IN THE MATTER OF THE INQUIRIES ACT 2005
AND IN THE MATTER OF THE INQUIRY RULES 2006

UK COVID-19 INQUIRY

EIGHTH WITNESS STATEMENT OF SIR CHRISTOPHER WORMALD

---

1. I, Sir Christopher Stephen Wormald, Permanent Secretary of 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 September 2022 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 structure of the Department and the role it played in the UK Government's response to the COVID-19 pandemic between 1 January 2020 and 24 February 2022.

3. This corporate statement covers the period from 1 August 2021 to 24 February 2022. Where it is necessary to refer to events outside that date range, I will make that clear and explain why I have referred to that event. The period 1 January 2020 to 31 July 2020 is covered in my Third Witness Statement dated 29 March 2023, the period 1 August 2020 to 31 July 2021 is covered in my Fifth Witness Statement dated 28 July 2023. I will refer to these two statements as my First Witness Statement for Module 2 and my Second Witness Statement for Module 2, respectively.

4. As this is a corporate statement on behalf of the Department, it necessarily covers matters that are not within my personal knowledge or recollection. This statement is to the best of my knowledge and belief accurate and complete at the time of signing. 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 need be.

SECTION 1: CENTRAL GOVERNMENT STRUCTURES AND BODIES CONCERNED WITH THE UK RESPONSE TO THE PANDEMIC AND THEIR RELATIONSHIPS

Summary Overview

5. This section of this statement covers changes that occurred during the period 1 August 2021 and 24 February 2022 in terms of the Department's role, responsibilities and its relationships with Departmental agencies and other government departments (OGDs).

6. As set out in my First Witness Statement for this Module at paragraph 6, the Department's purpose is to support and advise the Government's Health and Social Care Ministers by shaping policy and assisting in the setting of the strategic direction for the health and care system. Through this, the Department fulfils the Secretary of State's statutory duty under s. 1 of the National Health Service Act 2006 (the NHS Act) to continue the promotion in England of a comprehensive health service designed to secure improvement in the physical and mental health of people in England and in the prevention, diagnosis and treatment of physical illness. The Department secures funds for the NHS and remains accountable for this funding, which is allocated to the most appropriate local level.

7. In my First and Second Witness Statements for this Module dated 29 March 2023 and 28 July 2023, I set out at paragraph 8 and paragraph 7 respectively, the Department's strategic priorities in its Annual Report and Accounts for those Statements' respective time periods. In the time period covered by this witness statement, 1 August 2021 to 24 February 2022, the Department's Annual Report and Accounts 2021/22 (for the year ending 31 March 2022) **(CW8/1 - INQ000257323)** set out our strategic priorities as follows:

   a. Protect the public's health through the health and social care system's response to COVID-19;
   b. Improve healthcare outcomes by providing high-quality and sustainable care at the right time in the right place and by improving infrastructure and transforming technology;
   c. Improve healthcare outcomes through a well-supported workforce;

d. Improve, protect, and level up the nation's health, including reducing health disparities; and
e. Improve social care outcomes through an affordable, high-quality, and sustainable adult social care system.

8. The Department's 2021/2022 Annual Report and Accounts recognised:

> "*In 2021-22, COVID-19 has continued to be the most significant challenge the country and the public sector has met in a lifetime. The Department is not in the same position as it was before COVID-19, and we have faced many competing demands. Our key priorities for the reporting year were developed to help the Department manage this and articulate our vision of how we enable everyone to live more independent, healthier lives for longer*" (**CW8/1 - INQ000257323**).

9. Generally, the Department does not directly fund or deliver adult social care and much of the funding for adult social care is raised locally. The Care Act 2014 places the duty to plan and secure adult social care services on 152 local authorities in England who commission services through a predominantly outsourced market of approximately 14,000 provider organisations. The Department is responsible for setting national policy and the legal framework, while the Department for Levelling Up, Housing and Communities (DLUHC) oversees local government funding and the financial framework.

10. In my First Witness Statement for this Module dated 29 March 2023, I set out at paragraphs 10 - 12 the role of the Chief Medical Officer (CMO), the Chief Scientific Adviser (CSA) and the Director-General (DG) for Global and Health Protection. In the time period covered by this witness statement:

a. Professor Sir Chris Whitty remained the CMO;
b. Shona Dunn remained as Second Permanent Secretary;
c. Professor Sir Jonathan Van-Tam remained the Deputy Chief Medical Officer (DCMO) until March 2022. His role covered emergency response and preparedness, infectious diseases, vaccines, and therapeutics;
d. Dr Thomas Waite became interim Deputy Chief Medical Officer (DCMO) for COVID-19 from July 2021 and was appointed substantively as DCMO in April 2022;

e. Dr Jeanelle de Gruchy was appointed as DCMO and took up post in October 2021 supporting the CMO on health improvement issues, and as co-lead of the Office for Health Improvement and Disparities (OHID);
f. Professor Lucy Chappell was appointed the CSA in April 2021 and she took up the post in August 2021, taking over from Professor Sir Chris Whitty as CSA. Her role is to advise on scientific aspects of health and act as the Chief Executive Officer of the National Institute for Health Research (NIHR);
g. Clara Swinson remained as Director General for Global Health and Health Protection;
h. Andy Brittain remained as Director General for Finance;
i. Michelle Dyson remained as Director General for Adult Social Care;
j. Jonathan Marron was appointed Director General for the OHID at the Department in October 2021; and
k. Matthew Style was appointed as Director General for NHS Policy and Performance in November 2021, taking over from Lee McDonough.

11. The Ministerial team in position at the start of the time period covered by this statement:

a. Secretary of State for Health and Social Care – Rt Hon Sajid Javid MP;
b. Minister of State – Edward Argar MP;
c. Minister of State for Social Care – Helen Whately MP;
d. Minister of State for Mental Health, Suicide Prevention and Patient Safety – Nadine Dorries MP;
e. Parliamentary Under Secretary of State – Jo Churchill MP;
f. Parliamentary Under Secretary of State – Lord Bethell; and
g. Parliamentary Under Secretary of State (Minister for COVID-19 Vaccine Deployment) – Rt Hon Nadhim Zahawi MP (Joint with BEIS).

12. On 15 September 2021, the PM announced new ministerial appointments. The Department's ministerial team, and its special advisors, were as follows until the end of the time period covered by this statement:

a. Secretary of State for Health and Social Care – Rt Hon Sajid Javid MP;
b. Minister of State – Edward Argar MP;
c. Minister of State – Gillian Keegan MP;
d. Parliamentary Under Secretary of State – Maggie Throup MP;
e. Parliamentary Under Secretary of State – Maria Caulfield MP;

f. Parliamentary Under Secretary of State – Lord Kamall;
g. Special Advisor Allan Nixon left his role in October 2021;
h. Special Advisors Emma Dean, Damon Poole, Michael Stott, Adam Memon, Sam Coates, Pete Backhouse, and James Hedgeland were in post in the period covered by this witness statement; and
i. Special Advisor Alice Hopkin joined the team in January 2022.

13. Decision-making in the Department (as in OGDs) is largely carried out through submissions to the Secretary of State and other Departmental Ministers, which set out an issue and recommendation and provide information to note. The relevant Ministers take decisions based on this advice, and sometimes will call meetings to discuss this advice before making a decision.

14. As set out in paragraph 76 of my First Witness Statement for this Module, the Gold structure was established on 11 June 2020. In the time period covered by this witness statement, decisions continued to be made by Gold meetings. Departmental ministers took decisions depending on the epidemiology and related actions through the Gold process; these meetings took place regularly, and often daily depending on business.

Devolved Governments and Other Government Departments

15. In the time period covered by this witness statement, there continued to be regular conversations and engagement with the Devolved Governments. A description of this engagement is set out at paragraphs 14-18 in my First Witness Statement for this Module. The UK Health Ministers continued to meet regularly, and often on a weekly basis depending on business to discuss respective approaches, UK wide issues and there continued to be regular meetings of the four UK CMOs. Further information as to the work between the UK Government and the Devolved Governments is set out in the Department's Supplementary Corporate Statement dated 4 August 2023 (draft).

16. COVID-Strategy (COVID-S) and COVID-Operations (COVID-O) continued to be the Cabinet Committees supported by the Cabinet Office (CO) to take collective decisions on the COVID-19 response.

17. As set out in my First Witness Statement for this Module at paragraph 18, the Department worked closely with OGDs during the response to COVID-19. This is because a public health emergency is not solely a health matter; many relevant actions are within the purview of OGDs and/or local authorities.

Arms-Length Bodies

18. In addition to the work the Department carries out, it also works through a number of arms-length bodies (ALBs) to deliver its strategic objectives. For more information on this, and the ALBs through which the Department works, see my First Witness Statement for this Module at paragraphs 20-21.

19. On 1 August 2021, Amanda Pritchard took up the post of Chief Executive Officer of NHS England (NHSE), to replace Sir Simon Stevens.

20. Throughout this statement, NHSE and NHS Improvement (NHSI) are referred to as NHSEI, reflecting that they operated under a single leadership model in the time period covered by this witness statement until July 2022, when NHS Improvement became part of NHS England.

Full operationalisation of the UK Health Security Agency (UKHSA)

21. In the period between the UKHSA being established on 1 April 2021 and launching on 1 October 2021, in order to protect operational continuity and provide for necessary staff consultations, Public Health England (PHE) and Test and Trace continued to deliver their existing functions and gradually transitioned their responsibilities and capabilities into UKHSA. UKHSA is an executive agency sponsored by the Department.

22. From 1 October 2021, UKHSA became fully operational **(CW8/2 - INQ000257071)**. By 1 October 2021, all PHE's health protection functions and Test and Trace's functions were transferred to UKHSA. PHE's other functions transferred to the Department, NHSEI, and NHS Digital, and PHE ceased to be operational. The functions of PHE and their current destinations are exhibited at **(CW8/3 - INQ000257090).**

23. Professor Dame Jenny Harries was appointed as Chief Executive of UKHSA in April 2021. Professor Dame Jenny Harries has had full executive operational responsibility of UKHSA since UKHSA became fully operational on 1 October 2021. In April 2021 Ian Peters was appointed Chair of the Advisory Board of UKHSA.

24. In September 2020, Professor Susan Hopkins was appointed interim Chief Medical Advisor at NHS Test and Trace and the Strategic Response Director for COVID-19 at

PHE. In October 2021 Professor Hopkins became Clinical and Public Health Transition Lead and the Chief Medical Advisor for UKHSA.

The Office for Health Improvement and Disparities (OHID)

25. OHID was established on 1 October 2021 with the aim of tackling health inequalities across the country **(CW8/4 - INQ000257257).** On the same day, the health improvement responsibilities of PHE were transferred to OHID. OHID, unlike UKHSA, is a unit within the Department.

26. The CMO, Professor Sir Chris Whitty, provides professional leadership to OHID, the DCMO, Dr Jeanelle de Gruchy advises government on clinical and public health matters and co-leads OHID, alongside the Department's Director General for the OHID, Jonathan Marron.

27. OHID works across the Department, the rest of Government, the healthcare system, local government, and industry to prevent ill health, with a particular focus in places and communities where there are significant health disparities. OHID brings together expert advice, analysis and evidence with policy development and implementation to drive health improvement.

Expert scientific and analysis advisory groups

28. Expert groups including the New and Emergency Respiratory Virus Threats Advisory Group (NERVTAG), the Scientific Pandemic Infections Group on Modelling (SPI-M), the Scientific Pandemic Infections Group on Modelling, Operational sub-group (SPI-M-O) and the COVID-19 Prophylaxis Oversight Group have been explained in my First and Second Witness Statements for this Module from paragraphs 22 and 32-33, respectively. They will also be addressed in the corporate witness statement of the Office of the Chief Medical Officer (OCMO). I will therefore not cover these groups in any detail in this statement.

International

29. In the time period covered by this witness statement, the Department continued its engagement with other countries to exchange information on their COVID-19 response. This included bilateral engagement and multilateral engagement with the

World Health Organization (WHO), the G7, the G20, the Global Health Security Initiative and the European Commission.

30. The G20 Health Ministers' Meeting, which took place in Rome on 5 and 6 September 2021, focused on building strong cooperation and collaboration to end the COVID-19 pandemic and support recovery around the world, and on better prevention, detection and responses to global health threats and emergencies. The nations agreed to work together to enhance timely global access to safe, affordable and effective COVID-19 vaccines, therapeutics and diagnostics, building on the work led by the PM at the UK-hosted G7 in June 2021 (referenced in my Second Witness Statement for this Module). The 2021 G20 Health Declaration was agreed at this meeting (**CW8/5 - INQ000257326)**.

31. G7 Health Ministers under the UK G7 Presidency released a joint statement in November 2021 on the Omicron variant and committed to continued close working to monitor and share information on the emerging situation **(CW8/6 - INQ000257126).**

32. The World Health Assembly gathered for a special session on 29 November 2021 to 1 December 2021 and agreed that an Intergovernmental Negotiating Body (INB) would be established to draft and negotiate a WHO convention, agreement or other international instrument on pandemic preparedness and response **(CW8/7 - INQ000257125; CW8/8 - INQ000257116).** The INB met for the first time on 24 February 2022. Negotiations are ongoing and are expected to continue until at least May 2024. Since it was established, the INB has met nine times to date, including four resumed sessions **(CW8//9 - INQ000257298; CW8/10 - INQ000257299; CW8/11 - INQ000257316).**

Emergency Response

33. In the time period covered by this witness statement, the Department's Operational Response Centre (ORC) continued to deliver the Department's emergency preparedness functions in relation to broader risks to the health system. These included major event planning for COP26, Afghan repatriation, fuel supply shortage, severe weather events such as storms Dudley and Eunice, and outbreaks of Avian Influenza in the UK. **(CW8/12 - INQ000257204; CW8/13 - INQ000257319)**

34. The ORC continued regular engagement with the Civil Contingencies Secretariat in the Cabinet Office to promote a shared understanding of all risks across the health and care sector. Some risks were COVID-19 related, for example pressures on NHS mortuary capacity following successive waves of COVID-19.

35. On 11 December 2021, the ORC stood up an incident team and its Director offered support to UKHSA in responding to the Omicron variant **(CW8/14 - INQ000287700).**

36. In response to the Omicron variant, an ORC team continued to operate within the Department and a weekly ORC Report continued to be prepared throughout, until the team was stood down at the end of January 2022 when infections and hospital admissions had begun to significantly reduce **(CW8//15 - INQ000287737; CW8/16 - INQ000287657; CW8/17 - INQ000287730 CW8/18) INQ000287735**. The aims of the ORC Report were to:

a. Identify the potential for incidents to occur and the impact that such incidents might have across the Health and Care sector. This was assessed regardless of cause and accounting for the effect of COVID-19 and the wider risk landscape;
b. Clearly indicate the Department's involvement in any incidents and whether that might be in a leading or supportive capacity, or merely tracking the situation for potential involvement; and
c. To evaluate the Department's capability and readiness to respond to future incidents.

37. The ORC Report was based on information gathered from a range of official sources, such as policy team weekly updates, information from NHSEI and PHE (then UKHSA) and Daily Situational Reports (SitReps) from OGDs. The ORC Report included a summary of live incidents and areas of concern, both domestic and international, and covered health and social care issues.

38. The ORC continued to deliver Concurrent Risk and Mitigation Board meetings **(CW8/19 - INQ000287609; CW8/20 - INQ000287608; CW8/21 - INQ000287610; CW8/22 - INQ000287607; CW8/23 - INQ000287614 CW8/24 - INQ000287613; CW8/25 - INQ000287612; CW8/26 - INQ000287611 CW8/27 - INQ000287615; CW8/28 - INQ000287616; CW8/29 - INQ000287618; CW8/30 - INQ000287619; CW8/31 -**

INQ000287620; CW8/32 - INQ000287621; CW8/33 - INQ000287623; CW8/34 - INQ000287624 CW8/35 - INQ000287625; CW8/36 - INQ000287627; CW8/37 - INQ000287626; CW8/38 - INQ000287628 CW8/39 - INQ000287629; CW8/40 - INQ000287630; CW8/41 - INQ000287632; CW8/42 - INQ000287631 CW8/43 - INQ000287633) to assist the Department in its broader preparation for winter 2021/22 and also maintained its bi-monthly Strategic Emergency Preparedness meetings (CW8/44 - INQ000287635; CW8/45 - INQ000287636 ; CW8/46 - INQ000287637; CW8/47 - INQ000287640; CW8/48 - INQ000287639; CW8/49 - INQ000287638; CW8/50 - INQ000287641; CW8/51 - INQ000287642; CW8/52 - INQ000287643; CW8/53 - INQ000287642) to assure the Emergency Planning, Resilience and Response mechanisms across the health and care system.

COVID-19 Battle Plan in this period

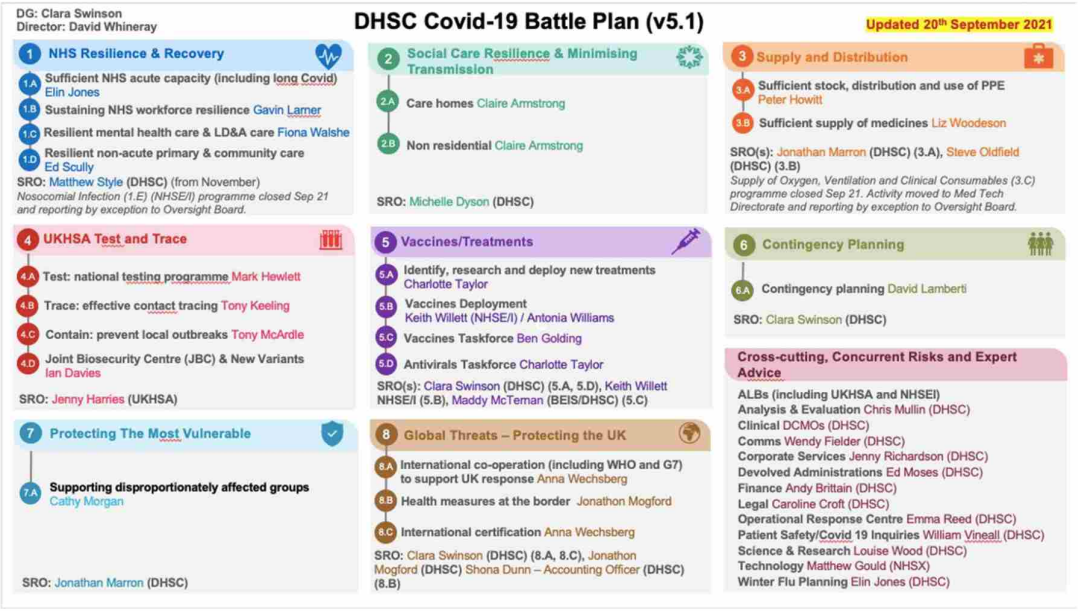
39. Throughout this period the Department continued to use the COVID-19 Battle Plan to oversee and coordinate the response. On 3 August 2021, Version 5.0 was shared with the Department's Executive Committee (ExCo) (**CW8/54 - INQ000287671; CW8/55 - INQ000256990**). Changes were made to keep the Battle Plan up to date following the UK's completion of the steps in the Roadmap earlier that summer. Changes included:

    a. The recognition of the Vaccines Taskforce as its own workstream 5.C;
    b. The renaming of Workstream 6 and Workstream 6.A from 'Non Pharmaceutical Interventions (NPIs) – Reducing Transmissions' to 'Contingency Planning' and the closing of workstream 6.B 'Coronavirus Act 2020';
    c. The establishment of the 8.C Workstream for 'International Certification';
    d. Adding workstream 7.B 'Clinically Extremely Vulnerable'; and
    e. Adding an explicit reference to "long covid" under the NHS Acute Capacity (1A) workstream.

40. On 20 September 2021, the Battle Plan was updated (to version 5.1) with minor further amendments: **(CW8/56 - INQ000287686)**, which were shared with the ExCo on 7 October 2021:

    a. Removing the Clinically Extremely Vulnerable workstream to reflect policy announcements in September 2021;
    b. The closing of workstream 1.E 'Nosocomial Infections'; and

c. The closing of workstream 3.C 'Sufficient Supply of Oxygen, Ventilation and Clinical Consumables'.



