Witness Name: Dame June Munro Raine CBE
Statement No.: 3
Exhibits: JR/1 - 10
Dated: 20 December 2024

UK COVID-19 INQUIRY

MODULE 4

WITNESS STATEMENT OF DAME JUNE MUNRO RAINE CBE

I, **June Munro Raine**, will say as follows: -

1. I make this further statement in response to a Rule 9 request for a supplementary witness statement for Module 4 dated 10 December 2024, which seeks information regarding whether the Medicines and Healthcare products Regulatory Agency (referred to as the "MHRA" or "Agency"), has published, or plans to publish, a scientific paper in relation to the Yellow Card Vaccine Monitor.

2. As with my previous statement, this statement covers the period relevant to Module 4, i.e. between 30 January 2020 and 28 June 2022 as stated in the Rule 9 request, although I refer to certain events outside this period in order to answer the Inquiry's questions. Unless stated otherwise, matters in my statement will refer to England, Wales, Scotland and Northern Ireland as the MHRA is the regulator for the UK nations. In Northern Ireland, the competent authority for EU authorised products is the European Medicines Agency (EMA).

3. Also as with my previous statement, the preparation of this witness statement has required the involvement of specialists and officials within the MHRA and my legal advisers. This statement is to the best of my knowledge and belief accurate and complete at the time of signing. Notwithstanding this, the MHRA continues to prepare for its involvement in the Inquiry. As part of these preparations, it is possible that additional relevant material may be identified. In that eventuality the additional material will be provided to the Inquiry and a supplementary statement will be made if required.

Yellow Card Vaccine Monitor

4. I have discussed the nature and role of the Yellow Card scheme in vaccine signal detection and the Yellow Card Vaccine Monitor (YCVM) at paragraphs 342-353 and 375-377 of my Module 4 statement, respectively.

5. The YCVM was an extension of the traditional Yellow Card scheme (one of the four pillars of the MHRA's Covid-19 Vaccines Surveillance Strategy), which enabled individuals to register prior to vaccination to submit data pertaining to their Covid-19 vaccine such as any potential side effects they experienced. The YCVM enabled long-term follow up of individuals with or without reported suspected side-effects associated with their Covid-19 vaccine, particularly for those in a group which may have been excluded or under-represented in clinical trials, such as pregnant women. This involved regularly collecting data from these individuals over time to understand how the vaccine may affect them in the long term, supporting evaluation of its safety and effectiveness.

6. As I have discussed in paragraph 375 of my Module 4 statement, the purpose of the YCVM was to allow further characterisation of the Covid-19 vaccines' safety profiles. Its purpose was not to detect very rare risks, but to provide a further approach to evaluate the frequency and severity of side effects experienced by YCVM participants from groups that were under-represented in clinical trials.

7. Individuals were generally invited to register before receiving a Covid-19 vaccine, with the timing of invitations largely determined by the deployment of the vaccine programme to new groups of individuals. In addition to random invitations, all pregnant women were also encouraged to register with the YCVM in information provided to them when they were considering or having a Covid-19 vaccine [**JR/1 – INQ000000000**; **JR/2 – INQ000000000**].

Publication of YCVM data

8. In July 2021, the MHRA presented an interim review of the YCVM data to the Pharmacovigilance Expert Advisory Group of the Commission on Human Medicines (CHM) [**JR/3 – INQ00000000**].

9. In April 2022, the MHRA first discussed the publication of YCVM data. Subsequently the approach to publication of a paper on the methodology including its data was formalised in a paper on the surveillance strategy [**JR/4 – INQ000000000**]. This paper summarised

the activities conducted under the MHRA's Covid-19 vaccine surveillance strategy, the outcomes of that work and how to make these data more widely available. It also proposed taking forward scientific publications on the methodologies deployed within the surveillance strategy, to provide a scientific record and reference point for the regulatory and academic communities. In June 2022 this approach was endorsed by the CHM Covid-19 Vaccines Benefit Risk Expert Working Group (VBREWG) and subsequently by the CHM [**JR/5 – INQ000494365**; **JR/6 – INQ000494360**].

10. On 13 April 2023, the MHRA received a request under the Freedom of Information Act 2000 seeking publication of YCVM data pertaining to pregnant women, including responses to a number of questions regarding the data. As per the MHRA's response of 19 July 2023 to the request, we intended to publish the information as part of a wider publication on the Yellow Card Vaccine Monitor and the data collected through it, as was endorsed by the CHM [**JR/7 – INQ0000000000**].

11. The MHRA did not consider that the public interest was best served by releasing a subset of the YCVM data ahead of its formal publication in totality. This approach was supported by the CHM. The MHRA took this decision for the following reasons.

12. Firstly, publication in a peer-reviewed journal ensures independent rigorous review of the YCVM methodology. The Agency views this as important as the YCVM approach has not previously been a feature of safety monitoring within UK regulatory vigilance systems.

13. Secondly, publication of the YCVM data in a scientific journal allows the data collection and statistical methods applied to be described alongside the analyses so that the strengths and limitations of the approach are clearly set out and the results fully and correctly interpreted. Publication of raw data alone would not allow this. This is important as the interpretation of suspected adverse reaction reports following exposure to a vaccine in pregnancy needs careful consideration and simple summary data cannot, on their own, enable a conclusion to be reached on the observed safety profile.

14. For example, the risk of pregnancy loss in the normal population varies by both maternal age and gestational age, i.e. stage of pregnancy. Without a broader description of the cohort in terms of these characteristics alongside a clear description of how patients were recruited and how data were requested and submitted, the percentage of patients in the cohort who received a Covid-19 vaccine and who reported experiencing pregnancy loss is open to misinterpretation.

15. All reports of suspected side effects recorded through YCVM were immediately and automatically passed into the MHRA's enhanced signal detection processes for Covid-19 vaccines. This assured timely ongoing safety monitoring activities. In contrast, the compilation of data into a format suitable for publication, meeting data and format standards to ensure compliance with regulatory reporting obligations, is a complex undertaking which necessarily takes time.

16. On 6 November 2024, the MHRA submitted a full draft article on the YCVM to the journal 'Drug Safety' which has now sent this to independent reviewers as the first step of the normal peer-review process. On 12 November 2024, to enable access to the data and information while the process of peer review takes place, the MHRA published the draft paper on the YCVM on an online pre-print server [**JR/8 – INQ000000000**].

17. To summarise, the pre-print article detailed the analysis of data from 36,604 randomly selected individuals registered to the YCVM to seek further information on the vaccines received and adverse events they experienced. With regard to pregnancy and menstrual disorders, the data raised no safety concerns in pregnant and breastfeeding patients, and reporting of menstrual disorders appeared stimulated by media interest, as seen in spontaneous reporting systems. Overall, the data generated though YCVM are broadly reassuring and provided a complementary data source for monitoring the safety of Covid-19 vaccines.

18. The MHRA expects amendments to be made to the paper as part of the peer-review process though the underlying data and conclusions within the publication as summarised above will not change. Once available, a link to the final published version will be added to the pre-print version to ensure readers can see where changes have been made following review.

19. Despite the extensive information and careful analysis published in the pre-print article, the MHRA has noted that there has already been misinterpretation of the Agency's approach and of the YCVM data. This is evidenced by publications which misrepresent the MHRA's position on the data and risk exacerbating vaccine hesitancy not only in vulnerable groups but across the general population, with the attendant potential for harm to public health [**JR/9 – INQ000000000**; **JR/10 – INQ0000000000**].

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data

Dated: 20 December 2024