

## **SUMMARY OF THE COMMISSION ON HUMAN MEDICINES MEETING HELD ON MONDAY 30 NOVEMBER 2020 AT 13:00 VIA VIDEOCONFERENCE**

### **PAPER**

The Commission met to discuss an application for a COVID-19 vaccine submitted under Regulation 174 of the Human Medicines Regulations 2012. Regulation 174 provides for the supply of a medicinal product on a temporary basis in response to a public health emergency which may cause harm to human beings. The spread of COVID-19 is considered to meet this criterion.

The Commission considered and discussed the range of measures to be implemented by Public Health England (PHE) in collaboration with other groups, including the MHRA, to further understand the impacts of vaccination, and to monitor COVID-19 disease in the community. The Commission noted that the measures included, but were not limited to: observed and expected rates of hospitalisation outcomes, follow-up of specific populations (includes data on pregnancy), an enhanced surveillance system to evaluate vaccine failures, genetic analyses for the identification of possible vaccine escape strains, registers for specific conditions if a signal is noted, and integration of data from epidemiological studies.

The Commission were assured by the procedures put in place to monitor the outcome of vaccination in relation to, for example, observed and expected rates of hospitalisation outcomes and follow-up of specific populations.

Following presentations from NHS England, NHS Wales, NHS Northern Ireland and NHS Scotland, the Commission considered and discussed the models and practicalities required for vaccine deployment.

The Commission heard up-to-date summaries on the non-clinical, clinical and quality data submitted in support of the application.

The Commission discussed aspects around the manufacture of the vaccine and considered whether the data provided were adequate to reassure the Commission that standards of quality of the vaccine could be maintained across its distribution, storage and administration. The Commission were reassured by the safeguards provided by independent quality testing at NIBSC.

The Commission discussed aspects around the nonclinical and clinical data submitted in support of the application. The Commission was satisfied that the data were sufficient to meet appropriate standards of efficacy and safety, with specific mitigations in place, although it was acknowledged in a less urgent situation additional long-term data would be welcome.

The specific mitigations include providing advice in the product information on the use of COVID-19 mRNA Vaccine BNT162b2 in women of childbearing age, pregnant women, lactating women, immunocompromised persons and those receiving immunosuppressant therapy. Precaution is also provided in relation to the use of COVID-19 mRNA Vaccine BNT162b2 in persons that have previously received another COVID-19 vaccine.

The Commission considered and discussed the risk management plan (RMP) and the range of post-authorisation measures to be implemented to support the temporary authorisation of COVID-19 mRNA Vaccine BNT162b2 in line with Regulation 174.

The Commission concluded that, based on the current data, the benefit /risk profile for the vaccine is positive and the measures put in place to maintain this balance are sufficient. Therefore, the Commission recommended a temporary authorisation of COVID-19 mRNA Vaccine BNT162b2 under Regulation 174, subject to certain conditions.

## **PROCEDURAL ITEMS**

In addition, the Commission completed its usual procedural business including the need to observe the confidentiality of the meeting, to declare interests, apologies, announcements and approval of minutes. Professor Ralston, Professor Friedland, Professor Gilson, Professor Lachmann, Professor Macleod, Dr Mann, Professor Meredith, Dr Misbah, Professor Sir Munir Pirmohamed, Professor Price, Professor Turner and Professor Weir declared interests in one or more agenda items and the appropriate action was taken.

- i. A list of Commissioners and invited experts who attended the meeting is at **Annex A**.
- ii. Medicines Healthcare products Regulatory Agency staff may be present for all or part of the meetings or for specific items.
- iii. The meeting started at 09:30 on Monday 30<sup>th</sup> November 2020 and finished at 13:25.

The next meeting will take place on Thursday 3<sup>rd</sup> December 2020 at 10:00 & Friday 4<sup>th</sup> December 2020 at 09:30.

