Witness Name: Dame Jenny Harries

Statement No: 7

Exhibits: JH7/01 – JH7/114

Dated: 04 July 2024

UK COVID-19 PUBLIC INQUIRY

MODULE FOUR CORPORATE STATEMENT ON BEHALF OF THE UK HEALTH SECURITY AGENCY (Part II: VTF/UKHSA)

Section 1: INTRODUCTION

1.1. I, Professor Dame Jenny Harries, of the UK Health Security Agency, 10 South Colonnade, Canary Wharf, London E14 4PU, will say as follows:

1.2. I am the Chief Executive Officer ("CEO") of the UK Health Security Agency ("UKHSA"). Prior to taking on that role, I was Deputy Chief Medical Officer ("DCMO") for England from 15 July 2019 to 31 March 2021.

1.3. I make this statement on behalf of UKHSA for Module 4 of the UK COVID-19 Inquiry ("the Inquiry") which will inquire into vaccines and therapeutics. The statement responds to a request for evidence dated 17 October 2023 from the Inquiry under Rule 9 of the Inquiry Rules 2006 ("the Rule 9 request").

1.4. Before my appointment as DCMO, I was Regional Director for the South of England within Public Health England ("PHE") from 2013 to 2019. Alongside this, I was interim Deputy National Medical Director for PHE from 2016 to 2017 providing specific support for strategic incident response. From April 2017 until I commenced the DCMO role, I also formally held the strategic incident Deputy Medical Director role at PHE. I have been a member of several national advisory groups including the Joint Committee on Vaccination and Immunisation ("JCVI"), the National Advisory Committee on the NHS Constitution, the National Health Service England ("NHSE") Clinical Priorities Advisory Group and the Women's Health Taskforce.

1.5. Prior to joining PHE, I worked as a Director of Public Health in Norfolk & Waveney, Swindon and Monmouthshire, and was additionally a Chief Officer in the two former Local Authorities. My background is as a clinical doctor with specialist training in public health medicine. I hold a medical degree (MBChB) and Fellowship of the Faculty of Public Health ("FFPH") by examination alongside other formal qualifications. These include a BSc in pharmacology, a master's degree in public health ("MPH"), a master's degree in business administration ("MBA"), a postgraduate diploma in health economics evaluation and a postgraduate certificate in strategic planning and commissioning. I am also a Fellow of the Chartered Management Institute, a visiting Professor of Public Health at the University of Chester, and an Honorary Fellow of the Faculty of Occupational Medicine ("FFOM"), the Faculty of Public Health and the Royal College of Paediatrics and Child Health ("FRCPCH").

1.6. The UKSHA is an executive agency of the Department for Health and Social Care ("DHSC") and carries out certain statutory functions on behalf of the Secretary of State for Health and Social Care. Fully operational from 1 October 2021, UKHSA's role is to protect the public not only from infectious diseases but also from external hazards such as chemical, radiological, nuclear, and environmental threats. It brings together expertise from several predecessor organisations. These include PHE, NHS Test and Trace, the Joint Biosecurity Centre ("JBC") and the Vaccine Task Force ("VTF").

1.7. This is the eighth corporate statement which UKHSA has provided to the Inquiry. I, have provided four corporate statements on behalf of UKHSA for Modules 1 to 3. Professor Isabel Oliver, UKHSA's interim Chief Scientific Officer has provided two corporate statements for Module 1. Professor Susan Hopkins, UKHSA's Chief Medical Advisor, has provided a corporate statement for Module 3.

1.8. The questions set out in the Rule 9 request separate into those relating to the role of PHE (and UKHSA as its successor organisation) and those concerning the VTF. The role of PHE/UKHSA has been addressed in a separate statement. This statement addresses the role of the VTF. As there are few senior staff in UKHSA with operational knowledge of the VTF prior to the last two months of the time-period with which this Module is concerned, the content of this statement is necessarily reliant on documents available to UKHSA. It is important to note that not all of the VTF's functions were transferred to UKHSA. Key functions were transferred to DHSC and to the Office for Life Sciences ("OLS"), which comes under both DHSC and the Department for Science, Innovation and Technology ("DSIT")[1]. DHSC and DSIT are better able to assist the Inquiry on those VTF functions which they inherited, and the work done to establish the VTF.

1.9. This statement adopts the following thematic structure:

(1) Section 2: The Objectives set for the VTF (paragraphs 2.1 - 2.9).
(2) Section 3: Chronology of Key Events (paragraph 3.1).
(3) Section 4: The Structure, Leadership and Processes of the VTF (paragraphs 4.1 - 4.25).

[1] On February 2023, BEIS was split to form the Department for Business and Trade ("DBT"), the Department for Energy Security and Net Zero ("DESNZ") and DSIT. Following this split, the OLS became a joint unit sitting between DSIT and DHSC.

(4) Section 5: Development, Procurement, Manufacture and Approval of Vaccines (paragraphs 5.1 – 5.109).
(5) Section 6: Vaccine Supply and Management (paragraphs 6.1 – 6.25).
(6) Section 7: Vaccine Safety (paragraphs 7.1 – 7.10).
(7) Section 8: Reviews of the Work of the VTF (paragraphs 8.1 – 8.18).
(8) Section 9: Lessons for the Future (paragraphs 9.1 – 9.7).

1.10. As requested by the Inquiry, key documents are exhibited to this statement.

1.11. I understand that, in Module 4, the Inquiry will focus on the period from 30 January 2020 to 28 June 2022. This statement focuses on the VTF's work from its formal creation in April 2020 until June 2022 but, where relevant to the Rule 9 request, includes information concerning the VTF from June 2022 until the transition of VTF responsibilities to UKHSA, DHSC and the OLS in October 2022.

Section 2: THE OBJECTIVES SET FOR THE VTF

2.1. Securing access to a COVID-19 vaccine was essential to combating the pandemic to save lives, reduce hospital admissions and support the reopening of society and the UK economy. Governments and medical organisations worldwide focused significant resources on the goal of rapidly developing one or more viable vaccines.

2.2. The Rt Hon Sir Alok Sharma MP, then Secretary of State for Business, Energy, and Industrial Strategy ("BEIS"), formally announced the establishment of the VTF on 17 April 2020 with the remit to "*drive forward, expedite and co-ordinate efforts to research and then produce a coronavirus vaccine and make sure one is made available to the public as quickly as possible*". At that time, the taskforce was led by Sir Patrick Vallance, then Government Chief Scientific Adviser ("GCSA") and Professor Sir Jonathan Van-Tam, then DCMO. See 17 April announcement at **[Exhibit: JH7/01 INQ000065356]**.

2.3. While the objectives of the VTF were refined over time, its focus remained COVID-19. A letter of 2 June 2020, from the then Cabinet Secretary, confirming the appointment of Dame Kate Bingham as the VTF's first Chair, identified the two "*immediate aims*" of the VTF as being to ensure:

(1) *"… the whole UK population, or relevant subpopulations, can be vaccinated against COVID-19 as soon as is practicable*."

(2) "*adequate global distribution of vaccines to bring the quickest possible end to the pandemic and the economic damage it inflicts.*" See Dame Kate Bingham's appointment letter at **[Exhibit JH7/02 INQ000069537]**.

2.4. There was, however, also a focus on developing long-term capacity for the UK by asking the VTF to "*help to develop and agree a wider UK long-term vaccine strategy, to include a broad* '[UK]' *biotherapeutic and vaccine manufacturing capacity so the UK is prepared for future potential pandemics*" **[Exhibit: JH7/03 INQ000283321]**. By the time the VTF's functions were transferred to other bodies including UKHSA, its objectives, with the first two still directed towards COVID-19, were defined as follows (particularised at the outset of the VTF review **[Exhibit: JH7/03 INQ000283321]**):

(1) "*secure access to promising vaccine(s) for the UK population and achieve lasting immunity.*"

(2) "*make provision for international distribution of vaccines.*"

(3) "*strengthen the UK's onshore capacity and capability in vaccine development, manufacturing and supply chain to provide resilience for this and future pandemics.*"

2.5. As the announcement of 17 April 2020 and the letter of appointment of Dame Kate illustrate, the VTF's remit was to coordinate the end-to-end process of COVID-19 vaccine development and utilisation, from discovery to clinical trials and on to distribution both on a domestic and international level. Industry and research institutions were to be provided with the necessary support and resources.

2.6. The VTF was established at pace, in a major crisis, as a temporary structure with (i) a remit to coordinate across Government, industry and academia in order to secure rapid access to a COVID-19 vaccine for the UK, and (ii) the substantial resources needed to deliver this critical mission. It drew its staff from across the Civil Service, private sector and academia and scaled up over time and was funded flexibly to do so. This provided a breadth of expertise, ranging from clinical and scientific knowledge, through to supply, programme management, delivery and commercial. The combination of specialist biotechnical knowledge and expertise in Government working, crisis response and operational planning allowed for effective, rapid and centrally coordinated support to be

put in place to address the challenge of developing a safe and effective COVID-19 vaccine within an accelerated timeline.

2.7. Working with key actors in Government, industry, and academia, the VTF was able to procure a portfolio of COVID-19 vaccines, enabling the UK to start its deployment programme in December 2020. In doing so, the UK became the first country in the world to secure advanced procurement deals and to deploy a regulated COVID-19 vaccine outside of clinical trials. The WHO recently reported that COVID-19 vaccination is estimated to have saved at least 1.4 million lives in Europe (see WHO media release at **[Exhibit: JH7/04 INQ000412458]**).

2.8. The VTF's work contributed to the continued availability of vaccines needed for booster campaigns and the extension of the COVID-19 vaccine programme to children. By the time of the transition of VTF responsibilities to UKHSA, DHSC and the OLS in October 2022, over 150 million doses of COVID-19 vaccines had been administered in the UK (**[Exhibit: JH7/03 INQ000283321]**).

2.9. The work of the VTF has rightly been hailed as a success. However, it is important to recognise that, whilst the approach that the VTF took during the COVID-19 pandemic has been particularly commended, its achievements were ultimately dependent on the efforts and actions of actors across the health system, including PHE/UKHSA, DHSC, the Devolved Governments, NHS delivery partners, the Medicines and Healthcare products Regulatory Agency ("MHRA"), the National Institute for Heath and Care Research ("NIHR"), and the Foreign, Commonwealth and Development Office ("FCDO"), as well as industry suppliers and academia. Key bodies with which the VTF worked in relation to the development, procurement, manufacture, and approval of COVID-19 vaccines are set out in the table below:

Category	**Name**
Government Departments	BEIS (Including the Government Office for Science ("GOS"), and the OLS which reports to both BEIS and DHSC)
	DHSC
	Office of the Chief Medical Officer ("OCMO")
	Cabinet Office
	No. 10
	FCDO

	Department for Digital, Culture, Media and Sport ("DCMS")
	Department for International Development ("DfID")
	Ministry of Defence ("MOD")
	Home Office (Border Force)
	HM Treasury
	Government Legal Department ("GLD")
	Government Commercial
	Department for International Trade ("DIT")
Arms-Length Bodies/related Government organisations	JCVI
	PHE
	UKHSA
	NHSE
	MHRA
	NIHR
	Scottish Government
	NHS Scotland
	Welsh Government
	NHS Wales
	Northern Ireland Executive
	Health and Social Care Northern Ireland
	UK Research and Innovation ("UKRI")
	National Police Coordination Centre
Industry Bodies	Association of the British Pharmaceutical Industry ("ABPI")
	BioIndustry Association ("BIA")
	Cell and Gene Therapy Catapult ("CGTC")
NGOs and other bodies	Coalition for Epidemic Preparedness Innovations ("CEPI")[2]
	Gavi, the Vaccine Alliance[3]

[2] CEPI is a global partnership between public, private, and civil society organisations which work together to accelerate the development of vaccines.
[3] A partnership between WHO, UNICEF, the World Bank and the Bill and Melinda Gates Foundation.

Section 3: CHRONOLOGY OF KEY EVENTS

3.1. The table below sets out key events relevant to the work of the VTF. Some of these events are considered in more detail later in this statement.

Date	Event	Exhibit(s)
23 March 2020	UK Government announced the allocation of funding to six coronavirus projects including two vaccine trials. This announcement was part of a £20 million research response funded by DHSC through the NIHR and UKRI.	See press release **[Exhibit: JH7/05 INQ000309583]**.
26 March 2020	Following a virtual G20 Summit, UK Government announced a further £210 million in UK aid to the CEPI, a global public-private partnership, to help develop a COVID-19 vaccine that will be available throughout the world.	See press release **[Exhibit: JH7/06 INQ000309584]**.
17 April 2020	Establishment of the VTF.	See press release **[Exhibit: JH7/01 INQ000065356]**.
21 April 2020	UK Government announced funding to research teams based at the University of Oxford (£20 million) and Imperial College London (£22.5 million) to fund clinical trials.	See Ministerial press briefing **[Exhibit: JH7/07 INQ000309586]**.
21 April 2020	University of Oxford began clinical trials (for what was to become the Oxford/AstraZeneca adenovirus-based vaccine).	
30 April 2020	Announcement of partnership between University of Oxford and AstraZeneca.	See transcript of Prime Minister's coronavirus statement **[Exhibit: JH7/08 INQ000309587]**.
16 May 2020	Dame Kate Bingham appointed chair of the VTF.	See press release **[Exhibit: JH7/09 INQ000309589]**.

17 May 2020	BEIS announced new UK Government funding of £84 million for the vaccines being developed by the University of Oxford (£65.5 million) and Imperial College London (£18.5 million).	See press release **[Exhibit: JH7/10 INQ000234369]**.
	University of Oxford agreed a global licensing agreement with AstraZeneca for the commercialisation and manufacturing of their potential vaccine. The UK would be the first country to have access to this vaccine. Under the agreement, AstraZeneca was to deliver 100 million doses in total.	
	UK Government announced funding of £93 million to accelerate the construction of the Vaccines Manufacturing and Innovation Centre ("VMIC"), Oxfordshire, to allow manufacture of vaccines to commence in Summer 2021. As part of this, £38 million was allocated for a rapid deployment facility to allow manufacturing at scale of the University of Oxford/AstraZeneca vaccine in Summer 2020.	See press release **[Exhibit: JH7/11 INQ000309591]**.
15 June 2020	Announcement that clinical trials of the Imperial College London vaccine were to begin.	See press release **[Exhibit: JH7/12 INQ000309593]**.
20 July 2020	UK Government announced: (1) That it is the first Government to sign a binding agreement with Pfizer/BioNTech for its mRNA vaccine and has secured 30 million doses of their vaccine for the UK. (2) Has made an in-principle agreement with Valneva for 60 million doses of their live attenuated virus vaccine. (3) Has made an in-principle agreement with AstraZeneca for one million doses of a treatment to protect patients, such as those with cancer, who cannot receive a vaccine.	See press release **[Exhibit: JH7/13 INQ000309594]**.

