

# Questions to WHO

## in preparation of the 5<sup>th</sup> Intersessional Meeting

### on 23 September 2019<sup>1</sup>

#### submitted by 19 August 2019

#### 5.0 General Questions

Questions from European Union	
	1) Does the term 'preparations' refer only or also to medicinal preparations requiring a medical prescription?
	2) The term 'preparation' is considered in the recommendations to include 'extracts and tinctures'. It would therefore be helpful to have some clarification regarding whether the term 'preparations' also includes non-medicinal preparations (such as butane hash oil) and isolates (i.e. THC or CBD isolates which are more than 95 % THC or CBD)?
	3) Does the term refer only to industrial, registered medicinal products, or does it also refer to magistral formulae prepared by a pharmacist, both requiring a medical prescription? Are non-medicinal products included (see e.g., recommendation 5.5)?
<b>WHO response</b>	<b>The term 'Preparations of cannabis' as defined in Article 1 of the 1961 Convention, covers all preparations whether for medical or other purposes, whoever produces them, including preparations of delta-9-THC or CBD obtained from the cannabis plant, with a purity over 95% of delta-9-THC and butane hash oil.</b>
	4) What kind of controlled preparations are currently meant by 'Preparations of cannabis', and what would change if the WHO recommendations were agreed upon? For example, would the recommendations change the amounts of CBD and THC covered by the definition of 'preparations of cannabis', and would moving THC to the 1961 Convention change this definition (reference is made, e.g. to leaves)?
<b>WHO response:</b>	<b>The WHO recommendations will not change the definition of 'preparations of cannabis' as defined in Article 1 of the 1961 Convention or what is included in that definition.</b>  <b>With regard to the leaves of the cannabis plant, the 1961 Convention specifies that the standalone leaves of the cannabis plant are not included in the definition of cannabis. Leaves are, as such, not considered a preparation (a "mixture, solid or liquid..." per Article 1 of the 1961 Convention) of delta-9-THC.</b>

<sup>1</sup> These questions built up on the answers already provided by WHO, INCB and UNODC during and after the 4<sup>th</sup> intersessional meeting on 24 June 2019, namely (1) WHO's answers to questions submitted before the 4<sup>th</sup> intersessional meeting, circulated on 2 July 2019; (2) INCB's answers to questions submitted before the 4<sup>th</sup> intersessional meeting, circulated on 2 July 2019; (3) WHO's answers to the follow-up questions asked during the 4<sup>th</sup> intersessional meeting and submitted in writing by 27 June 2019, circulated on 30 July 2019; (4) UNODC's answers to the follow-up questions asked during the 4<sup>th</sup> intersessional meeting and submitted in writing by 27 June 2019, circulated on 30 July 2019.

	<p>5) There are inconsistencies regarding what should be considered a preparation of cannabis and this should be further clarified. It has been confirmed, for example, that preparations of CBD have no abuse potential and that they should be excluded from scheduling (by a footnote – recommendation 5.5). It was explained during the fourth intersessional meeting that CBD API originating from the cannabis plant would also be excluded. Is this similar to noscapine, which is also not scheduled? Noscapine is obtained from concentrate of poppy straw (CPS) but is not considered a preparation of CPS.</p>
<p><b>WHO response:</b></p>	<p><b>With regard to noscapine, the Committee recognised that there is no entry in the Schedules that specifically exempts it from control, even though it is derived from the opium plant and preparations of noscapine will contain trace amounts of morphine.</b></p> <p><b>The Committee also recognised that there was a diversity of views as to whether cannabidiol derived from cannabis would be controlled under the existing Schedules and took into account that countries were seeking guidance on the control of preparations of cannabis without psychoactive effects e.g. cannabidiol preparations.</b></p> <p><b>The Committee therefore considered it appropriate to make a recommendation that provided guidance on the level of delta-9-THC that could be acceptable in cannabidiol preparations.</b></p>

#### Questions from United States

	<p>1) We have some mention of flexibility and the ECDD listening to the questions and the responses, and the concerns that member states have, and we would like to know if the ECDD believes that it has the flexibility to react to the interests expressed by governments. In other words, would the ECDD consider looking again at the recommendations and perhaps modifying those to be more specific to perhaps steer in a slightly different direction, based on what governments have raised?</p>
<p><b>WHO response:</b></p>	<p><b>The WHO's cannabis recommendations are the product of a thorough and multi-step scientific process with involvement of Member States and stakeholders in accordance with the WHO Expert Advisory Panel Regulations and the WHO Guidance on the WHO review of psychoactive substances for international control.</b></p> <p><b>WHO does not plan to revisit these recommendations through the ECDD or otherwise. WHO awaits the CND's consideration of these recommendations and the CND's guidance and continues to stand available to support discussions as guided by the CND.</b></p>
	<p>2) Several of the recommendations seemed to be contingent on outcomes of others, for example the recommendation to add pharmaceutical preparations to Schedule III of the 1961 Convention seems to depend on the approval of the recommendation to move Delta 9 THC to the 1961 Convention but this is not written into the recommendation. We would like to know what would happen if the underlying recommendation to move from the 1971 Convention is not adopted, does this have an impact on the other recommendations?</p>
<p><b>WHO response:</b></p>	<p><b>If delta-9-THC is not added to the Schedules of the 1961 Convention and deleted from the Schedules of the 1971 Convention, this will not have implications on the other ECDD recommendations.</b></p>

	For example, the Schedule III recommendations would still be relevant as they would cover the preparations of cannabis that satisfied the Schedule III criteria. The medication Sativex would be an example of such a preparation.
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## 5.1 Cannabis and Cannabis Resin

Questions from European Union	
	1) There is a need to clarify whether ‘Cannabis and cannabis resin’ refers only to industrial, registered medicinal products and magistral formulae for medical use that contain cannabis plant extract. It would be helpful if the non-medical use of such products were also clearly defined.
<b>WHO response:</b>	<b>Based on the definitions in the 1961 Convention, ‘Cannabis and cannabis resin’ includes preparations made from either the plant or the resin from the plant, whether these preparations are used medically or non-medically.</b>
	2) What information or studies have been taken into account in recommending excluding cannabis and its resin from Schedule IV of the 1961 Convention? Have studies into adverse effects, probably resulting from cannabis consumption mainly among young people, been assessed?
<b>WHO response:</b>	<b>The ECDD relies on thorough scientific critical reviews that assess harms and therapeutic use of substances. These reviews have been prepared by experts in their respective fields, but the ECDD may also consider additional scientific information during its deliberations. The critical reviews for cannabis and cannabis resin are published on the WHO ECDD website and include comprehensive lists of references of peer-reviewed scientific publications.</b>

Questions from United States	
	3) This question relates to a response by WHO to a question by Mexico: why scheduling the plant as a whole as opposed to its component parts? The response was that cannabis and cannabis resin must be scheduled per the treaty. Was this the result of a legal opinion of WHO, or INCB, or UNODC, or perhaps of the UN? We would be interested to know the source for this because this seems to be a pivotal issue. We have checked the passage of the commentary cited during the response and it does not seem to support the WHO conclusion.
<b>WHO response:</b>	<b>The WHO recommendation on cannabis and cannabis resin is to maintain their placement in Schedule I of the 1961 Convention. WHO does not have a position on whether cannabis and cannabis resin must be scheduled per the 1961 Convention as a matter of law and is not in a position to provide an answer to this question. The response provided to Mexico may have been related to the control of cannabis per the articles of the 1961 Convention (as opposed to the scheduling of cannabis).</b>  <b>In this regard, WHO understands that several articles of the 1961 Convention expressly address cannabis (e.g. Articles 1, 2.7, 22) and that WHO scheduling recommendations could not affect the measures provided through the wording of the aforementioned articles.</b>

