Australian Government
Department of Health
Therapeutic Goods Administration

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

22 August 2019

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

- The decisions made by a delegate of the Secretary pursuant to regulation 42ZCZR;
- The reasons for those final decisions; and
- The date of effect of those decisions.

1 Advisory Committee on Medicines Scheduling (ACMS #26) – Final decisions made pursuant to regulation 42ZCZR

1.1. Final decision in relation to cetirizine

Final decision:

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and not amend the current Poisons Standard in relation to cetirizine.

Date of effect of the decision: **22 August 2019**.

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

I have made a final decision to confirm my interim decision to retain the Schedule 4 and Schedule 2 entries for cetirizine in the current Poisons Standard for the reasons set out in my interim decision and those referred to below. In making my final decision, I have taken into account the public submissions received before the second closing date in response to the call for further submissions published on 6 June 2019 under regulation 42ZCZP of the Regulations.

I have taken into account the critical argument in opposition of the interim decision that a change in pack size does not change the access to health professional advice. I consider the standard recommendations (such as the Therapeutic Guidelines series) relevant to this matter, which are that where allergic rhinitis is intermittent (i.e. less than 4 days per week or less than 4 consecutive weeks), and mild to moderate in nature, intranasal or oral antihistamines can be used alone or with intranasal corticosteroids. Intranasal corticosteroids are considered more effective where nasal obstructive symptoms are present. For patients with nasal congestion or more severe disease with sleep disturbance, impairment of daily activities and/or impairment of work or school performance, intranasal corticosteroids +/- oral/intranasal antihistamines are recommended. Having considered the standard treatment recommendations that, for more severe allergic rhinitis or nasal congestion other treatment may also be required, I confirm my interim decision that increasing the general sales level pack size may delay a person seeking advice in a pharmacy and may mean that best practice treatment is similarly delayed. My view is that in order for consumers to receive best practice, they need to talk to a pharmacist. A small pack size of cetirizine will encourage consumers to seek advice from a pharmacist more regularly than would be the case for a larger pack size.

The claims in the public submission that most consumers who purchase medicines in a general sales outlet are repeat purchasers, are familiar with the medicine and buy for convenience, are relevant. Among other things, I find that the provision of other information by pharmacist such as non-pharmacological and/or self-management advice such as avoidance of allergens, use of saline nasal sprays and direct steam inhalation plays an important role in managing the symptoms. In addition, I am of the view that lengthening the time before a consumer seeks advice is not in the interest of promoting public health.

I have taken into consideration the views expressed in the public submissions that Australia is lagging behind other nations with similar regulatory controls over medicines regarding pack sizes available at the general sales level. While the criticisms on pack size restrictions are generally correct, I find that the regulatory checkpoints underpinning supply overseas are not always equivalent. For example, although packs of up to 100 tablets are available outside pharmacies in Denmark, stores which sell medicines must be authorised by the Danish Medicines Agency and have to complete a number of e-learning modules before they can be authorised. In authorised stores, medicines must be stored behind the counter without customer self-selection in the same manner as Schedule 2 medicines must be stored in licensed country stores in Australia. For the reasons referred to be above, I have not given substantial weight to regulation of cetirizine in international markets.

I am not persuaded that removing the Appendix K entry is in the interest of protecting public health, particularly as the impetus for Appendix K was to reduce vehicle accidents. I accept that at 10 mg cetirizine does not usually cause drowsiness when taken at the recommended dose. In confirming my decision to retain the Appendix K entry, I have given substantial weight to the increased risk of sedation associated with cetirizine use in combination with alcohol and any other medication that can cause memory impairment or affect psychomotor skills.

1.2. Final decision in relation to glyceryl trinitrate

Final decision:

Pursuant to regulation 42ZCZR of the Regulations, a delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to glyceryl trinitrate as follows:

Appendix H – New Entry

GLYCERYL TRINITRATE.

INDEX – Amend Entry

GLYCERYL TRINITRATE

Schedule 4
Schedule 3
Appendix G
Appendix H

Date of effect of the decision: **1 October 2019**.

