Pharmaceutical Society of Australia

Consultation: Proposed Schedule 3 substances to be added to Appendix H of the Poisons Standard

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Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission to the Therapeutic Goods Administration (TGA) on the proposed Schedule 3 (S3) substances to be added to Appendix H of the Poisons Standard to allow them to be advertised direct to consumers.

About PSA

PSA is the peak national professional pharmacy organisation representing Australia's 31,000 pharmacists[1] working in all sectors and locations.

PSA's core functions include:

- providing high quality continuing professional development, education and practice support to pharmacists
- developing and advocating standards and guidelines to inform and enhance pharmacists' practice
- representing pharmacists' role as frontline health professionals.

PSA is also a registered training organisation and offers qualifications including certificate and diploma-level courses tailored for pharmacists, pharmacy assistants and interns.

[1] Pharmacy Board of Australia. Registrant data. Reporting period: 1 January 2018 – 31 March 2018. At: www.pharmacyboard.gov.au/About/Statistics.aspx

Comments on Appendix H substances list

PSA acknowledges that significant changes are being made by the TGA around reforms to advertising arrangements. PSA strongly supports important recent amendments such as:

- inclusion of a mandatory statement for all advertisements of S3 products: *Ask your pharmacist – they must decide if this product is right for you.*
- new requirement for advertising not to conflict with public health campaigns (e.g. sun protection campaigns, breast screening promotions, active living / weight loss messaging)
- revised warning statements (e.g. If symptoms persist, worsen or change unexpectedly see your healthcare professional) and additional warning statements for allergies and known side-effects.

In this consultation, PSA provides comments in the following areas:

- current Appendix H list
- proposed additions to Appendix H
- proposed exclusions from Appendix H
- identification of risks and benefits for selected substances.

Current Appendix H list

Following the outcome of the Sansom review, the TGA has proposed a revised approach for advertising of S3 substances, where the default position is that S3 medicines will be placed in Appendix H and permitted to be advertised unless advertising is considered to cause harm through its influence on the supply or use of those medicines.

PSA notes the following 19 (out of 85) S3 substances are currently listed in Appendix H: butoconazole, clotrimazole, diclofenac, dimenhydrinate (for the prevention and relief of motion sickness), diphenoxylate, econazole, esomeprazole, fluconazole, hydrocortisone, ibuprofen, lansoprazole, miconazole, naproxen, nystatin, omeprazole, pantoprazole, rabeprazole, ulipristal (for emergency post-coital contraception), vitamin D.

PSA notes that these substances are being considered by the TGA in bulk to remain in Appendix H. To this end:

- PSA agrees with the retention of these substances in Appendix H.
- PSA suggests that, in future, TGA should consider the ability to include classes of medicines in Appendix H where the safety profile of individual substances in that class can be considered to be equivalent (e.g. emergency post-coital contraception, proton pump inhibitors).

Justification codes and reasons

PSA notes the five categories of justification used in the consultation paper for exclusion of a substance from Appendix H. PSA proposes two additional criteria (labelled as PSA1 and PSA2) as listed here. These codes have been used below to explain PSA's position on specific substances.

Reference	Description
1a	Negative impact on public health due to potential misuse, abuse or diversion
1b	Negative impact on public health due to potential interactions (drug-drug, drug-food)
1c	Negative impact on public health due to additional risks associated with dosage form
1d	Negative impact on public health due to other specified factors (e.g. has sedating properties, or there are safer alternatives)
2	No longer a relevant ARTG entry / out dated substance
PSA1	Conflicts with effective and judicious medicine use principles
PSA2	Substance prone to off label use by consumers – advertising may exacerbate inappropriate use and have flow-on negative impact on public health

Proposed additions to Appendix H

In total, 24 substances are proposed to be added to Appendix H. PSA's view (with associated rationale) on the proposals is provided in the table.

