FOI 22/1225 Risk benefit analysis Covid-19 vaccines

REQUEST
23 December 2023

can you please provide the risk assessments the MHRA completes(ed) in order to approve a vaccine (for example the covid vaccines) for emergency approval and subsequent full safety approval along with the risk : benefit trade-offs for those who receive these vaccines, moreover the risk : benefit for perfectly healthy people and children. Additionally, what specific conditions / requirements does the MHRA need to consider to declare a pharmaceutical product, I.e. vaccine, safe for emergency use?

Furthermore, as the post pandemic research has been released and proves beyond any question that perfectly healthy people, especially healthy children, did not and do not need any covid vaccine in order to fight off the disease; can you supply the information which identifies, with the assessment and evaluations you completed, that these vaccines should be given to the above groups of people, which is the majority in all countries.

MHRA RESPONSE
20 January 2023

Dear

Thank you for your information request, dated 23 December 2022.

We are pleased to provide you with the information requested, see below.

The risk/benefit analysis is available in the Public Assessment Reports (PARs) for each vaccine that are available on the MHRA and EMA websites. It should be noted that none of the vaccines were authorised for “emergency use.” The authorisation of the vaccines under Regulation 174 permitted the supply of identified vaccine batches, based on the safety, quality and efficacy data submitted to MHRA. The assessment of the reproductive toxicity of each vaccine is available in Sections 4.6 and 5.3 of the SmPC for that vaccine.

The Public Assessment Reports (PARs) published by MHRA and the EMA provide assessment of the data submitted from clinical trials, including the demographics of the subjects in the clinical studies (such as age). The vaccines have been shown to be safe and efficacious in the populations where each vaccine has been authorised for use.

Public Assessment Reports [PARs] for each vaccine) are available on the MHRA website. Links to these are provided below:
https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna

The MHRA put a comprehensive surveillance strategy in place for monitoring the safety of the COVID-19 vaccines during the national roll out. You will find details of our ongoing safety assessment here:

https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email.

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

MHRA Customer Service Centre

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU