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Pauline's Puzzling Proposal: Does it achieve its intended purpose?

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On 9 March 2023, Senator Pauline Hanson introduced the *Improving Access to Medicinal Cannabis Bill 2023* (**Bill**) in the Senate, which proposes to improve access to medicinal cannabis for all Australians and also for animals.

The long title of the Bill is *'A Bill for an Act to amend the law relating to the regulation of products made or that contain cannabis, and for related purposes'*.

The Purported Amendments

The Bill amends the Therapeutic Goods (Poisons Standard – February 2023) Instrument 2023 (the **Poisons Standard**). The proposed amendments are:

- in section 6 of the Poisons Standard, insert the definition of 'total tetrahydrocannabinol (**THC**) content' which is defined as the 'total amount of delta-9-tetrahydrocannabinol and delta-9-tetrahydrocannabinolic acid''. This definition is consistent with the definition of 'total THC content' in the Customs (Prohibited Imports) (Importation of Hemp Seeds and Hemp Derived Products) Approval 2018;
- repeal and substitute the Schedule 3 entry for cannabidiol (**CBD**), such that the following changes are made to the entry:
    - The condition that the CBD is either plant derived or, when synthetic, only contains the (-)-CBD enantiomer is removed; and
    - The definition of CBD is amended so that any cannabinoids, including CBD, must be only those naturally found in cannabis[1] and the CBD content of the preparation does not exceed 10% including not more than 1% THC.[2]
- repeal and substitute the Schedule 4 entry for CBD, such that the following changes are made to the entry:
    - Remove the condition that hemp seed oil at a concentration of 75 mg/kg or less is excluded for the Schedule 4 entry for cannabidiol;
    - Add the condition that CBD is excluded when separately specified in the Schedule 4 cannabis entry;

[1] The current Schedule 3 entry for 'cannabidiol' specifies that cannabinoids other than CBD, must comprise 2% or less of the total cannabinoid content of the preparation. The amendment thereby removes this requirement.
[2] The current Schedule 3 entry for 'cannabidiol' specifies that CBD must comprise 98% or more of the total cannabinoid content of the preparation.

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- Add the word 'extract' after the word 'cannabidiol' to clarify this entry does allow CBD extracts;

- reschedule cannabis from Schedule 8 to Schedule 4, noting that there are otherwise no major changes to the wording of the entry;
- reschedule nabiximols from Schedule 8 to Schedule 4, noting that there are no major changes to the wording of the entry;
- repeal the Schedule 8 entries for cannabis, nabiximols and THC;
- reschedule THC from Schedule 8 to Schedule 4, with slightly modified wording to account for THCs that are not Schedule 4, (*i.e.* when captured by the CBD entry in Schedule 3 or separately specified in the cannabidiol entry in Schedule 4);
- repeal and substitute the Schedule 9 entry for cannabis, such that the following changes to the entry are made:
  - Broadening the scope of the products that are excluded from the Schedule 9 entry for cannabis to exclude products that contain less than 1% of total processed hemp fibre containing 0.1% or less of THC, hemp fibre products manufactured from such fibre (rather than just hemp fibre containing 0.1% or less of THC and hemp fibre products manufactured from such fibre) and hemp seeds containing 75 mg/kg or less of CBD and 10 mg/lg or less of THC;
  - The THC level is increased from 0.01 to 1%; and
  - The exception now includes the new listing for cannabis in Schedule 4;
- repeal and substitute the Schedule 9 entry for THC, such that the following changes to the entry are made:
  - Broadening the scope of the products that are excluded from the Schedule 9 entry for THC to exclude products that contain less than 1% of the total THC content rather than just excluding processed hemp fibre containing 0.1% or less of THC, and hemp fibre products manufactured from such fibre;
  - The THC level is increased from 0.01% to 1%;
  - The exception now includes the new listing for THCs in Schedule 4; and
- In the index, the references to cannabis, nabiximols and THCs as Schedule 8 substances are replaced with Schedule 4 to reflect the down-scheduling of these substances.

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The Amendments Explained

The Explanatory Memorandum states that the Bill proposes to:

- reschedule medicinal cannabis to schedule 4, allowing its prescription by any medical practitioner;
- adopt a definition for cannabis that allows a higher level of THC, up from 0.1% to 1%, which the Explanatory Memorandum says is below the recognised level for any hallucinogenic response and harmonises Commonwealth law with state and territory laws;
- allow whole plant cannabis products with a limit of 1% THC and 10% CBD to be sold over the counter at a chemist or by veterinarian to persons over 18; and
- retain the listing for hemp as a food product with existing limits unchanged.

According to the Explanatory Memorandum, these proposed changes supposedly:

- remove the need for the Approved Prescriber Scheme (**APS**) and Special Access Scheme (**SAS**) to access medicinal cannabis; and
- allow for the inclusion of medicinal cannabis products on the Pharmaceutical Benefits Scheme (**PBS**) (the PBS being an Australian Government program that subsidises medicines to make them more affordable).

The Poison Standard

Poisons and medicines are categorised into different schedules, which are set out in the Poison Standard depending on their intended use(s) and potential for harm. Different levels of control apply to the different schedules with respect to how substance is labelled, sold, bought, stored and disposed of. The lower the schedule, the less stringent the control.

At present, most medicinal cannabis products are Schedule 8 substances, a category which the Poisons Standard describes as 'controlled drugs', being substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use, to reduce abuse, misuse and physical and/or psychological dependence. A limited class of cannabis products containing predominantly CBD are also listed in Schedule 4 (prescription-only) and in Schedule 3 (available without prescription but only from a pharmacist).