	NHS COVID-19 vaccine research registry (Permission to Contact) launched to enable volunteers to sign up to participate in clinical studies.	
23 July 2020	Funding of £100 million announced for the CGTC in Braintree, Essex.	See press release **[Exhibit: JH7/14 INQ000309595]**.
29 July 2020	UK Government announced agreement that it had secured access to 60 million doses of the Sanofi Pasteur/GSK protein subunit vaccine.	See press release **[Exhibit: JH7/15 INQ000309596]**.
3 August 2020	UK Government announced that it has entered into an 18-month agreement with Wockhardt, a pharmaceutical and biotechnical company, to provide "fill and finish" services at its facility in Wrexham.	See press release **[Exhibit: JH7/16 INQ000309597]**.
5 August 2020	UK Government and Valneva, a biotech company, confirmed multi-million-pound joint investment in a manufacturing facility in Livingston, Scotland, as part of an in-principle agreement to secure early access to 60 million doses of Valneva's vaccine candidate.	See press release **[Exhibit: JH7/17 INQ000309598]**.
14 August 2020	Government announced new in-principle agreements that secured 60 million doses of the Novavax protein subunit vaccine and 30 million doses of the Janssen adenovirus-based vaccine. There was also an in-principle agreement to a global clinical study of the Janssen vaccine.	See press release **[Exhibit: JH7/18 INQ000309599]**.
26 September 2020	UK Government announced £571 million contribution to COVAX[4] to join and strengthen the joint vaccine purchasing scheme. £500 million of this sum was to support access in lower-income countries through the COVAX facility.	See transcript of PM's speech to United Nations General Assembly **[Exhibit: JH7/19 INQ000309601]**.

[4] The COVAX facility was a worldwide initiative aimed at achieving equitable access to COVID-19 vaccines and directed by the GAVI vaccine alliance, CEPI, and the World Health Organization. COVAX came to a close on 31 December 2023.

20 October 2020	UK Government announced investment of £33.6 million to support the implementation of human challenge studies in the UK[5]. The primary aim was to discover the smallest amount of virus it takes to cause a person to develop COVID-19 infection, but the study also provided data on virological and clinical characteristics including the amount of virus detectable (viral load) in samples from study participants over time, the incubation period, key symptoms, and their progression.	See press release **[Exhibit: JH7/20 INQ000399446]**.
16 November 2020	UK Government announced that it had secured access to 5 million doses of the Moderna mRNA vaccine.	See press release **[Exhibit: JH7/21 INQ000309606]**.
29 November 2020	UK Government announced that it had secured an additional 2 million doses of the Moderna vaccine.	See press release **[Exhibit: JH7/22 INQ000309609]**.
2 December 2020	MHRA approval of Pfizer/BioNTech's COVID-19 vaccine.	See press release **[Exhibit: JH7/23 INQ000309610]**.
8 December 2020	First administration of a COVID-19 vaccine in the world (outside of clinical trials) as deployment of Pfizer/BioNTech's vaccine began.	See NHS England news article **[Exhibit: JH7/24 INQ000237370]**.
8 December 2020	Publication of VTF's 2020 Achievements and Future Strategy Report.	See published Report **[Exhibit: JH7/25 INQ000309612]**.
30 December 2020	MHRA approval of Oxford/AstraZeneca's COVID-19 vaccine.	See press release **[Exhibit: JH7/26 INQ000309616]**.
8 January 2021	MHRA approval of Moderna's COVID-19 vaccine. UK Government announced agreement to purchase an additional 10 million doses of the Moderna vaccine, bringing the total to 17 million doses.	See press release **[Exhibit: JH7/27 INQ000309618]**.

[5] A clinical study where volunteers are intentionally exposed to an infective agent in a safe and controlled environment.

1 February 2021	UK Government signed a deal for an additional 40 million doses of Valneva's vaccine candidate, bringing the total to 100 million Valneva doses.	See press release **[Exhibit: JH7/28 INQ000309623]**.
4 February 2021	Com-COV clinical study[6] launched to determine the effects of using different vaccines for the first and second dose.	See press release **[Exhibit: JH7/29 INQ000309624]**.
5 February 2021	UK Government and CureVac announce a new partnership to rapidly develop new mRNA vaccines to tackle new future variants of COVID-19, securing 50 million doses if required.	See press release **[Exhibit: JH7/30 INQ000309625]**.
10 February 2021	Wockhardt confirmed the extension of their Covid-19 vaccination contract for 24 months to ensure the UK had uninterrupted fill and finish capacity until August 2022.	See press release **[Exhibit: JH7/31 INQ000309626]**.
17 February 2021	World's first COVID-19 human challenge study received approval from the UK's clinical trials ethics body.	See Government press release **[Exhibit: JH7/32 INQ000309627]**.
19 February 2021	Prime Minister confirmed that the UK will share the majority of any future surplus vaccines from the UK's supply to the COVAX procurement pool to support developing countries.	See press release **[Exhibit: JH7/33 INQ000309628]**.
1 March 2021	DHSC and BEIS announced that responsibility for the VTF is to move jointly to those Departments.	See press release **[Exhibit: JH7/34 INQ000309629]**.
3 March 2021	At Budget 2021, the Chancellor confirmed funding of: (1) £28 million to boost PHE vaccine efficacy testing capability, including against different virus variants, and the UK's support for clinical trials. (2) A further £5 million (additional to a previous £9 million investment in clinical-scale mRNA manufacturing) to support the Centre for	See Government news story **[Exhibit: JH7/35 INQ000309630]**.

[6] A study by the National Immunisation Schedule Evaluation Consortium conducted across 9 National Institute for Health Research support sites.

	Process Studies ("CPI") to create a library of vaccines that will work against Covid-19 variants for possible rapid response deployment. (3) £22 million to fund the world's first trial of interchanging different vaccines as part of a two-dose regime, and for a new internationally significant study to assess the effectiveness of the different vaccines as a third dose (COV-BOOST and Com-COV trials).	
20 March 2021	Additional UK Government funding of £47.6 million announced for VMIC to support the delivery of the facility.	See press release **[Exhibit: JH7/36 INQ000309631]**.
28 April 2021	UK Government purchased an additional 60 million Pfizer/BioNTech COVID-19 vaccines to support the booster vaccination programme.	See press release **[Exhibit: JH7/37 INQ000309635]**.
5 May 2021	UK Government announced investment of £29.3 million through the VTF in PHE's new testing facilities at Porton Down, to fast-track COVID-19 variant vaccines.	See press release **[Exhibit: JH7/38 INQ000309636]**.
28 May 2021	MHRA approval of Janssen's COVID-19 vaccine.	See press release **[Exhibit: JH7/39 INQ000309637]**.
11 June 2021	UK Government announced it will donate 100 million surplus coronavirus vaccine doses to the world within the next year.	See Government news story **[Exhibit: JH7/40 INQ000309641]**.
14 June 2021	Sir Richard Sykes appointed as the new chair of the VTF.	See press release **[Exhibit: JH7/41 INQ000309642]**.
28 July 2021	FCDO announced the UK will begin donating 9 million COVID-19 vaccines bilaterally and offered to COVAX.	See press release **[Exhibit: JH7/42 INQ000309651]**.

23 August 2021	UK Government agreed to purchase 35 million more doses of the Pfizer/BioNTech vaccine, to be delivered from the second half of 2022.	See news story **[Exhibit: JH7/43 INQ000309653]**.
3 September 2021	UK Government announced that the UK and Australia will share 4 million COVID-19 vaccine doses to benefit each other's vaccine rollout programmes.	See news story **[Exhibit: JH7/44 INQ000309654]**.
22 September 2021	UK Government announced that the UK and South Korea will share over 1 million COVID-19 vaccine doses to benefit each other's vaccine rollout programmes.	See press release **[Exhibit: JH7/45 INQ000309658]**.
2 December 2021	UK Government announced it had signed new contracts through the VTF to buy a total of 114 million additional Pfizer/BioNTech and Moderna doses for 2022 and 2023.	See Government news story **[Exhibit: JH7/46 INQ000309670]**.
2 December 2021	COV-BOOST clinical trial finds booster shots significantly strengthen immunity to COVID-19.	See COV-BOOST and Lancet articles respectively **[Exhibit: JH7/47 INQ000412459 and Exhibit: JH7/48 INQ000412452]**.
30 December 2021	UK Government confirmed that it had met its target to donate 30 million coronavirus vaccine doses by the end of 2021, as part of the UK's pledge to donate 100 million doses to the world.	See press release **[Exhibit: JH7/49 INQ000309666]**.
1 February 2022	First Human Challenge Programme clinical paper published.	See published paper **[Exhibit: JH7/50 INQ000309681]**.
3 February 2022	MHRA approval of Novavax's COVID-19 vaccine.	See press release **[Exhibit: JH7/51 INQ000309682]**.
21 February 2022	A new UKHSA research facility opened at UKHSA's Porton Down site as part of a new Vaccine Evaluation Centre.	See UKHSA news story **[Exhibit: JH7/52 INQ000309686]**.

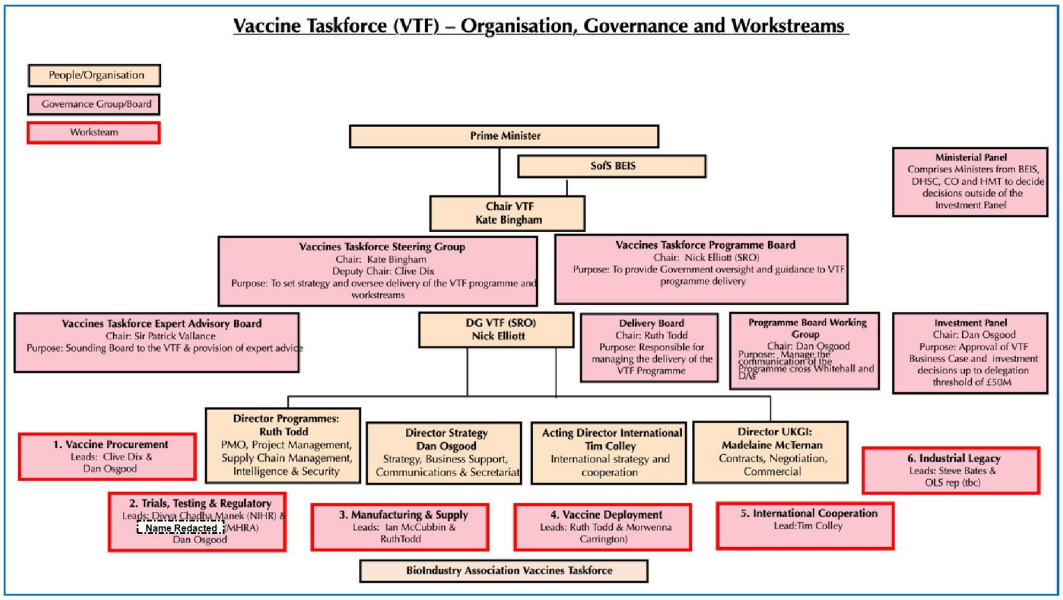
31 March 2022	UK Government announced a grant of £15.9 million to chemical producer Croda International Plc, a British speciality chemicals company, to increase the UK's capacity to manufacture key vaccine ingredients for mRNA vaccines	See press release **[Exhibit: JH7/53 INQ000309691]**.
14 April 2022	MHRA approval of Valneva's COVID-19 vaccine.	See MHRA press release **[Exhibit: JH7/54 INQ000412457]**.
15 June 2022	UK Government announced that core functions of the VTF will move to UKHSA and the OLS.	See Government news story **[Exhibit: JH7/55 INQ000348128]**.
22 June 2022	UK Government announced that Moderna was to open a vaccine research and manufacturing centre in the UK.	See press release **[Exhibit: JH7/56 INQ000309694]**.
1 October 2022	Transfer of key vaccine supply responsibilities of the VTF to UKHSA, the OLS and DHSC.	See Government news story **[Exhibit: JH7/55 INQ000348128]**.

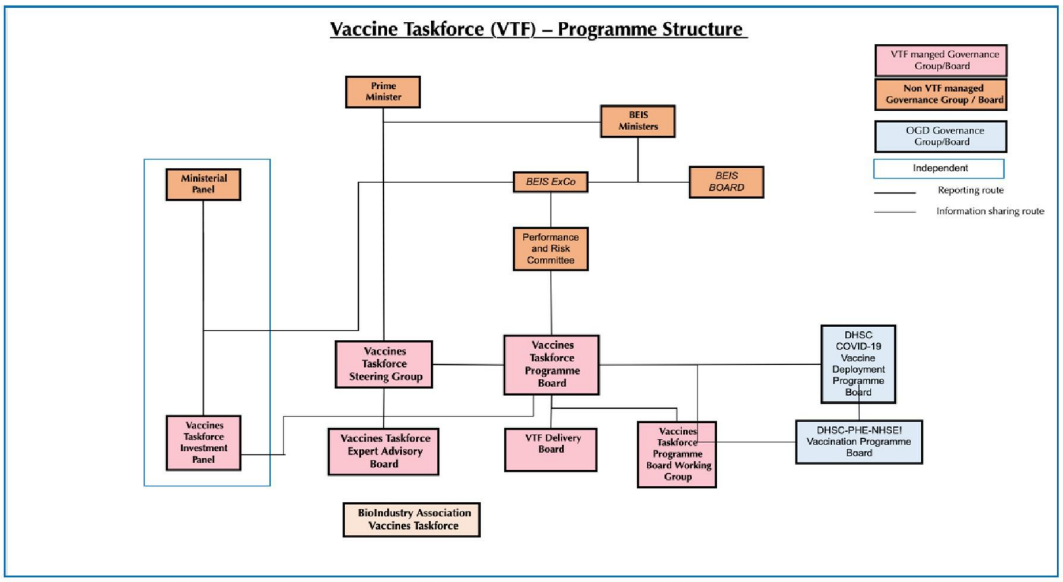
Section 4: THE STRUCTURE, LEADERSHIP AND PROCESSES OF THE VTF

4.1. The Inquiry has requested information about the structure of the VTF, key individuals responsible for its operation and with whom the VTF interacted. It has also asked about the processes which the VTF operated, including in relation to decision-making, funding, accountability and in dealing with the devolved nations.

Decision-Making Structure and Leadership

4.2. The VTF's key decision-making structures are set out in the two organograms dating from July 2020 below (taken from the VTF Governance Overview PowerPoint **[Exhibit: JH7/57 INQ000410496]**). An update to the VTF's Governance Overview, further detailing the structure, was produced in January 2021 **[Exhibit: JH7/58 INQ000412428]**.