41. This version of the Battle Plan was discussed at the ExCo Star Chamber on 18 October 2021 and was subsequently shared with Secretary of State for information, on 15 November 2021.

COVID-19 Oversight Board

42. The Oversight Board, chaired by Clara Swinson, remained the main structure in the Department through which the COVID-19 Programme was monitored and key risks considered. Between August 2021 and November 2021, the Oversight Board met fortnightly **(CW8/57 - INQ000257002; CW8/58 - INQ000257013; CW8/59 - INQ000257046; CW8/60 - INQ000257067; CW8/61 - INQ000257093; CW8/62 - INQ000257103; CW8/63 - INQ000074342; CW8/64 - INQ000257156)**. This moved to weekly from December 2021 to January 2022 in response to the Omicron variant and then moved back to fortnightly in February 2022 **(CW8/65 - INQ000257157; CW8/66 - INQ000257285; CW8/67 - INQ000257229; CW8/68 - INQ000257104; CW8/69 - INQ000257259; CW8/70 - INQ000257284; CW8/71 - INQ000257286; CW8/72 - INQ000257313)**. More information on the role of the Oversight Board can be found in my First Witness Statement for this Module at paragraphs 48-49 and 58 and my Second Witness Statements for this Module in at paragraphs 43-58, respectively.

SECTION 2: ACCESS TO AND USE IN DECISION MAKING OF MEDICAL AND SCIENTIFIC EXPERTISE, DATA AND MODELLING

43. As in my First and Second Witness Statements for this Module, before turning to consider how the Department's response to the COVID-19 pandemic was structured, I will set out some context about the circumstances in which decisions were taken in this period.

44. In the time period covered by this witness statement, the Department, alongside the rest of Government, was responding to the ongoing COVID-19 pandemic. The Government's aim throughout responding to the pandemic remained to protect the lives and livelihoods of citizens across the UK, and this became increasingly possible with low levels of disruption for the population given the use of effective vaccines. While many areas of life were returning to normal, there were a number of COVID-19 waves, including the emergence of Omicron. The period ends with the Government's 'Living with Covid' strategy which remains in place today.

45. The four tools of our response (vaccines, therapeutics, testing and NPIs) had each developed to a much more mature state than in 2020 which enabled the 'Living with Covid' plan to be established after the first Omicron wave. Whilst these tools were complementary, over this period, the emphasis shifted from primarily NPIs to pharmaceutical interventions, as vaccine coverage – and vaccine-derived immunity – increased. There was the roll-out of millions of effective and safe vaccines; effective clinical management of the disease including through the use of existing and new treatments; and very high levels of testing capacity and genome sequencing, including the active involvement of the population in very high levels of self-testing. The effectiveness of these three tools meant that the need for NPIs in this period was much reduced and was developed into contingency arrangements (called a 'Plan B' in the 'COVID-19 Response Autumn and Winter 2021 Plan'), for the emergence of a potentially more dangerous variant, and this was put in place in the Omicron response.

46. To take each of the four tools in turn:

    a. The procurement of a range of vaccines, effective regulation and advice, and the deployment capability of the NHS for vaccine rollout put the UK in a strong position. The Government continued to follow expert advice from the JCVI on who to vaccinate, when and with which vaccination and were able to stand up

contingency plans for a 'surge' response after the emergence of Omicron. More information on the vaccine rollout can be found in Section 2 of this witness statement.

b. The use and future procurement of therapeutics continued in this period, including substantial purchase of new COVID19-specific antivirals. Details of this can be found in Section 2 of this witness statement

c. Testing capacity and volumes were extremely high by the end of December 2021, testing and genomic sequencing, led by UKHSA, peaked at circa 3.8 million Polymerase Chain Reaction (PCR) tests per week. By November 2021 many countries worldwide, including the UK, were reaching their highest rates of genomic sequencing. Genomic sequencing from Southern Africa and the testing of travellers arriving in Hong Kong allowed the rapid identification of a novel variant of concern. Variant B.1.1.529 (Omicron) began to be identified as soon as the first four sequences had been uploaded by South African researchers to the online sequence database GISAID on 22 November 2021.

d. On NPIs, by July 2021, the Government had removed most legal restrictions, including legal limits on social contact, as well as reopening remaining premises and easing restrictions on large events and performances, in England at Step 4 of the Roadmap. The Government decided to ease restrictions as it coincided with the end of the school term for the summer period when more activities take place outdoors and when there is less pressure on the NHS. The Government's 'COVID-19 Response Autumn and Winter Plan 2021' set out the future approach, including a Plan B set of contingency measures which were to be introduced if the data suggested that the NHS was likely to come under unsustainable pressure. This included urgent public communications on the level of risk, domestic certification for entry to certain settings or venues, the use of face coverings, and guidance to work from home (where this was possible).

47. The UK was one of the first countries to respond to the Omicron variant, initially through travel restrictions, then through accelerating and extending the COVID-19 vaccine booster campaign. The Government was able to implement Plan B contingency measures in England at short notice because mitigations had already been planned

for and developed. The Department's response to the Omicron variant is explained in greater detail later in this statement at paragraphs 69-88, 97-111 and 144-175.

48. COVID-19 response remained the main business of the Department in this period, with changes continued to be managed through the Battleplan. There was also increasing attention in the summer of 2021 to embed the changes from the pandemic response into more 'business as usual' work; re-establish 'business as usual' procedures, for example in finance and staffing; a focus on elective recovery in the NHS; renewed focus on reform in Adult Social Care; and the consolidation of NHS Test and Trace, the Joint Biosecurity Centre and the health protection functions of PHE into a broad health protection agency. Embedding these changes was paused for the Omicron response and was then continued in the run-up to the agreement of the 'Living with Covid' strategy. Plans to stop, embed or transfer COVID-19 response work continued throughout the rest of 2022.

Vaccines prior to the Omicron variant

49. In the time period covered by this witness statement, the Department continued to closely follow the advice of the Joint Committee on Vaccination and Immunisation (JCVI), an independent group of experts who advise on which vaccines the Government health departments in the four UK nations should use and how they should prioritise vaccination at population level. In this statement 'JCVI advice' refers to advice from the JCVI to the Government health departments in the four UK nations.

50. The main objective of the COVID-19 vaccination programme was to protect those who were at highest risk from serious illness or death, and to maintain capacity in health and social care systems. The table below shows the JCVI priority list of eligible groups according to clinical risk as of 30 December 2020. The order of priority for each group in the population corresponded with data on the number of individuals who would need to be vaccinated to prevent one death, estimated from UK data obtained from March to June 2020,

Priority	**Risk group**
1	Residents in a care home for older adults and staff working in care homes for older adults
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 (not including pregnant women and those under 16 years of age)
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

Table 1: Table of COVID-19 vaccination first and second phase priority, date 30 December 2020 **(CW8/73 - INQ000234638; CW8/74 - INQ000256951; CW8/75 - INQ000256950; CW8/76 - INQ000257325).**

51. The JCVI prioritisation was supported by the COVID-19 Actuaries Response Group. The rationale in support of the prioritisation of the multiple risk groups was explored by estimating the number of vaccinations required to prevent one COVID-19 death per group; the results of this are shown in Table 2 below. This shows that the number of vaccinations required to save one life increases significantly going from vaccination group 1-10; therefore, supporting JCVI's prioritisation in Table 1.

Vaccination group	Number of COVID deaths[a]	Approximate population number (million)	No. needed to vaccinate to prevent one COVID death
1. Care home residents	22,800	0.5m	20
2. ≥80 years old	18,900	3.0m	160
3. ≥75 years old	6300	2.2m	350
4. ≥70 years old	5600	3.3m	600
5. ≥65 years old	3100	3.3m	1000
7. ≥60 years old	2000	3.8m	2000
8. ≥55 years old	900	4.4m	4000
9. ≥50 years old	500	4.7m	8000
10. Everyone else	600	37.0m	47,000

Table 2: The table above shows the estimated COVID deaths in each group, approximate population of each group and the vaccinations required to prevent one COVID death. The data in this table was based on mortality data up to 20 November 2020 and assumed that the vaccine was 100% effective in the prevention of death ***(CW8/77 - INQ000257328).***

52. In my Second Witness Statement for this Module dated 23 August 2023, I set out at paragraph 114-116 that:

> *"By mid-April 2021, all adults over 50, the clinically vulnerable and frontline health and social care workers had access to COVID-19 vaccination. This met the target to offer a first vaccine dose to priority Groups 1-9 by 15 April 2021.*
>
> *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. Groups 10 to 12 are:*

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

> *However, a new target of offering all adults a first dose, and two thirds of adults their second dose, by 19th July 2021 was set in June. By 18 July 2021, the vaccine programme met this target."*

53. By August 2021, over 85 million COVID-19 vaccines had been administered in the UK **(CW8/78 - INQ000256987)**.

54. Prior to August 2021 individuals aged under 18 were vaccinated either because they fell into one of the JCVI priority cohorts (i.e., they were 16+ and were either identified as at risk or a carer, were clinically extremely vulnerable, or were a health or social care worker) or based on JCVI advice that children under 16 who were at very high

risk of exposure and serious outcomes, such as those with severe neuro-disabilities that require residential care, should be offered vaccination. From August 2021 all individuals 16- to 17-years old, children aged 12 and over with specific underlying health conditions that put them at serious risk of COVID-19, and children aged 12 and over who were household contacts of an immunosuppressed individual, were also eligible to receive a vaccination.

55. On 4 August 2021, the Government accepted advice from the JCVI to offer all non-at-risk 16- to 17-year-olds a first dose of the vaccination; the roll-out for non-at-risk 16- to 17-year-olds began the following day, 5 August 2021 **(CW8/79 - INQ000256991; CW8/80 - INQ000256992)**. 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 **(CW8/81 - INQ000257007).**

56. Also on 23 August 2021, an agreement was made for 35 million more doses of the Pfizer-BioNTech vaccine, to be delivered from the second half of 2022 **(CW8/82 - INQ000257006)**.

57. On 1 September 2021 the JCVI advised the Government that it should provide a third primary dose to people aged 12 and over with severely weakened immune systems as part of their primary COVID-19 vaccination schedule. The Secretary of State accepted this advice from the JCVI on the same day **(CW8/83 - INQ000257018; CW8/84 - INQ000257011; CW8/85 - INQ000257010)**.

58. On 3 September 2021, the JCVI advised on the vaccination of non-at-risk 12- to 15-year-olds. The JCVI's advice was that the benefits from vaccination were marginally greater than the potential known harms for 12- to 15-year-olds with no underlying health conditions. However, the JCVI's view was that the margin of benefit, based primarily on a health perspective, was considered too small to support advice on a universal programme of vaccination of otherwise healthy 12- to 15-year-old children at this time. 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 **(CW8/86 - INQ000257024)**. The Government accepted the suggestion that the UK CMOs should be consulted **(CW8/87 - INQ000287669)**.

59. On 13 September 2021, following further advice from the UK CMOs which, in turn, was based on the UK CMOs consulting senior leaders of the medical and public health professions, the Government agreed to offer a first dose of Pfizer-BioNTech vaccine to all children and young people 12- to 15-years-old not already covered by existing JCVI advice **(CW8/88 - INQ000257036; CW8/89 - INQ000257035)**.

60. On 14 September 2021, the JCVI advised that a booster dose of an mRNA vaccine should be offered to all those who received vaccination in Phase 1 of the COVID-19 vaccination programme (JCVI priority cohorts 1-9). The JCVI advised a preference for the Pfizer-BioNTech vaccine for the booster programme, regardless of which vaccine brand someone received for their primary doses **(CW8/90 - INQ000257044)**.

61. This advice was accepted by the Government on 14 September 2021 and announced by the Minister for COVID-19 Vaccine Deployment, Nadhim Zahawi, in the House of Commons (**CW8/91 - INQ000257043).** In the press statement, it was announced that the Booster Programme rollout would start the following week **(CW8/92 - INQ000257042)**. The booster programme prioritised the offer of COVID-19 booster vaccines to:

    a. Care home residents;
    b. Health and social care workers;
    c. People aged over 50;
    d. Those aged 16-49 years-old with underlying health conditions that put them at higher risk of severe COVID-19;
    e. Adult carers; and
    f. Adult household contacts of immunosuppressed individuals.

62. There was flexibility in the programme, allowing all those eligible to receive their booster from six months after their second dose of the COVID-19 vaccine. This approach was announced on 29 October 2021 and allowed more vulnerable people to be given boosters quicker, with the flexibility being needed for effective vaccination in residential care home settings and given the proximity to the winter months, where there was a concern of the impact of any waning in vaccine protection given many of the most vulnerable had been vaccinated ahead of less vulnerable groups.

63. On 20 September 2021, the NHS began the COVID-19 vaccine rollout for non-at-risk 12- to 15-year-olds. Appointments for this group began on 22 October 2021 **(CW8/93 - INQ000257054; CW8/94 - INQ000257085)**.

64. After the JCVI recommendation to offer a third primary dose to those who were severely immunosuppressed, NHSEI wrote to NHS trusts and General Practitioners (GPs) (on 2 September 2021, 30 September 2021, and 25 January 2022) asking that doctors identify and contact people in this group, either to offer them a third primary dose or to provide them with a referral letter so that this could be accessed elsewhere **(CW8/95 - INQ000257021)**. Those who did not come forward were contacted by the lead clinical specialist in their NHS Trust, inviting them to receive their third primary dose as soon as possible **(CW8/96 - INQ000257258)**.

65. From 1 October 2021, the technical briefing documents on COVID-19 variants of concern and variants under investigation in England were published by UKHSA; prior to this date they were published by PHE **(CW8/97 - INQ000257072)**. The technical briefing documents contained epidemiological data and updated analysis of COVID-19 variants currently circulating in the UK.

66. On 19 October 2021, the Secretary of State asked for advice on shortening the dose interval of COVID-19 vaccinations **(CW8/98 - INQ000287683; CW8/99 - INQ000111934; CW8/100 - INQ000287681)** and on 29 October 2021, clinical guidance was updated to allow COVID-19 boosters to be given sooner than six months after their second dose to certain vulnerable people where this made operational sense. The UKHSA Green Book, which sets out the latest information on vaccines and vaccination procedures for vaccine preventable infectious diseases in the UK, was updated to reflect this **(CW8/101 - INQ000257096; CW8/102 - INQ000257325)**. The JCVI recommended booster vaccines to be scheduled at a six-month interval from the second primary dose. This interval automatically helped to prioritise older and more vulnerable patients. For operational reasons, administration was brought forward to a minimum of five months in certain circumstances including:

a. In a care home setting to enable all residents to be vaccinated in the same sessions; and/or
b. Where an otherwise eligible individual attends a clinical appointment for another reason (for example to receive influenza vaccine).

67. On 15 November 2021, the Government accepted the JCVI advice to extend the booster offer to all adults aged 40- to 49-years-old **(CW8/103 - INQ000257106)**.

68. The same day, the Green Book was updated to reflect that the four-week period between natural infection and COVID-19 vaccination should be extended to 12 weeks in those aged under 18 years who are not at high risk, to further reduce the already very small risk of side effects such as myocarditis **(CW8/104 - INQ000257105)**.

Vaccines post Omicron variant

69. On 25 November 2021, the UKHSA designated variant B.1.1.529 as a variant under investigation (VUI) **(CW8/105 - INQ000257119)**. The B.1.1.529 variant was characterised by many mutations across the viral genome, including 35 across the spike gene, many at known antigenic epitopes. These are biologically significant mutations which can change the behaviour of the virus. This in turn can impact the transmissibility and the effectiveness of interventions such as vaccines and other treatments. A virus with one or more new mutations is referred to as a "variant" of the original virus.

70. On the same day NERVTAG held an extraordinary meeting that concluded:

> *"17. … if introduced into the UK, B.1.1.529 would likely be capable of initiating a new wave of infections. We cannot exclude that this wave would be of a magnitude similar, or even larger, than previous waves.*
>
> *18. … Although data on disease severity associated with B.1.1.529 are not yet available, a large wave of infections will be accompanied by a wave of severe cases and the subgroup cannot rule out that this may be sufficient to overwhelm NHS capacity"*
>
> *…*
>
> *"Despite current uncertainty about the characteristics of B1.1.529, there are sufficiently worrying signals for the subgroup to advise that:*
>
> *20. Introduction of B.1.1.529 into the UK might have very serious consequences and, therefore, early, and robust actions to prevent introduction and onward transmission are warranted.*

21. Actions should be taken to enhance the early detection of B.1.1.529 in the UK and, if necessary, to implement containment measures.

22. Acceleration of the vaccine boosting campaign should be considered, which might provide some residual or significant VE against B1.1.529, and at a minimum would help control concurrent Delta impact.

23. The optimal use of available antiviral products should be reconsidered considering the new threat posed by B.1.1.529.

24. Actions should be taken to enhance the characterisation of B.1.1.529 e.g. computational biology, obtaining live virus samples and constructing pseudo viruses.

25. Preparations should be made for the modification of countermeasures i.e. vaccines and monoclonal antibodies" **(CW8/106 - INQ000074374)**.

71. On 26 November 2021, the WHO Technical Advisory Group on SARS-CoV-2 Virus Evolution named the B.1.1.529 COVID-19 variant, first detected in Botswana and South Africa, as the Omicron variant of concern **(CW8/107 - INQ000257120)**.

72. On 27 November 2021, two cases of COVID-19 with mutations consistent with B.1.1.529 were identified in the UK. The two cases were linked to travel from southern Africa **(CW8/108 - INQ000257123)**.

73. The Omicron variant, which emerged in late 2021 had several differences or mutations compared with the original ('wild type') variant. Cumulatively, these mutations meant that lab studies on blood from people who had been vaccinated indicated a lower level of activity against Omicron than against wild type. This, in addition to the waning effect of COVID-19 vaccines over time, meant that a further vaccine booster programme needed to be rolled out rapidly in order to bolster the population's immune response to Omicron **(CW8/109 - INQ000067508)**.

74. In response to a request from the Secretary of State, on 29 November 2021, the JCVI advised the following immediate measures in light of the emergence of the Omicron variant **(CW8/110 - INQ000257121; CW8/111 - INQ000257124)**:

a. Booster vaccination eligibility should be expanded to also include all adults aged 18 years to 39 years;
b. Booster vaccination should be offered in order of descending age groups, with priority given to the vaccination of older adults and those in a COVID-19 at-risk group. Booster vaccination should not be given within 3 months of completion of the primary course;
c. Severely immunosuppressed individuals who had completed their primary course (3 doses) should be offered a booster dose with a minimum of 3 months between the third primary and booster dose. Those who had not yet received their third dose may be given the third dose now to avoid further delay. A further booster dose can be given in 3 months, in line with the clinical advice on optimal timing; and
d. Both the Moderna (50 microgram) and Pfizer-BioNTech (30 microgram) vaccines should be used with equal preference in the COVID-19 booster programme. Both vaccines have been shown to substantially increase antibody levels when offered as a booster dose **(CW8/110 INQ000257121; CW8/113 - INQ000111982; CW8/114 - INQ000287690)**.

75. On 29 November 2021, the JCVI's advice was accepted by the Government, and the Government outlined its ambition to administer 500,000 COVID-19 booster vaccinations a day in a bid to tackle the spread of the Omicron variant **(CW8/115 - INQ000287691; CW8/113 - INQ000111982; CW8/117 - INQ000257140; CW8/115 - INQ000287691; CW8/119 - INQ000257142)**.

76. To speed up the vaccination programme, military support was drafted in and additional sites were opened **(CW8/120 - INQ000257184)**. Approximately 3,000 sites were opened to support the emergency response, more than double the number in early 2021.

77. NHSEI asked every local area to increase their number of vaccination appointments and extend the opening hours of vaccination sites. New pop-up sites were established in convenient sites for communities (from buses in parks and shopping centres, to sports stadiums and leisure centres). GP teams were asked to clinically prioritise their services to free up maximum capacity to support the vaccination programme, alongside delivering critical appointments such as those for cancer, urgent and emergency care.

