Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA Central Freedom of Information Team
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MHRA Website

Our Ref: **FOI2024/00641**

14 November 2024

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 19 October. You wrote:

> *"I appreciate your response on 23 August 2024 regarding the use of Repevax during pregnancy. However, I would like to address several critical concerns that raise significant ethical and medical questions about my vaccination experience.*
>
> *First and foremost, the lack of post-vaccination follow-up is troubling. The post-marketing surveillance data suggests that vaccinations should be monitored for side effects for at least 14 days following administration. Unfortunately, I did not receive any follow-up communication regarding potential side effects associated with Repevax. This oversight undermines patient safety and raises concerns about the monitoring processes in place.*
>
> *Additionally, throughout this process, I have only been presented with clinical trial data for Adacel and not for Repevax. I still would like to see this information regarding the clinical trials. Given that Repevax was the vaccine administered to me, this lack of transparency regarding its clinical trials is particularly concerning. Without access to relevant clinical data, I feel my ability to provide informed consent was compromised.*
>
> *Moreover, I would like to highlight the type of vaccine that was administered. Current guidelines recommend Tdap vaccines for pregnant women; however, I received a DTaP vaccine at 39 weeks. This discrepancy raises questions about adherence to established guidelines and whether the appropriate vaccine was provided in my case.*
>
> *Informed consent is a fundamental ethical requirement in medical practice. At no point during my vaccination process was I informed that I was part of a specific vaccination program or study. This lack of communication regarding my participation in such a program is deeply concerning and suggests that my rights as a patient were not adequately respected.*
>
> *Furthermore, the absence of available data regarding fertility tests and breastfeeding safety is alarming. As a patient, I should have been informed of any potential risks that could affect both my health and the well-being of my infant. The lack of clarity in this area is unacceptable, particularly given the potential implications for maternal and infant health.*

The Summary of Product Characteristics (SPC) clearly states that a doctor should assist in determining whether a pregnant woman should receive Repevax. However, I feel that adequate guidance was not provided in my situation, and my specific circumstances were not carefully evaluated prior to vaccination.

Additionally, I am concerned about the ongoing monitoring for potential links between Repevax and conditions such as chorioamnionitis and facial paraylis. The absence of established evidence for a causal relationship is alarming, and I question how many instances need to be documented before a connection is acknowledged."

Finally, the combination of inadequate follow-up, lack of transparency regarding clinical trials, and the absence of informed consent raises serious ethical concerns. Patients deserve to be fully informed about the risks and benefits of vaccinations, particularly during pregnancy when both maternal and fetal health are at stake.

I have also emailed relevant departments, regarding the mis-labelling as Tdap, these global health companies that are using the terminology Tdap-IPV under the usage of Repevax, However Repevax is a D-tap vaccine, containing the Inactivated Polio Virus. The correct vaccine that is Recommended for pregnant women is T-dap, with out the IPV. (Inactivated Polio Virus)

I urge the MHRA to take these concerns seriously and to ensure that future vaccination programs prioritize patient safety, transparency, and ethical standards.

I am also writing to request information under the Freedom of Information Act regarding the safety monitoring of the Repevax vaccine in the UK, with the yellow card reporting scheme.
Specifically, I would like to know how many cases of chorioamnionitis have been reported through the Yellow Card Scheme associated with the use of Repevax since its introduction in the UK and how many cases of facial paralysis has been reported through the Yellow card scheme also since its introduction.

Please provide any relevant data, reports, or summaries that detail the number of reported cases, as well as any information regarding the investigation or assessment of these reports by the MHRA.

Thank you for your attention to this matter. I look forward to your prompt response."

Merged/combined with the above request was also the below:
"I am looking for reports on the whooping cough vaccines such as Repevax, Boostrix and Adacel. There is no information on your website about these products and I am assuming that is because they are vaccines. I have contacted the MHRA specifically requesting information on Repevax vaccine. could you kindly tell me where I can find all reports on this subject please?"

MHRA request clarification from you
I have identified the following requests for information from your correspondence above.

1. "I am also writing to request information under the Freedom of Information Act regarding the safety monitoring of the Repevax vaccine in the UK, with the yellow card reporting scheme.

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I am looking for reports on the whooping cough vaccines such as Repevax, Boostrix and Adacel. There is no information on your website about these products and I am assuming that is because they are vaccines. I have contacted the MHRA specifically requesting information on Repevax vaccine. could you kindly tell me where I can find all reports on this subject please?"

2. "Additionally, throughout this process, I have only been presented with clinical trial data for Adacel and not for Repevax. I still would like to see this information regarding the clinical trials. Given that Repevax was the vaccine administered to me, this lack of transparency regarding its clinical trials is particularly concerning. Without access to relevant clinical data, I feel my ability to provide informed consent was compromised."

My apologies for writing to you later in the timeline for handling this request that I would have liked. Unfortunately, I am unable to deal with your FoI request without clarification of the information you seek with regards to question 2.

Under Section 16 of the FoI Act we should assist you in helping you focus your request.

I would like to clarify if your request relates to all clinical information submitted to support the use of Repevax in pregnancy, or it relates to all clinical trial data MHRA hold for this vaccine.

To assist, I am providing the clinical overview and an additional list of references used to support the work-sharing procedure (DE/H/0215/001/WS/140). The purpose of this procedure was to add use in pregnancy to the Repevax marketing authorisation. The clinical overview is an 84 page document and you will note that numerous studies and trials are referenced within. To return to the clarification, on reading the clinical overview and references, and provided the data and information in the overview is insufficient for your purposes, then you could make a clarified information request for a specific trial or study/s that interest you.

However, if your present request intends to cover all clinical trial data MHRA hold for Repevax this would be considered a too burdensome request to be handled by MHRA. This is primarily because we would need to:

- Search and retrieve the volumes of clinical trial information from our physical archive. The Repevax vaccine MA history traces back to 2002 MAH: Sanofi Pasteur MSD Ltd., (PL 06745/0121)

- Check clinical data for personal information which can be scattered throughout clinical trial documentation.

- Check whether or not clinical data was submitted throughout the lifecycle of the vaccine for example, to support variations (changes) to the marketing authorisation (product licence) that may have occurred.

To help make any future information request of this nature to fall within the thresholds of the Act, I would suggest requesting the clinical overview for the initial authorisation (PL 06745/0121). Onwards, if detailed within this overview there are a small number of trials and/or studies of interest to you, you could then request these. Please note that documentation to support a single clinical trial can run to 1000s of pages, and in some cases 10s of thousands.

We will consider any revised request however we cannot guarantee that any revised request will fall within the cost limit.

In terms of question 1. my colleagues inform me that the information to address this question has been prepared. However, the ICO advise us against providing information to part meet an information request, this is to avoid a public body selectively answering some parts but not others within information requests. Presumably, you still require this information, therefore, please submit question 1 separately to FOI.request@mhra.gov.uk and we will issue the response we hold promptly.

General guidance on FOI requests

It may be helpful if we explain the role of the FoI Act. It provides a legal right of access to recorded information held by a public authority like the MHRA, subject to certain exemptions that may apply. The Act does not oblige a public authority to create new information to answer questions; nor does it require a public authority to give an opinion or explanation, generate answers to questions, or create or obtain information it does not hold.

If you ask a question, rather than requesting recorded information, we will provide you with the recorded information that best answers the question. Once we have provided the recorded information, we have met our obligations under the Act; interpreting the information provided is up to you.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information