IN THE MATTER OF THE INQUIRIES ACT 2005

AND IN THE MATTER OF THE INQUIRY RULES 2006

THE UK COVID-19 INQUIRY

WRITTEN CLOSING SUBMISSIONS ON BEHALF OF

THE DEPARTMENT OF HEALTH AND SOCIAL CARE

Introduction

1. The Department of Health and Social Care ("the Department") starts this submission by expressing its deepest sympathies to all those who lost relatives and friends during the pandemic, and to those who continue to deal with the consequences of the pandemic. We would also like to take this opportunity to thank the many staff and volunteers who make the development, testing and deployment of drugs and vaccines possible.

2. As set out in the Department's opening statement, the recognition that the new virus was a threat to the UK in January 2020 and, consequently the early decision by the Department to invest in the development of new vaccines and trialling therapeutics ultimately helped to save many millions of lives worldwide. It minimised the wider health, economic, and social costs of tackling the virus and facilitated the reopening of the economy.

3. As Mr Keith KC set out in his opening statement on behalf of the Inquiry on 14th January 2025:

> *"…. the evidence suggests overwhelmingly that the UK Covid-19 vaccines successfully protected the people of the United Kingdom against a virus that was killing and liable to kill hundreds of thousands of people."*[1]

[1] Transcript of Module 4 Public Hearing on 14 January 2025- Page 23 Line 8-12 - https://covid19.public-inquiry.uk/wp-content/uploads/2025/01/14183416/2025-14-01-Module-4-Day-1-Transcript.pdf

4. The rapid development and roll out of multiple successful vaccine candidates were not only testament to decades worth of investment in the UK's science system and clinical research delivery system, but to the hard work and resilience of those individuals conducting the research and those who worked tirelessly to ensure a successful deployment.

5. The UK, using the staff and infrastructure of the National Institute for Health Research (NIHR) and the NHS, and the volunteering spirit of patients, undertook some of the leading trials of repurposed drugs globally.

6. Successful collaboration with partners from across the health and care family as well as the creation of the Vaccines Taskforce (VTF) and the Therapeutics and Antivirals Taskforces enabled fast and effective cross-government working as well as engagement with the private sector, all of which contributed to the development and delivery of the vaccines and therapeutics programmes.

7. The Department has acknowledged in its opening statement and oral evidence that there are areas where it could have gone further, faster. This includes addressing vaccine concerns in ethnic minority groups whose distrust of government was high.

Research

8. The research community played a vital role in developing and testing not only an effective vaccine, but also therapeutic treatments that enabled better recovery rates in patients.

9. While the *Technical report on the COVID-19 pandemic in the UK* by the UK CMOs and other authors ("the Technical Report") suggests that the UK approach to clinical trials was less effective for phase 1 and 2 trials than for phase 3 and 4 trials, it is important to remember that the UK has a good track record in early phase clinical trials – both academic and industry-led. They were less successful than the phase 3 trials during COVID-19 but still contributed to the global research effort. Early phase trials (phase 1 and 2, generally) are complex and experimental. As they are exploratory, they depend on the state of international knowledge. In order for phase 1 and 2 trials to be successful, it is essential that there are good products available to be trialled. During the early part of the COVID-19 pandemic, there was

very limited evidence to point to candidate novel therapeutics to test, as well as lack of availability for those that were postulated. This problem was not unique to the UK, with limited international examples available for comparison. The UK was not an outlier and its Phase 1 and 2 works did contribute to the global scientific knowledge, but did not have the substantial impact that it had in Phase 3 studies.

10. Due to funder remit, the majority of the trials that were funded by the Department via the National Institute of Health and Care Research (NIHR) were later stage trials (Phase 3 / 4) on repurposed drugs which would typically have an impact on public health within 12 months.

11. Clinical trials were conducted both in the UK and abroad to make sure that the research captured both the numbers required for the trials and diversity of participants. One lesson learned from the pandemic is the importance of fostering good coordination of early phase studies from the beginning of any infectious disease outbreak, and the NIHR infrastructure has now embedded this for any future pandemic.

Prioritisation and roll out

12. The overall strategy for vaccine prioritisation was designed to protect the most vulnerable first by offering vaccination in line with the Joint Committee on Vaccination and Immunisation's (JCVI) prioritisation advice, who considered how best to minimise death and serious disease.

13. Throughout the pandemic, the JCVI assessed priority groups based on scrutinising the best available knowledge and outcomes of research to identify those who were most vulnerable to serious outcomes. The JCVI looked with care at the consequence of vaccination on pregnancy, those with disabilities, people with Down's syndrome and autism, people with learning difficulties and vulnerable people across all parts of the community.

14. Decisions in relation to the vaccination of children were taken in the same way as other prioritisation decisions, with the JCVI providing advice to the Department. It was important to balance the wider societal benefits of vaccinating children who

were at much lower risk from COVID-19 infection and the concern at that time of potential links between the very small risk of potential harm that could be caused by the vaccine for example from myocarditis and pericarditis. This balancing exercise was correctly described by Professor Wei Shen Lim in his evidence given on 23rd January 2025 as *"a hugely fine balance, quite unlike the balance of an older person who might have an adverse effect from vaccination".*[2]

Vaccine Hesitancy

15. It is acknowledged that vaccine hesitancy is likely to be higher among certain minority ethnic groups with historically lower vaccine uptake, as well as among vulnerable communities and individuals. In relation to vaccine hesitancy, although much was done during the pandemic to tackle the spread of mis and dis-information, there is more that could be done. The Department accepts that building trust in access to health care across all parts of the population is very important in ensuring health equalities and agrees with Professor Heidi Larson in her evidence given on 16th January 2025 that *"we shouldn't wait for the next pandemic".*[3]

16. As set out in the Department's opening statement for this module, there are several initiatives underway to combat the spread of mis and dis-information including a provision in the Online Safety Act to tackle harmful health content, closer working with community and faith leaders, and maximising convenience through improved access to vaccine services at easy to access locations.

