Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2026/00538**

09 June 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 15 May. You wrote:

> *Dear Sir/Madam,*
>
> *Under the Freedom of Information Act, I would like to request information relating to adverse reaction reports associated with Keytruda (pembrolizumab) within the United Kingdom.*
>
> *Specifically, I would like to request the following information:*
>
> *1. The total number of Yellow Card reports submitted in relation to Keytruda (pembrolizumab).*
> *2. The number of reports where the outcome was recorded as fatal or resulting in death.*
> *3. The categories or types of adverse reactions most commonly associated with fatal outcomes linked to Keytruda.*
> *4. Any available data regarding immune-mediated toxicity or organ failure associated with pembrolizumab treatment.*
> *5. Any internal safety reviews, investigations, or assessments carried out by the MHRA concerning fatal adverse reactions associated with Keytruda.*
>
> *I would appreciate receiving the information in electronic form where possible.*
>
> *This request is made in the public interest and for personal understanding regarding the safety profile and reported adverse outcomes associated with this medication.*
>
> *Thank you for your time and assistance. I look forward to your response within the statutory timeframe.*

MHRA Response

Regarding your request for any available data regarding question 1,2,3 and 4 with pembrolizumab treatment, the MHRA publishes reported side effects of a drug in the form of interactive Drug Analysis Profiles (iDAPs) which can be accessed using this website: https://yellowcard.mhra.gov.uk/idaps. You can view profiles for each drug requested using the link e.g. pembrolizumab. Here, you can find data relating to the substance of interest including the number of reports, a complete list of all suspected adverse reactions and a filter

function to further break down the data. It is important to view this data in the context of the essential information and guidance provided on the webpage.

Regarding any internal safety reviews, investigations, or assessments carried out by the MHRA, as you may know, a safety signal is information on a new or known adverse event that may be caused by a medicine and requires further investigation. The MHRA is responsible for detecting and managing safety signals for UK products. Routine signal detection activities for pembrolizumab have been conducted since marketing authorisation was granted by the European Medicines Agency (EMA) on 17 July 2015. Signal detection is a continuous process which identifies potential alerts and supports drug safety.

A Safety Topic is created by the MHRA to record potential safety signals being identified. Once evaluated, these safety signals may result in regulatory action, such as updates to product information, or may contribute to wider reviews alongside other sources of data.

Please note, not all signal assessments will be associated with a Safety Topic for a variety of reasons. Examples of this include safety signals identified and reviewed within normal regulatory procedures for medicines, such as periodic safety update reports (PSUR) and safety signals arising from medical literature or of an urgent nature, which may be taken directly to an appropriate expert advisory group.

To provide the information requested for point 5 above we have reviewed the Safety Topics on our database and refined by those that include at least one report with a fatal outcome. As such we can confirm that we have four Safety Topics on our database of relevance to your request. The Safety Topics concern pembrolizumab and pemphigoid, myocarditis, myasthenia gravis and pneumonia. The signal assessments concerning pemphigoid, myocarditis and myasthenia gravis determined that current evidence does not suggest a causal association and as such were closed with no further action.

I can confirm that “pneumonia” was added to the SPC in 2017 after review by the MHRA and pharmacovigilance risk assessment committee (PRAC), after review in a periodic safety update report (PSUR). The summary of product characteristics (SPC) for pembrolizumab can be found at the following link: : MHRA Products | Home.

Please be assured that signal detection activities are a continual review of evidence and as such all reports are reviewed at regular intervals alongside other sources of evidence.

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.

Re-use of our information
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https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/