Medicines & Healthcare products
Regulatory Agency

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gov.uk/mhra

[redacted]

13 February 2024

FOI 24/052

Dear [redacted]

Thank you for your information request, dated 16 January 2024, where you asked the following:

Your request

"Please can you provide all the safety data for each vaccine and any trials that took place to prove they are safe. Can you also provide the breakdown of exactly what's inside each vaccine."

Our response

Unfortunately, MHRA estimate that compliance with this request would exceed the appropriate limit under Section 12 of the Freedom of Information (FOI) Act 2000, which is set at 24 working hours per request. Public authorities are not obliged to work past the appropriate limit under Section 12(1) of the FOI Act 2000 and we are, therefore, refusing your request.

The request, as worded, covers an enormous scope of data, documents and information held by different groups and teams of the Agency. More than 10 different vaccines are used in the UK childhood immunisation schedule and there are a great deal of pre- and post-authorisation safety reports and studies for each one. Because of the extent of the information, held in multiple places, retrieval of all relevant information would take in excess of 24 hours.

We have examined the case folder for one vaccine, Rotarix (PLGB 19494/0256). It took one hour to open the zip file on our data storage system and deduce that there are over 100 sub-folders of data (each containing numerous PDF files) within module

5 (the clinical data module). To extract and compile of all this clinical information would itself exceed 24 working hours for 1 vaccine alone. The same process would then have to be followed for the non-clinical data. There are more than 10 vaccines in the childhood schedule. This would, therefore, be an extremely time-consuming task. We should also note that, in addition to the data held by our Healthcare Quality and Access (HQA) team, we would then need to retrieve further relevant information held by other teams and Groups within the MHRA.

Much of the information you requested, including vaccine ingredients, is available in the public domain in the product information for each of the vaccines (see below).

Advice and Assistance

The MHRA and European Medicines Agency (EMA) publish Public Assessment Reports (PARs) which contain the assessment of the quality, safety and efficacy data that was submitted with the application for each of the vaccines.

The current UK immunisation schedule can be found here:

Complete routine immunisation schedule - GOV.UK (www.gov.uk)

Links to the sites where you can search for UK or European PARs can be found below.

Medicines | European Medicines Agency (europa.eu)

MHRA Products | Home

Please search for the vaccine brand name, which can be found within the links that were provided in your request, for example the Rotavirus vaccine is called Rotarix.

The Summary of Product Characteristics and Patient Information Leaflets contain information on the safety and efficacy of the vaccines and contain a list of the vaccine ingredients. These can also be found at the above MHRA Products link.

The Green Book, which is published by the UK Health Security Agency is another useful resource. It contains very detailed information on the principles, practices and procedures of vaccination (part 1) and on the particular diseases, vaccinations and the vaccines themselves (Part 2). Please refer to the link below:

Immunisation against infectious disease - GOV.UK (www.gov.uk)

Another useful source of independent information on the safety of vaccines is the Vaccine Knowledge Project:

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Home | Vaccine Knowledge Project (ox.ac.uk)

Please be assured that 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 assessed and cumulative information reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

We hope that the information provided above gives you a satisfactory answer to your request for information about vaccine safety. If you would like more information, you may submit a refined request, for example, for a particular study report for a named clinical study or a Clinical Overview submitted for a particular product.

We now consider this request closed. If you do submit a refined request, this will be a new request and the 20 working days statutory time limit will begin from the date your refined request is received.

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: info@mhra.gov.uk

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

Or online via: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/"

Yours sincerely,

FOI Team