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Consultation: Proposed amendments to the Poisons Standard - Advisory Committee on Medicines Scheduling meeting, June 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 November 2019 meeting of the Advisory Committee on Medicines Scheduling (ACMS).

PSA's comments relate to proposed amendments to paracetamol, hyoscine butylbromide, calcifediol monohydrate, lidocaine, and paracetamol and ibuprofen.

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.

[redacted]

Recommendations

Paracetamol *– PSA seeks clarification of the proposed amendments for paracetamol liquid preparations, noting that the proposed limits on concentration, total volume and total mass per container do not appear to be mathematically logical or feasible.*

Hyoscine butylbromide *– PSA supports the inclusion of liquid oral preparations of hyoscine butylbromide with a recommended single dose not exceeding 20 mg of hyoscine butylbromide in a pack containing 100 mg or less of hyoscine butylbromide in Schedule 3 but not in Schedule 2.*

Calcifediol monohydrate *– PSA supports the proposal to create a new entry in Schedule 4 for calcifediol monohydrate for human internal therapeutic use except in preparations containing 10 micrograms or less of calcifediol monohydrate per recommended daily dose.*

Lidocaine *– PSA does not support the proposed amendment to the Schedule 2 entry of lidocaine which would exempt from scheduling lidocaine in aqueous sprays for oromucosal use containing 0.6 per cent or less of total local anaesthetic substances.*

Paracetamol and ibuprofen *– PSA does not support the proposed amendment to the scheduling of paracetamol in combination with ibuprofen. Given the ongoing efforts of regulatory reform of paracetamol-containing products, PSA suggests consideration of further reforms of the lower risk range of paracetamol products is urgently needed.*

Comments on proposed amendments

1.1 Paracetamol

The main change in the current proposal to amend the Schedule 4 (S4) and Schedule 2 (S2) entries of paracetamol in the Poisons Standard is the inclusion of the following in S2:

> *…liquid preparations for oral use containing no greater than 50 mg per mL of paracetamol in 100 mL with a maximum of 50 g paracetamol per container…*

Unfortunately PSA found this proposal to be ambiguous for the following reasons:

- The wording suggests the upper limits in concentration, total volume and total mass per container must all be met (i.e. not exceeded).
- If the limits in concentration (50 mg per mL) and volume (100 mL) are both met, stipulation of the third criterion of ‘a maximum of 50 g per container’ seems somewhat illogical (although it would be fulfilled).
- If the upper limit in concentration for S2 is 50 mg per mL, products currently available as ‘infant drops’ which typically contain 100 mg per mL will move to S4. The reason for such an amendment is not clear and, more importantly, is concerning as it would have a very significant impact on consumers, pharmacists, sponsors and the health system.

- If the upper limit in volume for S2 is 100 mL, commonly available larger bottles of paediatric liquid products (e.g. 200 mL) will become S4. These products are used not only by families with multiple children (cost considerations) but also by adults/people with disabilities or with swallowing difficulties. These vulnerable people would be disadvantaged if a prescription is required for the larger volume products. PSA would therefore suggest that, if any change is to be made based on the volume of the liquid formulations, it would be more appropriate to reschedule the larger packs to Schedule 3 and retain the 100 mL bottles in S2.

Thus, PSA seeks clarification of the proposed amendments for paracetamol liquid preparations, noting that the proposed limits on concentration, total volume and total mass per container do not appear to be mathematically logical or feasible.

1.2 Hyoscine butylbromide

Hyoscine butylbromide is indicated for the treatment of spasms of the gastrointestinal tract, biliary spasm and renal spasm and as a diagnostic aid in radiology.

Hyoscine butylbromide is currently listed in Schedule 2 (S2) of the Poisons Standard:

> *…as the only therapeutically active substance, in divided preparations for oral use, containing 20 mg or less of hyoscine butylbromide per dosage unit in a pack containing 200 mg or less of hyoscine butylbromide.*

The proposed amendment is to add the following to the current S2 entry:

> *…in undivided preparations for oral use with a recommended single dose not exceeding 20 mg of hyoscine butylbromide in a pack containing 100 mg or less of hyoscine butylbromide.*

The rationale for this proposal appears to be to harmonise the scheduling of different dose forms (oral tablet and liquid) of hyoscine butylbromide containing equivalent amounts per dose unit as well as in the entire pack.

