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16 October 2019

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email: Medicines.Scheduling@tga.gov.au

Dear Sir/Madam,

Re: Proposed amendments to the Poisons Standard - November 2019 Meetings

We refer to the notice inviting comment under subsection 42ZCZK of the *Therapeutic Goods Regulations 1990* and would like to provide comment on the Delegate's invitation for public comment for proposed amendments to be considered at the November 2019 meeting of the ACMS.

The comments submitted below address matters raised in s.52E of the *Therapeutic Goods Act 1989*.

CHP Australia (Consumer Healthcare Products Australia) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. CHP Australia also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. CHP Australia would like to comment on Item 1.1 – Mometasone.

The comments are provided in a separate attachment.

CHP Australia appreciates the opportunity to provide public comment in relation to ACMS agenda.

As an industry representative, CHP Australia is a key stakeholder in scheduling matters and we are keen to provide further input as required. We look forward to the Delegate's interim decisions and greater detail on the final scheduling proposals.

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Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

Steve Scarff

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Item 1.1 - Mometasone

CHP Australia does not support the proposal in relation to mometasone as written.

While we support the proposed new Schedule 3 entry for mometasone, we remain concerned that the proposed amendment seeking to introduce a pack size limit of 200 actuations or less to the Schedule 2 entry for intranasal mometasone directly conflicts with recent decisions to remove actuation limits from other intranasal corticosteroids (so that they aligned with the current Schedule 2 mometasone entry).

Proposed new S3 and Appendix M entry for mometasone

CHP Australia supports the proposed new S3 entry and Appendix M entry for mometasone for dermal use containing 0.1% or less of mometasone in packs containing 15 g or less, for the following reasons:

- CHP Australia believes that mometasone for dermal use containing 0.1% or less of mometasone, in packs containing 15g or less, substantially meets the Schedule 3 scheduling factors.
- The medicine is substantially safe with pharmacist intervention – noting that pharmacists currently intervene in the supply of lower potency dermal corticosteroids, which have very similar precautions and contraindications to higher potency corticosteroids.
- The proposed 15g pack size is smaller than the 30g which is currently allowed for other dermal corticosteroids, e.g. hydrocortisone and clobetasone. This minimises risk associated with use over large areas of skin and means that consumers will need to present to their pharmacist or doctor for repeat supply if needed.
- CHP Australia believes that the proposed Appendix M entry significantly mitigates any risks of misuse or use for any conditions for which dermal mometasone may be contraindicated, e.g. infection, rosacea, perioral dermatitis. Consumers will only receive supply if they have been assessed by a doctor, received a formal diagnosis and been prescribed mometasone in the previous 6 months. These are quite restrictive conditions, meaning that a pharmacist will be required to refuse supply if there is any uncertainty regarding the patient's condition, and if they have not received a diagnosis and prescription in the past 6 months.
- We assume from the proposed wording of the Appendix M entry that pharmacists would need to ascertain (with evidence) that a particular patient or consumer has been diagnosed and received a prescription in the past 6 months, effectively meaning that they can only have this

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certainty if there is a dispensing record of previous supply of dermal mometasone within the previous 6 months.

- Pharmacists therefore will have little autonomy to provide a diagnosis and initial supply of dermal mometasone; this can only be done by a medical practitioner under the terms of the proposed Appendix M entry.

Proposed amendment to the S2 entry for mometasone

- CHP Australia does not support the proposed amendments to the S2 entry that seeks to introduce a pack size limit of 200 actuations for intranasal mometasone.
- CHP Australia questioned why this was introduced initially, as part of the item 1.5 (mometasone furoate) proposal in the agenda of the March 2019 meeting of the ACMS. There was no explanation for its inclusion as part of that invitation for public comment (and there is no explanation for its inclusion on the November agenda either).
- It should be noted that the update to the Poisons Standard dated 1 February 2019 removed the actuation limit of 200 actuations or less from the entry for budesonide in aqueous nasal sprays (see the Final Decision here: https://www.tga.gov.au/book-page/12-budesonide-0), on the basis that there was no actuation limit for other intranasal corticosteroids, i.e. mometasone.
- Similarly, a decision was made to remove the actuation limit for fluticasone, and this was included in the 1 October 2018 update to the Poisons Standard, (see the Final Decision here: https://www.tga.gov.au/book-page/13-fluticasone-0).
- Both decisions (for budesonide and fluticasone) and the corresponding updates to the Poisons Standard were made to align both of these intranasal corticosteroid entries with that of intranasal mometasone, which does not have an actuation limit.
- CHP Australia finds it very concerning that the Delegate is now seeking to include an actuation limit for mometasone, which directly contradicts the final decisions made in September 2018 and June 2018 and Poisons Standard updates of 1 October 2018 and 1 February 2019.
- When deciding to remove the actuation limit for fluticasone, the Delegate's interim decisions stated that "*There is no difference in the risks of the substance by allowing more doses per pack*[1]." Similarly, for budesonide, the Delegate stated that "*Removing the actuation limit will*

[1] https://www.tga.gov.au/book-page/13-fluticasone

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allow new larger pack sizes and provide a longer duration of treatment"; "*This change to the scheduling of budesonide in the Poisons Standard will align the Schedule 2 entry with other intranasal corticosteroids*" and "*Making budesonide available in a larger pack size is unlikely to impact the risk-benefit profile significantly*[2]".

- CHP Australia is very concerned that within the space of a year, two inconsistent scheduling decisions have been made. Consistent, non-arbitrary decision making is important for industry.
- CHP Australia requests removal of the actuation limit for intranasal mometasone as we do not believe that there ought to be a limit introduced for mometasone after it has already been decided that similar limits are not needed for other equivalent intranasal corticosteroids and after the Delegate had so recently determined that making budesonide available in a larger pack size was unlikely to impact the risk-benefit profile significantly.

[2] https://www.tga.gov.au/book-page/12-budesonide