78. The Government met its aim of offering every eligible adult a booster dose of the COVID-19 vaccination by the end of 2021 **(CW8/121 - INQ000287715)**.

79. On 1 December 2021, the Government purchased 114 million additional doses of Pfizer-BioNTech and Moderna COVID-19 vaccines for 2022 and 2023, with the intention of helping to futureproof against a reasonable worst-case scenario (RWCS) and to ensure continuity of vaccine supply **(CW8/122 - INQ000257145)**.

80. On 10 December 2021, UKHSA published analysis in Technical Briefing 31 which revealed that vaccine effectiveness against symptomatic disease with the Omicron variant was significantly lower than with the Delta variant with just two doses, but a booster dose increases protection back up to over 70% **(CW8/123 - INQ000287699)**. The emergence of the highly transmissible Omicron variant created additional need for antivirals within the UK population, particularly for those at greatest risk of severe disease progression. In response, the Department expanded the COVID-19 booster programme to the most at-risk.

81. In December 2021, NHSEI wrote to Chief Nurses, Chief Midwives, Medical Directors, and all GP and pharmacy contractors in the following terms:

> "*We write to ask all healthcare colleagues to make every contact count this winter with pregnant women – and those planning pregnancy – to advise them of the benefits of COVID-19 and flu vaccination; and to signpost acute physicians to best practice guidance on the management of COVID-19 infection in pregnancy, including medication*" **(CW8/124 - INQ000257144)**.

82. On 12 December 2021, in response to the circulation of the Omicron variant, the PM, together with NHSEI, gave a broadcast to the nation, calling for people to get vaccinated **(CW8/125 - INQ000257180)**; this launched an urgent national Omicron appeal for the public to 'Get Boosted Now'.

83. By 17 December 2021, 50% of the eligible population in the UK had received their COVID-19 booster vaccine making it one of the fastest rollouts in the world **(CW8/126 - INQ000257215)**.

84. On 22 December 2021, the JCVI advised that 5- to 11-year-olds in a clinical risk group, or who were a household contact of someone who is immunosuppressed, should be

offered primary course vaccination with two doses of the Pfizer-BioNTech COVID-19 vaccine **(CW8/127 - INQ000147458)**.

85. On 17 January 2022, the NHS began the booster rollout to at risk 12- to 15-year-olds **(CW8/128 - INQ000257251)**.

86. On 31 January 2022, the vaccine rollout began for 5- to 11-year-olds in a clinical risk group, or who were household contact of someone who was immunosuppressed **(CW8/129 - INQ000257265)**.

87. On 16 February 2022, the Government accepted JCVI advice to the UK health departments to offer two doses of the Pfizer-BioNTech paediatric vaccine on a non-urgent basis to 5- to 11-year-olds who are not in a clinical risk group **(CW8/130 - INQ000257288; CW8/INQ - INQ000257288)**. JCVI noted that the recommendation should not displace the delivery of other non-COVID-19 childhood vaccinations, or any other part of the COVID-19 vaccination programme. The Government announced that the Department and NHSEI would advise on their plans for operationalising this latest JCVI recommendations in due course.

88. On 21 February 2022, the Government accepted advice from the JCVI to UK health departments to offer additional spring booster doses **(CW8/130 - INQ000257288)**. This advice also set out that winter would remain the season when the threat from COVID-19 is greatest both for individuals and for health communities, so their interim view was to plan for an autumn booster programme focused on a wider group of people vulnerable to minimise serious outcomes from COVID-19 due to age or clinical condition.

Antivirals and Therapeutics prior to the Omicron variant

89. In my Second Witness Statement for this Module dated 23 August 2023 (fifth statement - INQ000253807), I set out at paragraph 161 and 163-164 that:

> *"The Antivirals Taskforce (ATF) was officially established in April 2021 (CW5/180 - INQ000256958). The Secretary of State proposed the programme to the PM and (Chancellor of the Duchy of Lancaster (CDL), and it was agreed that an ATF would be established to bring focus and momentum to this programme (CW1/181 - INQ000256956). Antivirals are a type of therapeutic medication used specifically to treat viral infections. They aim to minimise the symptoms of an infection and*

shorten its duration. They also can help reduce transmission of a virus. Rather than killing the virus directly, antivirals usually suppress the virus's ability to infect and multiply in cells and so are most effective when used early on in infections. The ATF was tasked with the objective of having at least two oral antiviral treatments available for UK patients by the end of 2021 that could be used as a community treatment – that is, one that does not require administration in a secondary care setting (CW5/182 - INQ000257447)."

"The TTF [Therapeutics Taskforce] continued to identify and make available new treatments, with particular focus on neutralizing monoclonal antibody treatments (also called mAbs or MABs). These are proteins made in laboratories that act like proteins called antibodies in our bodies that help stimulate the immune system and have been used to treat a number of conditions including cancer and inflammatory and autoimmune disorders, including allergies. The TTF was proactively engaging with suppliers of potential monoclonal antibody treatments.

In May 2021, against the backdrop of data on vaccine efficacy, duration of immunity and hugely successful vaccines rollout and uptake, and momentum in establishing the Antiviral Taskforce (ATF), the Therapeutics Taskforce's (TTF) objectives were re-focused to prioritise treatments for individuals whose immune systems put them at greater risk of COVID-19. This included those for whom the vaccine was not effective or who could not have a vaccine."

90. A Conditional Marketing Authorisation (CMA) for casirivimab/imdevimab (REGN-COV, or Ronapreve) from Roche was issued in August 2021, along with a temporary authorisation for supply to Northern Ireland under regulation 174 of the Human Medicine Regulations 2012 (as amended). I provide more detail on temporary authorisations (also known as 'emergency authorisations') and relevant amendments made to the Human Medicines Regulations 2012 in paragraphs 91-93 of my Second Witness Statement for this Module. This temporary authorisation ensured supply across all of the UK, making it the first novel COVID-19 monoclonal antibody treatment to receive authorisation in the UK **(CW8/133 - INQ000257109; CW8/134 - INQ000257005)**. Details of the procurement of casirivimab/imdevimab is explained at paragraph 166 of my Second Witness Statement for this Module.

91. On 11 August 2021, the Therapeutics Taskforce (TTF) agreed a deal to procure approximately 100,000 doses of a second monoclonal antibody, sotrovimab (marketed

as Xevudy) from GlaxoSmithKline (GSK), pending CMA approval **(CW8/135 - INQ000256974)**.

92. An interim clinical access policy setting out the cohort of hospitalised patients who may be eligible for treatment with casirivimab/imdevimab was published on 17 September 2021 **(CW8/136 - INQ000257053; CW8/137 - INQ000257052)**.

93. On 1 October 2021, the No.10 Private Office agreed to the initial procurement of 480,000 courses of molnupiravir (marketed at Lagevrio) from Merck, Sharpe and Dohme (MSD) and 250,000 courses of nirmatrelvir + ritonavir (Paxlovid) from Pfizer, subject to the Medicines and Healthcare Products Regulatory Agency (MHRA) issuing a CMA **(CW8/138 - INQ000257074)**. This was announced on 20 October 2021 **(CW8/139 - INQ000257082)**.

94. Another antiviral candidate was considered earlier in the ATF programme. This was an oral product jointly developed by Atea Pharmaceuticals and Roche under the product name AT-527. In October 2021, the medicine failed to meet the main objectives of a phase II trial to demonstrate efficacy in non-hospitalised patients and the ATF decided to not pursue future procurement.

95. CMAs were issued for molnupiravir and Paxlovid on 4 November 2021 and 31 December 2021, respectively **(CW8/140 - INQ000257098; CW8/141 - INQ000287716; CW8/142 - INQ000287717; CW8/143 - INQ000287718; CW8/144 - INQ000287719)**. On the same dates the MHRA also issued relevant temporary authorisation for supply to Northern Ireland under regulation 174 of the Human Medicine Regulations 2012 (as amended)CW8/, which ensured supply across the whole of the UK.

96. In November 2021, the ATF Operations Board approved the proposal for NHSEI to send pre-notification letters to the highest risk cohorts in England. These patients were identified by an Independent Advisory Group commissioned by the DCMO and led by Professor Iain McInnes **(CW8/145 - INQ000067432; CW8/146 - INQ000257112)**. From December 2021, these letters informed high-risk patients that they could be eligible for early treatments should they test positive for COVID-19 through a PCR test **(CW8/147 - INQ000257191)**. High-risk patients automatically received a PCR test kit to keep at home, which was processed as a priority on receipt. Following a positive

test result, a patient's local COVID Medicines Delivery Unit ('CMDU') or their equivalent in the Devolved Governments would contact them to discuss treatment options.

Antivirals and Therapeutics post Omicron variant

97. On 28 November 2021, in response to the threat of Omicron, the ATF submitted a Ministerial Panel Business Case to the Secretary of State on procurement options to significantly increase the number of oral antiviral treatments available to patients in need of treatment. The Secretary of State reviewed the submission on 29 November 2021 and asked to proceed with the procurement of an additional 3 million courses of Paxlovid and 1.25 million courses of molnupiravir. The Secretary of State's steer was incorporated into the Business Case before it was submitted to HMT and shared with the No.10 Private Office later that day.

98. Following discussions between the ATF, HMT and the No.10 Private Office, the ATF submitted a note to the No.10 Private Office on 30 November addressing concerns raised by HMT on the procurement of additional antiviral treatments **(CW8/148 - INQ000287693)**. The Ministerial Panel Business Case was resubmitted alongside the note to the Secretary of State that same day and on 1 December 2020, he reiterated his decision to proceed with the procurement of an additional 3 million courses of Paxlovid and 1.25 million courses of molnupiravir **(CW8/149 - INQ000287694)**. Later that day, the Business Case and note were submitted to the Ministerial Panel for agreement **(CW8/150 - INQ000287695)**.

99. Additionally, on 1 December 2021, the Department received a note from HMT setting out their view that "on balance, this points to delaying any decision on further procurement until we have tested our deployment model, understand better the future risks of variants – including Omicron – and allow time for new products to enter the market" **(CW8/151 - INQ000287692)**.

100. On 2 December 2021, the MHRA issued a CMA for sotrovimab and a temporary authorisation for supply to Northern Ireland under regulation 174 of the Human Medicine Regulations 2012 (as amended), which ensured supply across the whole of the UK.

101. On 8 December 2021, the PANORAMIC trial was launched and the ATF provided the systemic support necessary in the delivery of this study at the required scale and pace and encouraged the Devolved Governments and key organisations (such as

the NIHR, NHSEI, UKHSA and NHS Digital) to also work collaboratively. Patients enrolled in the PANORAMIC study were randomised to either receive the oral antiviral molnupiravir plus standard of care or standard of care only.

102. On 14 December 2021, the Department was informed of the PM's decision to proceed with the proposed purchase of 4.25 million additional courses of antiviral treatments and that HMT should provide the additional funding required **(CW8/152 - INQ000287703)**. On 15 December 2021, this was approved by HMT **(CW8/153 - INQ000287706)** and Lord Agnew agreed to the Business Case submitted to the Ministerial Panel on 1 December 2021 **(CW8/154 - INQ000287704)**. The BEIS Secretary of State previously agreed to the Business Case on 2 December 2021 **(CW8/155 - INQ000287696)**.

103. On 15 December 2021, UKHSA, experts from the Variants Technical Group and academics from Imperial College London, the University of Cambridge, the University of Liverpool and the University of Oxford reviewed neutralisation data of casirivimab/ imdevimab (Ronapreve) against the Omicron variant. The ATF and TTF subsequently received advice from these experts and academics on 16 December 2021 **(CW8/156 - INQ000257201; CW8/157 - INQ000257202)**. The advice stated that the data showed *"a very substantial loss in neutralisation when casirivimab/imdevimab (Ronapreve) is tested against Omicron"*. This suggested that *"Ronapreve at the standard 1200mg and 2400mg doses would be ineffective"* against the Omicron variant. On the same day, Regeneron Pharmaceuticals announced that *"Currently authorized REGEN-COV® (casirivimab and imdevimab) antibodies have diminished potency versus Omicron but are active against predominant Delta variant"* **(CW8/158 - INQ000257212)**.

104. On 16 December 2021, the UK CMOs published updated interim clinical access policy to advise that sotrovimab would be available for hospitalised and non-hospitalised patient use from 20 December 2021 and that casirivimab/imdevimab *"is [was] likely to be materially compromised against the increasingly prevalent Omicron variant"* **(CW8/161 - INQ000257208)**. Sotrovimab was made available to patients in the community through CMDUs and their equivalents in the Devolved Governments **(CW8/160 - INQ000257147; CW8/161 - INQ000257208)** and as Omicron became the dominant variant, casirivimab/imdevimab was fully removed from clinical policies on 24 February 2022 **(CW8/162 - INQ000257311)**.

105. On 19 December 2021, following Ministerial Panel agreement, Lord Kamall and the Secretary of State agreed the procurement of an additional 4.25 million antiviral treatments, comprising an additional 1.75 million courses of molnupiravir (Lagevrio) and 2.5 million courses of nirmatrelvir + ritonavir (Paxlovid) **(CW8/163 - INQ000257221)**. This was announced on 22 December 2021 **(CW8/164 - INQ000287707)**.

106. This supply was intended to provide a layer of protection in both the short- and long-term for those people whose immune systems meant they were at higher risk from COVID-19. The supply was also intended to provide an important insurance policy against vaccine-escaping variants emerging in the future that might require a wider use of oral antivirals to manage pressures arising as a result.

107. Alongside rolling out approved treatments to patients, the UK continued to put other promising medicines, including those that were not antivirals or monoclonal antibodies, through clinical trials in order to find further effective treatments and broaden the therapeutic options available to treat patients with COVID-19. In the UK, this research was primarily completed through a portfolio of Government-funded clinical trial platforms, many of which were formed at the outset of the pandemic. The treatments that were added to the clinical trial platforms following a decision in conjunction with the CMO and following a recommendation by the UK COVID-19 Therapeutics Advisory Panel included:

a. Cysteamine into the REMAP-CAP clinical trial (intensive care) on 21 June 2021 **(CW8/165 - INQ000256963)**;
b. Ivermectin into the PRINCIPLE clinical trial (primary care) on 23 June 2021 **(CW8/166 - INQ000256964)**; and
c. Empagliflozin and sotrovimab into the RECOVERY clinical trial (secondary care) on 28 July 2021 and 23 December 2021, respectively **(CW8/167 - INQ000257225)**.

108. By the time Omicron became the dominant variant in the UK, in January 2022, the PANORAMIC trial had recruited 10,000 participants in just over two months, making it the fastest recruiting randomised controlled primary care trial in the UK to hit that milestone **(CW8/168 - INQ000257300)**. By the end of April 2022, the PANORAMIC trial had recruited 25,000 participants, including 600 patients into a virology sub-study,

making it the largest interventional primary care trial in the UK and the largest study worldwide into COVID-19 antiviral treatments **(CW8/169 - INQ000287748)**. The nirmatrelvir plus ritonavir (Paxlovid) arm was opened in April 2022 **(CW8/170 - INQ000257154)**.

109. The TTF supported the development of a second prophylaxis trial targeted at vulnerable groups. The PROTECT-V trial, which aimed to identify safe and effective pre-exposure prophylactics for vulnerable patients received funding approval on 13 April 2022 and commenced on 1 June 2022 **(CW8/171 - INQ000257320)**.

110. Throughout the pandemic the ATF, TTF and then the Antivirals and Therapeutics Taskforce (ATTF) (which formed in April 2022 when the ATF and TTF combined **(CW8/172 - INQ000257315; CW8/173 - INQ000257266; CW8/174 - INQ000257267; CW8/175 - INQ000257273; CW8/176 - INQ000257274; CW8/177 - INQ000257317; CW8/178 - INQ000257318)** engaged with international partners, bilaterally and multilaterally, to share strategies and learning on the use, deployment and evaluation of COVID-19 antivirals and other therapeutics. This engagement continued to inform Government policy; evaluating the similarities and differences in approaches helped to strengthen the UK's approach, particularly when new variants emerged. The UK's engagement with G7 countries facilitated the development and agreement of the key principles in the G7 Clinical Trials Charter on 4 June 2021 which set the strategic direction for how the UK can collaborate with international partners on clinical trials **(CW8/179 - INQ000256962).**

111. The G7 Clinical Trials Charter's principles went on to support policy development for a new WHO resolution on strengthening clinical trials. A zero draft of the resolution text was developed during this period by the UK and circulated to other WHO Member States. While there is no formal definition, a zero draft is a first draft of a resolution or other text to begin negotiations. It is not formally agreed by any Member State but allows them to have some text on which to aid negotiations going forward. Zero drafts are normally drafted by the proponent(s) of an idea or concept, or the chair(s) or bureau of a group in order to progress discussions. The zero draft is then replaced by further iterations as negotiations proceed.

SECTION 3: NON-PHARMACEUTICAL INTERVENTIONS, CONTINGENCY PLANNING AND RESPONSE

112. In the time period covered by this statement, the virus adapted in the UK and globally and the Government responded accordingly. Health and social care aspects of the response continued to be the main business of the whole Department, working with its ALBs. The Department planned for and responded to waves, based on scientific and clinical advice, and continued to use the Battle Plan to organise its response. The most significant drivers of events during this period were the Step 4 Roadmap release, implementation of Plan B of the COVID-19 Autumn and Winter Plan, the Omicron variant, and the publication of 'Living with COVID-19' on 21 February 2022.

113. As set out in my Second Witness Statement for this Module, on 19 July 2021 the Government relaxed the majority of restrictions as part of the move to Step 4 of the Roadmap. On that day, the PM set out the Government's plan to introduce, by the end of September 2021, vaccination as a mandatory condition of entry into nightclubs, and other venues where large crowds gather. Additionally, the Government set out, as part of its pathway through the summer, that it would undertake a review in September 2021, which would assess whether to continue or strengthen measures needed in preparation for autumn and winter (a description of the advice on the autumn review point may be found in 'COVID-19 Response: Summer 2021' **(CW8/180 - INQ000256993)**, a Government publication that set out the shape of Step 4 of the Roadmap.

114. Because of the increased levels of social mixing and close social contact, the Government expected that during winter 2021-22 COVID-19 would co-circulate alongside other respiratory viruses, including seasonal influenza virus. Therefore, COVID-19 could add substantially to the 'winter pressures' that the NHS would ordinarily face **(CW8/181 - INQ000257041)**.

115. In relation to funding for the DHSC response to the pandemic, on 16 July 2021 I wrote to the Prime Minister's (PM) Chief of Staff, Daniel Rosenfield, about the implications of the proposed three-year health and care funding settlement **(CW8/182 - INQ000287750)**. The letter followed a trilateral meeting that had taken place on the same day between the PM, the Chancellor and the Secretary of State for Health. My letter made some general points about the implications of the funding proposals, which included implications for adult social care and on addressing waiting lists for elective hospital care. My letter also specifically addressed the potentially negative impact of

the funding proposals on the response to the pandemic in three areas: test and trace; vaccine delivery; and, access to antivirals. In relation to Test and Trace, I described the significant consequences of reducing funding from £15bn to £1.3bn on providing an at scale test and trace programme with national capability to detect a vaccine-resistant COVID variant and reduce its spread. For vaccine delivery, I described the implications of the funding proposals on providing a more than a single annual booster for adults or vaccinating those below the age of 18 were the public health advice to recommend this. In relation to access to antivirals, I explained the uncertainty about whether the proposed funding would be sufficient. In addition to highlighting those areas, I identified further potential impacts on the Department's functions that might occur as a result of the proposed settlement, including the "*…significant risk to delivery of the commitments in the NHS long term plan to expand mental health services, cancer care and diagnostics*." Annexes A and B to the letter set out in more detail some of the challenges presented by the proposed health and care settlement.

