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Department of Health and Aged Care

Inquiry into the Improving Access to Medicinal Cannabis Bill 2023

Submission from the Department of Health and Aged Care

to the Community Affairs Legislation Committee

May 2023

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Introduction

The Department of Health and Aged Care (the Department) welcomes the opportunity to make a submission to the Community Affairs Legislation Committee's Inquiry in relation to the Improving Access to Medicinal Cannabis Bill 2023 (the Bill).

The Therapeutic Goods Administration (the TGA), within the Department's Health Products Regulation Group (HPRG), is responsible for administering the *Therapeutic Goods Act 1989* (the TG Act). The objects of the TG Act include the establishment and maintenance of a national system of controls for therapeutic goods.

The regulation of therapeutic goods is shared with the states and territories. The Poisons Standard, which is made under the TG Act, is designed to facilitate uniform controls applying to medicines and chemicals in all jurisdictions. It classifies medicines and chemicals into Schedules according to the level of regulatory control over the availability of the medicine or chemical required to protect public health and safety. The Schedules are published in the Poisons Standard and are given legal effect through state and territory legislation.

The Bill proposes to amend the Poisons Standard, principally to down-schedule substances used in medicinal cannabis products (i.e. moving substances to a schedule with less regulatory restrictions). This submission explains the existing regulatory framework and identifies several concerns in relation to the specific amendments proposed in this Bill.

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Executive Summary

The Department considers there to be serious safety-related concerns with the proposed down-scheduling of substances in medicinal cannabis products, and practical concerns that the proposed amendments in the Bill would not give effect to the intended outcomes. In light of these concerns, the Department does not support the Bill.

The Department's concerns in relation to the Bill include that:

- The current entries in the Poisons Standard for substances in medicinal cannabis products were implemented following a very careful and considered assessment of the most appropriate pathways to access such products, based on available scientific knowledge, input from scheduling committees, expert advice, and the views of the public. The proposed amendments in the Bill do not appear to have undergone the same level of careful consideration and do not appear to be based on the detailed evidential analysis ordinarily conducted for scheduling decisions.
- The Poisons Standard is given effect through state and territory legislation. The ordinary scheduling process contains mechanisms for state and territory consultation. States and territories are not required to adopt scheduling changes and may be less inclined to do so where the ordinary processes that involve them are not pursued.
- Down-scheduling substances contained in medicinal cannabis products would not have the effect of making those products automatically eligible for inclusion on the Pharmaceutical Benefits Scheme (PBS). A product's inclusion on the PBS and the scheduling of substances that are contained within that product are two independent processes. A medicinal cannabis product would generally need to be included in the Australian Register of Therapeutic Goods (the Register) to be eligible for PBS listing. Down-scheduling substances included in a medicinal cannabis product would not make the product eligible for PBS listing. The proposed amendments would, therefore, not achieve this desired outcome.
- Down-scheduling substances contained in medicinal cannabis products would also not remove the need for medical practitioners to obtain Special Access Scheme (SAS) approval or Authorised Prescriber Scheme (APS) authorisation to prescribe medicinal cannabis products. These schemes provide a pathway for access to therapeutic goods that are not included in the Register. If a product is not in the Register (regardless of the scheduling of the substances it contains), an SAS approval or APS authorisation or other exemption to inclusion in the Register would be needed. The proposed amendments would, therefore, not achieve this desired outcome.

Background

Therapeutic goods legislative framework

The TG Act (and legislative instruments made under the TG Act) sets out the legal requirements that apply to the import, export, manufacture, and supply of therapeutic goods in Australia.

Generally, medicines must be entered on the Register, as 'registered' or 'listed' medicines, before they can be lawfully supplied in, or exported from, Australia. This ensures that registered medicines have been subject to pre-market scrutiny and that, for listed medicines, the sponsor of the goods has certified that the goods meet specified requirements (e.g. that the goods comply with all applicable standards), before they are available for consumers.

The responsibility for applying to the TGA to have a medicine registered resides with the sponsor of that medicine. A sponsor, in relation to a medicine, is a person or company that:

i. exports, or arranges the exportation of, the medicine from Australia.

ii. imports, or arranges the importation of, the medicine into Australia; or

iii. in Australia, manufactures, or arranges for another person to manufacture, the medicine, for supply (whether in Australia or elsewhere).

The TG Act operates in conjunction with state and territory medicines and poisons legislation. The TG Act generally regulates import and supply of medicines by sponsors. State and territory legislation generally regulates possession, retail supply and wholesale supply of medicines (see further below).

Scheduling of medicines and chemicals

The TGA also plays a vital role in the scheduling of medicines and chemicals in Australia. Under the TG Act, the Secretary of the Department or delegate (in practice a senior medical or scientific officer in the TGA) is conferred with the power to make decisions about the scheduling of substances. The Poisons Standard is a legislative instrument. The *Therapeutic Goods (Poisons Standard—February 2023) Instrument 2023* (the February 2023 Poisons Standard) is the current Poisons Standard.