4.3. The key bodies were:

(1) VTF Steering Group.

(2) VTF Programme Board.

(3) VTF Delivery Board/VTF Delivery Group.

(4) Ministerial Panel.

(5) BEIS Projects and Investments Committee.

(6) Investment Panel.

4.4. While we discuss below the key figures in the VTF, the Inquiry has been provided with details of the members of the VTF Steering Group and senior civil servants (or equivalent-level contractors) holding specific roles within the VTF, from its establishment in April 2020 to the transition of VTF responsibilities to UKHSA, DHSC and the OLS in October 2022. It is worth noting that there was extensive cross-pollination across the various key decision-making bodies, with individuals participating in more than one body.

4.5. The VTF was led by a Steering Group, comprising industry experts and the senior leadership of the VTF. Dame Kate Bingham chaired the Steering Group until December 2020, with Dr Clive Dix as Deputy Chair. Sir Richard Sykes succeeded Dame Kate as Chair in June 2021 (Dr Dix acted as interim Chair between the two appointments).

4.6. Four Directorates sat below the Steering Group:

(1) strategy;

(2) international;

(3) commercial (to lead negotiations with suppliers);

(4) and programmes (to oversee the day-to-day delivery of the commercial agreements made by the VTF).

4.7. These Directorates were led by Nick Elliott as VTF Director General and Senior Responsible Owner ("SRO"[7]) until December 2020, following which Madelaine McTernan became VTF Director General and SRO of the Programme. Lower-tier governance was also in place to support the VTF's Directors and other members of its leadership team to manage day-to-day activity.

4.8. The VTF Steering Group provided strategic oversight of the VTF's work and specifically its six workstreams: vaccine procurement, trials testing and regulatory, manufacturing and supply, vaccine deployment, international cooperation, and industrial legacy (members of the Steering Group led on these workstreams). The VTF Steering Group made recommendations to the VTF Programme Board and Ministers. It acted as an escalation point for decisions on strategy and for managing programme-level risks and issues. As well as the Chair and Deputy Chair, its initial membership included the Director General, Directors of the four Directorates, representatives from industry, the NIHR, MHRA, and DHSC (Professor Sir Jonathan Van-Tam). The Steering Group was

[7] The SRO is the person ultimately accountable for ensuring that a project or programme is governed effectively and delivers on its objectives.

supported by the Expert Advisory Board, whose expertise were drawn from industry, academia and regulatory bodies. This board was stood down once other structures were in place. See the Steering Group's Terms of Reference **[Exhibit: JH7/59 INQ000309558]** and VTF Governance Overview **[Exhibit: JH7/57 INQ000410496]**.

4.9. The membership of the VTF Steering Group evolved over time and, following changes including the MHRA stepping back in July 2020 (explained later in this statement) and the creation of a new Onshoring Directorate in 2021, eventually consisted of:

(1) Chair;

(2) Director General and five Directors covering the VTF's strategy, commercial, vaccine supply, onshoring and international functions;

(3) Scientific adviser;

(4) Manufacturing adviser;

(5) and Clinical and public health adviser (DCMO).

4.10. The VTF Programme Board, chaired by the VTF Director General and SRO, was established to provided cross-Government oversight and guidance to VTF programme delivery. Its membership included Permanent Secretaries from BEIS, the MOD, as well as senior officers from DfID, DHSC and Cabinet Office (including the Chief Commercial Officer). The Chair of the Steering Group and the Directors of the four Directorates also sat on the VTF Programme Board. The Board reported to BEIS and was responsible for ensuring the delivery of the VTF programme and its objectives, and made decisions on any changes of programme scope, timescales and plans, and the treatment of cross-cutting risks, issues, and dependencies. See the Programme Board Terms of Reference **[Exhibit: JH7/60 INQ000309560]**.

4.11. The VTF Delivery Group, chaired by the VTF Director of Programmes (one of the four Directorates), had oversight of all VTF programme workstreams, and was responsible for managing the delivery of the VTF programme. The Delivery Group "*provided a first line of defence assurance on policy development, delivery and governance of the VTF.*" Where decisions or issues could not be resolved within the Delivery Group, these were escalated to the VTF Programme Board. See the Delivery Group Terms of Reference **[Exhibit: JH7/61 INQ000309559]**.

4.12. The Ministerial Panel provided commercial and financial approvals for vaccine procurement contracts over £150 million, bringing together Ministers from relevant departments "*to support responsive decision-making on investments ... at the pace*

required for the ongoing commercial negotiations". The Secretary of State for BEIS chaired this Panel and was joined by the Secretary of State for DHSC, the Chief Secretary to the Treasury and the Minister of State for Cabinet Office. See the Panel Terms of Reference **[Exhibit: JH7/62 INQ000309566]**.

4.13. The BEIS Projects and Investment Committee ("PIC") initially reviewed all VTF investments prior to submission for Ministerial approval. Subsequently, the VTF Investment Panel, established in September 2020, took responsibility for signing off business cases up to £150 million, provided the spend was not novel, contentious, or repercussive. The BEIS PIC continued to scrutinise business cases which fell outside these criteria before they were submitted to the Ministerial Panel for final sign-off. Membership of the VTF Investment Panel included the Directors of the four Directorates as well as representatives from BEIS, Cabinet Office, and HM Treasury. See the Investment Panel Terms of Reference **[Exhibit: JH7/63 INQ000330759]**.

Ministerial Oversight

4.14. As the organogram above[8] shows, the Chair reported directly to the Prime Minister as well as to the Secretary of State for BEIS. In November 2020, the Rt Hon Nadhim Zahawi MP was appointed as the Minister for COVID Vaccine Deployment, in a joint Ministerial role between BEIS and DHSC, to oversee the work of the VTF nationally, as well as the deployment of the vaccine in England. That provided additional Ministerial oversight, to support the work of the Secretaries of State in BEIS and DHSC.

4.15. Joint responsibility between BEIS and DHSC for the work of the VTF was established in March 2021, with Ministerial accountability to Parliament for core VTF activity split across departmental lines: vaccine supply and international distribution was overseen by DHSC, and onshoring of vaccine capability by BEIS. Primary Cabinet-level Ministerial responsibility moved from the Secretary of State for BEIS to the Secretary of State for DHSC. The change did not alter the role of the VTF and the Minister for COVID Vaccine Deployment continued to oversee the VTF across the two Departments. See Government press release **[Exhibit: JH7/34 INQ000309629]**.

Funding of the VTF

[8] At paragraph 4.2.

4.16. Following the submission of a "Programme Business Case", HM Treasury agreed, in a letter dated 11 September 2020, a ring-fenced funding of £5.23 billion to cover the costs of the programme through to the end of the 2022/23 financial year. In doing so, HM Treasury set out in detail the governance and accountability processes required as conditions of funding. HM Treasury also agreed a delegated threshold of £150 million. See letter from HM Treasury **[Exhibit: JH7/64 INQ000330586[redacted]]**.

4.17. Subsequently, HM Treasury, in the spending review published on 25 November 2020, accepted a request for additional funding for the VTF. This took the VTF budget to £6.1 billion to the end of the 2022/2023 financial year. See HM Treasury letter **[Exhibit: JH7/65 INQ000232123]**.

4.18. On 21 July 2021, a funding agreement was received from HM Treasury, which agreed an increase of funding for the VTF programme to £9.35 billion running through to the end of the 2022/23 financial year. See HM Treasury letter **[Exhibit: JH7/65 INQ000232123]**.

4.19. The VTF, like all parts of the UK Government, was bound by the established rules of managing public money and subject to Accounting Officer clearances. All projects and programmes within the VTF required oversight and approval, via business cases overseen by the BEIS PIC at the development stage, ahead of submission for consideration and approval by the Investment Panel or Ministerial Panel. Whilst the programme adhered, wherever possible, to the standard BEIS PIC process, an expedited PIC process was also created to support the pace required for COVID-19 business cases produced by the VTF. This reduced approval review times from 4 weeks to 7-9 days, without omitting any of the standard elements of the review. See the Ministerial Panel and Investment Panel processes document **[Exhibit: JH7/66 INQ000412424]**.

4.20. Pre-pandemic business-as-usual spend for BEIS saw business cases considered through the BEIS Commercial Process or BEIS Commercial Assurance Board for spend under £20 million. If over £20 million, then business cases would be reviewed through the BEIS PIC and Ministers. The VTF had unique delegated spending arrangements designed to help it work at pace:

(1) The VTF SROs (both Nick Elliott and Madelaine McTernan) had delegated spending authorisation of up to £50 million. See Nick Elliott's appointment letter **[Exhibit: JH7/67 INQ000412430]**.

(2) As outlined above[9], spending of up to £150 million was overseen by the VTF Investment Panel (and previously by BEIS PIC), provided that the spend was not novel, contentious, or repercussive.

(3) Spends of £150 million or more were approved by the VTF Ministerial Panel. Business cases went through an expedited approval at BEIS PIC and then onto the VTF Ministerial Panel, where HM Treasury and Cabinet Office approvals were granted through senior official and Ministerial representation.

VTF independence

4.21. The VTF was enabled to operate at a much greater pace than would usually be possible within standard Civil Service structures, for example through the availability of budget delegations significantly above what would be acceptable under normal circumstances. However, while the VTF developed close working relationships with industry, this was within clearly defined commercial boundaries. Most importantly, the VTF's activities were overseen by Ministers and, through that oversight the VTF, like all Government departments, accountable to Parliament.

VTF conflict of interest management

4.22. As COVID-19 vaccines were an asset of strategic national importance, and all team members regularly held, or had access to, commercially sensitive information as part of their work, the VTF established an enhanced conflict of interest policy as an early priority. See conflict of interest policy **[Exhibit: JH7/68 INQ000330737]**. This policy applied to all members of the VTF, including non-civil servants employed as contractors or consultants, and set out how potential conflicts would be addressed. In addition, all team members held appropriate security clearance.

[9] At paragraph 4.13.

The work of the VTF in relation to the Devolved Nations

4.23. Procurement of medicines is usually a devolved competency under current devolution agreements, meaning Scotland, Wales, and Northern Ireland buy their own medicines, although all vaccines (except influenza) are procured centrally on behalf of all four nations. For COVID-19 however, the UK Government and the Devolved Governments of Scotland, Wales and Northern Ireland reached agreement early in the pandemic that the VTF would act on behalf of all four nations in its pursuit of a vaccine.

4.24. The Governments of the four nations entered into individual agreements so that the UK Government acted, as an agent, on behalf of the Devolved Governments for the purpose of purchasing COVID-19 vaccinations and antibodies (including entering into any related manufacturing and supply agreements). See agreements for Scotland, Wales, and Northern Ireland respectively: **[Exhibit: JH7/69 INQ000309562]**; **[Exhibit: JH7/70 INQ000309563]**; **[Exhibit: JH7/71 INQ000309564]**. These agency agreements were revised in December 2021 to replace reference to PHE with UKHSA and by updating the vaccine projects listed in the agreement to reflect UK-approved COVID-19 vaccines and additional projects. These revised agreements, and a proposal for the VTF to continue to procure COVID-19 vaccines and antibodies on behalf of the Devolved Governments through to Winter 2024, were agreed by the respective Governments between December 2021 and January 2022.

4.25. On a day-to-day basis, supply colleagues across all four UK nations worked closely to ensure that health services across the UK were working from the same set of information and assumptions. Examples of the VTF's contribution to this collaboration included the sharing of short and medium-term supply projections from suppliers, to enable health services across the UK to plan for the supply arriving to them. Further detail on the VTF's work to support vaccine delivery in the devolved nations is provided elsewhere in this statement.

Section 5: DEVELOPMENT, PROCUREMENT, MANUFACTURE AND APPROVAL OF VACCINES

5.1. The Inquiry has requested information as to how the VTF endeavoured to accelerate the development, procurement, manufacture, and approval of safe and effective COVID-19 vaccines. In undertaking its work, the VTF recognised that:

(1) Given global competition there was a need to move quickly to secure the raw materials, equipment and manufacturing slots required for large scale manufacturing.

(2) The pace at which the pandemic was evolving meant that all involved needed to work in a flexible and adaptable way.

(3) Rapid access to expert advice across a range of disciplines was critical including through involving expertise from both the public and private sectors.

5.2. Working with others in Government and in the private sector, the aim of Government was to reduce the usual development timeline for a vaccine to approximately 12-18 months through the VTF. The VTF established individual project teams which worked directly with relevant third parties (such as vaccine developers, manufacturers, and others) on matters such as clinical development, processes for enabling accelerated regulatory submissions and assessments, manufacturing, sourcing of participants for clinical trials, security and logistics. The VTF was able to provide extensive support to vaccine developers and to work more closely with the vaccine industry than Government procurement functions had done previously in areas such as manufacturing and supply chain management (the latter involving cross-working with PHE/UKHSA).

Procurement of the initial VTF vaccine portfolio

5.3. When the VTF was established, the likelihood of any individual COVID-19 vaccine candidate proving to be both safe and effective, was judged to be low. In June 2020, the likelihood of any individual vaccine proving safe and effective was estimated at between 5% (pessimistic scenario) and 10% (optimistic scenario). A first-generation vaccine may have been only partially effective meaning a second generation of vaccines might have been needed. To maximise the overall likelihood of finding at least one safe and effective vaccine, a multiple "*shots on goal*" approach was adopted (endorsed by the expert advisors to the VTF). The VTF therefore set out to secure a portfolio of promising vaccine candidates that could be in clinical trials by 2020 and had the potential for delivery in 2021.

5.4. A relevant factor was the need to procure sufficient doses of vaccine to ensure that the UK was able to be effectively vaccinated as soon as possible. PHE/UKHSA vaccine and

clinical experts in the JCVI Secretariat provided figures to the VTF, informed by interim advice from the JCVI, which suggested a priority population of 30 million.

5.5. A staged process was used to identify vaccine candidates. The VTF established a vaccine assessment team, whose members had clinical, immunology and manufacturing expertise, which worked to reduce an initial list of 190 potential vaccine candidates to 41 candidates deemed suitable for further investigation. At the next stage, the list of candidates was further reduced to 23, which were then subject to a due diligence exercise. That exercise included analysis of the following criteria for vaccine selection:

(1) Modality – to ensure the greatest chance of delivering an effective vaccine for population protection, different types of vaccines using different underlying technologies (platforms) were actively considered. This was important to mitigate the risk that if one vaccine type failed, other vaccines using the same technology type would also fail. The different vaccine technologies included use of viral vectors, nucleic acid vectors and protein/adjuvant combinations.

(2) Target – the specific target or antigen against which the vaccine was directed, such as the spike protein or proteins M, E and N.

