

# NOTICE OF DETERMINATION CORE PARTICIPANT APPLICATION MODULE 4 - PERSEUS GROUP

## 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 <u>Provisional Outline of Scope</u> 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 30 June 2023 the Inquiry received an application from the Perseus Group ("the Applicant") for Core Participant status in Module 4.
- 4. I made a provisional decision not to designate the Perseus Group as a Core Participant in Module 4, thereby declining its application ("the Provisional Decision"), on 17 July 2023. The Applicant was provided with an opportunity to renew the application in writing by 4pm on 24 July 2023.

 On 24 July 2023, the Perseus Group submitted a renewed application for Core Participant status in Module 4. This notice sets out my determination of the application for Core Participant status in Module 4.

# **Application**

- 6. 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.
- 7. In accordance with the approach set out in my Opening Statement and the Inquiry's <a href="Core Participant Protocol">Core Participant Protocol</a>, I have 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**

8. In its original application, the Applicant described itself as a multidisciplinary team of experts from various fields, including medicine, pharmaceutical manufacture and regulation, and safety management in other safety critical sectors. The members of this group were not identified. The application was put on the basis that the Applicant satisfied the requirements of Rule 5(2)(b). Th application stated that the Applicant had identified serious failings in the work of the Medicines and Healthcare products

Regulatory Agency (MHRA), namely its licensing and post-marketing surveillance of the Covid-19 vaccines.

- 9. In its renewed application, the Applicant identifies its spokesperson and explains that he retired in 2017 as a Senior Civil Servant in the Ministry of Defence responsible for the safety of explosives. It is said that the spokesperson held personal letters of delegation for safety which came from the Secretary of State for Defence for licensing the explosives as 'safe for service use'. The Applicant suggests that this is analogous to the MHRA's role in respect of medicines. Other members of the group are described as "medical Consultants of various disciplines (e.g. Paediatrics, Pathology) and those with expertise in pharmaceutical supply chains and manufacture".
- 10. The renewed application sets out a number of alleged safety failings on the part of the MHRA and what are described as serious safety concerns about Covid-19 vaccines. It is said that, if made a Core Participant, the Applicant will be able to assist the Inquiry with expert scrutiny of documents disclosed to the Inquiry and advice about what other documents to request and what questions to ask of witnesses. The Applicant contends that it can also support the Inquiry in formulating and testing potential recommendations regarding medicine safety.

### **Decision for the Applicant**

- 11. I have considered with great care everything that is said in the Applicant's renewed application. I have also reminded myself of what was said in the original application to enable me to assess the merits of the application for Core Participant status as a whole. Having done so, in my discretion, I have decided not to grant the Applicant Core Participant status in Module 4.
- 12. I am grateful to the Applicant for taking care to set out more detail in its renewed application. As a group which has raised concerns around the safety of the Covid-19 vaccines, the Applicant can be said to have an interest in matters relevant to Module 4. However, this in itself does not amount to a significant interest for the purposes of Rule 5(2)(b). Even if that were not the case, in the exercise of my discretion, and having regard in particular to the need to manage the Inquiry effectively and efficiently, I would decline to designate the Applicant as a Core Participant in relation to Module 4.

I reiterate that I am determined to run the Inquiry as thoroughly and as efficiently as possible. It would not be practicable to grant Core Participant status to every individual or body with an interest in the safety regime applied to the Covid-19 vaccines.

- 13. I have taken into account the fact that there are a number of ways in which the Applicant can participate in Module 4 without being a Core Participant. It is not necessary for an individual or organisation to be a Core Participant in order to provide evidence to the Inquiry. The Applicant may have relevant information to give in relation to matters being examined in the Inquiry and I have asked the Module 4 legal team to liaise with the Applicant to make sure the concerns it raises are reflected in the Inquiry investigation.
- 14. The Applicant asks, if its renewed application is unsuccessful, how the Inquiry will receive the requisite expert level of challenge on matters of Covid-19 vaccine safety. I can reassure the Applicant that as part of Module 4 I expect to instruct an independent expert on vaccine safety issues. More generally, I have every confidence in the independent legal team whom I have appointed specifically for the purpose of pursuing all legitimate lines of inquiry with the investigatory and analytical rigour that a statutory inquiry of this scale and importance demands.
- 15. For all of these reasons, having considered all of the information provided by the Applicant, and in light of the Provisional Outline of Scope for Module 4, I consider that the Applicant does not have a significant interest in an important aspect of the matters to which Module 4 relates. Taking into account all relevant considerations, I have decided that the Applicant should not be designated as a Core Participant in Module 4 and I confirm that this is my final decision.
- 16. I will keep the scope of Module 4 under review. My decision not to designate the Applicant as a Core Participant in Module 4 does not preclude it from making any further applications in respect of later modules. I will consider any future applications the Applicant may wish to make on their merits at the time they are made.

Chair of the UK Covid-19 Inquiry
4 August 2023