



# Medicines & Healthcare products Regulatory Agency

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Our Ref: **FOI2025/00351**

2<sup>nd</sup> May 2025

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 2 April. You wrote:

*I'm a neurologist in the UK planning to do some research on PML and wanted to check if you're able to provide some up to date information on figures for the UK based on yellow card reporting? I noticed that on the Gov UK site they had figures up to 2008 (Info on progressive multifocal leukoencephalopathy (PML) from Yellow Card reports - GOV.UK<<https://www.gov.uk/drug-safety-update/info-on-progressive-multifocal-leukoencephalopathy-pml-from-yellow-card-reports>>), and case reporting for the years following on would be very helpful.*

## MHRA Response

I can confirm that up to and including 26 April 2025 the MHRA has received 317 UK suspected spontaneous Adverse Drug Reaction (ADR) reports of progressive multifocal leukoencephalopathy (PML). Additionally, 57 of these spontaneous suspected ADR reports listed PML as the fatal suspected reaction.

The tables below show details of the number of UK spontaneous suspected ADR reports of PML each year and the most frequently reported suspect drug substances.

*Table 1: Number of UK spontaneous suspected ADR reports of PML received between 01 January 2009 and 26 April 2025*

Year	Number of PML reports
2000	1
2003	1
2004	1
2006	4
2007	1
2008	10
2009	6
2010	6
2011	8
2012	10
2013	10

2014	19
2015	23
2016	31
2017	29
2018	30
2019	24
2020	14
2021	19
2022	17
2023	26
2024	16
2025	9

*Table 2: The five suspect drugs most frequently reported to the MHRA along with a PML reaction term received up to and including 26 April 2025.*

Suspected drug	Number of PML Reports
Natalizumab (monoclonal antibody)	96
Rituximab (monoclonal antibody)	92
Cyclophosphamide (antineoplastic agent)	30
Prednisolone (Corticosteroid)	20
Fingolimod (receptor modulator)	17

Please note that there may be some degree of diagnostic uncertainty within these reports and PML can be reported when it is suspected but may later be refuted. Additionally, the numbers of reports between 2000 and 2009 may have changed slightly due to updates received regarding these cases. For example, the drugs suspected of being associated with the reactions may have changed or the diagnosis of PML may have changed following further assessment that was then reported to us. Furthermore, we cannot determine the extent of under or over reporting and, as I am sure you are aware, PML can occur without any drug exposure. You may wish to read the drug safety updates targeted at specific drugs here: [leukoencephalopathy - Drug Safety Update - GOV.UK](#). You may also be interested to look at the published weekly data from UK labs on notifiable infections which goes back to 2014. This data is not stratified by underlying cause(s) such as drug exposures: [Notifiable diseases: causative agents reports for 2025 - GOV.UK](#) (See polyomavirus JC for PML cases).

Please also note that when considering the provided spontaneous ADR data, it is important to be aware of the following points:

- The MHRA takes all reports, including those with a fatal outcome very seriously. All reports with a fatal outcome are reviewed alongside all available evidence including an assessment of post-mortem details if available, to consider whether the medicine may have caused the event, or whether the event and fatal outcome were likely to be purely coincidental and due to underlying illness.
- Please 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 may be influenced by multiple factors including the seriousness of ADRs and their ease of recognition.
- A reported reaction does not necessarily mean it has been caused by the drug, only that the reporter had a suspicion it may have. The fact that symptoms occur after use

of a drug, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the drug. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- 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 assessed, and cumulative information is 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

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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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