(3) The immune response and protection thought likely to be generated against the virus.

(4) Route of administration of the vaccine (such as injection, oral or nasal routes).

(5) Safety - of the investigative vaccine.

(6) Timing - ongoing consideration of when each of the potential vaccine products was likely to be shown to be effective and safe and available for practical use in the population.

(7) Scale – the potential for rapid mass production and deployment (including cold chain distribution and logistics) once proven to be safe and clinically effective.

5.6. Commercial discussions with individual vaccine developers followed on from the identification and assessment of vaccine candidates providing the best prospects.

Funding for vaccine development was subsequently allocated on the basis of due diligence findings, in-depth discussions with vaccine developers, and the need to have a broad portfolio of vaccine contenders across multiple modalities. While cost-considerations and value for money were considered, priority was given to successful delivery at pace.

5.7. The VTF secured access to a portfolio of seven vaccines through this process from the following suppliers (the trade name of the vaccine is shown in brackets):

(1) Janssen (Jcovden).
(2) Moderna (Spikevax).
(3) Novavax (Nuvaxovid).
(4) Pfizer/BioNTech (Comirnaty).
(5) Sanofi/GSK (VidPrevtyn Beta).
(6) Oxford/AstraZeneca (Vaxzevria).
(7) Valneva (VLA2001).

5.8. The VTF also signed Heads of Terms with CureVac and funded development of a self-amplifying RNA ("saRNA") vaccine at Imperial College London but did not progress to procurement for these vaccines.

5.9. In line with MHRA requirements for all organisations in the UK which manufacture, assemble, import or distribute medicines, and in order to procure and distribute vaccines, the VTF (through BEIS) was required to secure from the MHRA a Wholesale Distribution Authorisation ("WDA"). The MHRA are better placed to explain the criteria which must be satisfied before it grants a WDA. A conditional WDA (Human) licence was granted by the MHRA on 17 July 2020 and subsequently confirmed in September 2020.

Procurement to meet booster vaccination requirements

5.10. Following the success of cross-system work to develop and deploy the first vaccines against COVID-19 in late 2020 and early 2021, the focus of the VTF evolved to preparing for the need for booster vaccination and the potential impact of COVID-19 variants. The VTF initiated projects to investigate vaccines to tackle virus variants in late 2020 and early 2021 in response to the capacity of coronaviruses for mutation and immune evasion, including Project COVER and clinical trials and assays work with DHSC and the NIHR (discussed further below).

5.11. These projects, alongside ongoing discussion with vaccine developers around their plans to develop vaccines to tackle virus variants, informed the VTF's approach to procuring booster vaccines. That approach was updated as more information was received.

5.12. An overview of the contractual arrangements the VTF made with vaccine developers is set out later in this statement. For present purposes, those arrangements allowed the VTF to exercise contractual options to procure further vaccine doses. The VTF also began discussions to procure additional doses of vaccines outside of these options to support the proposed booster strategy. So, in April 2021 and then August 2022, Ministers approved the purchase respectively of an additional 20 million doses and a further 35 million doses of the Pfizer-BioNTech vaccine for the 2022 booster programme.

5.13. On 26 November 2021, the Omicron variant was declared a Variant of Concern by WHO. Following discussions among senior decision-makers and clinical advisors, including input from the JCVI and the Chief Medical Officer, a business case was put to Ministers on 28 November 2021 setting out the plan for a "*reasonable worst case scenario*" in 2022 and 2023, and recommending the purchase of additional doses of the Pfizer and Moderna mRNA vaccines. Following Ministerial approval, in December 2021, the Government announced the purchase of a further 114 million doses of mRNA vaccines (from Pfizer/BioNTech and Moderna) in light of the emergence of the Omicron variant to support future campaigns in 2022 and 2023. See announcement **[Exhibit: JH7/46 INQ000309670].**

5.14. The VTF also procured sufficient doses of COVID-19 vaccines to support the ongoing offer of a first and second primary dose of COVID-19 vaccine that remained open to the UK population throughout the pandemic. The offer for a first and second dose of COVID-19 vaccine ended on 30 June 2023 following JCVI advice that, from Autumn 2023, a primary course COVID-19 vaccination should consist of a single dose of COVID-19 vaccine. See the Health Secretary's statement at **[Exhibit: JH7/72 INQ000412447]**. Eligibility for the offer of primary vaccination was the same as for an Autumn 2023 booster vaccination. See JCVI statement at **[Exhibit: JH7/73 INQ000412448]**.

5.15. In February 2022, Ministers agreed to hold sufficient "surge" inventory to provide one vaccine dose to everyone in the UK until the end of 2022 in case vaccination of the whole population was required. In February 2023 the decision was taken to change the

policy on the appropriate contingency stock from 64 million (enough to boost the entire population) to 7.5 million doses (enough to boost those in the highest risk groups while procuring further inventory if required for the wider population).

Manufacturing

5.16. It was recognised at an early stage that the UK did not have the capacity to manufacture enough vaccines for the whole population by itself and was reliant on imports for vaccines and other biopharmaceutical products. It was also recognised that a global shortage of the "fill and finish" capacity, needed to put formulated vaccine product into vials, could cause a bottleneck in supply. As a result, the VTF took early steps to secure and scale up the UK's vaccine manufacturing capabilities.

5.17. Prior to the pandemic, plans had been put in place to expand the UK's vaccine manufacturing capacity through development of the Vaccines Manufacturing and Innovation Centre ("VMIC") in Harwell in Oxfordshire, funded through UK Research and Innovation ("UKRI"). Additional funds were invested in VMIC, through the VTF, so that the facility was able to open in Summer 2021, a year ahead of schedule and with an expanded capability.

5.18. While VMIC was being constructed, the VTF provided funding for a rapid deployment facility which was described as "virtual VMIC" (or "vVMIC"). This focused on the existing manufacturing facilities available at Oxford Biomedica (a contract development and management organisation ("CDMO")[10]) where new bioreactors were temporarily located. These bioreactors were to be moved to VMIC when it was completed. There was similarly early investment in fill and finish capacity at the manufacturing facility operated by Wockhardt (an Indian pharmaceutical company) in North Wales. Both sites proved vital to the UK supply chain of the Oxford-AstraZeneca vaccine, with Oxford Biomedica producing drug substance for over 76 million doses and Wockhardt providing fill and finish for over 87 million doses **[Exhibit: JH7/03 INQ000283321]**.

5.19. VMIC is an example of the use of funding, through the VTF, not only as part of the immediate response to the pandemic but with a view to developing resilience over the longer term. Other examples are the financial support provided to the CPI in Darlington

[10] A CDMO provides services to other pharmaceutical companies including, for example, manufacturing at commercial scale.

to develop mRNA manufacturing capability, and the CGTC facility in Braintree. See published review of the VTF **[Exhibit: JH7/03 INQ000283321]**. As responsibility for onshoring vaccine manufacture now lies with the OLS, its parent department DSIT is better placed than UKHSA to assist the Inquiry with questions as to the sale of VMIC and vaccine manufacturing capacity (including the work of CPI and CGTC) in the UK.

Development and clinical studies

5.20. The VTF supported DHSC, NIHR and the MHRA to facilitate the rapid delivery of clinical trials and produced a document outlining the UK's research offer for vaccine developers in June 2020[11] **[Exhibit: JH7/74 INQ000489905]**. The UK's health research infrastructure was able to host several important trials of COVID-19 vaccines. Indeed, with the exception of the Pfizer/BioNTech vaccine, all the developers in the UK's original vaccine portfolio conducted some of their studies into the safety and efficacy of their product in the UK.

5.21. A key challenge was the lack of scalable mechanisms for the recruitment of the numbers of healthy volunteers that were needed for large-scale clinical trials, including vaccine efficacy studies. As a result, the speed of early enrolment was not as rapid as it could have been and was expected to become a bigger issue as the number of vaccine trials needing volunteers increased.

5.22. To address this, the VTF collaborated with NIHR Clinical Research Network, all four UK nations and NHS Digital to create the world's first national citizen registry to accelerate the enrolment of volunteers into clinical trials in July 2020 (the Permission to Contact programme). This programme was funded by the VTF and delivered by the NIHR and was used for both Government-commissioned clinical trials and developer trials, including by Oxford/AstraZeneca, Novavax and Janssen. The digital approach to building the NHS Permission to Contact registry allows any member of the UK public interested in taking part in clinical trials for vaccines to sign up, giving their permission to be contacted about upcoming trials.

[11] The version of this document exhibited here is in draft but is in the final form as available to UKHSA.

VTF-funded clinical studies

5.23. The VTF funded clinical studies to look at the effect of different combinations of vaccines. The VTF worked closely with the NIHR, DHSC and Professor Jonathan Van-Tam to identify gaps in knowledge of the vaccines and consider where Government-backed trials could fill these. The VTF funded clinical studies to look at the effect of different combinations of vaccines. These studies were undertaken by members of the National Immunisation Schedule Evaluation Consortium ("NISEC") and delivery was project managed by the VTF. They included:

(1) Com-COV and Com-COV2: Clinical studies conducted by the Oxford Vaccine Group to assess the effectiveness of using a different approved vaccine for the second dose to the first dose (Pfizer/BioNTech and Oxford/AstraZeneca in Com-COV and Pfizer/BioNTech and Oxford/AstraZeneca with Moderna or Novavax in Com-COV2) versus receiving the same vaccine for first and second dose.

(2) COV-BOOST: Clinical study conducted by the University Hospital Southampton NHS Foundation Trust to assess the effect of using one of seven COVID-19 vaccines as a third dose following two doses of either the Oxford/AstraZeneca or Pfizer/BioNTech vaccines. The results of this study were published in December 2021.

(3) Preg-CoV: Clinical study conducted by St George's Vaccine Institute aimed at developing evidence-based guidelines for vaccinating pregnant women.

(4) ComFluCOV: A collaboration between the University of Bristol, University Hospitals Bristol and Weston NHS Foundation Trust and the University of Oxford, this study examined the safety of administering COVID-19 vaccines at the same time as Winter flu vaccines.

(5) OCTAVE DUO: This study was co-funded with UKRI and undertaken by the OCTAVE (Observational Cohort Trial-T-cells Antibodies and Vaccine Efficacy in SARS-CoV-2) consortium. Its purpose was to examine the efficacy of booster doses in immunocompromised patients.

5.24. The data produced by these studies was available to the JCVI when advising in relation to the vaccine programme (one example being the COV-BOOST study, see **[Exhibit: JH7/75 INQ000412453]**).

The Assays Capability Project

5.25. Through BEIS, the VTF entered into an agreement with PHE by which the latter, using its laboratory facilities at Porton Down, would conduct assays to ensure availability of evidence for the regulatory approval process, vaccine supply decisions and health policy advice. The VTF funded work to increase laboratory capacity at PHE/UKHSA to support the development of assays and PHE/UKHSA to undertake critical studies including:

(1) Clinical testing to support regulatory licensing of new COVID-19 vaccines.

(2) Laboratory-based evaluation of vaccines to inform Government decisions on vaccination policy.

(3) Performing risk assessments on Variants of Concern, including those with potential for "vaccine escape" (i.e., the potential for the evolution of variants that render vaccines less effective).

5.26. This capability was available to the COVID-19 vaccine developers within the VTF portfolio, and the human challenge and clinical studies (discussed elsewhere in this statement). Having the tests of the vaccines in the VTF's portfolio conducted in PHE/UKHSA laboratories, including evaluation against new Variants of Concern and interest, meant that the UK had early access to high quality robust data that was vital for shaping the COVID-19 vaccination strategy.

5.27. As the emergence of new viral variants continued and Variants of Concern were designated, testing for antibody neutralisation in the laboratories at PHE/UKHSA Porton Down became more important. Serum samples[12] taken from participants enrolled in the VTF-funded NISEC studies, and from developers (with their agreement via the VTF project teams), were tested urgently and the data shared with Professor Jonathan Van-Tam, relevant senior clinicians and the VTF's senior leadership as rapidly as possible.

[12] Serum samples are derived from blood samples taken from individuals. These samples can be used to measure a range of biological parameters including aspects of the immune response to vaccination or infection with pathogens (e.g., COVID-19).

This provided early data to indicate the level of vaccine escape and helped inform the work of the OCMO, senior clinicians and VTF leaders.

5.28. Altogether, the VTF made available £65 million of investment funding for two new, state-of-the-art laboratory facilities at PHE/UKHSA Porton Down and to scale up its existing capabilities. See press release **[Exhibit: JH7/38 INQ000309636]**.

5.29. This investment increased PHE/UKHSA's existing capacity, quadrupling the number of serum samples that could be tested each week to measure the levels of COVID-19 virus antibodies produced in the blood from vaccines. Upon completion, both facilities were handed over to PHE/UKHSA. UKHSA has established the Vaccine Development and Evaluation Centre ("VDEC"), which builds on the existing clinical immunology capabilities at UKHSA Porton Down, and will help to maintain this critical capability beyond March 2024 when VTF support for these facilities ended with the potential to secure further funding through additional work with industry and academia.

Human challenge programme

5.30. A human challenge study (also described as a "characterisation study") is a carefully managed medical research study, during which volunteers are intentionally exposed to an infective agent in a safe way with healthcare support. Such an approach offered the chance to accelerate development of promising vaccines against COVID-19, potentially bringing them to the population more quickly.

5.31. In partnership with the NHS, academia[13] and the private sector, the VTF helped develop and fund a human challenge study for COVID-19. The study used a high-containment unit at the Royal Free Hospital, London. Healthy adult volunteers between the ages of 18-30 years were experimentally inoculated with COVID-19 with the aim of causing upper respiratory infection but with minimal or no illness and obtaining data on the course of the virus and the immune response to infection. Volunteers were monitored for at least a year after participating in the study to ensure their long-term wellbeing.

5.32. The first human challenge programme clinical paper was published on the pre-print server Research Square in January 2022 **[Exhibit: JH7/76 INQ000412440]**. It details the outcomes in 36 young, healthy participants with no immunity to the virus and shows

[13] The project was led by researchers from Imperial College London.

that experimental infection of volunteers is reproducible and resulted in no severe symptoms in healthy young adult participants, laying the groundwork for future studies to test new vaccines and therapeutics against COVID-19.

5.33. On 13 August 2021, a decision was made by the VTF Steering Group to complete the initial human challenge characterisation study but to discontinue funding thereafter for any further human challenge studies. The reasoning was that, following the success of the Oxford/AstraZeneca, Pfizer/BioNTech, and Moderna vaccines, priorities had changed from when the use of human challenge studies had first been proposed. See minutes from the VTF Senior Leaders' Meeting **[Exhibit: JH7/77 INQ000412423]**.

