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2nd July 2019

Transparency, Reforms and Evaluation Support Section
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration.

RE: Interim decisions and invitation for further comment on substances referred to the March 2019 ACMS/ACCS meetings

Dear Sir/ Madam,

As you are aware, Ego Pharmaceuticals, a world-leading Australian manufacturer of both cosmetic and therapeutic skin care products, has recently applied for downscheduling of mometasone from S4 to S3 (referred to as the Application). We have reviewed the interim decision of the delegate of the Secretary in relation to the proposed downscheduling and would like to offer the following additions and clarifications to help address the delegate's concerns.

The primary concern, that the diagnosis, management and monitoring of the medical condition requires medical intervention before mometasone is used, is a valid one, but it can be addressed by applying suitable restrictions around the medicine's supply via an Appendix M entry.

We would like to propose the following Appendix M entry for mometasone:

The medicine (mometasone) should only be supplied if the patient has had a formal diagnosis by a medical practitioner (or periodic review of the condition) within the last 6 months and specifically recommended mometasone.
This is to be determined by a patient questionnaire.

This entry is in line with point 7 of the Proposed Criteria from the TGA's "Proposed criteria for Appendix M of the Poisons Standard to support rescheduling of substances from Schedule 4 (Prescription only) to Schedule 3 (Pharmacist only)." A possible example of the patient questionnaire is attached to this letter (Attachment 1).

Specific concerns

Consumers and/or pharmacists are not best placed to perform a differential diagnosis in the supply of mometasone (e.g. fungal infections, herpes zoster, infection)

We recognise the potential for incorrect diagnosis, and the need for appropriate medical intervention with the use of potent corticosteroids such as mometasone. The proposed Appendix M entry takes this into account, requiring the patient to have had their condition diagnosed by a medical practitioner, and for that medical practitioner to have specifically recommended mometasone. A review period of 6 months helps ensure the diagnosis is current and that the medical practitioner remains involved in the ongoing support of the patient and their condition.

Retention of mometasone in Schedule 4 will support better patient outcomes as any failures in the treatment of conditions with existing mild to moderate potency over-the-counter corticosteroids will be a signal that medical intervention is required.

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This concern is addressed by the proposed Appendix M entry, which requires patients to seek an updated diagnosis and recommendation before mometasone can be supplied by the pharmacist.

Mometasone is classified as a Class III (potent) topical corticosteroid and there are systemic adverse events associated with medically unsupervised and inappropriate use.

As outlined in the proposed Appendix M entry, patients will not be able to acquire mometasone without an appropriate diagnosis and recommendation from a medical practitioner. We maintain that pharmacists are best placed to discuss the potential side effects of the medicine, and to determine, with the help of a patient questionnaire, whether the treatment is proving effective. Systemic adverse events to various degrees are associated with every class of topical corticosteroid if used inappropriately, however, as outlined in the Application, systemic absorption of mometasone is minimal and adverse events are rare compared to other topical corticosteroids.

Inappropriate application of topical mometasone to the face can lead to significant skin problems including corticosteroid induced rosacea on the face (perioral dermatitis) and skin atrophy.

We recognise the potential for mometasone to cause perioral dermatitis. To address this concern we propose updating the labels to include the following warning for increased prominence:
Do not use on the face, or for more than 4 weeks without advice from a medical professional.
The advice not to use on the face will also be included in the CMI, as detailed in Part 2 (D) of the Application. In addition, the pharmacist training and support materials (poster and mini leaflet) caution against using the product on the face, which will help mitigate this risk.

The downscheduling of mometasone will not necessarily offer any additional benefit to the community given that existing provisions allow for 3 days emergency supply for a previously diagnosed condition in the absence of a prescription.

