



## Questions and answers relating to WHO's recommendations on cannabis and cannabis-related substances

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## 5.0 General Questions

a) Written answers circulated on 2 July 2019

<b>China</b>	1) The research on the use of cannabis and cannabis plant in the fields of medicine and food, and the research outcomes, according to WHO. Elaboration on the evidence that benefits of research and utilization of preparations of cannabis are greater than risks.
	2) How to research and develop CBD while reasonably control the amount of delta-9-THC in the preparations, given that CBD and delta-9-THC exist concurrently in cannabis plant
<b>European Union</b>	1) How do these recommendations link with the warning issued by the International Narcotics Control Board, at the occasion of the launch of its Annual Report 2018, of the dangers of non-medical cannabis developments?
	2) How will the implementation of these recommendations affect cannabis-related products, for example CBD-products, on the market?
	3) Would you think it might be helpful to have a Glossary which lists and explains more clearly and separate the cannabis related terms due to the medical use or non-medical use (illicit use)?
	4) A lack of clarity was identified in relation to the following aspects related to the WHO recommendations on cannabis and cannabis-related substances: <ul style="list-style-type: none"> <li>- the impact on food products: the current legislation, both at international and at national, does not allow the presence of THC in food products, including the sorts that are considered technical and for food production for example seeds, seed oil, leaves, etc. The legislation requires zero presence of THC, however in practice this is not feasible and small amount of THC is present in these products. For this reason, in some European Union countries national THC limits in food exist, whereas in some others do not consider the national limit as it would violate international conventions.</li> <li>- the impact on the use of CBD in food, having in mind that there is a high interest of producers in adding CBD to foods. It is to be noted that deliberate addition of CBD to food is considered a novel food.</li> </ul>
	5) Member States should be able to form their own opinion on the relevant information regarding the process and the content of the WHO recommendations. This information should be easily accessible and understandable also by those who are not scientists or legal experts. For example, this information concerns: voting procedures: for example, it should be clear that it does not just concern one vote but 6 votes on the 6 recommendations; scheduling and the related control measures; relevant background information on the recommendations: - It is not very clear where to find the right information on the WHO - ECDD website. The full report and peer reviews, or references to where to find them on the website could also be actively distributed.
	6) Since cannabis and cannabis-related substances are not included only within the schedules but also within the Conventions themselves, the relationship between the re-scheduling recommendations and the articles in the Conventions should be clear. For example: how does the recommendation on cannabidiol preparations relate to article 28.2 of the 61 Convention? (In many countries CBD is produced from the flowering tops of industrial hemp.)
<b>Turkey</b>	1) Any studies by the WHO about the laboratories where genetically modified cannabis plants with higher levels of THC are cultivated.
	2) What are the possible and existing methods to cultivate cannabis with THC ratios over 0,2-0,3 %?

## Answer by WHO

Cannabis has never been subject to a formal review by the WHO Expert Committee on Drug Dependence (ECDD) since its original placement within the International Drug Control Conventions. However, CND Resolutions 52/5 requested WHO to provide an updated report on cannabis (subject to the availability of extrabudgetary resources). CND Resolution 50/2 also requested WHO, in consultation with INCB, as appropriate, to undertake a review of dronabinol and its stereoisomers when additional information became available. In Addition, a number of countries have asked WHO to collect and analyse scientific evidence on harms and therapeutic use, due to the fact that some countries are currently exploring the feasibility of regulated access to cannabis and cannabis preparations for medical use.

In recent years, more robust scientific research has been conducted into the harms and therapeutic applications of cannabis and cannabis preparations. Importantly, since the adoption of the Single Convention on Narcotic Drugs, scientific research has clearly identified delta-9-THC to be the main psychoactive compound of cannabis. In the Last few years, the WHO ECDD considered the amount of new evidence to be sufficient to carry out a formal review, to ensure a coherent and relevant level of international control that adequately considers current information about the harms and therapeutic uses of cannabis. This provided the basis of the ECDD review of cannabis.

The ECDD's recommendations seek to prevent the harms caused by the use of cannabis and cannabis preparations and ensure that they are available when and where they are needed for medical and scientific purposes.

In the context of the historical precedence of cannabis' original placement within the Conventions, of the development of new illicit cannabis preparations, and the new cannabis-related medicines entering into the market, the review of cannabis and cannabis-related substances was complex.

Because of the complexity of these reviews, WHO recognizes the importance of communicating the rationale for the ECDD recommendation in a language that is well understood by experts, policymakers and other interested parties in countries. WHO will continue to engage in dialogue with these groups, within forums such as the CND intersessional as well as through bilateral meetings if requested.

WHO will also continue to work in close collaboration with Member States and other UN agencies such as UNODC and INCB to address the questions, concerns, and comments expressed by countries with regards to the scope of WHO's recommendations. For instance, WHO has received several questions regarding the production of cannabis, its industrial uses as hemp, and its use in food products. While these are important matters for Member States and the International community to consider, these issues are not within the mandate of the ECDD. WHO is prepared to address these issues in other forums involving other relevant UN agencies and interested parties.

WHO acknowledges the challenges faced by countries in enforcing balanced control policies that protect people from the harm arising from misuse of cannabis and ensure access to cannabis-based preparations for medical use for people who need them. WHO is aware of the public-health and social challenges caused by the misuse of cannabis, as has been highlighted by INCB in its 2018 report. WHO is committed to work closely with Member States and other UN agencies such as UNODC and INCB to ensure a smooth and efficient implementation of the recommendations, provided they are endorsed by CND.

### b) Written answers circulated on 30 July 2019

<b>Canada</b>	In addition to our written questions which had been submitted in advance, we also asked what complementary or supplementary considerations the WHO's guidance on the WHO review of psychoactive substances under international control had added to the ECDD's consideration of the criteria stipulated in the Conventions, in developing its recommendations regarding cannabis?
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## Answer by WHO

The *Guidance on the Who review for psychoactive substances for international control* was approved by WHO's Executive Board in January 2010. The Guidance sets out guidelines establishing the underlying principles of the review procedure, working arrangements within the Secretariat and with external bodies, and the nature of the documentation to be prepared in relation to the ECDD process. The guidelines cover WHO's responsibilities under Article 3 of the 1961 Convention and Article 2 of the 1971 Convention concerning whether or not to recommend international control of substances, as well as the assessment of exempted preparations under Article 3 of the 1971 Convention.

As per the Guidance, WHO performed its review of cannabis and related substances by carrying out a two-stage process to first determine, through a so-called pre-review, whether there was adequate information about cannabis and cannabis-related substances to justify a so-called critical review, before arriving at its recommendations through this critical review process. The Guidance explains that the Expert Committee shall recommend a critical review if it finds that information may justify the scheduling or a change in the scheduling of the substance.

The set template for the review of psychoactive substances included in the Guidance, ensures that the same assessment criteria are applied to all substances that are under review, to comply with the Conventions.

The review process ensures that the recommendations are based on scientific and public health principles, and that assessments made by the Expert Committee are based on robust evidence primarily about the harms, dependence potential, and abuse potential of substances whilst also ensuring that therapeutic and scientific uses are considered so as not to restrict access to substances in this regard.

The Guidance ensures that WHO systematically collects data and additional information from Member States and other interested parties, and that ECDD documentation is available on the WHO website for the sake of transparency and commentary.

The *Guidance* is available on the WHO website.

<b>Mexico</b>	1) Do the medical and scientific communities have the same tools now that they had when the Single Convention and the other two Conventions were crafted?
	2) Does the knowledge about the different components of Cannabis is the same in 2019 than 50, 60 or more years ago?
	3) Is there now a better understanding by the scientific and medical communities both of the different components of Cannabis, well beyond the differentiation captured in the Single Convention, as well as the differences of their characteristics and properties?

## Answer by WHO

There has been a vast change in our understanding of cannabis since the establishment of the 1961 Single Convention. At that time, there was little understanding of the hundreds of compounds present in cannabis, and it was not known which compounds had psychoactive properties and which did not. There was also little research that investigated the medical uses of cannabis. Furthermore, when the Conventions were established, cannabis resin was the only known preparation that was derived from cannabis.

Since the establishment of the Conventions, there have been a number of developments that increased our scientific understanding of cannabis and its components and enabled us to better understand their respective harms and therapeutic applications. For example, whilst cannabis resin was the only known preparation of cannabis at the time it entered into the Conventions, we now recognize that there are a range of preparations that could be derived from cannabis, and that these could have varying strengths and levels of psychoactivity. In addition, delta-9-THC has been recognized as the main active constituent of cannabis while compounds such as

cannabidiol have been shown not to have psychoactive effects. There has been increasing research on the medical use of cannabis, and there is also more research into non-medical preparations.

<b>Mexico</b>	4) Could you confirm if the “single species concept” was still widely accepted by the time of the drafting of the Single Convention?
	5) Could you confirm if the original concept of Cannabis as a “single species” has finally been fully overcome? Should it be not the case, could you elaborate in which circles is this outdated notion still en vogue?
	6) Is there a different perception regarding the Poppy plant and seeds versus opium and heroin, or the Coca plant and leaves versus cocaine than there is between Cannabis as a plant and as a narcotic drug? Did this difference prevail in the Single Convention? If so, what were the reasons?

### Answer by WHO

The history of the taxonomy of cannabis dates back several hundred years and is complex. At the time of drafting of the Single Convention, cannabis was widely regarded as a single species with two or more sub-species. It is currently considered as monospecific (*Cannabis sativa* L.) with two subspecies (*Cannabis sativa* L. subsp. *sativa*, and *cannabis sativa* L. subsp. *indica*) and four varieties.

*Cannabis sativa* subsp. *Sativa* is a plant of limited intoxicant ability,  $\Delta$ 9-THC usually comprising less than 0.3% (dry weight) of upper third of flowering plants (sometimes up to 1%) and usually less than half of cannabinoids of resin. This plant is cultivated for fibre or oil or growing wild in regions where such cultivation has occurred.

*Cannabis sativa* subsp. *indica* (Lam.) is a plant of considerable intoxicant ability,  $\Delta$ 9-THC usually comprising more than 1% (dry weight) of upper third of flowering plants and frequently more than half of cannabinoids of resin. This plant is cultivated for intoxicant properties or growing wild in regions where such cultivation has occurred.

Morphine and cocaine as active principles of opium poppy and coca leaf are in the same convention and the same schedule (1961, Schedule I) as opium poppy and coca leaf respectively. Meanwhile, cannabis plant is in the 1961 Convention and  $\Delta$ 9-THC, the active principle of cannabis, is in the 1971 Convention. This can be explained by the fact that  $\Delta$ 9-THC was unknown when the 1961 Convention was established.

<b>Jamaica</b>	1) What are plans of the UNODC, in particularly the INCB, as regards assisting Member States in the application/implementation of the recommendations in the event they are successfully adopted.
	2) What is the timeline for which the proposed recommendations will be placed before the CND for a decision.

### Answer by UNODC

UNODC is ready to support Member States, upon request and availability of resources, in the implementation of the international drug control conventions and of decisions and resolutions by the Commission on Narcotic Drugs. After decisions on scheduling have been made by the Commission, and if Member States are of the view that they require assistance in implementing them, UNODC would be in a position to assess needs in order to plan and provide the required technical assistance.

c) Written answers circulated on 4 October 2019

<b>European Union</b>	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)?

**Answer by WHO**

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>European Union</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)?
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**Answer by WHO**

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.

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>European Union</b>	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.
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**Answer by WHO**

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.

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.

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>United States</b>	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?
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### Answer by WHO

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.

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>United States</b>	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?
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### Answer by WHO

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.

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.

<b>United States</b>	3) 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
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	may arise if recommendations are adopted in whole or in part, and the potential impact on rights and responsibilities under the Conventions.
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### Answer by UNODC

UNODC would not be able to reply in a most comprehensive manner to the proposal for an analysis of all rights and responsibilities of Parties under each treaty, or to purport to evaluate the impact at the national level of each of the recommendations, should they be adopted by the Commission. We observe that the impact of re-scheduling substances would likely differ from country to country, depending on the domestic implementation measures already in place, so each Party would be best positioned to conduct such an evaluation.

That said, the 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances contain several similar or closely drafted provisions on different activities, sometimes with more or less subtle distinctions. We understand that reference to some examples of potential differences in handling substances, if moved from a schedule of one Convention to a schedule of another Convention, might be of assistance. For example:

- The 1961 Convention has a stricter system of periodic returns of estimates of requirements for narcotic drugs – Parties are required to annually provide that information to the INCB, under the 1961 Convention. So called voluntary “assessments of annual medical and scientific requirements” are asked by the INCB to Parties to the 1971 Convention at least once every three years, on the basis of resolutions of the ECOSOC that invite Governments to communicate from time to time their assessments of medical and scientific requirements of psychotropic substances.
- Limitation of stocks is foreseen in more detail for all narcotic drugs under the 1961 Convention (article 30(2)(a) of the 1961 Convention), whereas the 1971 Convention contains only a broad reference to limitation of stocks (“by such measures as it considers appropriate”) in its article 5(2), applicable to Schedules II, III and IV.
- Equally, the 1961 Convention addresses limitation of manufacture and importation in its article 29(2)(c), with reference to periodical permits required from licensed manufacturers, which is not a measure foreseen in the 1971 Convention.

For a list of examples of control measures applicable to the different treaties, with reference to the provisions dealing with the similar measures, see Annexes 1 and 2. We also refer to the response by the INCB, which has identified further important distinctions between the control measures for each treaty.

With regard to the reference in the question relating to treatment of traditional uses, we are of the view that the example on how the 1961 and the 1971 Conventions may address traditional uses of cannabis, although illustrating a different perspective of each treaty to a similar issue, may be of limited relevance to the current discussion.

The 1961 Convention allowed for transitional reservations, for up to 25 years after entry into force of the treaty, including for cannabis and cannabis resin for non-medical purposes under art. 49(1)(d), in the context of being traditional and previously permitted. This transitional reservation was utilized by some countries, but the timeframe of such reservations has already expired.

The 1971 Convention offers the possibility, upon signature, ratification or accession, of reservations by States on whose territory there are plants growing wild which contain psychotropic substances (...) which are traditionally used by certain small, clearly determined groups in magical or religious rites (art. 32, paragraph 4, 1971 Convention). The possibility of reservations for traditional uses, allowed under the 1971 Convention, has not been specifically claimed by any country for THC. Therefore, a move of THC to the 1961 Convention would in principle not affect the enjoyment of such an option under the 1971 Convention.

d) Written answers circulated on 21 October 2019

<b>United States</b>	1) 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 WHO?
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### Answer by INCB

The recommendations of the ECDD if endorsed by the CND will have implications for the daily work of the INCB and of the competent national authorities in each country.

In some cases, there will be more clarity in relation to reporting (5.2. and 5.3 move to 1961 and deletion from 1971 of dronabinol and Tetrahydrocannabinol (isomers of delta-9-tetrahydrocannabinol). Endorsement of the recommendations by the CND will result in some changes in the control of these drugs. Instead of assessments which are required for drugs in Schedules II, III and IV of the 1971 Convention, pursuant some ECOSOC resolutions, Governments will need to submit estimates, pursuant to article 19 of the 1961 Convention.

