IN THE UK COVID-19 PUBLIC INQUIRY

BEFORE BARONESS HEATHER HALLETT

IN THE MATTER OF:

THE PUBLIC INQUIRY TO EXAMINE THE COVID-19 PANDEMIC IN THE UK

Covid-19 Bereaved Families for Justice UK & NI Covid-19 Bereaved Families for Justice

Closing Submissions For Module 4

Introduction

1. On 30 January 2025 Dr Clive Dix, former chair of the Vaccine Task Force (VTF) gave powerful evidence about a variety of matters including the lack of vaccine manufacturing capacity in the UK. He spoke about a failed effort during the pandemic to broker an agreement between the UK's second biggest pharma company – GSK – and the government to produce Covid vaccines in the UK. He gave evidence about the failure of the Vaccine Manufacturing and Innovation Centre (VMIC) project which was abandoned without producing a single vaccine dose, and the limitations of the Moderna Innovation and Technology Centre (MITC) which is due to become operational later this year, but which will be limited to one technology: mRNA. He also told us about rumoured problems with the much-vaunted major expansion of the AstraZeneca vaccine plant at Speke.

2. What neither Dr Dix nor the rest of us knew at that point was that the day before he gave his evidence, AstraZeneca had informed civil servants that they were abandoning the project altogether. That decision was only made public on the last day of Module 4 hearings: an unfortunate coincidence. AstraZeneca blamed a cut in the promised UK Government grant. Ministers blamed a cut in the amount AstraZeneca planned to invest in research and development (R&D).

3. The reasons for the failure of these projects are less important than the fact of the failures. Dr Dix and other witnesses tell a sorry tale. It amounts to this: scientists, government, officials, big pharma all understood the need to onshore vaccine innovation and manufacturing well *before* the covid pandemic: the VMIC narrative illustrates that. Everyone knew *during* the pandemic that the UK was short of its own vaccine

manufacturing base; the attempt to broker a project with GSK illustrates that. As the Covid emergency *subsided*, everyone realised this problem remained, hence the MTIC and AstraZeneca initiatives.

4. The success of developing efficient vaccines was remarkable, and a result of excellence in scientific research in the UK. As we have heard, many lives were saved. However, success in this area must not be allowed to mask huge failures in others, and as we know, success in developing a vaccine next time may be much more difficult. The continued excellence of the scientific research base demands proper resourcing, and it requires innovative and portfolio thinking. Putting all the eggs in the mRNA basket is planning to replicate a response to the last emergency, not the next one.

5. What the successes in vaccine development, and the manufacturing failures set out above illustrate, are the two basic building blocks which are required with respect to the subject matter considered in each of the modules of this Inquiry: proper resourcing, and planning. If one of those building blocks is not there, the house will fall down.

6. It is not for this Inquiry to set out what *level* of resourcing should be provided to maintain UK science research excellence, or to rectify the absence of onshore vaccine manufacturing, but it *is* for this Inquiry to set out what will happen and what will be repeated if adequate resourcing is not provided. Similarly, the Inquiry can only give guidance to future planning, but it *must* emphasise the massive problems and loss of life and economic damage caused by an absence of planning last time.

7. Below we set out the evidence of lack of capacity and lack of planning as at 1 January 2020 which affected both vaccines and therapeutics. It is important to separate the two, for the obvious reason that there was over-emphasis on the former at the expense of the latter. Proper planning should have revealed that as a likely error, and a catastrophic one had the development of a vaccine proved more difficult.

8. We recognise the huge efforts to mitigate both the effects of the pandemic and the lack of planning: by research scientists, those involved in the VTF, the regulators, and the many public servants who did their utmost to fill the gaps from a standing start. The lessons have been succinctly recognised by two witnesses.

9. Nadhim Zahawi, former Minister for Vaccine Deployment, admitted that the UK government and its officials were trying to build the plane whilst it was flying, whilst Yvonne

MacNamara from the Traveller Movement commented that you can't build an ark once the flood has happened. Have those lessons been learned? Does the evidence show that in 2025 there is better resilience, actual planning or has the partially built plane lost a wing, and the ark been left to rot? It would appear that the latter is, depressingly, the case. If that is correct, this Inquiry should sound the alarm.

10. We commend the evidence of Derek Grieve that the Scottish Government sought to take a human rights-based approach to vaccine roll out, which we take to mean that it was an approach based upon the needs and prioritisation of real people. However, we comment that to do so should have meant having proper planning and mechanisms in place *before* the pandemic. As we expand upon below, neither the UK nor the devolved administrations did.

11. On the subject of the devolved administrations generally, we note that some obvious measures had not been considered in advance of the pandemic. For example, the JCVI procedures had not changed since devolution, and there were no plans to distribute vaccine and therapeutic supplies to the DAs despite the fact that they had their own roll out mechanisms.

12. A lack of planning generally means that enduring and structural problems are not considered or are overlooked. In terms of health inequalities, simple access issues should be picked up and addressed outside of the emergency. Data systems should have been designed to have all relevant information to assist emergency trialling and research. Local administrations and primary healthcare staff - GPs and nurses – should be tasked to identify vulnerable individuals and remote communities, and remedy how to provide access for them.

13. Instead, some of the evidence has misunderstood or misrepresented systemic failures as those of the individual or the marginalised community. The poor access migrants have to healthcare because of hostile environment policies will obviously negatively translate regarding vaccine uptake. The marginalisation of GRT communities, and structural and institutional racism will negatively impact vaccine access for some ethnic minority communities. Likewise for Disabled people and those with mental ill health. All of these issues are enduring and well known. None were planned for with respect to vaccine roll out, adequately or at all. Professor Gillian Richardson, SRO for the Welsh Vaccination Programme referred to issues relating to colonialism, indicating an awareness of

underlying structural and institutional problems, but not a pre-existing plan to address them.

14. The wider issues of structural and institutional discrimination, and the intersections between them are beyond the scope of the Inquiry, but the failure to identify and plan for them in terms of not only the likely disparities of outcome in a pandemic, but specific plans including vaccine roll out are not. Some measures were instituted along the journey but how different might have been outcomes if simple solutions had been baked into planning from before the emergency. For example, historical distrust of vaccines is based on real facts and terrible results came from novel drug roll outs in poorer and less regulated countries. We have given the example of a novel antibiotic given to children in Nigeria in the 1990s, previously trialled only on adults and subsequently withdrawn because of serious adverse effects.

15. Describing low uptake in some ethnic minority communities as hesitancy or suggesting they are 'hard to reach' ignores the real problem and the solutions. If there are known trust issues, the solution is to ensure properly diverse trials and to publish the fact of those trials and their diversity far and wide, and through mediums which reach the whole community. There has been evidence of the use of trusted voices, clinicians or faith and community leaders, and vaccination venues located within spaces used by marginalised communities but only after the initial roll out. Those ideas should have been baked into the planning and tested well before the emergency.

16. The 'hesitancy' was with policymakers who failed to see the systemic and enduring problems of different forms of discrimination, and have effective plans in place from the outset.

Research, development, procurement and manufacturing

17. The Inquiry must properly recognise the UK's strengths in life sciences going into the pandemic, and their contribution to the pandemic response. However, complacency must be avoided. The Inquiry must also take note of the gaps and limitations on research, development and manufacturing in the UK in the period leading up to Covid-19 and assess what capacity the state had to lead a scientific response to the pandemic. It is the Inquiry's task to consider whether the UK's pharmaceutical response to Covid was inhibited by avoidable constraints, whether arising from lack of planning and preparedness or decision-

making during the course of the pandemic. This is crucial if we are to ensure that these constraints are not repeated in the future.

A. Preparedness: the situation in 2020

18. It was well-established in Module 1 that a non-flu pandemic was not or should not have been unforeseen by the UK. Notably, and as we set out in our Opening Submissions, in 2017 and 2018 the WHO's Research and Development Blueprint Initiative emphasised the urgent need for accelerated research and development for drugs and/or vaccines for a range of diseases, including MERS, SARS and disease X [INQ000183447]. Prominent scientists from across the world, including the UK, had participated in the Prioritization Committee.

19. By early 2020 valuable work consistent with this agenda had been done, including by Professor Dame Sarah Gilbert at the University of Oxford on the ChAdOx1 vaccine platform, which became the foundation for the Oxford AstraZeneca vaccine. Nevertheless, Professor Sir Andrew Pollard's view was that we were *"not well prepared to make vaccines for disease X or even a coronavirus"* [INQ000474399_10, §23]. Professor Gilbert herself notes that outbreak pathogen vaccine development followed *"the usual slow, stepwise progression"* with "*multiple long pauses to seek additional funding*" with an emphasis "*on containing small outbreaks quickly, and not pandemic preparedness"* [INQ000474278, §19].

20. Sir Jeremy Farrar's view is that despite the WHO initiative, between February 2018 and early 2020 very little attention was paid to the concept of disease X globally or in the UK, whether by reference to vaccines or therapeutics [INQ000496107_001; _004]. The Inquiry will also recall Professor Wendy Barclay's written evidence that preparedness to find therapeutics for Disease X or Covid was at an even lower status than for vaccines and, crucially, that the funding that supports research into new vaccines and delivery was (and remains) suboptimal and fragmented [INQ000474315_07, §28; §26].

21. As to government, Dame Kate Bingham's succinct summary was that there was no apparent plan for the vaccine response to 'Disease X' As she saw it, "*[b]y 2020 the DHSC's expertise and plans in the vaccine field were narrow and constrained"* and "*based too much on influenza models".* Significantly, successive governments had failed to build or maintain relationships with innovators and key companies in the vaccine field [INQ000474406_011, §§7.3-7.4].

