IN THE UK COVID-19 INQUIRY

MODULE 4

OPENING STATEMENT ON BEHALF OF
CLINICALLY VULNERABLE FAMILIES ('CVF')

A. INTRODUCTION AND SUMMARY

1. This opening statement is made on behalf of Clinically Vulnerable Families ('**CVF**'). CVF is a grassroots organisation born of the pandemic. It represents a group of vulnerable individuals who have underlying health conditions, some of whom are immunosuppressed, who are at high risk of severe outcomes from Covid-19, including greater mortality and Long Covid. Prior to the pandemic, people had not been designated as 'clinically vulnerable' ('**CV**'), 'clinically extremely vulnerable' **('CEV')** or 'at highest risk';[1] nor had their safety and wellbeing been placed so centrally, and so precariously, into the hands of government.

2. Whilst shielding in formal terms may be a thing of the past, many CV people continue to shield and lead limited lives to this day. CVF's mission – to support, inform and advocate for those in clinically vulnerable households – remains pressing. The emergency phase of the pandemic may have passed, but for vulnerable people it is by no means over and indeed some still face as significant a risk, and in some respects a higher one because of the removal of mitigation measures, from contracting Covid-19 as they did in early 2020. In a world in which continually evolving Covid-19 variants pose an ongoing and insufficiently mitigated threat, many CV people are unable to exercise their freedoms safely, particularly in light of the problems already highlighted by the documentation in Module 4 in respect of access to vaccinations, therapeutics and prophylactics. This is one of the reasons this Inquiry is so important to CVF.

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[1] A brief note on terminology: whilst the term 'clinically extremely vulnerable' has been retired by the government (with reference to those 'whose immune system means they are at higher risk' continuing), the term 'clinically vulnerable' remains in active use today. It encompasses all those who remain at higher clinical risk to Covid-19 and who qualify for vaccines based on risk: see the UK Health Security's Agency's 'Covid-19: Green Book', ch. 14a, pp.25-26 [INQ000408795_0001].

3. CVF hopes to assist the Inquiry by giving a voice to a group who have been largely forgotten since the inaptly named 'Freedom Day'. It seeks to highlight the uneven impact of the pandemic on people that continue to face greater risks to their lives from Covid-19 than any other category of person. It also seeks to emphasise the urgent need to learn lessons and put in place basic yet effective systems and processes, to ensure that this group can access the protections that will enable them to once again participate and flourish in society, on an equal footing to others.

B. SUBMISSIONS

4. These submissions[2] focus on the following key areas of concern for CVF: (1) the balance between vaccines and therapeutics, (2) vaccine prioritisation and eligibility, (3) vaccination of children, (4) accessibility of vaccine delivery, (5) access to antivirals, and (6) prophylactics.

Vaccines vs Therapeutics[3]

5. CVF remains concerned that although the Inquiry has said Module 4 will examine vaccines and therapeutics in parallel (*per* the Module 4 List of Issues), the examination of therapeutics will ultimately fall through the cracks. This has already been apparent from the fact that in 10 weeks of hearings in Module 3, and despite the use of therapeutics being on the issues list, the topic was barely mentioned in oral examination.

6. CVF submits that both topics – vaccinations and therapeutics – are of equal importance. Plainly there was more *public* attention on vaccinations during the pandemic, perhaps because of the huge focus on vaccination in government communications. CVF of course accepts that far more people were entitled to vaccination than therapeutics meaning it was likely to attract some more attention. However, from a public health perspective, both are hugely important. As Sir Chris Whitty has noted, "*although vaccines proved the most effective in Covid-19, at the start of the pandemic this was far from a given*,"[4] and it has often been therapeutics which have been responsible for "*de-risking*" previous pandemics.

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[2] CVF's submissions are structured around the topics outlined in the Inquiry's Provisional List of Issues, dated 01.10.2024.
[3] For the purposes of this document, overarching references to "therapeutics" refer to both therapeutics (the treatment of disease) and prophylactics (the prevention of disease).
[4] Professor Sir Chris Whitty, §4.5 [INQ000474401_0010].

