Witness Name: Paul Schreier,
Chief Executive Officer (Interim),
for and on behalf of the Wellcome Trust Limited,
as trustee of Wellcome Trust
Statement No.: M1/WT/01
Exhibits: PS/01, PS/02, PS/03, PS/04, PS/05,
PS/06, PS/07, PS/08, PS/09
Dated: 25/05/2023

UK COVID-19 INQUIRY

WITNESS STATEMENT OF THE WELLCOME TRUST LIMITED AS TRUSTEE OF WELLCOME TRUST

The Wellcome Trust Limited, a company limited by guarantee registered in England (company number 2711000) as Trustee of Wellcome Trust a charity registered in England and Wales (charity number 210183), will say as follows: -

Introduction

1. Wellcome Trust (Wellcome) has been asked by the Inquiry to answer various questions relating to the period between:
   - 11 June 2009, which is when the World Health Organization ("WHO") announced that the scientific criteria for an influenza pandemic had been met for what became known as the 2009-2010 Swine Flu Pandemic; and
   - 21 January 2020, which is the date on which the WHO published its 'Novel Coronavirus (2019-nCoV) Situation Report - 1',

   as well as the period thereafter.

2. The Inquiry's questions have directed our response and where appropriate we have used the specific questions asked by the Inquiry as headings in our response.

3. It is important to note that during the time frame referred to by the Inquiry Wellcome has grown and changed significantly as an organisation, and recent staff turnover means

that several key Wellcome personnel who were employed before and during the Covid-19 pandemic are no longer at Wellcome. In particular, Wellcome's former Director Sir Jeremy Farrar has now left and taken up a new role at the World Health Organisation; Sir Jeremy was a member of the Government's scientific advisory group SAGE during the pandemic, in an independent and personal capacity, and as such he may well have material and direct experience and evidence that is pertinent to the Inquiry, which Wellcome does not have. We understand that Sir Jeremy has provided evidence to the Inquiry separately. We cannot, and have not sought to, cover the same ground as we imagine Sir Jeremy will cover, and have focussed our response instead on our general policy observations in response to the Inquiry's questions; these have been contributed to by various teams across Wellcome, and represent an organisational opinion rather than the expertise of any one individual. By doing this, we hope to support the Inquiry in achieving its aims.

History and overview

4. Wellcome is a UK-based charitable foundation which supports science to advance solutions to urgent global health challenges. Wellcome was founded in 1936, upon the death of Sir Henry Wellcome.

5. Wellcome's mission is funded through our endowment and investment portfolio (which currently stands at £38 billion). Our charitable expenditure last year was £1.4 billion, and Wellcome's board is committed to spending £16 billion over the decade from 2022/23 to 2032/33.

Legal and Governance

6. Wellcome is a charity registered in England and Wales (charity registration number: 210183,). The sole trustee of the Wellcome Trust is The Wellcome Trust Limited, a company limited by guarantee registered in England (company number 2711000) (Wellcome).

7. Wellcome's Board of Governors guides and oversees Wellcome in achieving our mission. Wellcome's day-to-day activities are managed by a leadership team made up of senior managers from across the organisation.

8. Paul Schreier became Chief Executive Officer (Interim) in February 2023, taking up post following the end of term of Sir Jeremy, who was Director of Wellcome between 2013 and February 2023.

Issues and/or groups of people which Wellcome supports and/or represents and the work Wellcome conducts in relation to this.

9. Our research spend and advocacy is focused across four global programmes to support science-based solutions for health and well-being: discovery research into life, health and wellbeing; the catastrophic health impacts of the climate crisis; escalating threats from infectious diseases; and mental health problems holding millions of people back. Wellcome has an international focus across our programmes. Wellcome works with partners across research, industry, civil society and governments globally to achieve our goals.

10. In Infectious Disease our work currently, and over the past decade, has included working with partners to support strengthening of global epidemic and pandemic preparedness, for example our programmes on Ebola and Zika. This work has placed a particular focus on activities to support research and development (R&D) for known diseases with epidemic potential (such as Ebola), as well as building capabilities to rapidly deliver new tools (particularly vaccines) for novel epidemics and pandemics. This has included work to develop and fund international collaborations such as the Coalition for Epidemic Preparedness Innovations (CEPI), launched in 2017.

Wellcome's views in relation to the general state of the UK's emergency and pandemic planning, preparedness and resilience, at the time the Covid-19 pandemic struck

11. Given our mission, our historical and current focus is on the research and development (R&D) response to epidemics and pandemics, and we have been international in our outlook to this work.