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

I have decided to confirm my interim decision to create an Appendix H entry for glyceryl trinitrate. I note that no public submissions were received before the second closing date in response to the call for further submissions published on 6 June 2019 under regulation 42ZCZP of the Regulations.

1.3. Final decision in relation to isosorbide dinitrate

Final decision:

Pursuant to regulation 42ZCZR of the Regulations, a delegate of the Secretary has made a final decision to confirm the interim decision and not amend the current Poisons Standard in relation to isosorbide dinitrate.

Date of effect of the decision: **22 August 2019**.

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

I have decided to confirm my interim decision not to amend the current Poisons Standard in relation to isosorbide dinitrate. I note that no public submissions were received before the second closing date in response to the call for further submissions published on 6 June 2019 under regulation 42ZCZP of the Regulations.

1.4. Final decision in relation to paracetamol (modified release)

Final decision:

Pursuant to regulation 42ZCZR of the Regulations, a delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to paracetamol (modified release) as follows:

Schedule 4 – Amend Entry

PARACETAMOL:

a) when combined with aspirin or salicylamide or any derivative of these substances **except** when separately specified in these Schedules;

b) when combined with ibuprofen in a primary pack containing more than 30 dosage units;

c) in ~~slow~~ modified release tablets or capsules containing more than 665 mg paracetamol;

d) in non-~~slow~~ modified release tablets or capsules containing more than 500 mg paracetamol;

e) in individually wrapped powders or sachets of granules each containing more than 1000 mg paracetamol;

f) in tablets or capsules enclosed in a primary pack containing more than 100 tablets or capsules **except** in Schedule 2;

g) in individually wrapped powders or sachets of granules enclosed in a primary pack containing more than 50 wrapped powders or sachets of granules **except** when included in Schedule 2;

h) for injection.

Schedule 3 – Amend Entry

PARACETAMOL:

a) when combined with ibuprofen in a primary pack containing 30 dosage units or less **except** when included in Schedule 2; or

b) in modified release tablets or capsules containing 665 mg or less paracetamol.

Date of effect of the decision: **1 June 2020**.

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

I have made a final decision to confirm my interim decision insofar as it relates to the up-scheduling of paracetamol in modified release (MR) tablets or capsules containing 665 mg or less of paracetamol to Schedule 3 and the reasons for this decision. In making my final decision, I have taken into account the public submissions received before the second closing date in response to the call for further submissions published on 6 June 2019 under regulation 42ZCZP of the Regulations.

I have given consideration to the view that Schedule 3 will not provide sufficient control to reduce the frequency of deliberate self-poisoning with MR paracetamol. Specifically, there was a concern expressed that pharmacists will be unable exert sufficient controls against the purchase of MR paracetamol for suspected problematic or inappropriate use, in view of the experience with codeine and other Schedule 3 products. Notwithstanding the important role of the direct involvement of pharmacists in consumer education, in making my decision, I took into account that up-scheduling to Schedule 3 may also act to reduce some impulsive intentional overdose due to placing additional barriers to sales. Among other things, I have relied on evidence that restriction to access will likely reduce method specific attempts, and may reduce overall attempts. On balance, I am satisfied that a Schedule 3 entry for MR paracetamol is appropriate, it provides additional oversight by pharmacists, and may provide a barrier to impulsive purchasing associated with intentional overdose.

I have not made a decision on the request for labelling exemptions from each state and territory health authority as raised in the pubic submissions, as these matters are considered under other legislation at the time of making my decision.

I have taken into account the compelling evidence in the public submissions that a 1 October 2019 implementation date provides insufficient time for sponsors of MR paracetamol medicines to carry out all of the regulatory, manufacturing, transportation and distribution steps necessary to comply with the proposed changes. In recognition of the concerns raised in the public submissions on the practicality of the implementation date for businesses affected by the proposed changes I have decided on a 1 June 2020 implementation date.

