Medicines & Healthcare products Regulatory Agency

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MHRA Website

[redacted]

Our Ref: **FOI2025/00308**

17 April 2025

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 26 March. You wrote:

> *I was wondering if you had any available iDAPs information on the Shingrix vaccine please? I have a patient who is enquiring about a possible link between the vaccine and developing Bell's palsy, there is no report of this as a potential side effect within the published SPC.*

MHRA Response

We confirm that we hold the information you have requested and provide it below.

As of the 16th of April 2025, the MHRA has received 3 UK spontaneous suspected adverse drug reaction (ADR) reports associated with Shingrix vaccine reporting the suspect reaction of Bell's palsy. We have received a total of 2352 reports – please find attached a Vaccine Analysis Print (VAP) for the Shingrix vaccine which provides a breakdown of these reports and the reactions reported.

Please refer to the enclosed information sheet for guidelines on how to interpret the VAP.

When viewing this data you should note:

- The likelihood of experiencing an adverse reaction when taking a vaccine cannot be estimated from the information in VAP. This is because we have limited information about how many people have taken the vaccine without experiencing a reaction.
- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the vaccine may have caused the adverse reaction. The existence of an adverse reaction report on a VAP does not necessarily mean that the vaccine has caused the reaction.
- It is not possible to compare the safety of different vaccines by comparing the numbers presented in the vaccine reports. Reporting rates can be influenced by many factors including the seriousness of the adverse reactions, their ease of recognition and the extent of use of a particular vaccine. Reporting can also be stimulated by promotion and publicity about a product.

It is important to note that these are not necessarily proven side effects and you should refer to the product information which can be found here: https://products.mhra.gov.uk/ for details on the possible side effects of a vaccine. As you have stated, Bell's Palsy is not listed in the

Summary of Product Characteristics (SPC) for the Shingrix vaccine and is not currently a safety topic of concern, however please be assured that the MHRA continuously monitors the safety of all vaccines and any emerging evidence relating to possible risks is carefully reviewed. 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 individually assessed and cumulative information reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

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

Yours sincerely,

MHRA Central Freedom of Information Team
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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.

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