Recommendation 5.1 (deletion of cannabis and cannabis resin from schedule IV) will not have impact on the control measures already applied because the two substances will remain in schedule I of the 1961 convention.

The deletion of extract and tinctures (5.4) may be problematic for the monitoring of other cannabinoids that are not explicitly scheduled. The secretariat notes that the lack of a definition of extracts and tinctures has not facilitated control over these substances. However, this broad category if retained 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. This, however, would require a clearer and unequivocal operational definition of this category to be agreed upon by Member States to avoid differences in the understanding of the drugs under control.

Recommendation 5.5 on cannabidiol preparations. The main question in regard to this recommendation relates to its practical implementation at the national level. In most countries, chemical analysis down to the required threshold will not be possible because of lack of access to appropriate identification techniques. In those countries where chemical analysis to the required accuracy of 0.2 per cent of THC is possible, it might not be feasible, or considered not to be a good use of resources and may not be employed. In addition, this recommendation will also give rise to an important question on the control of cannabis that is being cultivated for the extraction of CBD to be used for the mentioned CBD preparations.

It is not clear to which preparations recommendation 5.6. would apply. The term "compounded pharmaceutical preparations" is applicable to a large number of preparations. It is not defined what "readily available means". The convention states that if the drug in the preparations "is not readily recoverable", the Commission may, in accordance with the recommendation of the World Health Organization, add that preparation to Schedule III. If this recommendation is endorsed by the Commission on Narcotic Drugs, the inclusion of these preparations in Schedule III will eliminate the need for some controls, such as those applicable to the international trade of these preparations but not for the controlled substance contained in the preparations (delta-9-THC). Manufacture of delta-9-THC will need to be monitored and Governments will have to report statistics on its utilization for Schedule III preparation.

<b>United States</b>	2) How will this change what we do now, and will we be undertaking any additional burdens?
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### Answer by INCB

With cannabis, cannabis resin, THC and other components all listed in one Convention, instead of two, monitoring and reporting of these drugs might actually be easier as only one control system, namely that of the 1961 Convention, will apply, eliminating a possible source of confusion and misunderstanding of whether a particular component of cannabis will be under one or the other Convention. This may lead to more clarity in reporting and facilitate international transactions among Governments. As regards the INCB and its secretariat, the emergence and continuous increase of the cultivation of cannabis for medical purposes, has placed additional burden on the secretariat as there is an increasing need to provide advice on the treaty provisions to new producers of cannabis and review data estimates and statistics submitted by Governments.

<b>United States</b>	3) Does the INCB have the necessary resources to handles the significant influx of information the INCB will receive?
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#### **Answer by INCB**

The limited resources of the INCB and its secretariat have been strained by the need to monitor at the global level the cultivation, manufacturing, trade and consumption of cannabis and cannabis-derivatives, leading to problems in terms of timely and effective processing of the governments' requests. The Secretariat believes that it will need more regular budget resources to effectively perform the functions mandated by the conventions. This would be true especially in the first years after the approval of the recommendations. There would be the need for the Board and governments to make some changes in their respective operations including the implementation of new legislation. In future, if the cultivation of cannabis for medical and scientific purposes will continue to grow there will continue to be the need for effective monitoring at global level.

At country level Parties permitting the cultivation of the cannabis plant for the production of cannabis or cannabis resin, are required to apply to such cultivation the system of controls as provided in article 23. This includes the establishment of an agency responsible for designating areas and issuing licences for cultivation, purchasing and taking physical possession of such crops as soon as possible, as well as having the exclusive right of importing, exporting and whole sale trading and maintaining stocks other than those held by manufacturers. INCB has the obligation to monitor these provisions

<b>United States</b>	4) How will the INCB use it?
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#### **Answer by INCB**

The information will be used to monitor the global cultivation, manufacture, trade and consumption as it is the case for all controlled substances as well as to ensure a balance between supply and demand of cannabis raw material and cannabis derivatives to ensure availability for medical and scientific purposes but also to avoid, as prescribed by the conventions, the accumulation of quantities in excess of those required for the normal conduct of business, having regard the prevailing market conditions.

<b>United States</b>	5) 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?
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#### **Answer by INCB**

The international drug control conventions do not establish a threshold of cannabinoids, under which the cannabis plant could not be considered to be under international control. The purposes of cultivation of the cannabis plant remain relevant for the determination of applicable measures.

The Board has stated in its 2018 report that the 1961 Convention limits the cultivation of cannabis for industrial purposes to fibre and seed. The cultivation of the cannabis plant for industrial purposes other than those explicitly indicated in article 28, paragraph 2, should not be considered licit.

The adoption of a practical threshold related to capability of detection or liability to abuse may be considered as a possible method through which a State party could differentiate cannabis plant cultivated for purposes of the production of cannabis or cannabis resin, from other purposes, as long as this method is used in line with the objectives of the 1961 Convention, including to prevent the misuse of and illicit trafficking of cannabis. However, the extraction of the cannabinoids from the plant would require the use not only of the leaves but of the whole plant including the flowering top (under control as cannabis) that may contain small percentages of THC that in the plant itself may not be considered suitable for abuse but in the process of extraction of the cannabinoids may result in significant quantities becoming available.

e) Written answers circulated on 26 November 2019

<b>China</b>	1) Under the impact of recreational cannabis legalization on global drug control, is the current global situation of adolescents using cannabis under control? How can we effectively prevent teenagers from using drugs, especially cannabis? What are the WHO and INCB positions and recommendations?
	2) How do WHO and INCB determine that rescheduling Cannabis in the international drug control conventions could reduce cannabis abuse? Is there any research and evidence to prove its effectiveness?
	3) As in some of those countries with recreational cannabis legalization, the number of adolescents who abuse cannabis or synthetic cannabis has not decreased, and cannabis price in the illegal market being lower than the legal one in some of those countries. For this situation, what opinion and countermeasures do WHO and INCB have?
	4) For medical use of cannabis in some countries, due to poor management, some has flowed into the illegal drug market. Does it reflect that legal regulation cannot guarantee the effective management and operation of the market? Then, should the management be formulated for contracting countries to apply and comply before rescheduling Cannabis in the international drug control conventions?
	5) In response to the recreational cannabis legalization in some countries, a large number of cannabis products, such as candy, cakes, etc., contain high level of THC than cannabis. How would WHO and INCB respond to the possible health problems and medical burden caused by the addiction?

**Answer by WHO**

Although important, these questions do not fall within the mandate of the Expert Committee on Drug Dependence (ECDD) as defined within the Conventions. It could be worth considering having these discussions in a different forum.

Cannabis is a scheduled substance under the 1961 Convention. The scheduling system within the International drug control conventions is meant to prevent abuse, dependence and harm to health caused by psychoactive substances such as cannabis, including in youth populations.

## Answer by INCB

### Question 1 and 3

The Board devoted Chapter I of its 2018 Annual Report to this matter:

“Cannabis and cannabinoids for medical, scientific and “recreational” use: risks and benefits”

[https://www.incb.org/documents/Publications/AnnualReports/AR2018/Annual\\_Report\\_Chapters/03\\_Chapter\\_I\\_Annual\\_Report\\_2018\\_E.pdf](https://www.incb.org/documents/Publications/AnnualReports/AR2018/Annual_Report_Chapters/03_Chapter_I_Annual_Report_2018_E.pdf)

### Question 2

The Board has no role in the scheduling process and therefore cannot address this question.

### Question 5

The Board has no authority or resources to respond to the health consequences of a possible increase in cannabis use. The Board will continue to remind countries that Article 38 of the Single Convention of 1961 underscores the importance of measures to prevent and treat drug dependence. This article, as amended by the 1972 Protocol, and Article 20 of the Convention on Psychotropic Substances of 1971 states that “The Parties shall give special attention to and take all practicable measures for the prevention of abuse of drugs and for the early identification, treatment, education, after-care, rehabilitation and social reintegration of the persons involved and shall co-ordinate their efforts to these ends.” Further, the conventions also state that “Parties shall as far as possible promote the training of personnel in the treatment, after-care, rehabilitation and social reintegration of abusers of psychotropic substances” as well as “assist persons whose work so requires to gain an understanding of the problems of abuse of drugs”.

<b>Japan</b>	We appreciate that the WHO recommendation is aimed at rationalization of regulations concerning THC's regardless of their origin (natural material or chemical composition). In this context, how should synthetic cannabinoids, which are currently placed in Schedule II of 1971 convention (e.g. ADB-FUBINACA, FUB-AMB, etc.), be regulated under the conventions?
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## Answer by WHO

With regard to synthetic cannabinoids, the Committee considered the issue of whether it will also 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 recommendations regarding the transfer of dronabinol are 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.

<b>Nigeria</b>	1) How would the recommendation and the alleged therapeutic use of cannabis outweigh the ill effects associated with its consumption which poses serious threat to public health?
	2) Do we have scientific evidence on the consequences of the therapeutic use of cannabis?

### Answer by WHO

There is evidence from a large number of clinical trials on the therapeutic effectiveness and use of cannabis preparations. In this regard, a number of cannabis-based medicines have been granted marketing authorisations in a number of countries including for the management of muscle spasticity in multiple sclerosis and for the treatment of epilepsy. Some of this is summarised in the critical reviews prepared for the 41st ECDD meeting and available on the WHO website: [https://www.who.int/medicines/access/controlled-substances/ecdd\\_41\\_meeting/en/](https://www.who.int/medicines/access/controlled-substances/ecdd_41_meeting/en/).

Another source of such information can be found in the US National Academy of Science review “The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research”.

<b>Nigeria</b>	3) Is the WHO worried about the implication of any negative perception to cannabis rescheduling in view of the persistent increase in its abuse?
	4) If the recommendation is considered a minimum requirement for member states as alleged by WHO, what is the use of it when the impact and abuse remain global?

### Answer by WHO

The issues raised in the questions do not fall within the mandate of the ECDD as defined within the Conventions. The ECDD recommendations are informed by thorough review of scientific evidence and are formulated as clearly as possible and on the basis of scientific facts. The ECDD is only able to use the criteria as set out in the Conventions and cannot include for consideration other more general matters.

<b>Nigeria</b>	5) If the basis of the WHO’s decision was to ensure availability, is the recommendation the only means of addressing the challenge in view of the persistent increase on abuse under the current control regime?
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### Answer by WHO

It is assumed this question refers to the availability of preparations proposed to be controlled under Schedule III of the 1961 Convention. In reaching its recommendation, the Committee applied the criteria for control of preparations under Schedule III as set out in Article 3 para 4 of the 1961 Convention. The availability of a medicine is not part of the criteria that should be used to determine the suitability of a preparation for inclusion in Schedule III and was therefore not considered by the Committee.

<b>Nigeria</b>	6) Against the backdrop of perceived lack of clarity and ambiguity in the recommendation, would the WHO consider withdrawing the recommendations for further review based on better scientific evidence, clearer vision, and proper assessment of the implications?
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### Answer by WHO

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.

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>Nigeria</b>	7) What will the INCB do differently that will improve its efficiency in fulfilling its mandate under the drug control Conventions?
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#### **Answer by INCB**

The INCB will need to monitor the global cultivation, manufacture, trade and consumption as it is the case for all controlled substances. The INCB will also have to ensure a balance between supply of and demand for cannabis raw material and cannabis derivatives to ensure availability for medical and scientific purposes but also to avoid, as prescribed by the conventions, the accumulation of quantities in excess of those required for the normal conduct of business, having regard the prevailing market conditions.

<b>Nigeria</b>	8) Is the INCB worried that WHO made the recommendation despite the INCB 2018 Report stating that cannabis is not the first line of treatment and could be replaced by other non-psychoactive substances?
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#### **Answer by INCB**

In Chapter I of its 2018 Annual Report the Board stated that recent reviews of the evidence from clinical trials indicate that: (a) there is weak evidence that dronabinol may be useful in treating nausea and vomiting in cancer patients; (b) there is moderate evidence that nabiximols may be useful in treating neuropathic pain and muscle spasticity in patients with multiple sclerosis; and (c) there is moderate evidence that CBD may reduce seizure frequency in some genetic intractable childhood epilepsy syndromes. Cannabinoids are not a first-line treatment for any of those conditions. The INCB has urged in the past all Governments that have established programmes for the use of cannabis for medical purposes to ensure that the prescription of cannabis for medical use is performed with competent medical knowledge and supervision and that prescription practice is based on available scientific evidence and consideration of potential side effects. There is a large variety of cannabis-based preparations in various regions of the world, with different dosage forms, concentrations of psychoactive ingredients, for the alleviation of a wide range of symptoms, using different routes of administration. If the symptoms of certain clinical conditions may be relieved by treatment with cannabis derivatives, it is important for countries to carefully establish the therapeutic value of such treatment through the collection of concrete evidence, and to clearly establish the active principles and the dosages to be used.

<b>Nigeria</b>	9) If the INCB has faced serious challenges of persistent abuse of cannabis under the current control regime, is there any guarantee that the recommendation will not further aggravate the bad situation?
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#### **Answer by INCB**

We refer again to the Chapter I of its 2018 Annual Report.

“Cannabis and cannabinoids for medical, scientific and “recreational” use: risks and benefits”

[https://www.incb.org/documents/Publications/AnnualReports/AR2018/Annual\\_Report\\_Chapters/03\\_Chapter\\_I\\_Annual\\_Report\\_2018\\_E\\_.pdf](https://www.incb.org/documents/Publications/AnnualReports/AR2018/Annual_Report_Chapters/03_Chapter_I_Annual_Report_2018_E_.pdf)

<b>Pakistan</b>	What is the scientific evidence to prove that benefits of research and utilization of preparations of cannabis are greater than its risks?
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### Answer by WHO

The issue of available scientific evidence concerning the therapeutic use of cannabis preparations has been addressed above. The ECDD is only able to use the criteria as set out in the Conventions and cannot include for consideration other more general matters such as the outcome of a risk benefit analysis of research and use of cannabis preparations.

<b>Russian Federation</b>	1) Is there anything unique in cannabis and its preparations that another drugs can't do for treating conditions like pain, epilepsy, spasticity, nausea/vomiting, etc.?
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### Answer by WHO

For a number of conditions, there is now evidence that cannabis preparations have therapeutic advantages not possessed by other substances. This is also being recognised by national regulatory authorities in a number of countries (currently more than 30 countries) that have approved cannabis-based medicines for the management of muscle spasticity and the treatment resistant epilepsy. Such approvals normally requires the demonstration of therapeutic advantage.

<b>Russian Federation</b>	2) Cannabis is one of the most commonly abused drugs in the world and has some other negative effects (adverse events). In terms of risk/benefit ratio, is there any evidence based fundamental advantages of cannabis and its preparations over the other drugs already approved to treat conditions I mentioned in the Question 1 ?
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### Answer by WHO

There is evidence that cannabis preparations have advantages for some medical conditions that are not provided by other existing medications. These have been extensively documented in numerous publications that cannot be reviewed in the space available here. However, reference can be made to analyses such as the one from the US National Academy of Science review "The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research" made the following conclusions (p.128):

There is conclusive or substantial evidence that cannabis or cannabinoids are effective:

- For the treatment of chronic pain in adults (cannabis)
- As antiemetics in the treatment of chemotherapy-induced nausea and vomiting (oral cannabinoids)
- For improving patient-reported multiple sclerosis spasticity symptoms (oral cannabinoids)

There is moderate evidence that cannabis or cannabinoids are effective for:

- Improving short-term sleep outcomes in individuals with sleep disturbance associated with obstructive sleep apnea syndrome, fibromyalgia, chronic pain, and multiple sclerosis (cannabinoids, primarily nabiximols).



