Witness Name: Professor Sir Mene Pangalos
Statement No.: First
Exhibits: MP/1 – MP/23
Dated: 10 October 2024

UK COVID-19 INQUIRY

WITNESS STATEMENT OF PROFESSOR SIR MENE PANGALOS

I, **PROFESSOR SIR MENE PANGALOS** will say as follows:

1. I joined AstraZeneca in 2010 as Executive Vice President, Innovative Medicines & Early Clinical Development (IMED) Biotech Unit. Between January 2019 and my retirement in March 2024, I held the role of Executive Vice-President, BioPharmaceuticals Research & Development (***R&D***) of AstraZeneca. I was a member of AstraZeneca's Senior Executive Team (***SET***)[1] from 2012 until my retirement. As Executive Vice-President, BioPharmaceuticals R&D, I had overall responsibility for AstraZeneca's BioPharmaceuticals discovery, research and early- to late-stage development activities. I am authorised by AstraZeneca to make this witness statement on its behalf. I have been asked to provide this witness statement as part of AstraZeneca's response to the UK COVID-19 Inquiry's Rule 9 Request for Evidence dated 27 September 2023 (the ***Rule 9 Request***) and the Inquiry's further requests for information received on 7 August 2024.

2. The matters covered in the Rule 9 Request are wide-ranging and extend beyond the knowledge of any one individual. In giving this statement, I am speaking on behalf of AstraZeneca as a whole and, in some places, I will refer to information provided to me from various sources and individuals. Unless stated otherwise, the facts and matters to which I refer in this witness statement are within my own knowledge and are true. Where the facts and matters to which I refer in this witness statement are not within

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[1] AstraZeneca's SET is a body through which AstraZeneca's CEO exercises authority delegated to him by the Board of Directors. AstraZeneca's CEO leads the SET and has executive responsibility for the management, development and performance of the business. The CEO, CFO and the SET also take the lead in developing AstraZeneca's overall strategy for review, constructive challenge and approval by the Board of Directors as part of AstraZeneca's annual strategy review process.

my own knowledge, they are true to the best of my knowledge, information and belief. Where information has been provided to me by third parties, I identify the source of that information and believe it to be true.

3. Whilst a draft witness statement was prepared by AstraZeneca's legal representatives based on discussions with me, I reviewed and amended that draft and ensured that this statement is expressed in my own words, before signing the statement of truth below.

4. The documents I refer to for the purposes of providing the evidence in this witness statement are listed in the attached Annex by the Unique Reference Number (***URN***) assigned to these documents by the Inquiry. When referring to a document in the body of this witness statement, I also cite the URN. I have worked with AstraZeneca's legal representatives to identify documents for inclusion in this way, having regard to the Inquiry's request to disclose key documents at this stage.

5. Nothing in this witness statement is intended to waive any privilege of AstraZeneca or any member of its corporate group, or any associated individual, and I am not authorised to, and do not, make any such waiver.

Content and structure of this statement

6. My statement covers AstraZeneca's response to the COVID-19 pandemic and is focused on its role in the development, manufacture, approval and supply of the Oxford AstraZeneca vaccine (the ***Oxford/AstraZeneca Vaccine***).[2]

7. AstraZeneca's role in response to the COVID-19 pandemic, in particular through its work to develop, manufacture and supply the Oxford/AstraZeneca Vaccine, was a global initiative. As the matters in the Inquiry's Rule 9 Request are necessarily focused on the UK, in producing my statement I have endeavoured to focus on the UK position. However, the matters covered by the requests touch upon many aspects of AstraZeneca's global pandemic response over the Inquiry's relevant period of 30 January 2020 to 28 June 2022. Therefore, I have, in as limited a way as possible, addressed events outside of the UK where it was necessary to do so to respond to the Rule 9 Request.

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[2] The Oxford/AstraZeneca Vaccine is also known as AZD1222; Vaxzevria; ChAdOx1 nCoV-19; or the AstraZeneca COVID-19 vaccine.

8. The structure of my statement is as follows:

(a) **Section A:** My background and role at AstraZeneca

(b) **Section B:** AstraZeneca's role during the global pandemic

(c) **Section C:** AstraZeneca's collaboration with Oxford University to develop the Oxford/AstraZeneca Vaccine

(d) **Section D:** AstraZeneca's early interactions with the UK Government and the UK Supply Agreement

(e) **Section E:** AstraZeneca's role in the manufacture of the Oxford/AstraZeneca Vaccine

(f) **Section F:** AstraZeneca's supply of the Oxford/AstraZeneca Vaccine in the UK

(g) **Section G**: Future pandemic preparedness

SECTION A: MY BACKGROUND AND ROLE AT ASTRAZENECA

9. By way of my background, I hold a Bachelor of Science degree in Biochemistry and Molecular Biology from Imperial College London and a PhD in the Neuropharmacology of Alzheimer's Disease and Depression from University College London. After completing my PhD, I worked as a Visiting Research Fellow at the Mount Sinai Medical Centre in the United States from 1992 to 1995, and subsequently, as a Post-Doctoral Scientist at Bristol Myers Squibb, from 1995 to 1996. Alongside my work in the pharmaceutical industry, which I discuss below, I have also worked in academia, as a Visiting Professor of Neuroscience at Kings College London from 2005 to 2015 and as an Adjunct Professor of Neuroscience at the University of Pennsylvania from 2007 to 2010.

10. I hold Honorary Doctorates from Glasgow University and Imperial College London. I am also a Fellow of the Royal Society, the Academy of Medical Sciences, the Royal Society of Biology and Clare Hall, University of Cambridge, and an Honorary Fellow of the British Pharmacological Society. I was a member of the Life Sciences Vision Advisory Group and serve as a non-executive director on the boards of the Francis Crick Institute and Absci Corp. I am on the scientific advisory boards of Isomorphic Labs, Flagship Pioneering Medicines and the PTEN Research Foundation. I will be joining the Advisory Board of Biogen Inc. in January 2025 and will be joining Omega Funds as a Venture Partner in October 2024. I previously co-chaired the UK Life Sciences Council Expert Group on Innovation, Clinical Research and Data and was a member of the Life Sciences Industrial Strategy Implementation Board. I previously served as a non-executive director on the board of the Cambridge Judge Business School.

11. As I noted above, I joined AstraZeneca in 2010 as Executive Vice President, Innovative Medicines & Early Clinical Development (IMED) Biotech Unit. Prior to joining AstraZeneca, I held senior R&D roles at Pfizer, Wyeth and GSK.

12. In 2016, I became Executive Chair on AstraZeneca's Board of Science Committee, which provides assurance to AstraZeneca's Board of Directors, on the quality, competitiveness and integrity of AstraZeneca's R&D activities.[3]

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[3] See Exhibit MP/1 - INQ000506055, AstraZeneca, 'Annual Report 2022' (*AstraZeneca* 2022), page 94.

13. In 2019, I became Executive Vice-President, BioPharmaceuticals R&D: in this role I had overall responsibility for AstraZeneca's BioPharmaceuticals discovery, research and early to late-stage development activities. From 2020 onwards, I oversaw AstraZeneca's R&D response to the COVID-19 pandemic. I was honoured and privileged to receive a knighthood from Her Majesty the Queen in the New Year 2020 Honours List for services to UK science.

14. After a long career in the pharmaceutical industry and 14 years with AstraZeneca, in July 2023, I announced my retirement from AstraZeneca, which began in March 2024.

SECTION B: ASTRAZENECA'S ROLE DURING THE GLOBAL PANDEMIC

15. AstraZeneca is a global, science-led biopharmaceutical company, headquartered in Cambridge, with operations in over 100 countries and more than 80,000 employees worldwide. AstraZeneca focuses on the discovery, development and commercialisation of medicines, primarily for the treatment of diseases in three therapy areas: Oncology; Biopharmaceuticals (including Cardiovascular, Renal & Metabolism, Respiratory & Immunology, Vaccines & Immune Therapies and Neuroscience); and Rare Diseases.

16. AstraZeneca's R&D function has more than 13,000 employees globally, with four strategic centres in Cambridge, UK; Boston and Gaithersburg, US; and Gothenburg, Sweden, as well as seven other R&D centres and offices. Every year, AstraZeneca's innovative medicines help millions of patients worldwide.

Investigating our existing portfolio of medicines

17. From the earliest days of the pandemic, AstraZeneca mobilised its R&D teams to focus on the discovery of new ways to tackle the SARS-CoV-2 virus. This was a novel virus, and, from the outset, we were part of the scientific community seeking to learn about the virus and advance our understanding as to how best to tackle and treat this disease.