12. In the years prior to the Covid pandemic, the UK Government had shown a high-level recognition of the significant and growing level of threat posed by infectious disease outbreaks. Between 2008 and 2020, the Government's biennial National Risk Register, in our view, rightly, identified that epidemics and pandemics posed major, wide-ranging threats to the UK and international community. This level of risk was reflected in several key commitments made by the UK, often using official development assistance (ODA)

funds to support global efforts to improve pandemic and epidemic preparedness. In turn, the UK and its research institutions emerged as world-leaders in certain fields of preparedness and response, such as disease modelling. The UK was identified as the second best-prepared country in the world to respond to epidemics or pandemics by the respected Global Health Security (GHS) Index in 2019, albeit against a backdrop of inadequate overall levels of preparedness globally.

13. However, the UK's focus on global health appears to have waned in the run up to 2020, and in key areas there seemed to be a disconnect between the assessed level of risk of an epidemic or pandemic, and investments in preparedness and response. In particular, we did not see evidence of the UK Government acting on the lessons from earlier, lower-level outbreaks – such as the H1N1 swine flu pandemic in 2009 and West African Ebola outbreak in 2014. In our view, the UK's response to Covid was weaker as a result of these opportunities being missed.

14. Our response focuses on three areas of UK preparedness:

15. **i. Ability to mobilise clinical trials for vaccines and therapeutics during an outbreak.** The RECOVERY trial was a highlight of the UK's pandemic response, utilising the scale of the NHS and agility of regulators to test treatments. However, the fact that this trial had to be set up during the pandemic shows a lack of preparedness. During a disease outbreak it is essential that effective countermeasures, particularly vaccines and therapeutics, can be developed and deployed quickly and safely. This depends on being able to rapidly establish robust clinical trials to develop evidence of safety and efficacy of either new or existing products. Earlier outbreaks have made clear the need to prepare for clinical trials that can quickly leverage the scale of the NHS in an outbreak, or establish research in other global settings, for example:

- Following the 2009 swine flu pandemic, and as set out in more detail in paragraph 24 below, it was recognised that an opportunity had been missed to systematically establish an evidence base about the efficacy of antiviral treatments such as oseltamivir (Tamiflu.)
- By contrast, the West African Ebola epidemic of 2014 provided evidence of the challenge – but also the value – of quickly establishing clinical trials in the heat of an outbreak to test new vaccines.

16. **ii. Supporting vaccine development and dose sharing for a more effective global response.** The development of multiple safe, effective vaccines within 12 months of the

start of the pandemic was a critical success factor in efforts to bring it under control. The UK Government played a key role in supporting rapid R&D efforts initiated in early 2020, and had made some important investments in vaccine R&D before the pandemic. However, the government's pre-2020 approach to supporting R&D into vaccines, therapeutics, and other tools to respond to epidemics and pandemics was not, in our view, comprehensive, and could have had greater impact.

17. Once vaccines were available, we think that the UK Government did not do enough to ensure a globally equitable approach to dose sharing. This ultimately increased the risk to UK citizens and prolonged the acute phase of the pandemic, as it delayed efforts to bring Covid under control around the world. The 2009 H1N1 swine flu pandemic demonstrated the likelihood of an 'arms race' of vaccine procurement emerging, with high-income countries moving rapidly to secure and protect supplies of vaccines for their own populations, to the detriment of low- and middle-income countries (LMICs). The Covid pandemic repeated this pattern. Whilst we believe it is absolutely right that the UK Government wanted to prioritise a domestic vaccine deployment to at-risk individuals in its own population, we did not see adequate consideration being given either in pre-pandemic planning or response to the importance of securing an adequate supply of vaccines to LMICs and enabling their deployment.

18. **iii. The use of scientific advice to government.** The UK Government's use of scientific and technical advice during the Covid response frequently did not appear to adhere to its own published principles. Despite the Government's assertions that it was "following the science" in its response, in our view there appeared to be a consistent lack of transparency about how scientific advice was informing policy decisions, particularly where these deviated from the scientific advice and evidence available. This ultimately contributed to a damaging politicisation of science during the pandemic, simultaneously undermining public confidence in both the scientific community advising government, and the government response itself. The UK has well-established Principles of Scientific Advice to Government, published in their current form in 2010. These are centred on having clear roles and responsibilities, the independence of scientific advisers and their advice, and the need for transparency and openness. These principles apply as much in an emergency as they do during 'business as usual', and are reflected in the similarly well-established operating framework for the Scientific Advisory Group for Emergencies (SAGE). However, it is not clear to what extent these principles were followed.

