IN THE MATTER OF THE INQUIRIES ACT 2005

AND IN THE MATTER OF THE INQUIRY RULES 2006

UK COVID-19 INQUIRY

SIXTH WITNESS STATEMENT OF CLARA SWINSON

MODULE 4 CORPORATE STATEMENT CONCERNING VACCINES AND THERAPEUTICS

1. I, Clara Swinson, Director-General for Global and Public Health at the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU, will say as follows:

INTRODUCTION

2. I make this statement in response to a request from the UK COVID-19 Public Inquiry (the Inquiry) dated 20 July 2023 made under Rule 9 of the Inquiry Rules 2006 (the Request) asking for a corporate statement on behalf of the Department of Health and Social Care (the Department) providing an overview of the role of the Department in vaccine delivery in England, Wales, Scotland and Northern Ireland.

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

4. The Inquiry has asked the Department several questions for which other organisations are responsible. The Vaccine Task Force (VTF) was responsible for the development, procurement, and contractual arrangements of vaccines as well as associated innovations and lessons learned. Therefore, I refer the Inquiry to the UK Health Security Agency (UKHSA) and the Department for Science, Innovation and Technology (DSIT) to answer questions on these areas in greater depth. I will describe the Department's role, in as much as I can evidence, on in the VTF and other topics in so far as the Department was involved. Questions on the Vaccine Manufacturing Innovation Centre (VMIC) are best directed to DSIT. Questions on procedures and local roll-out are best directed to NHS England (NHSE).

5. This statement provides an overview of the role, function and responsibilities of the Department in the development and deployment of vaccines. I have also provided two further Statements. The first (Statement B) covers the development and use of antivirals and therapeutics. The second (Statement C) considers issues relating to public messaging, disparities in vaccine coverage and vaccine uptake, tackling misinformation and disinformation, and vaccine safety issues in the period between 30 January 2020 and 28 June 2022.

6. A request was made to Professor Lucy Chappell on 20 November 2023 asking for a corporate statement on behalf of the National Institute for Heath and Care Research (NIHR). To the extent that the request of 20 July 2023 on the Module 4 statements requests information that relates to NIHR, relevant information is now covered in Professor Chappell's statement. (this change was made, in discussion with the Inquiry, following the draft Module 4 statements submitted on the 19 January 2024). This latter statement is referred to in a number of places, reflecting the important joined-up work between the Department and NIHR.

7. This statement has been structured into five sections that set out the information that addresses the Inquiry's questions:

    a. **Section 1: Corporate Overview** sets out key decision makers, the Department's role in the development and deployment of COVID-19 vaccines. It also describes key agencies, boards and committees and the Department's role in relation to the Devolved Administrations.
    b. **Section 2: Vaccine Development** describes the role of the Department in vaccine development, including pre-pandemic preparedness, and the

knowledge and processes that already existed or that were developed to support our vaccine response to COVID-19.

c. **Section 3: Vaccine Prioritisation** describes some of the key decisions made about prioritisation of vaccine deployment including, descriptions of Phase 1 and Phase 2 prioritisation, data that supported decision-making, as well as logistical considerations, and consideration of particular groups such as prisoners and children.

d. **Section 4: Vaccine Deployment** provides an overview of the processes, data collection, and planning involved in deployment of vaccines, including engagement with the devolved administrations, the role of integrated care systems, and deployment to specific groups.

e. **Section 5: Lessons Learned** sets out some of the lessons the Department learned and was able to take actions on, and our commitment to continuous improvement as we continue to learn and adapt how we plan and prepare for future health emergencies.

8. I have outlined the key dates in respect of the Department's role in COVID-19 vaccines as they relate within each section.

SECTION 1: CORPORATE OVERVIEW

9. This section sets out key decision makers and the Department's role in the development and deployment of COVID-19 vaccines. It also describes key agencies, boards and committees and the Department's role in relation to the Devolved Administrations.

Key Decision Makers

10. A list of key decision-makers in the Department in respect of the topics outlined in the Provisional Outline of Scope for Module 4 was provided to the Inquiry on 10 November 2023 **(CS6/1 - INQ000399472)** and an updated list on the 22 December 2023 **(CS6/2 - INQ000474257).**

11. For ease, I list those most involved key decision-makers in respect of the topics outlined in the Provisional Outline of Scope for Module 4 in relation to vaccines.

12. The Ministers with the greatest involvement in vaccines and therapeutics:

a. Secretary of State for Health and Social Care – Rt Hon Matt Hancock MP from 9 July 2018 to 26 June 2021.

b. Secretary of State for Health and Social Care – Rt Hon Sajid Javid MP from 26 June 2021 to 5 July 2022.

c. Parliamentary Under Secretary of State (Minister for Technology, Innovation and Life Sciences) – Lord Bethell 9 March 2020 to 17 September 2021.

d. Parliamentary Under Secretary of State (Minister for COVID Vaccine Deployment) – Rt Hon Nadhim Zahawi MP (joint with the Department for Business, Energy & Industrial Strategy (BEIS)) from 28 November 2020 to 15 September 2021.

e. Parliamentary Under Secretary of State (Minister for Vaccines and Public Health) – Maggie Throup MP from 16 September 2021 to 7 September 2022.

f. Parliamentary Under Secretary of State (Minister for Technology, Innovation and Life Sciences) – Lord Kamall from 17 September 2021 to 20 September 2022.

13. To ensure there was no conflict of interest, a separate Minister was given responsibility for COVID-19 vaccine licensing. The Ministers with responsibility for licensing and dates they were in the relevant post (noting that these are dates in post rather than dates the Minister held responsibility for licensing):

    a. Parliamentary Under Secretary of State (Minister for Technology, Innovation and Life Sciences) – Lord Bethell from 9 March 2020 to 17 September 2021.

    b. Minister of State (Department of Health and Social Care) – Rt Hon Nadine Dorries MP from 6 May 2020 to 15 September 2021.

    c. Parliamentary Under Secretary of State (Minister for Patient Safety and Primary Care) – Maria Caulfield MP from 17 September 2021 to July 2022.

d. Minister of State (Minister for Care and Mental Health) – Gillian Keegan MP from 16 September 2021 to 7 September 2022.

e. Parliamentary Under Secretary of State (Department of Health and Social Care) – James Morris MP from 8 July to 8 September 2022.

14. Officials in the Department:

a. Sir Chris Wormald the Permanent Secretary from May 2016 to the present;

b. David Williams the Second Permanent Secretary from March 2020 to April 2021;

c. Shona Dunn the Second Permanent Secretary from April 2021 to June 2024;

d. Professor Sir Chris Whitty the Chief Medical Officer (CMO) for England from October 2019 to the present and the Departmental Chief Scientific Advisor (CSA) from January 2016 to August 2021.

e. The Deputy Chief Medical Officers:

i. Professor Sir Jonathan Van-Tam the Deputy Chief Medical Officer (DCMO) from October 2017 to March 2022. His role covered emergency response and preparedness, infectious diseases, vaccines, and therapeutics;

ii. Professor Dame Jenny Harries, the DCMO for health improvement from July 2019 to May 2021; and

iii. Professor Thomas Waite, interim DCMO for COVID-19 in July 2021 and substantively appointed DCMO leading on health protection in April 2022. His responsibilities cover emergency response and preparedness, infectious diseases, vaccines and therapeutics.

f. I (Clara Swinson) have held the role of Director General for Global and Public Health from November 2016 to the present.

g. Professor Lucy Chappell the Departmental Chief Scientific Adviser from August 2021 to the present.

h. Steve Oldfield the Chief Commercial Officer from October 2017 to October 2022.

i. Andy Brittain the Director General for Finance from April 2021 to the present.

j. Dr Louise Wood, the Director of Science, Research and Evidence from December 2016 to June 2022.

k. Emma Reed the Director of Emergency Preparedness and Health Protection, including routine vaccine policy and COVID-19 vaccine in the initial months of the pandemic.

l. Antonia Williams, a new role as the Director of Vaccine Deployment from November 2020 to December 2021.

m. Paul Macnaught, the Director of Vaccine Deployment from January 2022 to September 2022.

Departmental Role

15. As set out in Sir Chris Wormald's Fifth Witness Statement, dated 25 August 2023, the tools available in most pandemics and epidemics especially of respiratory pathogens, are testing, non-pharmaceutical interventions (NPIs), vaccines and therapeutics. All pandemics in recent history have been addressed by scientific understanding leading to pharmaceutical countermeasures, such as vaccines and treatments. In the first part of 2020 when there was very little known about the new virus, testing and NPIs were dominant in our response. Between late 2020 and summer 2021, the scientific and clinical understanding of the virus became increasingly well-developed, although there were still unknowns. The balance of the tools available had therefore changed substantively by

summer 2021 to a vaccines-led approach. Continued use of testing, therapeutics and NPIs were also important.

16. As noted by the 'Technical report on the COVID-19 pandemic in the UK for future UK Chief Medical Officers, Government Chief Scientific Advisers, National Medical Directors and public health leaders in a pandemic' (referred to as the Technical Report) discovering, developing and approving a new vaccine has in recent history generally taken between 10 and 20 years. In developing a vaccine for SARS-CoV-2, there was an unprecedented focus on expediting existing processes and creating agile alternatives in order to deliver a safe and efficacious vaccine to the population as soon as possible **(CS6/3 - INQ000177534)**.

17. The Department's overarching role was to respond to the pandemic, mitigating its impact and to support development of a vaccine, treatments, or a combination. This was the position which allowed the country to move to a situation where it was living with COVID-19. The Department's role in the development and deployment of vaccines was to support the Government and Secretary of State in planning for and delivering a successful vaccination programme in response to COVID-19. The Department is the overall sponsor and convenor of the different parts of the health "family"; it connects into the rest of Government and makes the case for health issues and resources; and works with international health partners.

18. In the development of vaccines and therapeutics, the Department carried out the following roles:

    a. Research and development: Commissioned, funded and delivered research, using new and existing NIHR infrastructure which was scaled up. As mentioned above in paragraph 6, the role of the NIHR is covered in a separate statement provided to the Inquiry by Professor Lucy Chappell.

    b. Legislation: Amended secondary legislation to enable faster roll-out, and to take account of the changes arising from EU exit.

    c. Deployment: Led preparation for, and then facilitated planning and vaccine deployment at scale, building on existing arrangements for the annual flu programme, expanded and scaled; setting an expectation on NHS England and Improvement (referred to in this statement as NHSE) readiness for roll-

out; and relevant ministerial decisions, including a dedicated minister for large parts of this time period.

d. Authorisation and approval: Ministers were responsible for authorising vaccines on the advice of the Medicines and Healthcare Products Regulatory Agency (MHRA), informed by the Commission on Human Medicines (CHM).

e. Prioritisation approach: Commissioning and responding to the advice of the Joint Committee on Vaccination and Immunisation (JCVI).

f. International engagement and collaboration: Working with the World Health Organisation (WHO) and others, and provision of vaccines for COVID-19 Vaccines Global Access scheme (COVAX) and actions under the UK chair of the G7 in 2021.

g. Campaigns and communications: The Cabinet Office (CO) led on paid marketing campaigns and communications on vaccine uptake and published regular data on gov.uk. The Department led on vaccine communications, this includes strategic communications, media relations, external affairs, social media via owned channels etc. The Department had its own dedicated team to lead delivery of the vaccine communications strategy.

h. Vaccine security: Once a vaccine had arrived in the UK, responsibility moved from the VTF to a new vaccine security function (discussed in more detail in paragraph 58).

i. Vaccine uptake: Real-time NHS data fed into regular ministerial vaccines meetings and as part of the Bronze/Silver/Gold meetings which included identifying areas and groups with low uptake and helping develop strategies to tackle this.

j. Cross-UK collaboration: The Department coordinated with the other nations and with overseas territories on relevant planning and preparation.

k. Interaction with other vaccine programmes: For example, co-administration with seasonal flu programme.

l. Holding the health system to account: Sponsorship of relevant arm's-length bodies (ALBs) including their prioritisation of the vaccine programme,

especially. MHRA, Public Health England (PHE) and UKHSA, NHSE and the Health Research Authority (HRA) and working with the VTF.

m. Briefing ministers: There were frequent and regular meetings between the Secretary of State and officials and the relevant ALBs to ensure alignment and fast decision making. There were also numerous written submissions for decision and information.

19. Within the Department, the Executive Committee (ExCo) and COVID-19 Oversight Board oversaw the Department's implementation of the COVID-19 Battle Plan. The Battle Plan was the Department's internal tool to organise the Department's programme to deliver the response to COVID-19. The iterations of the Battle Plan show the development of the Department's involvement in planning for and delivering the vaccine and the increasing role of NHS England:

a. In version 1.0 (22 March 2020), vaccines were part of workstream 4 'technology – accelerating new interventions' (**CS6/4 - INQ000106297)**.

b. In version 2.0 (11 May 2020), vaccination was part of workstream 5 'technology – accelerating new interventions' in a sub workstream 5.B 'support efforts on vaccines and prevention' with the DCMO (Jonathan Van-Tam) named as the programme director and Clara Swinson as the Senior Responsible Officer (SRO) **(CS6/5 - INQ000107087; CS6/6 - INQ000106504; CS6/7 - INQ000106505; CS6/8 - INQ000106506)**.

c. In version 3.0 (21 July 2020), the workstream was further amended to 5 'vaccines and treatments research and deployment' sub workstream 5B 'support efforts on vaccines and prevention' with the DCMO (Jonathan Van-Tam) named as the programme director and Clara Swinson as the SRO **(CS6/9 – INQ000106542; CS6/10 - INQ000106543; CS6/11 – INQ000106544)**.

d. In version 3.1 (1 October 2020) Neil Permain (NHSE) and Emma Reed were jointly named as the programme director and Amanda Pritchard (NHSE) as the SRO **(CS6/12 - INQ000401296)**.

e. In version 3.3 (15 January 2021) Emily Lawson (NHSE) and Antonia Williams were jointly named as the programme director and Emily Lawson as the SRO.

f. In version 4.0 (9 February 2021), workstream 5 was renamed to 'vaccines/treatment – research and deployment'. Emily Lawson (NHSE) and Antonia Williams were jointly named as programme directors for 'vaccine deployment' sub-workstream 5A and Charlotte Taylor was named as programme manager for the 'Identify, research and deploy new treatments' sub-workstream 5B. Clara Swinson and Emily Lawson (NHSE) were jointly names as SROs **(CS6/13 - INQ000401334)**.

g. In version 5.1 (20 September 2021) the Battle Plan was amended to reflect the transfer of the VTF into the Department from BEIS which became workstream 5.C with Ben Golding (VTF) listed as the programme director and Madelaine McTernan (VTF) as the SRO. The 'vaccines deployment' workstream was led by Keith Willet (NHSE) and Antonia Williams jointly and Keith Willett listed as SRO **(CS6/14 - INQ000287686)**.

h. In version 6.0 (28 April 2022), vaccines moved to workstream 1 to reflect its part in the Living with COVID-19 plan. Workstream 1A was listed as 'vaccines deployment' with Steve Russell (NHSE) as the programme director and SRO and Paul Macnaught as DHSC Policy Lead. Workstream 1B was listed as the 'vaccines taskforce' with Ben Golding (VTF) as the programme director and Madelaine McTernan (VTF) as the SRO **(CS6/15 - INQ000401403)**.

20. The UK has one of the most extensive immunisation programmes in the world and this is supported by the Department's Routine Immunisation team within the Global Health Group. The initial stages of the department's vaccines response were led from that team. In November 2020, because of the scale and the speed of the task, the Department set up a new directorate in my Group with Antonia Williams taking on the role of COVID-19 Vaccine Deployment Director. This new directorate was responsible for providing comprehensive, evidence-based advice to the Department's ministers on the policy framework and policy and legislative issues associated with the deployment of COVID-19 vaccines and providing strategic coordination across responsible bodies to enable the safe and effective roll-out of the vaccine programme. This team was approx. 50 full time equivalent (FTE) staff members at its peak.

Supporting the development and procurement of a safe and effective vaccine

21. The development of COVID-19 vaccines was a key priority for the Department and the Government, and planning for a vaccine was part of the Department's response to COVID-19 from the very start. A meeting with the Secretary of State about COVID-19 as early as 27 January 2020 covered vaccine development. The notes record that the CMO commented that it is difficult to quickly develop a vaccine that can be deployed, and the DCMO outlined that the typical timeline for vaccine development is five years, but we could hope for 12-18 months if it all went well. He also commented that no one has ever made a vaccine for a coronavirus **(CS6/16 - INQ000106067)**. A safe and effective vaccine was never a foregone conclusion and there was no certainty that any of the vaccine candidates the Government invested in would pay off to the degree they did.

22. At the start of the pandemic, prior to the establishment of the VTF, the Department was instrumental in supporting early vaccine research and clinical trials, building on existing NIHR-funded research and capacity, consideration of the development of UK vaccine manufacturing, working with the secretariat for the JCVI on assessing potential COVID-19 vaccine candidates, involved in cross-government discussions led by the Foreign and Commonwealth Office (FCO) for the early development of COVAX, and in convening the 'health family', described from paragraphs 42 to 61, below, to set out the strategy for deployment, should one of the vaccine candidates eventually be deployed.

Supporting planning for and delivering the roll-out of the vaccine

23. The deployment of the vaccine was a whole health and care system endeavour in which the Department played a leadership role. Planning for deployment began in March 2020, in parallel with possible vaccine development. The Department continued preparation and planning throughout the spring and summer and provided advice to ministers in June 2020 on deployment, preparation and planning assumptions **(CS6/17 - INQ000106484)**. Further advice to ministers on finance in July 2020 was followed by work to change regulations to expand the vaccination workforce, amongst regular briefing and parliamentary requests **(CS6/18 - INQ000479893)** and proposed legislative changes **(CS6/19 - INQ000501428)**. Governance arrangements, initially led by the Department, became joint with VTF and were led by NHSE for the operationalisation of the deployment programme. The CO lead on communications continued, with DHSC providing policy support and seconding personnel with expertise in vaccination programmes to the CO.

24. There were regular, and for large parts of this period daily, meetings with the Secretary of State and, when appointed, the Minster for COVID Vaccine Deployment, on vaccine readiness and roll-out from Autumn 2020, 152 meetings took place in total. Examples of meeting readouts from the 7 December 2020 **(CS6/20 - INQ000234207)** and 1 September 2021 **(CS6/21 - INQ000257014)** are exhibited. These meetings were with the Department's officials, the NHS, the VTF, and others as appropriate depending on the stage of the pandemic and current issues. There were also regular, often weekly, Prime Minister (PM) meetings on vaccines which the Secretary of State attended. These were supported by the Covid taskforce and the Cabinet Office would hold the relevant information.

25. From early in the pandemic, ministers and officials in the Department led the whole health and care system endeavour to prepare and plan for vaccine deployment, working with the devolved administrations, the VTF, NHSE, PHE, MHRA, our research institutions, our armed forces, and local and regional government at every level to enable roll-out of COVID-19 vaccines across the country as soon as they were approved for use.

26. This activity was wide ranging and included liaising with Parliament, drafting and consulting on legislative changes to expand the vaccinator workforce and working with PHE to develop training and national protocols. The Department secured funding for NHS innovative data systems and the costs of deployment, sharing expertise with the VTF on vaccine procurement and advanced purchase agreements. The Department also worked with the MHRA on setting up enhanced surveillance of safety signals, through to working with analysts and modellers to estimate vaccine requirements, both for the UK, but also for devolved administrations (DAs), Overseas Territories (OTs) and Crown Dependencies (CDs), leading discussions with international partners to share the JCVI's methodology and learnings. This helped ensure effective implementation plans were in place.

27. It was the culmination of months of intense preparation and hard work that enabled the UK to be the first country in the world to authorise and deploy the Pfizer/BioNTech and Oxford/AstraZeneca COVID-19 vaccines in December 2020. As outlined in the Living With COVID-19 publication from February 2022, the UK was also the first G20 member to vaccinate 50% of its population with at least one dose and to provide boosters to 50% of the population **(CS6/22 - INQ000086652)**.

28. On the JCVI's advice, the UK prioritised those at highest risk from COVID-19 for vaccination early in the roll-out. This is covered in further detail in Section 3 paragraphs

204 – 208. The speed and highly targeted nature of the vaccination programme helped the Government to minimise the wider health, economic and social costs of tackling the virus, as well as minimising deaths and serious illness and avoiding the NHS becoming overwhelmed. On 10 November 2020, the Secretary of State announced that he had tasked the NHS to prepare and be ready for a vaccination programme to begin from any date after 1 December 2020 **(CS6/23 - INQ000489930)**. On 11 November 2020 the Secretary of State chaired the first of an, often daily, series of meetings on the progress of vaccine deployment. Attendees included the DCMO (Jonathan Van-Tam), and departmental, VTF and NHSE officials.

29. The Department had overall responsibility for policy on vaccine deployment in England. It changed legislation to allow for quicker and more flexible deployment of the vaccine in England. NHSE had responsibility for the operationalisation of vaccine deployment and its uptake in England. PHE and later UKHSA were responsible for capacity planning, forecasting, demand planning, vaccine storage, logistics and distribution, supporting the VTF on vaccine procurements and leading on consumables required for the administration of vaccines. PHE also led on clinical advice and training, updating the 'Green Book' (information for public health professionals about vaccines) and provided the secretariat for the JCVI. The Until the establishment of the VTF, the Department's Science, Research and Evidence Directorate VTF led on research and development including candidate selection and clinical trials, manufacturing, including fill and finish capacity, and industry liaison. Slides from 4 September 2020 show how the Department worked with the JCVI, VTF, PHE, NHSE and other government departments (OGDs) to secure the 'Voyage of the Vaccine' **(CS6/24 - INQ000401291)**.

