Module 4: Counsel to the Inquiry's Note for the second Preliminary Hearing on Wednesday 22 May 2024

Introduction

1. The first Preliminary Hearing in Module 4 of the Covid-19 Inquiry took place on Wednesday 13 September 2023. This Note introduces the agenda and the issues for the second Preliminary Hearing in Module 4, which will take place on Wednesday 22 May 2024.

2. Those who have been granted core participant status on Module 4 have been provided with regular progress updates over the past few months. However, this preliminary hearing is an opportunity to draw this information together and ensure that it is up to date, as well as allowing a public update on the Inquiry's work so far. Any brief written submissions from Core Participants in response should be received by 4pm on 13 May 2024.

3. The agenda for the Preliminary Hearing in Module 4 is as follows:

    (i) Introductory remarks from the Chair

    (ii) Submissions from Counsel to the Inquiry, regarding:

        a. Update on scope
        b. Update on Rule 9 requests
        c. Parliamentary privilege
        d. Disclosure to Core Participants
        e. Expert Witnesses
        f. Every Story Matters
        g. Timetable concerning provision of:
            a. Provisional List of Issues document
            b. List of witnesses
            c. Proposals for Rule 10 process
        h. Future hearing dates.

(iii) Submissions from Core Participants

Update on Module 4 scope

4. Module 4 is concerned with Covid-19 vaccines and therapeutics. The Provisional Outline of Scope for Module 4 stated (as at 5 June 2023):

> *"This module will consider and make recommendations on a range of issues relating to the development of Covid-19 vaccines and the implementation of the vaccine rollout programme in England, Wales, Scotland and Northern Ireland. Issues relating to the treatment of Covid-19 through both existing and new medications will be examined in parallel. There will be a focus on lessons learned and preparedness for the next pandemic. Thematic issues relating to unequal vaccine uptake will be examined, to include the identification of groups which were the subject of unequal uptake, potential causes of such unequal uptake and the Government response. The module will address issues of recent public concern relating to vaccine safety and the current system for financial redress under the UK Vaccine Damage Payment Scheme.*
>
> *In particular, this module will examine:*
>
> *1. The development, procurement, manufacture and approval of vaccines during the pandemic, including the effectiveness of UK-wide decision-making, in particular, the role of the UK Vaccine Taskforce. What lessons can we learn from innovative practices that were successfully introduced during the pandemic for future pandemic preparedness?*
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> *2. The development, trials and use of new therapeutics during the pandemic, in addition to the use of existing medications.*
>
> *3. Vaccine delivery in England, Wales, Scotland and Northern Ireland, including roll-out procedures such as: arrangements on the ground and public messaging; Joint Committee on Vaccination and Immunisation recommendations on eligibility / prioritisation and decisions taken by policy makers; the ethics of prioritisation decisions and impact on particular groups such as those with comorbidities.*
>
> *4. Barriers to vaccine uptake, including vaccine confidence and access issues and the effectiveness, timeliness and adequacy of Government planning for and response to inequalities relevant to vaccine uptake.*
>
> *5. Vaccine safety issues including post marketing surveillance, such as the Yellow Card monitoring and reporting system and a suggested correlation between Covid-19 vaccines and cardiovascular issues.*

6. Whether any reforms to the UK Vaccine Damage Payment Scheme are necessary."

5. At the Preliminary Hearing of 13 September 2023, many of the Core Participants made written and oral submissions concerning the issue of scope. In her ruling (https://covid19.public-inquiry.uk/wp-content/uploads/2023/09/21144701/2023-09-21-Ruling-following-the-first-Module-4-Preliminary-Hearing.pdf), published on 21 September 2023, the Chair noted that the majority of the evidential areas that had been raised were already reflected in the Rule 9 requests that had been sent out or which were in the process of being drafted. However, she indicated that the submissions would be subject to further consideration by her and the Inquiry team.