Substances are scheduled according to the risk of harm that they pose and the level of access control that is required to protect public health and safety. The Poisons Standard also includes model provisions for controls on substances, including about containers and labels and supply, possession, and use of substances.

Separately, each state and territory have enacted medicines and poisons laws that give legal effect to the access controls that apply to substances listed within the Schedules to the Poisons Standard. State and territory laws regulate the safe storage, prescribing, supply, and use of medicines in their jurisdiction. Generally, these laws describe who can lawfully distribute, prescribe, and administer scheduled substances.

The power to make scheduling decisions is vested in the Secretary of the Department and, in practice, is exercised by a delegate of the Secretary who is a senior medical or scientific officer within the TGA. When exercising this power, the Secretary (or delegate) must take several matters into account. These include the risks and benefits of the use of the relevant substance and the purposes for which it is to be used, the toxicity, dosage, formulation, labelling, packaging and presentation of the substance, and the potential for misuse or abuse of the substance. The Secretary may also consider any other matters that they consider necessary to protect public health.

Ordinarily, the scheduling delegate makes decisions after seeking advice from an expert advisory committee and public consultation.

Advisory Committees

In 2010, amendments to the TG Act established two expert advisory committees, being the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS). Collectively, the functions of these committees are to make recommendations to the Secretary (or their delegate) on the level of access appropriate for medicines and chemicals.

In accordance with the TG Act and the *Therapeutic Goods Regulations 1990* (the Regulations), the Commonwealth, each state, the Australian Capital Territory, and the Northern Territory, are each entitled to nominate a member of the ACMS and ACCS (nominated members). This reflects the fact that the scheduling arrangements form part of a Commonwealth/state/territory co-operative scheme for the regulation of therapeutic goods. In addition to each nominated member, each committee can comprise of up to eight 'appointed members', which must have expertise in at least one field prescribed by the Regulations. These fields include, among others, the regulation of scheduled medicines in Australia, toxicology or pharmacology, pharmacy practice, and medical practice. The Regulations also provide that membership of the ACMS and ACCS must, to the extent reasonably practicable, represent the widest possible range of the prescribed fields of expertise.

In exercising their power to make decisions in relation to the scheduling of a medicine or chemical, the Secretary (or their delegate) must have regard to any recommendations or advice that has been provided by the ACMS and/or the ACCS.

The process for scheduling decisions that are referred to an advisory committee is outlined in Figure 1.

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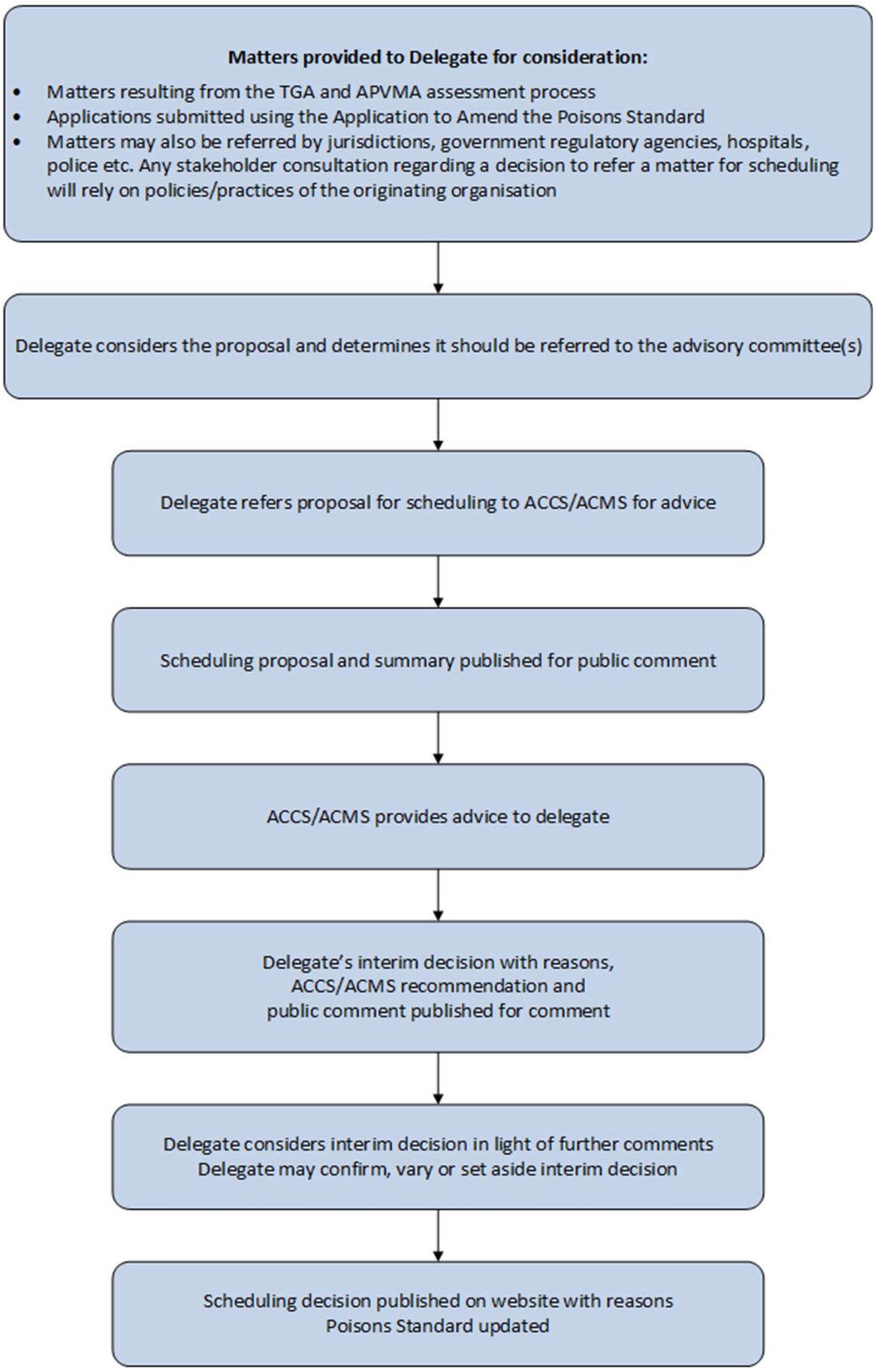

