Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2025/00385**

19 May 2025

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 16 April. You wrote:

> *Thanks for your reply, I would like to narrow the scope of my request to these 15 vaccines as you have described then:*
>
> * *Infanrix hexa 6-in-1 vaccine*
> * *Vaxelis 6-in-1 vaccine*
> * *Rotarix Rotavirus vaccine*
> * *Bexsero MenB vaccine*
> * *Pneumovax pneumococcal vaccine*
> * *Prevenar 13 pneumococcal vaccine*
> * *Menitorix Hib/MenC vaccine*
> * *MMRVaXPro MMR vaccine*
> * *Priorix MMR vaccine*
> * *Cell-based quadrivalent influenza vaccine*
> * *Boostrix IPV 4-in-1 vaccine*
> * *Repevax 4-in-1 vaccine*
> * *Gardasil 9 HPV vaccine*
> * *Revaxis Td/IPV vaccine*
> * *MenQuadfi MenACWY vaccine*

MHRA Response

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

Please find attached the Product Analysis Prints (PAPs) for the below products, which provide a breakdown of these reports, and the reactions reported up to and including 14/05/2025. Please refer to the enclosed information sheet for guidelines on how to interpret the PAPs:

Please be aware that on a Yellow Card report, it is not mandatory to provide the brand name of a vaccine. Where a Yellow Card has been received for a vaccine but the brand name not provided these reports would not be included in the PAPs. The table below provides a list of the vaccine brands you have requested data for and the corresponding active ingredients.

Table 1: Vaccine brands requested and corresponding active ingredients

Vaccine brand	**Active ingredients**
Infanrix hexa 6-in-1 vaccine	DTPA HEPB HIB IPV VACCINE
Vaxelis 6-in-1 vaccine	DTPA HEPB HIB IPV VACCINE
Rotarix Rotavirus vaccine	ROTAVIRUS
Bexsero MenB vaccine	MENINGOCOCCAL GROUP B VACCINE
Pneumovax (understood to be requesting both Pneumovax 23 and Pneumovax II)	PNEUMOCOCCAL POLYSACCHARIDE NON-CONJUGATED VACCINE
Prevenar 13 pneumococcal vaccine	CORYNEBACTERIUM DIPHTHERIAE & STREPTOCOCCUS PNEUMONIAE
Menitorix Hib/MenC vaccine	HIB/MEN C CONJUGATE VACCINE
MMRVaXPro MMR vaccine	MMR VACCINE
Priorix MMR vaccine	MMR VACCINE
Boostrix IPV 4-in-1 vaccine	DTPA IPV VACCINE
Repevax 4-in-1 vaccine	DTPA IPV VACCINE
Gardasil 9 HPV vaccine	HUMAN PAPILLOMA VIRUS
Revaxis Td/IPV vaccine	DT IPV VACCINE
MenQuadfi MenACWY vaccine	MENINGOCOCCAL A,C,W135,Y VACCINE

As no specific pneumovax vaccine was specified in your request, we have provided a Vaccine Analysis Print (VAP) which provides a breakdown of all UK spontaneous reports where the suspect vaccine was reported as one of the following products: “pneumovax 23”, “pneumovax II”.

We also note you requested a VAP for “*Cell-based quadrivalent influenza vaccine*”, however due to the way medicines and vaccines are structured in our system we would be able to provide you with a VAP for either a specific brand of the cell based influenza vaccine or a VAP for all flu vaccines, which can be separated according to whether they are live or inactivated. Please do submit a further request detailing this if required.

Please also be aware that:

- As these data do not necessarily refer to proven side effects, you should refer to the relevant product information for details on the possible side effects of these vaccines.

The product information can be found by searching for the name of the vaccine of interest on: MHRA Products | Home MHRA Products | Home.

When viewing this data you should also 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.

Please be aware that 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
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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