18. One of the first things we did was to review our pipeline of future and existing medicines to understand if they could protect organs from damage or suppress the body's overactive immune response in severely ill patients. This resulted in our initiating clinical trials for acalabrutinib (CALAVI), dapagliflozin (DARE-19) and tozorakimab (ACCORD-II).

19. *Calquence* (the brand name for acalabrutinib) is a prescription medicine used to treat adults with mantle cell lymphoma who have received at least one prior treatment for their cancer, or adults with chronic lymphocytic leukaemia or small lymphocytic lymphoma. The CALAVI Phase II trials investigated the use of *Calquence* in patients hospitalised with respiratory symptoms of COVID-19. In November 2020, we announced the high-level results that the trials did not meet their primary efficacy endpoint. The addition of *Calquence* to best supportive care did not increase the proportion of patients who remained alive and free of respiratory failure.[4]

20. *Forxiga* (the brand name for dapagliflozin) is a prescription medicine used in the treatment of patients with heart failure, kidney disease and type-2 diabetes. Cardiac, renal and metabolic comorbidities have been associated with poor outcomes and death in patients hospitalised with COVID-19. The DARE-19 Phase III trial evaluated the safety and efficacy of *Forxiga* in patients hospitalised with COVID-19 who also have risk factors for developing serious complications, including hypertension, type-2 diabetes, atherosclerotic cardiovascular disease, heart failure or chronic kidney disease. In April 2021, we announced the high-level results that the trial did not meet the primary endpoint of prevention, measuring organ dysfunction and all-cause mortality, or the primary endpoint of recovery measuring a change in clinical status (from early recovery to death), at 30 days.[5]

21. Tozorakimab (also known internally as MEDI3506) is a fully-human monoclonal antibody that neutralises IL33, a broad-acting damage-response cytokine that is released in response to viral infections and tissue damage. IL33 may drive and amplify the overactive inflammatory response in the lungs of patients who are severely ill with COVID-19. By neutralising IL33, tozorakimab could potentially stop the cycle of pulmonary injury found in COVID-19 pneumonia, and thereby prevent clinical progression of lung damage and risk of death. The ACCORD Phase II trial investigated the safety and efficacy of using repurposed and new medicines for the treatment of

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[4] For additional information on these clinical trials see Exhibit MP/2 - INQ000506060, AstraZeneca, 'Update on CALAVI Phase II trials for Calquence in patients hospitalised with respiratory symptoms of COVID-19' (*AstraZeneca*, 12 November 2020).

[5] For additional information on this trial see Exhibit MP/3 - INQ000506061, AstraZeneca, 'Update on the DARE-19 Phase III trial for Farxiga in COVID-19' (*AstraZeneca*, 12 April 2021).

COVID-19 in adult hospitalised patients as an add-on to standard of care. A phase III trial is currently underway.[6]

Evusheld: responding to unmet need and increased burden of COVID-19 for high-risk populations

22. Through our internal scientific expertise in infectious disease and proprietary antibody discovery technology, we undertook research to identify novel coronavirus-neutralising antibodies as a preventative or treatment approach to the COVID-19 disease. These are known as monoclonal antibodies (***mAbs***). These antibodies can be given preventatively before exposure to the virus, as well as to treat and prevent disease progression in patients already infected with the virus. These research and discovery efforts culminated in our medicine known as *Evusheld*, a highly efficacious long-acting antibody (***LAAB***), indicated for prevention (pre-exposure prophylaxis) and early-stage treatment of COVID-19, for use in immunocompromised individuals. *Evusheld* has been authorised for use in more than 30 markets around the world. I understand that Dr Edward Piper (Vice President, UK Medical & Scientific Affairs Director of AstraZeneca) addresses these efforts further in his witness statement to the Inquiry.

Working in partnership to respond to government, healthcare systems' and patient needs in the COVID-19 crisis

23. We had identified a need to introduce diagnostic testing for COVID-19 across our sites to help support the continuity of supply of our medicines. As part of this, we saw an opportunity to support the UK Government's national testing efforts by:

    (a) teaming up with the University of Cambridge, Charles River Laboratories and others, to set up a testing laboratory for high throughput screening for COVID-19 testing and to explore the use of alternative chemical reagents for test kits in order to help overcome supply shortages. Staff from AstraZeneca were working seven days a week to complete the set-up of the laboratory in just five weeks, when this process would usually take six months to complete. By December 2020, the laboratory had already processed two million tests;

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[6] Additional information on this clinical trial can be found at Exhibit MP/4 - INQ000506057: AstraZeneca, 'Efficacy and Safety of Tozorakimab in Patients Hospitalised for Viral Lung Infection Requiring Supplemental Oxygen – TILIA' (*AstraZeneca*, 1 August 2024).

(b) providing expertise in automation and robotics to help expand the capacity of the national testing system;

(c) supporting the sourcing of key consumables and testing equipment which were in short supply by facilitating connections between the UK Government and some of our key suppliers; and

(d) providing process optimisation support to the UK's national testing centres in Milton Keynes, Alderley Park and Glasgow for COVID-19, alongside other partners.

24. AstraZeneca also partnered with the World Economic Forum's COVID Action Platform to donate nine million face masks to healthcare workers in 49 countries, with Italy being the first country to receive a shipment of masks in March 2020. AstraZeneca also donated half a million masks to the UK in April 2020.

Maintaining the supply of our life-saving medicines

25. We needed to procure PPE and secure in-house testing services not only to ensure that our scientists could work on responses to the COVID-19 pandemic, but also to ensure that we continued to produce, supply and distribute AstraZeneca's existing portfolio of essential medicines, including treatments for cancer, heart-failure, kidney disease, type 2 diabetes and asthma. These medicines are vital for patients around the world. I am proud to say that we continued to supply our medicines throughout the pandemic.

R&D continuity in 2020 and accelerating clinical digital innovation

26. Across the pharmaceutical industry, the COVID-19 pandemic also impacted ongoing R&D activities. Companies across the industry reported disruption to clinical trials, with nearly an 80% decrease in new patients entering trials in 2020 and more than one million existing patients worldwide facing disruption due to pandemic restrictions, including lockdowns. At AstraZeneca, we responded by adapting the way we work and finding more digital solutions to achieve clinical trial continuity for the R&D activities in our core therapy areas.

The Oxford/AstraZeneca Vaccine: developed and delivered in 18 months, supplied to the world at no-profit during the pandemic period

27. AstraZeneca's most significant contribution to ending the pandemic was our collaboration with the University of Oxford (***Oxford***) to develop, manufacture, supply and distribute a vaccine for the prevention of COVID-19.

28. This collaboration began in April 2020, following discussions I had with Oxford and with the CEO of AstraZeneca to see if we could help Oxford with their work to develop a vaccine. From this point onwards, AstraZeneca worked throughout the pandemic in collaboration with the team at Oxford, as well as other scientists, government bodies, manufacturers and NGOs around the world. At a time when the world was pinning its hope for a return to "normality" on the development of vaccines, this collaboration was a pivotal moment in the response to the pandemic. It was based on a shared objective to develop a globally accessible vaccine and to ensure fair and equitable distribution worldwide.

29. By the time our collaboration began in April 2020, Oxford was already running clinical trials, and these continued throughout 2020. Alongside Oxford, AstraZeneca also initiated its own global pivotal trials. I understand that my colleague, Dr Justin Green (Global Product Lead for Vaxzevria at AstraZeneca), will address the scale and scope of the clinical trials programmes in his witness statement to the Inquiry.

30. From the outset of AstraZeneca's involvement with Oxford, we invested significant resources (both financially and in terms of our people's time and attention) into the clinical trials and the parallel scale-up of manufacturing and building the infrastructure for supply. We made these investments, without knowing the outcome, because it was the right thing to do.

31. On 23 November 2020, Oxford and AstraZeneca announced the positive high-level results from the pivotal clinical trials that Oxford had undertaken.[7] [8] The interim analysis showed that the Oxford/AstraZeneca Vaccine was highly effective in preventing both symptomatic COVID-19 disease and severe outcomes, including hospitalisation from COVID-19.[9] In February 2021, early results based on real world data (in this case,

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[7] See Exhibit MP/5 - INQ000413710, AstraZeneca, 'AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19' (*AstraZeneca*, 23 November 2020).

[8] See Exhibit MP/6 - INQ000397440, Oxford University, 'Oxford University breakthrough on global COVID-19 vaccine' (*Oxford University*, 23 November 2020).

