



Medicines & Healthcare products
Regulatory Agency

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

Our Ref: **FOI2026/00901**

11 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 13 August. You wrote:

Dear MHRA Freedom of Information Team,

I am requesting information held by the MHRA concerning suspected adverse drug reactions reported through the Yellow Card Scheme for the MMRV vaccines Priorix-Tetra and ProQuad.

I would like the information below for reports received from 1 January 2026 up to the latest date for which data are available.

Please provide the following separately for:

- 1. Priorix-Tetra*
- 2. ProQuad*

For each vaccine, please provide:

- The total number of UK Yellow Card reports received.*
- The total number of suspected adverse reactions recorded within those reports.*
- The number of reports/reactions coded as:*
 - Febrile convulsion*
 - Febrile seizure*
 - Convulsion*
 - Seizure*
 - Pyrexia/fever*
 - Loss of consciousness*
 - Encephalitis/encephalopathy*
 - Meningitis*
 - Other serious neurological adverse reactions*
- The number of reports classified as serious.*
- The number of reports involving hospitalisation.*
- The number of reports involving death, if any.*
- The number of reports in children aged approximately 12–24 months, if this age-specific information is held.*

I would also like to request the relevant Vaccine Analysis Print (VAP), or equivalent underlying Yellow Card data extract, for Priorix-Tetra and ProQuad covering the period

above.

Please provide the data in a form that allows the adverse-reaction terms to be identified separately, rather than providing only an overall adverse-event total.

Please also state:

- *The precise reporting cut-off date used for the data.*
- *Whether the figures represent UK reports only or include reports from outside the UK.*
- *Whether a single Yellow Card report can contain multiple adverse-reaction terms and, if so, whether the reaction figures represent reports or individual reaction records.*
- *Whether any reports have been excluded, for example because they were duplicates.*
- *Whether the data include reports submitted by members of the public as well as healthcare professionals and pharmaceutical companies.*

I understand that Yellow Card reports are reports of suspected adverse reactions and do not, by themselves, establish causation. I am therefore not asking MHRA to determine whether the vaccine caused any reported event. I am specifically requesting the number of reports/reactions recorded in the Yellow Card database.

If any part of this request is considered too broad, please provide the information that can be released and advise which specific part would need to be narrowed, rather than treating the entire request as a refusal.

If the requested information is already publicly available, please provide the specific URL, dataset, table or VAP containing the figures, rather than a general link to the Yellow Card website.

MHRA Response

We confirm that we hold the information you have requested.

We have searched our database for any reports from 01/01/2026 up to and including 04/09/2026 and confirm that for Priorix-Tetra vaccine we have received 17 UK spontaneous suspected Adverse Drug Reaction (ADR) reports, and for ProQuad we have received 63 UK spontaneous suspected ADR reports.

Please find attached the Vaccine Analysis Print (VAP) for all UK spontaneous suspected ADR reports for Priorix-Tetra and ProQuad received from 01/01/2026 up to and including 04/09/2026. Please note we excluded pharmaceutical companies in this search. Within the VAP you can view the types of reactions that have been reported for each vaccine. These are displayed by primary System Organ Class (SOC) and reported to the level of preferred terms (PTs) as defined by the Medical Dictionary for Regulatory Activities (MedDRA). MedDRA is a standardised medical terminologies tool¹.

The attached guidance sheet provides you with further information on how to interpret this print.

Per the provided VAP, our search for Priorix-Tetra reports from 01/01/2026 up to and including 04/09/2026 identified 1 report where a fatal outcome was reported and no fatal reports for ProQuad vaccine were identified. Please note, there were no identified duplicate cases.

You also requested a breakdown of reports for seriousness and hospitalisation. Please see Table 1 below that provides a breakdown of reports by seriousness for ProQuad and Priorix-Tetra vaccines. We received 7 reports where the reporter flagged that the patient had been hospitalised for ProQuad and 1 report for Priorix-Tetra.

We received 28 reports for ProQuad vaccine and 10 reports for Priorix-Tetra vaccine where the patient's age was reported as 12-24 months. Please note that age is not a mandatory field when completing a yellow card report therefore this figure only includes cases where age has been provided by the original reporter.

Table 1: All UK spontaneous reports associated with ProQuad and Priorix-Tetra vaccines received from 01/01/2026 to 04/09/2026, broken down by report seriousness.

	ProQuad	Priorix-Tetra
Seriousness	Number of reports	
Serious - fatal	0	1
Serious – non-fatal	28	8
Non-serious	35	8

A Yellow Card report is considered serious according to two criteria; firstly, a reported reaction can be considered serious according to our medical dictionary and secondly, the original reporter may consider each reported reaction to be serious according to 6 criteria. The seriousness criteria for adverse event reporting were determined by a working group of the Council for International Organizations of Medical Sciences (CIOMS). Reporters can select one or more of the following criteria by ticking the appropriate box on the Yellow Card. The criteria are: (1) patient died due to reaction (2) life threatening (3) resulted in hospitalisation or prolonged inpatient hospitalisation (4) congenital abnormality and (5) involved persistent or significant disability or incapacity or (6) if the reaction was deemed medically significant.

It might be helpful to note that you can find information for data you seek at our interactive Drug Analysis Prints (iDAPs) Portal [What is being reported | Making medicines and medical devices safer.](#)

Here you will be able to access a complete listing of all suspected adverse drug reactions (ADRs) that have been reported to the MHRA via the Yellow Card scheme for the requested vaccines. The website also allows you to filter the data by year received, seriousness, and patient age group, if you wish.

When reviewing the data within an iDAP it is important to do so in the context of the essential guidance at the bottom of the report to ensure that you do not misinterpret the data. MMRV vaccine data is not currently available on our website due to a technical issue which we are working to resolve.

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

- Please note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who experience adverse events and therefore cannot be used to determine the incidence of a reaction. Adverse event reporting rates may be influenced by multiple factors including the seriousness of adverse events and their ease of recognition.
- A reported reaction does not necessarily mean it has been caused by the drug or vaccine, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a drug or vaccine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the drug or

medical device. Underlying concurrent illnesses, a range of recognised complications or patient/user factors may be responsible and such events can be coincidental. The data provided, therefore, is not a summary of known or proven adverse reactions and must not be interpreted and used as such.

- The number of reports is accurate at the time of data extraction and minor changes in numbers can occur if the reporter provides further detail later.
- The MHRA continuously monitors the safety of medicines and medical devices through a variety of pharmacovigilance processes, including the Yellow Card scheme. As part of our signal detection processes, adverse event reports received by the Yellow Card scheme are assessed, and cumulative information is reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed

Please be aware that the VAP provided should not be used as a list of side effects to the Priorix-Tetra or ProQuad vaccine. All established undesirable effects for these vaccines can be found in the Summary of Product Characteristics (SmPC) for healthcare professionals and the Patient Information leaflet (PIL), both of which can be found on the MHRA products website [MHRA Products | Home](#)

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

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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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>