Witness Name: Clive James Dix

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Dated: 10th October 2024

UK COVID-19 INQUIRY

FIRST WITNESS STATEMENT OF CLIVE JAMES DIX PhD

I, **CLIVE JAMES DIX**, will say as follows:

1. Introduction

1.1 I make this witness statement in response to the request for evidence made of me by the UK Covid-19 Inquiry dated 28 February 2024 ("the Rule 9 Request").

1.2 Pursuant to the Rule 9 Request I have been asked to address various matters relating to the work of the Vaccine Task Force ("the VTF") during the COVID-19 pandemic and my involvement with the VTF.

1.3 I have prepared this statement with the assistance of the Government Legal Department ("GLD"). I make this statement on the basis of my own personal knowledge, as refreshed by documents which have been made available to me following searches undertaken by GLD and the UK Health Security Agency ("UKHSA").

2. Background

2.1 I graduated from Leeds University with a First-Class degree in Pharmacology, following which I obtained a doctorate in Anti-oestrogen action. After several Post Doctoral Fellowships at the Royal Free Hospital in London I worked as Section

Leader (Cell Biology) at Ciba-Geigy Pharmaceuticals, following which I moved to Glaxo/Glaxo Wellcome/GSK where my final position was Director of Research, UK. Between 2001 and 2016 I held several Chief Executive Officer (CEO), Chairman and Non-Executive Director posts at a range of pharmaceutical companies specialising in vaccine research and development, some of which I co-founded. I currently hold the role of Non-Executive Director at Precision Health Technology Accelerator, and am the Executive Chairman of C4X Discovery (a position I have held since 2010).

2.2 I have significant experience and knowledge of the pharmaceutical business and finance community supporting this sector, an in depth understanding of all facets of the drug discovery and development process, and broad knowledge of the science and commercial landscape of vaccines, cardiovascular, respiratory, inflammatory and infectious disease sectors.

2.3 I served as Deputy Chair of VTF between June 2020 and December 2020, and as Chair of the VTF from December 2020 to April 2021.

3. VTF Structure, Role, People and Processes

Appointment

3.1 On 6 May 2020 I approached Kate Bingham, the then Chair of the VTF. I had known Kate for over 15 years, and she had backed me to lead two biotech companies. I wanted to offer my help to Kate. I was formally appointed as her deputy on 4 June 2020 with specific responsibility for selecting a portfolio of promising vaccines. The process of appointment was handled by Kate, and I have no knowledge of what that entailed. All vetting was conducted by Ruth Todd of BEIS in her capacity as Head of the VTF Office. I joined the VTF in May 2020 on secondment from my company C4X Discovery, which invoiced the VTF for 3 days' work per week (although I worked full time on the VTF).

3.2 In December 2020 I was asked by Sir Patrick Vallance and Nadhim Zahawi to step in as Chair of the VTF. I did so on an unpaid basis. I did not receive a satisfactory letter of appointment for this role and resigned in April 2021, at which time Sir Richard Sykes was appointed as the VTF's external Chair. He was later appointed VTF's Chair in June 2021.

3.3 I was not a member of the VTF External Advisory Board and attended only one meeting in late June 2020 to inform them of the process I had established to identify vaccines.

The purpose and objectives of the VTF and my role on it

3.4 The VTF was formed because there was no infrastructure in the UK to work across industry, academia and government. The VTF Steering Group was a group of very experienced academics, industrial people and people with good strategic vision and ability to make things happen. As can be seen from the VTF Steering Group's Terms of Reference (**Exhibit CD1/01 – INQ000309558**), the purpose of the VTF Steering Group was to set the programme direction and strategy and to oversee the delivery of the VTF.

3.5 When. I joined the VTF Kate Bingham had agreed 3 major objectives with the Prime Minister. These were 1) to find the vaccines as soon as possible to protect UK citizens; 2) to help the world access vaccines; and 3) to leave a legacy that would help with future pandemics (see the VTF Objectives Document (**Exhibit CD1/02 – INQ000421906**). By 20 June 2020 detailed 6-month goals had been identified and agreed by the VTF Steering committee (see **Exhibit CD1/03 – INQ000503508**). These fell under 7 headings:

i) Procure rights to a diverse range of vaccines which have the potential to vaccinate safely to protect the high-priority populations in the UK by the first half of 2021.

ii) Establish robust supply chains where necessary to ensure there is sufficient supply for the high-priority populations by the first half of 2021; build plans for longer term supply.

iii) Provide funding for all prioritised vaccine clinical trials to be run through NIHR with industrial scale diagnostics and MHRA regulatory support to enable rapid demonstration of clinical safety and efficacy in the high-priority populations. Ensure the pharmacovigilance systems are in place for long-term clinical follow-up of everyone vaccinated.

iv) Develop and evaluate detailed operational plans with DHSC for deployment as soon as a vaccine becomes available.

v) Collaborate with other countries (where appropriate) to improve access to develop, supply and distribute the most promising vaccines internationally to low- and high-income countries.

vi) Establish long-term vaccine strategy plans to prepare for future pandemics within the long-term industrial strategy for life sciences.

vii) Educate and inform Government, Parliament and commentators about COVID-19 vaccine development, challenges and the science involved.

