MCIA
Medicinal Cannabis Industry Australia

27 January 2022

Advisory Committee on Medicines Scheduling (ACMS)
Therapeutic Goods Administration

By email: medicines.scheduling@health.gov.au

Re: Proposed Amendments to the Poisons Standard (Medicines/Chemicals)

Medicinal Cannabis Industry Australia (MCIA) welcomes the opportunity to make this submission to the Therapeutic Goods Administration (TGA) in relation to proposed introduction of Schedule 7 entries for cannabis and tetrahydrocannabinols for use in analytical and scientific research. The amended entries would allow access to cannabis and its derivatives for use in research without Schedule 9 requirements, which can include specific approval from State and Territory health departments.

About MCIA

MCIA is the peak industry organisation for Australia's licensed medicinal cannabis industry. This encompasses all activities of medicinal cannabis licence holders across research, cultivation and manufacturing and interaction with patients, the medical profession and communities.

MCIA's focus is on building an industry that enhances wellbeing through facilitating access to quality Australian medicinal cannabis products for Australian and global patients.

MCIA provides stewardship for an economically sustainable and socially responsible industry that is trusted and valued by patients, the medical community and governments. The Australian industry and its products are built on sound science and underpinned by industry processes and standards that ensure patients, the medical community and governments have confidence in the sector and its products.

Background

The Therapeutic Goods Administration (TGA) is undertaking consultation for a private submission to amend the scheduling for cannabis and tetrahydrocannabinols.

Currently, cannabis and tetrahydrocannabinols fall under Schedule 9 of the Poisons Standard when used for research and analytics. The manufacture, possession, sale or use of these substances is prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.

The applicant is seeking to introduce new entries in Schedule 7 and Appendix J for cannabis and tetrahydrocannabinols, for research and analytics, as follows:

Schedule 7 – New Entry

CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) for analytical and scientific research, and excluding human or veterinary therapeutic use, when present in:

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a) products cultivated or produced, or in products manufactured, in accordance with the Narcotic Drugs Act 1967; and/or

b) imported for the purpose of analytical and scientific research; and/or

c) therapeutic goods imported as therapeutic goods, or precursor material for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or

d) therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989*

except when

i) separately specified in the NABIXIMOLS in Schedule 8; or

ii) separately specified in the TETRAHYDROCANNABINOL entry in this Schedule; or

iii) captured by the CANNABIDIOL entry in Schedule 4 or Schedule 3; or

iv) hemp seed oil containing 75 mg/kg or less of cannabidiol and 10 mg/kg or less of tetrahydrocannabinols.

and

Schedule 7 – New Entry

TETRAHYDROCANNABINOLS, including carboxylic acid forms and the decarboxylated forms, when extracted or manufactured from cannabis and for use for analytical and scientific research, and excluding any human or veterinary therapeutic use, when present in:

a) products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or

b) material imported for the purpose of analytical and scientific research; and/or

c) therapeutic goods imported as therapeutic goods, or precursor material for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or

d) therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989*

Except when

i) it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applies; or

ii) separately specified in the NABIXIMOLS entry in this Schedule; or

iii) captured by the CANNABIDIOL entry in Schedule 4 or Schedule 3; or

iv) hemp seed oil at a concentration of 10 mg/kg or less.

Current scheduling is impacting research in medicinal cannabis

MCIA is supportive of the intent behind this proposal as recognises that the current Schedule 9 requirements are adversely impacting on research organisations and limiting the potential for foundational and preclinical research that could benefit the medicinal cannabis industry.

MCIA recently conducted a survey amongst organisations undertaking research in relation to medicinal cannabis which highlighted a number of issues relating to the currently scheduling of CANNABIS (including TETRAHYDROCANNABINOLS), with the key areas of concern being:

- Inclusion of non psychotropic cannabinoids
- Laboratories dealing in very low concentrations of THC i.e. at levels where little or no risk of diversion
- Witnessing of destruction (noting that the compliance requirements are established by States and Territories)

As such MCIA believes that the industry would benefit from a more appropriate listing of CANNABIS and TETRAHYDROCANNABINOLS for research settings where they are using non-psychotic compounds or very low concentrations of THC. The MCIA supports enabling high-quality research into the broad diversity of bioactive compounds present in CANNABIS, which we believe will benefit both patient safety and the development of novel therapeutics.

While not directly impacted by the scheduling amendment proposed, MCIA also believes that the industry would benefit from flexibility around witness requirements for the destruction of these substances and would propose that destruction should be able to be witnessed by an ODC "Authorised Person".

MCIA believes that the reasons for the proposal scheduling as outlined in the submission and repeated below are valid and would deliver benefit for patients and the medicinal cannabis sector e.g.

- Schedule 7 entries for cannabis and tetrahydrocannabinols will facilitate foundational and preclinical research of these substances without Schedule 9 controls.
- These substances are available in the Poisons Standard for therapeutic use in humans, and the proposed changes specify use only for research and analytics necessary to support and further therapeutic use.
- The proposal does not intend inclusion of any synthetic isomer of tetrahydrocannabinol which does not normally occur within the cannabis plant.
- Human or animal therapeutic use would be excluded under the proposed Schedule 7 listing. The application also proposed that cannabis and tetrahydrocannabinol are added to Appendix J - Schedule 7 Poisons Requiring Additional Controls on Availability of Use, Part 2 with an authorisation consideration of 'a' (restricted to analytical or research purposes only).
- Specialist analytical laboratories are generally experienced in, and have the skills, infrastructure and licences to handle Schedule 7 Dangerous Poisons. The risk of diversion of samples and standards required to undertake analytics and research (including preclinical animal studies) would appear to be small.
- The provisions in Parts 1 – 3 of the Poisons Standard pertaining to a Schedule 7 Dangerous Poison, appear appropriate for cannabis and tetrahydrocannabinol for analytical and research purposes, with regards to labelling, containers, storage, disposal, record keeping, restrictions on sale, supply, possession and use, and advertising.

MCIA supports the proposed amendments

The MCIA recognises that the legislative framework which permits the cultivation, manufacture and supply of medicinal cannabis is a relatively new development in Australia and in various other countries. As a result, there has been limited opportunity for research and development in respect of cannabinoid science.

Further, we note that even with the passing of amendments to the *Narcotic Drugs Act 1967 (Cth)* (the **Act**) there remains a number of regulatory restrictions, including within the Poisons Standard, which impede research and development activities and restricting access to the compound by researchers who would otherwise have been able to participate in the critical scientific review of this substance.

MCIA supports the proposed introduction of Schedule 7 entries for cannabis and tetrahydrocannabinols for use in analytical and scientific research. We note that the Public Consultation cites "Key uses/expected use" as "Medicines", while the remainder of the proposal clearly excludes therapeutic use, and MCIA reiterates its support for expected use in analytics and scientific research. The amended entries

would allow access to cannabis and its derivatives for use in research without Schedule 9 requirements, which can include specific approval from State and Territory health departments.

The proposal to include cannabis and its derivatives, when used in research, in Schedule 7 is consistent with the principles of scheduling, including purpose of use, and the level of control. While known toxicities of cannabinoids do not meet the definition of toxicity in Schedule 7, the provisions for controls, such as handling, storage and use, in Schedule 7 better meets the risk profile in laboratory settings compared with Schedule 9.

It is our belief that the rescheduling proposed will accelerate critical investigation into these compounds and support more informed decision making in the future, in respect of any further amendment to the Poisons Standard and/or more broadly in the better understanding of the safety and efficacy of cannabis based medicines.

Yours sincerely

Rosemary Richards
Executive Manager