22. In terms of infrastructure, Professor Sir John Bell notes that while approval had been granted in 2017 for VMIC to facilitate early vaccine development both in academia and in industry, *"there were not even stakes in the ground"* when the pandemic hit in early 2020 (see further below) [INQ000499442_16, §51]. Evidence from a range of witnesses including Matt Hancock [3/69/13-16] and Alexandra Jones [5/4/18-/5/21] attests to the UK's pre-pandemic lack of manufacturing capacity across the piece, including initial stages, scale-up and fill and finish. In his written evidence Lord Vallance summarises the position: "*[p]rior to the pandemic the UK industrial base for domestic discovery, development and large-scale manufacturing of vaccines was relatively low and had decreased over several decades"* [INQ000474482_012, §24].

B. <u>The pandemic response</u>

Vaccines

23. A considerable amount of evidence about systemic constraints on the UK's response was provided by Dame Kate Bingham and Dr Clive Dix of the VTF. Dame Kate was forthright in both her oral and written evidence about the UK government's capacity to lead a pharmaceutical response to Covid-19, noting that "*the lack of any real planning, industry relationships and skills were why the VTF had to be established at such short notice*" [INQ000474406_011, §§7.4]. Dr Dix echoes this view, observing in writing that the VTF was formed *"because there was no infrastructure in the UK to work across industry, academia and government"* [INQ000474423_03, §3.4]. Prior to their arrival, the Civil Service had defaulted to use of management consultants in this area, perpetuating a vicious cycle which in Bingham's view prevents the development of in-house government expertise in this sector.

24. Once in place, the VTF was required to navigate significant challenges presented by government structures, including relations with the Cabinet Office which were "*not easy*" and most notably HMT processes which were described by Dame Kate Bingham as "*completely rigid and not fit for purpose"* [6/38/2-5]. Dame Kate also notes "*contradictory feedback*" from different members of the Treasury, some of whom encouraged the exploration of opportunities to build long-term resilience and others who displayed an aversion to spending other than on the short-term UK government response [INQ000474406_018, §§14.3-14.5, 15.1]. This evidence chimes with the experience of Eddie Gray and Sir Sajid Javid in respect of spending on antivirals (as to which, see further below).

25. As set out in our opening submissions, it is instructive to assess the performance of the VTF against its stated objectives, which were broadly threefold, namely to secure access to promising vaccine(s) for the UK population; to make provision for the international distribution of vaccines and to support industrial strategy by establishing a long-term vaccine strategy plan to prepare the UK for future pandemics [INQ000421906]. On Dame Kate's own analysis, the VTF's success in respect of the first goal was not matched in respect of the second and third.

26. As to the ambition of extending vaccines globally, Dame Kate made a compelling case that the UK did not do enough early enough despite the strong moral and clinical case for global vaccine access. In oral evidence, she noted that *"we were not even in the top ten of countries donating vaccine […] in 2021, when it matters"*, expressing the view that the UK must *"play an active role at the time when it matters, rather than afterwards"* [6/13/6-15].

27. Given its focus on future planning, the Inquiry will also no doubt be particularly concerned by Dame Kate's assessment that the VTF performed "*very modestly*" insofar as its third goal of securing UK resilience to future pandemics is concerned [6/14/16-19]. We address the question of long-term resilience in detail below but note here that the evidence shows a much more mixed picture of the UK pharmaceutical response outside the initial successes of the VTF as led by Bingham and Dix. In this regard it is useful to consider two high profile elements of the vaccine response, namely VMIC and the cancellation of the Valneva contract.

28. Professor Bell explains that VMIC came out of the Life Sciences Strategy he led in 2017 and aimed to support both academia and industry in vaccine development by assisting with manufacture for critical early phase studies. According to Alexandra Jones of DSIT (formerly BEIS), VMIC was expected to have an emergency response capability which would be able to produce 1m-3m doses of vaccine within 3 months [INQ000474338_32, §104]. The limited company formed to advance the project, VMIC UK Ltd, received £65m of public funding in 2018 but VMIC was still *"under construction"* when the pandemic arrived, due to what Professor Bell describes as "*dithering*"; this was recognised to be a "*major mistake*" [INQ000499442_16, §51].

29. This mistake was compounded during the pandemic. Ms Jones confirmed that further government funding in the order of £140 million was provided to VMIC UK Ltd to accelerate and expand the Centre. Notwithstanding this significant influx of public money, the project

was never completed and ultimately the site was sold to a private company in April 2022 [INQ000474338_32, §§110 - 112]. Ms Jones explained that the sale was to Catalent, "*a contract management and development organisation that had committed to turn it into a manufacturing facility and create up to 400 jobs in that area*" [5/13/7-10]. However, while this was not clear from her statement, Ms Jones confirmed in oral evidence that Professor Bell was correct in his understanding that the site had been "*mothballed*" [5/14/8-11]. Not only, therefore, was VMIC unable to contribute to the pandemic response, but it is now clear that it will play no role in UK resilience for the future or the UK economy more widely. Although the position is still not entirely clear, it appears from Ms Jones' evidence that the UK government recouped £80m from the sale, a fraction of the public investment that went into VMIC [5/13/25-14/7].

30. We share the concerns expressed by Dame Kate Bingham and others about the collapse of what should have been a vital piece of infrastructure both for the Covid-19 and future resilience, largely due in Professor Bell's opinion to "*failures of Government*" [Bingham INQ000474406_60 §47.11; Bell INQ000499442_17, §55]. We note Professor Pollard's view that *"VMIC could have filled some of [the] gap in capability for small to medium scale production and allowed more rapid innovation in vaccines in the UK post-pandemic"* [INQ000474399_12, §27]. Professor Gilbert's assessment is that *"[t]he UK has no national capability in vaccine manufacturing, which VMIC could have provided […] VMIC […] could have produced much larger number of doses of vaccines, which in some cases could be sufficient to respond to an outbreak without any other manufacturer being required."* [INQ000474278_13, §57]

31. As foreshadowed in CTI's opening submissions, the Inquiry has also heard a significant amount of evidence about the termination of a government contract with Valneva for the supply of millions of doses of its whole inactivated viral vaccine. This contract was agreed in September 2020 with the active involvement of Clive Dix but cancelled in September 2021, shortly after his departure from the VTF and, according to his understanding, on the advice of his successor as Chair or the then Director General of the VTF. The ultimate decision-maker in this respect was the Health Secretary, Sir Sajid Javid, who said that this was *"a very clear decision"* based on advice that Valneva was ineffective as a third dose [8/58/13-59/4].

32. Addressing this issue in his statement, Professor Van-Tam recalls concerns being raised within the VTF steering group that the vaccine may not receive MHRA licensure, and that the clinical data was less impressive than the data they had seen for the Pfizer/BioNTech,

Moderna and AstraZeneca vaccines. He was doubtful that the JCVI would have recommended the inclusion of the Valneva product in the vaccine programme [INQ000474404_75, §5.3]. Professor Harries expressed the view that this was "a well-considered decision"; felt that Valneva "could not deliver against its contract" and the product was not likely to be put forward as a JCVI-recommended vaccine [5/213/2-215/8].

33. However, both Dr Dix and Dame Kate Bingham express trenchant criticism of both the decision to terminate the Valneva contract and the manner in which this was done. Dame Kate's statement describes the decision as inexplicable and the advice on which it was based as "wrong". In his oral evidence Dr Dix expanded on the latter point, explaining that *"the data they used to make that decision was poor",* based on a "*flawed study*", and told the Inquiry straightforwardly that he "*can't believe there's an expert that would ever make a decision based on that data"* [12/78/20 – 80/20]. Dame Kate Bingham also makes serious criticisms about the manner in which the contract was terminated, expressing her concern that the cancellation *"looked like we acted in bad faith"*; noting that*" by alleging breach of contract, the Government sought to avoid even paying for the costs which Valneva had already incurred in good faith"* and describes the cancellation as 'improper'[INQ000474406_47.13-47.15].

34. It is understood that resources are finite and that difficult decisions will always have to be made in an emergency response. It is also noted that the specific criticisms about the basis for decision-making have not been canvassed directly with those responsible for providing advice on this issue. However, these criticisms should be taken seriously, coming as they do from individuals with profound expertise in the sector. So too should the evidence from Bingham and Dix as to the impact on relations with industry. In the latter respect their views are echoed by Professor Bell, who observes that the termination of the Valneva contract "*was received badly by industry and was not good for efforts to make the UK a home for vaccine companies"* [INQ000499442_33, §96] In his statement Professor Pollard makes reference to the impact of this in terms of the UK's versatility, noting that since the contract was cancelled it may now be less likely that the UK will have the capability to manufacture this type of vaccine in the future [INQ000474399_20, §42]

Therapeutics and prophylactics

35. The UK response on therapeutics must be assessed in light of their crucial importance, particularly to the clinically vulnerable: as Professor White notes, *"even when we have vaccines that are working well, we still need drugs to treat infections as an important public*

health insurance policy. These drugs can prevent and treat those people who are not protected by, or did not receive a vaccine" [INQ000474743, §1.3]. In oral evidence, Professor White confirmed that if they had been available in 2020, new therapeutics would have had a dramatic impact on the course of the pandemic, and this must be the aim in a future pandemic [12/8/17-24]. Again, while CBFFJ UK and NI CBFFJ recognise and commend achievements including the RECOVERY trial's findings on dexamethasone, we invite the Inquiry to guard against complacency and scrutinise with care the wider picture of how the UK performed on therapeutics.

36. The Inquiry is well-aware of the distinctions between the approaches adopted by the UK government in respect of vaccines on the one hand and therapeutics on the other. While there were undoubted differences between the two areas, the level of priority afforded to therapeutics must be evaluated, with account being taken of the view expressed by Dame Kate Bingham as to the peculiarity of using a different model in respect of vaccines on the one hand and therapeutics, including prophylactics, on the other [INQ000474406_43, §38.15]. In our submission, this was not a case of either/or and there had to be proper concentration on both.

