CSFD POSITION PAPER[1]

The WHO recommendations on the rescheduling of cannabis and cannabis-related substances

1. Background

1.1. Cannabis under the international drug conventions

Cannabis and cannabis resin are controlled drugs under the international drug control conventions. Cannabis is currently listed in Schedule IV of the 1961 Single Convention on Narcotic Drugs. Schedule IV is the most restrictive schedule in the Convention. It is intended for drugs that are "particularly liable to abuse and to produce ill effects", and that do not have "substantial therapeutic advantages" that offset the risk of harm.[1]

> "If the World Health Organization finds that a drug in Schedule I is particularly liable to abuse and to produce ill effects (paragraph 3) and that such liability is not offset by substantial therapeutic advantages not possessed by substances other than drugs in Schedule IV, the Commission may, in accordance with the recommendation of the World Health Organization, place that drug in Schedule IV."
>
> Single Convention on Narcotic Drugs 1961, Article 3.5

All drugs in Schedule IV are simultaneously listed in Schedule I, which is reserved for "substances that are highly addictive and highly liable to abuse."[2]

In addition, cannabis extracts and tinctures are listed in Schedule I of the 1961 Convention, and some of the psychoactive components of cannabis are listed in Schedule II of the 1971 Convention on psychotropic substances.[3]

This means that the production, distribution, sale and possession of cannabis is only allowed for "medical and scientific purposes". Production, distribution, sale and possession of cannabis for non-medical use remains prohibited under the drug conventions.[4]

1.2. Medical use of cannabis in Europe

All countries in the EU have signed the international drug control conventions that place cannabis under international control. However, the conventions permit medical use.

Most EU countries allow the medical use of cannabis and cannabinoids in some form. Several cannabinoid-based drugs have been granted marketing authorization in European countries, e.g. Marinol, Syndros, Cesamet, Canemes, Sativex and Epidiolex. Some countries permit medical use of

[1] Although the CSFD strives to achieve consensus on contributions sent to EU institutions, this is not always possible on some drug policy topics. Please note that the following organisations decided not to support this contribution: Celebrate Recovery/Proslavi Oporavak, ECAD - European Cities Network for Drug Free Societies, EUSPR - European Society for Prevention Research, IREFREA - Instituto Europeo de Estudios en Prevención, San Patrignano, UTRIP, WFAD - World Federation Against Drugs, WOCAD.

cannabis preparations (cannabis flower, granulates or oil extracts). However, no country recommends smoking as a route of administration.[5]

So far, few cannabinoid-based drugs have been granted EU-wide marketing authorization from the European Medicines Agency, including Epidiolex, which is used in the treatment of two rare childhood epilepsy conditions. [6]

Some countries allow exceptional or "compassionate" access schemes that give patients with serious illnesses who do not respond to traditional treatment access to unapproved medicines. This usually requires a prescription from a physician, and in many cases the patient will have to cover the costs of the medicines. According to the EMCDDA, access to cannabis preparations in Europe is mainly given through such exceptional access schemes. Only four countries (Germany, Czechia, The Netherlands and Italy) have established access programmes for cannabis.[7]

The EMCDDA describes the regulation of cannabis and cannabinoids for medical use in Europe as "complex patchwork of approaches." Moreover, the legal framework is developing, with ongoing policy processes and legal changes since the last review was published in 2018.

1.3. Status of Cannabidiol (CBD)

In recent years, there has been a growing interest in the non-psychoactive cannabinoid, Cannabidiol (CBD). Because CBD is extracted from the cannabis plant, some have argued that it is subject to the UN drug control conventions. However, the legal status of CBD is complex and varies from country to country.[8] The WHO recommendations seek to clarify this situation by making clear that CBD is not under international control, as it is not psychoactive.