Approval of Vaccines

5.34. The approval of vaccines was a role for the MHRA as the independent regulator. However, the VTF worked with the MHRA, the OLS and DHSC to discuss opportunities to compress the vaccine approval processes and timelines, whilst ensuring that any approved vaccine was safe and effective (which was throughout a matter for the MHRA). In normal circumstances, a drug supplier would receive Marketing Authorisation (also known as a product licence) for a particular drug. Regulation 174 of the Human Medicine Regulations 2012 allows the Secretary of State for Health to permit the use of unlicensed medicines (including vaccines) to meet specified public health needs such as those arising from a pandemic. The VTF supported work by DHSC and the MHRA on the application of the temporary authorisation route under Regulation 174. See VTF presentation on Regulatory Pathways for COVID-19 Vaccine Candidates **[Exhibit: JH7/78 INQ000412422]**. It also worked with the MHRA to ensure that the UK regulatory system was understood by vaccine suppliers and reflected in their planning.

5.35. The VTF also worked to accelerate safe and effective vaccine development and approvals by coordinating across partners to drive the concurrent delivery of all vaccine development, manufacturing, approvals and deployment planning activities. Circumstances meant that the VTF could procure vaccines 'at risk' (i.e., before data on their safety and efficacy was available), ensuring that supply was ready for use by the NHS quickly following any approvals given by the MHRA where safety and effectiveness criteria were met. For example, the Pfizer/BioNTech vaccine was the first COVID-19 vaccine in the world to receive regulatory approval when the MHRA approved it on 2 December 2020, and it was first administered less than a week later, on 8 December 2020.

Overview of the VTF approach to contractual arrangements with vaccine developers

5.36. The overarching approach to the procurement of COVID-19 vaccines was based on the urgent need to acquire safe and effective COVID-19 vaccines and the "*multiple shots on goal*" principle. This, combined with the fact that COVID-19 was a novel pathogen against which no vaccine had ever been developed, and the risk appetite of the UK Government, meant that the UK Government was willing to make commitments and orders "*at risk*" before a proven and licensed efficacious vaccine product was manufactured.

5.37. In the circumstances, contracts were directly awarded to vaccine manufacturers on the basis of Regulation 32(2)(c) and (to a lesser extent) 32(2)(b)(ii) of the Public Contracts Regulations 2015. The VTF approached securing contracts with vaccine developers by treating each as a bespoke deal, rather than a competitive procurement activity. This approach recognised that each developer had a unique product that was potentially the only successful vaccine and allowed each deal to be tailored accordingly **[Exhibit: JH7/03 INQ000283321]**.

5.38. Orders were made on the basis of number of doses as opposed to specific named vaccines to allow flexibility as new vaccine products, such as those targeting new strains of COVID-19, became licensed and proved to be safe and effective. Contracts were worded to allow the VTF the flexibility to adapt purchases to vaccines against future variants. The UK Government provided an unlimited and broad indemnity for most losses arising from the products, including death and personal injury.

VTF vaccine portfolio

5.39. The remaining part of this section sets out an overview of arrangements entered into with individual vaccine developers and manufacturers.

Oxford/AstraZeneca

5.40. Prior to the formation of the VTF in April 2020, the University of Oxford had already received funding from the UK Government and CEPI to develop a vaccine against COVID-19. This work built upon earlier work funded by the UK Vaccines Network developing a vaccine against the Middle Eastern Respiratory Syndrome ("MERS")

coronavirus. The team at Oxford were keen to enter into an agreement with a commercial manufacturer to be able to manufacture their vaccine at scale.

5.41. The UK Government supported the University of Oxford in its negotiations for a commercial manufacturing deal with AstraZeneca. A partnership between Oxford and AstraZeneca was announced on 30 April 2020. On 17 May 2020, it was announced that Oxford had agreed a global licensing agreement with AstraZeneca, which meant that, if the vaccine was successful, AstraZeneca would work to make up to 30 million doses available by September 2020 for the UK, as part of an agreement to deliver 100 million doses in total. It was also announced that the UK Government would provide £65.5 million funding to support the vaccine being developed at the University of Oxford (see **[Exhibit: JH7/10 INQ000234369]**).

5.42. The VTF's assessment was that the Oxford/AstraZeneca vaccine was a strong candidate for the prevention of COVID-19 and that the manufacturing process was well planned for by AstraZeneca. Results of the Phase 1 & 2 clinical trials, published in the Lancet in July 2020, indicated no early safety concerns and strong immune responses (see **[Exhibit: JH7/79 INQ000231521]**).

5.43. Ministerial approval having been given to the purchase of 100 million doses of the Oxford/AstraZeneca vaccine, the Secretary of State for BEIS entered into a Vaccine Supply Agreement with AstraZeneca on 28 August 2020. In common with many vaccine developers with whom the UK Government was engaging, AstraZeneca considered the efforts and the activities it was undertaking to be extraordinary given the rapid development of a candidate vaccine, accelerated clinical testing, concurrent pursuit of interdependent activities and that it was operating during the pandemic on a "not for profit/no loss" basis. Rather than the standard terms that might apply in usual circumstances, here AstraZeneca were to use "Best Reasonable Efforts" to supply the vaccine.

5.44. On 30 December 2020, the MHRA approved the Oxford/AstraZeneca vaccine for use in the UK. See press release **[Exhibit: JH7/26 INQ000309616]**. As discussed above, the availability of a rapid deployment facility at Oxford Biomedica, as well as Wockhardt providing fill and finish capacity, was vital to the supply of the vaccine. The first vaccine outside a clinical trial was administered on 4 January 2021. From the initial order of 100 million doses of the Oxford/AstraZeneca vaccine, the Government took delivery of 99,755,240 doses (it was subsequently agreed that no further deliveries need be made).

Pfizer/BioNTech

5.45. Pfizer, based in the United States and one of the world's largest pharmaceutical companies, partnered with BioNTech, a biotechnology company based in Germany, to develop, under license, a programme of COVID-19 vaccine candidates, based on BioNTech's proprietary mRNA-based technology.

5.46. The VTF identified this vaccine candidate as one which was likely to be one of the first to receive regulatory approval with the potential that such approval would be given before the end of 2020. Indicative of the pace at which the VTF was able to operate, a binding agreement to supply 30 million doses of the Pfizer/BioNTech vaccine was publicly announced on 20 July 2020, four days after the Secretary of State for BEIS had given agreement to proceed. See press release **[Exhibit: JH7/13 INQ000309594]**. This was the first binding COVID-19 vaccine supply agreement signed by Pfizer with any Government in the world.

5.47. On 6 October 2020, the VTF Ministerial Panel approved the procurement of 40 million doses of the Pfizer/BioNTech vaccine. See Ministerial Panel readout at **[Exhibit: JH7/80 INQ000412419]**. Given the urgent need for a vaccine, the supply agreement allowed for an advance payment to support Pfizer and BioNTech's at-pace development, clinical trials and manufacture at risk.

5.48. On 2 December 2020, following advice from the Commission on Human Medicines (the Government's independent expert scientific advisory body), MHRA approved the use of the Pfizer/BioNTech vaccine in the UK. See press release **[Exhibit: JH7/23 INQ000309610]**. This approval was given on a "rolling review" basis, under Regulation 174 of the Human Medicine Regulations 2012. This was the first COVID-19 vaccine regulatory approval in the world. Deployment systems were already in place as the result of equivalent significant work by PHE/UKHSA, DHSC, the Devolved Governments and the NHS in each of the four UK nations to ensure vaccination could begin as quickly as possible following approval. As a result, the first vaccine (to be administered outside of clinical trials) was given less than a week later, on 8 December 2020.

5.49. Subsequently, it was decided to purchase further doses of the Pfizer/BioNTech vaccine:

(1) On 2 February 2021, the VTF Investment Panel agreed that 539,370 vaccine doses should be purchased through the COVAX joint procurement pool. This was intended to enable higher income countries to share the costs and risks of investing in a diverse vaccine portfolio. However, the UK obtained very few vaccines through this route because of the success of its procurement programme.

(2) On 29 March 2021, the VTF Ministerial Panel approved the purchase of an additional 40 million doses of the Pfizer/BioNTech vaccine (with a contingency option of an additional 20 million doses to be purchased at a later date), for revaccination over Autumn/Winter 2021/2022. 40 million doses was considered as being sufficient to cover the JCVI priority groups for revaccination, with the contingency of 20 million doses to be used should other vaccines in the UK vaccine portfolio prove unsuitable for use in the revaccination programme.

(3) On 9 April 2021, the VTF Ministerial Panel agreed that the contingency option should be exercised. This followed from advice received from the JCVI to preferentially offer the under-30s age group an alternative to the Oxford/AstraZeneca vaccine. This was as a result of a small number of cases of concurrent thrombosis (blood clots) and thrombocytopenia (low platelet count) in younger people, which had been reported following the administration of the Oxford/AstraZeneca vaccine. Increasing the UK's order of the Pfizer/BioNTech vaccine ensured that at least one approved vaccine would be available to revaccinate all adults in the Autumn if required.

(4) On 9 August 2021, the VTF Ministerial Panel approved the purchase of the additional 35 million doses of the Pfizer/BioNTech vaccine for the 2022 booster programme. Subsequently, on 30 November 2021, and to support a booster programme, the VTF Ministerial Panel approved the purchase of an additional 54 million doses of the Pfizer/BioNTech vaccine for 2022 and 2023 (alongside 60 million doses of the Moderna Vaccine).

5.50. As the COVID-19 virus mutated, with concern around the Omicron variant identified in November 2021, Pfizer and BioNTech began work on the creation of a bivalent vaccine. The VTF responded to this virus mutation ahead of the Autumn 2022 COVID-19 booster campaign, by sending a change control note to Pfizer on 18 August 2022, requesting a supply change to the new bivalent vaccine, subject to regulatory approval. This change

to the order was possible due to the early contractual work in securing doses of vaccine, rather than specific vaccine types. Pfizer/BioNTech were granted MHRA regulatory approval in the UK for its bivalent Original/Omicron booster vaccine on 3 September 2022. The change to the contract was signed by both parties on 5 September 2022, and the bivalent vaccine was rolled out at the start of the programme on 7 September 2022.

5.51. Authorisation for the use of the Pfizer/BioNTech bivalent vaccine in infants and children aged 6 months to 4-years-old, was granted by the MHRA on 6 December 2022. See MHRA news story **[Exhibit: JH7/81 INQ000412434]**. The JCVI met on 31 October and 1 November 2022 and, following confirmation of MHRA approval, issued advice on the offer of vaccines to those aged 6 months to 4-years-old, in a clinical risk group, on 9 December 2022. See published JCVI advice **[Exhibit: JH7/82 INQ000412435]**.

Sanofi/GSK

5.52. Sanofi Pasteur, based in France, and GSK, based in the UK, are leading pharmaceutical companies, well established in vaccine development, and proven in population-scale bulk supply. In April 2020, Sanofi and GSK entered into a collaboration and licence agreement to develop and manufacture the Adjuvanted Pandemic Vaccine, an adjuvanted recombinant protein vaccine for COVID-19. See press release **[Exhibit: JH7/83 INQ000412441]**.

5.53. On 29 July 2020, the Government announced that it had entered into an agreement to secure early access to the Sanofi/GSK vaccine. See press release **[Exhibit: JH7/15 INQ000309596]**.

5.54. The VTF's assessment was that the Sanofi/GSK vaccine candidate was one where there was high confidence in relation to delivery and anticipated efficacy. The companies had said that Sanofi's antigen was highly stable, and the manufacturing process was used for commercially available flu-vaccines. GSK's adjuvant was already in successful use with other vaccines. While delivery of the Sanofi/GSK vaccine was projected to be later than had been proposed for other vaccines in the VTF portfolio, its inclusion in the portfolio with its well-established norms, was considered as a balance to other, more novel and innovative vaccines, and therefore as providing a backstop vaccine.

5.55. With Ministerial approval, a Capacity Reservation Agreement was signed on 14 September 2020 to secure access to manufacturing capacity for up to 60 million doses

of the Sanofi/GSK vaccine. An Advanced Purchase Agreement was signed on 20 September 2021. It was anticipated that delivery of the vaccine would begin in the third quarter of 2021. However, delays to the timelines for clinical trials and regulatory processes pushed that date back to November 2022. Having missed the primary vaccination market, Sanofi/GSK created a variant vaccine (Beta monovalent) as a booster-only vaccine.

5.56. With Ministerial approval, in September 2021, the VTF reduced its original order from 60 million doses to 7.5 million doses (approximately 900,000 wildtype monovalent vaccines, with the remainder comprising Beta monovalent vaccines), the rationale being that the vaccine could potentially play a useful role in future adult booster campaigns. Subsequently, due to delays to clinical trials, the anticipated regulatory timeline and the short shelf-life of the wildtype vaccine stocks, the VTF decided to convert supply to Beta monovalent only.

5.57. The Sanofi/GSK vaccine was authorised by the MHRA on 21 December 2022 for use as a heterologous booster dose[14] given as a single injection in those aged 18 and over. See published decision **[Exhibit: JH7/84 INQ000408435]**. This vaccine was used in the Spring 2023 vaccination campaign and beyond, as set out in the JCVI advice of 22 February 2023 **[Exhibit: JH7/85 INQ000412455]**.

Janssen / Johnson & Johnson Innovative Medicine

5.58. Janssen, a pharmaceutical company based in Belgium, developed it's COVID-19 vaccine candidate based on their Adenovirus26 platform. Janssen's vaccine candidate was one of two adenovirus-based vaccines in the VTF portfolio (the other being the Oxford/AstraZeneca vaccine).

5.59. The VTF's assessment was that, as a vaccine candidate being developed by a highly experienced team with solid manufacturing experience and a well-developed supply chain, the Janssen vaccine was worth considering as part of a balanced portfolio. It was assessed as providing a low-risk contingency against the risk of significant delays to the supply and deployment of the Oxford/AstraZeneca vaccine and to other potential vaccines in the portfolio in quarters 3 and 4 of 2021, as well as providing options for

[14] Heterologous booster dose refers to the administration of a booster vaccine that is different to the vaccine previously administered.

potential 2022 deployment. The Janssen vaccine was also the only vaccine in the VTF portfolio that was initially developed as a single-dose regimen rather than two-dose, (although this was later amended to a two-dose regimen following Phase 3 clinical trials).

5.60. On 14 August 2020, the UK Government announced an in-principle agreement that secured 30 million doses of Janssen's vaccine. See press release **[Exhibit: JH7/18 INQ000309599]**.