3.6 The membership of the VTF Steering Group by 25 May 2020 consisted of Kate Bingham, Nick Elliott, Paro Konar / Stef Murphy, Ian McCubbin, Madelaine McTernan, Ruth Todd, Divya Chadha Manek, Steve Bates, Emma Moir and I (see **Exhibit CD1/04 – INQ000421909**). The membership changed over time (see, for example, the membership list in December 2021 (**Exhibit CD1/01 – INQ000309558**) and the January 2021 membership list at **Exhibit CD1/05 – INQ000421899**).

3.7 Immediately on joining the VTF I built a small expert team with technical and industrial expertise that could help select the most promising vaccines based on a portfolio approach and carry out due diligence on the potential vaccines. The team consisted of John Tite, Giovanni Della Coppa, Helen Horton, Ian McCubbin, Divvya Chadha Manek, Steve Chatfield and later Paul Kellam, and Kate Hilyard supported by Devina Banerjee. The portfolio was deliberately diverse, composed of different types of vaccine candidate – from mRNA and DNA vaccines so that we could ensure that all the vaccine candidates did not share the same risks of failure. The team was established in a matter of weeks and started immediately prioritizing vaccines from a total of around 200 candidates. We had a contract with Airfinity Ltd, a UK-based data and analytics company specialising in monitoring and forecasting trends in the global disease and public health industries, which had a database of all potential vaccines in development. The team systematically looked at the data available and prioritised firstly on ability to get into the clinic and then on the history of the vaccine type to deliver a meaningful vaccine. Through this desktop research and some contact with companies the list was reduced to around 15 before we approached the relevant companies to carry out deep due diligence before making recommendations.

3.8 The due diligence involved assessing the clinical development plans, manufacturing plans and capabilities and the timing of these events. We met with the companies as a team and asked them to share their data and plans, and the team then wrote up their consideration on the aspects they were expert in, i.e. manufacturing, preclinical data, clinical data if any and overall plan credibility. I oversaw the due diligence reports to ensure a fair and consistent process, such reports then being presented to the Steering Board to inform views on taking a candidate forward (**Exhibit CD1/06 – INQ000503513**).

3.9 Examples of due diligence reports produced are the Imperial College London LMP-nVoVsaRNA report dated 16 June 2020 (**Exhibit CD1/07 – INQ000503509**), the Oxford University and Astra Zeneca ChAdOx1 n CoV-19 report dated 19 June 2020 (**Exhibit CD1/08 – INQ000503514**) and the Pfizer-BioNTech SARS-CoV-2 Vaccine Programme report dated 15 July 2020 (**Exhibit CD1/09 – INQ000503512**).

3.10 The overall strategy was to have vaccines based on different technologies to maximize the chance of success. Our initial thoughts were that we may need up to 12 vaccines to ensure we had a chance to find a safe and effective vaccine. In the end we selected seven for advanced procurement and all seven were eventually approved by the UK regulator, Medical and Healthcare products Regulatory Agency ("MHRA"): Oxford-AstraZeneca, Pfizer-BioNTech, Moderna, Janssen, Novavax, Sanofi-GSK and Valneva.

3.11 I was involved in finding and interviewing a number of individuals who could bring industrial expertise to the VTF. It was apparent when I started that the Civil Service had no industrial, scientific or vaccine R&D expertise. Through my networks I formed an experienced team (see paragraph 3.7 above) to assess the vaccines that were being developed. The team consisted of industry vaccine experts that covered research, product development clinical development of vaccines. The VTF Office carried out on boarding including vetting and conflict of interest checks, although the team were working without contracts from the day they were approached and sometimes it took weeks before they were officially contracted. In all cases they were taken through on boarding by civil servants in a process overseen by Ruth Todd.

3.12 In terms of alternatives to vaccines, Matt Hancock or Sir Patrick Vallance I believe asked Kate Bingham to consider antivirals, (drugs which stop a virus

replicating as opposed to vaccines which stimulate the body to make an immune response) and I gave my opinion on that having had experience of antiviral drug discovery and development. I felt this was highly unlikely to help within the time frame and would distract from the task in hand, as antivirals need a very long development time and extensive long-term safety to be approved and there were few if any antivirals in development for Covid. An indication of the type of discussions which were being had in relation to the potential for use of neutralising antibodies in July 2020 can be found in the minutes of the 17 July 2020 meeting of the VTF Steering Group (**Exhibit CD1/10 – INQ000507383**, page 3. See, too, the PowerPoint presentation from July 2020 at **Exhibit CD1/11 – INQ000421900**). We agreed to help find prophylactic and therapeutic antibodies to protect the 0.5 million or so immunocompromised citizens (addressed further below).

