Medicines & Healthcare products Regulatory Agency

MHRA

Dr Rosamond Jones
By Email: [redacted]

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Medicines & Healthcare products Regulatory Agency

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Dear Dr Jones,

Use of COVID-19 vaccines in children and young people

Thank you for your email of 6th June 2021 concerning the safety and ethical concerns surrounding COVID-19 vaccination in children.

The recent extension of indication for the Pfizer/BioNTech COVID-19 Vaccine has been limited to adolescents in the 12-15 year age group. The safety data of the vaccine in this age group has been carefully considered by the MHRA, the independent advisory body, the Commission on Human Medicines (CHM) and two of its own advisory groups: the COVID-19 Vaccine Benefit / Risk Expert Working Group and the Paediatric Expert Advisory Group. All these expert groups reviewed the safety data and recommended that the age range for the vaccine can be extended to the 12-15 year olds. These data include the adverse events reported in the clinical trials and the real-world evidence currently available from the significant use of the vaccine in the 16+ age group. The opinion of the CHM and the independent experts was that the benefit / risk ratio for the 12-15 year olds was similar to that of the 16- 24 years olds.

As with any clinical trial, limited numbers of subjects take part, but in this case other countries have been vaccinating the 12-15 year age cohort and the safety data are shared with international regulatory bodies. Overall information from the clinical trial and from countries where over half a million doses of the vaccine have been administered to young adolescents shows that the vaccine has a positive benefit-risk ratio in this age group. However, we will be monitoring very closely all available data emerging from the global use of COVID-19 vaccines in children including the potential risk of myocarditis/ pericarditis. This will include the use of the Moderna COVID-19 vaccine which has also been recently approved for use in children aged 12 and above.

Regarding your question on how we can ensure that the placebo group in the adolescent trial do not receive the vaccine thus nullifying the long-term follow-up, the trial was performed in the US and is not under our regulatory jurisdiction. However, if trial subjects are unblinded and offered the vaccine, we expect that they will still be followed up for two years post vaccination.

You will no doubt be aware of the announcement from the JCVI on 4th August. In this announcement the JCVI have advised that all 16 and 17 year olds receive their first dose of the Pfizer-BioNTech vaccine. As previously advised by the JCVI, children aged 12 to 15 with specific underlying health conditions that

put them at risk of severe COVID-19 should be offered 2 doses of Pfizer-BioNTech vaccination with an interval of 8 weeks between doses. Children and young people aged 12 years and over who are household contacts of an immunosuppressed person should also be offered 2 doses of the Pfizer-BioNTech vaccine. The associated press release for this announcement can be viewed here: https://www.gov.uk/government/news/jcvi-issues-updated-advice-on-covid-19-vaccination-of-young-people-aged-16-to-17

You state that healthy children are not dying of COVID-19 in the UK, which may be the case but that is not to say that some adolescents do not have serious health problems after COVID-19. In addition, adolescents with underlying health conditions that put them at a potentially higher risk from COVID-19 need to be considered and this was the basis of the JCVI advice mentioned above.

Regarding your questions on the animal studies performed with the Pfizer/BioNTech vaccine, we are aware of the data you submitted. The animal studies have been described in the Public Assessment Reports from the MHRA and other regulatory authorities and these documents will be updated in due course to include further information on the review of the benefits and risks of vaccinating adolescents.

You also asked about compensation for any vaccine-related injury or death. Information on the Vaccine Damage Payment Scheme, which is outside the MHRA's remit, can be found at the following link: https://www.gov.uk/vaccine-damage-payment.

Yours sincerely

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