Medsafe encourages those making comments on this harmonisation item to consider classification and supply of cannabidiol (CBD) in the context of New Zealand legislation.

Down-scheduling of CBD by the Australian Therapeutic Goods Administration (TGA)

The down scheduling of low CBD from Schedule 4 (Prescription Medicine) to Schedule 3 (Pharmacist Only Medicine) in 2021 by the TGA in Australia is limited to only those products that are approved by the TGA by assessing safety, efficacy and quality. Approved products are on the Australian Register of Therapeutic Goods (ARTG). Currently there are no TGA approved CBD product on the ARTG. Furthermore, those products not on the ARTG list are still considered unapproved medicines which can only be accessed through the Special Access Scheme (SAS) or Authorised Prescriber (AP) scheme by a medical practitioner for supply.

The following documents are relevant to the decision to down schedule in Australia:

https://www.tga.gov.au/sites/default/files/review-safety-low-dose-cannabidiol.pdf

https://www.tga.gov.au/scheduling-decision-final/notice-final-decision-amend-or-not-amend-current-poisons-standard-cannabidiol

The Schedule 3 (Pharmacist Only Medicine) entry for cannabidiol in the Australian Poisons Standard now reads:

CANNABIDIOL in oral, oromucosal and sublingual preparations included in the Australian Register of Therapeutic Goods when:

- *a) the cannabidiol is either plant derived or, when synthetic, only contains the (-)-CBD enantiomer; and*
- *b) the cannabidiol comprises 98 per cent 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 per cent or less of the total cannabinoid content of the preparation and of which tetrahydrocannabinol (THC) can only comprise 1 per cent of the total cannabinoid content; and*
- *d) the maximum recommended daily dose is 150 mg or less of cannabidiol; and*
- *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.*

Regulation of CBD products in New Zealand under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019

When the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 came into effect, it also brought about an amendment to the Medicines Regulations 1984 to add Regulation 4A, that requires CBD products to meet the minimum quality standard imposed by Part 1 of the Cannabis Regulations.

CBD products are required to show they meet the required minimum quality standard in order to be verified for supply. They remain unapproved medicines in NZ. They are supplied to Medical Practitioners under the provisions of section 29 of the Medicines Act, following that practitioner's authorisation (i.e. prescribing) under section 25 of the Act. Down scheduling CBD would not result in any changes to the requirements to the supply of a CBD product under this regulatory scheme.

Medsafe harmonisation with the Australian TGA

Medsafe requests that the Medicines Classification Committee (MCC) considers the classification of substances in Australia, noting that New Zealand and Australia have been working towards harmonisation of classification decisions in both countries. However, classification of medicines must take into consideration New Zealand legislation and context. In the case of CBD, it's important to note that any down-scheduling of CBD would only impact supply of products that have Ministerial consent (i.e. pursuant to section 20 or 23 of the Medicines Act 1981).

Impact of CBD scheduling in New Zealand

If CBD were to be down-scheduled, and therefore available as pharmacist only in New Zealand, this would only impact products that have ministerial consent. It would not impact products that have been verified through the medicinal cannabis agency. These would remain unapproved medicines for the purposes of the Medicines Act 1981 and would remain prescription medicines that may be supplied in accordance with section 25 and 29 of the Act.

A CBD medicine intended to be sold over the counter would require ministerial consent (approval). For example, this would require provision of appropriate efficacy data to support any approved indications. Details can be found on Medsafe website.

https://www.medsafe.govt.nz/medicines/regulatory-approval-process.asp

Comments on this harmonisation agenda item

The scope of the Medicines Classification Committee is to consider the classification of medicines as prescription medicines, restricted medicines, or pharmacy-only medicines. Medicines that are not classified are considered to be 'general sale'. Supply of unapproved medicines that have been verified under the medicinal cannabis regulations is outside the scope of the MCC. The Misuse of Drugs (Medicinal Cannabis) Regulations 2019 are outside the scope of the MCC.

Medsafe encourages those making comments on this harmonisation item to consider classification and supply of CBD in the context of New Zealand legislation.