116. I received a response from the PM's Chief Of staff, dated 27 July 2021, which indicated that since my letter, the PM, Chancellor and the Secretary of State for Health had reached agreement on increased funding for Health and Social Care and referenced a letter from Stuart Glassborow of 21 July 2021 **(CW8/183 – INQ000287650)** which had set out the terms of the agreement. The letter from the PM's Chief of Staff also said that if the situation surrounding COVID-19 "*…deteriorates significantly and unexpectedly from next year, and the Prime Minister agrees a return to emergency footing, it may be necessary for HMT to consider the case for additional funding'* **(CW8/184 - INQ000287751)**. The letter also stated that "*…no specific policy decisions on vaccines, the testing regime or the UKHSA* [UK Health Security Agency] *have yet been taken*" and that it would be for Ministers to take such decisions as part of the ongoing response to the pandemic.

117. In the period covered by my Second Witness Statement for this Module, CO led on COVID-19 Status Certification policy This concerned checks on COVID-19 status certification for entry to certain settings, such as nightclubs and other venues where large crowds gather, in England. However, the governance for certification changed in the time period covered by this witness statement. On 15 July 2021, Departmental officials shared advice with the Secretary of State that recommended that the Department should take responsibility for policy on COVID-19 Status Certification to access settings and that the process for transition of this responsibility would be agreed

after Step 4 had completed **(CW8/185 - INQ000256977)**. The Secretary of State did not favour the option that the Department should take the lead role for the policy and the rationale for the policy remaining with CO was outlined in a letter that was sent on 26 July 2021 from the Secretary of State's private office to the Chancellor of the Duchy of Lancaster (CDL's) private office **(CW8/186 - INQ000256980)**. On 18 August 2021, the Secretary of State's private office provided a further steer to Departmental officials that the Department would draft the certification regulations, liaising with the CO on the policy intentions, but that the CO would retain ownership **(CW8/187 - INQ000257003)**. On 2 September 2021, the Secretary of State agreed to sign the regulations when needed, on the condition that CDL provided support with parliamentary handling **(CW8/188 - INQ000257023)**.

118. On 28 July 2021, the Secretary of State reviewed a joint paper from the Department and the COVID-19 Taskforce **(CW8/189 - INQ000256981)**, in parallel with the CDL. The paper provided an update on progress on mandatory certification, including options for bringing implementation forward; options for communicating more clearly the intention to introduce certification; setting out what policy decisions would need to be made in order to do so; and an update on delivery. The first option for implementation was to introduce vaccine-only certification, which required visitors aged 18 or over (with some limited exemptions) to show proof of vaccination before entering certain settings, from 30 September 2021, when all adults had been offered a full course of vaccination. This was the recommended option. The second option required proof of vaccination or regular testing from 23 August 2021, before transitioning to a vaccine only requirement from 30 September 2021. On 2 August 2021, the Secretary of State fed back that he agreed with the recommended option to introduce mandatory vaccine-only certification at the end of September 2021. He commissioned further advice on the settings in which such certification should be required. **(CW8/190 - INQ000256988)**

119. Departmental officials briefed the Secretary of State on 6 August 2021 for a PM-chaired meeting on COVID-19 Status Certification with the Secretaries of State of the Department of Culture Media and Sport (DCMS) and the Department of Business Energy and Industrial Strategy (BEIS), the CDL, the CMO, and the Chief Whip **(CW8/191 - INQ000113084; CW8/192 - INQ000256997)**. This briefing advised on the purpose of certification and the timelines and key questions to develop the policy.

120. The meeting had originally been planned for 9 August 2021 but was held on 10 August 2021 **(CW8/193 - INQ000287658)**. The Secretary of State responded on 10 August 2021 to the advice of 6 August 2021, saying that he preferred that certification be applied initially only to nightclubs (as size of venue was not a good proxy for risk as it does not account for crowding or close contact). He also suggested that solutions for UK residents vaccinated abroad needed to be found before further announcements; that vaccine-only certification should be introduced if needed to reduce transmission; and a vaccine-only certification should be available to the workforce of those covered by the policy. A revised briefing reflecting these steers was provided later that day ahead of a pre-brief before the meeting with the PM that day **(CW8/194 - INQ000256998)**.

121. Ministers agreed at a meeting chaired by the PM on 10 August 2021 to prepare for COVID-19 Status Certification to be introduced on 30 September 2021, with regulations to be made around 20 September 2021, with the final decision (on whether to proceed) to be made shortly before 20 September 2021. The policy would apply to all nightclubs and other large or very large settings meeting specified criteria (e.g., over 500 attendees in an unseated, indoor setting) **(CW8/195 - INQ000257000)**.

122. On 16 August 2021, Departmental officials provided advice to the Secretary of State on whether to include 16- to 17-year-olds within the scope of a COVID-19 Status Certification policy, recommending not to extend certification requirements to this cohort until they had become eligible for full vaccination **(CW8/196 - INQ000066672)**. On 19 August 2021, the Secretary of State agreed with the recommendations **(CW8/197 - INQ000257004)**.

123. On 17 August 2021, the Secretary of State's office circulated formal actions from the PM-chaired meeting on 10 August 2021 **(CW8/187 - INQ000257003)**. These required the Department to develop either:

a. A model of a paid-for supervised testing for those employees subject to a vaccine-or-test regime (rather than a vaccine-only model); or
b. If that was not viable, to consider alternative options. The Department was also required to identify robust criteria for acceptable proof of vaccine status for vaccine-only certification (including NHS App, non-digital proofs and routes for devolved administration, crown dependencies, overseas territories, and other international visitors) to enter in-scope settings.

124. Advice on international proofs of certification and on the testing model was provided on 23 August 2021 and 1 September 2021 respectively **(CW8/199 - INQ000066722; CW8/200 - INQ000287663; CW8/201 - INQ000287665; CW8/202 - INQ000287664)**.

125. On 23 August 2021, a submission to the Secretary of State recommended that the acceptable evidence for demonstrating vaccination status required for international arrivals at the border (arrival into England) should also be accepted for domestic, mandatory, vaccine-only certification for entry to relevant settings **(CW8/203 - INQ000287662)**.

126. On 27 August 2021, the CO commissioned the Department to provide two joint papers to inform the approach to mandatory certification for a Small Ministerial Group (SMG) scheduled for 7 September 2021 **(CW8/204 - INQ000257009)**. The first paper, about the approach to visitors to domestic settings in scope of certification policy, was led by the COVID-19 Taskforce, with input from the Department. The second, about the approach to the workforce of those settings, was led by the Department, with input from BEIS and DCMS.

127. On 1 September 2021, the Secretary of State received joint advice from the COVID-19 Secretariat and Departmental officials about the settings proposed to be within scope of a mandatory vaccination certification scheme. The Department's note recommended a wider list of settings covering 'nightclub like' settings **(CW8/205 - INQ000287668)**. The Secretary of State also received Departmental officials' advice on workforce certification and the approach to voluntary certification, as well as a draft CO SMG paper on workforce certification **(CW8/206 - INQ000066776; CW8/207 - INQ000287666; CW8/208 - INQ000287667; CW8/209 - INQ000257016; CW8/205 - INQ000287668)**.

128. The Secretary of State responded on 1 September 2021 that he agreed to seek collective agreement for the inclusion of cruises in COVID-19 Status Certification; to use an objective definition of nightclubs; to set out what settings he thought should be in scope of mandatory certification; and indicated his agreement to the proposal to introduce voluntary certification for low and medium risk settings **(CW8/211 - INQ000257019; CW8/212 - INQ000257020; CW8/213 - INQ000257017)**.

129. On 1 September 2021, I met the Secretary of State, the Minister for COVID-19 Vaccine Deployment, DCMO and NHSEI to discuss schools and vaccines, and in particular the proposal to roll out the vaccine to those aged 12- to 15-years-old **(CW8/214 - INQ000257014)**.

130. On 2 September 2021, the Secretary of State responded to a submission on the workforce in settings covered by mandatory certification that he had received the previous day, agreeing that vaccine-or-test certification should be applied to the workforce; and that free Lateral Flow Device (LFD) tests that were provided through existing Government channels should be supervised by employers. He wanted tests to become chargeable to employers at a later date **(CW8/215 - INQ000257022)**.

131. On the same day, a briefing was provided to the Secretary of State ahead of a COVID-O that had been scheduled for the following week to discuss the autumn review of COVID-19 measures. This set out that Departmental officials had understood that No. 10 and the CO were minded to hold back certification as a contingency measure if required later and were also considering whether to confirm this in the September Review announcement **(CW8/216 - INQ000257027)**. Alongside the COVID-O briefing, a further submission on workforce testing was provided on 9 September 2021, which sought confirmation of the Secretary of State's preferred approach ahead of the COVID-O meeting **(CW8/217 - INQ000257026)**. It recommended introducing regulations requiring in-scope settings (such as nightclubs) to supervise the testing of their workforce; applying testing to all staff in those workplaces (not just those in customer facing roles); and creating legal duties for venue operators (to support compliance).

132. On 11 September 2021, Departmental officials provided advice to the Secretary of State ahead of a COVID-O meeting about an autumn review point for COVID-19 measures. This advised that the Secretary of State should agree to the general position proposed in the COVID-19 Taskforce paper about the implementation of a proposed 'Plan A'. This would focus on continuing the vaccine rollout, with the option to introduce further restrictions on people and on businesses/settings, if pressure on the NHS became unsustainable. It also recommended developing 'Plan B' measures involving the reintroduction of certain non-pharmaceutical interventions, which could be deployed if needed to control transmission **(CW8/218 - INQ000257028; CW8/219 - INQ000257029)**. On 12 September 2021, Departmental officials provided updated advice to reflect concerns from UKHSA about the proposed Test and Trace chapters

in the draft COVID-19 Response Autumn and Winter 2021 Plan **(CW8/220 - INQ000257033; CW8/221 - INQ000257034)**.

133. On the same day, Departmental officials provided the Secretary of State with a plan for a certification consultation and the COVID-19 Taskforce's paper on the approach to mandatory COVID-19 Status Certification for the SMG the following day. These documents covered several issues, including the settings in scope, the approach to hospitality and workforce testing **(CW8/222 - INQ000257030; CW8/223 - INQ000257032; CW8/224 - INQ000257031)**.

134. At the SMG on 13 September 2021, it was agreed that mandatory certification would be kept as a contingency measure as part of a Plan B, and that the Department should produce draft regulations, a policy statement, and guidance ready for publication during the week commencing 20 September 2021 **(CW8/225 - INQ000257051)**. On the same day, COVID-O agreed to publish the 'COVID-19 Response Autumn and Winter 2021 Plan' (the Autumn and Winter Plan), which was done the following day **(CW8/226 - INQ000257049)**.

135. On 14 September 2021, a submission was provided to the Secretary of State detailing a proposed consultation approach on mandatory vaccine certification **(CW8/227 - INQ000066896)**. On 20 September 2021, the Secretary of State agreed with the approach, and wrote to the CDL to set out the proposal **(CW8/228 - INQ000257055; CW8/229 INQ000257048**

136. Further, on 14 September 2021 the Secretary of State gave an oral statement in the House of Commons on autumn and winter planning **(CW8/230 - INQ000257045)**, and the Government published the Autumn and Winter Plan **(CW8/231 - INQ000065168)**, which set out the Government's plan for managing COVID-19 in the autumn and winter in England. Plan A included five pillars:

a. Building defences through pharmaceutical interventions: vaccines, antivirals and disease modifying therapeutics;
b. Identifying and isolating positive cases to limit transmission: Test, Trace and Isolate;
c. Supporting the NHS and social care: managing pressures and recovering services;

d. Advising people on how to protect themselves and others: clear guidance and communications; and
e. Pursuing an international approach: helping to vaccinate the world and managing risks at the border.

137. The Autumn and Winter Plan set out that the Plan B measures would be deployed only if the data were to indicate that further measures would be necessary to protect the NHS. The Plan B measures were:

a. Communicating clearly and urgently to the public that the level of risk had increased, and with it the need to behave more cautiously;
b. Introducing mandatory vaccine-only COVID-status certification in certain settings;
c. Legally mandating face coverings in certain settings; and
d. The Government would consider asking people to work from home if they could, for a limited period.

138. On 21 September 2021, the Secretary of State received a submission on options for publication and for a public consultation about certification policy, alongside the policy statement and draft regulations for his review **(CW8/232 - INQ000066995)**. The Secretary of State received revised documents, which he approved on 26 September 2021 **(CW8/233 - INQ000257066; CW8/234 - INQ000111828; CW8/235 - INQ000257064)**. The policy statement and call for evidence were published on 27 September and the call for evidence ran until 11 October 2021.

139. On 12 October 2021, a submission was sent to the Secretary of State providing a summary of the initial responses to the call for evidence **(CW8/236 - INQ000257081)**.

140. The Secretary of State met Departmental officials on 21 October 2021 to discuss the decision-making process for the introduction of Plan B **(CW8/237 - INQ000257086)**. Following the meeting, he received a revised submission about implementation readiness for Plan B **(CW8/238 - INQ000257088; CW8/239 - INQ000257087)**.

141. On 26 October 2021, two submissions on certification were provided to the Secretary of State **(CW8/240 - INQ000067332)**. The first of these recommended changes to mandatory certification policy as part of Plan B, based on the responses to the Call for

Evidence about how and where workforce testing was required and under what circumstances larger premises would not have to conduct checks of all attendees' COVID-19 status. The second submission provided advice about the wearing of face coverings in settings where certification applied **(CW8/241 - INQ000067336; CW8/242 - INQ000257094)**. On 27 October 2021, the Secretary of State agreed to the proposal, with the proviso that he would review whether mandatory certification was required **(CW8/243 - INQ000287684)**.

142. On 1 November 2021, a submission was sent to the Secretary of State on the potential impacts of certification **(CW8/244 - INQ000154223)**.

143. On 5 November 2021, the Secretary of State received the final report for the Event Research Programme (ERP), which had been in place over the period April 2021 – July 2021 **(CW8/245 - INQ000067370; CW8/246 - INQ000067371; CW8/247 - INQ000067372)**. This was referenced in my Second Witness Statement for this Module **(INQ000253807)**. The final report consisted of three elements that summarised the transmission risk at different ERP events. On 15 November 2021 the Secretary of State agreed to publication **(CW8/248 - INQ000257107)**. The final report was submitted to the PM for clearance and then published on 26 November 2021 **(CW8/249 - INQ000287689)**.

144. On 22 November 2021, Departmental officials submitted advice to the Secretary of State setting out the core principles of a proposed response to COVID-19, for the spending review period 2022-2025, i.e., beyond the Autumn and Winter Plan (focussing particularly on the first year) **(CW8/250 - INQ000257113; CW8/251 - INQ000257114; CW8/252 - INQ000257115)**. The Secretary of State requested an updated version in light of the emergence of Omicron, to detail the links with the UKHSA COVID strategy. The Secretary of State received updated advice on 1 December 2021, and he agreed the overall approach on 3 December 2021, subject to drawing out the risks further **(CW8/253 - INQ000257146; CW8/254 - INQ000257149)**.

145. On 27 November 2021, the PM held a press conference about the Omicron variant and signalled that the Government would be taking targeted and proportionate measures to slow down the spread of Omicron **(CW8/255 - INQ000114458)**.

146. The same day, Departmental officials briefed the Secretary of State ahead of an expected COVID-O meeting on 28 November 2021 about the overall delivery readiness for Plan B and outstanding delivery questions including details on the mandatory COVID-19 Status Certification policy **(CW8/256 - INQ000111937; CW8/257 - INQ000111938)**.

147. On 30 November 2021, new rules came into force as part of the response to the threat posed by the Omicron variant, alongside considering its impact on for example, vaccine efficacy as well as other pharmaceutical and non-pharmaceutical interventions. These included:

a. Face coverings compulsory in shops and on public transport;
b. All international arrivals to take a Day-2 PCR test and self-isolate until they receive a negative test result;
c. All contacts of suspected Omicron cases to self-isolate, regardless of their age or vaccination status.

148. On 7 December 2021, Departmental officials provided advice to the Secretary of State on the Omicron response options **(CW8/258 - INQ000257151)**. This advice recommended a series of interventions from across the Battle Plan and the approach to Government communications. Further advice was provided outlining indicators for using NPIs, an overview of NPIs used to date, and options for strengthening Plan B measures **(CW8/259 - INQ000257152)**.

149. Later that day the Secretary of State met officials to discuss this advice; he agreed an action plan containing the priority interventions required to tackle Omicron. Following this meeting, the Secretary of State wrote to the PM, stressing the need for immediate action **(CW8/260 - INQ000257179)**.

150. On 8 December 2021, the Secretary of State was provided with further advice on introducing mandatory certification in response to Omicron **(CW8/261 - INQ000257155)**. The submission recommended further work be undertaken on vaccine-and-test certification, as well as the alternative option of closing higher risk settings.

151. The Secretary of State was provided with a briefing from Departmental officials, about face coverings, certification and self-isolation for the COVID-O meeting on 8 December

(CW8/262 - INQ000257164; CW8/263 - INQ000257165; CW8/264 - INQ000257166). The COVID-19 Taskforce's COVID-O paper recommended introducing vaccination-or-test certification, with the option to include boosters at a later date.

152. At the COVID-O meeting on 8 December 2021, based on the paper provided by the COVID-19 Taskforce **(CW8/265 - INQ000257167)**, the Committee agreed that a vaccine-or-test model of mandatory certification in certain venues would be introduced from 15 December 2021 as part of a wider package of Plan B interventions, including mandating face coverings in more settings and asking people to work from home when they could **(CW8/266 - INQ000064261)**. These changes were announced by the PM on the same day **(CW8/267 - INQ000114457)**.

153. On 9 December 2021, Departmental officials provided the Secretary of State with further advice on outstanding policy issues about mandatory COVID-19 Status Certification **(CW8/268 - INQ000257172)**. This included advice about the criteria for conducting spot-checks at large venues or events, where it was unsafe to conduct checks on all attendees. For example, where queues formed at entrances or turnstiles to large events, as proof of COVID status was checked, this undermined the usually safe crowd processing procedures. This risk would be determined by venue or event operators through an assessment of risk, with a methodology to be approved by the local authority. Departmental Officials also provided advice about the period for local authority enforcement notices. These were issued by local authorities to businesses to require compliance with the regulations, to remedy any unsafe practices or to temporarily close businesses where necessary. The Secretary of State agreed to these recommendations on the same date **(CW8/269 - INQ000257173)**.

154. On 12 December 2021, the UK CMOs increased the UK COVID-19 Alert Level from Level 3 to Level 4, owing to a rapid increase in cases of the Omicron variant **(CW8/270 - INQ000257181)**.

155. The regulations to implement Mandatory Domestic Certification (The Health Protection (Coronavirus, Restrictions) (Entry to Venues and Events) (England) Regulations 2021), were agreed at the COVID-O on 8 December 2021, and were made on 13 December 2021 **(CW8/266 - INQ000064261)**.

156.On 14 December 2021, the Secretary of State requested advice, to be shared with No. 10, on further interventions to slow the spread of Omicron. Initial advice recommended strengthened public communications and indicated that further restrictions might be needed **(CW8/272 - INQ000257193)**.

157.On 17 December 2021, officials drafted a note for the Secretary of State to send to the PM about actions to address the Omicron variant **(CW8/273 - INQ000251921)**. This recommended going further than Plan B measures, in line with the measures introduced in Step 2 of the Roadmap, which included closing indoor hospitality and mass events. This was sent on the same day.

158.The PM announced on 21 December 2021 that no further measures would be introduced in England before Christmas **(CW8/274 - INQ000257218)**.

159.On 23 December 2021, Departmental officials updated the Secretary of State on the two contingency options that had been prepared by the COVID-19 Taskforce and No.10, should further measures be required between Christmas and New Year (in response to Omicron) **(CW8/275 - INQ000074615)**. On 24 December 2021, in response to this advice, the Secretary of State confirmed that planning should continue in the event of worsening hospital data necessitating further restrictions and commissioned Departmental officials for advice on the likely impact of both of the contingency options that had been prepared by the CO **(CW8/276 - INQ000257227)**.

160.On 30 December 2021, the Secretary of State met Departmental officials to discuss Omicron and actions to be considered over the coming weeks **(CW8/277 - INQ000257232; CW8/278 - INQ000257231; CW8/279 - INQ000257235)**.

161.On 4 January 2022, Departmental officials provided the Secretary of State with a speaking note for the Cabinet meeting on 5 January 2022 **(CW8/280 - INQ000257237)**. The speaking note recommended retaining Plan B measures until 26 January 2022, given that Omicron cases were continuing to increase.

162.Departmental officials briefed the Secretary of State ahead of a Cabinet meeting on 19 January 2022 recommending that public messaging should stress the need for people to exercise caution, even as Plan B measures started to come to an end **(CW8/281 - INQ000287731; CW8/282 - INQ000287732; CW8/283 - INQ000287733;**

CW8/284 - INQ000287734). At this meeting, Cabinet agreed for England to return to Plan A and to allow Plan B regulations to expire, thereby ending mandatory measures, such as COVID-19 Status Certification , which would be replaced with a voluntary model for businesses to apply to close contact and crowded settings **(CW8/285 - INQ000257253)**. On the same day, the PM made an oral statement in the House of Commons, confirming that England would return to Plan A on 27 January 2022 **(CW8/286 - INQ000257252)**.

163. On 21 January 2022, the Secretary of State received advice on outstanding policy questions for re-establishing voluntary COVID-19 Status Certification. **(CW8/287 - INQ000257256)**.

164. On 27 January 2022, alongside England returning to Plan A, and all measures under Plan B being lifted, the Government announced that a 'Living with COVID-19' plan would be published as the virus became endemic, regularly occurring within an area or community **(CW8/288 - INQ000257260)**.

165. The work to agree a Departmental strategy for 2022-23, and the appropriate funding, was postponed because of the need to respond to the more immediate Omicron risks. As part of this response, the Treasury agreed at the end of 2021 both emergency spending to respond as necessary in-year to Omicron and any unavoidable cost implications for 22/23.

166. On 2 February 2022, Departmental officials provided the Secretary of State with a submission setting out the process for developing a Departmental view on the future COVID-19 strategy, the key outstanding issues, and a summary of what was anticipated in the COVID-19 Taskforce's publication on Living with COVID-19 (due to be discussed at a Quad meeting, a meeting between the CDL, the PM, Secretary of State, and the Chancellor of the Exchequer, on 8 February 2022 **(CW8/289 - INQ000257268)**. On 3 February, Departmental officials provided an oral briefing to the Secretary of State on the future strategy for COVID-19CW8/.

167. On 5 February 2022, Departmental officials provided a briefing for the Secretary of State ahead of an expected Quad meeting on 8 February 2022, where it was anticipated that elements of the Living with COVID-19 strategy would be agreed **(CW8/290 - INQ000257271; CW8/291 - INQ000257270 CW8/292 - INQ000257269;**

CW8/291 - INQ000257270). This briefing included the Department's strategic narrative on how to manage COVID-19 in the spending review period, alongside a set of core principles to guide the strategy. The Secretary of State provided comments on the briefing on 7 February 2022, and further advice in the context of the Spending Review was submitted on 8 February 2022 **(CW8/294 - INQ000257276)**.

168. On 9 February 2022, Departmental officials provided a second iteration of the COVID-19 strategic narrative in advance of the Quad meeting, now on 11 February 2022, where it was intended to agree to remove domestic restrictions while also prioritising guidance, surveillance, vaccines, antivirals, and testing to protect the most vulnerable **(CW8/295 - INQ000287741; CW8/296 - INQ000287742)**.

169. On 11 February 2022, a final Departmental briefing on the Living with COVID-19 strategy was provided to the Secretary of State for the Quad meeting **(CW8/297 - INQ000257282)**. No.10 provided a readout of the meeting, outlining the PM's steer to end domestic requirements and universal testing, reduce immediate costs of COVID-19 response, and ensure we retain sufficient resilience capabilities **(CW8/298 - INQ000257283)**.

170. On 18 February 2022, the Secretary of State was briefed ahead of a second Quad meeting the same day, on future years strategy. This included a paper by UKHSA setting out the proposed future strategy and agreed approach for minimising testing and prioritising a resilient and flexible contingency plan **(CW8/299 - INQ000257291; CW8/300 - INQ000064431)**. At this point, UKHSA's budget for 2022/23 was not yet agreed. The key actions following this Quad were for UKHSA to set out a minimum bid to send options to No.10 for agreement **(CW8/301 - INQ000257292)**.

171. Following the Quad meeting on 18 February 2022, alongside the advice that UKHSA submitted on their budget for 2022/23, Departmental officials provided letters for the Secretary of State's private office on the Living with COVID-19 funding package on 19 and 20 February 2022 **(CW8/302 - INQ000257293; CW8/303 - INQ000257297; CW8/304 - INQ000198245)**.

172. On 18 and 20 February 2022, the Secretary of State received copies of the Living with COVID-19 strategy **(CW8/305 - INQ000257296; CW8/306 - INQ000257295)**. On 20

February 2022, briefing was provided to the Secretary of State ahead of a call with the PM about the Living with COVID-19 Strategy funding package.

173. On 21 February 2022, the Secretary of State received a speaking note from Departmental officials for a Cabinet meeting to sign off the Living with COVID-19 strategy. Departmental officials shared with their CO counterparts the Secretary of State's list of concerns. This included a request for a new section setting out the need for reprioritisation of existing budgets and a number of clarifications and amendments to the strategy. Later the same day the PM made a statement in the House of Commons and the Living with COVID-19 strategy was published. This set out the plan for removing remaining legal restrictions while protecting people most vulnerable to COVID-19 and maintaining resilience **(CW8/307 - INQ000257327)**. The plan covered removing domestic restrictions while encouraging safer behaviours through public health advice; protecting the vulnerable through pharmaceutical interventions and testing; maintaining resilience against future variants, including through ongoing surveillance, contingency planning and the ability to reintroduce key capabilities in an emergency; and securing innovations and opportunities from the COVID-19 response, including investment in life sciences.

174. There were no significant areas of divergence between the Secretary of State, the Department, the Cabinet Office and Number 10 with regards to our response to Omicron. The Government's response to Omicron was agreed by Ministers with appropriate Collective Cabinet Responsibility following advice from departments (as set out in paras 13-17, above), including the Department.

175. Throughout the pandemic the Department's advice to our Secretary of State often differed to the advice given by other departments to their Secretary of States or by the Cabinet Office to Number 10. This reflects differing departmental interest in their respective policy areas. The reaching of a single collective position is a recognised part of the policy making process. Once a decision was made by the relevant Cabinet Committee on the Government's response to Omicron, the Department and the Secretary of State were united behind that collective decision. My view is that this represents the normal debate about policy before finalisation rather than fundamental differences of opinion. I have flagged in this Statement where the Department was not initially in agreement with the PM on going further than Plan B measures, and the reprioritisation of existing budgets at paragraphs 157-158 and 173, respectively, and with HMT on purchasing more antiviral treatments at paragraphs 97-99, 102 and 105

SECTION 4: POLICY APPROACHES

NHS Capacity

176. On 3 December 2021, the Government published 'The health and social care approach to Winter', which set out the wide range of preparations made to ensure that health and social care services remain resilient, joined up and available to patients **(CW8/308 - INQ000257148)**. As the Autumn and Winter Plan noted, it was expected that the winter of 2021/22 might be particularly challenging due to the emergence of the Omicron variant. Since the beginning of autumn, every local part of the NHS had been planning for winter with actions being taken to respond to anticipated pressures.

177. In the time period covered by this witness statement, the Secretary of State took steps to improve the capacity of the NHS by ensuring that the most appropriate use was made of existing capacity, including through interventions designed to reduce admissions and increase bed capacity. The latter was focused on improving the flow of patients through the health system and looking at the resilience of the social care system as well as using virtual beds and the independent sector. It was estimated that these interventions might increase capacity by 6000 to 10,000 beds. Plans were also put in place to create additional capacity of up to 4,000 temporary Nightingale beds by converting non-medical areas of hospitals or using temporary structures. These surge beds were only to be used if other measures were exhausted. On 30 December 2021, NHSEI announced it was setting up Nightingale surge hubs at hospitals across the country **(CW8/309 - INQ000257230)**. The first eight of the surge hubs were planned at the following hospitals:

a. North West – Royal Preston;
b. North East and Yorkshire – Leeds, St James' site;
c. Midlands – Solihull Hospital and Leicester General Hospital;
d. East of England – Lister Hospital, Stevenage;
e. London – St George's;
f. South East – William Harvey Hospital, Ashford; and
g. South West – North Bristol.

Ventilators and the Ventilator Challenge

178. The 'ventilation and equipment' and 'logistics and warehouse operations' workstreams within the 'Oxygen, Ventilators and Clinical Consumables Programme' and led by the

Department, were merged by March 2021 in response to the expected reduction in NHS demand for ventilators, which required longer term storage solutions. The Oxygen, Ventilators and Clinical Consumables Programme's 'future data' workstream was split into two parts: the first focused on data and assets to ensure consistency and clarity of programme data; the second focused on future organisational design to ensure that resources could be reallocated quickly.

179. From March 2021 to September 2021 the Oxygen, Ventilators and Clinical Consumables Programme resources were approved by Ministers with a principal objective of establishing a new MedTech Directorate in the Department to oversee key policies, stockpiles, medical technology development and supply and supplier issues **(CW8/310 - INQ000256961)**. Planning during this period focused on potential future surges during the winter of 2021/22 and providing support to NHSEI. The Oxygen, Ventilators and Clinical Consumables Programme closed in September 2021 following the establishment of the MedTech Directorate under Steve Oldfield, the Chief Commercial Officer and Director General for Life Sciences. The MedTech Directorate transferred to the NHS Policy and Performance Group led by Matthew Style in October 2022 **(CW8/311 - INQ000287672)**.

Electives (part of the NHS Capacity workstream of the COVID-19 Battle Plan)

180. On 7 September 2021, the Government published 'Build Back Better: our plan for health and social care'. This provides an overview of work to tackle the electives backlog in the NHS and put the NHS on a sustainable footing. In 'Build Back Better', the Government announced plans to spend more than £8 billion from 2022-23 to 2024-25, in addition to the £2 billion Elective Recovery Fund and the £700 million Targeted Investment Fund (TIF) that was made available to systems in 2021-22 to support NHS systems and providers to go further on elective recovery **(CW8/312 - INQ000257025)**.

181. On 25 October 2021, the Chancellor of the Exchequer presented his Autumn Budget and Spending Review (SR21) to Parliament. The Government confirmed the NHS in England was to receive an extra £5.9 billion in capital for new beds, equipment and technology, to help clear the record backlog built up during the COVID-19 pandemic **(CW8/313 - INQ000257089)**. This was split as follows:

a. £2.3 billion to increase the volume of diagnostic activity;
b. £2.1 billion to modernise digital technology on the frontline; and
c. £1.5 billion towards expanding capacity **(CW8/314 - INQ000253812)**.

182. On 24 December 2021, NHSEI published 2022-23 operational guidance **(CW8/315 - INQ000257303)**. This guidance reconfirmed the ongoing need to restore services, meet new care demands and reduce care backlogs.

183. On 8 February 2022, NHSEI published the 'Delivery Plan for Tackling the COVID-19 Backlog of Elective Care'. This plan sets out a clear vision for how the NHS will recover and expand elective services up to March 2025 **(CW8/316 - INQ000287739)**.

Independent Sector

184. Independent sector providers have, throughout the history of the NHS, been commissioned to provide NHS services to aid with operational needs. In addition, NHS Trusts can sub-contract services they have been commissioned to provide to independent sector providers. These arrangements allow NHS commissioners and Trusts to secure the capacity needed at any given time to meet the health needs of their local population.

185. Arrangements with independent sector providers returned to the pre-pandemic business as usual arrangements from 1 April 2021, this reflected the reduced rates of COVID-19 at the time. Also, it was in line with Treasury conditions for the additional spend provided for national contracting arrangements in the financial year 2020/21 which came to an end on 31 March 2021.

186. Throughout the period of the return to "business as usual arrangements" (1 April 2021 to 6 January 2022), NHSE sought to ensure independent sector capacity was effectively utilised by NHS bodies in order to reduce backlogs for elective treatments which were exacerbated by the pandemic. A target of 120% of baseline, pre-pandemic activity for the NHS from independent providers was put in place, with a national NHS team to aid in coordination and resolving issues.

187. The Independent Healthcare Provider Network (IPHN) is the membership network for independent healthcare providers across the UK. On 7 December 2021, the Secretary of State met with IHPN Chair, Lord Patel, and IHPN CEO, David Hare, to discuss the continuing partnership between the independent sector and NHS. During this meeting, the Secretary of State noted the potential challenges ahead presented by the Omicron variant and the importance of contingency planning between the NHS and independent sector providers. The Secretary of State asked IHPN to start discussions with their

members on how they could best support the NHS through the impact of this new variant **(CW8/317 - INQ000287698; CW8/318 - INQ000287697)**.

188. On 20 December 2021, as the potential impact of the Omicron variant became clearer, the Secretary of State asked officials for advice on what steps would be required to enable a return to national contracting with independent sector providers, to again provide maximum NHS capacity in the event of high levels of COVID-19-related hospitalisations **(CW8/319 - INQ000287708; CW8/320 - INQ000287709)**.

189. On this basis, a statutory direction was prepared giving NHSE legal powers for responding to an emergency. In this case, the direction gave NHSE the power to commission services from independent sector providers, which were normally commissioned by Clinical Commissioning Groups (CCGs) (as the local commissioning arrangements at the time), for the purpose of responding to the emergency presented by the Omicron variant **(CW8/321 - INQ000287606; CW8/322 - INQ000287605)**. This direction was prepared by officials and lawyers and signed by William Vineall, the Director of NHS Quality, Safety and Investigations, on behalf of the Secretary of State.

190. An agreement was reached with BEIS officials and the Secretary of State to implement an Exclusion Order (a statutory instrument used to allow an exemption from Competition Law for an exceptional and compelling reason of public policy) to facilitate coordination between independent sector providers **(CW8/323 - INQ000287710; CW8/324- INQ000287711)**. The Exclusion Order excluded activity under the national contracting arrangements from the scope of competition law in the following ways:

a. Sharing information about capacity to provide certain services;
b. Co-ordination on deployment of staff;
c. Sharing or loan of facilities;
d. Joint purchasing of goods, facilities or services; and
e. Division of activities, including agreement to limit or expand the scale or range of services supplied by one or more providers.

191. The Direction (referred to in paragraph 189) was made on 23 December 2021, and IHPN were informed of the intention of the Secretary of State for BEIS to make the exclusion order in the new year, with effect from 7 December 2021 to 31 March 2022 **(CW8/325 - INQ000287712; CW8/326 - INQ000287713; CW8/327 - INQ000287714**

192. With these measures in place, NHSE was able to make arrangements with independent sector providers. Draft Heads of Terms were sent out and agreed in principle with a range of independent sector providers on 24 December 2021 **(CW8/328 - INQ000287726)**. These terms were based on the Q4 2020-21 contracting arrangements, providing for a minimum income guarantee and the option to activate surge capacity, taking over 100% of independent sector facilities in systems where surge is activated. Given the providers involved, an estimate of up to 3,000 fully staffed beds could be accessed by the NHS through these arrangements.

193. On 7 January 2022, Amanda Pritchard, the NHS England Chief Executive, wrote in her capacity as the NHSE Accounting Officer to the Secretary of State seeking a ministerial direction to proceed with the national contracts with independent sector providers, on the basis of value for money concerns. Ministerial directions are formal instructions from Ministers requiring their department to proceed with a proposal, despite concerns from their Accounting Officer. A written direction is required from a Secretary of State, when a decision for spending does not meet all four tests of regularity, propriety, value for money and feasibility (**CW8/329 - INQ000287720**; **CW8/330 - INQ000287721**; **CW8/331 - INQ000287722**; **CW8/332 - INQ000287723**; **CW8/333 - INQ000287724**; **CW8/334 - INQ000287725**).

194. The request noted that the national contracting arrangements had been explored because of the request by the Secretary of State for NHSE to maximise the NHS use of the independent sector. The request from the NHS England Chief Executive identified value for money risks in the proposed contract and highlighted the proposed mitigations NHSE had put in place. The letter also noted that NHSE believed the terms reached were the most favourable which were possible given the time available for the negotiations to take place considering the need to act quickly against the Omicron variant **(CW8/330 - INQ000287721)**. However, due to the value for money risks, Amanda Pritchard, in her position as Accounting Officer, sought a written ministerial direction for this spending. The Second Permanent Secretary consulted the Principal Accounting Officer and they concurred with her assessment **(CW8/336 - INQ000287728)**. On 8 January 2022, a submission was sent to Ministers by Department officials recommending agreement to the ministerial direction sought by NHS England and this was agreed by Ministers the same day **(CW8/337 - INQ000287727)**.

195. On 8 January 2022, the Secretary of State responded, directing NHSE to proceed with the contracts on the basis that the risks of the reasonable worst case scenario of Omicron infections overwhelming NHS capacity outweighed the potential costs of the arrangements..

196. The national contracts came into effect and were announced on 10 January 2022. 10 independent providers were signed up to these arrangements. .

197. The Exclusion Order agreed with BEIS was made on 10 February 2022 and came into force on 9 March 2022, with retrospective application to 7 December 2021 to cover the time from which the Secretary of State asked IHPN to start discussions on supporting the NHS through Omicron **(CW8/338 - INQ000287743 CW8/339 - INQ000287744)**.

198. During the January 2022 to March 2022 period, the surge element of the arrangements was not triggered in any system across England. Independent sector providers covered by these arrangements continued to deliver NHS activity at above baseline levels, and above the minimum income guarantee set out within the arrangement. This contributed towards efforts to reduce elective backlogs.

NHS Staffing

199. The circumstances for medical students' graduation remained the same in the time period covered by this witness statement as my Second Witness Statement for this Module at paragraphs 326 – 328.

200. Also as explained in my Second Witness Statement for this Module, vacancy numbers and rates were noticeably lower during the pandemic because many vacant posts were filled by agency or temporary staff.

201. As of February 2022, there were over 1.2 million full-time equivalent staff in NHS hospitals and commissioning bodies in England **(CW8/340 - INQ000257926)**. This was almost 34,500 (2.9%) more than in February 2021; this includes almost 4,300 (3.5%) more doctors and over 11,400 (3.9%) more nurses and health visitors **(CW8/341 - INQ000257321)**.

Emergency Register

202. For the time period addressed in this statement, August 2021 to February 2022, the position on the emergency register remained largely the same as set out in my Second Witness Statement for this Module. Please refer to paragraphs 334-338 of my Second Witness Statement for this Module for further details on emergency registers.

International Recruitment

203. From 31 March 2020 until 31 September 2021, the Government agreed to extend visas for frontline health and care workers. For more information on these announcements, please refer to paragraphs 329-330 of my Second Witness Statement for this Module dated 23 August 2023.

204. On 23 February 2023, Home Office Management Information indicated that there was a total of 19,912 extensions granted to health workers, care workers and their dependents, under these policies. The NHS programme of international nurse recruitment continued during the pandemic period, despite challenging travel barriers. Additional funding was provided to the NHS in 2020/21 to increase the rate of arrival of nurses from overseas **(CW8/342 - INQ000257099)**.

Volunteers

205. During the period with which this statement is concerned the position as regards to volunteers was the same as explained in my Second Witness Statement for this Module at paragraphs 339-341.

Discharge

206. The National Discharge Taskforce was established in December 2021, during the Omicron wave, to drive improvements in hospital discharge, especially delayed discharges, and support regional and local system arrangements. The Taskforce's aim was to ensure discussion was taking place between the key areas of hospital discharge.

207. The Terms of Reference were finalised on 20 December 2021 **(CW8/343 – INQ000287749** and state that the Taskforce would not be a decision-making forum on current or future interventions. It did not make decisions itself and relied on the governance structures of the Department, NHSEI, and DLUHC to authorise its activities and proposals through their own structures. To that end, the role of the Taskforce was stated as:

a. Ensure clear join up between local government and NHS, by providing a forum for a single conversation on discharge at a national level;
b. Provide national oversight of delivery of current discharge interventions towards the PM's ambition of reducing delayed discharges;
c. Monitor implementation of current interventions through collection and analysis of key datasets; and
d. Highlight possible areas for further interventions, utilising members' insights into national and local discharge practice but with any actions being taken by individual organisations.