They also documented conditions for which cannabis preparations were not effective or for which there was insufficient evidence. The research supporting these conclusions is extensively described and analysed in that publication.

A risk benefit analysis for cannabis goes beyond the mandate of the Expert Committee on Drug Dependence (ECDD) as defined within the Conventions. The ECDD is only able to use the criteria as set out in the Conventions.

<b>Russian Federation</b>	<p>3) How does the current international control regime of cannabis and cannabis resin impede access to them for scientific research and production of various medical preparations? How do the WHO arguments correlate with the fact that since early 2000s the global market for medical cannabis has considerably grown and continues to expand? Today dozens of pharmaceutical companies worldwide conduct clinical research, cultivate and import raw cannabis and increase the manufacture of cannabis-based medical products.</p> <p>Nothing in the conventions seem to prevent them from expanding from these legitimate activities.</p>
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### Answer by WHO

In its recommendations, the Committee made an observation about the impact on research of scheduling, but this was not critical to any of the decisions made. In particular, the decision to recommend deletion of Cannabis and Cannabis Resin from Schedule IV was based both on the level of liability to abuse and to produce ill effects of cannabis and preparations of cannabis and the therapeutic value of cannabis preparations, while recognising the characteristics of substances currently included in Schedule IV.

Reference can be made to analyses such as the one from the US National Academy of Science review “The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research” that addresses the Challenges and Barriers for Conducting Cannabis Research, p.377 to p.394.

<b>Russian Federation</b>	<p>4) For the past decades ECDD has repeatedly reviewed the impact of cannabis on public health. Every time it had arrived at the conclusion that the available scientific data is insufficient to justify any change in the international control of this narcotic drug. What kind of new clinical research triggered WHO to suddenly change its position? Could the WHO provide the list of such publications? Has the WHO carried out comprehensive research on medical use of cannabis as well as its side effects?</p>
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### Answer by WHO

Cannabis has never been subject to a formal review by the WHO Expert Committee on Drug Dependence (ECDD) since its original placement within the International Drug Control Conventions. The reasons for the review have been previously explained. For example, in the report of the 41st ECDD meeting it was noted:

In response to CND Resolution 52/5 (2009), which requested an updated report on cannabis from WHO (subject to the availability of extrabudgetary resources) and to CND Resolution 50/2 requesting WHO, in consultation with INCB, as appropriate, to undertake a review of dronabinol and its stereoisomers when additional information became available, and recognizing that a formal review of the scheduling of cannabis had not previously been carried out by the ECDD, WHO undertook to review the scheduling of cannabis and cannabis-related substances.

A review of the medical use of cannabis and cannabis preparations was included in the review process that informed the ECDD deliberations. Information on this review can be found in the critical review reports for the 41st

ECDD meeting available at the following link: [https://www.who.int/medicines/access/controlled-substances/ecdd\\_41\\_meeting/en/](https://www.who.int/medicines/access/controlled-substances/ecdd_41_meeting/en/)

## 5.1 Cannabis and Cannabis Resin

**Recommendation 5.1:** The Committee recommended that cannabis and cannabis resin be deleted from Schedule IV of the 1961 Convention.

a) Written answers circulated on 2 July 2019

<b>Canada</b>	<p>The Committee recommended maintaining cannabis and cannabis resin in Schedule I of the Single Convention on Narcotic Drugs on the grounds of “high rates of public health problems arising from cannabis use and the global extent of such problems”. Canada notes that the test, set out in article 3 of the Single Convention, to determine whether substance should be controlled under Schedule I or II, is based on the similarity principle. Article 3, paragraph 3(iii) requires the committee to assess whether a substance is liable to similar abuse or dependence as other substances in schedule I or II, and whether a substance is productive of similar ill effects as substances in schedule I or II.</p> <p>In light of the requirements set out in the Single Convention, could the committee provide clarity on the criteria it relied on to reach its recommendations for Schedule I?</p> <p>More specifically:</p> <ol style="list-style-type: none"> <li>1) Recognizing that this is not an element of the criteria, Canada would nonetheless appreciate insight into the ECDD’s assessment of the public health problems associated with cannabis, including how they compare with other scheduled substances (e.g. cocaine, fentanyl, heroin and morphine) and non-scheduled substances (e.g. alcohol and tobacco)?</li> <li>2) How does the committee reconcile its recommendation to maintain cannabis under Schedule I with the fact that the committee “did not consider that cannabis is associated with the same level of risk to health of most of the other drugs that have been placed in Schedule I”?</li> <li>3) Does the committee consider that cannabis is liable to similar abuse or dependence and productive of similar ill effects as other substances in Schedule II?</li> </ol>
<b>China</b>	<ol style="list-style-type: none"> <li>1) The considerations for first including cannabis and cannabis resin in Schedule IV of the 1961 Convention and whether such considerations are considered not valid nowadays</li> <li>2) Elaborate the evidence which has indicated that cannabis plant and cannabis resin are not particularly liable to produce ill-effects similar to the effects of the other substances in Schedule IV, and the factors that have been taken into consideration in reaching that conclusion</li> <li>3) The criteria, and the relative weight that should be given to such criteria, for removing drugs from Schedule IV, noting that WHO also recognises the public health problems arising from cannabis use and the global extent of such problems. Whether the removal of cannabis from Schedule IV would increase the negative effects caused by legalization of cannabis, given that the harms of legalization of cannabis in some regions and countries have been proved.</li> </ol>
<b>European Union</b>	<ol style="list-style-type: none"> <li>1) In reference to the statement that “...the evidence presented to Committee did not indicate that cannabis plant and cannabis resin were particularly liable to produce ill-effects similar to the effects of the other substances in Schedule IV of the 1961 Single Convention on Narcotic Drugs...”, <ul style="list-style-type: none"> <li>- could the WHO show and explain the evidence presented to the Committee?</li> <li>- could the WHO indicate how many studies and which analyzes have been taken into consideration?</li> <li>- Have studies about adverse events probably derived from cannabis consumption, mainly among young people been assessed?</li> </ul> </li> </ol>

	2) Could the WHO elaborate on why cannabis remains in schedule I and it was not recommended to be moved to schedule II?
<b>Russian Federation</b>	1) How does the current international control regime of cannabis and cannabis resin impede access to them for scientific research and production of various medical preparations? How do the WHO arguments correlate with the fact that since early 2000s the global market for medical cannabis has considerably grown and continues to expand? Today dozens of pharmaceutical companies worldwide conduct clinical research, cultivate and import raw cannabis and increase the manufacture of cannabis-based medical products. Nothing in the conventions seem to prevent them from expanding these legitimate activities.
	2) Assuming that some barriers do exist how will the deletion of cannabis and cannabis resin from Schedule IV of the 1961 Single Convention, while they remain in Schedule I, help to remove these barriers? Both Schedules envisage similar control measures. The only difference is that Parties may adopt any special measures of control which in their opinion are necessary in the prevailing conditions in that country. In other words, States that consider it appropriate to widely use cannabis for therapeutic purposes are allowed to do so provided that they fully comply with the specific requirements of Article 28.
	3) For the past decades ECDD has repeatedly reviewed the impact of cannabis on public health. Every time it had arrived at the conclusion that the available scientific data is insufficient to justify any change in the international control of this narcotic drug. What kind of new clinical research triggered WHO to suddenly change its position? Could WHO provide the list of such publications? Has the WHO carried out comprehensive research on medical use of cannabis as well as its side effects?
	4) The evidence for cannabis and cannabinoids efficacy for different medical conditions (diseases) is very weak - virtually not established. Results of clinical trials in this area are controversial with most of them having a weak study design. Are there any strong scientific evidence based rationales to remove cannabis from Schedule IV of the 1961 Single Convention?
	5) Cannabis use entails a number of adverse effects, including psychotic disorders. Cannabis and cannabinoids safety has never been well documented. Can we be 100% sure that cannabis use for medical purposes is safe enough and will not be accompanied by serious health problems?
	6) How does weakening of the control measures for cannabis correspond to the challenge of countering drug-related criminal activities? Despite the current control regime, cannabis remains the most abused drug worldwide. It is becoming even more popular among youth. Growing potency of its psychoactive ingredients exacerbates the negative effects of its abuse. Don't you think that a risk/benefit ratio is not favourable for cannabis re-scheduling?
<b>Singapore</b>	What evidence did the Committee consider as its basis for the recommendation that "cannabis resin" be deleted from Schedule IV of the 1961 Convention? While the Committee's report states that the 'Committee considered information regarding the therapeutic indications of cannabis and ongoing research into its possible medical applications', there was no mention of the therapeutic indications of cannabis resin or the research done on the possible medical applications of cannabis resin. The Critical Review Report contains little information on the possible medical applications of cannabis resin. Thus, the Committee's rationale for recommending the deletion of cannabis resin from Schedule IV of the 1961 Convention is not clear.
<b>Thailand</b>	In accordance with article 3 of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, a recommendation made by WHO is to delete cannabis plant and cannabis resin from Schedule IV of the Convention. Does this mean that cannabis plant will no longer be controlled? If so, how can WHO control cannabis-related substances without controlling cannabis plant?

<b>United States</b>	1) In recommending removal from Schedule IV, is the WHO making a determination that the liability of cannabis to be abused and to produce ill effects is offset by substantial therapeutic advantages not possessed by other substances?
	2) Was the ECDD's recommendation based on the finding that cannabis does not share similar liability to produce ill-effects as other Schedule IV substances, or on new data showing that the cannabis plant has therapeutic use?
	3) The ECDD report says that "cannabis and cannabis resin should be scheduled at a level of control that will prevent harm caused by cannabis use and at the same time will not act as a barrier to access and to research and development of cannabis-related preparation for medical use." Why does scheduling act as a barrier to access for these purposes, when the treaties mandate that countries make scheduled substances sufficiently available for medical and scientific purposes? To be consistent with treaty obligations, shouldn't we focus on efforts to remove the barriers, not accommodate them?
	4) The report indicates that "preparations of cannabis have shown therapeutic potential for treatment of pain and other medical conditions such as epilepsy and spasticity associated with multiple sclerosis" as partial justification for removing the cannabis plant from Schedule IV. Based on the ECDD findings, we are curious why the ECDD did not recommend adding these specific preparations with therapeutic value to Schedule III?
	5) Did the ECDD consider other factors that warranted keeping cannabis in Schedule I?

### Answer by WHO

The decision of the Committee was to recommend that cannabis and cannabis resin, which are currently included in Schedule I and Schedule IV of the 1961 Convention, be controlled only under Schedule I.

Under the 1961 Convention, decisions as to scheduling particularly for Schedules I and II, are based on similarity in liability to abuse and to produce ill-effects (convertibility is also a criterion but is not relevant for cannabis). The Committee has to take into account that cannabis also refers to preparations of cannabis and not just to the plant.

Substances in Schedule I, but not in Schedule IV, include the two other plants included in the 1961 Convention, coca leaf and opium, as well as the drugs cocaine, morphine, methadone and many other opioids.

The drugs in Schedule II are those considered to be weak opioids such as codeine and its derivatives. There are only ten such substances included in Schedule II. That evidence is outlined in the Committee's report and more detail can be found in the critical review. However, some of the main points were as follows:

- In controlled laboratory studies, cannabis produces effects on mental state and behavior typical of abused drugs.
- Dependence on cannabis is recognized and it includes the development of withdrawal symptoms on cessation of regular use. Approximately 1 in 10 cannabis users develop a cannabis use disorder.
- Cannabis has adverse effects that include impairment of cognitive function, impairment of driving, increased risk of psychosis, but it is not lethal and does not increase the lethality of other drugs.
- For some cannabis preparations with high THC content, the risks will be elevated above those due to cannabis in plant form.

Based on the evidence base, the Committee considered that the abuse and ill effects associated with cannabis and cannabis preparations exceed those of codeine (and similar drugs) and were more similar to drugs in Schedule I.

With respect to Schedule IV, it should be recognized that only a small subset of the drugs in Schedule I are also included in Schedule IV. Apart from cannabis and cannabis resin, they comprise a subset of opioids that have been considered at various times to be particularly liable to abuse and to produce ill-effects, and to have no

substantial therapeutic advantages. The drug most recently included in Schedule IV is carfentanil, an extremely potent and dangerous opioid that is not used in human medicine. As noted, neither opium nor coca leaf are included in Schedule IV. The Committee considered that neither the liability to abuse nor the liability to produce ill-effects of cannabis were commensurate with the other substances, such as carfentanil, Schedule IV.

The Committee also acknowledged that in 1961, when the Convention was established and cannabis was included in Schedule IV, cannabis and cannabis preparations were not recognized to have any therapeutic use or therapeutic potential. There is no evidence that cannabis preparations have therapeutic advantages not possessed by other substances. This is being recognized by national regulatory authorities in a number of countries; for example, Sativex (containing both THC and CBD) has been approved for medical use in more than 30 countries. Based on both the level of liability to abuse and to produce ill effects of cannabis and preparations of cannabis, and the recognized therapeutic value of cannabis preparations, while acknowledging the characteristics of substances currently included in Schedule IV, the Committee considered that cannabis should not be included in Schedule IV.

With regard to the issue of impact on research, the Committee made an observation about the effect of scheduling that has been reported from some countries, but this was not critical to the decision to recommend deletion from Schedule IV. That impact will vary from country to country, depending on how Schedule IV is implemented.

With regard to the question “How does the committee reconcile its recommendation to maintain cannabis under Schedule I with the fact that the committee did not consider that cannabis is associated with the same level of risk to health of most of the other drugs that have been placed in Schedule I?”, it is important to consider the full sentence which is as follows: “While the Committee did not consider that cannabis is associated with the same level of risk to health, as that posed by most of the other drugs placed in Schedule I, it noted the high rates of public health problems arising from cannabis use and the global extent of such problems.” The problems referred to are detailed in the report, but included the high rate of cannabis disorders and the impact on driving.

With regard to the inclusion of cannabis preparations in Schedule III, the Committee has done so for cannabis-based pharmaceutical preparations with delta-9-THC (dronabinol) as the main compound.

It is important to note that the international control measures in place for a drug included in Schedules I and IV are the same as those for a drug in Schedule I. Therefore, there would be no weakening of the international control of cannabis if it was included only in Schedule I. For Schedule IV drugs, countries are encouraged to consider additional control measure, but such measure are not mandated by the 1961 Convention.

It is important to note that the levels of international control as recommended by WHO ECDD should be considered as a minimum requirement, and it is at the discretion of Member States to implement more stringent levels of control depending on the specific country context.

### **Answer by INCB**

The Expert Committee on Drug Dependence (ECDD) recommends that cannabis and cannabis resin be deleted from Schedule IV of the 1961 Single Convention on Narcotic Drugs. The deletion of cannabis and cannabis resin from Schedule IV would affect the possible implementation of stricter control measures at the national level, which are described in article 2, paragraph 5 of the 1961 Convention.