5.61. Phase 1/2 clinical studies, on both young and older adults as well as individuals who had tested positive for presence of the virus in the blood, were undertaken in Belgium and the United States. Interim analysis from these trials was published on 25 September 2020 showing that the safety profile and immunogenicity after a single vaccination were supportive of further development. See Johnson&Johnson statement **[Exhibit: JH7/86 INQ000412443]**.

5.62. On 23 September 2020, Janssen announced the launch of its large-scale, pivotal, multi-country Phase 3 trial (ENSEMBLE) for its COVID-19 vaccine candidate. The Phase 3 clinical studies investigating either a single dose or two dose primary schedule were undertaken during late 2020 and early 2021 in parallel. See article **[Exhibit: JH7/87 INQ000412449]**.

5.63. The VTF Ministerial Panel considered the procurement of Janssen's vaccine on 18 December 2020 and approved procurement on 12 January 2021. On 15 January 2021, the VTF entered into an Advance Purchase Agreement with Janssen Pharmaceutica NV for the supply of 30 million doses. It should be noted that, as the Janssen vaccine was originally conceived as a single-dose regimen, this procurement was thought to provide equivalent population coverage to 60 million doses of other vaccines.

5.64. On 14 May 2021, Ministers agreed by correspondence to amend the contract and decrease the order size by 10 million doses. This decision was taken in response to manufacturing issues that meant Janssen were unable to deliver vaccines in quarter 3 2021 and contractual restrictions, originally instigated by Janssen, which prevented the Janssen vaccine being used for boosting. The Advance Purchase Agreement was subsequently amended and signed on 17 May 2021, reducing the order from 30 million to 20 million doses with the understanding that the ceded 10 million doses would be redirected by Janssen to COVAX.

5.65. As part of the UK's participation in COVAX, the UK was offered an option to purchase additional doses of the Janssen vaccine. The UK decided not to take up the option as this option offered limited advantage when assessed against existing orders and the UK's planning assumptions.

5.66. The Janssen vaccine was approved by the MHRA on 28 May 2021 as a single dose primary course. This was later revised to recommend a second dose of vaccine at least 2 months after the first dose to optimise protection. See MHRA decision **[Exhibit: JH7/88 INQ000361141]**.

5.67. Following JCVI advice on boosters, the VTF assessed that the 20 million Janssen vaccine doses that the VTF had procured were not needed for the domestic programme, and a decision was endorsed on 29 October 2021 by HM Treasury to donate the surplus doses to COVAX.

Novavax

5.68. Novavax, a biotechnology company based in the United States, developed its COVID-19 vaccine candidate, a recombinant nanoparticle vaccine combined with an adjuvant (Matrix M).

5.69. The VTF's assessment was that Novavax's vaccine was a credible candidate and there was confidence the company could run the proposed programme. On 14 August 2020, the Government announced an in-principle agreement that secured 60 million doses of the Novavax vaccine. See press release **[Exhibit: JH7/18 INQ000309599]**.

5.70. On 22 October 2020, the VTF Ministerial Panel, having agreed to proceed with a supply agreement, signed such an agreement with Novavax ending at the earliest on the 30 November 2023.

5.71. In February 2021, the UK decided to take up the offer to procure Novavax through COVAX and was allocated 14.7 million doses. These doses were subsequently donated to Gavi in May 2022.

5.72. The supply agreement required, as a baseline deliverable, issuance/grant of a Marketing Authorisation for the Product in the Territory for an indication in the Field by 31 January 2022. The Novavax vaccine was given regulatory approval for use in adults by the MHRA

on 3 February 2022. See the MHRA decision **[Exhibit: JH7/89 INQ000412444]**. Approval for use in 12-17-year-olds followed on 26 August 2022. See MHRA news story **[Exhibit: JH7/90 INQ000309700]**.

5.73. Following Ministerial approval, and given delays in supply, the changed vaccine landscape and vaccination requirements of the UK, the VTF obtained a contractual amendment reducing the number of doses from 60 million to be procured, to 1-16 million (signed on 1 July 2022). The amended agreement committed the UK Government to an order of 1 million doses only, the cost of which would be covered by the existing COVID-19 vaccine budget. The additional (up to) 15 million doses were conditional on the JCVI recommending the Novavax vaccine for the general adult or adolescent population by 30 November 2022 and 30 November 2023 and the Secretary of State for DHSC approving the recommendation.

5.74. A firm order of 1 million doses was delivered in August 2022. As the JCVI stated publicly on 3 September 2022, its recommendation for the Autumn 2022 booster campaign included that the Novavax vaccine "*may be used 'off-label' as a booster dose for persons aged 18 years and above when no alternative clinically suitable UK-approved COVID-19 vaccine is available*". The JCVI did not recommend the use of this vaccine for the Autumn 2023 booster campaign. As the agreed conditional events had not occurred, the additional (up to) 15 million doses were not delivered.

Valneva

5.75. Valneva, a biotechnology company based in France, developed its COVID-19 vaccine candidate using a whole inactivated virus vaccine technology, a well-established platform for developing effective vaccines.

5.76. The Valneva vaccine was the only inactivated whole virus candidate in the VTF portfolio. The VTF's assessment was that as a candidate for the portfolio, the Valneva vaccine represented a low-cost option being developed by a highly experienced team and brought an additional platform which was a well-established route for developing effective vaccines.

5.77. On 11 September 2020, the Ministerial Panel approved the decision to procure 60 million doses of Valneva's vaccine for delivery by the end of 2021. A Supply Agreement was signed on 13 September 2020. Part of the funding package was paid in advance to

support the expansion of Valneva's manufacturing facility in Livingston, Scotland. Initial funds were also used to support the Phase 1 and 2 clinical trials conducted by Valneva.

5.78. On 28 January 2021, the VTF Ministerial Panel approved the purchase of a further 40 million doses of the Valneva vaccine.

5.79. The VTF worked closely with Valneva to strengthen its critical path to regulatory approval. As already mentioned, the UK Government funded Valneva's Phase 1 (December 2020) and Phase 2 clinical studies (April 2021).

5.80. The low prevalence of the virus in the population and an anticipated decrease in the number of clinical trial participants made it more difficult for Valneva to complete the Phase 3 clinical trials needed to obtain the information required by the MHRA in order to consider the vaccine for conditional approval. The VTF and Valneva had originally agreed that such conditional approval would be in place by October 2021 (albeit it was for the MHRA to determine whether there was sufficient information to meet its criteria).

5.81. On 10 September 2021, having reached a point when it was clear that Valneva would not be able to supply doses of its vaccine as per the supply agreement of 13 September 2020, the VTF (on behalf of the Secretary of State for Health) notified Valneva of its intention to terminate that agreement. A settlement agreement was subsequently reached with Valneva. That some contracts were not pursued reflected a point made earlier in this statement i.e., that a portfolio approach was adopted to obtaining vaccines with contracts being placed with different suppliers, as well as the Government's wish to match supply to demand.

Moderna

5.82. Moderna Inc., a biotechnology company based in the United States, developed its proprietary COVID-19 vaccine candidate known as mRNA-1273. This was a monovalent vaccine.

5.83. While the VTF's assessment was that the Moderna vaccine was likely to be protective, the view was that further reassurance as to manufacturing capability was needed before a decision on investment could be made. On 6 August 2020, the VTF Delivery Board decided not to pursue procurement of the Moderna vaccine given the risk in commercial

terms, the need for Moderna to build new manufacturing capability and the timeline for deliveries.

5.84. On 6 October 2020, and with a view to obtaining some mitigation against failure of other vaccines, the VTF Ministerial Panel asked the VTF to continue negotiations and to bring a supply agreement back to the Panel for a final decision.

5.85. On 16 November 2020, Moderna published positive efficacy results from its Phase 3 studies of its potential COVID-19 vaccine, showing it to have nearly 95% efficacy. See the Government's response to Moderna publication **[Exhibit: JH7/91 INQ000309604]**; and the publication itself **[Exhibit: JH7/92 INQ000412456]**.

5.86. On 16 November 2020, the VTF Ministerial Panel gave approval for procurement of up to 7 million doses of Moderna's vaccine. The resulting agreement, made on 16 November 2020, guaranteed the delivery of 5 million doses in the second quarter of 2021 (March/April to June). There was the potential to increase this by an additional 2 million, subject to confirmation from Moderna.

5.87. The supply agreement put the UK Government in a better commercial position than previously envisaged. Further, by this time Moderna had developed its European supply chain and confirmed alliances with Lonza Group (based in Switzerland) and Rovi (based in Spain), so addressing the manufacturing capability concern.

5.88. On the 19 November 2020, Moderna confirmed they could supply the additional 2 million doses of their vaccine to the UK, bringing the total to 7 million. The necessary amendment agreement was made on 23 November 2020. Of the additional doses, 1 million doses were expected in April 2021 and the other 1 million doses in May 2021.

5.89. Moderna offered additional doses of their vaccine, available in the second and third quarters of 2021. The VTF Ministerial Panel decided that progress should continue towards acquiring the additional doses. On 31 December 2020, the VTF Ministerial Panel approved the purchase of an additional 10 million doses of Moderna's vaccine for delivery in the third quarter of 2021. The Panel decided not to purchase an additional 30 million doses of the vaccine due in the fourth quarter of 2021 as there was reassurance that vaccine coverage within the portfolio was sufficient and continued to provide a variety of options and approaches to vaccinate the UK population safely and efficiently throughout 2021.

5.90. On 31 December 2020, the second amendment agreement was entered into for the additional 10 million doses. It allowed for the possibility that the existing order of doses could be substituted for ones of a vaccine developed for a variant strain of the virus.

5.91. On 8 January 2021 the MHRA approved the use of Moderna's vaccine in adults aged 18 and over in the UK. See press release **[Exhibit: JH7/27 INQ000309618];** and MHRA published decision **[Exhibit: JH7/93 INQ000408426]**.

5.92. In April 2021, the UK received its first doses of the Moderna vaccine and roll out began on 7 April 2021.

5.93. On 17 August 2021 the MHRA extended the approval for use of the Moderna vaccine in 12–17-year-olds in the UK. See press release **[Exhibit: JH7/94 INQ000412445]**.

5.94. On 14 April 2022, the MHRA approved the vaccine to be extended for use in 6–11-year-olds in the UK. See MHRA news story **[Exhibit: JH7/95 INQ000309692]**.

5.95. On 30 November 2021, the Ministerial Panel agreed to the purchase of an additional 60 million doses of the Moderna vaccine for 2022 and 2023 (29 million in 2022 and 31 million in 2023). An interim agreement was entered into with Moderna to reserve and secure the 60 million doses on the same day. The interim agreement was replaced with a more detailed agreement, entered into on 5 April 2022.

5.96. As the COVID-19 virus mutated and novel variants were identified, Moderna began work on the creation of a bivalent vaccine (a vaccine which targets two separate strains of a virus). Ahead of the Autumn 2022 COVID-19 booster campaign, a substitution notice was sent to Moderna on 15 August 2022, requesting a supply change to the new bivalent vaccine, subject to regulatory approval.

5.97. On 15 August 2022, Moderna's bivalent Original/Omicron vaccine was the first bivalent COVID-19 booster vaccine to be approved by the MHRA. See MHRA press release **[Exhibit: JH7/96 INQ000309699]**, and the bivalent vaccine was rolled out at the commencement of the booster programme on 5 September 2022. See MHRA publication **[Exhibit: JH7/97 INQ000412446]**.

Additional work with vaccine developers

5.98. In addition to the vaccines in its portfolio, the VTF also entered into agreements with Imperial College London and CureVac to develop potential vaccines. While this work did not lead to procurement contracts with these developers, it is discussed briefly here for completeness.

CureVac

5.99. The use of mRNA vaccine technology was particularly important to establishing a capability to be able to respond to new virus variants. CureVac is an mRNA vaccine developer based in Germany. The due diligence assessment (discussed above) led to an in-principle agreement with CureVac in early February 2021. At that time, clinical trials were not completed, and regulatory approval was still required.

5.100. On 16 June 2021, CureVac reported that the endpoint criteria were not met in their Phase 2b/3 clinical trial. See CureVac press release **[Exhibit: JH7/98 INQ000412451]**. CureVac withdrew its vaccine from regulatory approval later in 2021 following clinical trial data readouts, and, as a consequence, the VTF did not proceed to a final contract. See published VTF review **[Exhibit: JH7/03 INQ000283321]**.

Imperial College London

5.101. The vaccine development work at Imperial College London received UK Government funding from UKRI and NIHR prior to the establishing of the VTF, with the latter announcing further funding in May 2020 (DSIT may be able to assist the Inquiry with details of the earlier support).

5.102. The vaccine being developed by Imperial College London was a novel platform that used a self-amplifying (sa)RNA modality – this provided another form of vaccine modality that complemented the VTF portfolio during the early stages of vaccine development.

5.103. In June 2020, a business case was approved for investment in the manufacture of the vaccine for 85 million doses. Subsequently it was decided that UK Government should look to reduce the total number of doses procured from 85 million (which would provide full population coverage) to 35 million (which would cover vaccination of high-risk population groups and frontline workers).

5.104. Following a decision by Imperial College in January 2021 that they would not be progressing to Phase 3 clinical trials with their vaccine, the VTF formally closed the project on 9 March 2021.

Work on antibodies

5.105. Securing a preventative and therapeutic antibody was thought to be critical to tackling COVID-19 during the early days of the pandemic both because the prospect of a safe and effective vaccine being developed in a short period of time was considered to be low, and to provide an alternative option to protect those who could not be vaccinated.

5.106. As part of its initial remit, the VTF was tasked by the Prime Minister with securing access to potential antibody products to respond to the pandemic, and to build long-term capacity and capability to ensure the UK is prepared to tackle future pandemic emergencies.

5.107. A number of antibody treatments for COVID-19 were being developed around the world, but no effective antibody treatment existed at the time. The VTF's approach to antibody procurement in this context is set out in the Antibodies Strategy document **[Exhibit: JH7/99 INQ000412418]**. The key priorities were set out as follows – "saving lives now" (sourcing treatments for a second potential wave of COVID-19 infections, focusing on treatments for acute cases); "saving lives later" (providing protection for at-risk populations who could not benefit from a potential vaccine); and "plan for tomorrow" (bringing antibodies successfully through clinical trials, and increasing UK supply chain resilience and manufacturing capabilities).

5.108. Six antibody candidates were initially investigated, with just two progressing for further work (AstraZeneca and Roche/Regeneron). Following a Ministerial decision, it was decided not to procure the AstraZeneca product (known as AZD7442 and later Evusheld) on 25 February 2021 **[Exhibit: JH7/100 INQ000412421]**. The decision was informed by several factors including delays to the clinical trials of AZD7442; that the progress of the COVID-19 vaccination programme meant the drug would play less of a role than originally envisaged; that its short shelf-life meant a significant risk of wastage if bought in bulk, and the potential that COVID-19 mutations might mean the product was less effective than anticipated.

