Position paper

CBD is not a narcotic

European Medicinal Cannabis Association (EUMCA)[1]
Authored by Clever Leaves

Summary

The controversy as to the narcotic status of CBD was recently addressed by the WHO, which after a critical review of evidence, recommended to the United Nations Commission on Narcotic Drugs to include a note in the international list of narcotic drugs from the 1961 Single Convention clarifying that CBD is not a controlled substance even if it is extracted from cannabis. Regarding the issue of CBD purity, a limit of 0.2% THC maximum is being proposed by the WHO.

During meeting of the 63rd session of the United Nations Commission on Narcotic Drugs (CND) in Vienna on December 2nd, 2020 it is important to asses that uncertainty about the legal status CBD; especially of plant-derived CBD, is a barrier to its medical use. While a few countries e.g. USA, Germany, Denmark and the UK have explicitly removed pure CBD and CBD preparations from their narcotic lists, the ambiguity over its legal status still persists in many EU Member States in parallel with current unregulated market of consumer products of unknow quality. The adoption of purity standards for CBD preparations, if not at UN level, can be done at regional or national level based on equilibrated regulations to guarantee protection of users in balance with access; UK, Australia and South Africa are pioneering with recent proposals of regulation for oral CBD products.

Introduction: Why CBD is not a Narcotic

Pure CBD is a white, odourless crystalline powder; synthesised chemically or obtained from plants (e.g. Hemp) and highly purified by solvent extraction and crystallisation. It is not a narcotic. It can be formulated into pharmaceutical grade products for medicinal use. These should not be confused with preparations in circulation that are labelled as containing CBD but, in addition can contain amounts of Tetrahydrocannabinol (THC) over levels that can be tolerated in food.

Based on clinical studies that support its efficacy and safety, CBD is currently consumed in about 30 countries and has marketing authorization as a medicine approved in the USA, Europe and Australia. The scientific literature available today allows the recognition of its medical use and affirms that CBD is neither a narcotic nor psychotropic substance and lacks any risk of addiction. This was recently recognized by the European Court of Justice Case C663/18 (Kanavape) who acknowledges CBD produced legally from any part of cannabis plant is subject to free trade within the EU.

However, in most countries the legal status of CBD is not fully defined, particularly when derived from the cannabis plant; the use of which is highly regulated or even prohibited. Because some regulators around the world have not specified a purity threshold for when highly pure CBD becomes a chemical entity; different from cannabis and cannabis extracts or preparations, they still treat CBD as a narcotic. This is the case in Canada and Brazil. Italy recently included plant-derived

[1] Prepared by Clever Leaves and adopted by EUMCA General Assembly.

CBD solutions for oral use in its list of controlled medicines, under the same category of all cannabis and dronabinol medicines, even though CBD itself was not previously included in the list of controlled substances. However, the decision has been withdrawn for further analysis.

This controversy as to the narcotic status of CBD was recently addressed by the WHO, which after a critical review of evidence, recommended to the United Nations Commission on Narcotic Drugs to include a note in the international list of narcotic drugs from the 1961 Single Convention clarifying that CBD as a molecule is **not** a controlled substance even if it is extracted from cannabis. Regarding the issue of CBD purity, a limit of 0.2% THC maximum is being proposed by the WHO.

The purpose of this paper is to set out the legal, political and technical analysis that forms the basis for the conclusion that access to health and medical treatment should be prioritized when countries are called to take a position regarding the status of pure CBD at the national level.

Position paper about CBD classification

Cannabidiol (CBD) is one of more than 400 components of the cannabis plant and one of more than 100 molecules grouped as Phytocannabinoid (natural cannabinoids). According to scientific evidence reviewed and summarized in 2019 by the World Health Organization, *"CBD exhibits no effects indicative of any abuse or dependence potential"*. The UN has stated for CBD that *"… it has been demonstrated as an effective treatment of epilepsy in several clinical trials…*and*….may be a useful treatment for a number of other medical conditions"*[2].

Despite this' a number of countries, continue to implement a very restrictive interpretation of the 1961 Single Convention on Narcotic Drugs; considering CBD to be a narcotic drug. In such a scenario, CBD may only be produced, traded and used for medical and scientific purposes by following the restrictive procedures derived from the 1961 Single Convention (licensing for cultivation/manufacture, quotas, annual estimates, import/export permits, inspections, statistical reports, etc.) This does not reflect the legal reality in most CBD-producer countries, including the USA. This position is also in contrast to how synthetic CBD is treated by some regulators, who do not classify it as a narcotic drug, despite being the identical chemical entity to that derived from plant sources.

