them. It would have been unthinkable to have acquired these precious vaccine doses and then not been able to deliver them to the public because of a lack of appropriate storage equipment.

2.31 Once the vaccine rollout had begun, I continued to provide advice and persistent challenge to the senior leadership team of Dame Emily Lawson (then NHSE CCO), Sir (now Lord) Simon Stevens (NHSE CEO) and Professor Sir Keith Willett (NHSE SRO Vaccine Deployment). The Health Secretary and the Prime Minister had frequent meetings with Dame Emily, Sir Simon and Sir Keith and their team, and I regularly attended those meetings to provide a clinical perspective as required. By way of example only, on 2 February 2021, I attended a vaccine deployment meeting with the Prime Minister, the Health Secretary and others. At that meeting I advised in relation to accelerating the rollout of second doses, a note of the meeting records my advice as follows:

"The DCMO's (JVT) steer is that we should not accelerate 2nd doses:

- *People must still have the same vaccine for their second jab as they had for their first, though studies are ongoing on mixing vaccines. The means [sic] that while supply overall is expanding, supply of the specific vaccines needed for each second dose are not expanding at the same rate.*
- *A pre-print release today indicates that Oxford/ AZ efficacy is 82.5% after the second dose based on a 12 week interval, but 54.9% based on a 6 week interval"* **(JVT3/028 – INQ000421505)**.

2.32 On a number of occasions, I was contacted directly by members of the public, health workers or academics with discrete concerns relating to the vaccine rollout. It would have been completely impractical for me to read, let alone respond, to all of them. However, where I was made aware of a specific issue that I considered ought to be investigated, I did my best to forward it to the relevant person and add my advice where

appropriate. For example, in mid-January 2021, Professor Catherine Noakes (SAGE member and expert aerobiologist) emailed me about two issues she had identified:

2.32.1. On 11 January 2021, she emailed me to ask:

> *"Has anyone thought about travel to mass vaccination centres? I worry that all the 80 year olds who are being asked to travel to a centre some distance from their home will be driven there by adult children in the confined space of a car. Should we be giving specific advice on safe travel to get your vaccine to reduce the risk they get infected on the way?"*
>
> I forwarded the email to Emily Lawson and said:
>
> *"This is a fair point. If olders travel in closed cars to the MVCs [Mass Vaccination Centres] with younger asymptomatic but infected relatives, that's a problem and will produce apparent vaccine failures. Does the advice suggest where possible that it is travel with a single person from your support bubble. If so and if face coverings are worn the risk is possibly not greatly elevated over and above the risks from the bubble in the first place. It is very true that almost every elderly person I saw yesterday had someone with them who was younger"* **(JVT3/029 – INQ000153605)**.

2.32.2. On 16 January 2021, Professor Noakes emailed me to express concerns about poor ventilation at vaccine centres. She asked, *"Can you raise that we really urgently need ventilation to be part of vaccine covid safety?"*. I responded, expressing my support for the importance of ventilation and my concern about the example vaccine centre that she had alerted me to. However, I also suggested that the same problems were unlikely to exist at other centres, which were often very large, high-ceilinged halls. I acknowledged the practical difficulties in finding suitable accommodation for vaccine centres and confirmed that I would pass the message on to Dame Emily. I also raised the potential issue of transmission from vaccinator to vaccine recipient and expressed my support for testing vaccinators by Lateral Flow Device before they start their shift. I forwarded Professor Noakes' email and my response to Dame Emily and Dido Harding **(JVT3/030 – INQ000153628)**.

2.33 Similarly, on 5 December 2020, I received an email from a member of the public which raised the issue of how Ramadan might impact the vaccine rollout given that many UK citizens would be fasting between mid-April and mid-May and would not receive a vaccine during daylight hours. I forwarded the email to Dame Emily and other DHSC colleagues, commenting that this was *"Undoubtedly something we must consider and cover"* **(JVT3/031 – INQ000153425)**.

2.34 I also volunteered from early January 2021 to be a COVID-19 vaccinator at various sites in Nottinghamshire and Lincolnshire. Typically, I did roughly one half-day shift per week. I did this because I felt it was my duty as a doctor to help, and as DCMO to lead by example. However, being a vaccinator helped me both psychologically and physically during this intense period. I found it both cathartic and therapeutic. I saw at first hand the sense of relief of those who came forward to be vaccinated that we were turning a corner. That was particularly so for older people and the vulnerable who would likely have been most affected by lockdown and were now able to leave the house. For me personally, that experience justified the immense effort I felt that I and many others, had put into obtaining safe and effective vaccines for the UK. Finally, vaccinating gave me real-time insight into the practical problems and challenges 'on the ground' that I could then feed back into my regular meetings with Dame Emily and others.

2.35 I am asked for my views on the impact that any particular roll-out procedures used throughout the UK had on the speed and breadth of vaccine uptake. As explained in the OCMO Module 4 Corporate Statement (paragraph 6.28), in December 2021 the OCMO advised that the precautionary 15-minute waiting/observation time following receipt of certain mRNA vaccines should be suspended. I was aware that the waiting/observation time was slowing down the rollout and my view was that, balancing the risks and benefits, this was the right thing to do from a public health perspective.

2.36 Based on my experience as a frontline vaccinator, it is my view that the NHS adopted a pragmatic approach to the delivery of excess vaccine doses. For example, at the end of the day if a vial containing 10 doses had not been entirely administered, vaccinators would administer them to people that had not necessarily been called for vaccination yet, rather than allowing them to potentially go to waste. I recall personally vaccinating a number of police and ambulance workers towards the end of a shift when we had

run out of priority group candidates. In my view, that was an eminently sensible approach to adopt.

2.37 I am also asked for my views on whether adequate consideration was given in rollout procedures to the needs of marginalised or vulnerable communities. I should say from the outset that it was neither my, nor the OCMO's, role to design the rollout procedures and consider their suitability for marginalised or vulnerable communities. That came within the remit of NHSE and PHE. Some of the most vulnerable communities generally were also the most vulnerable to COVID-19 (i.e. the elderly and those with serious long-term illnesses). A great deal of consideration was given to those communities when it came to designing the vaccine rollout. JCVI's vaccine prioritisation was based on age and clinical vulnerability. Therefore, by definition, rollout procedures had to take into consideration the needs of these vulnerable communities. My understanding is that those procedures were appropriate and adequate, and that is reflected in the high vaccine coverage that was achieved in those groups.

2.38 I did get personally involved on one occasion when a member of the public contacted me about her two very elderly parents living on a remote farm. By then, they should have been called for vaccination, but this had not happened, for reasons I do not know. I contacted the relevant local team manager, and I understand that the two elderly people were then quickly picked up by the system.

2.39 It is well known that vaccine uptake tends to be lower in marginalised, deprived, and minority ethnic communities. It was therefore foreseeable that a similar pattern would be observed when it came to delivery of the COVID-19 vaccines, as indeed it was. It is also therefore arguable that more should have been done in the planning phase to consider this. However, I was not close enough to that work to offer a meaningful view on its adequacy. I was singularly focused on getting as much of the population vaccinated as possible and that included efforts to encourage uptake amongst vaccine hesitant groups (as discussed below). From my perspective, the key goal was achieving more than 70% vaccine coverage across the population as a whole, which would be to the benefit of the un-vaccinated as well as the vaccinated. I did not have the capacity or expertise to engage in any meaningful sense with the question of *which* 70%.

2.40 The reasons for disparities in vaccine coverage between different communities in the UK are myriad and complex. I do not have the necessary expertise to comment on them with authority, and my role did not extend to advising on them. However, based on my experience, I understand that language, culture, and education barriers all play a part, as do historic approaches to vaccine trials (including poor recruitment from ethnic minority communities). During the vaccine rollout, I was deployed across media outlets by Government communications teams to address questions and concerns that vaccine hesitant members of the public had (examples provided below at paragraph 2.77). However, beyond that, I was not involved in addressing these issues and I am therefore unable to comment on the steps that were taken.

Safety

2.41 As explained in the OCMO Module 4 Corporate Statement, vaccine safety relative to the risks of infection of unvaccinated people, i.e. risk-benefit, was firstly a matter for the MHRA in terms of licensure, and secondly for JCVI in terms of recommendations for deployment priority.

2.42 The Inquiry has asked for a chronology of when and how each of the known risks associated with each COVID-19 vaccine first came to my attention. No vaccines or drugs are without risk, the question to consider when giving clinical advice is whether the benefits exceed the risks. For example, all of the vaccines had the potential to induce mild to moderate flu-like side-effects (such as headache, muscle ache, malaise and feeling feverish). These generally did not last more than a day or two. Plainly, these side-effects did not represent a risk that would outweigh the benefits of protection against infection with COVID-19. I will therefore focus on the more serious risks that were identified (i.e. those that had an impact on the MHRA's and JCVI's advice) and only those that were associated with vaccines that were administered in the UK.

Oxford/AstraZeneca – Transverse myelitis

2.43 On Monday 13 July 2020, I received information that the Oxford/AstraZeneca vaccine trials had been halted worldwide on the previous Friday due to a possible case of transverse myelitis (i.e. inflammation of the spinal cord) following vaccination. I emailed the CMO as follows:

"I have just heard that the Oxford Chadox vaccine trials were halted worldwide on Friday. The DSMB [Data and Safety Monitoring Board] *and MHRA safety committees are meeting today or have met over the weekend. The precise details are opaque but it appears to be the same safety signal as was seen with Chadox Ebola. The rumours are (MHRA would not confirm or deny on the VTF call) that there is a case of transverse myelitis after vaccination in the UK cohort."* **(JVT3/032 – INQ000152480)**.

2.44 The following day, I received an email from Dr Kirsty Wydenbach of the MHRA to say that the MHRA had approved the restart of the trials **(JVT3/033 – INQ000421492)**.

2.45 On 20 July 2020, the Oxford/AstraZeneca phase 1/2 trial results were published in the Lancet and Professor Pollard forwarded me a copy of the paper and accompanying press release. The press release summarised the results as follows, *"The results of the Phase I/II trial published today in the scientific journal, The Lancet, indicate no early safety concerns and induces strong immune responses in both parts of the immune system"* **(JVT3/034, 035 & 036 – INQ000152544, INQ000152542 & INQ000152543)**.

2.46 On 6 September 2020, the Oxford/AstraZeneca trials were paused again in order to investigate a possible adverse event. I cannot recall precisely when I was informed about this, but the documents show that I was engaged in email correspondence and discussions about it on 9 and 10 September **(JVT3/037 – INQ000152789)**. On 11 September, Dr Martin O'Kane of the MHRA sent me an update on the situation. His summary set out the steps that had been taken by Oxford's independent Data and Safety Monitoring Board, the CHM and the MHRA to review the relevant safety data. It also confirmed that each of those bodies had agreed that the trials could resume **(JVT3/038 – INQ000152797)**.

2.47 The risk of transverse myelitis following vaccination continued to be carefully monitored, but to date, it has not materialised to any significant extent. The Oxford Vaccine Group's safety and efficacy trial data, published on 8 December 2020, contained the following information about the risk:

"Three cases of transverse myelitis were initially reported as suspected unexpected serious adverse reactions, with two in the ChAdOx1 nCoV-19 vaccine study arm, triggering a study pause for careful review in each case. Independent clinical review of these cases has indicated that one in the experimental group and one in the control group are unlikely to be related to study interventions, but a relationship remained

possible in the third case. Careful monitoring of safety, including neurological events, continues in the trials." **(JVT3/039 – INQ000153551).**

2.48 As of 8 March 2023 (when the MHRA changed the format of its Yellow Card reporting), the MHRA's summary in relation to the risk of transverse myelitis was as follows:

"Transverse myelitis (TM) is a rare acute neurological disorder where parts of the spinal cord are inflamed. TM is known to be associated with a number of viruses, such as the herpes and influenza virus. The MHRA has continually monitored reports of suspected transverse myelitis following COVID-19 vaccination since the start of the vaccination programme.

As of 26 October 2022, we have received 129 reports of suspected TM following administration of COVID-19 Vaccine AstraZeneca, 42 reports following administration of monovalent COVID-19 Vaccine Pfizer/BioNTech and 8 reports following administration of monovalent COVID-19 Vaccine Moderna. There were no reports received with a fatal outcome following suspected TM. Whilst the incidence rate of this adverse event with any of the COVID-19 vaccines used in the UK remains extremely rare (less than 1 report per 100,000 doses of each vaccine), the available evidence reviewed by the MHRA suggests an association between TM and COVID-19 Vaccine AstraZeneca is possible.

Due to the serious nature of this adverse event and as a precaution, the product information has been updated to raise healthcare professionals' and patients' awareness of the signs and symptoms associated with TM which may include muscle weakness, localised or radiating back pain, bladder and bowel symptoms and changes in sensation. It is recommended that patients who had an episode of transverse myelitis following the first dose of COVID-19 Vaccine AstraZeneca should not receive a second dose of this vaccine." **(JVT3/040 – INQ000421360).**

Pfizer/BioNTech – Anaphylaxis

2.49 Anaphylaxis (i.e. allergic reaction) is always a potential risk with vaccination. This is something that the MHRA, JCVI and the NHS were alive to before the vaccine rollout began. On 7 December 2020, I received a letter (by email) from the British Society for Allergy and Clinical Immunology concerning what they described as the *"extremely small risk of anaphylaxis with Pfizer/ BioNTech COVID-19 vaccine due to allergy to*

PEG [polyethylene glycol]*"*. I forwarded the letter to Dr Philip Bryan and Dr June Raine of the MHRA, copying Dr Mary Ramsay (Head of Immunisation at PHE) **(JVT3/041 & 042 – INQ000153442 & INQ000153443)**. In the late evening of 8 December, I spoke to Professor Powis who informed me of two suspected cases of anaphylactoid reactions in individuals shortly after they had received the vaccine. There followed a series of related discussions involving the OCMO, the UK CMOs, NHSE, MHRA and CHM. A contemporaneous note that I prepared recording the timeline of those discussions is exhibited **(JVT3/043 – INQ000153462 – 9 December 2020)**.

