Australian Government
Department of Health
Therapeutic Goods Administration

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

23 May 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* (the **Regulations**). In accordance with regulations 42ZCZS, this notice publishes:

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

# 2 Final decisions on proposed amendments referred to the Advisory Committee on Chemicals Scheduling (Joint ACMS-ACCS #25, June 2020)

## 2.1 Final decision in relation to isothiazolinones, methylisothiazolinone and methylchloroisothiazolinone

### *Final Decision*

Pursuant to regulation 42ZCZR of the Regulations, a Delegate has made a final decision to confirm the interim decision and not amend the current Poisons Standard in relation to isothiazolinones, methylisothiazolinone (MI) and methylchloroisothiazolinone (MCI).

### *Materials considered*

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

- The application to amend the current Poisons Standard with respect to isothiazolinones, MI and MCI (the **Application**);
- The 15 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations.
- The advice received from the 25th meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the **Committee**);
- The three public submissions, including two written submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- 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; and (d) the dosage;
- The Scheduling Policy Framework 2018 (the **SPF**), pursuant to paragraph 52E(2)(a) of the Act; and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

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

I have made a final decision to confirm my interim decision not to amend the current Poisons Standard with respect to isothiazolinones, MI and MCI. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses after the second call for public submissions, published on 11 March 2022 under regulation 42ZCZP of the Regulations. I note that two written submissions were received, both supportive of the interim decision.