Wellcome's views on the extent to which the UK's emergency and pandemic planning and preparedness adequately took into account pre-existing inequalities and vulnerabilities of different groups in society

19. Wellcome's work relevant to pandemic planning and preparedness has historically not specifically considered issues of inequalities and vulnerable groups within the UK.

What was done adequately in relation to the UK's emergency and pandemic planning, preparedness and resilience

20. As mentioned above, repeated iterations of the National Risk Register between 2008 and 2020 highlighted that pandemic influenza, or non-pandemic disease outbreaks, posed major and wide-ranging threats to the UK and the global community. The UK's UK Biological Security Strategy, published in 2018, rightly highlighted that the risk associated with emerging infectious disease was rising on account of underlying factors such as climate change. Since these documents represented the Government's overarching assessment of major risks to UK interests, the inclusion of pandemics and disease outbreaks as top-tier risks provided a clear basis for the Government to prioritise measures to improve the UK's ability to detect and respond to new disease outbreaks.

21. Several significant research commitments by the UK Government in the years preceding the pandemic reflect this understanding of the risk of disease outbreaks and the need to strengthen global capabilities to respond to them. Examples of these commitments include the following.

- The co-funding by the Medical Research Council (MRC) and then Department for International Development (DfID), with the Gates Foundation and Wellcome, of the International Severe Acute Respiratory and emerging Infections Consortium (ISARIC), targeting global research efforts on responding to epidemic outbreaks.
- Active UK participation in global consortia focused on coordination in preparedness and response, including GLOPID-R (the Global Research Collaboration for Infectious Disease Preparedness) and WHO global coordinating mechanisms such as the R&D Blueprint.
- In 2016, the inception of the UK Vaccines Network, bringing together UK experts in vaccinology and epidemiology, along with funders, industry and government partners.
- The establishment in 2018 of the Vaccine Manufacturing Innovation Centre (VMIC) to support vaccine research in to new and re-emerging disease threats.

22. Investments of this type helped the UK to assume a global leadership role in some aspects of epidemic and pandemic preparedness. They enabled the UK to play a significant part in efforts to mobilise global responses to MERS (Middle East Respiratory Syndrome) in 2012 and the West African Ebola epidemic in 2014, and to respond effectively to the small number of infections imported to the UK. It is therefore clear that the research investments made by the UK Government to strengthen global response epidemic and pandemic response efforts were laudable in their intent and were individually impactful. However, in our view, they collectively did not represent a comprehensive package of activities that were proportionate to the known level of risk.

What could have been done better in relation to the UK's emergency and pandemic planning, preparedness and resilience

23. We are highlighting three notable areas, based on Wellcome's experiences in this field, in which we believe that the UK's epidemic and pandemic preparedness efforts fell significantly short of what was foreseeably needed. These are all areas in which, in our opinion, there was a failure to learn lessons from recent outbreaks.

24. **i. There were inadequate plans in place for the rapid mobilisation of clinical trials to explore new treatments.** As highlighted above, the UK's RECOVERY trial can be considered a significant success of the Covid response, enrolling patients at an unprecedented pace and scale across the NHS and generating invaluable insights into the efficacy of treatments such as dexamethasone. However, this approach to delivering a large-scale clinical trial for therapeutics was not a central part of the UK's pandemic response plan, and RECOVERY was initiated from outside of government, working in partnership with regulators and NHS provider organisations. This lack of planning was despite the lessons of the 2009 H1N1 pandemic, which showed that there was inadequate evidence about the role and efficacy of antiviral treatments. The need to close this gap, including with plans to research efforts during any future outbreak, was highlighted in work carried out by Wellcome and the Academy of Medical Sciences [Exhibit PS/01 - INQ000190689], with involvement from the Department of Health, in 2015. We see this as a lack of focus more generally on the role of therapeutics, as opposed to vaccines, in countering a pandemic.

25. **ii. The UK's efforts to strengthen vaccine research prior to 2020 were valuable, but in our view at lower scale than was required, and not fully integrated with global**

activities. The Government rightly recognised that vaccine R&D was a key plank of the ability to respond globally to a pandemic or epidemic, and made some notable investments in the UK and internationally to support vital R&D activity. However, we believe it could have done more in the years leading up to 2020 to maximise the impact of these investments in the development of medical countermeasures.