4) What specifically did the ECDD consider as “cannabis resin” for the purposes of this review? Does this refer to the sticky saplike excretions of the cannabis plant or to purified, extracted resinous products such as butane hash oil?	
<b>WHO response:</b>	<b>Cannabis resin is a substance that is naturally exuded from the plant and can be considered part of the plant. In contrast, butane hash oil and other illicit preparations are produced by use of solvents and other means. Cannabis resin is currently controlled in the same way as cannabis, the two forming one entry in the Schedules of the 1961 Convention; the Committee did not seek to change this.</b>
5) Is there any reason the ECDD could not make a recommendation that differentiates between low THC concentration and high THC concentration cannabis resin?	
<b>WHO response:</b>	<b>It was the Committee’s understanding that differentiating cannabis or cannabis resin on the basis of the concentration of the active compounds, particularly delta-9-THC (dronabinol), could be perceived as proposing to change the definitions in Article 1 of the 1961 Single Convention, since these definitions do not currently address concentrations.</b>  <b>The Committee sought to avoid such perceptions (whether they would be correct or not) and did, therefore, not make proposals that may be viewed as changing the definitions or creating new sub-categories within the definition of cannabis in Article 1 of the 1961 Convention.</b>
6) Is the ECDD aware of any therapeutic use of cannabis resin? Of butane hash oil?	
<b>WHO response:</b>	<b>The Committee is not aware of any therapeutic use of cannabis resin or of butane hash oil, although cannabis resin may have traditional medical uses in some countries.</b>
7) The public perception of cannabis as not being dangerous is one of the leading factors contributing to the global increase in cannabis use/abuse, yet the ECDD addressed cannabis and cannabis resin as one and without regard to the quantity of psychoactive substances in the product consumed. We have concerns that such an approach obfuscates the risks of consuming products with high concentrations of cannabis (for example hashish and hash oils) and may undermine the science by equating the less dangerous substances with the significantly more dangerous ones. Is there any reason the ECDD could not make a recommendation that addresses the concentration of psychoactive substances? Is it the position of the ECDD that the recommendations related to cannabis and cannabis resin must be decided together, or could the CND decide to accept the ECDD recommendation related to cannabis but not cannabis resin?	
<b>WHO response:</b>	<b>This is partly answered by 5), above. Additionally, as noted in 4), above, cannabis resin is currently controlled in the same way as the cannabis (plant) and the Committee did not seek to change this.</b>

## 5.2 Delta-9-tetrahydrocannabinol (Dronabinol)

Questions from European Union	
1) Does 'dronabinol' mean the active substance produced by chemical synthesis, for both medical and non-medical use?	
<b>WHO response:</b>	<p><b>Dronabinol is the International Non-proprietary Name (INN) for the Δ-9-THC stereoisomer (–)-trans-Δ9-THC. It is the only delta-9-THC stereoisomer that occurs naturally in the cannabis plant and is generally the only stereoisomer that has been studied. It is also the stereoisomer that is used medically.</b></p> <p><b>The name “dronabinol” denotes this stereoisomer irrespective of whether it occurs naturally or if it is chemically synthesised and whether it is used medically or for other purposes.</b></p>
2) If dronabinol were moved to the 1961 Convention, could the leaves be internationally controlled under the 1961 Convention, even though cannabis leaves are, according to the same convention, exempt from control?	
<p>The WHO already expressed their view, at the CND intersessional meeting on 24 June, that the leaves would be controlled by the 1961 Convention, even if THC were moved to the same convention. In addition to this, the views of the INCB and the UNODC Division for Treaty Affairs would be appreciated.</p> <ul style="list-style-type: none"> <li>• The WHO document states that cannabis leaves should be considered a preparation of THC. However, the definition of 'preparation' is a 'mixture, solid or liquid, containing a drug'. A leaf of a plant has not been considered a 'mixture' before – could this be addressed?</li> <li>• Coca leaf is explicitly included in Schedule I of the 1961 Convention. If leaves are to be considered as scheduled substances, could the possibility of scheduling cannabis leaves explicitly and defining what should be understood by 'cannabis leaf' be considered?</li> <li>• The current definition of cannabis excludes the seeds and leaves when they are not accompanied by the tops. Does the WHO's interpretation of this recommendation render this definition obsolete? It is understood that the identification of the main psychoactive ingredient (THC) could have an effect on previous definitions.</li> <li>• Could other separate parts of the plant (which, in practical terms, have a very low or no active drug content) also be considered a preparation of THC or cannabis?</li> </ul>	
<b>WHO response:</b>	<p><b>The 1961 Convention extends to the control of cannabis leaves when they are accompanied by the tops and to the misuse of, and illicit traffic in, the leaves of the cannabis plant that are unaccompanied by the tops (Article 28.3).</b></p>
3) What is the basic rule for scheduling a substance under the provisions of the 1961 Convention or the 1971 Convention? If the mode of action is a decisive criterion, why do all synthetic cannabinoids remain in the 1971 Convention when it has now been recommended that the natural cannabinoid dronabinol and THC-isomers be moved to the 1961 Convention?	
<b>WHO response:</b>	<p><b>The rules for scheduling a substance are different for the 1961 Convention and the 1971 Convention and are set out in the respective Conventions. With regard to synthetic cannabinoids, the Committee considered the issue of whether it will also</b></p>

be necessary to move those synthetic cannabinoids currently placed in Schedule II of the 1971 Convention (such as JWH-018, AM-2201, and ADB-CHMINACA) to the 1961 Convention if the recommendation regarding the transfer of dronabinol (delta-9-THC) is adopted.

However, the Committee recognised that while these synthetic cannabinoids have some pharmacological effects similar to delta-9-THC, there are important differences.

In particular, the Committee noted that the synthetic cannabinoids have effects more similar to amphetamine and amphetamine analogues than to delta-9-THC (such as the cardiovascular and stimulant effects) and other effects more similar to hallucinogens such as LSD than to delta-9-THC (such as the extent and likelihood of hallucinations). Both amphetamine and LSD are scheduled under the 1971 Convention.

### Questions from United States

- 1) This question is a follow on to the response we received with respect to the moving Delta 9 THC from the 1971 Convention. The definitions of cannabis and cannabis plant are set forth in the 1961 Convention and they exclude the leaves when the leaves are not attached to the plant. There is a concern that if we move Delta 9 THC from the 1971 Convention where THC is controlled whether it is in the leaves or in the flowering tops, or in the stalks, it is a controlled substance. --do we run the risk that we are causing some internal contradiction in the '61 treaty itself because we have measures that say the leaves are not under control but then we would be scheduling THC. This could in effect be an amendment to the '61 and this could explain why in '71 putting Delta 9 THC was the first thing that was done when that treaty entered into force.

**WHO response:** The question states that “...we have measures that say the leaves are not under control...” and references the “...exclusion of the leaves from control under the '61...”.

WHO understands that the 1961 Convention does extend to the control of cannabis leaves when they are accompanied by the tops. WHO also understands that the 1961 Convention extends to the misuse of, and illicit traffic in, the leaves of the cannabis plant that are unaccompanied by the tops (Article 28.3).

In response to the respective part of question 4, WHO is not aware of the negotiating history of the 1961 Convention on this point / whether there may have been a connection between the then existing control of the leaves through the 1961 Convention and the scheduling of delta-9-THC in the 1971 Convention.

The WHO recommendations on cannabis are for scheduling within the Conventions; they do not propose to amend the text of the articles of the Convention(s).