37. As to therapeutic trials Professor Whitty noted that the UK performed effectively in respect of repurposed drugs such as dexamethasone but acknowledged that the system of choosing novel drugs for phase I and II studies "*got off to a slightly shaky start*" [5/63/15-20]. Although understated, this is consistent with the evidence of others including Sir Jeremy Farrar, who says more robustly that in the initial stages of the pandemic *"time was lost in frustrating discussions, dysfunctional planning and execution in setting up a component of the Therapeutics Taskforce for triage of earlier stage assessment of potential therapeutics in Phase I and II trials*, expressing the view that in future this should be established from Day One [INQ000496107_05]. Professor Bell observes that the story around Phase II studies of novel agents was "*much less edifying for the UK academic research community*" describing a "*clumsy and clunky"* process with *"a very real lack of clarity as to who was responsible for what"*, resulting in *"a complete shambles"* [INQ000499442_13, §39, §177]. We note that his proposal that a single lead should be hired for the whole programme had been roundly rejected by academic centres and funders alike.

38. In due course the Antiviral Taskforce was established in order to secure antiviral medicines for winter 2021. The appointment of Eddie Gray as external Chair quickly ran into "disappointing" procedural obstacles similar to those identified by Dame Kate Bingham,

meaning that his appointment took two months to be finalised, representing 25% of the time available for the project to be completed. More serious still is Mr Gray's evidence of his experience of intra-governmental decision-making on budgets (including behaviour amounting to "*little more than mischief-making by the Treasury*") and spending relating to this crucial area of pandemic response [INQ000474342_03, §§6-8; _25, §60].

39. Mr Gray is at pains to acknowledge both the evolving climate around Covid response by the time of his involvement in 2021 and the legitimacy of government concerns about balancing expenditure with affordability, albeit in the context of public health as a core government responsibility which cannot and should not be easily set aside. However, instead of the expected process by which balancing decisions between public health and affordability were made by appropriately senior and accountable individuals, Mr Gray saw a "*slow journey away from the [DHSC] advocating what it felt was the appropriate public health response towards a position of finding a proposal that 'the Treasury would accept*' in the context of an unequal and flawed balance of power between HMT and other departments. Ultimately Mr Gray became concerned that the rationale for the ATF's proposals were being "*lost or obfuscated*" [INQ000474342_27 §72].

40. These concerns and the frustrations they evoked ultimately required Mr Gray to circumvent intra-governmental processes in order to secure the intervention of both the Secretary of State and the Prime Minister to obtain the antivirals the ATF considered were necessary. On 15 September 2021 he wrote directly to the Prime Minister, describing a *"war of attrition*" over making funds available which was putting the UK position in jeopardy, and noting that if affordability were to outweigh the public health case this should be openly and clearly acknowledged as a decision made with that understanding, rather than an inevitable consequence of interdepartmental disagreement and procedures [INQ000410527_03]. Two and a half months later, Mr Gray wrote to Sir Sajid Javid "*with a dreadful sense of déjà vu and not a little annoyance*", finding himself "*once again mired in the treacle of interdepartmental process and argument*" [INQ000309476]

41. It is noteworthy that these frustrations have been echoed in the evidence of Sir Sajid Javid, who describes the Treasury as having to be "dragged" through this process, which took far longer than it should have. Sir Sajid summarises his wider view of the HMT approach, as follows:

> *I saw firsthand that the approach to funding the vaccine and the willingness to take risks did not even last the length of the pandemic […] in the circumstances, it is not*

helpful to adopt an overly risk adverse approach, particularly when the drugs concerned had been seen as necessary by a multitude of experts. The Treasury should not automatically presume that it needs to conduct further value for money assessments, or that such is required. I am aware that spending departments are seen by the Treasury as constantly demanding money, but particularly in this instance, such monies were necessary and valuable. [INQ000474381_09, §§23-24].

42. This remarkable evidence resonates not only with the experience of Dame Kate Bingham, but also with entries made by Lord Vallance in his evening notes as to the approach of the Treasury on antivirals (see further below). We submit that an approach such as the one described here inhibits an effective pandemic response and must be remedied for the future.

Evusheld

43. Other Core Participants will no doubt address the Inquiry in detail in respect of this issue, and the Inquiry will have in mind the evidence given by Lara Wong of the Clinically Vulnerable Families Group and by Kamran Mallick of the Disabled Peoples' Organisations about the impact of the decision not to make Evusheld available in the UK. We address Evusheld here in overview because of its obvious public importance and because we submit it is illustrative of the approach taken by government to this crucial element of the pandemic response.

44. Again, the Inquiry has heard strong evidence from Dame Kate Bingham and Dr Dix on this subject which cannot be disregarded. Dame Kate expresses the view that the decision not to purchase Evusheld was a "*serious mistake*", meaning that the UK was the only Western country not to protect its immunocompromised people using long-acting antibodies, plausibly costing lives and condemning many more people to suffer through long term shielding [INQ000474406_43, §38.13]. Dr Dix too mentions his belief that the UK was the only country who made such a decision, which he describes as "incorrect" and "very disappointing" [INQ000474423_§9.1]. Professor Bell expresses the view that *"this could have been an effective treatment for the immunocompromised who were poorly looked after"* and confirms that *"the UK was an outlier in that it did not adopt these antibodies early even though they were discovered here"* [INQ000499442_64, §184].

45. Both Bingham and Dix have also expressed their belief that concern at DHSC over Evusheld was, in Dame Kate's words, "*driven in part by the potential cost of purchasing*

the requisite amounts of Evusheld" [Bingham INQ000474406_43, §38.14; Dix INQ000474423_§9.1]. In his oral evidence, Dr Dix was asked about the rationale proffered by Professor Whitty and Professor Van-Tam in respect of their advice around Evusheld and rejected each reason in turn, expressing the clear view that "*most of those are excuses, and the actual reason that it wasn't purchased was cost.*" His explanation was as follows:

> So, shelf life is – it's an error […] we did all the diligence […] on these antibodies. The shelf life was, at the time when we put the recommendation in, already six months, but with a statement that all of the antibodies in this category in the past had had shelf lives of over 18 months to 2 years and that they were likely to have the same.
> Shelf life isn't even an issue, because you don't get a medicine of any type into your hands until it's approved. And once it's approved, you agree a delivery schedule to have it at the rate that you can use it. So that just isn't an argument, it's fatuous.
> In terms of giving it over and over again, this antibody protected people for six months, and we were talking about buying enough to give people two doses, to get them through this early stage of the pandemic and free them from a lockdown. So I don't understand, over and over again. Two doses, six months.
> And then there were some discussions about it being difficult to deliver to the patient and they needed specialist clinics. It was intramuscular, it was an injection in the bum […] so these arguments sound great but I honestly don't believe they're valid at all. [12/87/14-89/22]:

46. We submit that this evidence must receive careful consideration and casts a shadow over the reliability of the evidence of Professors Whitty and Van-Tam on this issue, particularly given that it is consistent with evidence of the wider attitude towards antivirals across government. In an email chain on 20 August 2021 Charlotte Taylor explained that she had just had a conversation with Lord Vallance about prophylaxis in relation to Evusheld and told him that there was "*limited enthusiasm for prophylactic use across the system*," which he considered to be misguided [INQ000066712]. The extracts disclosed from the evening notes of Lord Vallance are also instructive in respect of the attitude of HMT and DHSC towards antivirals: see in particular entries dated 26 and 30 March 2021 (at the point the ATF was being established); 27 and 29 November 2021 (only days before Mr Gray's frustrated email to the Secretary of State on 1 December) and 14 February [INQ000506873].

47. Finally, in respect of the later phase of decision-making, we note that Helen Knight of NICE recognised that in hindsight "*the UK public health and regulatory system could have looked more intensively at whether or not Evusheld was effective against SARS-CoV-2 variants*" [INQ000474611_55, §136]. Professor White told the Inquiry that decision making was comparatively *"rather slow"* and says in writing that "*questions over the efficacy of Evusheld remained unanswered but could have been answered rapidly by contemporary pharmacometrics studies*", adding in oral evidence that in such circumstances the outcome "might" have been different and there was "possibly" a window of opportunity for Evusheld [12/22/20 – 25/14]. Professor White also comments on the passive approach adopted by the committees charged with reviewing the evidence and providing advice. We submit that an active and comprehensive approach should have been taken in this important area and is clearly needed for the future.

C. Legacy – where are we now?

48. The Inquiry will be particularly keen to establish the UK's current position with regard to research and development, procurement and manufacture of vaccines and medicines to inform its recommendations for the future. CBFFJ UK and NI CBFFJ submit that the evidence indicates that the UK response and actions post-pandemic were not faithful to the initial 'legacy' approach as set out in the third goal of the VTF and that in many respects the UK is less prepared now than in 2020. The thrust of this evidence is illustrated by Professor Bell's overall view that many aspects of the pandemic response "*have gone backwards*" and we share his concern that there "*seems to be almost no grip at all as to what we are going to do in the future should we encounter another pandemic*" [INQ000499442_69, §198]. The Inquiry will recall Lord Bethell's assessment that we are in worse shape today than we were five years ago [11/68/25 – 69/4]. These views are agreed by others to the extent that they are pervasive

Relationships with industry

49. Powerful evidence about the adverse impact of government decision-making on relations with industry has been given, most prominently by Dame Kate Bingham and Dr Clive Dix. Strikingly, in his written evidence Dr Dix says this: *I do not believe we have any resilience. In fact, we have less resilience now because a lot of the manufacturers have walked away from the UK because of how badly they were treated in the tail end of the VTF* [INQ000474423_15, §6.2]. Such views from two independent voices who are strongly connected with industry deserve the Inquiry's attention. While government witnesses

including Professor Harries emphasised ongoing relationships with industry, as set out above we note with serious concern the collapse of the planned AstraZeneca vaccine plant in Speke.

