FOI 23/102

2nd March 2023

Dear

Thank you for your email dated 3rd February 2023, where you asked for information on the following:

• How many incidents of Topical Steroid Withdrawal have been reported to the Medicines & Healthcare products Regulatory Agency via the Yellow Card scheme?

• How many incidents were reported in children? (under 18)

• How many incidents were reported in adults? (over 18)

• How many incidents were reported in people under the age of 35?

• Please could you provide me with a list of the topical steroid creams that have been reported and the number of reports of Topical Steroid Withdrawal associated with them?

• How many incidents of Topical Steroid Withdrawal were reported to the Medicines & Healthcare products Regulatory Agency between January 2022 and January 2023?

• How many incidents of Topical Steroid Withdrawal were reported to the Medicines & Healthcare products Regulatory Agency between January 2018 and January 2019?

Topical steroid withdrawal reactions have been reported in some long-term users of topical corticosteroids after they stop use. In 2021 following concerns from patients and their families about topical steroid withdrawal reactions, the MHRA conducted a review of the evidence and considered the need for regulatory action to minimise the risk of this side effect. The MHRA Drug Safety update and a link to the Public Assessment Report (PAR) can be found via this link: Topical corticosteroids: information on the risk of topical steroid withdrawal reactions - GOV.UK (www.gov.uk).

The search included Yellow Cards reported between 1963 (inception of the database) and 29 January 2020 whereby manual review of Yellow Card reports took place during assessment of the safety issue, in order to determine if the reports met certain case criteria relating to Topical Steroid

Withdrawal. Up to the 29 January 2020 the MHRA received 99 adverse drug reactions reports related to Topical Steroid withdrawal.

Under the FOIA we are not required to carry out another assessment exercise in order to categorise reports received since this date, but to provide data we hold as is structured on our database. It is important to note that topical steroid withdrawal reactions can be difficult to diagnose. This can result in under-recognition of the effect when it occurs and reporting of the event using slightly different descriptions. The MHRA uses the Medical Dictionary for regulatory Activities (MedDRA) to code adverse drug reactions in our database. We have selected MedDRA preferred terms which we consider to be relevant to topical steroid withdrawal[1] to conduct a search of our database for reports received between 30 January 2020 and 22 February 2023 totalling 154 reports.

The data includes all probable and possible cases from the review published in 2021 and cases identified using the search strategy described above, however these are not confirmed cases of topical steroid withdrawal and the data should be treated with caution. I can confirm that up to an including 22/02/2023 the MHRA has received a total of 263 spontaneous suspected Adverse Drug Reaction (ADR) reports for adverse reactions related to topical steroid withdrawal. Of these reports 3 were received between January 2018 and January 2019 and 52 were received between January 2022 and January 2023.

Please note that a single Yellow Card report may contain more than one suspect drug, therefore the number of ADR reports for each drug will not equal the total number of unique reports.

Table 1. Spontaneous ADR reports of withdrawal reactions for topical steroids

Drug name	Number of ADR reports
Beclometasone	1
Betamethasone	147
Clobetasol	40
Hydrocortisone	91
Mometasone	63
Triamcinolone	2

Table 2. Spontaneous ADR reports of withdrawal reactions for topical steroids and age range*

Patient age range (years)	Number of ADR reports
<18	18
>18	148
<35	119

*Please be aware that it is not mandatory to provide the patient age when submitting a Yellow Card report to the MHRA, therefore the data provided only includes reports where the patient age was specifically reported.

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

- A reported reaction does not necessarily mean it has been caused by the vaccine, medicine or device only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a vaccine, medicine or device, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to 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 or compare the safety profile of different vaccines, medicines or devices. ADR and Device incident reporting rates are influenced by the seriousness of adverse reactions, their ease of recognition, the extent of use of a particular medicine or device, and may be stimulated by promotion and publicity.

Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

You may be interested to know that you can view suspected adverse reactions reported to the MHRA via the Yellow Card scheme on our website as interactive Drug Analysis Profiles (iDAPs). iDAPs provided on our website are regularly updated, however please be aware that there is a time lag of around one month from receipt of a report to it appearing in the iDAP.

I hope the information provided is helpful, but 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 of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,

Vigilance and Risk Management of Medicines Division