6. In her ruling she made, furthermore, certain specific rulings concerning:

    a. Her intention to examine differences across England, Wales, Scotland and Northern Ireland and identify any impact those differences may have had in practice.

    b. The scope of Module 4 in relation to the use of therapeutics, including the development and trials of new therapeutics and repurposed medications, as well as decision-making on eligibility at a national level. She ruled that the Provisional Outline of Scope for Module 4 should be amended so that it read: "*The development, trials and steps taken to enable the use of new therapeutics and repurposed medications during the pandemic*."

    c. The UK's role in addressing global vaccine inequity. Although the matter would be kept under review, she was minded to ensure that the focus of Module 4's investigation was instead on the four nations of the UK.

    d. The issue of Vaccine as a Condition of Deployment (VCOD). She considered that Module 4 was required to explore: 1) whether VCOD was, or would have been, effective at limiting transmission and what was known by policy makers about such effectiveness and when; and 2) the impact the policy may have had in exacerbating vaccine hesitancy among particular groups. She ruled that the Provisional Outline of Scope for Module 4 be amended to reflect this with the following addition at the end of paragraph 3: "*Vaccine as a Condition of Deployment, in particular its effectiveness in limiting transmission and impact on vaccine hesitancy.*"

    e. The degree of focus on therapeutics as part of the Module 4's work. She re-stated her commitment to ensure that the important topic of therapeutics was rigorously and comprehensively examined by the Inquiry.

7. The Outline of Scope, whilst now amended to reflect the above rulings, necessarily remains provisional. It is neither practical nor advisable to identify with detail at this stage all the issues that will be addressed at the Module 4 public hearing. As noted during the first Preliminary Hearing, the issues that will be explored at the hearing depend to a large extent on the R9 statements and documents obtained under the Rule 9 process, and will need to be further distilled in light of the material that is obtained. That distillation will be reflected in the Provisional List of Issues, which will be made available in due course.

8. Nevertheless, given the submissions that were advanced at the first Preliminary Hearing and the fact that some material providers have, quite properly, raised queries concerning the scope of Module 4, it may be helpful to make the following matters clear.

9. The Aims of the Inquiry are twofold. First, to "Examine the COVID-19 response and the impact of the pandemic in England, Wales, Scotland and Northern Ireland, and produce a factual narrative account", with particular reference to the public health response, the response of the health and care sector, and the economic response. Second, to "Identify the lessons to be learned from the above, to inform preparations for future pandemics across the UK".

10. In so far as vaccines and therapeutics are concerned, the Inquiry's terms of reference enjoin it to examine the following linked issues:

    - Preparedness and resilience;
    - how decisions were made, communicated, recorded, and implemented;
    - decision-making between the governments of the UK;
    - the roles of, and collaboration between, central government, devolved administrations, regional and local authorities, and the voluntary and community sector;
    - the availability and use of data, research and expert evidence;
    - legislative and regulatory control and enforcement;
    - shielding and the protection of the clinically vulnerable;
    - the impact on the mental health and wellbeing of the population, including but not limited to those who were harmed significantly by the pandemic;
    - the impact on health and care sector workers and other key workers;
    - the impact on children and young people, including health, wellbeing and social care;
    - the development, delivery and impact of therapeutics and vaccines;

11. However, given the immensely wide potential remit, the Inquiry must, as the Chair has observed, focus on matters of real importance. It is simply not possible to scrutinise every aspect of the development, delivery and deployment of vaccines and therapeutics during the pandemic, or to examine issues with the degree of specificity and forensic detail more commonly associated with 'single event' inquiries, that is to say inquiries into matters narrowly limited by scope, time or impact. Even though a

wide range of issues will necessarily be addressed as part of the Inquiry's factual narrative, the focus must remain throughout on how relevant systems and processes can be improved and on identifying meaningful lessons for the future.

12. Accordingly, the focus of Module 4 is on 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; on preparedness and the core decision-making (including of course the the decisions of the Vaccine Taskforce and the Antivirals and Therapeutics Taskforce); on the general impact of those decisions, especially on marginalised groups and communities.

13. Included in the above are specific vaccine-related issues such as misinformation and disinformation, the reasons for vaccine hesitancy/lack of confidence and the steps taken to address this and to increase uptake, post marketing surveillance including the Yellow Card monitoring scheme, and the UK Vaccine Damage Payment Scheme. Insofar as therapeutics are concerned, Module 4's examination will include, specifically, the decision-making relating to the non-vaccine prophylactic Evusheld. Further details are provided below, in the context of the expert reports that are being sought.