- 2) This question gets to a potential inconsistency that we may be stumbling into if we move Delta 9 THC from the 71 Convention to the '61 Convention. Because the '61 Convention exempts the cultivation of cannabis for industrial purpose or horticultural purposes - (does anyone in practice use the horticultural exemption?) but clearly member states do look to the industrial purposes. The explanation we had on the effect of scheduling Delta

	<p>9 THC - that this would override the exclusion of the leaves from control under the '61, then it would appear that it would also override the industrial purpose exemption because then anything containing THC would be part of the scheduling. Please address.</p>
<b>WHO response:</b>	<p><b>The 1961 Convention clearly exempts from control cannabis that is grown for industrial or horticultural purposes. Current international regulation is consistent with this, even though cannabis grown for industrial or horticultural purposes contains delta-9-THC which is controlled under the 1971 Convention. The same would apply if delta-9-THC was controlled under the 1961 Convention.</b></p>
	<p>3) If additional control measures are necessary to decrease the extent or likelihood of abuse of delta-9-THC, did the ECDD consider returning delta-9-THC to Schedule I of the 1971 Convention to enhance controls over it, rather than transferring it to Schedule I of the 1961 Convention?</p>
<b>WHO response:</b>	<p><b>The ECDD did consider returning delta-9-THC to Schedule I of the 1971 Convention to enhance the degree of control rather than transferring it to Schedule I of the 1961 Convention.</b></p> <p><b>The criterion for recommending that dronabinol (delta-9-THC) be included in Schedule I of the 1961 Convention was the criterion of similarity in liability to abuse and to produce ill effects to cannabis and preparations of cannabis. It is also the case for opium and coca leaf that the plant and the drug that is included in the plant (morphine and cocaine, respectively) are controlled within the same Schedule and the same 1961 Convention.</b></p> <p><b>The Committee also considered relevant to this issue substances such as butane hash oil containing high levels of delta-9-THC that could be considered either as preparations of cannabis or of dronabinol (delta-9-THC). Control of these substances is facilitated if there is no ambiguity as to the applicable Convention and Schedule.</b></p>
	<p>4) Did the ECDD take into consideration the additional reporting burdens that transferring delta-9-THC from the 1971 Convention to the 1961 Convention would place on Member States when developing this recommendation?</p>
<b>WHO response:</b>	<p><b>The ECDD did not take into consideration the additional reporting burdens that transferring delta-9-THC from the 1971 Convention to the 1961 Convention would place on Member States when developing this recommendation as such considerations are not within the mandate of the ECDD. However, in making such recommendations, the ECDD considered the views of the INCB regarding implementation of the recommendations.</b></p>
	<p>5) The ECDD did not make a recommendation related to preparations of THC under the 1971 Convention. Is this because the prior ECDD recommendation to the CND still stands? That recommendation did not address the concentration of THC found in preparations. In light of the new findings related to cannabis, would it be appropriate to move delta-9-THC to Schedule I of the 1971 Convention to get the more significant controls needed?</p>
<b>WHO response:</b>	<p><b>The recommendation is to move dronabinol (delta-9-THC) to Schedule I of the 1961 Convention. WHO understands that a prior recommendation to move dronabinol from Schedule II to Schedule III of the 1971 Convention has lapsed since 2014.</b></p>
	<p>6) If a preparation produced from the cannabis plant contains trace amounts of delta-9-THC, under the 1961 Convention, would that preparation be treated as a preparation</p>

	<p>containing two drugs – cannabis and dronabinol? The 1971 Convention provides that if a preparation contains more than one controlled substance, the measures applicable to the most strictly controlled of those substances apply to the preparation. Is there a similar rule in the 1961 Convention?</p>
<b>WHO response:</b>	<p><b>Currently, a preparation produced from the cannabis plant that contains trace amounts of delta-9-THC, could be regulated under the 1961 Convention as a cannabis preparation. If the amounts of delta-9-THC are at trace levels, then it is unlikely to be considered as delta-9-THC regulated under the 1971 Convention.</b></p> <p><b>The second part of the question refers to Article 3.1 of the 1971 Convention; unlike Article 3.1 of the 1971 Convention, the parallel provision in Article 2.3 of the 1961 Convention does not state that preparations containing more than one substance are subject to the measures applicable to the most strictly controlled of those substances.</b></p>
	<p>7) Did the WHO Office of the Legal Counsel concur with the determination that the 2010 revision superseded the 2006 legal opinion on moving a substance from the 1971 to the 1961 Convention? Can this opinion be shared with Member States?</p>
<b>WHO response:</b>	<p><b>The question makes reference to a discussion concerning the possible transfer of buprenorphine at the 34th ECDD in 2006. The report of the 34th ECDD in 2006 noted that the guidelines that were applicable to the ECDD process at the time did “not give guidance on the transfer of a substance from the 1961 to the 1971 Convention or vice versa”.</b></p> <p><b>Since 2010 this situation has changed. The “Guidance on the WHO review of psychoactive substances for international control”, through its new paragraph 45, now provides guidance on the circumstances under which the WHO ECDD may recommend transferring a substance from one convention to another.</b></p> <p><b>For WHO and the ECDD this Guidance, endorsed in 2010 by the WHO Executive Board, has authority and supersedes previous guidance that may have been provided by the Secretariat; the WHO Office of the Legal Counsel concurs with this.</b></p>
	<p>8) What additional harms to health could potentially result if delta-9-THC continued being controlled under the 1971 Convention?</p>
<b>WHO response:</b>	<p><b>Recommending that a substance be moved from one Convention to another should generally be made only if specific new control measures are necessary, in order to decrease the extent or likelihood of abuse or the use of the substance in illicit drug manufacturing.</b></p> <p><b>Consistent with this principle, the Committee recommended that dronabinol (delta-9-THC) be scheduled under the 1961 Convention in particular because of illicit preparations containing high levels of delta-9-THC, such as butane hash oil, as discussed above. The existence and use of such high potency and harmful products is a relatively new phenomenon.</b></p> <p><b>However, the additional harms to health due to failure to transfer a drug from one Convention to another or one Schedule to another cannot be directly measured.</b></p>
	<p>9) If this recommendation is enacted, will it also be necessary to move all synthetic cannabinoids currently placed in Schedule II of the 1971 Convention (such as JWH-018,</p>



AM-2201, and ADB-CHMINACA), which have pharmacological effects similar to delta-9-THC, to the 1961 Convention as well?

<b>WHO response:</b>	<p>The Committee considered the issue of whether it will also be necessary to move all synthetic cannabinoids currently placed in Schedule II of the 1971 Convention (such as JWH-018, AM-2201, and ADB-CHMINACA) to the 1961 Convention if the recommendation regarding the transfer of dronabinol (delta-9-THC) is adopted. However, the Committee recognised that while these synthetic cannabinoids have some pharmacological effects similar to delta-9-THC, there are important differences.</p> <p>In particular, the Committee noted that the synthetic cannabinoids have effects more similar to amphetamine and amphetamine analogues than to delta-9-THC (such as the cardiovascular and stimulant effects) and other effects more similar to hallucinogens such as LSD than to delta-9-THC (such as the extent and likelihood of hallucinations). Both amphetamine and LSD are scheduled under the 1971 Convention.</p>
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### 5.3 Tetrahydrocannabinol (isomers of THC)

#### Questions from European Union

Does the term 'Tetrahydrocannabinol' refer only to the active substance extracted from the cannabis plant, for both medical and non-medical use?