7. CVF considers that in government at least, there was a disproportionate focus upon finding a vaccine from the very beginning of the Covid-19 pandemic. Matt Hancock has explained that *"from the first meeting in which we discussed this new disease on 6 January 2020 ... we focussed on a vaccine as the route out of the pandemic*."[5] CVF submits that this early prioritisation continued in the months which followed and is evident both in the different processes adopted for regulatory approval of vaccines and therapeutics, and in the approach to funding and investment. As Dame Kate Bingham has observed: "*part of the UK's pandemic response used a rapid vaccines procurement model, and part (such as Evusheld) went through a therapeutics process which was governed by the National Institute for Health and Care Excellence (NICE) ... which was much slower. I do not know why a different approach was taken to vaccines on the one hand and therapeutics and antivirals on the other.*"[6] Sir Sajid Javid has also stated that he "*spent too much time arguing for the procurement of ... antivirals with the Treasury*" and that the process "*can be contrasted with [the Treasury] approach to the vaccines, where they were willing to spend money on vaccines that may not be needed and to pay for what was required*".[7] Sir Sajid has warned that "*we were lucky that [the Treasury approach] did not cause serious damage*". CVF would submit that the low prioritisation of therapeutics and prophylactics was very likely to have caused serious damage, it has cost lives.

8. For CV and CEV people who have underlying health conditions, many of whom are immunosuppressed, who are at high risk of severe outcomes from Covid-19, including greater mortality and Long Covid, therapeutics and prophylactics represented their lifeline and their "*route out of the pandemic*".

9. <u>It is important that the Inquiry does not overbalance its attention on vaccines at the expense of therapeutics</u>. It is self-evident that the vaccination programme was in many ways a success, and would be (no doubt with some modifications, for example the issues identified below regarding access for CV people) a model for a future pandemic. And yet over 200,000 people died after contracting Covid-19, a majority of whom were CV. An important question for this module is whether the general population were protected by the vaccine

[5] Matt Hancock, §23 [INQ000474375_0007].
[6] Dame Kate Bingham, §38.15 [INQ000474406_0043].
[7] Sir Sajid Javid, §268 [INQ000474381_0077].

rollout but the severely immunosuppressed were left behind and, because of the failure to provide adequate protections including prophylactics, left essentially unprotected against a virus which was far more likely to be deadly to them than to the general population.

Vaccine Delivery

10. The initial roll out of the Covid-19 vaccination programme was full of promise. For many CV people, particularly CEV people who were still shielding, the vaccine offered the first opportunity to see a way back to normal life and a chance to reconnect with family and friends they had not been able to see for the preceding 10 months. For the CV people whose jobs required them to remain on the frontline and risk their lives, and therefore were unable to informally shield themselves from the virus, the vaccine offered reassurance and safety. At this time no one knew how much protection the new vaccines might offer.

Prioritisation and Eligibility (Issue 3(c)) and Communications (Issue 3(d))

11. Whilst CEV and CV people were, rightly, amongst the first to receive a vaccination and CVF welcomed their inclusion in the priority cohorts, many of CVF's members reported confusion around their eligibility for priority vaccination.

12. There were CEV people who were not automatically called for vaccination because they had not been recorded CEV or the coding had not worked. Many more CV people (who were not CEV) were never officially identified and were therefore left doubting their own eligibility. Without the knowledge that they were eligible for priority vaccination, CV people were understandably less likely to advocate for themselves. CVF share the concerns of the Disabled People's Organisations ("DPO") that many people with underlying health conditions were not contacted, and that there were reports of the prioritisation lists being misapplied by health services.[8] CVF are concerned that these systems issues, in combination with a lack of clarity in the communications to vulnerable people, both in terms of wider public messaging and individual communications, resulted in CV and CEV people not being sufficiently aware of their status and therefore not receiving the protection of the vaccine as early as they should have done, all the while continuing risk-taking behaviours.

[8] Disabled People's Organisations, §20 [INO000474256_0006].

