IN THE UK COVID-19 INQUIRY
MODULE 3

<u>ADDITIONAL</u> SUBMISSIONS ON BEHALF OF
CLINICALLY VULNERABLE FAMILIES ('CVF')
FOR THE PRELIMINARY HEARING ON 27th SEPTEMBER 2023

A. INTRODUCTION

1. These further submissions are made in order to address, briefly, a point which arose during the Module 4 First Preliminary Hearing on 13th September 2023. These submissions relate to the division of the respective scopes of Modules 3 and 4 and have been filed with both the Module 3 and Module 4 teams.

2. We hope that the Inquiry will permit these submissions to be filed three days after the Module 3 written submissions deadline, given that (a) they could not have been made until after 13th September when Counsel to the Inquiry ('**CTI'**) for Module 4 clarified the Inquiry's intentions in relation to the scopes of Modules 3 and 4, and (b) they have been filed as expeditiously as possible in the circumstances.

3. In summary, CVF submits that it is neither practical nor desirable for the Inquiry's investigation of therapeutics to be divided across Modules 3 and 4. Therapeutics is a discrete topic which should be investigated holistically by a single team, as is the Inquiry's (sensible) approach to vaccinations. CVF are concerned that the Inquiry's approach of separating investigation of the "*development*" from investigation of the "*use*" of therapeutics, as indicated in CTI's oral submissions, risks preventing a full and effective investigation of an issue which is of fundamental importance to the clinically vulnerable.. Moreover, it appears an unequal and inconsistent approach is being taken in relation to therapeutics as compared to the approach to investigating vaccinations, which mirrors the disproportionate focus on vaccinations throughout the pandemic.

B. SUBMISSIONS

(i) The scopes of Modules 3 and 4

4. The Provisional Scope for Module 4 includes the following relevant text (emphases added):

> *"Issues relating to the treatment of Covid-19 through both existing and new medications will be examined in parallel."*
>
> *"The development, trials and use of new therapeutics during the pandemic, in addition to the use of existing medications.*"

5. CTI's note for the Module 4 Preliminary Hearing, at para. 34, also identified a number of questions which the Inquiry in Module 4 is likely to be considering, which included:

> *"Was enough done to ensure fair and adequate access to vaccines and therapeutics, including for those from marginalised groups and communities?"* [emphasis added]

6. The Provisional Scope of Module 3 makes no explicit reference to therapeutics or anti-virals, although it does mention treatment for patients with Covid-19 in general (see para. 5).

7. The Module 3 Provisional List of Issues does not mention therapeutics or anti-viral explicitly. There is a general reference to the "*treatment of Covid-19*" and how it changed throughout the pandemic at para. 5a.

8. Given the above, CVF were surprised by CTI's oral submission at the first Module 4 hearing that:

> 1 There is close interplay between modules 3 and 4,
> 2 a point that your Ladyship referred to in opening
> 3 remarks, particularly when it comes to the topic of
> 4 therapeutics. As you know, my Lady, Module 3 concerns
> 5 the impact of the Covid-19 pandemic on healthcare
> 6 systems in the four nations of the UK.
> 7 The provisional outline of scope for Module 3
> 8 explains that, amongst other things, Module 3 will be

> examining healthcare provision and treatment for patients with Covid-19, healthcare systems' response to clinical trials and research during the pandemic, as well as decision-making about the nature of healthcare to be provided for patients with Covid-19. Module 3 will therefore examine the use of therapeutics in practice. That is, how therapeutics were used once effective treatments had been identified and approved. Module 4, on the other hand, will focus on the preceding phases, the steps taken to enable the use of therapeutics. We will do this by examining the development and trial of new therapeutics and repurposed medications, as well as decisions around eligibility.
>
> [transcript p. 17, emphasis added]

9. To summarise, our updated understanding of the division of scope between Modules 3 and 4, based on CTI's oral submissions, is as follows:

    a. Module 4 will examine the development and trial of therapeutics including decisions around eligibility;

    b. Module 3 will examine the use of therapeutics in practice;

    c. Module 4 will examine the development and trial of vaccinations including decisions around eligibility and the use of vaccinations in practice.

10. In CVF's submission, the approach as set out in the Provisional Scope of Module 4 and CTI's Note for the first Module 4 preliminary hearing, as opposed to the approach outlined in CTI's oral submissions, should be followed, for these reasons:

11. **First**, there should be a consistent and equitable approach taken by the Inquiry to vaccinations and therapeutics.

12. The purpose of Module 4 is to investigate "*vaccines and therapeutics*". The Module 4 Provisional Scope states clearly that this will include the development and implementation

of the vaccine programme, and *"the treatment of Covid-19 through both existing and new medications"* and the "*development, trials and use of new therapeutics"*.

13. We do not know why there appears to have been a change in approach, but CVF are concerned – as stated in oral submissions at the Module 4 Preliminary Hearing, that the consequence will be that therapeutics fall through the cracks and are not given the attention they require in order for the Inquiry to fulfil its terms of reference and conduct a full investigation.

14. On a practical basis, Module 3 is already likely to be extremely full given its wide scope, covering the impact of a virus, which infected millions of people, on the healthcare systems of England, Wales, Scotland and Northern Ireland. There is good reason, in our submission, to separate vaccines and therapeutics to a discrete module, as it will allow the Inquiry to ringfence the amount of time and resources it will devote to these topics which are of fundamental importance – both to understanding how the UK has managed and continues to manage, the Covid-19 pandemic, but also to the approach to future pandemics.

