IN THE MATTER OF THE INQUIRIES ACT 2005

THE UK COVID-19 INQUIRY

MODULE 4: VACCINES AND THERAPEUTICS

OPENING STATEMENT ON BEHALF OF THE

DEPARTMENT FOR SCIENCE, INNOVATION AND TECHNOLOGY

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1. The Department for Science, Innovation and Technology (DSIT) is grateful for the opportunity to assist the Inquiry through the provision of evidence in this Module. It wishes to start by expressing its sincere sympathy for the enduring loss suffered by those affected by the pandemic: those bereaved as a consequence of Covid-19, those who were separated from their loved ones and who were not reunited, and those that continue to live with the life-altering effects of long Covid.

2. The Inquiry will hear, in Module 4, evidence of extraordinary and historic achievements. Never before has a pandemic been abated during its course through the development of an effective vaccine. This is a remarkable accomplishment, one that saved millions of lives directly, and enabled a return to "normal life" for most at unprecedented speed, thereby avoiding still more devastating social, economic and health outcomes. Many deserve credit, most notably the scientists, engineers, administrators, regulators and health care professionals that contributed to the development and deployment of the vaccine. A further group was also vital: those members of the public who

altruistically volunteered in their tens of thousands to participate in clinical trials both of vaccines and therapeutics, and in the vaccination programme. They too played their part in saving the lives and livelihoods of others within the UK and globally.

3. That success, though, is only part of the story. The value of this Module lies in examining both what worked and what did not and in acknowledging the difficult trade-offs that the prioritisation of work on vaccines and therapeutics required. It is also important to analyse clearly the risks that had to be taken and mitigated in order for the vaccine to be produced and deployed. Such an analysis will best serve the shared endeavour of those participating in the Inquiry: learning lessons that will allow the UK to be in a better position to face the next pandemic.

Roles of DSIT, BEIS, the GCSA and others

4. The contribution of DSIT in matters relevant to this Module of the Inquiry largely focuses on the creation, support and oversight of the Vaccines Taskforce (VTF), a temporary unit which sat within the Department for Business, Energy and Industrial Strategy (BEIS). BEIS existed until February 2023, at which point DSIT was formed and took over some of the functions and responsibilities of BEIS, including its science portfolio. DSIT hosts the Office for Life Science and the Government Office for Science (GOS) which is headed by the Government Chief Scientific Adviser (GCSA).

5. The Inquiry will hear from Alexandra Jones, the current Director General of Science, Innovation and Growth at DSIT (and previously the Director of Science, Research and Innovation at BEIS) whose statement on behalf of the Department sets out her significant personal involvement in the establishment of the VTF, the Department's contribution to the development and

manufacturing of vaccines more generally, as well as matters relating to therapeutics and the National Core Studies Programme.

6. From 13 February 2020 to 8 January 2021, BEIS was led by Lord Sharma (then Sir Alok Sharma), who served as Secretary of State for Business, Energy and Industrial Strategy. Lord Sharma will give evidence to the Inquiry about his role in supporting the work of the VTF, international collaboration on vaccines, and work on therapeutics, among other matters.

7. Lord Vallance, who as Sir Patrick Vallance served as GCSA, played a critical early role in matters falling within the scope of Module 4. This was particularly so in the first few months of 2020 when he was pivotal to initiating the VTF and further co-ordinated early and effective work on the discovery and development of vaccines and therapeutics. While the Inquiry has chosen not to call Lord Vallance to give evidence in this Module, we are confident that his written evidence and reflections for future needs, the latter drawn to a great extent from the important and ongoing work of the 100 Days Mission (100DM), will be considered fully by the Inquiry and Core Participants.

Vaccines and the work of the VTF

8. In light of the scope of Module 4, the central focus of the evidence provided to the Inquiry by Lord Vallance, Lord Sharma and Alexandra Jones, is the creation of the VTF in early 2020, and departmental support and oversight of the VTF's programme throughout 2020. Despite this emphasis on the first few months of the pandemic, it will be important for this Module, and indeed other Modules, to consider the full course of the pandemic and the different lessons that can be drawn at each juncture.