2.50 On 8 December 2020, the MHRA issued updated guidance to vaccination centres relating to the 'Risk of allergic reactions' **(JVT3/044 – INQ000072090)**. On 9 December the MHRA issued further updated guidance, which included the advice that *"Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment"* **(JVT3/045 – INQ000421371).** On 12 December, Dr Bryan sent the 'MHRA Assessment of Pfizer/BioNTech COVID-19 Vaccine Yellow Card Data' as of 11 December (i.e. a summary of reported vaccine safety incidents) to me and others. That note included the following:

"Data available to MHRA indicate that, as of end of 10 Dec, at least data ~23k doses of Pfizer-BioNTech COVID-19 vaccine have been administered in England. A verbal update from NHSEI on 12 December suggest at least an estimated 56k may now have been administered across the UK.

…

Twenty-eight (28) describe possible mild allergic events which were not identified or treated as anaphylaxis by the reporter. However, such events can be (as with other vaccines) indistinguishable from possible anxiety events (e.g. localised rashes, generalised itchiness, tingling lips, clamminess, facial paraesthesia, tachycardia etc). See table 2 below.

The first two reports of anaphylaxis (and another allergic event not considered to be anaphylaxis) [see table 3], were reviewed in detail by an Independent Expert Group convened by Professor Sir Munir Pirmohamed on 9 December. The MHRA has since received a further 4 cases that report suspected anaphylaxis/anaphylactoid and/or were treated as such – see table 4 below. None of these reported an obvious past history of severe allergy and, based on the available details, it is not clear if these were

actually allergic reactions (and at least could be consistent with an anxiety event). These individuals all recovered (details in table below) and will be followed up by MHRA to obtain further clinical details.

Based on the advice of the Expert Group, the MHRA took regulatory action on 9 December to reduce the risk of anaphylaxis following Pfizer-BioNTech COVID-19 vaccine.

…" **(JVT3/046 – INQ000421495)**.

2.51 As explained in the OCMO Module 4 Corporate Statement (paragraph 6.28), on 14 December 2021, the UK CMOs and lead DCMOs for vaccination jointly advised their respective health ministers that the precautionary 15-minute waiting/observation time following receipt of certain mRNA vaccines should be temporarily suspended in view of the upswing of the Omicron variant, the consequential need to accelerate the vaccine programme, and the relatively small number of serious anaphylactic reactions that had been seen by that time **(JVT3/047 – INQ000203961)**.

Oxford/AstraZeneca – Thrombosis with Thrombocytopenia Syndrome (TTS)

2.52 As set out in the OCMO Module 4 Corporate Statement (paragraphs 6.88 - 6.103), in March 2021, the MHRA responded to reports of blood clots and low platelets with suspected association with the Oxford/AstraZeneca vaccine and the suspension of the use of that vaccine by certain countries. To the best of my knowledge and recollection, I was first alerted to this potential safety signal on 14 March 2021, when Dr Philip Bryan of the MHRA forwarded an alert to me from the Norwegian Medical Products Agency concerning reports of thromboembolic events in temporal relationship with administration of the Oxford/AstraZeneca vaccine **(JVT3/048 & 049 – INQ000421508 & INQ000492029)**.

2.53 The impact of such events on the MHRA's and JCVI's advice is set out in more detail at paragraphs 6.88 to 6.103 of the OCMO Module 4 Corporate Statement. As set out in those paragraphs, these events were extremely rare. However, there was some evidence to suggest that whilst still very rare, young people were more likely to be affected than older people.

2.54 JCVI and CHM met separately on 1 April 2021 to review the latest evidence from the MHRA and PHE on the reported adverse events associated with the AstraZeneca

vaccine. Professor Lim subsequently wrote to the Health Secretary on the issue **(JVT3/050 & 051 – INQ000416155 & INQ000416156)**. As explained in paragraph 6.92 of the OCMO Module 4 Corporate Statement, the JCVI Secretariat forwarded the letter to me on the same day.

2.55 Dr Laura Squire, OBE (the COVID-19 Vaccine Deployment Deputy Director at DHSC), took lead responsibility for drafting a response to Professor Lim's letter. On the evening of 1 April 2021, Dr Squire emailed a proposed outline for response to me; I confirmed I was happy with the proposed line of reply **(JVT3/052 – INQ000504724)**. Subsequently, the OCMO advised on draft versions of the response that were circulated **(JVT3/053, 054, 055, 056 & 057 – INQ000504725, INQ000504726, INQ000073113, INQ000504728 & INQ000073114)**. A final version of the draft letter was emailed to me on the morning of 2 April 2021 **(JVT3/058 – INQ000504729)**.

2.56 The steps that followed are set out at paragraphs 6.96 - 6.103 of the OCMO Module 4 Corporate Statement, including the 7 April press briefing I led alongside Dr Raine and Professors Lim and Pirmohamed. That briefing was my most significant contribution to public messaging in relation to this risk.

2.57 The Inquiry has asked if I had any concerns at the time, or now, around the timeliness of information surrounding the risk of the AstraZeneca vaccine being communicated to the public. The decision as to when and to what extent the public are informed about an adverse risk is very difficult. Professor Lim's letter emphasised JCVI's position that those who would receive the vaccine should be fully informed as to the benefits and risks of vaccination. However, JCVI recognised that a coordinated response from JCVI, MHRA, PHE and DHSC would not be realistically possible until 6 April 2021. I do consider that the decision to wait until after the Easter weekend was a small and legitimate delay, which balanced the importance of communicating information in a timely manner, whilst ensuring that the message was still clear and agreed by all relevant agencies. This ensured a coordinated and complete approach so as to maintain public confidence in a vital vaccine programme.

2.58 The Inquiry has asked for my views as to why the UK regulatory and advisory bodies took longer than other European agencies to act in assessing the reported risks and to make a safety decision. As set out above at paragraph 2.52, by the time I was notified of the emerging reports, the MHRA was already aware of the situation. It was actively assessing the available data, to which it provided an initial response on 18

March, and published detailed findings on 7 April (see paragraphs 6.90 and 6.98 of the OCMO Module 4 Corporate Statement). From the evidence available at the time, we were aware of a rare risk of thrombosis (blood clots) and thrombocytopenia (low platelet count), presenting in approximately 9 cases per million doses. The risk was impacted by age, and during mid-March and early April 2021, the vaccine programme was still in the process of vaccinating the higher age cohorts (70+ years). This meant that the risks to those receiving the vaccine at this time, would have been further reduced. As the UK's medicines regulatory body, responsibility sits with the MHRA to assess and make decisions on the safety of a vaccine product for use in the UK. I trusted the MHRA to review the data and to make timely and appropriate safety decisions.

2.59 Looking back, I do wonder if factors such as Brexit tensions, the somewhat unrefined nature of the AstraZeneca data[4], speculative concerns about efficacy in older populations, and the priority of supply of the vaccine to the UK, meant that for other European countries, AstraZeneca was not deemed as a priority vaccine within their national vaccination programmes. This may or may not have contributed to the approach taken by other European regulatory bodies in response to the early safety signal. I do not consider it follows that the MHRA was not quick to act.

2.60 I have given thought as to whether there are any future lessons that can be learned from the decisions taken in relation to a reported vaccine adverse event. It might be useful to organise exercises involving all relevant UK agencies (government, regulators, advisory bodies and health authorities) to test the effectiveness of decision-making and communications for a potential vaccine safety signal. I am not aware of any previous exercises which have tested internal decision-making in a similar circumstance to that of April 2021. Whilst I do recall an exercise conducted from Heathrow Airport in 2005/6, this was a rehearsal of cross-Europe communications and information sharing for a pandemic flu vaccine safety signal rather than national decision-making and communication within the UK.

[4] AstraZeneca data was extracted from a subset of a clinical trial taking place in South Africa and the UK. Whilst the quality of the AstraZeneca data did not present any doubts as to the vaccine's efficacy, the data was not as easily interpretable as the Pfizer/BioNTech vaccine data.

mRNA Vaccines – Myocarditis & Pericarditis

2.61 Towards the end of April 2021, reports emerged of scientists in Israel investigating a potential signal of myocarditis in young men following vaccination with the Pfizer/BioNTech vaccine. On 28 April 2021, Professor Lim emailed Dr Jenn Matthissen of the MHRA (copying me in) to ask, *"Please can you advise if you know any more about these reports in the news over the weekend regarding young men getting myocarditis and any association with mRNA vaccines?"*. Dr Matthissen replied as follows:

"Yes we are aware of the reports and have spoken with the company (Pfizer) about this and are also reaching out to Israel. We have very recently reviewed myo/pericarditis with Pfizer and our observed vs expected and rapid cycle analysis are not signalling, and no concerns in the content of the spontaneous reports either. We're running a re-review of our epi data just in case, and are keeping very close tabs on this.

We're not aware of any signals with Moderna either and have no UK cases." **(JVT3/059 – INQ000492030)**.

2.62 Also on 28 April 2021, I emailed my contact at the UK embassy in Israel to ask if she could put me in touch with someone at the Israel Ministry of Health who would be able to provide some more information. She responded that she would look into it. **(JVT3/060 – INQ000504730)**. I also replied to Professor Lim and Dr Matthissen to say that I had reached out to contacts in Israel to try and obtain some more information **(JVT3/059 – INQ000492030)**. On 30 April 2021, I exchanged further emails with my contact in Israel and set out the information that it would be useful to have **(JVT3/061 – INQ000492031)**. On 12 May 2021, I received an email from my contact to say that they were trying to arrange a meeting between the MHRA and the Israel Ministry of Health. I forwarded that email to Dr Raine, Professor Pirmohamed and CMO. On the same day, Dr Raine forwarded me a paper that had been prepared by the MHRA reviewing the latest safety data on myocarditis and pericarditis following administration of COVID-19 vaccines. A summary of the paper that Dr Raine forwarded to me explained as follows:

"We took the attached paper to EWG last week on this issue looking across all the vaccines. For Pfizer we had 16 reports of pericarditis, 19 of myocarditis, one case

reporting both pericarditis and myocarditis and one report of viral pericarditis up to the 05/05 DLP. For AZ there are a total of 61 cases reporting pericarditis or myocarditis; 41 report pericarditis and 21 report myocarditis (1 case reports both). There is one case of myocarditis for the Moderna vaccine, all up to the same DLP.

EWG agreed with our conclusion that there was insufficient evidence to support a causal association for any of the vaccines given the extensive usage, epi and spontaneous data." **(JVT3/061 & 062– INQ000492031 & INQ000421511)**.

2.63 On 18 May 2021, representatives of the MHRA met with counterparts from the Israeli Ministry of Health to discuss this potential safety signal. Dr Matthissen of the MHRA communicated a readout of that meeting to me on 30th May, the essence of which was that whilst the Israeli health authorities did indeed see a myocarditis signal in their data, they were as yet unsure if this was definite, and no such signal was being seen so far in UK or EU data, although there was a low intensity signal emerging in the USA.

2.64 On 8 June, I sent an email to CMO with some thoughts on various aspects of the vaccine rollout. In that email I noted as follows:

"There is a low intensity signal now in UK MHRA data on myocarditis with Pfizer; mainly dose 2; mainly mild and transient but I think 2 deaths. Signal definitely stronger in younger adults. No obvious trigger such as intense exercise (d/w US DoD and Israelis). No need for label change but sense JCVI may see it as material in consideration of secondary school age children" **(JVT3/063– INQ000421514)**.

2.65 Throughout the summer of 2021, this safety signal continued to be carefully monitored by the MHRA and the CHM. JCVI was also regularly updated on the matter, and it formed a key part of its deliberations on the question of vaccinating children (this issue is discussed in more detail at paragraphs 6.44 - 6.55 of the OCMO Module 4 Corporate Statement). When JCVI issued its *Updated statement on COVID-19 vaccination of children and young people aged 12-17 years* on 4 August 2021, it included the following summary:

"In recent weeks, reports have been submitted in the UK and other countries of the extremely rare occurrence of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart), following the use of Pfizer-BioNTech BNT162b2 and Moderna mRNA-1273 vaccines. These extremely

rare adverse reactions have been more frequent shortly after the second dose, and in younger individuals and males; the data from the United States indicate about 60 reported cases per million second doses in younger males, with reporting rates after the first dose being 6 to 7-fold lower. The mechanism of action underlying these rare events is not currently known. Israel and the United States have reported most of the cases and experience from these countries indicate that the reported cases of myocarditis following mRNA vaccination are of a 'milder phenotype' with the vast majority of persons recovering swiftly from the acute episode, compared to more typical cases of myocarditis (which are mostly viral or idiopathic in aetiology). Follow up of reported cases in Israel and the United States is on-going. These reports will continue to be closely evaluated by MHRA and JCVI." **(JVT3/064 – INQ000401363.)**

2.66 With regard to public communications on this matter:

2.66.1. On 4 August 2021, I appeared at a vaccine technical briefing alongside Dr Raine and Professor Lim on the issue of vaccinating children. The myocarditis signal was discussed at that briefing **(JVT3/065 – INQ000497054)**.

2.66.2. On 19 October 2021, I undertook an interview with BBC Sport on the issue of vaccine uptake amongst elite athletes, and as part of that addressed the risk of myocarditis following vaccination **(JVT3/066 – INQ000421521)**.