Substance (*also in S2)	**PSA position + justification code**	**PSA's comment**
clobetasone	Agree	Addition to Appendix H would promote consistency with current inclusion of hydrocortisone.
famciclovir	Agree	Oral famciclovir for cold sores is of equal efficacy to non-scheduled topical products, with compliance benefit from single use and ease of administration. These non-scheduled products have a long history of being advertised responsibly.
ketoprofen	Agree	Addition to Appendix H addresses inconsistency of other non-steroidal anti-inflammatory drugs being able to be advertised (e.g. diclofenac, ibuprofen).
levonorgestrel	Agree	Addition to Appendix H addresses inconsistency with ulipristal for the same indication and adverse effect profile being listed in Appendix H. See also PSA's comment under the section titled "Identification of risks and benefits for selected substances".
paracetamol*	Agree	Addition to Appendix H addresses inconsistency that small packs of paracetamol and ibuprofen combination analgesics can be advertised, where larger packs currently cannot be advertised. There appears to be no public health justification for this current restriction.

Substance (*also in S2)	**PSA position + justification code**	**PSA's comment**
chloramphenicol	Disagree 1a PSA1 PSA2	PSA considers the proposal to add to Appendix H is not in the public interest as: • Consumers currently pressure pharmacists to supply off-label and outside of scheduling restriction (ophthalmic use only). This is likely to be exacerbated by advertising. • Two thirds of cases self-resolve.[2] • Differential diagnosis is difficult,[3] and advertising may promote greater self-diagnosis by consumers. The following cases have been reported by pharmacists: ***Case example 1*** Parent requests chloramphenicol eye drops for a child less than 6 months of age who is not present in the pharmacy. Following taking a brief history, the pharmacist declines supply and refers the customer to a doctor for further investigation. Pharmacist explains this is outside of the approved indication for S3 chloramphenicol and professional practice protocols which recognise additional difficulty in differential diagnosis of ocular conditions in infants. Parent becomes upset and abusive that the child will not be able to attend child-care without the drops and leave the pharmacy angry and dissatisfied. ***Case example 2*** Mother requests chloramphenicol eye ointment stating she was advised to purchase 'over the counter' without a prescription to treat a bacterial infection in a child's nose. Consumer dissatisfied with refusal of pharmacy to supply outside of scheduled indication of ophthalmic use. ***Case example 3*** Adult presents at dispensary counter requesting chloramphenicol for their pet dog, citing a verbal recommendation from a veterinarian that it was available in the pharmacy without a prescription. Adult becomes angry when supply is declined by the pharmacist citing S3 medicines can only be supplied for human ophthalmic use without a prescription.

[2] Sansom LN ed. Australian pharmaceutical formulary and handbook. 24th edn. Canberra: Pharmaceutical Society of Australia; 2018.

[3] Eye infections. In: eTG complete. Melbourne: Therapeutic Guidelines; 2018.

Substance (*also in S2)	**PSA position + justification code**	**PSA's comment**
metoclopramide (for nausea associated with migraine)	Disagree PSA2	PSA considers this proposal to add to Appendix H is not in the public interest as: • Consumers currently pressure pharmacists to supply off-label and outside of scheduling restriction (nausea associated with migraine use only). This is likely to be exacerbated by advertising. The following is an example of cases reported by pharmacists: ***Case example 1*** Consumer enters pharmacy requesting a product for vomiting. The pharmacist, after taking a brief history, excludes serious pathophysiology and recommends rest and oral rehydration. Consumer dissatisfied with interaction and requests a combination S3 product containing metoclopramide. Upon being advised by the pharmacist that the product cannot be supplied for conditions other than migraine induced nausea the consumer becomes abusive.
adrenaline	Agree	See PSA's comment under the section titled "Identification of risks and benefits for selected substances".
glyceryl trinitrate, isosorbide dinitrate	Agree	See PSA's comment under the section titled "Identification of risks and benefits for selected substances".
glucagon	Agree	See PSA's comment under the section titled "Identification of risks and benefits for selected substances".
naloxone	Agree	See PSA's comment under the section titled "Identification of risks and benefits for selected substances".
salbutamol, terbutaline	Agree	See PSA's comment under the section titled "Identification of risks and benefits for selected substances".
ciclopirox*	Nil comment.	
fluorides*	Nil comment.	
isoconazole*, oxiconazole*, tioconazole*	Nil comment.	
podophyllotoxin*, podophyllum emodi (podophyllin)*, podophyllum peltatum (podophyllin)*	Nil comment.	
salicylic acid	Nil comment.	
triamcinolone*	Nil comment.	

