Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA Central Freedom of Information Team
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Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

Our Ref: **FOI2026/00456**

22 May 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 26 April. You wrote:

> *I am writing to request information under the Freedom of Information Act 2000.*
>
> *Please provide a statistical summary of all Yellow Card reports (including suspected adverse drug reactions and, where applicable, medical device incident reports) relating to products within the BNF category "Emollient and Barrier Preparations" for the period 1 January 2021 to the date of this request.*
>
> *I would prefer this information to be provided in a machine-readable format (e.g. CSV or Excel).*
>
> *To support understanding of patterns and trends in patient-reported outcomes, I would be grateful if the data could be provided in an aggregated format (rather than case-level data) including the following, where available:*
>
> * *Product or brand name*
> * *Number of reports per product, broken down by year*
> * *Reaction term (using MedDRA terminology), with counts per term*
> * *Outcome/severity categories (e.g. fatal, life-threatening, hospitalisation, medically significant, non-serious), with counts*
> * *Reporter type (e.g. patient, general practitioner, specialist), with counts*
>
> *In addition, I would be particularly interested in reports indicating that a product may have been ineffective or associated with worsening of the underlying condition. If available, please include:*
>
> * *Counts of reports coded with terms such as "condition aggravated", "drug ineffective", "treatment failure", or similar MedDRA terms indicating lack of efficacy or worsening symptoms*
>
> *Where recorded and extractable, I would also be grateful for:*
>
> * *Any available information on suspected active substances and/or excipients associated with reports (for example paraffin, sodium lauryl sulfate, or isopropyl myristate)*

If it is not possible to extract data by excipient, I would be content to receive the data by product name only.

MHRA Response

We are unable to deal with your FoI request without clarification of the information you seek. The reason for this is we are unable to identify the list of specific products you are requesting information about.

Under Section 16 of the FoI Act we should assist you in helping you focus your request. To help us do so, we would like to know **the name of each product you are interested in receiving information about.**

Please be aware that the MHRA publishes reported side effects of a drug in the form of interactive Drug Analysis Profiles (iDAPs) which can be accessed at this website https://yellowcard.mhra.gov.uk/idaps. You are able to filter on iDAPs on a range of parameters including reporter type and seriousness.

You can view iDAPs for any **substance** of interest using the link. We understand that your request relates to specific products, as opposed to substances, however, we hope this information provides you with the information in your final question around "any information on suspected active substances".

If we are provided with the specific names of the products of interest in your response, we can look to extract and provide you with the following information defined at each bullet point below; please confirm in your response whether this is satisfactory:

- Product analysis prints for each of the products of interest.

Individual "product analysis prints" can be provided for each product of interest. Each print breaks down all UK spontaneous suspected ADR reports received by the MHRA for the product by reported reaction terms. You can view an example format of a product analysis print here: https://mhra.disclosurelog.co.uk/disclosures/7b033291-8c72-4194-9063-2c4371e420a6?preserveHistory

Typically, these prints are provided in PDF format, however, we can provide them in a CSV format if that would be helpful, please clarify.

- Table showing number of reports for each product, broken down by year

- Table showing number of reports for each product, broken down by reporter type

- Table per product showing number of reactions that fell into each "seriousness" criteria (*results in death, is life-threatening, results in or prolongs hospitalisation, results in persistent or significant disability or incapacity, is a congenital anomaly*).

Please note that within the MHRA's new surveillance systems, seriousness criteria is now populated for each suspected adverse drug reaction within a report rather than at the report level. More than one seriousness criteria can be chosen per reported reaction.

- Table showing the number of reports for each product where MedDRA terms "condition aggravated", "drug ineffective", "treatment failure", and any other MedDRA terms indicating lack of efficacy or worsening symptoms were reported.

Regarding excipients, please be aware that it is not mandatory on a Yellow Card report to provide information about excipients.

We will consider any revised request however we cannot guarantee that any revised request will fall within the cost limit. Please do take this into account when considering the number of products you are requesting information for and consider restricting your request to a maximum of 8 products. There is a cost limit of £600 specified in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. This represents the estimated cost of at least one person spending 3½ working days (equivalent to 24 staff-hours) in determining whether the Agency holds the information, and locating, retrieving and extracting it.

We recommend that you familiarise yourself with the Information Commissioners Office guidance on how to submit an FOI to a public authority. We have provided these links below to aid in future requests:

https://ico.org.uk/for-the-public/official-information/preparing-and-submitting-your-information-request/

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
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/