26. The 2014 Ebola epidemic showed that the UK lacked the capacity to rapidly develop new vaccines to respond to new outbreaks, particularly for high-risk pathogens. This was partially addressed through the founding of the VMIC in 2018, and the allocation of significant funding (>£100m) to the UK Vaccine Network. This enabled investments that proved vital during Covid such as support for Oxford University's research into MERS, which yielded the Oxford/AstraZeneca Covid vaccine. Very early on in the pandemic, the UK Government also took commendable steps to significantly increase investment in urgent vaccine research, with further direct support to the Oxford/AstraZeneca team as well as a substantial commitment to CEPI, the Coalition for Epidemic Preparedness Innovations.
27. However, the UK had not joined CEPI until 2019, two years after its launch, initially committing just £10m compared to initial joint commitments totalling $460m by Wellcome, the Gates Foundation, and the governments of Germany, Japan and Norway. Where the Government did make complementary investments to strengthen vaccine development efforts, such as the founding of the VMIC and creation of the UK Vaccine Network, we don't think these were always comprehensive in their approach – for instance by placing limited emphasis on influenza. (We will address the decision by the government in 2022 to sell VMIC in later answers.) Additionally, we would have liked to have seen more done to ensure that these investments were well aligned with international efforts such as CEPI, and to ensure a wider uplift in global vaccine R&D capability and manufacturing capacity.

28. **iii. There appeared to be a lack of focus in the Government's planning on the need to ensure equitable access to vaccines globally, as well as meeting domestic needs.** In its response, the government understandably placed an emphasis on securing UK supplies of Covid vaccines as soon as they were available. In pursuing this goal, the Vaccine Taskforce was commendably successful. The decision to support multiple platforms, and diversify orders across a range of vaccine candidates while still in development, ensured the UK ended up with significantly more doses than it needed to offer vaccination to its citizens.
29. However, within these vaccine procurement efforts, we think that greater consideration should have been given to the importance of ensuring an equitable global supply of

vaccines, with the UK part of a collective failure by high-income countries to support LMICs in vaccinating their at-risk populations. We believe greater emphasis should have been placed on either bilateral or multilateral efforts to support the supply and deployment of vaccines in low- and middle-income countries. This apparent lack of consideration of equitable global supply in the UK's pandemic plans (like those of other high-income countries) led to significant avoidable suffering in those poorer countries unable to access vaccines for their populations. But it was also ultimately to the detriment of the UK population, as it delayed efforts to bring Covid under control globally and prolonged the acute phase of the pandemic.

30. The 2009 H1N1 pandemic had shown the likelihood of an 'arms race' of vaccine procurement by competing national governments. The UK Government's highly assertive (and effective) approach to securing an early supply of multiple Covid vaccines suggests that they understood this and had factored it into their pandemic planning. It appeared that the UK government did not think more widely in these plans than the need to secure a domestic supply, which was a short-sighted view of how medical countermeasures would need to be deployed globally to bring a pandemic under control.
31. Global efforts did emerge during the pandemic to address collective shortcomings in securing adequate supplies of vaccines and other countermeasures for LMICs, such as the WHO's Covax initiative. The UK Government could have more actively exercised global leadership to support and engage with these efforts, and make more of the spare vaccine doses procured by the UK available to LMICs, sooner. While the UK Government did use its presidency of the G7 to put dose-sharing on the agenda for the Carbis Bay Leaders' Summit in June 2021, the commitments by the UK and the rest of the G7 fell far short of what was needed, providing only enough doses to vaccinate 10% of LMIC populations over the following 12 months.

Wellcome's engagement with government, and communication of its views to those in government, on the state of the UK's emergency and pandemic planning, preparedness and resilience and lessons learned:

a. prior to 21 January 2020; and

b. after 21 January 2020.

32. Prior to 21 January 2020 Wellcome engaged with the UK Government on several issues connected to global pandemic preparedness and shared concerns on the state of readiness. A significant proportion of these interactions were as a funder and partner, rather than direct issue advocacy. After 21 January 2020 Wellcome also engaged with

the UK Government in relation to its role in the international response. Below are several examples of this engagement in those areas that we prioritised.

33. **i. Ability to mobilise clinical trials for vaccines and therapeutics during an outbreak.**

34. • **Foundational work on clinical trials for tools to control epidemics.** Prior to the pandemic, Wellcome co-funded a range of Zika and Yellow Fever research efforts with the UK Government (DfID), leading to the establishment in 2018 of the Joint Initiative for Research on Epidemic Preparedness and Response (JIREP). Wellcome has also collaborated with UK Government partners on research into outbreak responses, with notable investments made on Ebola in the Democratic Republic of Congo and Rwanda (2018-2019), and during the Covid response. This joint funding also supported the International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC) as a central hub to support international research. Wellcome has also advocated for better preparedness for clinical trials in epidemics. This work ultimately contributed to the establishment of the RECOVERY trial in the UK, as well as the trial's international extension (through the Covid Therapeutics Accelerator).

