[redacted]

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18 January 2019

Advisory Committee on Medicines Scheduling
Therapeutic Good Administration
Department of Health
Canberra ACT 2601

To the Advisory Committee on Medicines Scheduling,

RE: Proposed amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS/ACMS meetings, March 2019

On behalf of the Australasian College of Dermatologists (ACD), thank you for the opportunity to provide comment on the proposed amendments to the Poisons Standard referred to the March 2019 meeting of the Advisory Committee on Medicines Scheduling (ACMS #26).

This submission relates to the proposed rescheduling of mometasone furoate, a synthetic corticosteroid used for the treatment of allergic rhinitis and certain inflammatory skin conditions.

As outlined in the attached submission, the College does not support the proposed amendment to the Poison Standard in which mometasone furoate for the treatment of inflammatory and pruritic dermatoses would be reclassified from a Schedule 4 to Schedule 3 medicine. The College has a number of concerns relating to the proposed over-the-counter availability of mometasone furoate, based on significant patient safety and cost implications.

Thank you for your consideration in this matter. If you have any queries relating to this submission, please contact [redacted]

Kind regards,

[redacted]

Therapeutic Goods Administration

Consultation on the proposed amendments to the Poisons Standard referred to the Advisory Committee on Medicines Scheduling (ACMS #26): Mometasone

Submission of the Australasian College of Dermatologists

January 2019

About the Australasian College of Dermatologists

The Australasian College of Dermatologists (ACD) is the sole medical college accredited by the Australian Medical Council for the training and continuing professional development of medical practitioners in the specialty of dermatology. As the national peak membership organisation, the College represents over 500 specialist dermatologist Fellows (FACD) and 100 trainees across the country.

The College is the leading authority in Australia for dermatology, providing information, advocacy and advice to individuals, communities, government and other health stakeholders on skin health and dermatological practice.

Purpose

The Therapeutic Goods Administration (TGA) has called for public submissions on scheduling proposals referred to the March 2019 meeting of the Advisory Committee on Medicines Scheduling (ACMS #26). The ACD welcomes the opportunity to put forward this submission on the proposed amendments to scheduling of mometasone furoate, a synthetic corticosteroid of mid to high potency used to treat allergic rhinitis and inflammatory skin conditions.

Mometasone is currently listed in Schedules 2 and 4 of the Poisons Standard. Under Schedule 2, mometasone is delivered as an aqueous nasal spray (50 µg or less per actuation; maximum recommended daily dose no greater than 200 µg) for the prophylaxis or treatment of allergic rhinitis. All other preparations of mometasone are referred to under Schedule 4; this refers to topical formulations for the treatment of inflammatory and pruritic dermatoses. Several prescription-only commercial preparations are available at a dosage of mometasone furoate 0.1% w/w (1 mg/g). These are available as a cream, ointment or lotion.

The applicant proposes the following specific changes to the scheduling of mometasone:

> *Schedule 2 - Amended entry*
>
> MOMETASONE in aqueous nasal sprays delivering 50 micrograms or less of mometasone per actuation when the maximum recommended daily dose is no greater than 200 micrograms ~~for the~~ and when packed in a primary pack containing 200 actuations or less, for the short term prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years and over.
>
> *Schedule 3 - Proposed New Entry*
>
> MOMETASONE as the only therapeutically active substance in preparations for dermal use containing 0.1 percent or less of MOMETASONE in packs containing 15g or less.
>
> *Schedule 4 - Amended Entry*
>
> MOMETASONE except when included in Schedule 2 or 3.

ACD response

While the College is in agreement with the proposed changes to Schedule 2, we do not support amendments which would remove the prescription-only requirement for mometasone for the topical treatment of skin conditions.

The applicant puts forward that over-the-counter (OTC) availability of mometasone is justified on the following grounds:

- There will be no complications or untoward clinical problems when used according to the labelling and with pharmacist advice
- Mometasone has superior efficacy and comparable side effect profile compared with other OTC topical corticosteroids, such as hydrocortisone and clobetasone
- Considerable cost savings to the government are expected, as well as to the consumer through awareness and access
- It will provide the consumer with an alternative choice of topical corticosteroid for the relief of inflamed and itchy skin due to psoriasis, dermatitis and eczema, particularly in the flare-up situation.

The College has a number of concerns relating to the OTC availability of mometasone, outlined below for the consideration of the ACMS. It must be noted that mometasone is one of the most potent PBS-subsidised corticosteroid preparations available in Australia. Setting a precedent by rescheduling this agent to S3 may pave the way for other topical corticosteroid preparations to similarly be reclassified. This would have significant implications on patient safety and costs, as well as the ability of medical practitioners to manage chronic inflammatory dermatoses according to best practice.