30. The Department integrated advice from the JCVI, NHSE, PHE/UKHSA, MHRA, CHM, the CMOs and the Moral and Ethical Advisory Group (MEAG) so that ministers could take an informed view on difficult and complex issues, with the benefit of expert advice from wider bodies as well as from the Department's own advisory teams. The Department's advice to ministers ensured that vaccines were developed and ready to deploy as soon as possible.

31. As vaccines received regulatory approval and were deployed, the Department continued to integrate expert clinical and scientific advice to support development of the vaccines programme and respond to changing circumstances, including the emergence of new variants.

Role of the Department's Finance Function

32. The Department's Annual Report and Accounts 2020-21 record **(CS6/25 - INQ000399466)** that the VTF, led by BEIS, was established in quarter one of the 2020-21 financial year, to accelerate progress on the development and deployment of COVID-19 vaccines. During that year COVID-19 vaccines were procured by BEIS, then donated to the Department, and the fair value of these items are recorded as income, and so were therefore essentially 'gifted' to the Department from BEIS.

33. As discussed at paragraph 44, on 1 August 2021, the VTF transferred from BEIS to the Department, and accountability for vaccine supply and international distribution moved to the Department. This included formal Accounting Officer (AO) responsibility. The Department must always be able to assure that the four AO tests in Managing Public Money are being met, and additionally seek HM Treasury (HMT) approval if going beyond the Department's delegated limits. In this case both were applicable. Formal financial responsibility for vaccine procurements moved to UKHSA in October 2022 when the VTF moved to UKHSA and was established as a permanent function.

34. The Department was responsible for the development of business cases for vaccine deployment and worked with NHSE to develop these and submit them to ministers for approval. The Department also sought HMT approval where required for business cases and government announcements.

The Vaccine Taskforce (VTF)

35. The Department's preparatory work for a vaccine began in January 2020, prior to the establishment of the VTF in April 2020, as outlined in the Battle Plan discussed at paragraph 19 above. The Department was not responsible for establishing the VTF or appointing its chair or members but did contribute to and support VTF's work from its inception.

36. The Department published a review of the VTF on 31 August 2023, which explains the purpose and scope of the taskforce, how its objectives evolved over time, key facts and figures and a review of progress against the VTF's objectives, which were firstly to secure access to promising vaccine(s) for the UK population and achieve lasting immunity, secondly to make provision for international distribution of vaccines and finally to strengthen the UK's onshore capacity and capability in vaccines development,

manufacturing and supply chain to provide resilience for this and future pandemics. **(CS6/26 - INQ000399474)**.

37. As the Review sets out, the VTF was set up in BEIS in early April 2020, to bring together the collective efforts of government, academia and industry to help find a COVID-19 vaccine. Its steering group comprised both external experts and senior civil servants. The steering group was initially chaired by Dame Kate Bingham (until December 2020), and then by Clive Dix (interim chair between December 2020 and summer 2021), and subsequently Sir Richard Sykes, from his appointment in June 2021 until the taskforce closed **(CS6/27 - INQ000489934)**.

38. The VTF was structured with a strategy directorate, an international directorate, and a commercial directorate to lead negotiations with suppliers. It also included a programmes directorate to oversee the day-to-day deliver of the agreements that the taskforce made. These directorates were overseen by a Director General; this was Nick Elliot between April 2020 and December 2020 and Madelaine McTernan between December 2020 and September 2022 **(CS6/28 - INQ000489957)**.

39. Given that the VTF was originally set up to gather the collective efforts of government, academia and industry in efforts to develop a vaccine, recruiting staff from all sectors was imperative. The VTF Review sets out that:

> *"the VTF mobilised and recruited staff from across the Civil Service, private sector and academia. This provided a breadth of expertise, ranging from clinical and scientific knowledge, through to supply, programme management, delivery and commercial."*

40. Formal accountability was through the usual Civil Service procedures. The DG of the VTF was Senior Responsible Officer throughout. Day-to-day ministerial decisions were taken by the Secretary of State and/or Business Secretary, with advice and assurances provided in the usual way by permanent secretaries and/or accounting officers.

41. In terms of the financial decisions to deliver its objectives, the VTF Review describes that:

> *"A ministerial panel took all key spending decisions. The panel was made up of the:*
>
> - *Health and Social Care Secretary;*
> - *Business Secretary;*

- *Chief Secretary to the Treasury;*
- *Minister for Government Efficiency at the Cabinet Office."*

42. Early decisions on funding interventions were key to supporting the VTF's objectives. The VTF Review explained that:

> *"In July 2020, the VTF agreed a £5.2 billion programme business case with HM Treasury, supported by funding from the reserve, to fund interventions to help the VTF meet its objectives. At the start of the pandemic, the chances of a single vaccine being found to be safe and efficacious against COVID-19 in the near term were widely believed to be slim: the VTF itself quantified the optimistic scenario of a vaccine proceeding from the pre-clinical phase through to full safety and efficacy as a likelihood of 10%. Therefore, right at the heart of the VTF's efforts to meet its objectives was a portfolio approach to vaccine procurement - increasing the overall chances of finding a single successful vaccine through multiple 'shots on goal'."*

43. The Ministerial Panel met 11 times: on the following dates:

a. 27 August 2020 **(CS6/29 - INQ000401292)**.

b. 11 September 2020 **(CS6/30 - INQ000401294).**

c. 6 October 2020 **(CS6/31- INQ000479144)**.

d. 22 October 2020 **(CS6/32- INQ000401300).**

e. 16 November 2020 **(CS6/33- INQ000401303; CS6/34- INQ000401304).**

f. 18 December 2020 **(CS6/35 - INQ000401309)**.

g. 31 December 2020 **(CS6/36 - INQ000401325).**

h. 12 January 2021 **(CS6/37 - INQ000401328).**

i. 28 January 2021 **(CS6/38 - INQ000489942)**.

j. 11 March 2021 **(CS6/39 - INQ000401343).**

k. 29 March 2021 **(CS6/40 - INQ000401346; CS6/41 - INQ000501433).**

44. On 9 February 2021, Sir Chris Wormald (the Department's Permanent Secretary) and Sarah Munby (BEIS Permanent Secretary) wrote to Simon Case (the Cabinet Secretary) to set out the proposed approach agreed between BEIS and the Department, concerning the accountability of the VTF, for his agreement (**CS6/42 - INQ000401335).** On 17 February 2021, Simon Case responded to confirm that he agreed that the reformulation of the VTF as a joint unit which was accountable to both BEIS and the Department represented a sensible approach which had the potential to both maximise the opportunities for change and minimise disruption **(CS6/43 - INQ000401338)**. On 1 April 2021, Sarah Munby wrote to Sir Chris Wormald to confirm that it had been agreed that the VTF should become a joint unit of BEIS and the Department, reporting into the joint BEIS/DHSC Minister for Vaccines in the first instance **(CS6/44 - INQ000401348).** A Memorandum of Understanding (MOU) was signed on behalf of BEIS and the Department on 21 July 2021 **(CS6/45 - INQ000479895)**; **CS6/46 - INQ000401360)**. The MOU confirmed that the VTF would become a joint unit from 1 August 2021. Thereafter, accountability for vaccine supply and international distribution moved to the Department, and BEIS retained accountability for the VTF's work to support onshoring of vaccine capability **(CS6/47 - INQ000401361; CS6/45 - INQ000479895)**

45. From October 2022, the vaccine supply responsibilities of the VTF moved to UKHSA and established as a permanent function. Responsibility for the vaccine onshoring programme moved to the Office for Life Sciences (OLS), a joint unit of the Department and what is the now Department for Science, Innovation and Technology (DSIT).

46. The Department did not have a role in identifying and managing conflicts of interest within the VTF when the VTF was established. When the VTF became a joint unit of BEIS and the Department in 2021, the Department managed conflicts of interest in accordance with the Department's standard processes.

Departmental Agencies, Board and Committees

47. In this statement I cover the departmental, agencies boards and committees most relevant to COVID-19 vaccines below. Those most relevant to antivirals and therapeutics are covered in Statement B.

The Office of the Chief Medical Officer (OCMO)

48. Sir Christopher Wormald's First Witness Statement dated 25 November 2022 explains that the CMO acts as the UK Government's principal medical adviser, and the professional head of all Directors of Public Health in local government and the medical profession in government. The CMO provides public health and clinical advice to ministers in DHSC and across government on both communicable and non-communicable diseases. The CMO is an independent position at permanent secretary level. The current post holder is Professor Sir Chris Whitty who took office in October 2019.

49. The CMO is assisted by the DCMOs, one of whom is specifically responsible for health protection, which includes infectious threats. The DCMO for health protection was Professor Sir Jonathan Van-Tam from October 2017 to March 2022. The second main DCMO normally covers health improvement (non-communicable diseases) but is in an emergency expected also to cover health protection issues. Professor Dame Jenny Harries was the DCMO for health improvement from July 2019 to May 2021, but due to the pandemic spent much of her time on health protection issues related to COVID-19. Professor Thomas Waite became interim DCMO for COVID-19 in July 2021 and following the departure of Professor Sir Jonathan Van-Tam was substantively appointed DCMO leading on health protection in April 2022.

50. Scotland, Wales and Northern Ireland also have CMOs and DCMOs for devolved health issues. The UK CMOs meet regularly.

The Chief Scientific Advisor (CSA)

51. The CSA, who acts also as the head/CEO of the NIHR, advises on scientific aspects of health. Professor Sir Chris Whitty was the CSA from 2016 to 2021. Professor Lucy Chappell became CSA in August 2021.

National Institute for Health and Care Research (NIHR)

52. Sir Christopher Wormald's First Witness Statement dated 25 November 2022 explains that NIHR is funded and managed by DHSC. It is one of the nation's major funders of health and care research. Its mission is to improve the health and wealth of the nation through research. It also receives UK Aid funding to support research for people in Low-and Middle-Income Countries (LMICs). It is one of the largest national clinical research funders

in Europe and the world's most integrated health research system. It involves patients and the public at every stage and trains and supports health researchers.

53. NIHR was established in 2006 under the Government's health research strategy. The Science, Research and Evidence (SRE) Directorate's senior management team provides executive leadership for the NIHR from within the Department. NIHR is primarily funded by the Department and as a research system it:

    a. Funds, supports and delivers high quality research

    b. Engages and involves patients, carers and the public

    c. Attracts, trains and supports researchers

    d. Invests in the healthcare infrastructure and workforce

    e. Partners with other public funders, charities and industry

    f. Funds applied global health research and training

54. Dr Louise Wood was the Director of the SRE Directorate from December 2016 to June 2022. Professor Chris Whitty was the head of the NIHR until August 2021 when Professor Lucy Chappell joined as CSA. Dr Louise Wood was the co-lead of NIHR and led on operational management of the NIHR during the pandemic.

55. As outlined above, Professor Lucy Chappell's statement to the Inquiry details the role of the NIHR in relation to matters covered by Module 4.

UK Vaccine Network (UKVN)

56. The UKVN is part of the Department's Global Health Security programme and is an advisory group that brings together industry, academia and relevant funding bodies to advise the Department on vaccine research and development investment. The UKVN Project is a portfolio of Official Development Assistance (ODA) investments made by the Department since 2016, with the Medical Research Council (MRC) and the Biotechnology and Bioscience Research Council (BBSRC), providing up to £6 million of aligned research funding. Sir Christopher Wormald's First Witness Statement dated 25 November 2022

explains that the UKVN invests in early-stage clinical development of vaccines and vaccine technologies to address the market's failure to develop vaccines against diseases of epidemic potential in LMICs.

57. The UKVN was established in June 2015 in the wake of the West African Ebola outbreak (2014 to 2016). Since 2016, the UKVN has funded research into vaccine development against emerging epidemic threats. This includes investments which enabled the rapid development of the Oxford/AstraZeneca COVID-19 vaccine. The UKVN is chaired by the CMO.

UK Covid Vaccine Security Team (UKCVS)

58. In December 2020, the Cabinet Secretary appointed Richard Alcock as the SRO for UKCVS. The SRO was accountable directly to the Cabinet Secretary until March 2021 when he reported to the relevant AO in the Department, which was David Williams until April 2021 and Shona Dunn thereafter **(CS6/48 - INQ000401340)**. The UKCVS was set up to support the SRO in his task to ensure and assure the end-to-end security of vaccine deployment across the UK, from manufacture to injection. Further details about the UKCVS are given at paragraphs 324 - 328 below.

Arm's-Length Bodies (ALBs)

59. Sir Christopher Wormald's Tenth Witness Statement dated 27 October 2023, paragraph 40 explains that "*in addition to the work that the Department carries out directly, it also works through a number of ALBs to deliver its strategic objectives. Each ALB has a senior sponsor in the Department, with a small supporting team.*"

60. ALBs are accountable to Parliament, either directly or via the Secretary of State. The Secretary of State, or the Department on his behalf, sets their strategic direction and holds them to account for delivery of a range of agreed objectives. The ALBs perform a range of diverse functions to support the Department in delivering its objectives.

61. There are different categories of ALBs – Executive Agencies (EAs), Special Health Authorities (SHAs), Executive Non-Departmental Public Bodies (ENDPBs) and Advisory Non-Departmental Public Bodies (ANDPBs) – which I set out below for clarity in order of legal proximity to the Department.

62. The following bodies are particularly relevant to the scope of Module 4 in relation to vaccines.

Executive Agencies (EAs)

63. Sir Christopher Wormald's Tenth Witness Statement dated 27 October 2023 at paragraph 43 explains that EAs may be considered as the 'shortest arm' of the Department. Unlike other ALBs, they are not legally separate from the Department (i.e., they do not have a separate legal identity) but are operationally independent whilst remaining accountable to it. There are two EAs:

Public Health England (PHE) and the UK Health Security Agency (UKHSA)

64. From 2013 to 2021 PHE was an EA of the Department. It was a distinct delivery organisation with operational autonomy that existed to protect and improve the nation's health and wellbeing, reduce inequalities and prepare for public health emergencies. It provided government, local government, the NHS, Parliament, industry, public health professionals and the public with evidence-based professional, scientific and delivery expertise and support, and carried out some statutory functions of the Secretary of State. PHE had responsibility for four critical functions:

    a. Fulfil the Secretary of State's duty to protect the public's health;

    b. Secure improvements to the public's health, including supporting the system to reduce health inequalities;

    c. Improve population health supporting sustainable health and care services; and

    d. Ensure the public health system maintains the capability and capacity to tackle today's (and future) public health challenges.

65. On 1 April 2021 UKHSA was established as a new EA of the Department. As part of a wider restructuring of national public health bodies in England, it took on the majority of the functions of PHE, NHS Test and Trace, and the Joint Biosecurity Centre (JBC) in planning for and responding to infectious diseases, chemical, biological and nuclear incidents and other health threats. To protect operational continuity and provide for necessary staff consultations and stakeholder engagement, these responsibilities were

transitioned to UKHSA over a six-month period, with UKHSA becoming operational from 1 October 2021. UKHSA is our permanent standing capacity to prepare for, prevent and respond to threats to health.

66. The Department sets out the Government's priorities formally to PHE/UKHSA in an annual remit letter from the minister with responsibility for health security, and the priorities are aligned to the department's wider objectives. These priorities are prepared in consultation with UKHSA and they are discussed as part of quarterly senior accountability meetings between the department and UKHSA, normally chaired by the Senior Departmental Sponsor and attended by UKHSA's CEO.

67. Since its establishment in 2021 Professor Dame Jenny Harries has been the CEO of UKHSA and Ian Peters has been the Chair of the Advisory Board. PHE was chaired by Professor Dame Julia Goodfellow from 2018 until it ceased to exist, with Duncan Selbie as its CEO until August 2020, then Michael Brodie as its interim CEO until it ceased to exist. Baroness Dido Harding was the CEO of NHS Test and Trace from its establishment until it ceased to exist.

68. UKHSA's responsibilities are primarily for England, and also UK-wide on reserved health matters such as responding to radiation, and in partnership with lead agencies in Scotland, Wales and Northern Ireland on devolved issues where relevant. It provides clinical, scientific and operational leadership for the public health system at a national and local level on health security and health protection, and a cohesive response across public health functions.

69. I am the UKHSA's Senior Departmental Sponsor, and I act as the UKHSA's designated, consistent point of contact within the Department and manage the overall relationship with the Department and ministers, supported by the Department's sponsor team.

70. UKHSA is responsible for procurement of vaccines for the routine programmes. PHE and then UKHSA's role in COVID-19 vaccine deployment was to provide public health advice on all aspects of vaccination, including updates to the Green Book and the development of patient group directions (PGDs) for the administration of COVID-19 vaccines. UKHSA also had responsibility for supply, storage and distribution of the vaccine within the UK, and provides the secretariat of the JCVI.

Medicines and Healthcare products Regulatory Agency (MHRA)

71. Sir Christopher Wormald's Tenth Witness Statement dated 27 October 2023 explains that the MHRA is an EA which regulates medicines, medical devices and blood components for transfusion in the UK. During the relevant period it was chaired by the late Sir Michael Rawlins, until September 2020, and then Stephen Lightfoot until July 2023. Dame June Raine has been its CEO since August 2019.

72. The MHRA is responsible for:

    a. Ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy;

    b. Securing a safe supply chain for medicines, medical devices and blood components;

    c. Promoting international standardisation and harmonisation to assure the effectiveness and safety of biological medicines;

    d. Educating the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use;

    e. Enabling innovation and research and development that is beneficial to public health; and

    f. Collaborating with partners in the UK and internationally to support its mission to enable the earliest access to safe medicines and medical devices and to protect public health.

73. The MHRA also carries out a number of regulatory activities such as inspecting facilities and carrying out safety tests; approving and inspecting clinical trials; monitoring the safety of medicines while on the market; regulating the importation of licensed medicines; and helping to set and enforce advertising regulations for medicines. The MHRA has powers of enforcement under the Consumer Protection Act 1987, the Medical Devices Regulations 2002, and the General Product Safety Regulations 2005. These powers include issuing

compliance, prohibition, restriction, and suspension notices, with further non-compliance resulting in prosecution.

74. The MHRA decides whether manufacturers should be granted licences to make, assemble or import medicines and vaccines and whether licences can be varied as information about the medicines and vaccines develop. It does this under powers delegated to it by the Secretary of State. The decisions are based on safety, quality, and effectiveness data.

75. For the MHRA to authorise a vaccine, experienced scientists and clinicians carefully and scientifically review the safety, quality and effectiveness data. The data must include results from the lab and clinical trials in humans, manufacturing and quality controls, product sampling, and testing of the final product. Once the MHRA have thoroughly reviewed the data, the MHRA will seek advice from the Government's independent advisory body, the CHM. The CHM will critically assess the data too before advising MHRA, and therefore the UK Government, on the safety, quality and effectiveness of any potential vaccine.

76. During the pandemic, a designated junior minister took the final decision on the licensing of new vaccines on behalf of the Secretary of State, following recommendations in each case from the MHRA. An explanatory note from September 2021 sets out the principles underpinning the decision-making **(CS6/49 - INQ000480666)**. The Secretary of State took decisions on supply and the roll-out of vaccines, and therefore the Secretary of State accepted the recommendation from the MHRA that a different minister within the Department would take decisions on regulatory approval **(CS6/50 - INQ000401299)**, to ensure that as far as possible licensing decision-making was independent of supply and purchasing decisions. Ministers with responsibility for licensing of COVID-19 vaccines can be found at paragraph 13 above.

Executive Non-Departmental Public Bodies (ENDPBs)

77. Sir Christopher Wormald's Tenth Witness Statement dated 27 October 2023 explains that ENDPBs are separate legal entities that are set up in primary legislation and have a greater degree of independence from the Department than SHAs or EAs.

78. These Bodies carry out administrative, commercial, executive or regulatory functions. They are not under day-to-day ministerial control, although a minister will be responsible

to Parliament for their performance and effectiveness. The Department's ENDPBs are described below.

NHS England and Improvement

79. NHSE leads and oversees the NHS in England. It is an ENDPB of DHSC. It was established on 1 April 2013 and has various statutory functions and duties in relation to the health service in England. NHSE is accountable to the Secretary of State and is responsible for allocating budgets to Integrated Care Boards ("ICBs", formerly Clinical Commissioning Groups (CCGs)), holding them to account, as well as leading on commissioning specialised services and primary care. During the relevant period the Board was chaired by Lord David Prior (until March 2022) and then by Richard Meddings. The CEO was Sir Simon Stevens (April 2014 - July 2021) and then Amanda Pritchard from August 2021. Ms Pritchard had previously been the Board's Chief Operating Officer as well as the CEO of NHS Improvement (NHSI).

80. NHS Improvement ("NHSI") was the operational name given to the umbrella organisation including Monitor and the NHS Trust Development Authority. NHSI operationally merged with NHSE in 2018. From the point of that operational merger, until NHSE and NHSI formally merged on 1 July 2022 under the Health and Care Act 2022, this merged entity was known as NHS England and Improvement or NHSEI. Since that merger, NHSE also has regulatory functions in relation to NHS providers.

81. References in this statement to NHSE include the merged NHSEI entity which was operating during the relevant period.

NHS Digital

82. NHS Digital (NHSD) (the operational name for the Health and Social Care Information Centre), was initially established as a Special Health Authority in 2005 and was converted to an Executive Non-Departmental Public Body under provisions in the Health and Social Care Act 2012. During the relevant period it was chaired by Noel Gordon (until September 2020) and then by Laura Wade-Gery. CEOs were Sarah Wilkinson (until June 2021) and then Simon Bolton (interim) until NHSD ceased to exist following incorporation into NHSE. A fuller overview of NHSD's responsibilities can be found in Sir Christopher Wormald's Tenth Witness Statement dated 27 October 2023.