<b>WHO response:</b>	<p>In the entry for Schedule I of the 1971 Convention, tetrahydrocannabinol refers to the six identified isomers of THC including their stereochemical variants. This entry in the Schedules does not include delta-9-tetrahydrocannabinol (which includes the stereoisomer dronabinol) as it is covered by a separate entry in Schedule II.</p> <p>This use of tetrahydrocannabinol includes these isomers irrespective of whether they occur naturally or whether they are chemically synthesised and whether they are used medically or for other purposes. In practice, most of these isomers do not occur naturally and none are used medically or non-medically.</p>
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#### Questions from United States

If this recommendation is enacted, will it also be necessary to move all synthetic cannabinoids currently placed in Schedule II of the 1971 Convention (such as JWH-018, AM-2201, and ADB-CHMINACA) which have pharmacological effects similar to isomers of THC, to the 1961 Convention as well?

<b>WHO response:</b>	<p>The Committee considered the issue of whether it will also be necessary to move all synthetic cannabinoids currently placed in Schedule II of the 1971 Convention (such as JWH-018, AM-2201, and ADB-CHMINACA) to the 1961 Convention if the recommendation regarding the transfer of the isomers of THC is adopted.</p>
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However, the Committee considered that there is insufficient evidence regarding the effects of the isomers of THC to allow comparison with the synthetic cannabinoids. There would therefore be insufficient justification to move these synthetic cannabinoids on the basis of similarity to the isomers of THC.

#### 5.4 Extracts and Tinctures of Cannabis

##### Questions from European Union

- 1) Does the term 'extracts and tinctures' refer only to products for medical use and requiring a medical prescription? If they also refer to other types of products (i.e. including products which are not for medical use such as butane hash oil), would it be more appropriate to leave 'extracts and tinctures' in Schedule I?

<b>WHO response:</b>	<p><b>Extracts and tinctures can include products for medical use as well as products used outside of medical contexts. The reasons for recommending removal of 'Extracts and tinctures of cannabis' have been outlined in the report of the 41st ECDD meeting and in the responses to questions presented at the CND intersessional meeting of the 24th June 2019. The latter response was as follows:</b></p> <p><b>In its recommendation to remove 'Extracts and tinctures of cannabis', the Committee was not seeking to decrease the level of control of any cannabis related substance or narrow the scope of control. Should the recommendation be adopted, no such decrease in control will occur.</b></p> <p><b>Under Article 1 of the 1961 Convention, "preparation" is a general term covering mixtures, solids, or liquids containing a substance in Schedule I or II, and they are generally subject to the same measures of control as that substance. In the case of opium and coca leaf, products derived from those plant sources are subject to the same measures of control as preparations, and the same is true of cannabis.</b></p> <p><b>In the case of cannabis, currently there are three main types of illicit products derived from the plant:</b></p> <ol style="list-style-type: none"> <li><b>1. extracts (obtained by use of a solvent; for example, butane hash oil),</b></li> <li><b>2. tinctures (obtained using alcohol as a solvent), and</b></li> <li><b>3. products derived without the use of a solvent but by application of heat and pressure.</b></li> </ol> <p><b>All three types of products are controlled as preparations of cannabis.</b></p> <p><b>However, under 'extracts and tinctures' only the first two types are controlled.</b></p> <p><b>The Committee therefore concluded that by relying on control of preparations of cannabis there is greater certainty of control of products</b></p>
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	<p>derived without the use of a solvent but by application of heat and pressure. These products are indistinguishable from those derived as extracts or tinctures.</p> <p>While the Committee also noted that there was some potential for extracts and tinctures to include non-psychoactive preparations that are used medically (such as those containing CBD), the principal reason for recommending that ‘extracts and tinctures’ be removed, was so that there is greater certainty regarding control of all illicit products derived from cannabis, as cannabis preparations will be controlled in the same way as cannabis (Article 2 of the 1961 Convention).</p>
	<p>2) In its responses to questions on recommendations 5.4. and 5.5., the WHO stated that it considered that THCA would be controlled as a ‘preparation of cannabis’. Both the WHO and the INCB also responded that the removal of ‘extracts’ from the schedules would only allow the control of cannabinoids explicitly listed in the schedule. Could it be clarified more specifically when THCA would be under international control and when it would not be? And could the WHO elaborate on the rationale behind calling these ‘preparations of cannabis’ (in responses to questions on recommendation 5.4) if the presence of THC is required? This seems to contradict the objective of recommendation 5.4.</p>
<p><b>WHO response:</b></p>	<p><b>It is not the view of the WHO that the removal of ‘extracts and tinctures’ from the Schedules of the 1961 Convention would only allow the control of cannabinoids explicitly listed in the schedule.</b></p> <p>Subject to INCB’s and UNODC’s confirmation, it seems that any preparation of cannabis and cannabis resin would, in principle, remain controlled if the ECDD recommendations were adopted, unless such preparations fulfilled the requirements of the proposed footnote to the Schedule I entry (recommendation 5.5) or fell within the scope of the proposed entry to Schedule III and were subject to the lesser degree of control of that Schedule (Recommendation 5.6).</p>

### Questions from Singapore

	<p>1) In its report, the Committee recognised that ‘extracts and tinctures’ of cannabis include <i>‘medical preparations such as that containing an approximately equal mixture of delta-9-tetrahydrocannabinol (dronabinol; Δ9-THC) and CBD [ie, cannabidiol] and non-medical preparations with high concentrations of Δ9-THC such as butane hash oil.’</i> Given that Article 2 of the 1961 Convention automatically exempts preparations from certain control measures, what control measures does the Committee envisage for non-medical preparations with high concentrations of Δ9-THC such as butane hash oil?</p>
<p><b>WHO response:</b></p>	<p><b>The exempted control measures referred to are as follows:</b></p> <ul style="list-style-type: none"> <li>- Article 19 relating to estimates of drug requirements. Subject to UNODC’s and INCB’s advice and guidance, this does not seem relevant for illicit preparations such as butane hash oil.</li> <li>- Article 20 relating to returns on information. Subject to UNODC’s and INCB’s advice and guidance, this does not seem relevant for illicit preparations such as butane hash oil.</li> </ul>

	<p>- Article 29 para 2(c) relates to licensed manufacturers. Subject to UNODC`s and INCB`s advice and guidance, this does not seem relevant for illicit preparations such as butane hash oil.</p> <p>- Article 30 para 1 (b) (ii) relates to control of licensed places where trade or distribution takes place. Subject to UNODC`s and INCB`s advice and guidance, this does not seem relevant for illicit preparations such as butane hash oil. <b>Butane hash oil as a preparation of a cannabis should be controlled under Schedule I of the 1961 convention.</b></p>
2)	<p>At the 4th Intersessional Meeting of the 62nd session of the CND, the INCB Secretariat acknowledged that “the lack of a definition of extracts and tinctures has not facilitated control over these substances.” We note that the INCB Secretariat, in the same Statement, stated that if “extracts and tinctures of cannabis” is retained, it “could be used to cover intermediate products of cannabis or it could allow the control of preparations with cannabinoids other than those explicitly listed in the schedule.” The INCB Secretariat elaborated that this required a “clearer and unequivocal operational definition of this category to be agreed upon by Member States to avoid differences in understanding of the drugs under control.” In line with the INCB Secretariat’s statement, we seek clarification on what the proposed “operation definition” of “extracts and tinctures” would be.</p> <p>We are concerned that is the lack of an operational definition of “extracts and tinctures” may possibly result in the loosening of the control measures.</p>
	<p><b>WHO refers this question to INCB</b></p>