9. The responsibility for the discovery, development, manufacturing and deployment of vaccines and therapeutics does not, and should not, sit within the remit of the GCSA's role. Indeed, none of the six main issues identified in the outline scope for Module 4 fell within the GCSA's role and responsibilities. The expertise on these matters lay within the Department for Health and Social Care (DHSC) and its scientists, medics, advisers, specialist executive agencies and arm's length bodies. Lord Vallance's involvement stemmed largely from his professional background in medicine, pharmacology and industry. One cannot rely on having this specialist expertise within role of the GCSA in the future, nor should this be expected or assumed. The role of the GCSA is to advise on all scientific areas across government and the challenges the country may face, whether that be pandemics, AI or the climate crisis.

10. In January and February 2020, Lord Vallance's focus was on gathering knowledge of the virus and the work being done to combat it, coordinating funding mechanisms to allow for the establishment of early and effective clinical trials, and identifying gaps and vulnerabilities that needed addressing before significant work was underway to discover, develop and manufacture vaccines and therapeutics. To this end, before the end of January 2020, Lord Vallance had already begun discussing the potential of mRNA vaccine technology with key individuals in academia, industry and government, and set up meetings with research funders with the aim of ensuring that research programmes on vaccines and other areas were rapidly funded, coordinated and delivered. Lord Vallance also sought to understand the vaccines and therapeutics landscape globally by encouraging work to that end from key individuals in industry and academia, most notably those from the Coalition for Epidemic Preparedness Innovations (CEPI).

11. By March 2020, several active research projects were underway and a £30m "fighting fund" was approved by the Government at the request of Lord Vallance and the CMO, a proportion of which was released to fund vaccine

development work at the University of Oxford. With some research and development efforts in motion and equipped with a comprehensive understanding of the global and UK landscape of vaccine development and manufacturing capabilities - particularly due to the brilliant work of CEPI - Lord Vallance saw an urgent need for a dedicated task force to coordinate work on the discovery, development, manufacturing and procurement of vaccines in the UK.

12. By this time, it was clear that DHSC did not have the capacity to meet the acute and immediate demands of the evolving pandemic alongside work on developing vaccines. Lord Vallance took the view that a body with the sole focus of vaccine discovery, development, manufacturing and procurement needed to be established, and asked Alexandra Jones to support him in setting this up.

13. Initially, an Expert Advisory Board (EAB) was assembled in March 2020 by Lord Vallance and Alexandra Jones with the aim of providing expertise to guide DHSC and BEIS through the entire process. The EAB comprised of key individuals across industry, academia, and the life sciences sector including Dr Richard Hatchett (CEPI), Dr Dame June Raine (MHRA), Professor Dame Sarah Gilbert (University of Oxford) and Dame Kate Bingham (SV Health Investors). The EAB was the precursor to the VTF, and it first met formally on 3 April 2020, with Lord Vallance acting as Chair. The EAB anticipated many of the challenges and risks – as well as opportunities - that would be faced in the process of developing and delivering a vaccine. The innovative involvement of the regulatory body responsible for licensing potential vaccines, the MHRA, as part of the EAB was to prove prescient and important in the UK's vaccine development programme.

14. It rapidly became clear to Lord Vallance and others within GOS and BEIS that the EAB needed a dedicated operational structure with decision making authority, supported by a team within Whitehall with ministerial oversight, to

make real progress. This resulted in the development of the Programme Board, which worked in parallel alongside the EAB, and was led by Alexandra Jones.

15. This evolving structure, and the rapid progress of efforts in vaccine discovery and development, led to the proposal for, and then the creation of, the formal VTF.