Many countries regulate CBD as a drug, but with CBD increasingly found in consumer products, it could potentially also fall under regulatory systems for medicines, cosmetics and foodstuffs.[9]

In 2019, the European Commission proposed to classify CBD as a "novel food", which would require pre-market authorisation from the European Food Safety Authority.[10] However, in 2020, the EC suspended pending authorisation applications, arguing that CBD is an extract of cannabis that is better regulated as drugs under the UN drug control conventions.[11]

Nevertheless, a wide array of CBD products, including topicals, oils and edible products, are available online and from retail outlets in many European cities. At present, this industry operates in a legal gray zone.[12]

2. The WHO recommendations on the rescheduling of cannabis and cannabis-related substances

In 2018, the WHO's Expert Committee on Drug Dependence presented the results of the first-ever review of cannabis and cannabis-related substances, which was undertaken at the formal request of the UN Commission on Narcotic Drugs (CND).[13] The review resulted in the six recommendations that will be up for vote at the CND, after several delays, in December 2020.

2.1. Clarifying the scope of the WHO recommendations

Prior to describing the set of recommendations put forward by the WHO, it is important to clarify the implications of changing the international scheduling of cannabis, and cannabis-related substances, for Member States. Scheduling recommendations only aim to establish a minimum level of

international control on certain substances, but they do not prohibit states from establishing more stringent restrictions,[14] and they do not mandate the creation of legally regulated markets, either for medical or non-medical use.

In particular, when it comes to the WHO recommendations on cannabis rescheduling, it should be clarified that:

- **If adopted, the WHO recommendations would not obligate Member States to regulate cannabis for medical use, or to establish medical cannabis programmes**. While the WHO acknowledges the therapeutic value of cannabis, it does not recommend the establishment of medical cannabis programmes. The role of the WHO '*is not to recommend the use of substances for medical treatment, but rather to advise on the scheduling of substances based on evaluations of potential for harm, dependence and abuse from a public health perspective, as well as their therapeutic usefulness*'.[15]

- **The WHO does not recognise a particular therapeutic value, or a particular therapeutic use, of cannabis and cannabis-related substances**. Instead, Recommendation 5.1 (removing cannabis from Schedule IV of the 1961 Convention) simply recognises that it is not accurate to state that cannabis has no medical use at all. Schedule IV is reserved for substances with no therapeutic value; for instance, the latest substance added to Schedule IV was carfentanil, '*an extremely potent and dangerous opioid that is not used in human medicine*'.[16]

- **Even if the WHO recommendations are not adopted, Member States will remain free to legally regulate medical cannabis, and to set medical cannabis programmes**. Medical cannabis programmes have been current under the current scheduling structure, and will continue to be developed even if the WHO recommendations are not adopted.

2.2. A short overview of the WHO recommendations

The WHO has come forward with six recommendations concerning the rescheduling of cannabis, which have been summarised by the UNODC in the following chart:

