WORLD TRADE ORGANIZATION

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** AUSTRALIA **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Therapeutic Goods Administration, Department of Health **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** Department of Foreign Affairs and Trade Email tbt.enquiry@dfat.gov.au
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medicinal cannabis products (being therapeutic goods that contain, or are manufactured from, any part of the cannabis plant) and any ingredients used in the manufacture of those products (including, but not limited to, the cannabis plant). For the purposes of this notification, 'cannabis plant' means any plant, or part of a plant, of the genus Cannabis, including, but not limited to, the flowers, fruiting tops, seeds, stems and leaves of the plant.; PHARMACEUTICAL PRODUCTS (HS 30)
5.	**Title, number of pages and language(s) of the notified document:** Reforms to medicinal cannabis manufacturing, labelling and packaging requirements.
6.	**Description of content:** The Therapeutic Goods Administration (TGA) is seeking comment on a package of reforms in relation to the manufacturing, labelling and packaging requirements for Medicinal Cannabis Products made available in Australia or supplied to Australians. Background In recent years, Australian Governments at Commonwealth, State and Territory levels have implemented legislative and policy changes to allow the cultivation, manufacture and supply of medicinal cannabis for patients in Australia. The TGA administers Australia's national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods in Australia. Typically, therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG). If they are not included in the ARTG, these goods can only be lawfully supplied in, imported into, or exported from Australia if they are subject to an exemption, approval or authority. Therapeutic goods not on the ARTG are referred to as 'unapproved products'. Currently, most medicinal cannabis products are unapproved products. Unapproved medicinal cannabis products can be accessed via the Authorised Prescriber Scheme (AP), Special Access Scheme (SAS) or clinical trials.

The TGA requires certain standards for medicinal cannabis products accessed in Australia, as set out principally in TGO 93. At present, Australian manufacturers must comply with Good Manufacturing Practice (GMP) standards, whereas a similar requirement does not apply to product imported into Australia.

Reform proposal

There has been a significant increase in the supply and use of medicinal cannabis products in Australia. In light of this, the TGA recently undertook a review of the regulation of medicinal cannabis products manufacturing, labelling and packaging, which included a public consultation held between December 2020 and January 2021. The TGA has subsequently developed a package of reforms, described below.

TGO 93 and the Regulations are proposed to be amended to require the following:

- Imported medicinal cannabis products will be required to be manufactured on sites with acceptable GMP standards. Sponsors (the companies importing the goods) must maintain evidence to show compliance for each batch of medicinal cannabis products. The TGA will provide sponsors with clear guidance on the GMP practices and evidence required, which will be in accordance with existing recognised global standards and/or accreditation. This measure provides greater certainty on the quality and safety of products available to Australian patients. It extends broadly the same standards to offshore manufacturers currently required of Australian manufacturers. For the avoidance of doubt, the TGA will not be requiring sponsors of offshore manufacturers to comply with a unique Australian manufacturing standard. Sponsors will be able to rely on a manufacturer's adherence to an internationally accepted GMP standard (of a type acceptable to the TGA) that may be specific to that manufacturer's country.
- Extemporaneous compounding by medical practitioners and pharmacists will require approval from the TGA under the Special Access Scheme (SAS). Medicinal cannabis manufactured outside of Australia can still be used in extemporaneous compounding.
- TGO 93 will be amended to include requirements for (a) a child resistant closure on high risk goods, which is normal practice for medicines that present a poisoning risk (b) labelling that better identifies the active ingredients and (c) clarity on microbiological testing requirements. Clear guidance on the requirements – and a reasonable transition period – will be provided.

7. **Objective and rationale, including the nature of urgent problems where applicable:** The objectives of the package of reforms are to:

- Provide assistance to patients and medicinal practitioners to identify equivalent products within the large range of products available. This will be achieved by requiring more information on product labels.
- Provide greater certainty to Australian patients and medical practitioners around quality and safety by ensuring that both Australian and international medicinal cannabis manufacturers are subject to similar manufacturing standards.
- Provide clarity for sponsors and manufacturers operating in multiple jurisdictions as to the minimum safety and quality requirements in Australia.
- Improve regulatory oversight of extemporaneous compounding of medicinal cannabis products by medicinal practitioners and pharmacists.

Consumer information, labelling; Protection of human health or safety; Quality requirements

8. **Relevant documents:**

Proposed reforms which will be implemented through updates to:

(a) the existing Standard for Medicinal Cannabis Therapeutic Goods (Standard for Medicinal Cannabis) (TGO93) Order 2017;

	(b) the Therapeutic Goods Regulations 1989; and (c) the Narcotic Drugs Regulations 2016. (together, the Regulations) The proposal for comment is the suite of reforms, in principle. The updated TGO and Regulations are currently being drafted and are intended to reflect the reform proposal described in this notification. An initial consultation was held between December 2020 and January 2021. The consultation paper and a subsequent statement are online at http://www.tga.gov.au/consultation/consultation-potential-reforms-medicinal-cannabis-manufacturing-labelling-and-packing-requirement
9.	**Proposed date of adoption:** The proposed amendments to TGO 93 and to the Regulations are proposed to be finalised and published in March 2022. The TGA intends to provide a reasonable transition period. **Proposed date of entry into force:** This period will be determined in consultation with industry and is likely be up to 12 months.
10.	**Final date for comments:** 20 February 2022
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:**