16. In late March 2020, Lord Vallance took steps to gain support for, and approval of, the VTF across Government. It was agreed that BEIS, with its strong existing links to industry including life sciences, would lead cross-government work on vaccines. Lord Sharma welcomed this approach, approved the creation of the VTF and tasked officials to support its work. Lord Sharma took overall ministerial lead on vaccines strategy and Alexandra Jones initially led the Whitehall team responsible for the VTF and appointed the initial taskforce. Key appointments included Dame Kate Bingham, Ian McCubbin, and Nick Elliott.

17. Meanwhile, throughout March and April 2020, Lord Vallance worked with others to identify and build relationships with those developing potential vaccine candidates both in industry and research, most notably with the University of Oxford and AstraZeneca, Moderna and Pfizer. By the end of April 2020, the Oxford/AstraZeneca deal had been struck and the UK had promising relationships developing with Moderna and other key partners in industry and manufacturing.

18. The structure of the VTF drew heavily on the seven guiding principles set out in the "Principles for running a successful mission," a document produced as part of the 2019 Science Capability Review, which had been initiated by Lord Vallance as GCSA. Importantly, at its inception the VTF had a single, straightforward objective: to get a Covid-19 vaccine available for the relevant part of the UK population by the end of the year, if possible. Despite a degree of overlap between work on developing and manufacturing vaccines and therapeutics, it was decided that, to avoid compromising the singular objective

of the VTF and spreading leaders too thinly, work on therapeutics should lie elsewhere.

19. Once the VTF was formally established, its role and scope were agreed, and Dame Kate Bingham was appointed on 5 May 2020, both Alexandra Jones and Lord Vallance limited their involvement in the work of the VTF to providing *ad hoc* advice on specific matters when asked. Others providing evidence to this Module, including UKHSA (who, along with DSIT and DHSC, took on shared legacy responsibilities for the VTF), Dame Kate Bingham and Dr Clive Dix, will be better placed to comment on the activities and governance of the VTF from May 2020 onwards.

20. In August 2020, the Ministerial Investment Panel was established with the aim of establishing a single structure to consider the business cases for investments within the VTF programme, whilst maintaining the necessary assurance and control. The development of the Panel, which met to clear decisions above a certain value, significantly sped up decision-making. The Panel was chaired by Lord Sharma from its inception to 31 December 2020, shortly before he left his post in early January 2021.

21. On 2 December 2020, the MHRA approved the first Covid-19 vaccine for use in the UK and five days later 91-year-old Margaret Keenan became the first person in the world to receive a Covid-19 vaccination outside the setting of a clinical trial. The VTF had met its primary objective: to have a Covid-19 vaccination available for the UK population by the end of 2020. This was a singular and unprecedented achievement, resulting from the diligence and expertise of the scientists, technicians and clinicians involved, supported by the VTF, the MHRA, other government departments and agencies and, critically, members of the public who volunteered to participate in clinical trials. At the start of the pandemic there could be no guarantee that an effective vaccine would be developed at all, let alone prepared for use within twelve months. Millions of lives have been saved worldwide as a result. Familiarity with the

success of the vaccines programme should not dull the extraordinary achievement that it represents.

22. There are a number of factors that were key to the success of the VTF, and which will be applicable to similar efforts in the future:

    a. Content experts were brought in rapidly: members of the VTF (both external and internal to Government) had deep experience across a variety of disciplines and sectors, such as Dame Kate Bingham with experience in the Life Sciences Sector, Nick Elliot (civil servant within the Ministry of Defence and a former senior army officer with experience of project management), Ian McCubbin (pharmaceuticals manufacturing expert), and Madelaine McTernan (civil servant and former senior investment banker with experience of commercial negotiations). This unique public-private collaboration involving scientists, industry and Government permitted rapid and informed decision-making on vaccine selection, negotiations, manufacturing and delivery.