[9] See Exhibit MP/7 - INQ000506069, Merryn Voysey et al, 'Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK' (2021) 397 The Lancet.

from Public Health Scotland) confirmed the high degree of effectiveness of the Oxford/AstraZeneca Vaccine against all severe outcomes.[10] [11]

32. It can be challenging to report on the results of clinical trials, and Oxford's design of these trials was complex. With hindsight, it is clear that the results were not well understood outside the scientific community. The public narrative focused on the reported differences between different vaccines' efficacy at preventing symptomatic disease and compared the different vaccines on that basis. This in turn contributed to confusion among the public about how effective the different vaccines were overall. In my view, the narrative around efficacy should have focused on what I – and many in the scientific community – considered to be the key issue, which was how effective any vaccine was at preventing severe outcomes such as hospitalisation and death.

33. Following interaction with regulators on the basis of the available analysis from these trials, we sought regulatory approval for the Oxford/AstraZeneca Vaccine. On 30 December 2020, the UK became the first country to announce the approval of the Oxford/AstraZeneca Vaccine for the active immunisation of individuals aged 18 or older. Approval from the European Union followed in January 2021. Ultimately, over 128 regulatory authorisations were granted worldwide.

34. The Oxford/AstraZeneca Vaccine went on to play a key role in tackling the biggest public health emergency of my lifetime. In its first year of use alone, it is independently estimated that the Oxford/AstraZeneca Vaccine saved over six million lives worldwide.[12]

35. The global distribution of the Oxford/AstraZeneca Vaccine was due in part to the success of COVAX. COVAX is a global initiative, which was launched in April 2020 by Gavi, the Vaccine Alliance (***Gavi***)[13] and the Coalition for Epidemic Preparedness

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[10] A study in February 2021 estimated the Oxford/AstraZeneca Vaccine to be 94% effective against hospitalisation due to COVID-19 in a real-world setting. See Exhibit MP/8 - INQ000147534, Vasileiou et al, Effectiveness of First Dose of COVID-19 Vaccines Against Hospital Admissions in Scotland: National Prospective Cohort Study of 5.4 Million People. Further data was subsequently published in respect of a slightly different dataset which reported an efficacy rate of 88% against hospitalisation (Vasileiou et al, Interim findings from first-dose mass COVID-19 vaccination roll-out and COVID-19 hospital admissions in Scotland: a national prospective cohort study, The Lancet, Volume 397, Issue 10285, 2021, Pages 1646-1657, ISSN 0140-6736).

[11] See Exhibit MP/9 - INQ000235195, Public Health Scotland, 'Vaccine linked to reduction in risk of COVID-19 admissions to hospitals' (*Public Health Scotland*, 22 February 2021).

[12] See Exhibit MP/10 - INQ000506053, Airfinity, 'AstraZeneca and Pfizer/BioNTech saved over 12 million lives in the first year of vaccination' (*Airfinity*, 13 July 2022).

[13] Gavi is a public-private international organisation created to improve access to vaccines for children living in low- and middle-income countries.

Innovations (***CEPI***)[14], working closely with the WHO. It "*[brings] together governments, global health organisations, manufacturers, scientists, private sector, civil society and philanthropy, with the aim of providing innovative and equitable access to COVID-19 diagnostics, treatments and vaccines*", focusing in particular on the distribution of vaccines to low- and middle-income countries. The Oxford/AstraZeneca Vaccine transformed the global response to the COVID-19 pandemic due to its ability to be stored, transported and handled at normal refrigerated conditions (2-8 degrees Celsius) for at least six months and administered within existing healthcare settings.[15] AstraZeneca was the first pharmaceutical company to join COVAX in June 2020. By the end of 2021, more than 250 million doses of the Oxford/AstraZeneca Vaccine were delivered to 130 countries through COVAX[16], making AstraZeneca the largest contributor to COVAX that year.

36. By November 2021, less than twelve months after the first regulatory approval of the Oxford/AstraZeneca Vaccine, AstraZeneca and its manufacturing network had supplied more than two billion doses of the vaccine to more than 170 countries. At the time of writing, AstraZeneca has supplied over 3 billion doses of the Oxford/AstraZeneca Vaccine to more than 180 countries.

37. AstraZeneca, working together with Oxford, made a vaccine for the world, developed and delivered in 18 months and supplied at no profit during the pandemic period. It is an achievement that I am personally very proud to have been involved with. Many people worked above and beyond to achieve this, putting their own lives to one side. We faced many challenges throughout and there are undoubtedly lessons to be learned for future pandemic preparedness (the most pertinent of which I describe in Section G of my statement).

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[14] CEPI is a partnership between public, private, philanthropic, and civil society organisations to develop vaccines to stop epidemics and to enable equitable access to vaccines for people during outbreaks.

[15] See Exhibit MP/5 - INQ000413710, AstraZeneca, 'AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19' (*AstraZeneca*, 23 November 2020).

[16] See Exhibit MP/11 - INQ000506054, AstraZeneca, 'Annual Report 2021' (*AstraZeneca*, 2021).

SECTION C: ASTRAZENECA'S COLLABORATION WITH OXFORD UNIVERSITY TO DEVELOP THE OXFORD/ASTRAZENECA VACCINE

AstraZeneca's initial engagement with Oxford

38. In early 2020, as a result of AstraZeneca's work to establish testing facilities and screen potential monoclonal antibodies, I was invited to join the External Advisory Board to the UK Vaccine Taskforce (the ***VTF***) around the end of March.

39. It was through my involvement with the External Advisory Board to the VTF that I heard about a potential vaccine for COVID-19 under development by Oxford. Oxford and AstraZeneca have a longstanding relationship so I contacted Sir John Bell, the Regius Professor of Medicine at Oxford to discuss how AstraZeneca could help Oxford's efforts. Sir John Bell explained that Oxford was looking for a pharmaceutical company with which it could collaborate on the manufacture and distribution of the vaccine at scale, if development efforts proved successful. I then raised this with the CEO of AstraZeneca, and it was agreed that AstraZeneca would offer to work with Oxford.

40. We were the right partner for Oxford because we could leverage our experience as a global pharmaceuticals company of successfully developing, manufacturing and supplying biological medicines worldwide, in order to globalise the Oxford programme. We could support Oxford with the clinical development of the vaccine as well as helping them complete regulatory filings around the world and establish a network to manufacture, supply and distribute any potential vaccine.

41. In these conversations, Oxford made clear that they were committed to ensuring broad and equitable access to any vaccine that was successfully developed. AstraZeneca agreed with this ambition. From our perspective, this was crucial because the only way out of the pandemic was to ensure that as many people as possible were vaccinated, regardless of their country or ability to pay. As a result, AstraZeneca and Oxford agreed to an approach whereby during the pandemic period, the Oxford/AstraZeneca Vaccine would be made available on a not-for-profit basis.[17]

AstraZeneca's contractual arrangements with Oxford

[17] See Exhibit MP/11 - INQ000506054, Chair of the Board and the Chair of the Remuneration Committee's reply to an investor letter to all pharmaceutical companies, highlighting AZ's commitment to equitable access to vaccines: AstraZeneca, 'Annual Report 2021' (*AstraZeneca*, 2021), page 100.

42. Reflective of the speed with which the pandemic was progressing, we agreed an initial framework for our collaboration with Oxford within weeks of those initial discussions, together announcing the start of our collaboration on 30 April 2020.

43. The UK Government also had some input into the framework for collaboration because the Oxford/AstraZeneca Vaccine was being developed in the UK, and Oxford had received funding from the UK Government for vaccine development. On 17 May 2020, AstraZeneca UK Limited and Oxford entered into a research and licence collaboration agreement (the ***Licence Agreement***) with Oxford University Innovation Limited (a company established and owned by Oxford, responsible for technology development and commercialisation of intellectual property developed at, or by, Oxford).

44. Broadly speaking, the split of responsibilities under the Licence Agreement was that Oxford would continue to conduct its sponsored clinical trials with ongoing funding and support from AstraZeneca. AstraZeneca was responsible for all other activities, including the development, regulatory approval, manufacturing, supply and commercialisation of the Oxford/AstraZeneca Vaccine.

45. Consistent with our and Oxford's shared commitment to equitable access, AstraZeneca agreed to supply the vaccine on a not-for-profit basis to all countries during the pandemic period and afterwards, it would continue to be supplied to low-income countries on a not-for-profit basis.

46. In respect of UK manufacturing and supply, AstraZeneca agreed to help ensure that there was sufficient UK onshore manufacturing to meet the UK's demand for the Oxford/AstraZeneca Vaccine and use its best reasonable efforts to supply the vaccine in the UK.

