Australian Government
Department of Health
Therapeutic Goods Administration

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

22 April 2021

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 and regulation 42ZCZX of the *Therapeutic Goods Regulations 1990* (the **Regulations**). In accordance with regulations 42ZCZS and 42ZCZX, this notice publishes the:

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

2 Final decision in relation to psilocybin and MDMA [N, α-Dimethyl-3,4-(methylenedioxy)phenylethylamine]

Note that the final decision for psilocybin and MDMA [N, α-Dimethyl-3,4-(methylenedioxy)phenylethylamine] are not published in this notice.

Amended timing on the scheduling process for these substances will be published on the TGA website following the completion of the independent review.

3 Final decisions on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #32, November 2020)

3.1 Final decision in relation to amygdalin and hydrocyanic acid

Proposal

The applicant proposed an amendment to move amygdalin as a natural component in Traditional Chinese Medicines (TCM) for oral use in adults from Schedule 10 to Schedule 4; exempt amygdalin from scheduling when the maximum recommended daily dose is ≤5 mg amygdalin; and exempt from scheduling hydrocyanic acid for therapeutic use when present as a natural component of amygdalin in TCM for oral use in adults

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 amygdalin and hydrocyanic acid.

Materials considered

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

- The application to amend the current Poisons Standard with respect to amygdalin and hydrocyanic acid;
- The 129 public submissions, including two written submissions, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Meeting of the Advisory Committee on Medicines Scheduling (ACMS #32);
- The 154 public submissions, including 15 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*, 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 (e) the potential for abuse of a substance;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018);
- The Scheduling handbook: Guidance for amending the Poisons Standard; and
- An external expert evaluation of the private application.

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 amygdalin and hydrocyanic acid. 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 received after the second call for public submissions, published on 3 February 2021 under regulation 42ZCZP of the Regulations.

I note that that 14 of 15 written public submissions were opposed to the interim decision, and that a majority of these submissions came from registered Chinese Medicine (CM) practitioners. Several respondents advised that the amount of toxic amygdalin and cyanogenic glycosides is reduced to a safe level after processing by qualified practitioners. However, as with any substance, the proposed Poison Standard entry relates to the amount of amygdalin in the final product and so my concerns regarding safety remain pertinent. I also reiterate that a CM practitioner, unless also registered as a medical practitioner, does not have the authority to prescribe Schedule 4 medicines.

The interim submissions additionally outline that the diversion of amygdalin as a cancer treatment is not within the uses prescribed through CM practitioners and that access to amygdalin-containing food products is not within the scope of scheduling decisions. Although, I am aware that cancer treatment is not among the indications suggested by TCM, I remain wary of the long history of diversion – especially given the lack of evidence for therapeutic benefit. I also note that chronic use patterns associated with medicines raise a unique set of risks that do not necessarily relate to foods. In light of the public submissions, I remain of the view that products containing even low doses of amygdalin cannot be safely supplied as medicines.

3.2 Final decision in relation to bilastine

Proposal

The applicant proposed an amendment to include bilastine in Schedule 2 in preparations for oral use, and Schedule 4 for all other uses.

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 bilastine as follows:

Schedule 4 - Amend Entry

BILASTINE *except when included in Schedule 3.*

Schedule 3 - New Entry

BILASTINE in divided oral preparations containing 20 mg or less in adults and adolescents 12 years of age and older.

Appendix H – New Entry

BILASTINE

Index – Amend Entry

BILASTINE

Schedule 4
Schedule 3
Appendix H

Materials considered

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

- The application to amend the current Poisons Standard with respect to bilastine;

- The 127 public submissions, including three written submissions, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Meeting of the Advisory Committee on Medicines Scheduling (ACMS #32);
- The 84 public submissions, which included no 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*, 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, formulation, labelling, packaging and presentation of a substance.
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); 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 to amend the current Poisons Standard with respect to bilastine. 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 received after the second call for public submissions, published on 3 February 2021 under regulation 42ZCZP of the Regulations. I note that no written public submissions were received in response to the interim decision.

Implementation date

1 June 2021

3.3 Final decision in relation to budesonide and formoterol

Proposal

The applicant proposed an amendment to move budesonide and formoterol from Schedule 4 to Schedule 3 when combined in an inhaler, for use as an anti-inflammatory reliever in the treatment of medically diagnosed asthma.

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 budesonide and formoterol.

Materials considered

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

- The application to amend the current Poisons Standard with respect to budesonide and formoterol;
- The 138 public submissions, including 12 written submissions, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Meeting of the Advisory Committee on Medicines Scheduling (ACMS #32);

- The 88 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*, in particular (a) the risks and benefits of the use of the substance; (b) the purposes for which a substance is to be used and the extent of use of the substance; (c) the toxicity of the substance; (d) the dosage, formulation, labelling, packaging and presentation of the substance; (e) the potential for abuse of the substance; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018);
- The Scheduling handbook: Guidance for amending the Poisons Standard; and
- The Australian Asthma Handbook.