Seeds and leaves of the cannabis plant are exempted from the scheduling as narcotic drugs in the 1961 Single Convention. The cultivation of cannabis for industrial (seeds and fibres) or horticultural purposes is also exempted from the licensing and controls. This provision has been adopted by many countries at the national level by establishing a category of cannabis cultivars statutorily defined as hemp, with proven THC levels in mature flowers below a certain threshold and by setting a maximum THC content for those strains. Nonetheless, it is common that governments require producers to request a hemp license and do not allow the harvesting and extraction of hemp flowers for cannabinoids production[3].

Therefore, regulations with respect to extracting pure CBD from hemp and utilizing it for medicinal purposes are unclear in every nation's legislation and the criteria vary widely. The current evidence,

[2] https://www.who.int/medicines/access/controlled-substances/WHOCBDReportMay2018-2.pdf?ua=1
[3] Tran L., (2019), "CBD in Europe—Making the Single Market Real" ACTIVE, January 2020

in conjunction with legal and political analysis demonstrated in the following points, aims to support the position that synthetic and plant-derived CBD and products containing pure CBD should not be scheduled as a narcotic drug.

1. **Definitions.** Restrictive interpretations consider CBD as a cannabis oil/extract/preparation, even if pure, but since there is no legally binding definition for cannabis oils and extracts in the 1961 Single Convention, interpretations are debatable based on technical and scientific evidence. Moreover, the legal definition of preparations under international law implies a "mixture" of ingredients. But pure CBD is a single molecule and neither contains cannabis nor is a mixture

2. **CBD in relation to international treaties.** International treaties clearly define what cannabis, resin, THC and preparations are, and define explicitly the list of drugs under international control (green and yellow lists), as well as the procedure to include new items.

   When cannabinoids were discovered, only tetrahydrocannabinol (THC) and its stereoisomers[4] were included in the 1971 Convention on Psychotropic Substances. There was no generic category to include all cannabinoids. In contrast, many opium poppy and coca leaves metabolites and derivatives were included in the 1961 Convention under the entries for morphine, codeine, thebaine, ecgonine together with the explicit inclusion of their isomers, esters and ethers, whenever their existence is possible. In consequence, because CBD has not been included in any of the official lists, it is not covered by a generic designation. Therefore, there is no grounds to state that CBD is a controlled substance.

3. **Access.** Not only the World Health Organization, but also the US Food and Drug Administration and the European Medicines Agency, through the approval of Epidiolex/Epidyolex, have recognized the medical value of CBD from clinical evidence and its safety profile. Defining pure CBD as a narcotic drug presents a hurdle to access for patients that legitimately require this option of treatment. A document from the United Nations General Assembly Special Session of 2016 on the World Drug Problem[5], and recent reports from the International Narcotics Control Board[6], recognize the impact of the imbalance in drug policies over the proper access of controlled substances for medical use, as well as the inequity so implied. Those instruments provide operational and policy recommendations, that if applied to CBD, will translate into a lack of support for its control as a narcotic drug.

4. **WHO critical review.** WHO has recognized the confusion regarding the scheduling status of CBD and the resulting impact on adequate access to health and medicines. For that reason, it has proposed to include a footnote on the list of narcotic drugs in the Single Convention, in order to clarify that CBD or CBD mixtures with less than 0.2% of THC are not narcotic

[4] CBD is not a stereoisomer of THC.
[5] https://www.unodc.org/documents/postungass2016/outcome/V1603301-E.pdf
[6] http://www.incb.org/incb/en/publications/annual-reports/annual-report-supplement-2018.html

drugs. Following the Convention's procedure, this recommendation should be approved by the Commission on Narcotic Drugs of the Economic and Social Council of the United Nations, where political, economic and social implications are discussed. From a scientific evidence perspective, the WHO arguments are solid and should be supported by all countries

In alignment with this approach, the USA[7], France[8] and the UK[9] have already de-scheduled Epidiolex/Epidyolex from their list of narcotic products and in Germany it is not considered as such[10]. From an access and sustainability perspective, this de-scheduling should be extended to pure CBD and all pure CBD containing products for medicinal use under supervision not only to branded medicines. Colombia[11] and Denmark[12] have already amended their national list of narcotic laws to de-schedule cannabis and cannabis preparations with less than 0.2% of THC, the USA[13] has done the same for hemp and hemp extracts, including CBD with up to 0.3% of THC, and Switzerland[14] has done so for hemp with less than 1% THC. In Italy, the Ministry of Health recently included plant-derived CBD solutions for oral use as controlled medicines, under the same category as all cannabis and dronabinol medicines and also benzodiazepines, without expressly referring to pure CBD as a non-narcotic entity. This creates high barriers and restrictions of access for a scientifically proven safe medicine. It is understood that the decision has been withdrawn for further analysis[15].