13. This became an even greater issue when it came to the administration of vaccine boosters and third primary doses for severely immunosuppressed people. CVF is concerned that the ever-changing eligibility[9] for vaccine boosters caused significant confusion, among CV people whom the boosters were intended to protect and also within the health services providing these vital doses. As CVF member Juliet has explained "*my GP doesn't do covid boosters and I never get invited for them, even though I'm eligible. Each one has been a fight to find out what is going on and when I can book one and I have had to take the initiative and book them myself online.*"[10] There was even less awareness in general practices of the third primary dose programme. For CVF member Catherine, the confusion delayed her third dose considerably and she eventually received it weeks after she should have done, "*it was distressing and incredibly frustrating, I spent many hours phoning and emailing.*"[11]

Vaccination of Children

14. CVF was very concerned by the slow rate of expansion of the Covid-19 vaccination programme to children. The vaccination of children is of particular importance to CVF due to (a) the impact on clinically vulnerable children at higher risk of severe outcomes from Covid-19 and (b) the impact on households, i.e. non-CV children who have clinically vulnerable parents, siblings, and household contacts. For these families, the very considerable delay between the roll out of the vaccine in December 2020 and the eventual vaccine offer to healthy 12 to 15-year-olds in September 2021 and 5 to 11-year-olds in February 2022 had a significant detrimental impact. CVF notes that Covid-19 vaccination has never been offered to healthy children under 5 years old.[12]

15. CVF is dismayed by the lack of consideration of these children by all bodies involved in the decision making in this area, from the Joint Committee on Vaccination and Immunisation ('JCVI') and the Office of the Chief Medical Officer ('OCMO') to the Department of Heath and Social Care ('DHSC') and Health Ministers.

[9] CVF, Annex A [INQ000474526_0119].
[10] CVF, §38 [INQ000474526_0017].
[11] CVF, §49 [INQ000474526_0022].
[12] For further detail of the timings that vaccinations were approved and offered to each age group, see CVF, §107-218 [INQ000474526].

16. CVF members like Mary despaired that the government had prioritised healthy 18-year-olds over their vulnerable children: *"I had a massive battle to try and get my clinically vulnerable son his vaccine as he was 14. .... I wrote to everyone in authority I could think of and got nowhere. It was horrendous. ... The medical professionals couldn't quantify his risk but equally didn't want to stick their heads above the parapet and say he could get a vaccine."*[13]

17. CVF submits that the decision-making around the vaccination of children was exceptionally cautious and wholly out of step with the approach taken by other countries. It was also inexplicably slow: the JCVI provided its initial advice on 2 December 2020 against the vaccination of children[14] but did not advise again until summer 2021.[15]

18. As Sir Sajid Javid has explained, the government unequivocally accepted the advice of JCVI on whether to vaccinate children, until September 2021 when he sought the advice of the Chief Medical Officers of all four nations.[16] CVF submits that the JCVI's singular focus on the potential risks from the vaccine vs the potential benefit of the vaccine to the individual child was too narrow. It failed to take into account other important factors, including (a) the more severe outcomes from Covid-19 for clinically vulnerable children (not just those with severe neuro-disabilities, Down's Syndrome, underlying conditions resulting in immunosuppression, and those with severe learning disabilities), (b) the risks of sequelae (Long Covid), and (c) the impact of the vaccine on reducing transmission (particularly as this would have benefitted clinically vulnerable household contacts of healthy children). This was despite there being was growing evidence in 2021 of both Long Covid in children[17] and the effect of the vaccine on reducing transmission.[18]

19. CVF agrees with Dr Kasstan-Dabush and Dr Chantler who have stated that "*the flexibility to invoke broader evidence and criteria is integral to making appropriate recommendations when required*".[19] CVF submits that the remit of JCVI should be extended so that it may

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[13] CVF, §143 [INQ000474526_0062].
[14] Paper from JCVI titled Advice on priority groups for COVID-19 vaccination, dated 02/12/2020 [INQ000234638_0005].
[15] Draft paper from Joint JCVI titled Statement on Childhood vaccination of children and young people aged 12-17 years, dated 07/07/2021 [INQ000387481].
[16] Sir Sajid Javid, §87 [000474381_0029].
[17] Updated statement from the JCVI regarding COVID-19 vaccination of children and young people aged 12 - 17 years, dated 04/08/2021 [INQ000401363_0002].
[18] Sir Chris Whitty, §6.55 [INQ000474401_0050].
[19] Dr Kasstan-Dabush and Dr Chantler, §70 [INQ000474623_0025].

consider the broader evidence outlined above. Alternatively, there must be processes in place which require decision-makers to take into account such evidence, even if the JCVI may not.

