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**COMMISSION ON HUMAN MEDICINES (CHM)**

**COVID-19 VACCINE SAFETY EXPERT WORKING GROUP**

Minutes of the meeting held on **Thursday 23rd July 2020** at **11:00** via Videoconference

**Participants Present**

**Members**

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

**Invited Experts**

[REDACTED]  
[REDACTED]

Ms H McDonald  
Professor E Miller  
Professor A Scott

[REDACTED]

Ms J Walker

**Visiting Expert**

Professor S McCormack  
Professor R Shattock

**Observers**

[REDACTED]

[REDACTED]

[REDACTED]

1 Professor L Smeeth

[REDACTED]

1 Joined at item 5

**Professional Staff of MHRA Present**

**Supporting Specific Items**

Dr K Donegan

**MHRA Observers**

Dr S Branch  
Dr P Bryan  
[REDACTED]  
Dr P Myles  
Dr S Ramroop  
Ms N Rose

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[REDACTED]  
[REDACTED]  
[REDACTED]

*Agreed by the Committee and the Chair at its 27/10/2020 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)

  
**2. Minutes of the meeting held on Thursday 25<sup>th</sup> June 2020**

- 2.1 The minutes were approved

**3. Matter Arising****4. Detailed proposal for near real time COVID-19 vaccine safety surveillance using the Clinical Practice Research Datalink**

- 4.1 The EWG considered a paper describing the proposed use of data from the Clinical Practice Research Datalink (CPRD) for near real time active COVID-19 vaccine safety surveillance. The paper described the approach of using sequential testing within the CPRD designed to rapidly detect any increases in risk for pre-identified adverse events of special interest for administration of a COVID-19 vaccine.

- 4.2 Overall, the EWG broadly supported the proposed approach.

- 4.3 The EWG highlighted the need to include the active monitoring of multisystem inflammatory syndrome which has been observed in adults as well as children with COVID-19. It was noted that work was ongoing on a case definition. The EWG discussed whether multisystem inflammatory syndrome would be recorded in primary care. They advised that rapid linkage to secondary care data would be required to fully evaluate any risk.

- 4.4 The EWG also recommended that projections be made about the volume and strength of the safety data that would be available at different time points following initial vaccine deployment as this information would be valuable in

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supporting recommendations for vaccine roll out to different prioritisation groups.

- 4.5 The EWG raised the need for careful pre-specification of the risk windows used for each adverse event of special interest and the need for sensitivity analyses. The EWG also supported the need to identify how hypothesis testing epidemiological studies could be rapidly and robustly conducted in the event a safety signal was raised.
- 4.6 The EWG agreed they would like to see more advanced plans for the proposed active surveillance approaches as they evolved.

5 **Presentation from Professor De Lusignan – RCGP Research and Surveillance Centre: Monitoring COVID-19 and vaccine safety**

- 5.1 The group heard a presentation from Professor Simon de Lusignan on the work and capabilities of the RCGP Research and Surveillance Centre with regards to monitoring seasonal flu vaccine safety and COVID-19.

6. **Any Other Business**

- 6.1 None.

6. **Date and time of future meetings (All meetings will start at 10:00)**

**Tuesday 27th October**  
**Wednesday 11th November**

The Meeting started at 11:01 and ended at 12:14

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