5. **Penal implications.** If pure CBD is regarded as a narcotic drug because it is considered a cannabis extract/oil/preparation, then member countries, according to Art. 3 of the 1988 UN Convention Against Illicit Traffic of Narcotic Drugs, shall be committed to prosecute as criminal offences under domestic law, the cultivation of cannabis plant for its production, manufacture, extraction, preparation, offering, distribution, sale, delivery, brokerage, dispatch, transport, importation or exportation of CBD and CBD containing products, because all would be contrary to the provisions of the Single Convention. This is not happening in the tolerated grey or unregulated markets of several countries. Surely, it is inconsistent to partially and conveniently implement the scheduling of CBD in some specific non-medical products, but at the same time to dismiss the enforcement of the criminal commitments related to narcotics in the international treaties. Recent decision from Court

[7] https://www.cannabisbusinesstimes.com/article/dea-deschedule-epidiolex-gw-pharmaceuticals-cbd/
[8] https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000041459990&categorieLien=id
[9] http://ir.gwpharm.com/news-releases/news-release-details/gw-pharmaceuticals-announces-epidyolexr-cannabidiol-has-been
[10] https://www.bundestag.de/resource/blob/681702/7e584f6acd93c0a5dc7330c10e569e1c/WD-9-046-19-pdf-data.pdf
[11] https://www.minsalud.gov.co/Normatividad_Nuevo/Resoluci%C3%B3n%20No.%200315%20de%202020.pdf
[12] https://www.retsinformation.dk/eli/lta/2018/665
[13] https://www.justice.gov/opa/pr/dea-announces-steps-necessary-improve-access-marijuana-research
[14] https://www.admin.ch/opc/de/classified-compilation/20101220/index.html
[15] https://mjbizdaily.com/italy-backtracks-on-medical-cbd-decree/

of Justice of the European Union (CJEU) in Case C663/18 (Kanavape), reflects the disproportion between the risk profile of CBD and its classification as a narcotic drug[16].

6. **Grey-Black Market and prioritization of enforcement resources.** In general terms, the lack of a risk-balanced drug policy has been, even if unintended, a driving force for the New

7. Psychoactive Substances phenomenon (Legal Highs)[17] that has evolved with the appearance of hundreds of new, riskier and more accessible drugs as a legal alternative for those tightly controlled, i.e., the more than 200 Synthetic Cannabinoid Receptor Agonists (SCRA) have emerged on the illicit market in the last 10 years[18]. For CBD, a grey market of "light cannabis" is a reality in many countries where those SCRAs or poor quality …even contaminated… CBD from unknown sources, can cause severe health problems [19]. Consumers and patients with serious illnesses can be victims of these products.

   Drug Law enforcement authorities, with limited resources and more dangerous drugs on the illicit market, should have the option not to focus on pure CBD products which are not narcotic. Countries can develop their own regulation models for pure CBD access as a safe consumer product, such as the Novel Foods category in the UK[20] or South Africa[21], where quality and consumer protection, instead of fear of addiction, are the driving force. The European Industrial Hemp Association also proposes a separation between CBD-based medicines and CBD-based food and food supplements, depending on the CBD purity and concentration, which is another alternative for setting a regulated market that is not based on classifying plant-derived CBD as a narcotic substance[22].

8. **Source.** Regarding the source for CBD, restrictive understandings of the exceptions for hemp in the Single Convention (industrial use of cannabis), consider that only seeds and fibres can be accepted as industrial uses of cannabis, but it is inconvenient from a development perspective to accept that the Single Convention abolished in 1961 any possibility to build new industrial uses for this botanical resource.

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[16] https://www.allenovery.com/en-gb/global/news-and-insights/publications/highest-european-court-confirms-that-cannabidiol-is-not-a-narcotic-drug-and-that-eu-member-states-may-not-prohibit-its-marketing

[17] Madras B.K. (2016) The Growing Problem of New Psychoactive Substances (NPS). In: Baumann M., Glennon R., Wiley J. (eds) Neuropharmacology of New Psychoactive Substances (NPS). Current Topics in Behavioral Neurosciences, vol 32. Springer, Cham.