Adult Social Care (ASC)

208. On 26 June 2021, the Minister of State for Care and Mental Health commissioned officials to begin work on a 2021 to 2022 Adult Social Care (ASC) COVID-19 Winter Plan, broadly following the format of the previous year's, with the addition of greater content on influenza **(CW8/344 - INQ000234495)**.

209. On 19 July 2021, a full proposal of exactly what the ASC Winter Plan should include was sent to the Minister of State for Care and Mental Health and the Secretary of State for their review (CW8/345 - INQ000256978; CW8/346 - INQ000256979). Departmental officials underlined that all the proposed additional support and measures were contingent on additional funding being secured from HMT. They also proposed that Sir David Pearson's review ('the review') **(CW8/347 - INQ000279947)** of the previous winter plan be published alongside this year's plan.

210. On 2 August 2021, officials received feedback that Ministers agreed with the proposed plan content and the simultaneous publishing of the review. Ministers stressed the need for content on influenza infection prevention and control, and how visits to care facilities would be maintained over the winter months **(CW8/348 - INQ000066578; CW8/349 - INQ000066579)**.

211. On 12 August 2021, officials held a workshop with a range of internal and external sector stakeholders to discuss winter planning **(CW8/350 - INQ000066638)**. In advance of the meeting, stakeholders were invited to write to the Department and share what they considered were the key issues that needed addressing, and what

potential solutions they would like the Department to explore. Organisations invited were: DLUHC, NHSEI, Care Quality Commission (CQC), PHE, Association of Directors of Adult Social Services (ADASS), Local Government Association (LGA), UK Home Care Association (UKHCA), National Care Association (NCA), Associated Retirement Community Operators (ARCO), Carers UK, Healthwatch, Age UK, Alzheimer's UK, Think Local Act Personal (TLAP), National Care Forum (NCF), Care England, Skills for Care, Association of Mental Health Providers (AMHP), HC-One and Barchester (care home operators).

212. On 13 August 2021, the Secretary of State asked ASC officials to consider and draw up plans for a joint Health and Social Care Winter Plan, which would be published instead of the standalone ASC Winter Plan that was already in development **(CW8/351 - INQ000257001)**. Departmental officials recommended that an overarching Winter Plan with discrete health and care chapters be agreed on. This plan evolved over the subsequent weeks and on 11 September 2021 it was agreed in a Quad that a joint Health and Social Care Winter Plan should not be published; instead, a joint Health and Social Care Winter Narrative would be published, following the separate publications of the NHS planning guidance and the ASC Winter Plan **(CW8/352 - INQ000287675)**.

213. On 13 September 2021, the Secretary of State and Michelle Dyson, the Director General for ASC, were commissioned by CO to update scenarios for the autumn/winter 2021/22 period in relation to circulation modelling of COVID-19 and influenza, and their effects **(CW8/353 - INQ000257037)**. These updated scenarios were used for winter planning purposes by the relevant ASC policy teams.

214. Also on 13 September 2021, Departmental officials shared the complete draft of the ASC Winter Plan with the Secretary of State, the Minister of State for Care and Special Advisers **(CW8/354 - INQ000257040; CW8/355 - INQ000066917; CW8/356 - INQ000257038)**. Ministers were supportive of the content and approach, with very minimal amendments requested.

215. On 17 September 2021, Departmental officials shared the draft copy of the Winter Plan with relevant OGDs and with our ALBs, inviting them to comment and suggest any amendments that were required from their point of view and seeking their confirmation that they were happy for the Department to publish the plan. The recipients were: NHSEI; NHS Transformation Directorate (NHSX); NHS Test and

Trace; PHE; CQC; the COVID-19 Taskforce; the Ministry of Housing, Communities and Local Government (MHCLG), now referred to as DLUHC; and HM Treasury (HMT).

216. Also on 17 September 2021, the Department shared a redacted draft copy of the Winter plan with external stakeholders who attended the workshop on 12 August 2021 (see paragraph 211 for full list of those stakeholders), similarly inviting them to review the draft wording and provide comments.. These stakeholders provided a wide range of comments, which Departmental officials considered carefully and integrated where appropriate.

217. On 30 September 2021, a COVID-O meeting on ASC Readiness for Autumn and Winter was postponed to allow more time for cross-Government agreement on the funding and support that would be announced **(CW8/357 - INQ000257068)**.

218. On 20 October 2021, at the rearranged COVID-O meeting, the Committee agreed to publish the standalone ASC COVID-19 Winter Plan **(CW8/358 - INQ000257084)**.

219. On 3 November 2021, the Department published the 2021/22 ASC COVID-19 Winter Plan **(CW8/359 - INQ000087232)** alongside the completed review of the ASC COVID-19 Winter Plan 2020/21. The 2021/22 ASC COVID-19 Winter Plan contained an annex, which included a response to each of the review's recommendations.

220. On 3 December 2021, the joint narrative, 'The health and social care approach to winter', was published **(CW8/308 - INQ000257148)**.

Adult Social Care: Stakeholder Engagement

221. Throughout the period Departmental officials continued to meet regularly with stakeholder groups formed to discuss specific issues.

222. In September 2021, the Department established the COVID-19 ASC working group of stakeholders. The group's remit was to provide feedback to the Department, support the translation of policy into practice, and contribute to the communication and dissemination of information and advice to the sector **(CW8/361 - INQ000067051)**. The group met fortnightly and brought together Departmental policy teams and NHS, CQC, HSE and PHE, as well as local government, charities and representative organisations.

223. On 24 November 2021, in response to the spread of the Omicron variant, the Department set up the Winter Steering Group **(CW8/362 - INQ000067455)**, which met monthly. It brought together Departmental policy teams with clinical experts in UKHSA, NHSEI, representatives of local authorities, directors of public health and the CQC to review planning and response and ensure any intelligence and data was shared among key actors.

224. In December 2021, the Winter Operational Group was also set up and chaired by the Department. It brought together the LGA, ADASS CQC and the Regional Assurance Team to consider operational pressures in the system, with a particular focus on workforce. This group ran twice weekly through to the end of January 2022 when it moved to weekly meetings. **(CW8/363 - INQ000257216)**

225. On 6 January 2022, the Department set up the ASC Vaccine Boosters Taskforce, chaired by Sir David Pearson, to drive uptake of boosters across the sector **(CW8/364 - INQ000257243; CW8/365 - INQ000257241)**. This brought together senior representatives from the NHSEI Vaccination Programme, the Department's ASC Vaccines team, LGA, ADASS, provider and ICS representatives and communications colleagues to share best practice and drive uptake of influenza and booster vaccines by ASC staff and recipients of care. In discussion with Michelle Dyson, the Director General for ASC, and the NHS National SRO for Vaccine Deployment, the Taskforce was stood down on 24 February 2022, having met initially twice a week and then weekly. **(CW8/366 - INQ000287747**

Adult Social Care: Funding

226. On 1 July 2021, the fourth round of the Infection Control and Testing Fund (ICTF) was announced. This was a £251 million fund (£142.5 million for infection control, and £108.7 million for testing), provided to ASC providers via local authorities to support COVID-19 related pressures for the three-month period July 2021 to September 2021 **(CW8/367 - INQ000061246) (CW8/368 - INQ000256971; CW8/369 - INQ000256969; CW8/370 - INQ000256970; CW8/371 - INQ000256965; CW8/372 - INQ000256972; CW8/373 - INQ000256973; CW8/374 - INQ000111472 CW8/375 - INQ000256968; CW/376 - INQ000256966)**.

227. On 30 September 2021, the fifth round of the ICTF was announced. This was a £388.3 million fund provided to ASC providers via local authorities to support COVID-19 related pressures for the six-month period from October 2021 to March 2022. This fund included £25 million specifically to support care workers to access COVID-19 and influenza vaccines over the winter months **(CW8/377 - INQ000066663; CW8/378 – INQ000066576)**.

228. On 21 October 2021, the Department announced the £162.5 million Workforce Retention and Recruitment Fund, which aimed to support local authorities working with ASC providers to recruit staff, as well as retain the existing workforce through overtime payments, staff banks of people ready to work in social care, and further capacity to support staff health and well-being through occupational health **(CW8/379 - INQ000257083)**.

229. On 10 December 2021, the Department announced a £300 million extension to the Workforce Retention and Recruitment Fund, which was paid to ASC providers and was able to be used to pay for bonuses, bring forward planned pay rises for ASC staff, fund overtime, and fund staff banks, with the aim of increasing ASC workforce numbers until the end of March 2022 **(CW8/380 - INQ000257190; CW8/381 - INQ000257177; CW8/382 - INQ000257176; CW8/383 - INQ000257207)**.

230. On 29 December 2021, the Department announced the £60 million ASC Omicron Support Fund for local authorities to support the sector and protect people from COVID-19 infection following the emergence of the Omicron variant **(CW8/384 - INQ000257228)**. Guidance for this fund was published on 10 January 2022 **(CW8/385 - INQ000257240)**.

Adult Social Care: Testing and Vaccines

231. Throughout the period addressed in this statement the vaccination of residents in care homes, as well as adult social care staff, continued to be a priority.

232. To encourage vaccination in the ASC workforce, the Department communicated regularly with the sector through various media including webinars, blogs and publications, targeting regions and cohorts where uptake was low.

233. On 16 September 2021, within two days of updated advice from the JCVI, booster doses began being rolled out. By 5 November 2021, the NHS had announced that

booster vaccines had either been delivered or booked in at every older adult care home in England **(CW8/386 - INQ000287685)**.

234. From 15 December 2021, weekly testing requirements for staff in high-risk settings (care homes, high-risk extra care and supported living, and day care centres) increased from two to three LFD tests a week in addition to one PCR test each week **(CW8/387 - INQ000092200)**.

235. On 16 February 2022, all ASC workers in England were moved to a new asymptomatic testing regime **(CW8/388 - INQ000257264)**. Staff were no longer required to complete PCR tests but were subject to daily lateral flow tests on the days they were working and before they began work. This change applied to care homes, extra care and supported living, homecare, eligible day care centres, and personal assistants.

Adult Social Care Data Collection and Monitoring

236. As mentioned in my First Witness Statement for this Module (at paragraphs 182 to 192), the ASC Capacity Tracker was developed to enable the system to better manage hospital discharges by identifying available capacity in care homes.

237. In my Second Witness Statement for this Module at paragraphs 355- – 361 I set out that work had commenced in September 2020 on the ASC COVID-19 dashboard with support from the company Palantir Technologies (Palantir). This was introduced to provide a single point of information for local, regional, and national government and was migrated in July 2021 to the Department, and subsequently /UKHSA owned and managed, environment 'EDGE' (the Environment for Data Gathering and Engineering). The Capacity Tracker continued to be amended, reflecting measures supported by the second round of the ICF and in late 2020, the Department produced an ASC Situational Report (SitRep) on COVID-19. This included outbreaks data from PHE, deaths and other notifications data from CQC and data on PPE availability, workforce pressures/absence.

238. In August 2021:

a. A data feed from Test and Trace was added to Capacity Tracker to give providers access to data on testing;

b. A data collection on Influenza vaccine uptake among care home residents and staff (including those providing face to face support) was added – this is now an established seasonal data collection;
c. A data collection on COVID-19 vaccine booster dose two uptake was added to the Capacity Tracker for care home residents and staff (including those delivering face to face support); and
d. The Department's Adult Social Care SitRep continued with further developments.

239. In September 2021 COVID-19 booster uptake data was added to the regular SitRep as soon as its data quality allowed **(CW8/389 - INQ000257060; CW8/390 - INQ000257061)**.

240. In October 2021:

a. Data that allowed additional monitoring of vaccination as a condition of deployment (VCOD) in care homes was added to the care home data collection, to cover staff vaccinated abroad and staff aged under 18; and
b. A new daily report that focused on positive tests and COVID-19 deaths was added to the SitRep.

Adult Social Care: Visiting

241. The ASC Visiting guidance was updated on 16 August 2021 to state that visitors to care homes should still avoid visiting (for the duration of their would-be isolation period) if they were a close contact of someone with COVID-19 **(CW8/391 - INQ000287661)**. This update was in response to national guidance on self-isolation which stated that fully vaccinated individuals would no longer need to self-isolate if they had been identified as a close contact of someone with COVID-19. This meant that potentially people who were close contacts could visit care homes and spread infection, therefore guidance was updated to protect residents and staff.

242. On 25 November 2021 the visiting guidance was further updated to reduce restrictions by:

a. Placing more emphasis on visits taking place wherever was most practical and comfortable for the resident;

b. Enabling an outbreak to be considered over (and indoor visiting to recommence) in 7 to 8 days (rather than 14) following two rounds of whole home PCR testing 4 to 7 days apart.
c. Stating that physical contact should be supported to help health and wellbeing **(CW8/392 - INQ000287688**.

243. Advice around influenza and other transmissible viruses was also added, along with guidance on how care homes could support residents on visits outside of the care home.

244. The ASC Visiting guidance was updated again on 14 December 2021 to add the following new restrictions due to the new Omicron variant of COVID-19:

a. Reduced the number of visitors each care home resident could receive to 3 (not including essential care givers or preschool age children);
b. Required resident testing or self-isolation following visits out of the care home; and
c. Increased testing requirements for staff and essential caregivers **(CW8/393 - INQ000287702)**.

245. The ASC Visiting guidance was updated again on 31 January 2022 to reduce restrictions by:

a. Confirming there was no limit on visitor numbers;
b. Confirming that following a normal visit out, residents did not need to test or self-isolate; and, following an emergency hospital stay or other high-risk visit out, residents should self-isolate for 10 days, with testing arrangements to end isolation sooner **(CW8/394 - INQ000287738)**.

Vaccination as a Condition of Deployment in Older Adult Care Homes

246. The Government ran a public consultation from 14 April 2021 to 26 May 2021 on a proposal to make COVID-19 vaccination a condition of deployment (VCOD) for those entering residential adult social care settings to protect people with care and support needs, as well as care staff, from infection. **(CW8/395 - INQ000256957)**

247. From 11 November 2021, two doses of the COVID-19 vaccine became a statutory condition of deployment for all care home workers and anyone entering a care home unless they were exempt under the regulations **(CW8/396 - INQ000086799)**.

Vaccination as a Condition of Deployment in the Health and Wider Social Care Sector

248. The Department conducted a public consultation, from 9 September 2021 to 22 October 2021, seeking views on whether or not to extend vaccination requirements to other health and care settings for COVID-19 and also for flu **(CW8/397 - INQ000257101)**.

249. On 9 November 2021, following that consultation, the Secretary of State announced the Government's intention to legislate, apply, and extend vaccination as a condition of deployment (VCOD) to a wider range of CQC-regulated health and social care settings, subject to certain exemptions and conditions **(CW8/398 - INQ000257100)**. The Department also published a VCOD impact assessment online **(CW8/399 - INQ000257174)**. The intent was to require health and social care workers, including volunteers who had direct, face-to-face contact with service users to provide evidence of receiving a complete course of the COVID-19 vaccination as a condition of being deployed. The measure aimed to ensure protection against COVID-19 infection for people receiving care and support, as well as those who cared for them. This did not include those who could provide evidence of a medical exemption from COVID-19 vaccination **(CW8/400 - INQ000257254)**.

250. On 14 December 2021, Parliament agreed the relevant regulations and these were made on 6 January 2022. Guidance for employers in healthcare in England and guidance on the delivery of CQC-regulated activities in wider adult social care settings was published on 14 January 2022 and 20 January 2022 **(CW8/401 - INQ000257250; CW8/400 - INQ000257254)**, respectively. The regulations were due to come into force on 1 April 2022. In advance of this date, there was a 12-week grace period to allow people sufficient time to be vaccinated.

251. When VCOD was first introduced in care homes, and then extended to wider health and social care settings, it was supported by the clinical evidence and based on the severity of the dominant variant of COVID-19; the Delta variant. The weight of clinical evidence in favour of VCOD outweighed the risks. The changes in the pandemic as a result of the emergence of the Omicron variant of COVID-19, which was intrinsically

less severe, as well as the continued success of the vaccination programme, with many more people protected, meant that the balance of costs and benefits needed to be reconsidered. Evidence was considered by the Secretary of State, who concluded that it was no longer proportionate to require vaccination as a condition of deployment and that all VCOD regulations should be revoked, subject to consultation. This was put to and agreed by the COVID-19 Operations Committee on 31 31January 2022 **(CW8/403 - INQ000091577)**.

252. On 31 January 2022, the Government announced a short consultation on ending vaccination as a condition of deployment in all health and social care settings. The consultation received over 90,000 responses from across the health and social care sector, as well as from members of the public. The vast majority of the consultation responses received supported revocation, with 90% of respondents agreeing that the requirement for COVID-19 vaccination as a condition of deployment should be revoked in all health and social care settings. Following this consultation, the regulations were revoked on 15 March 2022 **(CW8/404 - INQ000257312)**.

Personal Protective Equipment (PPE): COVID-19

253. In August 2021, the Department's donations of face masks for use as a contingency supply of face coverings to transport operators continued. In this period the Department donated 17.9 million face masks to reduce transmission of COVID-19 **(CW8/405 - INQ000256994; CW8/406 - INQ000256995)**.

254. In September 2021, the Department made an agreement with HMT that any international donations of excess PPE would not count toward the Official Development Assistance (ODA) budget because the UK was the primary beneficiary as the savings made on the storage costs generated by the donation of PPE exceeded the value of the PPE donated.

255. Additionally, in September 2021 vaccination centres were invited to register for the PPE e-Portal. This was an online PPE ordering system which allowed authorised health and social care settings access to the range of free PPE available for delivery **(CW8/407 - INQ000257050)**.

256. In October 2021 there was a public consultation on whether to extend the central provision of free PPE to the health and care sector for a further year to the end of March 2023 **(CW8/408 - INQ000257077; CW8/409 - INQ000257078; CW8/410 -**

INQ000257079; CW8/410 - INQ000257079). Overall, the consultation responses showed that the overwhelming majority of health and care providers were strongly in favour of extending the provision of free PPE **(CW8/412 - INQ000287729)**.

257. Over December 2021 and January 2022, the Department delivered a donation of face masks to education settings including primary and secondary schools. An estimated 89 million face masks were donated.

258. In January 2022, following the public consultation in October 2021 and careful consideration of the trajectory of the pandemic, the need to protect front-line health and care staff and the impact on businesses who operate in the PPE market, free PPE for frontline health and care staff was extended until 31 March 2023 **(CW8/413 – INQ000257249)**.

259. Additionally, in January 2022, the Department announced that Portal 2.0 would replace the PPE e-Portal for eligible user groups (predominantly primary care and social care but also the public sector more broadly). User testing and a soft launch for the new platform began in January 2022, thereby beginning a phased user transfer from the PPE e-Portal to the new system.

260. Furthermore, in January 2022, Ministers agreed plans to pilot online auctions of excess stock (commencing in March 2022) and to advertise these auctions on GOV.UK **(CW8/414 - INQ000257275; CW8/415 - INQ000257277)**.

261. From 27 January 2022, the legal requirement to wear a face covering no longer applied. However, the government suggested that the public continued to wear a face covering in crowded and enclosed spaces where they may come into contact with people they did not normally meet **(CW8/416 - INQ000287736)**.

262. In February 2022 the Government announced the shift to Living with COVID-19 strategy. Guidance was published which advised that people continue to wear a face covering in crowded and enclosed spaces, where they would come into contact with people they would not normally meet **(CW8/417 - INQ000257263)**.

263. In February 2022 advice was sent to Ministers seeking permission to recycle more excess stock of and use energy from waste to increase the reduction in stock.

264. On 1 April 2022, the guidance on face coverings in public places was withdrawn **(CW8/418 - INQ000257262)**.

Testing

265. In this section, on behalf of the Department, UKHSA have provided information on changes in testing policy, which was led by NHS Test and Trace and subsequently, UKHSA following its full operationalisation on 1 October 2021. **(CW8/419 - INQ000075721)**.