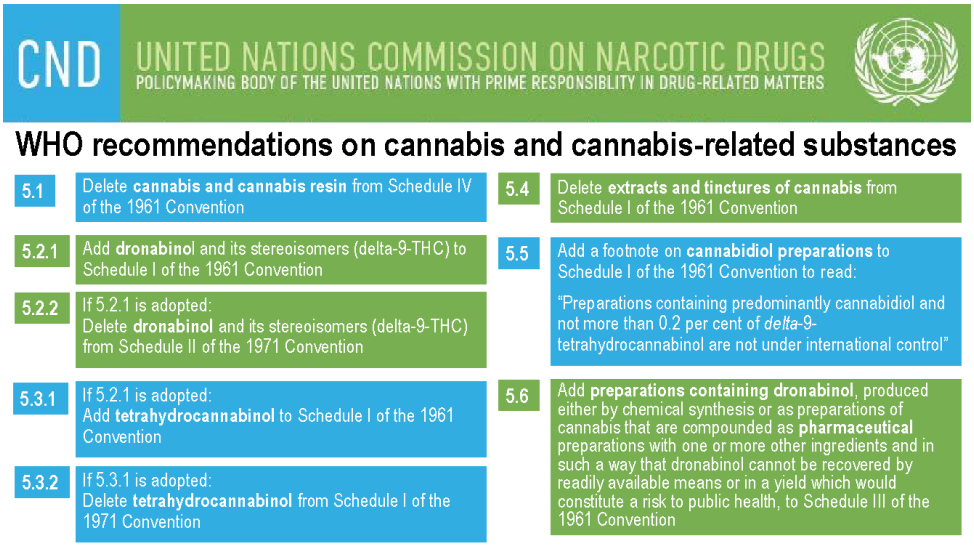

Figure 1. WHO Recommendations on cannabis and cannabis-related substances (Source: CND)[17]

- **Recommendation 5.1. Acknowledging the therapeutic value of cannabis and cannabinoids**

As mentioned above, cannabis is currently scheduled in Schedule I and IV of the 1961 Convention. The WHO does not propose to change the status of cannabis under Schedule I, which means that it is still considered to be highly addictive and liable to abuse, in line with other substances such as cocaine or heroin. However, the WHO proposes to remove cannabis from Schedule IV, which is reserved for substances with little or no therapeutic value.

The removal of cannabis from Schedule IV would mean that the therapeutic value of cannabis would be recognised by the UN drug control system for the same time, as the WHO has acknowledged that *´there is now evidence that cannabis preparations have therapeutic advantages not possessed by other substances´*.[18] In doing so, the international drug control system would show that it is able to update the scheduling framework in light of evolving scientific evidence, even on highly politicised matters.

However, both the WHO and the INCB has also noted that the international control measures in place for a drug included in Schedules I and IV are the same as those for a drug in Schedule I. Therefore, there would be no weakening of the international control of cannabis if it was included only in Schedule I.[19]

- **Recommendations 5.2 and 5.3. Moving THC into Schedule I of the 1961 convention**

Recommendations 5.2 and 5.3 propose a set of interconnected proposals[20] to reschedule the main psychoactive component of cannabis, namely dronabinol/Δ9-THC, (Recommendation 5.2), as well as six stereoisomers collectively called tetrahydrocannabinol (Recommendation 5.3.). This would be done by adding these substances to Schedule I of the 1961 Convention, together with cannabis, (Recommendation 5.2.1 and 5.3.1.), and by removing them from Schedule I and II of the 1971 Convention (Recommendations 5.2.2 and 5.3.2). The basis of the recommendation is the principle of similarity, which requires that the cannabis plant and its main psychoactive components should be scheduled together, in the same category.[21]

- **Recommendations 5.4 and 5.5. Exempting from international control CBD preparations with no more than 0.2% THC**

Recommendation 5.4. proposes the deletion of the sentence 'extracts and tinctures of cannabis' from Schedule I of the 1961 Convention. The goal of this recommendation is to simplify the language of the convention, by referring to all products containing cannabis as 'preparations', rather than differentiating between currently undefined terms such as 'extracts', 'tinctures', and 'products'.[22]

Recommendation 5.5 proposes to exempt from international control preparations containing non-psychoactive cannabidiol (CBD), as long as they do not contain more than 0.2% THC. According to the WHO, CBD *´shows no potential for abuse or dependence and any ill-effects are minimal´*.[23] Exempt preparations could range from medicinal oil to food and wellness products, while preparations containing higher levels of THC, such as butane hash oil and edibles, would still be subject to the same control as cannabis itself.[24]

The WHO decision to establish the threshold of admissible THC at 0.2% has been questioned in several corners. Critics have pointed out that several Member States have already established legal

frameworks for selling CBD preparations with higher percentages of THC for non-medical or scientific uses, including countries Ghana (0.3%), or Switzerland (1%).[25]

- **Recommendation 5.6. Reducing the level of control on pharmaceutical preparations containing THC**

