Medicines & Healthcare products
Regulatory Agency

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[redacted]

20 May 2024

MHRA reference: **FOI 2024/00041**

Dear [redacted],

Thank you for your information request, which we received on **19 April 2024**. You asked for:

> *“I am replying to your last email with your reply on an attached letter, you stated "As you will see from the current product information for Repevax, the authorised uses of this vaccine include ‘Passive protection against pertussis in early infancy following maternal immunization during pregnancy’.*
>
> *This indication was added to the Repevax product information on 1 April 2019 following an assessment by the MHRA of the evidence on the safety and effectiveness of the use of this vaccine in pregnancy to protect infants from whooping cough during the first few months of life"*
>
> ***Can you please provide me with the assement [sic] details, following the safety and effectiveness of Repevax in pregnancy from 2019.***
>
> ***Also, where would the evidence for this assessment come from in 2019? If it had been stopped since 2014, Surely there must of Been a clinical trial on pregnant women to conclude that this was safe and effective to use. Please can I have this information.”***

You also made a follow-up to your request where you mentioned:

> *" Thank you for your previous correspondence.*

I have reviewed the information provided in previous emails, including the attachment of Chapter 24 from the Green Book. Upon examining the document, it appears that Boostrix is recommended for use during pregnancy, while Repevax is designated for a pre-school booster.

Additionally, you mentioned an assessment conducted by the MHRA in April 2019 regarding the safety and efficacy of Repevax in pregnancy. Although I appreciate your efforts in submitting a Freedom of Information request for this information, I also found evidence from Sanofi themselves in May 2019 indicating that Repevax is intended for a pre-school booster, with no mention of pregnancy in the risk assessment.

Given these contradictory pieces of information, I am seeking clarification on the disparities between the MHRA assessment from April 2019, which I have yet to review, and the risk assessment conducted by Sanofi in 2019.

I would greatly appreciate any insight or clarification you can provide on this matter to help resolve my confusion regarding the appropriate use of the Repevax vaccine."

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

In relation to the original request of 19th April 2024, we confirm that we hold the information you have asked for. However, Section 27 (international relations) of the Freedom of Information Act exempts the release of this information. This is because the Federal Institute for Drugs and Medical Devices (Bfarm) based in Germany should be contacted concerning requests for documents for procedures where they were the Reference Member State.

The addition of use during pregnancy for REPEVAX suspension for injection in a pre-filled syringe (PL 46602/0005) was granted as a Type II variation as a mutual recognition procedure (DE/H/0215/001/WS/140) where Germany was the Reference Member State and the UK were a Concerned Member State. We have explained the mutual recognition process and what this means for Repevax below.

"The mutual recognition procedure (MRP) is a European authorisation route resulting in a mutually recognised product. Mutual recognition must be used when a product is already authorised in at least one EU Member State on a national basis and the Marketing Authorisation Holder wishes to obtain a Marketing Authorisation (MA) for the same product in at least one other Member State.

The Member State that has already authorised the product is known as the Reference Member State (RMS). The RMS submits their evaluation of the product to other Member State(s), these are known as Concerned Member States (CMS).

The CMS is asked to mutually recognise the MA of the RMS. If the applicant is successful, the CMS will then issue a MA for that product permitting the marketing of that product in their country."

Source: Heads of Medicines Agencies: Medicines Approval system (hma.eu)

In the case of Repevax, this means that the drug approval authority for Germany (The Federal Institute for Drugs and Medical Devices or Bundesinstitut für Arzneimittel und Medizinprodukte, known as BfArM) led the evaluation of the variation to add use in pregnancy to the product information for Repevax. In this process they sought comments from the CMS which included the UK. However, the final variation assessment report is the property of BfArM. Because the assessment reports can contain commercially sensitive and confidential information, it is our view that to release this report could strain, albeit only in a small manner, the relationship between Germany and the UK. The assessment report will detail the evidence submitted to support the approval for the addition to the COVAXIS and REPEVAX products for the use of Tdap5 and Tdap5-IPVvaccines in pregnancy.

Public interest
In some cases, regulators may redact the reports of another national competent authority (medicines regulator) to remove information that is considered commercially sensitive, personal information. However, as BfArM produced this report their staff will be best placed to identify such information. Further, to lessen the impacts on resourcing it is our standard practice for the RMS to handle document requests rather than CMS/s, and this helps to serve the public interest by balancing the resource burden across member states / regulators. As a courtesy, we have contacted BfArM in advance to make them aware that a request is likely to be with them shortly.

We appreciate that releasing the information would provide the public with a better understanding of the evaluation of this variation, however, we do not wish to cool relations between the UK and Germany, in doing so, while we only perceive a low impact in this particular case, it is moreover, the wider impact of altering our established policy which has been developed considering how best to maximise public health resource.

An FOI request can be submitted to BfArM through their contact form here: https://www.bfarm.de/EN/Service/Contact/Seite_1/contact_node.html

Your follow-up / additional request
In terms of your follow-up request we note that the assessment report may provide an understanding of the details regarding use in pregnancy, therefore, we recommend requesting this document from BfArM before exploring any further questions. In terms of your follow-up request, please also bear in mind a request for

Medicines & Healthcare products
Regulatory Agency

'*insight or clarification'* would not be considered valid under FOI, which is a request for information held by a public body or authority. If the report from BfArM does not hold the answers we would suggest re-submitting this question as a general enquiry to *info@mhra.gov.uk.*

For your general advice, when reviewing your request, we noted that the photograph of a risk management plan attached had a data lock point of 14 May 2019. In the context of drug safety, data lock points are a specific date which allows a cut off point for including data. For the photograph attached, this indicates that the data included will be from before 14 May 2019 but does not indicate when the report may have been written.

If contacting BfArM we advise mentioning the 'risk assessment conducted by Sanofi in 2019' that you mentioned in your email, and clarifying if you are referring to the Risk Management Plan.

Please also note, in the unlikely event that Bfarm are not able to meet your request, please contact us and we will see which further steps/options can be taken info@mhra.gov.uk.

For your information, we have also located an MHRA publication which may be of interest to you: https://www.bmj.com/content/349/bmj.g4219

This concludes our response to your request.

If you have a query about this response, please contact us at foi.request@mhra.gov.uk.

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

HQ&A FOI Team

Healthcare, Quality and Access Group

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Regulatory Agency

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

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