I note that this deferred implementation date for the rescheduling to take effect will allow more time for industry to carry out a communication plan for consumers and healthcare professionals, and this would be in the interest of promoting public health.

2 Joint meeting of the Advisory Committee on Chemicals and Medicines Scheduling (ACCS-ACMS #21) – Final decision(s) made pursuant to regulation 42ZCZR

2.1. Final decision in relation to paracetamol

Final decision:

Pursuant to regulation 42ZCZR of the Regulations, a delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to paracetamol as follows:

Schedule 4 – Amend Entry

PARACETAMOL:

a) when combined with aspirin or salicylamide or any derivative of these substances **except** when separately specified in these Schedules;

b) when combined with ibuprofen in a primary pack containing more than 30 dosage units;

c) in slow release tablets or capsules containing more than 665 mg paracetamol;

d) in non-slow release tablets or capsules containing more than 500 mg paracetamol;

e) in individually wrapped powders or sachets of granules each containing more than 1000 mg paracetamol;

f) in tablets or capsules enclosed in a primary pack containing more than 100 tablets or capsules **except** in schedule 2;

g) in individually wrapped powders or sachets of granules enclosed in a primary pack containing more than 50 wrapped powders or sachets of granules **except** when included in Schedule 2;

h) for injection;

i) for the treatment of animals.

The delegate decided that a new listing be created in Part 2 – Control on medicines and poisons, section 2.4 – child-resistant closures as follows:

Paracetamol included in Schedule 4, when packed and labelled for the treatment of animals

Nominal capacity: All sizes

Date of effect of the decision: **1 October 2019**.

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

I have decided to confirm the interim decision made by the delegate at the time, to schedule paracetamol for animal use in Schedule 4 of the Poisons Standard to allow it to be made available with a prescription from a veterinary practitioner. I note that no public submissions were received before the second closing date in response to the call for further submissions published on 6 June 2019 under regulation 42ZCZP of the Regulations.

3 Advisory Committee on Chemicals Scheduling (ACCS #24) – Final decision(s) made pursuant to regulation 42ZCZR

3.1. Final decision in relation to Polymer in Durazane 1500

Final decision:

Pursuant to regulation 42ZCZR of the Regulations, a delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to Polymer in Durazane 1500 as follows:

The delegate made the decision to use the chemical names, CYCLOSILAZANES, DI-ME, ME HYDROGEN, POLYMERS WITH DI-ME, ME HYDROGEN SILAZANES, REACTION PRODUCTS WITH 3-(TRIETHOXYSILYL)-1-PROPANAMINE (CAS 475645-84-2) in the Poisons Standard.

Schedule 7 – New Entry

CYCLOSILAZANES, DI-ME, ME HYDROGEN, POLYMERS WITH DI-ME, ME HYDROGEN SILAZANES, REACTION PRODUCTS WITH 3-(TRIETHOXYSILYL)-1-PROPANAMINE (CAS 475645-84-2) **except** when included in Schedule 6.

Schedule 6 – New Entry

CYCLOSILAZANES, DI-ME, ME HYDROGEN, POLYMERS WITH DI-ME, ME HYDROGEN SILAZANES, REACTION PRODUCTS WITH 3-(TRIETHOXYSILYL)-1-PROPANAMINE (CAS 475645-84-2) when presented in a wipe and when packaged in a container with a child-

resistant closure, with chemical resistant gloves and labelled with the following effect:

DO NOT USE WITHOUT PROTECTIVE GLOVES; and

KEEP OUT OF EYES.

Appendix E, Part 2 – New Entry

CYCLOSILAZANES, DI-ME, ME HYDROGEN, POLYMERS WITH DI-ME, ME HYDROGEN SILAZANES, REACTION PRODUCTS WITH 3-(TRIETHOXYSILYL)-1-PROPANAMINE (CAS 475645-84-2)

Standard Statements: **A** (For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once)); **E2** (If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor, or for at least 15 minutes.); and **S1** (If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.).