Research and development

50. The Inquiry must heed the evidence of the prominent scientists before it on the current state of research and development for vaccines and therapeutics in 2025. Professor Horby says that despite initiatives such as the WHO R&D Blueprint and the 100 Days Mission "*we are not where we should be in terms of research and development for major infectious threats. There is no coordinated and credible UK national or international programme for identifying, funding, commissioning and tracking the required research and development.*" [INQ000474624_29, §129] Professor Pollard considers that, like the US, we must consider microbial threats in the same way as military defence, meaning that *there should be strategic leadership on vaccines […] that is credible on the international stage with a properly funded ecosystem to invest properly to increase security*". In his view we are not close to this goal [INQ000474399_ 47, §105].

51. As to the content of such research and development, this is effectively summarised by Professor Gilbert, who notes that we now have a better understanding of how to develop vaccines against another novel coronavirus but need to develop the same level of understanding for other families of virus. She adds that this work is being done elsewhere in the world but should be continuing in the UK [INQ000474278_19, §85]. Professor Pollard's evidence is to similar effect, emphasising firstly that this cannot be limited to one technology [INQ000474399_44, §102] and secondly that it cannot be certain that a vaccine would ever be achieved.

52. Clearly, this means that greater priority must be afforded to therapeutics and antivirals. Sir Jeremy Farrar sets out in his statement that his work on ensuring that therapeutics are not neglected is an uphill task, and that we don't presently have the balance right [INQ000496107_06]. Professor Bell notes that work on antivirals must be developed now during 'peace time', emphasising that we are totally unprepared to deal with this now and a systematic programme should be implemented [INQ000499442_64, §§181-183]. The Inquiry heard similar evidence from Professor Whitty as to the need to develop a library of prototype antivirals [5/68/9-69/17] and see also the written evidence of Lord Vallance at [INQ000474482, §127].

Manufacturing

53. As to manufacturing infrastructure, the Inquiry will have well in mind the evidence relating to the government's strategic partnership with Moderna, and the possibilities this opens up for onshore mRNA manufacturing. However, we again note the evidence of Professor Pollard, who observes that there is *no big pharma manufacturing available in the UK using other vaccine platforms (except for the live attenuated influenza vaccines) and so we do not have capability if mRNA turns out to be the wrong platform for a particular disease"* [INQ000474399 13; §§3; 42-43]. While recognising the importance of mRNA technology, Professor Barclay identifies the danger that mRNA may not be the optimal platform for every new disease and the risk that without further investment for continued innovation, funders and policy makers may now believe the problem is solved [INQ000474315_12, §46].

54. This evidence clearly resonates with the need identified by Professor Van-Tam, Dame Kate Bingham, Dr Dix and others for a portfolio approach, memorably referred to by Professor Van-Tam as a form of spread betting. In his written evidence Lord Vallance observes that *"[t]his portfolio approach is not usual in government but is an essential model when dealing with the uncertainty of innovation"* [INQ000474482, §107] a view also expressed in a report commissioned from McKinsey and Company, which found that "*resilience requires multiple vaccines and biotherapeutics candidates in as many modalities as possible and the ability to develop, produce and distribute quickly and at scale* [Jones, INQ000474338_52, §215]. Other witnesses including Professor Pollard speak with one voice on the imperative not to rely on only one vaccine platform.

55. While Ms Jones indicated that the UK still has 'investments across different technologies', there was nothing in her evidence to suggest any developed plan for manufacturing capacity in respect of any vaccine technology other than mRNA. It is a matter of acute concern to CBFFJ UK and NI CBFFJ that as a result of decision-making during and in the wake of the pandemic, the UK does not have manufacturing capacity across a range of vaccine modalities. We also note the evidence about the need for additional manufacturing capacity for monoclonal antibodies, which is needed in case a vaccine is not the way out of the next pandemic: Vallance [INQ000474482; §126]; Sharma [4/37/2-13]. Again, Ms Jones said that this was part of the work being done through the life sciences innovative manufacturing fund, but was unable to provide information about dedicated sites for manufacturing of antibody and antiviral manufacturing in the UK. It is of note that the only

specific site referred to by Ms Jones in respect of diversity in manufacturing capability in the UK was the proposed initiative from AstraZeneca in Speke which has now collapsed.

Clinical trials

56. Another area of concern for future resilience is clinical trials. Matt Hancock's evidence that clinical trial capability has degraded very significantly since the pandemic was echoed by others including Lord Bethell and Ben Osborn of Pfizer, who noted that the UK's ranking in respect of industry phase III trials has dropped recently from fourth to tenth in the world [8/146/15-147/20]. This clearly needs attention, including in respect of funding, notably because of the capacity of the NHS to deliver on clinical trials. Sir Jeremy Farrar notes that the NHS is uniquely placed to lead work on clinical trial capacity globally, but warns that there is *"a grave danger this is now being undermined in the UK and the global leadership in clinical science is at risk of being lost"* [INQ000496107_07].

57. In light of the evidence about the problems associated with phase II trials during the pandemic, we note Lord Vallance's indication that it may be useful to consider now what a large common protocol phase 2 programme might look like in the event of a pandemic. It appears from this that such action has not yet been taken. Similarly, Professor Pollard recommends work to develop principles to guide design of clinical trials for different scenarios so that rapid development can follow a plan that has been scenario tested [INQ000474399_045, §102(e).

58. We also invite the Inquiry to pay close attention to the observations of Professor Horby and others in respect of maintaining the knowledge, expertise and capacity gained through platform trials in the pandemic that *"the clinical research platforms established in the UK during the pandemic have been effectively stood down by UKRI and NIHR and any under-spend recovered. RECOVERY was asked to return unspent funds despite us presenting a case to UKRI and NIHR for using these funds to maintain the platform and study influenza, the most likely next pandemic threat"* [INQ000474624_27, §124. Professor Landray notes in this regard that the RECOVERY trial has diversified into the study of treatments for influenza and pneumonia but receives no grant funding from UK government, a situation that he assesses runs contrary to the recommendations of the 100 Days Mission and is not in the best interest of preparedness for future pandemics. [INQ000474660_86, §333]

59. On this theme, we also commend to the Inquiry Professor Khoo's evidence as to the importance of publicly-funded trial platforms, noting that the explicit assumption that early-phase drug development is industry's responsibility does not work for pandemic preparedness, which requires investment in drug development for an unknown pathogen which might never develop. [INQ000474449-15]

Strategic planning

60. A key theme among witnesses on the issue of resilience is fragmentation and the lack of a coherent plan. Professor Bell notes that many of the initiatives to prepare for the future have emerged in an ad hoc way [INQ000449442_34, §99]. As set out above, Professors Pollard and Horby also emphasise the need for strategic leadership and planning, with Professor Horby explicitly recommending the development of a national research and development strategy [INQ000474624_29, §129]. Professor Gilbert's assessment in respect of vaccines is blunt: *The UK is not well prepared to produce vaccines for the next pandemic. There is no co-ordination and no plan. There is no national capability*." [INQ000474278_19, 82]

61. The evidence before the Inquiry supports Professor Gilbert's view. While UKHSA might be expected to assume responsibility for strategic planning, it was clear from the evidence of Professor Harries that it does not have the requisite oversight of what she referred to as the 'whole continuum' of preparedness, including manufacturing and technological coverage. Recognising the wider importance of UKHSA's role, Dr Dix nevertheless gave clear and compelling evidence about its inability to provide leadership on vaccines and the reality of VDEC as a testing centre, lacking the required vision or leadership on innovation [12/96/2-20]. We note also Lord Bethell's lament that UKHSA has been 'denuded' and the evidence of several witnesses as to its limited budget. As to manufacturing capacity, when confronted by the Chair with the all too plausible scenario of a pandemic arriving tomorrow, Ms Jones of DSIT was in our submission unable to provide any reassurance as to the ability of the UK to respond effectively [5/25/5 – 27/15].

62. It is a matter of acute concern that this is the picture five years after the start of the pandemic, and that a witness such as Professor Bell, with his strong network of connections across academia, government and industry, feels that the UK (and others) have 'downed tools' on pandemic preparedness in this sector. To use his words, it is imperative that the UK government 'gets a grip' and implements a coherent strategic plan for vaccines and therapeutics [INQ000449442_69, §198].

Funding

63. Finally, CBFFJ UK and NI CBFFJ turn to the need for proper funding, which is implicit in all of the above, and which was recognised by the Inquiry in its Module 1 report, but which bears emphasis here. To borrow Professor Van-Tam's analogy, we recognise that pandemic preparedness, like freedom, is not free. However, we note also Professor Pollard's assessment that '*infectious diseases are capable of wiping out large numbers of people and yet we spend a trivial annual budget on research and development to defend our community",* that budget representing a very small fraction of the amount spent on defence annually [INQ000474399 11; §25]. This must change if the UK is to build on its achievements in Covid and prepare to meet the next pandemic.

Vaccine rollout across the UK

64. The Inquiry has evidence from its experts and others as to the speed and success of the rollout of vaccines across the UK. Again, CBFFJ UK and NI CBFFJ UK invite the Inquiry to scrutinise the evidence to identify areas of strength which need to be maintained and built upon, and areas where there is a need for improvement, bearing in mind that the next pandemic may have different characteristics from Covid. For our families, the fundamental questions include (i) whether the UK had proper planning to allow it to devise and implement an equitable and effective rollout strategy at speed in Covid, and whether it would be able to do so in the next pandemic; and (ii) whether decisions as to rollout were evidence-based, transparent, effective and equitable, in particular with regard to prioritisation, dosage intervals and rollout to particular groups, including Disabled people, children and pregnant people.

65. CBFFJ UK and NI CBFFJ invite the Inquiry to keep these questions at the forefront of its consideration of rollout and deployment, alongside the range of issues raised by our clients' experiences as set out in the written and oral evidence of the bereaved.