    b. An 'at-risk' investment mindset was taken: the VTF took a portfolio approach, understanding that most vaccine candidates would not turn out to be a success, and of those that were safe and effective, some would take longer than others to be available for deployment. The vaccines landscape was fundamentally different by the end of the vaccine rollout. Several vaccines had been authorised, mRNA had been proven as a technology, and new facilities had been developed. Not everything in the portfolio turned out to be needed. This portfolio approach, with strong mitigations, is not usual in Government but proved an essential model to deal with the inherent uncertainties of innovation.

c. Procurement was part of the process: from the beginning, research and development (R&D) investments and risks were linked to procurement and to manufacturing.

d. Single objective: the VTF had a mission-based approach and its single objective was clear and measurable.

e. Single point of accountability: the VTF had a full-time, expert leader, with requisite powers and dexterity to make quick decisions. That said, the VTF was not independent from Government; it was accountable and reported to ministers, which provided an important degree of scrutiny.

f. Private sector engagement was key: the private sector was attracted with a suite of offerings from regulatory engagement to infrastructure offers (clinical trials and manufacturing), to risk sharing.

g. Legacy: long term legacy was built into the thinking from the beginning. This meant that longer term strategic investments could be made as part of the process and companies felt some stronger sense of stability and certainty.

23. The above factors meant that the VTF worked at significant pace to ensure access to a suite of vaccine candidates. As noted by the Wellcome Trust, vaccine development (if successful) typically takes a minimum of 10 years. The VTF and BEIS worked on an accelerated timetable to make a vaccine available within a year, and the vaccine was deployed just eight months after the formation of the VTF. Quick decisions, taken at the right time, were handled well through the governance structures of the VTF, and later also by the creation of the Ministerial Investment Panel.

24. The race to discover, develop, and manufacture a vaccine for use across the UK population is rightly viewed as a global success story, and the VTF had a significant part to play in that. While it is natural for the Inquiry to focus on where the UK's pandemic preparedness and response fell short, it is equally as important to draw lessons from innovative ways of working in the hope that they can be embedded in 'peace time' and replicated in future emergencies.

25. DSIT has reflected on the successes of the VTF and is seeking to use mission-type approaches and support closer working between Government, academia and industry as well as the third sector and the NHS. For example, the OLS "Healthcare Goals" which stemmed from the UK Life Sciences Vision published in July 2021 (and were originally termed "Healthcare Missions") aim to make progress in a number of disease areas, by advancing early disease prevention, diagnosis, treatment, monitoring, and developing breakthrough products and technologies to save lives. DSIT also sponsors the Advanced Research and Invention Agency (ARIA), which has been given a high degree of flexibility and autonomy to pursue ambitious scientific and technical breakthroughs even if there may be a high risk of failure.

26. A fundamental reason for the success of the VTF was that those responsible for it were prepared to fail. Historically, success rates for developing vaccines for viral infectious diseases are low, with one study finding a 10% probability of progressing from phase 2 trials to licensing within 10 years. A lesson to be drawn is that innovation in life sciences comes with risk and that this needs to be acknowledged rationally and sensibly, if an environment conducive to such vital innovation is to be developed and maintained. Part of that is to encourage and embed Government's use of risk mitigation strategies in such circumstances, drawing on the example of the portfolio approach to vaccine development and procurement. In a future pandemic, a successful response is likely to require a similar willingness to take informed decisions on expending time, money and resource when the prospects of success are uncertain.

Therapeutics

27. The involvement of DSIT in the field of therapeutics was limited as responsibilities for the area lay elsewhere, notably with DHSC, the NHS, and the relevant advisory groups and regulatory bodies. However, the research, development, and deployment of therapeutics was of central importance to the UK's response to Covid-19, and to the UK's contribution to the global response.