20. Some CVF members who could afford to resorted to travelling to Europe to obtain vaccinations for their children. CVF Member Amos describes feeling "*extremely concerned regarding the lack of any protections for CV families and children. We watched on while many other countries made them available, for children. The UK did not follow suit. We decided, as many other families did, that we would drive to Germany in order for our daughter to receive her covid vaccinations. The Doctor was baffled by the fact that she could not obtain a vaccine in the UK.*"[20]

21. Another CVF member describes her deep frustration over the delayed vaccination for children noting that: *"despite assurances that children were less affected by the virus, our friends suffered the heartbreaking loss of a child with the same genetic condition as my daughter. This tragedy, which we believe was potentially preventable with earlier vaccination, highlights the unacceptable delay in administering vaccines to children, over a year after healthy adults had the chance to have been vaccinated two or even three times. Despite having the official go-ahead, we struggled to find someone to vaccinate our 11-year-old daughter. It wasn't until January 2022, during a hospital stay for another illness, that a senior paediatric consultant managed to arrange her vaccination. The delay had posed a significant risk, as she could have contracted the virus during that time. This period was especially stressful, with vulnerable under-12s without vaccination, yet required to attend school. ... The government's apparent disregard for clinically vulnerable children's safety during this critical time was both alarming and disappointing."*[21]

22. Once the vaccine was eventually offered to 12 to 15-year-olds in September 2021, CVF members then experienced multiple difficulties in actually accessing a vaccine for their child. CVF agrees with Dr Kasstan-Dabush and Dr Chantler's conclusion that "*school-age children were disadvantaged in areas of the UK that relied (at least initially) on school-based delivery only.*"[22] This was a particular barrier to access for children in clinically

[20] CVF, §205 [INQ000474526_0092].
[21] CVF, §170 [INQ000474526_0077].
[22] Dr Kasstan-Dabush and Dr Chantler, §251 [INQ000474623_0076].

vulnerable households who had no safe option but to homeschool in order to avoid entering the high-risk school environment. But there were further problems once delivery was extended beyond schools: the option for GP surgeries to 'opt out' of providing the vaccine to children and the requirement that vaccination centres be 'green lit' for children created additional hurdles and reduced the available options.

23. Dr Kasstan-Dabush and Dr Chantler have suggested that "*several lessons emerge from UK Covid-19 vaccine roll-out processes for children, notably the language of 'non-urgent offers'*"[23] in respect of 5 to 11-year-olds which they concluded "*indicated a softer recommendation for parents to consider.*"[24] They have suggested that further investigation is required to assess whether the language may have influenced parental decision-making and risk perceptions.[25]

24. CVF submits that it is highly likely that the delays in decision-making around children, combined with the discouraging language used once the vaccines were approved for children, contributed to the lower uptake among children.[26] Low uptake is of great importance to both CV children and CV adults, whose safety was in part dependent on a highly vaccinated population.

Barriers to Uptake

Accessibility of vaccinations (Issue 4(a))

25. A significant feature of the initial rollout of the Covid-19 vaccine was the use of large vaccination centres. Many CVF members have found the centres unsafe for the clinically vulnerable, with some members even contracting Covid-19 as a consequence. CVF are concerned that patients who were eligible for vaccination did not come forward, or did not obtain a vaccination as early as they should have done, because of their concerns about the risks of such centres.

26. CVF was particularly concerned about the severe crowding, the lack of ventilation and the poor air quality in the buildings used. These are critical factors for an airborne virus such as

[23] Dr Kasstan-Dabush and Dr Chantler, §371(a) [INQ000474623_0106].
[24] Dr Kasstan-Dabush and Dr Chantler, §275 [INQ000474623_0083].
[25] Dr Kasstan-Dabush and Dr Chantler, §148 [INQ000474623_0043].
[26] Dr Kasstan-Dabush and Dr Chantler, §170 [INQ000474623_0052].