When Ego submitted an application to downschedule mometasone in 2012, we included with our application several letters of support (Attachment 2) from the public that described common frustrations experienced by patients using mometasone for their condition. Obtaining a prescription often requires taking time off work, paying the appointment fee, wasting their time and their doctor's time just to access a medication that they have been using successfully for many years. Recent figures show that the average wait time to see a medical specialist in Victoria is 17 days, while patients have to wait on average 29 days to see a dermatologist. Even when making an appointment with their GP, wait times are often longer than 3 days. While the 3-day emergency supply without prescription may be helpful in some cases, it falls short of providing all patients with the necessary access to their medication, considering the long wait times they can face. The Appendix M entry proposed above will help streamline this process while still including the medical practitioner in the ongoing management of the patient's condition.

Inclusion in Appendix H

Ego Pharmaceuticals is not seeking the inclusion of mometasone in Appendix H.

Thank you for the opportunity to respond to the delegate's interim decision.

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Yours sincerely,

[redacted]

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ATTACHMENT 1

Proposed Patient Questionnaire for the supply of topical Mometasone Furoate (S3)
Pharmacist Use Only

Name:_____

Q1. Have you seen a medical practitioner about your condition?
- ☐ No - See A1
- ☐ Yes - Go to Q2

Q2. Date you last saw your medical practitioner:___/___/_____

Q3. Did your doctor recommend mometasone for your condition?
- ☐ No - See A2
- ☐ Yes - Go to Q4

Q4. Have you used mometasone in the past?
- ☐ No -
- ☐ Yes - Go to Q5

Q5. When did you last use mometasone and for how long?
Last used:_____
Duration:_____

A1. A diagnosis and recommendation from a medical practitioner is required before mometasone can be supplied.
A2. A milder corticosteroid may be more appropriate for your condition. Please talk to your pharmacist.

ATTACHMENT 2
Letters of Support

3 September 2012

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601
SMP@health.gov.au

To the ACMS

I would like to express my support for the proposed rescheduling of mometasone from S4 to S3 for topical use being considered at the October ACMS meeting.

Mometasone is already available as a S2 for allergic rhinitis, but when I need to use mometasone for my eczema I have to go to the GP for a prescription. Given that I work full time, getting to a GP involves an afterhour's visit to a clinic, paying $65, and then going to a Medicare office to get my rebate. This is a time consuming and frustrating cycle, just to get a medication that I have been using for many years whenever I get a flare-up of my eczema.

I would welcome the freedom that having mometasone available from the pharmacy would give me. I would be able to purchase a new tube very easily and would not have to frantically get to a GP when I felt my eczema flaring up or getting worse. I am very sure that those suffering from other conditions such as psoriasis that use mometasone would also be pleased to have it available from their pharmacy.

Making mometasone S3 would be a big assistance in my life as I look after my skin, and I am sure would be of use to many other Australians.

Yours sincerely

September 4, 2012

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

SMP@health.gov.au

To the Secretary of the ACMS,

Mometasone

I am writing to you regarding the "Invitation for public comment - ACMS and ACCS meetings, October 2012", particularly the proposal to reschedule Mometasone from Schedule 4 to Schedule 3 in preparations for topical use containing 0.1 percent or less of mometasone in packs containing 30 g or less of the preparation when labelled for the treatment of adults and children 12 years and over.

I have been an eczema sufferer all my life and have found mometasone to be invaluable in helping me control my skin condition. But unlike the medications that I use for my asthma and hay fever, every time I need a new tube of mometasone I have to go to the doctor for a prescription. Given that I know and understand my eczema and know what I need to treat it, the fact that I have to continually go to the doctor to get a prescription is a waste of my time and money, the doctor's time and the government's money.

I now have two small children which make a visit to the doctor even more difficult. If I could just go to the pharmacy to get the medication for my eczema it would be a great relief both time wise and financially.

I fully support mometasone for topical use being available as schedule 3. Pharmacists are excellently trained healthcare professionals who would know how to handle mometasone, and having it available without prescription would save consumers like myself time and money, while also providing easier access to medicines that can help our eczema. I would have no hesitation in talking to the pharmacist about the treatment or about any problems if I ever had any although having used this product for many years I know to stop using it when my eczema settles down.

Making mometasone schedule 3 would be a very positive move.

Yours sincerely,

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