Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

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

www.gov.uk/mhra

12 October 2023

Dear [redacted]

FOI 22/552

Thank you for your email of 15 March 2022, where you requested:

"Documents and any correspondence held by yourselves or originated by yourselves relating to the safety, quality and effectiveness of Covid-19 vaccines in the 5-11 year old age group, and any analyses of, or information pertaining to risks and harms."

We have been reviewing our records and we have identified that we do not have a record of responding to your request. Please accept our sincere apologies for the long delay in responding to you.

However, on review of your request we have considered it to be exempt under Section 12 of the Freedom of information 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.

In the UK, the only vaccines authorised for use in 5-11 year olds are the mRNA vaccines, COVID-19 vaccine Pfizer/BioNTech (Comirnaty) and COVID-19 vaccine Moderna (Spikevax). Therefore the scope of your request concerns:

- The quality, safety and efficacy information submitted by the respective company to support the application for a GB marketing authorisation for the vaccines.
- The MHRA's assessments of the aforementioned information
- Minutes from any meeting of the Commission on Human Medicines or its Expert Working Group on COVID-19 vaccine Benefit-Risk
- Any post authorisation safety data or assessments concerning COVID-19 vaccines use the 5-11 year age group. This may include Yellow Card data, recorded discussions at MHRA signal detection meetings and assessment reports including data concerning this age group.
- Any internal emails concerning safety of COVID-19 vaccines in 5-11 year olds.

This information is held in several different repositories within MHRA which would require separate searches to identify documents of potential interest, followed by review of retrieved documents to determine whether they contain relevant information.

Based on the breadth of information requested, identification of all information that may be relevant to your request would involve the use of a Discovery Search Tool. Based on experience in using this tool to perform Agency-wide searches for documents, the time taken to set up and refine the search criteria then extract and review the results to identify relevant records would take in excess of 24 hours.

In accordance with Section 16 of the FOI, concerning the provision of advice and assistance to those requesting information under FOI, you are advised to narrow the scope of your request, for example, to one vaccine and a specific type of information, subset of data or safety topic. However please note that other exemptions may affect release of the requested data.

We hope you find this helpful, and once again, we apologise for the delay in responding.

Yours sincerely,

FOI Team,

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
Water Lane
Wilmslow
Cheshire
SK9 5AF

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