Covid-19 and therefore any failure to make safe the very buildings that vulnerable people had to visit in order to receive protection from the virus was unacceptable. CVF members also found that both staff and other patients were constantly removing their masks while inside the vaccination centres. As CVF member Maria describes: *"I was invited to a separate area which was laid out with seats quite close together to my surprise. There I was offered a cup of tea or coffee and biscuits, a nice touch but I was concerned about the removal of masks. There was no obvious ventilation and so I decided that I would not accept their offer of refreshment and I kept my FFP3 mask on the whole time."*[27] CVF member Vicky was also concerned by her experience of the administration of the first vaccine in a hospital setting, describing it as *"very scary as was very busy, masks constantly being removed. Waiting room was packed, staff removing masks to chat, eat and drink. No windows or doors open – I left without waiting 15 minutes and waited outside instead as felt unsafe."*[28]

27. As Dr Kasstan-Dabush and Dr Chantler have identified, mass vaccination sites "*were not always suitable, and possibly not safe, for a number of vulnerable cohorts in the JCVI prioritisation list, including people in older age groups, CEV and people who have physical or learning disabilities.*"[29] The experts agreed that "*clinically vulnerable people were likely to have heightened concerns about attending mass vaccination centres due to risk of transmission in places of higher footfall.*"[30]

28. Many CVF members had to travel significant distances to vaccination centres. CVF agrees with Dr Kasstan-Dabush and Dr Chantler that "*mass vaccination sites also did not offer equity in access if the primary mode of access was by car or private transport.*"[31] A more pressing concern, particularly for CVF members who had been shielding, was the risk of contracting Covid-19 associated with travelling long distances to be vaccinated, either from public transport or in the close confines of a car where they were being driven by someone who was potentially infected. The latter was also an issue identified by Sir Jonathan Van-Tam as warranting investigation.[32] CVF member Julie found that *"as a non-driver in a semi-*

[27] CVF, §30 [INQ000474526_0014].
[28] CVF, §31 [INQ000474526_0014].
[29] Dr Kasstan-Dabush and Dr Chantler, §99(b) [INQ000474623_0031].
[30] Dr Kasstan-Dabush and Dr Chantler, §250 [INQ000474623_0076].
[31] Dr Kasstan-Dabush and Dr Chantler, §99(b) [INQ000474623_0031].
[32] Sir Jonathan Van-Tam, §232 [INQ000474404_0023].

rural area, I found it very difficult to get my first vaccine. I had to wait for my daughter to be free to be able to take me. When I discussed the issue with my GP surgery, I was told that it would be ok to travel for nearly an hour on a crowded bus to get the vaccine."[33]

Therapeutics

29. Helen Knight, the Chief Executive of the National Institute of Clinical Excellence, reflected in her evidence for Module 4 that "*the system as a whole would need to do more to develop therapeutics*" for the highest risk patients in the event of another pandemic.[34] CVF submits that it should be an urgent priority to assess whether more could have been done to develop and implement effective therapeutics, and whether a different and better approach could be adopted in future.

30. In addition to the concerns outlined below in respect of access to antivirals, CVF invites the Inquiry to investigate why it took until October 2021 for a procurement decision to be taken on oral antivirals[35] with the first patients receiving treatment in December 2021,[36] one year after the vaccine roll out programme commenced, and to consider whether this demonstrated insufficient priority relative to the vaccination programme.

Systems and processes established for determining eligibility for therapeutics (Issue 6(j))

31. CVF is concerned that the list of people eligible for therapeutics has always been and continues to be particularly limited, especially given the underlying conditions and age profile of people admitted to hospital and sadly dying of Covid-19.

32. CVF considers that there should be an urgent review of the eligibility for therapeutic treatment and would urge an expansion of the current eligibility categories. This is a pressing need because there are still vulnerable people who would benefit from antiviral medicine but are not receiving it because they are not currently eligible.

[33] CVF, §50 [INQ000474526_0022].
[34] Helen Knight, Chief Executive of NICE, §144, [INQ000474611_0058].
[35] Eddie Gray, §27.26 [INQ000474372_0011].
[36] Gareth Arthur, §163 [INQ000474328_0043].

Systems and processes established for the deployment of antivirals (Issue 6(k))

33. From CVF's perspective, the Inquiry must ensure that not only is national decision-making on eligibility for therapeutics examined, but the issue of how this translated to access to antiviral medicines in practice. CVF considers that the Covid-19 antiviral pathway is fraught with access issues and barriers which have prevented many vulnerable people from receiving the lifesaving treatment that they need. It is significantly more restrictive when compared to other medications like influenza antivirals, which can simply be prescribed by a GP. At the time of writing, a BBC News report[37] has highlighted that vulnerable people are "*unfortunately still dying from Covid*" and many are not aware of their eligibility for the antivirals that could reduce the risk of hospitalisation and death whilst also speeding up recovery.