However, if the above recommendation is endorsed by the Commission on Narcotic Drugs, control measures at the international level will not change. Cannabis and cannabis resin will continue to be subject to Schedule I control measures. The reporting requirements for Governments under the provisions of the Convention will not change. Estimates and statistics are mandatory for all drugs in Schedule I and will continue to be submitted by Governments. The Board can therefore continue to monitor the use of these two drugs and will be in a position to anticipate future increases in their use (through estimates) and analyse past developments and potential diversion (through statistics).

b) Written answers circulated on 30 July 2019

<b>Canada</b>	Under recommendation 5.1, we asked whether ECDD was able to take into consideration comparisons between cannabis and other substances which are not controlled under the Conventions, including alcohol and tobacco. This was particularly relevant in light of ECDD's consideration of the harms associated with use, such as rates of substance use disorders and driving under the influence of cannabis.
<b>Mexico</b>	<p>1) If <math>\Delta^9</math>-THC is the only psychoactive constituent of Cannabis then, why continue to refer to Cannabis as whole, when addressing the narcotic effects of just one of its constituents?</p> <p>2) Could you elaborate on why <math>\Delta^9</math>-THC was and continue to be paragoned to fentanyl, heroin and other opioids, given that in terms of toxicity and mortality are completely different? Is there any medical or scientific reason, other than the prevailing lack of knowledge and understanding, that would continue to justify the inclusion of THC within the same List as those substances?</p> <p>3) If the Committee "did not consider that Cannabis is associated with the same level of risk to health of most of the other drugs that have been placed in Schedule I", then why it still "recommended that Cannabis and Cannabis resin continue to be included in Schedule I of the 1961 Single Convention on Narcotic Drugs"?</p> <p>4) If toxicity and mortality are out of the question as Cannabis doesn't relate at all to the other two substances on these fields, what are then the other "public health problems arising from Cannabis use and the global extent of such problems", referred in the report? What is the metric for determining that there are "high rates" of those public health problems? What would be the difference between those "health problems" and problems arising from the consumption of other substances such as sugar, not to mention alcohol or tobacco, or modern practices such as "work burn out"?</p>
<b>Nigeria</b>	<p>1) Nigeria Drug Use Survey indicate that 14million used drug in 2017 and cannabis was the most abused and given the INCB Report on the medical use of cannabis as not the first line of treatment, what is the justification for the rescheduling when the abuse is high and the harm and impact not abating?</p> <p>2) Secondly, in view of Article 3 of the Single Convention particularly in paragraphs 3 and 5, can we justify the recommendations in view of the fact that information on the therapeutic value is not available or substantial enough to offset the impact of the abuse?</p>
<b>Pakistan</b>	<p>1) What was the criteria for first including the cannabis and cannabis resin in schedule IV of the Single Convention on Narcotic Drugs of 1961.</p> <p>2) What are findings/scientific evidence which have compelled WHO to recommend deletion of the cannabis and cannabis resin from schedule IV.</p> <p>3) Whether the removal of cannabis from schedule IV would not increase the repercussions caused by its legalization.</p>
<b>Russian Federation</b>	Which criteria did the ECDD apply to recommend the exclusion of cannabis from Schedule IV of the 1961 Single Convention on Narcotic Drugs? Why was the argument about alleged barriers to scientific research and medical use of cannabis, which was initially used by the WHO, replaced by the principle of similarity? How does the similarity criterion correlate with the provisions of Article 3 Paragraph 5, where it is clearly stated that a drug could be placed in Schedule IV if it "is particularly liable to abuse and to produce ill effects and that such liability is not offset by substantial therapeutic advantages not possessed by substances other than drugs in Schedule IV". Are cannabis or its derivatives used as the first line or only treatment option for any medical condition?

**Answer by WHO**

## ***Schedule I***

The 1961 Single Convention makes specific reference to the control of cannabis in several articles, along with two other plants, namely opium poppy and coca leaf, and provides definitions of cannabis, cannabis plant, and cannabis resin. These provisions would continue to apply if the CND followed WHO's recommendations concerning cannabis and related substances.

The ECDD recommended that cannabis continue to be included in Schedule I of the 1961 Convention because it was considered that cannabis is liable to similar abuse and productive of similar ill effects as drugs in Schedule I of the 1961 Convention (article 3.3.iii).

That evidence is outlined in the Committee's report and more detail can be found in the critical review. However, some of the main points were as follows:

- In controlled laboratory studies, cannabis produces effects on mental state and behaviour typical of abused drugs.
- Dependence on cannabis is recognised and it includes the development of withdrawal symptoms on cessation of regular use. Approximately 1 in 10 cannabis users develop a cannabis use disorder.
- Cannabis has adverse effects that include impairment of cognitive function, impairment of driving, increased risk of psychosis, but it is not lethal and does not increase the lethality of other drugs.
- For some cannabis preparations with high THC content, the risks will be elevated above those due to cannabis in plant form.

When making a recommendation regarding Schedule I or Schedule II, the Conventions require the Expert Committee to assess a substance's similarity in terms of liability to abuse and producing ill effects with other substances already within these schedules. It is not within ECDD's mandated role to carry out comparisons with substances not controlled under the Conventions such as alcohol or tobacco.

Regarding the Expert Committee's recommendation that cannabis remain in schedule I of the 1961 Convention, the Committee recognised that preparations, as defined in Article 1, of cannabis are, in principle, subject to the same measures of control as cannabis itself.

The Committee was aware that there are preparations of cannabis being produced illicitly that have high levels of THC and produce harms to public health. Public health problems arising from cannabis use include high rates of abuse and dependence that are considered as a cannabis use disorder. There are also high rates of driving under the influence of cannabis, which the Committee considered to pose a threat to public health.

## ***Schedule IV***

The Committee considered that cannabis and cannabis resin did not meet the threshold of being "particularly" liable to abuse and to produce ill-effects, which would warrant including in Schedule IV.

It arrived at this conclusion on the basis that cannabis is not more liable to produce abuse and ill-effects than other Schedule I substances. Substances in Schedule I, but not in Schedule IV, include the two other plants included in the 1961 Convention, coca leaf and opium poppy, as well as the drugs cocaine, morphine, methadone and many other opioids. The Committee carefully considered the information on the level of ill-effects produced by cannabis as well as the abuse associated with the use of cannabis. The evidence clearly indicates that cannabis, including preparations from cannabis, do not produce a level of ill effects that is greater than these other substances currently in Schedule I but not in Schedule IV. While there are significant ill-effects associated with cannabis use, these effects cannot be considered to be greater than those of substances such as cocaine and morphine. The Committee also concluded that while cannabis abuse is a significant problem, the level of abuse of cannabis and cannabis preparations does not exceed the level of abuse of substances such as morphine and cocaine.

As an additional consideration, cannabis is equally not liable to produce ill-effects or abuse in a manner comparable to drugs in schedule IV. The Committee carefully considered the evidence regarding abuse and ill-effects of these



substances and compared them to cannabis. It is clear from this evidence that the substances currently in Schedule IV, with the exception of cannabis, are especially dangerous with a high risk of death associated with their use and such as opioids. Cannabis is not associated with such risk. With regard to liability to abuse, the evidence does not indicate that cannabis is associated with a liability comparable to that of other substances in Schedule IV. For example, the level of physical dependence is much lower for cannabis than for the other drugs in Schedule IV which all produce opioid physical dependence.

### ***Demonstrated therapeutic advantages***

The Expert Committee acknowledged that in 1961, when the Convention was established and cannabis was included in Schedule IV, cannabis and cannabis preparations were not recognised to have any therapeutic use or therapeutic potential. There is now evidence that cannabis preparations have therapeutic advantages not possessed by other substances.

Effective therapeutic use of cannabis preparations has been demonstrated in a number of clinical trials for a range of therapeutic indications, such as the control of muscle spasticity associated with multiple sclerosis. The granting of marketing authorisation by medicines regulatory authorities in a large number of countries of the cannabis preparation known as Sativex, for the control of muscle spasticity, is further recognition of such clinical effectiveness and added value.

Some patients with chronic pain have also been shown to obtain relief from cannabis preparations when other available medications have not been effective. Many clinical trials on therapeutic use of cannabis preparations are ongoing and have shown cannabis to be an effective analgesic with demonstrated reduction in diabetic peripheral neuropathy and central neuropathic pain related to spinal cord injury and disease among patients with treatment-refractory pain.

From current evidence, cannabis preparations are not likely to be first line medications for most indications for which they are used, but it is considered to be common and good medical practice to have multiple levels of interventions available. This is because first line interventions do not work for all, or sometimes multiple levels of interventions must be used concurrently for the treatment of medical conditions. What is important is that cannabis preparations, even as a second or third line therapeutic option, have the potential to produce beneficial effects in patients who do not obtain such benefits from other medications. This means that the cannabis preparations have therapeutic advantages not possessed by the other substances used therapeutically.

<b>Russian Federation</b>	How does the similarity criterion correlate with the provisions of Article 3 Paragraph 5, where it is clearly stated that a drug could be placed in Schedule IV if it "is particularly liable to abuse and to produce ill effects and that such liability is not offset by substantial therapeutic advantages not possessed by substances other than drugs in Schedule IV?"
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### **Answer by UNODC**

While the similarity criterion would be fundamental to include a substance in Schedule I of the 1961 Convention (pursuant to its article 3, paragraph 3), the requirement for a drug – already contained in Schedule I – to also be placed in Schedule IV of the 1961 Convention can be found in its article 3, paragraph 5, i.e. a finding by the World Health Organization that a drug in Schedule I "is particularly liable to abuse and to produce ill effects (paragraph 3) and that such liability is not offset by substantial therapeutic advantages not possessed by substances other than drugs in Schedule IV". Similarity to the substances already included in Schedule IV is not listed as a requirement. Such consideration is also not explicitly excluded, as long as the recommendation is based on the above-mentioned requirement. The criteria to be taken into account in the deletion of a drug from a Schedule, pursuant to article 3, subparagraph 6(b) of the 1961 Convention, are the same employed under the preceding paragraphs for the inclusion of drugs. Reference is made to the response by the World Health Organization on how it has addressed this issue in its recommendation.

c) Written answers circulated on 4 October 2019

<b>European Union</b>	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.
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**Answer by WHO**

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>European Union</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?
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**Answer by WHO**

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>United States</b>	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.
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**Answer by WHO**

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).

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>United States</b>	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?
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### Answer by WHO

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>United States</b>	3) Is there any reason the ECDD could not make a recommendation that differentiates between low THC concentration and high THC concentration cannabis resin?
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### Answer by WHO

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.

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>United States</b>	4) Is the ECDD aware of any therapeutic use of cannabis resin? Of butane hash oil?
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### Answer by WHO

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>United States</b>	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?
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### Answer by WHO

This is partly answered by 3), above. Additionally, as noted in 2), above, cannabis resin is currently controlled in the same way as the cannabis (plant) and the Committee did not seek to change this.

<b>United States</b>	6) 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?
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#### Answer by UNODC

Article 1(d) of the 1961 Convention contains the following definition: “*Cannabis resin*’ means the separated resin, whether crude or purified, obtained from the cannabis plant.”

As clarified in the *Commentary*, the 1961 Convention “does not exclude any part of the cannabis plant as source of the resin” (United Nations, *Commentary on the Single Convention on Narcotic Drugs, 1961, 1973*, p. 5).

<b>United States</b>	7) 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?
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#### Answer by UNODC

The World Health Organization explicitly included in its notification to the Secretary-General a recommendation to the Commission that applies to both cannabis and cannabis resin. We would refer the scientific justifications to the WHO on the reasons why WHO considered it appropriate to assess together these substances, which have separate definitions, but are subject to the same rules.

As a matter of practice, the Secretariat presents to the Commission the scheduling recommendations as they have been made by the WHO. The practice followed by the Commission has been to vote on the recommendations as they are presented.

<b>United States</b>	8) Does the recommendation to add certain pharmaceutical preparations of cannabis to Schedule III depend on the 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?
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#### Answer by UNODC

While the World Health Organization could be in a better position to advise, we understand that the recommendation on cannabis and cannabis resin and the recommendation on “pharmaceutical” preparations of cannabis appear to not have been made subject one to another by the WHO, i.e. there is no conditionality among them. In principle, both recommendations would be voted on separately.

The provisions of the 1961 Convention do not impede Parties from permitting activities relating to a substance contained in schedules I and IV (in this case, cannabis, as defined in the 1961 Convention) for medical and scientific purposes, subject to the control measures defined in the treaty. The 1961 Convention also does not contain provisions that would impede the inclusion in Schedule III of certain preparations of drugs that are in Schedules I and IV.

We observe that the term “botanical cannabis” is not included in the 1961 Convention. There are treaty provisions applicable to the cultivation of the cannabis plant, but the term cannabis is defined in article 1 of the 1961 Convention.

d) Written answers circulated on 21 October 2019

<b>United States</b>	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?
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**Answer by INCB**

Estimates and statistics need to be provided for drugs scheduled in Schedule I of the 1961 Convention. If THC is moved to Schedule I of the 1961 Convention, an estimate will be required. Currently, Governments submit assessments for delta-9-THC quantities and Governments have to apply a different control system to the plant and some of its associated components.

e) Written answers circulated on 26 November 2019

<b>Colombia</b>	Having in mind the definition for cannabis resin from the Single Convention on Narcotic drugs, and its critical review report form 41st ECDDA meeting, is the term “cannabis resin” only applicable when it is obtained from cannabis plants without any solvent?
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**Answer by WHO**

The 1961 Convention uses the following definition: “Cannabis resin” means the separated resin, whether crude or purified, obtained from the cannabis plant. A resin is a substance that is exuded from a plant. It is produced naturally, differentiating it from substances such as butane hash oil which are produced using a solvent. Cannabis resin can be considered part of the cannabis plant and is currently controlled in the same way as the cannabis plant. The Committee did not seek to change this principle.

<b>Russian Federation</b>	1) The evidence for cannabis and cannabinoids efficacy for different medical conditions (diseases) is very weak - virtually not established. Results of clinical trials in this area are controversial with most of them having a weak study design. Are there any strong scientific evidence based rationales to remove cannabis from Schedule IV of the 1961 Single Convention?
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**Answer by WHO**

With respect to Schedule IV, it should be recognised that only a small subset of the drugs in Schedule I are also included in Schedule IV. Apart from cannabis and cannabis resin, they comprise a subset of opioids that have been considered at various times to be particularly liable to abuse and to produce ill-effects and to have no substantial therapeutic advantages. The drug most recently included in Schedule IV is carfentanil, an extremely potent and dangerous opioid that is not used in human medicine. As noted, neither opium nor coca leaf are included in Schedule IV. The Committee considered that neither the liability to abuse nor the liability to produce ill-effects of cannabis were commensurate with the other substances, such as carfentanil, in Schedule IV. The Committee also recognised that in 1961 cannabis and cannabis preparations were not recognised to have any therapeutic use or

therapeutic potential. There is now evidence that cannabis preparations have therapeutic advantages not possessed by other substances. That evidence was discussed in response to a previous question, under Item 5.0 above.

Based on both the level of liability to abuse and to produce ill effects of cannabis and preparations of cannabis and the therapeutic value of cannabis preparations, while recognising the characteristics of substances currently included in Schedule IV, the Committee considered that cannabis was not similar to these substances and therefore should not be included in Schedule IV.