5.109. Following approval by the Investment Panel, on 5 March 2021 the VTF procured 50,000 doses of Roche/Regeneron's antibody product named REGN-COV2, a specific combination of two monoclonal antibodies. In mid-May 2021, this agreement was transferred to the COVID-19 Therapeutics Taskforce (part of DHSC), when the Therapeutics Taskforce took on the work on antibodies (albeit with some limited support thereafter from the VTF).

Section 6: VACCINE SUPPLY AND MANAGEMENT

6.1. The Inquiry has asked about the role of the VTF in the delivery of COVID-19 vaccines to the public. The VTF worked with PHE/UKHSA, FCDO and a range of partners to support preparations for COVID-19 vaccine deployment in the UK, Crown Dependencies and Overseas Territories, and also managed vaccine supply so that vaccines could be deployed to where they were most needed.

COVID-19 vaccine deployment to the public

6.2. Following the establishment of the VTF, multiple partners were involved in the end-to-end planning and management of COVID-19 vaccine delivery to the public in the UK. The VTF was responsible for the procurement of COVID-19 vaccines, supporting developers, ensuring delivery to central PHE/UKHSA warehousing facilities, and working with partners in the four UK nations to align vaccine supply with their requirements, where possible. PHE/UKHSA, DHSC, the Devolved Governments and the NHS, in each of the four UK nations, had responsibilities in the deployment of COVID-19 vaccine to the UK public. Vaccine doses were allocated to the four UK nations based on the Barnett formula, ensuring that each had access to a population-based share of the VTF's portfolio. Separately, COVID-19 vaccines were also deployed to the Crown Dependencies, Overseas Territories (in collaboration with the FCDO) and UK Government staff in embassies and military bases overseas (in collaboration with the FCDO and MOD).

6.3. Effective cross-partner collaboration was critical to ensure that all parts of the system were ready to receive and safely deploy new COVID-19 vaccines as soon as possible following initial authorisation, and to enable the effective and efficient management of the vaccine rollout. As well as the partners listed above, vaccine deployment preparations were also supported by the MHRA, which shared factual information on the likely authorisation dates of new COVID-19 vaccines to inform operational planning.

6.4. The VTF Programme Board decided on 6 August 2020 that initial vaccine deployment planning should focus on the Oxford/AstraZeneca and Pfizer/BioNTech vaccines. These were assessed to be the only two candidates that could potentially be available to deploy in 2020. Accordingly, from 10 August 2020, the VTF, working with health system partners and vaccine suppliers, began to develop lead scenarios for these vaccines to inform operational planning. These scenarios were regularly updated as new information became available.

6.5. The scenarios produced by the VTF included details of key product characteristics (including administration and packaging details, storage conditions and consumable requirements) and supply forecasts (dates and volumes of each predicted shipment) for the lead vaccine candidates, both of which were needed to inform advance preparations for the vaccine rollout. The VTF also worked closely with deployment partners in the run-up to the first vaccine deliveries in December 2020 to ensure that they remained informed of the latest developments and end-to-end preparations remained aligned.

6.6. Following the start of the vaccine rollout, the VTF held individual weekly "*supply and demand*" review meetings with PHE/UKHSA, the NHS and Health Ministries in the four UK nations to support the effective management of vaccine supply.

6.7. In July 2021, the VTF and NHSE established an operational planning forum with representation from PHE/UKHSA, DHSC, the Devolved Governments and the Crown Dependencies to support enhanced information sharing and coordination ahead of the first booster campaign (see forum presentation **[Exhibit: JH7/101 INQ000429196])**, and met regularly with the FCDO to support ongoing planning for COVID-19 vaccine deployment to the Overseas Territories. The VTF was also a core member of the DHSC-coordinated UK Deployment Programme Senior Responsible Owners' call, which provided a senior forum for the individuals responsible for the vaccine deployment in each of the four UK nations to coordinate and resolve issues.

6.8. This approach facilitated joined-up planning on a UK-wide basis, ensuring that all partners were ready to deploy the first COVID-19 vaccines as soon as they were received from suppliers. Regular communication subsequently enabled partners to identify and respond at pace to emerging challenges, including changes in JCVI advice and vaccine supply forecasts, and to identify opportunities to improve processes in support of preparations for later vaccines and campaigns.

Support for the JCVI

6.9. The JCVI is responsible for advising the UK Government on vaccination and immunisation programmes, including eligibility and priority groups for vaccination. The JCVI secretariat is provided by PHE/UKHSA (see the PHE/UKHSA statement for further detail). The VTF attended the JCVI COVID-19 sub-committee as an observer, and supported JCVI decision-making by providing it with regular updates on the vaccine pipeline and product options. Evidence from VTF-supported clinical trials was also provided to the JCVI. For example, advice for the original booster programme in Autumn to Winter 2021 was informed by evidence from the COV-BOOST study (discussed above).

6.10. The VTF worked closely with the NHS and Health Ministries in each of the four UK nations to ensure that inbound vaccine supply reflected vaccination programme demand plans based on the latest JCVI advice. This allowed the VTF to respond rapidly to ensure the ongoing alignment of vaccine supply and demand following changes to JCVI advice on the use of the Oxford/AstraZeneca vaccine in April and May 2021 in response to emerging knowledge of adverse side effects (discussed below).

Approach to vaccine supply management

6.11. The proactive management of vaccine supply was essential to align inbound vaccine deliveries with demand, minimise expiry of vaccine and ensure that best use was made of the vaccines procured by the VTF. This was particularly important in 2021 when COVID-19 vaccines had a short shelf-life, meaning that effective management of vaccine deliveries was vital to reduce expiry risk and ensure the efficient use of a critical resource. Supply chain management was further complicated by the requirement for mRNA vaccines to be stored in freezers, and restrictions on their travel time and handling.

6.12. Following the launch of the COVID-19 vaccine rollout, the VTF utilised an Integrated Business Planning ("IBP") process for the management of vaccine supply. This process was based on industry best practice, implemented by key individuals recruited into the VTF for their specialist skills and experience, and, with the use of forecast/scenario modelling, represented an innovative approach to vaccine supply chain management within Government.

6.13. The IBP process allowed the VTF to align vaccine supply and demand to the best extent possible by bringing together the latest information on the planned evolution of the VTF's vaccine portfolio, vaccination programme strategy, individual nation demand plans, vaccine developer supply forecasts and available storage capacity in central PHE/UKHSA warehouses. As noted previously, the accepted likelihood at the start of the national programme of any individual vaccine candidate ultimately proving successful was less than 10%. Therefore, when success rates proved higher, reasonable risk mitigation supply planning would have inevitably led to over-provision. The IBP process allowed for rapid and responsive mitigation plans to be utilised to effectively manage forecast supply against utilisation and the ever-changing epidemiology. Open sharing of data across partners was crucial to the effective functioning of this process, and the VTF employed a scenario-based approach to planning to manage the numerous uncertainties impacting upon the programme.

6.14. In addition to close working with the NHS and PHE/UKHSA to minimise the time from delivery of vaccine by suppliers to safe local distribution and deployment to individuals, the specific mitigating actions that the VTF took to manage vaccine supply included. See VTF Review **[Exhibit: JH7/03 INQ000283321]**.

(1) Revising delivery schedules with suppliers wherever possible to best match supply and expected demand.

(2) Reducing the volume of doses ordered through vaccine contracts.

(3) Donation of vaccines identified as surplus to domestic needs.

(4) Optimising the supply of doses with other countries allowing vaccines to be used where and when they were needed.

6.15. Active management of vaccine supply by the VTF, PHE and NHSE helped to keep stock loss in the programme for England up to the end of October 2021 to an estimated 4.0% of all doses received. The IBP process also informed PHE/UKHSA work to scale central storage and distribution capacity (including ultra-low temperature freezers) to meet evolving COVID-19 vaccination programme requirements.

6.16. In September 2021, the UK Government announced initiatives to share 4 million Pfizer/BioNTech vaccine doses with Australia, and 1 million doses with the Republic of Korea. See news story **[Exhibit: JH7/44 INQ000309654]** and press release **[Exhibit: JH7/45 INQ000309658]**. This arrangement was mutually beneficial and ensured that doses which were not immediately required in the UK were used to support international vaccination efforts. The same volume of doses was returned later in the year. Sharing doses meant those countries had immediate access to vaccines they could use in their domestic campaigns and enabled the UK to better align timings of its own supply with its requirements. See VTF Review **[Exhibit: JH7/03 INQ000283321]**.

6.17. The VTF also worked with vaccine developers to identify and address issues with the potential to disrupt vaccine supply. This work was critical given the UK vaccine programme's dependence on complex international supply chains, during a period of intense geopolitical uncertainty in which vaccines were a scarce global commodity. Key areas of focus included supply chain assurance, delivery management, logistics and distribution, and assessment and response to security risks. The VTF was therefore able to identify and develop mitigations for a range of risks to vaccine supply, including shortages of key commodities (such as cardboard) and single-use consumables (including bioreactor bags and filters).

6.18. The VTF met regularly with senior leaders at vaccine suppliers to work through and agree solutions to problems as they arose, and held daily operational meetings with suppliers to ensure continuity of supply in the crucial December 2020 to April 2021 period. Joint working-level teams were established to create shared plans and measure progress against them, and sharing of data at regular intervals ensured that problems were solved using a shared understanding of the evidence and information. This approach represented a different, more collaborative way of working with suppliers to identify and solve problems, adding value to the terms of the relationship set out in contractual provisions. See VTF Review **[Exhibit: JH7/03 INQ000283321]**.

Vaccine donations

6.19. At the G7 Summit in June 2021, the then Prime Minister, Boris Johnson MP, announced that the UK would donate 100 million surplus COVID-19 vaccines, as part of a G7 commitment to make available at least 1 billion doses in support of WHO's call to vaccinate at least 70% of the world's population by the end of 2022.

6.20. The VTF worked with the FCDO and PHE/UKHSA to deliver on this commitment. It identified surplus doses available for donation through the IBP process. Following agreement with suppliers and subsequent amendment, all VTF supply agreements contained provisions to enable international donations. These were supplemented for confirmed donations by tripartite agreements between the UK Government, the supplier and COVAX and/or the UK Government, the supplier, and the recipient country (for direct donations).

6.21. By June 2022 the UK had offered 100.2 million doses of COVID-19 vaccine for donation: 50.5 million doses of Oxford/AstraZeneca, 20 million doses of Janssen, 15 million doses of Moderna and 14.7 million doses of Novavax. Uniquely, the Novavax donation was achieved by funding Gavi to procure doses rather than by vaccine doses being transferred directly. See VTF Review **[Exhibit: JH7/03 INQ000283321]**. VTF vaccine donations were delivered either directly to recipient countries or via COVAX.

6.22. In 2022, requests for donations significantly reduced due to the greater availability of vaccines and lack of demand from COVAX and lower income countries. As a result, not all of the 100.2 million vaccine doses offered for donation were taken up. By June 2022, 84.4 million doses had been donated, comprising 76.5 million doses processed via COVAX and 7.9 million doses delivered directly by the UK to countries in need. UK donations benefitted 42 countries. See VTF Review **[Exhibit: JH7/03 INQ000283321]**.

Public messaging on vaccine uptake

6.23. The VTF had a dedicated communications team who worked closely with communications teams in both BEIS, DHSC, MHRA and PHE/UKHSA (as well as with other teams across Government where needed) to ensure that messages around vaccines were consistent and regularly publicised, where possible. The team comprised both communications and scientific specialists to ensure that communications were targeted, tailored to audiences, and scientifically accurate. Their work included, for example, drafting press notices, answering press queries, and handling requests from the public (such as Freedom of Information requests) and MPs (such as Parliamentary Questions).

6.24. The VTF was involved in communications to the public about the progress in efforts to secure safe and effective vaccines (including for example entering into in-principle agreements to purchase vaccine doses). Communications strategies concerning issues

around vaccine uptake and public health messaging/campaigns were mostly led by other Departments and bodies, with the VTF providing relevant factual information as appropriate.

6.25. Although the VTF was not the lead team in these areas, working with others it undertook a number of activities that supported efforts to promote vaccine uptake. These included:

(1) Drafting press notices, lines to take and handling plans for major vaccine efficacy, procurement and production announcements.

(2) Placement of articles in the media to promote vaccine awareness and uptake.

(3) Production of media support packages for VIP visits to highlight the work being done to develop vaccines.

(4) Working with DCMS to counter mis-/dis-information messages where identified.

(5) The production of a series of podcasts, one of which addressed vaccine safety and hesitancy.

(6) Working with the NIHR to promote the COVID-19 vaccine research registry (Permission to Contact).

(7) Working on communications strategies for the Human Challenge project, including around recruitment and media announcements.

Section 7: VACCINE SAFETY

7.1. All VTF vaccine contracts required that the vaccine be approved by the relevant regulatory authorities, which for the UK was the MHRA. That meant that all COVID-19 vaccines offered in the UK had to meet the stringent safety standards of the MHRA as the independent regulator.

7.2. The MHRA worked with the VTF to ensure that relevant aspects of the UK regulatory system for medicines were understood and factored into VTF planning. The MHRA initially attended meetings of the VTF Steering Group. To preserve its independence as the regulator, and to avoid any perception of a conflict of interest, it was agreed however

that the MHRA would no longer attend these meetings. This was formally confirmed in September 2020 in a written exchange between Dr June Raine, Chief Executive of the MHRA, and Dame Kate Bingham on 22 and 23 September 2020 (**[Exhibit: JH7/102 INQ000330587]** and **[Exhibit: JH7/103 INQ000429195]**).

7.3. Whether a vaccine was authorised as meeting safety, quality and efficacy standards was throughout solely a matter for the MHRA. Information on suspected COVID-19 vaccine safety concerns post-authorisation were identified by the MHRA through its well-established Yellow Card system.

7.4. Where a vaccine had been approved for use, awareness on an ongoing basis of the clinical assessment of vaccine safety was relevant to the efficient management of supply and product delivery. During the pandemic, the VTF kept track of any potential safety-related issues continuously through a standing section on policy studies at the VTF Programme Board. This provided an evolving overview of the progress of vaccine studies and trials, and included regulatory and clinical updates for all vaccines in the VTF portfolio for shared awareness. The VTF's close working relationships with vaccine suppliers allowed it to be ready to respond to any announced changes to MHRA authorisation conditions or JCVI advice.