Planning

66. As to planning, we note at the outset two overarching points from the expert evidence of Dr Chantler and Dr Kasstan-Dabush.

67. Firstly, the experts observe that the UK government invested £120m on vaccine development between 2016-21 as part of preparedness efforts but "*no proportional commitment was made to strengthen UK immunisation deployment systems to enable rapid implementation of a universal vaccine programme in an emergency scenario and avoid foreseeable disparities in coverage*" [INQ000474623_07, §7]. They go on to emphasise that UK immunisation systems need to be in a state of readiness to be pivoted if the 100 Days Mission is to be fulfilled in the event of a pandemic. In oral evidence Dr Kasstan-Dabush reiterated that *"I think it is just having the routine programme in a state of readiness that can be pivoted in a public health emergency when that inevitably happens. I don't think we had that in Covid-19. It had to be built in realtime. The goal should be to have that strong, robust, resourced routine programme that can be pivoted"* [10/202/13-19].

68. All of this echoes the evidence of Ms MacNamara about building the ark after the flood has started, and chimes with the written evidence of Professor Pollard that we *"do not have sufficient investment in routine immunisation services to maintain high vaccine coverage and access to and confidence in vaccines in peacetime, that would make uptake better in a pandemic"* [INQ000474399_11, §25]. Clearly, this needs to be remedied for the future.

69. Secondly, and relatedly, the experts note in their report that "*development of the UK Covid-19 vaccination programme required integration of multi-disciplinary and multi-sector expertise"* yet *"stakeholders with immunisation implementation experience (e.g. NHS England & Public Health England) were not included as core participants in key programme boards tasked with planning roll-out processes until September 2020"* [INQ000474399_9, §12]. While in oral evidence Dr Chantler said it was reassuring to be told that PHE may have been a member of the programme board of VTF from May 2020 onwards, she maintained that *"it would have been better if they were involved in the formal taskforce overall, given that they […] have the primary responsibility for routine immunisation programmes"* [10/150/14 – 151/20]. It is submitted that there is a clear and obvious advantage from a planning perspective in involving those responsible for vaccine as early as possible in order to enhance effectiveness, maximise accessibility and ultimately encourage higher vaccine uptake.

Prioritisation

70. CBFFJ UK and NI CBFFJ understand the JCVI's rationale for advising a predominantly age-based approach to prioritisation having regard to the available data on morbidity and mortality and the imperative to save lives and protect the most vulnerable.

71. However, we note that beyond age there were other known vulnerabilities arising from race / ethnicity, disability and occupation which presented arguments for prioritisation. In particular, the role of workplace inequalities in the differential impact of the pandemic on ethnic minorities and pre-existing barriers to vaccine uptake among ethnic minority and migrant groups should have been considered in prioritising early vaccine eligibility. Such vulnerabilities were foreseeable even in advance of the pandemic, and we submit that proper planning at an early stage would have enabled consideration of how they might be factored into a vaccine deployment strategy, not least by proper focus on the data that would be required to enable such vulnerable groups to be identified quickly and accurately. This would have allowed people in high-risk minority ethnic groups to be appropriately prioritised for Covid immunisations, and for appropriate targeted communications to have been developed at speed.

72. Several witnesses, including Professor Harries and Dr Kasstan-Dabush, pointed to the simplicity of the age-based approach as an advantage in terms of rollout. Again, we submit that proper planning in the form of advance identification of vulnerable groups would have enabled a more nuanced approach to prioritisation to be implemented without a loss of speed. This gap should be remedied in advance of the next pandemic.

73. The Inquiry will recall the moving evidence given by Jean Rossiter about her son Peter and the circumstances leading up to his death in August 2021. Peter received his first vaccine dose in May of that year and tested positive for Covid very shortly after receiving his second dose in July. Mrs Rossiter was subsequently told by Pfizer that given the timing of the infection Peter would not yet have been fully protected by the second dose. Peter was a teacher and key worker who went to work throughout the pandemic to provide education for the children of other key workers who were themselves unable to practise social distancing. As a result, Peter was exposed to much greater risk of infection than many other people [2/52/24-57/13]. While the Inquiry will not conduct an examination of Peter's individual case, his story provides a powerful illustration of the arguments for prioritisation according to occupation, and in particular for key workers. In this regard we note that the JCVI advice of 30 December 2020 expressly left open the possibility of prioritising the vaccination of those at increased risk of exposure to Covid due to their occupation in phase two of the rollout. The advice notes that JCVI considered this to be a

matter of policy for DHSC to consider in collaboration with other government departments, but it does not appear that this was taken forward [INQ000354469_14-15].

74. In their report, Drs Chantler and Kasstan-Dabush refer to the public interest during the pandemic in prioritising occupations such as education for vaccination. They note statistical evidence from Module 2 that teachers and educational professionals had the lowest age-standardised mortality of occupational groups but among the highest risks of infection [statement of Professor Diamond INQ000271436] and go on to conclude that *"pandemic preparedness efforts may benefit from examining the impact of expanding definitions of 'essential services' and determining which professions should be given advanced access to vaccination'* [INQ000474623_20, §§46-48]. We respectfully agree that this work should be undertaken now, to include examination of the experience of the US states which prioritised teachers for vaccination as alluded to by the experts and extending to other occupations, such as transport workers.

Dosage intervals

75. Peter Rossiter's experience also highlights the issue of dosage intervals and the decision to extend the interval between the first and second vaccine doses beyond that recommended by the manufacturer (In Peter's case, Pfizer). While it appears there was a theoretical basis for the proposition that extending the period between doses would be likely to enhance the protective effect of the vaccine, it was apparent from the evidence of Professor Lim and Professor Van-Tam that this controversial decision was driven by constraints in supply.

76. It is submitted that this 'hard-nosed reality' as described by Professor Van-Tam leads us back to the question of planning for rapid vaccine development: greater supply capacity would avoid the need for trade-off between volume of first doses and maintenance of the recommended dosage interval. By the time Peter was vaccinated, the interval had been revised from 12 to 8 weeks but this remained significantly longer than the original timescale of 21 days as advised by the manufacturer even in much less constrained supply conditions. Whatever the overall public health effect, Peter's case illustrates the grave potential impact at an individual level and the corresponding need for decisions of this kind to be made on a clear evidence base rather than in response to supply constraints.

Rollout to excluded groups

77. We address the need for racial diversity in clinical trials below, but the Inquiry has heard a considerable amount of evidence about the exclusion of children and pregnant women from clinical trials and the impact on their access to, uptake of and advice relating to vaccines. This has particular resonance to CBFFJ UK and NI CBFFJ having regard to the experience of their members as set out in the supplementary statement of Jean Rossiter [INQ000474666]. We note the evidence of Professor Whitty in particular as to the problems inherent in excluding people systematically from studies but the Inquiry has not heard any evidence about how practically this issue might be addressed, not only during pregnancy but also for children. This is clearly a matter which requires attention now in preparation for a future pandemic which may pose even greater risks to these groups.

Data

78. The Inquiry continues to hear a large volume of evidence about the problems and challenges associated with data in the pandemic. This is a cross-cutting issue throughout this Module and the Inquiry as a whole, but does have particular significance in rollout and delivery because of the importance of being able to accurately identify cohorts for vaccination and also potentially to assist in monitoring and addressing lack of confidence [Whitty 5/53/15-54/14]. Professor Whitty's evidence that "*we have slipped backwards since our time in the pandemic in terms of bringing data together*" [5/50/1-5] is a matter of obvious concern, and one the Inquiry will have well in mind when it comes to recommendations. This must be addressed with proper attention to security, data protection and privacy concerns to ensure that trust is maintained and built on and that people remain supportive of data sharing for health purposes.

Lessons learned across the four nations

79. While limited, the evidence on rollout across the four nations has helpfully highlighted both alignment and variation in how vaccines were delivered across the four nations, and it is important in our submission that lessons should be learned from this comparative evidence. One step towards effective learning would be to implement the suggestion of Drs Chantler and Kasstan-Dabush for a UK-aligned approach to evaluation of vaccination programmes [10/156/10-23]. We also commend to the Inquiry the evidence of Mr Grieve and Dr Richardson as to the need to update the governance arrangements in respect of JCVI to reflect the devolution settlement and ensure that there is proper representation of the devolved administrations in these vital structures.

Vaccine rollout in Northern Ireland

80. NICBBFJ understands that the time frame for M4 necessarily required a lot of witness evidence to be packed into a short amount of time, with the overwhelming focus being on those at the heart of the UK government effort to develop and deliver the vaccines. However, our client group remain extremely disappointed that a total of just under one hour was dedicated to evidence directly concerning Northern Ireland in the oral hearings. We raised concerns in relation to previous modules that specific evidence and issues relating to NI were not likely to receive sufficient attention. In M4, the position was particularly stark. Whilst we know the Inquiry will take full account of the written evidence received in relation to NI, there is no doubt that the absence of live witness evidence and the related ability to probe NI specific witnesses, diminishes confidence and engagement of our families with the very important issues raised in this module.

81. The practical impact of this is that many of the issues we raised in our opening submissions – including the extent of the deficiencies identified in preparedness, data collection and the logistical "teething problems" inherent in any mass roll-out of the Covid vaccination programme were not explored with the relevant witnesses as much as NI CBFFJ would have wished.

82. To give just one example, the use of mobile teams to deliver the vaccine to care home staff and the elderly in the early days of the programme has rightly been highlighted as a positive aspect of NI's approach [5/179/7-15]. Dr Chada praised this flexibility and highlighted it was combined with the engagement of GPs to vaccinate the housebound and clinically extremely vulnerable in the earliest stages [10/123/09-10/124/20]. Yet, it was in those early weeks that Michelle Reid of our client group was told by her housebound father's GP that no mandate yet existed for vaccination at home. Thus, when her father tested positive for Covid on 24th January 2021 and later died on 6th February 2021, Michelle understandably did not feel the benefits of any mobile delivery approach. Although NI CBFFJ raised the issue of how speedy and effective the early rollout was in getting to housebound individuals in our opening (see §10 and §25) very little of the documentary and written witness evidence appears to provide an evaluation of this aspect of delivery.