## 5.5 Cannabidiol Preparations

Questions from European Union	
1) If recommendation 5.5 were adopted (and even if national legislations could be made more restrictive), would all products extracted from cannabis containing CBD and no more than 0.2 % THC fall outside the scope of the Convention?	
<b>WHO response:</b>	<b>All products extracted from cannabis containing predominantly CBD and not more than 0.2 % delta-9-THC would fall outside the scope of the Convention if the recommendation is adopted.</b>
2) Does recommendation 5.5. only relate to CBD preparations that are registered as pharmaceutical products, magistral formulae or intermediate material for making compound pharmaceutical products? What is the precise definition of 'preparations of pure CBD', especially regarding the content of CBD and of other cannabinoids? The WHO recommendation only specifies 'not more than 0.2 percent of delta-9-tetrahydrocannabinol'.	
<b>WHO response:</b>	<p><b>Recommendation 5.5 relates to all CBD products that satisfy the criteria set out in the recommendation as follows: "Preparations containing predominantly cannabidiol and not more than 0.2 per cent of delta-9-tetrahydrocannabinol are not under international control."</b></p> <p><b>The Committee considered that most of the preparation should be CBD, and not more than 0.2% delta-9-THC (by weight as a proportion of the total weight of cannabis plant material). The word predominantly was used to describe the proportion of CBD and this was intended to mean that almost all of the content was CBD. The recommendation does not refer to 'pure CBD'. The Committee considered that the percentage of CBD to be used in practice could be left to individual Member States in consultation with INCB.</b></p>
3) If medicines considered pure CBD preparations should not be controlled under the 1961 Convention, it is understood that CBD products such as food products that are not registered as medicines or magistral formulae should be considered as being controlled as 'preparations of cannabis or THC'. Could this be confirmed?	
<b>WHO response:</b>	<p><b>Under the existing scheduling arrangements, CBD containing food products are not controlled if the CBD is produced synthetically or if it is derived from cannabis plants produced for industrial or horticultural purposes and containing traces of delta-9-THC. If the CBD is derived from cannabis produced for purposes other than industrial or horticultural ones, then the food products are currently controlled as preparations, or extracts and tinctures, of cannabis.</b></p> <p><b>If the recommendations of the WHO are adopted, then CBD- containing food products will not be controlled under the Conventions, provided they meet the requirements of the proposed footnote to the entry for Schedule I. Individual Member States can impose their own controls, however, food products that do not meet the requirements of the proposed footnote to the Schedule I entry would still be controlled.</b></p>

	<p>4) THC traces contained in CBD-based products, even if lower than 0.2 %, could have medium-/long-term side effects in the event of regular/heavy use. Have the medium-/long-term effects of THC (even if lower than 0.2 %) contained in CBD products been considered? Is there any data indicating its effect on driving capacity?</p>
<p><b>WHO response:</b></p>	<p><b>Following consumption of the maximum adult dose of CBD, the dose of delta-9-THC based on the maximum concentration of 0.2%, will be below the level that would produce significant effects. It is only possible to experience effects of THC by consumption of very high doses of CBD that would produce significant adverse effects from the CBD itself such as weakness, diarrhoea, general malaise and insomnia.</b></p> <p><b>These effects make it extremely unlikely that anyone would do this on more than one occasion and therefore abuse and dependence of THC from CBD products with less than 0.2% of delta-9-THC is therefore not a significant concern.</b></p>
	<p>5) The recommended footnote reads as follows: ‘Preparations containing predominantly cannabidiol and not more than 0.2 percent of delta-9-tetrahydrocannabinol are not under international control.’ This wording can be understood to mean that all cannabidiol (CBD) preparations are covered by this footnote – not just medicinal products, as explained by the WHO.</p>
<p><b>WHO response:</b></p>	<p><b>It has never been the position of WHO that only medicinal products are covered by this footnote. See the previous answer 3), above. The wording of the footnote encompasses both medicinal and non-medicinal products.</b></p>
	<p>6) The aim of the 1961 Convention is ‘to limit the possession, use, trade in, distribution, import, export, manufacture and production of drugs exclusively to medical and scientific purposes’. However, there are both licit (cannabis medicines) and illicit products (like butane hash oil or other cannabis extracts) covered by the Convention and the footnote does not differentiate between them. Thus, the footnote may also be interpreted in such a way that all preparations containing predominantly CBD and no more than 0.2 % THC would not be under international control, but all preparations containing little or no CBD and no more than 0.2 % THC would be. Why is the CBD content decisive in determining whether a product containing a low amount of THC is under international control or not?</p>
<p><b>WHO response:</b></p>	<p><b>The footnote was included because CBD, whether synthetic or derived from the cannabis plant, has no abuse or dependence potential and therefore it is not appropriate that it be regulated by the Conventions.</b></p> <p><b>As CBD preparations derived from the cannabis plant will contain trace amounts of delta-9-THC, the footnote specified that CBD was excluded from control as long as the level of delta-9-THC in CBD preparations was not greater than 0.2%. The footnote is not relevant to preparations that contain little or no CBD but rather to preparations that contain predominantly CBD.</b></p>
	<p>7) Considering the high number of low-THC products on the market worldwide (declared as, e.g., food, food supplements, cosmetics), it should be made clear which low-THC products, irrespective of their CBD content, are regulated by the 1961 Convention (or the 1971 Convention) and may be illicit, and which ones are exempt. With this in mind, the</p>

control of cultivation should also be clarified. Could the INCB and the UNODC Division for Treaty Affairs give their positions on this issue?

**WHO response:** WHO refers this question to INCB and UNODC

### Questions from Norway

Norway sees the need to operationalize the concepts of “pure CBD”. We also find the 0.2 percent THC limit reasonable. We think the footnote must apply to all preparations from the cannabis plant regardless of the amount of CBD.

The proposal from WHO applies to “preparations containing predominantly CBD”. We are afraid that this wording may be misinterpreted so that preparations with low CBD and traces of THC (for instance preparations from seeds contaminated with THC) will be controlled under the Single Convention on Narcotic Drugs.

In this context we refer to the question from Romania on behalf of the EU prepared for the 4th Intersessional Meeting in June 2019 (c.f. Question 4 under Section 5.5): “Would preparations with a THC-content not exceeding 0,2 % be generally excluded from the control-regime or only preparations with “predominantly CBD”? What difference does it make if the preparation contains predominantly CBD or other substances that are not under international control?”

Norway therefore propose this wording of the footnote:

*“Preparations from cannabis containing not more than 0,2 percent of delta-9-tetrahydrocannabinol, are not under international control”*

Will this be in line with WHO's intentions?

**WHO response:** **The only evidence concerning the potential for abuse, dependence and harm to health is for preparations that are predominantly CBD. No evidence of abuse and dependence was shown for CBD preparations with 0.15% of delta-9-THC. The Committee therefore recommended that preparations containing predominantly cannabidiol and not more than 0.2 per cent of delta-9-tetrahydrocannabinol not be controlled.**

**The Committee did not seek to exclude from control preparations with cannabis components other than CBD (cannabigerol or cannabidavarin), with no more than 0.2% THC, as there was no evidence of their effects. If such evidence emerges in the future, then a more general recommendation regarding preparations with not more than 0.2% delta-9-THC may be appropriate.**

### Questions from Singapore

In its report, the Committee recognised the limited robust scientific evidence on the therapeutic use of cannabis. However, the Committee also stated that some oral pharmaceutical preparations of cannabis have therapeutic advantages for treatment of conditions such as certain forms of pain and epilepsy. This recommendation potentially exempts preparations, apart from oral pharmaceutical preparations, from certain control measures under the 1961 Convention. Could the Committee clarify the intention behind and basis for this recommendation?