Figure 1 – Scheduling decisions referred to an advisory committee: process diagram (Scheduling handbook: Guidance for amending the Poisons Standard, Version 1.1, July 2019: www.tga.gov.au/sites/default/files/scheduling-handbook-guidance-amending-poisons-standard.pdf)

Scheduling policy framework

In making a scheduling decision, the TG Act also requires the decision-maker to comply with any guidelines made by the (previously named) Australian Health Ministers' Advisory Council (AHMAC). AHMAC, which has been renamed as the Health Chief Executives Forum, is responsible for policy principles on scheduling and other poisons regulatory controls and developed the *Scheduling policy framework for medicines and chemicals* (the Scheduling Policy).

The Scheduling Policy outlines the national policy for applying access restrictions on all medicines and chemicals in Australia. It requires that all scheduling decisions include consideration of a standard set of factors (which are specific to each Schedule) to ensure that public health objectives are consistently met, and public health risk considerations are applied uniformly.

Schedule 3 (Pharmacist Only Medicines)

Substances in Schedule 3 to the Poisons Standard are those that require professional advice to be used safely, but which should be available to the public from a pharmacist without a prescription. In accordance with the Scheduling Policy, the factors that would indicate that it is appropriate to list a substance in Schedule 3 are that:

1. The medicine is substantially safe with pharmacist intervention to ensure the quality use of the medicine, noting that there may be potential for harm if the medicine is used inappropriately.
2. The use of the medicine is not expected to produce dependency at either the established therapeutic dose or at supratherapeutic doses, noting that where the risk of misuse, abuse or illicit use is identified, the risk can be minimised through pharmacist-consumer consultation;
3. The risk profile of the medicine is well-defined and the risk factors for adverse effects, interactions and contraindications are known, identifiable, and manageable by a pharmacist;
4. Where the medicine is intended for recurrent or subsequent treatment of a chronic condition, pharmacist intervention is required to monitor the safe use of the medicine following recommendation by a medical practitioner or other authorised prescriber; and
5. The use of the medicine at established therapeutic dosage levels may mask the symptoms or delay diagnosis of a serious condition.

Schedule 4 (Prescription Only Medicines)

Substances in Schedule 4 to the Poisons Standard are those that have common therapeutic uses but, due to their propensity to be used, misused and diverted, require more stringent controls on possession and supply. In accordance with the Scheduling Policy, the factors that indicate that a substance should be included in Schedule 4 are that:

1. The ailments or symptoms that the substance is used for require medical, veterinary or dental intervention;

2. The use of the substance requires adjunctive therapy or evaluation or specialised handling for administration;
3. The use of the substance at established therapeutic dosage levels may produce dependency but has a moderate propensity for misuse, abuse or illicit use;
4. The seriousness, severity and frequency of adverse effects are such that monitoring or intervention by a medical, veterinary or dental practitioner is required to minimise the risk of using the substance;
5. The margin of safety between the therapeutic and toxic dose of the substance is such that it requires medical, veterinary or dental intervention to minimise the risk of using the substance;
6. The seriousness or severity and frequency of the interactions of the substance (medicine-medicine, medicine-food, or medicine-disease) are such that monitoring or intervention is required by a medical, veterinary or dental practitioner;
7. The use of the substance has contributed to, or is likely to contribute to, communal harm; and
8. The experience of the use of the substance under normal clinical conditions is limited.