14. It follows that although the Inquiry will examine the nature and efficacy of the regulatory regime for the approval of vaccines and therapeutics, including the considerations that underpinned relevant decision-making, how risk/benefit assessments were undertaken, the operation of the post-approval monitoring system, and how the relevant bodies identified and responded to reports of side-effects, it will not be examining other than at high level the vaccine and therapeutic trials or the complex scientific analysis that led to regulatory and governmental approval.

15. In addition, although the Inquiry will address the safety-related debate over vaccines, it will not be reaching a concluded view on the safety of specific vaccines, or attempt to quantify the precise risks of vaccination. Nor will it be interrogating the scientific analysis underpinning decision-making on how such risks were managed or addressed (though it will investigate the steps that were taken to mitigate known risks of the vaccines).

16. In relation to the commercial negotiations and contractual arrangements for the development and supply of particular vaccines and therapeutics, the following matters are, at present, considered outside the scope of the Inquiry:

    a. Unit prices and pricing structures, payment schedules, any discounted rates applied as part of the supply agreement, and the value of any such discounts (whether referred to in internal discussions, negotiations or agreements, or otherwise).

b. Details of pharmaceutical companies' internal supply schedules, supply chains and manufacturing processes.

c. Information about the scope, licensing, terms and details of pharmaceutical companies' intellectual property rights.

d. Details of pharmaceutical companies' Chemistry, Manufacturing and Controls (CMC) processes (i.e. the various procedures used to assess the physical and chemical characteristics of drug products, and to ensure their quality and consistency during manufacturing).

17. By contrast, the following matters are relevant to the Inquiry's examination:

    a. The amounts spent by the UK Government on vaccines / therapeutics generally, and on specific vaccines and therapeutics.

    b. The approach to the application of discounted rates.

    c. The existence of liability and indemnity arrangements, and the setting up of such arrangements.

    d. The termination of the arrangements for the production and development of vaccines/therapeutics (for example, the Valneva contract).

18. In relation to issues of eligibility and priority for vaccination, the Inquiry will examine the processes by which these issues were addressed and decisions were reached. This will include an examination of how the balance was struck between relevant considerations, such as vulnerability to the virus, age, and likely contra-indications. The inquiry will not however seek to examine or determine the scientific considerations underpinning these processes or what the risks in fact were.

<u>Update on Rule 9 requests</u>

19. Since the first preliminary hearing in September 2023, Rule 9 requests have been sent to 95 additional individuals and organisations. As at the date of this note, Module 4 has sent over 120 Rule 9 requests for witness statements and associated documents.

20. The Module 4 Solicitor team update notes of March and April 2024 provided details of the recipients and an overview of the topics about which they have been asked but, in summary, Rule 9 requests have been sent to the following notable recipients:

    a. UKHSA, in relation to its predecessor organisation, Public Health England, and matters relating to the Vaccine Taskforce;
    b. Department for Science, Innovation and Technology including in relation to

matters relating to the Vaccine Taskforce;
c. Ministers with responsibility in relation to vaccines and therapeutics;
d. Former Chairs and Director Generals of the Vaccine Taskforce;
e. Former Chief Scientific Adviser, Sir Patrick Vallance;
f. Key figures within the Antivirals and Therapeutics Taskforce and its predecessor bodies;
g. Medicines and Healthcare Products Regulatory Agency (MHRA);
h. Pharmaceutical companies with agreements to supply Covid-19 vaccines in the UK;
i. Joint Committee on Vaccination and Immunisation (JCVI);
j. Department of Health and Social Care;
k. Welsh Government, incorporating the role of the Health and Social Services Group;
l. Scottish Government;
m. Department of Health Northern Ireland;
n. Office of the Chief Medical Officer and the CMO offices in the Devolved Nations;
o. National Institute for Health and Care Excellence (NICE);
p. Chief Investigators and those leading the platform trials for new and repurposed therapeutics for Covid-19;
q. Key figures involved in vaccine delivery and roll out, such as Dame Emily Lawson OBE;
r. CP groups, and other organisations representing interested individuals, including the bereaved and vaccine injured and those from vulnerable and marginalised communities.

21. We are grateful to recipients of Rule 9 requests for the efforts they have made to comply with the Inquiry requests in a timely manner. In some cases, short extensions to deadlines have been agreed to allow departments, organisations and individuals to focus on providing responses to requests made in earlier Inquiry modules.

