

## **Removal of CBD (with Less Than or Equal to 0.2% THC from Schedule of the SUSMP)**

### **SUBSTANCE**

- Cannabidiol; CBD; 2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3- benzenediol

### **CAS Number**

- CAS number: 13956-29-1 **Chemistry**

- IUPAC Name: 2-[(6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol

**Delta Tetra support remove plant-derived forms of CBD which have 98% or more CBD but less than or equal to 0.2% THC from the SUSMP and instead, regulate them in the same way that other herbal medicines are regulated in Australia (via listing, assessed- listing or registering on the ARTG).**

As of 31 January 2020, according to the TGA website, there are 63 Authorised Prescribers and approximately 31,000 cannabis prescriptions have been written under the SAS-B since 2016. The cost of a 30ml bottle of CBD ranges from around \$150-300 in Australia, whilst in Europe, the cost is around 30 Euros. According to market analysis by Cannabis Access Clinics, the estimated average monthly cost of medicinal cannabis for Australian patients is \$370 , unaffordable for most Australians.

CBD is considered by the World Health Organization (WHO) to have relatively low toxicity (WHO - Cannabidiol (CBD) Critical Review Report – Expert Committee on Drug Dependence Fortieth Meeting Geneva, 4-7 June 2018 – Page No.13). The risk to public health is low. CBD is regarded as having a good safety profile, is well tolerated, with no potential for abuse or dependence. Side effects associated with CBD have been found to be mild.

CBD does not produce the effects seen with THC including the potential euphoric effects of THC (which are dose-dependent and depend on individual factors). Across many controlled and open label trials, CBD has been found to be generally well tolerated.

CBD has a range of potential actions including analgesic, antiemetic, anticonvulsant/anti-epileptic, antipsychotic, anxiolytic and antidepressant, anti-inflammatory, antioxidant, neuroprotective, anti-tumoral and anti-cancer, anti-asthmatic and immunomodulatory. CBD may be used in proprietary forms including oils, oils in capsules, sublingual and intranasal sprays, suppositories, and externally (creams, salves, transdermal patches). In Australia, CBD oils used orally are the most popular form of CBD product at this current time, typically available in bottles with a dropper.

In our opinion, this is consistent with the intention of Section 52E of the *Therapeutic Goods Act 1989* which is to provide access to substances of potential benefit to the public whilst ensuring public safety, by taking into account such factors as toxicity and

potential for abuse. This is also consistent with how other herbs and herbal extracts are regulated in Australia.

Furthermore, regulation of proprietary forms of CBD as a complementary medicine under the ARTG ensures quality, safety and efficacy. Australia has one of the best regulatory systems for complementary medicines in the world. Therefore, public safety will not be compromised with removal of CBD formulations (as defined earlier) from Schedule 4 of the SUSMP and its proposed regulation as a complementary medicine.

Many herbs and their active constituents have the potential to interact with certain pharmaceuticals. There is no reason to single out CBD derived from plant sources from other herbs or herbal extracts. Concerns with respect to potential CBD-pharmaceutical interactions could be handled via labelling (this could also include a maximum recommended daily dosage), as they are with other herbal medicines and complementary medicines. A search of the TGA and ADRAC websites indicates no reports of adverse reactions or adverse interactions between CBD and pharmaceuticals in Australia since prescribing was legalised in 2016.