

NOTICE OF DETERMINATION CORE PARTICIPANT APPLICATION MODULE 5 - SIMON MICO

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 24 October 2023 the Inquiry opened Module 5 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 17 November 2023.
- 2. The Provisional Outline of Scope for Module 5 provides that this module will consider and make recommendations regarding the procurement and distribution to end-users across the four nations of the United Kingdom of key healthcare related equipment and supplies, including PPE, ventilators and oxygen. Further modules will be announced and opened in due course, to address other aspects of the Inquiry's Terms of Reference.
- On 17 November 2023 the Inquiry received an application from Mr Simon Mico, the Managing Director of Bio-Diagnostics Limited, for Core Participant status in Module 5.
- 4. I made a provisional decision not to designate Mr Mico as a Core Participant in Module 5, thereby declining Mr Mico's application ("the Provisional Decision"), on 13 December 2023. Mr Mico was provided with an opportunity to renew the application in writing by 4pm on 21 December 2023.
- 5. On 20 December 2023, Mr Mico submitted a renewed application for Core Participant status in Module 5. This notice sets out my determination of Mr Mico's application for Core Participant status in Module 5.

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 <u>Core Participant Protocol</u>, 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 5.

Summary of Application

8. Mr Mico's original application was made on the basis of Rule 5(2)(a). Bio-Diagnostics Limited produces a diagnostic technology, the COVID-19 BioCard, which identifies an individual's level of immunity to Covid-19 and variants. The BioCard was registered with the MHRA in the summer of 2020. The Applicant states that they applied on two occasions, through the Government 'Gatekeeper' scheme, for these tests to be used to support the national pandemic response, however no devices were procured for use in the NHS. The Applicant believes that these applications were improperly handled. The Applicant submits that prior to vaccines becoming generally available in 2021, access to a technology which reliably identified who had acquired immunity

from asymptomatic exposure, could have had diverse and significant benefits. In particular, it could have enabled those with no immunity to be prioritised.

9. In his renewed application, Mr Mico makes the case that an accurate test for immunity such as the COVID-19 BioCard had the greatest potential to avert avoidable deaths. It asserts that the BioCard could have attained a CE mark from the MHRA sooner had its development received support from a government channel. The renewed application states that the 'Gatekeeper' scheme was set up to expedite the heavily regulated MHRA CE mark system, but it took years for the Gatekeeper system to validate the BioCard.

Decision for the Applicants

- 10. 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 his 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 consider that neither Mr Mico nor Biodiagnostics Limited played a sufficiently direct and/or significant role in relation to the procurement and distribution of key equipment and supplies during the pandemic. I again acknowledge that the renewed application raises important issues which may be addressed during the course of the work of Module 5. However, having regard to the provisions of Rule 5(2)(a) and (b) in particular, I have decided not to designate him as a Core Participant in Module 5.
- 11. I am determined to run the Inquiry as thoroughly and as efficiently as possible, bearing in mind the Inquiry's wide-ranging terms of reference and the need for the Inquiry process to be rigorous and fair. Given the vast numbers of people who were involved with, or adversely affected by, the Covid-19 pandemic, very many people in this country could potentially have an interest in it and not everyone can be granted Core Participant status for the purposes of the Inquiry hearings.
- 12. It is also not necessary for an individual or organisation to be a Core Participant in order to provide evidence to the Inquiry. Mr Mico may have relevant information to give in relation to matters being examined in the Inquiry, and the Inquiry will be contacting a range of individuals, organisations and bodies to seek information, to

gain their perspective on the issues raised in the modules and, where appropriate, to

ask for witness statements and documents.

13. The Inquiry will also listen to and consider carefully the experiences of those who

have suffered hardship or loss as a result of the pandemic, through the listening

exercise. I made clear in my Opening Statement that this listening exercise is a

significant and important task which will lead to summary reports of the impact of the

pandemic to be used as evidence during the Inquiry's module hearings. The Applicant

will have the opportunity to contribute to the Inquiry through the listening exercise if

he chooses.

14. For all of those reasons, having considered all of the information provided by Mr Mico

in light of the Provisional Outline of Scope for Module 5, I have therefore decided that

he should not be designated as a Core Participant in Module 5 and I confirm that this

is my final decision.

15. I will keep the scope of Module 5 under review. My decision not to designate Mr Mico

as a Core Participant in Module 5 does not preclude him from making any further

applications in respect of any later modules. I will consider any future applications Mr

Mico may wish to make on their merits at the time they are made.

Rt Hon Baroness Heather Hallett DBE

Chair of the UK Covid-19 Inquiry

12 January 2024