Health Research Authority (HRA)

83. The HRA is an ENDP created by the Care Act 2014. Its statutory functions are as follows:

    a. Protecting and promoting the interests of actual and potential participants in health and social care research and the general public by facilitating and promoting high quality research that is safe and ethical.

    b. Establishing and recognising research ethics committees to assess the ethics of health and social care research.

    c. Promoting the co-ordination and standardisation of practice by removing duplication and streamlining the regulation of health and social care research across the regulatory system.

    d. Publishing guidance on principles of good practice in the conduct and management of health and social care research.

    e. Promoting transparency in research, for example by promoting the publication and dissemination of research findings and conclusions; and

    f. Providing independent recommendations on the processing of identifiable patient information where it is not always practical to obtain consent, for research and non-research projects.

84. During the relevant period it was chaired by Professor Sir Terence Stephenson. The CEO is Dr Matt Westmore who took up the position in February 2021, prior to that Teresa Allen was the CEO.

85. The HRA has a director-level Senior Sponsor within the Department's SRE Directorate who, along with the sponsorship team, also within SRE, holds it to account.

86. The HRA supported vaccine development by developing a fast-track approvals service for urgent COVID-19 research. It worked in partnership with the MHRA to bring together Research Ethics Committee (REC) review and Clinical Trials Authorisation from MHRA. The HRA also provided advice and support on arrangements put in place relating to confidential patient information in COVID-19 research studies.

Special Health Authorities (SHAs)

87. Sir Christopher Wormald's Tenth Witness Statement dated 27 October 2023 at paragraph 52 explains that SHAs are separate legal entities that are created by secondary legislation to carry out the functions of the Secretary of State. They therefore have more independence from the Department than EAs being further removed from direct ministerial oversight, though are subject to ministerial direction.

88. The NHS Business Services Authority (NHSBSA), provides a range of critical business support services to NHS organisations, NHS contractors, patients, and the public. During the relevant period it was chaired by Silla Maizey until April 2022 and then Sue Douthwaite, with Michael Brodie as its CEO.

89. NHSBSA supports the strategic aims of the health and social care system by acting as a delivery partner for the Department's policy teams and the wider health family, providing at-scale services to citizens, the NHS workforce and contractors and driving efficiency in the provision of these services **(CS6/51 - INQ000411750)**.

90. NHSBSA is held to account for its delivery and performance through quarterly accountability meetings with its Senior Departmental Sponsor. Given the breadth of its business, the Department's policy teams meet regularly with NHSBSA to review and hold it to account for delivery against key performance indicators for each of its services.

91. Of direct relevance to this Module, since 1 November 2021, the NHSBSA has operated the Vaccine Damage Payment Scheme (VDPS) on behalf of the Department. NHSBSA is responsible for the operational activities required to run the VDPS: the administration of claims, payments, and mandatory reversals (if a claimant disagree with a decision they can request a mandatory reversal, so that their case is looked at again). The detailed responsibilities of NHSBSA in this regard are contained within an MOU between the Department for Work and Pensions (DWP), the Department, and NHSBSA, and in a Service Level Agreement between DHSC and NHSBSA. Further information about the VDPS is provided in Statement C.

92. NHSBSA was chosen for this role because it specialises in managing services which make payments to individuals. For example, it runs the NHS Pension scheme and the Electronic Staff Record (which is the starting point for payments to all staff working in secondary

care). The NHSBSA has also been responsible for administering Infected Blood Scheme payments to recipients in England (noting the recent establishment of the Infected Blood Inquiry).

Advisory Non-Departmental Public Bodies (ANDPBs)

93. ANDPBs provide independent, expert advice to ministers and consist of external experts who operate in a personal capacity. They are free from political control but are not separate legal identities as they have a role in the processes of government.

94. The Department's ANDPBs include the Commission on Human Medicines (CHM). The CHM was established in October 2005. It is an ANDPB which advises ministers of the safety, efficacy and quality of medicinal products, including vaccines. Its functions are set out in Regulation 10 of the Human Medicines Regulations 2012 (SI 2012; no. 1916).

95. The CHM describes its functions as:

    a. To advise the Health Ministers and the Licensing Authority (LA) – the MHRA – on matters relating to human medicinal products including giving advice on the safety, quality and efficacy of human medicinal products where either the CHM thinks it appropriate or where it is asked to do so.

    b. To consider those applications that lead to LA action as appropriate (e.g., where the LA has a statutory duty to refer or chooses to do so).

    c. To consider representations made (either in writing or at a hearing) by an applicant or by a licence or marketing authorisation holder in certain circumstances; and

    d. To promote the collection and investigation of information about adverse reactions to human medicines so advice can be given **(CS6/52 - INQ000399473)**.

96. The CHM is supported in its work by Expert Advisory Groups (EAGs), covering various areas of medicine. In addition, the CHM calls on experts not readily available through its membership. It consists of external experts who operate in a personal capacity.

97. The Commissioners are ministerial appointments conducted through a standard public appointments process. Under regulation 9(4) of the Human Medicines Regulations 2012 (SI 2012/1916) these appointments must be made by the Secretary of State and the Minister for Health, Social Services and Public Safety in Northern Ireland. Under regulation 9(6), Scottish ministers must be consulted before the power of appointment can be exercised.

98. Professor Sir Munir Pirmohamed was appointed as Chair of the CHM for four years from February 2021. Professor Stuart Ralston was Chair of the CHM from 2013 to February 2021.

Committees

99. The Department took advice from several independent committees and scientific advice groups. Of relevance to this statement are:

The Joint Committee on Vaccination and Immunisation (JCVI)

100. Sir Christopher Wormald's First Witness Statement dated 25 November 2022 at paragraph 166 explains that the JCVI is an independent Departmental Expert Committee (DEC).

101. The JCVI conducts its work in accordance with terms of reference which are publicly available **(CS6/53 - INQ000145984)**. Its role is:

> *"To advise UK health departments on immunisations for the prevention of infections and/or disease following due consideration of the evidence on the burden of disease, on vaccine safety and efficacy and on the impact and cost effectiveness of immunisation strategies. To consider and identify factors for the successful and effective implementation of immunisation strategies. To identify important knowledge gaps relating to immunisations or immunisation programmes where further research and/or surveillance should be considered."* **(CS6/53 - INQ000145984).**

102. The Terms of Reference also include that:

> *"There are established requirements for the production of mathematical modelling studies on the impact and cost effectiveness of vaccination strategies. Development of these studies includes comprehensive evidence gathering including literature review*

to support the modelling that is usually supplemented by data from vaccine manufacturers. The studies follow the criteria, methodology and practice of NICE for cost effectiveness analysis and are based on the situation within the UK" (emphasis added)." **(CS6/53 - INQ000145984).**

103. The JCVI's recommendations are presented to the Secretary of State who, if a number of requirements are met, is, in accordance with Regulation 2 of the Health Protection (Vaccination) Regulations 2009, legally bound to implement those recommendations "so far as is reasonably practicable". These requirements include that the JCVI recommendation "must be based on an assessment which demonstrates cost-effectiveness". Note that the Health Protection (Vaccination) Regulations 2009 apply to the Secretary of State's England-only decision-making only.

104. The Secretary of State is not legally bound to implement the JCVI's recommendations where Regulation 2 does not apply, for example, where the JCVI has not undertaken a cost effectiveness analysis. Where Regulation 2 does not apply, the Secretary of State will still give weight to the recommendations advanced by the JCVI. The JCVI did not undertake cost effectiveness analysis of COVID-19 vaccines in the period covered by this statement (covered further in paragraph 203).

105. The current chair of the JCVI for all matters except COVID-19 is Professor Sir Andrew Pollard (2013 to the present). Professor Sir Andrew Pollard recused himself from any discussion at the JCVI on COVID-19 vaccination due to a potential conflict of interest as a result of Professor Pollard's role as Director of the Oxford Vaccine Group, which was developing a COVID-19 vaccine. A specific JCVI COVID-19 subcommittee met very frequently between September 2020 and July 2021 in addition to the main JCVI Committee sessions on COVID-19. Professor Wei Shen Lim chaired both the subcommittee and main JCVI committee on COVID-19. After July 2021 subcommittee meetings on COVID-19 were discontinued. The main committee meetings on COVID-19 which Professor Lim continues to chair. Minutes of JCVI meetings, including COVID-19 meetings, are publicly available online.

106. The JCVI provides advice to all four UK nations. UKHSA provides the secretariat.

New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG)

107. NERVTAG did not have a role in advising the Department on vaccines – that is the role of the JCVI. NERVTAG is a standing committee of DHSC and advises the CMO and the Department on threats posed by new and emerging respiratory viruses.

Moral and Ethical Advisory Group (MEAG)

108. Sir Christopher Wormald's Third Witness Statement dated 29 March 2023 at paragraph 163 explains that MEAG was set up in October 2019 as a successor to the Committee for Ethical Aspects of Pandemic Influenza (CEAPI) to provide advice to policy teams. Its establishment followed the recommendations of Exercise Cygnus (2016), which found that the public reaction to a reasonable worst case pandemic influenza scenario needed to be better understood. MEAG was a group of experts and advisers who advise government on moral, ethical and faith considerations to support the development of policies and response plans both in advance of, and during, a pandemic.

109. The chairs of MEAG were Professor Sir Jonathan Montgomery and Jasvir Singh.

110. MEAG advised the UK Government, and its secretariat was provided by the Department. MEAG was stood down by the Department at the end of the three-year initial period set out in the group's terms of reference **(CS6/54 - INQ000401404)**. It was considered that a regular committee was no longer the most efficient or effective way for the Department to receive ad hoc subject specific advice on moral and ethical issues relating to policy making. Under a successor model the Department maintains a directory of experts, which includes some former members of MEAG. This has been put in place for policy officials to access ethics specialists where necessary for policy development and in times of emergency. The Department continues to have a strong relationship with the MEAG former co-chairs and draws on their experience and expertise.

111. In some instances, the Department requested advice from the MEAG, provided the group with papers to facilitate the discussion and Departmental officials were in attendance. MEAG provided advice to the Department on vaccine prioritisation and roll-out on the following dates:

a. On 13 May 2020, MEAG discussed the moral and ethical aspects of the delivery of any future COVID-19 vaccination programme. They discussed

issues around vaccine prioritisation, the vulnerability of those who work in jobs which cannot be done from home, timeframes for the vaccine's development and the need for a communications strategy to encourage the uptake of vaccinations **(CS6/55 - INQ000401387)**.

b. On 9 September 2020, MEAG discussed options to increase their visibility and sought to identify opportunities to add value by improving links with policy makers and securing greater influence over decision-making. They identified the COVID-19 vaccination programme as one of the key policy areas **(CS6/56 - INQ000401398)**.

c. On 21 October 2020, MEAG met to discuss the use of foetal cell lines and porcine in immunisation **(CS6/57 - INQ000401389)**.

d. On 18 November 2020, there was a short discussion on vaccine roll-out and PGDs in which they discussed the important of involving professional regulators in planning the roll-out of the vaccination programme and the need to consider the legal complexities of using PGDs to vaccinate **(CS6/58 - INQ000401388)**.

e. On 2 December 2020, MEAG discussed immunity certification and identified that there may be concerns related to whether it would be necessary and proportionate, whether the public understood the science behind vaccination, and whether the public would trust the motivation behind certification **(CS6/59- INQ000401397)**.

f. On 3 March 2021, the group discussed the JCVI's interim Phase 2 vaccination programme advice, in which they discussed a number of options including around prioritising roll-out by age rather than occupation. They discussed levels of vaccine uptake among minority ethnic communities, uptake among younger adults, the use of leftover doses, as well as what might need to be considered for future phases of the vaccine roll-out **(CS6/60 - INQ000401396)**.

g. On 31 March 2021, the group discussed introducing a requirement for older adult care home providers to only deploy staff who have been vaccinated against COVID-19. They discussed a range of issues, including the importance of understanding the level of existing risk, the effectiveness of the vaccines on

reducing transmission, the importance of other avenues of encouraging vaccine uptake, and what effects the policy have on the civil liberties of care home staff **(CS6/61 - INQ000401347)**.

h. On 28 April 2021, the group discussed conditions where there should be exemptions to COVID-status certification. They discussed issues including the importance of establishing the principles behind exemptions, the risks of allowing any exemptions, the status of children, the practical challenges of administering exemptions, and the ethics of treating tests, natural immunity and vaccination as equivalent **(CS6/62 - INQ000401399)**.

The Department's Role in relation to the UK Government & Devolved Administrations

112. Sir Christopher Wormald's Third Witness Statement dated 29 March 2023 at paragraph 14 sets out that whilst health and social care policy is largely devolved to the Welsh and Scottish Governments and the Northern Ireland Executive, the Department has some reserved policy areas with UK-wide responsibility, including international relations. Public health is a devolved matter, and this meant that certain arrangements to respond to the pandemic could be and indeed were made separately by the devolved administrations.

113. Sir Christopher Wormald's Third Witness Statement at paragraph 18 also notes that the existence of a public health emergency does not change the terms of the existing devolution settlements under which public health, NHS and care functions are predominantly devolved.

114. The UK Government procured COVID-19 vaccines on behalf of the UK, CTs and OTs. The volumes procured were to cover the population of the UK as a whole. Once vaccines started arriving in the UK, they were distributed to each nation for their own deployment programmes.

115. I am asked about vaccine delivery across the nations of the UK. My Third Witness Statement dated 4 September 2023 explains that vaccine deployment was the responsibility of each nation, but there was strong collaboration on the approach to the roll-out of the COVID-19 vaccines. The Secretary of State and the Minister for COVID-19 Vaccine Deployment had regular engagement with the health ministers from the devolved

administrations to coordinate UK-wide deployment. The UK CMOs met regularly and the SROs for deployment spoke regularly.

SECTION 2: VACCINE DEVELOPMENT

116. The development of COVID-19 vaccines in 2020 built on the Department's previous preparedness work and would not have been possible without the UK's robust research infrastructure, supported by the Department, which was able to adjust to the emergency conditions of the pandemic. This Section of the statement describes:

a. The Department's preparedness for the rapid development of a vaccine before 2020.

b. The role of research and clinical trials in development of COVID-19 vaccines.

c. An explanation of the process of regulatory approval for COVID-19 vaccines.

d. An explanation of the approach to routine vaccination.

e. An explanation of the process of procuring COVID-19 vaccines.

f. A summary of the process of development for each of the vaccines approved for use in the UK.

g. A description of international supply and distribution and the development of COVAX; and

h. A summary of innovations carried out to support vaccine development in the UK.

Preparedness before 2020

117. The Department, along with the wider health family, was in a strong position to roll-out a vaccination programme for COVID-19 due to its extensive knowledge and experience in delivering vaccines programmes, such as the annual flu vaccine programme and the routine childhood immunisation schedule.

118. As a result of this knowledge and the close collaboration with UKHSA and NHSE in delivering routine immunisation programmes there was existing infrastructure that could be drawn on in order to roll-out the COVID-19 vaccination programme as quickly as possible. Further information on the relationship between the Department, UKHSA and NHSE in delivering routine immunisations can be found in paragraphs 136-138.

119. Furthermore, the UKHSA-led Green Book has been published in the UK since 2006 to keep health professionals and immunisation practitioners up to date with developments in the field. The Green Book provides details on the principles, practices and procedures which are considered in current vaccination programmes, as well as diseases, vaccinations and vaccines. It is well established in clinical settings, giving frontline staff confidence in the quality and consistency of vaccination procedures. The chapters are updated as necessary and as advised by the JCVI **(CS6/63 - INQ000101064)**.

120. In preparation for an influenza pandemic, the Government held an advanced purchase agreement (APA) contract to enable procurement of an influenza vaccine. This provided the UK with reserved production capacity for influenza vaccine doses for the entire UK population and to be available within four to six months of an influenza pandemic outbreak. The Government did not use the APA as it was for an influenza vaccine.

121. The Department also maintained stockpiles of clinical consumables to support delivery of a pandemic vaccine and other therapeutics. The Department used these stockpiles of combined needles and syringes, and sharps bins from our pandemic stockpile to support COVID-19 vaccine deployment **(CS6/64 - INQ000401278; CS6/65 - INQ000057480; CS6/66 - INQ000401280)**.

122. Additionally, alongside this pandemic influenza specific preparedness, the Department supported research and development of vaccines for novel diseases or pathogens of pandemic potential. This was taken forward in light of the Ebola lessons learned report prepared by the Department, NHSE and PHE and led to the development of the UKVN, which covered pathogens including Ebola, Middle East respiratory syndrome (MERS), and 'Disease X' **(CS6/67 - INQ000183378)**.

Lessons learned from Other Epidemics

123. The Department was also able to utilise lessons learned on vaccines developed for previous epidemics and pandemics. The UKVN was established in June 2015 in the wake of the West African Ebola outbreak from 2014 to 2016, which illustrated a serious market failure in the development of vaccines against emerging pathogens that cause epidemics in LMICs. The UKVN has been chaired since its inception by Professor Sir Chris Whitty. The UKVN has advised the Department on a programme of ODA-funded investments in vaccine development against emerging epidemic threats since 2016 (referred to as the UKVN Project).

124. In 2016 a working group of the UKVN undertook a prioritisation exercise to prioritise pathogens on which the UKVN Project should focus investment to maximise the global health security impacts of the UK HMG investment. This process predated the subsequent WHO Research & Development (R&D) blueprint priority pathogen list, although the resulting lists had significant overlaps. A summary of the prioritisation process used by UKVN is available **(CS6/67 - INQ000183378).**

125. The prioritised UKVN list at the time included 12 viruses, including MERS as pathogens for investment. Although it is not possible to do research into a vaccine for a disease not yet in existence (i.e. 'Disease X'), there can be research into other priority pathogens, including pathogens of pandemic potential, which can potentially be pivoted to researching vaccines for a novel disease when it emerges. The sustained investments in MERS vaccine development and in vaccine platform technologies that could be rapidly deployed against new threats were essential for the UK research community to rapidly develop COVID-19 vaccines.

126. The UKVN had a significant impact on both the UK's preparedness for, and rapid response to, the COVID-19 pandemic, as it:

a. Strengthened the UK vaccine research base over the period of 2016 to 2021. UKVN began funding vaccine R&D projects in 2016 and by the end of March 2020, the UKVN had committed £77 million in funding for vaccine development projects against a list of 12 priority pathogens that cause epidemic outbreaks in LMICs and towards innovations in vaccine manufacturing including platform development and scale-up processes.

b. Provided advice to the UK Government in 2016 including on:

    i. A review of UK vaccine manufacturing capacity, which contributed to the industrial strategy decision to fund the Vaccine Manufacturing and Innovation Centre (VMIC);

    ii. Production of policy tools to increase policy makers' understanding of the vaccine development process;

c. Helped to build the UK Government's relationship with the Coalition for Epidemic Preparedness Innovations (CEPI), an alliance to finance and coordinate the development of new vaccines to prevent and contain infectious disease epidemics, from 2018 onwards. The CEPI became a key international organisation in the international COVID-19 vaccine response; and

d. Developed relationships between HMG departments and policy teams that enabled initiation of a rapid research call between MRC and NIHR in 2020.

e. The Oxford University team, funded by, the UKVN, as well as other funders, started using adenovirus-based technology for MERS vaccine development in 2016.

127. In 2016, A UKVN grant supported the preclinical development and phase 1 clinical trials of a MERS vaccine using the ChAdOx1 platform[1] **(CS6/68 - INQ000501430).** The vaccine targeted the spike protein and successfully completed phase 1 clinical trials in 2019. In January 2020, researchers showed that the MERS vaccine was a candidate to be adapted to the novel coronavirus. This went on to become the Oxford/AstraZeneca COVID-19 vaccine. The knowledge gained from development of a vaccine for MERS on the same vaccine platform was important in allowing the rapid development of a vaccine against COVID-19, which is also a coronavirus.

[1] Since the early 2000s Oxford University teams have been working on vaccine candidates based on a "platform" - ChAdOx. A vaccine platform is an underlying technological approach, in this case using an adenovirus, which can be adapted to target different pathogens. A number of other UKVN awards have been for vaccine candidate development using the ChAdOx platform, but the most significant is the award made for preclinical development and phase 1 clinical trials (i.e. the first in humans) for a Middle Eastern Respiratory Syndrome - MERS - vaccine candidate. This was especially valuable in tackling Covid-19 because MERS is also a coronavirus, so the target viruses were more closely related in structure. DHSC via UKVN was one of several funders of the ChAdOx1 MERS vaccine research.

128. Similarly, the UKVN also funded two vaccine manufacturing research hubs from 2017. The award focused in part on improving vaccine platform technology to allow rapid vaccine development against 'Disease X', and associated research to improve vaccine manufacturing processes. The hubs were based at Oxford and University College London (joint award) and Imperial College London. Between December 2017 and March 2021, they were awarded a total of £17 million in funding. This investment meant that both hubs contributed expertise to the Oxford and Imperial COVID-19 vaccine development efforts, most notably the process for the rapid scale up of the Oxford/Astra-Zeneca vaccine. These manufacturing research hubs were funded in addition to development of specific vaccine candidates against the identified priority pathogens, including the Oxford MERS vaccine candidate.

129. The Department benefited from strong existing research infrastructure (especially NIHR and UK Research and Innovation) to facilitate rapid mobilisation of COVID-19 research. Lessons learned during the 2009 H1N1 influenza or 'swine flu' pandemic and the subsequent independent Hine review of governmental response, for example, helped to develop linked data systems.

Research and Clinical Trials

130. I am asked about the Department's role and involvement in research and clinical trials for each of the COVID-19 Vaccines.

