

IN THE MATTER OF THE INQUIRIES ACT 2005

AND IN THE MATTER OF THE INQUIRY RULES 2006

THE UK COVID-19 INQUIRY

**WRITTEN OPENING 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.
2. The recognition that the new virus was a threat to the UK and the early decision by the Department to invest in the development of new vaccines and 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. This rapid UK reaction to develop and test vaccines and drugs would not have been possible without the decades’ worth of government investment in the UK’s science system and research infrastructure, supported by the Department and building on our previous preparedness work, especially through the networks of the National Institute for Health and Care Research (NIHR).
4. It was due to the existing work on vaccine development, which built on decades of global research, as well as the culmination of months of intense preparation and hard work, that enabled the UK to be the first country in the world to have authorised two COVID-19 vaccines by the end of December 2020. Margaret Keenan became the first person in the world to receive the Pfizer COVID-19 vaccine on the 8 December 2020.
5. The Department’s decision to test existing therapeutics and subsequently novel ones was fast and ultimately effective. Several therapeutic options were shown by UK trials to be effective beyond reasonable doubt; dexamethasone was one of the first and most important of these, but several others followed. Equally importantly therapeutic options which had some support based on reasonable first principles such as convalescent plasma and chloroquine were shown not to have any useful effect.

6. While health policy is usually a devolved matter, in the case of vaccines and therapeutics, the Department acted on behalf of the four nations to both help develop and procure them.
7. The Department does not want the positive future lessons learned from things that went right, including the rapid recognition of threat, the speed and rigour of scientific response and of vaccine acquisition and deployment, to be lost among areas where even more could have been done.
8. With hindsight, the Department acknowledges that more could have been done quicker to address vaccine concerns in certain groups, who were also in high-priority cohorts. Historically there has been lower vaccine uptake amongst some religious and minority ethnic groups and while much work was done to target different populations, this could have been done earlier on in the vaccine roll-out especially in relation to specific groups and there are important reasons they may be less able, or willing, to take up vaccination.

The role of the Department and action in relation to research, vaccines and therapeutics

9. As the witness statements of the Department in relation to this module explain in detail, the Department's role in the development and deployment of vaccines and therapeutics was to support the Government and Secretary of State in planning for and delivering a successful therapeutic and vaccination programme in response to COVID-19. There were many bodies and organisations involved in the final successful rollout of vaccines and therapeutics, and the Department wishes to make clear it, and its Arm's Length Bodies were only a part of a wider national and international effort. Our written evidence sets out the role of the Department in the end-to-end development and deployment of vaccines and therapeutics, working with other parts of government, across the UK and internationally.
10. The Department worked closely with partners from across the health and care family, including Public Health England (PHE), and later the UK Health Security Agency (UKHSA), NHS England (NHSE) and the Medicines and Healthcare Products Regulation Authority (MHRA) to ensure COVID-19 vaccines could be delivered at pace and on an unprecedented scale.
11. Each organisation undertook the same role that it plays in the development and roll out of routine immunisations but scaled up for a mass vaccination programme, with the exception of the Vaccines Taskforce (VTF) which from April 2020, when it was established, took on responsibility for the procurement of COVID-19 vaccines.
12. As set out in the Department's corporate witness statements, the four main tools available in most pandemics and epidemics, especially of respiratory pathogens, are testing, non-pharmaceutical interventions (NPIs), vaccines, and therapeutics. The former can be put in place whilst the scientific community begin to develop the latter.

13. The Department's early decision to act quickly in the area of therapeutics and vaccines was crucial to minimising wider societal harms and also meant that we could provide data for the international effort against Covid-19.

Research

14. For decades the government under all administrations had invested heavily in the UK's science system and clinical research delivery system which put the country on the front foot in developing vaccines and therapeutics to treat COVID-19. 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.

15. The Department was instrumental in commissioning and funding early vaccine research and clinical trials through the NIHR, and in pre-covid times through the UK Vaccines Network (UKVN) specifically for coronavirus vaccine research. The existing research infrastructure provided a solid foundation on which to build and was invaluable in the rapid development of a successful vaccine. It was also essential for the testing or repurposed and novel therapeutic treatments.

