**Interest in ‘Medicinal Cannabis’ and the Classification of Cannabidiol**

Recent public debate and media comment about access to ‘medicinal cannabis’ has been clouded by use of the use of imprecise terminology.

‘Cannabis’ commonly refers to the plant or plant material, but it may also refer to preparations derived from the plant. Cannabis plant is named in the Misuse of Drugs Act (MoDA) 1975 as a Class C controlled drug. Cannabis preparations, derived from cannabis plant are listed in MoDA as Class B controlled drugs (e.g. hashish, hash oil). The plant itself and the various preparations can show considerable variability in chemical content. There is debate in the literature as to whether there is more than one species of cannabis plant. While some distinguish between species such as *cannabis sativa* and *cannabis indica*, other authorities treat cannabis as a single variable species with particular characteristics that can be enhanced by selective breeding and horticultural practices.

Cannabis is known to contain more than a hundred distinctive chemicals, known as cannabinoids. The principal psychoactive constituent is tetrahydrocannabinol (THC). Another major cannabinoid is cannabidiol (CBD). This constituent is not psychoactive. Strains of cannabis developed for their psychoactive potency contain high levels of THC and, usually, low levels of CBD. Strains of cannabis developed for hemp fibre and/or hemp seed production generally contain high levels of CBD but low levels of THC. In many countries, including NZ, cannabis plants used for hemp fibre or hemp seed production are subject to a regulatory limit on the level of THC they may contain. The NZ hemp industry is small.

Any “medicinal cannabis” that is produced by processing cannabis plant will very likely fall within the classification of a Class B Controlled Drug, being a “cannabis preparation”, which is “any preparation containing any tetrahydrocannabinols …. produced by subjecting cannabis plant material to any kind of processing”. Cannabis plant is, nevertheless, ‘prescribed’ in certain jurisdictions in the USA. At the other extreme, if “medicinal cannabis” refers to a ‘pure’ (THC-free) pharmaceutical-type preparation made from extracted cannabis plants (e.g. containing the chemical CBD), arguably this would not be considered a cannabis preparation.

Last year the Associate Minister of Health, Hon Peter Dunne, approved the use of ‘Elixinol’ a product from the USA containing CBD, to be administered by clinicians treating Wellington patient, Alex Renton, in an attempt to help control his severe condition, status epilepticus. Although evidence from controlled clinical trials in humans is limited, there is some support for the use of CBD as an anticonvulsant and in treatment of Dravet syndrome (a rare form of epilepsy). Mr Dunne’s approval was considered necessary because of a view that CBD is a Class B1 controlled drug. I disagree with that view and return to the topic later in this paper. This instance has been referred to in recent discussions and in the media as an example of the legal use of ‘medicinal cannabis’. I consider this to be misleading. CBD is but one of the constituents of cannabis. To use an analogy, codeine is found in the opium poppy (along with morphine and other opiate alkaloids) but we do not refer to someone using codeine as using ‘medicinal opium’.

There is considerable interest in the use of cannabis or cannabinoids in medical treatment or to improve symptoms. Pharmacological research has been undertaken over recent years to explore the role that constituents or combinations of constituents found in cannabis might offer in a variety of medical conditions. There is some limited evidence suggesting that cannabis can be used to reduce medical treatment side effects, such as nausea and vomiting during chemotherapy, improved appetite in people with HIV/AIDS, and in the treatment of chronic pain and muscle spasms.

A synthetic THC equivalent, dronabinol, and a synthetic cannabinoid, nabilone are marketed in branded pharmaceutical products in the US and some other countries.

An oromucosal spray derived from strains of cannabis containing a mixture of THC and CBD has been approved for use in NZ under the product brand name ‘Sativex’. Sativex® is approved by Medsafe as an add-on treatment for improvement of symptoms in patents with moderate to severe spasticity due to MS who have not responded adequately to other anti-spasticity medication. Because it is a cannabis preparation, Sativex® is classified as a Class B(1) drug product under Misuse of Drugs Act 1975.

There is interest from hemp growers in NZ to seek information pertaining to the CBD content of the hemp plants they grow and harvest. Their desire may be to be able to extract CBD from these hemp plants and hemp fibre for therapeutic use and/or as an alternative to the imported ‘Elixinol”. In addition the hemp industry is wanting to utilise their hemp plant waste material, which potentially contains high levels of CBD with concomitant low levels of THC. However they may unwittingly be preparing “cannabis preparations” with the associated Class B classification. Note that the classification of a substance under legislation is one thing but approval to market a product containing a substance for therapeutic use is a different question altogether that is not discussed in this paper.

The classification of CBD as a Class B1 controlled drug, requiring Ministerial approval for use, is based on advice provided to the Ministry of Health. That advice treats CBD as an isomer of THC. The Drug Chemistry Team at ESR and I disagree with that advice, not on chemical grounds but on the basis of the application of the ‘fine print’ of the Misuse of Drugs Act legislation, which limits the inclusion of isomers ‘within the specific chemical designation’. In my opinion, THC and CBD do not have the same chemical designation. By virtue of CBD being listed as a prescription medicine in the Medicines Regulations, approved products containing CBD would then not require Ministerial approval for use. Please note that this should be considered to be a separate issue to access to access to ‘medicinal cannabis’.

Summary

1. In discussions, there needs to be a clear mutual understanding of the meaning intended by use of the phrase ‘medicinal cannabis’, but preferably it should not be used at all as its definition is too broad and not well accepted. Subsequent discussion of cannabis-derived medicinal preparations should clearly indicate whether the product referred to is indeed a purified chemical substance such as CBD, or some form of (extracted) plant material.

2. In my opinion, the classification of purified CBD as a Class B1 controlled drug, requiring Ministerial approval for use, is incorrect. Instead, as CBD is listed as a prescription medicine in the Medicines Regulations, its use should not need Ministerial approval.

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12 April 2016

Acknowledgement: I acknowledge helpful discussions with members of the Drug Chemistry Team in the writing of this paper.