28. Most notable was the UK's contribution through the provision of large-scale clinical trials, facilitated by the use made of the UK's National Health Service. During the pandemic, a decision was made to prioritise the Phase 3 RECOVERY trial, and suspend others, to focus resource into establishing and managing the trial. The Chair may feel that this was the right approach, despite the inevitable consequence of delay to other studies. What is unarguable, is that due to the efforts of clinicians, healthcare workers and administrators, and the tens of thousands of patients who volunteered to participate in the trials, the UK provided high quality data that led to the first rapid identification and deployment of effective therapeutic responses to Covid-19 that saved lives around the world. The use of the low-cost and widely available steroidal drug dexamethasone alone has been credited with saving a million lives.[1]

29. RECOVERY was not just about dexamethasone. It identified other effective treatments and, equally importantly, it demonstrated that other treatments such as hydroxychloroquine were not effective, thereby preventing their inappropriate use and the potentially harmful consequences that might have followed. Such an approach is typical of the UK's tradition of evidence-based medicine and is the correct one to adopt even in the extreme pressures of a pandemic.

[1] As set out in the 100 Days Mission report dated 12 June 2021 at p.11. Publicly available at https://assets.publishing.service.gov.uk/media/60c20a14e90e07438ee5748f/100_Days_Mission_to_respond_to_future_pandemic_threats__3_.pdf

30. Developing effective and rigorous clinical studies at a national scale poses immensely challenging practical issues, from data sharing to consistency of protocols and reporting. There is also a need to decisions to be taken on where efforts for patient recruitment should be focussed. The concentration, for good reason, on Phase 3 clinical trials in the UK meant that fewer patients and resources were available for the Phase 2 ACCORD trials, which led to a revised approach to the structure of the trials. A balance must always be struck between work on Phase 1 and 2 trials (which are important in developing new therapeutics), and Phase 3 and 4 trials (at which phase the most promising medicines or repurposed therapeutics are studied at large scale). During this pandemic, the UK was stronger on Phase 3 and 4 trials, reflecting work on therapeutics that was more focussed on repurposed drugs than new drugs. That prioritisation was understandable given the pressing need for effective treatments to be made available as soon as possible, and it led to the significant successes of the RECOVERY trial. It is again important to draw the lesson for future pandemics that such focus will, inevitably, have consequences for the resource available for other clinical trials.

31. The VTF had some responsibilities in relation to prophylactic antibodies, as the approaches to discovering and making antibodies are related to the scientific issues which arise in relation to vaccines. The use of prophylactic antibodies was principally considered before the advent of an effective vaccine, at which point the relevant bodies naturally decided against significant procurement, although these antibodies do have a role in treatment and in prophylaxis in certain high-risk groups.

32. Finally, the National Core Studies (NCS) Programme, in particular the studies on clinical infrastructure trials and immunity, supported efforts to find effective therapeutics.

Lessons for the future

33. DSIT shares the Inquiry's intention to focus on which lessons may be learned from the Covid-19 pandemic. The legacy of the UK's response is important, and successes must not be taken for granted. Innovations in academic, industry, and government, about which the Inquiry will hear in detail in the course of this Module, must be embedded within Government to ensure utility for the future. As set out previously, it was a matter of chance that the background of Lord Vallance was in medicine and in pharmacology and included experience in industry; the GCSA could come from a background in any scientific discipline. It is vital that the Government can access the right expertise from the outset of any future pandemic, and that expertise will not be found in Government alone.

34. Preparedness and planning for vaccines and therapeutics must also be a global endeavour, and successes will need to be replicated globally. To that end, it is vital to implement the recommendations of the 100DM. While Lord Vallance no longer serves as co-chair, the group remains led by a collection of worldwide experts, and aims to provide a roadmap on how to develop and deploy safe, reliable, and effective diagnostics, therapeutics, and vaccines within the first 100 days of a pandemic.

35. The development of diagnostics, vaccines, and therapeutics for any new pathogen involves risk. It can remain far from certain which, if any, vaccine candidate will succeed for a significant period of time. Sometimes, of course, a vaccine is simply not identified. No effective vaccine for HIV has yet been approved, more than 40 years after the virus was discovered as the cause of AIDS.