Schedule 8 (Controlled Drugs)

Substances in Schedule 8 to the Poisons Standard are those that have an established therapeutic value but, by reason of their novelty or properties, carry a substantial risk of producing dependency. In accordance with the Scheduling Policy, the factors that would indicate that it is appropriate to list a substance in Schedule 8 are that:

1. The substance is included in Schedule I or II of the United Nations Single Convention on Narcotic Drugs 1961 (the Single Convention), or in Schedule II or III of the United Nations Convention on Psychotropic Substances 1971 (the PS Convention); and
2. The substance has an established therapeutic value but its use, at established therapeutic dosage levels, is recognised to produce dependency and has a high propensity for misuse, abuse or illicit use.

Schedule 9 (Prohibited Substances)

Substances in Schedule 9 to the Poisons Standard are those over which a high level of control is required through prohibition of manufacture, possession, sale or use, in order to prevent abuse misuse, or diversion into illicit activities. The benefits of using such substances are substantially outweighed by the risks, and the dangers of use are such as to warrant limiting the use of these products strictly to controlled medical and scientific research. In accordance with the Scheduling Policy, factors that would indicate that it is appropriate to list a substance in Schedule 9 are that:

1. The substance is included in either Schedule IV to the Single Convention or in Schedule I to the PS Convention; and
2. The substance has no currently established therapeutic value and is likely to present a high risk of dependency, abuse, misuse, or illicit use.

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Concerns with the Bill

Proposed down-scheduling of medicinal cannabis

The Explanatory Memorandum (EM) to the Bill states that the intention of the Bill is to improve the availability of medicinal cannabis for all Australians and their pets by:

- re-scheduling medicinal cannabis to Schedule 4;
- adopting a definition for cannabis that allows a higher level of tetrahydrocannabinol (THC), up from 0.1% to 1%, which is below the recognised level for any hallucinogenic response and harmonises Commonwealth law with state law (all states are currently 1%); and
- allowing whole plant cannabis products with a limit of 1% THC and 10% cannabidiol (CBD) to be sold over the counter at a chemist or veterinarian to persons over 18.

The main changes proposed to the Poisons Standard are to:

- amend the entries for cannabis and THC in Schedule 9 to exclude cannabis and THC products containing less than 1% of total THC content from those entries. This would result in some cannabis and THC products currently covered by Schedule 9 being down-scheduled and others becoming unscheduled;
- move the entries for cannabis, THC, and nabiximols from Schedule 8 to Schedule 4, thereby making a greater range of medicinal cannabis products available as prescription medicines (Schedule 4), instead of as controlled drugs (Schedule 8) which are subject to greater regulatory controls (though the Bill does not move or amend the Schedule 8 entry for dronabinol (synthetic THC)); and
- make changes to the entry for CBD in Schedule 3 which would expand in some ways, and potentially limit in others, the range of CBD products available as Schedule 3 medicines which can be sold over the counter at a pharmacy or by a veterinarian. The entry would be extended to include topical preparations and to allow a greater percentage of cannabinoids (other than CBD) that can be included. But the CBD content would be limited to 10% of the preparation (whereas there is no current restriction on the CBD content) and it may exclude synthetic CBD.

The following tables set out the current scheduling of the relevant substances, the proposed re-scheduling that the Bill would give effect to, and comments outlining concerns with the proposed re-scheduling of the cannabis substances (the main changes are italicised).

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SCHEDULE 9

Item	Current Scheduling	Proposed Scheduling	Comments
1	CANNABIS (including seeds, extracts, resins, and the plant and any part of the plant when packed or prepared), **except**: (a) when separately specified in these Schedules; or (b) *processed hemp fibre containing 0.1% or less of tetrahydrocannabinols and hemp fibre products manufactured from such fibre*; or (c) hemp seed oil containing 75 mg/kg or less of cannabidiol and 10 mg/kg or less of tetrahydrocannabinols.	CANNABIS (including seeds, extracts, resins and the plant and any part of the plant when packed or prepared), **except**: (a) when separately specified in these Schedules; or (b) *when the product contains less than 1% of total tetrahydrocannabinol content*; or (c) hemp seeds and hemp seed oil containing 75 mg/kg or less of cannabidiol and 10 mg/kg or less of tetrahydrocannabinols.	The EM indicates that this amendment is intended to increase the THC limit (above which the plant is regulated as a narcotics drug rather than as a medicine) to 1. This would have the effect that some Schedule 9 substances will be down-scheduled to Schedule 4. It will also have the effect that some such products may become unscheduled as a result of the exclusion of products from the Cannabis entry in Schedule 9 of 'products' containing less than 1% of total THC content by paragraph (b) of each new entry in Schedule 9, if such products are not covered by the proposed new Schedule 4 or Schedule 3 entries. If implemented, the consequence of this would be that restrictions about access to some cannabis products including medicines will be significantly relaxed (from regulation as a Schedule 9 substance to no access controls under the Poisons Standard), posing a risk to consumer health and safety.

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Item	Current Scheduling	Proposed Scheduling	Comments
2	TETRAHYDROCANNABINOLS and their alkyl homologues, **except**: (a) when included in Schedule 4 or Schedule 8; or (b) *processed hemp fibre containing 0.1% or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre;* or (c) in hemp seed oil at a concentration of 10 mg/kg or less.	TETRAHYDROCANNABINOLS and their alkyl homologues, **except**: (a) when separately specified in these Schedules; or (b) *the product contains less than 1% of total tetrahydrocannabinol content;* or (c) in hemp seed oil at a concentration of 10 mg/kg or less.	Same as for Item 1.