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 budesonide and formoterol. 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 received after the second call for public submissions, published on 3 February 2021 under regulation 42ZCZP of the Regulations.

I note that two written submissions were received, both opposing the interim decision. These argued that the product would deliver better patient outcomes compared to over the counter use of short acting beta agonists. The submissions also noted that pharmacists are already familiar with the medicine, and can ensure patient safety in conjunction with Appendix M criteria. In light of these points, and taking into consideration the restrictions proposed for the Appendix M entry, I remain of the view that the potential benefits for inclusion in Appendix M are outweighed by the risks of inappropriate use of the substance.

While the two written post-meeting submissions opposed the interim decision, the majority of pre-meeting public submissions did not support the proposed rescheduling – including responses from several asthma peak representative bodies. Taking into consideration all submissions received, I remain of the view that the risks, and need for medical practitioner oversight, significantly outweigh the benefits of increased access.

4 Final decisions on proposed amendments referred to the Advisory Committee on Chemicals Scheduling (ACCS #29, November 2020)

4.1 Final decision in relation to azoxystrobin

Proposal

The applicant proposed an amendment to exempt azoxystrobin from scheduling in preparations with a concentration of 10% or less. Azoxystrobin is currently in Schedule 5.

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 azoxystrobin.

Materials considered

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

- The application to amend the current Poisons Standard with respect to azoxystrobin;
- The 124 public submissions, which included no written submissions, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Meeting of the Advisory Committee on Chemicals Scheduling (ACCS #29);
- The 75 public submissions, which included no 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*, 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 Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); 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 to not amend the current Poisons Standard with respect to azoxystrobin. 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 received after the second call for public submissions, published on 3 February 2021 under regulation 42ZCZP of the Regulations. I note that no written public submissions were received in response to the interim decision.

4.2 Final decision in relation to triticonazole

Proposal

The applicant proposed an amendment to exempt triticonazole from scheduling in preparations with a concentration of 20% or less. Triticonazole is currently in Schedule 5.

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 triticonazole.

Materials considered

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

- The application to amend the current Poisons Standard with respect to triticonazole;
- The 124 public submissions, which included no written submissions, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Meeting of the Advisory Committee on Chemicals Scheduling (ACCS #29);

- The 77 public submissions, which included no 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*, 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 Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); 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 to not amend the current Poisons Standard with respect to triticonazole. 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 received after the second call for public submissions, published on 3 February 2021 under regulation 42ZCZP of the Regulations. I note that no written public submissions were received in response to the interim decision.

5 Final decisions on proposed amendments referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #26, November 2020)

5.1 Final decision in relation to azelaic acid

Proposal

The applicant proposed amendments to the scheduling of azelaic acid with the intent that it is down-scheduled to general sales level (unscheduled) in topical preparations with a concentration of 10% or less. The proposal would also create a new Schedule 5 entry for all therapeutic and cosmetic preparations with a concentration greater than 10%. Azelaic acid is currently unscheduled for preparations with less than 1% for non-human use. Dermal preparations are in Schedule 2 (pharmacy only) and the remainder of products are in Schedule 4 (prescription only).

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 azelaic acid.

Materials considered

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

- The application to amend the current Poisons Standard with respect to azelaic acid;
- The 129 public submissions, including seven written submissions, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;

- The advice received from the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #26);
- The 91 public submissions, including one written submission, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, 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 (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); 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 to not amend the current Poisons Standard with respect to azelaic acid. 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 received after the second call for public submissions, published on 3 February 2021 under regulation 42ZCZP of the Regulations.

I note that one written public submission was received, from Accord Australasia, which was partially supportive of the interim decision. The submission highlighted that cosmetic azelaic acid products have fewer restrictions in comparable overseas markets, such as the EU, US and New Zealand, and that the view expressed in the submission was that Australia should harmonise its scheduling controls with these countries. This scheduling decision does not preclude future applications to harmonise scheduling controls. However, the current application did not include sufficient supporting evidence to warrant rescheduling at this time.

5.2 Final decision in relation to 2-hydroxyethyl methacrylate (2-HEMA)

Proposal

The applicant proposed an amendment to the Schedule 5 entry for 2-hydroxyethyl methacrylate to exempt concentrations of 1% or less from scheduling.

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 2-hydroxyethyl methacrylate as follows:

Schedule 5 – Amend entry

2-HYDROXYETHYL METHACRYLATE **except:**

a) when included in dental restorative preparations for therapeutic use; or

b) in nail preparations when labelled "Avoid contact with skin"; or

c) in other preparations containing 0.1 per cent or less of 2-hydroxyethyl methacrylate when labelled "Avoid contact with skin".

