



Ms Liz Evans
By Email: UKMedicalFreedom@protonmail.com

Reference: CEO 18912, CSC 53270

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**Medicines & Healthcare products
Regulatory Agency**

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Dear Ms Evans,

Use of COVID-19 vaccines in children and young people

Thank you for your email of 7th June 2021 concerning the safety and ethical concerns surrounding COVID-19 vaccination in children.

The safety data of the Pfizer/BioNTech COVID-19 Vaccine in the 12-15 year age group have 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 its expert, independent advisors 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.

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.

Together with other regulatory bodies, we have published 'Public Assessment Reports' describing the data submitted by the company and the reasons for our regulatory actions, please see:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/944544/COVID-19_mRNA_Vaccine_BNT162b2_UKPAR_PFIZER_BIONTECH_15Dec2020.pdf

This document has been updated to include information on the clinical trials involving 12 – 15 year olds.

Yours sincerely

A handwritten signature in blue ink that reads "June M. Raine".

Dr June Raine CBE
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