Lastly, the WHO recommends adding pharmaceutical preparations containing THC that are compounded in such a way that THC cannot be recovered by readily available means, or in a yield which would constitute a risk to public health, to Schedule III of the 1961 Convention. This would mean that such preparations would be subject to a lesser degree of international control than cannabis and THC, which are scheduled under Schedule I of the 1961 Convention.[26] By presenting this recommendation, the WHO seeks to acknowledge that pharmaceutical products such as Sativex have been existing in regulated markets with no instances of 'abuse or dependence'. [27]

3. CSFD conclusions and recommendations

The CSFD welcomes:

- The WHO commitment and effort to develop ***an in-depth scientific review of cannabis*** **after prolonged inactivity** since 1961. These delays have been counter-productive, if we consider that the international scientific community has produced a significant body of research on medical cannabis, and that many states have adopted national health policies that include medical cannabis for different pathologies. The CSFD welcomes and supports the WHO scientific leading role at a global drug system level.

The CSFD welcomes and particularly supports:

- The ***acknowledgement of the therapeutic value of cannabis and cannabinoids*** (***Recommendations 5.1***), based on a wide and thorough scientific review. The recommended rescheduling, while recognizing the therapeutic properties of cannabis, does not analyze the efficacy of medical cannabis and cannabinoids for different pathologies. Nevertheless, this acknowledgement is a crucial premise to develop new scientific and clinical research. The Recommendation 5.1 is on-line with the goals of International Conventions, aimed at ensuring ***adequate availability of controlled substances for medical purposes*** while preventing their 'abuse' and diversion in a balanced approach (WHO)[28].

- The recommendation to delete ***extracts and tinctures*** of cannabis from Schedule I of the 1961 Convention (***Recommendation 5.4***), while other articles of the Conventions continue to control non-therapeutic cannabis products effectively, as clearly demonstrated by the WHO[29].

- The WHO position on ***cannabidiol (CBD)*** with regards to its value as a medicine and the evidence-based acknowledgement that it is not a psychoactive substance, and the proposal to exclude it from the Conventions (***Recommendation 5.5***).

Nevertheless, the CSFD ***remarks that the THC percentage established by the WHO is controversial,*** as there are differences in the value of THC established by the States which adopted medical cannabis preparations (also higher percentages), as well as concerns about the calculation of THC content, which is not defined. The CSFD asks for further, rapid and accurate scientific evidence, with regard

to this point of Recommendation 5.5

The CSFD recommends

- Considering the continuous and rapid advancement of scientific research on cannabis, ***a more regular review of cannabis plant and products*** is needed to update scheduling systems with new scientific and evidence based data. The prolonged silence on cannabis from international research bodies unveils a persisting difficulty in the dialogue between science and politics. The CSFD strongly supports the WHO leading role in scientific and clinical research and in the further developing evidence-based scheduling criteria. In that regard, the CSFD calls for the further depoliticisation of scheduling criteria, and recommends that the WHO continues to address the concerns raised with regards to the principle of similarity, and the fact cannabis is scheduled together with substances that, according to the WHO itself, are no associated to the same levels of risk to health.

- The respect of a ***balanced approach*** between availability of controlled substances for medical use and prevention of 'abuse' and diversion, both at international and at national level, according to the Conventions objectives. The UN Committee on Economic, Social and Cultural Rights, has stated in the new General Comment on Science that "t*he precautionary principle should not hinder and prevent scientific progress",* and that states have the obligation to fulfill the right to enjoy the benefits of scientific progress and its applications[30]. The CSFD recommends that States and international bodies promote the research on, and facilitate access to, evidence-based medical cannabis treatments.

- To facilitate and support the involvement of civil society and patients' organizations in all the steps of the research and decision making process dealing with medical cannabis, in a human rights and right to health perspective. The CSFD in particular asks for ECOSOC-accredited NGOs participation at the CND process on deliberations and vote on the WHO recommendations, and stress the risks of limiting this participation due to the proliferation of "informal sessions" (i.e. Topical meetings) which exclude civil society or weaken their role.

