

**COMMISSION ON HUMAN MEDICINES (CHM)  
COVID-19 VACCINES BENEFIT RISK EXPERT WORKING GROUP**

Minutes of the meeting held on **Thursday 23<sup>rd</sup> June 2022** at **10:30** via videoconference

**Participants Present**

**Members**

Professor Sir M Pirmohamed (Chair)  
Professor G Dougan  
Mr VI G Fenton-May  
Ms S Hunneyball  
Professor K Hyrich  
Mr R Lowe  
Dr S Misbah  
Professor S Price  
Dr A Riordan  
Professor C Robertson<sup>1</sup>  
Professor K M G Taylor  
Dr R Thorpe  
Professor M Turner  
Professor S Walsh  
Mrs M Wang<sup>2</sup>  
Professor C Weir

**Apologies**

Professor J Breuer  
Professor N French  
Professor D Goldblatt  
Sir M Jacobs  
Professor H J Lachmann  
Professor P J Lehner  
Professor Y Perrie

**Invited Expert**

██████████<sup>3</sup>  
██████████<sup>4</sup>  
██████████<sup>5</sup>  
██████████<sup>4</sup>

**Observers<sup>6</sup>**

██████████  
██████████  
██████████  
██████████

**Secretariat**

██████████

**Professional Staff of MHRA Present**

**Principal Assessors**

██████████ - LD  
██████████ - VRMM

**Presenters supporting specific items**

██████████ - VRMM  
██████████ - LD  
██████████ - VRMM  
██████████ - VRMM  
██████████ - LD

**MHRA Observers**

██████████ - MHRA-Policy  
██████████ - VRMM  
██████████ - VRMM  
██████████ - LD  
██████████ - LD

**Government Legal**

██████████

████████████████████

5<sup>th</sup> May 2023

<sup>1</sup> joined during item 3  
<sup>2</sup> joined during item 2  
<sup>3</sup> participated for items 3 & 4  
<sup>4</sup> participated for item 2  
<sup>5</sup> participated for item 3 only  
<sup>6</sup> observed up until item 5

**Key**

LD = Licensing Division  
VRMM = Vigilance & Risk Management of Medicines

1. Introduction and Announcement

1.1 The Chair reminded Members, invited Experts and observers that the content of papers and proceeding of the meeting are strictly confidential and should be treated as ‘Official – sensitive commercial’ and should not be disclosed. There is no consent for members / participants to record the meeting, take screenshots or photographs of presentations. The meeting was recorded by the MHRA Secretariat for minute taking purposes only. The Chair & Members including all participants gave full consent to the recording prior to the start of the meeting.

1.2 Conflict of Interest Policy (Annex I to the minutes)

The Chair reminded members and participants that, in accordance with the CHM Code of Practice, they should declare any financial interests (personal or non-personal, specific or non-specific) which they have, or which an immediate family member has, in any of the agenda items. Members were also reminded to declare any other matter which could reasonably be perceived as affecting their impartiality.

1.3 Participants declared interests and other relevant interests for this meeting listed at **Annex II** to the minutes.

1.4 Apologies were received from Professors Breuer, French, Goldblatt, Lachmann, Lehner, Perrie, and Sir Michael Jacobs for this meeting.

1.5 The Chair welcomed the following invited experts to the meeting:

[Redacted]  
[Redacted] University of  
Cambridge; [Redacted]  
[Redacted]

[Redacted]  
[Redacted]  
[Redacted] University of Edinburgh

[Redacted]  
[Redacted] Bristol Heart Institute

[Redacted]  
[Redacted] St George’s University Hospitals NHS Foundation Trust

1.6 The Chair welcomed the following observers to the meeting:

[Redacted]  
[Redacted] Public Health Scotland

[Redacted]  
[Redacted] Public Health Wales



**3. New Fatal Report of myocarditis following Pfizer vaccination**

**3.1** The EWG was informed that, in June 2022, it had received a Yellow Card report from a consultant paediatric cardiologist concerning a previously well adolescent [REDACTED] who suffered a sudden out-of-hospital cardiac arrest [REDACTED] 5 days after receiving the second dose of the Pfizer-BioNTech COVID-19 vaccine. [REDACTED] suffered a hypoxic brain injury due to the cardiac arrest and later died in hospital.