131. The Department, in conjunction with the NIHR commissioned and prioritised COVID-19 research, including funding and delivering vaccines and therapeutics research studies. As this work was achieved through the NIHR, further detail is provided in the statement of Professor Lucy Chappell dated X.

Rapid and Rolling Calls

132. Understanding COVID-19 and its impact on humans and the healthcare service was important for development of vaccines and therapeutics. NIHR prioritised funding for studies in vaccines, therapeutics, epidemiology, virus natural history, and clinical characterisation and management. As this work was principally undertaken by NIHR in conjunction with UKRI, I refer to the statement of Professor Lucy Chappell dated X.

National Immunisation Schedule Evaluation Consortium (NISEC)

133. The VTF funded vaccine policy research commissioned by the Department's SRE Directorate through the NIHR and delivered by the NISEC. This is covered in more detail in Professor Lucy Chappell's statement.

NHS Vaccine Research Registry

134. I am asked about the role of the NHS Vaccine Research Registry (VRR) and what lessons can be learned from it. Recruiting vaccine clinical trial volunteers at pace was boosted by the establishment of the NHS COVID-19 VRR. The VRR was developed by the NIHR, the VTF, and NHSD and was launched in July 2020. It allowed people to quickly and easily sign up to participate in clinical trials of COVID-19 vaccines.

135. As this work was principally undertaken by the NIHR, I refer to Professor Lucy Chappell's statement dated X for further details on relevant lessons learned, as well as Section 5 of this statement.

Approach for Routine Vaccine Programmes

136. In normal times, the Department conducts engagement with industry, UKHSA and the JCVI on a regular basis to monitor the development of new vaccines. In order to be considered for use in a national vaccine programme, a vaccine requires:

a. MHRA approval; and

b. The JCVI to have issued advice or a recommendation to Government concerning the use of the vaccine.

137. The Department considers advice provided by the JCVI and uses this to inform new policy, such as the introduction of a new immunisation programme or a change to an existing programme. Policy decisions take into account factors including:

a. The operational feasibility of any new programme or changes to an existing programme, as informed by UKHSA and NHSE. This may include the cohort, delivery method and costs, programme start date and any requirement to phase the introduction, any delivery risks and impact on other priorities; and

b. The affordability and cost-effectiveness. UKHSA is responsible for procuring most products for the national routine programmes (excluding COVID-19 and adult flu programmes) and prepares business cases for approval. HMT's approval is also often required as part of this process where a vaccine is considered novel or contentious. A tender process then establishes the vaccine cost and whether the programme would be considered cost-effective before ministers (and HMT where appropriate) approve the expenditure.

138. The Department, UKHSA and NHSE work together to implement any changes to the national immunisation programmes. Steps are taken to ensure that the programme is monitored (quarterly coverage data is collected and shared) and that action is taken to address any concerns that may arise where possible. This may include communications campaigns.

COVID-19 Vaccine Procurement

139. I have explained the different roles played in delivering the COVID-19 vaccine by the Department, the VTF, and other parts of Government. The Department was not involved in the creation or conduct of these contracts, and I would expect UKHSA to speak in more detail in their witness evidence to these contractual arrangements. However, I recognise that it may be helpful to share a summary of the COVID-19 vaccines ordered by the UK Government through the VTF. I am, therefore, including the table below, which is taken from the VTF Review. Please note that the date the Oxford /AstraZeneca vaccine was approved is incorrect in the published table (it was approved on 30 December 2020 as discussed in paragraph 211, and not 2 December as the table suggests).

Table 1: Vaccines Ordered by UK Government through VTF, as taken from VTF Review. (CS6/26 - INQ000399474)

Vaccine	Date	Original doses secured bilaterally (millions)	MHRA approved	Deployed in the UK	Additional information
Oxford AstraZeneca	17 May 2020	100	Yes (2 December 2020)	Yes	Contract completed (50 million deployed and 50 million donated)

Sanofi-GSK	29 July 2020	60	Yes (21 December 2022)	Yes (spring 2023)	Order reduced to 7.5 million doses November 2021
Janssen	14 August 2020	30	Yes (28 May 2021)	No	Order reduced to 20 million doses and donated May 2021
Moderna	16 November 2020	17	Yes (8 January 2021)	Yes	60 million extra doses secured December 2021, to cover 2022 and 2023 deployment
Novavax	14 August 2020	60	Yes (3 February 2022)	Yes	Further 14.7 million doses ordered through COVAX donated. Bilateral 60 million dose order reduced to 1 to 16 million doses in July 2022
Pfizer-BioNTech	20 July 2020	40	Yes (2 December 2020)	Yes	Further 500,000 doses ordered through COVAX. 60 million extra doses secured April 2021 for primary and booster campaigns. 35 million extra doses secured in August 2021 for autumn booster campaign. 54 million extra doses secured December 2021, for 2022 and 2023 deployment
Valneva	14 September 2020	60	Yes (14 April 2022)	No	Contract terminated September 2021

Development of Specific COVID-19 Vaccines

140. I am asked about the procedure for approval for each of the COVID-19 vaccines. Approval of COVID-19 vaccines was led by the MHRA, an agency of the Department, with submissions to Ministers as necessary. Sir Christopher Wormald's Fifth Witness

Statement dated 23 August 2023 gave a comprehensive description of the Oxford/AstraZeneca's vaccine development and approval process. This statement provides a summary below (paragraphs 141- to 152) of the key processes that are relevant to the narrative of this statement, and provides additional evidence where points are expanded on further than they have been previously. Information relevant to other COVID-19 vaccines is provided from paragraph 153 As this work was primarily led by the VTF, further detail should be sought from UKHSA.

Oxford/AstraZeneca Vaccine

141. The Department and NIHR responded at pace to the emerging threat of the pandemic by pivoting research focus to COVID-19 and launching rapid and rolling calls in early February 2020. The Government invested £10.5 million across six successful applicants working on vaccine and therapeutics development, of which the University of Oxford was one.

142. On 7 February 2020, the University of Oxford announced that it had begun research into the development of a vaccine for the novel coronavirus. By 18 March 2020, it had identified a vaccine candidate for COVID-19 and on 27 March 2020, clinical trials opened **(CS6/69 - INQ000234337).**

143. Between February and April 2020, discussions and meetings had begun on challenges around accelerating and scaling pharmaceutical manufacturing and procurement, around key products or potential vaccine candidates. The Government was keen to support the University of Oxford in finding a manufacturing partner for its vaccine candidate that met the UK Government's aims for scalability and supply.

144. When the team at the University of Oxford was approached by American company Merck, the Government Chief Scientific Advisor (GCSA), Sir Patrick Vallance, held a meeting with the University to discuss the proposed relationship between Merck and Oxford University on 2 April 2020. This was reflected in advice submitted to the Secretary of States for the Department and BEIS dated 3 April 2020 **(CS6/70 - INQ000234341; CS6/71 - INQ000234722)**. The submission highlighted that most of the institutions developing vaccines were often academic groups or small companies and that scaling the manufacture of any vaccine would be challenging but that the Department was working with the BioIndustry Association to consider those challenges.

145. The Secretary of State expressed his desire that the Government support the University of Oxford in exploring its options with a diverse range of pharmaceutical manufacturers such as GlaxoSmithKline (GSK) and AstraZeneca **(CS6/72 - INQ000234347)**. Madeline McTernan (then Director of UK Government Investments) highlighted in response on 23 April 2020 that Sir John Bell, the Government's Life Sciences Champion, thought Merck was the best option and so pressing ahead with discussions was sensible but that did not stop other options being explored **(CS6/72 - INQ000234347).**

146. Over the course of April, the University of Oxford explored its options with a range of pharmaceutical manufacturers. Sir Christopher Wormald's Statement fifth statement to the Inquiry, of 25 August 2023, set out how, on 25 April 2020, the PM wrote a letter to the Chancellor of the University of Oxford, the Right Honourable Lord Patten of Barnes, and Vice Chancellor, Professor Louise Richardson. The letter acknowledged that the University's objectives aligned with the Government's and that they had commenced discussions with third parties in order to identify the best partner to deliver these objectives. The PM asked to be kept informed about negotiations and that the Chancellor of the Exchequer spoke with the Chancellor and Vice Chancellor of the University of Oxford on HMG's objectives to ensure that a deal did not risk giving "walk-in rights" (more commonly known as "step-in-rights"[2]) to other countries which could put UK and global supply at risk **(CS6/73 - INQ000234348)** and **(CS6/74 - INQ000234349)**.

147. On 27 April 2020 Madeline McTernan, while emphasising that all negotiations were ongoing, updated the Secretary of State's private office on negotiations between University of Oxford and pharmaceutical companies. GSK were not in a position to partner on manufacturing, but potential collaboration was being explored, and discussions with Merck were slowing down because it was not clear they would be able to deliver sufficient quantity of vaccine for the UK (**CS6/75 - INQ000234351)**. At the same time, the University of Oxford was opening discussions with AstraZeneca, who were interested in building a manufacturing facility in the UK **(CS6/75 - INQ000234351)**. At this point, with the establishment of the VTF earlier in the month, VTF was engaging directly in discussions.

148. Ministers were kept up to date with and cleared decisions on progress of discussions and on 30 April 2020, the University of Oxford announced a partnership with AstraZeneca for the development and potential largescale distribution of a COVID-19 vaccine candidate **(CS6/76 - INQ000489920)**. In early May, the Secretary of State, alongside the BEIS Secretary of State and the Chancellor, agreed two business cases for manufacturing costs

contracts for clinical trials **(CS6/77 - INQ000401285; CS6/78 - INQ000234368; CS6/79 - INQ000234362; CS6/80 - INQ000234367; CS6/81 - INQ000234366)**.

149. On 17 May 2020, Dr Louise Wood, provided consent on behalf of the Department, in accordance with NIHR terms, for the licensing agreement, following due diligence by the VTF, between the University of Oxford and AstraZeneca **(CS6/82 - INQ000234370; CS6/83 - INQ000234369)**.

150. The Ministerial Vaccines Panel met on 27 August 2020 to discuss the final business case relating to the Oxford/AstraZeneca COVID-19 vaccine (referred to as AZD1222), and the panel approved it **(CS6/84 - INQ000234458; CS6/85 - INQ000503564 CS6/86 - INQ000503564; CS6/87 - INQ000401288; CS6/88 - INQ000257389**).

151. On 24 November 2020, the DCMO (Jonathan Van-Tam) and the Director of the COVID-19 Vaccine Deployment programme wrote to the Chief Executive of the MHRA, Dr June Raine, to ask the MHRA to consider recommending temporary authorisation for the Oxford/AstraZeneca vaccine under Regulation 174 **(CS6/89 - INQ000059052**). Regulation 174 permits temporary authorisation of medicinal products (including vaccines) in certain circumstances includingY6 where there is a suspected or confirmed spread of pathogenic agents which may cause harm to humans. I explain more about the process of licensing vaccines at paras 222-223 below.

152. On 29 December 2020, the MHRA sent a submission to the Parliamentary Under Secretary of State at the Department, who was acting as the Minister for the LA, recommending that temporary authorisation for the Oxford/AstraZeneca vaccine, with a number of conditions, be given under Regulation 174 **(CS6/90 - INQ000401311; CS6/91 - INQ000401312; CS6/92 - INQ000401313).** The submission was approved the same day **(CS6/93 - INQ000401316; CS6/94 - INQ000059390; CS6/95 - INQ000401324).**

mRNA Vaccines

153. As explained by the Green Book, the Pfizer/BioNTech and Moderna COVID-19 vaccines are mRNA (messenger ribonucleic acid) vaccines. They contain the genetic sequence (mRNA) for the spike protein which is found on the surface of the SARS-CoV-2 virus, wrapped in a lipid envelope (referred to as a nanoparticle) to enable it to be transported into the cells in the body. When injected, the mRNA is taken up by the host's

cells which translate the genetic information and produce the spike proteins. These are then displayed on the surface of the cell. This stimulates the immune system to produce antibodies and activate T-cells which prepare the immune system to respond to any future exposure to the SARS-CoV-2 virus by binding to and disabling any virus encountered.

Pfizer

154. On 17 November 2020, the Department wrote to the MHRA asking them to consider authorising UK supply of the Pfizer/BioNTech vaccine under Regulation 174 **(CS6/96 - INQ000071697).**

155. On 30 November 2020, the CHM held a final meeting to consider Pfizer/BioNTech vaccine authorisation. The MHRA sent a submission to the Parliamentary Under Secretary of State at the Department with a recommendation to approve the Pfizer/BioNTech vaccine to be deployed under Regulation 174 **(CS6/97 - INQ000110129).**

156. On 1 December 2020, the Parliamentary Under Secretary of State at the Department approved the recommendation to deploy the Pfizer/BioNTech vaccine under Regulation 174 (**CS6/98 - INQ000410479).** The MHRA wrote to Pfizer confirming the authorisation decision (**CS6/99 - INQ000386014**; **CS6/100 - INQ000112703).**

157. On 2 December 2020, DHSC issued a press notice detailing the decision (**CS6/101 - INQ000399448).**

Moderna

158. On 24 December 2020, the Department wrote to the MHRA asking them to consider authorising the UK supply of the Moderna vaccine under Regulation 174 **(CS6/102 - INQ000401310)**.

159. On 6 January 2021, the MHRA sent a submission to the Parliamentary Under Secretary of State at the Department with a recommendation to approve the Moderna vaccine under Regulation 174 **(CS6/103 - INQ000489940; CS6/104 - INQ000489941).**

160. On 7 January 2021, in response to a submission the Parliamentary Under Secretary of State approved the recommendation to deploy the Moderna vaccine under Regulation

174 **(CS6/105 - INQ000059502)**. The MHRA wrote to Moderna confirming the authorisation decision (**CS6/106 - INQ000401326**; **CS6/107 - INQ000401327).**

161. On 8 January 2021, the Department issued a press notice detailing the decision **(CS6/108 - INQ000234703).**

Vaccines Not Deployed in the Period Covered by this Statement

162. Valneva, Janssen, Novavax were authorised, as detailed below, but were not deployed in the time period covered by this statement.

Valneva

163. The Valneva vaccine was authorised with a Conditional Marketing Authorisation (CMA) on 13 April 2022.

164. I am asked about the termination of the Valneva contract. As mentioned at paragraph 45, the vaccine supply responsibilities of the VTF moved over to UKHSA in October 2022. The Department does not hold this information. I expect that UKHSA would be best placed to provide details on the decision to terminate the Valneva contract, and any further information about contact entered into with Valneva.

Novavax (Nuvaxovid)

165. On 2 February 2022, the Novavax COVID-19 vaccine, Nuvaxovid, was authorised by the MHRA, after it had generated appropriate data to demonstrate quality, safety and efficacy **(CS6/109 - INQ000501432; CS6/110 - INQ000489952)**. Minister Caulfield agreed to the recommendation approval to grant a GB Conditional Marketing Authorisation for Novavax's Nuvaxovid, a COVID-19 vaccine **(CS6/111 - INQ000489953)**.

166. In a letter to Secretary of State on the 2 March 2022 the Chair of the JVCI, Professor Wei Shen Lim, suggested that consideration of introducing Nuvaxovid, as part of the COVID-19 vaccination programme should be deferred until later in the year as at that point it was only authorised for primary course vaccination and not as a heterologous booster **(CS6/112 - INQ000489954)**.

167. Ministers accepted this approach on the 23 March 2022 **(CS6/113 - INQ000401401)**.

Janssen (Johnson and Johnson)

168. The Janssen vaccine was approved for use on 28 May 2021 **(CS6/114 - INQ000489946; CS6/115 - INQ000489947; CS6/116 - INQ000489956; CS6/117 - INQ000399477)**. The original conditional marketing authorisation (CMA) granted by the MHRA was approved via the European Commission (EC) Decision Reliance Route. This was valid in Great Britain only and was converted to a full GB marketing authorisation (MA) on 20 February 2023. The Janssen COVID-19 vaccine is authorised in Northern Ireland under the MA issued by the EMA.

International Supply and Distribution

169. The UK was a major donor of COVID-19 vaccines, championing the establishment of the global initiative COVAX to support research, manufacturing, procurement and distribution of COVID-19 vaccines for the benefit of all countries. COVAX established a joint procurement pool for higher income countries, with the intention of enabling them to share costs and risks of investing in a diverse vaccine portfolio (the success of the UK's own vaccination programme meant it did not extensively make use of this).

170. COVAX initially aimed to make two billion doses of vaccines available by the end of 2021, with the hope of enabling participating countries to protect high risk and vulnerable people and healthcare workers. It also established a fund to support 92 lower income countries to get equal access to vaccines. By September 2022, COVAX had delivered over 1.7 billion vaccines to 146 countries.

171. As well as championing the establishment of COVAX, the UK Government made a significant contribution. It provided £548 million through the Foreign, Commonwealth and Development Office (FCDO) aid budget to support COVAX objectives.

172. In addition, as the VTF review outlines:

> *"The UK was able to offer 100 million doses for donation and to deliver 84.4 million doses by June 2022. In 2022, delivery of donations was constrained by lack of demand from COVAX and lower income countries. Of the 84.4 million doses delivered, over 75 million were delivered to COVAX, and 7.9 million were delivered directly by the UK to*

countries in need. These donations benefitted 42 countries." **(CS6/26 - INQ000399474).**

Innovations Made by the Department to Support COVID-19 Vaccines

173. Innovations which supported COVID-19 vaccine deployment included the VTF itself, research innovations to support clinical trials and legislative changes including to support innovations in MHRA processes. All of these led to an accelerated timeline from identification of the potential need to deployment at scale.

Departmental Support for the VTF

174. The VTF was a novel approach to cross-governmental procurement and programme design. Among other innovations, the creation of a ministerial panel was a unique set up in the pandemic to streamline approvals so that they were done in parallel, rather than consecutively, across necessary departments, including the Department, BEIS, CO and HMT.

175. The Department has deep expertise in clinical trials, vaccine regulation, development and deployment, and links with the scientific community. The Department's collaboration with the VTF allowed the VTF to build on this experience to ensure that its agile approach to vaccine development and procurement incorporated the Department's expertise and relationships with members of the 'health family'.

176. If a vaccine is procured centrally, the process is managed by UKHSA. Estimates of the amount of vaccine required are based on a number of factors, including:

a. The JCVI's advice about the cohorts needing to be vaccinated - this includes consideration of the population in each cohort as well as the WHO's advice about the target rate/percentage needed to meet the public health objective;

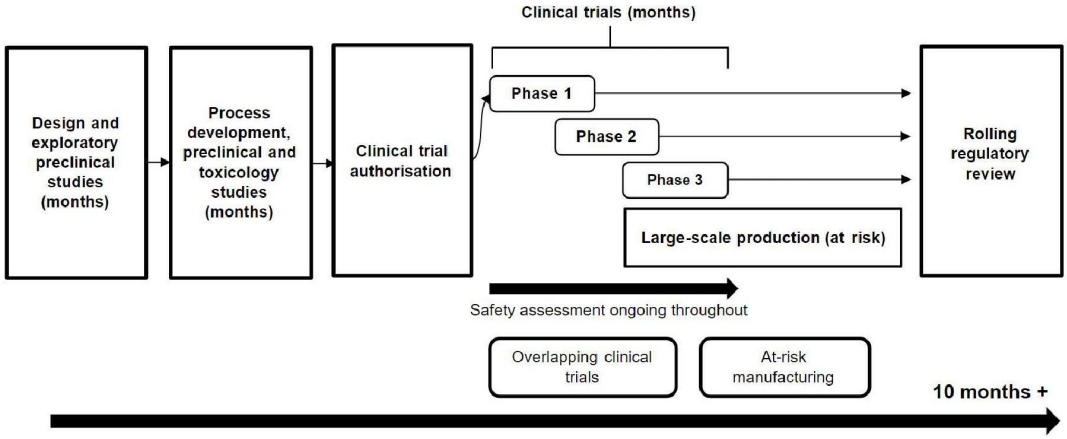
b. NHSE's and UKHSA's advice about the practicalities of the programme, based partly on historic uptake data, but also taking account of the other priorities for the vaccinating workforce, as well as the interaction with other vaccination programmes; and

c. Any allowances, usually in terms of over ordering stock, that might need to be made to mitigate supply chain risks such as manufacture and distribution, as well as risks with storage and managing local demand.

177. This then provides an overall figure for procurement, which is then used to support the business case, and then put to ministers to approve, after various financial checks, before the vaccines can be purchased. Adult seasonal flu vaccines are procured locally.

178. The VTF represented a novel approach to vaccine procurement, commensurate with the challenges of COVID-19 and the uncertainty surrounding vaccine development. We expect that the Department for Science, Innovation and Technology (DSIT) and UKHSA will be able to provide further details on this.

179. The Department played an important role in ensuring that procurement, clinical trial and regulatory functions could operate effectively concurrently and therefore reduce the time needed to bring vaccines to market. The below graphic, from Chapter 9 of the 'Technical Report' illustrates how elements of vaccine development took place in parallel including at a high level the clinical trials, procurement and production **(CS6/118 - INQ000399139)**.



Clinical Trials

180. I am asked about innovations in relation to clinical trials. The Department supported a wide range of innovations to streamline the clinical trials process.

181. It was a research award requirement that award-holders undertaking work relevant to the coronavirus public health emergency share their research data and findings as rapidly and widely as possible to generate impact. During the COVID-19 pandemic researchers were asked to report quarterly to the NIHR, the Department and the researchers also engaged directly.

182. Officials in SRE worked closely with the Department's press office and NIHR communications teams when new results were emerging from commissioned research projects. In some cases, researchers gave Science Media Centre briefings to share the results with the press.

183. I refer to Professor Lucy Chappell's statement dated X for more details on innovations in relation to clinical trials.