2.66.3. On 15 November 2021, I appeared at another vaccine technical briefing alongside Dr Raine and Professor Lim. Again, the myocarditis signal was discussed. I said that *"...confidence has grown over safety, in particular, the very low risks of suspected myocarditis compared with the long term benefits of a life without COVID illness and COVID disruption"* **(JVT3/067 – INQ000497051)**.

Pharmacovigilance

2.67 I am asked by the Inquiry for my views on the UK's pharmacovigilance systems. I believe that the MHRA has some of the most robust pharmacovigilance systems in the world and I am not qualified to offer a view on how they might be improved. From my perspective, it is not a question of improving anything in respect of the MHRA's independence, but rather ensuring that it continues to be fiercely protected. As

explained in the OCMO Module 4 Corporate Statement, we in the OCMO were extremely protective of the MHRA's independence and on 16 November 2020, the CMO and the GCSA jointly wrote to Dr Raine reiterating our support as follows, *"It is very unlikely, but if at any time you feel under pressure that impinges on your total independence and want support please do let either or both of us know, as the whole system depends on the integrity of MHRA on behalf of the public"* **(JVT3/068 – INQ000071886)**.

2.68 In preparing this statement, I have been shown a WhatsApp message from Matt Hancock to the CMO on 9 January 2021 in which he expresses concerns about the UK's pharmacovigilance systems and, in particular, says that he worries *"the details will be shonky"* **(JVT3/069 – INQ000129666)**. I do not recall Mr Hancock ever raising such concerns with me.

2.69 I am not in a position to evaluate the levels of public confidence and trust in the MHRA. My impression was that the vast majority of people had never heard of the MHRA before the pandemic. It is possible that increased visibility could improve levels of public confidence.

Manufacturing

2.70 As set out in paragraph 6.16 of the OCMO Module 4 Corporate Statement, there were three key pharmaceutical companies (Pfizer, Moderna, AstraZeneca) who played a significant role in the UK's vaccine manufacturing capabilities.

2.71 The Vaccine Manufacturing and Innovation Centre ("VMIC") was launched in 2018, as the UK's response to addressing the structural gap in late-stage vaccine manufacturing processes. The centre was designed not only to support the UK's emergency preparedness efforts for future epidemic threats, but also to develop new technologies for other health treatments, such as personalised cancer vaccines and vectors for gene therapy. The centre was largely funded through the UKRI, with additional funding received from commercial partners. In early 2022, VMIC was sold off to the US-headquartered pharmaceutical company, Catalent.

2.72 I was first informed about VMIC's launch during a meeting with Steve Chatfield (UKVN) in 2018. The vaccine manufacturing process is complex, requiring significant Research and Development resources to successfully meet national product demand. Often, the

'bottleneck' in vaccine production occurs once the vaccine product is ready to be filled into vials. VMIC was not designed to facilitate such large-scale production efforts, which realistically, can only be achieved by the big pharmaceutical companies. I was therefore surprised by the decision that had already been taken to approve funding for VMIC.

2.73 Despite efforts to accelerate VMIC's construction in April 2020, vaccines from the leading pharmaceutical companies were approved for use by the MHRA in December 2020 - January 2021. It became clear that VMIC had not been used in the manner intended, and had not played a vital role in the vaccine manufacturing programme. Whilst I was not involved in the sale of VMIC, for these reasons, I did not have any concerns about this decision.

2.74 As for the current state of vaccine manufacturing in the UK, AstraZeneca has a manufacturing site in Speke, Liverpool. I am aware of the recent announcement that the firm plan to invest a further £650 million in the UK, building on the site's current role in supplying their childhood vaccination programme. I am also aware of Moderna's manufacturing facility in Oxfordshire, which is due to become operational in 2025. I was not involved in any deal negotiations between Moderna and the UK Government. My personal recommendations for improving the UK's ability to manufacture its own vaccines are discussed below at paragraph 5.5.2.

Public messaging

2.75 As the lead DCMO for vaccines, I had a prominent public facing role when it came to communicating information about COVID-19 vaccination. As explained in the OCMO Module 4 Corporate Statement, I acted as the OCMO's primary interlocutor between the Government's technical advisory bodies (JCVI and the MHRA), Ministers and the general public. I usually appeared alongside Professor Lim and Dr Raine at the vaccine technical briefings that were intended to provide the public with clear information and advice. These long-form briefings were held without Ministers present, as the advice was entirely scientific and technical. In addition, I also regularly presented at the politician-led No.10 press briefings on matters relating to the vaccine programme.

2.76 In November 2020, in addition to the engagements referred to above, and in preparation for the vaccine rollout, I pre-recorded a number of videos with the DHSC

social media team that each conveyed some of the key information about the vaccines, to be deployed across the DHSC media channels **(JVT3/070 & 071 – INQ000153126 & INQ000421493 – 5 & 21 November 2020)**.

2.77 Once the vaccine programme had begun, I undertook a large number of media engagements aimed at disseminating accurate information and encouraging vaccine uptake. The following is a summary of some of the key engagements that I undertook:

2.77.1. 2 December 2020 – I appeared alongside the Prime Minister and Sir (now Lord) Simon Stevens at a No.10 press conference to provide information about the impending vaccine rollout and encourage uptake **(JVT3/072 – INQ000497055)**.

2.77.2. 2 December 2020 – I appeared on an ITV News Q&A special and specifically addressed some of the concerns that black and ethnic minority people were expressing about the vaccines, amongst other issues **(JVT3/073 – INQ000504736)**.

2.77.3. 2 December 2020 – we released a DHSC video in which I answered questions such as "what is a vaccine?", "what's in a vaccine?", "how do vaccines work?", "are there any risks to taking a vaccine?" etc. **(JVT3/074 – INQ000497053)**.

2.77.4. 3 January 2021 – I wrote an article for the Mail on Sunday in which I specifically addressed the decision to extend the interval between the first and second doses **(JVT3/075 – INQ000421501)**.

2.77.5. 24 January 2021 – I wrote an article for the Telegraph in which I discussed how vaccines work, the importance of sticking to Government guidance even after being vaccinated and the decision to extend the dosing interval **(JVT3/076 – INQ000421504)**.

2.77.6. 27 January 2021 – I appeared on a Channel 4 News Q&A special, again addressing vaccine-related questions and concerns from members of the public, including the issues of vaccine hesitancy in black and ethnic minority communities and vaccine misinformation **(JVT3/077 – INQ000497057)**.

2.77.7. 10 February 2021 – I appeared on another ITV News Q&A special, again addressing vaccine-related questions and concerns from members of the public **(JVT3/078 – INQ000504735)**.

2.77.8. 24 February 2021 – I appeared on ITV's *Good Morning Britain*, Sky News and Channel 5 News, again addressing vaccine-related questions and concerns from members of the public and journalists **(JVT3/079, 080 & 081 – INQ000497052, INQ000497056 & INQ000497050)**.

2.77.9. 29 July 2021 – I appeared on a BBC News Q&A special, addressing vaccine-related questions and concerns from members of the public, particularly young people **(JVT3/082 – INQ000497058)**.

2.77.10. 19 October 2021 – I undertook an interview with BBC Sport on the issue of vaccine uptake amongst elite athletes **(JVT3/066 – INQ000421521)**.

2.77.11. 22 October 2021 – I wrote an article for the Sun encouraging people to get a booster vaccine **(JVT3/083 – INQ000421522)**.

2.77.12. 30 November 2021 – I wrote an article for the Sun again encouraging the uptake of booster vaccines in the face of the emerging Omicron variant **(JVT3/084 – INQ000421519)**.

2.78 At the beginning of March 2021, I helped to prepare a DHSC 'Frequently Asked Questions' document about the vaccines that included "JVT says" sections. That document responded to some of the more common concerns that were apparently engendering hesitancy in some quarters. For example, what the side effects of the vaccines might be, whether they were capable of affecting fertility and why the dosing interval had been extended **(JVT3/085 – INQ000072957 – 5 March 2021)**. As previously stated, no vaccines are without risk, so the question when offering clinical advice to the public is whether the benefits *exceed* the risks. I do consider the OCMO's contributions to public messaging about vaccines adequately reflected both the risks and benefits of vaccination.

2.79 As set out in the OCMO Module 4 Corporate Statement (paragraphs 6.79 - 6.103), the vaccine advice in relation to women who were pregnant, children and individuals under the age of 30/40, developed over time as more data became available. We were of course conscious that this made public messaging more difficult and meant that even

more time and effort was needed to carefully communicate with members of the public. However, my fundamental approach of trying my best to communicate the unadulterated scientific facts in as plain language as possible remained unaffected.

2.80 The Inquiry has asked whether, when providing information to the public about vaccines, both relative risk and absolute risk statistics should be referred to and these concepts explained. It is standard medical practice to lay out both the benefits and risks of any medical intervention, allowing the patient to make an informed treatment choice. As set out in the OCMO Module 4 Corporate Statement at paragraph 6.73, relative and absolute risk statistics are only useful if also presented alongside benefits. Generally, relative risks can be misleading when communicated to non-experts if the effect size is very rare – for example, a 50% increased risk of a side effect that occurs in one in a million people is still a very rare risk at population-level. The same is true for efficacy: 50% protection against a disease that only kills one in a million is a minute increase in population protection but substantial protection for a single individual. This does not mean that such statistics should not be used, but they should be put into context. This reduces the risk of harming public confidence in a vaccine product and reduces the risk of vaccine hesitancy.

Disinformation/ misinformation

2.81 My understanding is that DCMS was the cross-Government lead department for combatting disinformation and misinformation about the COVID-19 vaccine programme. I was aware that disinformation and misinformation existed, and that social media played a role in its proliferation. I was also, in broad terms, aware that work was being undertaken across Government to address it. However, my involvement in that work only extended to providing accurate information when asked. Be it via quotations for Government publications, through specially commissioned video content, or press engagements (as described above). I am not qualified to comment on the motives behind the spread of disinformation and misinformation, or the adequacy of the steps taken to counter it.

2.82 When faced with disinformation or misinformation, my personal approach was simply to denounce it and focus on delivering accurate information. For example, when I spoke at the No.10 press conference on 9 November 2020, following the announcement of the Pfizer/BioNTech Phase 3 trial results, I said this:

"Vaccine misinformation has been out there ever since the first vaccines were made. It is exactly that, misinformation, and I don't propose we give it any further airtime. If you look at the staggering likelihood of hospitalisation or death rising with increasing age, I predict very strongly there will be a very significant demand in the elderly in particular for this vaccine, and the ones that follow" **(JVT3/017 – INQ000071551)**.

2.83 Similarly, on 2 December 2020, I was asked on ITV News whether the vaccine programme was trying to implant microchips into people. I regarded that as a frankly ridiculous question and said, *"I'm not sure that is even a sensible question…"* **(JVT3/073 – INQ000504736)**. A more common question posed to me was whether the vaccines could affect fertility. For example, when I appeared on Channel 4 News on 27 January 2021, I spoke to the Chair of Balham Mosque and Tooting Islamic Centre, who explained that he had spoken to many people and had heard *"conspiracy theories and worries"* about the vaccine leading to infertility. In response, I explained that these were simply rumours and that there was *"absolutely no data whatsoever"* to support them. I also said that I did not know of any vaccines that affect fertility and that all I can therefore do is *"refute that head on… I believe that to be an unfounded rumour"* **(JVT3/077 – INQ000497057)**. Similarly, when I addressed that particular piece of misinformation on *Good Morning Britain* on 24 February, I described it as *"nonsense"* and explained that *"there's just no evidence at all that there are any issues in relation to planning a family or fertility"* **(JVT3/079 – INQ000497052)**.

Hesitancy

2.84 My understanding is that, in general, public confidence in the COVID-19 vaccines in the UK was very high. However, a certain amount of hesitancy is to be expected in any vaccine programme.

2.85 I do not have the knowledge or expertise to comment authoritatively on the causes of any public mistrust. However, based on my experience, some of the hesitancy that was witnessed can be attributed to: concerns around fertility (particularly in young females), concerns around vaccine ingredients (particularly in relation to alcohol and animal products), and concerns about the rigour of the testing and regulatory process given the speed with which the vaccines were developed and approved. In addition, I had some limited personal experience of speaking to people who had had a bad reaction (i.e. they had experienced fever and prostration) following their first dose and were therefore adamant that they weren't going to have a second dose. My contribution

to addressing vaccine hesitancy was the public engagements that I have outlined above.

2.86 In mid-2021, it became apparent that there was a degree of vaccine hesitancy among elite athletes in the UK. This was potentially significant because of the influence that such individuals often command, particularly in a younger demographic that was already displaying greater hesitancy as compared with older generations. In August and September 2021, I therefore undertook a number of engagements that were intended to improve vaccine uptake amongst professional footballers. On 2 August, I held a virtual meeting with the captains of the English Premier League ("EPL") football teams at which I provided information about the vaccines and encouraged the players to have them. On 13 September, I did the same with captains and managers of teams from the English Football League ("EFL"). I also recorded video messages, at the request of the EPL/EFL, to be distributed to players and fans more broadly **(JVT3/086 – INQ000073834 – 3 September 2021)**.

2.87 I am asked by the Inquiry about my role in relation to a Covid-O paper titled *Vaccine Uptake: COVID-19 Vaccine Confidence Communications Plan: BAME Audience Update* **(JVT3/087 – INQ000092296)**. That document was prepared by DHSC in advance of a Covid-O meeting on 25 January 2021. I did not contribute to its preparation, and I was not invited to attend the meeting.

