FOI 23/039

27th January 2023

Dear

Thank you for your information request dated 19th January 2023, where you asked the following information:

"Would you be able to provide the list of all epidemiological studies (for example the ones using CPRD and/or OpenSAFELY as data sources, or any other systems available) done on adverse reactions of vaccines, specially HPV vaccines and Covid-19 vaccines ?"

Regarding studies CPRD using CPRD data:

 This information is exempt under Section 21 of the FOIA - Information accessible by other means. The information you have requested is already published on the CPRD website, as CPRD publishes a summary of studies using CPRD data on its website -<u>Approved studies using CPRD Data | CPRD</u>. Peer-reviewed publications from research using CPRD data are listed on the <u>bibliography page</u>.

Regarding studies conducted by MHRA including in collaboration with others:

- Bell's palsy and parenteral inactivated influenza vaccine. Stowe et al. Hum Vaccin. 2006 May-Jun;2(3):110-2.
- Investigation of the temporal association of Guillain-Barre syndrome with influenza vaccine and influenzalike illness using the United Kingdom General Practice Research Database. Stowe et al. Am J Epidemiol. 2009 Feb 1;169(3):382-8.
- Post-licensure comparison of the safety profile of diphtheria/tetanus/whole cell pertussis/haemophilus influenza type b vaccine and a 5-in-1 diphtheria/tetanus/acellular pertussis/haemophilus influenza type b/polio vaccine in the United Kingdom. Andrews et al. Vaccine. 2010 Oct 18;28(44):7215-20.
- Risk of convulsions in children after monovalent H1N1 (2009) and trivalent influenza vaccines: a database study. Stowe et al. Vaccine. 2011 Nov 28;29(51):9467-72.
- Bivalent human papillomavirus vaccine and the risk of fatigue syndromes in girls in the UK. Donegan et al. Vaccine. 2013 Oct 9;31(43):4961-7.
- Safety of pertussis vaccination in pregnant women in UK: observational study. Donegan et al. BMJ. 2014 Jul 11;349:g4219.
- Risk of Narcolepsy after AS03 Adjuvanted Pandemic A/H1N1 2009 Influenza Vaccine in Adults: A Case-Coverage Study in England. Stowe et al. Sleep. 2016 May 1;39(5):1051-7.
- Safety of multicomponent meningococcal group B vaccine (4CMenB) in routine infant immunisation in the UK: a prospective surveillance study. Bryan et al. Lancet Child Adolesc Health. 2018 Jun;2(6):395-403.
- COVID-19 vaccination and Guillain-Barré syndrome: analyses using the National Immunoglobulin Database. Keh et al. Brain. 2022 Feb 18;awac067.
- Safety of COVID-19 vaccination and acute neurological events: A self-controlled case series in England using the OpenSAFELY platform. Walker et al. Vaccine. 2022 Jul 30;40(32):4479-4487.

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 you receive this response and addressed to: <u>info@mhra.gov.uk</u>

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