47. The decision to supply the Oxford/AstraZeneca Vaccine on a not-for-profit basis during the pandemic period reflected AstraZeneca and Oxford's wider commitment to ensure that the vaccine could be deployed to save lives around the world if the clinical trials were successful. As I describe below, among other things, this would involve building global supply chains and engaging appropriate contract manufacturers to secure capacity for billions of doses for developing countries.

48. Oxford and AstraZeneca also collaborated on other parallel initiatives relating to the pandemic. For example, in June 2020, AstraZeneca committed 7 million dollars to Oxford for the development of a centre for pandemic preparedness and vaccine research.

Collaboration between Oxford and AstraZeneca through the JDC and JSC

49. As is typical for pharmaceutical collaborations, AstraZeneca and Oxford established governance bodies for decision-making. A Joint Development Committee (***JDC***) was formed for discussion and decision-making related to clinical development, manufacturing and supply and a Joint Steering Committee (***JSC***) was formed for escalations and certain categories of significant decision-making or investment.

50. The JSC and the JDC consisted of representatives from AstraZeneca and Oxford, together with appointed non-voting representatives from the UK Government. I was a member of and chaired the JSC from its inception. Initially each committee met every month, or thereabouts. After July 2021, meetings were held less frequently.

51. Under normal circumstances, a JSC would not meet this frequently and would not include executive management until the later stages of a product's development, when budgeting and financial commitments are typically greater. However, with the decision to establish manufacturing and supply chains at the same time as the ongoing clinical development of the Oxford/AstraZeneca Vaccine, and given the intended scale and speed at which all parties wanted to work, it made sense to include senior decision-makers from both AstraZeneca and Oxford from the outset. This allowed decisions to be made and actioned promptly and with confidence that each organisation would be able to deliver on them. The non-voting participation of the UK Government allowed it to stay apprised of the latest developments concerning the progress of the Oxford/AstraZeneca Vaccine, reducing the need for duplicative meetings or briefings.

52. The meetings of the JSC and JDC covered a breadth of topics related to the development, manufacture and commercialisation of the vaccine, and the focus of those meetings changed over time. For example, in July/August 2020, discussions were focused on ongoing clinical trials, scaling up the manufacturing process through CMOs and building the supply chain network including through sublicensing agreements. By the end of 2020, discussions had moved to aligning approaches between regulatory authorities and preparing for regulatory submissions as well as discussions regarding ongoing trials in the United States, UK, Brazil, South Africa and Kenya and the specific details regarding the supply map for the UK. From early 2021 and thereafter, discussions centred around the roll out of the Oxford/AstraZeneca Vaccine, responding to new variants of the COVID-19 virus and supplying the Oxford/AstraZeneca Vaccine to low- and middle-income countries through COVAX.

AstraZeneca's subsequent sub-licences with key supply partners

53. To support the manufacturing and supply of doses and global access to the Oxford/AstraZeneca Vaccine, AstraZeneca subsequently sublicensed rights to key third party organisations around the world. These key supply partners took a sub-licence of the IP rights to allow them to manufacture the vaccine, under their own regulatory authorisations and labels within their specified geographic territory.

54. For example, in June 2020, AstraZeneca UK Limited reached a licensing agreement with the Serum Institute of India (***SII***) to supply one billion doses for low- and middle-income countries, with a commitment to provide 400 million doses before the end of 2020. SII is the world's largest manufacturer of vaccines and had already been identified by Oxford as a potential collaboration partner for equitable supply of the vaccine worldwide.

The role of Vaccitech

55. I understand that the Inquiry is interested in AstraZeneca's relationship with Vaccitech, a company that was linked to Oxford and which owned the viral vector which was used to develop the Oxford/AstraZeneca Vaccine. The relationship was limited. I had a few conversations with senior individuals there around the time of negotiating the Licence Agreement. We did not have any significant interaction with the company as part of our ongoing collaboration with Oxford for the development of the Oxford/AstraZeneca Vaccine.

SECTION D: ASTRAZENECA'S EARLY INTERACTIONS WITH THE UK GOVERNMENT AND THE UK SUPPLY AGREEMENT

AstraZeneca's early interactions with the UK Government

56. From the early days of the pandemic, AstraZeneca participated in various UK working groups established to connect senior industry leaders with the UK Government. Calls were convened to ascertain the types of support manufacturers across various sectors in the UK might require from the UK Government in order to continue to operate. AstraZeneca highlighted the importance of protecting the supply and distribution of medicines in these conversations. It was evident that as a global life sciences business, AstraZeneca could offer additional support to the UK Government which AstraZeneca's CEO and AstraZeneca's UK Marketing Company President repeated in letters to senior ministers and the Prime Minister.

57. From March 2020 onwards, AstraZeneca participated in the COVID-19 Industry Group established by the UK's Office for Life Sciences (***OLS***, currently part of the Department for Health and Social Care and the Department for Science, Innovation and Technology). This group was led by the Director of the OLS and met to discuss the life sciences sector's operational challenges and solutions as the pandemic progressed.

58. AstraZeneca's principal contact with the UK Government regarding the development, manufacture and supply of the Oxford/AstraZeneca Vaccine in the UK was through the VTF, which I discuss throughout this statement.

The UK Supply Agreement with the UK Government

59. As I have said above, AstraZeneca and Oxford announced the start of our collaboration on 30 April 2020. AstraZeneca and the UK Government were also engaged in discussions about the contractual arrangements in relation to the UK supply of the Oxford/AstraZeneca Vaccine at this time. Throughout these discussions, the UK Government and AstraZeneca worked closely together and maintained a collaborative relationship. In May 2020, AstraZeneca UK Limited agreed upon the terms of a vaccine supply agreement with the UK Government. This was then formally documented by means of the "Supply Agreement for AZD1222" (the ***UK Supply Agreement***), which AstraZeneca UK Limited and the UK Government (Department for Business, Energy and Industrial Strategy (***BEIS***)) formally executed on 28 August 2020. The UK Supply Agreement was amended and restated on 8 November 2021.[18]

60. The UK Supply Agreement is a commercial agreement. It contained several bespoke terms reflecting the circumstances of the pandemic and the investment that AstraZeneca needed to take to supply any successful vaccine:

    (a) if approved, AstraZeneca agreed to supply 100 million doses of the vaccine on a priority basis to the UK Government and on a not-for-profit basis, in accordance with the Licence Agreement;

    (b) the UK Government agreed to make payments to AstraZeneca in advance for the supply of the potential vaccine. This reflected the context of the pandemic,

[18] See Exhibit MP/23 - INQ000503569: AstraZeneca UK Limited and UK Government (BEIS), 'Agreement to amend and restate the supply agreement for AZD1222' (8 November 2021).

and the fact that AstraZeneca would invest significant resources before there was a proven vaccine; and

(c) the UK Government also agreed to indemnify AstraZeneca in respect of losses arising from certain third-party claims. This was an essential element of the Supply Agreement without which AstraZeneca would not supply the Oxford/AstraZeneca Vaccine. It is my understanding that the UK Government entered into similar indemnification arrangements with other manufacturers to support the supply of their vaccines to the UK.

61. Under normal circumstances, it is my understanding that supply agreement negotiations typically take place after commercial manufacturing processes have been established. Those negotiations will then be grounded in known factors such as manufacturing lead times, production yields, dosage and storage requirements and the associated costs and possible causes of delay.

62. However, we were having to negotiate supply agreements at an earlier stage in the development process, based on estimates from Oxford's clinical manufacturing processes. In April 2020, Oxford provided AstraZeneca with estimated drug substance yields of 5,000 to 8,000 doses/litre. However, the development data, generated during the manufacturing development process in May to August 2020, indicated that the actual manufacturing process yield would be significantly lower at 1,900 to 2,500 doses/litre. This meant that there was considerable uncertainty around the volume of product that might be produced and the timescales within which this could be achieved. Added to this, governments were announcing and amending restrictions by the day and AstraZeneca faced the challenge of building a global supply chain in real-time, while grappling with this rapidly developing landscape. There were new challenges to resolve such as coordinating human trials during a national lockdown or adapting the vaccine to combat the new variants of the rapidly mutating COVID-19 virus. As such, it was essential that the Supply Agreement accommodated these variables. For example, while a standard supply agreement may bind the parties to a strict delivery schedule, with penalties for late delivery, the UK Government rightly acknowledged that the commercial manufacturing process required a balance between the need for certainty and the need for flexibility. This remained important because the subsequent scale-up of the manufacturing process demonstrated the yield to be more variable than estimated, with several manufacturers for both UK and international supply chains achieving considerably less as the process was established and optimised.

SECTION E: ASTRAZENECA'S ROLE IN THE MANUFACTURE OF THE OXFORD/ASTRAZENECA VACCINE

Introduction

63. In typical circumstances, the establishment of commercial manufacturing processes takes about a year or more. In response to the pandemic, this process development stage was condensed to just a few months by building on Oxford's existing clinical manufacturing processes and running various development stages in parallel. Subsequent optimisations to the manufacturing processes were developed simultaneously and over time with commercial supply.

Oxford's early clinical development of the Oxford/AstraZeneca Vaccine

64. The path to the commercial manufacture and supply of the Oxford/AstraZeneca Vaccine relied first on the pre-clinical, early clinical and biomanufacturing development work carried out by scientists at the Jenner Institute and the Oxford Vaccine Group (part of Oxford). Notably, they had undertaken years of research into adenovirus-vectored vaccine technology[19]), which was then used to develop the Oxford/AstraZeneca Vaccine. This technology had been used to produce candidate vaccines against a number of pathogens including influenza, Zika and another coronavirus, Middle East Respiratory Syndrome (***MERS***). My sense is that this scientific research, coupled with early financial investment, including from the UK Government, put the Oxford team in a strong position to develop a candidate vaccine for COVID-19 infection.

Building on Oxford's existing clinical manufacturing processes

65. When we partnered with Oxford, the Jenner institute had already made material for clinical trials using their bench scale process. We joined as Oxford was in the middle of working with an existing UK consortium of CMOs to develop a process using a 200-litre disposable bioreactor and disposable equipment for purification that could be replicated across the UK. Oxford had also developed a strategy around centralised testing that is an important part of manufacturing development. We were able to build

[19] Adenovirus-vectored vaccine technology is often referred to as "viral vector" technology or the "ChAdOx1" platform.

on Oxford's existing knowledge to develop the manufacturing and supply processes for commercial supply of the Oxford/AstraZeneca Vaccine.

Running the manufacturing and technology transfer processes in parallel

66. The manufacturing processes and the building of suitable supply chains in respect of a vaccine typically develop in line with its progression through clinical development, so that when the vaccine is ready to be launched on a commercial scale, a central supply and distribution chain, including regulatory approval, is already in place. Because of the pandemic, however, the route to commercial manufacture and supply had to be achieved on a truncated timeline. We therefore ran the establishment of the various manufacturing processes in parallel with the technology transfer process to CMOs in order to shorten timeframes. The challenge of running the two in parallel meant we needed to resource a large technical team to support CMOs throughout the manufacturing and supply of doses.

67. The fact that AstraZeneca was able to achieve this was due to our efforts to build the necessary infrastructure to develop, manufacture, supply and distribute the Oxford/AstraZeneca Vaccine. It was also due to our having rapidly built a large team comprising highly skilled workers from across nearly every part of the company. This included, among others, clinical researchers, biopharmaceutical development experts, supply chain experts, engineers, quality professionals, clinical teams and regulatory experts. We also leveraged the experience of our colleagues who had worked in the development of our influenza vaccines. In terms of our internal structures, the main functions involved at AstraZeneca were the Global Product Team, the Global Supply Team, whose membership included cross-functional support from our Chemistry, Manufacturing and Controls (***CMC***), Global Regulatory and other functional areas of the business.

68. By taking this approach, AstraZeneca and Oxford were able to supply initial doses of the Oxford/AstraZeneca Vaccine within three months of the positive high-level results of the Oxford clinical trials, and just nine months following the announcement by the WHO of the start of the COVID-19 pandemic.

Establishing the UK Supply Chain

69. In this section of my statement, I will focus on the main stages involved in the manufacture of the Oxford/AstraZeneca Vaccine and the work required to establish a commercial supply chain in the UK.

70. Upon entering into collaboration with Oxford in May 2020, AstraZeneca took over responsibility for the creation of a comprehensive manufacturing process and supply chain network that could be reproduced in multiple manufacturing sites across the world to enable mass production of the Oxford/AstraZeneca Vaccine. Ultimately, we established a global supply network of more than 25 supply partners across over 15 countries and constructed more than a dozen distinct supply chains with a regional approach.

71. By way of overview, there were four main stages involved in this work, which can be summarised as follows:[20]

    a) Process development;

    b) Fermentation, harvesting and purification of the drug substance;

    c) Producing the final drug product (the vaccine) (including fill and finish and labelling and packaging); and

    d) Delivery of the vaccine to communities.

Stage (1): Process development

72. AstraZeneca (particularly the CMC team) worked closely with the team at Oxford to create a comprehensive manufacturing process that could be reproduced in multiple manufacturing sites to enable production of the Oxford/AstraZeneca Vaccine at commercial scale.

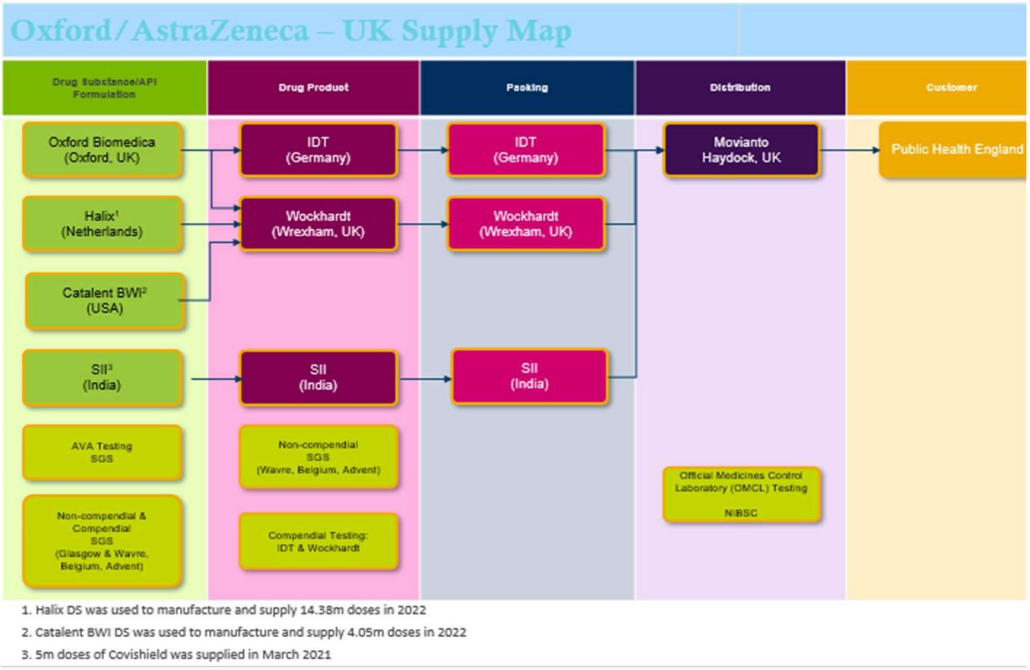
73. In the UK, the starting point for AstraZeneca was the existing UK consortium of CMOs that had been assembled by Oxford with help from the BioIndustry Association (***BIA***) that had convened a working group, which fed into the VTF.

74. Full details of the established UK supply chain are set out in Figure 1 below. Halix Pharmaceutical, Oxford Biomedica (UK) Limited and IDT were all part of Oxford's

[20] See Exhibit MP/12 - INQ000397439, AstraZeneca, 'Making the COVID-19 Vaccine Factsheet' (*AstraZeneca*, February 2021).

existing UK consortium of CMOs for the manufacture and supply of a vaccine. Wockhardt, which also played an important role in the manufacturing chain, was, I believe, originally identified by the VTF (as I explain below).

Figure 1: Overview of UK supply chain for the Oxford/AstraZeneca Vaccine



Contracting with CMOs to establish the UK supply chain:

75. Because there was an existing UK consortium of CMOs, AstraZeneca was able to move quickly to enter into its own agreements with each of the UK CMOs to ensure the reservation of manufacturing capacity for commercial supply. In normal circumstances, contractual negotiations with supply networks can take many months, even over a year, but in this landscape, we used short form contracts to secure capacity in a matter of weeks. These were entered into in May 2020, and within a few months we subsequently agreed more detailed, longer-term contracts (signed between August - October 2020).

76. With Wockhardt, the contracting process was slightly different because the UK Government had already secured 12 months of manufacturing capacity from them (involving fill and finish of the vaccine into vials) for the vaccine supply in the UK. We

then entered into a commercial contract with Wockhardt, based on this existing arrangement.