<b>Russian Federation</b>	2) Cannabis use entails a number of adverse effects, including psychotic disorders. Cannabis and cannabinoids safety has never been well documented. Can we be 100% sure that cannabis use for medical purposes is safe enough and will not be accompanied by serious health problems?
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### Answer by WHO

There are now a number of cannabis-based preparations containing dronabinol and a combination of dronabinol and cannabidiol approved for various medical indications in a number of countries. For approval of the medical use of these preparations extensive safety data has been provided. Some of this information is also in the public domain through the published results of a range of clinical trials. While there are adverse effects with such medications as there are with any medications, these have not been considered so severe as to prevent medical use.

The ECDD has never recommended smoked cannabis for medical use and any recommendation for or against such use would be outside the mandate of the ECDD.

<b>Russian Federation</b>	3) How does weakening of the control measures for cannabis correspond to the challenge of countering drug-related criminal activities? Despite the current control regime, cannabis remains the most abused drug worldwide. It is becoming even more popular among youth. Growing potency of its psychoactive ingredients exacerbates the negative effects of its abuse. Don't you think that a risk/benefit ration is not favourable for cannabis re-scheduling?
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### Answer by WHO

The removal of Cannabis and Cannabis Resin will not change the level of international control. The international control measures in place for a drug included in Schedules I and IV are the same as those for a drug in Schedule I. Therefore, there would be no weakening of the international control of cannabis if it was included only in Schedule I. For Schedule IV drugs, additional control measures can be enforced at national level by individual countries, but such measures are not mandated.

A risk benefit analysis of the type proposed is beyond the mandate of the ECDD based on the requirements of the Conventions.

<b>Russian Federation</b>	4) Why was the argument about alleged barriers to scientific research and medical use of cannabis, which was initially used by the WHO, replaced by the principle of similarity?
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### Answer by WHO

The rationale used by the ECDD regarding Schedule IV has been explained in the answer to question 1, above. With regard to the issue of impact on research, the Committee made an observation about the effect of scheduling, but this was not critical to the decision to recommend deletion from Schedule IV. This question has been addressed in question 3 of Item 5.0 above.

<b>Singapore</b>	Would recommendation 5.1 change any barriers of access to cannabis for medical and scientific purposes? And if so, in what ways?
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### **Answer by WHO**

The international control measures in place for a drug included in Schedules I and IV are the same as those for a drug in Schedule I. However, for Schedule IV drugs, countries are encouraged to consider enforcement of additional national control measures. The controls on medical access and research for drugs in Schedule IV are therefore under the control of each individual country. Some countries may choose to impose a greater level of control that impairs research and medical use and there was some information that impairment of research do occur in some countries for substances in Schedule IV.

Countries may also be mindful of the interpretation of Schedule IV as described in the Commentary on the Single Convention on Narcotic Drugs, 1961. On p.94 it is noted that the Technical Committee of the Plenipotentiary Conference which adopted the treaty described the substances listed in Schedule IV as those:

- (a) Having strong addiction-producing properties or a liability to abuse not offset by therapeutic advantages which cannot be afforded by some other drug; and/or
- (b) For which deletion from general medical practice is desirable because of the risk to public health.

The criterion set out in (b) could be interpreted as an indicator that substances included in Schedule IV should never be used for medical use. Furthermore, in para 7 on p.95 it is noted that the recommendation of WHO and the decision of CND to include a drug in Schedule IV will be largely motivated by a desire to eliminate it from medical practice. The deletion of Cannabis and Cannabis Resin from Schedule IV would maintain the same level of international control but without the implication that cannabis, cannabis resin and preparations made from them should never be used for medical purposes.

## 5.2 Delta-9-tetrahydrocannabinol (dronabinol)

**Recommendation 5.2.1:** The Committee recommended that dronabinol and its stereoisomers (delta-9-tetrahydrocannabinol) be added to Schedule I of the 1961 Convention.

As indicated in the “Guidance on the WHO review of psychoactive substances for international control”, to facilitate efficient administration of the international control system, it is not advisable to place a substance under more than one Convention.

Accordingly:

**Recommendation 5.2.2:** The Committee recommended the deletion of dronabinol and its stereoisomers (delta-9-tetrahydrocannabinol) from the 1971 Convention, Schedule II, subject to the Commission’s adoption of the recommendation to add dronabinol and its stereoisomers (delta-9-tetrahydrocannabinol) to Schedule I of the 1961 Convention.

### a) Written answers circulated on 2 July 2019

<p><b>Canada</b></p>	<p>The Committee recommended that dronabinol and its stereoisomers (delta-9-THC) be added to Schedule I of the 1961 Single Convention on Narcotic Drugs (Recommendation 5.2.1).</p> <p>What new evidence let the committee to conclude that a departure from the committee’s previous recommendations – namely that dronabinol and its stereoisomers be listed under Schedule II of the 1971 Convention (26<sup>th</sup> and 27<sup>th</sup> meeting) or Schedule III of the 1971 Convention (34<sup>th</sup> and 35<sup>th</sup> meetings) – was warranted?</p>
<p><b>European Union</b></p>	<p>The WHO has previously reviewed delta-9-tetrahydrocannabinol (THC) on multiple occasions, and each time has recommended the scheduling under the 1971 Convention. In order to recommend placement in the 1971 Convention, the ECDD must first consider and reject control under the 1961 Convention. What new information caused the ECDD to overrule its three previous conclusions that THC should not be controlled under the Single Convention on Narcotic Drugs of 1961?</p> <p>In 2006 at the 33rd ECDD meeting, buprenorphine was found to meet the criteria for both the 1961 and the 1971 Conventions. The WHO Office of the Legal Counsel confirmed that in such a circumstance, the general legal rule of Lex posterior supra lex anterior applied to the situation, and that from a legal point of view the scheduling of buprenorphine should be continued under the 1971 Convention. In light of this legal opinion, how has the WHO come to the conclusion that THC should be moved from the 1971 Convention to the 1961 Convention?</p> <p>For harmonization purposes, the WHO’s Expert Committee on Drug Dependence (ECDD) recommends avoiding the division of cannabis and its various constituent substances between the various schedules contained in the 1961 and 1971 Conventions, as is currently the case. It is important to highlight the possible consequences of this change in the schedules in terms of perception and proportionality regarding the danger posed by these substances. Even though the potential for abuse and the level of danger of delta-9-THC and its isomers are well established, these substances are now to be placed in Schedule 1 alongside substances such as fentanyl analogues, which are far more dangerous and represent a far greater potential for abuse.</p> <p>Although for many years the ECDD had proposed that dronabinol be subject to a less restrictive regime, its latest recommendations take quite the opposite approach. The ECDD is suggesting that these substance be transferred from the 1971 Convention on Psychotropic Substances to the 1961 Single Convention on Narcotic Drugs, and placed in Schedule I. This molecule is the active substance in Marinol (in France, a personal temporary authorisation issued by the</p>



	<p>National Agency for Medicines and Health Products Safety is required to access this drug following the failure of other treatments - opioids, tramadol, etc.).</p> <p>Delta-9-tetrahydrocannabinol (THC) is the main psychotropic substance contained in cannabis. This designation covers four stereoisomers (molecules made up of the same atoms but which have different spatial positions):</p> <ul style="list-style-type: none"> <li>(-)-trans-delta-9-tetrahydrocannabinol (also known as dronabinol);</li> <li>(+)-trans-delta-9-tetrahydrocannabinol;</li> <li>(-)-cis-delta-9-tetrahydrocannabinol;</li> <li>(+)-cis-delta-9-tetrahydrocannabinol.</li> </ul> <p>Of these four, only the first (–)-trans isomer occurs naturally. It is called dronabinol when it is obtained synthetically. The other three stereoisomers are obtained synthetically.</p> <p>Question – What are the reasons for the WHO’s change in position on dronabinol?</p>
<p><b>United States</b></p>	<ol style="list-style-type: none"> <li>1) The WHO has previously reviewed delta-9-tetrahydrocannabinol (THC) on multiple occasions, and each time has recommended placement within various schedules of the 1971 Convention. As part of those reviews, did the ECDD consider and reject THC for control under the 1961 Convention? If so, what information led the ECDD to recommend placement in the 1961 Convention during the current review?</li> <li>2) Will moving this substance to the 1961 Convention result in additional reporting burdens on Member States? If so, was the ECDD aware of this?</li> <li>3) According to paragraph 45 of the WHO document “Guidance on the WHO review of psychoactive substances for international control”, “any proposal to move a substance from one convention to another should 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, and will not unduly limit availability for legitimate medical and scientific purposes.” What evidence was used by the ECDD to meet this criterion?</li> <li>4) The leaves of the cannabis plant are explicitly excluded from the scope of controls on cannabis in the 1961 Convention, however since the leaves contain THC, they are considered to be internationally controlled under the 1971 Convention. Would moving THC from the 1971 Convention to the 1961 Convention create a situation whereby the leaves of the cannabis plant that contain THC would no longer be internationally controlled?</li> <li>5) In 2006 at the 33rd ECDD meeting, buprenorphine was found to meet the criteria for both the 1961 and the 1971 Conventions. The WHO Office of the Legal Counsel confirmed that in such a circumstance, the general legal rule of Lex posterior supra lex anterior applied to the situation, and that from a legal point of view the scheduling of buprenorphine should be continued under the 1971 Convention. In light of this legal opinion, how has the WHO come to the conclusion that THC should be moved from the 1971 Convention to the 1961 Convention?</li> <li>6) The ECDD report specifically cites facilitating the implementation of the control measures of the Conventions in Member States as an impetus for this recommendation, however, the World Health Organization is empowered by the Conventions to deliver “an assessment of the substance, including the extent or likelihood of abuse, the degree of seriousness of the public health and social problem and the degree of usefulness of the substance in medical therapy”, and this assessment is “determinative as to medical and scientific matters”. From where does WHO derive legal authority to make recommendations based on the ease with which Member States are able to implement the control measures of the Conventions?</li> <li>7) If this recommendation is approved by the CND, but the later recommendation to add pharmaceutical preparations of cannabis to Schedule III is not taken, what would be the effect?</li> </ol>

## Answer by WHO

The following is an extract from the report of the 41st ECDD meeting which addresses several issues raised in regard to dronabinol:

*Dronabinol ((-)-trans- $\Delta$ 9-THC), the active stereoisomers of  $\Delta$ 9-THC, was originally understood to refer only to this substance in its medicinal form. It is currently included under Schedule II of the 1971 Convention, but there have been several recommendations to change its status. Earlier recommendations to the CND were based on the understanding that  $\Delta$ 9-THC as a pure substance existed only in this medicinal form. However, particularly in the past 10 years, there has been increasing use of illicit substances prepared from the cannabis plant. These substances contain  $\Delta$ 9-THC with a range of purities, and particularly its active stereoisomer (-)-trans- $\Delta$ 9-THC or dronabinol, up to 90% purity.*

Thus, the difference between the recommendations some years ago and the recommendations currently under consideration, is the recognition that relatively pure forms of dronabinol exist not just as medicines, but also as illicit substances.

It is also important to recognise that while it has been said in the past, and is still frequently stated, that dronabinol refers to the medicinal form of THC, or dronabinol is the synthetic form of THC, neither are correct. Dronabinol is the international non-proprietary name for (-)-trans- $\Delta$ 9-THC, whether it is found naturally in the cannabis plant or as a medicine. The inappropriate use of the term 'dronabinol' as a reference only to the medicinal form of THC has caused considerable confusion.

The reasons for the recommendation on dronabinol are described in the report of the 41st ECDD. In particular, it should be noted that the criterion for recommending that dronabinol be included in Schedule I of the 1961 Convention was the criterion of similarity in liability to abuse 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.

After the Committee consulted with INCB, it noted that:

*... placing  $\Delta$ 9-THC under the same Convention and in the same schedule as cannabis, Schedule I of the 1961 Single Convention on Narcotic Drugs, would greatly facilitate the implementation of the control measures of the Conventions in Member States.*

While this was not a criterion for the recommendation, and did not directly influence the recommendation, the ECDD did acknowledge that there were advantages to Member States should this recommendation be adopted.

The "Guidance on the WHO review of psychoactive substances for international control" through its paragraph 45, mandates WHO ECDD to recommend the move of psychoactive substances from one Convention to another. For WHO and the ECDD, this Guidance endorsed in 2010 by the WHO Executive Board, superseded previous advice concerning the transfer of substances from one Convention to another.

The same paragraph 45, states that a "proposal to move a substance from one Convention to another, should 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". In line with this paragraph, the Committee recommended that dronabinol be scheduled under the 1961 Convention in particular because of illicit preparations containing high levels of THC, such as butane hash oil. The existence and use of such high potency and harmful products is a relatively new phenomenon.

## Answer by INCB

The ECDD recommends that dronabinol (delta-9-tetrahydrocannabinol;  $\Delta$ 9-THC) and its stereoisomers should be added to Schedule I to the 1961 Single Convention and deleted from Schedule II of the 1971 Convention on Psychotropic Substances.

Endorsement of this recommendation by the Commission on Narcotic Drugs will result in some changes in the control of these drugs. Instead of assessments which are required for drugs in Schedules II, III and IV of the 1971 Convention, pursuant some ECOSOC resolutions, Governments will need to submit estimates, pursuant to article 19 of the 1961 Convention. The mandate to submit estimates is stricter than for assessments, as it is a treaty mandate. Submitted estimates are subject to confirmation by the Board and Governments must furnish estimates annually (instead of three-year intervals under the assessment system).

If cannabis and its active principles are controlled under the same Convention, this will facilitate the control and reporting at the level of Governments as the same set of control measures will apply to cannabis, cannabis resin, dronabinol and its stereoisomers as well as tetrahydrocannabinol and its stereoisomers (as per the next recommendation). This will facilitate the work of the Board to monitor the global situation and to provide Governments with a comprehensive overview of the global production, consumption and trade of cannabis and its active components.

b) Written answers circulated on 30 July 2019

<b>Canada</b>	Under recommendation 5.2, we asked for clarification about what had changed to lead the ECDD to develop a different recommendation regarding dronabinol than it had on previous occasions.
<b>Mexico</b>	1) If $\Delta$ 9-THC was already identified by 1971 as being the only narcotic agent present in Cannabis, why did the international regime on Cannabis control was never updated?
	2) What would be the rationale for ECDD to compare the “active and naturally occurring stereoisomer of $\Delta$ 9-THC known as dronabinol” to synthetic versions? Is it even scientifically sound to address together and to paragon any natural product with synthetic ones?
	3) Does $\Delta$ 9-THC at concentrations as high as 90% of exists naturally or is the result of human manipulation or bioengineering? If it is not naturally produced then, is it scientifically sound to address the natural concentrations of $\Delta$ 9-THC together with manipulated versions?
	4) Are you familiar with the work on sugar and yeast of companies such as San Francisco based CB Therapeutics?
	5) Could you elaborate on the last paragraph in relation to the requests received by Member States and information by UN agencies? Who, what and why? Could you elaborate on why listing dronabinol and $\Delta$ 9-THC “would greatly facilitate the implementation of the control measures of the Conventions in Member States”?
	6) Bearing in mind that ECDD undoubtedly affirms that Cannabis cannot be associated to the same level of risk to health than other substances scheduled in Lista 1 of the Single Conventions, at the same time it recommends to place individually dronabinol and TCH on that List. Is it not a contradiction?