34. The "*entire focus*" of the procurement of antivirals was said to be to "*help those in high risk groups*", and to provide a "*valuable tool for those who could not be vaccinated or who were still at particular risk".*[38] The system set up for providing antivirals to those who needed them was intended to "*ensure that treatments were delivered quickly following symptom onset since GP practices did not need to confirm eligibility or discuss treatment options.*"[39]

35. However, in practice, the burden has been on the patient – who would almost certainly have been experiencing Covid-19 symptoms or risking imminent illness – to secure the medication, all within a system which was and is not currently fit for purpose. CVF members describe GPs referring to 119, 119 referring to 111, and 111 referring back to 119 or the GP. Even if eventually referred to the Covid-19 Medical Decisions Unit ('CMDU'), people have been dismayed to find that the Unit is closed over weekends or bank holidays. Professor Nicholas White has confirmed that antiviral drugs *"were most effective as soon as people felt ill and were diagnosed with Covid-19 in the community",* explaining that an early effective treatment could prevent severe illness and hospitalisation.[40] However, all of the delays outlined above eat into the crucial 'five-day pathway' to access antivirals.

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[37] "Mistaking Covid as a cold may put people at risk", BBC News, 4 December 2024.
[38] Sir Sajid Javid, §264 [INQ000474381_0076].
[39] Clara Swinson, §179 [NO000474335_0058].
[40] Professor Nicholas White (draft report), §5.21.

36. CVF members have also reported issues with the assessments undertaken by the CMDUs: people who were eligible as per the eligibility list who may have been referred via multiple doctors or healthcare professionals were not offered treatment at the clinical decision point, either because the decision-maker did not know that a condition really qualified people as higher risk, or because the person was not exhibiting sufficiently severe symptoms or, indeed, their symptoms had become too severe due to delays, leading to advice that they should go to hospital. This is despite the guidance for antivirals being clear that they should be given as rapidly as possible to eligible people at a mild/moderate stage of disease. It has been said that the way antivirals work is in fact "*incompatible with a symptom led approach*".[41] CVF reports real examples among their members where things went wrong in respect of access to antivirals, in some cases with tragic consequences.[42]

37. More recently, in 2023, there was a change in commissioning and eligible people who contracted Covid-19 were now required to contact their GP practice, NHS 111 or hospital specialist. This added a confusion to the process as people now need to try and communicate with these healthcare professionals and it is the experience of many CVF members that obtaining a GP appointment within the tight 5-day timeframe is very challenging, and in some cases impossible, through lack of access to primary care.

38. CVF is also concerned that eligible patients have had no ability to obtain antivirals 'in advance', for example ahead of high-risk activities such as travelling abroad, or bank holiday weekends (where experience has shown that CMDUs have been closed).

39. CVF do not believe that the process of accessing antivirals was, or is, fit for purpose. Systems for recording patients' eligibility for antivirals (and the lateral flow tests required to demonstrate Covid-19 infection) must be implemented now as an urgent priority, for example by including a flag on eligible patients' digital health care record and providing prescription cards that they can show to demonstrate their eligibility.

40. CVF agrees with the observations of the former Chair of the Antivirals Taskforce, Eddie Gray, that we know who are likely to be the most vulnerable to a future pandemic and those people could be "*identified in advance and if possible, given antivirals immediately upon*

[41] Lord Bethell, §68 [IN0000474434_0023].
[42] CVF, §63 [INQ000474526_0029].

declaration of pandemic for use in case of infection."[43] CVF submits that antivirals must be made accessible to those who need them the most, rapidly and comprehensively.

Prophylactics

Non-vaccine prophylactics (Issue 6(g))

41. For those who are immunosuppressed and unable to mount an effective response to vaccination, prophylactic treatment was, in effect, their vaccine. Yet unless they were in the position to travel to the USA or Europe, or pay for the treatment themselves when it became privately available in England in late October 2022, those at highest risk remained unprotected and many continue to shield as a result. Access to preventative treatment is an urgent need, as many immunosuppressed individuals have been living in isolation or limited lives for over four years, with no end in sight.

