Australian Government
Department of Health
Therapeutic Goods Administration

Consultation Paper: Substances proposed to be added to Appendix H of the Poisons Standard

Version 1.0, May 2018

TGA Health Safety Regulation

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submissions made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

Background

In January 2018, the revised Scheduling Policy Framework (SPF) was published and came into force. As part of the review of the SPF, it was agreed that the policy intent for advertising of Schedule 3 substances should be to allow these substances to be advertised directly to consumers unless it is determined they should not be.

A mandatory statement for inclusion on all advertisements for products containing Schedule 3 substances was developed in collaboration with a group of stakeholders representing consumers, industry and healthcare professionals. The new statement, "Ask your pharmacist - they must decide if this product is right for you", is included in the draft revised Therapeutic Goods Advertising Code (the Code)[1].

In addition to the mandatory statement, the stakeholder group also assisted in developing new guidelines for determining if a substance is suitable to be advertised (included as Appendix 1), and initial comments on the substances are presented in this paper.

Purpose

Currently there are only 19 of 85 Schedule 3 substances included in Appendix H. To facilitate the transition of substances to Appendix H, the current Schedule 3 substances will be considered in bulk and specific applications from stakeholders will NOT be required.

Using the factors described in the Guideline, and considering feedback from earlier targeted consultation activities in February 2018 and March 2018, the current Schedule 3 substances have been classified into two lists – those that can be advertised (to be added to Appendix H) and those that are not suitable for advertising together with a justification.

Stakeholders are invited to comment on the substances proposed for inclusion in these lists.

The guideline at Appendix 1 is included for information, and is not part of the consultation.

What will happen after the consultation?

Based on consultation responses, similar to the scheduling process, a delegate of the Secretary of the Department of Health will do one or more of the following for each substance:

1. Make a decision to add a substance to Appendix H
2. Decide not to add a substance to Appendix H
3. Reconsider the initial proposal in this paper and seek further comment on an alternative proposal
4. Refer the substance to the Advisory Committee for Medicines Scheduling (ACMS) for further advice.

It is anticipated that this process will be largely complete by the end of 2018.

[1] Consultation on the draft revised Code closed on 27 April 2018.

The Substances

Current Appendix H substances (for reference)

- 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

Proposed additions to Appendix H

- ADRENALINE
- CHLORAMPHENICOL
- CICLOPIROX*
- CLOBETASONE
- FAMCICLOVIR
- FLUORIDES*
- GLYCERYL TRINITRATE

- GLUCAGON
- ISOCONAZOLE*
- ISOSORBIDE DINITRATE
- KETOPROFEN
- LEVONORGESTREL
- METOCLOPRAMIDE (specified for nausea associated with migraine)
- NALOXONE
- OXICONAZOLE *
- PARACETAMOL*
- PODOPHYLLOTOXIN*
- PODOPHYLLUM EMODI (podophyllin)*
- PODOPHYLLUM PELTATUM (podophyllin)*
- SALBUTAMOL
- SALICYLIC ACID
- TERBUTALINE
- TIOCONAZOLE*
- TRIAMCINOLONE*

(* substance also has a Schedule 2 entry which can already be advertised)

Proposed exclusions from Appendix H

Justification for exclusion is per the following table

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
2	No longer a relevant ARTG entry / out dated substance

Substance	Justification
ALCLOMETASONE	2
ALIMEMAZINE	1d - sedating 2
AMINOPHYLLINE	1c 1d - safer alternatives 2
AZATADINE	1d - sedating 2
BROMPHENIRAMINE	1d - sedating 2
BUCLIZINE	2
CHLORBUTANOL	1a 2
CHLORPHENAMINE (CHLORPHENIRAMINE)	1d - sedating 2
CIMETIDINE	1b 1d - sedating 2
CLEMASTINE	1d - sedating 2
CYCLIZINE	1a 1b 2
CYPROHEPTADINE	1d - sedating
DEXCHLORPHENAMINE (DEXCHLORPHENIRAMINE)	1d - sedating
DIHYDROCODEINE	1a
DIIODOHYDROXYQUINOLINE (iodoquinol)	2

Substance	Justification
DIMETHINDENE	2
DIPHENHYDRAMINE	1d - sedating
DITHRANOL	1d - safer alternatives
DOXYLAMINE	1d - sedating
ERYTHRITYL TETRANITRATE	2
FLAVOXATE	2
GLYCOPYRRONIUM	2
INOSITOL NICOTINATE	2
MACROGOLS	1a
MAGNESIUM SULFATE	1a
MALATHION	1d - safer alternatives
MANNITYL HEXANITRATE	2
MEPYRAMINE	1d - sedating 2
METHDILAZINE	1d - sedating 2
NICOTINIC ACID	2
NICOTINYL ALCOHOL	2
ORLISTAT	1a
PHENIRAMINE	1d - sedating
PROCHLORPERAZINE	1a
PROMETHAZINE	1d - sedating
PSEUDOEPHEDRINE	1a

Substance	Justification
SANTONIN	1d - safer alternatives 2
SODIUM PHOSPHATE	1a
SODIUM PICOSULFATE	1a
SULFACETAMIDE	2
THEOPHYLLINE	1d - safer alternatives 2
TRIPROLIDINE	1d - safer alternatives 2

Appendix 1 - Guidelines for advertising medicines containing Schedule 3 substances

(See separate document)

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication #