Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Notice of final decision to amend (or not amend) the current Poisons Standard

15 November 2022

TGA Health Safety Regulation

Contents

1 Notice of final decisions to amend (or not amend) the current Poisons Standard

This web publication constitutes a notice for the purposes of regulation 42ZCZS of the Therapeutic Goods Regulations 1990 (Cth) (the **Regulations**). In accordance with regulation 42ZCZS, this notice publishes:

- the decision made by a delegate[1] of the Secretary of the Department of Health and Aged Care (the **Delegate**) pursuant to regulation 42ZCZR;
- the reasons for the final decision; and
- the date of effect of the decision.

2 Final decisions on a proposed amendment referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #29, November 2021)

2.1 Final decision in relation to cannabis and tetrahydrocannabinols

Proposal

The applicant proposed amendments to the existing entries for cannabis and tetrahydrocannabinols (THCs) in: (i) Schedule 8, to allow prescription of these substances for veterinary use, except for use in animals bred for human consumption; and (ii) Appendix D, to restrict any possession of these substances, other than in accordance with a prescription (the **Proposal**). Currently, therapeutic use of cannabis and THCs is restricted to human use only, except for the Schedule 4 (prescription only) entry for cannabidiol (CBD).

Final decision

Pursuant to regulation 42ZCZR of the Regulations, and after assembling further information, the Delegate has made a final decision to confirm the interim decision to not amend the Poisons Standard in relation to cannabis and tetrahydrocannabinols.

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to cannabis and tetrahydrocannabinols (the **Application**);
- The 116 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations, including 35 written submissions;
- The advice received from the 29th meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the **Committee**);

[1] For the purposes of s 52D of the *Therapeutic Goods Act 1989* (Cth).

- The 30 public submissions, including 16 written submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the **Submissions**);
- Subsection 52E(1) of *the Therapeutic Goods Act 1989* (Cth) (the **Act**), in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (f) any other matters considered necessary to protect public health;
- The Scheduling Policy Framework 2018 (the **SPF**), pursuant to paragraph 52E(2)(a) of the Act;
- The Scheduling handbook: Guidance for amending the Poisons Standard; and
- Information regarding regulation of cannabis and tetrahydrocannabinols received from States and Territories.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision to not amend the current Poisons Standard with respect to cannabis and tetrahydrocannabinols (THCs). My reasons for making the final decision are those set out in the interim decision with the following qualifications and additional observations.

I have considered the Submissions and note that there were 14 written submissions expressing opposition to the interim decision, with one submission in support.[2] Several of the written submissions included discussions of personal experiences with medicinal cannabis and detailed the positive effects. However, these submissions did not address safety concerns or the lack of evidence of therapeutic value for use of these substances in animals, as outlined in the interim decision.

Several of the Submissions stated that implementation of the Proposal would expand the evidence base concerning the treatment of animals with cannabis and THCs by providing further avenues for research. I acknowledge that while research has been completed thus far, more evidence of the therapeutic benefits in veterinary use is needed. However, I am of the view that further clinical studies on animals, with larger population sizes and varying doses, should be pursued under the current scheduling because allowing these substances to be prescribed for veterinary use through a Schedule 8 entry would be premature and not consistent with the SPF factors.

The accessibility of medications that are used in veterinary practice through 'off-label' provisions was cited again in the Submissions as supporting evidence for the down-scheduling of cannabis and THCs. Cannabinoid medications such as Epidyolex are claimed to be currently prescribed off-label for the treatment of animals. However, given the largely unknown safety and efficacy of these treatments for veterinary use, the off-label use does not provide a compelling reason consistent with the scheduling factors for Schedule 8 to amend the Poisons Standard with regards to cannabis and THCs.

I find that there is insufficient evidence for the argument that providing veterinary access will help mitigate inadvertent marijuana exposure to animals and children. Currently, any cannabis products that are being accidentally ingested are most likely intended for human consumption,

[2] One written submission was received which did not express support or opposition to the interim decision.

and the addition of veterinary access to products containing cannabis and THCs has the potential to increase the number of adverse events related to accidental ingestion.

I acknowledge that, despite being provided for in Schedule 8 of the Poisons Standard, human therapeutic use of these substances still involves some titration and adjustment of doses. However, human patients are able to communicate about tolerance, effectiveness and any discomfort experienced with varying doses. Attempting to establish tolerance in different animal species by relying on behavioural observations outside of a clinical setting is not an accurate or safe method of establishing therapeutic doses. As mentioned previously, cannabis and THCs are available for supply in research settings and as such, the potential to establish further evidence of safety and efficacy for veterinary use can be obtained without implementing the proposed amendment.

While the Poisons Standard sets some level of control on the availability of medicines and poisons, the specific requirements regarding access, prescription, storage, administration, disposal, and possession are established through the relevant legislation in each State and Territory. I therefore sought information from the health authorities in each State and Territory regarding the practical effects of implementing the Proposal. Advice received indicated that access to the substances for the purpose of veterinary research is already possible, and therefore, there are no issues with access for this purpose under the current Schedule. This information supports my final decision to not amend the Poisons Standard in relation to cannabis and THCs.

While I acknowledge the current evidence for the potential benefits of the veterinary use of these substances, I consider these benefits to be presently outweighed by the associated risks set out in the interim decision. I agree with the expressed need for alternative pain relief for animals and that the use of cannabis and THCs has the potential to provide this. However, given the current evidence of safety and efficacy of these substances in a veterinary setting, the current scheduling remains appropriate for cannabis and THCs. A change to the scheduling of these substances may be appropriate should additional relevant evidence emerge.