

## FOI 22/1188 - Pfizer/BioNTech COVID-19 vaccine authorised for use in infants and children aged 6 months to 4 years

### MHRA RESPONSE

23 January 2023 to request made 10 December 2022

Dear

Thank you for your email.

Please find below answers to the questions you have raised below.

**1/ On Dec. 6, 2022, MHRA [announced](#), "Pfizer/BioNTech COVID-19 vaccine authorised for use in infants and children aged 6 months to 4 years." Does the MHRA stand by this decision?**

Yes

**2/ This decision was apparently taken by the MHRA Executive Committee, comprising June Raine, Claire Harrison, Laura Squire, Marc Bailey, Alison Cave, and Glenn Wells. Is this correct?**

**3/ When was this decision taken? Did all the committee members vote for this decision? If not all, which members voted for the decision?**

After receiving an application for use of the Comirnaty vaccine in infants and children aged 6 months to 4 years, the MHRA sought the advice of the Commission on Human Medicines (CHM) and its COVID-19 Vaccine Benefit Risk Expert Working Group (VBR EWG). On 24 November 2022, the CHM considered the data supporting the application and advised following consideration of the safety, quality and efficacy data that the vaccine should be authorised in infants and children aged 6 months to 4 years. On the advice of the CHM, the MHRA recommended to the Minister of State that the vaccine should be authorised in infants and children aged 6 months to 4 years. The Minister of State made the licensing decision.

**4/ Where can the public watch a replay of the meeting at which this decision was taken?**

CHM do not make decisions on applications, they advise the Licensing Authority (MHRA) who then make the decision. This application was discussed at 24<sup>th</sup> November CHM meeting. Having considered all the available data, CHM advised MHRA that the benefit-risk was positive. MHRA then recommended the authorisation to Ministers, who then made the decision. CHM meetings are not routinely recorded, therefore there is no recording of the 24<sup>th</sup> November 2022 meeting.

**5/ Where are the meeting minutes available?**

Finally the minutes of the meeting are still in progress and we hope that they will be agreed at the January CHM meeting.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office  
Wycliffe House  
Water Lane  
Wilmslow  
Cheshire  
SK9 5AF

Yours sincerely

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