22. More than 80 draft statements have been received and are either being reviewed with a view to the giving of feedback or have been finalised, but are awaiting final confirmation and/or signing. The process has been slowed down to some extent by the need to remove duplicate exhibits and replace them with versions of those documents that have already been disclosed, with a view to giving a final set of INQs to insert into the final statement.

23. The Inquiry anticipates sending out a further 15 or so Rule 9 requests during the course of the next two months. These are likely to include R9 requests to:

    a. Former First Minister of Scotland, Nicola Sturgeon;
    b. Former First Minister of Wales, Mark Drakeford
    c. Former Scottish Cabinet Secretaries for Health and Social Care, Jeanne Freeman and Humza Yousaf;

d. Chief Pharmaceutical Officers in all four nations of the UK;
e. Senior Responsible Owner in relation to vaccine deployment in Scotland, Derek Grieve (Head of Operational Vaccines Division for the Scottish Government);
f. Senior Responsible Owner in relation to vaccine deployment in Northern Ireland, Dr Naresh Chada (Deputy Chief Medical Officer, Northern Ireland).

24. In the Autumn, decisions will be taken as to whether further new, or follow-up, Rule 9 requests to organisations and witnesses are required, as issues come into greater focus.

25. The Inquiry invites Core Participants, as they become aware of the identity of those individuals and organisations who have received Rule 9 requests from the Inquiry, to advance suggestions as to who should additionally receive a Rule 9 request.

26. In the case of the major government departments, it is clear from the initial responses that many tens of thousands of documents are potentially responsive to the initial Provisional Outline of Scope. The process of assessing such a quantity of responsive material would lead to an unconscionable delay in the Inquiry's timetable and render impossible its stated determination to produce timely recommendations.

27. With respect to some document providers, therefore, the Inquiry has adopted a targeted approach by which, rather than requiring all documents potentially relevant to particular themes or areas to be provided, it has instead sought documentation relevant to the key narrative events and the key decisions of those bodies and persons relevant to the processes and systems concerning the development, procurement, manufacture, approval (including safety) and delivery of vaccines and therapeutics. Having been analysed, this documentation will then be the subject of further focused requests.

28. In line with the Ruling made by the Chair following the first Preliminary Hearing, it will remain the position that Core Participants will not be provided with copies of the Rule 9 requests made by the Inquiry. However, they will continue to be kept properly informed through the Module 4 solicitor updates.

Parliamentary privilege

29. Unsurprisingly, a great many Parliamentary debates, reports and other material, including a significant number of NAO reports, have addressed Covid-19 or pandemic related issues. Accordingly, a significant number of Rule 9 statement providers have, in entirely good faith, sought, in the course of a number of the Modules, to submit draft Rule 9 statements which refer to written or oral evidence that they had provided to

Parliamentary select committees or the National Audit Office (NAO)[1], or cite from and/or exhibit select committee reports.

30. This has given rise to the question of whether such practices could lead to a breach of Art IX of the Bill of Rights 1689, which provides that "*the Freedome of Speech and Debates or Proceedings in Parlyament ought not to be impeached or questioned in any Court or Place out of Parlyament*", in essence, a breach of Parliamentary privilege.

31. It is correct to say that the issue of whether a statutory inquiry under the Inquiries Act 2005 is a "*Court or Place out of Parlyament*" has not been determined by the courts. Nevertheless, there is at least a good argument that it is:

    a. On the face of it, this inquiry is '*any Court or Place out of Parlyament*', giving those words their ordinary and natural meaning, and reading them disjunctively, as they are plainly meant to be, and purposively.

    b. The Joint Committee on Parliamentary Privilege of March 1999 opined that 'place' included a tribunal, and that, were the matter to arise in the context of the Tribunals of Inquiry (Evidence) Act 1921 - the predecessor Act to the Inquiries Act 2005 - the privilege would apply. It recommended that 'place' should be defined in statute to include any tribunal having power to examine witnesses on oath so that any statutory inquiry would be such a 'place'. This would bring the position into line with the statutory position in Australia under the Parliamentary Privileges Act 1987 (Australia) which has replaced the words 'court or place' with 'any court or tribunal'.

    c. The subsequent Government consultation paper proceeded on the premise that the privilege extended to both tribunals and courts. The Joint Committee on Parliamentary Privilege's report of June 2013 recommended that no statutory changes were needed.

    d. In *DK and RK (Parliamentary privilege, evidence)* [2021] UKUT 61 the Upper Tribunal held that Parliamentary privilege applied to it. The Upper Tribunal is a statutory tribunal conferred with statutory powers to do court-like things and make findings under the Tribunals, Courts and Enforcement Act 2007.