266. For context, the process around taking a confirmatory PCR test after a positive result from an LFD test shifted regularly as the pandemic developed and the Department's response evolved. For example, the practice of taking a confirmatory PCR test after a positive LFD test result was paused in January 2021 because there was a high prevalence of infection, meaning it was highly likely that a positive LFD COVID-19 result was a true positive.

267. From 30 March 2021 to 10 January 2022, the requirement to take a confirmatory PCR test was reinstated for all positive LFD tests and stopped again on 11 January 2022 **(CW8/420 - INQ000256955; CW8/421 - INQ000256953; CW8/422 - INQ000256952)**. A positive LFD test result continued to trigger contact tracing; however, Test and Trace introduced improvements that meant anyone self-isolating from a positive LFD test was automatically informed that they could stop isolating if the confirmatory PCR was taken promptly and was negative. These individuals were then removed from contact tracing. Anyone who received a positive LFD result was instructed to self-isolate until they did a confirmatory PCR. If the confirmatory PCR came back positive, they were expected to continue self-isolating for 10 full days from their initial positive result.

268. By August 2021 mass testing had been conducted as part of the mass testing 'Moonshot' programme in: Liverpool in November 2020, schools and universities in November 2020 and various workplaces in December 2020, consequently providing information on the effective use of LFDs. This approach of pilots and rapid evaluation enabled lateral flow testing to be rolled out quickly and from April 2021 everyone in the country had access to the 'universal offer' of testing.

269. On 16 August 2021 it was announced that people in England and Northern Ireland who had received both vaccines, and those aged under 18, were no longer required to self–isolate if they had been in contact with someone who had tested positive for

COVID-19 **(CW8/423 - INQ000049232)**. Instead, they were advised to take a PCR test, wear a face covering indoors, and limit their contact with anyone classed as clinically vulnerable.

270. On 19 November 2021, new lateral flow guidance was published, aimed to enable greater protection to the public when undertaking 'high risk' activities such as attending large events or travelling **(CW8/424 - INQ000257110; CW8/425 - INQ000257111)**. The government guidance advised everyone to continue taking free rapid lateral flow tests regularly, particularly before mixing in crowded indoor spaces or visiting vulnerable people. Testing is the quickest and easiest way to find out if someone has the virus, even if they show no symptoms. This coincided with the public health campaign called 'Stop COVID-19 hanging around' which was launched in England on 5 November 2021.

271. On 14 December 2021 daily contact testing began. Guidance stated that fully vaccinated contacts of a COVID-19 case, whether Omicron or not, were advised to take a daily LFD test for 7 days to slow the spread of COVID-19 **(CW8/426 - INQ000257192)**. Omicron and testing capacity and supply was discussed at a COBR meeting on 15 December 2021 **(CW8/427 - INQ000257203; CW8/428 - INQ000257213)**.

272. On 22 December 2021 new guidance enabled the 10-day self-isolation period for people who had tested positive for COVID-19 to be reduced to 7 days in most cases in England. People who received a negative LFD test result on day 6 and day 7 of their self-isolation period, with tests taken 24 hours apart, no longer had to self-isolate for the full 10 days and self-isolation ended after day 7. Those who left self-isolation on or after day 7 were strongly advised to limit close contact with other people in crowded or poorly ventilated spaces, work from home and minimise contact with anyone who is at higher risk of severe illness if infected with COVID-19. There was no change to the guidance for unvaccinated contacts of positive COVID-19 cases, who were required to self-isolate for 10 full days after their date of exposure to the virus.

273. UKHSA's analysis suggested that a 7-day isolation period alongside two negative LFD test results had nearly the same protective effect as a 10-day isolation period without LFD testing for people with COVID-19. The latest evidence on how long cases transmit the virus for supported this approach. Additionally, this approach limited the spread of the virus whilst simultaneously supporting essential public services and supply chains

over the winter. Studies also demonstrated that LFD tests were just as sensitive at detecting the Omicron variant as they were for the Delta variant **(CW8/429 - INQ000257220; CW8/430 - INQ000257322)**.

274. From 11 January 2022 in England, people who received positive LFD test results for COVID-19 were required to self-isolate immediately and to only take a confirmatory PCR test if:

a. They wished to claim the Test and Trace Support Payment;
b. They had been advised to take a PCR test because they were in a clinically vulnerable group who may need early access to treatment; and/or
c. They were advised to take a PCR test as part of a research antiviral or surveillance programme **(CW8/431 - INQ000257245; CW8/432 - INQ000257246; CW8/433 - INQ000257244; CW8/434 - INQ000257236)**.

275. At a COVID-O on 12 January 2022 it was agreed that from the following day, self-isolation for those with COVID-19 could end after 5 full days provided a person had two negative results from LFD tests **(CW8/435 - INQ000091522 CW8/436 - INQ000257247)**.

276. On 31 January 2022, guidance was published to scale back the restrictions introduced with the emergence of Omicron and lower the self-isolation period for residents after admission to a care home, from 14 to 10 days for those who test positive, with further reductions if they tested negative on days 5 and 6. This was in line with the removal of Plan B national restrictions **(CW8/437 - INQ000257261)**.

277. From 1 February 2022 the requirement to take a confirmatory PCR test following a positive LFD test result was removed.

278. On 24 February 2022, in line with the Living with COVID-19 strategy, the government ended all legal testing requirements in England and asked the public to follow safe and responsible practices.

Shielding

279. In my Second Witness Statement for this Module dated 23 August 2023, I set out at paragraph 380 that:

"On 19 July 2021, guidance for the full CEV cohort was updated to advise them to follow the same guidance as the rest of the population ***(CW5/678 - INQ000234996)****."*

280. On 23 July 2021, a submission was sent to the Department's Parliamentary Under Secretary of State and the Secretary of State, which provided the following recommendations on the future of shielding policy and the maintenance requirements for the Shielding Patient List (SPL) **(CW8/438 - INQ000061457)**:

a. "That you agree to formally end the shielding programme and move away from a model of centralised shielding/precautionary advice for the CEV cohort as a whole, back to the pre-pandemic model whereby those susceptible to infectious disease receive risk advice from their NHS clinician.
b. That you consider whether you would want to write out to 3.8 million CEV people informing them of the end to the shielding programme.
c. That you agree to maintain the SPL only until the JCVI publishes its final advice on booster vaccinations in August, after which, a decision should be taken about the SPL's ongoing usefulness to the vaccines programme."

281. The submission noted that the full CEV cohort (3.8 million people) were included in JCVI's initial priority groups for vaccination in early 2021, and that 91% had received one dose and 88% had received two doses. A study by PHE suggested that for the majority of individuals who were CEV, there was little reduction in vaccine effectiveness compared to those not identified as high-risk. As a result, senior clinicians including the DCMO and the Chief Executive of UKHSA, advised that it was highly unlikely that the Government would need to advise the full CEV cohort to shield again.

282. It was recognised that some with conditions making them specifically immunocompromised or immunosuppressed may not respond as well to COVID-19 vaccines as the rest of the population. In such cases, these patients were advised to consult with their clinician, similar to pre-pandemic approaches. This approach best allowed for nuances in vaccine effectiveness, including the permanency of any immunosuppression, and individual risk to be properly addressed to ensure individuals received the most appropriate and tailored advice.

283.On 28 July 2021, the Private Office to the Parliamentary Under Secretary of State, Minister Churchill, informed the Secretary of State that she was content to stop the Shielding Programme. Minister Churchill commented that it was important to have a communications plan in place and suggested two options on when and how to announce the decision **(CW8/439 - INQ000287653)**.

284.On 2 August 2021, given the size of and considerable public interest in the decision, the Secretary of State requested a meeting to discuss the submission referenced in paragraph 280 **(CW8/440 - INQ000287656)**.

285.A meeting was subsequently scheduled on 11 August 2021 and was attended by the Secretary of State, the DCMO's, Jenny Harries and Thomas Waite,DCMO, the Chief Executive of UKHSA and Department officials. The meeting concluded with the Secretary of State confirming that he would recommend to COVID-O that the Shielding Programme and Shielding Patient List (SPL) should be stood down and that the announcement should be clinically led. Ministers were asked to write to all those who had received advice due to being on the SPL to notify of them of the decision, on the basis of clinical advice **(CW8/441 - INQ000287659)**.

286.Following an evidence review that concluded that children and young people were, in general, not considered to be at high risk of serious illness from COVID-19, they were formally removed from the Shielding Patient List (SPL) on 23 August 2021 **(CW8/442 - INQ000066720)**.

287.On 6 September 2021, it was agreed at a COVID-O meeting that the term CEV and any associated bespoke policy for them, particularly in regard to shielding, should formally end. The committee agreed that the SPL and associated Shielding Programme and contingency support offer should be stood down. The committee recognised this may need to change in the future if there was a vaccine-escaping variant of concern or similar change in clinical risk **(CW8/443 - INQ000092106; CW8/443 INQ000092106)**.

288.On 17 September 2021, letters from the Department and the NHS were sent to the full CEV cohort informing them of this decision **(CW8/445 - INQ000066932)**.

289. In response to the Omicron variant, consideration was given to the contingency plans that may be required for people at higher risk of serious illness from COVID-19, depending on the variant's prevalence and severity. The Department's Mental Health and Disabilities, Shielding and Volunteering Directorate sent a submission on 3 December 2021 to the Minister for Vaccines and Public Health noting this contingency planning work, whilst confirming that shielding was not currently being considered as an intervention due to the limited understanding at the time of Omicron **(CW8/446 - INQ000257150)**. Contingency planning discussions commenced with CO and DLUHC to consider what plans could be put in place should they be required by those at higher risk.

290. On 12 December 2021, the Secretary of State received verbal clinical advice from DCMO, Thomas Waite, and the Chief Executive of UKHSA, Jenny Harries, and DCMO to not reintroduce shielding **(CW8/447 - INQ000257182; CW8/448 - INQ000067646; CW8/449 – INQ000067654)**.

291. In the context of rapidly rising cases of the Omicron variant and in response to meetings with Ministers, officials, NHSEI and the Antiviral and Vaccine Taskforces, the UKHSA Chief Executive convened two clinical roundtables on 14 and 16 December 2021 **(CW8/450 - INQ000287701; CW8/451 - INQ000067696); CW8/452 - INQ000287705); CW8/453 - INQ000067681; CW8/454 - INQ000257210); CW8/455 - INQ000257211)**. It was agreed that while shielding should not be reintroduced, a single 'higher risk' group of immunosuppressed people should be confirmed to include those already identified and any other clinically relevant groups, and that this 'higher risk' group should be provided with advice on public health measures they may wish to consider to support them during the current Omicron wave. This was confirmed in a submission to the Secretary of State on 20 December 2021 **(CW8/456 - INQ000067731)**. Consideration was given to other forms of support such as access to Statutory Sick Pay (SSP), if working from home was not feasible, the delivery of medicines, priority access to PCR testing and access to antiviral treatments and monoclonal antibody treatment if they caught COVID-19 **(CW8/450 - INQ000287701; CW8/451 – INQ000067696)**.

292. On 24 December 2021, the Government issued updated public health advice to two separate groups. The first group, previously considered to be CEV, were advised to follow the same guidance as the general public and this advice was reiterated on 24

December 2021. The second group were people aged 12 and over, who were immunosuppressed or had a specific other medical condition. The advice to this group was to follow a range of precautions to reduce their risk of catching COVID-19.

293. On 7 February 2022, the Secretary of State agreed to a submission received on 4 February 2022 regarding the establishment of the Enhanced Protected Programme (EPP) **(CW8/459 - INQ000287740)**.

294. The EPP was a coordination programme, overseen by a Clinical Oversight Group chaired by the Chief Executive of UKHSA. The secretariat for the programme was provided by DHSC and it aimed to ensure that cohorts at higher risk of serious illness from COVID-19 (due to immunosuppression or a specific other medical condition) were identified and received appropriate interventions, support and communication. The EPP served to improve the coordination between various advisory, clinical and delivery groups or advice, principally the TTF (and then ATTF), NHSEI, JCVI, NHS Digital and to a lesser extent the Vaccines Task Force.

295. Department and UKHSA officials worked with the Chief Executive of UKHSA to coordinate and bring further coherence to a number of interrelated programmes across the health systemCW8/. Accountability for constituent programmes and policy (across vaccines, antivirals and therapeutics) remained within each organisation.

296. The EPP sought to:

a. "Confirm the cohorts in scope, rationalising and aligning cohorts where necessary or helpful;
b. Coordinate the government's response to the cohorts in scope, highlighting areas requiring further work;
c. Commission teams and organisations with work to ensure a joined-up approach across the health system;
d. Ensure a process is instigated for reviewing inclusion within cohort(s);
e. Ensure interventions for identified cohorts can be practically implemented
f. Ensure identified cohorts (and the interventions that they are eligible for) can be understood by patients and clinicians; and
g. Centrally coordinate all communications to cohort(s), including public health advice".

297.The EPP was closed on 19 April 2023.

Vulnerable Groups

298.As set out in my Second Witness Statement for this Module at paragraph 458, I chaired a Star Chamber session held on 28 May 2021, which considered the potential impact of a third wave of COVID-19 upon more deprived communities. The session concluded that over the long term, the focus of the levelling up agenda and the formation of the Office for Health Promotion (now OHID) and UKHSA would provide greater depth in expertise and linkages to regional public health leadership to help target health inequalities **(CW8/460 - INQ000234962**.

299.In addition, consideration of vulnerable groups at the COVID-19 Oversight Board continued through the COVID-19 Battle Plan Workstream 7 (Protecting the most vulnerable). Its objective was updated as agreed by the Oversight Board on 4 August 2021 to the following: "*To identify the additional support needs of those who may be disproportionately affected by COVID-19 along with the arrangements in place to meet these needs and to escalate any concerns to the Oversight Board.*"

300.To support the Oversight Board, the Health Inequalities and Vulnerable Groups (HIVG) team provided fortnightly workstream updates to the DHSC COVID-19 Oversight Board between April and November 2021 **(CW8/461 - INQ000287646 CW8/461 INQ000287646; CW8/463-INQ000287647); CW8/464-INQ000287648 CW8/465-INQ000287655; CW8/466-INQ000287660; CW8/467-INQ000287670; CW8/468-INQ000287676 CW8/469 - INQ000287687**.

301.The COVID-19 Programme Management Office (COVID-19 PMO) commissioned delivery plans from all Battle Plan workstreams on 24 September 2021, in preparation for a 'Star Chamber' assurance meeting, which was held on 18 October 2021.

302.The aims of this Star Chamber were to review and assure the Executive Committee (ExCo) of the readiness of the Battle Plan delivery for Autumn/Winter, based on CO scenarios and to ensure that SROs had the support they needed in place.

303.The Star Chamber slides for the workstream summarised key activity to mitigate the impacts of the pandemic on disproportionately impacted groups and included support

for rough sleepers; Test and Trace work to support vulnerable groups; and guidance for people previously considered to be clinically extremely vulnerable **(CW8/470 - INQ000287679)**.

304. As noted in the Star Chamber slides, the core work of the Workstream included **(CW8/471 - INQ000287680)**:

a) Work already highlighted with the NCRC SPOC data (continued work with analysts and request to the NCRC for data summaries);
b) Exploration of joint working with the Cabinet Office Taskforce Disproportionately Impacted Groups team;
c) Alignment of Levelling Up proposals with the COVID-19 response where appropriate; and
d) Review of the Minister for Equalities 4th Quarterly Report, which would review the effectiveness and impact of policies in response to COVID-19, once published.

305. At the Star Chamber meeting and following a discussion of the key issues, the following actions were agreed **(CW8/472 - INQ000287682)**:

a) Refresh approach to supporting vulnerable groups for the Battle Plan, to reflect the pre-eminence of tackling disparities, and agree objectives, scope and interactions with and across Battle Plan workstreams; and
b) Explore future use of QCOVID and other data/digital approaches to Identify who the most vulnerable groups are, their characteristics, emerging trends in the data and how this can be used by OHID.

306. Following recommendation 'a' above, each of the Battleplan workstreams was tasked with considering their approach to vulnerable groups. Recommendation 'b' was assigned to UKHSA.

307. Reporting responsibility transferred to OHID when it was established as a new Department Group on 1 October 2021 and had a focus on health improvement and prevention of chronic, non-communicable diseases. OHID officials and the COVID-19 PMO held discussions on how best the Star Chamber action could be progressed and where ownership for actions should sit. In Clara Swinson's Fourth Witness Statement for this Module, she set out at paragraph 24 that *"During the formation and*

implementation of policies, potential impacts are taken into account and routinely assessed." As part of this, policy teams ensured that their policy areas took into account inequalities and a wide range of wider considerations in their routine work.

Schools

308. In early September 2021 schools reopened for the autumn term; there was no requirement to keep pupils in separate groups, or 'bubbles', nor to routinely send home groups of pupils when one contact tested positive for COVID-19 **(CW8/473 - INQ000257314)**.

309. The Department for Education (DfE) recommended that all secondary age pupils receive two LFD tests in school, at the start of the September 2021 term, and at the start of the January 2022 term **(CW8/473 - INQ000257314)**. Thereafter, secondary pupils, and all school staff, were encouraged to test at home twice weekly.

310. In January 2022 pupils returned to school after the Christmas and New Year break; face coverings were temporarily introduced for secondary-age pupils in classrooms and when moving around the school, unless exempt **(CW8/473- INQ000257314)**. By 27 January 2022, face coverings were no longer required in these settings. This decision was made in response to national infection data showing the prevalence of COVID-19 was on a downward trajectory. **(CW8/473 - INQ000257314)**.

311. From 21 February 2022, staff and pupils in mainstream schools were no longer expected to undertake routine twice-weekly LFD testing **(CW8/473 - INQ000257314)**.

SECTION 5: PUBLIC HEALTH COMMUNICATIONS

312. From July 2021 to September 2021, CO led on the following communications campaign: 'Vaccines: Don't Miss Out.' From October 2021 to December 2021, CO led on Autumn/Winter protective behaviours (this included guidance on testing, ventilation, and face coverings). From December 2021 to February 2022 CO led on the 'Get Boosted Now' campaign. From January 2022 to March 2022, CO led on Winter protection, including testing (behaviours).

313. Campaign materials and messaging were reviewed by policy teams and CMO/DCMO's office for clinical accuracy and to ensure alignment with policy. Input

was also sought from other parts of the health system including, for example, NHSEI, Test and Trace and the CSA when relevant.

SECTION 6: LEGISLATION AND REGULATIONS AND THEIR PROPORTIONALITY AND ENFORCEMENT

314. A significant volume of legislation was made by the Department between 1 August 2021 – 28 February 2022, primarily to implement policies in the areas of social distancing, face coverings, international travel and self-isolation. This section outlines the key legislation made in those areas during the relevant time period; it is not a comprehensive list of all the legislation made during that time. To help ensure that any legal restrictions in place during this period remained necessary and proportionate, most of the regulations discussed below (other than amendment regulations) imposed a legal duty on the Secretary of State to carry out a review (usually at least once every 28 days) regarding whether the restrictions in those regulations continued to be necessary for the purposes of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection in England with COVID-19.

315. Please refer to paragraphs 253 – 254 of my First Witness Statement for Module 2 dated 23 December 2022 which outlines the decision-making processes and the powers relied upon in the 1984 Act to make the relevant legislation, including use of the emergency procedure. The information in those paragraphs also applies to the legislation made in the time period covered in this statement.

316. I refer to Clara Swinson's Fourth Witness Statement for Module 2 (Impacts of Legislation (Supplementary Statement), which provides detailed information on the impact of legislation and regulations on various sectors of the population in relation to Module 2 of the Inquiry. This supplementary statement includes the advice given, assessments undertaken, and encompasses (where relevant) the impact on civil liberties along with details of steps taken to monitor and mitigate the potential impacts that had been identified and I do not repeat that information here.

