UK regulator approves use of Pfizer/BioNTech vaccine in 5 to 11-year olds

Press release

A new paediatric formulation of the Pfizer BioNTech COVID-19 vaccine has been approved for children aged 5 to 11 after meeting the required safety, quality and effectiveness standards.

A new age-appropriate formulation of the Pfizer BioNTech COVID-19 vaccine (Comirnaty) for use in children aged 5 to 11 years old has been approved today by the Medicines and Healthcare products Regulatory Agency (MHRA) after finding that it is safe and effective. This approval was given following a robust review of safety data that shows a positive benefit-risk profile for this vaccine to be used in this age group.

“Parents and carers can be reassured that no new vaccine for children would have been approved unless the expected standards of safety, quality and effectiveness have been met.

“We have concluded that the Pfizer/BioNTech COVID-19 vaccine is safe and effective for 5 to 11-year olds, with no new safety concerns identified. We have carefully considered all the available data and reached the decision that there is robust evidence to support a positive benefit risk for children in this age group.

“Our detailed review of all side-effect reports to date has found that the overwhelming majority relate to mild symptoms, such as a sore arm or a flu-like illness. We have in place a comprehensive safety surveillance strategy for monitoring the safety of all UK-approved COVID-19 vaccines and this includes children aged 5 to 11 years old.”

Today’s approval is for a formulation specially designed for 5-11 year olds and given at a lower dose compared to that used in individuals aged 12 and above (10 micrograms compared with 30 micrograms).

As with other age groups, it is given as two injections in the upper arm. It will be for the Joint Committee on Vaccination and Immunisation (JCVI) to make the final recommendation on the dosing interval.

In coming to this decision, the MHRA has liaised closely with other international regulators and public health bodies and carefully considered global data on use in 5-11-year olds. These data demonstrate a favourable safety profile compared with that seen in other age groups. Over 5.5 million dosages of the vaccine in 5-11s have now been administered in the US alone.

Notes to Editor

1. This new authorisation to the Conditional Marketing Authorisation (CMA) granted by the MHRA is valid in Great Britain only and was approved via the European Commission (EC) Decision Reliance Route. This is when the marketing authorisation application made by the company references the decision made by the EMA's Committee for Medicinal Products for Human Use (CHMP). The MHRA reviews this application, together with due consideration of the EC decision, before making an independent decision on the quality, safety, and effectiveness of the vaccine.
2. The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK. All work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
3. The Medicines and Healthcare products Regulatory Agency ('the agency') has three centres. The MHRA, the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The agency is an executive agency of the Department of Health and Social Care.
4. The Commission on Human Medicines (CHM) advises ministers and the MHRA on the safety, efficacy and quality of medicinal products. The CHM is an advisory non-departmental public body, sponsored by the Department of Health and Social Care.

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