1. The role of the pharmacist in skin disease management

In Australia, mometasone is ranked as a Class III topical corticosteroid (*NB.* Class I: mild; Class II: moderate; Class III: potent; Class IV: very potent).[1] International classifications similarly place mometasone at the higher end of the potency scale (USA: Class 2/3 [potent/upper mid-strength]; UK: Class II [high]).[2]

Pharmacists' assessment of symptoms and subsequent treatment recommendations have a valuable place in healthcare, and lower-potency topical corticosteroids in the context of pharmacist-only usage advice can be safe and effective for many minor and acute skin conditions. However local and systemic adverse effects when used incorrectly can occur and knowledge of correct usage is all the more important as potency increases. For example, differences in absorption between anatomical locations, frequency and duration of use, and knowledge of adjunctive skin care treatments are critical factors to consider when guiding health consumers.[2]

Of utmost importance is disease responsiveness to topical corticosteroids. Certain conditions respond well to low potency agents, such as intertriginous psoriasis, children's atopic dermatitis, seborrhoeic dermatitis and other intertrigos. Those that respond moderately require mid-potency corticosteroids (i.e. psoriasis, adult atopic dermatitis and nummular eczema), while poorly responding conditions (i.e. those with chronic, hyperkeratotic, lichenified or indurated lesions) are best treated with high-potency agents. Corticosteroid use is not advised for some conditions (rosacea, perioral dermatitis or acne) and contraindicated in others (skin infections).[2]

Pharmacists are not trained to differentiate between these varied skin conditions. For example, distinguishing skin infections (i.e. impetigo or eczema herpeticum [severe herpes infection on areas of skin eczema]) from moderate or moderately severe eczema requires a medically trained eye. Incorrect use is likely to exacerbate or increase infections such as tinea incognito. Particularly challenging in the pharmacy setting is providing correct treatment advice for skin rashes in the groin area, where potential diagnoses could include fungal infection,

sebaceous dermatitis, psoriasis or lichen simplex. Pharmacists are not only unable to examine these areas, they are not trained to distinguish between these conditions nor dispense S4 agents should such treatments be indicated.

In the view of the College, pharmacists should not be put in a position to advise the use of higher potency corticosteroids without a medical diagnosis and where there is a greater risk of adverse effects if used incorrectly. Limiting the permitted volume to 15g packs is an ineffective risk mitigation measure. Given the potency of mometasone, the College maintains that its use should continue to remain under the management of a medical practitioner where a treatment plan can be put in place and treatment response monitored. The applicant's assertion that no complications or untoward clinical problems will occur with the rescheduling of mometasone is not substantiated.

2. Safety and adverse effects

Mometasone is usually not used in sufficient quantities to cause any significant systemic absorption. However its topical use may, if used inappropriately, cause significant problems in the skin. Because it is widely prescribed and often not applied according to doctors' instructions, it is currently the commonest cause of corticosteroid induced rosacea on the face (perioral dermatitis) and is a significant cause of atrophy of the skin, particularly in flexural areas, such as the groin and axillary regions.[3,4]

Adverse effects such as perioral dermatitis can occur within only a few weeks of regular use and can persist for months or even years.[3] Appropriate treatment usually consists of avoiding the use of the offending topical corticosteroid preparation and prescription of oral tetracycline group antibiotics for a period of at least six weeks; thus medical supervision to correctly identify and treat side effects is required.[3]

Risks associated with topical corticosteroid use increases with potency. The College rejects the statement that mometsone has a side effect profile comparable to lower potency OTC topical steroids such as hydrocortisone.

3. Exploration of benefits of acute care availability

As described, diagnostic assessment of skin conditions by a medical professional is necessary especially where contraindications to topical corticosteroids exist (e.g. zoster / herpes / fungal infections) and may require pathological confirmation. The College suggests that the ACMS consider whether the benefits of accessing a high potency corticosteroid at a pharmacy outweighs the disadvantages to patients where a medical diagnosis and different pharmacological treatment is required, but is delayed or not sought. Health system costs as well as individual patient outcomes should be considered in this context.

The College does not agree that rescheduling will have a cost benefit to the consumer, as is put forward by the applicant. Currently, patients with dermatoses are able to receive streamlined authority PBS prescriptions of mometasone. Should S3 scheduling occur, then increased amounts on authority cannot be prescribed, greatly increasing cost to consumers especially those with widespread or chronic disease. If dermatologists are unable to prescribe large amounts then systemic treatment may in turn be needed for disease control – an approach to be avoided due to potentially severe side effects.

An additional concern to the College is a perception within certain community groups that topical corticosteroid use is unsafe, manifesting in steroid-phobia. Misuse or inappropriate use inflames this phobia, as side effects are more likely and can result in lack of compliance to treatment regimens or abandoning treatment entirely. Unfortunately this is compounded by conflicting pharmacy advice to limit treatment duration, frequency and volume application. Insufficient drug exposure to the affected area may not adequately treat the condition and this may be wrongly interpreted as unresponsiveness.[2] Education of pharmacists, patients and the community

is needed to combat misinformation about topical corticosteroids, and those with higher potency certainly should remain regulated and prescribed with medical supervision.

4. Overseas dispensing restrictions

The applicant states that 'Internationally, mometasone has been marketed in the USA, Canada, UK and Europe since 1987 and in New Zealand since the mid-1980s.' Mometasone continues to be prescription-only in the UK. The College suggests that ACMS review the current status of international dispensing restrictions beyond product marketing.

References

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