**3.2** [REDACTED] acute myocarditis was one of several possible diagnoses being considered by the physicians involved, [REDACTED]

**3.3** All the available information was presented to the EWG. The EWG's advice was sought on the strength of the evidence for a possible causal relationship between the sudden death and COVID-19 vaccination and whether additional information was required.

**3.4** The EWG, including invited cardiology experts, noted that the post-mortem examination and histopathology results were awaited and would be critical to understanding the case. The recent COVID-19 diagnosis was considered to be potentially relevant. Results of the pending genetic testing were also considered to be very important. The EWG noted positive results for parvovirus and enterovirus in this case but commented that they may also be detected as bystander findings, so clinical infection history was important to collect, such as a history of diarrhoea, vomiting and fever. Overall, the EWG could make no definitive conclusion about causality given the lack of key data.

**4. Updated analysis of myocarditis/pericarditis with mRNA vaccines**

**4.1** The EWG was presented with an update on the Yellow Card reports of suspected myocarditis and pericarditis with AstraZeneca, Moderna and Pfizer COVID-19 vaccines up to 08 June 2022. The update to EWG also included new literature and international data which had become available since the last update on this topic on 6 May 2022.

**4.2** The EWG noted that reports of suspected myocarditis/pericarditis remain very rare with all three COVID-19 vaccines deployed in the UK, although as previously observed were more frequently reported with the mRNA vaccines. The EWG heard that reporting rates had stabilised, and the rates are similar between first and second doses with consistently lower rates seen after the third/booster dose. The EWG noted that the available data on long-term outcomes in the Yellow Card reports have not indicated any long-term consequences however long-term outcomes will remain under review.

The EWG agreed that overall, Yellow Card data findings for AstraZeneca COVID-19 vaccine remained very similar to those reported at the time of the previous EWG review.

**4.3** The EWG noted new international data from Israel and USA demonstrating a similar pattern of reporting of myo/pericarditis following mRNA COVID-19 vaccines as observed in the UK, including reduced rates of reporting after the third/booster dose compared with the primary vaccination series.

**4.4** The EWG also noted that new data in the literature reporting cardiac MRI findings in patients who developed myocarditis following administration of COVID-19 vaccine did not raise any new concerns regarding long-term outcomes in these patients.

NOT FOR PUBLICATION

4.5 The EWG were updated on new information regarding Novavax COVID-19 vaccine and myo/pericarditis. The EWG were informed that the signal was first raised in Australia and that pericarditis has now been added to the Australian Novavax COVID-19 product information as a possible adverse reaction. The EWG were also informed that the EU PRAC has started a review of myo/pericarditis and Novavax COVID-19 vaccine and that the US FDA has also identified myo/pericarditis as a potential risk. The EWG were informed that the MHRA has requested a review of myo/pericarditis and Novavax COVID-19 vaccine from the company and that this issue would be brought to the EWG for advice once the data are available.

4.6 The EWG concluded that the benefit/risk ratio of AstraZeneca, Pfizer and Moderna COVID-19 vaccines remained positive and that no regulatory action was required based on the data presented.

The EWG agreed that routine updates to the Group on myo/pericarditis following COVID-19 vaccination are no longer required and it would be more appropriate to present focused assessment of cases of interest or significant new data to the Group going forward.

5. Update on 4<sup>th</sup> Dose by [REDACTED]

5.1 [REDACTED] gave a short update on the 4<sup>th</sup> vaccine dose.

6. Vaxzevria – heterologous booster indication (GB national)

6.1 [REDACTED]

7. COVID-19 vaccine Janssen – Heterologous booster dose in individuals 18 years and older (EC reliance)

7.1 [REDACTED]

7.2 [REDACTED]

7.3

[Redacted]

8. Comirnaty - Heterologous booster dose in individuals 18 years and older (EC reliance)

8.1

[Redacted]

8.2

[Redacted]

8.3

[Redacted]

8.4

[Redacted]

8.5

[Redacted]

9. Minutes of the following meetings for review & approval

- Friday 03 December 2021
- Friday 10 December 2021
- Wednesday 19 January 2022
- Friday 04 March 2022
- Friday 18 March 2022
- Tuesday 29 March 2022
- Wednesday 13 April 2022
- Friday 06 May 2022

9.1 All the above minutes have been endorsed as a true and accurate record of the meetings.

10. **Any Other Business**

None.