Social Distancing

The Health Protection (Coronavirus, Restrictions) (Entry to Venues and Events) (England) Regulations 2021

317. The Health Protection (Coronavirus, Restrictions) (Entry to Venues and Events) (England) Regulations 2021 CW8/were made at 11:56 on 13 December 2021. Regulations 1 and 20 (which amended the Health Protection (Coronavirus, Wearing of Face Coverings in a Relevant Place) (England) Regulations 2020 (the First Face Coverings Regulations) came into force on 14 December 2021 and all other provisions came into force at 06:00 on 15 December 2021. **(CW8/474 - INQ000236144; CW8/475 - INQ000257187; CW8/476 - INQ000236145; CW8/477 - INQ000236146; CW8/478 - INQ000257188; CW8/479 - INQ000257189; CW8/480 - INQ000236147; CW8/481 - INQ000236148; CW8/482 - INQ000112000; CW8/483 - INQ000112003; CW8/484 - INQ000112002; CW8/485 - INQ000112004; CW8/486 - INQ000112001)**

318. These regulations imposed a series of legal obligations on people and implemented a policy of ensuring that access to settings with large crowds, mixing and close contact where the risk of COVID-19 transmission may be increased was restricted to attendees/visitors who could demonstrate their COVID Status or exemption. These regulations also made minor amendments to the Health Protection (Coronavirus, Wearing of Face Coverings) (England) Regulations 2021 (the Second Face Coverings Regulations) (**CW8/487 - INQ000257130; CW8/488 - INQ000257131; CW8/489 - INQ000257132; CW8/490 - INQ000257133; CW8/491 - INQ000257135; CW8/492 - INQ000257134; CW8/493 - INQ000257136; CW8/494 - INQ000257137; CW8/495 - INQ000257138; CW8/496 - INQ000257139).**

319. These regulations provided powers to an 'authorised person' to enforce the restrictions and requirements in the regulations, which was defined as: a constable, a police community support officer, or a person designated by the relevant local authority or the Secretary of State. These regulations included provision for a fixed penalty notice to be issued for £10,000 if a person made, adapted, supplied or offered to supply false evidence of COVID-19 status to another person which the person knew was false or misleading.

320. All provisions within these regulations were due to expire at the end of 26 January 2022, with two exceptions:

a. Regulation 7(7) (which set out the period of time that statements and records must be retained for), which was due to expire at the end of 26 April 2022;
b. Regulation 20, which amended the Second Face Coverings Regulations, did not have an expiry date.

321. Regulation 7(7) duly expired at the end of 26 April 2022. The Second Face Coverings Regulations, as explored in paragraphs 322-326 below, were extended to 26 January 2022. All other provisions within these regulations duly expired at the end of 26 January 2022.

Face Coverings Regulations

The Health Protection (Coronavirus, Wearing of Face Coverings) (England) Regulations 2021

322. The Second Face Coverings Regulations were made at 13:35 on 29 November 2021 and came into force at 04:00 on 30 November 2021.

323. The Second Face Coverings Regulations required members of the public to wear face coverings indoors in a number of relevant places including while inside certain indoor settings in England, including shops, shopping centres, banks, transports hubs, and when using public transport services, except in limited cases.

324. The Second Face Coverings Regulations provided powers to a 'relevant person' to enforce the requirements in the regulations, which was defined as: a constable, a police community support officer, a TfL officer, operator of a public transport service or a person designated by the Secretary of State.

325. These regulations were due to expire at the end of 20 December 2021.

The Health Protection (Coronavirus, Wearing of Face Coverings) (England) (Amendment) Regulations 2021

326. The Health Protection (Coronavirus, Wearing of Face Coverings) (England) (Amendment) Regulations 2021 were made at 13:55 on 9 December 2021 and came into force on 10 December 2021 **(CW8/497 - INQ000236135; CW8/498 - INQ000236136; CW8/499 - INQ000257169; CW8/500 - INQ000236137; CW8/501 - INQ000236138; CW8/502 - INQ000236139; CW8/503 - INQ000257170; CW8/504 - INQ000257171)**. These regulations amended the Face Coverings Regulations, in response to the latest evidence about the Omicron variant, to expand the mandatory wearing of face coverings to a greater number of settings. These regulations also extended the period for which the Face Coverings Regulations were in force until 26 January 2022.

International Travel Regulations

327. The regulations mentioned below provide an indication of the volume of regulations about international travel that were made in the time-period covered by this witness statement. Indeed, amending regulations were frequently made, often on a weekly basis, to update the category 1 ("green-list"), category 2 ("amber-list") and category 3 ("red-list") country and territory lists and to introduce exemptions from and modifications to the testing and self-isolation requirements for specified persons arriving in England.

328. Amendments were also quickly made to reflect the changing nature of COVID-19. For example, following the detection of a new variant of concern (Omicron):

a. Certain countries were added to the list of category 3 ("red-list") countries and territories;
b. The option for eligible travellers (that is, travellers to England from countries which were not on the red-list who were fully vaccinated or met certain other, limited criteria such as being exempt from vaccination) to complete an LFD test rather than a PCR test was removed (meaning that all travellers were required to complete a PCR test on or before day 2 of their arrival, unless an exemption applied);
c. A new requirement was imposed for all travellers who tested positive with the Omicron variant to notify UKHSA of the names of all the people living in their household.

329. Once more was known about the Omicron variant, many restrictions and requirements were relaxed or removed. For example, LFD testing was reintroduced as an option for day 2 tests for eligible travellers (instead of a day 2 PCR test).

330. I have set out some examples below of regulations made in respect of international travel during the relevant period. However, due to the extensive number of regulations made during this time period, this is not an exhaustive list.

The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 7) Regulations 2021

331. The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 7) Regulations 2021 were made at 11:10 on 30 July 2021 and partly came into force at 04:00 on 2 August 2021 **(CW8/505 - INQ000236092;**

CW8/506 - INQ000287654; CW8/507 - INQ000236093; CW8/508 - INQ000236094; CW8/509 - INQ000256982; CW8/510 - INQ000256983; CW8/511 - INQ000236095; CW8/512 - INQ000236096; CW8/513 - INQ000236097; CW8/514 - INQ000256984; CW8/515 - INQ000256985; CW8/516 - INQ000256986). The remaining provisions (amending mandatory and optional testing requirements after arrival in England and amending the Health Protection (Notification) Regulations 2010) came into force on 23 August 2021.

332. These regulations amended the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021 (the ITOL Regulations) to:

a. Introduce an exemption to the self-isolation and day 8 test requirements for individuals who had been fully vaccinated in the United States, the European Union and other relevant countries when arriving in England from a category 2 ("amber- list") country;
b. Exclude certain individuals operating transport services from the requirement to undertake workforce tests and require operators to ensure that passengers have evidence to support an exemption; and
c. Make a number of amendments that related to testing to improve data accuracy, test result reporting and to require day 8 tests to be genome sequenced.

The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 13) Regulations 2021

333. The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 13) Regulations 2021 were made at 09:43 on 1 October 21 and came into force at 04:00 on 4 October 2021 (save for regulation 25(3)) **(CW8/517 - INQ000236110; CW8/518 - INQ000257069; CW8/519 - INQ000236111; CW8/520 - INQ000236112; CW8/521 - INQ000257070; CW8/522 - INQ000236113; CW8/523 - INQ000236114; CW8/524 - INQ000236115; CW8/517 - INQ000236110)**. These regulations amended the ITOL Regulations to include:

a. Implementing changes to border requirements by removing all category 1 ("green-list") countries and moving to requirements based on whether a person was a red-list arrival or a non-red list arrival. For non-red list arrivals,

requirements depended on whether a person met the requirement to be an eligible traveller which is linked to vaccination status;

b. Expanding the "eligible traveller" category to include individuals vaccinated in a larger list of countries and remove the pre-departure test requirement for this category of individuals; and

c. Removing the obligation for operators to check for evidence where a person is a verified eligible traveller.

The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 24) Regulations 2021

334. The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 24) Regulations 2021 were made on 14 December 2021 and came into force at 04:00 on 15 December 2021 **(CW8/526 - INQ000257194; CW8/527 - INQ000257198; CW8/528 - INQ000257199; CW8/529 - INQ000257196; CW8/530 - INQ000257197; CW8/531 - INQ000257195; CW8/532 - INQ000257200).** These regulations amended the ITOL Regulations to remove all countries from category 3 (the "red-list") and to remove all countries from the list from which departing planes were not permitted to land in England.

The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 25) Regulations 2021

335. The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 25) Regulations 2021 were made at 15:59 on 15 December 2021 and came into force at 16:00 on 15 December 2021 **(CW8/533 - INQ000236149; CW8/534 - INQ000257205; CW8/535 - INQ000257206; CW8/536 - INQ000236150; CW8/537 - INQ000236151).** These regulations amended the ITOL Regulations to permit category 3 ("red-list") passengers who were required to isolate immediately before 16:00 on 15 December 2021 to complete their period of self-isolation at a place other than the place specified in their managed isolation package (unless they did not meet the conditions in the regulations or they, or a close contact of theirs, had tested positive for coronavirus).

The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) Regulations 2022

336. The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) Regulations 2022 were made at 10:50 on 6 January 2022 and came into force in a staggered way from 04:00 on 7 January 2022 to 04:00 on 10

January 2022 **(CW8/538 - INQ000236152; CW8/539 - INQ000236153; CW8/540 - INQ000236154; CW8/541 - INQ000236155; CW8/542 - INQ000236156; CW8/543 - INQ000257238; CW8/544 - INQ000236157; CW8/545 - INQ000257239)**. These regulations amended the ITOL Regulations to include:

a. Removing the requirement for eligible travellers to possess a negative test result upon arrival in England;
b. Removing the requirement for eligible travellers to self-isolate on arrival;
c. Re-introducing LFD testing as an option for day 2 tests for eligible travellers who arrived in England (instead of a day 2 PCR test);
d. Re-introducing the obligation to notify UKHSA of certain information in relation to the LFD test results; and
e. Expanding the "eligible traveller" category to recognise vaccinations certified by a number of new countries. The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 2) Regulations 2022.

The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 2) Regulations 2022

337. The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No.2) Regulations 2022 were made at 10:18 on 10 February 2022 and came into force in a staggered way between 04:00 on 11 February 2022 and 3 March 2022 **(CW8/546 - INQ000236158; CW8/547 - INQ000257281; CW8/548 - INQ000236162; CW8/549 - INQ000236163; CW8/550 - INQ000257280; CW8/551 - INQ000236161; CW8/552 - INQ000236159; CW8/553 - INQ000236160)**. These regulations amended the ITOL Regulations to include:

a. Removing the requirement for eligible travellers to complete a post-arrival test;
b. Removing the requirement for non-eligible travellers to complete a day 8 test and undertake a ten-day self-isolation period upon arrival;
c. Expanding the "eligible traveller" category to recognise vaccinations certified by 16 additional countries and territories internationally; and
d. Introducing updates to streamline the Passenger Locator Form, current exemption scheme and penalties for operators.

The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 3) Regulations 2022

338. The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 3) Regulations 2022 were made on 22 February 2022 and came into force on 24 February 2022 **(CW8/554 - INQ000236168; CW8/555 - INQ000257307; CW8/556 - INQ000257308; CW8/557 - INQ000236171; CW8/558 - INQ000236169; CW8/559 - INQ000236170; CW8/560 - INQ000257309; CW8/561 - INQ000257310)**. These regulations amended the ITOL Regulations to:

a) Remove the legal obligation for travellers who had not been in a category 3 ("red-list") country in the previous 10 days and did not meet the conditions of an eligible traveller ("non-eligible travellers") to self-isolate following the receipt of a positive post-arrival test result;
b) Removing the legal obligation for non-eligible travellers to self-isolate upon a void or inconclusive test result, or upon a failure to test; and
c) Ensuring that the obligations on the bespoke workforce testing cohort were no more onerous than those on the general population.

339. The ITOL Regulations were revoked at 4am on 18 March 2022 following the decision to revoke all border health measures.

Self-Isolation Regulations

The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) Regulations 2021

340. The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) Regulations 2021 were made at 10:05 on 15 July 2021 and partly came into force on 19 July 2021 **(CW8/562 - INQ000236079; CW8/563 - INQ000236080; CW8/564 - INQ000236081; CW8/565 - INQ000256975; CW8/566 - INQ000236082; CW8/567 - INQ000236083; CW8/568 - INQ000256976)**. The remaining amendments came into force on 16 August 2021, in respect of exemptions to the legal duty to self-isolate that related to vaccine status and the removal of the duty to self-isolate for children.

341. Both these regulations and the Self-Isolation Regulations (as discussed in paragraphs 432-434 of my second statement for Module 2), which these regulations amended, expired on 28 September 2021.

The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) Regulations 2021

342. The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) Regulations 2021 4 were made on 22 July 2021 and came into force on 11 November 2021 **(CW8/569 - INQ000236091; CW8/570 - INQ000287652; CW8/571 - INQ000287651; CW8/572 - INQ000287649 CW8/573 - INQ000236090; CW8/574 - INQ000066696; CW8/575 - INQ000058363)**.

343. These regulations amended the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (the 2014 Regulations) to provide that the registered person for nursing and personal care in care homes must secure that, subject to certain exceptions, a person does not enter the care home premises unless they provide evidence that they have been vaccinated with a complete course of an authorised vaccine against COVID-19.

The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) (No. 3) Regulations 2021).

344. The Health Protection (Coronavirus), Restrictions) (Self-Isolation) (England) (Amendment) (No. 3) Regulations 2021 (the Third Self-Isolation Regulations) were made at 10:40 on 22 September 2021 and came into force at 23:55 on 27 September 2021 (**CW8/576 - INQ000236103; CW8/577 - INQ000287673); CW8/578 - INQ000236106; CW8/579 - INQ000236104; CW8/580 - INQ000236105; CW8/581 - INQ000236107; CW8/582 - INQ000236108; CW8/583 - INQ000287674 CW8/584 - INQ000257058; CW8/585 - INQ000257062; CW8/586 - INQ000257063; CW8/587 - INQ000287677; CW8/588 - INQ000287678**). These regulations amended the Self-Isolation Regulations to:

a. Clarify when a household contact would be exempt from self-isolation due to being fully vaccinated;
b. Extend the exemption from the duty to self-isolate for fully vaccinated persons to those who had received doses of two different (MHRA) authorised vaccines in the UK; and
c. Clarify the requirements on those taking part in a testing scheme, in a situation where they tested positive with a lateral flow test but receive a subsequent negative confirmatory PCR test result.

345. The Third Self-Isolation Regulations extended the date of expiration of the Self-Isolation Regulations and the Health Protection (Coronavirus, Restrictions) (England) (No. 3) Regulations from the end of 27 September 2021 to the end of 24 March 2022.

The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) (No. 4) Regulations 2021

346. The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) (No. 4) Regulations 2021 (the Fourth Self-Isolation Regulations) were made at 13:55 on 29 November 2021 and came into force at 04:00 on 30 November 2021 **(CW8/589 - INQ000236125; CW8/590 - INQ000257127; CW8/591 - INQ000236127; CW8/592 - INQ000236128; CW8/593 - INQ000236126; CW8/594 - INQ000257128); CW8/595 - INQ000257129**. These regulations amended the Self-Isolation Regulations to respond to the emergence of the Omicron variant and provided that the exemptions from the duty to self-isolate did not apply to adults who were close contacts of someone who had tested positive for coronavirus and was suspected of, or confirmed as, having the Omicron variant. This instrument was produced by the COVID-19 Self-Isolation Policy Team within UKHSA. It was signed by Minister Throup.

The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) (No. 5) Regulations 2021

347. The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) (No. 5) Regulations 2021 (the Fifth Self-Isolation Regulations) were made at 11:08 on 8 December 2021 and came into force on 9 December 2021 except for regulation 2(3)(a)(iii), which included more detail around the evidence required for a "close contact" of a positive case to demonstrate that they were medically unable to be vaccinated and therefore exempt from the requirement to self-isolate, which came into force on 18 January 2022 **(CW8/596 - INQ000257158; CW8/597 - INQ000257160; CW8/598 - INQ000257159; CW8/599 - INQ000257162; CW8/600 - INQ000257163; CW8/601 - INQ000257161)**.

348. These regulations amended the Self-Isolation Regulations to provide greater consistency across the Self-Isolation Regulations and the International Travel Regulations specifically in relation to treatment of individuals who were fully vaccinated. As with the Fourth Self-Isolation Regulations, this instrument was produced by the COVID-19 Self-Isolation Policy Team within UKHSA. It was signed by the Secretary of State.

The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) (No. 6) Regulations 2021

349. The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) (No. 6) Regulations 2021 (the Sixth Self-Isolation Regulations) were made at 11:55 on 13 December 2021 and came into force at 06:00 on 14 December 2021 **(CW8/602 - INQ000236140; CW8/603 - INQ000257186; CW8/604 - INQ000236142; CW8/605 - INQ000257185; CW8/606 - INQ000236143; CW8/607 - INQ000236141)**. These regulations amended the Self-Isolation Regulations to remove the distinction between close contacts of a known or suspected Omicron case and close contacts of all other positive cases.

350. All close contacts were no longer required to self-isolate if: they were fully vaccinated (provided that the contact took place more than 14 days after they had completed their course of vaccinations); they were taking part in a vaccine trial; they could provide evidence that for clinical reasons they should not be vaccinated; or they were a child. As with the Fifth Self-Isolation Regulations, this instrument was produced by the COVID-19 Self-Isolation Policy Team within UKHSA. It was signed by Minister Throup.

The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2022

351. The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2022 were made on 6 January 2022 and came into force on 7 January 2022 except for regulation 4, which made further amendments to regulation 12 of the 2014 Regulations and which came into force after a period of 12 weeks (beginning with the day after the day on which these regulations were made).

352. These regulations amended the 2014 Regulations to make provision in respect of conditions relating to entry into a care home where that care home was used by a registered person, in respect of the regulated activity of providing accommodation for persons who required nursing or personal care. The registered person was required to secure that (subject to certain exceptions) a person only entered the care home premises if they could meet certain vaccination conditions.

The Health Protection (Coronavirus, Restrictions) (Self-Isolation etc.) (Revocation) (England) Regulations 2022

353. The Health Protection (Coronavirus, Restrictions) (Self-Isolation etc.) (Revocation) (England) Regulations 2022 were made at 09:55 on 22 February 2022 and came into force on 24 February 2022. These regulations revoked the Self-Isolation Regulations

with the effect of removing the legal requirement (in England) to self-isolate for those who tested positive for COVID-19 and those who were contacts of positive cases **(CW8/608 - INQ000236164; CW8/609 - INQ000236165; CW8/610 - INQ000236166; CW8/611 - INQ000257301; CW8/584 - INQ000257058; CW8/613 - INQ000236167; CW8/614 - INQ000287745; CW8/615 - INQ000287746 CW8/616 - INQ000257304; CW8/617 - INQ000257305; CW8/618 - INQ000257306)**. These regulations also revoked the Health Protection (Coronavirus, Restrictions) (England) (No. 3) Regulations 2020 which had the effect of removing the temporary powers granted to local authorities to give directions to impose prohibitions, requirements or restrictions on individual premises, events or public outdoor places, provided that strict legal tests were satisfied, to reduce the risk of transmission of COVID-19.

354. While there was no longer a legal requirement to self-isolate, those who tested positive for COVID-19 received guidance **(CW8/619 – INQ000256954)** advising them to stay at home and avoid contact with others for at least five full days. Where individuals were unable to stay at home, the guidance set out steps they could take to reduce the risk to others. As with the Fifth and Sixth Self-Isolation Regulations, this instrument was produced by the COVID-19 Self-Isolation Policy Team within UKHSA. It was signed by Minister Throup.

Coronavirus Act 2020

355. Please see paragraph 435 of my second statement for Module 2 which confirmed that the Coronavirus Act 2020 (CVA) remained in force. The CVA continued in force for the time period covered by this witness statement and the relevant two-monthly reports from this time period are exhibited at **(CW8/620 - INQ000237619 – CW8/621 - INQ000287617; CW8/622 - INQ000287622; CW8/623 - INQ000235011 CW8/624 - INQ000287634; CW8/625 - INQ000287645; CW8/626 - INQ000235013; CW8/627 - INQ000235014; CW8/628 - INQ000236175 CW8/629 - INQ000236176 CW8/630 - INQ000236177)**.

Statement of Truth

356. 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.

Personal Data

Signed: _____

Dated: 30August 2023