Vaccine as a condition of deployment ("VCOD")

2.88 The issue of VCOD for healthcare workers did not begin with the emergence of COVID-19. It has been a difficult and divisive issue for a long time. Indeed, the policy of mandatory flu vaccination for healthcare workers was being discussed within DHSC when news of the novel coronavirus was emerging at the beginning of January 2020 **(JVT3/088 – INQ000233736 – 6 January 2020)**.

2.89 In February and March 2020, when the Coronavirus Bill was being drafted, there was discussion around including a power to make vaccination mandatory for health and care workers. That did not necessarily mean vaccination with a COVID-19 vaccine, but potentially any licensed vaccine. I contributed to advice on this. On 7 February 2020, I received an email from Kevin Dodds (DHSC) that said *"in the SoS meeting on legislation today, there was also discussion on vaccination. Specifically, there was*

support for including in the possible CoV Bill a power to make vaccination mandatory for HCWs – the discussion was flu, but I assume it could apply to others. In addition, Lee and SoS discussed whether there would be public health benefit in extending the flu vaccine programme, even if only for some vulnerable groups, into the spring and summer as last winter's immunity wanes". On 8 February, I responded as follows:

"I am cautious:

1. There is evidence of antibody waning in the elderly by end of Feb sometimes a little earlier – sure – so it's a credible suggestion

2. Re-vaccination is feasible but will cost £20/head; it also consumes or diverts primary care resources

3. Flu A came early – to me it is not plausible it will now resurge and it has already dropped to baseline

4. Flu B could still come but now early Feb and not a peep – this does not mean it won't but by next week I will be saying 'now unlikely'

5. Flu B impacts predominantly children in most seasons

6. The exp date on seasonal flu in from recollection June so no specific expiry problem

7. It could be perceived as a desperate measure

8. Modellers say the N-CoV is unlikely to peak before April and the latest data suggest April – June. There is very little flu left around then.

9. If seasonality is a factor it goes away in the warm weather, then a resurgence in parallel with flu in autumn 2020 is a much more worrying proposition. That is what [sic] a bill that gives general powers to vaccinate makes more sense.

On the Bill it would be a great opportunity to obtain a general power to mandate licensed vaccines for public sector workers full stop, based on public health need at the time. I would de-sensitise this by not mentioning flu specifically. I would angle it towards PH need/ rationale and a licensed vaccine. This avoids the military fearing the bill affects them and means the government has powers to vaccinate squaddies with

unlicensed vaccines for combat deployment purposes. I remember clearly this did not land well in Gulf 1 when I was in green" **(JVT3/089 – INQ000151420)**.

2.90 On 4 March 2020, Ellie Rose (DHSC) emailed the OCMO to say *"We are getting a lot of push back from EDS (part of the Cabinet Office) on the mandatory vaccination clause. This may result in it being removed from the Coronavirus Bill. We need to clarify if CMO and DCMO would be prepared to defend this measure as 'necessary'"*. A member of the OCMO team responded to confirm that *"CMO and DCMO are in agreement that whilst it would be preferable, they wouldn't go as far as stating that it was necessary"*. On 5 March, I added the following, *"I have no capacity to deal with this. CMO and me clear it was a nice to have. It's [sic] usefulness is predicated on an autumn wave which we are trying to avoid through carefully titrated mitigation measures. We can let it drop"* **(JVT3/090 – INQ000421481)**. Ultimately, Ministers decided not to include such a provision in the bill.

2.91 The issue re-emerged once the UK had a safe and effective COVID-19 vaccine. In February 2021, Professor Harries was asked to contribute to advice that was to be put to Ministers on making vaccination a condition of working in a care home **(JVT3/091 – INQ000153737 – 15 February 2021)**.

2.92 The matter was discussed at a Prime Minister-led vaccine deployment meeting on 9 March 2020. I was not present at that meeting, but the CMO was. I have seen a note of the meeting, which records the following:

"…the PM asked the Health Secretary, CDL, and CMO for their views on mandating vaccinations amongst social care workers. The Health Secretary was supportive, and CDL noted that we could move quicker on health and social care workers than on the wider issue his review is dealing with. CMO noted that this was a political decision, and that there is a compelling argument that those working with vulnerable patients have a professional duty to get vaccinated. The PM decided that we should prepare to move ahead with the mandation of vaccination for social care workers initially and at a faster pace than other sectors, and consider mandating vaccination for all healthcare workers subject to further conversations with the NHS and ongoing efforts to increase uptake.

ACTION: CDL / Health Sec to take this forward within the context of CDL's wider review, and CDL to provide an update on timelines across the whole piece this week. **(JVT3/092 – INQ000063519)**.

2.93 On 17 March 2021, there was a COVID-O meeting to discuss VCOD in health and adult social care settings. The OCMO was represented at that meeting by Professor Harries. Ministers decided to pursue the policy for social care workers, but agreed that more work was needed, including by way of public consultation **(JVT3/093 – INQ000092064)**.

2.94 On 22 March 2021, the CMO's view on the issue was conveyed to the Cabinet Office in the following terms:

"CMO's view is that we need to be extremely upfront about the fact that some people will have side effects as a result of the vaccination. No medicine is without risk. Decision makers need to be clear that mandation means the risk of someone who would not have otherwise had the vaccine having a very serious side effect.

An example that highlights the principle is the recent discussion on blood clots.

A detailed review into five UK reports of a very rare and specific type of blood clot in the cerebral veins (sinus vein thrombosis) occurring together with lowered platelets (thrombocytopenia) is ongoing. This has been reported in less than 1 in a million people vaccinated so far in the UK, and can also occur naturally. The 1 in a million figure will change if more instances are reported and as more vaccinations are given. A causal association with the vaccine has not been established." **(JVT3/094 – INQ000073054)**.

2.95 Advice was sought from the CMO again in May 2021. The following advice was provided in response:

"CMO's view is that if this policy is taken forward that there is logic to having a stratified approach as there will be different levels of risk based on the different groups of patients that staff interact with. The top of that hierarchy of patients (e.g. those most at risk) are those who the vaccination is less likely to fully work in e.g. immunocompromised patients. Then it would be patients who are at risk from COVID-19 e.g. the elderly, the CEV. Then those who are at low risk from COVID e.g. children.

There is also a logic to looking at the work that staff normally do. E.g. providing brief advice on a ward round is lower risk than an hour session/procedure.

There is also a risk to vaccination, as for every medicine, including vaccines, we should consider it likely that there will be very rare but very serious side effects. This should be accounted for when taking decisions" **(JVT3/095 – INQ000073398 – 27 May 2021)**.

2.96 My understanding is that the public consultation on VCOD in care homes ran from 14 April to 26 May 2021. Following that process, officials in DHSC prepared a paper for consideration by Ministers which recommended publication of a Government response and next steps towards implementing VCOD in care homes. That paper was sent to me for comment on 8 June 2021. My response was, *"No comments. It makes very good PH and infection prevention sense"* **(JVT3/096 & 097 – INQ000421513 & INQ000421515)**. At a COVID-O meeting on 15 June 2021, Ministers agreed to move forward with the proposals set out in the paper **(JVT3/098 – INQ000092238)**. It was also noted that further work would be undertaken on the questions of extending the policy to cover health workers more broadly and vaccination against flu as well as COVID-19. No one from the OCMO was invited to attend that meeting, which was unsurprising given that this was largely a political decision and CMO advice had already been provided.

2.97 On 3 June 2021, I was asked by DHSC to advise on the rationale for extending the VCOD policy to include all healthcare workers for both flu and COVID-19 vaccinations, with a view to the Secretary of State announcing a public consultation on the subject on 17 June. I was on leave at the time, but replied as follows:

"…There is a very strong evidence base for nosocomial spread of CV19 prior to Dec 2020. Also CV19 has very severe consequences.

Mandating flu in SC [Social Care] is not so easy on the grounds that flu is less serious; but almost all the evidence of vaccinating workers to protect residents comes from SC and long term residential HC [Health Care] settings, so that can be relied upon.

Mandating flu in HC is far more difficult as the evidence that is (sic) protects patients in acute care settings is far less extensive and much more equivocal.

Somewhere back when (after 2017) PHE has done some work on this – worth refreshing IMO.

I would not want a legal instrument for flu and covid combined to derail for covid because flu crashed and burned and the legislation was 'collective' (probably talking

legal rubbish but you get my drift). Better to have two separate legal instruments for mandating each separately. Less risk we lose the lot in one go.

This is just advice. It is a political decision whether to attempt mandation of vaccines for HCWs." **(JVT3/099 – INQ000421516 – 3 June 2021)**.

2.98 On 17 June 2021, I followed up with the following documents that I considered might assist:

2.98.1. *A rapid evidence appraisal of influenza vaccination in health workers: An important policy in an area of imperfect evidence* (Jenkin et al, 2019) – This was a paper that I co-authored with my team from Nottingham University as part of work done for WHO. Our conclusions were as follows:

"The evidence on most questions related to influenza vaccination in HWs is mixed and often of low-quality. Substantial heterogeneity exists in terms of study designs and settings, making comparison between studies difficult. Notwithstanding these limitations, a majority of studies suggests that influenza vaccination benefit HWs and their employers; and HWs are implicated in transmission events. The effects of vaccinating HWs on patient morbidity and mortality may include reductions in all-cause mortality and influenza-like illness (ILI). Taken together, the evidence suggests that HW vaccination is an important policy for HWs themselves, their employers, and their patients" **(JVT3/100 – INQ000269386)**.

2.98.2. How to implement seasonal influenza vaccination of health workers: An introduction manual for national immunization programme managers and policy makers (WHO, 2019) – I explained in my email that this was "*more of a practical manual*" **(JVT3/101 – INQ000269387)**.

2.98.3. Vaccination of health care workers to protect patients at increased risk for acute respiratory disease (Dolan et al, 2012) – This was a paper that I co-authored. It concluded as follows:

"The existing evidence base is sufficient to sustain current recommendations for vaccinating HCWs on the grounds that some protection of high-risk patients against influenza seems likely. However, vaccination should be considered 1 element of a broad package of infection prevention and control

measures, such as good hand and respiratory hygiene, environmental cleaning, protection against respiratory droplets, and cohorted care during outbreaks. Well-designed studies that strengthen the evidence based might increase compliance with guidelines, resulting in improved coverage" **(JVT3/102 – INQ000269382)**.

2.98.4. *A systematic review of mandatory influenza vaccination in healthcare personnel* (Pitts et al, 2014) – This was a paper published in the American Journal of Preventive Medicine that I did not contribute to. It concluded as follows:

"Evidence from observational studies suggests that a vaccine mandate increases vaccination rates, but evidence on clinical outcomes is lacking. Although challenging, large healthcare employers planning to implement a mandate should develop a strategy to evaluate HCP and patient outcomes. Further studies documenting the impact of HCP influenza vaccination on clinical outcomes would inform decisions on the use of mandatory vaccine policies in HCP" **(JVT3/103 – INQ000269383)**.

2.98.5. WHO Guidance: Ethical implementation of mandatory vaccination **(JVT3/104 – INQ000269384)**.

2.99 On 21 June 2021, I was copied to an email from Charles Watson (Flu Policy, DHSC) to Professor Mark Wilcox (NHSE), which explained, *"This morning we discussed the need for clinical advice to inform the consultation re vaccination being a condition of deployment (VCOD) in wider ASC settings and also health care for both the Covid-19 and Flu vaccines. This consultation builds on the VCOD policy currently being implemented in care homes… In light of the tight timescales, I would be grateful if you could provide advice on the following questions/ issues for both flu and Covid-19 in health care settings"*. I responded to this email, re-attaching the above documents and providing the following advice in response to the questions posed (the questions are in black text and my responses are in red).

"1. Your clinical advice on the risks to patients and staff to inform the scope of the VCOD policy i.e. from a clinical perspective could this policy be limited in scope to only patient facing roles in areas perceived as high risk (e.g. inpatient hospital settings) or are the risks to patients broader? Currently we are considering all CQC regulated

activities which includes multiple settings e.g. Hospitals, General Practice, Dentistry, care in the community etc.

The late Sir Paul Cosford (and his office) did useful early work on defining settings where outbreaks of flu were most likely to lead to catastrophic patients losses. It was all the usual suspects: haem-onc, transplantation, renal etc.

2. For care homes, SAGE recommended a minimum 80% & 90% uptake coverage for staff and residents respectively for Covid vaccination. Is there a safe operating minimum Covid vaccination level for healthcare regulated activities across NHS settings? Alternatively, is there any clinical rationale that would support different coverage rates in different healthcare settings?

Nancy Arden looked at this in the early 1990s (showing my age). It was an Abstract presented to Options for the control of influenza III in Courchevel. I could locate if I had time. It concluded that vaccination coverage needed to be 80% or higher in NH for there to be a marked drop off in the likelihood of outbreaks (of flu).

…

4. Are there specific settings/ activities which should be prioritised?

See above. If mandation were decided on by Ministers, I would be inclined to keep it programmatically simple and say all NHS staff who ever have reasons to enter patient areas (including admin and clerical staff who anecdotally were very keen to have HCW status for COVID vaccination). I think that is pretty much everyone except ground staff.

…

7. Visiting professionals and social visitors – Whether the requirement should apply to visiting professionals / visitors? Or would testing / PPE be sufficient for some people.

IMO it should apply across the board unless there are sound reasons (on a one off basis) why the visit was unforeseen and there was no time for vaccination. But if it is within one's written JD that you may have to attend patient areas in healthcare facilities as part of your role then I really think if Ministers decide to do this, it applies.