SCHEDULE 8

Item	Current Scheduling	Proposed Scheduling	Comments
3	# NABIXIMOLS (botanical extract of *Cannabis sativa* which includes the following cannabinoids: tetrahydrocannabinols, cannabidiol, cannabinol, cannabigerol, cannabichromene, cannabidiolic	*Repeal the entry – include in Schedule 4* instead: # NABIXIMOLS (botanical extract of *Cannabis sativa* which includes the following cannabinoids: tetrahydrocannabinols, cannabidiol,	The EM indicates that the intention of this amendment is to down-schedule nabiximols to a Schedule 4 substance, and it would have that effect. However, the consequence would be that consumers would be exposed to greater risk

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Item	Current Scheduling	Proposed Scheduling	Comments
	acid, tetrahydrocannabinolic acids, tetrahydrocannabivarol, and cannabidivarol, where tetrahydrocannabinols and cannabidiol (in approximately equal proportions) comprise not less than 90% of the total cannabinoid content) in a buccal spray for human therapeutic use.	cannabinol, cannabigerol, cannabichromene, cannabidiolic acid, tetrahydrocannabinolic acids, tetrahydrocannabivarol, and cannabidivarol, where tetrahydrocannabinols and cannabidiol (in approximately equal proportions) comprise not less than 90% of the total cannabinoid content) in a buccal spray for human therapeutic use.	from this medicine than under the current scheduling restrictions. As controlled drugs currently, specific storage and stocktaking requirements apply to these products under legislation enacted in each State and Territory. If down-scheduled to a Schedule 4 substance, these access controls would not apply.
4	# TETRAHYDROCANNABINOLS when extracted from cannabis for human therapeutic use, when: (a) included in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or (b) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Act; and/or (c) in therapeutic goods supplied in accordance with the Act; **except** when:	*Repeal the entry – include in Schedule 4 instead:* # TETRAHYDROCANNABINOLS when extracted from cannabis for human therapeutic use, when: (a) included in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or (b) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or	The EM indicates that the intention of this amendment is to down-schedule tetrahydrocannabinol from Schedule 8 to a Schedule 4 substance, and it would have that effect. However, the consequence of this amendment would be increase safety and public health risks, noting the high risk of dependency or illicit use of these substances, and that in some individuals high doses of these products can produce psychoactive effects. There is also the potential for misuse and abuse, requiring significant access controls. As controlled drugs currently, specific storage and stocktaking

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Item	Current Scheduling	Proposed Scheduling	Comments
	(d) 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 (e) separately specified in the NABIXIMOLS entry in this Schedule; or (f) captured by the CANNABIDIOL entry in Schedule 4 or Schedule 3; or (g) in hemp seed oil at a concentration of 10 mg/kg or less.	(c) in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989*; **except** when: (d) 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 (e) captured by the CANNABIDIOL entry in Schedule 3; or (f) separately specified in the CANNABIDIOL entry in this Schedule; or (g) separately specified in the NABIXIMOLS entry in this Schedule; or (h) in hemp seed oil at a concentration of 10 mg/kg or less.	requirements apply to these products under legislation enacted in each State and Territory. If down-scheduled to a Schedule 4 substance, these access controls would not apply.
5	# CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use, when:	*Repeal the entry – include in Schedule 4 instead*:	The EM indicates that the intention of this amendment is to down-schedule tetrahydrocannabinol from Schedule 8 to a

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Item	Current Scheduling	Proposed Scheduling	Comments
	(a) cultivated or produced, or in products manufactured, in accordance with the *Narcotic Drugs Act 1967*; and/or (b) for use in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or (c) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Act; and/or (d) in therapeutic goods supplied in accordance with the Act; **except**: (e) when 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 (f) when separately specified in the NABIXIMOLS entry in this Schedule; or	# CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use, when: (a) cultivated or produced, or in products manufactured, in accordance with the *Narcotic Drugs Act 1967*; and/or (b) for use in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or (c) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or (d) in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989*; **except**: (e) when it is in a product to which item 4, 8, 10, 11 or 12 of	Schedule 4 substance, and it would have that effect. However, the consequence of the amendment would be to increase safety and public health risks, noting the high risk of dependency or illicit use of these substances, and that in some individuals high doses of these products can produce psychoactive effects. There is also the potential for misuse and abuse, requiring significant access controls. As controlled drugs currently, specific storage and stocktaking requirements apply to these products under legislation enacted in each State and Territory. If down-scheduled to a Schedule 4 substance, these access controls would not apply.