The Vaccines Damages Payment Scheme (VDPS)

17. Since the NHS Business Services Authority (NHSBSA) took over the administration of the VDPS from the Department for Work and Pensions (DWP) in November 2021, it has worked to improve the operation of the scheme by

[2] Transcript of Module 4 Public Hearing on 23 January 2025- Page 98 Line 1-3 - https://covid19.public-inquiry.uk/wp-content/uploads/2025/01/23183658/2025-01-23-Module-4-Day-8-Transcript.pdf
[3] Transcript of Module 4 Public Hearing on 16 January 2025- Page 172 Line 13-14 - https://covid19.public-inquiry.uk/wp-content/uploads/2025/01/16212003/2025-01-16-Module-4-Day-3-Transcript.pdf

modernising the process, improving claimants' experiences, and providing timely outcomes.

18. This includes scaling up the operations of the VDPS to allow cases to be processed at greater pace, each claimant being given a named caseworker.

19. The Department recognises that there are continuing concerns over the VDPS, and Ministers recently met with the families of some of those who have suffered serious harm following COVID-19 vaccination, many of whom raised the need for reform of the VDPS. Ministers have agreed to look at the issues raised.

Therapeutics

20. While it was the vaccine roll out that protected the vast majority of the population from COVID-19, therapeutics also played an important role in minimising serious illness and death from COVID-19.

21. The Department's decision to test existing therapeutics and subsequently novel ones was fast and ultimately effective. Those that proved to be most effective were procured for use. As set out in the Department's opening statement for this module, over 5 million doses of antiviral and therapeutic treatments were procured between March 2020 and March 2023.

22. While the vaccination programme was high profile in comparison to the therapeutics programme, because ultimately more of the population would be able to benefit from it, the therapeutics programme was not any less of a priority.

23. At the beginning of the pandemic, there were no known medicines to treat patients with the virus and finding a treatment was a priority. Therapeutics are highly personalised, and what will work for one person may not be suitable for another, making the landscape extremely complex.

24. As has been explored in the oral evidence given by various witnesses, the Department ultimately chose not to proceed at that time with an advance purchase of the prophylactic Evusheld.

25. The Inquiry may consider that it is important to remember that Evusheld did not receive approval from the Medicines and Healthcare products Regulatory Authority (MHRA) until 17 March 2022. It therefore could not have been deployed before that time. By this date shielding had long finished, and most of the vulnerable population had been vaccinated several times. Secondly, by Spring 2022 (the first time Evusheld could have been deployed) there was emerging evidence that the Omicron variant was sufficiently different to previous variants, meaning that the effectiveness of the 2 antibody cocktail was significantly diminished; this was reflected in international opinion leading to its licence being withdrawn for example by the FDA in the USA. Thirdly there was by this stage evidence, that has since strengthened, that vaccination did in fact provide substantial protection to those who were immunosuppressed; all the trial evidence was in unvaccinated populations.

26. As with Evusheld the possibility of using the Valneva vaccine was considered with considerable care within Departmental submissions but scientific advice and the recommendation from the VTF was to cancel the contract.

27. No part of the Department's decision making as regards to Evusheld or Valneva was based upon cost over health.

28. The Department accepts that lessons must be learned from the way in which decisions over treatment are communicated with those who were immunosuppressed or immunocompromised and were left in uncertainty for a period of time as to whether there would be a suitable prophylactic available.

Lessons learned

29. As has been identified in the opening and closing submissions of modules 1, 2 and 3, the Department has conducted significant learning to enable better preparedness and responses to a pandemic, based around five lessons and the Technical Report. The most important lessons of particular importance with respect to this module, which it outlines are:

a. The importance of moving from NPIs to medical interventions as soon as possible

b. The need to support both vaccine and therapeutic research as it is never clear at the start of a pandemic which medical interventions will be most important, nor the balance between them.

c. Strong investment in research and development prior to any emergency, including a pandemic, is central to the ability of the scientific community to respond quickly when an emergency occurs.

30. As recognised in previous modules but reiterated in this one, the increase in available data and data flows must be improved across the health system from primary care data, GP practice data and secondary care data to better support patient treatment. Bringing data together effectively is also essential to observational studies and clinical trials

31. The Department accepts that communication across sections of the community, including people who are immunosuppressed, during the pandemic could have been improved. More work needs to be done to ensure that communication across all parts of the community is achieved in a future pandemic.

Conclusion

32. The Department wishes to reiterate its thanks to all those who helped navigate and support the country's response: NHS staff, paid and unpaid care workers, volunteers, the civil servants, the scientists, industry, pharmacists, charities, religious organisations, the military and, of course, the general public. The Department would also like to take the opportunity to thank all those who volunteered as part of clinical trials, be that for vaccines or therapeutics.

33. The Department stands ready to assist the Inquiry in its work.