…" **(JVT3/105 – INQ000269380).**

2.100 On 25 June 2021, Gavin Larner (Director of Workforce, DHSC) emailed me to ask for advice on the clinical evidence for VCOD. He said, *"I am unclear as to whom in the Department has the responsibility for convening the right scientific expertise and developing a single piece of advice for Ministers"*. I replied as follows:

"I am unclear too. I have done a lot of work on the flu area for WHO prior to 2017 and taking months – it's all been published; all of that work has been passed to Elin and PHE. I don't have any bandwidth to repeat it and it is not a 3 day job.

1. *There is essentially no evidence base for the effect of Covid vaccination of HCW on protection of patients/ residents*
2. *There is plenty of evidence that nosocomial Covid-19 is a problem in acute healthcare and in residential care*
3. *There is evidence now that CV-19 vaccines reduce transmission and protect from infection (symptomatic and asymptomatic, less so for the latter)*
4. *On flu there is evidence for higher attack rates in HSCWs*
5. *There is adequate evidence that vaccination of staff vs. flu protects residents – but this evidence has been built up mainly in residential care where it's easier to study*
6. *There is evidence that the most effective strategy for increasing flu uptake is mandation – but this evidence is very largely from USA*
7. *There is some old rather scanty data that show 80% uptake of flu is needed in a care home (across both residents and staff) to reduce the probability of outbreaks*

If time is short and the deadline is hard then I suggest the WHO work in this area on flu (we concluded it in early 2019) at least has agreement by an international body of experts." **(JVT3/106 – INQ000153996)**.

2.101 My understanding is that following the closure of the public consultation on the wider implementation of VCOD (22 October 2021), Ministers decided to extend the policy across healthcare settings. To the best of my knowledge and recollection I did not provide any further advice on this policy after 25 June 2021.

2.102 I am not in a position to offer a view on the effects of VCOD or any lessons from its implementation during the pandemic.

Vaccine Dosing Schedule

2.103 Paragraphs 6.56 – 6.69 of the OCMO Module 4 Corporate Statement set out the contributions of the UK CMOs and DCMOs to the vaccine advice and decision-making in relation to vaccine dosing intervals. I do not repeat this material again.

2.104 On 22 December 2020, I wrote to Dr Raine asking the MHRA expert working group and CHM to consider whether second dosing of BNT162b (Pfizer/BioNTech vaccine) could be moved to an extended interval in order to allow a larger proportion of the population to receive their first vaccine dose **(JVT3/107 – INQ000416131)**. At this time, a new strain of the SARS-CoV-2 virus (Alpha) had been detected within the UK. Whilst laboratory analysis was still underway, majority scientific opinion suggested a low probability that the vaccine would have substantially less protective efficacy against the new strain. As discussed at paragraph 6.63 of the OCMO Module 4 Corporate Statement, I sent a similar letter to Dr Raine with regards to extending the dosing interval for AstraZeneca's AZD1222 vaccine.

2.105 Discussions led by the MHRA took place in the intervening period before the MHRA's announcement on 30 December 2020 that the AstraZeneca vaccine had been approved for use in people aged 18 years or older and that the second dose could be administered between four and twelve weeks after the first. At the same time, MHRA announced that the CHM had reviewed further data for the Pfizer/BioNTech vaccine and the advice had been updated to say that the second dose should be given at least twenty-one days after the first (see paragraph 6.67 of the OCMO Module 4 Corporate Statement). Ahead of the MHRA's announcement, I communicated their agreed dosing interval conditions for BNT162b to DHSC colleagues and Pfizer/BioNTech representatives:

2.105.1. On 29 December 2020, in the context of discussions about the MHRA's temporary authorisation of AstraZeneca's ChAdOx1/AZD1222 vaccine, I commented to a DHSC colleague that, *"MHRA has also clarified some conditions for Pfizer/BioNTech. But notably on vaccine interval it says AZ*

second dose may now be given 4-12 weeks post first and for PFZ the interval must be at least 3 weeks." **(JVT3/108 – INQ000153546)**.

2.105.2. Later that same day, I attended a meeting with Pfizer/BioNTech representatives, where I set out the MHRA's dosing interval conditions and JCVI advice **(JVT3/109 – INQ000504723)**.

2.106 I played a key role in communicating the MHRA's decision to the public and to the healthcare profession. In addition to the letter to the medical profession on 31 December 2020 which I signed alongside the UK CMOs (see paragraph 6.68 of the OCMO Module 4 Corporate Statement), I have included below examples where I contributed to communication efforts on dosage intervals:

2.106.1. On 29 December, I advised on public-facing lines to be used in the DHSC communications material, explaining the move to a larger gap between doses **(JVT3/110 - INQ000153542)**.

2.106.2. On 29 December, I provided my comments to colleagues from the Wellcome Trust and the DHSC regarding the communication of any shift to a single dose strategy. I stated:

"1. Supply situation clearer now

2. New data from AZ show longer interval is beneficial (CHM will state this tomorrow)

3. No good reason to believe this will be detrimental to Pfizer based on first principles

4. But clear on both it's still a 2-dose schedule

5. However to share the benefits faster and more evenly across the high risk population (Phase 1) modelling is now clear that prioritising dose 1 is the right strategy

6. Operationally also easier for the NHS allowing them to get their heads down and go 'as fast as supplies allow' until the end of March

Not necessarily in correct order. If pressed: New variant adds to rather than subtracts from the problem by frontloading disease now in Jan and Feb." **(JVT3/111 – INQ000153535)**.

Inequalities

2.107 My understanding is that the COVID-19 vaccines were, in general, more accessible than any vaccine in UK history. A vast amount of cross-Government work went into ensuring that those who wanted to receive the vaccine could do so quickly and easily once they became eligible. Despite this, I am also aware of data showing that vaccine uptake was generally lower across the more deprived sections of society. Plainly this is an important issue that needs to be addressed. However, I am not qualified to assist the Inquiry on it in any meaningful way.

Children and Young People

2.108 Paragraphs 6.44 - 6.55 of the OCMO Module 4 Corporate Statement set out in detail, the OCMO's advice on offering the COVID-19 vaccines to children and young people, specifically those aged between 12-15 years. I recall being involved in group discussions with the UK CMOs, however it was the CMOs who did most of the debating on this issue and prepared the statement published on 13 September 2021. I regularly attended JCVI meetings as a medical adviser and observer, and I recall shadowing JCVI's discussions as to the risks and benefits of vaccinating children over 12 (**JVT3/112 – INQ000354513 – 10 June 2021**, **JVT3/113 – INQ000354515 – 15 June 2021**, **JVT3/114 – INQ000354518 – 29 June 2021**, **JVT3/115 – INQ000354520 – 1 July 2021** & **JVT3/116 – INQ000354527 – 29 July 2021**).

2.109 An example of my specific contribution to the UK CMOs' deliberations is the paper I forwarded to the CMO on 10 September **(JVT3/117 & 118 – INQ000154099 & INQ000073902).** I considered this paper to be material to the ongoing discussions since the figures indicated that the risk of myocarditis after one dose of the Pfizer vaccine in boys (and therefore also in girls) was lower than the risk of being hospitalised for 120-days with COVID-19. This paper articulated the general debate at the time which balanced the risks associated with vaccination against the risks of COVID-19 infection, morbidity and mortality.

2.110 I did provide discrete pieces of advice on the vaccination of specific groups of children. I have provided examples below:

2.110.1. On 16 January 2021, I advised DHSC colleagues on vulnerable children receiving the COVID-19 vaccine. I expressed my contentedness that *"specialised considerations might be made to vaccinate a very small number of ultra high risk children"* **(JVT3/119 – INQ000153630)**.

2.110.2. On 23 November 2021, the CMO and I advised the Surgeon General on the vaccination of children of service personnel **(JVT3/120 – INQ000074330)**.

2.111 The UK CMOs advice from 13 September 2021 was that vaccination would likely *reduce*, not *prevent*, transmission. At the time of their advice, there was already reasonably strong evidence from several studies that there was (at least) a short-term reduction in transmission as a result of vaccination, especially in those who had never experienced infection previously. More detail on the available evidence, both at the time of the UK CMOs advice and now, is set out at paragraph 6.55 of the OCMO Module 4 Corporate Witness Statement. It is my understanding that the UK CMOs' decision considered not only the evidence of transmission, but supported the benefits of reducing educational disruption.

2.112 The Inquiry has asked for my views as to whether, based on the current evidence, the COVID-19 vaccines are effective at limiting transmission. It is important to remember that there were several strains of the virus which impacted the efficacy rate of the vaccine. Not only is the virus continuing to undergo evolution at an unprecedented rate, but the vaccine has also been reformulated at least three times. Notwithstanding, it is only fair to remark that the initial data showing that vaccines had an effect on limiting transmission do not hold true for current vaccination against current variants where it is clear that the effect on transmission is extremely limited, and the major effect continues to be the protection of at-risk patients from severe illness and poor outcomes. Therefore, I do not consider it helpful to assess the current evidence on vaccine transmission for the purpose of conducting a retrospective comparison.

Section 3: Therapeutics

3.1 The UK was relatively well prepared to deploy influenza antiviral drugs in the event of an influenza pandemic. It had a large stockpile and had deployed antivirals at scale during the swine flu pandemic in 2009-10. The Achilles Heel of these arrangements was continued controversy about the effectiveness of these drugs (neuraminidase

inhibitors). There had been a systematic failure over many years of the policy, research and pharmaceutical industry communities to come together and resolve this issue. All of the above is contextually relevant to what happened in 2020-21, but not directly so because these 'flu drugs' do not work against COVID-19. The 'advantage' of an influenza pandemic is that pre-existing drugs exist that have been developed for seasonal influenza. Whereas there were no known treatments for coronaviruses of any kind in 2020.

3.2 My role in relation to COVID-19 therapeutics was similar to my role in relation to vaccines. I worked at the interface between policy, research and procurement to try and ensure that the UK had soonest possible access to safe and effective treatments for COVID-19. As part of my role, I routinely advised and updated the CMO and Ministers (including the Prime Minister) on any significant developments on therapeutics.

3.3 Sir Mark Walport (former GCSA and the first Chief Executive Officer of UKRI) coordinated the phase 1 and 2 clinical trials of potential therapeutics and I tried to support him in that work. I recall there being many parties involved across academia and the biopharmaceutical industry. There were also many strong opinions and many vested interests which complicated discussionsp about the division of responsibilities amongst those involved. I specifically recall tensions between Sir Mark and Sir Jeremy Farrar. The Inquiry has directed my attention to Chapter 9 of the UK CMOs Technical Report **(JVT/146-INQ000203933),** where it is stated that "*Generally the UK was stronger in phase 3 and 4 trials than on phases 1 and 2.".* The factional approach to the phase 1 and 2 trials did create a real battleground, and I do consider these issues to have created inefficiencies in terms of getting phase 1 and 2 trials up and running. Additionally, as set out in the OCMO Module 4 Corporate Statement at paragraphs 7.43 – 7.44, phase 1 and 2 trials tend to have to be more industry driven, and include much smaller numbers and the relative advantage of the UK is therefore smaller in an emergency. In contrast, the UK has historically been one of the leaders in methodology for phase 3 and 4 trials, including the design, running and statistical analysis of these trials which includes more complex methodologies such as platform trials and cluster-randomised trials, and in particular non-industry (academic or charity) led trials. Alongside this, there is a centralised NHS (most health services are more fragmented), a strong tradition of evidence-base medicine in clinical training, and through the NIHR an existing trials support architecture, and in HRA and MHRA respected regulators.

Patients and citizens more widely have a strong tradition of volunteering for trials. The relatively centralised decision-making allowed for rapid decision-making. I agree with the CMO that it was unsurprising that the UK had some of the fastest, largest and most productive phase 3 and 4 studies for COVID-19.

3.4 As set out above, the work to develop treatments for COVID-19 began early in 2020. From late-January, I was engaged in discussions about repurposing existing medications for use in the treatment of COVID-19. The note referred to above at paragraph 2.5 that I provided for Ministers on 24 January summarised treatments for COVID-19 as follows in respect of treatments for COVID-19:

"There are no specific treatments proven to be effective yet.

Patients will be kept isolated and offered supportive care. There are various unlicensed experimental treatments and one licensed medicine which may prove useful but are unproven at the present time.

In the absence of proven treatments, the majority of care for severe WN-CoV cases is likely to be supportive.

Most severe cases will probably show evidence of bilateral primary viral pneumonia to a greater or lesser extent. Based on first principles, risk factors for severe illness are likely to be comorbidities and obesity.

Supportive care is almost certain to involve prolonged oxygen supplementation. Many cases will require intubation and mechanical ventilation, and if instigated early this is likely to improve outcomes" **(JVT3/002 – INQ000047554)**.

3.5 On 4 February 2020, the NIHR and UKRI launched the first rapid research call, which offered funding for COVID-19 research. The CMO and I were heavily involved in its inception and launch. I briefed the panel on the epidemiological situation and what kind of research was required. The first part of the call was for research relating to vaccines and treatments, with a deadline of 13 February.

3.6 For obvious reasons, the early focus was on trialling repurposed existing medications. If successful, the repurposing of already known and licensed medications would be a significantly faster route to obtaining safe and effective treatments than developing novel therapeutics from scratch. At the same time, it was vital that we focussed our

resources on the medications that had the best chance of proving useful in the treatment of COVID-19.

3.7 On 13 February 2020, I set out my consolidated advice on therapeutics for the CMO. I reproduce that advice in full here:

"Dear Chris,

Scenario:

1. As you know I have been tasked with looking at whether there are certain drugs, which are potentially useful for the specific treatment of novel coronavirus infections, based on the possible scenario that if Covid-19 affects the UK significantly, we may wish to treat a large number of UK citizens, either with drugs we hope will be effective; or with drugs we know are effective.