77. I understand the Inquiry has also expressed interest in the role of the Vaccine Manufacturing & Innovation Centre (***VMIC***) in the manufacturing of the Oxford/AstraZeneca Vaccine. I believe, based on our discussions with Oxford, that the VMIC did play a role in guiding the initial consortium of CMOs that was established by Oxford and the BIA. However, as regards AstraZeneca's role in the development process of the Oxford/AstraZeneca Vaccine, the VMIC did not form part of the UK supply chain for the Oxford/AstraZeneca Vaccine and as a result, we had little interaction with the VMIC.

78. I understand that the VMIC was sold in April 2022 to Catalent, a CMO with headquarters in the US. It is not for me or AstraZeneca to comment on how the sale of the VMIC might affect the UK's future vaccine manufacturing capabilities, which will depend on what other investments the UK makes in this area. However, as I say in the final section of my statement, ensuring the availability and adequacy of vaccine manufacturing facilities and capacity in the UK remains an essential part of the UK's ability to prepare for and respond to a future pandemic.

<u>The technology transfer process</u>:

79. Central to AstraZeneca's mass supply capability was defining the CMC of the production process. This involved developing an optimised, repeatable manufacturing process to deliver maximum yields and to ensure high-quality product across AstraZeneca's supply chain.

80. This manufacturing process was then transferred to the CMOs to establish supply at their respective facilities. As quality testing was required throughout the manufacturing process, as well as to support product release in market, AstraZeneca also built an extensive network of laboratories, to which AstraZeneca's analytical methods were transferred.

81. The technology transfer workstream in the UK and globally was managed by AstraZeneca's CMC team. This comprised scientists specialised in various areas, including development, analytics, quality and CMC regulatory and many external consultants. This team worked with the network of CMOs to transfer their knowledge and knowhow about the technology underlying the viral-vectored vaccine, and AstraZeneca's validated protocols and standard methods for vaccine production.

Every step of each stage of the manufacturing process – from growing and harvesting the vector vaccine drug substance to filling vials with the finished vaccine product, packing and labelling them – was outlined in these technology transfer protocols in detail.[21]

82. As members of the CMC team were unable to travel due to the pandemic, they had to use virtual technology to provide real-time technical support and coaching to production teams at each CMO site. Ultimately, it was critical that each CMO was carefully and personally supported in their individual adoption of the technology transfer.

AstraZeneca's work to optimise efficiency of the process development stage:

83. Given the urgent need that there would be for any successful vaccine and the challenges we faced with drug substance yields, AstraZeneca was constantly looking for ways to increase manufacturing capacity from the CMOs to ensure sufficient supply at a commercial scale to meet the enormous demand. For example, to enable the manufacture of the Oxford/AstraZeneca Vaccine to be scaled up, the team identified a method to significantly reduce the amount of virus needed at the start of the process to infect producer cells from which the vaccine is harvested, making the process more efficient. Other process improvements included increasing the concentration of the vaccine drug substance, which significantly reduced the amount of freezer storage required at the sites, as well as reducing the transportation and raw material requirements.[22]

Stage (2): Fermentation, harvesting and purification of the drug substance

84. Before starting production of the Oxford/AstraZeneca Vaccine, AstraZeneca provided each CMO with sufficient COVID-19 virus seed stock and sufficient cell banks with the (harmless) host cells to initiate vaccine production.

85. AstraZeneca's procurement team also worked to source large quantities of other raw materials (compounds that aid in the vaccine manufacturing process and/or that make up the final formulation), components (such as vials and stoppers) and consumables

[21] See Exhibit MP/13 - INQ000506059, AstraZeneca, 'Pushing boundaries to deliver COVID-19 vaccine across the Globe' (*AstraZeneca*, December 2021).

[22] Ibid.

(such as filters and tubing). Highly coordinated, continuous supply of all these essential items for vaccine production was required at each CMO. This was a very complex sourcing process, involving multiple steps. The global scarcity of materials, export control restrictions and the need to manage the risk of contamination at every stage of the process made it even more challenging.

86. The drug substance was then produced by a process whereby host cells were grown in a series of bioreactors, of increasing scale, and then infected by the virus seed. Once the virus had replicated in the cell culture, the bioreactor harvest was purified by a series of filtration and chromatography steps.

Stage (3): Producing the final drug product (the vaccine) (including fill and finish and labelling and packaging)

87. The drug substance was then combined with formulation buffers to achieve a final formulation and the final drug product was then transported for 'fill and finish' into multi-dose vials. The multi-dose vials were then packaged at each of the CMOs, pursuant to defined storage and handling conditions to ensure product stability and shelf life. In respect of the UK supply chain, Wockhardt and IDT were the CMOs responsible for this manufacturing process (as shown in Figure 1 above).

88. Each batch of finished vaccine product was then tested to ensure that it met quality standards. All manufacturing documentation and test results were reviewed in multiple steps by the quality organisations of the CMOs and AstraZeneca. The batch specific lot release protocol was then submitted for approval to the National Institute for Biological Standards and Control (***NIBSC***). Once it had received a Regulation 174 authorisation, the Oxford/AstraZeneca Vaccine was released by AstraZeneca into the distribution chain for onward supply to Public Health England (***PHE***).

89. In order to minimise the risk of unnecessary delays in releasing the doses to PHE, AstraZeneca agreed an innovative approach to the packaging of the Regulation 174 equivalent of the patient information leaflet (***PIL***). The PIL is not available until the clinical trials have concluded and the product has been authorised. It is then printed and individually inserted into each vial box of vaccine. These boxes are then assembled as a batch ready for any final inspection and delivery. Each stage of this process takes time. The innovation we agreed for the Oxford/AstraZeneca Vaccine was that we would instead print tear-off pads of the PIL to be supplied alongside each batch release. This saved considerable time by allowing batches to be prepared

concurrently, with the approval process and the printing of PILs to take place separately. QR codes were also printed on each of the vial boxes that could be scanned for access to the latest Regulation 174 PIL.

Stage (4): Delivery of the Oxford/AstraZeneca Vaccine

90. In a traditional drug supply chain, the finished product may be stored for weeks or months until it is needed to meet public health requirements. However, in the COVID-19 pandemic, it was essential that every dose of the Oxford/AstraZeneca Vaccine was available for administration as quickly as possible. This meant that each batch of the Oxford/AstraZeneca Vaccine was typically released to PHE for onward distribution to vaccination sites within hours of the final release certificate being received from NIBSC. [23] This required close collaboration between AstraZeneca, Movianto and the UK Government agencies. Immediately releasing, rather than building-up a stockpile of inventory, in this way, is known as "just-in-time supply" and it led to some early challenges with the supply of doses because government agencies are not used to fluctuations in available stock. In the UK, our close working relationship with the VTF was instrumental in making this work.

Quality Assurance and Testing

91. Quality assurance and testing was conducted at multiple stages of the process that I have just described. For example, each supplier underwent the standard AstraZeneca supplier qualification process to ensure they adhered to Good Manufacturing Practice, that appropriate Quality Systems were in place and that they held a manufacturing licence issued by the relevant regulatory authority.[24]

92. It was confirmed that the essential conditions, controls, testing and expected outcomes for the manufacturing process were achieved at each manufacturing site as part of the manufacturing process qualification.[25]

93. Once manufacturing for UK supply was underway, regular and robust quality assurance processes were put in place to reduce the possibility of unexpected changes to the vaccine during production. Where possible, the Quality team at

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[23] Ibid.

[24] Ibid.

[25] Ibid.

AstraZeneca worked closely with CMOs to monitor the manufacturing process. This took place through virtual tours, which allowed the AstraZeneca team to view the CMO partner's production processes remotely. AstraZeneca worked closely with its CMO partners to capitalise on and share learnings in real-time – both best practices and challenges – in order to continually optimise the process and share these developments across the global supply network.[26]

Overcoming challenges in the process to manufacture and supply the Oxford/AstraZeneca Vaccine

94. As I have noted already, the work that AstraZeneca carried out to manufacture and supply the Oxford/AstraZeneca Vaccine in response to the pandemic was unprecedented in terms of its scale and complexity and the speed with which it had to be carried out. Unsurprisingly, there also proved to be many challenges for AstraZeneca to overcome.

95. These challenges included the complicated logistics of setting up and transferring the vaccine technology to a large number of CMOs both in the UK and globally. This was particularly so, given: the logistical challenges posed by the pandemic and by remote working; the lack of available consumables, critical equipment and raw materials for use in the manufacturing process; and the unpredictability of anticipated yields of drug substance from any given CMO, which impacted on the quantities of vaccine doses that could ultimately be manufactured and supplied. The potential for governments to restrict or prevent imports or exports at any time created additional uncertainty. However, despite these challenges, AstraZeneca successfully established a global supply chain for the Oxford/AstraZeneca Vaccine within months of the declaration of the pandemic. This was a significant accomplishment for our teams.