35. **ii. Supporting vaccine development and dose sharing for a more effective global response.**

36. • **Vaccine development.** Wellcome supported the foundation of CEPI with several partners in 2017, and the UK Government joined in 2019 with an initial £10m contribution. Since its inception, we have engaged with the UK on CEPI's role to develop critical interventions such as vaccines to improve preparedness and the response to epidemics. This was primarily considering global preparedness and the UK's role within that, but these efforts to improve international readiness also enhance the UK's global health security.

37. In 2022, the UK Government hosted an international summit in support of CEPI's replenishment and the 100-Day Mission to develop new tools more quickly to tackle pandemics. During this, c.$1.5bn was pledged to CEPI by multiple donors to support its five-year plan. This included a £160m pledge from the UK Government, while Wellcome had earlier committed a further $150m.

38. The engagement with the UK Government over CEPI and its replenishment was constructive and led primarily by the FCDO. In addition to the respective funding announcements, the UK Government mobilised its diplomatic networks to support CEPI's efforts as well as hosting the conference itself. In relation to influenza vaccine

development, Wellcome asked for the UK to engage in the Global Funders Consortium, but while they attended the first meeting, their input has been relatively small into the global discussion.

39. We have also advocated for the UK Government to engage in efforts to develop a broadly protective influenza vaccine (i.e., one that is not limited to a specific strain or strains.) In 2017, a global consortium of funders was created to consider this and improve current seasonal influenza vaccines. The DHSC engaged in early discussions, but it has been unclear how prominent influenza vaccine development has featured as a research priority for the UK Government. For example, influenza is not considered part of the diseases of interest for the UK Vaccine Network.

40. ● **Vaccine manufacturing.** The Vaccine Manufacturing Innovation Centre (VMIC) was established from the learnings generated after the West Africa Ebola epidemic in 2014-2015. Wellcome committed to invest with the UK Government (through Innovate UK) in a Centre that would enable the UK to manufacture vaccines for emerging infectious diseases. Unfortunately, the establishment of the Centre did not happen in time to be utilised in the Covid-19 response, although the expertise available was involved in the response. We were disappointed when we became aware in 2022 that the UK government no longer wished to invest in VMIC on the basis that they regarded that domestic manufacturing capability was not a weakness during Covid-19.

41. ● **Access to Covid Tools Accelerator (ACT-A) and dose sharing** - This global effort was established during the pandemic in 2020. It brought together a wide range of international stakeholders, including Wellcome, to accelerate and better coordinate the efforts to develop and provide access to vaccines, therapeutics, diagnostics, and other interventions. The UK Government was one of several that provided funding to support this part of the international response. One issue that Wellcome advocated for was equitable access to vaccines internationally, including through rapid dose sharing when there was a lack of supply. We specifically called for the creation of a framework that the G7 could agree, to accelerate donations with greater collective responsibility. We also called for the G7 to donate and deliver at least one billion doses as soon as possible in 2021, as a starting point to be built on for the larger global need. We published two policy papers in October 2021 – one covering proposals on how the G20 and vaccine manufacturers should act to address the ongoing inequities in access [Exhibit PS/02 - INQ000190690], and another with proposals on improving global pandemic preparedness by 2025 [Exhibit PS/03 - INQ000190691].

42. While the UK Government was receptive to calls to use its G7 presidency in 2021 to focus on dose sharing issues, the commitments made by G7 members (and the UK itself) fell short, in terms of the number of doses committed and pace of sharing these (see our response to question 6 above.)

43. **iii. The use of scientific advice to government.** The main connection for Wellcome with scientific advice to the UK Government was through our then Director, Sir Jeremy Farrar. He engaged regularly on these issues, including discussions on the UK's domestic preparedness and response, through his role in the SAGE group. He is providing a separate response to the Inquiry, which will address his views on these issues.

Wellcome's views in relation to the extent to which the government adequately engaged and communicated with it on the state of the UK's emergency and pandemic planning, preparedness and resilience and lessons learned:

a. prior to 21 January 2020; and

b. after 21 January 2020.

44. Prior to 21 January 2020 Wellcome primarily engaged with the UK Government on these issues as a co-funder and partner. We feel that the engagement and communication was good when we sought to engage on this basis.

45. During the pandemic Wellcome also engaged with the government on issues related to the international response, such as ACT-A and vaccine dose sharing. While we would view the opportunities to engage and communicate with different parts of government as adequate, as per our responses above, there were instances where the UK Government could have done more to address the points raised and lessons identified in earlier outbreaks. These would have improved global preparedness and therefore the UK's health security.

