News story

The MHRA concludes positive safety profile for Pfizer/BioNTech vaccine in 12- to 15-year-olds

This follows a rigorous review of the safety, quality and effectiveness of the vaccine in this age group.

From:

Medicines and Healthcare products Regulatory Agency (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)

Published

4 June 2021

An extension to the current UK approval of the Pfizer/BioNTech COVID-19 vaccine that allows its use in 12- to 15-year-olds has today been authorised by the Medicines and Healthcare products Regulatory Agency (MHRA). This follows a rigorous review of the safety, quality and effectiveness of the vaccine in this age group by the MHRA and the Government's independent advisory body, the Commission on Human Medicines (https://www.gov.uk/government/organisations/commission-on-human-medicines) (CHM).

Dr June Raine, MHRA Chief Executive said:

"We have carefully reviewed clinical trial data in children aged 12 to 15 years and have concluded that the Pfizer/BioNTech COVID-19 vaccine is safe and effective in this age group and that the benefits of this vaccine outweigh any risk.

"We have in place a comprehensive safety surveillance strategy for monitoring the safety of all UK-approved COVID-19 vaccines and this surveillance will include the 12- to 15-year age group.

"No extension to an authorisation would be approved unless the expected standards of safety, quality and effectiveness have been met.

“It will now be for the Joint Committee on Vaccination and Immunisation (JCVI) to advise on whether this age group will be vaccinated as part of the deployment programme.”

Professor Sir Munir Pirmohamed, Chair of the Commission on Human Medicines said:

“We have been very careful to take into consideration the younger age group and the benefits of this population being vaccinated against any potential risk of side effects. There has been a thorough assessment and review of this data which was also looked at specifically by the CHM’s Paediatric Medicines Expert Advisory Group who are scientific experts within this age group, as well as the CHM’s COVID-19 Vaccines Benefit Risk Expert Working Group.

“We have concluded that based on the data we have seen on the quality, effectiveness and safety of the vaccine, its benefits do outweigh any risk. The MHRA will continue to scrutinise all of the suspected side effects data received through the rigorous surveillance programme in place through the Yellow Card scheme (https://coronavirus-yellowcard.mhra.gov.uk/) and other safety surveillance measures for all of the COVID-19 vaccines used in the UK.

“Over 2000 children aged 12-15 years were studied as part of the randomised, placebo-controlled clinical trials. There were no cases of COVID-19 from 7 days after the second dose in the vaccinated group, compared with 16 cases in the placebo group. In addition, data on neutralising antibodies showed the vaccine working at the same level as seen in adults aged 16-25 years. These are extremely positive results.”

Background

- The Pfizer/BioNTech COVID-19 vaccine is already approved for use in adults and adolescents aged 16 years and above (https://www.gov.uk/government/news/uk-medicines-regulator-gives-approval-for-first-uk-covid-19-vaccine).
- No new side effects were identified and the safety data in children was comparable with that seen in young adults. As in young adults, the majority of adverse events were mild to moderate and relating to reactogenicity, such as a sore arm or tiredness.
- More information can be found in the Product Information for the Pfizer/BioNTech vaccine (https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19).
- The Medicines and Healthcare products Regulatory Agency (https://www.gov.uk/government/organisations/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.
- The Medicines and Healthcare products Regulatory Agency (‘the agency’) has three centres. The MHRA, the National Institute for Biological Standards and Control (NIBSC) (https://www.nibsc.org/) and the Clinical Practice Research Datalink (CPRD) (https://www.cprd.com/). The agency is an executive agency of the Department of Health and Social Care.
- The Commission on Human Medicines (CHM) (https://www.gov.uk/government/organisations/commission-on-human-medicines) 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 (https://www.gov.uk/government/organisations/department-of-health-and-social-care).

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Published 4 June 2021

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