16. Having an existing research infrastructure through NIHR and the NHS, alongside the Medical Research Council (MRC) meant the UK already had a solid foundation upon which to build. It was able to quickly pivot and focus on COVID-19 research which proved to be invaluable in the rapid development of a successful vaccine and therapeutics. Following the extra investment made by NIHR and UKRI the AstraZeneca vaccine was successfully procured before the VTF was established.

17. Such systems cannot be built overnight. The strong foundation provided by the UK's robust research infrastructure that already existed in January 2020 was maintained and prioritised even outside of a pandemic, allowing it to swiftly pivot its focus to COVID-19 research. The Department has commented in other modules about the importance of capabilities being in place before a crisis, and this is one such example.

Vaccines

18. Even before a global pandemic had been declared, the Department started planning for the potential development of a safe and effective vaccine, with it first being discussed in January 2020. By the end of August of 2020, the VTF's Terms of Reference had been agreed as had the business plan for the manufacture at scale of the AstraZeneca's vaccine.

19. It was not a foregone conclusion that the UK or any country would find and develop a safe and effective vaccine, especially as no one had ever made and trialled an effective vaccine for a human coronavirus before. For HIV, the last pandemic with a global impact on this scale, a vaccine has still not been developed over 40 years since the virus was identified.

20. Without a vaccine many more people would have lost their lives or been taken seriously ill as a result of contracting COVID-19. By September 2021 the UK COVID-

19 vaccine programme had prevented over 230,800 hospitalisations, between 23.7 and 24.1 million infections and between 119,500 and 126,800 deaths.

21. Vaccines provided a way out of the restrictions that were imposed to prevent the spread of the virus. The impact on society of NPIs such as lockdowns and social distancing cannot be underestimated. While they can significantly reduce and delay the spread of a disease, they often have negative societal consequences.
22. The UK government also played a significant role in the COVID-19 Vaccines Global Access scheme (COVAX) ensuring that lower income countries also had access to a safe and effective vaccine, enabling wider global benefits such as lifting restriction on international travel to be achieved.

Therapeutics

23. While it was the vaccine roll out that protected the vast majority of the population from COVID-19, therapeutics were essential in at least two ways: first to begin effective in-hospital treatments for those with serious illness in the first and second waves before vaccines were developed, and secondly in providing treatment for the smaller number of people who contracted serious illness after the vaccine roll out had provided some level of population coverage, and those who are unable to receive the vaccine.
24. Drugs to treat COVID-19 came from two broad approaches; existing drugs repurposed to reduce bad disease outcomes (examples include dexamethasone and existing immunomodulatory drugs) and novel drugs to target this specific infection, generally antivirals. The Department, through NIHR and the NHS, started preparing to test drugs at the very start of the pandemic, before the first death from COVID-19 in the UK.
25. The UK had some of the earliest definitive trial results which influenced international as well as UK practice because of this speed of response and a firm commitment to undertaking clinical trials in the face of uncertainty. The demonstration that dexamethasone reduced deaths in those on oxygen for COVID-19 by around a third was one striking finding from this research, rapidly adopted in the NHS.
26. The Department led on the development and procurement of therapeutics, purchased at volumes to provide for the whole of the UK. This work was led by the Therapeutics and Antiviral Taskforces and resulted in the NHS having access to treatments and antivirals for the UK population. Over 5 million doses of antiviral and therapeutic treatments were procured between March 2020 and March 2023. This included molnupiravir and nirmatrelvir + ritonavir among others.

Safety

27. Safety is paramount when considering vaccine candidates. While the timeframe for vaccine development and deployment was accelerated, the same rigorous approvals process was applied by MHRA to COVID-19 vaccines with steps that would usually be carried out sequentially being carried out in parallel.

28. While vaccine safety is always an absolute priority, there is also always a balance of risks to be considered, and it must be remembered that there are no drugs or vaccines that are without any risks; the risk of the treatment must be smaller than the risk of someone not being treated. In the case of the COVID-19 vaccines, the question was whether being vaccinated carried fewer risks than being unvaccinated for a disease where there was a high chance of acquiring infection.
29. COVID-19, especially in those who had not previously been infected or vaccinated, had significant risks and was a very common, life-threatening disease; the vaccines had high vaccine efficacy. For COVID-19 vaccines, whilst their principal impact is to reduce the risk of death, severe disease and acquisition of the virus for the individual vaccinated, as more people were vaccinated, the transmission rate was decreased.
30. The MHRA is responsible for vaccine safety and surveillance. During the pandemic, the safety of the deployed COVID-19 vaccines was monitored continuously through the MHRA's COVID-19 vaccine surveillance strategy. When safety concerns were identified, the Department acted quickly on the advice of the MHRA and the JCVI.

