

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

Minutes of the meeting held on **Thursday 6<sup>th</sup> January 2022** at **12:30** via videoconference

**Participants Present**

**Members**

Professor Sir M Pirmohamed (Chair)  
Professor J Breuer  
Professor G Dougan  
Mr VI G Fenton-May  
Professor N French  
Professor D Goldblatt  
Ms S Hunneyball  
Professor K Hyrich  
Sir M Jacobs  
Professor H J Lachmann  
Professor P J Lehner  
Mr R Lowe  
Dr S Misbah  
Professor Y Perrie  
Professor S Price  
Dr A Riordan<sup>1</sup>  
Professor C Robertson<sup>1</sup>  
Professor T Solomon  
Professor K M G Taylor  
Dr R Thorpe  
Professor S Walsh  
Mrs M Wang

**Apologies**

Professor M Turner  
Professor C Weir

**Secretariats**

[REDACTED]  
[REDACTED]

**Lawyers**

[REDACTED]

**Professional Staff of MHRA Present**

**Principal Assessors**

Dr J Bonnerjea – LD  
[REDACTED] – VRMM

**Presenters supporting specific items<sup>2</sup>**

[REDACTED] - LD  
[REDACTED] - LD  
[REDACTED] - VRMM  
[REDACTED] - LD

**MHRA Observers**

[REDACTED] - VRMM  
[REDACTED] - VRMM  
[REDACTED] - LD  
Dr S Branch - VRMM  
[REDACTED] - LD  
[REDACTED] - MHRA-Policy  
[REDACTED] - LD  
[REDACTED] - VRMM  
Dr J Singh - LD  
[REDACTED] - VRMM  
Mr P Tregunno – VRMM  
[REDACTED] – LD  
[REDACTED] – LD  
[REDACTED] – Comms  
[REDACTED] – IE&S

[REDACTED]

13<sup>th</sup> April 2022

<sup>1</sup> joined during item 2

<sup>2</sup> supported specific items

**Key**

LD = Licensing Division

VRMM = Vigilance & Risk Management of Medicines

NIBSC = National Institute for Biological Standards & Control

Comms = MHRA Communications

IE&S = Inspection, Enforcement & Standards

**1. Introduction and Announcement**

**1.1** The Chair reminded Members 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 Turner & Weir for this meeting.

**2. Novavax COVID-19 vaccine: Nuvaxovid**

**2.1** The EWG heard the quality, non-clinical and clinical assessment of the rolling review of Nuvaxovid.

**2.2** The EWG heard that Nuvaxovid was approved by the EMA in December 2021. On quality, the EMA detailed 2 specific obligations and 46 recommendations. The 2 specific obligations were considered by the MHRA assessor to translate to Major Objections, which would under typical circumstances preclude authorisation. Similarly, it was suggested by the assessor that a number of specific recommendations (REC) might be better represented as Major Objections.

**2.3** The EWG discussed the non-clinical aspects, and based on the data currently provided, agreed that approval can be supported with the proviso that reports for ongoing studies (long term immunogenicity evaluations in baboons and rhesus monkeys, and a biodistribution study of the adjuvant in mice) are submitted in due course.

**2.4** The EWG was presented with a summary of the approved EU Risk Management Plan (RMP) for Novavax COVID-19 vaccine. The EWG noted that a UK addendum to the EU RMP was proposed by the MHRA in order to fully align this RMP with the MHRA core RMP guidance for COVID-19 vaccines.

**2.5** The EWG agreed that the EU RMP with the proposals for an UK addendum were acceptable. The EWG discussed that if Novavax COVID-19 vaccine was approved for use in the UK, it would be likely to be used as a booster dose and it would therefore be important to collect data on previous COVID-19 vaccine exposure and any history of COVID-19 infection in both the proposed post-authorisation studies and in spontaneous reports.

**NOT FOR PUBLICATION**

- 2.6** The EWG noted the imbalance of cerebrovascular accidents in the clinical trials and questioned whether cerebral venous sinus thrombosis could be excluded in these cases and advised close monitoring of this issue post-authorisation.
- 2.7** Given the issues raised in the quality assessment of this vaccine, the EWG highlighted the importance of being vigilant for any safety signals relating to quality inconsistencies and emphasised the importance of obtaining information on batch numbers in both the proposed studies and in Yellow Card reports.
- 2.8** The EWG commented that given the previous extensive deployment of other COVID-19 vaccines in the UK, US and Europe, deployment of Novavax COVID-19 was more likely in countries with limited pharmacovigilance capabilities, which may reduce the availability of robust post-marketing safety data for this vaccine.
- 2.9** The Chair highlighted that quality issues have been discussed at previous meetings of the EWG, however, there have been some changes to processes, as well as a change of manufacturing site that require the EWG to revisit the updated dossier.
- 2.10** The EWG acknowledged that the numerous issues related to quality, preclude authorisation at this stage of the rolling review and noted that company's response is expected by 20 January 2022. The EWG outlined that once assessment of the response is complete, or is nearing completion, Nuvaxovid should be brought to CHM. Commissioners in collaboration with the COVID-19 VBR EWG quality experts will then have an opportunity to consider if the responses address the major quality issues; those related to stability, purity, and consistency of the finished product.

**3. Any Other Business**

None.

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

The next meeting has been scheduled for **Thursday 13<sup>th</sup> January 2022 at 12:30.**

The Meeting today started at 12:35 and ended at 14:37.

**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).

**Professor Breuer**– NPNS – Professor Breuer is on the data safety monitoring committee, DSMB, a study looking at combining vaccines being run by Matthew Snape in Oxford. There does not appear to be any involvement of the vaccine manufacturers and is for already licensed vaccines. The study is funded by the NIHR (Dec 2020).

**Professor French** - Other relevant interest - Provides clinical care when in covering the acute medical wards where patients with COVID-19 are cared. NPNS in GSK - In September 2020 a sub-contract was signed with the Liverpool School of Tropical Medicine to undertake work evaluating the safety and effectiveness of GSK's RTS's malaria vaccine in Malawi. GSK are the primary funders to the LSTM.

**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.

**Sir Michael Jacobs** - Other relevant interest - As part of the academic role at the Liverpool School of Tropical Medicine, Sir Michael is a member of the Study Management Team and antiviral drug prioritisation group for the AGILE proof of concept (phase I/II) platform study. Sir Michael is also part of the team that submits new antiviral compounds against SARS-CoV2 for consideration by NIHR for testing on this platform. No commercial or financial interest in the trial or any of the compounds, or any pharmaceutical or biotechnology company.

**Professor Lachmann** – Other relevant interest as a volunteer participant in the Oxford vaccine study and no other involvement in the study.

## NOT FOR PUBLICATION

**Professor Lehner** - Other relevant interest – Professor Lehner previously held a DPAC (Discovery Partnership with Academia) agreement with GSK, but this has been completed. Professor Lehner's participation in his local hospital D and T governance committee deliberations would form the normal activity and professional responsibility in his post and does not interfere with the EWG considerations (Sept 2020).

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

**Professor Perrie** - NPNS in Pfizer & AstraZeneca arising from a contract for a grant (March 2018), which includes contributions from these companies to the University of Strathclyde, Janssen in writing a grant for a PhD (now funded), GSK – arising from an EU grant to University of Strathclyde (Jan 2019-Dec 2019).

**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.

**Professor Solomon** - Other relevant interests – Professor Solomon provides clinical care for patients with Covid-19; chaired the MRC/NIHR committee which awarded funding for development of the Oxford Vaccine.

**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.