2. Any such drugs are likely to be in significant worldwide demand, particularly once known to be effective; therefore one scenario is that UK will be unable to acquire the supplies it needs, in whole or in part if it waits for theoretically the ideal time to make a final decision.

3. One option to mitigate that risk is to acquire supplies of drugs now which look, in principle (use for SARS/MERS, in vitro or animal data), like they might be effective.

4. A further factor in considering early acquisition is the likely safety of any target drugs and physician familiarity; older, commonly used and re-purposed drugs are more likely to meet these criteria and more likely to be available from multiple manufacturers.

5. Making a decision to acquire now runs a clear risk that what is acquired will not ultimately prove to be useful, meaning that resources will have been wasted.

6. Making a decision to acquire later, based on more certain evidence, runs the risk of being unable to secure supplies in time or in sufficient quantity.

7. Putting in place contracts to acquire and being able to trigger these at very short notice (next day) should evidence in favour of use emerge is another potential approach, but may be tricky to implement.

8. If the UK were to acquire drugs for use, it would be a separate issue (for later discussion) to decide if we wished to deploy these products in the UK under clinical trial arrangements (potentially an adaptive 2 x 2 factorial design) or based on unlicensed use (physician-patient discussion) on a 'give-it-a-go' treatment (with some observational data collection); or a combination of either/or in parallel.

Drugs:

9. In trying to come to a recommendation for you to consider, I have drawn on: a) NERVTAG advice; b) advice from M. Jacobs and J. Dunning on behalf of the HCID network; c) a discussion with the ID physicians treating the UK's first two case of Covid-19; d) informal discussions with the EMA Head of Anti-Infective medicines; e) the WHO Covid-19 Blueprint; f) informal conversations with you; g) the WHO literature review. My advice is as follows:

10. Remdesivir: there is broad agreement that the in-vitro signal is that this unlicensed drug (intravenous route) from Gilead shows potent anti-coronavirus activity; a clinical trial is underway in China but there are concerns whether the timing of treatment in that study was optimal; there are unresolved questions about the adequacy of tissue levels. Gilead has been very clear that stock is only available worldwide as part of an international clinical trial. UK participation is possible but realistically will be in hospitalised patients only.

11. Kaletra (lopinavir / ritonavir). There are supportive data from SARS treatment of human cases, in vitro data, and animal models. There is a rumour that the current Chinese trial shows no difference but also that the study is underpowered. Other rumours from China suggest it is effective. Treatment timing and dosage used may be factors. The drug is safe, has some known-side-effects, but is familiar to many physicians and orally administered making it suitable in theory for use in both primary and secondary care.

12. Chloroquine. The EC50 looks very impressive for Covid-19. Against this, the drug looks effective against several other virus pathogens in vitro but has failed to demonstrate clinical effectiveness. Likely, high doses are required. The drug is very safe, orally administered, and comparatively very cheap. Many physicians have prescribed it during their careers. Chinese physicians remarked to WHO this week (without supporting data) that chloroquine 'is working' in Covid-19 cases.

13. Corticosteroids. There is clinical equipoise about corticosteroids, which has been confirmed in the recent WHO discussions in Geneva this week. A clinical trial of corticosteroids was trailed by WHO as a research priority. The UK has an NIHR pandemic sleeping contract for an RCT of corticosteroids in severe pandemic influenza. This can be reassigned to Covid-19 and I respectfully suggest we give consideration to activating this trial relatively soon.

14. Other possible therapies include interferon-β1a (parenteral and inhaled) and convalescent plasma, both possibly deployable as part of a clinical trial. NERVTAG and HCID have both expressed caution about the safety of interferon therapy; convalescent plasma would not offer any kind of scalable solution for widespread treatment.

Conclusion:

15. The only practical options for consideration for rapid stock acquisition, consistent with a degree of evidence in favour and ability to operationalise in a widespread way in NHS service are Kaletra and Chloroquine.

16. As neither product carries any assurance of effectiveness, acquisition would be a calculated risk, to which we cannot attach meaningful mathematical odds at the present time, given a) the uncertainties about drug effectiveness; b) the uncertainty about whether Covid-19 can be contained in China or SE Asia.

17. One option would be to use both in a 2 x 2 factorial design, whilst offering unlicensed use on a give-it-a-go alongside, since both are products with relatively assured safety profiles.

Your thoughts would be appreciated as we need to feedback to Steve Oldfield in the near future. Subject to your views we could put a consolidated view to NERVTAG but my overriding view is that this is a policy and possibly a ministerial decision once we have a consolidated CMO Office view." **(JVT3/121 – INQ000151455)**.

3.8 In response to my note, the CMO agreed that we should pursue acquisition of Kaletra and Chloroquine. I then initiated further correspondence with Steve Oldfield and others within DHSC about procurement strategies **(JVT3/122 – INQ000151493)**.

3.9 In the interests of focussing our resources on the most promising medications, I helped to establish the NERVTAG COVID-19 Therapeutics Sub-Committee. This sub-Committee was set up to provide further advice to the CMO and DHSC on potentially viable existing pharmaceuticals that could be repurposed for COVID-19 **(JVT3/123 – INQ000151510 – 25 February 2020)**.

3.10 The NERVTAG COVID-19 Therapeutics Sub-Committee met for the first time on 27 February 2020. I attended that meeting and provided an introduction and guidance on the work that needed to be done **(JVT3/124 – INQ000221764)**. The Sub-Committee agreed to distribute the work across three subgroups that would look at: i) drugs; ii) supportive care; and iii) endpoints and populations. The drugs subgroup met on 2 March 2020. I did not attend that meeting, but its deliberations and recommendations are set out in the minutes **(JVT3/125 – INQ000221962)**. The supportive care and endpoints and populations subgroups both met on 3 March; again, I was not in attendance, but the recommendations are set out in the minutes **(JVT3/126 & 127 – INQ000416126 & INQ000221964)**. On 9 March, the Sub-Committee reconvened for a meeting that I did attend. The minutes of that meeting summarise the Sub-Committee's overarching recommendations to DHSC as follows:

"1. Support a clinical trial evaluating chloroquine in mildly ill out-patients with COVID-19 at risk of complications.

2. Support a platform trial in moderately ill inpatients with COVID-19. The interventions to prioritise will need to consider data on efficacy in betacoronaviruses, safety data, and availability. The committee consider the current order of priorities to be:

- Remdesivir

- Lopinavir / ritonavir

- Interferon

- Low dose corticosteroids

- Chloroquine

3. Review the viral domain of the REMAP-CAP (Randomised, Embedded, Multifactorial Adaptive Platform Trial for Community-Acquired Pneumonia) study and

potential burden of the study for ICU staff. This review would inform a decision whether to support scaling up the trial to include patients with COVID-19.

4. Support a clinical trial of standard oxygen therapy vs. non-invasive ventilation in patients with a ceiling of care (i.e. not for intubation and mechanical ventilation).

5. Consider the most appropriate mechanism for ongoing surveillance of emerging evidence on therapeutic agents for COVID-19 which could be evaluated." **(JVT3/128 – INQ000221978).**

3.11 As set out in paragraph 7.7 of the OCMO Module 4 Corporate Statement, the NERVTAG COVID-19 Therapeutics Sub-Committee delivered the initial recommendations for inclusion in the RECOVERY trial, including low dose corticosteroids, of which dexamethasone was chosen as the specific corticosteroid. The sub-committee's recommendations provided a steer to research on therapeutics which lasted over a considerable period of time.

3.12 On 5 March 2020, I provided the following further advice to the CMO on Kaletra:

"Further to my last email when I advised you that Kaletra might prove to be a suitable Covid-19 treatment based on in vitro data and very limited data from SARS and MERS. We agreed at that time to ask DHSC Commercial to begin to acquire UK stock on a no regrets basis, although stocks were limited. I am now writing with an update:

1. You and I have both heard of the clinical trial in China which might well show beneficial results when published.

2. The data I have glimpsed suggest that against a composite severe outcome end point including but not limited to death, the likely result will be that a 25% control arm incidence will be reduced to about 16% in hospitalised patients, and treated rather late in the illness.

3. And that LOS (Length of Stay (in hospital)) is reduced by about 3 days.

4. I think these are both very meaningful clinical benefits and the LOS reduction might be critical for how the NHS copes.

5. The UK wave may peak in 2-3 months but with mitigations might peak 1-2 months later (and be flatter). This may mean that further stocks of Kaletra may be useful for the next 6 months.

6. In the meantime our RWC scenario has been modified. With something like 33M cases of illness and a hospitalisation rate of 10% (illustrative) we could well benefit from acquiring 3.3M treatment courses. In reality we might also give this drug pre-hospital if it reduces the likelihood of admission (but this is a bit more speculative).

7. The drug is safe, licenced for HIV medicine and familiar to physicians.

8. We already plan to evaluate Kaletra as part of a UK RCT. However, were that to be positive, as we believe the Chinese study will be, we would face a dilemma in terms of what to do with a good result, if by then we cannot acquire the stock" **(JVT3/129 – INQ000047969)**.

3.13 On 2 April 2020, I was invited to and attended an expert panel to conduct a rapid review of potential therapeutics candidates that could be deployed immediately to UK clinical trials **(JVT3/129A – INQ000399358.)** After the initial meeting took place that day, I was invited on the 3 April to a shortlisting call to arrive at a list of approximately 3-4 priority candidates that would be sent to final review (if further NIHR/UKRI funding was needed) and then fast-tracked into national priority trials in the NHS.

3.14 Paragraph 7.30 of the OCMO Module 4 Corporate Statement sets out further examples of the advice I provided in relation to the procurement of other therapeutic treatments.

3.15 The Inquiry has asked about my role in selecting potential therapeutic treatments for entry into clinical trials. Whilst the CMO and I contributed to discussions, decisions were primarily made by expert committees. This applied to both novel and repurposed medicines.

3.16 I am asked by the Inquiry about the influence that previous epidemics and pandemics (such as MERS, SARS-CoV-1, Ebola, influenza and HIV) had on the development of new or repurposed therapeutics during the COVID-19 pandemic. Past experience and clinical studies, particularly relating to MERS, SARS-CoV-1 and influenza (all respiratory viruses that shared characteristics with COVID-19) were certainly influential in guiding early thinking around potential treatments. The advice set out above reflects that. From a personal perspective, in advising which known medications should be

trialled and purchased, I drew on my clinical knowledge and experience, including that relating to Influenza, MERS and SARS-CoV-1.

3.17 As the above makes clear, one of the possible treatments under consideration from early in the pandemic was corticosteroids. I had previously undertaken research (in collaboration with Professor Lim and others) on the use of corticosteroids in the treatment of influenza. That research was inconclusive **(JVT3/130 – INQ000421518 – 24 February 2019)**. However, there were sound biological reasons for thinking that an anti-inflammatory medicine, such as corticosteroids, might be useful in the treatment of viruses that cause inflammation of the lungs (such as influenza and SARS) and there was some data to support that view. As my advice of 13 February 2020 makes clear, I was in favour of trialling corticosteroids as a treatment for COVID-19. Ultimately a decision was taken to trial the corticosteroid, dexamethasone, through the RECOVERY trial **(JVT3/131 – INQ000151571 – 10 March 2020)**. As is now well-known, dexamethasone was shown to significantly reduce mortality in the sickest patients. It has been credited with saving substantial numbers of lives in the UK and internationally.

3.18 At the beginning of April 2020, the Therapeutics Taskforce ("TTF") was set up within DHSC with the remit of coordinating the Government's efforts to deliver safe and effective treatments for COVID-19 as quickly as possible. As set out above at paragraph 1.9, I find it difficult to now separate the work I was involved in as part of the TTF and as part of the ATF. On 30 March, I attended a meeting with the GCSA and peers from the Wellcome Trust to discuss the establishment of the TTF, which included consideration of the group's strategic priorities and governance **(JVT3/132 & 133 – INQ000504719 & INQ000504720)**. I was subsequently copied into email discussions throughout early April focused on the practicalities of establishing the TTF. On 2 June, I chaired the first TTF meeting, which took in views on the draft terms of reference **(JVT3/134 – INQ000504722)**. I chaired the TTF Executive Board, which focussed on strategic decisions on procurement of therapeutics. These decisions were supported by reviewing evidence from trial outcomes and input from advisory groups. The TTF Executive Board took over the role of the NERVTAG COVID-19 Therapeutics Sub-Committee and eventually evolved into the Therapeutics Taskforce Oversight Board chaired by Lord Bethell (between May 2021 and September 2021) and Clara Swinson (between December 2021 and February 2022).

3.19 In addition to my role on the TTF, I was also a member of the ATF, which was set up in April 2021 to specifically focus on the procurement of COVID-19-specific antiviral treatments. My recollection of the specific details of my involvement in establishing the ATF are vague, however I was sighted on discussions in early April relating to the taskforce's proposed remit and governance **(JVT3/134A & 134B - INQ000416153 & INQ000416154 – 1 April 2021)**. Eddie Gray was appointed to chair the ATF, and the GCSA assisted in recruiting him for this role. I welcomed this decision since I was aware of Mr Gray's capabilities having worked with him much earlier in my career in the pharmaceutical industry, when he had been a senior officer at SmithKline Beecham UK, and I a more junior colleague. In April 2022, the ATF and the TTF were merged to create the Antivirals and Therapeutics Taskforce, which continued to coordinate the end-to-end provision of treatments for COVID-19 in the UK until it was stood down on 31 March 2023. I relinquished any role with the ATF or TTF when I left DHSC in March 2022. Throughout the pandemic I remained involved in providing clinical advice to Ministers and other officials on what drugs to procure and in what quantities. More detail is provided in the OCMO Module 4 Corporate Statement.