With regards to hyoscine butylbromide in liquid preparations, PSA notes the following:

- In New Zealand, hyoscine butylbromide in the forms and amounts equivalent to S2 in Australia are classified as Restricted. While there were not major concerns about the inherent safety of the substance, the scheduling of hyoscine butylbromide across the two countries was not harmonised in 2005 as the New Zealand regulator was concerned about "the very broad indication for abdominal pain" and felt "there should be an opportunity to refer consumers to a medical practitioner if they were suffering from abdominal pain".[1]

- Due to its physicochemical characteristics, hyoscine butylbromide cannot readily cross the blood-brain barrier and is therefore associated with a lower frequency of central nervous

[1] New Zealand Medicines and Medical Devices Safety Authority (Medsafe). Minutes of the 33rd meeting of the Medicines Classification Committee. 9 Jun 2005. At: **https://www.medsafe.govt.nz/profs/class/Minutes/2001-2005/mccMin9June2005.htm**

system side effects. Nevertheless there are reported cases[2,3] of intentional misuse of hyoscine butylbromide (in tablet form), through crushing and smoking, reportedly for its hallucinogenic effects. The Product Information for a registered product of hyoscine butylbromide also states that it may cause drowsiness.[4] The liquid form may be considered a more convenient option by those who intentionally misuse the product.

- PSA agrees with the suggestion that oral liquid dose form of hyoscine butylbromide may be of benefit for paediatric and elderly patients, or other patient groups with dysphagia and difficulty swallowing the tablet formulation. These are regarded as more vulnerable population groups where the risk of adverse effects is higher and professional intervention would be beneficial to ensure patient safety and quality use of medicines.

All of the above indicate a preference for pharmacist oversight in the handling and provision of liquid preparations of hyoscine butylbromide. Therefore, PSA believes liquid oral preparations of hyoscine butylbromide with a recommended single dose not exceeding 20 mg of hyoscine butylbromide in a pack containing 100 mg or less of hyoscine butylbromide should be included in Schedule 3 rather than S2.

1.3 Calcifediol monohydrate

While calcifediol monohydrate, as a derivative of vitamin D, is covered by existing entries for vitamin D in the Poisons Standard, PSA understands the rationale for creating a specific entry as follows:

- Calcifediol monohydrate provides the same health benefits as colecalciferol, therefore it is reasonable to be similarly included in Schedule 4 (S4).

- Given the potency of calcifediol monohydrate has been identified to be approximately three times greater than colecalciferol, a lower limit of 10 micrograms (compared to the 25 micrograms for colecalciferol) to be applied to the S4 entry seems appropriate.

Therefore PSA supports the proposal to create a new entry in S4 for calcifediol monohydrate for human internal therapeutic use except in preparations containing 10 micrograms or less of calcifediol monohydrate per recommended daily dose.

1.4 Lidocaine

The proposed amendment to the Schedule 2 (S2) entry of lidocaine would result in 0.6 per cent throat sprays being exempted from scheduling. Throat lozenges containing 2 per cent or less of lidocaine are currently exempt from scheduling and available through non-pharmacy outlets.

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[2] Public Health England. Misuse of hyoscine butylbromide [redacted]) [letter]. 25 Jun 2015. At: https://medicines.necsu.nhs.uk/wp-content/uploads/2015/07/MisuseXofXhyoscineXbutylbromideXletterXV5XFinal.pdf

[3] Jalali F, Afshari R, Babaei A. Smoking crushed hyoscine/scopolamine tablets as drug abuse. Subst Use Misuse 2014;49(7):797–7.

[4] Australian Product Information – [redacted] (hyoscine butylbromide). 19 Sep 2018.

The following issues have been considered by PSA:

- PSA understands consumers may prefer to have a choice of dose forms available when self-selecting a therapeutic product for the relief of minor mouth and throat infections and sore throats. However, PSA does not believe it is appropriate to have the sprays available from a location where professional advice is not available at the time a therapeutic choice is made.

- The use of lidocaine in throat sprays warrant additional vigilance because inadvertent misuse or overuse of topical lidocaine by the general population or use by people with methaemoglobinaemia even at commonly accepted doses can have significant negative outcomes.

- Throat sprays could also be regarded to be more susceptible to unintentional misuse or overuse because of the ease of administration of multiple doses.