Prioritisation and roll out

31. NHSE led the deployment of COVID-19 vaccines in England and the Department worked closely with them, playing a key role in strategic coordination across the responsible bodies to enable safe and effective rollout of the vaccine programme. This included liaising with the MHRA on the regulation of COVID vaccines, advising Ministers on JCVI's recommendations on the rollout of specific vaccines, eligibility for vaccination and prioritisation, and strategic planning for future phases of the vaccine programme. We also liaised with the other nations of the UK so that there was a coherent and consistent offer to all parts of the UK.
32. The overall strategy for vaccine prioritisation was designed to protect the most vulnerable first by offering vaccination in line with JCVI's prioritisation advice. As part of this strategy, the UK made the trade-off decision to prioritise giving the first dose to a wider cohort of people, which gave baseline immunity, over giving additional protection through a second dose in the first part of 2021. This was not without controversy at the time, but in retrospect has been accepted as a very effective life-saving strategy in the early roll out.
33. As a result of the efforts of all partners across the health family, around 132 million COVID-19 vaccinations were administered across all 4 nations of the UK in 2021, as part of the largest vaccination programme in British history. By the end of 2021 over 90% of the UK population aged 12 or over had taken up the offer of a first dose of the vaccine and 82.4% a second dose.
34. NHSE also led on the roll out of therapeutics in clinical settings for the treatment of COVID-19. This covered use in hospital inpatients, updated clinical guidelines, and setting up of ninety-two COVID Medicine Delivery Units (CDMUs) for community

treatments. Over 110,000 patients received community-based COVID treatments through CMDUs between January 2022 and June 2023

Lessons learnt

35. 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 on the COVID-19 pandemic in the UK* by the UK CMOs and other authors. The 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; and
 - b. Strong investment in research and development is central to the ability of the scientific community to respond quickly.
36. It is important to note, however, that in future pandemics we cannot assume that a vaccine would be available or as effective. Still after 40 years, there are no vaccines for HIV, the last major pandemic, the prevention and treatment of which is based on therapeutic drugs. It is therefore important we continue to support a full research base, and whilst capacity to develop and scale up vaccines remains essential, we need simultaneously to maintain the capacity in therapeutics.
37. There was also no certainty that a novel drug would be found to treat COVID-19 and the UK was a global leader in testing re-purposed existing drugs for use as therapeutics.
38. The early emphasis on developing a vaccine and on therapeutics enabled the government to transition away from a testing and NPI-led response. Each part of the system played an important role, and more importantly, they played to their strengths. Research teams conducted thorough research and trials, the VTF took responsibility to commercial and procurement arrangements, the private sector worked to develop and scale up successful candidates, NHSE were able to use their expertise to ensure smooth deployment, while the Department played the role of the strategic coordination, ensuring the system could work together cohesively.
39. The Department considers there is much to be learned in how we could better tackle inequalities and help communities and minority ethnic groups with historically lower vaccine uptake, including vulnerable communities and individuals, to feel confident and able to take up effective vaccines as they become available.
40. Since the pandemic, the Department has worked with its partners including UKHSA and NHSE to make it easier to get vaccinated, particularly for groups that are traditionally under-served.
41. The NHS Vaccine strategy, published in December 2023, aims to maximise convenience with more vaccination services at locations that the public can easily access such as: libraries, leisure centres, social clubs or sports grounds, family hubs,

support services and places of worship, or at local cultural and community events; with flexible opening hours; and booking options.

42. The Department and NHSE have also worked with faith networks to develop tailored outreach plans and have joined up with community and faith leaders to provide additional vaccination venues and awareness events for example through health fairs and community heritage events.
43. The Department further recognises the need to combat online mis- and disinformation, in relation to vaccines and the government's introduction of the Online Safety Act aims to reduce harmful health content such as this.
44. The Department would like to reiterate its thanks to all those who helped navigate and support the country's response: NHS staff, care workers, volunteers, the military and, of course, the general public.
45. The Department stands ready to assist the Inquiry in its work.