96. As above, one of the main ways in which AstraZeneca did this was to run multiple processes in parallel instead of consecutively. This, in itself, required a significant level of planning and close support from the AstraZeneca teams.[27]

97. The urgency with which AstraZeneca worked on the Oxford/AstraZeneca Vaccine has made the company more agile in its manufacturing and testing processes more

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[26] Ibid.

[27] See Exhibit MP/14 - INQ000506058, AstraZeneca, 'Innovating Production and Manufacture to meet the Challenge of COVID-19' (*AstraZeneca*, December 2021).

generally, and the multiple successful collaborations and partnerships AstraZeneca formed will strengthen our ability to respond rapidly to future health needs.[28]

SECTION F: ASTRAZENECA'S SUPPLY OF THE OXFORD/ASTRAZENECA VACCINE IN THE UK

Preparations for the supply of the Oxford/AstraZeneca Vaccine in the UK – in the period leading up to the MHRA's approval

98. In the period leading up to the approval of the Oxford/AstraZeneca Vaccine by the UK's Medicines and Healthcare products Regulatory Agency (***MHRA***), a huge amount of effort was spent in preparing the logistics for the supply and delivery of doses to the UK population. Decisions about which groups of the population would receive doses and in which order were made by the JCVI. AstraZeneca's work focused on how to logistically prepare for the roll-out process. A key feature of our work during this period was frequent and effective communication with the VTF, NHS England (***NHSEI***), PHE and the Devolved Nations' administrations.

99. There were frequent discussions and reports between us both in preparation for the supply of the Oxford/AstraZeneca Vaccine and once it was being supplied. These discussions became more frequent in around October 2020. Around this time, there were daily communications between AstraZeneca, the NHSEI and PHE, with the VTF effectively acting as a communications channel. This structure for regular and constant communication enabled the various teams to update their supply expectation and respond to fluctuations in stock from the "just-in-time supply" model. There were many moving parts to coordinate in preparation for the supply and delivery of the Oxford/AstraZeneca Vaccine and discussions focused on many logistical issues, including for example, storage and transport of the vaccine and provision of the printed Regulation 174 Information for UK recipients, equivalent of PIL.

100. Another forum for strategic communications was the meetings known as the launch readiness meetings, which were put in place in December 2020 for senior leaders at AstraZeneca and the VTF to exchange updates and discuss logistical issues such as vaccine handling details, packaging / labelling information and communications plans. Further meetings involving senior members from AstraZeneca and the VTF were held

[28] See Exhibit MP/13 - INQ000506059, AstraZeneca, 'Pushing boundaries to deliver COVID-19 vaccine across the Globe' (*AstraZeneca*, December 2021).

later in December 2020. These meetings were forward-looking, and discussions focused on more strategic points like lead times and delivery milestones.

101. I and others in the leadership team at AstraZeneca with responsibility for supply-related matters received weekly, sometimes daily, updates on developments relating to the Oxford/AstraZeneca Vaccine and took an active role in the supply and delivery processes.

102. In parallel to navigating the logistics of supplying the Oxford/AstraZeneca Vaccine, the Regulatory and Operations functions at AstraZeneca supplied data and analysis from the clinical trials to the MHRA on a rolling basis. There were open channels of communication between AstraZeneca and the MHRA and the working relationship was, in my view, productive and effective.

103. By early December 2020, when regulatory approval seemed to be in sight, the volume of updates and action points between AstraZeneca and the VTF increased significantly. Throughout this key period the VTF and AstraZeneca maintained frequent communication regarding their respective action points, on issues such as communications with the public, shipment arrival updates, submissions to the MHRA and training of healthcare professionals. Particularly detailed plans covered the period immediately preceding approval and the day of approval itself.

104. On 29 December 2020, the UK Licensing Authority, acting on the advice of the MHRA, granted a temporary authorisation under Regulation 174 of the Human Medicines Regulations 2012.[29] [30] A Conditional Marketing Authorisation was granted for the Oxford/AstraZeneca Vaccine by the MHRA on 24 June 2021, which was renewed a year later. On 19 June 2023, a standard Market Licensing Authorisation for the Oxford/AstraZeneca Vaccine was granted by the MHRA.

The supply of the Oxford/AstraZeneca Vaccine in the UK throughout 2021

105. Supply of the Oxford/AstraZeneca Vaccine began as soon as the MHRA had provided its approval for emergency supply in the UK. The engagement and interactions between AstraZeneca and the VTF, NHSEI, PHE and the Devolved Nations'

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[29] See Exhibit MP/15 - INQ000506056, AstraZeneca, 'AstraZeneca's COVID-19 vaccine authorised for emergency supply in the UK' (*AstraZeneca*, 30 December 2020).

[30] See Exhibit MP/16 - INQ000506064, Oxford University, 'Oxford University welcomes UK regulatory emergency use authorisation of coronavirus vaccine' (*Oxford University*, 30 December 2020).

administrations continued in a collaborative manner. The supply process was a complex operation and there was urgent demand to get the vaccines to the public, in view of the second wave of the pandemic associated with the Alpha variant.[31] As I mentioned above, as soon as doses were ready for supply, they were delivered. This meant there was no residual inventory of stock that could be used to fall back on if there were any manufacturing delays for whatever reason. Managing communications to the UK Government regarding anticipated volumes of doses of the Oxford/AstraZeneca Vaccine was also challenging. The unpredictability of the development of a viral-vectored vaccine at such scale, across such a network of CMOs, meant that only at the end of the manufacturing process for a given batch could we effectively establish the yields.

106. On the other hand, the technology underpinning the Oxford/AstraZeneca Vaccine made it possible to store and transport it at normal refrigeration temperatures. At this stage, the available mRNA vaccines had to be stored and transported at much lower temperatures.[32] This meant that the Oxford/AstraZeneca Vaccine could be transported more easily to remote areas of the UK. As I have said, the fact that the Oxford/AstraZeneca vaccine could be stored, transported and handled at normal refrigerated conditions was also important for its use in low- and middle-income countries around the world.

107. The supply of the Oxford/AstraZeneca Vaccine was monitored closely by AstraZeneca and the VTF. Supply plans that were being exchanged to assist with this monitoring exercise showed the number of doses to be released each week, and these were used by the VTF to plan vaccination sites and to inform the ministerial and prime ministerial briefings. Updates on batch deliveries continued to be exchanged throughout 2021.

108. From July 2021 onwards AstraZeneca and the VTF also worked closely together to facilitate donations of vaccine doses through COVAX, arranging for doses to go straight from the manufacturing site to their distribution hub, thereby maximising the available shelf life.

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[31] See Exhibit MP/17 - INQ000506063, ONS, 'Coronavirus (COVID-19) Infection Survey technical article: waves and lags of COVID-19 in England, June 2021' (*ONS*, 29 June 2021).

[32] See Exhibit MP/18 - INQ000506065, Piotr Kowalski et al, 'Stability Modelling of mRNA Vaccine Quality Based on Temperature Monitoring throughout the Distribution Chain' (2022) 14(2) Pharmaceutics.

Interactions with Devolved Nations' administrations and supply to Scotland, Wales and Northern Ireland

109. AstraZeneca was also in contact with senior ministers and other representatives from the Devolved Nations' administrations regarding the supply of the Oxford/AstraZeneca Vaccine to Scotland, Wales and Northern Ireland. These discussions focused on logistical matters regarding the supply of the Oxford/AstraZeneca Vaccine, including, for example, anticipated supply volumes and the technical details regarding its storage, packing and delivery. In the period leading up to the initial roll-out of the Oxford/AstraZeneca Vaccine in late 2020, these calls took place with representatives from all of the Devolved Nations together, typically on a weekly basis. AstraZeneca would occasionally join additional calls with the representatives of a single Devolved Nation to discuss any queries they had raised separately regarding, for example, vaccine trial data, efficacy and dosing guidance. I was also personally involved in ad hoc calls with senior representatives from NHS Scotland to discuss their real-world data concerning vaccine efficacy and dosing guidance, for example.

Decisions by the UK Government in 2021 regarding the Oxford/AstraZeneca Vaccine

110. With UK regulatory approval on the horizon at the end of 2020, the focus of the VTF changed to supply management. As I mentioned above, the communications and planning with the VTF around the "just-in-time supply" of the Oxford/AstraZeneca Vaccine worked well over this period. However, the VTF was noticeably less well-equipped to address R&D and procurement decisions in 2021 because Kate Bingham and other senior decision-makers with relevant experience and direct relationships with senior ministers had stepped down from their roles. These personnel changes occurred more widely around this time.