36. In the Covid-19 response, the VTF's portfolio approach was critical as it was not possible to know from the outset which (if any) vaccines would be safe and effective. The success of the VTF lay in its adoption of a clear and urgent national mission, and it represented a successful public-private collaboration

between scientists, industry, and Government, with governance structures which allowed for effective decision-making.

37. Managed and mitigated risk taking, including financial risk, must be supported. However, the uncertainty inherent in the effort meant that it was important to invest in therapeutics, and other counter measures, in light of the possibility that attempts to identify a vaccine would not succeed.

38. Looking to the future, sufficient infrastructure must exist prior to the next pandemic and be capable of withstanding the work required. The experience of Covid-19 has demonstrated that large scale clinical trials are essential. These must be operational as soon as possible from the onset of a pandemic. The swift commencement of large-scale trials is necessary both to reach conclusions with a sufficient degree of scientific confidence, and to avoid delays in reaching those conclusions. It is noteworthy that many hundreds and even thousands of clinical trials around the world were too small or poorly designed to give any reliable conclusions. RECOVERY by contrast did. Each trial requires sufficient resource, and a small number of well-designed large trials is preferable to several underpowered attempts.

39. That task is made significantly easier by a strong research infrastructure, which can be repurposed during a pandemic. It is at least difficult, and sometimes impossible, quickly to establish the structures which enable research to be undertaken effectively. The research infrastructure must be maintained and supported between pandemics, and in a position to be repurposed at the onset of the new emergency. It is critical that such infrastructure has the benefit of access to the appropriate data streams, which must be interoperable. The need for robust and adequate data streams was shown clearly in relation to the use of electronic health records to assess the effects of treatment and vaccines. Data capabilities which currently exist must be maintained and developed further in order to put the UK in the best position for the next pandemic. To this end,

DSIT is creating a National Data Library to provide researchers and businesses simple, ethical and secure access to public data assets.

40. The same is true of R&D and manufacturing. It is either slow and difficult, or even impossible, to establish the necessary infrastructure from scratch during an emergency. In this pandemic, the response benefitted from research done on coronaviruses and various vaccine platforms prior to the outbreak of Covid-19. A key recommendation of the 100DM was that it is necessary to prepare prototype diagnostics, therapeutics, and vaccines, to treat pathogen classes of the greatest pandemic potential. These prototypes could then be adapted quickly in order to respond to a novel specific pathogen threat. This requires collaboration between government, academic and industry. The Covid-19 pandemic showed that the UK had a diminished industrial base for certain types of manufacturing. While the UK was fortunate that companies were willing to invest in manufacturing capability, that cannot be assumed for the next pandemic. It is important to identify which industrial sectors and supply chains are needed, and invest in those sectors, now. The recent announcement in the Autumn 2024 budget of £520m in funding is an important component of increasing health resilience by strengthening manufacturing capacity and capability.

41. We must also look ahead and agree in advance 'rules of the road' so that no time is wasted when next emergency transpires. The recommendations of the 100DM are that such agreements should include guidance on supply chains, indemnification, data sharing, as well as a system to share data and biological samples, and use standardised assays. The international institutions which exist between pandemics must be ready to adapt, relying on the use of best practice established during that time. There should be established networked manufacturing and clinical trials which are ready to be activated, automatic financing for diagnostics, therapeutics, and vaccines, and streamlined regulatory approval processes. Those developments would enable rapid

prioritisation, speed and scale, and equitable access to diagnostics, therapeutics, and vaccines.

Conclusion

42. The role of DSIT, GOS and the GCSA in matters relevant to Module 4 was limited, but important. At its heart lay two functions. The first was to help identify, encourage, co-ordinate and direct the extraordinary talents of the UK science base which were to prove so vital in the global response to Covid-19. The second was to assist Government in making the best use of that science base. DSIT wishes to pay tribute to all of those who worked so hard and so effectively to produce the vaccines and therapeutics that saved so many lives and so many livelihoods. There will be another pandemic, which will require similar efforts. Those efforts will rest on the same science base and the effectiveness of the response will correlate closely with its strength.