List of any key articles or reports Wellcome has published or contributed to, and/or evidence it has given (for example to Parliamentary Select Committees) regarding the UK's emergency and pandemic planning, preparedness and resilience, in the context of the issues and/or groups of people which Wellcome supports and/or represents and the work we conduct in relation to this.

46. Key articles that we have published or contributed to, and which are relevant to the points covered elsewhere in our answers, include the following. (All URLs accessed 16 May 2023.)

- *Use of neuraminidase inhibitors in influenza.* Wellcome Trust and the Academy of Medical Sciences report. October 2015. https://acmedsci.ac.uk/policy/policy-projects/treating-influenza [Exhibit PS/01 - INQ000190689] and supplementary material https://acmedsci.ac.uk/file-download/37991-560d1067b93c0.pdf [Exhibit PS/04 - INQ000190692]
- *The cost of not preparing for infectious disease.* Wellcome explainer. First published October 2018; revised September 2021. https://wellcome.org/news/cost-of-not-preparing-for-infectious-diseases [Exhibit PS/05 - INQ000190693]
- *Advancing epidemics R&D to keep up with a changing world: progress, challenges and opportunities.* Wellcome Trust report, published August 2019. https://wellcome.org/sites/default/files/advancing-epidemics-rd-2019.pdf [Exhibit PS/06 - INQ000190694]
- *What people think about global access to Covid-19 treatments and vaccines.* Analysis of Wellcome-commissioned public polling by YouGov. May 2020. https://wellcome.org/reports/what-people-think-about-global-access-covid-19-treatments-and-vaccines [Exhibit PS/07 - INQ000190695]
- *Achieving equitable access to health technologies – what have we learnt from Covid-19 so far?* Wellcome policy report, published April 2021. https://cms.wellcome.org/sites/default/files/2021-04/achieving-equitable-access-health-technologies.pdf [Exhibit PS/08 - INQ000190696]
- *Improving global pandemic preparedness by 2025.* Wellcome Trust policy report, published October 2021. https://cms.wellcome.org/sites/default/files/2021-10/Wellcome-improving-global-pandemic-preparedness-2025.pdf [Exhibit PS/03 - INQ000190691]
- *Addressing Covid-19 vaccine inequity by June 2022.* Wellcome Trust policy report, published October 2021. https://cms.wellcome.org/sites/default/files/2021-10/Wellcome-addressing-Covid19-vaccine-inequity-by-June-2022.pdf [Exhibit PS/02 - INQ000190690]
- *Covid-19 vaccines: the factors that enabled unprecedented timelines for clinical development and regulatory authorisation.* Wellcome commissioned report, published March 2022. https://cms.wellcome.org/sites/default/files/2022-03/unprecedented-timelines-covid19-vaccine-clinical-development-authorisation.pdf [Exhibit PS/09 - INQ000190697]

The above is not intended to be an exhaustive list.

Wellcome's view on which decisions we consider that the government should have made differently with the benefit of hindsight into the UK's response to the Covid-19 pandemic

47. We will highlight two areas of the government's response where the particular circumstances of Covid meant that they could not have foreseen all of the challenges that emerged.

48. **i. Given the complexity and duration of the disruption caused by the pandemic, we believe the government would have benefited from setting transparent policy objectives for their response that explicitly recognised the trade-offs that would need to be made when acting on scientific advice.** As addressed above, the government's approach to the use of scientific advice appeared on occasion to run counter to its own established *Principles of Scientific Advice to Government.* The advice provided by SAGE, as well as by the Chief Medical Officer, Government Chief Scientific Advisor, and official scientific advisors and advisory committees across government, were all key to addressing the significant uncertainties about the pandemic and its progression. There seemed to be a lack of transparency, though, about the advice being received and how it was being used, particularly when ministers were making challenging policy decisions. It is right that the role of advisors is to advise, and that ministers must ultimately make the decisions (considering multiple factors and challenging trade-offs when weighing up scientific and technical advice, and often needing to make decisions that prioritise one issue or piece of advice over another, more so than ever during emergencies). But the government was rarely explicitly clear about where it was making trade-offs, for example between the need to take measures to slow the spread of Covid and legitimate concerns about economic impacts, mental health, or child welfare. The complexities of these were, in our view, instead masked by repeated assertions that the government was simply "following the science" in all its policy decisions, without a transparent acceptance of the trade-offs it was needing to make. Had the government been clearer about the competing policy objectives it was balancing, and in turn transparent about how it was using different sources of scientific and technical advice to inform decisions, greater public confidence in the UK response might have been maintained, and the damaging politicisation of scientific advice avoided.

