

NOT FOR PUBLICATION

COMMISSION ON HUMAN MEDICINES (CHM)

COVID-19 VACCINE SAFETY EXPERT WORKING GROUP

Minutes of the meeting held on **Tuesday 27<sup>th</sup> October 2020** at **10:00** via Videoconference

**Participants Present**

**Members**

Dr S Misbah (Chair)  
Professor I J Douglas  
Professor S De Lusignan  
Dr R Payne  
Professor Sir M Pirmohamed  
Professor S Quenby  
Professor C Robertson  
Professor C Semple

**Apologies**

Professor J S Friedland  
Sir M Jacobs

**Invited Experts**

■ [REDACTED]  
■ [REDACTED]  
■ [REDACTED]  
Professor E Miller  
■ [REDACTED]  
Professor A Scott  
Ms J Walker

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

**Professional Staff of MHRA Present**

**Supporting Specific Items**

Dr P Bryan  
Dr K Donegan

**MHRA Observers**

Dr S Branch (VRMM)

[REDACTED]

**External Presenters**

Dr L Berry  
Dr M Davies  
Professor J Heap  
Dr I Mackenzie  
Professor S Maskell  
Professor T Macdonald  
Professor F Mair  
Dr E Rooke  
Professor S Shakir  
Dr A Thomas

**Visiting Expert**

Professor A Pollard

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
■ [REDACTED]  
■ [REDACTED]

*Agreed by the Committee and the Chair on 10/11/2020 meeting as a true and accurate record of proceedings.*

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**1. Introduction and Announcement**

- 1.1 The Chair reminded Members, Invited Experts, Visiting Expert and Observers that the papers and proceedings are confidential and should not be disclosed.

The Chair reminded participants to unmute themselves when they wish to speak.

**1.2 Conflict of Interest Policy**

In the pre-deployment phase, the intention is for the remit of the EWG to be non-product specific and focused on methodological/technical activity.

In the post-deployment surveillance phase, the activities will become product-specific (and subject to any relevant conflict of interest)

- 1.3 Apologies were received from members, Professor Friedland and Sir Michael Jacobs.

- 1.4 The Chair welcomed the following presenters:

**Professor Simon Maskell & Professor John Heap** from the University of Liverpool who presented item 4 - Using Social Media to Monitor the Safety of COVID-19 Vaccines

**Professor Tom MacDonald, Dr Evelien Rooke, Dr Isla Mackenzie** from MEMO Research, University of Dundee who presented item 5 - SARS-CoV-2 Vaccination For COVID-19 Disease Safety Study (VAC4COVID Study)

**Professor Saad Shakir, Dr Miranda Davies, Professor Frances Mair, Dr Louise Berry, Dr Alison Thomas** from the Drug Safety Research Unit who presented item 6 - The One Million Study [Registry] Consortium for monitoring the post-authorisation Safety of COVID-19 Vaccine(s) in the UK

The external presenters were admitted to the meeting only for their individual presentations and left after responding to questions.

**2. Minutes of the meeting held on Thursday 23<sup>rd</sup> July 2020**

- 2.1 The minutes were approved as a true and accurate record of the proceedings.

**3. Matters Arising**

- 3.1 None.

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**4. Presentation from Professor Simon Maskell and John Heap, University of Liverpool - Using Social Media to Monitor the Safety of COVID-19 Vaccines**

4.1 Professor Sir Munir Pirmohamed declared a specific non-personal interest in the presentation from University of Liverpool on use of social media for vaccine AE reporting. At the chair's discretion, Sir Munir was permitted to participate by answering specific questions from the chair, but not raise spontaneous comments or questions.

4.2 The group heard a presentation from Professor Simon Maskell on a planned study for monitoring the safety of COVID-19 vaccines.

4.3 Professor Maskell agreed to provide responses by email to a number of questions that had been raised in the meeting.

**5. Presentation from Professor Tom MacDonald, MEMO Research, University of Dundee - SARS-CoV-2 Vaccination For COVID-19 Disease Safety Study (VAC4COVID Study)**

5.1 Professor Chris Robertson declared a personal specific interest. He is involved in the MEMO consortium with Professor Tom Macdonald of Dundee. At the chair's discretion, Professor Robertson was permitted to participate by answering specific questions from the chair, but not raise spontaneous comments or questions.

5.2 The group heard a presentation from Professor Tom MacDonald on the planned VAC4COVID study.

**6. Presentation from Professor Saad Shakir, Drug Safety Research Unit - The One Million Study [Registry] Consortium for monitoring the post-authorisation Safety of COVID-19 Vaccine(s) in the UK**

6.1 The group heard a presentation from Professor Saad Shakir and Dr Miranda Davies on the planned registry study by The One Million Study Consortium.

**7. Summary**

7.1 The group thanked all the presenters for contributing to the meeting today. The presentations were valuable to the EWG in informing their advice to the MHRA regarding their strategy for monitoring the use and safety of COVID-19 vaccines.

7.2 The Group noted that the purpose of the presentations was not to advise on whether MHRA should participate or commission such research, but for their awareness in the context of the surveillance activities on which it was advising MHRA.

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- 7.3 The group noted that COVID-19 vaccine vigilance was becoming an increasingly busy landscape. They advised that there was a need to be prepared for the identification of safety signals arising from a range of sources and that a clear pathway should be laid out for further assessment and triggering hypothesis testing studies in the event that a safety signal was raised by any of the studies.
- 7.4 The potential for duplicate identification of adverse events following vaccination in multiple studies was raised by the group. They advised that attempts be made to identify duplicate reports and that this risk be considered when implementing signal detection and assessment processes.

8. **Any Other Business**

- 8.1 None.

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

**Wednesday 11<sup>th</sup> November 2020 at 10:00**

The Meeting started at 10:02 and ended at 12:13

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