Reporting structure

3.13 The work was reported by myself to Kate Bingham and the VTF Steering Group on an ongoing basis. Once we got to final recommendations I worked with Kate and the team to establish what the companies could deliver and what help the Government could offer to ensure we could deliver the vaccines to the UK should their trials be successful and the MHRA approve them. The VTF had an agreement with the Government to incentivise companies to work in the UK as part of the plan and could offer help in a number of areas, including clinical trial support, the vaccine registry, clinical sample testing, manufacturing fill and finish capacity, manufacturing facilities, and for smaller companies financial investment to expand manufacturing. Where such offers were taken up we would ask the Commercial team to incorporate them into the contracts.

3.14 The Vaccines Taskforce Ministerial Panel was introduced in August 2020 to provide commercial and financial approvals for vaccines activity over £150 million, following scrutiny by the BEIS Projects Investment Committee (see the minutes of the first meeting at **Exhibit CD1/12 – INQ000503510**). Kate Bingham attended these meetings up to the point of her departure, after which I attended them as Interim Chair. This cross-departmental panel, which included HM Treasury, enabled rapid decision-making and worked extremely well.

3.15 Separately from the Ministerial Panel meetings I had weekly meetings with Nadhim Zahawi (Parliamentary Under-Secretary of State for COVID-19 Vaccine

Deployment from November 2020 to September 2021) to keep him appraised of progress. I also attended ad hoc meetings as the need arose, including three or four meetings with Matt Hancock during his tenure as Health Secretary to appraise him of progress and plans on activities he wanted updating on. I attended approximately four or five meetings of the Joint Committee on Vaccination and Immunisation ("JCVI") as we were finalising which vaccines we wanted to produce, to ensure they were aware of the types of vaccines that might become available. Around September or October 2020 I also met with Lord Bethel who was interested in the work on antibodies.

3.16 I had multiple calls with Sir John Bell (UK Life Sciences Champion appointed by the Prime Minister) and Sir Patrick Vallance (Government Chief Scientific Adviser), sometimes for advice and sometimes to let them know of progress.

3.17 Within the VTF I worked closely to help Ruth Todd, who led on delivery and project management, with expert input. I also had a good working relationship with Nick Elliott when he was Director General for the task force. I met with Madelaine McTernan who was the Commercial Director to brief her on the vaccines we had chosen and to discuss what we could include in the contracts with the companies with whom we were hoping to sign advanced deals, to incentivise them and advance contracts with the UK. All of my meetings were conducted over MS Teams. Some were formal diarised meetings, others were ad hoc as required to move things along.

My departure from the VTF

3.18 I had been approved to take over from Kate Bingham as interim Chair by 2 December 2020 (see **Exhibit CD1/13 – INQ000421904**). I started work in the role from that point in good faith and my appointment was publicly announced. I received a draft letter of appointment from the DG, Madelaine McTernan, who by then had taken over from Nick Elliott, which essentially limited my role to chairing meetings (**Exhibit CD1/14 – INQ000421905**). I wrote my own draft (**Exhibit CD1/15 – INQ000169724**) and discussed it with Nadim Zahawi as Maddy's draft was not acceptable to me – as VTF Chair I was accountable to the outside world and needed to be sure things weren't being done that I had not at least seen and felt were right. I had seen Kate Bingham's appointment letter which stated that all VTF business would be signed off by her after Steering Group discussion. The DG would not agree to this in my case. I said I needed a direct line of report to a

Minister, which Kate had had, to ensure that the chain of command was sensible – in particular, that work was not blocked by Civil Service behaviour which was overly process driven and which did not fit with the urgency of what we were trying to do.

3.19 I was also concerned about a number of decisions which were taken without my input. One example was the purchase of tens of millions of vaccine doses from India, which I completely disagreed with. I felt the decision was immoral as the vaccines were already assigned to India. The decision was based on apparently arbitrary targets for UK vaccinations set by the Health Secretary, and at a time when vaccination of the most vulnerable individuals in the UK had already been completed the purchase of vaccines from India was in my view unnecessary. I also felt that the decision eroded the VTF's important second objective of helping the rest of the world access vaccines, and went against our contract with AstraZeneca which included assistance for developing countries. I was, however, left out of all discussions and the UK Government entered an agreement to buy the vaccines. I had a long discussion with Nadhim Zahawi during which I emphasised my need for an appropriate letter of appointment, although I made clear that even with such a letter I would have had to resign over the purchase of the Indian vaccines.