**Answer by WHO**

Delta-9-THC was identified as a major active compound in cannabis in 1971 but at that time, the evidence wasn't convincing that it was the only psychoactive compound. Now it is known that it is the main psychoactive compound and the ECDD recognised that while dronabinol can be chemically synthesised, there is no difference in the effects of natural and synthetic dronabinol.

This is outlined in the report of the 41<sup>st</sup> ECDD meeting as follows:

“In previous ECDD reviews, the active and naturally occurring stereoisomer of  $\Delta$ 9-THC known as dronabinol had been considered in a synthetic form as a pharmaceutical preparation. Following a recommendation from the ECDD at its twenty-seventh meeting, dronabinol was placed in Schedule II of the 1971 Convention on Psychotropic Substances. However, the CND did not adopt a subsequent recommendation to place dronabinol in Schedule III of the 1971 Convention on Psychotropic Substances.

The Committee noted that whereas in these previous ECDD review  $\Delta$ 9-THC, and especially its active stereoisomer dronabinol, had been considered in a synthetic form as a pharmaceutical preparation,  $\Delta$ 9-THC today also refers to the main psychoactive component of cannabis and the principal compound in illicit cannabis-derived psychoactive products. Some of these products contain  $\Delta$ 9-THC at concentrations as high as 90%. Butane hash oil is an example of a cannabis-derived product containing high-purity delta-9 THC which have recently emerged.”

The criterion for recommending that dronabinol 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. Cannabis preparations with high purity delta-9 THC produce ill-effects and abuse potential that are at least as great as those produced by cannabis, which is placed in schedule I of the 1961 Single Convention.

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. Placing delta 9-THC, the principal active compound in cannabis, in the same Schedule as cannabis would be consistent with this approach.

The Committee considered new information that had arisen about delta-9-THC since its last recommendation in 2012, and recognised the emergence of high potency THC preparations such as butane hash oil since that time. These substances require significant human interventions to produce them, and there are no naturally occurring forms of cannabis that contain this content. Cannabis and cannabis preparations have to be considered together because the Conventions mandate that if a drug is included in a schedule then preparations of that drug are also included in the same schedule. There is no specification about the type of preparation or the strength of preparations. What this means is that cannabis in plant form which has an average THC content of 10-15% would also be grouped with preparations that have 90% - but this is the nature of the Conventions.

In the case of an illicit preparation with high levels of THC, currently this could be controlled as a preparation of cannabis under the 1961 Convention, but it could also be controlled under the 1971 Convention as a preparation of dronabinol. There are now preparations that range from low THC concentration to nearly pure THC, and therefore there is some ambiguity about whether they would be controlled as preparations of cannabis, or preparations of dronabinol. The implementation of the WHO recommendation to schedule dronabinol under the 1961 Convention would address this ambiguity.

There are a large number of companies producing and carrying out research on cannabis products. The Committee does not generally look at the work of private industry other than that which is reported in scientific peer reviewed papers, recognizing that commercial developers have proprietary interests which may influence or may be perceived to have influenced research outcomes.

<b>Russian Federation</b>	Are there precedents for moving substances from one convention to the other?
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### Answer by UNODC

The Commission on Narcotic Drugs has not considered any recommendation to move substances from schedules of the 1961 Single Convention on Narcotic Drugs to schedules of the 1971 Convention on Psychotropic Substances or from the 1971 Convention to the 1961 Convention. The World Health Organization is mandated to make scheduling recommendations under both the 1961 and the 1971 Conventions. The 1971 Convention does not

contain provisions on a possible relationship with the 1961 Convention, although during the negotiation process for an instrument on psychotropic substances, one issue under discussion was whether to elaborate a protocol to the 1961 Convention or a separate treaty. If the Commission would deem it necessary to obtain more information on the relationship between the above-mentioned treaties under applicable principles and rules of public international law, it may consider formulating a specific question and requesting, through the secretariat, a legal opinion from the United Nations Office of Legal Affairs.

c) Written answers circulated on 4 October 2019

<b>European Union</b>	1) Does 'dronabinol' mean the active substance produced by chemical synthesis, for both medical and non-medical use?
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**Answer by WHO**

Dronabinol is the International Non-proprietary Name (INN) for the  $\Delta$ -9-THC stereoisomer (-)-trans- $\Delta$ 9-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.

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>European Union</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> <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>
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**Answer by WHO**

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>European Union</b>	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?
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### Answer by WHO

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 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.

<b>European Union</b>	4) 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?
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### Answer by UNODC

“Leaves” are explicitly excluded from the definition of the term “cannabis” in the 1961 Convention, when not accompanied by the tops. They remain under control pursuant to article 28, paragraph 3, of the 1961 Convention, which requires States parties to “adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant”.

If dronabinol were moved to the 1961 Convention, the leaves of the cannabis plant containing THC and its isomers, including dronabinol, especially in levels that would facilitate their extraction and possible abuse, would continue to be controlled, following the same reasoning that currently allows for their control under the 1971 Convention. The validity and reach of article 28, paragraph 3, of the 1961 Convention would remain unchanged, and it would continue to be applied together with control measures applicable to dronabinol (and THC). If moved to a schedule of the 1961 Convention, THC would constitute a scheduled substance on its own, separate from cannabis or cannabis resin, and both synthetic and naturally extracted THC would continue to be covered.

<b>Singapore</b>	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?
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### Answer by UNODC

In principle, the Commission votes on each recommendation by the WHO separately. Recommendations are in general independent from each other. When the WHO recommendation explicitly contains conditionality, then such recommendation would depend on the outcome of the vote on another recommendation. For example, recommendation 5.2.2 (to delete dronabinol from the 1971 Convention), and 5.3.1 (to add tetrahydrocannabinol to schedule I of the 1961 Convention) are phrased as being subject to the adoption of 5.2.1 (to add dronabinol to Schedule I of the 1961 Convention). Recommendation 5.3.2 (to delete tetrahydrocannabinol from Schedule I of the 1971 Convention) is phrased as being subject to the adoption of 5.3.1 (to add tetrahydrocannabinol to Schedule I of the 1961 Convention).

Replying to the question, if recommendation 5.2.1. would not be adopted by the Commission, then recommendation 5.3.1. would not be put to a vote (in relation to moving tetrahydrocannabinol).

If recommendation 5.2.1. would be adopted by the Commission, then recommendation 5.3.1. would be voted, and could be adopted or not adopted.

The Commission's attention is drawn to the different majority requirements of the 1961 and the 1971 Conventions, which could possibly affect the outcomes of voting on the individual recommendations.

<p><b>United States</b></p>	<p>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.</p>
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### Answer by WHO

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).

<p><b>United States</b></p>	<p>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</p>
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	purpose exemption because then anything containing THC would be part of the scheduling. Please address.
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### Answer by WHO

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>United States</b>	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?
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### Answer by WHO

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.

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.

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>United States</b>	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?
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### Answer by WHO

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>United States</b>	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?
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### Answer by WHO

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>United States</b>	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?
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### Answer by WHO

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.

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>United States</b>	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?
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### Answer by WHO

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”.

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.

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>United States</b>	8) What additional harms to health could potentially result if delta-9-THC continued being controlled under the 1971 Convention?
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### Answer by WHO

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.

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.

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>United States</b>	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?
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### Answer by WHO

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.

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.

<b>United States</b>	10) 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?
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### Answer by UNODC

Cannabis is a narcotic drug scheduled under the 1961 Convention, and therefore it is included in the system of estimates and statistical returns established under that treaty. Both the 1961 and the 1971 Conventions provide for the possibility of changes in their scope of control to be conducted through amendment to their schedules. These Conventions empower the Commission on Narcotic Drugs to make decisions in this regard. Therefore, we understand that amendments to the schedules are matters under the authority of the Commission, pursuant to articles 3 and 2 of the 1961 and 1971 Conventions, respectively.

<b>United States</b>	11) 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
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	they not choose at that time to place it in the same Convention and Schedule as cannabis
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### Answer by UNODC

We looked into the *Official Records* of the “United Nations Conference for the adoption of a Protocol on Psychotropic Substances” and found no particular explanation for the decision to include THC in the 1971 Convention instead of the 1961 Convention.

#### d) Written answers circulated on 21 October 2019

<b>Singapore</b>	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?
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### Answer by INCB

Endorsement of recommendation 5.2 by the Commission on Narcotic Drugs will result in some changes in the control of these drugs. Instead of assessments which are required for drugs in Schedules II, III and IV of the 1971 Convention, pursuant some ECOSOC resolutions, Governments will need to submit estimates, pursuant to article 19 of the 1961 Convention. The obligation to submit estimates is stricter than for assessments, as it is a treaty mandated. Submitted estimates are subject to confirmation by the Board and Governments must furnish estimates annually (instead of three-year intervals under the assessment system).

If cannabis and its active principles are controlled under the same Convention, this will facilitate the control and reporting at the level of Governments as the same set of control measures will apply to cannabis, cannabis resin, dronabinol and its stereoisomers as well as tetrahydrocannabinol and its stereoisomers (as per the next recommendation). This will also facilitate the work of the Board to monitor the global situation and to provide Governments with a comprehensive overview of the global production, consumption and trade of cannabis and its active components.

<b>United States</b>	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.
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### Answer by INCB

Currently, it is not always clear to Member States which control provisions apply to cannabis-based preparations containing THC or delta-9-THC and if these should be reported as cannabis extracts (1961 Convention) or THC (1971 Convention). In the last years there are an increasing number of products containing these drugs.

Originally when scheduled, delta-9-THC was considered a synthetic compound, obtained from chemical synthesis (dronabinol). However, in recent years, delta-9THC has also been prepared by extraction from cannabis, and as such could also be considered as a substance prepared by purification (refining) of cannabis extract (controlled under the 1961 Convention). Manufacture of delta-9-THC from natural extractions has advanced to the point where

they are chemically indistinguishable from synthetically derived delta-9-THC. With regard to international trade, it became difficult to report correctly given that some consignments do not specify the type of derivation of the substance in trading details. In addition, preparations containing a mixture of naturally and synthetically derived delta-9-THC are now entering the market. These preparations are particularly difficult to provide accurate figures for given that natural and synthetic derivations are reported under different conventions. Therefore, delta-9-THC figures analysed and published do not necessarily provide an accurate image of international trade in the substance.

When considering delta-9-THC of purely natural origin – in practical terms this means that the cultivation of cannabis plant, estimates or manufacture is undertaken in line with provisions of the 1961 convention. However, the import of the final product is reported under 1971 convention (including assessments of annual requirements, import licenses etc). There is a disconnect between the processes that makes monitoring difficult and data received do not provide for a full picture.

<b>United States</b>	2) Are the current control measures placed on delta-9-THC under Schedule II of the 1971 Convention insufficient to deter abuse or illicit use?
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#### Answer by INCB

The control mechanism of psychotropic substances established by the 1971 convention and relevant ECOSOC resolutions, is generally a well-established and functioning regime. Substances in schedule II are subjected to quarterly statistical return reporting and require an import/export authorization, which should always be in line with declared assessments of annual medical/scientific requirements.

However, regarding delta-9-THC, there is a general discrepancy in data due to the disconnect mentioned earlier and thus in global monitoring of the actual trade in and consumption of the substance. It is thus difficult to evaluate to what extent are the control measures effective.

<b>United States</b>	3) What specific new control measures does the 1961 Convention place on delta-9-THC that would decrease the extent or likelihood of abuse?
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#### Answer by INCB

Instead of assessments which are required for drugs in Schedules II, III and IV of the 1971 Convention, pursuant some ECOSOC resolutions, Governments will need to submit estimates, pursuant to article 19 of the 1961 Convention. The obligation to submit estimates is stricter than for assessments, as it is a treaty obligation. Submitted estimates are subject to confirmation by the Board and Governments must furnish estimates annually (instead of three-year intervals under the assessment system).

<b>United States</b>	4) 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?
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#### Answer by INCB

No.

<b>United States</b>	5) 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?
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### Answer by INCB

No. As already said the control requirements under the 1961 Convention are stricter.

Article 3 of the 1971 Convention refers to exempted preparations and it permits a State party to exempt from some controls preparations that contain psychotropic substances other than those listed in Schedule I. An exemption may be made only when the preparation presents negligible or no risk of abuse and the psychotropic substance cannot be readily recovered in a quantity liable to abuse. To take advantage of that provision, a State party must notify the Secretary-General in writing of the name and composition of the exempted preparation and the measures of control from which it is exempted.

e) Written answers circulated on 26 November 2019

<b>China</b>	Please provide evidence in support of the need to reassign dronabinol and THC from the schedules of the Convention on Psychotropic Substances of 1971 ("the 1971 Convention") to Schedule I of the 1961 Convention. The "WHO responses to CND on the 41st ECDD recommendations" document notes that paragraph 45 of the 41st ECDD report clearly states that "Any proposal to move a substance from one convention to another should 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, and will not unduly limit availability for legitimate medical and scientific purposes." In that regard, please provide evidence explaining the need to reassign dronabinol and THC from the schedules of the 1971 Convention to Schedule I of the 1961 Convention and how to effectively reduce the extent or possibility of their abuse or use in illicit drug production. Please also provide a response as to whether the reassignment of the two substances from the 1971 Convention to the 1961 Convention, and the placement of cannabis preparations under Schedule III of the 1961 Convention, will result in the relaxation of controls on cannabis and cannabis substances.
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### Answer by WHO

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, as indicated in the "Guidance on the WHO review of psychoactive substances for international control" through its paragraph 45.

Consistent with this principle, the Committee recommended that dronabinol be scheduled under the 1961 Convention in particular because of illicit preparations containing high levels of delta-9-THC, such as butane hash oil. The existence and use of such high potency and harmful products is a relatively new phenomenon. Currently, there is a lack of clarity as to whether these substances such as butane hash oil should be controlled as preparations of cannabis (under the 1961 Convention) or as preparations of dronabinol (under the 1971 Convention).

The reasons for the recommendation on dronabinol are described in the report of the 41st ECDD. The main criterion for recommending that dronabinol 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.

After the Committee consulted with INCB, it noted that:

... placing  $\Delta$ 9-THC under the same Convention and in the same schedule as cannabis, Schedule I of the 1961 Single Convention on Narcotic Drugs, would greatly facilitate the implementation of the control measures of the Conventions in Member States.

While this was not a criterion for the recommendation, and did not directly influence the recommendation, the ECDD did acknowledge that there were advantages to Member States should this recommendation be adopted.

The isomers of THC included in Schedule I of the 1971 Convention and recommended to be included in Schedule I of the 1961 Convention, along with the isomer dronabinol ((-)-trans- $\Delta$ 9-THC), comprise a varied group of substances, most of which do not occur naturally. For none of them is there convincing evidence that would satisfy the criteria for inclusion in Schedule I of the 1971 Convention, as they are currently scheduled, and for at least one there is no such evidence. However, as the group of substances that is currently scheduled under a single drug name (tetrahydrocannabinol), they can be considered similar to dronabinol, as some do have dronabinol-like properties based on the limited evidence available.