Legislative Changes

184. I am asked about innovations to speed up the approvals process. Different vaccines followed different authorisation routes depending on when approved and/or which approval route was used; some manufacturers made national applications to the MHRA, some used the 'reliance' route where vaccines were approved via the European Medicines Agency (EMA) first. All COVID-19 vaccines were given Conditional CMAs although some were initially approved using Regulation 174 of the Human Medicines Regulations 2012.

185. If a manufacturer of a medicine wants to market a medicine in the UK, they apply to the MHRA for a MA, or 'licence', They have to provide evidence of the quality, safety and efficacy of that medicine. That evidence is assessed and if the MHRA is satisfied that the benefits of the medicine outweigh the risks for the proposed use, a licence or MA is granted. That MA can be amended through the variations process if there are changes that need to be considered – those changes could be about the drug itself, how and where it is manufactured, the target population, dosage or what the drug is used for. Depending on the nature of the change, a further assessment may be required before the MA can be amended.

186. In 2020, the MHRA introduced a national CMA scheme for new medicinal products in Great Britain effective from 1 January 2021. In Northern Ireland, MA applications for products which fell within mandatory scope of the Centrally Authorised Procedure as laid down in Regulation (EC) No 726/2004, still had to be submitted to the EMA. The EU has

a similar scheme, and the criteria were the same. Like the MA, a manufacturer has to apply. The CMA was intended for medicinal products that address an unmet medical need. Examples would be for serious and life-threatening diseases where no satisfactory treatment methods are available or where the product offers a major therapeutic advantage, as was the position in the early years of COVID-19. The MHRA can grant a CMA where comprehensive clinical data is not yet complete, but it is judged that such data will become available soon. Once the full data is available, the company could be granted an MA. The CMA can be amended in the same way as the MA.

187. Regulation 174 of the Human Medicines Regulations allows a product to be marketed in the UK without an authorisation (i.e., no CMA or MA). It allows that on a temporary basis in a range of circumstances including where there is a suspected or confirmed spread of pathogenic agents. The Department writes to the MHRA to request that they consider granting approval under regulation 174 and MHRA considers the available evidence, again focusing on quality, safety and efficacy.

188. In October 2020, the Government made changes to the Human Medicines Regulations to allow the MHRA to grant temporary authorisation of a COVID-19 vaccine without needing to wait for approval by the EMA. Until the end of the transition period of the UK's withdrawal from the EU (31 December 2020), the UK would usually have had to wait for the EMA to approve a vaccine before looking to distribute it. However, in an emergency, EU countries have permission to use their own regulator to issue a temporary authorisation.

189. The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 ("the HMR amending regulations") were made on 15 October 2020 and the relevant amendments came into force on 17 October 2020 (**CS6/119 - INQ000234566; CS6/120 - INQ000489921; CS6/121 - INQ000489922; CS6/122 - INQ000489923; CS6/123 - INQ000489924)**. These regulations included measures to support temporary authorisations to supply any unlicensed products in response to public health threats and more flexible deployment of COVID-19 and influenza vaccines.

190. Regulation 174 of the Human Medicines Regulations already provided for temporary authorisation of the supply of unlicensed medicines in response to public health threats (which became known as 'emergency authorisations'). This provision was subsequently developed to include conditions attached to emergency authorisations. This change was

needed to provide certainty about the nature of the MHRA's power in this area and the conditions attached to emergency authorisations.

191. As set out in the explanatory note prepared by the Department and MHRA, there were also some modifications to the existing arrangements for partial immunity from civil liability, which are an intrinsic part of the emergency authorisation scheme. These modifications were implemented through the HMR amending regulations, which amended the Human Medicines Regulations to clarify the scope of the partial immunity from civil liability given by regulation 345 of the Human Medicine regulations. Before 17 October 2020, that partial immunity was afforded to some parties involved in the supply of products whose unlicensed use was recommended by the licensing authority in response to certain types of public health threat: manufacturers enjoyed the immunity, while pharmaceutical companies who outsourced manufacture of their products did not. The Department considered this to be anomalous and that the immunity should extend to all relevant pharmaceutical companies whether or not they did their own manufacturing.

192. The HMR amending regulations also provided for the expansion of the workforce legally able to administer a COVID-19 or influenza vaccine under an approved National Protocol and allowed vaccinations to happen on sites other than registered pharmacies.

193. National Protocols were introduced as a requirement as part of the amendments to the Human Medicines Regulations which expanded the workforce to allow for administration of COVID-19 and influenza vaccines by registered healthcare professionals who do not normally vaccinate, and people who are not registered healthcare professionals, to safely administer a licensed or temporarily authorised COVID-19 or influenza vaccine.

194. The partial immunity from civil liability given by regulation 345 of the Human Medicines Regulations also applied to registered health care professionals who treated patients with temporarily authorised products. A further modification made by the HMR amending regulations was to extend this to other professionals who may be asked to administer COVID-19 or influenza vaccines under the new National Protocols. It was determined that it would be fair and appropriate for the same immunity to extend to the expanded vaccination workforce.

195. National Protocols are developed by PHE/UKHSA and allow for a safe agreed way of administering a particular vaccine, under appropriate supervision, in accordance with the

manufacturer's recommendations and the JCVI advice, after the vaccine has been approved for use by the MHRA, as part of the national COVID-19 vaccination programme.

SECTION 3: VACCINE PRIORITISATION

196. As research into potential vaccines took place and the VTF negotiated on behalf of the Government, work took place within the Department to plan for deployment of a vaccine, including consideration of who should be prioritised to receive that vaccine. This section of the statement explains how decisions were taken on prioritisation of vaccines, and the considerations that went into those decisions, including about vaccination of children and dosage intervals.

Decision-Making and Accountability

197. Decisions on vaccine prioritisation are taken by government ministers of UK health departments. In England, they are taken by the Secretary of State for Health and Social Care on the advice of the JCVI, a statutory standing advisory committee constituted for the purpose of advising the UK health departments on the provision of vaccination and immunisation services. For the period in question, the JCVI was asked to provide advice on prioritisation for the COVID-19 vaccine. A detailed explanation of the JCVI's role is included in Section 1 of this witness statement.

198. The Department received advice from the JCVI, and policy officials provided this advice alongside a range of advice on other factors to inform ministerial decision-making, including the Department's legal obligations, financial implications of decisions, input from MEAG and analysis on equalities and a formal impact assessment from Departmental analysts on the economic impact of vaccine deployment.

Prioritisation Phases

199. On 30 November 2020, the Secretary of State agreed to a two-phase vaccination programme **(CS6/124 - INQ000234199; CS6/125 - INQ000234198)**, and prioritisation was considered in two phases.

Phase 1

200. In light of the unfolding pandemic and its consequences, regular contact took place between the Department and the JCVI to discuss a possible vaccination programme. The JCVI met to consider COVID-19 vaccines from May 2020 and a formal COVID-19 subgroup was established in September 2020. The JCVI met twice weekly (compared with twice annually pre-pandemic), reviewing emerging evidence on a rolling basis to give advice on approaches on vaccination well in advance of vaccine authorisation, allowing timely recommendations. Weighting of JCVI's usual priorities in decision-making also evolved, with vaccine supply, procurement and delivery capacity becoming higher priority considerations than usual, and programmatic cost a lower priority than usual.

201. This approach, along with other preparations detailed in this statement, meant that the UK was able to start vaccination within days of an authorisation, which was a major advantage in being able to respond to the pandemic as effectively as possible.

202. In advising the Secretary of State during the relevant period, the JCVI did not undertake or consider an assessment of cost-effectiveness. This was because such an assessment would not have served a useful purpose when the Government had already contracted the necessary vaccines and put in place arrangements for their delivery. Instead, the JCVI focused on the critical matters of clinical effectiveness and the groups who should be vaccinated in what order, i.e., prioritisation. These were matters which required expert judgement and analysis, and for which purpose the JCVI had been specifically established as a statutory advisory committee.

203. In circumstances where the JCVI produces advice or recommendations not within the terms of regulation 2(2) of the 2009 Regulations, and which the Secretary of State is not statutorily obliged to accept, nonetheless the Secretary of State would generally expect to place considerable reliance on the JCVI's advice as representing expert judgement. When the Secretary of State is presented with a recommendation from the JCVI based upon a coherent strategy, careful consideration of relevant evidence by experts, and detailed modelling, there would need to be a compelling reason not to accept it, particularly in the unprecedented circumstance of a global pandemic.

204. In June 2020, the JCVI advised ministers, then published interim advice **(CS6/126 - INQ000106485)** on priority groups for vaccination including the priority vaccination of

frontline health and social care workers and those at "increased risk of serious disease and death from COVID-19 infection stratified according to age and risk factor".

205. On 25 September 2020, the JCVI published updated interim advice advising that care home residents and staff receive vaccines first, followed by people aged over 80 and health and social care workers, before rolling out to the rest of the population in order of age and risk **(CS6/127 - INQ000070847)**. This interim advice identified 11 priority groups.

206. On 13 November 2020, the Department submitted a paper on vaccines prioritisation for COVID-O to consider. The paper sets out the estimated population percentage for each identified priority group. COVID-O agreed in principle the JCVI recommendations on prioritisation, subject to further consideration of provision for Clinically Extremely Vulnerable (CEV) individuals. At this meeting, the COVID-O committee also agreed that the PM would take the final decision on Phase 1 prioritisation **(CS6/128 - INQ000090898; CS6/129 – INQ000401301)**.

207. The JCVI subsequently updated its interim draft advice on vaccinating CEV individuals to advise that persons aged less than 70 years who were deemed clinically extremely vulnerable should be offered vaccine alongside those aged 70-74 years of age. There were two key exceptions to this, pregnant women with heart disease and children **(CS6/130 – INQ000059103)**. This advice was provided to the Secretary of State with accompanying advice from the Department on 27 November 2020 **(CS6/131 - INQ000059104).**

208. On 30 November 2020, the Secretary of State received further advice setting out the JCVI's updated recommendations on prioritisation. He accepted this advice, which at this point only referred to the Pfizer/BioNTech vaccine **(CS6/125 – INQ000234198)**. The JCVI advised that prioritisation should be given to care home residents and staff first, followed by individuals over 80 and health and social care workers (as defined by Chapter 14A of the Green Book at Annex B), then to the rest of the population in order of age (decreasing by five years) and clinical need **(CS6/124 – INQ000234199)**.

209. Shortly after, the Pfizer/BioNTech vaccine was formally approved by MHRA for use in the UK on 2 December 2020 (see paragraph 156 - 157 above).

210. On 29 December 2020, the Parliamentary Under Secretary of State received a submission updating him on the MHRA approval of Oxford/AstraZeneca, which was due to be published on 30 December **(CS6/132 - INQ000489935)**.

211. On 29 December 2020, the Secretary of State received a submission setting out the JCVI's draft advice on prioritisation, which was to be published later that day. The advice would consider both the Pfizer/BioNTech and the Oxford/AstraZeneca vaccines **(CS6/133 - INQ000401314; CS6/134 - INQ000501434; CS6/135 - INQ000489936; CS6/136 - INQ000489937)**. He also received a draft joint statement from the four UK CMOs, welcoming the MHRA approval of the Oxford/AstraZeneca vaccine and endorsing the JCVI advice on prioritisation **(CS6/137 - INQ000059403)**. The Department's submission was accompanied by advice on the Public Sector Equality Duty (PSED) **(CS6/138 - INQ000401315)**. The vaccine was subsequently approved by MHRA on 30 December 2020 (see paragraph 152 above).

212. The Secretary of State considered mitigating inequalities in accepting the JCVI's recommendation on Phase 1 prioritisation, and in particular considered advice given by the JCVI on CEV individuals, Black, Asian and minority ethnic groups, societal factors, occupational considerations and gender **(CS6/124 - INQ000234199; CS6/139 - INQ000066761; CS6/140 - INQ000489933)**. The Secretary of State also received a full economic impact assessment of the programme. The Secretary of State received advice on the PSED, which included consideration of the impact of the programme a number of different protected characteristics. The Secretary of State accepted the advice, subject to it being unchanged in the final version, and noted the PSED, impact assessment and family test **(CS6/141 - INQ000401318; CS6/142 - INQ000489938)**. A final version of the JCVI advice was sent to the Secretary of State on the 30 December 2020 **(CS6/143 - INQ000059401).** Secretary of State cleared the submission; **(CS6/144 - INQ000489939).**

213. Later, on 30 December 2020, the JCVI confirmed and published its final advice on Phase 1 prioritisation **(CS6/143 - INQ000059401);** this was the first time both the Pfizer/BioNTech and the Oxford/AstraZeneca vaccines were included as part of the advice for vaccination.

214. The JCVI's final recommendations for prioritisation identified nine priority groups to be offered the vaccine in the first phase of a national programme. In accordance with the outcome of the research it had scrutinised, these priority groups were mainly arranged by age, with all individuals over the age of 50 being in the first phase. This phase also included in group 1, residents of a care home for older adults; in group 4, individuals identified as being "clinically extremely vulnerable" and who have been shielding during the pandemic; and in priority group 6, individuals with a range of existing conditions which render them

particularly susceptible to the impact of infection from COVID-19. Carers of residents in care home for older adults were placed into priority group 1 and frontline health and social care workers (of whatever age) into priority group 2.

215. More specific advice on group 6 included *"all individuals aged 16 years to 64 years with underlying health conditions which put them at a higher risk of serious disease and mortality"*. Priority Group 6 also included those in receipt of a carer's allowance, or those who are the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill.

216. A summary of the prioritisation groups in the JCVI's advice published on 30 December 2020 is outlined in Table 2.

Table 2: The Phase 1 Prioritisation Cohorts:

1	Residents in a care home for older adults and their carers
2	All those 80 years of age and over and frontline health and social care workers
3	All those 75 years of age and over
4	All those 70 years of age and over and clinically extremely vulnerable individuals
5	All those 65 years of age and over
6	Adults aged 16 to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality
7	All those 60 years of age and over
8	All those 55 years of age and over
9	All those 50 years of age and over

217. The JCVI's advice was established using mathematical modelling, which was based upon evidence which firmly indicated that, because age was so strongly associated with COVID-19 mortality, offering vaccination to older age groups first was the optimal strategy for both minimising future deaths and minimising quality adjusted life year losses.

218. On 30 December 2020, the Government published a statement setting out that the UK's four CMOs welcomed the approval of the Oxford/AstraZeneca vaccine and that they supported the JCVI's advice to prioritise delivering first vaccine doses to as many people

on the Phase 1 priority list in the shortest possible timeframe **(CS6/137 - INQ000059403)**. Further detail is set out at paragraph 211.

219. On 9 February 2021, the Department advised ministers on the proposed method of implementation for COVID-19 vaccination for Cohort 6, including the definition of unpaid carers, who were also included in Cohort 6, and settings of multiple occupancy **(CS6/145 INQ000059858)** The Secretary of State approved this submission on 11 February 2021 **(CS6/146 – INQ000401337)**.

220. On 24 March 2021 the Department advised ministers to accept the JCVI advice **(CS6/147 - INQ000060481)** about vaccination of household contacts of severely immunosuppressed individuals and for this group to be given the same prioritisation as Cohort 6 **(CS6/148 - INQ000060458)**. The Secretary of State approved this approach on 25 March 2021 **(CS6/149 - INQ000060476)**.

221. On the 24 August 2021, the JCVI produced draft advice on providing a third primary dose of a COVID-19 vaccine to persons who are immunosuppressed **(CS6/150 - INQ000066760)**. On 27 August 2021, the Secretary of State received this advice, alongside advice from the Department **(CS6/151 - INQ000401373)**, and on 28 August 2021 he agreed to offer a third primary dose to those with severe immunosuppression at or around the time of their first or second primary dose of COVID-19 vaccination **(CS6/152 - INQ000401375)**.

222. The Government ensured that HMG staff overseas and military personnel also received the vaccine. Due to operational reasons (including avoiding vaccine wastage) in limited circumstances this was done outside the JCVI Phase 1 prioritisation advice **(CS6/153 - INQ000111482)**. Ministers approved limited exceptions to Phase 1 prioritisation, including for critical vaccine supply chain workers **(CS6/154 - INQ000110365)** and MHRA batch testers **(CS6/155 - INQ000111153)**.

223. On 19 February 2021 a submission was sent to the Minister for COVID Vaccine Deployment on vaccinating HMG staff living overseas **(CS6/153 – INQ000111482)**. It was agreed by the Minister on 24 February 2021 **(CS6/156 - INQ000060092)**. A further submission was sent for information on 24 June 2021 updating on progress **(CS6/157 - INQ000111480)**. On 21 October 2021 a submission was sent for information to the Minister for Vaccines and Public Health and Secretary of State on the topic of second doses of vaccines for child dependents of HMG staff overseas **(CS6/158 -**

INQ000111918). It was acknowledged without comment on 1 November 2021 **(CS6/159 - INQ000067353)**.

Phase 2

224. The advice that was sent to Secretary of State to inform his decision on 30 November 2020 for a two-phase approach to prioritisation (as set out in paragraph 199) of vaccine deployment set out that the prioritisation of Phase 2, the wider population (those less at risk of serious illness and death) would be based on:

a. data which emerged from Phase 1.

b. the current national epidemiological position, and

c. the availability of a potentially expanded range of vaccines at that time. **(CS6/124 - INQ000234199)**.

225. A submission dated 22 January 2021 was sent to the Secretary of State and Minister for COVID Vaccine Deployment noted that prioritisation decision-making for Phase 2 of the vaccination programme was more complex, because of various unknowns including the impact of the vaccine on transmissions, duration of immunity, level of uptake (particularly by disproportionately impacted groups) and efficacy against novel strains **(CS6/160 - INQ000401329).** The Secretary of State agreed the approach to resolving decisions about prioritisation suggested in this submission on the same day **(CS6/161 - INQ000401330)**. The Minister for COVID Vaccine Deployment also agreed the submission **(CS6/162 - INQ000401331).** In particular, the submission suggested seeking:

a. Clinical, scientific, epidemiological and public health advice from the JCVI.

b. Modelling advice from Scientific Pandemic Influenza Group on Modelling, Operational sub-group (SPI-M-O).

c. Advice on operational considerations, including pace of roll-out, supply trajectory, identification and verification of cohorts and the interaction between Phase 1 and Phase 2 from NHSE.

d. Policy advice on prioritising certain groups from across government to be led by the CO; and

e. Advice on ethical considerations from MEAG.

226. On 28 January 2021, the Secretary of State attended a Small Ministerial Group (SMG) meeting with the Chancellor and the Minister for COVID Vaccine Deployment to discuss Phase 2 prioritisation. The ministers agreed the approach to Phase 2 should align with the overarching priority of further reducing mortality, morbidity and hospitalisations, which would protect the NHS and also support reopening the economy. Ministers agreed to take advice from the JCVI on the best strategy for achieving this and noted that the JCVI may advise continued prioritisation based on age to reduce hospitalisation which they would support. A note of this meeting was sent to the PM **(CS6/163 - INQ000401333)**. The PM agreed with the recommendation of the SMG and asked that the JCVI provide their recommendation on how to prioritise vaccines to further reduce mortality and morbidity in Phase 2, and took the view that any political decisions should be secondary to this, and only considered if the JCVI were unable to make a recommendation which reduces mortality and morbidity **(CS6/164 - INQ000401332)**.

227. At a COVID-(O) meeting on 9 February 2021 **(CS6/165 - INQ000091773)**, ministers agreed that the Government's priority for Phase 2 of the deployment programme should be to further reduce mortality, morbidity and hospitalisations and to seek advice from the JCVI on how best to achieve this objective.

228. On 26 February 2021, the JCVI published interim advice which recommended an age-based approach to Phase 2 prioritisation. COVID-(O) met on this day and agreed with the JCVI interim advice "*that under 50s should be prioritised for vaccination through an age based approach to best meet the Government's objective to reduce mortality, morbidity and hospitalisation as quickly as possible*," and that when the JCVI interim advice is published, the Government should welcome the advice and accept it in principle and subject to final advice the following month **(CS6/166 - INQ000092368)**.

229. On 3 March 2021 Department officials set out the interim JCVI advice, which had already been published and was circulated to MEAG members. The Group discussed and MEAG members supported the interim advice approach and MEAG agreed an age-based approach to prioritisation **(CS6/60 – INQ000401396)**.

230. The JCVI provided final advice for Phase 2 Deployment to ministers on 12 April 2021 **(CS6/167 - INQ000399280; CS6/168 - INQ000111699; CS6/169 - INQ000111700)**. The submission enclosing that advice to ministers explained:

a. *"In line with the interim advice, the JCVI has recommended an age-based approach with adults aged 18-49 prioritised in descending age order as follows:*

- *All those aged 40-49 years*
- *All those aged 30-39 years*
- *All those aged 18-29 years.*

b. *This age-based approach is based on strong evidence that hospitalisations and risk of critical care admissions increase with age, including for individuals who are under 50 years of age. Mathematical modelling of vaccination strategies indicate that rapid vaccine deployment is the most important means to maximise public health benefits against severe outcomes from COVID-19."*

231. Therefore, priority groups 10 to 12, for Phase 2 of the prioritisation were:

Priority	**Risk group**
10	All those aged 40-49 years
11	All those aged 30-39 years
12	All those aged 18-29 years

232. The JCVI advice on Phase 2 prioritisation considered the Scientific Pandemic Insights Group on Behaviours (SPI-B) rapid evidence analysis on variation in vaccine uptake by socio-demographic factors **(CS6/170 - INQ000111706)**.

233. All four devolved administrations of the UK agreed to follow the JCVI's recommended approach to Phase 2 **(CS6/171 - INQ000399462)**.

Data and Parameters

234. I am asked about the data and parameters used to determine prioritisation. Paragraph 75 in section 1 of this statement sets out the data that MHRA and the CHM considers in order to authorise a vaccine.

235. The JCVI secretariat is best placed to answer this in detail. As evidence about the epidemiology of COVID-19 and the impact and efficacy of the vaccine was still emerging, the JCVI's considerations were guided substantively by evidence from external academic groups (including the NIHR-funded study QCOVID) and on modelling from the University of Warwick associated with the JCVI and SPI-M-O overseen by the Scientific Advisory Group for Emergencies (SAGE). Data from PHE on sero-epidemiology was provided directly to external academic groups to inform their modelling and analysis.

Supply, Logistical Considerations & Practicalities

236. I am asked if supply and logistical issues had any effect on prioritisation decisions. There was understandable concern about the effect of constrained supply for the vaccination programme particularly in its early deployment, and the impact this might have on prioritisation. The issues involved were considered by PHE/UKHSA and the JCVI and included in formal advice to ministers and often in the daily ministerial calls. The JCVI had regular engagement with the VTF and NHSE so they could factor supply and deployment considerations into their advice to make sure it was practically applicable.

237. For example, a paper from Dr Mary Ramsay, Head of Immunisation at PHE, was sent to the Secretary of State on the 15 October 2020. The paper considered vaccination strategies to reduce reliance on non-pharmaceutical interventions and limiting adverse economic and unintended health consequences particularly in the start of the programme when vaccine supply would be constrained (**CS6/172 - INQ000071148; CS6/173 - INQ000489925; CS6/174 - INQ000489926)**. The paper was considered by a JCVI working group set up specifically to consider the issue but did not constitute formal JCVI advice. Two options were considered:

a. targeting high-risk groups for COVID-19 related morbidity and mortality (the approach of the JCVI); and

b. targeting economically active people who are at lower risk of severe disease but play an important role in driving transmission.

238. The paper concluded that in constrained vaccine supply, particularly at the start of the programme, option b "*risks a large number of preventable deaths, unless very stringent NPIs and/or shielding of the vulnerable is in place*". The paper noted that option b might be more challenging to implement, might have lower uptake, and could raise ethical concerns.

239. The Chair of the JCVI for COVID-19 reviewed the paper and commented within it. The Chair was of the view that the current strategy (option a - which prioritised those at highest individual risk), would have the highest impact on mortality and was the preferred strategy, particularly given the constraint on vaccine supply at the start of the programme. His view was that this strategy was preferable from both a clinical perspective, in relation to the aversion of morbidity and mortality, and ethical and economic perspectives.

240. On the 20 October 2020, the Secretary of State met with officials to discuss the paper. The Secretary of State agreed with the JCVI clinical priority groups, but then to expand to all low-risk citizens aged 18 and above **(CS6/175 - INQ000489927).**

241. In the event, due to the whole of government approach, the programme was able to proceed at a very fast pace, using the very substantial supply of millions of doses in the first few months and then ongoing for each roll-out. Hundreds of thousands of vaccines were delivered daily at peak times of the deployment campaign, and the roll-out covered the entire eligible population in just over seven months. This was the result of very substantial work and resourcing in effective development and manufacturing, secured supply through the VTF portfolio of vaccines, close monitoring of stocks, limitation of wastage and so on; and on the deployment side in increasing the workforce, using volunteers, establishing multiple vaccine sites, new call and recall systems, and public support.

242. The success of this roll-out in a time of globally limited supply was a substantial achievement and meant that concerns about supply constraints were minimised as the programme was delivered. The development of a range of effective vaccines within a year of emergence of COVID-19 could not necessarily be replicated with other pathogens; indeed, the HIV pandemic began over 40 years ago and there is still no vaccine. The

Technical Report includes this issue as a point of learning for the future **(CS6/3 - INQ000177534)**.

243. NHSE were responsible for the design of operational delivery models, operational plan for delivery, commissioning of estates, equipment and consumables, training, commissioning, training and deployment of workforce, and are best placed to comment on specific practical issues and lessons to be learned. NHSE implemented the JCVI's prioritisation programme according to four main principles:

a. Following the JCVI priority sequence to the extent possible.

b. Only deploying vaccine through delivery channels that assure patient safety and vaccine integrity.

c. Operational feasibility; and

d. Minimising wastage of precious vaccine.

244. The logistical considerations involved in vaccine deployment were substantial, for example, the Pfizer/BioNTech vaccine had complex storage and distribution needs; it had to be stored long-term at -70oC, was supplied in multi-dose vials, required dilution prior to use and had limited shelf life post thawing and post-dilution. These complexities were recognised in the JCVI advice **(CS6/125 – INQ000234198)**.

245. Supply considerations did inform decisions about dosage intervals, see paragraphs 276 to 279 below.

Safeguards for Prisoners

246. A risk register produced by PHE identified that there was a very high risk that the prison population may be overlooked in terms of risk and priority for vaccination **(CS6/176 - INQ000401293)**. A concern it recorded therein was that the epidemiology alone of that group may not be reflective of their vulnerability. This was because the detained population is much more vulnerable due to underlying co-morbidities and prisons are a setting for potential outbreaks. As a result of this risk being identified, it was noted as an action that the JCVI should consider all evidence on risk in relation to the prison population.

247. Annex A to the JCVI advice on priority groups for vaccination which was published on 30 December 2020 explained that **(CS6/177 - INQ000256951)**:

> *"Monitoring of vaccine coverage of most routine immunisation programmes relies on data extracted from primary care systems. If there are specific inclusion health or vulnerable groups that are not flagged in information systems (such as rough sleepers or vulnerable migrants), this will limit our ability to identify and address inequalities in vaccine uptake. PHE's national immunisation equity audit (2019) illustrated this point: while the audit identified inequalities in uptake by age, geography, socioeconomic status, ethnicity, religion, disability and health status, travellers, migrants,* ***prisoners****, and parental factors (lone parents, large families, parental age)..."* (emphasis added)

248. The JCVI advice went onto explain that it had developed a socio-ecological model of factors influencing inequalities in vaccination uptake (which was set out at Figure 1 of that advice) which was based on the 2019 audit. That model provided a framework for actions to mitigate inequalities that could be applied to the COVID-19 immunisation programme.

249. Ultimately, prisoners went on to be safeguarded in the same way as the rest of the population because prioritisation was done on the basis of clinical need, as was advised by the JCVI.

Children

250. Decisions in relation to the vaccination of children, defined as those under the age of 18 for the purposes of this statement, were taken in the same way as other vaccine roll-out/prioritisation decisions set out above under the heading "Decision-making and Accountability". The JCVI considered the emerging clinical and epidemiological data and provided advice. Ministers took decisions in relation to the vaccination of children with the benefit of this advice, in addition to submissions which also set out impact statements and wider policy considerations. An additional consideration in relation to the vaccination of children was the timing of regulatory approval. Vaccine regulatory approvals are only made for the population which a vaccine has been tested on, and so the MHRA's regulatory approval for use of a COVID-19 vaccine on children could not happen until data concerning the use of the vaccine on children had become available.

251. The JCVI's final advice on Phase 1 prioritisation, dated 30 December 2020 recommended prioritising those designated as CEV and those aged 16-64 with conditions that put them at increased clinical risk from COVID-19, as well as those under 16 who were at very high risk of exposure and serious outcomes, such as older children with severe neuro-disabilities that required residential care, with a note that "*clinicians should discuss the risks and benefits of vaccination with a person with parental responsibility, who should be told about the paucity of safety data for the vaccine in children aged under 16 years.*" **(CS6/178 - INQ000354469; CS6/177- INQ000256951)**.

252. Prior to August 2021 children were only offered a COVID-19 (off-label) vaccination where they were:

a. Aged 16+ and were at an increased clinical risk from COVID-19.

b. Aged 16+ and in receipt of a carer's allowance, or the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill.

c. Aged 16+ and a frontline health or social care worker; and

d. Under 16 and at a very high risk of exposure and serious outcomes from COVID-19. This would be classed as 'off label' use.

253. On 5 March 2021, officials wrote to the JCVI, on behalf of the Secretary of State, to request advice on planning considerations for potential population COVID-19 revaccination. The request included a question on the consideration of vaccination (and revaccination) of under 18s **(CS6/179 - INQ000060155)**. On 26 May 2021, following the letter of 5 March, the Secretary of State wrote to the JCVI to formally request advice on the vaccination of children and young people **(CS6/180 - INQ000061025)**. On 9 June 2021, the Secretary of State met with the Secretary of State for Education to discuss the clinical and policy advice on vaccinating children as well as operational considerations (subject to the contents of the JCVI advice which was still awaited at that stage) **(CS6/181 - INQ000401350)**. On 23 June 2021, the Secretary of State sent a further letter to the JCVI to request the committee's advice on (among other matters) how the children's vaccination programme should be designed to minimise both the COVID-19 case rate, and the chance of new variants emerging, in addition to minimising mortality, morbidity and hospitalisations **(CS6/182 - INQ000061182)**. The JCVI developed initial advice on deployment of COVID-19 vaccination to children and young people aged 12 – 17 years on 2 July 2021, which

was sent to the Secretary of State on the 5 July 2021 **(CS6/183 - INQ000309444).** This was discussed in a meeting which took place on 6 July 2021 (**CS6/184 - INQ000401357; CS6/185 - INQ000501431)**. On 8 July 2021, a submission was sent to the Secretary of State asking him to accept the JCVI's advice **(CS6/186 - INQ000309448)**. The Secretary of State accepted this advice on 12 July 2021 **(CS6/187 - INQ000401359)**. The JCVI advice was then published on 19 July 2021. Within this interim advice, the JCVI advised the following (Please note that below is a summary of JCVI, for comprehensive understanding the JCVI advice should be read in full, which is exhibited below):

a. Children and young people aged 12 years and over with specific underlying health conditions that put them at risk of serious COVID-19, should be offered the COVID-19 vaccination.

b. Children 12 to 15 years of age with severe neuro-disabilities, Down's Syndrome, underlying conditions resulting in immunosuppression, and those with profound and multiple learning disabilities, severe learning disabilities or who are on the learning disability register are considered at increased risk for serious COVID-19 disease and should be offered COVID-19 vaccination.

c. Young people aged 16 to 17 years of age who are at higher risk of serious COVID-19, as currently set out in the Green Book, should continue to be offered COVID-19 vaccination.

d. Children and young people aged 12 years and over who are household contacts of persons (adults or children) who are immunosuppressed should be offered COVID-19 vaccination on the understanding that the main benefits from vaccination are related to the potential for indirect protection of their household contact who is immunosuppressed.

e. Until more data become available, the JCVI did not advise routine universal vaccination of children and young people less than 18 years of age. The JCVI noted that it would keep this advice under review as more safety and effectiveness information become available on the use of COVID-19 vaccines in children and young people **(CS6/188 - INQ000354522)**.

254. On 29 July 2021, the JCVI considered again the potential harms and benefits of vaccinating children aged 12-17 years old, taking into account the latest available data

relating to children and young people **(CS6/189 - INQ000354527)**. On 3 August 2021, the JCVI advised that:

a. All 16–17-year-olds should be offered a first dose of Pfizer/BioNTech vaccine. This was in addition to the existing offer of two doses of vaccine to 16–17-year-olds from phase one who are in 'at-risk' groups.

b. No change was made in respect of 12–15-year-olds; and

c. Children and young people aged 12 years and over who are household contacts of persons who are immunosuppressed should be offered two doses of Pfizer/BioNTech vaccine **(CS6/190 - INQ000235154; CS6/191 - INQ000401363).**

255. On 3 August 2021, a submission was sent to the Secretary of State to seek his agreement to the JCVI's advice **(CS6/192 - INQ000111662).** On 4 August 2021, the Secretary of State accepted the JCVI's advice and the JCVI's advice was published **(CS6/190 - INQ000235154; CS6/193 - INQ000401362; CS6/194 - INQ000401364).** The roll-out for non-at-risk 16- to 17-year-olds began the following day, on 5 August 2021. By 23 August 2021 the Government met its target of offering a first dose of the Pfizer/BioNTech vaccine to all 16- to 17-year-olds in England **(CS6/195 - INQ000401366; CS6/196 - INQ000257007).**

256. On 31 August 2021, the JCVI provided advice on the vaccination of children aged 12-15 years with underlying health conditions. It recommended that the offer of COVID-19 vaccination should be expanded to include children aged 12-15-years-old with haematological malignancy, sickle cell disease, type 1 diabetes, congenital heart disease and other specified health conditions **(CS6/197 - INQ000401380).** On 3 September 2021, a submission was sent to the Secretary of State which advised him to accept the JCVI's advice, which he did later the same day **(CS6/198 - INQ000401379; CS6/199 - INQ000401381).**

257. On 2 September 2021, the JCVI advised the Government that the benefits of offering COVID-19 vaccination to all 12–15-year-olds marginally outweighed the potential harms, but that benefit was considered too small to support advice on a universal programme of vaccination of otherwise healthy 12-15-year-olds. **(CS6/200 - INQ000066868).** The JCVI advised the Government that it may wish to seek further views on the wider societal and

educational impacts from the four UK CMOs, with representation from JCVI in these subsequent discussions. A submission was sent to the Secretary of State the same day advising him to accept the JCVI's advice in this regard **(CS6/201 - INQ000401378).** Later the same day, the Secretary of State accepted the JCVI's advice suggesting that the UK CMOs should be consulted **(CS6/199 - INQ000401381).** On 3 September 2021, the JCVI's advice in this regard was published **(CS6/202 - INQ000361215).**

258. On 13 September 2021, the UK CMOs provided the advice that had been requested on 2 September 2021 **(CS6/203 - INQ000066869).** The CMOs advised that on an individual level, the view of the MHRA, the JCVI and international regulators was that there was a marginal advantage to someone aged 12-15 of being vaccinated over being unvaccinated. In addition, the UK CMOs considered that the additional likely benefits of reducing educational disruption, on balance, provided sufficient extra advantage in addition to the marginal advantage at an individual level. Accordingly, the UK CMOs recommended on public health grounds that ministers extend the offer of universal vaccination with a first dose of Pfizer/BioNTech COVID-19 vaccine to all children and young people aged 12-15 not already covered by existing JCVI advice. The same day, a submission was sent to the Secretary of State and he accepted the CMOs advice which was published the same day **(CS6/204 - INQ000066867; CS6/205 - INQ000066872; CS6/206 - INQ000066873; CS6/207 - INQ000066875; CS6/208 - INQ000257036; CS6/209 - INQ000489950; CS6/**210 **- INQ000401384).**

259. On the 8 November 2021, JCVI updated its advice on the vaccination of young people aged 16-17 years who are not in an at-risk group. A submission was sent to the Secretary of State which recommended that he accepted the JCVI's advice **(CS6/211 - INQ000111950)**. This advice was accepted by the Secretary of State on 11 November 2021 **(CS6/212 - INQ000067401).** On 15 November 2021, JCVI published advice that young people aged 16-17 years should be offered a second dose of Pfizer/BioNTech COVID-19 vaccine. This was accompanied by the publication of a ministerial statement **(CS6/213 - INQ000354546; CS6/214 - INQ000401390).**

260. On 12 November 2021, a letter was sent by the Secretary of State to the chair of the JCVI requesting initial the JCVI's advice on primary COVID-19 vaccination of children under 12 **(CS6/215 - INQ000067404).**

261. On 15 November 2021, the Green Book was updated to reflect precautionary advice that the four-week period between natural infection and COVID-19 vaccination should be

extended to 12 weeks in those aged under 18 who are not at high risk, to further reduce the already very small risk of side effects including extremely rare but more concerning ones such as myocarditis (inflammation of the heart muscle) **(CS6/213 - INQ000354546; CS6/216 - INQ000257105).**

262. On 28 November 2021, a submission was sent to the Secretary of State the Secretary of State advising that second doses should be offered to all 12-15-year-olds (amongst other matters) **(CS6/217 - INQ000401391)**. On 29 November 2021, the Secretary of State accepted this advice, and on the same day the JCVI published its advice (**CS6/218 - INQ000067522; CS6/219 - INQ000257124)**. The following day a ministerial statement was published to announce the change (**CS6/220 - INQ000257141)**.

263. On 16 December 2021, a submission was sent to the Secretary of State which advised that he accept the JCVI's recommendation to offer COVID-19 vaccination to at risk 5–11-year-olds and household contacts of individuals of any age who are immunosuppressed and accept the recommendation that a COVID-19 booster vaccine be offered to:

a. All young people aged 16-17.

b. Children aged 12-15 who are in a high-risk group or who are a household contact of someone who is immunosuppressed; and

c. Children and young people aged 12-15 who are severely immunosuppressed and who have had a third primary dose **(CS6/221 - INQ000401392; CS6/222 - INQ000309498; CS6/223 - INQ000489951)**.

264. On the 22 December 2021 the JCVI published advice on COVID-19 vaccination of children and young people **(CS6/224 - INQ000257219)**

265. In January 2022, NHS began its booster rollout to at-risk 12–15-year-olds and the roll-out began for 5–11-year-olds in a clinical risk group, or who were a household contact of someone who is immunosuppressed **(CS6/225 - INQ000257265).**

266. In early 2022, the JCVI reviewed evidence on the potential impact of extending the COVID-19 vaccination programme to children aged 5-11 who were not in a clinical risk group. On 10 February 2022, a submission was sent to the Secretary of State which advised him to accept the JCVI's advice to offer a COVID-19 vaccine to children aged 5-

11-years-old **(CS6/226 - INQ000112227; CS6/227 - INQ000112226).** A statement was published by the JCVI on 16 February **(CS6/228 - INQ000257288)** which demonstrated that consideration was given to the health benefits and harms of vaccination in the 5-11 age group, the potential benefits for their continued education, and the impact on NHS services of delivering a two-dose vaccination programme to around 5 million young children. The JCVI considered safety data from the MHRA and international surveillance systems, including from the United States, where millions of doses had been administered to children aged 5-11-years-old. The key considerations in the advice to extend the programme to 5-11-year-olds who were not in a clinical risk were outlined in the 10 February 2022 advice. The JCVI advice should be read in full to give a complete and proper understanding of its advice. I do, however, provide a summary below of the main points, but this should not be taken to replace a reading of the full advice. In summary, the advice noted:

a. Children aged 5-11 who were not in a COVID-19 clinical risk group were at low risk of developing severe COVID symptoms. Most children in this cohort who were infected had asymptomatic or mild disease. Among those admitted to hospital at the end of the Omicron wave, the average length of stay was 1-2 days, and a proportion of those admissions were precautionary.

b. Natural immunity would contribute towards protection. It was estimated that over 85% of all children aged 5-11 would have had prior infection by the end of January 2022.

c. Vaccination of this age group (other than those in a Covid clinical risk group) was anticipated to prevent a small number of hospitalisations and intensive care admissions and provide short-term protection against non-severe infection. However, the extent of these impacts was highly uncertain.

d. Overall, the potential health benefits of vaccination were greater than the potential health risks, including the commonly associated systemic and local reactions. The impact on school absences was indeterminate.

e. It was also noted that vaccination of this age group (other than those in a Covid clinical risk group) was not expected to have an impact on the wave of infection (Omicron variant) that was current at the time of the advice. Potential benefits

would apply mainly to a future wave, with greater benefits likely to be associated with a more severe wave **(CS6/228 – INQ000257288).**

267. In formulating the advice for 5-11-year-olds, the JCVI considered evidence on:

a. Potential direct health benefits and harms (the latter includes both the common and rare side effects of vaccination).

b. Indirect educational impacts of vaccination; and

c. Wider anticipated opportunity costs **(CS6/228 – INQ000257288).**

268. A detailed business case for offering the COVID-19 vaccination to children aged 5-11 years was produced in March 2022. This document demonstrates the strategic economic, commercial, financial and management factors that were considered in the making of the decision to offer the COVID-19 vaccines to all children aged 5-11 in the UK. In particular, it noted the following key benefits of vaccinating children aged 5-11:

a. Reduced paediatric intensive care admissions, hospital admissions and paediatric multisystem syndrome cases temporarily associated with COVID-19.

b. Reduced COVID-19 impact and infections for contacts of children aged 5-11 years, particularly household contacts who are immunosuppressed and most at risk.

c. Reduced educational disruption of children having to miss school; and

d. Reduced anxiety in the vaccinated population and their loved ones.

269. In early April 2022, a universal roll-out which offered COVID-19 vaccines to children aged 5-11 began across the UK **(CS6/229 - INQ000420554).**

Dosage intervals

270. Decisions on dosage intervals were taken following a detailed consideration of the JCVI advice and the conditions stipulated by the MHRA. The JCVI's role was to consider

how any vaccine programme could best be delivered so as to minimise the loss of life and protect the health and social care system There was frequent ongoing contact between the JCVI and the Department. The advice provided by the JCVI included the dosage intervals to be used for vaccinations.

271. On 2 December 2020, the JCVI advised that the Pfizer/BioNTech vaccine was to be used in the first phase of the vaccination programme and recommended that "*While there is some evidence to indicate high levels of short-term protection from a single dose of vaccine, a two-dose vaccine schedule is currently advised in accordance with regulatory approval.*" **(CS6/230 - INQ000234638).** The initial dosage interval for the Pfizer/BioNTech vaccine was at least 21 days **(CS6/231 - INQ000399478).**

272. On 30 December 2020, the MHRA authorised the Oxford/AstraZeneca vaccine for deployment across the UK. The authorisation included conditions that it should be administered in two doses with the second dose given 4 to 12 weeks after the first. The MHRA also clarified that for the Pfizer/BioNTech vaccine, the interval between doses must be at least three weeks. For both vaccines, data provided to the MHRA demonstrated that while efficacy was optimised when a second dose was delivered, both vaccines offered considerable protection after a single dose, at least in the short term, and the second dose completed the course and was likely to be important for longer term protection **(CS6/232 - INQ000203969).**

273. Given the fact that the data indicated high efficacy from the first dose of both Pfizer/BioNTech and Oxford/AstraZeneca vaccines, on the same day the JCVI advised that delivery of the first dose to as many eligible individuals as possible should be initially prioritised over delivery of a second vaccine dose in order to maximise the short-term impact of the programme **(CS6/178 - INQ000354469).** In addition, they advised that the second dose of the Pfizer/BioNTech vaccine may be given between 3 to 12 weeks following the first dose, and that the second dose of Oxford/AstraZeneca may be given between 4 to 12 weeks following the first dose **(CS6/233 - INQ000059402)**

274. A statement from the UKs CMOs, also on 30 December 2020 **(CS6/234 - INQ000059399**; **CS6/137 - INQ000059403; CS6/235 - INQ000401323)**, stated that:

a. *"The 4 UK Chief Medical Officers agree with the JCVI that at this stage of the pandemic prioritising the first doses of vaccine for as many people as possible on the priority list will protect the greatest number of at-risk people overall in the*

shortest possible time and will have the greatest impact on reducing mortality, severe disease and hospitalisations and in protecting the NHS and equivalent health services. Operationally this will mean that second doses of both vaccines will be administered towards the end of the recommended vaccine dosing schedule of 12 weeks. This will maximise the number of people getting vaccine and therefore receiving protection in the next 12 weeks.

b. *Based on JCVI's expert advice, it is our joint clinical advice that delivery plans should prioritise delivering first vaccine doses to as many people on the JCVI Phase 1 priority list in the shortest possible timeframe. This will allow the administration of second doses to be completed over the longer timeframes in line with conditions set out by the independent regulator, the MHRA and advice from the JCVI. This will maximise the impact of the vaccine programme in its primary aims of reducing mortality and hospitalisations and protecting the NHS and equivalent health services."* **(CS6/236 - INQ000399450).**

275. On 6 January 2021, the JCVI published further advice which advised prioritising first doses, with a maximum interval of 12 weeks between first and subsequent doses **(CS6/178 - INQ000354469)** in order to maximise the impact of the vaccination programme in response to the Alpha variant. This advice was accepted and from 30 December 2020 to May 2021, the recommended dose interval for all age groups in England was 12 weeks **(CS6/237 - INQ000401354).**

276. The JCVI advised on 14 May 2021 that "*Where vaccine supply allows, particularly in areas where B1.617.2* [the Delta variant] *is a major threat, the second dose of vaccine should be brought forward from 12 to 8 weeks. This is only possible because everyone in the Phase 1 priority groups has already been offered a first dose"* **(CS6/238 - INQ000354509).** On 14 May 2021, the Prime Minister announced that: *"following advice from the Joint Committee on Vaccination and Immunisation, we will accelerate remaining second doses to the over 50s and those clinically vulnerable right across the country so they are just eight weeks after the first dose"* **(CS6/239 - INQ000075759).**

277. On 13 June 2021, the JCVI were asked to urgently consider how to most effectively use vaccination as part of the wider response to the increase in the Delta variant (B1.617.2). The committee held an extraordinary meeting on the same day which recommended:

a. All efforts should be made to accelerate and promote vaccine uptake (first dose) in those who remained unvaccinated within priority cohorts 1 to 9.

b. For those waiting their second dose of any authorised COVID-19 vaccine, in any priority cohort, should be brought forward from 12 weeks to 8 weeks, where vaccine supply permits, and with priority, if supply limits this being done nationally, given to those areas where B1.617.2. is of highest threat.

c. The speed of continued roll out of the vaccine programme should be as fast as possible, including through maximising the capacity of vaccination centres and finally,

d. JCVI concluded that if the risk and threat from this variant is justified (and if the scale is communicated to the public), AstraZeneca vaccine should be offered to those 30 – 39 years of age, where necessary, if this speeds up vaccination and does not harm uptake. They concluded this would be within the scope of the previous JCVI advice of a vaccine preference in this age group having been conditional on adequate control of COVID-19 infection in the UK **(CS6/240 - INQ000340229).**

278. A submission went to ministers on the 14 May 2021 recommending that they implement JCVI advice and note the operational implications for deployment and agree the proposed communication handling **(CS6/241 - INQ000111171)**. The Secretary of State confirmed he was content on the same day and the Government announced that second doses for all over 40s would be accelerated by reducing the dosing interval from 12 weeks to 8 weeks **(CS6/242 - INQ000060933; CS6/243 - INQ000234938; CS6/237 - INQ000401354).**

279. On 2 July 2021, a note was sent to the Secretary of State and the Minister for COVID-19 Vaccine Deployment setting out options for shortening the vaccine dose interval **(CS6/244 - INQ000401353).** It recommended, based on clinical advice from the JCVI and the DCMO (Jonathan Van-Tam) and operational input from NHSE and supply input from VTF, that the Government should reduce the dose interval to 8 weeks and no lower for all age groups and all vaccine brands **(CS6/237 - INQ000401354).** The Secretary of State agreed with this recommendation the following day **(CS6/245 - INQ000401356).** On 5 July 2021, the Government announced that appointments for a second dose of the COVID-19 vaccine should be brought forward from 12 to 8 weeks for the remaining people in all

cohorts who have yet to receive their second dose. This was to ensure everyone has the strongest possible protection from the Delta variant of the virus at the earliest opportunity possible.

280. In addition, the Green Book guidelines for COVID-19 vaccine dosing intervals were updated on 1 July 2021 by UKHSA, in line with the latest JCVI guidance. The guidelines stated:

> *"For both adenovirus vector and mRNA vaccines, there is evidence of better immune response and/or protection where longer intervals between doses are used.*
>
> *Currently, JCVI is recommending an interval of eight to 12 weeks between doses of all the available COVID-19 vaccines. Operationally, this consistent interval should be used for all two dose vaccines to avoid confusion and simplify booking and will help to ensure a good balance between achieving rapid and long-lasting protection.*
>
> *The main exception to the eight-week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the minimal intervals outlined below may be followed to ensure that the vaccine is given while their immune system is better able to respond."* **(CS6/246 - INQ000489949).**

SECTION 4: VACCINE DEPLOYMENT

281. Following on from the description of vaccine development and decision-making on prioritisation of vaccine uptake, this section provides an overview of decision making on how vaccines would be deployed. This includes a description of plans for vaccine update and their implementation, as well as engagement with devolved administrations on deployment.

Decision Making and Accountability

282. The Secretary of State took decisions on vaccine deployment in England, based on advice from departmental officials and with essential input from PHE/UKHSA, NHSE and the VTF. The VTF was responsible for supply chain management and PHE/UKHSA was responsible for receipt of vaccine and some consumables to central store and for delivery to deployment organisations in England and the devolved administrations, the CTs and

OTs (the latter with the FCDO). Vaccine deployment was a devolved responsibility for the devolved administration.

283. BEIS/VTF worked closely with the Department, PHE/UKHSA, NHSE and the devolved administrations within the deployment programme, providing information in support of planning assumptions, managing risk affecting supply and monitoring risk associated with deployment.

284. The Secretary of State appointed a SRO for Vaccine Deployment throughout the period covered in this statement, responsible for areas including data infrastructure, access & equity, uptake, clinical oversight of the deployment programme, operational guidance, and the vaccine supply chain. The SROs were as follows:

a. Neil Permain, Director of NHS Operations and Delivery, and Ruth Todd, Programme Director, VTF, were joint SROs from March 2020 to October 2020.

b. Dame Emily Lawson, SRO for COVID-19 Vaccine Deployment, from November 2020 to July 2021 and October 2021 to March 2022.

c. Professor Keith Willett, SRO Vaccination Programme, from July 2021 to October 2021.

d. Steve Russell, SRO for COVID-19 Vaccine Deployment, from March 2022 to present.

285. Planning for vaccine deployment began at a very early stage, and DHSC officials were involved in planning as governance arrangement evolved as we moved closer to deployment of a vaccine.

Early Planning for Deployment

286. As soon as vaccines started to be developed in early 2020, the Department led planning towards the deployment of a potentially successful vaccine candidate. Meetings were rapidly stood up with all those required across the health sector to determine a critical path, such as MHRA, PHE and NHSE. Strong relationships and collaborative working led to an underlying principle that all would keep to their normal ways of working and expertise as much as possible, albeit scaled up for a mass vaccination.

287. On 19 June 2020 the Secretary of State and the Business Secretary held a 'deep dive' review of COVID-19 vaccine deployment. In a briefing for the Secretary of State, the Department advised that a range of considerations were being made to prepare for mass vaccination, including:

a. *"Workforce and training: given that routine vaccination programmes need to continue, including for flu, additional workforce may be required to support mass vaccination. This may include non-traditional immunisers. Any necessary changes to legislation and training needs are being considered.*

b. *Equipment and consumables: advanced purchase ahead of global demand.*

c. *Estates: Delivery models expanding those in place for flu, with potential use of Nightingale hospitals, drive-throughs being considered.*

d. *Call/recall and data capture: We will need expanded call/recall system and new data capture procedures for surveillance, monitoring disease, collect coverage data, vaccine safety and any associated adverse events.*

e. *Supporting infrastructure: including warehousing, transport, logistics, security, cold chain and end-destination 'clinic' storage.*

f. *Legal requirements: bringing forward MHRA's licensing powers, workforce.*

g. *Security: of vaccine, personnel and vaccination centres."* **(CS6/247 - INQ000401286).**

288. The Department advised on the legislative changes which facilitated innovations in vaccine development and deployment described at paragraph 175 to 179 above.

289. Beginning in July 2020, I chaired a Deployment Programme Board, which reviewed reporting of ongoing work and oversaw and managed ongoing risks and issues in preparation for a vaccine deployment programme, if a vaccine was approved **(CS6/248 - INQ000401298)**. After the initial establishment of the Board, and as it became clearer that

a vaccine was likely, a new Deployment Programme Board moved to being chaired by the SROs for deployment, with representation from the Department.

290. The COVID-19 & Flu Vaccine and Deployment Delivery Group was a working group chaired by NHSE that came together twice weekly to design solutions and collectively resolve problems.

291. In September 2020, the Secretary of State revised the governance for vaccine deployment activities and appointed a single SRO (listed above in paragraph 284) in NHSE for deployment.

292. On 10 November 2020, the Secretary of State announced in the House of Commons that he had tasked the NHS to prepare and be ready for a vaccination programme to begin from any date after 1 December 2020 **(CS6/23 - INQ000489930)**.

293. On 8 December 2020, the Pfizer/BioNTech vaccine began to be deployed across the UK and the first vaccines were given as part of the roll-out. On 15 February 2021, the NHS extended the roll-out to all those aged 65 and over as well as all those aged 16 or above with underlying health conditions **(CS6/249 - INQ000234751)**. These plans formed a key part of the COVID-19 Roadmap out of lockdown.

294. On 4 January 2021, the NHS rolled out the Oxford/AstraZeneca COVID-19 vaccine **(CS6/250 - INQ000234692)**.

295. On 8 January 2021, the Moderna COVID-19 vaccine gained regulatory approval from MHRA **(CS6/251 - INQ000399453)**. On 13 April 2021 the first Moderna COVID-19 vaccination was delivered in the UK.

296. On 11 January 2021, the UK Government published the UK COVID-19 Vaccines Delivery Plan (the Delivery Plan), which set out plans for delivering the target of vaccinating the top four priority cohorts by 15 February 2021, and then expanding the programme so all adults could be vaccinated by autumn 2021 **(CS6/252 - INQ000399454)**. The Delivery Plan was shared with the devolved administrations who published their own delivery plans.

297. The Delivery Plan set out three main routes through which the public could get vaccinated, with the aim of catering to different preferences and making access as easy as possible:

a. Hospital hubs, based at NHS trusts, which primarily vaccinated health and care staff.

b. Local vaccination services, comprising groups of primary care networks, led by general practitioners (GPs), community pharmacies and including settings such as mobile services, pop-up and walk-in clinics; and

c. Vaccination centres set up specifically for COVID-19 vaccinations and based in venues such as stadiums, theatres and hotels and run by NHS trusts, primary care networks or pharmacies.

298. On 14 February 2021, the NHS met its target of offering everyone in the top four priority groups a COVID-19 vaccine **(CS6/249 - INQ000234751)**.

299. By 31 March 2021, in England, 26,454,219 million people had received their first COVID-19 vaccine with another 3,519,105 having received their second dose, a combined total of 29,973,324 doses.

300. By mid-April 2021, all adults over 50, the clinically vulnerable and frontline health and social care workers had had the opportunity to access the COVID-19 vaccination. This met the target to offer a first vaccine dose to priority Cohorts one to nine by 15 April 2021 **(CS6/253 - INQ000257443)**.

301. From 13 April 2021, Phase 2 of the vaccine programme initially aimed to have offered a vaccination to all individuals in JCVI groups 10 to 12 by the end of July 2021 **(CS6/254 - INQ000257445** and **CS6/255 - INQ000257444)**. The vaccine programme met this target early **(CS6/256 - INQ000234990)**.

Devolved Administrations

302. There was substantial collaboration and a very high level of similarity across the UK, while of course deployment is a devolved matter for each devolved administration. At official level engagement included observer/member status at the JVCI's meetings, regular Vaccine Deployment SRO and policy official meetings and meetings of the four UK CMOs. At ministerial level, the Department co-ordinated meetings with the Minister for COVID Vaccine Deployment and devolved administration ministers to help align policy

approaches. Significant engagement with the devolved administrations also took place on uptake and assurance (including equity and indemnity), science and supply (including regulatory decisions), international dose sharing and overall vaccine strategy.

303. On 27 October 2020, a submission was sent to the Secretary of State recommending that: the i) devolved administrations were allocated a share based on a business as usual Barnett formula split of doses, after deducting the allocation to the CTs and OTs, ii) CTs were allocated a population proportionate share of a COVID-19 vaccine and iii) OTs were allocated a population proportionate share of a COVID-19 vaccine. The Secretary of State confirmed on 29 October 2020 that he was content with the approach and met with his counterparts in the devolved administrations to discuss on 5 November 2020 **(CS6/257 - INQ000399251; CS6/258 - INQ000058675; CS6/259 - INQ000489929)**. The Department worked closely with the devolved administrations to ensure that there was an aligned approach on prioritisation and deployment to retain UK-wide public confidence in vaccine delivery.

304. The four SROS ((the SROs for England are listed above in paragraph 284), Derek Grieve (Scotland), Dr Gillian Richardson (Wales) and Dr Naresh Chada (Northern Ireland)) met regularly to discuss deployment in meetings convened by the Department. The devolved administrations were present at the JCVI's meetings and were provided with the same advice about prioritisation of vaccinations. In addition, PHE/UKHSA has a function across all four devolved administrations and as such, the clinical advice contained within the Green Book was the same for all the devolved administration. As far as I am aware, there were no significant contrasting approaches from which lessons were learned.

305. Health is a devolved responsibility and as such, there were different local approaches to delivering health services and the devolved administrations delivered vaccine services appropriate to their own devolved health systems. The approach to delivery of vaccines in England is set out within this statement. As local approaches were taken, the Department is unable to comment on the specific adaptations on the grounds of geographical and demographic variation which were implemented by the devolved administrations, but information and experience was widely shared.

306. For completeness, it is important to note that the UK Government also secured COVID-19 vaccines to the CDs, and a Memorandum of Understanding was signed between BEIS, PHE and the CDs for vaccine deployment. The UK Government continues to ensure all permanently inhabited OTs have vaccines and boosters. This comes with logistical

challenges due to the remote geographic location of many of the territories. Deliveries of vaccines have been individually tailored depending on the vaccine candidate suitability and overseas territories roll-out.

Data collection

307. Data on vaccine coverage at the local level was collected by NHSE. The NHS published daily data on the number of first and second doses administered, broken down by region. Data on the number of first and second doses broken down by age category, ethnicity and STP/ICS were published weekly. In addition, PHE/UKHSA produced figures of those who were alive and living in England at the relevant time and had an NHS number. Figures could be viewed by local authority or by Middle Layer Super Output Areas and Lower-Level Super Output Areas (areas used for census data[2]).

308. These figures were provided to national decision makers, including senior officials and ministers, through a combination of ad-hoc and regular weekly meetings. Vaccine data was part of the regular data packs to the PM stocktake meetings, the CO official led meetings, frequent and often daily vaccine meetings with the Secretary of State and/or the Minister for COVID Vaccine Deployment, and the weekly cycle of Gold meetings.

Integrated Care Systems

309. I am asked what role Integrated Care Systems (ICSs) placed in supporting roll-out at local level. Detail of local level roll-out is a matter for NHSE. ICSs are partnerships of organisations that come together to plan and deliver joined up health and care services, and to improve the lives of people who live and work in their area. ICSs became legally established on 1 July 2022, through the Health and Care Act 2022. CCGs were the statutory bodies for the majority of the time period covered by this statement and played a central role in delivering roll-out, including monitoring capacity across the local system and ensuring vaccination sites were able to deliver vaccines to their local population.

[2] Middle layer Super Output Areas (MSOAs) are made up of groups of usually four or five Lower Level Super Output Areas (LSOAs). They comprise between 2,000 and 6,000 households and have a usually resident population of between 5,000 and 15,000 persons.

Deployment to Specific Groups

310. I am asked about how the roll-out procedure of the vaccine considered the needs of specific groups. On 13 February 2021 the Department published the UK COVID-19 Vaccine Uptake Plan (the Vaccine Uptake Plan) **(CS6/260 - INQ000087230),** which described the approach to vaccine roll-out. It also summarised how the needs of various groups and communities would be considered in the roll-out of the vaccine.

311. The Vaccine Uptake Plan noted:

> *"As we continue to offer vaccination in line with the JCVI priority groups, we need to ensure that everyone in each group has the opportunity to get vaccinated, the information they need to make an informed decision, and that no-one is left behind. We have assumed a benchmark uptake rate of 75%, based on comparable programmes. So far, we have exceeded our own expectations, seeing over 90% uptake in those over 75 years of age and our aim is to achieve as high uptake as possible in all other groups.*
>
> *We need a collective effort to save as many lives as possible and a relentless focus on ensuring our approach is fair to individuals and communities across the country. This plan provides an overview of how we are doing this at a national and local level and how we will intensify and focus our efforts to work in partnership with our communities to increase vaccine uptake and ensure equity of access."* **(CS6/260 – INQ000087230).**

312. The collective aim of the Uptake Plan was to improve vaccine uptake across all communities; underpinned by four enablers at national, regional and local level:

a. Working in partnership.

b. Removing barriers to access.

c. Data and information; and

d. Conversations and engagement.

313. The Vaccine Uptake Plan set out the benefit of *"community engagement in every corner of the UK"*, emphasising the need for local sectors to work together to vaccinate as many people as possible, including local authorities, and the voluntary, community and faith sectors. It also pointed out that there were already *"thousands of individuals and organisations across the country working together to help and encourage people to get vaccinated."* **(CS6/260 – INQ000087230).**

314. The Uptake Plan emphasised in particular the role of Directors of Public Health (DsPH). As is set out in more detail in Statement C of this Module, local DsPH played a key role in leading work to improve local population health by understanding local factors impacting health. The Uptake Plan also recognised the *"deep experience of immunisation and screening programmes"* of DsPH and their teams, *"which can play a critical role in understanding the whole population of an area."* The role of the DsPH in reaching out to more vulnerable group is a key part of this. As the Uptake Plan notes, engagement and removal of barriers was also part of this role:

> *"core to the role of local directors of public health is a statutory responsibility to advocate for an emphasis on reducing health inequalities and improving access in underserved groups."* **(CS6/260– INQ000087230).**

315. At a local level, Health and Wellbeing Boards and ICS/STPs also supported decision-making, offering *"support and understanding of where the vaccine needs to be taken to ensure diverse communities and unvaccinated groups are reached"* (Uptake Plan referenced). GP teams also played a role in taking vaccines to those who were housebound.

316. The emphasis on reaching difficult groups is also seen in the number of locations across the UK that were made available to vaccine deployment. Growing from 60 hospitals in early December 2020, to 2,700 locations by the time the Uptake Plan was published in February 2021, this ensured easier access to more people. The Vaccine Uptake Plan also set out how more centres would be opened as the vaccination programme was rolled out further, *"including, for example, places of worship, taking the vaccines to communities."*

317. The Vaccine Uptake Plan also stressed the need for cross-government working to deliver a co-ordinated plan and reach more groups. As well as DHSC, NHSE, PHE (as it was at the time), and MHCLG for local government, the Plan pointed out:

"there is a role for all parts of government to play to drive vaccine uptake, from the Department for Business, Energy and Industrial Strategy encouraging people to take up the offer of vaccination through employers, to the important work of the Department for Digital, Culture, Media and Sport (DCMS) on tackling misinformation." **(CS6/260 – INQ000087230).**

318. The Vaccine Uptake Plan also noted that many factors contributed to variations in vaccination uptake rates, which impacted different communities in different ways. As a result, it was anticipated that some communities might have required more support; and the Department worked with partners across health and social care, local government and the voluntary sector to ensure meaningful engagement and action. To continue to build public trust, the Department worked at a national and local level to prioritise:

a. Giving people information in formats that connected with them.

b. Information sharing from relatable leaders who understood people's specific circumstances. Sometimes this was also wider than GPs, clinicians or faith leaders but would be local community champions or local community links.

c. Understanding the power of individual choice and that choice should not be judged, for example seeking to understand fears and concerns, and then providing answers and evidence-based reasons to alleviate the fears; and

d. Ensuring appropriate, tailored outreach and engagement from familiar authorities are available where mistrust exists between individuals and healthcare professionals.

319. On 1 March 2021, Professor Wei Shen Lim, wrote to the Secretary of State with the JCVI's advice that local teams consider a universal offer to adults experiencing homelessness and rough sleeping alongside those in priority Cohort 6 as part of Phase 1 of the vaccine roll-out **(CS6/261 - INQ000354434).** The Department advised that JCVI's recommendations were supported by the Department, MHCLG, PHE and NHSE officials **(CS6/262 - INQ000111531)**. The Department's advice was accepted by the Secretary of State **(CS6/263 - INQ000401341)**. The Secretary of State replied to Professor Lim, and both letters were published **(CS6/264 - INQ000111533; CS6/265 - INQ000111532)**. A mobilisation guide produced by NHSE, dated 12 March 2021, was produced to support vaccination teams in mobilising services for people experiencing homelessness and rough

sleeping so that they could be vaccinated alongside Cohort 6 **(CS6/266 - INQ000414437).** As part of the mobilisation guide, a number of models that could be used to vaccinate people experiencing homelessness and rough sleeping were suggested, which included: holding dedicated clinics targeted at people experiencing homelessness at an existing vaccination site; adopting a roving vaccination model to visit any homelessness or rough sleeping setting; or a mobile vaccination vehicle to visit hostels/hotels. By way of example, Portsmouth City Council implemented a vaccination team working from a roving clinic which went out onto the streets to vaccinate rough sleepers, as well as producing myth-busting videos by community leaders **(CS6/267 - INQ000399460).**

320. Work was also done to ensure that booking vaccination appointments was as accessible as possible. The National Booking System provided written translations of letters and patient information including in Braille, easy read, large print, and audio versions. Booking services were also available over the phone, and GPs offered appointments through telephone, text, letter and online. GPs also used the National Immunisation Management System database to identify those who have not yet been vaccinated and to follow up with invitations and reminders to help make it easier for people to attend an appointment (an approach known as call and recall).

321. In terms of those with learning disabilities, the JCVI's advice that all people on the GP Learning Disability Register should be invited for a COVID-19 vaccination in priority Cohort 6 was accepted by the Government **(CS6/268 - INQ000489943).** However, it was noted that GP systems may not always capture the severity of someone's disability, meaning some adults who were more severely affected by learning disabilities may not be invited for vaccination alongside people with other long-term health conditions. To address this, the NHS worked with local authorities to identify adults in residential and nursing care, and those who require support, for example as part of assisted living in the community, and those in shared accommodation with multiple occupancy. This meant that at least 150,000 more people with learning disabilities were offered the vaccine more quickly.

322. The Vaccine Delivery Plan made provision for those who were housebound, residents of care homes or who would otherwise struggle to travel.

323. During roll-out, COVID-19 vaccines were offered free of charge in the UK to those eligible. All primary medical care services, whether provided at a GP surgery or elsewhere are available without charge to anyone in the country, regardless of immigration status.

UKCVS

324. In December 2020, at the suggestion of the Department, the Cabinet Secretary appointed Richard Alcock as the SRO for UK COVID-19 Vaccine Security **(CS6/269 - INQ000401308)**. The SRO was accountable directly to the Cabinet Secretary **(CS6/270 - INQ000401385)**. Shortly thereafter, the UK COVID-19 Vaccine Security Team (UKCVS) was set up to support the SRO in his task to ensure and assure the end-to-end security of vaccine deployment across the UK, from manufacture to injection **(CS6/270 - INQ000401385).** The UKCVS was a cross-Government unit staffed by civil servants, military staff deployed under military aid to the civil authorities (MACA) arrangements and some contractors **(CS6/270 - INQ000401385)**. It was originally funded by the NHS and later funded by the Department **(CS6/270 - INQ000401385)**. The UKCVS played a key role in protecting the public and in maintaining the trust and confidence in the UK COVID-19 vaccines and delivery programmes, and in ensuring that as many people in the UK were administered with the vaccines as possible **(CS6/270 - INQ000401385).** The main responsibilities of the UKCVS were to:

a. Ensure the protective security (physical and cyber) around the vaccine manufacturing facilities, with the support of operational partners in law enforcement, the Centre for the Protection of National Infrastructure and the National Cyber Security Centre (i.e., the National Technical Authorities).

b. Ensure the protective security of the transportation of all vaccines from the manufacturing sites to key distribution points around the country, by working with the Department, the NHS, the Department for Transport and the Ministry of Defence, as well as law enforcement and the NTAs.

c. Ensure the safety and security of vaccination sites, fixed and mobile, secure disposal of vaccine-related material, and security of record-keeping integral to the vaccine programme.

d. Maintain a robust risk and threat assessment framework to support the above, ensuring a comprehensive understanding of factors that can affect a successful vaccine roll-out and, with cross-government partners, proposing mitigations to reduce impact and ensuring their implementation.

e. Ensure the resilience of the UK's vaccine supply chain by working closely with the VTF, FCDO, and operational agencies **(CS6/270 - INQ000401385).**

325. In order to fulfil those responsibilities, the UKCVS assessed a wide range of threats including:

a. Vaccine diplomacy.

b. Supply shortages of vaccine.

c. Anti-vaccination and antagonist groups.

d. Mis- and disinformation.

e. Vaccine hesitancy.

f. Cyber issues.

g. Threats to personnel and protective security; and

h. Theft and fraud **(CS6/270 - INQ000401385).**

326. Also in December 2020, the UK COVID-19 Vaccine Security Board, chaired by the SRO, was set up. Its purpose was to provide oversight of the UK vaccine security programme and to advise the SRO on the activities that were required as part of the UK Vaccine Security Framework. The Board had set terms of reference **(CS6/271 - INQ000401386).** The membership of the Board comprised of representatives from across the UK and different government departments, as well as related bodies and organisations that had a role in ensuring the security of the vaccination programme. **(CS6/271 - INQ000401386).** The Board's responsibilities were to:

a. Understand, monitor, harden and protect the supply chain for vaccines, mitigating risks from deliberate and accidental damage.

b. Understand, monitor and protect the demand for the vaccines, ensuring misinformation, disinformation and any reporting does not damage demand.

c. Oversee and direct the security of supply and demand; and

d. Engage and align as appropriate with other Organisations, Bodies and Boards working to deliver COVID-19 vaccination deployment beyond the immediate focus of vaccine security, including, but not limited to the COVID-19 Vaccination Deployment Programme Board and the Health Intelligence and Effects Customer Committee.

327. During its operation, the UKCVS:

a. Produced intelligence products on threats, provision of security guidance and rapid responses to incidents.

b. Strengthened cyber defence capabilities including through an exercise to understand mitigations to a ransomware attack on critical systems.

c. Improved understanding of anti-vaccination narratives, methodology and actors, working to uncover mis/disinformation trends in diverse communities and working with technology firms to improve moderation to anti-vaccination content online; and

d. Secured a capability to provide threat reporting on High Profile Individuals **(CS6/272 - INQ000401402).**

328. The UKCVS was closed in September 2022, when it was agreed that vaccine security would be taken forward thereafter as a business-as-usual function within the existing vaccine programmes managed by the NHS and by the UKHSA **(CS6/273 - INQ000401406)**.

SECTION 5: LESSONS LEARNED

329. The Department continues to affirm that the single most important information that we have available, when reflecting on lessons learned, is the Technical Report published on 1 December 2022 **(CS6/3 - INQ000177534)**. This report includes chapters on research and on vaccines and therapeutics, and includes reflections and advice on research, and vaccines and therapeutics at pages 117-119 and 334-336 respectively.

330. From its own reflections and the evidence heard by the Inquiry in Modules 1 and 2, the Department continues to believe that five lessons stand out which are set out below. This section then also covers the work of the Department on both domestic and international measures to increase its resilience to future threats.

A toolkit of capabilities is more important than plans

331. Plans are only as good as the capabilities on which they are based. The UK was strong where there were already strong capabilities, for example research development, trial infrastructure, and large-scale deployment via the NHS. This was reflected in the Technical Report, which mentioned, example:

a. The learnings taken from the 2009 H1N1 influenza or 'swine flu' pandemic and subsequent independent review of governmental response;
b. Decades of global vaccine research and preparation, including pre-existing protocols for rapid vaccine implementation in the face of a new global pandemic;
c. Early set-up of clinical trials and embedding into NHS care; and
d. The joint approach across the four nations to combine resources, facilitating faster and more diverse clinical trial recruitment, equity of access for therapeutics and strengthened the UK's negotiating position.

332. The Module 1 Closing Statement and the Second Witness Statement of Sir Christopher Wormald, dated the 10 May 2023, explain that some of the most vital things done prior to the pandemic were the investments that NIHR made in infrastructure to support the development of vaccines, and the UKVN, which provided the foundations for creating new vaccines at speed. While the lessons learned through research and the NIHR are articulated in more detail in Lucy Chappell's statement, the Department is clear that learning lessons from previous pandemics and epidemics was vital to how to the healthcare system was to develop and to deploy COVID-19 vaccines, as was described in paragraph 123 - 129 above.

333. As is set out in more detail in Statement C of this Module, many successful innovative solutions were used to adapt delivery models and communications, expanding the health system's tools and capabilities to deliver effective solutions and improve inequalities of uptake. These measures, which contribute to our toolkit for future health emergencies, include:

a. The use of local community champions to build trust, tackling misinformation and disinformation swiftly **(CS6/274 - INQ000281367)**.

b. Adapting vaccination delivery to improve uptake at a local level, including expanding delivery to GPs, pharmacies, mobile units, pop-up and walk-in clinics, places of worship, etc. Along with out of hours and weekend clinics, and the availability of interpreters, introducing a range of measures like this reduced barriers to uptake.

c. A broad toolkit of communications methods, platforms and channels of delivery, including both generalised and targeted campaigns, cross-government campaigns, and utilisation of trusted influences, such as, clinicians, scientists and community leaders, all helped to ensure the importance of vaccinations were heard by a wider range of people.

d. Improved abilities to communicate medical and scientific information, including uncertainties and evolving science in a transparent way.

The underlying resilience of the system matters

334. Industry, academia, government and the public sector worked together in facilitating development and deployment of COVID-19 vaccines. The clinical trials process, supported by departmental civil servants proved both agile and robust. Although funding for clinical trials is principally delivered through the NIHR and covered in Professor Lucy Chappell's statement, the results of such trials were internationally well regarded and informed decision making in the UK and around the world. The Technical report reflects the important actions taken to speed up the process, for example:

a. The rapid research call released in February 2020 by NIHR and UKRI funded Oxford University to reorientate their adenovirus vector vaccine platform against the partially UKVN-funded MERS-CoV vaccine to develop a COVID-19 vaccine;
b. Use of existing technology allowed mRNA vaccines to enter trials very quickly, clinical trial phases were run in parallel rather than sequentially, and trials were targeted at high prevalence areas; and
c. The National Institute for Biological Standards and Control ("NIBSC") ensured quality of the final vaccine product through independent testing of each vaccine

batch, and also developed reagents to support quick and reliable vaccine evaluation.

335. The Department took steps to streamline vaccine development and approval while maintaining rigorous standards to respond quickly to an emergency situation. Resilience of the UK's regulatory system meant that the MHRA was able to innovate in how it reviewed data from clinical trials and manufacturing data in order to accelerate approval. The Technical Report explains:

> *"MHRA undertook a rolling review of data from clinical trials and manufacturing data as it became available to accelerate approval – the first time MHRA had instigated this process. By reviewing data from ongoing studies after initial analyses rather than as a package of all trial data at programme completion, blockages were identified and resolved earlier. MHRA authorised Pfizer, AstraZeneca and Moderna vaccines for emergency use on a temporary basis just under 8 months after trials started, and less than one year after the UK's first case."* **(CS6/3 - INQ000177534).**

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

336. Finding a safe and effective vaccine or therapeutic was a key priority for the Department from of the start of the pandemic. To achieve this objective, the Department scaled up its support for scientific research, via the NIHR very quickly. Once it was becoming apparent that we were likely to be in a position to deploy a vaccine, the Department's preparation facilitated effective deployment at pace.

337. A strong investment in scientific research collaboration, including funding of the NIHR, over many years meant that the scientific community was able to scale up research efforts quickly on vaccine development. While Professor Lucy Chappell's statement will cover the importance of research investment further, the Department recognises that the COVID-19 pandemic demonstrated that investment in research is fundamental to maintaining an ability to scale up our response to future pandemics at pace, including the establishment of the UK Vaccine Network in 2015, which was crucial for development of scientific knowledge about mRNA vaccines and establishing research infrastructure.

338. Successful scaling up deployment of vaccines at pace required careful planning and co-ordination, and our processes were tested at greater scale than before. Before vaccines had received regulatory approval, we had already begun to purchase vaccines and plan

readiness for deployment. This substantial pre-planning, involving careful coordination across a range of bodies, meant that the UK was read to deploy as soon as vaccines were available. A reliable and tested vaccination infrastructure meant that there was a well-established system of advice, approvals and distribution for national vaccine programmes, which could be built on and scaled effectively.

Diagnostics and data are crucial in a pandemic response

339. Use of diagnostics and data is an integral part of developing an effective vaccine, both in terms of research and development and in monitoring the impact and response of the vaccine. The Department worked closely with NIHR and the VRR on funding and development of clinical trials for vaccines. A more detailed account of the work of the NIHR on learning and applying lessons from the trials is set out in Lucy Chappell's statement.

340. During the pandemic extensive work was carried out by partners across the health family to maximise the benefits of data and analysis.

341. The pandemic response meant the Department had access to data much quicker than that of normal immunisation campaigns, facilitated via a Control of patient information notice (COPI) to require NHS Digital to share confidential patient information with organisations entitled to process it for COVID-19 purposes **(CS6/275 - INQ000101772)**.

342. This meant the health system was able to access data on vaccine delivery much quicker, ensuring the Department was able to act upon this data more effectively during the vaccine roll out by implementing lessons learnt in real time.

343. Overall, however, it is important to note that the Department identified key innovations during this period that continue to drive improvements; this includes, for example, better knowledge that helps us to continue to improve diversity in recruitment for clinical trials.

Prepare for future threats, not just for COVID-19

344. Rapid vaccine development worked very effectively for the reasons set out in section 4, above, but this cannot be guaranteed for future pandemics. The type of pathogen, scientific understanding, ease of design of effective vaccines, and similarities to other vaccines will be factors in our future ability to respond. The time to an effective vaccine, and whether an effective vaccine can be developed at all, are unknowns. For this reason,

it is essential that research and development, which the Department principally funds through the NIHR, is focused on therapeutics and diagnostics in addition to vaccines. The 100 Days Mission which is described below in paragraph 356, covers all three elements.

345. The Department considers that the country should prepare along the five routes of disease transmission; respiratory (e.g. covid, flu), touch (e.g. Ebola, Lassa), sexual/blood (e.g. HIV, Mpox), oral (e.g. cholera/ new variant Creutzfeldt-Jakob disease (nvCJD) following consumption of bovine spongiform encephalopathy (BSE) infected beef) and vector (e.g. plague, zika virus). The non-pharmaceutical interventions and the pharmaceutical interventions would differ for each route, as well as being complemented by an understanding of the specific elements after the emergence of any future novel pathogen. A strong science and research base, enabled by the necessary laboratory infrastructure and trained workforce, will help retain this capability, and again this will be covered further by Professor Lucy Chappell's statement.

346. A respiratory pathogen continues to be the most likely route of transmission in a future pandemic and, for this reason the Department is preparing a respiratory response plan, which will include influenza specific components such as existing influenza antivirals and vaccine capacity. The overall pandemic (and epidemic) strategy needs to cover all routes of transmission. The Government's National Risk Register outlines the Government's assessment of pandemic risk **(CS6/276 - INQ000283164).**

Domestic Measures

347. I am asked about contingency plans for the development of vaccines for future pandemics. The Department convened a Review of Emergency Preparedness Countermeasures to inform policy on countermeasures, including vaccines, for future pandemics and emerging infectious diseases. Building on the lessons of COVID-19 and the latest clinical and scientific evidence, the Review sought advice on materials that should be held, or otherwise contracted for, to expand UK preparedness to this wider range of risks. Policy development on vaccines and therapeutics as part of our Pandemic Preparedness Portfolio is ongoing based on the advice from the Review.

348. The Department's current clinical countermeasures programme includes an APA for an influenza vaccine. The contract secures the fulfilment of an order sufficient to provide doses for up to 70 per cent of the UK population on an assumed two-dose schedule at a pre-agreed unit price. The intention is to guarantee the UK timely access to a vaccine

(anticipated to be within 4-6 months of the onset of a pandemic) at a reasonable price in a highly competitive market, which would likely lead to significantly escalated process and slow delivery times if we relied on reactive procurements at the time instead.

349. The Government has had similar agreements in the past, but this is the first time the manufacturing process will be based entirely in the UK, giving better security of access if global demand ever outweighs supply. The vaccines will be tested, licensed, and approved and tailored to combat the specific pandemic flu strain identified at the time, and will be produced at CSL Seqirus's existing manufacturing plant in Liverpool in the event a pandemic is declared by the WHO **(CS6/277 - INQ000489955)**.

350. In December 2022, the Government and Moderna entered a strategic partnership to set up mRNA research and development and manufacturing facilities in the UK. Under the partnership, Moderna will build a new Innovation and Technology Centre in the UK, which will have the capacity to produce up to 250 million vaccines per year in the event of a health emergency. Developing vaccines on UK shores will mean it will be able to scale up production rapidly in the event of health emergency, significantly boosting our ability to respond to future pandemics. **(CS6/278 - INQ000194000)**.

351. The revised UK Biological Security Strategy (2023) builds upon the foundations laid by the Government in the 2018 Strategy. It has been updated to reflect lessons learned during the COVID-19 pandemic and explains how the Government will tackle threats head on from bioterrorism to animal and plant diseases by 2030 **(CS6/279 - INQ000208910)**.

352. Joined up working across Government, the health family and internationally is the only way to ensure that unprecedented global health challenges can be tackled effectively. Working together with industry, by investing and encouraging investment, is key to ensuring that we are able to continue to produce and secure life-saving vaccines.

International Partnerships

353. The UK held the Presidency of the G7 in 2021. The Department's ministers convened G7 health ministers regularly throughout the year to take stock of the progression of the pandemic and how countermeasures were being deployed, and to consider how the G7 collectively could take action to reduce the impact of the pandemic globally. The Secretary of State chaired an in-person meeting of G7 health ministers in Oxford on 3-4 June 2021 which agreed actions to strengthen global health security; improve the global architecture

for clinical trials; and to tackle antimicrobial resistance, which remains a serious threat to human and animal health. G7 ministers, under UK leadership, reaffirmed commitment to equitable global access to safe, effective and affordable access to vaccines, therapeutics and diagnostics, including through the COVAX initiative.

354. The G7 Therapeutics and Vaccines Clinical Trials Charter was developed and chaired by the UK during its G7 Presidency **(CS6/280 - INQ000234915)**. The Charter aimed to increase the quality of trials and avoid unnecessary duplication so resources are deployed more effectively, allowing robust clinical evidence that can inform policy and practice, saving lives. The Charter also aimed to embed international collaboration between G7 countries on clinical trials more routinely where mutually beneficial, supporting greater diversity of trial participants and accelerating sharing of data whilst ensuring data security.

355. Building on the Charter, the UK co-chaired negotiations for a new World Health Assembly resolution on clinical trials, adopted by all 194 WHO Member States at the 75th World Health Assembly May 2022. This resolution agreed a new set of principles for strengthening clinical trials practice, including greater international collaboration, coordination, global infrastructure strengthening and capacity building to enable well-designed and well-implemented clinical trials as the norm rather than the exception, drawing on the lessons learnt from the pandemic. The resolution set a mandate for the WHO to support countries in implementation, with a work programme underway to support delivery.

356. During the G7 Presidency, the UK set up an independent expert group, the pandemic preparedness partnership, to advise the Presidency on how to develop and deploy safe, effective diagnostics, therapeutics, and vaccines within the first 100 days of a pandemic. This partnership published a report on 12 June 2021, the 100 Days Mission report, which set out a roadmap for making the 100 Days Mission achievable through recommendations for governments, international organisations, and industry partners. This was an important initiative bringing together academic and scientific experts, industry leads, global health institutions and regulators in a collaborative process. Initially set up as a one-off process, the 100 Days Mission is now being taken forward by the International Pandemic Preparedness Secretariat, hosted by the Wellcome Trust and supported by the UK Government among others.

357. The UK Government is already funding research into new vaccine prototypes, including through funding the CEPI, the UKVN and the NIHR.

358. The FCDO committed £250 million to the CEPI to support the development of vaccines for COVID-19. The UK has since hosted the Global Pandemic Preparedness Summit in March 2022 which raised over £1.2 billion for the CEPI and included a UK pledge of £160 million, In addition to previous UK funding of £276 million since the CEPI's inception in 2017. The CEPI, together with its many partners globally, is developing vaccines against future health threats, including support to accelerate research for the Sudan ebolavirus vaccines.

359. Supporting a broad base of approaches to vaccine development has secondary benefits for domestic and international pandemic preparedness. This technology, capability and expertise will be of value in the response to future pandemic threats. CEPI is taking forward work to prepare for future 'Disease X' events. For example, the need to develop prototype vaccines against the different virus families that infect humans. These prototype vaccines may be based on rapid response platforms (e.g., mRNA) which can be adapted quickly when a new virus has been identified. They will form a 'library' of vaccine candidates that are ready to be adapted rapidly next time Disease X emerges.

Statement of Truth

360. 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: 4th September 2024