## **USEFUL WEBSITE LINKS**

### ***Drug Safety Update:***

<https://www.gov.uk/drug-safety-update>

### ***Members' declaration of interests:***

<https://www.gov.uk/government/publications/human-medicines-regulations-2012-advisory-bodies-annual-report-2019>

### ***European Medicines Agency updates:***

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/landing/news\\_and\\_events.jsp&murl=menus/news\\_and\\_events/news\\_and\\_events.jsp&mid=WC0b01ac0580022519](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/landing/news_and_events.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac0580022519)

### ***MHRA Website:***

<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

### ***Yellow Card Website:***

<http://yellowcard.mhra.gov.uk/>

Information is being withheld, under Section 43 of the Freedom of Information Act 2000, on the grounds that information regarding the issue under consideration and advice from the CHM remains confidential at the date of this summary and will remain so until a final decision has been taken. Any request for future information should be made direct to the MHRA (via [info@mhra.gov.uk](mailto:info@mhra.gov.uk)) and will be considered in accordance with the FOI Act.

## ANNEX A

### MEMBERSHIP OF THE COMMISSION ON HUMAN MEDICINES

#### Chair

**Professor Stuart Ralston** MB ChB MD FRCP FMedSci FRSE FFPM (Hon)  
Professor of Rheumatology, University of Edinburgh, Western General Hospital, Edinburgh

#### Members

**Ms Susan Bradford**  
Lay Representative

**Professor Jamie Coleman** MD MA (Med Ed) FRCP FBPhS  
Professor in Medical Education / Consultant Clinical Pharmacologist, University of Birmingham

**Dr Jamie Fraser** BSc MB ChB MRCP  
GP Partner, Southside Surgery, Inverness

**Professor Jonathan S Friedland** MA PhD FRCP FRCPE FRCPI FESCMID FMedSci  
Deputy Principal, St. George's, University of London

**Professor Richard J C Gilson** MD FRCP  
Professor of Sexual Health & HIV Medicine, Director of the UCL Centre for Clinical Research in Infection & Sexual Health & Deputy Director of the UCL Institute for Global Health

**Professor Malcolm R Macleod** BSc MBChB MRCP PhD FRCP (Edin)  
Professor of Neurology and Translational Neurosciences, University of Edinburgh and Honorary Consultant Neurologist, NHS Forth Valley

**Dr Rebecca Mann** BMBS FRCPCH  
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

**Professor Sarah Meredith**  
Professor of Clinical Trials, MRC Clinical Trials Unit at UCL, Institute of Clinical Trials and Methodology, University College London

**Dr Siraj Misbah** MBBS (Hons) MSc FRCP FRCPPath  
Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals

**Professor Poulam Patel** MD, PhD, MBBS, FRCP - **Apologies**  
Professor of Clinical Oncology, Academic Unit of Clinical Oncology, University of Nottingham

**Professor Sir Munir Pirmohamed** MB ChB (Hons) PhD FRCP FRCP (Edin) FBPhS, FFPM (Hon) FMedSci  
David Weatherall Chair of Medicine, University of Liverpool, NHS Chair of Pharmacogenetics, Director of the Wolfson Centre for Personalised Medicine, Director of the MRC Centre for Drug Safety Science

**Professor Shirley Price** MSc PhD FBTS FRSB ERT FHEA FRSC MBPharmacol Soc  
Emerita Professor of Toxicology, University of Surrey  
Visiting Professor of Toxicology, University of Hertfordshire

**Professor Marc Turner** MBBS PhD MBA FRCP FRCPATH FHEA  
Professor of Cellular Therapy; Medical Director Scottish National Blood Transfusion Service (SNBTS)

**Professor Christopher Weir** BSc (Hons) PhD MSc FRSS C.Stat  
Personal Chair in Medical Statistics and Clinical Trials, Usher Institute, University of Edinburgh

**Dr Martin Wilson** MB ChB, MPhil (Glasgow), FRCP(Edin)  
Consultant Physician in Care of the Elderly, Raigmore Hospital, Inverness

#### **Invited Experts**

**Professor Kevin M G Taylor** BPharm PhD FRPharmS  
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

**Mrs Helen M Ward** MSc, BSc (Hons), Senior Fellow HEA, RGN, RCN Nurse Practitioner, PGCEA, PG Cert NMP, Queens Nurse, Advanced Nurse Practitioner

#### **National Health Service**

#### **Public Health England**