It is also the case that as isomers of dronabinol they are very difficult to differentiate from dronabinol through usual chemical identification processes. The Committee took advice from INCB and recognised that the control of dronabinol would be compromised if these isomers were separately scheduled from dronabinol.

The reassignment of dronabinol and tetrahydrocannabinol from the 1971 Convention to the 1961 Convention will not relax controls on these substances.

Preparations in Schedule III of drugs controlled in Schedule I or Schedule II of the 1961 Convention are exempted from some of the requirements for control of those drugs. However, they are still subject to a significant level of control.

Article 2 para 3 of the 1961 Single Convention states:

Preparations in Schedule III are subject to the same measures of control as preparations containing drugs in Schedule II, except that article 31, paragraphs 1 (b) and 3 to 15 and, as regards their acquisition and retail distribution, article 34, paragraph (b), need not apply, and that for the purpose of estimates (article 19) and statistics (article 20,) the information required shall be restricted to the quantities of drugs used in the manufacture of such preparations.

This makes clear that the exemption for Schedule III products is for some of the requirements only, and not an exemption from control. This exemption is only for preparations containing dronabinol which are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that dronabinol is not readily recoverable. Each Member State can define what qualifies as a pharmaceutical preparation in their country.

The placement of cannabis pharmaceutical preparations under Schedule III of the 1961 Convention will not result in relaxation of controls on cannabis and cannabis resin.

<b>Japan</b>	According to the WHO recommendation, preparations containing delta-9-THC should be listed in Schedule III of 1961 Convention. However, all of the preparations included under Schedule III of the convention are clearly defined by the contents or concentrations. What specification does WHO consider to be applied to the preparations containing delta-9-THC?
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### Answer by WHO

The Committee considered that it was not necessary to recommend a maximum content of dronabinol, as it was specified that pharmaceutical preparations of cannabis and dronabinol in Schedule III would require that delta-9-THC is not readily recoverable. By comparison, almost all the substances in Schedule III currently (with opium as an exception) are readily recoverable.

<b>Russian Federation</b>	Does the ECDD have the treaty-mandate to produce recommendations on rescheduling narcotic drugs and psychotropic substances between the conventions?
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### Answer by WHO

The Committee is able to recommend deletion of a substance from a schedule of a convention and also to recommend adding a substance to the schedules of a convention. The recommendations of the ECDD were to delete dronabinol from control under the 1971 Convention and add it to the Schedules of the 1961 Convention and similarly for the isomers.

The “Guidance on the WHO review of psychoactive substances for international control”, through its paragraph 45, provides guidance on the circumstances under which the WHO ECDD may recommend adding a substance to one convention and deleting it from another. For WHO and the ECDD this Guidance, endorsed in 2010 by the WHO Executive Board, has authority.

<b>Singapore</b>	1) The Committee stated that some synthetic cannabinoids currently listed in Schedule II of the 1971 Convention e.g. JWH-018, AM-2201, and ADB-CHMINACA may have '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)'. Therefore, the ECDD concluded that these synthetic cannabinoids should remain in the 1971 Convention as amphetamine and LSD are scheduled under the 1971 Convention. What evidence did the ECDD consider to reach this conclusion that synthetic cannabinoids had effects more similar to amphetamine and amphetamine analogues?
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### Answer by WHO

The amphetamine like effects of synthetic cannabinoids include the cardiovascular effects, the ability to produce psychosis and stimulant effects. The cardiovascular effects of delta-9-THC are relatively mild, principally a mild tachycardia. In contrast, synthetic cannabinoids can produce a pronounced tachycardia (like amphetamine) and cardiac arrhythmia. Fatalities have occurred due to the cardiac effects of synthetic cannabinoids as they have with amphetamine.

Synthetic cannabinoids can produce a pronounced psychotic state that requires hospitalisation. This is a feature of cases of non-fatal intoxication due to synthetic cannabinoids, as is the case with amphetamine. In comparison, delta-9-THC has relatively mild psychotic effects.

Agitation and aggression have been features of cases of non-fatal intoxication due to synthetic cannabinoids, as is the case with amphetamine. In comparison, delta-9-THC does not produce such effects.

<b>Singapore</b>	2) Would synthetic cannabinoids or other NPS found to have effects that are similar to delta-9-THC or its stereoisomers be moved into the 1961 Convention in the event recommendation 5.2 and 5.3 are accepted?
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### Answer by WHO

It is not proposed that synthetic cannabinoids currently under control under the 1971 Convention be moved to control under the 1961 Convention. However, should the recommendations be adopted, synthetic cannabinoids considered in the future will be examined with regard to their similarity to delta-9-THC (controlled under the 1961 Convention if the recommendations are adopted) and to other synthetic cannabinoids (in Schedule II of the 1971 Convention) as well as other substances controlled under the 1971 Convention; recommendations for scheduling will then be made appropriately.

<p><b>United States</b></p>	<p>Currently, cannabis plants cultivated for industrial purposes are not controlled under the Single Convention. The WHO/ECDD's recommendation to add THC to the 1961 Convention schedule does not address whether the intent is to overcome this exemption. We are concerned that by adding THC to the 1961 schedule, without some explanation addressing this issue, implementation of the Single Convention would be subject to inconsistent interpretation and application. Considering that many governments are looking at regulating CBD production, this confusion would come at a most inopportune time. Would either the WHO/ECDD or the INCB have language to offer that might clarify this issue?</p>
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**Answer by WHO**

It has been previously noted that current international regulation is consistent with the exemption from control of cannabis grown for industrial or horticultural purposes even though such cannabis contains delta-9-THC which is controlled under the 1971 Convention. It is understood that the same would apply if delta-9-THC was controlled under the 1961 Convention.

**Answer by INCB**

According to article 28 of the 1961 Convention, States parties may permit the cultivation of cannabis for authorized medical and scientific purposes. Parties that permit such cultivation have an obligation to establish control measures in accordance with the Convention. In addition, the 1961 Convention limits the cultivation of cannabis for industrial purposes to fibre and seed. The cultivation of cannabis for the extraction of CBD would need to be monitored under the provisions of the 1961 Convention because it does not meet the definition of article 28 (2) as the cultivation cannot be considered as being "for industrial purposes" as specified in the 1961 Convention. Also, cannabis cultivated for the extraction of CBD would have some THC content and this would have to be controlled in accordance with its scheduling. As a way of reference, the Board has asked countries cultivating opium poppy variety rich in noscapine (an alkaloid not under international control) to report cultivation of that variety because of the presence of morphine content in that variety.



### 5.3 Tetrahydrocannabinol (isomers of THC)

**Recommendation 5.3.1:** The Committee recommended that tetrahydrocannabinol (understood to refer to the six isomers currently listed in Schedule I of the 1971 Convention) be added to Schedule I of the 1961 Convention, subject to the Commission's adoption of the recommendation to add dronabinol (delta-9-tetrahydrocannabinol) to the 1961 Convention, in Schedule I.

As indicated in the "Guidance on the WHO review of psychoactive substances for international control", to facilitate efficient administration of the international control system, it is not advisable to place a substance under more than one Convention.

Accordingly:

**Recommendation 5.3.2:** The Committee recommended that tetrahydrocannabinol (understood to refer to the six isomers currently listed in Schedule I of the 1971 Convention) be deleted from the 1971 Convention, subject to the Commission's adoption of the recommendation to add tetrahydrocannabinol to Schedule I of the 1961 Convention.

#### a) Written answers circulated on 2 July 2019

<b>European Union</b>	Does the term "tetrahydrocannabinol" refer only to the active substance extracted from the cannabis plant both for medical or non-medical use (illicit use)?
<b>Russian Federation</b>	Have there been any precedents of rescheduling narcotic drugs and psychotropic substances between the conventions in the past? Does the ECDD have the treaty-mandate to produce recommendations on such rescheduling?
<b>Thailand</b>	In accordance with article 3 of the 1961 Convention and article 2 of the Convention on Psychotropic Substances of 1971, a recommendation made by WHO is to add tetrahydrocannabinol (THC/isomer of delta-9-tetrahydrocannabinol) to Schedule I of the 1961 Convention and to delete THC from Schedule II of the 1971 Convention. How can WHO ensure that it will systematically be controlled for legitimate use only?
<b>United States</b>	<p>1) According to paragraph 45 of the WHO document "Guidance on the WHO review of psychoactive substances for international control", "any proposal to move a substance from one convention to another should 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, and will not unduly limit availability for legitimate medical and scientific purposes." What evidence was used by the ECDD to meet this criterion?</p> <p>2) In 2006 at the 33rd ECDD meeting, buprenorphine was found to meet the criteria for both the 1961 and the 1971 Conventions. The WHO Office of the Legal Counsel confirmed that in such a circumstance, the general legal rule of Lex posterior supra lex anterior applied to the situation, and that from a legal point of view the scheduling of buprenorphine should be continued under the 1971 Convention. In light of this legal opinion, how has the WHO come to the conclusion that THC should be moved from the 1971 Convention to the 1961 Convention?</p> <p>3) The ECDD report specifically cites facilitating the implementation of the control measures of the Conventions in Member States as an impetus for this recommendation, however, the World Health Organization is empowered by the Conventions to deliver "an assessment of the substance, including the extent or likelihood of abuse, the degree of seriousness of the public health and social problem and the degree of usefulness of the substance in medical therapy", and this assessment is "determinative as to medical and scientific matters". From where does WHO derive legal authority to make recommendations based on the ease with which Member States are able to implement the control measures of the Conventions?</p>

### Answer by WHO

The isomers of THC included in Schedule I of the 1971 Convention and recommended to be included in Schedule I of the 1961 Convention, along with the isomer dronabinol ((-)-trans- $\Delta^9$ -THC) comprise a varied group of substances, most of which do not occur naturally. For none of them is there convincing evidence that would satisfy the criteria for inclusion in Schedule I of the 1971 Convention, as they are currently scheduled, and for at least one there is no such evidence. However, as the group of substances that is currently scheduled under a single drug name (tetrahydrocannabinol), they can be considered similar to dronabinol, as some do have dronabinol-like properties based on the limited evidence available.

It is also the case that as isomers of dronabinol they are very difficult to differentiate from dronabinol, through usual chemical identification processes.

The Committee took advice from INCB and recognised that the control of dronabinol would be compromised if these isomers were separately scheduled from dronabinol.

### Answer by INCB

The ECDD recommends that tetrahydrocannabinol and its stereoisomers should be added to Schedule I to the 1961 Single Convention and deleted from Schedule I of the 1971 Convention on Psychotropic Substances.

As for previous recommendations, the endorsement of this recommendation by the Commission, will result in a number of additional control measures required for States under the 1961 Convention. One of these requirements will be that Governments will have to submit estimates for these isomers. With the addition of these substances to the 1961 Convention, the control of cannabis and its active principles will be in one schedule of the 1961 Convention and, as mentioned earlier, it would facilitate the reporting and monitoring requirements both for Governments and the Board.

b) Written answers circulated on 4 October 2019

<b>European Union</b>	Does the term 'Tetrahydrocannabinol' refer only to the active substance extracted from the cannabis plant, for both medical and non-medical use?
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### Answer by WHO

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.

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.

<b>United States</b>	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?
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### Answer by WHO

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.

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

**Recommendation 5.4:** The Committee recommended deleting extracts and tinctures of cannabis from Schedule I of the 1961 Convention.

a) Written answers circulated on 2 July 2019

<b>Argentina</b>	With respect to the proposal concerning extracts and tinctures: what is the rationale for scheduling preparations containing dronabinol and its stereoisomers but not preparations containing THC and its isomers?
<b>Canada</b>	<p>With respect to recommendation 5.4, the committee notes that the definition of preparations in the 1961 Single Convention on Narcotic Drugs may cover all products that are extracts and tinctures of cannabis as “preparations” of cannabis [emphasis added].</p> <p>Canada does not have any question for the ECDD with respect to this recommendation. However, we note that, should the recommendation be adopted by the Commission on Narcotic Drugs, the INCB will need to consult with States Parties regarding how best to operationalize the deletion of “Extracts and Tinctures” to ensure that all products previously captured under this category continue to be covered by the Convention as preparations of cannabis and cannabis resin.</p>
<b>China</b>	1) Removing “extracts and tinctures” of cannabis would seem to deregulate all cannabinoids found in cannabis, except those that are/are to be regulated under the 1961 Convention (e.g. delta-9-THC and the isomers of THC, pursuant to Recommendations (2) and (3)). Is this what recommendation (4) intend to achieve? If so, would WHO conduct a comprehensive review to support or justify whether other hundreds of cannabinoids found in cannabis should be so deregulated
	2) Can more examples be given on “preparations of cannabis”? What exactly would they cover? Would they include preparations containing cannabis compounds that are extracted or made from cannabis? A definition would seem necessary.
<b>Colombia</b>	1) Recommendation 5.4, as set out in the extract from the report of the forty-first meeting of the Expert Committee on Drug Dependence (“Cannabis and cannabis-related substances”), is to delete extracts and tinctures of cannabis from Schedule I of the Single Convention on Narcotic Drugs. Does this mean that the control measures applicable to those substances would depend on their THC content?
	2) In relation to the previous question, would requirements for extracts and tinctures be estimated on the basis of THC content?
<b>European Union</b>	<p>1) The Committee noted that, by this definition, the 1961 Single Convention on Narcotic Drugs may cover all products that are ‘extracts and tinctures’ of cannabis as “preparations” of cannabis and also, if the Committee’s recommendation to move dronabinol to Schedule I of the 1961 Single Convention on Narcotic Drugs was followed, as “preparations” of dronabinol and its stereoisomers”.</p> <p>Is this finding supported by an analysis pointing to this effect, or is there a need of further analysis in order to validate this finding?</p>
	2) The ECDD report cites as justification for its recommendation that “the fact that diverse preparations with a variable concentration of delta-9 THC are controlled within the same entry “Extract and Tinctures” and the same schedule, is a challenge for responsible authorities that implement control measures in countries. However, the World Health Organization is empowered by the Conventions to deliver “an assessment of the substance, including the extent or likelihood of abuse, the degree of seriousness of the public health and social problem and the degree of usefulness of the substance in medical therapy”, and this assessment is “determinative as to medical and scientific matters”. From where does WHO derive legal authority to make