49. **ii. The UK should understand, deploy and coordinate its strengths to deliver an effective emergency response.** The UK had considerable scientific and public health assets – in the public sector and beyond – that contributed to the response, for example the ONS and the Wellcome Sanger Institute that enabled essential real time monitoring and surveillance during the pandemic. In addition, this capability contributed significantly to the international response. Understanding this capability better could have enhanced the UK response, including its international leadership, enhancing UK health security in turn. Further, this understanding is important to ensure that weaknesses in capability are recognised and addressed.

Wellcome's views in relation to what lessons can be learned for future pandemics and other whole-system civil emergencies

50. **i. High-quality scientific advice must be central to the government's response to pandemics, lower-level disease outbreaks, and other major civil emergencies. The government should be transparent about how this advice is being used, providing clarity around their overall objectives and the trade-offs these necessitate.**

51. The Covid pandemic was the most complex public emergency in the UK in a generation, and the government response inevitably involved making difficult decisions and trade-offs in a complex and uncertain environment. In this situation, it was vital that the government's actions and their advice to the public was informed by high-quality scientific evidence. The UK Government was able to access some of the best scientific advice available globally during the pandemic, through well-established official channels.

52. However, as outlined in our answers above, there was a lack of public clarity from the government about its strategic objectives and its approach to balancing trade-offs between competing priorities. In turn, there was a lack of transparency about when and why scientific advice was (or was not) being followed in policy decisions to meet these objectives. This led to a regrettable politicisation of scientific advice, undermining public confidence in both the government's response and the advice itself.

53. This breakdown can be avoided in future large-scale emergencies by ensuring that the *Principles of Scientific Advice to Government* remain sacrosanct in an emergency, particularly in respect of the independence of scientific advice and the transparency in

its use. Alongside this, the government should be clear with the public about its strategic objectives during an emergency response, to provide transparency about how and where it is making trade-offs between competing priorities.

54. **ii. The government should consider how, as a major research funder, it can most effectively maintain a strong supporting ecosystem for work (in the UK and internationally) to deliver new vaccines, therapeutics, and other tools to respond to future epidemics and pandemics.**

55. As we emphasise in our answers, the ability of society to control or contain a pandemic or major infectious disease outbreak will ultimately depend on the availability of effective tools to prevent, detect, and treat infections. Covid, and earlier outbreaks, have demonstrated that well-targeted and coordinated investments in R&D activities between outbreaks significantly improve the ability to respond when they do occur. The UK Government did make some important investments in vaccine R&D prior to the pandemic, but these did not comprehensively address lessons from earlier outbreaks and were not sufficiently integrated with international efforts. Further, having made an important commitment to the creation of VMIC in 2018, the UK Government has now made the disappointing decision to divest from the initiative – suggesting that lessons about the importance of maintaining a strategic vaccine R&D and manufacturing capacity in the UK have not been embedded.

56. There is now an opportunity to reflect properly on the lessons of the past decade and ensure that the UK's investments in the R&D field achieve maximum impact in the future. The UK should ensure that its investments consider a broad range of epidemic and pandemic threats, including influenza, other known virus families, and capabilities to respond flexibly to an unknown 'Disease X'. They must consider therapeutics and other tools, as well as vaccines. They should strike a balance between targeted research funding by UK public funders, as well as sustained support for global mechanisms such as CEPI, which have clearly demonstrated their value during Covid as means to maximise the impact and effectiveness of global research efforts.

57. The unprecedented speed with which new vaccines were brought to market during Covid has also shown that new approaches to R&D and regulatory approval can transform how this happens in the future. It is commendable that since 2021, the UK Government has championed the '100-Day Mission', a coordinated set of actions to deliver novel vaccines, therapeutics and diagnostics within 100 days of a future pandemic being

declared, an initiative which Wellcome is now also supporting. It is vital that the UK continues to be an active champion of these ambitious goals, placing them at the centre of its strategic approach to R&D efforts for dealing with future epidemics and pandemics.

58. **iii. Learning from the success of the RECOVERY trial, plans should be in place to rapidly mobilise clinical trials for vaccines and therapeutics during future disease outbreaks, both within the UK and internationally. These need to be a core component of future epidemic and pandemic preparedness efforts.**

59. It was regrettable that despite lessons identified during the 2009 H1N1 pandemic and the 2014 Ebola outbreak, the government had not made adequate plans to mobilise clinical trials as part of the response phase to a pandemic. However, despite this lack of adequate plans, the RECOVERY trial was successfully mobilised. This provides a world-leading exemplar of how a clinical trial for therapeutics can be stood up rapidly during the most acute phase of a pandemic, and is a clear demonstration of effective collaboration between industry, NHS providers and the research community. By leveraging the scale of the NHS, it was possible to quickly generate invaluable insights into effective treatments for hospitalised Covid patients, saving thousands of lives globally. As such, it provides a clear template for how a rapidly mobilised, scalable clinical trial model can sit as a core part of the UK's plans for responding to future outbreaks in the UK and globally.