3.20 As more and more decisions were taken that I was not involved in and did not support and the issue of my letter of appointment never got resolved, the solution that was agreed with Nadhim following our discussions was for him to become Chair. He then chaired the Steering Group meetings until Sir Richard Sykes was appointed as Chair. I assumed this was a signal to me. I decided it was in everybody's interest that I bowed out gracefully.

4. Reflections on the key achievements of the VTF

4.1 We chose seven vaccines and all were approved by the MHRA. We worked tirelessly with the relevant companies to deliver vaccines and indeed were the first country in the western world to start vaccinating the population.

4.2 We also built a strong reputation that the UK could be the place of choice for vaccine development and clinical trial. When the VTF was set up, the UK was not prepared to engage with the vaccine industry and had little infrastructure to achieve rapid access to promising vaccines. We embarked on several initiatives

to build resilience for a future pandemic. See, in particular, the VTF Steering Group discussion paper "Vaccines – industrial legacy" dated 26 August 2020 (**Exhibit CD1/16 – INQ000421901**), "VTF Legacy Update" dated 30 September 2020 (**Exhibit CD1/17 – INQ000421902**), "Vaccine Taskforce: Domestic Policy/Legacy and Next Steps" dated 05 January 2021 (**Exhibit CD1/18 – INQ000421907**) and the "VTF Ministerial Panel Minutes" of 28 January 2021 (**Exhibit CD1/19 – INQ000489942**). We wrote a detailed recommendation document in December 2020, which I exhibit as **CD/20 – INQ000330659**. Disappointingly, however, my understanding is that this was blocked by the DG, Madeleine McTernan and not published at the time, contrary to Kate's and my expectations. No reasons were given, to my knowledge. In the report, Kate and I made several recommendations to develop system resilience and maintain the legacy of the VTF. This included the creation of a national vaccine agency whose remit would include vaccine scale-up and manufacturing as well as supply chain readiness. The document was not made public until it was submitted to the House of Commons Science, Innovation, and Technology Committee as part of its inquiry into learnings from the pandemic in January 2024.

4.3 Before the formation of the taskforce some decisions had already been made by BEIS and the VTF External Advisory Board (which included Sir Patrick Vallance, John Bell, Mene Pangalos, Jeff Almond and Robin Shattock). These were to fund the Oxford vaccine and to facilitate licensing the vaccine to AstraZeneca in order to get added expert resource to develop and deliver a vaccine. The Imperial College vaccine was also funded to speed up the development and clinical studies. In both cases I was asked to conduct due diligence on these vaccines post the decision to fund. The conclusion was that the Oxford/AZ vaccine showed promise and although manufacturing may require additional support it should continue to be supported.

4.4 However, after detailed diligence conducted by me and my team and completed in June 2020 (see **Exhibit CD1/07 – INQ000503509**) it was considered that the Imperial vaccine was unlikely to succeed, and the funding should be withdrawn. We considered the programme to be very high risk in the absence of links to a multinational pharmaceutical partner and without a proper supply chain, and indeed the clinical trials eventually failed. A decision was taken by Ruth Todd's office to verify our due diligence exercise using an external consultancy firm, Newton Consulting Ltd. I do not know why the decision was made to verify our

work. There was, in my view, a lack of expertise in life sciences among the external consultants and it took them a further six months to reach the same conclusions my team had reached. I was surprised that it took so many months and some expensive non-expert consultants to eventually come to the same conclusion.

4.5 I was also informed that there was a contract in final form with Moderna that had support from the Prime Minister, the Secretary of State for Health Matt Hancock and the support of Rishi Sunak and the Treasury. I was asked to carry out due diligence on the Moderna vaccine and was subject to considerable pressure from the government, relayed to me in numerous meetings by Nick Elliott, to agree that this was an acceptable vaccine. I could not do this as Moderna had a very immature supply chain and limited manufacturing capability, and next to no footprint in Europe. The contract to deliver vaccines in September 2020 for several hundreds of million pounds was nonrefundable and the due diligence said that it was unlikely to deliver any vaccine before spring of 2021. Eventually a contract to supply a few million doses in March or April 2021 was agreed and then delivered late.

4.6 We instead turned our attention to the Pfizer/Biontech vaccine and we persuaded them to work with the UK and the MHRA. We signed a deal that made the UK the first country to get the Pfizer vaccine which was delivered just before the Oxford AZ vaccine in December 2020.

4.7 There was a wealth of knowledge from research into SARs (Severe Acute Respiratory Syndrome) and MERs (Middle East Respiratory Syndrome) that helped with the design of COVID19 vaccines. The Oxford vaccine group capitalized on this to produce one of the first vaccines. With regards to preparedness the HMG/DHSS was somewhat complacent in respect of the need to manufacture vaccines at scale.

4.8 I was not involved in the discussions with regards EU procurement but in hindsight we were able to act faster with less red tape to get vaccines for the UK.

