MILLS OAKLEY

SUBMISSION TO COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024

12 April 2024

Introduction

This submission summarises the concerns identified by Mills Oakley regarding the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (**Bill**) and the new vaping reforms more broadly, which have reportedly been introduced to address the public health concerns regarding the supply of nicotine vaping products (particularly to young people).

The new legislation which underpins the vaping reforms has been analysed by the author of this document, who is also currently the Chair of the Australian Medicinal Cannabis Association (**AMCA**), the medicinal cannabis industry's largest peak body.

AMCA represents more than 370 individuals across the medicinal cannabis sector, including more than 30 industry organisations that have already expressed concern about the impact of the vaping reforms on their businesses and the patients they serve.

It is in that context that this submission has been prepared, which raises concerns about the unintended and potentially deleterious consequences of the vaping reforms for the medicinal cannabis sector.

What do the new vaping reforms achieve?

The new vaping reforms prohibit the importation of therapeutic vaping devices and accessories without the sponsor:

(a) submitting a *Sponsor notice – Vaping goods (Notice to import or supply in Australia therapeutic vaping goods)* (**Sponsor Notice**), which requires the sponsor to declare:

  (i) in the case of devices and accessories supplied with therapeutic vaping substances or other vaping devices/accessories, that their vaping good complies with applicable standards and that the only intended use for the vaping good is for smoking cessation or the management of nicotine dependence; or

  (ii) in the case of devices and accessories supplied on their own (*i.e.* where they do not contain and are not combined with a therapeutic vaping substance), that their vaping good complies with the 14 Essential Principles (**EPs**) listed in Schedule 1 to the *Therapeutic Goods (Medical Devices) Regulations 2002*

(**MD Regulations**), and that the only intended use for the vaping good is for smoking cessation or the management of nicotine dependence; and

(b) or a person on the sponsor's behalf, obtaining an import licence and permit for each importation of the goods.

For nicotine vaping goods, the *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021* (TGO 110) (**Standard**) commenced on 1 January 2024 and includes up-to-date requirements that will apply to such vaping goods that are imported or manufactured from 1 March 2024.

The Standard applies to, *inter alia,* "therapeutic vaping devices" and "therapeutic vaping device accessories" when they are included in a "therapeutic vaping pack" (that is, when they contain or are combined with therapeutic vaping substances or other vaping devices/accessories), but such devices and accessories, according to the MD Regulations, do not include cannabis vaping devices and accessories. Further, the Standard expressly states that it only applies to, *inter alia,* vaping devices and accessories that are intended to be used for smoking cessation or nicotine dependence (*viz* nicotine vaping products). Relevantly, the Standard provides that vaping devices and accessories must either comply with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* (**MDSO**) or the EPs.

Where nicotine vaping devices or accessories are imported on their own (that is, where they do not contain and are not combined with a therapeutic vaping substance), they must comply with the EPs. The MDSO provides that, where it applies to a device/accessory, compliance with the MDSO is taken to be compliance with the EPs.

How do the vaping reforms impact medicinal cannabis?

The MDSO provides for vaping devices and accessories other than those to be used with medicinal cannabis to meet a range of standards that are much less stringent than compliance with the EPs.

In the case of medicinal cannabis, however, our reading of the legislation is that importers of cannabis vaping devices and cannabis vaping accessories (which meet the definition of a medical device or medical device accessory under subsection 41BD(1) of the *Therapeutic Goods Act 1989* (**TG Act**)) may only import those goods into Australia if they are either:

(a) included in the Australian Register of Therapeutic Goods; or

(b) the subject of an exemption to which subsections 41HA and 41HB of the TG Act apply, which provide for supply under the Special Access Scheme, Authorised Prescriber Scheme or for use in clinical trials, in which case a notice (**MC Notice**) must be submitted to the TGA by the importer certifying that the devices/accessories comply with the 14 EPs,

and, in either case, an import licence and permit are obtained permitting the importation of the goods.

Because neither the Standard nor the MDSO apply to such cannabis vaping devices or accessories, importers cannot rely on the less stringent standards specified in the MDSO in order to demonstrate compliance with the EPs.

Until the vaping reforms were introduced, vaping devices and accessories for vaping/ inhalation purposes were easily obtainable because such devices and accessories could be accessed lawfully for recreational purposes and could therefore be purchased and applied for use with medicinal cannabis. Alternatively, patients could purchase such vaping devices and accessories under the personal importation scheme, allowing them to source vaping devices and/or accessories from overseas that were suitable for their needs.

With the new vaping reforms, supply pathways to cannabis vaping devices and accessories have been substantially restricted (for instance, the personal importation scheme has been closed), to the point that it is our opinion that it will severely impact access to medicinal cannabis for patients. There are only three devices included in the ARTG that are suitable to administer medicinal cannabis and given that the vast majority of medicinal cannabis products are flower and oil to be administered by inhalation or vaporisation, it is unlikely that these three inclusions will be able to supply the entire patient population that administers medicinal cannabis via these routes.

We have had a number of approaches from companies seeking clarity regarding the supply of cannabis vaping devices and accessories on the Australian market now that the reforms have commenced. What is emerging is that, even on a global basis, very few companies manufacture vaping devices and accessories that comply with the EPs, as most companies manufacture such goods for recreational purposes. Given the small percentage of the global market that the Australian population represents, we expect that most suppliers of vaping devices and accessories will simply not be prepared to generate technical files demonstrating compliance with the EPs, as this is a costly exercise which is not likely to be justified by any anticipated return on investment.

The TGA says that compliance with the EPs has always been “required” for unapproved devices that are used for therapeutic purposes. Whilst that may be correct, it disregards the fact that prior to the reforms, medicinal cannabis patients were able to access vaping devices and accessories in the ways described above. Since the reforms have now prohibited altogether the supply of recreational vaping devices and accessories and blocked the personal importation scheme for vaping devices and accessories of any kind, this has constructively impacted patient access to medicinal cannabis, because it has left medicinal cannabis patients in the invidious position of being able to access the medicines they need for their treatment, but with severely impeded access to the devices and accessories that are essential to administer those medicines.

Vaping is one of the most effective means of administering medicinal cannabis and the nearest alternative, smoking, is not a viable therapeutic option due to the lack of dosing specificity (compared to vaping), loss of terpene efficacy and, most importantly, the risks to patients, including with respect to carcinogenic potential.

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Recommendations

1. We strongly recommend that the Government introduce a medical device standard for cannabis vaping devices and accessories that mirrors the MDSO for nicotine vaping devices and accessories.
2. Given the complexity of the legislation that has been introduced, we recommend that the Government pause on passing or introducing any additional legislation to allow for more considered dialogue on the impact the reforms are having more broadly than on nicotine vaping, as there are other uncertainties arising out of the Stage 1 reforms that we and industry stakeholders are having difficulties resolving. We note, in this regard, that there has already been one instance in which the Government needed to quickly make amending regulations to correct an unintended consequence of the Stage 1 reforms, which initially had the effect of completely blocking the importation of vaping devices for use with medicinal cannabis.

The author of this document would be willing to appear before the Committee in any public hearing that is held in relation to the Bill, if it would assist the Committee's further understanding of the issues we have raised.

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