Therapeutic Goods Administration

Consultation on the proposed amendments to the Poisons Standard referred to the Advisory Committee on Medicines Scheduling (ACMS #27): Finasteride, Sanguarine, 1,4-dimethylpentylamine, and Phenpromethamine

Submission of the Australasian College of Dermatologists

About the ACD:
The Australasian College of Dermatologists (ACD) is the peak medical college accredited by the Australian Medical Council for the training and professional development of medical practitioners in the speciality of Dermatology. The ACD has a national membership of approximately 500 practising specialist dermatologists and 100 trainees across Australia.

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 June 2019 meeting of the Advisory Committee on Medicines Scheduling (ACMS #27). Proposed amendments for scheduling advice to the ACMS:

- Finasteride: amended Schedule 4 entry and new Schedule 3 entry
- Sanguinarine: new Schedule 10 entry
- 1,4-dimethylpentylamine (DMPA): new Schedule 10 entry (Not addressed in this submission)
- Phenpromethamine: new Schedule 10 entry (Not addressed in this submission)

ACD position:

- ACD does not agree with the rescheduling of finasteride
- ACD strongly agrees with the scheduling of sanguinarine as a Schedule 10 entry

Rationale:
Finasteride: *ACD does not agree with the rescheduling of finasteride*
Finasteride is currently listed in Schedule 4 of the Poisons Standard. The applicant has proposed an amendment to the Schedule 4 entry and a new Schedule 3 entry.

The College does not agree with the proposed rescheduling of finasteride to a Schedule 3 entry. The ACD strongly supports retaining finasteride as a Schedule 4 entry. The ACD is concerned that this suggestion has been proposed without a thorough investigation and discussion to support the

proposal. The ACD has a number of concerns relating to finasteride as a Schedule 3 entry. These are outlined below.

1. Post Finasteride Syndrome (PFS)

PFS is a disease that has been reported to occur in some male patients who have taken finasteride. Reports of symptoms include sexual[1], physical and neurological symptoms[2] that may persist after the patient has stopped taking finasteride. Patients should be informed of the risks of taking finasteride prior to treatment initiation and associated symptoms should be discussed prior to treatment.

There are a limited number of robust and high quality studies that specifically address the issue of PFS, thus uncertainly about the legitimacy of this syndrome remains. Nevertheless, it is critical that there is awareness around the potential impact on patients previously using finasteride, such as PFS. Any rescheduling of finasteride to a Schedule 3 entry needs to consider this.

The applicant's proposal for finasteride to be a Schedule 3 entry does not sufficiently address this concern. Furthermore discussion of sexual function in a retail pharmacy setting may be considered inappropriate for many patients.

2. Consumer risks

Finasteride treatment for Androgenetic Alopecia is a lifelong commitment and requires discussion with a medical professional prior to commencement of treatment. Furthermore, many young males with early hair loss have significant associated psychological issues and require holistic medical care. There are numbers within this group who are dysmorphic and incorrectly believe that they have Androgenetic Alopecia. Increasing the availability of finasteride without oversight of a medical practitioner may lead to inappropriate and unnecessary usage of this medication.

In addition, the use of finasteride in older males could result in changes to Prostate-Specific Antigen (PSA) levels. Given the controversy around PSA as a marker for prostate cancer, medical management of this and other potential side-effects, taking into account other conditions or co-morbidities, is essential.

[1] Giatti, S., Diviccaro, S., Panzica, G., Melcangi, RC. *Post-finasteride syndrome and post-SSRI sexual dysfunction: two sides of the same coin?* Endocrine. 2018 Aug; 61(2):180-193

[2] Further information available via *MedSafe: New Zealand Medicines and Medical Devices Safety Authority*: https://medsafe.govt.nz/profs/PUArticles/March2016/PostFinasterideSyndrome.htm

3. Increased risk of litigation for Pharmacists

Rescheduling finasteride could expose Pharmacists to a significant risk of litigation should it be prescribed incorrectly. This would be difficult for Pharmacists to defend in the absence of a documented full consultation.

Sanguinarine: *ACD strongly agrees with the scheduling of sanguinarine as a Schedule 10 entry*

There is currently no listing for sanguinarine in the Poisons Standards. The ACD agrees that sanguinarine should be listed as a Schedule 10 poison.

Sanguinarine is a benzophenanthridine alkaloid extracted from the herbaceous plant Sanguinaria Canadensis, also known as black salve. Although there are a number of in vitro studies demonstrating the apoptotic and anti-proliferative effects of sanguinarine, clinical evidence for its efficiency as a treatment for skin cancer is lacking. Similarly, the risks and full side effect profile of its use in humans have not been determined.

The production and manufacture of black salve as a treatment for skin cancer is unregulated[3]. Due to increasing use and accessibility of the internet, consumers are provided with greater opportunities to access non-evidence based information about diseases and remedies more readily. There are sites marketing black salve with claims that have not been scientifically tested of curing skin cancer, amongst other cancer types[4]. This presents a significant risk to self-treating patients, particularly those with low health literacy or those more vulnerable to this type of information.

There are a number of cases documented in the literature where the use of black salve has had detrimental outcomes for patients, including:

- "The tumour appeared initially to disappear but recurred several years later requiring extensive surgery. The patient later developed metastasis (secondary growth).
- Residual tumour found on biopsy although it appeared initially to have gone.
- Severe scarring"[5]

Given the lack of evidence of clinical efficacy, as well as the substantial risks to consumer safety associated with its use, ACD strongly supports the inclusion of this substance as a Schedule 10 poison.

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[3] McDaniel, S., Goldman, GD. *Consequences of using escharotic agents as primary treatment for nonmelanoma skin cancer.* Arch Dermmatol. 2002 Dec; 138(12): 1593 – 6

[4] Lim, A. *Black salve treatment of skin cancer: a review*. J Dermatolo Treat. 2018 Jun; 29(4): 338 - 392

[5] DermNet NZ 2005, accessed 9th May 2019, <https://www.dermnetnz.org/topics/escharotic-agents/>