32. However, the issue is not required to be resolved. The practices in the draft Rule 9 statements identified above could not crystallise into a breach unless and until the point is reached at which the material or exhibits that the statements seek to introduce into the Inquiry can in fact be impeached or questioned, by virtue of being formally introduced into the forensic process through the service of the final Rule 9 statements or, at the latest, by the questioning of witnesses upon such material. That point has

[1] The Parliamentary Papers Act 1840 extended Parliamentary privilege by giving absolute privilege to any document published by order of either House. This includes certain categories of document which departments are required to lay before Parliament, such as National Audit Office reports published by the Comptroller and Auditor General (who are both officers of the House). "The reports of the National Audit Office are documents that attract the protection of the Parliamentary Papers Act 1840": *DK and RK (Parliamentary privilege, evidence)* [2021] UKUT 61, at para 17.

not yet been reached and, if the practical steps identified below are adhered to, will never be reached.

33. It is plainly desirable that it not be reached. The Inquiry has endeavoured to ensure that the submission of such statements is not a precursor, and does not lead, to a breach of Parliamentary privilege. The need for the Inquiry to resolve whether it is breaching or has breached Parliamentary privilege, whether or not amounting to a contempt of Parliament (in itself a difficult and complex issue), would be a serious matter, would lead to complex and time-consuming legal argument, and would likely necessitate an intervention in the Inquiry process by Speaker's Counsel[2]. No inquiry should knowingly entertain the risk of a breach, where there is an obvious and straightforward practical alternative.

34. Such an alternative is available in this Inquiry. The Inquiry's approach has been to invite material providers, including core participants:

    a. not to exhibit to their Rule 9 statements records of the oral or written evidence or briefings given by them or others to select committees, unless it be to prove the fact that such evidence was given (and perhaps its date), but instead to replicate afresh the substance of that evidence (or, if preferred, word for word) in the Rule 9 statement. The prospective R9 statement-makers are of course well aware of what they have already said or provided to Parliament, and are therefore well-placed to ensure that their Rule 9 statements address all the matters that they would wish to raise.

    b. not to exhibit to their Rule 9 statements copies of select committee reports or to cite in those statements extracts from, or the findings or recommendations of, those select committee reports, unless reference is being made only as a matter of historical fact or to provide context. Of course, the select committee reports may themselves have little utility, given the obvious feature that it is for this inquiry to examine the relevant material and to reach its own conclusions.

    c. not to exhibit to their Rule 9 statements documents taken directly from select committee reports in the form in which they have been published as part of those reports, but instead exhibit those (presumably pre-existing) documents in their original form.

35. It should be made clear that the Inquiry has not sought to restrict reference to

[2] The Speaker's Counsel is Sairi Salimi. Quite properly, the Solicitor to the Inquiry, Martin Smith, wrote to her on 25 August 2022 to inform her of the Inquiry's intention to respect Parliamentary privilege and setting out the forensic processes which were to be adopted by the Inquiry in order to ensure that inadvertent breaches could be avoided. Those processes are the same as those described in this Note. In her response, Speaker's Counsel stated "In particular, it seems entirely legally and constitutionally sound to obtain fresh evidence from witnesses on matters where the inquiry might otherwise be led into "impeaching or questioning" proceedings in Parliament. Parliamentary material on the open record can of course be read as background material."

Parliamentary proceedings or to material protected by Parliamentary privilege where the purpose is simply to cite them as a matter of fact or history to show what was said and when. In doing so, such matters are not being 'questioned or impeached', contrary to Art IX of the Bill of Rights 1689. A mere reference to, or production in legal proceedings of, a select committee report or of what was said in Parliament does not of itself infringe Article IX. Nor is it problematic to list engagements with a select committee.