4.9 In terms of obtaining approval for VTF spending from the Treasury, Nick Elliott as DG of the VTF set up a cross-departmental committee that agreed a budget envelope and then sanction individual spends on vaccine manufacturing

contracts. This was a remarkable achievement that led to transparent and rapid decision making.

4.10 Apart from many Civil Servants treating their industry colleagues with suspicion the VTF worked extremely well. In my opinion the Civil Servants displayed a lack of trust of industry colleagues and an assumption that we were working for personal commercial gain. There were side remarks made here and there and odd behaviour towards us, and indeed I was excluded from meetings on commercial sensitivity grounds. By way of example, I was made to leave the room during a discussion about the Sanofi vaccine (on which I had conducted the due diligence) on the basis that my company had entered into a deal with Sanofi. I was told by Dan Osgood that there was a clear conflict of interest despite my having declared the deal and having no personal involvement in it, and the fact that it was in an area totally unrelated to vaccines. I do not think the suspicions and lack of trust affected the work of the VTF. The fact that the Chair had direct access to the Prime Minister and the Civil Servants reported to her made the whole activity work efficiently.

4.11 I personally worked very closely with Andy Pollard at Oxford University and there was a genuine collaborative and productive relationship with all of those involved with the Oxford/AZ vaccine.

4.12 The VTF set up formal mechanisms with key individuals. Ruth Todd established a project office that managed and monitored the deliverables from the vaccine manufacturers with key individuals responsible for the relationships. This worked extremely well.

4.13 The scale up of manufacturing processes was in the hands of the vaccine manufacturers, and the VTF had Ian McCubbin who was steeped in experience of pharmaceutical manufacturing who liaised with vaccine manufacturers to offer help with facilities etc. We gave them access to Clinical trial support, Vaccine fill and finish facilities and some investment to expand UK manufacturing capability, specifically for Valneva in Livingston and Novavax in the FujiFilm plant in the North of England. We helped establish a network of biologics manufacturing for the Oxford vaccine with Oxford Biomedica playing a major role in the delivery of the Vaccine.

4.14 I had little involvement with the Vaccine Manufacturing Innovation Centre and other efforts to onshore manufacturing of varied types of vaccines during my tenure, and evidence from others on the VTF steering group will be more meaningful. I do however consider that the sale of the VMIC to Catalent and its subsequently closure was a sad indictment of things moving in the wrong direction. The VMIC had been established as a centre for innovation. When the decision to establish a manufacturing centre linked to the VMIC was taken, responsibility for the manufacturing centre was also given to VMIC, incorrectly in my view. When the VMIC was sold, and Catalent subsequently closed the entire centre, the UK lost both the innovation and manufacturing capacity that was being developed, which in my view had a serious negative impact on the UK's ability to develop and manufacture vaccines at speed in the face of a future pandemic. More importantly though, what we don't have, and what we need, are very good relationships with the vaccine companies so we can persuade as many as possible to do their research, development and manufacturing in the UK. Those relationships were destroyed due to the way manufacturers were treated after the UK obtained the vaccines they wanted, including some companies having to close down sites in the UK, and I doubt that the UK has the leadership or willpower to persuade them back to the UK. Had we retained the VMIC it could have persuaded some of the smaller companies to come to the UK to get their vaccines formatted, which in turn could have led to vaccine manufacturing happening in the UK as well.

4.15 I was actively involved in shaping the deal with Valneva. The UK had a precious resource in Livingston Scotland. It was the only facility that had the ability to manufacture live inactivated viral vaccines outside of China. This technology is the work horse for rapid responses to new viral threats. As part of our deal, we were investing to expand capability and secure long-term access to the supply of these and other vaccines should a new threat arise. We helped Valneva build extra capacity so it could make 200 million doses. It produced a vaccine and it was in the process of doing the final clinical trial, which the MHRA had said if it was at least equal to AZ it would get approved. The expansion was ongoing when I left, with a contract close to completion on a future deal in which an excess vaccine could be supplied to the rest of the world and the UK would receive a royalty stream which would then offset some of the upfront investment. Soon after I left the VTF, HMG, on advice from the Chair or DG of the VTF, cancelled the Valneva contract and proceeded with to attempts to

recoup the costs. I was concerned and disappointed to hear of this and wrote to Richard Sykes to that effect on 18 September 2021 (**Exhibit CD1/21 – INQ000421915**). At this point the Secretary of State for Health told Parliament that the contract was cancelled on advice that the vaccine would not get approved. This advice, which I understand came from either Richard Sykes, Madeleine McTernan or Steve Glass, should not have been given because there was no data to show that the vaccine would not be approved. In my view, it was a piece of total incompetence. The Valneva clinical trial was weeks away from completion and no data was yet available. Once the data was submitted to the MHRA the vaccine was approved and shown to be at least comparable to the Oxford/AZ vaccine.