[18] http://www.emcdda.europa.eu/topics/synthetic-cannabinoids

[19] https://www.icci.science/en/article/news/press-cbd-cannabis-oil-produces-improving-risk-consumers-remain/

[20] https://www.food.gov.uk/business-guidance/cannabidiol-cbd

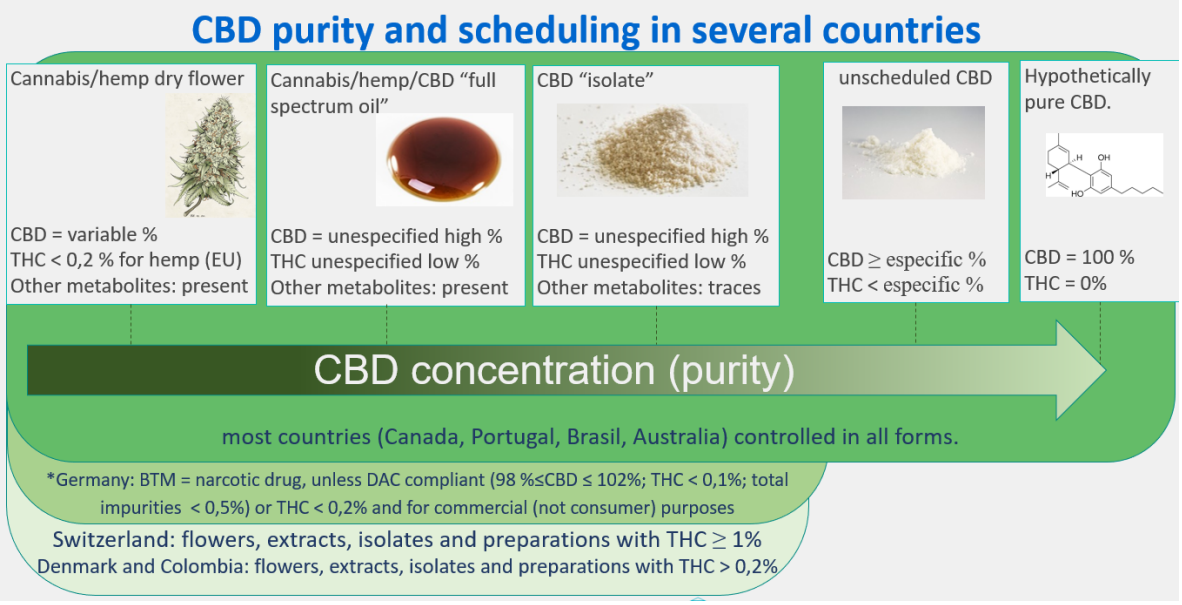
[21] http://www.sahpra.org.za/wp-content/uploads/2020/05/CDB-containing-products-communication-to-stakeholders.pdf

[22] http://eiha.org/media/2016/10/18-10-EIHA-CBD-position-paper.pdf

If the rationale behind Section 9 of Article 2 of the Single Convention is given a modern and comprehensive interpretation, then it is possible to develop a policy model with balanced controls over hemp cultivation and processing, allowing only pre-registered low THC strains, where the risk for hemp products to be abused or produce ill-effects, or to recover THC from them, are correctly handled. As result, hemp-derived pure CBD with properly validated analytical technical specifications, =should be accepted as a non-controlled drug by national legislations. As precedents, other substances from opium poppy like papaverine or noscapine, are not considered as narcotic drugs just because they come from a controlled plant, as the WHO has recognized during the Q&A sessions to its recommendations. WHO also recognizes hemp as a valid source for CBD [23].

Finally, it must be acknowledged that the Single Convention pursues two main goals. The first is to guarantee the access of controlled substance to patients. Since products containing pure CBD with <0.2% THC are not narcotic this goal does not apply. The second goal is to protect public health from narcotic substances that may be addictive or liable to abuse. CBD must not be so controlled as there is sufficient conclusive evidence that no such harm is caused to humans by pure CBD use, as it was acknowledged by European Court of Justice in Kanavape case.

Countries like Germany, Switzerland, Denmark and Colombia have already defined in their national law, technical specifications to set the limit when a cannabis extract becomes acceptably pure to be considered as non-controlled CBD, as can be seen in the following figure[24].



[23] https://www.who.int/medicines/access/controlled-substances/Responses-to-Structured-questions_5thISM_27-September2019.pdf?ua=1

In summary, the purpose of this document is to provide grounds to policy makers and regulators to take a step forward and eliminate barriers of access to pure CBD preparations for medicinal purposes. This does not mean that CBD should be openly available of any quality and any, concentrations or route of administration for people of all ages. Appropriate, hopefully harmonized regulation is necessary.

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Professor Trevor Jones CBE FMedSci, is chair of the European Medicinal Cannabis Association