<p><b>WHO response:</b></p>	<p><b>Cannabidiol (CBD) is a substance that can be synthesised or obtained from the cannabis plant. When obtained from the plant, under current regulations, it is controlled both as a preparation of cannabis (Schedules I &amp; IV) and as an extract or tincture of cannabis (Schedule I).</b></p> <p><b>Cannabidiol shows no potential for abuse or dependence and any ill-effects are minimal. It is not similar to any other substance controlled under the 1961 Convention. Cannabidiol does have effects on the brain, but like many other substances with such effects, it is not considered psychoactive as it has no significant effects on mental state. Based on this evidence, and its value as a medicine, the Committee considered that cannabidiol preparations should not be controlled under the 1961 Convention.</b></p> <p><b>The Committee considered the option of including preparations of cannabidiol in Schedule III of the 1961 Convention. However, that Schedule is for substances that are controlled and that satisfy the criteria for control. Cannabidiol does not satisfy those criteria. Inclusion in Schedule III lessens the degree of international control, but a number of controls are still required. Inclusion of cannabidiol preparations in Schedule III would mean that controls would be required for preparations of a drug that did not satisfy the criteria for inclusion in the schedules of the 1961 Convention.</b></p> <p><b>The option of a footnote was adopted after recognition of the precedents of exclusion of dextromethorphan and dextrorphan from control by this means. When produced from the plant (as is the case with the cannabidiol medicine approved in the US and recommended for approval in the EU), cannabidiol preparations will contain trace amounts of delta-9-THC as well as other cannabinoids and non-cannabinoid plant substances.</b></p> <p><b>The Committee considered that most of the preparation should be CBD, and not more than 0.2% delta-9- THC (by weight). The word predominantly was used to describe the proportion of CBD and this was intended to mean that almost all of the content was CBD. The Committee considered that the percentage of CBD to be used in practice could be left to individual Member States in consultation with INCB.</b></p> <p><b>The value of 0.2% for delta-9- THC was specified as WHO had requests from Member States to indicate what maximum percentage was considered appropriate and to ensure that the currently registered CBD medication was exempted from control. That medication has a delta-9-THC content not greater than 0.15% by weight as a proportion of the total weight of plant material.</b></p> <p><b>The Committee also acknowledged that chemical analysis of delta-9-THC to an accuracy of 0.15% may be difficult for some Member States and hence ECDD adopted a limit of 0.2%. On the basis of the Committee’s recommendation, even for a maximum adult dose of CBD, the level of delta-9-THC (max. 0.2%) will be below the level that would produce significant effects.</b></p>
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## Questions from United States

- 1) We are looking at the proposed percentage of THC and we would just note that in Epidiolex, it was stated that it was 0.15 %; our records indicate that it is 0.015% so substantially lower than that which was indicated in the critical review. If we had a 0.2% THC limit in a 30 ml bottle of CBD oil, that would contain 54 mg of THC. We have some concerns about these numbers and how the ECDD arrived at those. We also note that member states that cultivate cannabis for hemp purposes, industrial purposes, a number of states including the US have adopted numbers that are not at 0.2%; some are above AND some are below, and the above go up as high as 1%. One comment was made that perhaps this could be up to member states to decide but that would be in consultation with the INCB. We need a bit more explanation for this because the INCB has a role in the estimate process and the administration of statistics but they don't have a role in the scheduling process. That is the unique role of the WHO and member states. Could WHO address those concerns.

**WHO response:** **The specified level of 0.2% is by dry weight as a proportion of the total weight of cannabis plant material. This was done intentionally as different manufacturers (or the same manufacturer in different countries) may add different amounts and types of excipients to the material extracted from the plant. Different amounts of excipients will result in different final percentages of delta-9-THC for the same amount of delta-9-THC. What is important is the amount of delta-9-THC relative to the amount of cannabidiol (and other minor plant constituents that will be present in the product). By specifying the level of delta-9-THC as a proportion of the total weight of cannabis plant material, irrespective of the amount of excipients added, this is achieved.**

**Cannabis for industrial and horticultural purposes (commonly known as hemp) is specifically excluded from control by the 1961 Convention. There is therefore no relation between the level of delta-9-THC in such products and the maximum level of delta-9-THC being recommended for cannabidiol products.**

- 2) Why is a footnote necessary to exempt preparations of cannabidiol from control when preparations of noscapine and papaverine, which may contain trace amounts of controlled opiates, do not need to be specifically exempted by footnote?

**WHO response:** **The Committee recognised that noscapine and papaverine, which are derived from the opium plant and preparations of which will contain trace amounts of morphine, are not specifically exempted from control.**

**The Committee also recognised that there was a diversity of views as to whether cannabidiol derived from the cannabis plant would be controlled under the existing Schedules and took into account that countries were seeking guidance on the control of CBD preparations. The Committee therefore considered it appropriate to make a recommendation that provided guidance on the level of delta-9-THC that could be acceptable in cannabidiol preparations.**

- 3) If, in the future, the ECDD reviews another cannabinoid derived from the cannabis plant (such as cannabigerol or cannabidavarin) and finds that relatively pure preparations of

that substance are not liable to abuse, will it be necessary to further footnote the entry for cannabis and cannabis resin to exclude those preparations from international control?	
<b>WHO response:</b>	<b>The Committee recognised that it was possible that at some time in the future it would review another cannabinoid derived from the cannabis plant (such as cannabigerol or cannabidavarin) that is not liable to abuse but has some therapeutic value. The Committee considered that if this occurred, it may, depending on any recommendation that the Committee would provide, be appropriate to amend the footnote to include that substance as well as cannabidiol.</b>
4) Would the following be consistent with the ECDD recommendation related to CBD? A decision to amend the 1961 schedule entry for “cannabis and cannabis resin” by adding the words “, excluding non-psychoactive substances derived therefrom, whether or not such substances also contain psychoactive substances, provided such psychoactive substances are in such a small quantity that it cannot be easily recovered or abused”, and to amend the 1971 schedule pertaining to Delta-9-THC so that it reads “Delta-9-THC excluding that found with non-psychoactive substances where the THC is in such a small quantity that it cannot be easily recovered or abused.”	
<b>WHO response:</b>	<b>The only evidence concerning the potential for abuse, dependence and harm to health is for preparations that are predominantly CBD. No evidence of abuse and dependence was shown for CBD preparations with 0.15% of delta-9-THC. The Committee therefore recommended that preparations containing predominantly cannabidiol and not more than 0.2 per cent of delta-9-tetrahydrocannabinol not be controlled. The Committee did not seek to exclude from control other preparations as there was no evidence of their effects. If such evidence emerges in the future, then a more general recommendation regarding preparations with not more than 0.2% delta-9-THC may be appropriate.</b>
5) Does the 0.2% threshold in this recommendation refer to percent by dry weight or by concentration in a solution? If the preparation is a liquid or gas, would the threshold be 0.2 percent concentration of the solution or gas?	
<b>WHO response:</b>	<b>The level of 0.2% of delta-9-THC is by dry weight as a proportion of the total weight of plant material. If the preparation is in liquid format due to the addition of some liquid to the delta-9-THC (dronabinol), then the percentage will still be as specified. Delta-9-THC does not occur in gaseous form but can be vaporised with the application of heat.</b>
6) Does a solution with a THC concentration of 2 mg/mL present no, or a negligible, risk of abuse, and can the THC be recovered by readily applicable means in a quantity liable to abuse such that the solution, if uncontrolled, may give rise to a public health and social problem?	
<b>WHO response:</b>	<b>The question regarding solutions cannot be readily answered without knowing what type of solution. Delta-9-THC is poorly soluble in water and requires use of an organic solvent. If that solution is such that delta-9-THC can be readily recovered, then it would be subject to the level of control of preparations of delta-9-THC or cannabis and not the level of control of preparations in Schedule III. Medical forms of delta-9-THC are prepared with lipid and non-lipid solvents, most commonly sesame oil. Delta-9-THC is not readily recoverable from a solution with sesame oil and hence such solutions would satisfy the criteria for the proposed Schedule III level of control.</b>

	7) In lieu of a footnote, what other methods are available to clarify that preparations predominantly containing cannabidiol are not under international control?
<b>WHO response:</b>	<b>The Committee was not aware of any option other than a footnote for specifying that preparations predominantly containing cannabidiol with no more than 0.2% of THC are not under international control.</b>
	8) In lieu of a footnote, what other methods are available to clarify that cannabis or preparations of cannabis that contain only trace amounts of delta-9-THC are not under international control?
<b>WHO response:</b>	<b>The Committee was only aware of one other alternative for indicating that cannabis and preparations of cannabis that contain only trace amounts of delta-9-THC (dronabinol) are not under international control: this was to recommend changing the wording of the entry for cannabis and cannabis resin to specify that it contained more than 0.2% delta-9-THC (dronabinol).</b>  <b>It was the Committee`s understanding that differentiating cannabis on the basis of the concentration of the active compounds, particularly delta 9-THC (dronabinol), could be perceived as varying/proposing to amend the definitions that are included in Article 1 of the 1961 Single Convention since these definitions do not currently address concentrations. The Committee sought to avoid such perceptions (whether they would be correct or not) and did, therefore, not make proposals that may be perceived as changing the definitions or create new sub-categories within the definition of cannabis as defined in Article 1 of the 1961 Convention.</b>
	9) Can a preparation described by this recommendation also be described as a preparation that is compounded as a pharmaceutical preparation with one or more other ingredients and in such a way that delta-9-THC cannot be recovered by readily available means or in a yield which would constitute a risk to public health? If such a preparation can be equally described by both definitions, which recommendation takes precedence? What language of the 1961 Convention would lead to that result?
<b>WHO response:</b>	<b>Certain preparations containing predominantly CBD and less than 0.2% delta-9-THC could, indeed, also be described as preparations that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that delta-9-THC cannot be recovered by readily available means; To the extent that this is the case the ECDD considered that the proposed footnote addresses such preparations more specifically than the proposed entry for Schedule III and that such preparations should, therefore, be within the scope of the footnote rather than the scope of Schedule III preparations.</b>  <b>The Committee considered the option of including cannabidiol preparations in Schedule III of the 1961 Convention. However, that Schedule is for drugs that are controlled and that satisfy the criteria for control. Cannabidiol does not satisfy those criteria. Inclusion in Schedule III lessens the degree of international control, but a number of controls are still required. Inclusion of cannabidiol preparations in Schedule III would mean that controls would be required for preparations of a drug that did not satisfy the criteria for inclusion in the schedules of the 1961 Convention.</b>

	<b>The option of a footnote was adopted after recognition of the precedents of exclusion of dextromethorphan and dextrorphan from control by this means.</b>
10) What does it mean to have a preparation that is predominantly cannabidiol? Is that measured by a certain percentage? A percentage of what?	
<b>WHO response:</b>	<b>The word predominantly was used to describe the proportion of CBD and this was intended to mean that almost all of the content was CBD. The calculation is as dry weight as a proportion of the total cannabis plant content. The Committee considered that the percentage of CBD to be used in practice could be left to individual member states in consultation with INCB.</b>

## 5.6 Pharmaceutical Preparations of Cannabis and Delta-9-tetrahydrocannabinol (Dronabinol)

Questions from European Union	
1)	Could the WHO further clarify why this recommendation is based on the recoverability of THC 'by readily available means' and the lack of evidence of abuse of existing pharmaceutical preparations? More clarity would be appreciated on the assessment of the abuse potential of all possible preparations (meaning also the products which actually could be abused (e.g., orally) without any manipulating or "recovering of THC") that this recommendation may concern. Has the abuse potential of various non-medicinal edibles been considered?
<b>WHO response:</b>	<p><b>It should be noted that the proposal for Schedule III relates only to pharmaceutical preparations; that is, those intended for medical use. As was noted in the responses to questions presented at the CND intersessional meeting of the 24th June 2019: These pharmaceutical preparations encompass the ones requiring pre-market approval and the ones produced extemporaneously according to a prescription and to agreed good manufacturing practices. It was considered that individual Member States will have their own criteria for assessing whether a product is for medical use. The evidence from medical use of these preparations showed that they were not associated with abuse or dependence.</b></p> <p><b>There are no implications for the control of "non-medicinal edibles" arising from this recommendation.</b></p>
2)	Could the WHO further clarify the condition 'in such a way that delta-9-tetrahydrocannabinol (dronabinol) cannot be recovered by readily available means'? What technically are the 'readily available means' and what qualities does a preparation have to possess to fulfil the condition of non-recoverability? Why is this condition only relevant for pharmaceutical preparations?
<b>WHO response:</b>	<p><b>The general meaning of "recovered by readily available means" is that an average person with the resources available to them could not extract the THC. The resources available in a modern pharmaceutical company would not be considered "readily available means", for example.</b></p> <p><b>The use of specific manufacturing methods will ensure that the active principle of pharmaceutical preparations is not recoverable. As noted in answer 14), the recommendation relates only to pharmaceutical preparations. The limitation to "pharmaceutical" preparations is meant to ensure that only preparations with an acceptable public health risk-profile would enjoy the flexibility of Schedule III.</b></p>
3)	Why is the text that mentions abuse potential in the summary of product characteristics not considered relevant in making this recommendation?
<b>WHO response:</b>	<b>The ECDD considers scientific information that is based on sound experiments with appropriate data. In this instance, it has included data relating to abuse potential of medicinal products containing delta-9-THC.</b>

	<b>In contrast, there are a range of reasons why a statement relating to abuse potential may be included in a company’s product information. Such a statement may not necessarily have a sound scientific underpinning.</b>
4)	Could the maximum content of active substance in each administered dose be specified, as it is in the Yellow List for Schedule III substances (e.g., codeine, ethylmorphine, etc)? In the WHO’s reply, it is mentioned that ‘the active ingredient and the recommended dosage will vary according to factors such as the conditions being treated and the patient’s history’. This approach could be applied to other Schedule III substances, but the maximum amounts of these active substances in the preparations containing them are specified in Schedule III section of the Yellow List.
<b>WHO response:</b>	<b>The Committee considered that it was not necessary to recommend a maximum content of dronabinol (delta-9-THC) for this preparation, as dronabinol would not be recoverable. By comparison, almost all the substances in Schedule III currently (with opium as an exception), are readily recoverable.</b>
5)	Since there is no upper limit for concentration and the main criterion seems to be the assurance that the product will not be inhaled or smoked, are there any grounds for ensuring that products with an undefined concentration of delta-9-THC would enjoy the most flexible control measures and, e.g., the prescription requirement would be left for Member States to address nationally?
<b>WHO response:</b>	<b>Under the proposed recommendation, Member States could make their own specifications as to permitted delta-9-THC dosage levels. The limitation to “pharmaceutical” preparations is meant to ensure that only preparations with an acceptable public health risk-profile would enjoy the flexibility of Schedule III.</b>

### Questions from Singapore

6)	At the 4th Intersessional Meeting of the 62nd session of the CND, the INCB Secretariat acknowledged that the term “compounded pharmaceutical preparation” is applicable to a large number of preparations, and it is unclear what the definition of “readily available means” is. We seek clarification from the Committee on the following: (a) how can Member States determine whether $\Delta$ 9-THC (dronabinol) can or cannot be recovered by “readily available means”, or whether the yield would constitute a risk to public health? (b) are there any international standards of methodologies to enable laboratories or competent authorities to make this determination of whether there is risk to public health?
<b>WHO response:</b>	<b>This is similar to the term “readily applicable means” used with respect to opium preparations. The general meaning of “recovered by readily available means” is that an average person with the resources available to them could not extract the delta-9-THC. The resources available in a modern pharmaceutical company would not be considered “readily available means”, for example.</b>
7)	How does the Committee intend to list such preparations in Schedule III of the 1961 Convention? In other words, how would the specific item listed in Schedule III of the 1961 Convention be worded?

