Questions to WHO
in preparation of the 5th Intersessional Meeting
on 23 September 2019[1]
submitted by 19 August 2019

5.0 General Questions

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)?
	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)?
	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.
United States	1)	We have some mention of flexibility and the ECDD listening to the questions and the responses, and the concerns that member states

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

		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?
	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?

5.1 Cannabis and Cannabis Resin

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.
	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?
United States	1) 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.
	2) 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?
	3) Is there any reason the ECDD could not make a recommendation that differentiates between low THC concentration and high THC concentration cannabis resin?
	4) Is the ECDD aware of any therapeutic use of cannabis resin? Of butane hash oil?
	5) 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?

5.2 Delta-9-tetrahydrocannabinol (Dronabinol)

European Union	1) Does 'dronabinol' mean the active substance produced by chemical synthesis, for both medical and non-medical use?
	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? 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. • 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? • 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? • 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. • 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?
	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?
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.
	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 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.
	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?
	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?
	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?
	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 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?
	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?
	8)	What additional harms to health could potentially result if delta-9-THC continued being controlled under the 1971 Convention?
	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, AM-2201, and ADB-CHMINACA), which have pharmacological effects similar to delta-9-THC, to the 1961 Convention as well?

5.3 Tetrahydrocannabinol (isomers of THC)

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

5.4 Extracts and Tinctures of Cannabis

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?
	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.
Singapore	1)	In its report, the Committee recognised that 'extracts and tinctures' of cannabis include '*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.*' 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?
	2)	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. 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.

5.5 Cannabidiol Preparations

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

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?
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?
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.
	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?

	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?
	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."
	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?
	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?
	7) In lieu of a footnote, what other methods are available to clarify that preparations predominantly containing cannabidiol are not under international control?
	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?
	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?
	10) What does it mean to have a preparation that is predominantly cannabidiol? Is that measured by a certain percentage? A percentage of what?

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

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?
	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?
	3)	Why is the text that mentions abuse potential in the summary of product characteristics not considered relevant in making this recommendation?
	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.
	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?
Singapore	1)	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 Δ9-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?
	2)	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?
	3)	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?
	4)	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?
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?
	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?
	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 that 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.
	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?

5.7 Questions addressed to INCB

5.0 General questions	**United States**	1) We are trying to understand what all or some of the recommendations will mean for governments and for the INCB. What will be the practical impact of the recommendations for member states if all the recommendations are adopted, including on our relationships with the INCB and WH0? How will this change what we do now, and will we be undertaking any additional burdens? Does the INCB have the necessary resources to handles the significant influx of information the INCB will receive? How will the INCB use it?
		2) The INCB stated that the industrial uses are limited to fibers and seeds. The Convention does not expressly state a limitation. What is the basis for the INCB interpretation that the phrase "(fibres and seeds)" means exclusively fibers and seeds?
5.1 Cannabis and cannabis resin	**United States**	Cannabis and cannabis resin are currently scheduled under the '61 Convention. Does this also trigger the estimate and statistical system or does the fact that the plant is scheduled exclude the estimate system which is why it is now needed to move THC to the '61?
5.2 Delta-9-tetrahydrocannabinol (dronabinol)	**Singapore**	It was stated in INCB's comments that the endorsement of these 2 recommendations by the CND will result in a number of additional control measures required for States under the 1961 Convention. One of these requirements is that Member States will be required to submit estimates for these isomers. Can INCB elaborate on the other control measures which Member States will be required to implement in the event that recommendation 5.2 is accepted?
	United States	1) It was explained that a justification to move Delta 9 THC from the '71 Convention to the '61 Convention is that member states are encountering difficulties enforcing the convention arising from the scheduling of cannabis and THC under two separate conventions. Please give more information on the negative impact [of the current scheduling arrangement] on member states, and on the breadth of impact.
		2) This may be more of a philosophical question, but if the drafters of the 1971 Convention intended to put Delta 9 THC in the '71 Convention knowing that it was the active component of cannabis, and if the drafters of the '61 Convention did not include cannabis in the estimate system, if we amend the schedules with respect to THC are we not in effect amending the conventions but not using the amendment processes contained in those treaties?

