

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

Minutes of the meeting held on **Friday 12th August 2022** at **09:00** via videoconference

Participants Present

Members

Professor Sir M Pirmohamed (Chair)
Mr VI G Fenton-May
Professor N French¹
Ms S Hunneyball
Professor K Hyrich²
Professor H J Lachmann
Mr R Lowe
Dr S Misbah
Professor Y Perrie
Professor S Price
Dr A Riordan¹
Professor C Robertson
Professor K M G Taylor
Dr R Thorpe
Professor S Walsh
Mrs M Wang
Professor C Weir

Apologies

Professor J Breuer
Professor G Dougan
Professor D Goldblatt
Professor P J Lehner
Professor M Turner

Observer

Professor W S Lim

Secretariat

[REDACTED]
[REDACTED]

Key

LD = Licensing Division
VRMM = Vigilance & Risk Management of Medicines
NIBSC = National Institute for Biological Standards & Control
MHRA CEO = Chief Executive

Professional Staff of MHRA Present

Principal Assessors

Dr J Bonnerjea - HQA
[REDACTED] - S&S

Presenters supporting specific items

[REDACTED] - HQA
Dr S Hopper - HQA
[REDACTED] - HQA
Dr N Rose - MHRA-NIBSC

MHRA Observers

[REDACTED] - HQA
[REDACTED] - S&S
[REDACTED] - HQA
[REDACTED] - HQA
[REDACTED] - MHRA-Policy
[REDACTED] - S&S
[REDACTED] - Policy
[REDACTED] - HQA
Dame June Raine - MHRA CEO
[REDACTED] - S&S
[REDACTED] - MHRA-NIBSC
[REDACTED] - HQA
[REDACTED] - HQA

[REDACTED]

18th November 2022

¹ joined during presentations of item 2

² left during discussions of item 2

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, Dougan, Goldblatt, Lehner and Turner for this meeting.

1.5 The Chair welcomed the following observer to the meeting:

Professor Wei Shen Lim
Chair of JCVI

1.6 The Chair informed members that **Professor Tom Solomon** stepped down from the group on 1st June [REDACTED] and **Sir Michael Jacobs** stepped down on 25th July [REDACTED]. The Chair implored these members for their valuable contributions to the work of this group in the protection of public health over the last 2 years and expressed his appreciation and best wishes.

2. National Line Extension Application
Spikevax bivalent Original / Omicron 0.10 mg/mL dispersion for injection
MODERNA BIOTECH SPAIN SL
PLGB 53720/0004 – 0001

2.1 The Expert Working Group (EWG) heard a presentation concerning the assessment of the quality aspects of the bivalent Original / Omicron vaccine, containing [REDACTED]. The proposed dose is [REDACTED], to be used as a booster.

2.2 [REDACTED]

2.3

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2.4

[REDACTED]

2.5

[REDACTED]

2.6

The EWG advised that the quality package was appropriate for granting the application, subject to the Company meeting the specific obligations and the post-approval commitments in accordance with the timelines listed. It was emphasised that the Company needs to meet these specific obligations within the given timelines in order to maintain public confidence in the vaccines; it was confirmed that these will be published on the MHRA website.

2.7

[Redacted text block]

2.8

[Redacted text block]

2.9

[Redacted text block]

2.10

[Redacted text block]

2.11

[Redacted text block]

[REDACTED]

2.12

[REDACTED]

Certification

2.13 The EWG heard a summary of the independent batch testing of over 20 batches of the bivalent vaccine submitted to the national control laboratory (NIBSC at MHRA). Laboratory data were presented to aid expert opinion on the outcome of ‘purity testing’ of the batches comparing two different approaches.

2.14 The EWG concluded that the test data accumulated for the batches being evaluated were sufficient to enable certification of priority batches from the company.

3. **Any Other Business**

3.1 None.

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

The next meeting has been scheduled for **Thursday 25th August 2022 at 11:30.**

The Meeting today started at 11:32 and ended at 13:57.

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 3rd 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 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.

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

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).

NOT FOR PUBLICATION

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; some of the COPS paper are based in the same institute as Professor Weir (Usher Institute, University of Edinburgh). Other relevant interest arising from his department collaborates with Imperial College on a number of clinical trials.

Observer

Professor Wei Shen Lim - NPNS – arises from the institution (Nottingham University Hospitals NHS Trust) where Professor Lim works has received unrestricted investigator-initiated research funding from Pfizer for an unrelated prospective population-based cohort study of pneumococcal pneumonia in which Professor Lim is the Chief Investigator.