

**Handout for External Use:
Possible Responses to WHO/ECDD Cannabis Scheduling Recommendations**

The international scheduling process is an essential tool for countering the world drug problem. Over the last several years, bringing additional substances under international control faster and more efficiently has been a central pillar of the world's strategy to address the emerging threats of new psychoactive substances, fentanyl-related drugs and other synthetic opioids, and other dangerous substances. It is therefore vital that the international community continues to view the international scheduling process as functional, consensus driven, and responsive to scientific analysis. A failure to engage meaningfully with the WHO/ECDD's cannabis scheduling recommendations could incorrectly imply that the CND and the international drug control treaties are ill-suited to tackle modern challenges. We cannot allow this perception to dominate the narrative of the CND's debates over cannabis regulation; however, at the same time, Member States have expressed substantial confusion over the underlying meaning and potential impact of some of the WHO's recommendations on cannabis, and many delegations are keen to study them in more depth before taking action on some or all of these proposals.

In some cases, the WHO/ECDD's cannabis scheduling recommendations appear to have identified solutions to issues that not all CND members agree are problematic. The first step in building consensus is to identify clearly the issues the recommendations seek to address. Next, we must ask if we can agree on whether these issues are actually problematic. Finally, the Commission has a responsibility to consider the administrative, legal, socio-economic, and political considerations associated with the solutions proposed by the WHO/ECDD. Even if we decide that the costs of the solutions put forward by the WHO/ECDD outweigh the benefits, it is our responsibility to examine if we can propose alternative solutions, outside of the international scheduling process, that would address the issues identified by the WHO/ECDD.

In this spirit, the United States has developed discussion points and a wide range of possible solutions for each of the proposed WHO/ECDD recommendations. We have considered in this context that the CND has many different tools available to it beyond simply voting on scheduling decisions. This paper is intended only to serve as a starting point for further discussion among Member States, with a view to designing a pragmatic and balanced approach to discussing cannabis scheduling at the CND in the future. It is possible that the Commission may find itself in a position to take action on certain WHO recommendations in the short term – perhaps even at the 63rd CND in March 2020 – while preferring to engage in a longer-term process to analyze the content, justification, and potential impact of other WHO recommendations. This paper is intended to help facilitate discussion regarding those actions that may be more appropriate for short-term consideration, and those which may benefit from additional consultation and review.

Recommendation 5.1

Decision Text: Delete Cannabis and Cannabis Resin from Schedule IV of the 1961 Convention (retain in Schedule I).

Issue(s) Identified: Schedule IV classification may entail unnecessary barriers to research into the medical or scientific benefits as well as any consequent harms associated with use of the cannabis plant (and cannabis resin) and its constituent compounds (THC, CBD, etc.).

Is this Problematic: It is unclear what specific barriers Schedule IV entails that inhibits research into the scientific or medical benefits of cannabis. Germany, Israel, Australia, the United Kingdom, and several other countries, for example, have robust industries growing cannabis for medical and scientific purposes, despite cannabis' Schedule IV listing. On the other hand, the WHO has said certain unspecified countries may place additional control measures on substances listed in Schedule IV and noted the effect of scheduling that has been reported by some countries. Similarly, scientists, doctors, and researchers in many countries, especially in countries with less developed regulatory systems, may believe that substances listed in Schedule IV are too dangerous for experimentation. A Schedule IV listing could therefore be seen as causing a psychological chilling effect on cannabis research globally, even as the effect varies by country.