		3) Are the current control measures placed on delta-9-THC under Schedule II of the 1971 Convention insufficient to deter abuse or illicit use?
		4) What specific new control measures does the 1961 Convention place on delta-9-THC that would decrease the extent or likelihood of abuse?
		5) Would any additional control measures placed on delta-9-THC as a result of controlling it under the 1961 Convention place any additional limits on the availability of preparations containing delta-9-THC for legitimate medical and scientific purposes?
		6) Currently, cannabis extracts that contain delta-9-THC are internationally controlled as preparations under Article 3 of the 1971 Convention. If the Commission were to accept the recommendation to move delta-9-THC from the 1971 Convention to the 1961 Convention, would some degree of controls over these preparations be lost?
5.4 Extracts and tinctures of cannabis	**United States**	Please explain the rationale to remove extracts and tinctures? Does the INCB get information from member states currently through the estimate system, and is it useful? If tinctures and extracts are removed, does the INCB lose anything? Please explain what is meant by "the category is no longer adequate."

5.8 Questions addressed to UNODC

5.0 General questions	**United States**	1) It would be very helpful for member states if the UNODC would produce an analysis of the recommendations on all rights and responsibilities in the three UN drug conventions. We note for example, that there is some tension between the '61 and '71 conventions on the treatment of traditional uses of cannabis. Under the '61 convention, such uses are to be discontinued 25 years after ratification, but the '71 convention provides no such limit. A number of countries permit traditional uses, but a shift of THC to the '61 convention would eliminate that use. It would be helpful to get UNODC to prepare a thorough impact assessment, including identification of the Legal issues that may arise if recommendations are adopted in whole or in part, and the potential impact on rights and responsibilities under the Conventions.
		2) When a recommendation relates to a substance not under international control, and the recommendation is that the substance should not be under international control, is it necessary to hold a vote on the recommendation?
5.1 Cannabis and cannabis resin	**United States**	1) What is meant by "cannabis resin" in the treaty? Does it refer to purified resinous substance such as butane hash oils and hashish, or to some other formulation of cannabis?
		2) Is it possible to separate the schedule entry for cannabis and cannabis resin and consider the recommendation as two separate recommendations, one for cannabis and one for cannabis resin?
		3) Does the recommendation to add certain pharmaceutical preparations of cannabis to Schedule III depend on this recommendation [*on cannabis and cannabis*] resin being enacted? In other words, is it possible to retain botanical cannabis in schedules IV and I while adding therapeutic preparations of cannabis to Schedule III?
5.2 Delta-9-tetrahydrocannabinol (dronabinol)	**Singapore**	Can the Secretariat go through the voting process regarding recommendations 5.2 and 5.3? For example, if 5.2 is rejected by the Commission by means of voting, will that obviate the need to vote in relation to 5.3, or can there be a situation whereby 5.2 is agreed to but not the 5.3?
	United States	What were the topics of discussion that led to delta-9-THC being placed in the 1971 Convention at the time that it was drafted? Since the drafters of the 1971 Convention knew that delta-9-THC was the main psychoactive component of cannabis, why did they not choose at that

		time to place it in the same Convention and Schedule as cannabis?
5.4 Extracts and tinctures of cannabis	**European Union**	Could the UNODC Division for Treaty Affairs give their view on the implications of recommendation 5.5. in relation to Article 28 of the 1961 Convention? During the intersessional meeting on 24 June, the WHO and the INCB expressed different views on what kind of cultivation falls outside the scope of this article. This requires clarity. Reference is also made to the question of leaves.
5.5 Cannabidiol preparations	**United States**	1) Is an active pharmaceutical ingredient which may contain trace impurities of a controlled substance considered a preparation of that controlled substance under the Conventions?
		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?
		3) In lieu of a footnote, what other methods are available to clarify that preparations predominantly containing cannabidiol are not under international control?
		4) 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?
		5) How can the Commission clarify that a preparation that predominantly contains a non-controlled substance, but may also contain trace amounts of a controlled substance, when compounded in such a way that it presents no, or negligible risk of abuse and the controlled substance therein cannot be recovered by readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health and social problem, is not subject to international control?