The Civil Society Forum on Drugs (CSFD) is an expert group of the European Commission that was created in 2007 on the basis of the Commission Green Paper on the role of civil society in drugs policy in the EU. Its purpose is to provide a broad platform for a structured dialogue between the Commission and European civil society which supports drug policy formulation and implementation through practical advice. The CSFD is consistent with the EU Strategy on Drugs 2013-2020 and the new Action Plan on Drugs 2017-2020 both of which require the active and meaningful participation and involvement of civil society in the development and implementation of drug policies at national, EU and international level. Its membership comprises 45 CSOs from across Europe and representing a variety of fields of drug policy, and a variety of stances within those fields. Below is the list of CSFD members for the period 2018-2020:

1. *ABD - Associació Benestar i Desenvolupament*
2. *AFEW International*
3. *AIDES*
4. *Ana Liffey Drug Project*
5. *APDES - Agência Piaget para o Desenvolvimento*
6. *APH - Association Proyecto Hombre*
7. *ARAS - Romanian Association Against AIDS*
8. *Citywide Drugs Crisis Compaign*
9. *De Regenboog Groep*
10. *Dianova International*
11. *Diogenis Drug Policy Dialogue*
12. *EAPC - European Association for Palliative Care*
13. *EATG - European AIDS Treatment Group*
14. *ECAD - European Cities Network for Drug Free Societies*
15. *EFSU - European Forum for Urban Security*
16. *ENLACE*
17. *EURAD*
18. *EuroTC - European Treatment Centres for Drug Addiction*
19. *EUSPR - European Society for Prevention Research*
20. *FAD - Fundación de Ayuda contra la Drogadicción*
21. *Federation Addiction*
22. *FEDITO BXL*
23. *Forum Droghe*
24. *FUNDACIÓN ATENEA*
25. *GAT - Grupo de Ativistas em Tratamentos*
26. *HRI - Harm Reduction International*
27. *IDPC - International Drug Policy Consortium*
28. *INPUD - International Network of People who use Drugs*
29. *IREFREA - Instituto Europeo de Estudios en Prevención*
30. *MAT - Magyar Addiktológiai Társaság*
31. *Médicos del Mundo España*
32. *PARSEC Consortium*
33. *Polish Drug Policy Network*
34. *Prekursor Foundation for Social Policy*
35. *Proslavi Oporavak*
36. *Romanian Harm Reduction Network*
37. *Rights Reporter Foundation*
38. *San Patrignano*
39. *SANANIM*
40. *SDF - Scottish Drugs Forum*
41. *UNAD*
42. *UTRIP*
43. *WFAD - World Federation Against Drugs*
44. *WOCAD*
45. *YODA - Youth Organisations for Drug Action*