111. Along with these personnel changes, the VTF became increasingly bound by new internal structures, chains of command and processes, and the open and dynamic relationship we had positively experienced with the VTF under the leadership of Kate Bingham (until she stepped down at the end of 2020) became less effective and less transparent. While I cannot speculate as to why these changes occurred, their timing was unfortunate. From AstraZeneca's perspective it meant that when future decisions around variant vaccines and the selection of boosters was needed, we found the communication and decision-making of the VTF less open and collaborative. These challenges were later discussed with the VTF, as part of a joint review of the key

lessons learned from the development, manufacture and supply of the Oxford/AstraZeneca Vaccine.[33]

112. That said, AstraZeneca delivered 100 million doses to the UK. A huge part of AstraZeneca's achievement in doing so was the close communication and effective collaboration between AstraZeneca, the VTF, the MHRA and other agencies. It is essential that communications and collaboration between key committees and taskforces such as these continue at every point of a future pandemic so as to build lasting, effective relationships. These relationships must be grounded in consistency, transparency and trust.

SECTION G: FUTURE PANDEMIC PREPAREDNESS

113. AstraZeneca's supply of three billion doses of the vaccine worldwide, on a not-for-profit basis during the pandemic period, was a testament to a global humanitarian endeavour. One in which scientific minds across industry, academia and governments came together to overcome one of the biggest public health crises of our time. We should be proud of that achievement and build on it.

114. In my view, there are various factors that made this achievement possible and others which presented challenges, all of which should be reflected upon to ensure we are better prepared for a future pandemic.[34]

(a) First and foremost, and as I have noted above, important lessons around collaboration and openness are key to our collective future success. Public private partnerships and close collaboration between academia, governments, research institutes and industry were critical in the response to COVID-19 and will be critical in accelerating and strengthening any response to a future pandemic. A shared understanding of the monitoring systems required, the research needed, manufacturing options and funding mechanisms are just a few examples of the topics that need careful consideration in preparation. To this end, it is important, when the government makes commitments for the development of specific projects as part of a future pandemic response, that those commitments are met. Without guaranteed commitments from the

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[33] See Exhibit MP/19 - INQ000397436, DHSC and BEIS, 'Joint AZ/VTF Lessons Learned Workshop' (24 May 2022).

[34] See Exhibit MP/20 - INQ000397434, AstraZeneca, 'Future pandemic preparedness: AstraZeneca's commitment to ensuring no one is left behind in the wake of COVID-19' (*AstraZeneca*, August 2022).

government that parties feel able to rely on, they will be reluctant to commit to activities and development projects in a future pandemic.

(b) Second, as I mentioned earlier (in Section B of my statement), there was some public confusion regarding the efficacy of COVID-19 vaccines and the different ways in which efficacy can be assessed. With hindsight, there was too much focus on the efficacy of vaccines against symptomatic disease, rather than efficacy against severe disease, hospitalisation and death. It is clear now that the latter is more important than the former in ensuring that hospital capacity can be maintained, and lives saved. There should be a joint communications plan between public health officials and the organisations contributing to the pandemic response to ensure accurate and consistent information is provided to the public. The UK Government should also ensure that it provides as much advance notice as possible to relevant organisations of significant statements that it intends to release concerning topics of mutual concern. In my view, this would improve the overall quality of the political and media narrative. We also noted this at the time and discussed it in the joint AstraZeneca/VTF lessons learned review (referred to above).[35]

(c) Third, in my view, industry expertise should be involved in the design and conduct of clinical trials as early as possible in the development of a medicine intended for a pandemic response. This is because our role in industry is to turn science into medicines for the patients who need them through the work we do in R&D. Early industry expertise would assist with the challenges I have discussed above around communicating clinical trial results and overall public confidence in that information.

(d) Fourth, as I have mentioned, responding to a pandemic requires the up-front commitment of significant financial and human resources for many processes in the development of the vaccine: for example, AstraZeneca incurred several hundred millions of dollars of costs as its share of the total R&D expenditure for the Oxford/AstraZeneca Vaccine. Access to funding for R&D and the ability to negotiate appropriate advance purchase agreements, at pace, as we did for the UK Supply Agreement will be essential for any future pandemic response and I would encourage the UK Government to implement suitable template

[35] Ibid.

agreements on this basis, including with authority to agree the necessary indemnity provisions.

(e) Fifth, and similarly, it is vital that the UK Government continues to invest in globally strategic manufacturing facilities to provide production capacity in the event of a future pandemic. At the same time, we must recognise that no one country could ever be completely self-sustaining in terms of the requirements for manufacturing and supply, such that governments must take a broader and global view, keeping borders open to essential trade and supply during the course of any future pandemic. Only in this collaborative and open way can national supply chains remain and be secure. Governments will need to share information and allow for the movement of manufacturing supplies and the resulting products. As such, there should be sustained and early investment in a strong development and manufacturing network by and between governments, in collaboration with industry, to secure future capacity and patient access.

(f) Sixth, the global response to the COVID-19 pandemic saw great levels of cooperation between regulatory authorities and with industry, which helped to accelerate access to the Oxford/AstraZeneca Vaccine. Even greater international cooperation of health authority approaches is desirable in future, and future efforts should focus on harmonising those efforts. In the UK, interactions with the UK's MHRA were particularly productive. The MHRA considered submissions at regular, rolling intervals, providing a robust, expedited approval process and one which the MHRA should consider adopting more broadly for future medicines.

(g) Seventh, the COVID-19 pandemic highlighted the importance of real-world evidence to the ongoing evaluation of a medicine's efficacy. What is needed is further and continued investment and collaboration in this area, both in terms of the collection of data and the efficient sharing of that evidence across health services and with industry. Similarly, the same approach should be taken to access to samples for R&D and ongoing surveillance of communicable diseases. This is not just important between the national health services of the Devolved Nations, but globally.

(h) Finally, there should be collective action to invest in the prevention of diseases and ensuring the resilience of healthcare systems. Relevant entities and

organisations must work together collectively to act earlier to prevent and detect disease – not only through financing research, but also through healthcare governance, service delivery, workforce and the strategic use of medicines and technology. AstraZeneca, alongside the London School of Economics and the World Economic Forum, established the Partnership for Health System Sustainability and Resilience (***PHSSR***), now active across more than 30 countries worldwide, including 16 EU Member States, to develop and implement actionable policy solutions to improve the resilience and sustainability of healthcare systems. The PHSSR facilitates collaboration across sectors and borders to provide tools and resources for research and a platform to share key insights. Since its launch in 2020, the PHSSR has completed healthcare system assessments in 16 countries and regions, with its recommendations informing sustained engagement with policymakers and healthcare system stakeholders in each country.[36] Alongside AstraZeneca, its member organisations now include the London School of Economics, the WHO Foundation, the World Economic Forum, KPMG, Philips and the Centre for Asia-Pacific Resilience and Innovation (CAPRI).

115. Many of these themes will arise as the UK Government considers its future pandemic preparedness and the related technologies that might support those objectives. For example, the Inquiry has expressed an interest in the role of 'proactive vaccinology' in the future and has referred me to a paper by Hills, R A et al that was recently published in Nature Nanotechnology.[37] Until the details of a future virus or other pathogen are known, AstraZeneca cannot comment on whether this vaccine technology - which appears to be at an early stage - will be important for any future pandemic. It will however be essential for the UK to ensure that it has a diverse range of technologies and response platforms at its disposal so that it can maximise the chances of success when confronting a future pandemic event.

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[36] See Exhibit MP/21 - INQ000506066, PHSSR, 'Key Findings from Country Reports' (*PHSSR*, May 2023).

[37] See Exhibit MP/22 - INQ000506062, Hills, R A et al, 'Proactive vaccination using multiviral Quartet Nanocages to elicit broad anti-coronavirus responses' (2024) Nature Nanotechnology.

116. Each of the reflections that I have set out above will be important for strengthening the UK's future pandemic response. AstraZeneca remains committed to supporting the UK where it can in a future pandemic situation; however, the above reflections must be addressed to ensure a strong starting point for any future collaboration.

117. In concluding this statement, I hope I may be permitted to say that everything that we achieved in relation to the Oxford/AstraZeneca Vaccine and our other responses to the pandemic would not have been possible without the efforts and hard work of my colleagues at AstraZeneca, as well as of others at Oxford, the VTF, the MHRA, the NHS and beyond. Delivering on the shared goal of protecting the global population from the threat of COVID-19 was a once-in-a-lifetime achievement of which I am, and the team at AstraZeneca are, and everyone involved should be, incredibly proud.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data

Dated: 10th OCT 2024