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Item	Current Scheduling	Proposed Scheduling	Comments
	(g) when captured by the CANNABIDIOL entry in Schedule 4 or Schedule 3; or (h) hemp seed oil containing 75 mg/kg or less of cannabidiol and 10 mg/kg or less of tetrahydrocannabinols.	Schedule 5A to the *Therapeutic Goods Regulations 1990* applies; or (f) when separately specified in the CANNABIDIOL entry in this Schedule; or (g) when separately specified in the NABIXIMOLS entry in this Schedule; or (h) hemp seeds and hemp seed oil containing 75 mg/kg or less of cannabidiol and 10 mg/kg or less of tetrahydrocannabinols.	
6	# DRONABINOL (delta-9-tetrahydrocannabinol) when prepared and packed for therapeutic use.	Nil	The Bill does not make any changes to the current scheduling of dronabinol.

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SCHEDULE 4

Item	Current Scheduling	Proposed Scheduling	Comments
7	CANNABIDIOL in preparations for therapeutic use or analytical and scientific research where: (a) cannabidiol comprises 98% or more of the total cannabinoid content of the preparation; and (b) any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the preparation; **except** when: (c) included in Schedule 3; or (d) in hemp seed oil at a concentration of 75 mg/kg or less.	Repeal and replace entry in Sch 4: CANNABIDIOL *extract* in preparations for therapeutic use or analytical and scientific research where: (a) cannabidiol comprises 98% or more of the total cannabinoid content of the preparation; and (b) any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the preparation; **except** when: (c) included in Schedule 3; or (d) separately specified in the CANNABIS entry in this Schedule.	The EM indicates that the proposed new schedule entry adds the word 'extract' with the intent to clarify that this entry does allow cannabidiol extracts. It further indicates that protects existing extracts and synthetic cannabidiol products already in the markets and that may be in the approval process. This amendment would have the effect that cannabidiol *extracts* would be Schedule 4 substances if they meet the criteria for this schedule entry.

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SCHEDULE 3

Item	Current Scheduling	Proposed Scheduling	Comments
8	CANNABIDIOL in oral, oromucosal and sublingual preparations included in the Register when: (a) *the cannabidiol is either plant derived or, when synthetic, only contains the (-)-CBD enantiomer*; and (b) *the cannabidiol comprises 98% or more of the total cannabinoid content of the preparation;* and (c) *any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the preparation and* of which tetrahydrocannabinol (THC) can only comprise 1% of the total cannabinoid content; and (d) the maximum recommended daily dose is 150 mg or less of cannabidiol; and	CANNABIDIOL in oral, oromucosal, *topical* and sublingual preparations included in the Register when: (a) *the cannabidiol content of the preparation does not exceed 10%*; and (b) *any cannabinoids, including cannabidiol, must be only those naturally found in cannabis* of which tetrahydrocannabinol (THC) can only comprise 1% of the total cannabinoid content; and (c) the maximum recommended daily dose is 150 mg or less of cannabinoids; and (d) packed in blister or strip packaging or in a container fitted with a child-resistant closure; and (e) in packs containing not more than 30 days' supply; and	The EM indicates that the intention of this amendment is to allow whole plant cannabis products with a limit of 1% THC and 10% cannabidiol (CBD) to be sold over the counter at a chemist or veterinarian to persons over 18. The proposed new schedule entry has the effect that any cannabinoids, including cannabidiol, must be only those naturally found in cannabis and thus may exclude the forms of synthetic CBD permitted by the current entry. It also places a limit of 10% total CBD in the preparation, where there is currently no limit on the proportion of cannabinoids that are CBD. The new entry also includes topical preparations and does not limit the percentage of cannabinoids (other than CBD) that can be included.

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Item	Current Scheduling	Proposed Scheduling	Comments
	(e) packed in blister or strip packaging or in a container fitted with a child-resistant closure; and (f) in packs containing not more than 30 days' supply; and (g) for persons aged 18 years and over.	(f) for persons aged 18 years and over.	

The Department does not support these changes as the impact of the proposed amendments do not appear to have been comprehensively considered, nor do they reflect expert clinical opinions. The Department is also concerned that the proposed changes would, if enacted, pose significant risks to public health and safety, through removing or reducing access controls that are currently recommended to avoid risks such as misuse and abuse of these higher risk substances.

The proposed changes do not reflect the deliberative, scientific process in which scheduling changes are ordinarily made. The existing scheduling entries for medicinal cannabis have evolved over a period of 8 years. The changes were made following multiple rounds of public consultation and several rounds of expert advisory committee advice from the ACMS. As outlined above, the ACMS comprises not only nominated members from the Commonwealth and each of the states and territories, but also experts from a range of pharmaceutical, scientific, and public health disciplines. The delegate who makes the decisions is ordinarily a senior medical or scientific officer who has the relevant expertise to assess the matters required by the TG Act. The current scheduling of CBD and THC has been in place since the Poisons Standard was amended in March 2021.

The Department also has more specific concerns about the precise changes as outlined in the table above.