36. Accordingly, the issue of the extent to which Parliamentary privilege might preclude the admission into evidence in the Inquiry of such material was raised by CTI during the course of the preliminary hearings in Module 1 and Module 2 so that core participants could understand the general approach that the Inquiry had adopted. CTI argued, as they do here, that the issue was not required to be resolved, given the practical approach that had been adopted by the Inquiry.

37. The majority of the core participants in M1 and M2 agreed that the issue of principle did not require resolution. Some of the core participants described the Inquiry's approach as sensible and proportionate. In the event, the Chair was not invited to rule on the matter and accordingly made no ruling.

38. The matter has arisen again, however, because the core participant group The Migrant Primary Care Access Group (MPCAG)[3] has filed written submissions objecting to the Inquiry's request that certain passages and exhibits be removed from its draft Rule 9 statement. It refers to earlier instances in Modules 1 and 2 of the witness statements of Core Participants and witnesses referring to and exhibiting written evidence that had been submitted to Parliamentary committees, or detailing work that had been carried out for the purposes of such committees, or directly exhibiting select committee reports themselves. MPCAG argues that, in light of that earlier 'approach' of the Inquiry, it too should be allowed to exhibit the written evidence that it submitted to various select committees and refer to their findings.

39. The Chair may conclude that MPCAG puts the matter too high. MPCAG say in its written submissions, at paras 6-8, that it was asked in the 31 August 2023 Rule 9 request for 'evidence' that it had given to Parliamentary Select Committees. In fact The R9 request asked for a "summary" of the evidence MPCAG had given: "A summary of any reports your organisation has published or contributed to, and/or evidence it has given (for example to Parliamentary Select Committees) regarding the matters set out in the Provisional Outline for Scope of Module 4." At the same time, although the MPCAG feedback letter was sent on 3 January 2024 without any reference to Parliamentary privilege, they were subsequently informed by email that an amended feedback letter would follow. The issue of Parliamentary privilege was then addressed in an amended feedback letter sent on 15 February 2024.

[3] MPCAG comprises four organisations: Doctors of the World UK (DOTWUK), Medact, Joint Council for the Welfare of Immigrants (JCWI) and Kanlungan Filipino Consortium (Kanlungan). Kanlungan is one of three organisations forming part of the M3 core participant group Frontline Migrant Health Workers Group.

40. As for the Inquiry's approach in Modules 1 and 2, material providers were advised of the Inquiry's approach to Parliamentary privilege and, where, it appeared that the Rule 9 statement was seeking to impeach or question proceedings in Parliament, or where there was a real risk that it would do so, they were requested to remove such material from the statement.

41. Some material providers did refer to or exhibit the evidence that they had given to select committees, list their engagements with such committees, or produce copies of the select committee reports. However, where such material was produced as a matter of historical fact, and no point was sought to be made on its worth, no breach of Parliamentary privilege would be likely to crystallise. In a handful of instances, the material provider did provide its views and seek to comment on the evidence or issues before the select committee. It is accepted that, due to time constraints, not all of these references were removed from the final version of the Rule 9 statement. However, such evidence has not been relied upon by the Inquiry, and so there is no question of proceedings in Parliament having been impeached or questioned. Out of an abundance of caution, however, the Inquiry is now undertaking a review of the examples given by MPCAG and will apply any redactions to the published material where it considers necessary.

42. It is therefore open to the Chair to reject MPCAG's argument that there was an earlier allegedly different 'approach', or that any such 'approach' has given rise to procedural unfairness. There was no earlier different 'approach' and, even had there been, it could not have engendered a legitimate expectation on the part of MPCAG or given rise to any unfairness. The solution, insofar as MPCAG wishes to exhibit its own evidence to select committees, is for it to adopt the practical solution identified in paragraph 34 above.

43. The MPCAG contends however that the practical solution adopted by the Inquiry of simply requesting the makers of witness statements to reiterate in their statements to the Inquiry what they told the select committees is 'not feasible or practical'. It denies that summarising its earlier evidence is possible, because such evidence was 'lengthy, detailed and supported by reference to other studies' and suggests that a summary would not capture the detail and substance of the evidence, or MPCAG's recommendations.

44. CTI would respectfully disagree. The fact that a significant number of material providers and core participants have been able to adopt this practical solution suggests that MPCAG's concerns are over-stated.