Proposed exclusions from Appendix H

The following 42 substances are proposed for exclusion from Appendix H (i.e. not suitable for advertising). PSA's view (with associated rationale) on the proposals to continue to exclude these substances from Appendix H is provided in the table.

Substance	Justification code	PSA's comment (with justification code, where relevant)
alimemazine	1d – sedating, 2	Nil comment.
aminophylline theophylline	1c, 1d – safer alternatives, 2 1d – safer alternatives, 2	Agree (as per TGA rationale).
azatadine, brompheniramine, chlorphenamine (chlorpheniramine), clemastine, mepyramine, methdilazine	1d – sedating, 2	Agree (as per TGA rationale and PSA2). • Context of justification code PSA2: consumers sometimes place undue pressure on pharmacists to supply sedating antihistamines outside of scheduling restrictions, particularly in relation to age and cough / cold symptoms. This would likely be exacerbated through mass media advertising.
buclizine	2	
dexchlorphenamine (dexchlorpheniramine), diphenhydramine, doxylamine, pheniramine, promethazine	1d – sedating	
triprolidine	1d – safer alternatives, 2	
chlorbutanol	1a, 2	Nil comment.
cimetidine	1b, 1d – sedating, 2	Nil comment.
cyclizine prochlorperazine	1a, 1b, 2 1a	Agree (as per TGA rationale and PSA2). See also comments relating to metoclopramide.
cyproheptadine	1d – sedating	Nil comment.
dihydrocodeine	1a	Agree (1a, PSA2). • Opioid analogue – risk of abuse and misuse. • Consumers often place pressure on pharmacists to supply.
dithranol	1d – safer alternatives	Nil comment.
macrogols	1a	Nil comment.
magnesium sulfate	1a	Nil comment.

Substance	Justification code	PSA's comment (with justification code, where relevant)
malathion	1d – safer alternatives	Nil comment.
orlistat	1a	See PSA's comment under the section titled "Identification of risks and benefits for selected substances".
pseudoephedrine	1a	See PSA's comment under the section titled "Identification of risks and benefits for selected substances".
santonin	1d – safer alternatives, 2	Nil comment.
sodium phosphate, sodium picosulfate	1a	Nil comment.
sulfacetamide	2	Agree (PSA2). See also comments relating to chloramphenicol.
alclometasone, diiodohydroxyquinoline (iodoquinol), dimethindene, erythrityl tetranitrate, flavoxate, glycopyrronium, inositol nicotinate, mannityl hexanitrate, nicotinic acid, nicotinyl alcohol	2	Nil comment.

Identification of risks and benefits for selected substances

With regards to the following substances, PSA explored the risks and benefits in relation to the impact of compliant advertising on health consumers. PSA believes that further consultation on these substances may be beneficial.