In particular, the Bill proposes to down-schedule THC, nabiximols and cannabis in medicinal cannabis products from Schedule 8 (controlled drugs) to Schedule 4 (prescription-only medicines) to the Poisons Standard. The proposed amendments in the Bill do not appear to take into consideration the high risk of dependency or illicit use of these substances, and that in some individuals high doses of these products can produce psychoactive effects, and that there is the potential for misuse and abuse. The proposed amendments also do not appear to address the propensity of these substances to lead to dependence and abuse, requiring significant access controls. As controlled drugs, specific storage and stocktaking requirements apply to these products under legislation enacted in each state and territory. However, if down-scheduled, such restrictions would not apply to a Schedule 4 substance.

Eligibility for inclusion on the Pharmaceutical Benefits Scheme

The Explanatory Memorandum to the Bill states that *"[r]e-scheduling cannabis to Schedule 4 of the Poisons Standard will allow for inclusion on the Pharmaceutical Benefits Scheme (PBS) as a separate process"*. The Department notes that this amendment, if it were to become law, would not achieve the Bill's objective of allowing for the inclusion of medicinal cannabis on the PBS.

While the therapeutic goods legislative framework establishes a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods, the PBS, which is established under the *National Health Act 1953* (the NH Act)), is—quite separately—the mechanism through which the Government subsidises the cost of certain medicines for the treatment of Australian patients.

As a matter of policy, the PBS is generally administered on the basis that medicines are not listed on the PBS unless they are included on the Register. A medicinal cannabis product would generally need to be included in the Register to be eligible for PBS listing. As such, the Bill would not have the effect of providing for the inclusion of medicinal cannabis products on the PBS.

On 1 May 2021, Epidyolex, used in combination with at least two other anti-epileptic medicines, was included on the PBS. Epidyolex is registered on the Register and was the first medicinal cannabis product to be included on the PBS.

However, as the scheduling of a substance has no bearing on the eligibility of a product containing that substance to be listed on the PBS, the rescheduling of cannabis proposed in the Bill would not of itself allow for the inclusion of medicinal cannabis products on the PBS.

Availability and patient access to medicinal cannabis

Any medicinal cannabis product that is on the Register can be lawfully supplied in Australia, provided relevant state and territory supply laws are observed (e.g. where it is in Schedule 4 it must be prescribed by a relevant health practitioner).

While there are many registered export-only medicinal cannabis products, there are currently only two products that are registered for supply in Australia. These are Sativex (containing nabiximols), which was registered in 2012 and is indicated for the treatment of spasticity in certain patients with Multiple Sclerosis (MS), and Epidyolex (CBD) which was registered in 2020 and is indicated for the adjunct treatment of seizures associated with Lennox-Gastaut Syndrome or Dravet Syndrome in patients that are two years of age and older.

Access pathways for unapproved medicinal cannabis products

Under the TG Act, there are a number of mechanisms that enable access to therapeutic goods which are not on the Register (otherwise known as ‘unapproved’ therapeutic goods). These mechanisms include established pathways such as the SAS and APS, as well as the Clinical Trials Notification and Clinical Trials Approval schemes.

The SAS and APS pathways were designed to ensure that the TGA has oversight of unapproved therapeutic goods that are being used in Australia, and that patients who are using such products are doing so under the supervision of a registered medical practitioner who has been approved or authorised under the TG Act to prescribe them. The schemes facilitate the rapid identification of patient safety concerns that may be linked to unapproved therapeutic goods and balance the importance of ensuring patient access to new treatments with the broader community interest in therapeutic goods being evaluated for their quality, safety, and efficacy.

Further, the use of new treatments under these pathways supports future efforts to seek marketing approval in relation to those treatments. The Regulations also include reporting requirements designed to assist with post-market monitoring of therapeutic goods that are accessed under these pathways.

Since 2016, there has been a consistent and substantial increase in the number of both SAS approvals and APS authorisations that have been granted by the Secretary, which demonstrates that patient access to medicinal cannabis under the existing regulatory framework is expanding.

To date, over 400 different unapproved medicinal cannabis products have been prescribed via the SAS and APS patient access pathways. The contents and ratios of CBD and THC across these different products vary significantly, as does the dosage forms in which they are presented, which include oral solutions, capsules, wafers, tablets, lozenges, oil formulations, topical products (such as creams, gels, and tinctures), and products for inhalation. Further, medicinal cannabis products are being prescribed to treat a range of conditions, such as chronic pain management, psychological conditions (anxiety, post-traumatic stress disorder, insomnia), cancer pain and symptom management, and certain epileptic conditions.

Removing the requirement from accessing medicinal cannabis through the SAS or the APS

The Explanatory Memorandum to the Bill indicates that the Bill "*restores the primacy of the doctor/patient relationship and removes the need for the Approved Prescriber Scheme and Special Access Scheme for medicinal cannabis"*.

The Bill purports to achieve this outcome, specifically, by rescheduling substances in medicinal cannabis from Schedules 8 and 9 to Schedule 4 of the Poisons Standard. However, this proposed amendment would not have the effect of permitting access to all medicinal cannabis products via prescription through any medical practitioner, as opposed to a practitioner who is authorised or approved to prescribe such products under the SAS or APS.