83. Northern Ireland is a comparatively small jurisdiction and the constitutional arrangements were reflected in the vaccination programme. As Michelle O'Neill observed, "vaccination roll-out was principally delivered by the Department of Health with updates provided to the Executive Committee." [INQ000474425_0006, §6]

84. There was much to be proud of in NI and elsewhere but the evidence before the Inquiry demonstrates that the roll-out of the Covid vaccine has to be viewed in the context of chronic underfunding of the health and social care system in Northern Ireland. As the Chief Pharmaceutical Officer, Cathy Harrison observed: "*The size and scale of the requirement to vaccinate most of the population against Covid-19 was unprecedented and posed an enormous challenge to the Department and a HSC system that had been under pressure for several years in the lead up to the pandemic. I believe that rollout of a large-scale vaccination programme in early 2020 would have greatly added to the already very significant pressures on the HSC system and workforce in responding to the initial stages of the Covid-19 pandemic.*" [INQ000474533_0029 §89] NI CBFFJ believes that to suggest these pressures did not have any effect on the ability of NI to respond to the challenges of the mass Covid vaccine and therapeutic programme is unrealistic, particularly having regard to Dr Kasstan-Dabush's evidence as to the importance of a robust routine programme that can be pivoted in an emergency (see §67 above and [10/202/13 – 19].

85. Dr Chada told the Inquiry that historically, vaccine programmes in Northern Ireland had been implemented by the Public Health Agency. However, because of the size of the Covid programme, "more central control" within the Department of Health was required [10/112/4]. This weakness within Northern Ireland's routine programme may be thought to have been further underlined by the fact that when this decision was taken the Department of Health did not have a permanent Senior Medical Officer lead for vaccinations and health protection in place. (See Dr Chada INQ000474476_0002, §4) Dr Donnelly's written statement states that a retired SMO was brought in between October 2020 – April 2022 but it is not clear whether anyone continues to hold such a role (INQ000474429_0003 §§3 - 4]). It will have been noted that this effectively coincided with Dr Donnelly's own appointment as Head of the Northern Ireland vaccination programme.

86. The details of the Covid vaccination implementation programme in Northern Ireland, and the bureaucratic structures put in place, are set out in Dr Donnelly's statement (INQ000474429_2 §6b & §28). Although not a live witness for M4, Dr Donnelly's evidence provides an important account of how the vaccine programme in NI was delivered at a senior level. What emerges is that Ms Donnelly, along with a very small team was responsible for the planning and delivery of the NI vaccination programme, supported by Oversight and Implementation boards. Throughout the relevant period she reported to the CMO, Professor Sir Michael McBride, who appears to have had ultimate sign off on all major decisions. [INQ000474429_4, §7] No criticism is made of Ms Donnelly, but it is of

concern to our group that someone at her level and responsibility was not put in place until October 2020.

87. Although there is no clear evidence that it was linked to this delay in particular, the Inquiry will recall the evidence of the then Director General of the UK Department of Business, Energy and Industrial Strategy ("BEIS"), Ms Alexandra Jones[1], that the involvement of the devolved nations in the genesis of the UK taskforce had been limited and that this was something she would want to learn from in the future. [5/39/9 – 5/41/4].

88. As Dr Donnelly states at §6 of her statement, she was responsible for all aspects of logistics, vaccine deployment, communications, workforce and digital requirements. Dr Chada, as the Senior Responsible Officer, was primarily tasked with liaison with the other nations CMOs and played a part in discussions on operational and policy decisions but accepts in his written statement did not have a significant role in day to day operational implementation. [INQ000474476_002, §6b] Aside from highlighting that Dr Chada was perhaps less well placed as a witness to give the Inquiry the full picture regarding on the ground delivery, Dr Donnelly's evidence is a further example of how the system in NI was shown as being under staffed, often playing catch up and under resourced, with a vast amount of responsibility, both operational and strategic, being retained by the CMO.

89. Dr Donnelly's evidence also provides an illustration of what NI CBFFJ see as the NI Department of Health's repeated tendency in this Inquiry to fail to demonstrate the level of self-criticism required to meet their stated aim of learning the lessons of implementing future vaccination programmes as swiftly and effectively as possible. Thus, although Dr Patricia Donnelly stated that the lack of a single IT system capturing vaccination data was "a *major drawback* at the beginning of the programme [INQ000474429_019, §67] the Department, in their closing address, diluted this *"major drawback"* into a simple "*challenge to make sure that the operators were able to confidently use the system, and that it effectively interacted with our GPs' IT systems …".*

90. A routine vaccination system must self-evidently be robust and in possession of sufficient data to allow effective deployment to all communities, regardless of their ethnicity or vulnerability. In this regard, NI CBFFJ is concerned that, in its closing address, the Department made no reference to the evidence of the Chief Executive of the Public Health Agency, Aidan Dawson, that: "*The data collected in VMS is combined with geographical*

[1] Transcript 20/01/25 p40/41

data using postcode, to enable surveillance at different administrative geographies (e.g. Super Output Area, Local Government District) and by deprivation measures (NIMDM 2017). Whilst VMS collects ethnicity information, its use was limited during the pandemic due to population demographics having changed significantly since the last time this information was collected at population level (Census 2011). Similarly, surveillance uptake in at risk groups other than pregnancy was challenging to measure due to lack of access to registers of those groups (such as carers or the immunosuppressed)." [INQ000474364_0027, §115].

91. As we set out in our opening submissions at §§17-29, NI CBFFJ is concerned about the apparent delay in ensuring NI had a fully operational and integrated Vaccine Management System (VMS) particularly given the knowledge that Westminster was much earlier dedicating extraordinary resources and development capability to the search for a viable mass-produced vaccine. While we acknowledge that the need to develop the VMS as the pandemic unfolded must have been a considerable undertaking and that the VMS was, at least, "*operational from the first day of the vaccine programme on 8 December 2020*" [12/108/9] our members were not reassured by the Department of Health's approach to this topic.

92. In his written statement Dr Chada observed that the fact that the VMS has been retained and adopted by the PHA for other vaccination programmes made it a valuable legacy from the Covid vaccination programme. [INQ000474476_0055, §244] In his oral evidence, he described the VMS as "*quite a successful IT project*" but did not elaborate on the "*refinements*" that had been necessary during the pandemic or what had been done to put them right. [10/129/18] The Inquiry will note the written evidence from the head of the PHA that although he also feels VMS has been "*transformational*" "*there has not yet been a formal evaluation of the benefits of VMS*". [INQ000474364_11, §47]

93. There is a particular need for rigorous self-analysis of the implementation of Northern Ireland's Covid vaccination programme. As the Inquiry heard during the expert testimony in M4, there is a real absence of evaluative reviews, studies (and the data from which to conduct them) when it comes to the delivery of the programme in Northern Ireland [10/178/11-16], As a result, the expert evidence the Inquiry heard in M4 could offer very little direct analysis of the programme in NI, despite recognising certain NI approaches appeared to work well where they could. [10/178/11-16] The obvious difficulty is that analysis of what needs to be done to improve systems for the future is lacking. Accordingly,

we urge the Inquiry to recommend that the Department of Health undertakes to publish data analysis and evaluation of the vaccine rollout.

94. It is for these reasons that our client group believe it essential to look beyond the largely positive self-reports of the vaccine roll-out that emerge from the Department of Health witnesses. Looking beyond the undoubted successes in NI Covid vaccination programme is vital in order to ensure that preparedness for the next pandemic is as good as is realistically achievable.

95. NI CBFFJ raised the lack of a carers' register in NI as an issue in our opening at §§30-32. Dr Kasstan-Dabush saw this as a significant failing, called for a consistency of approach across the UK to create a system by which unpaid carers can be more easily identified in order to maximise vaccine prioritisation and make sure people get an offer when the time is right. [10/161/17-10/162/23]. Whilst Professor Sir Michael McBride's written report refers to the Department "*exploring options around the development of a centralised Carer's Register …*" he gave no further details and stated that "*colleagues within the SSPG will be best able to provide additional detail to assist the Inquiry*." It is not clear to us that such detail has been supplied to the Inquiry.

Vaccine confidence and uptake

Foreseeability

96. The Inquiry has heard extensive evidence over Module 4 as in previous modules of the impact of pre-existing systemic and institutional inequalities on various sections of UK society with the impact being greatest on ethnic minority communities, migrant communities, the GRT community, disabled people and those living in deprived areas across the UK. These inequalities were laid bare during the pandemic and loomed large in the vaccine roll out and uptake.

97. The Inquiry will no doubt have in mind the evidence of disparity in vaccine uptake in different communities and ethnicities across the UK in its assessment of the success of the Covid vaccination programme. Vaccination status (of two doses) differed remarkably by ethnicity, deprivation and lower priority age cohorts across the UK, [INQ000474623_0006]. By July 2022 almost 2 in 5 (40%) of Black Caribbean and 1 in 4 (25%) Black African and White Other adults remained unvaccinated compared to less than 1 in 10 (8%) of White British, [INQ000273843_0004].

98. Although barriers to vaccine uptake in some communities, particularly among Black and Asian ethnicities were well known, there was no provision in the UK's vaccine development programme between 2016 – 2021 to address "foreseeable disparities in vaccine coverage" [INQ000474623_0007]. There were also no programmes to address barriers to access and no proactive engagement in underserved communities about the value of vaccines where vaccine uptake was known to be low.

