



Medicines & Healthcare products
Regulatory Agency

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United Kingdom
[gov.uk/mhra](https://www.gov.uk/mhra)

[REDACTED]

17 November 2023

Dear [REDACTED]

FOI 23/843

Thank you for your FOI request dated 16th October 2023, where you requested:

“If you could interrogate the MHRA Yellow Card system to see how many reports there have been of patient harm over the past 5 years in relation to the absence of an alert on the Electronic Prescribing Medication Administration (EPMA) requiring review of the ongoing suspension of prescribed medication”.

We note that this was also logged with and responded to by our news centre however as you requested the information under the FOIA, please find our response below.

I can confirm that based on the current information, as your request stands, we do not believe that we hold the information that you have requested. It is not possible to identify the precise device involved and therefore it has not been possible to determine whether it is registered with the MHRA or to definitively identify relevant Yellow Card reports.

Patient safety is our priority and that is why we continuously review and monitor all Yellow Card reports submitted to us. When a safety issue is confirmed, we will act promptly to inform patients and healthcare professionals and take appropriate steps to mitigate any identified risk. We welcome any additional information that you may be able to provide on the specific device involved.

As this case seems to involve clinical practices, which are outside the remit of the MHRA, you may wish to contact NHS England at nhsengland.media@nhs.net as they may be able to provide the information you requested.

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 you receive this response and addressed to: info@mhra.gov.uk
Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

FOI Team,
Safety and Surveillance Group