ENDNOTES

[1] https://www.unodc.org/pdf/convention_1961_en.pdf
[2] https://www.unodc.org/documents/commissions/CND/Scheduling_Resource_Material/19-11955_Drug_Conventions_eBook.pdf
[3] https://www.unodc.org/pdf/convention_1971_en.pdf
[4] https://www.emcdda.europa.eu/publications/topic-overviews/cannabis-policy/html_en
[5] https://www.emcdda.europa.eu/system/files/publications/10171/20185584_TD0618186ENN_PDF.pdf
[6] https://ir.gwpharm.com/news-releases/news-release-details/gw-pharmaceuticals-receives-european-commission-approval
[7] https://www.emcdda.europa.eu/system/files/publications/10171/20185584_TD0618186ENN_PDF.pdf
[8] https://prohibitionpartners.com/report-uploads/CBD_-_The_Consumer_Report_(Executive_Summary).pdf
[9] https://www.openaccessgovernment.org/the-european-commissions-pause-on-cbd-novel-food-applications/92371/
[10] https://ec.europa.eu/food/safety/novel_food/legislation_en
[11] https://www.openaccessgovernment.org/the-european-commissions-pause-on-cbd-novel-food-applications/92371/
[12] https://prohibitionpartners.com/report-uploads/CBD_-_The_Consumer_Report_(Executive_Summary).pdf
[13] See Resolution 52/5 and Resolution 50/2.
[14] https://www.unodc.org/documents/commissions/CND/Scheduling_Resource_Material/Cannabis/Consultations_with_WHO_Questions_and_Answers_26_November_2019.pdf
[15] https://www.who.int/medicines/access/controlled-substances/Cannabis_Review_QA_26July2018.pdf
[16] https://www.unodc.org/documents/commissions/CND/Scheduling_Resource_Material/Cannabis/Consultations_with_WHO_Questions_and_Answers_26_November_2019.pdf, p. 22
[17] See: https://www.unodc.org/documents/commissions/CND/Scheduling_Resource_Material/Cannabis/Decision_tree_depicting_the_conditionalities_of_the_WHO_recommendation_on_cannabis_and_cannabis.pdf
[18] https://www.unodc.org/documents/commissions/CND/Scheduling_Resource_Material/Cannabis/Consultations_with_WHO_Questions_and_Answers_26_November_2019.pdf, p. 25.
[19] https://www.unodc.org/documents/commissions/CND/Scheduling_Resource_Material/Cannabis/Consultations_with_WHO_Questions_and_Answers_26_November_2019.pdf, p. 22.
[20] To understand the conditionalities, see: https://www.unodc.org/documents/commissions/CND/Scheduling_Resource_Material/Cannabis/Decision_tree_depicting_the_conditionalities_of_the_WHO_recommendation_on_cannabis_and_cannabis.pdf
[21] https://www.unodc.org/documents/commissions/CND/Scheduling_Resource_Material/Cannabis/Consultations_with_WHO_Questions_and_Answers_26_November_2019.pdf, p. 34.
[22] https://www.unodc.org/documents/commissions/CND/Scheduling_Resource_Material/Cannabis/Consultations_with_WHO_Questions_and_Answers_26_November_2019.pdf, p. 55
[23] https://www.unodc.org/documents/commissions/CND/Scheduling_Resource_Material/Cannabis/Consultations_with_WHO_Questions_and_Answers_26_November_2019.pdf, p. 65.
[24] https://www.tni.org/files/publication-downloads/cannabis_rescheduling_global_intro.pdf, p. 4.
[25] See footnote 27, https://www.tni.org/files/publication-downloads/cannabis_rescheduling_global_intro.pdf
[26] https://www.unodc.org/documents/commissions/CND/Scheduling_Resource_Material/Cannabis/Consultations_with_WHO_Questions_and_Answers_26_November_2019.pdf, p. 87.

[27] https://www.unodc.org/documents/commissions/CND/Scheduling_Resource_Material/Cannabis/Consultations_with_WHO_Questions_and_Answers_26_November_2019.pdf, p. 87.

[28] WHO (2011) Ensuring balance in national policies on controlled substances, Guidance for availability and accessibility of controlled medicines, p. 1.[pdf] Geneva: World Health Organization. Available at: https://apps.who.int/iris/bitstream/ handle/10665/44519/9789241564175_eng.pdf (Accessed: 07 January 2019)

[29] WHO (2011) WHO responses to CND on 41st ECDD recommendations, https://www.who.int/publications/m/item/responses-to-CNDon41stECDDrecs

[30] UN Committee on Economic, Social and Cultural Rights (2020) General Comment on Science, https://www.ohchr.org/_layouts/15/WopiFrame.aspx?sourcedoc=/Documents/HRBodies/CESCR/Discussions/2020/DGC_Science/DraftGC_science.docx&action=default&DefaultItemOpen=1