99. The Inquiry has heard evidence including the lived experiences of those from underserved communities and its instructed experts that the disparities in vaccine uptake by ethnicity were foreseeable as they were known prior to the pandemic and were consistent with those observed across routine immunisation programmes (such as childhood influenza) with people of Black Caribbean ethnicity in England being least likely to receive two doses of Covid 19 vaccine [INQ000474623_0006].

100. Lower uptake in the most deprived regions across the UK was also foreseeable. The Inquiry's experts have noted that disparities in Covid vaccine uptake in areas of higher deprivation reflect issues documented in the routine vaccination programme and differential health outcomes more broadly. It was known prior to the pandemic and vaccine roll out that areas of greater deprivation are more likely to be characterised by unequal access to health services and reduced coverage of direct patient care staff in primary services and a reduction in community pharmacies funding cuts, [INQ000474623_0080]. However, as the Inquiry will very likely conclude these factors were not taken into account in the pandemic response, vaccine development and its vaccine roll out.

101. Dr Gillian Richardson told the Inquiry that the inequity gap in Covid vaccine uptake in Wales was impacted by ethnicity and deprivation with there being a lower uptake among people living in the most deprived communities compared to those living in the least deprived communities and an even starker gap between minority ethnic groups compared to people of white ethnicity. She agreed that the disparities in uptake of the covid vaccine were foreseeable and ought to have been anticipated with active mitigation incorporated into the planning and decision making around the vaccine roll out. [10/104-5/22-25;1-6].

102. The foreseeability of low uptake of Covid vaccine among people from ethnic minority backgrounds was also confirmed by the members of FEMHO: "*Prior to the pandemic it was known (and ought to have been known by decision-makers) that in relation to any vaccine uptake programmes, health screenings and on all measures of health outcomes,*

ethnic minorities always fare poorer. Outcomes in every area of health are worse so it did not come as a surprise to for any of us when it was clearly also the case for covid19" [INQ000485278_0008].

103. The SAGE ethnicity subgroup also forewarned that the failure to overcome barriers to vaccine uptake created a significant risk of lower Covid vaccine uptake among people from ethnic minority backgrounds and advised on measures to overcome these barriers – including multilingual non stigmatising communication, increasing awareness, understanding and addressing different religious and cultural concerns and community engagement from trusted sources [INQ000250215_0001].

104. Professor Whitty acknowledged that factors impacting low vaccine uptake in ethnic minorities including deprivation and distrust were known prior to the vaccine roll out and that more should have been done prior to the pandemic to improve communication links between central government and the NHS, local leaders and local communities. Low vaccine uptake among ethnic minority communities was sufficiently on the radar and of concern to cause him to convene a meeting between the Office of the CMO and directors of public health for its discussion; however, it appeared to be a talking shop as there were no material outcomes addressing the issue. He accepted that the failure to engender trust and remove barriers to uptake among ethnic minority communities was a failure on the part of government [5/91-94/18-9].

Structural and institutional discrimination and racism

105. In addition to being foreseeable, pre-existing barriers to vaccine uptake among sections of the population and deeply rooted in structural discrimination across ethnicity, socio economic background, disability and among migrant communities and people with insecure immigration status: Chantler and Kasstan-Dabush [INQ000474623_0078-0083].

106. As the Inquiry is well aware, deprivation is a structural form of discrimination. Disenfranchisement and unfair social outcomes in areas of north-west England were barriers to vaccine uptake. The costs of travelling to vaccination delivery coupled with precarious work and family dynamics adversely impacted Covid vaccine uptake in these areas [INQ000474623_0078-0080].

107. Disabled people experience structural and institutional discrimination whereby health and statutory services are not always adapted to meet their needs and they are expected to adjust or fit in [INQ000474623_0078-0080]. The pandemic exposed, intensified and reinforced pre-existing inequalities with Disabled people being one of the most impacted and affected groups. Whilst it was established at the start of the pandemic that there were a number of Disabled people at personal risk of increased vulnerability from Covid, little account was taken of the structural exclusion and discrimination experienced by Disabled people [INQ000280027]. The Inquiry has heard evidence from which it can make findings that the vaccine programme roll out perpetuated structural neglect experienced by Disabled people throughout the pandemic, which include: reliance on GP records which did not capture the severity of patient's disability and impacted prioritisation in line with JCVI guidance, not all vaccination centres were adapted for disabled access and vaccine delivery points which were not conducive to sensory needs of people with learning disabilities, [INQ000474623_0078-0080-0081].

108. The Inquiry will recall the evidence of Professors Bambra and Marmot on the intersection between health inequality and structural and institutional racism:

> "…. the health of minority ethnic groups may also be adversely impacted by racism. Racism takes various forms …. institutional racism (exclusionary processes, attitudes and behaviour "which amount to discrimination through unwitting prejudice, ignorance, thoughtlessness and racist stereotyping which disadvantage minority ethnic people" operating within key organisations such as the NHS….; and structural racism (produced and reproduced by laws, rules, and practices, sanctioned and even implemented by various levels of government, and embedded in the economic system as well as in cultural and societal norms….[INQ00019583_0013/4]

109. Module 4 has heard and received compelling evidence of the link between lower vaccine uptake among people in the GRT community and non-white ethnicities and structural and institutional racism in healthcare, the UK society, safety and vaccine trial and access barriers [INQ000474623_0078-0079-80]. There is sufficient and compelling evidence upon which the Inquiry can make findings that systemic racism and institutional racism was experienced by ethnic minority communities in accessing primary health care services, poor quality care, persistence of health inequalities and experiences of racism and discrimination when accessing health care services contributed to the low uptake of Covid vaccines by people from the Black and Asian ethnicities and the GRT community.

110. Racism in UK society with its link to the colonial past has also contributed to the lower uptake of Covid vaccine among people from ethnic minority communities, particularly among people from Black and Asian heritage. The Inquiry will have in mind Professor Gillian Richardson's evidence of the link between the UK's colonial past and low vaccine uptake: "*The fears of members of some ethnic minority groups such as some Asian and black African individuals was in my opinion a result of mistrust of authorities based on past and present experiences, including the history of European colonialism and slavery*". She noted that it therefore necessary to build trust in these communities by engaging trusted voices and leaders [10/105-106/7-25;1-16].

111. People's experiences of racist policing practices, deaths in custody and the UK government's responses to more recent events such as its handling of the ongoing Windrush scandal and the Grenfell Tower Inquiry have rightly been identified by the Inquiry's experts as contributing to a reluctance to engage with statutory services [INQ000474623_0079].

112. FEMHO has through the lived experiences of its members and communities identified discrimination and racism as factors which contributed to low trust in public institutions and low vaccine uptake among people from ethnic minority backgrounds. We commend their evidence in this regard:

> "We feel strongly that government knew, or at least ought to have known, that these pre-existing inequalities would influence the impact of their decision-making, yet they failed to take into account, proactively plan for and/or mitigate against the disparities that inevitably arose. This may be a reflection of institutional diffidence about how to deal with race/ethnicity and risk; or frankly, may indicate a lack of conviction about the importance of these issues. One particularly important aspect of this failure when it came to vaccines and therapeutics was the absence of planning and effective early response to distrust amongst ethnic minority people. Public trust is and was of course fundamental to the success of the government's response to the Covid-19 pandemic. It has been recognised and acknowledged in commentary for many years that individuals from ethnic minority communities are more wary of dealing with and less likely to trust in institutional powers; not surprising given our personal and passed-down experiences of discrimination and racism", [IN0000485278_0004/5].

113. The Inquiry will also have in mind the effect of medical racism in the UK and internationally, including the reports of unethical medical experimentation of Pfizer on children in Nigeria in the 1990s and its impact on vaccine confidence and uptake particularly among people of Black ethnicities [INQ000474623_0079; IN0000485278_0005].

114. Despite the significant contribution of migrants to the UK workforce, accounting for a significant proportion of the frontline workforce (21% in health and social care and 28% in hospitality), barriers to vaccine access encountered by the migrant community were underpinned by "hostile environment" immigration policies which are rooted in structural racism and concomitant socio-economic inequalities. Language and communication issues as well as the digitisation of health care services exacerbated existing inequalities and hindered vaccine access [IN0000474705_0042].

115. For many of the bereaved families particularly those with protected characteristics and whose loved ones were failed because of structural and institutional inequalities mere acknowledgment of what went wrong and identifying what should have been done, without fundamentally addressing structural and institutional inequalities across our society does not go far enough.

116. Covid vaccine uptake among ethnic minority communities was further undermined by a lack of diversity in clinical trials in which only 7% of the participants were from ethnic minority backgrounds which was much lower than the demographics of 13 – 15% of the UK population [4/69/1-10]. Although the imperative for diversity in clinical trials was recognised with witnesses there appears to be no will in government to address the disparity. Indeed, it would appear from Dame Kate Bingham's evidence that measures and programmes aimed at improving diversity in Covid clinical trials were not supported by government:

> "We were particularly keen that our targeted campaign should reach those most at risk from infection, including the elderly, those with severe underlying diseases and frontline workers. We also especially wanted to attract people from black, Asian and minority and ethnic backgrounds who were disproportionately affected by [Covid] and who the evidence suggested might be among the more vaccine-hesitant to sign up ... the Cabinet Office then [suddenly] blocked expenditure from our budget for advertising the NHS Registry, even though these costs had already been approved…." [6 /70-71/13 -25;1-17]

117. A lack of diversity in clinical trials impacts vaccine trust and confidence – if individuals from Black, Asian and Minority Ethnic backgrounds are not included in vaccine trials in sufficient numbers then their communities cannot be satisfied of vaccine safety [IN0000485278_0010]. Further, structural and health inequality experienced by ethnic minority communities means that their health needs and outcomes are different from the majority of the population in the United Kingdom [IN0000485278_0008]. Diversity in clinical trials in the UK is therefore necessary to address safety and confidence concerns.