45. MPCAG further argues that it must be able to 'hold the government to account' and that this can only be done by 'direct reference to Parliamentary Select Committee participation and evidence, to establish the Government's direct knowledge of vaccine barriers during the pandemic' at the material time (presumably, the time of those select committees): see submissions of 10 April 2024, at paras 26, 28. Their stated wish is to 'highlight and establish the Government's direct knowledge at the material time' of 'inequality in healthcare and vaccine access amongst vulnerable migrants and

asylum-seekers, and identifiable barriers preventing access to vaccines and therapeutics for this cohort'.

46. MPCAG argues that it is only from the government's evidence to the various select committees that it can be proved what the government's knowledge of vaccine inequality and barriers was at the material time. 'Removal' of such evidence from its Rule 9 statement would, it is said, 'impede the work of the Inquiry'.

47. CTI suggests that, putting aside the merits of this endeavour (the government's knowledge at the time is likely to be no less apparent from its many policy and public statements), reliance upon the government's oral and written evidence and submissions to select committees for this purpose is unlikely to violate Parliamentary privilege in any event (assuming that the privilege does attach to this Inquiry).

48. The purpose behind any intended reliance upon Parliamentary records or material is key. What is not permitted under the doctrine of Parliamentary privilege is for the truth, worth or validity of what has been said or done in Parliament to be questioned. It is therefore not permissible to draw inferences from parliamentary material or to use it as evidence for or against disputed factual matters; to rely upon parliamentary material as evidence of the truth of a proposition; or to deny, dispute or question the worth, truth, genuineness or accuracy of the content of parliamentary material. To do so is to question or impeach Parliament (assuming that the Inquiry is a 'court or place' outside it).

49. However, if the purpose is simply to set out what the government itself knew at the time, by reference to the fact of what it said (to, for example, a Parliamentary committee), then there would be no breach.

Disclosure to Core Participants

50. As at the date of this note, two signed statements have been disclosed from the Department for Work and Pensions and the Joint Committee on Vaccination and Immunisation (JCVI). As noted above, a significant number of draft statements have been received. However, these are either under review by the Inquiry, awaiting a response from the statement providers to the feedback provided by the Inquiry or a signature.

51. As at the date of this note, the Module 4 team has disclosed a significant volume of material identified as relevant to the scope of Module 4 (the latest tranche was delivered on Friday 26 April 2024). This includes material provided by the Cabinet Office, Office of the Chief Medical Officer, Department for Health and Social Care, NHS England, the Department of Health Northern Ireland and publicly available reports identified as of particular relevance to Module 4.

52. The Inquiry expects to make further significant tranches of disclosure between this note and the preliminary hearing. The Module 4 team is also, with an eye over the relative scopes of Modules 3 and 4, reviewing closely the material received by the

Inquiry in Module 3.

Expert Witnesses

53. Significant progress has been made in instructing suitable experts:

    a. Vaccine safety: Prof Dani Prieto-Alhambra, Professor of Pharmaco- and Device Epidemiology at the Botnar Research Centre at University of Oxford, has been instructed to address the issues of vaccine safety regulation and monitoring. His report is expected to cover vaccine effectiveness and how it is assessed; what the side-effects of vaccines are generally known to be; the effect of vaccines on transmission; the Yellow Card reporting system; and what lessons can be learned in respect of the processes concerning vaccine regulation and surveillance. It is hoped that the final draft report will be provided to Core Participants in Autumn 2024.

    b. Vaccine roll-out and vaccine hesitancy: the Inquiry has instructed Prof Ben Kasstan-Dabush, Assistant Professor of Medical Anthropology at the LSHTM, and Dr Tracey Chantler, Associate Professor of Public Health Evaluation at the LSHTM and co-director of its Vaccine Centre (VaC). Their report will cover the issues of the roll-out processes for the UK Covid-19 vaccines; vaccine coverage (including known disparities in coverage); the type of data collected and published on UK Covid-19 vaccines coverage; the methods used to obtain data on UK Covid-19 vaccines coverage; disparities in coverage and the causes of disparities in coverage (including barriers to vaccine coverage such as accessibility, availability and convenience, and affordability); whether coverage issues were foreseeable and the steps taken to address coverage issues; the interplay between the UK Covid-19 Vaccines roll-out and pre-existing inequalities and structural discrimination; and the lessons that can be learned from the UK's planning for, and response to, the Covid-19 pandemic in relation to vaccine roll-out processes and barriers to vaccine coverage and disparities in vaccine coverage. A second draft report has been received by the Inquiry team and it is hoped that the final draft report will be provided to Core Participants in Summer 2024.