3.20 As explained in the OCMO Module 4 Corporate Statement (paragraphs 7.1-7.3), there were times during the pandemic when some people (including politicians, advisers, clinicians and members of the press) sought to promote the deployment of particular medical countermeasures before they were proven to work. The treatments that garnered particular attention were hydroxychloroquine/chloroquine, ivermectin and Vitamin D. It would not have been safe, ethical or useful in the long term to adopt this approach. We in the OCMO were assiduous in our efforts to ensure that treatments were first deployed within the confines of clinical trials and that treatments were prioritised for trial in a way that could be clinically justified. For example, in late March and early April 2020 there was particular ministerial interest in hydroxychloroquine/chloroquine following international reports of its use and efficacy. On 21 March 2020, I received a request from No.10 (via DHSC) for views on the use of chloroquine. In responding, I explained that: there were trials underway in China but no published human data yet; Chinese doctors were claiming in the media that it works; it was being considered for trial in the UK; the UK had taken 'no regrets' steps to acquire large quantities of hydroxychloroquine and smaller quantities of chloroquine; and the CMO's current advice was that hydroxychloroquine and chloroquine should only be used as part of UK clinical trials **(JVT3/135 – INQ000151622)**. On 28 March, in response to a suggestion that *"ministers have decided they definitely want roll out*

[including of hydroxychloroquine or chloroquine] *to start straight away without waiting for results of the trial"*, I explained as follows to colleagues within DHSC:

"Can we hold fire on that. GCSA and me and CMO are very firmly against treatment outside of a clinical trial because then we will never know if it works. And doing that makes it unethical to randomise. Then we never actually know if things work. This would I think be going against the science advice. I did however understand that if we get into a situation where we just have to do it and it's a political order to do so (that is to say: "I'm ordering you to treat with something" then likely our clinical advice would be to use HCQ (hydroxychloroquine)." **(JVT3/136 – INQ000421482)**

3.21 Ultimately, ministers did not decide to order the deployment of unproven treatments outside of clinical trials. That decision was vindicated by the fact that none of the interventions that were being pushed as appropriate for immediate deployment have proved to have significant efficacy in clinical trials and some have been associated with net harm **(JVT3/137 – INQ000399345)**.

3.22 I am asked by the Inquiry about any steps taken by Matt Hancock/DHSC to protect me and Professor Peter Horby (Chair of NERVTAG and an academic colleague) from pressure to call the results of trials before they were clinically valid. I understand that this is a reference to something that Mr Hancock has said in his witness statement submitted for Module 2 of the Inquiry. I have read the relevant part of that statement and I do not think Mr Hancock is referring to protection that he offered to me personally. I believe he is referring to protection offered to "the trials" (or more accurately, to the lead investigators of the trials). It would not have been my role to "call the results of trials". From my perspective, I do not recall such protection being required. My recollection is that Professors Martin Landray and Horby (who together led the RECOVERY trial) were very robust in ensuring that trial data were only announced once it was clinically appropriate to do so.

3.23 I am asked by the Inquiry about innovations that were introduced to accelerate the development of COVID-19 therapeutics. From my perspective, the most significant innovation was the NIHR UPH badging that diverted resources towards the most important clinic studies. This is discussed in more detail at paragraph 4.14 of the OCMO Module 4 Corporate Statement. In my view, the UPH badging system worked well and is something that could be repurposed in future similar health emergencies. With that said, as we acknowledge in the OCMO Module 4 Corporate Statement, UPH

prioritisation did, by necessity, mean that other studies received less support from NIHR sources. If such a system is to be deployed in the future, an assessment will have to be made about whether such a cost is justified by the benefits. In my view, it clearly was for COVID-19, but that might not always be the case.

3.24 Although perhaps not an "innovation", one factor that aided the acceleration of the development of COVID-19 therapeutics was the reactivation and repurposing of previously earmarked sleeping contracts for certain pandemic influenza studies. Having a protocol finalised, sites and investigators pre-designated, and 'in-principle' ethical approval in place, speeds up the time to recruitment of the first patients and ultimately delivers a quicker study result. In the same vein, the UK needs to ensure that if there is another pandemic or emerging pathogen crisis, something similar to the highly successful trials platform that was RECOVERY can be activated in 1-2 weeks not 1-2 months.

3.25 The Inquiry has sought my views as to whether the rapid development of new therapeutics and repurposed medications was prioritised over vaccines and vice versa. At the beginning of the pandemic, there was no initial strategic prioritisation since there was no certainty that new vaccines, new antivirals or repurposed drugs could be effective to protect against the spread of SARS-CoV-2. As discussed in paragraph 7.45 of the OCMO Module 4 Corporate Statement, in general drugs and vaccines did not compete. It was possible to start phase 3 and 4 trials on repurposed drugs straight away whilst the basic and preclinical work was undertaken for novel antivirals and vaccines. Most therapeutic drug trials are in already infected patients (so in the NHS) whilst vaccine trials are in the community (pre-infection). The difficult prioritisation was between the drugs or vaccines in class: generally vaccine studies did not compete with drugs because different people were being enrolled, but vaccine trials competed with one another, and drug trials in severely ill patients (or in primary care) competed with one another so a prioritisation was needed, and was set up.

3.26 I am also asked about my views on the Government's decision-making and processes for the procurement of antivirals. I do not have any strong opinions; however, I recognise that buying at risk does not come naturally to government. In addition, by the time serious discussions could take place about buying specific anti-COVID antiviral medicines, the UK population was already well vaccinated. Therefore, the

deployment of antivirals was always going to be in the context of any additional benefit in a well vaccinated population.

COVID-19 Neutralising Monoclonal Antibodies and Antivirals Access Independent Advisory Group

3.27 The COVID-19 Neutralising Monoclonal Antibodies (nMABs) and Antivirals Access Independent Advisory Group was established in late 2021 to identify a set of patient cohorts who were deemed to be at the very highest risk of an adverse COVID-19 outcome, namely hospitalisation and/or death. My recollections of any involvement I had in establishing the group and participating in the group's work are vague, however I have been shown various documents to assist my recollection.

3.28 On 3 June 2021, I was approached by Professor Anthony Kessel (NHSEI), asking for my thoughts on the establishment of a national expert group to develop the process and clinical policy for nMABs **(JVT3/137A – INQ000497961)**. A meeting between myself and Professor Kessel was arranged for 17 June. The first meeting of the nMABs IAG took place on 29 June 2021. I was not a member of the group.

3.29 The nMABs IAG considered the use of nMABs and antiviral drugs in highest risk clinical subgroups upon community infection with SARS-CoV-2, preparing an interim report dated 19 November 2021 **(JVT3/138 – INQ000067910)**. The report was emailed to me by the CMO's private secretary that same day. I was made aware that a call had been arranged later that afternoon to discuss the contents of the report with the CMO. I was also informed that Professor Iain McInnes (Chair of the group) had made himself available to discuss any follow up thoughts from myself and the CMO. The CMO and I were content with the group's recommendations and this was communicated to the UK CMOs and DHSC colleagues **(JVT3/139 – INQ000504731 – 22 November 2021 & JVT3/140 - INQ000504733– 23 November 2021)**. I do not recall any follow up action that was taken in relation to this report.

3.30 I am asked by the Inquiry about the nMABs IAG's report *"Defining the highest-risk clinical subgroups upon community infection with SARS-CoV-2 when considering the use of neutralising monoclonal antibodies (nMABs) and antiviral drugs: independent advisory group report"*, dated 30 May 2022. I do not have any recollection or knowledge of this report. The report was published after I had relinquished my role as DCMO in

March 2022. I am asked specific questions about the group's general approach and their consideration of specific patient groups (i.e. in terms of factors such as age and pregnancy). Professor McInnes would be better placed to answer these questions.

3.31 I am asked about the relationship between the nMABs IAG and the Therapeutics Clinical Review Panel (TCRP). I don't recall having any role in the TRCP's work, and I cannot speak to the relationship between these two groups.

Prophylactics

3.32 One strand of COVID-19 therapeutics research involved examining the prospect of acquiring prophylactic drugs. This work was taken forward by a specifically commissioned Prophylaxis Oversight Group (POG), which was chaired by Professor David Lalloo of the Liverpool School of Tropical Medicine. On behalf of the CMO, I had previously engaged in discussions with Professor Lalloo about chairing the group which would lead on the DHSC's prophylactics work. Professor Lalloo's group met for the first time on 10 July 2020 and thereafter coordinated the trial of potential prophylactics. I was invited to POG meetings through the remainder of 2020 and 2021; however, my attendance was minimal.

3.33 On 10 February 2021, I sent the following email to Professor Lalloo:

"Dear David,

I hope you are well. On behalf of CMO and GCSA could I ask your group to pick up a new task beyond the screening of possible medicines for prophylaxis?

As you know various antibodies, both monoclonal and duo-clonal, are being developed for SARS-CoV2 and some are now in Phase III clinical evaluation. The developers suggest they are for patients who can't respond to vaccines.

Among their problems are:

1. *No efficacy readout (yet)*
2. *Sometimes i.v. administration*
3. *Short shelf lives*

4. *Concerns about number needed to treat to avert one serious outcome, in an environment where the population is already highly vaccinated*

5. *High unit cost*

6. *Susceptibility to variants*

The list is not exhaustive and of course there are advantages too.

We wondered if your prophylaxis group could pull together a short 2 pager on what a good prophylaxis antibody would look like and, as importantly, how such a theoretical 'good offering' is likely to be used realistically in the context of current NHS service configuration.

We think such a paper might set out a clearer stall for developers of what good looks like to us, without of course implying that it is an automatic 'buy' if the desirable characteristics are met.

Could you take this one and how soon could the group pull something together?" **(JVT3/141 – INQ000153716)**.

3.34 Professor Lalloo provided the requested paper on 17 February 2021 **(JVT3/142 – INQ000421507)**. The POG summarised its conclusions as follows:

"a) There is a clear potential role for prophylaxis with the ideal monoclonal antibody preparation

b) The prime group that would benefit is those who are at increased risk of severe COVID disease but would do not [sic] respond to vaccine or cannot be vaccinated

c) Such groups are likely to be linked in with specialist services that could help support administration of such products, ideally in the community

d) The ideal monoclonal product would be easy to administer in a range of settings and provide long term prophylaxis, replacing protection from vaccines"

3.35 The first trial results confirming the efficacy of a prophylactic antibody treatment did not come until June 2021. By that time, it was clear that vaccines were having a dramatic effect on the likelihood of hospitalisation or severe illness and the number of patients that would be needed to be treated with prophylactic antibodies in order to

avert one hospitalisation or death, by that stage, was very high. Vaccines were also reducing incidence of the virus in the wider community and therefore the argument for deploying prophylactic antibody treatments in patients who did not respond well to vaccines was relatively limited. Furthermore, the available treatments were expensive to acquire (running into the hundreds of pounds per treatment), would need to be administered intravenously (with all the associated costs and practical difficulties) and would need to be administered every few months in order to provide continued protection. In my view it would therefore have been difficult to make the case for acquiring them. I remember conversations with the CMO in which we discussed how, in the presence of a highly effective vaccination programme, the number needed to treat ("NNT") with a monoclonal antibody in order to avert one case of hospitalisation, might well be high. Repeated administration of a monoclonal antibody would add to the issue of cost effectiveness and present a difficult problem of when treatment could be stopped, creating additional challenges. Although my recollection of timings is extremely vague, I do recall receiving reports of the emergence of resistance to Evusheld (a medicine which was a combination of two monoclonal antibodies) posed by the emerging Omicron COVID-19 variant. I remember wondering if the usefulness of monoclonals might well be limited by the likely emergence of resistance, therefore, recognising that this was difficult for patients who felt they were less able to benefit from a vaccine. I do not have any concerns in relation to the wider public health arguments.

3.36 The Inquiry has asked whether I was aware during my time as DCMO, of any indications from DHSC or any other Government department regarding the procurement of Evusheld during the time the VTF was responsible for identifying prophylactic treatments.

3.37 In February 2021, the VTF sought DHSC approval to secure a supply of Evusheld for prophylaxis use **(JVT3/142A & 142B – INQ000072734 & INQ000507425 – 5 February 2021)**. A supply of 50,000 doses was proposed by the VTF, based on the CMO's earlier recommendation that *"If there remains political appetite to buy on an at risk, precautionary basis the amounts bought should remain low. I would suggest under 50,000 doses"* **(JVT3/142C - INQ000071342 – 26 October 2020 & JVT3/142D – INQ0000507423 – 11 December 2020)**. When considering the VTF's proposal, I sent the following email to Charlotte Taylor:

"I do agree the broader issues are beyond the extant paper:

1. Given the UK vaccine strategy priority dose 1, really we won't have data on who vaccine non-responders after 2 doses are for several months (but Paul Moss is doing that work with various immunocompromised cohorts)

2. We have to order now and at risk

3. CMO steer is 50K max

4. And even 50K is a very expensive purchase with a highly limited shelf life and therefore window for deployment.

5. The number needed to prophylax (NNP) to avert 1 hospital admission argument is heavily stacked against the case for proceeding because our vaccine plans are so ambitious and materially different to US and German in scale and speed. This clobbers the residual exposure opportunity. And makes the NNP argument even more stacked. The NNP for averting one death is several fold higher again.

6. None of the above make this look cost-effective.

7. The problem about starting down this route is how we would stop (meaning withdraw the therapy)." **(JVT3/142E – INQ000507426 – 6 February 2021)**.

