

15 December 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022015823

Dear s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 31 October 2022. Please find a response to each of your requests below.

Please can you provide copies of all advice and decision papers by or on behalf of Medsafe to show why CBD products are classified as prescription only medicines.

Cannabidiol (CBD) is classified in New Zealand as a prescription-only medicine in Schedule One, Part One of the Medicines Regulations 1984. This follows a legislative change made in December 2018 with the passing of the Misuse of Drugs (Medicinal Cannabis) Amendment Act, where CBD was removed from the Misuse of Drugs Act 1975 as a controlled drug.

Information about the scheduling of CBD including papers relating to the minutes of meetings by the Expert Advisory Committee on Drugs (EACD) and the Medicines Classification Committee (MCC) can be found at:
www.medsafe.govt.nz/publications/OIA/CannabidiolAndTetrahydrocannabinol/Contents.asp.

I have found the gazette notice for Sativex (which contains both THC and CBD) and would be grateful for the names of and any such notices for products containing only CBD, as well as any other relevant information assessing or explaining the risks of these products, including the data sheets etc. Please include all reviews by any Committees or other advisors to Medsafe including information about the lowest levels of CBD which Medsafe says should and/ or does trigger the "prescription only" classification.

There seems to be considerable disproportionality between the "prescription only" status of say Comirnaty which is new, uses new technology and artificial mRNA, compared to the hemp plant and which has been linked to numerous deaths and serious ongoing adverse effects (including Myocarditis, pericarditis, menstrual and other hormonal disorders, neurological disorders, blood clots and ten pages or so of other disorders listed on the April 2021 Adverse Effects advice to Pfizer that was belatedly made public earlier this year. This is in stark contrast with CBD which is widely recognised by the NZ and other governments as being safe, and yet which currently has the same "prescription only" status. This is despite hemp products being widely used as food in many countries and many forms of cannabis sourced products increasingly being used for medicinal and nutritional purposes.

I note the government has proven itself able to act very promptly in creating exemptions to the Medicines Act when it suits it to do so. Examples include amending the Medicines Act in May 2021 within 24 hours or so of Ellis J's decision in the Kaitiaki Tuku Ihu Medical Society Inc "KTI" case and a second amendment in 2022 to facilitate further boosters (despite there being no sponsor for this). Please could you provide information to show any consideration given to freeing up access to CBD products through a similar process (preferably with public consultation).

Please could you provide any relevant information held by Medsafe assessing or reviewing this type of discrepancy and considering the human rights and/ or international law implications of restricting access to any or all parts of the hemp plant.

The Medicines Classification Committee (MCC) considers and makes recommendations on the classification of medicines as prescription medicines, restricted medicines, or pharmacy-only medicines. The classification of CBD was considered at the 69th meeting of the MCC in 2022. The agenda, comments, and minutes of this meeting are published on Medsafe website: <https://www.medsafe.govt.nz/committees/mcc.asp>

You can search for the classification of medicines on Medsafe's website at: www.medsafe.govt.nz/profs/class/classintro.asp. Cannabidiol is classified as a prescription medicine at any concentration. You can also search for products containing any active ingredient on Medsafe's website at: www.medsafe.govt.nz/regulatory/dbsearch.asp.

Regulatory guidance provided to the MCC by Medsafe is publicly available at: www.medsafe.govt.nz/profs/class/Agendas/Agen69/CBDHarmonisationRegulatoryGuidance.pdf.

Information on approved medicines containing CBD is publicly available at: <https://www.medsafe.govt.nz/regulatory/DBSearch.asp>.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely



Chris James
Group Manager
Medsafe