NOTICE OF DETERMINATION

CORE PARTICIPANT APPLICATION

MODULE 4 - MHRA

Introduction

1. In my Opening Statement on 21 July 2022, I explained that Modules would be announced and opened in sequence, with those wishing to take a formal role in the Inquiry invited to apply to become Core Participants for each module. On 5 June 2023, the Inquiry opened Module 4 and invited anyone who wished to be considered as a Core Participant to that Module to submit an application in writing to the Solicitor to the Inquiry by 30 June 2023.

2. The Inquiry has published the Provisional Outline of Scope for Module 4, which states that this module will consider 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. Further modules will be announced and opened in due course, to address other aspects of the Inquiry's Terms of Reference.

3. On 29 June 2023 the Inquiry received an application from the MHRA ("the Applicant") for Core Participant status in Module 4. This Notice sets out my determination of the application.

Application

4. Applications for Core Participant status are considered in accordance with Rule 5 of the Inquiry Rules 2006, which provides:

> *5.—(1) The chairman may designate a person as a core participant at any time during the course of the inquiry, provided that person consents to being so designated.*

(2) In deciding whether to designate a person as a core participant, the chairman must in particular consider whether—

(a) the person played, or may have played, a direct and significant role in relation to the matters to which the inquiry relates;
(b) the person has a significant interest in an important aspect of the matters to which the inquiry relates; or
(c) the person may be subject to explicit or significant criticism during the inquiry proceedings or in the report, or in any interim report.

(3) A person ceases to be a core participant on—
(a) the date specified by the chairman in writing; or
(b) the end of the inquiry.

5. In accordance with the approach set out in my Opening Statement and the Inquiry's Core Participant Protocol, I considered whether the application fulfils the requirements set out in Rule 5(2) in relation to the issues set out in the Provisional Outline of Scope for Module 4.

Summary of Application

6. The Applicant is the Medicines and Healthcare Products Regulatory Agency (MHRA), the UK's independent regulator of medicines (including vaccines and therapeutics), medical devices, and blood components for transfusion. The Applicant states that it is responsible for ensuring the safety, quality and efficacy of these things. The application explains that while the MHRA is an executive agency of the Department of Health and Social Care (DHSC), it is operationally independent of the DHSC and should, it contends, be a Core Participant in its own right.

7. The application is put on the basis that the MHRA meets the criteria in Rule 5(2)(a), (b) and (c). The Applicant states that it played a direct and significant role in relation to the matters to which Module 4 relates. It explains that it authorised the supply of eight Covid-19 vaccines, as well as four bivalent booster vaccines, in the UK. In terms of barriers to the uptake of vaccines, the application sets out that the MHRA's approval and post-market surveillance processes considered the evidence and specific data needs required for certain individuals, such as pregnant women, to be offered the vaccine. The Applicant explains that it is responsible for monitoring the safety of Covid-19 vaccines and operates the Yellow Card scheme, which collects and monitors

information on suspected safety concerns and is referenced in the provisional scope for Module 4. Further, the application sets out that the MHRA also reviewed trials of new and existing therapeutics, and approved or expanded the use of a number of therapeutics for the treatment of Covid-19.

8. The Applicant contends that, by virtue of its regulatory role, it has a significant interest in Module 4. This interest is said to arise in respect of both its involvement during the pandemic as well as assisting the Inquiry in learning lessons and preparing for any future pandemic. The Applicant notes that the Inquiry may make recommendations to the MHRA and it therefore wishes to contribute to the formulation of any such recommendations. The application also states that it may be subject to explicit or significant criticism during the Module 4 proceedings and sets out previous occasions when it has faced criticism in relation to the authorisation of Covid-19 vaccines, including in various inquests and during parliamentary debates.

Decision for the Applicant

9. I have considered with great care everything that is said in the application. Having done so, I have decided, in my discretion, to designate the MHRA as a Core Participant in Module 4.

10. Module 4 will consider 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. 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 public concern relating to vaccine safety and the current system for financial redress under the Vaccine Damage Payment Scheme.

11. I consider that the MHRA meets the criteria in Rule 5(2)(a) in that it played a direct and significant role in the matters to which Module 4 relates, in particular through its work authorising Covid-19 vaccines, monitoring the safety of those vaccines and approving therapeutics for the treatment of Covid-19. I also consider that the Applicant meets the

criteria in Rule 5(2)(b) as it has a significant interest in these important aspects of Module 4. I agree with the Applicant that it may be subject to explicit or significant criticism during Module 4 and therefore also satisfies the criteria in Rule 5(2)(c).

Legal Representation

12. Applications for designation as the Recognised Legal Representative of a Core Participant are governed by Rules 6 and 7 of the Inquiry Rules 2006, which provide:

> *6.—(1) Where—*
>
> *(a) a core participant, other than a core participant referred to in rule 7; or*
>
> *(b) any other person required or permitted to give evidence or produce documents during the course of the inquiry,*
>
> *has appointed a qualified lawyer to act on that person's behalf, the chairman must designate that lawyer as that person's recognised legal representative in respect of the inquiry proceedings.*
>
> *7.—(1) This rule applies where there are two or more core participants, each of whom seeks to be legally represented, and the chairman considers that—*
>
> *(a) their interests in the outcome of the inquiry are similar;*
>
> *(b) the facts they are likely to rely on in the course of the inquiry are similar; and*
>
> *(c) it is fair and proper for them to be jointly represented.*
>
> *(2) The chairman must direct that those core participants shall be represented by a single recognised legal representative, and the chairman may designate a qualified lawyer for that purpose.*
>
> *(3) Subject to paragraph (4), any designation must be agreed by the core participants in question.*
>
> *(4) If no agreement on a designation is forthcoming within a reasonable period, the chairman may designate an appropriate lawyer who, in his opinion, has sufficient knowledge and experience to act in this capacity.*

13. I am satisfied that the MHRA has appointed Ms Catherine Brydges of the Government Legal Department as its qualified lawyer in relation to this Module. I therefore designate Ms Brydges as the MHRA's recognised legal representative in accordance with Rule 6(1).

14. Directions will be given in relation to applications for an award under section 40(1)(b) of the Inquiries Act 2005 of expenses to be incurred in respect of legal

representation, at the forthcoming preliminary hearing. I will determine any such applications in accordance with the provisions of section 40 of the Inquiries Act 2005, the Inquiry Rules 2006, the Prime Minister's determination under section 40(4) and the Inquiry's Costs Protocol.

Rt Hon Baroness Heather Hallett DBE

Chair of the UK Covid-19 Inquiry

17 July 2023