Substance	PSA position	PSA comments
Current proposal to add to Appendix H • adrenaline (anaphylaxis) • glyceryl trinitrate, isosorbide dinitrate (angina) • glucagon (hypoglycaemia in Type 1 diabetes) • naloxone (opioid overdose) • salbutamol, terbutaline (asthma relief) • levonorgestrel (emergency contraception)	On balance, PSA supports inclusion of these substances in Appendix H as being in the public interest.	These substances are considered to be emergency / rescue medicines for serious health conditions. The conditions these products are used for are all *Restricted Representations.* This means the TGA must grant consent before any advertiser can refer to the benefits or use of the product in the advertising. The TGA can attach conditions to how the health condition is described or mentioned when granting consent. Without consent to use a *Restricted Representation*, advertising is limited to describing availability and instructions for product use (provided the health condition is not mentioned). Benefits of inclusion of these substances in Appendix H primarily relate to increasing access to these substances through increased awareness by those who may need them. For example: • Consumers who usually access medicines via prescription (e.g. PBS) can be made aware the medicines are available without a prescription via community pharmacy. • Pharmacies could place signage to alert to availability which may be useful in an emergency (e.g. anaphylaxis, overdose). • Health promotion could describe community pharmacy role in helping manage chronic conditions. Possible risks of advertising these substances may include: • *Normalise 'rescue therapy' rather than preventatives*: Should significant advertising activity relate to a particular 'rescue' medicine, there is potential to lead to sub-optimal patterns of medicine use. However, this is a concern sometimes expressed with regard to emergency oral contraceptives which is not borne out in evidence describing their pattern of use. • *Sponsor-produced comparative advertising* (e.g. comparing therapeutic characteristics of *Nitrolingual* pump spray vs *Anginine* sublingual tablets would not be in public interest as both products are effective in an emergency situation).

Substance	PSA position	PSA comments
Current proposal to exclude from Appendix H • orlistat	On balance, PSA considers the inclusion of orlistat in Appendix H as being in the public interest.	Inclusion of orlistat in Appendix H could increase awareness of this product proven to be effective in weight management. It is an interesting comparison that unscheduled weight management medicines are currently able to be advertised. Inclusion in Appendix H may be in the public interest as pharmacists would be able to communicate with consumers: • Relative benefits of orlistat compared with other non-prescription weight management products (subject to *Restricted Representations*). • Availability of orlistat, and the need to engage with the pharmacist prior to purchasing the product. This may need to be balanced against potential risks, including: • Risk of misuse by people outside of the product's indication (e.g. healthy BMI), although requirements of the *Therapeutic Goods Advertising Code 2018* and the essential professional role of a pharmacist in determining whether to supply the product mitigates this risk. *Other considerations:* • *Previous listing in Appendix H* We recognise orlistat previously had its Appendix H listing rescinded due to public concern with television advertising, particularly in relation to perceived potential impact on minors.[4] New requirements regarding weight loss advertising and public health messaging in the *Therapeutic Goods Advertising Code 2018* should appropriately manage these risks. • *Restricted representation* Obesity is a *Restricted Representation*, as are risk factors which support use in overweight BMI range (e.g. diabetes). Without consent to use these representations, the ability of pharmacists to communicate useful information online regarding the product's evidence base and role in weight management would be limited.

[4] 'Weight loss medication under review after outcry over ads', *The Sydney Morning Herald*, Sydney, 15 January 2007. At: **https://www.smh.com.au/news/national/weightloss-medication-under-review-after-outcry-over-ads/2007/01/15/1168709679201.html**

Substance	PSA position	PSA comments
Current proposal to exclude from Appendix H • pseudoephedrine	On balance, PSA's current view is the current exclusion of pseudoephedrine from Appendix H remains appropriate.	Some members have provided feedback identifying benefits of advertising pseudoephedrine which helps consumers be more aware of the availability and benefits of effective decongestant medicines for the management of cold and flu symptoms. PSA recognises the risk of diversion for illicit use and supports controls that limit the potential of pseudoephedrine for criminal diversion. To manage the issue of criminal diversion, a real-time monitoring systems exists to help identify unusual product requests. While available nationally, use of real-time monitoring for pseudoephedrine is only legally mandated in some states and territories. In the absence of this system being mandated, PSA is concerned inclusion in Appendix H may stimulate an increase in requests for pseudoephedrine without all pharmacists having access to a complete history of previous consumers requests. We therefore consider the current exclusion of pseudoephedrine from Appendix H remains appropriate.

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