Pros to adopting WHO recommendation:

- Although the body of robust science is growing, there remains limited scientific evidence from well-controlled clinical studies to determine the safety and effectiveness of potential therapeutic uses of the cannabis plant. At least a few safe, effective, and authorized medications have been developed from cannabis to date (Sativex, Marinol, Epidiolex, etc.) demonstrating that the constituents contained in the cannabis plant do have therapeutic uses. While a schedule IV classification does not prevent the use of cannabis for research purposes, a statement encouraging research would be beneficial to the advancement of collective knowledge of both the therapeutic utility as well as any associated harms of cannabis.
- Similarly, there is limited research regarding the problems associated with cannabis use and the public health threat of cannabis dependence. Encouraging countries to make cannabis available for research purposes would allow for advancing study of these important issues.
- Schedule IV only invites member states to consider "special measures of control" over substances that have "particularly dangerous properties," but does not place any additional mandatory controls on those substances. In practice, because cannabis is also listed in Schedule I of the 1961 Convention, most signatories already have domestic laws in place to regulate cannabis cultivation and distribution for medical and scientific purposes at or above the strictest levels required under the Conventions. Therefore, the recommendation has little practical impact on domestic laws or regulations.
- Before the current review, the WHO had never conducted a formal review and scientific analysis of cannabis. The WHO's recommendation to keep cannabis in Schedule I of the 1961 Convention (the strictest level of substantive control) after a thorough review of the available scientific literature could send a strong message that the high abuse potential

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and ill effects associated with use of cannabis and cannabis preparations are similar to other drugs in Schedule I and pose a significant public health risk.

Cons to adopting WHO recommendation:

- It is possible that civil society, the media, and the general public will view deleting cannabis from Schedule IV as a first step toward widespread legalization of marijuana use, especially without proper messaging.
- It is possible that a decision to remove cannabis from Schedule IV could be misinterpreted publicly to imply that Schedule IV control levels pose inherent barriers to research, and that the international drug control framework is incompatible with such scientific research. This challenge would be possible to mitigate through an explanatory statement by the CND to clarify that the international drug control framework is effective and both promotes research and responds to available scientific evidence.

Possible Solutions: Whether we decide to accept, reject, return, or postpone consideration of the recommendation, the CND may wish to consider adopting an explanatory statement, either attached to the decision itself or as a separate resolution, that contains the following elements:

- Thanks the WHO/ECDD for its recommendations.
- Acknowledges that cannabis was placed in Schedule IV of the 1961 Convention without the benefit of knowing about many of its constituent compounds, such as THC and CBD, and their effects on the human body.
- Highlights that the WHO/ECDD's recommendation to retain cannabis in Schedule I of the 1961 Convention after a thorough scientific review demonstrates the significant risks to health associated with cannabis use, especially high potency preparations.
- Stresses the need for further systematic research into both the health risks of cannabis and potential therapeutic uses.
- Reminds signatories that even Schedule IV listings do not prohibit scientific research and invites signatories to remove unnecessary barriers to research wherever possible, taking into consideration the need for controls to prevent diversion and other illicit activity.
- Invites UNODC, INCB, and international partners to continue providing technical assistance and capacity building efforts to law enforcement officials and public health practitioners to strengthen international control measures, address the public health consequences of cannabis abuse, and improve treatment techniques.

Recommendations 5.2.1, 5.2.2, 5.3.1, and 5.3.2

Decision Text:

- Add Dronabinol and its stereoisomers (delta-9- tetrahydrocannabinol) to Schedule I of the 1961 Single Convention on Narcotic Drugs (5.2.1).
- Delete dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol) from the 1971 Convention on Psychotropic Substances, Schedule II, subject to the Commission's adoption of the recommendation to add dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol) to Schedule I of the 1961 Single Convention on Narcotic Drugs (5.2.2).
- Add Tetrahydrocannabinol (understood to refer to the six isomers currently listed in Schedule I of the 1971 Convention on Psychotropic Substances) to Schedule I of the 1961 Single Convention on Narcotic Drugs, subject to the Commission's adoption of the recommendation to add dronabinol (delta-9-tetrahydrocannabinol) to the 1961 Single Convention on Narcotic Drugs in Schedule I (5.3.1).
- Delete Tetrahydrocannabinol (understood to refer to the six isomers currently listed in Schedule I of the 1971 Convention on Psychotropic Substances) from the 1971 Convention on Psychotropic Substances, subject to the Commission's adoption of the recommendation to add tetrahydrocannabinol to Schedule I of the 1961 Single Convention on Narcotic Drugs (5.3.2).

