THE AUSTRALASIAN COLLEGE OF DERMATOLOGISTS

Therapeutic Goods Administration

Consultation on the proposed amendments to the Poisons Standard referred to the Advisory Committee on Medicines Scheduling (ACMS #29): Adapalene

Submission of the Australasian College of Dermatologists

January 2020

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 550 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 dermatological practice.

Executive summary

The Therapeutic Goods Administration (TGA) has called for public submissions on scheduling proposals referred to the March 2020 meeting of the Advisory Committee on Medicines Scheduling (ACMS #29). The ACD welcomes the opportunity to put forward this submission on the proposed amendments to scheduling of adapalene, a third-generation topical retinoid used in the treatment of acne and off-label to treat keratosis pilaris as well as other skin conditions.

In summary, the College does *not* support the proposed rescheduling to remove the prescription only requirement for adapalene.

Adapalene

Adapalene is a retinoid currently listed in Schedules 4, Appendix F, Part 3 and Appendix L, Part 2 of the Poisons Standard. Under Schedule 4, adapalene is for topical use carrying warning statements not to use if pregnant and may cause birth defects. Oral and topical retinoids and synthetic retinoids are referred to under Schedule 4, with the oral preparation carrying the additional warning not to become pregnant during use or within a set period of stopping treatment.

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

Schedule 4 - Amend Entry

ADAPALANE **except** when included in Schedule 3.

Schedule 3 - New Entry

ADAPALANE in preparations for human external therapeutic use or human therapeutic or cosmetic use containing 0.1 per cent or less of adapalene.

Appendix H - New Entry

ADAPALANE

Appendix M - New Entry

ADAPALENE - The pharmacist will record the supply of this medicine in their dispensary software, and include the patient's name, address, date of birth and gender. The pharmacist will label product with patient's name and directions for use and date of supply. The pharmacist will verify that the patient is not intending to become pregnant, is pregnant or is breastfeeding. The pharmacist will upload a record of supply to the patient's My Health Record.

College response

The College agrees that the psychosocial aspects of skin conditions such as acne are indeed significant and early diagnosis is critical.

However, the College does not agree that providing over-the-counter access to adapalene provides a safe and effective solution for consumers. Rather patients' needs are best met by ensuring an accurate diagnosis is made by a medical practitioner, a tailored treatment plan put in place and treatment response monitored.

The College's concerns relating to the OTC availability of adapalene are as follows:

Adverse effects

- Adapalene is a known skin irritant, is difficult to use correctly, and requires significant counselling and management to use properly. As with many agents used in skin disease management, adverse effects when used incorrectly can occur and knowledge of correct usage is important. 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. In the view of the College, pharmacists should not be put in a position to advise on the use of these agents without a medical diagnosis and where adverse effects cannot be adequately monitored.
- As noted in the application, there is some controversy regarding teratogenic effects and these will inevitably pose a litigation risk, considering the background incidence of congenital deformity. If adapalene is downlisted to S3 there is likely to be a significant increase in usage which may increase the likelihood of this event.

Accurate diagnosis

- The College recognises that pharmacists' assessment of symptoms and subsequent treatment recommendations have a valuable place in healthcare, and use of many medicines in the context of pharmacist-only usage advice can be safe and effective for many minor and acute skin conditions. However, the College disagrees with the applicant's assertion that acne is a condition that can be diagnosed by a consumer with advice from their pharmacist, or indeed by the pharmacist themselves. While highly prevalent, acne can be confused with other skin conditions and can be a complex chronic disease requiring clinical management.
- Medical diagnosis is required to distinguish between acne and other skin conditions such as papular rosacea. Pharmacists are not trained to distinguish between these conditions and in the event of misdiagnosis, use of adapalene for a condition, such as papular rosacea, may induce significant aggravation. There may also be a need to examine other areas of the body such as the back and chest and the pharmacy setting is not an appropriate setting to do so.

Downstream effects for patient access

- The College also has some concerns for a potential downstream effect on the PBS status of combination adapalene / benzoyl peroxide. Acne can be an expensive condition to control, and for patients with limited budgets such as Health Care Card holders, the PBS is important in supporting access and must be maintained.

Adverse events arising from increased use for cosmetic purposes

- Adapalene is cosmetically active as an anti-aging agent which is currently likely to be the most common indication for off-label topical retinoids. Down-scheduling, and the inclusion of 'cosmetic use', is more likely to drive a skewed uptake of this agent for cosmetic purposes rather than for medicinal treatment of acne. In the absence of clinical expertise, this may result in poor management and an increase in adverse events as previously described.

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