4.16 These disastrous decisions led to Valneva stopping the further production of the vaccine, moth-balling the site and making many employees redundant. It meant that the UK missed an opportunity to provide a vaccine to the World which was also an important aim of the vaccine programme. Valneva lost the European contract because it was just about to sign it when the Government cancelled the contract. This has left the UK without any chance of using this technology for future threats. I am concerned that the cancellation of the Valneva contract has further damaged relations with industry. Through my own contacts I am aware that the industry took a dim view of the way Valneva was handled. Much of what we were able to achieve was possible due to the relationships we had across the industry. In the future, when different individuals are involved, the industry will look to the past treatment of companies like Valneva and will not consider the UK to be a place to invest in for anything to do with life science.

4.17 The VTF similarly gave considerable support to Novavax in the development, manufacture and clinical trials of its adjuvanted vaccine, enabling Novovax to set up part of its manufacturing supply chain in the UK. The Novavax vaccine was approved by the MHRA in February 2022 and is now widely considered to be one of the best vaccines available. However, subsequently (and after I had left as Chair of the VTF) UK Government withdrew from its contract for 60 million doses and Novavax ceased manufacturing in the UK, again leaving the UK without any chance of using this technology for future threats.

4.18 The NHS Vaccine Registry was set up by the VTF to ensure we could rapidly recruit individuals for clinical trials. I played no part in this or in public messaging

or communications in respect of it, but it is a matter of fact that it was a real success and helped to speed up clinical trials. I did not have any role in working with the relevant authorities in the devolved administrations in relation to the NHS Vaccine Registry.

5. Reflections in relation to the rapid development, procurement, manufacture and approval of Covid-19 vaccines

5.1 The whole area of rapid response and vaccine development lies with the vaccine industry. As noted above, the VTF recommended establishing a Vaccine Agency that as part of its role would build strong relationships with the industry and guide HMG investment into promising emerging technologies that would help speed up vaccine development and also to encourage those companies developing those technologies to be UK based. In the context of infectious diseases generally, we need strategic leadership that can sit on the top stage with Coalition for Epidemic Preparedness Innovations ("CEPI" is a foundation that takes donations to finance independent research projects to develop vaccines against emerging infectious diseases), work with the World Health Organisation ("WHO"), work with the other countries and know what they are doing in relation to pandemic preparedness. That leadership should continually be monitoring what is going on in the world, and setting up the activities internally which are needed, making sure that a clinical trial network will work and making sure the MHRA is ready for anything that might be coming our way.

5.2 During the lifetime of the VTF, the team carried out detailed due diligence on potential vaccines and recommended which one to forward procure using the established ministerial panel. This was a rapid process driven by individuals with many years of experience of the vaccine industry. We need to establish something permanent of a similar nature in peacetime to ensure we are ready to do this should it be required.

5.3 In the main if we attract more of the vaccine industry to the UK we will have the ability to call on this industry for Vaccine development and delivery. It remains my view as set out in our unpublished[1] recommendations that a permanent

[1] See para 4.2 above

Vaccine Agency should be established and that the Vaccine Registry should also become permanent.

6. Contingency planning for future pandemics

6.1 In respect of planning for future pandemics, I am not aware that any processes were established for feeding back the experience of the VTF to UKHSA and any other relevant governmental bodies. I do not know if the UKHSA has consulted with the industrial/commercial sector members of the VTF who gave up their time and delivered the outcome. I am also not sure what the final form of the VTF did to pass on learnings.

6.2 I my opinion the UK is now in a weaker position than it was prior to the Covid-19 pandemic. I do not believe we have any resilience. In fact, we have less resilience now because a lot of the manufacturers have walked away from the UK because of how badly they were treated in the tail end of the VTF. The vaccine industry feels badly treated by the HMG and instead of having strong collaborative relationship with the major vaccine players and some of the smaller established and innovative companies we have rolled the dice on Moderna being our solution. This is totally at odds to any strategy to build resilience and preparedness for the future.

6.3 We were able as part of HMG to work in a true collaborative partnering approach with the vaccine industry. This has now reverted to an adversarial /procurement mind set. The old saying is that we know the price of everything and the value of nothing.

6.4 I do not believe we have learned the lessons and unless we put some strategic leadership with industrial experience at the head of our decision making for future response, we will not gain from the experience of the VTF.

6.5 I have been asked for my views on 'proactive vaccinology' and on the recently developed so-called 'all-in-one' vaccine against a range of coronaviruses, including ones which have not yet emerged. In my opinion this simply cannot work. It is not possible to develop an antigen without knowing what the virus is, and a vaccine with every single antigen in the world in it could not be tolerated

by the immune system. I do not think it will be able to effectively tackle future unknown viruses.

7. Vaccine delivery in England, Wales, Scotland and Northern Ireland

7.1 The VTF recommended which vaccine to procure and played no other role in the roll-out of vaccines in England, Wales, Scotland and Northern Ireland. The VTF primarily through Ruth Todd ensured that the vaccine supply was available for the roll out by the NHS/DHSC.

