



Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of
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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2025/00331**

30 April 2025

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 31 March. You wrote:

Information on side effects of Hepatitis B vaccine, Energix please [personal information].

MHRA Response

We confirm that we hold the information you have requested. This information is attached as Annex 1, in the form of a Vaccine Analysis Print (VAP) for all UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the Enderix B vaccine up to and including 27/04/2025. Please find attached a Detailed Drug Analysis Print interpretation guide for your reference in relation to the VAP.

When considering spontaneous data, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. The fact that symptoms occur after administration of a vaccine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.
- It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine or vaccine, and may be stimulated by promotion and publicity about a drug or vaccine. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.
- The MHRA continuously monitors the safety of medicines and 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.

- As spontaneous data do not necessarily refer to proven side effects, you should refer to the product information of the vaccine which can be found here: <https://products.mhra.gov.uk/> for details on the possible side effects of the vaccine.

We hope this information is helpful. 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.

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