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Dear Healthcare Professionals,

Topical corticosteroids: information on the risk of topical steroid withdrawal reactions

Your attention is drawn to the Medicines and Healthcare products Regulatory Agency's (MHRA) announcement that rarely, severe adverse effects can occur on stopping treatment with topical corticosteroids, often after long-term continuous or inappropriate use of moderate to high potency products.

Topical corticosteroids are safe and highly effective treatments for skin conditions such as eczema, psoriasis, and atopic dermatitis when used correctly. They are available in different potencies: mildly potent (for example, hydrocortisone); moderately potent (for example, clobetasone); potent (for example, beclometasone); and very potent (for example, clobetasol).

During its review MHRA considered data gathered from Yellow Card reports and identified 55 reports indicative of topical steroid withdrawal reactions, most of which were reported by patients. MHRA also considered information available in the literature and from other regulators. MHRA is unable to estimate the frequency of these reactions. However, given the number of patients who use topical corticosteroids, MHRA understands reports of severe withdrawal reactions to be very infrequent.

Information about the risks and characteristics of topical steroid withdrawal reactions will be added to the Summaries of Product Characteristics and the Patient Information Leaflets for topical corticosteroid medicines.

Topical steroid withdrawal reactions are thought to occur after prolonged, frequent, or inappropriate use of moderate to high potency topical corticosteroids. Topical steroid withdrawal reactions can develop after application of a topical corticosteroid at least daily for longer than a year. In children they can occur within as little as 2 months of daily use. People with atopic dermatitis are thought to be most at risk of

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developing topical steroid withdrawal reactions. It has been reported that the signs and symptoms occur within days to weeks after discontinuation of long-term topical corticosteroid treatment. They are most commonly seen after treatment of sensitive areas such as the face or genitals.

The most common reaction is a rebound (or flare) of the underlying skin disorder such as atopic dermatitis. However, patients have described a specific type of topical steroid withdrawal reaction in which skin redness extends beyond the initial area of treatment with burning or stinging and that is worse than the original condition. It can be difficult to distinguish a flare up of the skin disorder, which would benefit from further topical steroid treatment, and a topical steroid withdrawal reaction.

A topical steroid withdrawal reaction should be considered if:

- burning rather than itch is the main symptom
- redness is confluent rather than patchy (which may not be so obvious in people with darker skin) (redness can be a spectrum of pink, red, and purple, or subtle darkening of the existing skin colour, which can vary depending on the skin tone of the individual)
- rash resembles atopic dermatitis but involves unusual sites and is 'different' to the skin condition that the patient has experienced before
- there has been a history of continuous prolonged use of a moderate or high potency topical corticosteroid

Skin biopsy is generally unhelpful to distinguish topical steroid withdrawal reactions from a flare of the underlying skin disorder because the histopathology overlaps.

If the patient's skin condition fails to improve, before prescribing a more potent corticosteroid, consider possible diagnoses such as rosacea, peri-oral dermatitis, infection and allergy to the topical corticosteroid or other topical medications, including moisturisers or cosmetics. Patch testing may identify some cases of contact allergy. If a severe rebound of atopic dermatitis is suspected, review the guidance on alternative treatments.

Advice for healthcare professionals:

- long-term continuous or inappropriate use of topical corticosteroids, particularly those of moderate to high potency, can result in the development of rebound flares after stopping treatment; there are reports of such flares taking the form of a dermatitis with intense redness, stinging, and burning that can spread beyond the initial treatment area
- when prescribing a topical corticosteroid, consider the lowest potency needed
- advise patients on the amount of product to be applied; underuse can prolong treatment duration
- inform patients how long they should use a topical corticosteroid, especially on sensitive areas such as the face and genitals

- inform patients to return for medical advice if their skin condition worsens while using topical corticosteroid, and advise them when it would be appropriate to re-treat without a consultation
- for patients currently on long-term topical corticosteroid treatment, consider reducing potency or frequency of application (or both)
- be vigilant for the signs and symptoms of topical steroid withdrawal reactions

Please refer to the following website in MHRA for details:

<https://www.gov.uk/drug-safety-update/topical-corticosteroids-information-on-the-risk-of-topical-steroid-withdrawal-reactions>

In Hong Kong, there are registered pharmaceutical products containing topical corticosteroids such as hydrocortisone, clobetasone and clobetasol. So far, the Department of Health (DH) has received 5 cases of adverse drug reaction related to corticosteroids dermatological preparations, but these cases are not related to steroid withdrawal reactions. In light of the above MHRA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,



(Ling PANG)

for Assistant Director (Drug)