Scheduling decisions are made by the Secretary of the Department of Health, who is empowered to amend the Poisons Standard on their own initiative or upon consideration of an application made by an individual, stakeholder or government body. The Secretary can

refer applications to the Advisory Committee on Medicines Scheduling and/or Advisory Committee for Chemicals Scheduling (who have relevant expertise including in toxicology, pharmacology, pharmacy practice and medical practice) for advice. Scheduling decisions involve a risk-benefit consideration, which involves taking into account factors such as:

- the toxicity of the substance;
- the purpose of use (including the diagnostic decision);
- potential for abuse and misuse;
- safety in use, including the need for specialist training or personal protective equipment; and
- the benefits/needs of access to the substance.

There is no evidence that these factors were considered in the drafting of the Bill.

The Bill proposes to amend the Poison Standard so that medicinal cannabis products currently in Schedule 8 are down-scheduled to Schedule 4.

Although the proposed amendments would decrease the regulatory burden relating to the labelling, storage, sale, supply and disposal of medicinal cannabis products, the down-scheduling would have no bearing on the requirement for prescribers to obtain approval or authorisation to supply medicinal cannabis products under the Special Access Scheme (**SAS**) and Authorised Prescriber Scheme (**APS**), respectively, or on the potential for medicinal cannabis products to be reimbursed under the PBS. This is because medicinal cannabis products, in the main, are not registered in the Australian Register of Therapeutic Goods (**ARTG**), meaning that:

- their supply to patients is only permissible under the exemption schemes promulgated by the SAS and APS; and
- reimbursement under the PBS is unavailable.

Accessing unapproved medicinal cannabis products

Therapeutic goods are registered by the Therapeutic Goods Administration (**TGA**) following an assessment which has established that their quality, safety and efficacy is satisfactory. It is an offence to import, export, manufacture or supply therapeutic goods that are not included in the ARTG, unless they are exempt goods.

The pathway to registration in the ARTG is an onerous one, requiring the submission of a complex dossier of clinical, preclinical, chemistry and manufacturing data to the TGA. The investment required to prepare such a dossier is prohibitive and costly, and is further complicated in the case of medicinal cannabis products because of the relatively limited

scientific evidence regarding the efficacy of medicinal cannabis products for most indications. As a result, there are only two medicinal cannabis products currently registered in the ARTG: Sativex and Epidyolex. All other medicinal cannabis products supplied in Australia are unapproved products, and can only be supplied in accordance with the Commonwealth access schemes for unapproved therapeutic goods (APS and SAS) (subject to also complying with individual state and territory requirements).

Regardless of whether a medicinal cannabis product is classified as a Schedule 4 or Schedule 8 medicine, medical practitioners are not lawfully able to prescribe unapproved medicinal cannabis products other than in accordance with the SAS or APS, or pursuant to a clinical trial that has been approved by a human research ethics committee. We therefore do not see how the Bill, as drafted, would possibly obviate the need for the SAS and APS.

Issues hampering access to medicinal cannabis

We do not agree that the existing scheduling framework combined with the SAS and APS frameworks is preventing Australians from accessing medicinal cannabis. While there are additional controls placed on Schedule 8 medicines compared with Schedule 4 medicines, every patient seeking access to a medicinal cannabis product for a legitimate therapeutic purpose is able to access it. If anything, the additional controls have some bearing on the administrative red tape affecting the cost of supply, but access *per se* is not materially affected by a medicine's scheduling.

In terms of access to medicinal cannabis, we note that the TGA reported that between July 2016 and July 2022 1,157,195 patients have been able to access medicinal cannabis through the APS,[3] and 344,695 SAS-B applications have been approved.[4] The issues concerning access to medicinal cannabis products relate to their, at times, prohibitive cost and also to the existing state and territory drug-driving laws that, in effect, cause patients with a legitimate need for medicinal cannabis to decline treatment because of fear of retribution under archaic laws which ought to have been amended when medicinal cannabis was first legalised in 2016.

While we are of the view that more affordable medicinal cannabis products would undoubtedly make medicinal cannabis more accessible, we do not agree that the proposed amendments to the Poison Standard will facilitate listing on the PBS. Applications for PBS listing require the preparation of detailed submissions that are reviewed by the Pharmaceutical Benefits Advisory Committee (**PBAC**), who make recommendations to the Minister for Health as to which medicines should be subsidised. In making recommendations

[3] Data available at: https://dashboard-data.health.gov.au/single/?appid=f330a1c6-d805-4c64-a6ef-76a69d32d8b7&sheet=a7cdc199-1658-4c94-87d0-9a3b76c520eb&select=clearall
[4] Data available at: https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-access-pathways-and-patient-access-data/medicinal-cannabis-special-access-scheme-category-b-data

to the Minister, the PBAC must consider the effectiveness and cost of therapy involving the use of the drug, which is usually established by comparing the effectiveness and cost of that therapy with that of alternative therapies currently on the PBS. As noted above, there is limited scientific evidence to support the use of medicinal cannabis products in most indications, such that it is unlikely that a company seeking to list a medicinal cannabis product on the PBS will have the requisite data to demonstrate its comparative effectiveness and cost. This problem is not ameliorated by rescheduling medicinal cannabis products from Schedule 8 to Schedule 4 – in fact, the scheduling of a medicine has no bearing whatsoever on its suitability to be listed on the PBS.

We want to make it very clear that we are the strongest proponents of improving access to medicinal cannabis products – it has been a focus of our work in the medicinal cannabis industry since legalisation. However, to put it mildly, we consider that the Bill is misguided and misinformed, and will do nothing in reality to improve access.

We encourage the government to engage in consultation with the medicinal cannabis industry to develop legislation and policy that will better support medicinal cannabis patients and facilitate access.