- This proposal does not affect consumer access to lidocaine therapy from a non-pharmacy outlet through the continued availability of the lozenge form.

- Safe and timely access to medicines is important for consumers. However, PSA does not agree that a medicine should be deregulated on the basis that people will be able to choose between different dose forms "without having to visit a pharmacy".

Therefore, on balance, PSA does not support the proposed amendment to the S2 entry of lidocaine.

1.5 Paracetamol and ibuprofen

PSA understands the amendments in this proposal would, in effect, result in a sequence of controls on medicines containing a combination of paracetamol and ibuprofen as follows:

Pack size	Schedule
12 dosage units or less	Exempt from scheduling
13 to 30 dosage units or less	Pharmacy Medicine (Schedule 2)
31 to 50 dosage units or less	Pharmacist Only Medicine (Schedule 3)
Greater than 50 dosage units	Prescription Only Medicine (Schedule 4)

PSA recalls that a proposal to amend the Schedule 3 (S3) entry for paracetamol, when combined with ibuprofen, was considered in 2018. The proposal sought to allow the S3 pack size to be increased from 30 dosage units (equivalent to 10 days' supply) to 50 dosage units (17 days' supply). The delegate's final decision published in November 2018 was to not amend the Poisons Standard on the basis that the perceived benefits of larger pack sizes from a convenience perspective were outweighed by the risks.[5]

[5] Therapeutic Goods Administration. Final decisions amending, or not amending, the current Poisons Standard, November 2018. 29 Nov 2018. At: https://www.tga.gov.au/sites/default/files/final-decisions-amending-or-not-amending-current-poisons-standard-november-2018.pdf

PSA agrees with the assessment that consumers should only have access to clinically appropriate quantities and that:

- the 30 pack size is adequate for the treatment of acute short-term pain, consistent with the approved S3 indication

- a larger (50) pack size may encourage treatment of chronic pain – this may delay consumers from seeking further health professional advice (and possible delayed diagnosis of a chronic condition), and can also increase the likelihood of misadventure and risk of toxicity in case of overdose.

PSA supports the various clinical review and regulatory reform measures being implemented in relation to paracetamol to improve public health and patient safety. PSA is not aware of any new evidence that would support the amendments being sought through the current proposal.

Although both paracetamol and ibuprofen have a long history of safe and effective use for self-limiting pain, analgesics generally and paracetamol in particular have been the subject of significant regulatory reforms to ensure their continued therapeutic availability but with less associated risk of inadvertent harm. The recent decision to reschedule modified release paracetamol to S3 is an example of TGA reforms being implemented around higher risk products. However, PSA believes these actions need to be accompanied by ongoing reforms to appropriately address lower risk products.

To this end, PSA suggests once again that the ACMS should consider amending the Poisons Standard to include paracetamol currently exempted from scheduling in Schedule 2.

- Widespread availability of paracetamol in various forms and brands from unregulated retail outlets compounds the possibility of duplication of therapy, ingestion of doses above recommended range or use over extended periods, through lack of understanding or confusion. There is no data collected on these types of incidents unless they result in a significant outcome such as a hospital admission. Anecdotally, for example, pharmacists are all too familiar with requests for paracetamol-containing analgesics or ‘cold and flu’ products by consumers who are “not taking any other medicines, just the lemon drink” i.e. [redacted].

- Although reduced maximum pack size of unscheduled paracetamol was implemented in Australia in 2013, there is no legal restriction on the number of packs that may be purchased in one transaction from non-pharmacy retail outlets, nor the means to generally monitor frequency of purchase. Anecdotally, some retail outlets do limit the ability to purchase multiple packs of paracetamol-containing medicines – but these are generally ad hoc policies, not an approach that is appropriate for a nationally significant issue such as medicine safety.

- PSA is aware there is some indication of a lower rate of paracetamol-related enquiries to Poisons Information Centres in some European countries where paracetamol was not available in non-pharmacy outlets. Unfortunately, however, the evidence does not appear to be definitive.

In summary, PSA does not support the proposed amendment to the scheduling of paracetamol in combination with ibuprofen. PSA suggests consideration of further reforms of the lower risk range of paracetamol-containing products is warranted.

Submitted by:

Pharmaceutical Society of Australia
PO Box 42
Deakin West ACT 2600
Tel: 02 6283 4777
www.psa.org.au

Contacts:

Shane Jackson, Chief Executive Officer

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