7.2 Once the vaccines were chosen the VTF ensured all of the knowledge required by other departments or bodies such as the JCVI was available so they could advise on prioritisation and quantities of vaccine. We were regularly consulted on all aspects of the vaccines including supply and worked to ensure that if the supplies were limited those involved in prioritisation knew the constraints.

7.3 Although I had little direct involvement in most of these aspects of the VTF activities I worked closely with the JCVI on the characteristics of the vaccines we had recommended.

7.4 The VTF initially set out a communication plan that Kate Bingham fronted for most of the time (see, for example, the discussion about communications and the first planned podcast in the minutes of the Steering Group meeting of 3 August 2020 (**Exhibit CD1/22** – **INQ000507384**. Other members of the VTF were asked to participate in podcasts and zoom meetings with various ethnic groups to help disseminate understanding of vaccines. As I recall, this was frowned upon by HMG comms and eventually stopped. In particular, the VTF podcast had been paused indefinitely by 17 November 2020, with one episode remaining unpublished (see **Exhibit CD1/23** – **INQ000421903** at page 2). In my opinion this was wholly short sighted.

7.5 My only experience of vaccine misinformation and what lay behind it was what I read in the media like everyone else. I have no specific insights into why or how to counter it. Social media is what it is and clearly can play a large part positive and negative on attitudes to vaccines. Overall we do not communicate science well and in a digestible way to allay the fears that some suspicious people think

It is all dangerous. The VTF wanted to have a proactive science-driven communications approach as mentioned before. For example, in January 2021, at a VTF Steering Group meeting, I suggested establishing well-rehearsed set of lines that a VTF representative could give to media when asked, to emphasise collaborative and cohesive team across VTF and DHSC (see the minutes of the 06 January 2021 meeting at **Exhibit CD1/24 – INQ000421908**). HMG comms did not want the VTF to participate in comms. In fact they were paranoid about VTF saying anything publicly.

8. Vaccine Safety and the MHRA

8.1 The VTF had no formal role in any aspects of vaccine safety. Once we recommended which vaccines to pre-order it was a matter for the vaccine manufacturers to work on the required clinical and safety data that the MHRA required to approve their vaccine. This is an independent activity with no input or influence of the VTF or any other body. HMG could have been more proactive explaining how although fast to approval did not short cut any scrutiny with regards to safety. Again this was not the remit of the VTF.

8.2 The MHRA is an established and fiercely independent body. The MHRA is recognised as one of the best regulators in the world and is considered to set the gold standard. I have no reason to believe that as a body MHRA is anything other than completely impartial.

8.3 A combination of the MHRA's reputation and the ability to do clinical trials efficiently should be put together as a selling point for the UK, and we should be attracting companies here on that basis. We managed this during Covid. The MHRA worked phenomenally quickly without compromising good practice. The setting up of the vaccine registry, which allowed us to get people into trials very quickly, could be broadened out. If the UK could be seen as a place for doing clinical trials and having strong but efficient regulatory oversight, which it does have, that could attract many companies to the UK. Patients could then see those things happening earlier and we could get better access for patients too. I am an absolute believer in that.

9. Prophylactics

9.1 I led an expert team in the immunology of antibodies to evaluate the emerging antibody therapies in both prophylactic and therapeutic modalities. We analysed all of the vaccines that could be used prophylactically, including the companies' ability to produce them and what their characteristics were. We found that the Evusheld cocktail had the best characteristics, for example, it worked on different parts of the virus or spike protein and it had an extended half-life, so it worked for six months. I considered it to be worth buying enough for two doses for each of the half a million or so immunocompromised population who would otherwise have to shield with no hope of being able to stop shielding until the pandemic was over. The outcome of this intense analysis was to recommend the Regeneron cocktail to be assessed in the Recovery trial run from Oxford and the Evusheld cocktail to be procured for prophylactic use in the immunocompromised population. Pre-approval deal on pricing was agreed with AstraZeneca. The recommendation was rejected by Chris Whitty and the DHSC, my understanding of which was that it was based on price /value for money as an intervention and that the cost was not justified because those individuals would need to shield anyway. The decision, which was incorrect in my opinion, ignored the psychological effect of shielding on vulnerable individuals. I believe the UK was the only country who made such a decision and it was very disappointing.

9.2 In my opinion prioritising non-vaccine prophylactics during the pandemic was not an option, due to their long development timelines. A small taskforce headed by Eddie Gray was put together in late 2020 / early 2021 to look at antivirals in development and it produced the low dose steroid which did well in the recovery trial, however the VTF was not involved in that. Instead we focused on the antibodies cocktail, and it is disappointing that it was rejected. I remain of the view that antibodies are the best option for the immunocompromised in any future pandemic, with appropriate manufacturing support, and indeed one of the proposals Kate Bingham put forward was to build a manufacturing site in the UK for a CDMO to run for manufacturing antibodies. This proposal was also rejected.