7.5. Thus, on 7 April 2021, the MHRA issued updated guidance following the identification, through the Yellow Card System, of a possible link between concurrent thrombosis (blood clots) and thrombocytopenia (low platelet count) following vaccination with the first dose of the Oxford/AstraZeneca vaccine. See press release **[Exhibit: JH7/104 INQ000408453]**. On the same day, the JCVI issued updated advice recommending that individuals under the age of 30 without underlying health conditions that put them at higher risk of severe COVID-19 disease should be offered an alternative vaccine. See JCVI statement **[Exhibit: JH7/105 INQ000413051]**. The JCVI subsequently issued further advice on 7 May 2021, which recommended the use of an alternative vaccine for healthy individuals under the age of 40 (see advice **[Exhibit: JH7/106 INQ000390090]**).

7.6. Following confirmation of these changes, of which the VTF did not have prior knowledge, the VTF worked closely with the NHS and health ministries in each of the four UK nations to ensure that planned vaccine supply continued to align with the resulting changes in forecast demand.

7.7. On 25 June 2021, the MHRA updated its authorisations for both the Pfizer/BioNTech and Moderna vaccines following very rare reports of myocarditis and pericarditis occurring after vaccination. See MHRA decisions **[Exhibits: JH7/107 INQ000412437** and **JH7/93 INQ000408426]**. JCVI guidance continued to review all safety information and no change in clinical advice was required.

Communication with the public on vaccine safety

7.8. Communications with the public as to any risks of vaccines were led by the MHRA, and COVID-19 vaccination programmes in the four UK nations. Decisions, for example, as to whether a particular group of the population would have been prioritised would have been for the MHRA (as the regulator), and the JCVI (as the provider of clinical advice). In England, the CMO and DCMOs, notably Professor Sir Jonathan Van-Tam, had a role in communicating with the public about the vaccine programme.

7.9. The VTF's primary purpose was procuring and supplying effective vaccines to the UK population. Its communications team worked alongside BEIS and later DHSC communications teams, vaccine developers and other Government bodies to keep the public informed as to the progress of the vaccine programme. For example, by providing information as to grants of research funding or vaccines procured. An important element of such messaging was to provide information on vaccine safety when required. That helped public confidence in the vaccine programme.

7.10. Thus, handling plans, which were approved by Ministers, were developed for all major vaccine efficacy announcements and emphasised safety as a key communications objective (as an example, please see the plan developed for the Vaxzevria vaccine **[Exhibit: JH7/108 INQ000421717]**). Press lines on the safety of vaccines were developed for major events such as the approval for use of the Pfizer/BioNTech vaccine in December 2020. See 'Vaccine Safety Lines' paper **[Exhibit: JH7/109 INQ000412420]**. It is important to note, however, that any information provided by the VTF as to the safety of a particular vaccine would have relied on information from relevant agencies (such as the MHRA) and vaccine developers. This ensured scientific accuracy and consistent messaging across the whole of the vaccines development enterprise.

Section 8: REVIEWS OF THE VTF

8.1. Several reviews of the VTF were (with one exception) undertaken during its life cycle. These were intended to provide additional assurance of the VTF's activities and to support the VTF leadership in identifying opportunities to improve its structures and processes. In addition to these reviews, there was independent oversight of the work of the VTF from the Public Accounts Committee ("PAC"), which published reports in February 2021 and July 2022, and the National Audit Office ("NAO"), which published reports in December 2020 and February 2022.

Critical Friend Review – June/August 2020

8.2. Critical Friend Reviews ("CFRs") form part of best practice guidance on the assessment of risks by the Infrastructure and Projects Authority ("IPA"). The IPA reports to Cabinet Office and HM Treasury, working across Government to provide independent assurance on major projects, and support the Government to improve the way in which projects are managed and delivered.

8.3. A CFR of the VTF was undertaken in two parts in June and August 2020 with a report being issued at each stage. This review was undertaken at pace, by way of interviews with key participants in the VTF programme over a short window of time. Each report notes that *"its conclusions and recommendations need to be understood and taken within the context of this constrained scope and methodology and the associated limited due diligence that has been possible."*

8.4. At the first stage, a BEIS team independent of the VTF was commissioned to examine the following "*key elements*": governance; assurance and approvals; and value for money. Their findings, based on interviews conducted from 1 to 5 June 2020, were issued on 10 June 2020. Ten recommendations were made around business case approvals, VTF internal governance, commercial and legal issues, use of scientific expertise, resourcing and people, and the relationship between the VTF and wider BEIS governance. See June Report **[Exhibit: JH7/110 INQ000412429]**.

8.5. The findings of the second stage were issued on 6 August 2020, following interviews conducted between 3 and 5 August 2020. See August Report **[Exhibit: JH7/111 INQ000421716]**. This report considered the following aspects: delivery confidence / project management; contract management; managing dependencies; and benefits and

evaluations. It noted that the VTF was a high-risk programme, highly complex, being delivered at pace and highly innovative in nature. It acknowledged that significant progress had been made to get the VTF programme in the best position possible and made eleven recommendations around project management functions and staff resourcing.

8.6. Nick Elliott, as VTF SRO, accepted the recommendations of the CFRs. He would be best placed to assist the Inquiry with the VTF's response to them.

IPA review

8.7. The VTF was designated a Government Major Projects Portfolio ("GMPP") programme from the fourth quarter of the 2020/21 financial year, as the result of which additional support and oversight was provided through the IPA. The latter conducted an Independent Peer Review in November 2020 as part of its remit to support continuous improvement in the way projects are delivered and provided their findings to the VTF on 26 November 2020 **[Exhibit: JH7/112 INQ000128467]**.

8.8. The review recognised that the VTF programme was not "*typical*" and was not dealing with a "*typical issue*". A number of areas relating to its structure had contributed to the VTF's early success. It had benefitted from Ministerial approval and budgetary support; it utilised novel contracting structures allowing it to enter into contracts at risk; and its governance was bespoke and agile with a ring-fenced budget and a dedicated Ministerial approval process. The review observed that the governance structure, whilst still evolving, did not show evidence of "*corners being cut*", but rather a "*sensible and practical approach*". It recommended that the VTF should retain the agility in the governance and approval mechanisms in place but that the governance structures should be refined to support the next phase of the programme. A number of other recommendations were made around contract management, leadership and resourcing, programme alignment with DHSC, and communications.

8.9. Nick Elliott accepted the findings of the IPA review and undertook to develop its recommendations in the next stages of the VTF programme (see page 8 of the report). The IPA review noted that the UK was, at least pre-pandemic, vulnerable in its ability to manufacture drug substances in bulk and to fill and finish the final product. As explained in paragraphs 5.16 to 5.18 above, the VTF took early steps to address this by for example funding a rapid deployment facility focused on the existing manufacturing

facilities available at Oxford Biomedica and investing in fill and finish capacity at the manufacturing facility operated by Wockhardt. As previously explained, UKHSA's remit does not extend to onshore manufacturing of vaccines; that lies with DSIT. That Department is better placed than UKHSA to explain present policy on UK manufacture of drug substances and fill and finish capacity.

Sykes review

8.10. Shortly after its establishment, Dame Kate Bingham, as chair of the VTF, invited Sir Richard Sykes, Chair of the Royal Institution and subsequently chair of the VTF, to conduct a review of the work of the VTF to be followed by a further review in six months' time.

8.11. Sir Richard's first review, dated 4 July 2020, focused on: the portfolio of potential vaccine candidates identified; short and long-term manufacturing capability in the UK; preparedness for clinical trials; risks / mitigations and timelines; and the scope, expertise, and capabilities of the VTF team (see Sir Richard's review **[Exhibit: JH7/113 INQ000410499]**). Sir Richard's overall conclusion was that, whilst the uncertainty around the development of vaccines meant that costs and timelines could easily change from those envisaged, the VTF had made an excellent start. He described the pandemic as a dynamic situation to which the VTF needed to be able to deploy financial and human resources rapidly. In his words, "*We are at war and we must pull out all the stops*." Sir Richard described the leadership of the VTF as being of high-quality and *"perfectly suited*" to addressing "*the complex task ahead*".

8.12. Sir Richard's follow up review was published in December 2020 as part of the "*UK Vaccine Task Force 2020 Achievements and Future Strategy. End of year report*" see published Report **[Exhibit: JH7/25 INQ000309612]**. This report examined the progress made by the VTF against its three core objectives:

(1) To secure access to the most promising vaccine(s) for the UK population as quickly as possible.

(2) To make provision for international distribution of vaccines so that the benefits of UK leadership and investment in this area could be widely shared.

(3) To support the UK's Industrial Strategy by establishing a long-term vaccine strategy to prepare the UK for future pandemics.

8.13. On the first objective, Sir Richard commended the work of the VTF in building a diverse portfolio of potential vaccines. He noted that the VTF had *"focused on vaccines that could be in the clinic in 2020, which could be manufactured at scale preferably in the UK, which had the potential to secure rapid regulatory approval and be delivered ready for deployment as rapidly as possible"*. Sir Richard continued that the VTF's approach had been to balance established vaccine platforms with more innovative platforms that were more clinically advanced.

8.14. On the second objective, Sir Richard highlighted the VTF's work in supporting the creation of COVAX and the investment committed by the UK, through the VTF, in funding the purchase of vaccine doses for lower-income countries.

8.15. On the third objective, Sir Richard commended the targeted funding provided by the VTF to support the UK's long-term pandemic preparedness in three broad areas. First, UK manufacturing through funding provided for VMIC, CGTC Braintree and Valneva (Livingstone). Second, the creation of clinical assets such as the NHS Clinical Registry and standardised assays. Last, the delivery of a comprehensive strategic communications campaign.

Government Review of the VTF

8.16. In August 2023, a review of the VTF was published **[Exhibit: JH7/03 INQ000283321]**. The review was planned prior to the transition of the VTF to its new 'receiver' organisations. It provided a stocktake and consideration of the extent to which the VTF had achieved the three strategic objectives as in place at the time its responsibilities transitioned to UKHSA, DHSC and the OLS in October 2022. It also sought to draw out learning that could be applied "*to future Government programmes, both in emergency circumstances, such as those in which the VTF was formed, and to business-as-usual activity.*"

8.17. The review measured the performance of the VTF by reference to its first two objectives. It limited consideration of the third objective to the pandemic response, noting that this was "*longer term in nature … and separate monitoring and evaluation plans are in place for it as part of the onshoring programme, which has now been transferred to the OLS*."

8.18. The review highlighted the following as key factors in the VTF delivering on its objectives:

(1) That it had been able to draw on the expertise of a range of specialists from the Civil Service, private sector, and academia.

(2) That it had been able to deal with vaccine developers in a different, more collaborative way through, for example, regular meetings between vaccine suppliers and the senior VTF leadership and setting up joint working level "*virtual teams*".

(3) Establishing effective systems to support proper oversight and risk assessment but also to facilitate swift decision-making.

(4) Investment in world-leading R&D studies such as COV-BOOST.

(5) Engagement with senior leaders across Government including the Prime Minister, Ministers, the CMO and DCMOs, the CGSA and the NHS.

Section 9: LESSONS FOR THE FUTURE

9.1. On 1 October 2022, the VTF's functions transitioned to UKHSA, the OLS and DHSC as follows:

(1) The VTF's Strategy and Analysis, Commercial and Project Management Office, Supply Management (including dose donations) and Supply Readiness functions were transferred to UKHSA. This included responsibility for the UK-Moderna Strategic Partnership ("MSP"), which will bring mRNA production capability into the UK and build resilience in the event of a new pandemic or health emergency.

(2) The VTF's work to strengthen the UK's onshore vaccine development, manufacturing and supply capacity and capability were transferred to the OLS.

(3) The VTF's international function transferred to DHSC and was integrated into its International Directorate.

9.2. VTF staff who transferred from BEIS to UKHSA formed the Covid Vaccines Unit ("CVU"), a new directorate within UKHSA. Clara Swinson, Director General of Global Health, and Health Protection at DHSC sent me, as Chief Executive of UKHSA, a VTF transition letter dated 30 September 2022 which noted:

(1) That UKHSA would "*wish to continue building on the VTF's legacy by retaining the best elements of its structure, approach, and culture*" including "*close engagement with suppliers, technical and commercial expertise, and centralised procurement.*" That engagement was to cover existing and future contracts for vaccine supply as well as the strategic partnership with Moderna (which, as at the date of the transition letter, had not been finalised).

(2) Given that the COVID-19 vaccine market remained "*relatively immature and vaccination demand remains uncertain*", UKHSA should "*retain the VTF's strategic approach of advance scenario planning (together with the Chief Medical Officer's team and the wider department) to assess likely need, as well as continued close working with suppliers on product availability as they update to new variants and pursue multivalent vaccines.*"

(3) UKHSA should foster and enhance the "*VTF's role in working closely with developers and clinical experts to explore opportunities regarding research and development, manufacturing, supply chains and delivery.*"

(4) The new unit to be set up within UKHSA would "*need to be capable of surging to respond to a health emergency, such as a new COVID-19 variant or novel pandemic threat.*"

9.3. The letter acknowledged that the role of the unit would evolve over time to cope with new challenges beyond COVID-19. See letter **[Exhibit: JH7/114 INQ000412439]**.

9.4. The VTF was established with a single aim – to secure a COVID-19 vaccine as swiftly as possible. Its efforts, working with partners in Government, academia, and industry, have rightly been praised. With Ministerial support, and reflective of the circumstances in which it was operating, the VTF was able to move at speed and take risks that would not have been acceptable in normal circumstances. The CVU continues to work on delivering safe and effective COVID-19 vaccines for current and future campaigns to

maintain public confidence and to ensure that vaccine stocks are used in the most efficient way. The director of the unit has responsibility for the MSP.

9.5. There are undoubtedly lessons for the future from how the VTF went about its work of procuring a COVID-19 vaccine. For UKHSA, how such lessons can be applied need to be considered in a wider context which includes that Government's risk appetite can change, that UKHSA has not inherited every element of the VTF, that it has a wider remit and that many of the skills and connections drawn into the VTF from across Government align with and complement those that already exist as part of UKHSA's internal capabilities and connections.

9.6. As recognised in the VTF transition letter, the work of the CVU will evolve in parallel with, for example, those elements from PHE now in UKHSA which had a vaccines remit. The challenge for UKHSA moving forward is to develop available organisational resources and to work with others in as flexible a way as possible so as to prepare not simply for the return of COVID-19 but for the risk that the country may face an epidemic or pandemic caused by a different pathogen. Developing and retaining surge capacity and links with academia, the pharmaceutical industry and research bodies is an existing workstream of critical importance to UKHSA's current business.

9.7. Given the importance of looking to the future, the Inquiry is referred to UKHSA's corporate statement on the activities of PHE, which seeks to address this important topic by bringing the different strands of UKHSA's work on vaccines in one place.

Statement of Truth

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

Signed: Personal Data

Dated: 04 July 2024