Appendix F, Part 3 – New Entry

CYCLOSILAZANES, DI-ME, ME HYDROGEN, POLYMERS WITH DI-ME, ME HYDROGEN SILAZANES, REACTION PRODUCTS WITH 3-(TRIETHOXYSILYL)-1-PROPANAMINE (CAS 475645-84-2)

Warning Statements: **2** (Corrosive); **10** (May produce severe burns); and **78** (Attacks skin and eyes).

Safety Directions: **1** (Avoid contact with eyes); **4** (Avoid contact with skin); **5** (Wear protective gloves when mixing or using.); and **35** (Wash gloves thoroughly, immediately after use.).

Index – New Entry

CYCLOSILAZANES, DI-ME, ME HYDROGEN, POLYMERS WITH DI-ME, ME HYDROGEN SILAZANES, REACTION PRODUCTS WITH 3-(TRIETHOXYSILYL)-1-PROPANAMINE (CAS 475645-84-2)

Schedule 7
Schedule 6
Appendix E, Part 2
Appendix F, Part 3

In addition, a new listing should be created in Part 2 – Control on medicines and poisons, section 2.4 – child-resistant closures as follows:

CYCLOSILAZANES, DI-ME, ME HYDROGEN, POLYMERS WITH DI-ME, ME HYDROGEN SILAZANES, REACTION PRODUCTS WITH 3-(TRIETHOXYSILYL)-1-PROPANAMINE (CAS 475645-84-2) when included in Schedule 6, when presented in a wipe.

Nominal capacity: All sizes

Date of effect of the decision: **1 October 2019**.

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

I have decided to confirm the interim decision to Schedule cyclosilazanes, di-Me, Me hydrogen, polymers with di-Me, Me hydrogen silazanes, reaction products with 3-(triethoxysilyl)-1-propanamine in Schedules 7 and 6 of the Poisons Standard and create new Appendix E and Appendix F listings. The scheduling entry should include the CAS number (475645-84-2) for additional clarity. I note that no public submissions were received before the second closing date in response to the call for further submissions published on 6 June 2019 under regulation 42ZCZP of the Regulations.

3.2. Final decision in relation to MCPB

Final decision:

Pursuant to regulation 42ZCZR of the Regulations, a delegate of the Secretary has made a final decision to vary the interim decision and amend the current Poisons Standard in relation to MCPB as follows:

Schedule 6 – New Entry

MCPB

Schedule 5 – Delete Entry

~~MCPB~~

Index – Amend Entry

MCPB
cross reference: (4-(4-CHLORO-2-METHYLPHENOXY)BUTANOIC ACID

~~Schedule 5~~
Schedule 6

Date of effect of the decision: **1 October 2019**.

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

Having considered the public submission received before the second closing date in response to the call for further submissions published on 6 June 2019 under regulation 42ZCZP of the Regulations, I have made a final decision to vary the interim decision. I have made a final decision to remove the Schedule 5 (caution) entry for MCPB and create a new Schedule 6 (poison) entry. I will set out my reasons for this decision below.

In making my decision, I must take into account the Scheduling Factors as specified in the Scheduling Policy Handbook 2018. At the time of making the interim decision, the Chemicals Scheduling Delegate was not persuaded that the eye irritation data alone submitted in the application met the Scheduling Factors for Schedule 6. Furthermore, the Delegate noted the concerns raised by the Committee – that the eye irritancy may be attributed to a potential formulation effect.

I note that one public submission in response to the interim decision was received and this submission was in agreement with the rationale concerning the potential formulation effect. In addition, this public submission also provided additional clarity regarding the toxicity profile of MCPB, specifically, the acute oral toxicity of MCPB.

I have now taken into account the critical arguments provided in the public submission and contrary to the interim decision, find that the toxicity profile of MCPB and its derivatives meet the Schedule 6 Scheduling Factors.

Therefore, I have considered the arguments presented in the public submission and I find that, on balance, a Schedule 6 entry is supported in the interests of protecting public health particularly against the harms associated with MCPB and its derivatives.