Issue(s) Identified: The justification for these recommendations cited by the WHO/ECDD is that moving control of these substances from the 1971 Convention to the 1961 Convention will "greatly facilitate the implementation of the control measures in Member States." During the June 23 and September 23 CND intersessional sessions the United States, United Kingdom, Germany, and several other Member States pressed the WHO/ECDD, INCB, and UNODC to explain what specific control measures would be improved. The only explanation provided by WHO/ECDD, INCB, and UNODC is that Member States will be better able to understand reporting requirements to the INCB. Therefore, the issue appears to be that the INCB's reporting mechanism for these substances is currently inadequate to address changes to how the substances are produced and categorized.

Is this Problematic: The U.S. agency responsible for reporting to the INCB has not reported any difficulties or confusion. Other countries may feel differently. This issue most likely impacts to the greatest degree large cultivators of licit cannabis, such as Australia. It may be beneficial, therefore, to focus inquiries on these countries. It should be noted that reporting under the 1961 Convention is mandatory and occurs yearly, whereas reporting under the 1971 Convention is voluntary and occurs once every three years.

Pros to adopting WHO recommendation(s):

- Additional reporting on cannabis may provide additional information policy makers can use to make informed decisions about programmatic efforts and other issues.
- Confusion about how to report to the INCB may be reduced among certain Member States.

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Cons to adopting WHO recommendation(s):

- The WHO/ECDD has provided no public health justification for these recommendations. They appear purely administrative in nature.
- The removal of THC and its isomers from the 1971 Convention and their placement in the 1961 Convention could raise issues concerning whether THC found in or derived from the leaves or from cannabis cultivated for industrial or horticultural purposes is still under control. Pursuant to the 1961 Single Convention, cannabis as scheduled does not include the leaves, and pursuant to article 28, cannabis cultivated for industrial or horticultural purposes is not subject to the Convention. The authority to schedule substances does not include the authority to amend or overrule the text of the Single Convention. Even if an argument can be made that THC would be scheduled regardless of where it was found, this internal contradiction could undermine the Convention and should be avoided.
- There may be unintended consequences associated with the scheduling change and domestic laws or regulations may need to be amended. For example, the 1971 Convention requires less frequent estimates and reporting of legitimate use by Member States than 1961 Convention. Understanding the full range of consequences will require significant time and effort.
- The workload of domestic agencies reporting to the INCB will triple with respect to cannabis reporting.
- The INCB has indicated it will require additional, unspecified, support from the UN Regular Budget to implement this recommendation.

Possible Solutions:

- Ask the INCB to advise the Commission on difficulties encountered by States Parties reporting on cannabis under the 1961 Single Convention and THC under the 1971 Convention, and to recommend revised forms to be applied specifically to capture the totality of data required. The Commission could adopt these forms pursuant to Article 18 of the Single Convention and Article 16 of the Convention on Psychotropic Substances, authorizing the Commission to request that Parties provide information to the Secretariat;
- Ask the INCB to convene an expert working group to examine ways to clarify and improve reporting mechanisms for Δ^9 -THC such as consolidating reporting for cannabis under one form, instead of separate forms for the 1961 and 1971 Conventions, similar to how forms are consolidated for opium reporting.
- Invite Member States to voluntarily provide information on cannabis cultivation yearly, or at other more frequent intervals, instead of once every three years, through a resolution or other decisional text.

Recommendation 5.4

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Decision Text: Delete “Extracts and Tinctures of Cannabis from Schedule I of the 1961 Convention.

