Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

11th July 2023

Dear [redacted]

FOI 23/111

Thank you for your email dated 9th February 2023, where you requested information held by the MHRA relating to the CPRD study "Meningococcal B vaccine: incidence of convulsion following vaccination and compliance with timing of vaccine doses in the UK". Apologies for the delay in responding to you on this request.

Specifically you asked:

Would you be able to provide all records related to this project, including:

All versions of the protocol
All reports / preliminary reports /manuscript
All numerical / statistical tables
All correspondences (including emails) associated to those tables, reports or any safety issue discussed in the study.

The results of this study have been published as part of a wider peer reviewed journal article on the safety of the Meningococcal B vaccine in the UK. The protocol including annexes and a copy of this manuscript/paper have been provided to you alongside this letter. All numerical / statistical tables produced are included in the manuscript.

The time required to search for all correspondences (including emails) associated to those tables and reports would be in excess of 24 hours, therefore provision of this information is exempt under Section 12 of the FOI Act. Section 12 of the Act allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information.

Yours sincerely,

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

FOI Team,
Safety and Surveillance Group

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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, 4-T, 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
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Cheshire
SK9 5AF