Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00596**

16 June 2026

Dea[redacted]

Thank you for your Freedom of Information (FoI) request received on 3 June. You wrote:

> *I am reviewing a local procedure for the issue of steroid emergency cards (further info on national patient safety alert here HIS-steroid-emergency-card-appendix-aw6458.pdf<https://www.healthcareimprovementscotland.scot/wp-content/uploads/2024/03/HIS-steroid-emergency-card-appendix-aw6458.pdf>).*
>
> *As part of this review, I wondered if it would please be possible to know if you have had any reports of adrenal crisis in patients receiving multiple short courses of anti-emetic dose dexamethasone (e.g. 6mg daily for 4 days every 3 weeks or 4mg twice daily for 3 days every 3 weeks etc)?*
>
> *I have had a look at the iDAPs for endocrine disorders with dexamethasone and can see there are multiple serious and fatal reports, but of course this does not give me information on the doses or whether the adverse event was specifically adrenal insufficiency.*

MHRA Response

We confirm that we hold the information you have requested.

It may be helpful to firstly provide some background information to allow interpretation of this data. The Yellow Card scheme is the UK system for collecting and monitoring information on suspected adverse drug reactions (ADRs). The scheme is run by the MHRA and currently relies on voluntary reporting of suspected ADRs by health professionals and patients. There is also a legal obligation for pharmaceutical companies to report serious ADR reports to their drugs. All reports, including from patients, are reviewed through a signal detection process to identify previously unrecognised concerns about medicines and consider if further action is necessary.

Further to your request, I can confirm the Yellow Card scheme has received a total of 8 UK spontaneous suspected ADR reports associated with adrenal insufficiency and dexamethasone. Upon reviewing these reports, I can confirm that no reports mention multiple short courses of dexamethasone.

Please note the accuracy of this data relies on the dosage information being correctly provided to us by the reporter in the original Yellow Card. Additionally, entering dosage information is not required to submit a report; reporters are only required to provide the drug name and characterisation of the drug. Therefore, this information may not be a complete representation of all reports from this area as reports may not specify the duration of the doses the patients were taking.

When considering the spontaneous ADR data detailed above, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the medicine or medicinal product, only that the reporter had a suspicion it may have. The fact that symptoms or events occur after use of a product, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the product. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.
- It is also important to note that Yellow Card data cannot be used to determine the incidence of a reaction or to compare the side effect profiles of different medicines or vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug or vaccine and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines or vaccines during the first one to two years on the market and then falls over time.

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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