Issue(s) Identified: The WHO/ECDD has explained that the term “extracts and tinctures of cannabis” is outdated and duplicative of the term “preparations of cannabis,” which are already controlled under the 1971 and 1961 Conventions. Additionally, some preparations extracted from the cannabis plant have psychoactive properties and some do not. The WHO/ECDD’s review emphasized that the variability in psychoactive properties is due principally to varying concentrations of THC, which is already scheduled under the 1971 Convention. Finally, the WHO/ECDD noted some preparations of cannabis have demonstrated therapeutic applications such as the authorized medicine Sativex.

Is this Problematic: The WHO/ECDD claims national regulatory agencies are confused by the extracts and tinctures terminology. The United States views the addition of extracts and tinctures as redundant with “preparations” and agree that eliminating the terminology would remove confusion concerning which regime controls in cases where a preparation that is also an extract or tincture has been moved to a different schedule than schedule I.

Pros to adopting WHO recommendation:

- Confusion among national regulatory authorities may be reduced.
- Adopting the recommendation would send a message that the CND is supportive of the WHO/ECDD’s findings.

Cons to adopting WHO recommendation:

- Similar to recommendations 5.2.1 – 5.3.2, recommendation 5.4 is administrative in nature; no public health justification is apparent.

Possible Solutions: As no Member State has raised any concerns about this particular recommendation, it is difficult to contemplate alternatives to accepting, rejecting, or postponing consideration of the recommendation.

Recommendation 5.5

Decision Text: Add a footnote to Schedule I of the 1961 Single Convention on Narcotic Drugs to read: “Preparations containing predominantly cannabidiol and not more than 0.2 percent of delta-9-tetrahydrocannabinol are not under international control.”

Issue(s) Identified: Advances in scientific knowledge have made clear that there are no “pure” preparations that can guarantee the absence of psychoactive components. Medicines, beauty products, natural remedies, and other compounds that are non-psychoactive in nature, but are derived from plants that have psychoactive components may contain residual trace amounts of psychoactive material that could also be considered an “impurity,” as compared to an active ingredient of such a preparation. Preparations of predominantly cannabidiol (CBD) are excellent examples of this conundrum. As CBD is derived from the cannabis plant, CBD products will normally contain residual trace amounts of THC. During the September 23 CND intersessional meeting, UNODC, INCB, and WHO/ECDD provided vastly different explanations of how the international drug control treaties should be interpreted to address this issue.

Is this Problematic: The international drug control treaties do not provide detailed guidance about how to deal with impurities or residual trace amounts of internationally controlled substances in preparations that are otherwise non-psychoactive in nature. This is a gap that may need to be addressed, but when in doubt, the parties should be guided by the object and purpose of the treaty.

Pros to adopting WHO recommendation:

- Selecting a specific numeric threshold amount for the residual substance provides clarity to Member States about how to domestically control preparations that contain such impurities.

Cons to adopting WHO recommendation:

- At the September 23 CND intersessional meeting the WHO/ECDD clarified that the 0.2 percentage figure selected is calculated on a dry-weight basis. However, the text of the recommendation does not make this clear, and we previously understood from the WHO/ECDD that the 0.2 percent figure was calculated by weight by volume in a final preparation or solution. A technical correction or clarification will likely be necessary before CND Member States can accept the recommendation, since the WHO recommendation text is not clear as currently worded.
- Many countries have already considered and developed policies to regulate CBD products and have chosen thresholds for allowable delta-9-THC content that are above or below the WHO/ECDD’s recommended 0.2 percent. For example, Switzerland uses a one percent threshold, and the United States a 0.3 percent threshold on a dry-weight basis. Adopting the resolution may therefore be inconsistent with some Member States’ existing domestic laws and may be unacceptable to a portion of the CND membership on grounds.

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- There are many other non-psychoactive components of the cannabis plant (perhaps as many as 200). Medical research is ongoing for some of these components, and as new products are developed, new footnotes may need to be added to cover these other components. This may, in effect, create an additional schedule for the 1961 Convention. The default assumption is and should be that non-psychoactive substances are not under international control. This footnote could turn this assumption on its head and create a cumbersome process of adding potentially endless footnotes to the schedules every time products are developed that mix psychoactive and non-psychoactive components.