118. It therefore follows that the health needs and outcomes of people from Black and Asian ethnicities in the UK may differ from people of the same ethnicity in Latin America, the USA, the Caribbean, African Countries and India and clinical trials conducted among people of African and Asian ethnicities outside of the UK would not address the health needs of the UK population.

119. The Inquiry has heard evidence from a number of witnesses that the lack of ethnic and racial diversity in clinical trials in the UK was overcome in clinical trials conducted in countries which have a larger African population or people of Afro descent such as South Africa and Brazil, [Professor Evans, Dame June Raine, Darius Hughes, Clara Swinson, Sir Jonathan Van Tam]. Such a course of "outsourcing" racial and ethnic diversity in clinical trials to countries which have a larger African population than that of the UK is problematic for a number of reasons. First, it does not address the lack of confidence attributed to lack of racial and ethnic diversity in clinical trials in the UK. Second, it risks exacerbating the lack of confidence in vaccines among ethnic minority communities in the UK and third it perpetuates structural racism in the health sector and delivery of healthcare.

120. The success of a vaccine programme will be determined by its uptake across geographical areas and ethnicities which is underpinned by confidence. The lack of diversity in clinical trials must be addressed head on by government, the regulators and pharmaceutical companies.

121. We note Darius Hughes' evidence of the FDA's requirement that clinical trials be fairly representative of the US demography and the process for ensuring that the trials for the Moderna vaccine was a fair representation of the US population, including pausing trials in centres with predominantly white recruits to wait for centres that were predominantly Hispanic, Black and Asian to catch up [9/6-8/13-1].

122. There is no regulatory requirement in the UK for clinical trials to reflect the ethnic make-up of the UK's population. We would invite the Inquiry to recommend that it be a regulatory requirement of drug registration that clinical trials should be representative of the UK population's ethnic makeup and diversity. Lack of ethnic diversity in clinical trials raises a public health issue as it impacts vaccine uptake and risks deepening structural health inequalities in ethnic minority communities.

123. We also commend the recommendations advanced by Dame Kate Bingham for the promotion of increased participation of people from ethnic minority backgrounds in clinical trials: an accessible registry to provide information about trials and eligibility, and enabling easy registration, engagement with communities through trusted individuals such as teachers and religious leaders to educate people about trials and encourage participation, and making information about trials accessible and easy to understand to build confidence and trust [6 /734/5-25;1-9]

Language

124. There is a strong sense of feeling among a number of the bereaved families that language such as *vaccine hesitant* and *hard to reach* used by the government and agencies to characterise low vaccine uptake among ethnic minority group perpetuates structural racism in the UK society, and wholly misrepresents the real systemic issues.

125. As the Inquiry has heard, vaccine hesitancy is defined as a "state of indecision about whether to get vaccinated", underpinned by the "5 Cs" – complacency, convenience, confidence, calculation, and collective responsibility [IN0000474705_0006]. The lived experiences of people from ethnic minority communities and migrants as well as the expert evidence would suggest that lower vaccine uptake among ethnic minority communities and migrant groups was largely attributable to barriers to vaccine access and a lack of proper engagement by government institutions in promoting vaccination rather than hesitancy. Drs Kasstan-Dabush and Chantler note: "*Disengagement from the covid 19 vaccine campaign is not appropriately classed as hesitancy in this context but decline of a vaccine offer is a consequence of lived experience of exclusion that affects how government recommendations are viewed*". Access barriers, including non-registration with GP/NHS and required proof of fixed address, rather than refusal were the primary barriers to Covid vaccination in the GRT community [INQ000474623_0079].

126. We commend FEMHO's evidence on the problematic nature of the term *hard to reach*: it implies a lack of agency, raises potential stigmatisation of communities, overlooks systemic barriers, oversimplifies diversity within ethnic minority communities and conveys a deficit model – by focusing on what ethnic minority communities lack rather than building their strengths and resilience [[IN0000485278_0016]. The consequence of poor and inadequate engagement and with people from ethnic minority and migrant communities left them *underserved*.

127. The resounding acknowledgment of inadequate efforts and failures in vaccine coverage of ethnic minority communities, in particular the GRT community, people of Black African and Caribbean ethnicities and migrant communities rings hollow. The failure to implement measures to address structural and institutional racism, or to plan mitigating factors, and the identified barriers which impacted vaccine coverage and uptake across ethnic minority communities sound louder. The Inquiry has heard evidence from many witnesses that more should have been done, yet no evidence of fundamental changes to address the failings. We invite the Inquiry to make urgent recommendations that address barriers to vaccine uptake and promote vaccine access across all sections of the UK's population.

Vaccine Damage Payment Scheme

128. CFBFFJ UK and NI CBFFJ have been moved by the evidence received during this module of the damage suffered by some of those people who agreed to help the Covid vaccine effort. They have also been shocked to learn of the numbers of people who have tried to claim vaccine damage payment under the Vaccine Damage Payment Scheme but been rejected. As the Inquiry has already commented their experiences have been "horrible". Having listened to the evidence in relation to Parliament's Vaccine Damage Payment scheme, including from Sarah Moore, CBFFJ and NI CBFFJ hope the Inquiry will agree that the scheme as it stands is outdated both in terms of its eligibility criteria and its available award. If the circumstances of the Covid vaccination programme are to repeat themselves, there is a real public interest in ensuring that people injured as a result of acting in the public good are not made to feel stigmatised as a result, and that they receive appropriate compensation for any damage they suffer.

Conclusions and Recommendations

129. In conclusion CBFFJ UK and NICBFFJ reiterate the submission that despite excellence in basic scientific research, the UK and each of its nations and jurisdictions was wholly unprepared for a vaccine and therapeutic response to a new emerging pandemic disease. There was an absence of planning to develop, trial, regulate, manufacture and roll-out vaccines and drugs. In terms of roll out, there was an absence of data and systems to utilise primary care to manage provision to the population or its most vulnerable. There was a lack of any regard to foreseeable issues of discrimination. There was no plan for the UK to work collaboratively with the DAs.

130. Although the above deficits have emerged from the evidence, the alarming fact is that on these issues the UK appears to be as unprepared now as it was at 1 January 2020. That must change. We urge the Inquiry to consider the following proposed recommendations:

a. Overall responsibility for UK vaccine and therapeutic policy and preparedness should be expressly included in the role of the Cabinet-level Emergency Preparedness and Resilience Committee (EPRC) which was the subject of Recommendation 1 of the M1 Report.
b. The role of the EPRC in this regard should be mirrored or complemented in each of the Devolution Administrations, and a regular coordination mechanism should be established. The structures of relevant UK agencies, including JCVI, should be reviewed to ensure full involvement of devolved agencies and DAs.
c. The EPRC should formulate an overall UK strategy for vaccines and therapeutics, which should include basic scientific research, R&D, trialling, regulation, manufacture, data, confidence, and roll-out. It should formulate the strategy in coordination with the Vaccine and Therapeutic Agency referred to below. The strategy should take account of devolved issues and the DAs should develop their own strategies in parallel and in coordination with the UK.
d. The strategy should ensure that therapeutics and anti-virals are sufficiently prioritised, and includes a 'hold the fort' project for the early stages of a pandemic to protect the most vulnerable and interrupt transmission until vaccines become available (assuming they do).
e. The EPRC strategy should include onshore manufacturing capacity on a portfolio approach, and supply chains.
f. The EPRC strategy should include a plan for prioritisation of access to vaccines and therapeutics, which should be agile enough to deal with unknown characteristics of the next biological risk, but identify primary care services and data sets which will be required. Prioritisation should take account of clinical, age,

and disability-related vulnerabilities, but also the particular needs of marginalised communities, key workers, and those in insecure employment.

g. The EPRC strategy should combat the negative effects of structural and institutional racism and other forms of such discrimination, in conjunction with general policies to address health inequalities. The strategy should be based upon access and confidence.

h. The strategy should ensure there is an emergency mass vaccination programme, coordinated with routine vaccination schemes.

i. The EPRC should be required to publish a regular statement setting out how each element of the Strategy will be resourced, with particular regard to (a) long-term funding required to ensure resilience, and (b) the funding of essential elements of the strategy which cannot be resourced on a commercial basis. Investment in R&D for medical countermeasures to a pandemic should be considered akin to defence spending and look on Disease X as a 'biological defence risk'.

j. The EPRC and lead Minister should be assisted by the appointment of a Vaccine Commissioner ('Tsar') with equivalent status and access to the NSA. This person can bring independent advice to government and form a bridge to the private sector.

k. An independent executive Vaccine and Therapeutic agency should be created under the umbrella of the DHSC, to manage the strategy.

l. Clinical trial standards should be set and published, and incorporated into approval by the MHRA for new vaccines and drugs. In particular, regard should paid to ensuring that the standards require, so far as is possible, that trial diversity reflects the population. Where that cannot be achieved, clear reasons should be published.

m. Where clinical or capacity reasons inhibit the diversity of trial cohorts (for example, children, pregnant women, those with learning disabilities), clear strategies should be developed to determine their safety for such groups, and published.

n. A National Health Data Service should be established, pursuant to the Sudlow review. A National Health data strategy should promote interoperability of NHS Datasets, a presumption of consent to sharing of data within healthcare (subject to proper safeguards), and controlled access to anonymised health data for R&D.

131. NICBBFJ propose the following focussed recommendations:

a. That the DoH undertakes to publish data analysis and evaluation of the vaccine roll-out (para 93)

b. The DoH audits the effectiveness and adequacy of the Vaccine Management System, including the range and adequacy of the data captured and analysed, and publishes the results [para 89 – 91]
c. That the DoH implements a NI centralised carers' register (para 95)
d. That the DoH recruits a Senior Medical Officer with responsibility for vaccinations and health protection (or confirms that the equivalent post has been filled) (para 85)

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