Medicinal cannabis products that are not on the Register would still need to be accessed through the APS or SAS (or another exception that allows supply of unregistered products), regardless of the scheduling of substances in the medicinal cannabis product. Accordingly, the rescheduling of the substances in medicinal cannabis products, as proposed in the Bill, would not alter this position.

In relation to the suggestion in the Explanatory Memorandum that removal of the need for the APS and SAS for medicinal cannabis would *'restore the primacy of the doctor/patient relationship',* the TGA's view is that the application of the SAS and APS to medicinal cannabis products (without modification) already embodies this tenet. This is because the APS and SAS empower the approved health practitioner or authorised medical practitioner to identify and prescribe (with minimal intervention by the TGA) treatments that they consider to be the most appropriate for their patient, in consultation with that patient and having regard to the patient's particular circumstances, despite the relevant treatment not being approved for supply by the TGA.

Domestic legal considerations

There are no legal barriers per se to an Act amending a legislative instrument, as the Bill proposes in relation to the current Poisons Standard. Subsection 13(5) of the *Legislation Act 2003* (the Legislation Act) recognises that this may occur. Importantly, however, the Legislation Act makes it clear that where an Act amends a legislative instrument, this does not prevent the instrument (as amended by the Act) from subsequently being amended or repealed in accordance with its enabling legislation (the note in Schedule 3 of the Bill reflects this). Accordingly, if the Bill were enacted, it would be open to the Secretary (or their delegate) to amend, or repeal and replace, the Poisons Standard (as amended by the Bill) as appropriate.

Further, by the time the Bill, if made, became law, the February 2023 Poisons Standard is likely to have been repealed and replaced. This is because regular updates are made to the scheduling of substances in Australia, with the Poisons Standard being repealed and replaced approximately three times every year. Accordingly, even if the Bill were to be enacted, it may not have any practical effect if it does not refer to the current Poisons Standard in effect at the time it commences (unless the Bill is amended to accommodate the possibility of amendments through the ordinary scheduling process affecting the Parliamentary amendments).

State and territory adoption of proposed amendments

The states and territories give legal effect to the Poisons Standard by adopting it (in part or in full) in their medicines and poisons legislation. Most, if not all, states and territories have the capacity to modify the application of the Poisons Standard in their jurisdictions through delegated legislation.

Noting that the down-scheduling of medicinal cannabis products may conflict with the Scheduling Policy for medicines (including psychoactive drugs, as agreed by all states and territories through AHMAC at the time), the states and territories may not all be supportive of the amendments the Bill purports to make. It is not clear whether the states and territories were consulted on the proposed amendments in the Bill, as is generally the case for amendments to the Poisons Standard that are referred to the ACSM. It is possible that the states and territories may modify or prevent the application of the proposed amendments. The states and territories may also be critical of amendments to the Poisons Standard being made by the Commonwealth Parliament given that this is part of a co-operative legislative scheme in which the states and territories are involved through the ordinary scheduling processes.

If any state or territory did not adopt the changes, this would result in different regulatory standards applying in different jurisdictions, causing confusion for patients, health practitioners, and industry. This would defeat the main purpose of the Poisons Standard, which is to establish a national system of control for substances, based on (among other things) consultation with the states and territories.

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Other concerns

Finally, the amendments proposed in the Bill have not been drafted in a way that enables the Bill to achieve its intended purposes. Entries to the Poisons Standard require careful legal drafting to ensure that they operate as intended, especially for products such as cannabis and cannabinoids that have entries in multiple Schedules. In this regard, it is not clear that the integration of the various amendments proposed in the Bill into the Poisons Standard have been properly considered. A number of the proposed new Schedule entries are unclear, particularly the manner in which the Schedule entries for certain substances cross reference the Schedule entries for other substances, and this may lead to uncertainty as to the precise scheduling of particular substances.

Conclusion

The Department acknowledges the community expectations that there should be a lawful source of cannabis for medicinal purposes, and that there has been increased attention in recent years to reports that suggest cannabis is beneficial in the treatment and symptomatic relief for some health conditions. In this regard, the Department notes that to date two medicinal cannabis products have been approved by the TGA for supply in Australia, being Sativex and Epidyolex, which are indicated for the treatment of certain patients with MS and epilepsy, respectively.

The Department also acknowledges that, subject to appropriate safeguards being in place, failure to enable the supply of cannabis for medicinal purposes, as well as further scientific study into this treatment option, could deny patients access to new, safe, and effective medicines and treatments. This formed one of the reasons for the amendments made to the *Narcotic Drugs Act 1967* in 2016 to provide a legislative framework that enables cannabis cultivation in Australia and provides Australian patients in need with access to medicinal cannabis for therapeutic purposes.

However, the amendments in the Bill undermine the current scheduling of substances in medicinal cannabis products (based on expert advice and scientific and clinical evidence, taking into account various factors including public health and safety) and would otherwise not achieve their intended outcomes. For the safety-related, practical, and legal concerns that are outlined in this submission, the Department does not support this Bill.