Possible Solutions: It is not the responsibility of UNODC, INCB, or the WHO to interpret the international drug control treaties. States Parties instead have a primary duty to identify and address any gaps in the international drug control treaties with regard to trace residual amounts and impurities of internationally controlled substances in preparations that are otherwise non-psychoactive in nature. We note, however, that the treaties acknowledge the principle that the offenses referred to in the conventions “shall be defined, prosecuted and punished in conformity with the domestic law of the Party.” In our view, this preserves the right of each State Party to determine whether there will be a threshold, and if so, what that threshold should be, guided by the general intent to prevent diversion to illicit purposes. States Parties therefore may wish to develop a policy paper, resolution, or other decisional text for consideration by a future CND that provides general guidance to States Parties on how preparations that are non-psychoactive in nature, but contain residual trace amounts of psychoactive components, should be addressed.

Some elements may include:

- Statements recognizing that CBD, although it is derived from the cannabis plant, is not psychoactive, is already used for therapeutic purposes in several medicines, and there is no evidence of its abuse. Therefore, it is contrary to the purposes of the Convention to subject it to international control once CBD is no longer part of cannabis.
- An acknowledgement that CBD should not be under international control, despite the fact that it contains residual trace amounts of THC; for example, by providing a definition of “pure” CBD, or by allowing Member States to determine what is considered pure.
- General guidance about how CBD products should be produced in such a way that THC is not readily recoverable or recoverable only in yields that would not pose a risk to public health. Care should be taken to ensure flexibility for Member States to set reasonable THC thresholds that make sense in domestic contexts.
- More generally, a recognition that the CND is the body empowered to make recommendations on all matters related to the aims of the conventions.

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Recommendation 5.6

Decision Text: Add preparations containing delta-9-tetrahydrocannabinol (dronabinol), produced either by chemical synthesis or as a preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that delta-9-tetrahydrocannabinol (dronabinol) 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.

Issue(s) Identified: Several existing authorized medicines such as Marinol and Syndros contain a psychoactive compound (Δ 9-THC). The WHO/ECDD recognized that such preparations have formulations with decreased likelihood of abuse and lack evidence of actual abuse or ill effects that would justify either Schedule I of the 1961 Convention or Schedule II of the 1971 Convention. However, the WHO/ECDD believes that adding these preparations to Schedule III of the 1961 Convention would not impeded access to these medicines while assuring some warranted measure of control.

Is this Problematic: The WHO/ECDD review acknowledges that existing evidence concerning the use of medicines containing Δ 9-THC indicates such medicines are not associated with problems of abuse and dependence and that they are not diverted for the purpose of non-medical use. Initially it was thought that this recommendation would not be undertaken unless the Commission decided to move THC from the 1971 Convention to the Single Convention, but when asked to clarify, the WHO/ECDD maintained that its recommendations were not linked. In our view, if THC is not moved to the 1961 Convention, there is no basis to consider moving preparations of THC into the 1961 Convention.

Pros to adopting WHO recommendation:

- A Schedule III listing exempts preparations with low abuse liability from certain control measures, but still provides some protection.

Cons to adopting WHO recommendation:

- A Schedule III listing imposes additional regulatory burdens on Member States.
- Additionally, the recommendation refers to “pharmaceutical” preparations, which is not a defined term under the Single Convention. Introducing an undefined term into the schedules may lead to further confusion. Further, without agreement as to what constitutes a “pharmaceutical preparation,” almost any preparation, including butane hash oil, could be so construed.

Possible Solutions: Preparations in Schedule III must contain drugs scheduled elsewhere in the 1961 Convention. If the recommendation to reschedule delta-9-THC from the 1971 Convention to the 1961 is not accepted, this may obviate the need to vote on recommendation 5.6.