Appendix E, Part 2

POISON	STANDARD STATEMENTS
2-HYDROXYETHYL METHACRYLATE	**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)). **E1** (If in eyes wash out immediately with water.), **S1** (If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.)

Appendix F, Part 3

POISON	WARNING STATEMENTS	SAFETY DIRECTION
2-HYDROXYETHYL METHACRYLATE	**28** ((Over) (Repeated) exposure may cause sensitisation)	**4** (Avoid contact with skin.)

Index

2-HYDROXYETHYL METHACRYLATE

Schedule 5
Appendix E, Part 2
Appendix F, Part 3

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

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

- The application to amend the current Poisons Standard with respect to 2-hydroxyethyl methacrylate;
- The 122 public submissions, which included no written submissions, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #26);
- The 82 public submissions, which included no 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*, 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 Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); 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 to amend the current Poisons Standard with respect to 2-hydroxyethyl methacrylate. 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 received after the second call for public submissions, published on 3 February 2021 under regulation 42ZCZP of the Regulations. I note that no written public submissions were received in response to the interim decision.

Implementation date

1 June 2021.

5.3 Final decision in relation to magnesium hydroxide

Proposal

The applicant proposed a new entry for magnesium hydroxide in Appendix B (substances considered not requiring control by scheduling).

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 magnesium hydroxide as follows:

Appendix B, Part 3 – New Entry

SUBSTANCE	REASON FOR LISTING	AREA OF USE
MAGNESIUM HYDROXIDE	A (Low toxicity)	7.1

INDEX – New Entry

MAGNESIUM HYDROXIDE

Appendix B, Part 3

Materials considered

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

- The application to amend the current Poisons Standard with respect to magnesium hydroxide;
- The 123 public submissions, including one written submission, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #26);
- The 89 public submissions, including one written submission, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, 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 (f) any other matters considered necessary to protect public health;

- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); 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 to amend the current Poisons Standard with respect to magnesium hydroxide. 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 received after the second call for public submissions, published on 3 February 2021 under regulation 42ZCZP of the Regulations. I note that one written public submission was received, from Accord Australasia, which was supportive of the interim decision.

Implementation date

1 June 2021

5.4 Final decision in relation to tetrahydrofurfuryl alcohol

Proposal

The applicant proposed a new Schedule 6 entry for tetrahydrofurfuryl alcohol, excluding its derivatives.

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 tetrahydrofurfuryl alcohol as follows:

Schedule 6 – New Entry

TETRAHYDROFURFURYL ALCOHOL, excluding its derivatives.

Index

TETRAHYDROFURFURYL ALCOHOL, excluding its derivatives.

Schedule 6

Materials considered

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

- The application to amend the current Poisons Standard with respect to THFA;
- The 122 public submissions, which included no written submissions, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #26);
- The 79 public submissions, which included no 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*, 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 Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); 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 to amend the current Poisons Standard with respect to tetrahydrofurfuryl alcohol. 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 received after the second call for public submissions, published on 3 February 2021 under regulation 42ZCZP of the Regulations. I note that no written public submissions were received in response to the interim decision.

Implementation date

1 June 2021

5.5 Final decision in relation to cannabidiol (private application)

Proposal

The applicant proposed to amend the Schedule 4 entry for cannabidiol to explicitly capture synthetic and semi-synthetic cannabidiol and to make an explicit 2% limit to any impurities in synthetic cannabidiol.

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 cannabidiol.

Materials considered

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

- The application to amend the current Poisons Standard with respect to cannabidol;
- The 228 public submissions, including 20 written submissions, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #26);
- The 238 public submissions, including 28 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*, 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; (e) the potential for abuse of the substance; and (f) any other matters considered necessary to protect public health;

- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); 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 to not amend the current Poisons Standard with respect to cannabidiol (CBD). 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 received after the second call for public submissions, published on 3 February 2021 under regulation 42ZCZP of the Regulations.

I note that that 27 of 28 written public submissions were opposed to the interim decision. Respondents advised that there is a general need for increased access to CBD, often citing personal experience of safe and efficacious use. These submissions did not directly relate to the scope of the current proposal, the intention of which was to include an explicit reference for synthetic CBD in the Schedule 4 CBD entry. With regard to increased access, I refer respondents to my recent decision on non-prescription access to CBD.

With respect to this proposal, I remain of the view expressed in my interim decision that whilst not explicitly stated in the current Schedule 4 entry, both synthetic and non-synthetic forms of CBD are already captured under this entry. I also considered the need to limit synthetic cannabinoid impurities in Schedule 4 in my interim decision. I still remain of the view that there is no justification for the inclusion of impurities in a synthetically derived CBD product. It is important to prevent presence of synthetic cannabinoids in CBD products as they are potentially of greater potency than naturally occurring cannabinoids and could exert a psychoactive effect at the 2% limit proposed in the application.