11. **Date and time of next meeting**

The next meeting has been scheduled for **Monday 4<sup>th</sup> July 2022 at 11:30.**

The Meeting today started at 10:31 and ended at 12:18.

**Members are reminded that the content of papers and proceeding of the meetings are to be treated as 'Official – sensitive commercial'. Members are also reminded that, in accordance with the Code of Practice, they should declare any financial interests (personal or non-personal, specific or non-specific) which they have, or which an immediate family member has, in any of the agenda items. Members must also declare any other matter which could reasonably be perceived as affecting their impartiality. Detailed guidance is set out in the Code of Practice**

**Conflict of Interest Policy for CHM COVID-19 Vaccine Benefit Risk EWG**

**Chair and Members**

- May not hold current personal interests in one or more companies associated with the development of COVID-19 vaccines
- May not currently be or have previously been involved in the development of COVID-19 vaccines

Invited to all meetings, receives all papers and presentations and is permitted full participation in discussion, including drawing up conclusions and recommendations

**Invited experts**

- May hold current personal interests in one or more companies associated with the development of COVID-19 vaccines
- May currently be or have previously been involved in the development of COVID-19 vaccines

May be invited to all relevant meetings, receives all papers and presentations and is permitted to participate in discussions when invited by the Chair. Does not contribute to conclusions and recommendations

**Observers**

Are invited to attend all meetings. Will not participate in drawing up conclusions and recommendations.



Annex II

The following participants declared interests and other relevant interests at the meeting today:

**Professor Sir Munir Pirmohamed** - NPNS AstraZeneca - Research grant to UOL to support PhD in drug interactions.

Other relevant interests in Pfizer, Janssen, Sanofi – Sir Munir is part of an EU-funded IMI consortium on gene therapy, and these companies are partners in the project. The University of Liverpool will get funding from the EU (but not from the partners), this IMI project commences on 3<sup>rd</sup> November 2020.

AGILE – this is a Liverpool early phase trial platform (between University of Liverpool and Liverpool School of Tropical Medicine). It is funded by the Wellcome Trust and UKRI/DHSC/NIHR. It is NOT evaluating vaccines, but only drugs to treat COVID-19. Sir Munir is not on the trial management group, and he is not directly involved in choosing the compounds for the study. Sir Munir has no involvement with any of the developers of the compounds to be studied (academic or industrial).

Sir Munir is a member of the UK COVID Therapeutics Advisory Panel (UK-CTAP), which is advising the CMO on which compounds need to be prioritised for the RECOVERY+ trial (RECOVERY is funded via NIHR/DHSC).

**Ms Hunneyball** - Other relevant interest – writes articles published in the Chemist and Druggist magazine, a trade magazine for pharmacists, but receives no payment for these articles. The information referred to in the articles is in the public domain. Ms Hunneyball makes it clear that these are her personal views and reflections and references all sources of information used.

**Professor Hyrich** – NPNS - Professor Hyrich was co-I on an investigator-initiated research grant exploring predictors of outcome in rheumatoid arthritis. NPNS Pfizer- she is a Co-I on a grant exploring adherence to JAK inhibitors in rheumatoid arthritis. NPNS in Abbvie, Professor Hyrich gave some lectures at an education conference on effectiveness of treatment for rheumatoid arthritis.

**Dr Misbah** - NPNS - Holds honorary Senior Lectureship with University of Oxford & Oxford University Hospitals NHS Foundation Trust.

**Professor Price** - NPNS in GSK and AstraZeneca – which relates to donations provided by both companies to the British Toxicology Society (BTS) to support their Annual Congress and Education and Training of which Professor Price is currently President of the Society (2020-2022).

**Dr Riordan** - Other relevant interests - Participant in Oxford University's ChAdOx1 nCoV-19 clinical trial –received immunisation 27/8/2020. NPNS - Postgraduate External Examiner for Oxford University (Postgraduate Diploma in Paediatric Infectious Diseases). Member of the independent Data Safety Monitoring Board for COV-BOOST trial.

**Mrs Wang** - Other relevant interests arising from being highly sensitive to insect stings, and plant products such as Hyacinth bulbs, as recorded on Mrs Wang's medical records. The family of Mrs Wang lives with several rare diseases and conditions, some of which result in epileptic fits.

**Professor Weir** - NPNS - Imperial College and Other relevant interest arising from his department collaborates with Imperial College on a number of clinical trials.