IN THE UK COVID-19 INQUIRY

MODULE 4

SUBMISSIONS ON BEHALF OF

CLINICALLY VULNERABLE FAMILIES ('CVF')

FOR THE SECOND PRELIMINARY HEARING, 22nd May 2024

A. INTRODUCTION

1. These submissions are made on behalf of Clinically Vulnerable Families ('**CVF**').

2. As the Inquiry will be aware, CVF were designated as a Core Participant ('**CP**') for Module 4 of the Inquiry on 17th July 2023. CVF was founded in August 2020 and currently represents those who are Clinically Vulnerable ('**CV**'), Clinically Extremely Vulnerable ('**CEV**') and the Severely Immunosuppressed, as well as their households, across all four nations. This group of vulnerable individuals were, and remain, at higher risk of severe outcomes from the disease, such as greater mortality[1] and long Covid,[2] than the greater population.

3. CVF continue to seek to ensure that the Inquiry considers the full impact of the pandemic on the CV, the CEV, and the Severely Immunosuppressed, their families and households, particularly within Module 4. Such individuals not only faced but continue to face greater risks to their lives than any other category of person. As such, any planning for future pandemics and/or consideration of the effectiveness of public health services needs to do so with the impact on the clinically vulnerable as a key group at the forefront of such planning. Moreover, mitigations are required now for new Covid-19 variants.

4. CVF are grateful to Counsel to the Inquiry ('**CTI**') and Solicitors to the Inquiry ('**STI**') for the helpful notes dated 2nd May 2024, together with other information circulated ahead of this hearing.

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[1] Pre-existing conditions of people who died due to coronavirus (COVID-19), England and Wales - Office for National Statistics

[2] Prevalence of ongoing symptoms following coronavirus (COVID-19) infection in the UK - Office for National Statistics

B. SUBMISSIONS

(1) Scope of Module 4

5. CVF welcome the confirmation at paragraph 10 of CTI's note that the Inquiry's terms of reference require it to examine specifically the "*shielding and the protection of the clinically vulnerable*", "*the impact on children and young people, including health, wellbeing and social care*", and "*the development, delivery and impact of therapeutics and vaccines*". CVF further welcomes the confirmation at paragraph 13 of CTI's note that Module 4 will include, specifically, examination of the decision-making relating to the non-vaccine prophylactic Evusheld.

6. CVF are also grateful for the Chair's re-stated commitment to ensuring that the issues relating to therapeutics are rigorously and comprehensively examined by the Inquiry.[3]

7. CVF notes the amendment to paragraph 2 of the Provisional Outline of Scope so that it reads, "*The development, trials and steps taken to enable the use of new therapeutics and repurposed medications during the pandemic*."

8. As the Inquiry will be aware, therapeutics and antivirals are issues of critical importance to CVF. From CVF's perspective, the Inquiry must ensure that not only is national decision-making on eligibility examined, also how this translated to access to therapeutics on the ground, which in CVF's experience varied greatly. CVF have referred in their Rule 9 evidence to serious examples of where things went wrong in respect of access to antivirals, in some cases with tragic consequences.

9. In this respect, CVF request that the Inquiry obtains data relating to the number of people who received antivirals, as against to those who were eligible according to the national eligibility criteria. We submit that this information is critical to assessing whether steps were in fact <u>successfully</u> taken to ensure the use of new therapeutics during the pandemic.

10. CVF are, however, concerned that the current wording of paragraph 2 of the Provisional Outline of Scope in relation to therapeutics may not allow for (or at least does not clearly require) a full examination of access to therapeutics and antivirals. CVF are reassured to some degree by paragraph 12 of CTI's Note which states that "*the focus of Module 4 is on*

[3] Ruling following the first Module 4 preliminary hearing on 13 September 2023, dated 21 September 2023, at para. 5(e).

*the systems, processes and outcomes relating to the development, procurement, manufacture, approval, eligibility for and **access to** vaccines and therapeutics during the Covid-19 pandemic, and how they can be improved*" (emphasis added). However, CVF wish to stress the importance of Module 4 examining the issue of access, separate from eligibility, both in order to understand the real lived experience of CV, CEV and Severely Immunosuppressed people, but more importantly in order for the Inquiry to make recommendations that could improve the processes for accessing antivirals. For CV, CEV and Severely Immunosuppressed people, this is critical, not just for future pandemics but right now as they continue to remain at risk of severe outcomes from Covid-19.

(2) Expert witnesses

11. From CVF's perspective, the Inquiry must ensure that it has the evidence necessary to properly consider the impact of the pandemic on children. CVF were reassured by the Inquiry's confirmation that the Inquiry's terms of reference enjoin it to examine the impact on children and young people and submit that this should follow through to the experts' instructions. CVF accordingly request that the reports on "*Vaccine roll-out and vaccine hesitancy*", "*Vaccine hesitancy/misinformation*", and "*Therapeutics*" cover those issues in the context of the specific challenges faced by children during the pandemic. It is hoped that the experts already instructed to draft the reports are able to address issues specific to children, but if they are not able to then it is requested that an additional expert is added to the team in order to do so.

12. CVF further request that the expert/s instructed to prepare the report on "Therapeutics" are asked to address the particular challenges faced by CV, CEV and Severely Immunosuppressed groups requiring access to therapeutics.

(3) Timetable for public hearings

13. CVF note that 13 days have been allocated in total for the Module 4 public hearings which are to run from Tuesday 14 January to Thursday 30 January. CVF are concerned that 13 days are unlikely to be sufficient to address both vaccines and therapeutics. In particular, CVF are concerned that the current length of hearing does not provide adequate time for important issues surrounding therapeutics to be considered with sufficient scrutiny.

14. In light of the Chair's ruling that therapeutics will be considered in both Module 3 and

Module 4,[4] CVF wish to ensure that issues surrounding therapeutics, specifically access to therapeutics, do not get lost within the much larger Module 3 or because there is insufficient time within Module 4. The issue of therapeutics must not fall between the modules, which we consider there is a particular risk of given that the modules are being run by different teams.

15. CVF would be grateful for an early indication from the Inquiry as to how it arrived at 13 days and the number of Module 4 hearing days that will be set aside for therapeutics, as well as how this interacts with the time which will be set aside for therapeutics in Module 3. CVF are of course Core Participants in both Modules 3 and 4, and so are well-placed to assist in ensuring that there is a 'joined-up' approach to therapeutics across both.

(4) Approach to provision of documents

16. CVF note the indication in paras. 26 and 27 of CTI's note that the Inquiry has adopted a "*targeted approach*" in relation to some document providers after it became clear that many tens of thousands of documents are potentially responsive to the Provisional Outline of Scope. The CTI's note indicates that a "*targeted approach*" means that rather than requiring all documents potentially relevant to particular themes or areas to be provided, the Inquiry has instead sought documentation relevant to the key narrative events and the key decisions of those bodies and persons concerning the development, procurement, manufacture, approval (including safety) and delivery of vaccines and therapeutics. Having been analysed, it is understood that this documentation will then be the subject of further focused requests by the Inquiry.

17. CVF note the potential for such an approach to place greater power in the hands of the document holder to steer or even skew a particular 'narrative' and we would welcome further clarification from the Inquiry as to the proposed framework and processes for ensuring that relevant documents are obtained.

C. CONCLUSION

18. CVF intend to make brief oral submissions at the second Preliminary Hearing on 22nd May 2024 and are available to discuss any issues arising from these submissions prior to the

[4] Ruling following the first Module 4 preliminary hearing on 13 September 2023, dated 21 September 2023, at para. 5(b).

hearing if that would be of assistance.

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