Pharmaceutical Society of Australia

Consultation: Proposed amendments to the Poisons Standard - Advisory Committee on Medicines Scheduling meeting, March 2019

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Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission on proposed amendments to the Poisons Standard being referred for scheduling advice to the March 2019 meeting of the Advisory Committee on Medicines Scheduling (ACMS).

PSA's comments relate to proposed amendments to: glyceryl trinitrate, isosorbide dinitrate, cetirizine hydrochloride and mometasone furoate.

About PSA

PSA is the only Australian Government-recognised peak national professional pharmacy organisation representing all of Australia's 31,000 pharmacists working in all sectors and across all locations.

PSA is committed to supporting pharmacists in helping Australians to access quality, safe, equitable, efficient and effective health care. PSA believes the expertise of pharmacists can be better utilised to address the health care needs of all Australians.

PSA works to identify, unlock and advance opportunities for pharmacists to realise their full potential, to be appropriately recognised and fairly remunerated.

PSA has a strong and engaged membership base that provides high-quality health care and are the custodians for safe and effective medicine use for the Australian community.

PSA leads and supports innovative and evidence-based healthcare service delivery by pharmacists. PSA provides high-quality practitioner development and practice support to pharmacists and is the custodian of the professional practice standards and guidelines to ensure quality and integrity in the practice of pharmacy.

Summary of PSA's position

Glyceryl trinitrate and isosorbide dinitrate *– PSA supports the proposal to amend Appendix H of the Poisons Standard to include glyceryl trinitrate and isosorbide dinitrate. PSA believes it is in the public interest to be able to increase awareness of the availability of these substances which are considered to be emergency / rescue medicines.*

Cetirizine hydrochloride *– PSA is opposed to the proposal to increase the pack size limit for cetirizine which is exempt from inclusion in Schedule 2.*

Mometasone furoate *– PSA does not object to the inclusion of mometasone for dermal use containing 0.1 percent or less in packs containing 15g or less in Schedule 3 but requests additional information in relation to appropriate Appendix M criteria.*

Comments on specific substances

Glyceryl trinitrate and isosorbide dinitrate

PSA provided comments previously through the public consultation on the proposal to include substances in Appendix H of the Poisons Standard. PSA understands that following consideration of those submissions, glyceryl trinitrate and isosorbide dinitrate were referred to the ACMS for further advice prior to the final decision being made.

While noting there are pros and cons to permitting advertising, on balance, PSA supported inclusion of both substances in Appendix H as being in the public interest.

Glyceryl trinitrate and isosorbide dinitrate are considered to be emergency / rescue medicines for serious health conditions. In the earlier submission, PSA commented that the benefits of inclusion of these substances in Appendix H primarily relate to facilitating access to these substances through increased awareness by those who may need them. PSA's main points were captured in the outcomes of the consultation published by the TGA relating to glyceryl trinitrate, viz.:

> *DTC advertising of this substance would increase awareness of the availability of this substance in an emergency / rescue situation.*

The published outcomes also cited the need for prior approval to use a *restricted representation* in advertising glyceryl trinitrate.

> *The use of restricted representation approval would strengthen the suitability of advertisements for glyceryl trinitrate.*

PSA re-iterates its support for the inclusion of glyceryl trinitrate and isosorbide dinitrate in Appendix H of the Poisons Standard.

Cetirizine hydrochloride

PSA understands the proposal seeks to amend the current exemption from Schedule 2 of cetirizine for oral use in divided preparations by increasing the primary pack size limit. If approved, this would result in packs containing not more than 20 days' supply to be unscheduled i.e. an increase from the current exemption limit of "not more than 10 days' supply". The requirement to label with a "recommended daily dose not exceeding 10 mg of cetirizine" would remain unchanged.

The reasons cited include that the proposal is consistent with the broader and less restrictive availability of similar cetirizine products in other countries (or "like major markets"), and that "the benefits are consumer focused".

There are several concerns that PSA would like to raise regarding the proposal, for ACMS's consideration.

- It is well regarded that the network of Australia's community pharmacies provides health consumers with convenient and timely access to pharmacists and medicines, both from a geographical perspective as well as the hours of their availability. In many locations, and in particular rural and remote areas, pharmacies are regarded as the pillar or hub of the community; sometimes a pharmacist is the only health professional in town. PSA would therefore contend that the benefits in the rescheduling proposal of "convenience, utility and affordability especially for those Australians that have reduced access to pharmacy for work or geographical reasons" are overstated.

- The rescheduling proposal cites that the risks associated with 20-day packs of cetirizine being unscheduled "are no different to that of the smaller pack sizes and multiple buys of smaller sizes". Pharmacists have a duty of care to consider the health and wellbeing of the patient as their first priority. Pharmacists promote the safe and judicious use of medicines, and this includes the provision of appropriate medicines and advice in accordance with the established reasonable therapeutic need of the patient. In the context of the quality use of medicines (QUM) policy, PSA believes it would not be appropriate for a scheduling decision to be partly or solely based on a comparison of the potential risks of a large pack size product to that of "multiple buys" of smaller pack sizes.

- Although cetirizine has a good safety profile, it is known to possess the highest sedation potential within the 'oral less sedating antihistamines' class which includes fexofenadine, loratadine and desloratadine.[1] PSA believes that this factor provides a reason to retain the proposed larger pack size cetirizine products to be available from a pharmacy setting. This arrangement will provide the opportunity for patients to have access to the advice of a pharmacist, if necessary, when the use of cetirizine is being considered.

- The use of cetirizine during pregnancy, although likely to be safe, is not recommended[2] as it does not have the same evidence of safety as sedating antihistamines based on history of use. Once again, access to health and medicine advice is available from a pharmacy at the point of decision making about medicine use.

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1 Sansom LN, ed. Australian pharmaceutical formulary and handbook. 24th edn. p. 552. Canberra: Pharmaceutical Society of Australia; 2018.

2 Randall KL, Hawkins CA. Antihistamines and allergy. Aust Prescr 2018; 41:42–5.

On balance, PSA is opposed to the proposal to increase the pack size limit of cetirizine which is exempt from inclusion in Schedule 2.

Mometasone furoate

PSA notes that the proposal to reschedule mometasone furoate for dermal use containing 0.1 percent or less in packs containing 15g or less to Schedule 3 is based around its efficacy and side effect profile, and inclusion of appropriate labelling as well as mandated pharmacist advice (as suggested by the proposed inclusion in Appendix M).

PSA does not object to this proposal but requests additional information in relation to what criteria are proposed for inclusion in Appendix M.

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