42. AstraZeneca developed a prophylactic – Evusheld – which helped to reduce the chances of infection and severity of Covid-19 in people who have had an unsatisfactory immunological response to Covid-19 vaccination or who are severely immunosuppressed. It was approved by the Medicines and Healthcare products Regulatory Agency ('MHRA') as safe and effective however it was not procured by the government. It was instead subjected to a prolonged NICE approvals process, in stark contrast to the process of rapid assessment adopted for the Covid-19 vaccines.

43. In CVF member Melanie's words, "*I am part of the cohort that cannot respond to vaccination. When Evusheld was approved by MHRA I was elated but devastated afterwards when I realised that NICE hadn't yet approved it. I still feel let down, ignored and dismissed.*"[44] CVF member Sally has similarly described feeling "*totally abandoned*"[45] as an immunocompromised person who does not respond to vaccination.

44. As a result, Evusheld has not been available at any time from the NHS, unlike its availability in other OECD countries. CVF submits that the lack of access to Evusheld in the UK has

[43] Eddie Gray, §93 [INO000474342_0033].
[44] CVF, §87 [INQ000474526_0038].
[45] CVF, §87 [INQ000474526_0038].

left severely immunosuppressed patients significantly unequal when compared to immune competent persons. Immunosuppressed people have not been given access to a prophylactic that would give them the same protection as someone who is successfully immunised. This has had substantial life-changing effects on CVF members' lives. They are often unable to partake in 'normal' life in the way that successfully vaccinated people can. This has affected many areas such as work, education, and socialising. It can even affect their basic needs such as buying food, collecting medicine and attending medical appointments. CVF members like Sally have been left with an unenviable choice when it comes to attending medical appointments, she has described: "*playing Russian Roulette with hospital appointments trying to second guess whether not getting treatment and tests is more dangerous than potentially getting Covid.*"[46]

45. Whilst it noted that Evusheld became less effective in respect of later variants of Covid-19, it still maintained some level of efficacy. CVF submits that there was a significant period of time when it would have saved the lives of immunosuppressed people and enabled basic freedoms that others take for granted, had it been available. The delays that resulted from the protracted decision-making process robbed CVF members of the opportunity to acquire this protection against earlier variants of the virus.

46. CVF is concerned that the reality of the situation was as observed by Professor Nicholas White: *"once excellent protective efficacy of the vaccines was demonstrated and the effective vaccine roll-out was under way, there was no longer a need for moderately effective chemoprevention [prophylactics]. This reduced the pressure to evaluate [prophylactics],."*[47] However, as Professor White also notes*: "there was still a need to protect vulnerable groups who could not receive or benefit from the vaccine",* and it is this fact which seems to have been forgotten by those responsible for procuring a prophylactic.

47. CVF agrees with Dame Kate Bingham's conclusion regarding the government's decision on Evusheld: "*by far the most significant harm was caused to hundreds of thousands of immunocompromised members of the UK public. The effect was that UK was the only Western country not to protect its immunocompromised people using long-acting*

[46] CVF, §87 [INQ000474526_0038].
[47] Professor Nicholas White (draft report), §5.60.

antibodies. It is very plausible that this decision cost lives and condemned many more people to suffer through long term shielding".[48]

C. CONCLUSION

48. CVF's concerns are linked by a common theme: the inescapable reality that the disproportionately severe impact of Covid-19 on the CV, and associated decision-making, have been insufficiently considered and mitigated since the emergence of Covid-19. The CV continue to feel the effects and continue to live in the shadow of the virus today.

49. It is for these reasons that CVF considers it is essential that the CV be identified as a specific group/protected characteristic, both under the Equality Act 2010 and in the Inquiry's Equalities and Human Rights Statement, to enshrine in law the ongoing threat to the CV of Covid-19 (and other pathogens), and ensure that vital protections for the CV can no longer be switched on and off at the whim of public officials.

50. CVF is grateful for the Chair's care and attention throughout this important module.

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13 December 2024

[48] Dame Kate Bingham, §38.13 [INQ000474406_0043].