3.38 On 10 February 2021, in response to the VTF's 5 February request, I wrote to Stuart Speding (VTF) recommending that we should not proceed with an advance purchase of Evusheld **(JVT3/142F - INQ000072735)**. This reasoning considered success of the advancing vaccination programme which not only afforded individual protection against the disease, but reduced the risk of community exposure for people who were not vaccinated or who did not respond well to vaccines. Therefore, the anticipated utility of prophylactic antibody treatments as an additional tool (particularly to protect clinically vulnerable groups) was considerably reduced. Whilst there was some evidence that neutralising antibodies had a prophylaxis utility or could be an effective treatment at an early stage of disease, at the time of this request, there were no clinical trial results for Evusheld, and such results were not expected until later that year. The expense of a large purchase of Evusheld was also considered, especially due to the shorter shelf-life of Evusheld (3-6 months), which meant that a bulk advance purchase could result in significant product waste. This was not a recommendation to never

procure and deploy Evusheld, instead, it was advised that the situation was monitored and revisited once there was clearer evidence on the efficacy and demand for the product. This recommendation was based on the clinical advice of the TTF and the CMO. Ultimately the decision of whether or not to procure Evusheld, both at this time and in the future, is a policy matter for the DHSC.

Prophylactics Procurement

3.39 The Inquiry has referred me to an email chain in which Charlotte Taylor discusses an internal DHSC call on 7 September 2020, to consider the transfer of responsibility for procurement of neutralising antibodies ("NAb") from the VTF to the TTF **(JVT/147 - INQ000152774)** I agreed at the time, and still agree, that the responsibility for NAb procurement is more appropriately positioned within TTF as the therapeutics delivery group. Whilst there was a feeling of excitement amongst the VTF about the potential promise of NAbs, there were VTF members who lacked direct clinical or NHS experience. Therefore, there was a risk that such members did not fully understand the logistical complexities of large-scale prophylactics rollout. To successfully administer a NAb would require attendance at a specialised medical facility (most likely a hospital) to receive the drug via intramuscular or intravenous route. Additionally, prophylaxis can only be achieved if the NAb is delivered at repeat intervals (months not years). Facilitating the rollout of regular treatments at specialist facilities for tens (potentially hundreds) of thousands of patients would be extremely challenging for the NHS, as well as potentially very costly.

3.40 I consider cost (including cost effectiveness) and practicality considerations to be entirely rational factors when making decisions on NAb procurement. My recollection is that I had left Government by the time substantive decisions on NAb procurement were made. Therefore, I do not know the extent to which these factors were weighted in the procurement decision-making context. I am confident that they would have been considered by my colleagues, alongside many other factors when weighing up their potential success and benefits in the context of a highly successful vaccine programme. In my response to Charlotte's email, I discussed the difficulties with the half-lives of NAbs - specifically the Mercury NAb - and the frequency with which a treatment would have to be delivered to successfully protect patients **(JVT/147 - INQ000152774)**. The high efficacy rates recorded for the deployed vaccines meant that the possibility of procuring and deploying NAb treatments at scale were relegated

in terms of importance. This considered the success of the vaccines in protecting those candidates within the high-risk and clinically vulnerable groups.

Section 4: SAGE

4.1 The Inquiry has asked me a number of questions related to SAGE. These are better put to the GCSA and/or GO-Science. The only observation I can usefully make is that in February 2021, there was a question raised about how SAGE could best support JCVI. At the time, I was concerned to ensure that SAGE advice did not encroach into areas that were the sole domain of JCVI. To the best of my knowledge and recollection, that ultimately did not become an issue. I set out my advice on this matter by email of 12 February 2021:

"This has been whirring away all night. Bothering me.

1. *I am really bothered that SAGE might try to reach into JCVI territory and for example start to venture its own views on the high-risk conditions that are not in group 6 after really diligent JCVI scrutiny. That is just one example but then it leaks and bang… two committees with opposing or alternate views and the professions and the public caught in the middle.*

2. *I am keen that the above is kept well away from SAGE and left with JCVI who has the statutory role and is a largely clinically qualified committee, whereas SAGE is neither.*

3. *Thus I suggest that all vaccine assessment (choice) over use and suitability, all assessments of priority status, and all assessments of programmatic VE lie solely with JCVI and its PHE support, and programme design***

4. *Where and what we could give SAGE to protect JCVI from overload and maintain focus on the key roles might be:*

5. *Advice to govt on post vaccination rules for those fully vaccinated on social contact, social distancing, quarantine, travel abroad*

6. *Advice to govt on whether face covering rules are different for the fully vaccinated*

7. *Advice to government of visiting a relative in a care home if the visitor is fully vaccinated* (meaning 2 or 3 weeks post second dose)*

8. *SAGE could not do 5-7 unless it received briefings from someone on things like post vaccination shedding and CT values etc. But that is the role fulfilled by SIREN and other bits of PHE.*

*I would also, separately like to discuss how we ask JCVI about autumn revaccination, potentially with a variant vaccine**"* **(JVT3/143 – INQ000153720)**.

Section 5: Lessons and reflections

General

5.1 When I joined DHSC, having worked in the private sector, I was struck by what I saw as a dysfunctional relationship between the Civil Service and the pharmaceutical industry. I found that some within the Civil Service displayed what appeared to be a reluctance to engage openly with the pharmaceutical industry. I put this down to Civil Service mistrust of these profit-seeking entities and concerns about potentially compromising a commercial position. When I spoke to former colleagues and associates within the industry, they expressed frustration about the stifling effect that this had on effective working relations and the ability to get things done. When I became a DCMO, I tried to encourage a more open dialogue and foster better relations between DHSC and the pharmaceutical industry. I considered that an effective working relationship between these two parties was important for the health security of the country. For example, there was a bi-annual meeting between the Association of the British Pharmaceutical Industry ("ABPI") and the DHSC Vaccine Group that colleagues told me was, historically, not an effective platform for dialogue. However, members of the ABPI have informed me that when I became DCMO and, simultaneously, Chair of that meeting, the mood changed, and it became a much more useful forum. I was of course conscious that it was not my place to step into the commercial side of the relationship. I therefore always made clear in my engagements with the pharmaceutical industry that I was approaching matters from a clinical or policy perspective and that commercial matters were never for the DCMO or the OCMO.

5.2 I believe that a more open dialogue between Government and the pharmaceutical industry was beneficial to both parties during the pandemic and is something that DHSC ought to continue to foster in the interests of being prepared for the next health emergency.

5.3 The Inquiry has asked if I had any concerns about the effect of the cancellation of the Valneva contract on the relationship between the UK and the pharmaceutical and bioscience industry. The UK Government terminated their arrangement with Valneva (a French biotech company) in September 2021, a deal which sought to procure over 100 million doses of Valneva's vaccine product, VLA2001. I remember concerns were raised at the time within the VTF steering group that the product may not receive MHRA licensure, which would have prevented any rollout of the vaccine at great procurement expense to the UK. In addition, I recall the clinical data was less impressive than the data we had already seen for the Pfizer/BioNTech, Moderna and AstraZeneca vaccines. Additionally, in September 2021, the UK did not have a shortage of vaccines, so the decision to terminate this procurement contract did not create any shortcomings in vaccine supply. Even if VLA2001 had been licensed in the UK, I am doubtful that JCVI would have made a recommendation to include the product in the ongoing vaccine programme. For these reasons, I was not concerned by this decision and I do not consider that it has caused any wider damage to the government's relationships with industry.

Vaccines

5.4 By any measure, the period between work starting on the COVID-19 vaccines and the vaccination programme beginning was extraordinarily short (approximately 10 months), given that in January 2020 our best-case scenario was that we might have a vaccine in experimental or unlicensed form within 12 months. I would identify the following six reasons for the pace at which we were able to achieve a positive outcome:

5.4.1. Firstly, as the CMO has explained in the OCMO Module 4 Corporate Statement, science is a collective and an international endeavour. The COVID-19 vaccines were, in part, the product of investment and research spanning multiple years and continents. They should serve as a stark reminder of the value of investing in scientific research and infrastructure during 'peacetime'.

5.4.2. Secondly, the creation of a totally dedicated workforce was instrumental to the vaccine success. The VTF comprised a group of highly motivated experts with a single-minded mission focus. There was zero tolerance for 'business as usual' working practices. Rather we had a collective mentality of anything that could be done today would be. That sense of urgency and purpose was injected into everything that the VTF did. I am asked by the Inquiry to reflect on the key successes of the VTF and any aspects of its role that could have been improved. The VTF delivered what it was set up to deliver and I cannot offer any suggested improvements with hindsight. I was completely psychologically invested in what was the most invigorating, productive and all-consuming work of my career. From my perspective, it was the perfect team coming together at an extremely difficult time and performing exactly as it should have performed. I was very often in awe of the individuals that I worked alongside in the VTF.

5.4.3. Thirdly, the emergency situation demanded pro-activeness, which meant that we in Government were immediately reaching out to pharmaceutical companies to enquire as to what they had in the development pipeline, as opposed to waiting to either hear about it in the science literature or for the companies to start pre-market access work.

5.4.4. Fourthly, in relation to manufacturing, in normal circumstances vaccine manufacturers operate autonomously, sourcing the raw materials and facilities that they require. In the case of COVID-19, the VTF reached out to industry with offers of assistance, asking questions such as "can we repurpose X?", "can we get more bioreactors at this site?", or simply "what can we do to help?". This strand of the VTF's work was led by Ian McCubbin, and Ian was exceptionally able in this role.

5.4.5. Fifthly, in respect of procurement, we were purchasing products that didn't exist and might never exist. I believe this had been done before in the UK, for example in 1999 but on a much smaller scale when there was a nationwide outbreak of group C meningococcal disease which had killed several teenagers. Pfizer were developing a vaccine. However, whilst it is not standard procedure and should not be, it is a sensible manoeuvre in severe public health emergencies.

5.4.6. Sixthly, I understand from conversations with Dr Raine that during the pandemic, the MHRA was more prepared to dispense with some of the formalities that are usually expected of documents that are presented to it. To be clear, that is not to say anything about the quality or rigour of the data presented to the MHRA, but only about the format in which it was presented. I also understand that the MHRA was more flexible than it might ordinarily be in terms of the order in which it was prepared to look at things.

5.5 With these points in mind, the following are some lessons that could be taken forward for future health emergencies in which a vaccine becomes an essential component of the Government's response:

5.5.1. When such an emergency appears on the horizon, there is no vaccine exploratory action that can be taken too early or with too much intensity. That was the attitude of the VTF.

5.5.2. At paragraph 2.2 above, I refer to my previous support for increasing the UK's vaccine manufacturing capacity. If the UK had access to greater onshore capabilities, it would remove some of the tensions from the system. For example, during the pandemic there was some concern around vaccine nationalism and vaccine-producing countries seeking to restrict exports. This would not have been as pronounced if the UK had greater capacity to successfully manufacture its own vaccines. In my view, serious consideration should be given to investing in our health manufacturing capabilities.

5.5.3. In such an emergency, the VTF (or an equivalent) should be stood up. To that end, DHSC or UKHSA should maintain a skills register that can be drawn on with speed to staff a VTF; this register should capture workers from the public and private sectors with the correct expertise and experience. The COVID-19 VTF was, at least in part, staffed through the GCSA's and my personal networks. That is not a sustainable model. Rather, we need to be able to call on a group of 5-10 specialists who can be mobilised quickly at all times. That means asking the questions now, "*what skills will we need and who can provide them?*".

5.5.4. Linked to that, is the need to maintain a collaborative working relationship and an open dialogue between the Civil Service (in the broadest sense) and the pharmaceutical industry.

5.6 The Inquiry has asked about any processes for feeding back experiences during the pandemic relating to vaccines to UKHSA and any other governmental bodies in respect of planning for future pandemics. I recall that there were various reviews of the VTF, which I contributed to when asked. I also contributed to the Technical Report. Otherwise, I cannot recall any such processes.

Therapeutics

5.7 I am asked by the Inquiry for my views on the key successes of the TTF and the ATF and any aspects which could have been improved. The TTF played a key role in getting dexamethasone evaluated through clinical trials and procuring enough of it in advance of the results so that when the positive readout came, it could be rolled out across the NHS at speed (i.e. within 12 hours).

5.8 In my role as clinical adviser to these taskforces, I was a strong and early advocate for procuring various drugs 'at risk' (i.e. before we knew whether they would be effective) including dexamethasone, hydroxychloroquine, azithromycin and kaletra (see, for example, a submission for Ministers on procurement of these drugs containing my advice that was accepted on 16 April 2020 (**JVT3/144 & 145 – INQ000421488 & INQ000421491)**. In my view, there was no choice but to adopt an 'at risk' approach to procurement because of the fiercely competitive market that existed at the time. If, for example, we had only bought enough dexamethasone to cover the clinical trials, then by the time we obtained a positive result there would very likely have not been enough product on the market to meet our clinical needs. The negative consequence of this approach is of course purchasing large quantities of drugs that do not prove to be effective. However, the alternative, of being unable to acquire a treatment that ultimately proves to be lifesaving, is in my opinion, significantly worse. The other important lesson to take from this period is the value of getting on and doing the right trials (i.e. those that will produce definitive results as early as possible).

5.9 Finally, I think it is important to recognise the contribution of all involved in developing, testing and delivering safe and effective vaccines and therapeutics to the public both

in the UK and elsewhere. As I have previously mentioned, the task forces brought together experts from a range of disciplines all of whom worked tirelessly for the greater good. Many citizens volunteered for the necessary clinical trials. Colleagues through the NHS and among the general public did not hesitate to volunteer to be vaccinators, and many worked to keep vaccination centres operating. Without the commitment and efforts of so many, the impact of the pandemic could have been even greater. I hope that commitment and effort will one day be formally recognised.

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 or without an honest belief of its truth.

Signed: Personal Data

Dated: 7 October 2024