<b>WHO response:</b>	<p>The proposed entry would be as follows:</p> <p><i>Dronabinol</i>  <i>produced either by chemical synthesis or as a preparation of cannabis, when compounded as a pharmaceutical preparation 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.</i></p>
	<p>8) Does the Committee intend to recommend a ‘per dosage unit’ of Δ9-THC and the ‘concentration level’ for this preparation, in line with how preparations are currently described in Schedule III of the 1961 Convention?</p>
<b>WHO response:</b>	<p>The pharmaceutical preparations recommended to be placed under Schedule III have dronabinol (delta-9-THC) as the active ingredient and the recommended dosage will vary according to factors such as the conditions being treated and patient history.</p> <p>The Committee felt it was not necessary to recommend a ‘per dosage unit’ of dronabinol and the ‘concentration level’ for this preparation, as dronabinol would not be recoverable. By comparison, almost all the substances in Schedule III currently (with opium as an exception) are readily recoverable. Member States have the option to set their own limits on dosage.</p>
	<p>9) At the 4th Intersessional Meeting of the 62nd session of the CND, the INCB Secretariat stated that (a) the endorsement of this recommendation would reduce controls over most preparations containing THC and CBD and (b) this could be applicable to a large number of preparations. Could the Committee elaborate on (a) the current control requirements of preparations containing THC and CBD; and (b) the impact of recommendation 5.6 on the current control requirements?</p>
<b>WHO response:</b>	<p>a. <b>Delta-9-THC is currently controlled under Schedule II of the 1971 Convention, but, if derived from the cannabis plant, could also be controlled under the 1961 Convention as a preparation of cannabis (Schedules I and IV) or an extract or tincture of cannabis (Schedule I).</b></p> <p>CBD is not controlled if the CBD is produced synthetically or if it is derived from cannabis plants produced for industrial or horticultural purposes; if the CBD is derived from cannabis produced for purposes other than industrial or horticultural ones, then it is controlled as a preparation of cannabis (Schedules I and IV) or an extract or tincture of cannabis (Schedule I).</p> <p>b. <b>Under the proposed changes, delta-9-THC would be controlled under Schedule I of the 1961 Convention, whether synthetically produced or obtained from the plant. Preparations of delta-9-THC for medical purposes that satisfied the criteria in recommendation 5.6 would be subject to the more limited controls required for Schedule III preparations as described in Article 2 para 4 of the Single Convention on Narcotic Drugs, 1961.</b></p> <p><b>If the proposed footnote to the entry for Schedule I was adopted, preparations that are predominantly CBD with not more than 0.2% of delta-9-THC, would not be controlled.</b></p>

## Questions from United States

- 1) Earlier cited was the emergence of highly concentrated illicit preparations of dronabinol as a major reason for the need for increased controls from Schedule II of the '71 Convention to Schedule I of the '61 Convention. Could WHO perhaps cite the evidence that these concentrated preparations specifically were implicated in increased risk or health problems to member states or associated with health problems specifically? WHO has used Syndros, which is an authorized medicine in some countries (including the United States), a concentrated preparation of dronabinol at 5 mg/ml, which is in our domestic schedule II as it had undergone some studies and shown to have some abuse potential during those studies. It is used as an example of a preparation that should be in schedule III of the '61 Convention, and so, this level of control implies that it has no abuse potential. It just seems incongruent that the reasons cited to increase controls for cannabis preparations was concentrated THC, whereas 5mg/ml in concentrated form is indicated as an example of schedule III in the '61. Could WHO please explain?

**WHO response:** **Illicit preparations containing high delta-9-THC concentrations such as butane hash oil are administered by vapour inhalation after heating the product. In contrast, pharmaceutical products such as Syndros are administered orally. There is substantial evidence that orally administered delta-9-THC has very low abuse potential in comparison to delta-9-THC administered by inhalation. Hence, Syndros has very low abuse potential and there is also no evidence of significant diversion to illicit use, whereas butane hash oil is abused to a significant extent.**

- 2) The recommendation says that preparations containing Delta 9 THC produced either by chemical synthesis or as preparations of cannabis that are compounded as pharmaceutical preparations with one or more other ingredients and In such a way that Delta 9 THC cannot be recovered by readily available means, or in a yield which would constitute a risk to public health be added to Schedule III of the '61 Convention. If delta 9 THC is not included in the '61 Convention, is it possible to define a preparation in schedule III of the '61 Convention by its content of a substance that is not controlled by the '61? This goes back to the question if the recommendations to move dronabinol out of the '71 convention are not adopted, is it possible to define a preparation in schedule III by its dronabinol content?

**WHO response:** **If delta-9-THC is not added to the schedules of the 1961 Convention and deleted from the schedules of the 1971 Convention, then the Schedule III recommendations would still be relevant as they would cover the preparations of cannabis that satisfied the Schedule III criteria. The medication Sativex® would be an example of such a preparation.**

- 3) Based on the recommended definition of preparations to be placed in schedule III, it seems like we may be introducing a contradiction in terms of cannabidiol preparations. Preparations containing predominately cannabidiol and less than 0.2% THC could also be described as preparations that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that Delta 9 THC cannot be recovered by readily available means, so there seems to be a tension between these recommendations, where one would say that such a preparation with a low THC content but predominately CBD, would not be scheduled, and the other seems to say that it would be placed in Schedule III. Please provide some clarity.

**WHO response:** **Indeed, certain preparations containing predominantly CBD and less than 0.2% delta-9-THC could also be described as preparations that are**



	<p>compounded as pharmaceutical preparations with one or more other ingredients and in such a way that delta-9-THC cannot be recovered by readily available means. To the extent that this is the case, the ECDD considered that the proposed footnote addresses such preparations more specifically than the proposed entry for Schedule III and that such preparations should, therefore, be within the scope of the footnote rather than the scope of Schedule III preparations.</p>
<p>4) Would a preparation containing predominantly cannabidiol and not more than 0.2% of delta-9-tetrahydrocannabinol fall under this definition? If such a preparation can be equally described by both definitions, which recommendation takes precedence? What language of the 1961 Convention would lead to that result?</p>	
<p><b>WHO response:</b></p>	<p><b>Certain preparations containing predominantly CBD and less than 0.2% delta-9-THC could, indeed, also be described as preparations that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that delta-9-THC cannot be recovered by readily available means. To the extent that this is the case the ECDD considered that the proposed footnote addresses such preparations more specifically than the proposed entry for Schedule III and that such preparations should, therefore, be within the scope of the footnote rather than the scope of Schedule III – preparations.</b></p> <p><b>The Committee considered the option of including cannabidiol preparations in Schedule III of the 1961 Convention. However, that Schedule is for drugs that are controlled and that satisfy the criteria for control. Cannabidiol does not satisfy those criteria. Inclusion in Schedule III lessens the degree of international control, but a number of controls are still required. Inclusion of cannabidiol preparations in Schedule III would mean that controls would be required for preparations of a drug that did not satisfy the criteria for inclusion in the schedules of the 1961 Convention.</b></p> <p><b>The option of a footnote was adopted after recognition of the precedents of exclusion of dextromethorphan and dextrorphan from control by this means.</b></p>