10. Lesson learning

10.1 The key lessons learned are set out in the VTF Recommendations report at **Exhibit CD/20 – INQ000330659**. The recommendations were made in 2020 but most of them remain relevant today. In particular, I still believe that:

10.1.1 A National Vaccines Agency should be established with an independent, industrially experienced Chairman and board, to bring together the work of the various strands of vaccine activities in academia and industry that will define the UK as a global leader in vaccine development and manufacturing. This is distinct from the existing Vaccine Development and Evaluation Centre, which is a centre that takes serum samples from clinical trials and tests them in live neutralisation assays. I do not think the existing VDEC is equivalent to the proposal for a National Vaccines Agency and the existence of the VDEC does not address my concerns about the UK's preparedness for a future pandemic. I believe the VDEC is underfunded and under resourced and it does not provide the essential strategic industry oversight and leadership that the Agency would do. Indeed, it my view, it would report in to a National Vaccines Agency. The Agency should be on the world stage, feeding into global pandemic preparedness, led by someone who is a world leader with an understanding of infectious diseases and vaccination, and who can be a spokesperson for the UK. In my view the Agency should be independent but it should report to the Department for Business and Trade, not Health, due to the economic effects of a pandemic. It should be a resource for any minister to call on it to help government make proper assessments of what vaccines to procure

10.1.2 A National Centre for Formulation and Deliver should be established to bring together capabilities across vaccine formulation, delivery, process development and scale-up.

10.1.3 The UK should enhance its clinical trial capability by:

(i) formalising a network between partner organisations to support research and development in clinical immunology, to support increased rich immunological data generation;

(ii) launching a Human Challenge Study Centre of Excellence to further the UK's clinical trial capacity for respiratory infections and diseases; and

(iii) expanding the UK vaccine registry capacity and refining the registry by enabling the linking of NHS datasets of consenting individuals to the vaccine register, maintaining active communication with registrants and the public, and enhancing researcher access. The 'Our Future Health' project is in my opinion too diffuse to deliver an effective UK vaccine registry which would enable rapid trials to take place.

10.1.4 The UK should enhance its manufacturing capability, responsiveness and breadth by:

(i) investing in plant-based manufacture of protein antigens to quickly and reliably generate the protein for protein-subunit based adjuvanted processes;

(ii) exploring potential opportunities to partner with the most promising mRNA based companies, academics and others to provide state of the art mRNA capacity to address future pandemics;

(iii) establishing bulk antibody manufacturing capability to ensure capacity to manufacture sufficient neutralising antibodies to meet the needs of the UK's immunosuppressed population and frontline workers;

(iv) assessing the UK's vaccines supply chain capability and build a mechanism which monitors and quality assures the resilience of global supply chains;

(v) exploring potential arrangements with UK based sterile manufacture facilities (CDMOs or pharmaceutical companies), who could provide surge capacity to fill and finish vaccines; and

(vi) developing a strategy to secure the supply of adjuvants.

10.1.5 The UK should launch a Future Vaccines Fund within UKRI funded by the private sector to advance innovation and support the research of novel formulations and formats.

10.1.6 The UK should also work to increase international engagement and collaboration by:

(i) Using the G7 chairman role to coordinate R&D funding into improved vaccine formats, promote expansion of global manufacturing capability, establish effective long-term information sharing, and encourage streamlining of global regulatory processes;

(ii) Establishing COVAX as an international multilateral organisation for future pandemic preparedness;

(iii) Increasing the proportion of STEM graduates within the Civil Service to 50%, and developing closer ongoing industry links to improve industrial understanding, to learn to partner with them and to create trust between the Civil Service and industry experts

10.2 I am firmly of the view that the VTF's early, proactive engagement with industry was key to the success of the VTF, and remains critical to ensuring the UK's preparedness to deal with future pandemics. Shortly after my departure from the VTF I sent a strategy document to Sir Richard Sykes, Nadhim Zahawi and to the Prime Minister's office highlighting the need for the UK to build a rapid response strategy and setting out recommendations for immediate action (**Exhibit CD/25 – INQ000421916** and **Exhibit CD/26 – INQ000421911**). Again I believe that most of those recommendations are relevant today, however, they have not been followed.

10.3 As a final observation, it is my firmly held view that the leadership within the Government, namely civil servants, needs to be scientifically and commercially trained. Our civil servants should be at the forefront of the CEPI and WHO discussions. To achieve that, we should be recruiting a very large percentage of civil servants with STEM training. The world in which we live now is science and technology based. It is data-driven. The machinery of government needs to adapt accordingly.

Statement of Truth

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

Signed: Personal Data

Dated: 10th October 2024