60. **iv. Improving global equity in access to vaccines and therapeutics must be an integral part of all high-income country governments' plans for future epidemics and pandemics.**

61. As we outline above, we believe that there was a collective failure by high-income governments to place an adequate emphasis – either in their pre-pandemic planning or during the response – on ensuring equitable global access to vaccines in LMICs. Where dose-sharing initiatives such as Covax were mobilised, these received inadequate support from high-income countries, including the UK. This caused considerable avoidable suffering in LMICs, as well as delaying the return to normality in the UK and across the world.

62. This predictable pattern of inequitable outcomes and 'dose hoarding' will be repeated in future epidemics and pandemics unless mechanisms to ensure more timely, equitable access to vaccines, therapeutics, and other countermeasures can be agreed at an

international level. The UK Government should now consider how it can place a greater emphasis on equitable global outcomes as part of its future pandemic planning, and engage proactively with emerging initiatives (including WHO-led efforts to establish a global Medical Countermeasures Platform and negotiations towards a global pandemic accord) to establish international mechanisms and agreements to ensure more equitable access to countermeasures during future outbreaks. These considerations should be integral to the UK's response planning for future pandemics.

63. **v. Good surveillance data is vital to inform the response to any outbreak, with the UK demonstrating the particular value of large-scale genomic sequencing, and population level incidence data.**

64. Covid provided a clear reminder that in a rapidly evolving epidemic or pandemic, the ability to respond effectively is contingent on having a clear picture of where and how the disease is spreading. The UK, however, was able to benefit from some of the highest-quality data on the domestic incidence of Covid available anywhere in the world, thanks to the mobilisation of the Covid-19 Genomics UK Consortium (COG-UK), and the innovative approach of the Office for National Statistics Covid Infection Study (CIS). Given the value of such high-quality genomic and population-level incidence data to national governments in an outbreak situation, the approaches to expanded and enhanced surveillance established by COG-UK and the CIS should be considered as an integral part of the UK's future epidemic and pandemic response plans.

65. In the earliest stages of the pandemic in 2020, the ramping up of the UK's response was severely hampered by incomplete data on case numbers and the progression of the first wave of disease. Throughout the pandemic, many governments around the world have struggled with fragmented disease surveillance data, particularly where access to diagnostic tests has been limited. As the threat of new Covid variants became clear during the pandemic, the value of coordinated, large-scale genomic sequencing to enable early identification and understanding of new variants was increasingly apparent.

66. Through the CIS (which Wellcome supported the setup of during the early stages of the pandemic), the ONS was able to provide robust data on geographical incidence across the UK on a weekly basis, through systematic sampling of people in the community. This high-quality data – to which we know other governments in Europe also turned to enhance their own understanding of the pandemic's progression – provided a solid base for decision-making by the UK government. It sets a benchmark for how national-level

studies can be rapidly mobilised and used during a pandemic or major epidemic. Wellcome is now supporting the translation of the lessons and outputs into a toolbox for LMIC partners to utilise for their own preparedness work.

67. With the creation of COG-UK, supported by Wellcome and the Wellcome Sanger Institute, it was possible to harness expertise in genomic sequencing across the NHS, universities, and other research institutions across the UK. By coordinating efforts and sequencing capacity in this way, and integrating it with diagnostic testing activities, it was possible to establish a rich understanding of the emergence and spread of new Covid variants across the UK. The ability to bring together such significant, high-quality sequencing capacity was the result of long-term investment in genomics in the UK, which should be maintained for its value to medical research as well as its strategic importance to disease surveillance.

Any other persons, entities or organisations which Wellcome believe may hold relevant information or material in relation to the points above

68. Organisations who have acted as partners or interested parties in work we have described above include:

- Academy of Medical Sciences
- Bill & Melinda Gates Foundation
- Coalition for Epidemic Preparedness Innovations (CEPI)
- Oxford Vaccine Group, University of Oxford
- Protas – the clinical trials organisation established by Sir Martin Landray, co-principal investigator for the RECOVERY Trial.
- Wellcome Sanger Institute

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:

Name: Paul Schreier

Personal Data

Signature: _____

in my capacity as Chief Executive Officer (Interim), for and on behalf of the Wellcome Trust Limited, as trustee of Wellcome Trust

Dated: 25 May 2023