    c. Vaccine hesitancy/misinformation: the Inquiry has instructed Prof Heidi Larson, Professor of Anthropology, Risk and Decision Science, Infectious Disease Epidemiology & Dynamics and Director of The Vaccine Confidence Project (VCP) at LSHTM, assisted by Dr Alexandre de Figueiredo (Research Fellow and Statistics Lead at the Vaccine Confidence Project), Rachel Eagan (Research Assistant) and Caitlin Jarret (Research Fellow). Her report will cover the issues of the measuring and monitoring of vaccine hesitancy; an overview of general trends both within the UK and internationally in relation to vaccine hesitancy and how these trends changed during the Covid-19 pandemic; vaccine hesitancy in respect of the UK Covid-19 vaccines as well as other UK vaccines;

an overview of any differences between the four nations of the UK, and with comparable countries, in relation to vaccine hesitancy; the reasons for vaccine hesitancy; an overview of common factual inaccuracies and misconceptions, if any, about Covid-19 and the UK Covid-19 vaccines, and the reasons for them; the policy of Vaccination as a Condition of Deployment (VCOD); the impact, if any, of VCOD and vaccine certification on hesitancy; the extent to which vaccine hesitancy in relation to the UK Covid-19 vaccines was foreseeable and preventable; an overview of the steps taken, if any, to prepare for and address vaccine hesitancy; and the lessons that can be learned from the UK's planning for, and response to, the Covid-19 pandemic in relation to each of the causes of vaccine hesitancy and the responses thereto. It is hoped that the final draft report will be provided to Core Participants in Summer 2024.

d. Therapeutics: the Inquiry is currently liaising with possible experts to provide a report that seeks to cover a number of topics including: the differences between therapeutics and vaccines and the relative importance of each in tackling a pandemic; an explanation of non-vaccine prophylactics; a description of the different types of therapeutics for Covid-19 (to include small molecule antivirals, neutralising monoclonal antibodies and drugs used to treat complications of severe disease such as excessive clotting or inflammation); an overview of preclinical trials; an overview of clinical trials and an explanation of the clinical trial phases in respect of new and repurposed therapeutics for the treatment of Covid-19; an overview of emerging science in respect of therapeutics and the likely impact on the response to a future pandemic. It is hoped that any expert instructed would be able to provide a final draft report in sufficient time to be provided to Core Participants in Autumn 2024.

Every Story Matters

54. The Module 4 Every Story Matters report is due to be provided to the Inquiry team in late Summer 2024 following which it will be reviewed by the Inquiry Legal Team and any feedback provided. Thereafter the report will be finalised and we anticipate that it will be shared with Core Participants in late Autumn 2024.

Timetable

55. In preparation for the public hearing, the Inquiry intends to circulate in September a provisional List of Witnesses along with a provisional List of Issues. Core Participants will of course be invited to respond.

56. Proposals for the Rule 10 process will be circulated in advance of the third Preliminary Hearing in October 2024.

57. As was the case in M2, impact evidence will be called at the public hearing from representative witnesses on behalf of appropriate Core Participant groups. Their statements are likely to be published. The Inquiry reiterates that the purpose of this is not to inquire into the impact of vaccines or therapeutics on individuals, but, rather, is to ensure that the Inquiry understands the broad consequences and impact of the pandemic and the government's response.

58. There will be an Impact Film broadly connected with the issues addressed in Module 4, and the Inquiry will be in touch with Core Participants to discuss filming opportunities.

Future Hearings

59. A further Preliminary Hearing for Module 4 will be held at Dorland House in October 2024. The specific date will be provided in due course.

60. As the Core Participants were informed in the STI March 2024 update Note, and as made clear on the Inquiry web-site, the public hearing in Module 4 will take place at Dorland House between Tuesday 14 and Thursday 30 January 2025.

Counsel to the Inquiry **2 May 2024**

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