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21 January 2022

Dear Enquirer,

FOI 21/1339

Thank you for your FOI request dated 20 December 2021, where you requested the following information:

- 1. All studies conducted or undertaken by MHRA or one of its offices comparing health outcomes between vaccinated and unvaccinated children and adolescents (under 18 years of age).
- 2. All studies conducted or undertaken by MHRA or one of its offices comparing health outcomes between vaccinated and unvaccinated adults (over 18 years of age).

The MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance processes including the Yellow Card Scheme. As part of our signal detection processes all adverse reaction reports received by the Yellow Card Scheme are individually assessed and cumulative information reviewed at regular intervals. We also work closely with our public health partners in reviewing the effectiveness and impact of the vaccines to ensure the benefits continue to outweigh any possible side effects.

The MHRA does not hold data on unvaccinated children and adolescents. The studies the MHRA has conducted to evaluate associations with safety concerns are in the public domain:

A study investigating HPV vaccines and the risk of fatigue syndromes in the UK: https://pubmed.ncbi.nlm.nih.gov/24001935/

A study evaluating the safety of the meningitis B vaccine in the UK: https://pubmed.ncbi.nlm.nih.gov/30169281/

You may also wish to contact the UK Health Security Agency on this matter.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,





FOI Team,

Vigilance and Risk Management of Medicines Division

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If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF

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