18 July 2018

Regulatory Reforms Team
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Therapeutic Goods Administration,

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

The Society of Hospital Pharmacists of Australia is the national professional organisation for more than 5,000 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals.

SHPA does not support the advertising of Schedule 3 medicines in any form of media. Direct-to-consumer (DTC) advertising has the potential to cause considerable public harm through misinformation and the stimulation of inappropriate consumer requests for medicines. SHPA believes that consumers should make decisions regarding their medicines to treat a condition in conjunction with their healthcare providers. This will ensure that consumers receive independent, evidence-based advice from qualified health practitioners.

Despite our position, SHPA acknowledges the TGA's decision to expand on DTC advertising. In response to the TGA's proposed additions to Appendix H, members from SHPA's Specialty Practice Groups have the following comments to make.

Adrenaline

SHPA recommends that adrenaline should not have an Appendix H entry and should not be advertised to consumers. Whilst adrenaline in a topical preparation for haemorrhoids is unlikely to result in any significant risks, adrenaline autoinjectors are having an increasing presence as a recreational drug in Australia[1]. Given that adrenaline autoinjectors should only be used in medical emergencies, and require demonstration and training on its proper use, it is inappropriate for these medicines to be broadly advertised. Furthermore, adrenaline autoinjectors have recently been in shortage which may be exacerbated by any unnecessary demand for this vital life-saving medicine.

Chloramphenicol

SHPA recommends that chloramphenicol should not have an Appendix H entry and should not be advertised to consumers. Promoting its use to the public will result in expectations and demands from the community for this medication, which may result in inappropriate use and supply. The vast majority of consumers are unable to determine the differences between viral and bacterial conjunctivitis, for which this medicine is indicated, as well as other eye-related differential diagnoses meaning that its use is likely to be ineffective.

The *Australian Medicines Handbook* notes that chloramphenicol should not be supplied over-the-counter if an eye is red and painful, particularly if the individual is a contact lens wears as these patients require further investigation[2]. There is also the extremely rare complication of aplastic anaemia which can be fatal, even with ocular preparations of chloramphenicol. Advertising would promote the indiscriminate supply of chloramphenicol to patients, which could result in the delay in delivery of necessary medical assessment to their detriment.

Clobetasone

SHPA believes clobetasone should not have an Appendix H entry and should not be advertised to consumers. Clobetasone is a much more potent steroid compared to the current alternative, hydrocortisone, and would exacerbate adverse effects such as skin dehydration and irritation to sensitive mucosa and eyes.

Consumers are already able to access lower potency steroid cream in the form of hydrocortisone in Schedules 2 and 3 to treat skin allergies and irritations, with pharmacists being able to recommend the higher potency clobetasone if clinically warranted. Broader community use of potent steroids is contrary to the quality use of medicines.

Famciclovir

SHPA believes famciclovir should not have an Appendix H entry and should not be advertised to consumers. A prompt treatment for cold sores is currently offered through the availability and advertising of topical aciclovir ointment, which is also the preferred treatment for high-risk populations such as patients who are pregnant and breastfeeding[2]. Advertising oral famciclovir would inappropriately divert appropriate use away from topical aciclovir, which is also typically the more economical option for consumers.

The provision of oral famciclovir should require assessment by pharmacist and subsequent potential recommendation of the oral formulation if deemed appropriate. Skin sores and lesions are also commonly misdiagnosed, and persistent and/or recurring skin conditions may require referral to a patient's general practitioner as it may be indicative of an undiagnosed medical issue, such as immunosuppression. Furthermore, famciclovir can cause adverse effects such as headaches, vomiting and diarrhoea[2].

Triamcinolone

SHPA believes triamcinolone should not have an Appendix H entry and should not be advertised to consumers. The Schedule 3 formulation of triamcinolone is a paste that has the risk of misuse especially if consumers use it as a long-term solution for chronic mouth ulcers. Patients with chronic mouth ulcers should be reviewed by a medical professional. Mucosal sores and lesions are also commonly misdiagnosed, and persistent and/or recurring conditions may require referral to a patient's general practitioner as it may be indicative of an undiagnosed medical issue, such as immunosuppression.

Glyceryl Trinitrate and Isosorbide Dinitrate

SHPA believes glyceryl trinitrate and isosorbide dinitrate should not have an Appendix H entry and should not be advertised to consumers. Glyceryl trinitrate and isosorbide dinitrate are used to treat chest pain or angina and can be potentially life-saving and prevent cardiac events.

Self-treatment without a formal diagnosis increases the risk of adverse drug reactions. Glyceryl trinitrate has been proven to increase the likelihood of hypotensive effects when taken with medicines such as sildenafil[2]. Although common, muscular pain should be directed to a GP or hospital for assessment, depending on the severity. Advertising glyceryl trinitrate and isosorbide dinitrate would prompt consumers to rely on these medicines rather than seeking appropriate medical or pharmacy care.

Salbutamol and Terbutaline

SHPA believes salbutamol and terbutaline should not have an Appendix H entry and should not be advertised to consumers. Direct to consumer advertising of salbutamol and terbutaline will likely lead to inappropriate use and poorer asthma control. There is a high incidence of incorrect inhaler use already in Australia with 90% of patients with chronic lung disease not using their inhalers correctly[3]. Advertising will perpetuate the cycle of poor asthma control and mask the underlying issues that should be investigated. Furthermore, advertising of a medicine can give consumers the impression a medicine is safe. Whilst salbutamol is a life-saving medicine in asthmatic episodes, its overuse can lead to tremors, palpitations and tachycardia. Supply of salbutamol and terbutaline should be based on a health professional's review for patients needing the medicine, even if it is for short-term relief, to reduce the potential for a delayed diagnosis

Metoclopramide

SHPA believes metoclopramide should not have an Appendix H entry and should not be advertised to consumers. As the use of metoclopramide is specified for nausea associated with migraines, there is a potential for misuse of this medicine for nausea unrelated to migraines, for which better treatments options are already available. Additionally, metoclopramide is a short-term relief which is to be used for a maximum of five days as the risk of tardive dyskinesia increases with cumulative dose and length of treatment.

Common adverse effects of metoclopramide include akathisia, drowsiness, dizziness and headaches. The *Australian Medicines Handbook* advises no driving or machine operating until the effects of the medicines on an individual is known[2]. These risks make metoclopramide inappropriate for direct-to-consumer advertising.

Levonorgestrel

SHPA believes levonorgestrel should not have an Appendix H entry and should not be advertised to consumers. Until 2015, levonorgestrel was the only oral emergency contraceptive available in Australia. Due to newer emergency contraception therapies containing ulipristal acetate entering the Australian market, there are further clinical considerations for pharmacists to determine the most appropriate form of emergency contraception for the patient.

There have been various studies conducted which compared the efficacy of both pills and have demonstrated that ulipristal acetate reduces the risk of pregnancy up until 120 hours after unprotected sex whereas levonorgestrel is not as efficacious[4,5]. However, its efficacy is dependent on an individual's menstrual cycle. Without appropriate counselling and advice, consumers would not be able to make an informed decision as to which emergency contraception is most appropriate for the patient.

Furthermore, determining the appropriateness of levonorgestrel for the patient is a complex process. Clinical consideration is given to the patient's breastfeeding status, menstrual cycle, previous pregnancies and time since intercourse to determine its appropriateness. As such, the *Pharmaceutical Society of Australia* has a specific guideline on the provision of emergency contraception for pharmacists[6].

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Johanna de Wever, General Manager, Advocacy and Leadership on jdewever@shpa.org.au.

Yours sincerely,

Kristin Michaels
Chief Executive

References

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