15. For the immune suppressed (1.8 million people according to NICE[1]), vaccinations are far less effective, meaning that anti-virals and other therapeutics, as well as other treatments such as Evusheld, are of fundamental importance to reducing their risk of death or severe disease from Covid-19. For the millions of those who are clinically vulnerable to Covid-19, therapeutics literally provide a life line if they contracted Covid-19.

16. Despite this, therapeutics received only a fraction of the attention of vaccines during the first years of the Covid-19 pandemic. This is perhaps explained by the UK government wanting to bring attention to its efforts to develop a vaccine, and be among the first states worldwide to implement a vaccine programme. However, from the perspective of preventing death and severe disease in a future pandemic or epidemic involving a new virus, there should be an equal focus on both vaccinations and therapeutics. Neither is a 'silver bullet' and as any virologist will agree, both are of crucial tools to tackling the outbreak of a virus.

[1] https://www.nice.org.uk/guidance/ta900/evidence/draft-guidance-consultation-committee-papers-pdf-13069467901 [page 20]

17. CVF is concerned that the Inquiry risks falling into the same trap: prioritising its investigation of vaccinations over therapeutics. We submit that this would be counter-productive and continue the prejudice which clinically vulnerable people experience relating to their specific needs.

18. CVF is also concerned that if the development of anti-virals is considered by a different module, and different Inquiry team, then this will preclude the Inquiry from reaching holistic conclusions on therapeutics. This would be a huge missed opportunity and also may ultimately prevent the Inquiry from reaching the right conclusions.

19. **Second,** we respectfully submit that in the context of therapeutics it is neither possible nor desirable to separate out the development and trial of therapeutics from their practical implementation, and therefore prevent consideration of evidence relating to the use of and access to therapeutics in Module 4. We submit that this division needs careful consideration and should not follow the rubric set out by CTI in oral submissions at the Module 4 Preliminary Hearing, i.e. between "*development and trial*" (Module 4) and "*use*" (Module 3).

20. To summarise, there are, roughly speaking, five aspects to consider in relation to anti-virals, namely:

    (1) Development;

    (2) Setting of eligibility criteria;

    (3) Process for referral;

    (4) Clinical assessment for access (by the Covid Medicines Delivery Unit);

    (5) Patients receiving anti-virals.

21. CVF submit that Module 4 should hear evidence on (1) to (5) above.

22. It is important to understand that steps (3) to (5) above could and still can be achieved in the community without any face-to-face contact with a clinician. A number of anti-virals are administered by the NHS in the community – far more similar to the vaccine implementation than to treatment for Covid-19 given in hospitals. Indeed, three of the key

antivirals (molnupiravir, sotrovimab or paxlovid) can only be obtained as an out-patient; by contrast, remdesivir can only be accessed as an in-patient. It is for this reason that CVF, whose members have significant experience of accessing or attempting to access anti-virals, considered that it was entirely logical and desirable to consider vaccines and therapeutics in a discrete module; not least because the equivalent processes in relation to each can fruitfully be compared.

23. The timeline from development of anti-virals to patients receiving them during the Covid-19 pandemic has been unusually short, for understandable reasons. This meant that often there was very little time between development, trial and use on patients, and this was very much a dynamic process where real world use was leading to the refinement of eligibility criteria and to changes in the way the anti-virals were used.

24. **Third**, it is simply not possible to analyse and reach conclusions on the 'development' stages as set out above without inviting evidence on the latter stages, where anti-virals were given to individuals. CVF is able to assist the Inquiry with numerous case studies from its members about the experience of accessing – or being unable to access – anti-virals and Evusheld. It is only through this evidence, we submit, that the Inquiry will be able to reach conclusions on the real-world impact of, for example, the eligibility criteria (which were, CVF will submit, both too narrow and too rigid).

25. CVF cannot understand how the Inquiry could reach any conclusions as to the adequacy or otherwise of the eligibility criteria for therapeutics (a topic which CTI confirms will be considered in Module 4) without taking evidence on who received anti-virals and who did not, and why.

26. **Fourth,** the provision of therapeutics for Covid-19 is an urgent, ongoing issue. CVF are concerned that by dividing the issue between Modules 3 and 4, the Inquiry will substantially delay any potential interim recommendations in relation the therapeutics. These could be hugely helpful for the people CVF represents; from CVF's perspective, the sooner, the better.

27. **Fifth**, none of the above should be taken as a submission that Module 3 should be prevented from considering therapeutics. Plainly, there will need to be some investigation in Module 3 of the use of therapeutics, for example in the context of how patients were treated for

severe Covid-19 in hospital. However, Module 3 should build upon an holistic investigation of the issues which will already have been undertaken, and at least reached preliminary conclusions, in Module 4.

28. CVF are of course able to submit its evidence on therapeutics in Module 3, however this was not our understanding when we provided our Rule 9 response and we suspect that will apply to many other organisations who have given Rule 9 evidence. It is also not clear in the Rule 9 request for Module 4 that the use of therapeutics should not be included in the statement. This demonstrates the practical difficulties of splitting the issue across two modules, rather than considering it holistically in Module 4.

C. CONCLUSION

29. CVF request, for the reasons set out above, that the division of the investigation of therapeutics across two modules will be reconsidered. We would be happy to discuss any of the above further and intend to supplement these submissions in our oral submissions at the Module 3 Second Preliminary Hearing.

KIM HARRISON
SHANE SMITH
Slater & Gordon
Solicitors for CVF

ADAM WAGNER
Counsel for CVF

Doughty Street Chambers
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