	<p>recommendations based on the ease with which Member States are able to implement the control measures of the Conventions?</p> <p>3) The ECDD has recommended that extracts and tinctures - currently placed in Schedule I of the 1961 Convention and consequently subject to the most rigorous control - simply be removed from the scope of application of the Single Convention. The ECDD justifies this removal by the fact that the term 'extracts and tinctures' covers a large variety of products (containing very different levels of THC) and that, in order to avoid hampering their 'promising therapeutic applications' (particularly of cannabidiol), it is appropriate to exempt them from control.</p> <p>This removal means that products containing very high concentrations of psychoactive substances are exempt from control. Moreover, it could appear contrary to the intention to subject THC to a more rigorous regime while allowing preparations containing it to be exempt from control in future (cf. butane hash oil).</p> <p>By way of reminder, there are numerous ways in which to extract active substances from plants:</p> <ul style="list-style-type: none"> <li>- An extract is a preparation obtained through the use of a solvent.</li> <li>- A tincture is a preparation obtained through maceration of the plant in alcohol for a variable length of time. Highly concentrated tinctures can be used in the manufacture of medicines.</li> <li>-</li> </ul> <p>In summary, extracts and tinctures of cannabis cover a large range of preparations; the latter are defined under the Single Convention as 'a mixture, solid or liquid, containing a drug'.</p> <p>What are the WHO's arguments in response to the risk that potentially highly concentrated products may be declassified?</p>
<b>Japan</b>	<p>If extracts and tinctures of Cannabis are deleted from Schedule I of the 1961 Convention, those extracts and tinctures can be subject, as "preparations", to the international control, only when they contain delta-9-THC. This can cause some problems as follows. How did WHO assess those problem?</p> <ul style="list-style-type: none"> <li>- Whether delta-9-THC can be detected in those extracts and tinctures depends on the detection limit. If a competent law enforcement authority has highly sensitive detection capacity, even a little amount of delta-9-THC can be detected and, accordingly, such extracts and tinctures are subject to the control. On the other hand, if the sensitivity of detection is low, delta-9-THC cannot be detected and, accordingly, those extracts and tinctures are not subject to the control. Those difference of detection capabilities among Member States and among their competent authorities can bring confusion and challenges to the international control system. For instance, a certain extract/tincture can be illicit in an importing country, while the same extract/tincture cannot be illicit in an exporting country.</li> <li>- We need to consider the impact of Tetrahydrocannabinolic acid (THCA), which can be easily converted via decarboxylation to delta-9-THC by heat or light. THCA is contained in fresh Cannabis. When we extract substances from fresh Cannabis, for instance by ethanol, those extracts contain mainly THCA and, on the contrary, a small amount of delta-9-THC. Those extracts cannot be subject to the international control due to its low concentration of delta-9-THC, however there is a risk that THCA in those extracts can be easily converted to delta-9-THC.</li> </ul>
<b>Singapore</b>	<p>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,</p>

	what control measures does the Committee envisage for non-medical preparations with high concentrations of $\Delta$ 9-THC such as butane hash oil?
<b>Turkey</b>	What are the details of the proposal to remove "Extracts and tinctures of Cannabis" from the Table I of the 1961 Convention?
<b>United States</b>	1) The ECDD report cites as justification for its recommendation that "preparations are defined as mixtures...containing a substance in Schedule I or II and are generally subject to the same measures of control as that substance. However, the 1961 Convention exempts preparations that are not listed in Schedule III from estimates (article 19), statistics (article 20), and provisions in articles 29 and 30 relating to licensure for manufacture and trade. What would be the consequence of exempting certain preparations of cannabis that are not named in the Schedules of the Conventions, such as butane hash oils, from these provisions?
	2) Currently, cannabis extracts that contain delta-9-THC are internationally controlled as preparations under Article 3 of the 1971 Convention. How would this recommendation be affected if the Commission were to accept the recommendation to move THC from the 1971 Convention to the 1961 Convention?

### Answer by WHO

In its recommendation to remove 'Extracts and tinctures', 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.

Under 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, if not entirely, 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.

In the case of cannabis, currently there are three main types of illicit products derived from the plant:

1. Extracts (obtained by use of a solvent; for example, butane hash oil).
2. Tinctures (obtained using alcohol as a solvent), and
3. Products derived without the use of a solvent but by application of heat and pressure.

All three types of products are controlled as preparations of cannabis there is greater certainty of control of products derived, without the use of a solvent but by application of heat and pressure. These products are indistinguishable from those derived as extracts and tinctures.

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).

With regard to products that contain mostly THCA and little THC, these are currently controlled as preparations of cannabis and would continue to be controlled in that way, should the recommendation to remove 'extracts and tinctures' be adopted.

Should dronabinol be moved to the 1961 Convention, preparations containing THC will be controlled, whatever method is used to produce them. Similarly, if the isomers of THC are moved to the 1961 Convention, preparations containing any of those isomers will be controlled, whatever method is used to produce them.

## Answer by INCB

The ECDD recommends that extracts and tinctures of cannabis be deleted from Schedule I of the 1961 Convention.

The secretariat notes that the lack of a definition of extracts and tinctures has not facilitated control over these substances. At the time of the adoption of the Single Convention, extracts and tinctures may have been small in number and subject to a very limited use in a few countries. With the advent of a multitude of preparations made from the cannabis plant over the past years and their international trade across borders with different brand names and packaging and different contents, the use of such a broad and general category that fits a large number of cannabis-based drugs may no longer be adequate to ensure proper control.

However, this broad category if retained 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. This, however, would require 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.

### b) Written answers circulated on 4 October 2019

<b>European Union</b>	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?
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## Answer by WHO

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:

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.

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.

In the case of cannabis, currently there are three main types of illicit products derived from the plant:

1. extracts (obtained by use of a solvent; for example, butane hash oil),
2. tinctures (obtained using alcohol as a solvent), and
3. products derived without the use of a solvent but by application of heat and pressure.

All three types of products are controlled as preparations of cannabis.

However, under 'extracts and tinctures' only the first two types are controlled.

The Committee therefore concluded that by relying on control of preparations of cannabis there is greater certainty of control of products 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.

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).

<b>European Union</b>	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.
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#### Answer by WHO

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.

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).

<b>Singapore</b>	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?
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#### Answer by WHO

The exempted control measures referred to are as follows:

- 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.
- 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.
- 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.



- 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. Butane hash oil as a preparation of a cannabis should be controlled under Schedule I of the 1961 convention.

<b>Singapore</b>	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.
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### Answer by WHO

WHO refers this question to INCB

#### c) Written answers circulated on 21 October 2019

<b>United States</b>	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."
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### Answer by INCB

The secretariat receives estimates mentioning extracts (more often) and tinctures that need to be converted into quantity of cannabis. However, the nature and characteristics of this extracts and tinctures varies considerably with different brand names and packaging and different contents. The use of such a broad and general category that fits a large number of cannabis-based drugs may no longer be adequate to ensure proper control.

The ECDD position that "preparations", as defined in the 1961 Convention, may cover all products that are "extracts and tinctures" of cannabis would require the insertion of a specific footnote in the schedule to appropriately define the level of control to the "preparations of cannabis".

#### d) Written answers circulated on 26 November 2019

<b>China</b>	We note that WHO "was not seeking to decrease the level of control of any cannabis-related substance or narrow the scope of control" through this recommendation, since preparations (which, according to WHO, include extracts, tinctures and products derived without the use of a solvent but by application of heat and pressure) of cannabis are also covered by the 1961 Convention by virtue of its Article 2(3). However, as "preparation" is defined as "a mixture, solid or liquid, containing a drug" (Article 1), we are not sure if this definition can, as a matter of
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	<p>interpretation, cover all “extracts and tinctures of cannabis”. For instance, is butane hash oil – the example quoted by WHO as an extract of cannabis – a mixture containing cannabis (i.e. flowering or fruiting tops of the cannabis plant), or a mixture made from cannabis? If the latter (i.e. mixture made from cannabis) does not cover the former (i.e. mixture containing cannabis), the retention of “extracts and tinctures of cannabis” can cover substances or products that are made from cannabis (whether they contain cannabinoids explicitly listed in Schedule I or otherwise) which would be regulated under the 1961 Convention. WHO may wish to provide clarification on this issue.</p>
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### Answer by WHO

If a preparation such as butane hash oil is made using the cannabis plant, then that preparation will contain elements of the plant. As parts of the plant are retained in such preparations, they are considered preparations of the plant.

Using the language of the question, mixtures made from cannabis are also mixtures containing cannabis.

There does not therefore seem any need to retain extracts and tinctures of cannabis.

<b>Colombia</b>	<p>Regarding the 5.4 recommendation of the 41st ECDDA report, to delete Extracts and tinctures of Cannabis from Schedule I of the 1961 Single Convention on Narcotic Drugs, based on the argument that those extracts and tinctures can be better considered as cannabis preparations:</p> <ol style="list-style-type: none"> <li>1) How can extracts and tinctures of cannabis be recognized as a “mixture, solid or liquid, containing cannabis” if cannabis, as the plant material, needs to be destroyed in order to separate cannabinoids and bring them into a new matrix?</li> </ol>
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### Answer by WHO

If a preparation is made using the cannabis plant, then that preparation will contain elements of the plant. As parts of the plant are retained in preparations, they are considered preparations of the plant.

<b>Colombia</b>	<ol style="list-style-type: none"> <li>2) What might be the practical difference between classifying tinctures, oils, extracts and all the different products like distillates, rosin, etc. that ECDDA described in the critical review report, either as cannabis preparations or as cannabis resin preparations?</li> </ol>
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### Answer by WHO

Whether the tinctures and other products cited in the question are classified as preparations of cannabis or of cannabis resin depends on whether cannabis or cannabis resin was used as the starting product. In practice, it will not be possible to determine which was used and therefore it is important that cannabis and cannabis resin are not separated and not potentially scheduled under different levels of control.

<b>Colombia</b>	<ol style="list-style-type: none"> <li>3) If recommendations 5.2.1, 5.2.2, 5.3.1 and 5.3.2 around reclassification of tetrahydrocannabinols are approved might tinctures, oils, extracts, distillates etc. also be considered as tetrahydrocannabinol preparations?</li> </ol>
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### Answer by WHO

Currently, tinctures, oils and other products cited in the question can be considered either as (a) preparations of delta-9-THC (dronabinol) or (b) preparations of cannabis or (c) as extracts and tinctures of cannabis. This means that they could be controlled under (a) the 1971 Convention Schedule II, or (b) the 1961 Convention Schedules I and IV or (c) the 1961 Convention Schedule I. The proposed changes will not alter the fact that tinctures, oils and other products cited in the question could be considered as preparations of delta-9-THC (dronabinol) or of cannabis, but will remove the ambiguity as to the level of control as they will be controlled under the 1961 Convention Schedule I irrespective of what type of preparation they are considered to be.

Similarly, with the isomers of THC, the ambiguity as to the type of control will be removed by the recommended changes.

<b>Colombia</b>	4) If countries have different interpretations of which narcotic drug, those preparations come from, how can this impact the harmonization and effective cooperation when it comes to import/export authorizations, estimates and statistics, especially when it is necessary to express the exact content of the narcotic drug?
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### **Answer by WHO**

As noted above, there is currently a great degree of ambiguity both in respect to whether a preparation of cannabis is a narcotic drug (as it is derived from cannabis) or a psychotropic drug (because it contains delta-9-THC) and, if a narcotic drug, whether it is a preparation or an extract or tincture. The proposed changes will mean that these preparations will all be considered narcotic drugs controlled under the 1961 Convention in Schedule I.

## 5.5 Cannabidiol Preparations

**Recommendation 5.5:** The Committee recommended that a footnote be added to Schedule I of the 1961 Convention to read “Preparations containing predominantly cannabidiol and not more than 0.2 per cent of delta-9-tetrahydrocannabinol are not under international control.”

a) Written answers circulated on 2 July 2019

<b>Argentina</b>	With regard to the proposal concerning preparations containing cannabidiol: as currently drafted, the proposed footnote to Schedule I of the 1961 Convention does not make clear whether all such preparations would be excepted from international control or only those specified by the Member States. What is the basis for the proposed exception?
<b>Canada</b>	<p>The committee recommended that cannabidiol (CBD) preparations containing no more than 0.2 per cent of delta-9-THC be removed from international controls (Recommendation 5.5). The committee noted that CBD preparations from the cannabis plant will contain trace amount of THC. The proposed threshold reflects the amount of THC found in Epidiolex, recognizing that a 0.15% threshold would be difficult to measure for some Member States.</p> <ol style="list-style-type: none"> <li>1) Could the committee provide additional information on how it reached the proposed threshold of 0.2% and, in particular, whether the committee considered this threshold in light of non-pharmaceutical preparations available in jurisdictions where individuals have access to cannabis for medical purpose (e.g. CBD oil)?</li> <li>2) Does the committee consider that the proposed threshold is appropriate under all circumstances and for any preparation of CBD?</li> </ol>
<b>China</b>	<ol style="list-style-type: none"> <li>1) “preparations” is generally defined in the 1961 Convention as “a mixture, solid or liquid, containing a drug”. Clarification is sought as to whether WHO’s recommendation is to confine the deregulation to <b>pharmaceutical</b> preparations. If the intention is to deregulate <b>all</b> preparations, medical or otherwise, whether WHO has assessed that all substances or products concerned have no adverse health effects</li> <li>2) Would there be a quantifiable threshold of CBD being “predominant”</li> <li>3) Whether WHO intends to restrict other non-cannabis substances present in the CBD preparations concerned, and if so, whether such intention should be clearly spelt out (e.g. by making reference to paragraph 3 of Schedule III to the 1961 Convention, which states “provided that such preparations do not contain any substance controlled under the 1971 Convention on Psychotropic Substances”)</li> <li>4) Whether the removal of CBD would make it over-commercialized, and the considerations of WHO regarding the measures to ensure the utilization of CBD is for medical or research purpose</li> </ol>
<b>Colombia</b>	With respect to recommendations 5.5 and 5.6, which refer to preparations containing <i>delta</i> -9-THC (dronabinol) and indicate that preparations containing not more than 0.2 per cent of <i>delta</i> -9-THC should not be subject to control, can the same approach be applied to all stereochemical variants of THC, whether they are of synthetic or natural origin? If not, what is the rationale for limiting the two recommendations to dronabinol or <i>delta</i> -9-THC respectively?
<b>European Union</b>	<ol style="list-style-type: none"> <li>1) “Footnote” The 1961 Single Convention authorizes the WHO to recommend adding a preparation to Schedule III if it finds that the preparation, “because of the substances which it contains is not liable to abuse and cannot produce ill effects and that the drug therein is not readily recoverable”. Given the finding of the 40th ECDD that cannabidiol, as a preparation of cannabis, is not “liable to similar abuse or...ill effects to substances controlled under the 1961 or 1971 Conventions”, why did the WHO recommend that preparations considered to be pure CBD should not be scheduled instead of recommending placement of these preparations in Schedule III?</li> </ol>

	<p>It seems that the proposal to add a footnote to the 1961 Convention differs from how the conventions deal with other substances. A reasonable alternative could be that so-called low-grade preparations are placed in schedule III of the 1961 Convention, in line with previous practice. It is not clear why there is need for a more extensive exception than for any other narcotic substance. Why is a more extensive exception needed, considering that a) it could have negative implications for the possibility to prosecute personal consumption of cannabis in states parties where this constitutes a criminal offence and b) the criminalisation of the personal consumption of cannabis is purely a national matter? Why is the recommended footnote preferred instead of using Schedule III exempted preparations?</p>
	<p>2) “Predominantly”  The THC amount is specified to not more than 0,2 %, however there is no explicit definition of how much exactly is “predominantly”.  Could this be specified? (e.g. more than 50.0 %, 85.0 % or “pure” which is mentioned in the text in Annex I, is “pure” 98.0%).</p>
	<p>3) “Inclusion of THC-acid content?”  Referring again to the definition of “predominantly” as well as the intended use and administration mode - can the preparations referred to in this recommendation contain also THCA? (a reference is made to ECDD - CRR on cannabis and cannabis resin stating: “THCA is devoid of intoxicating properties and is not a scheduled substance. A chemical reaction triggered by heat leads to the decarboxylation of [...] producing the corresponding decarboxylated species [...] Δ9-THC as occurs when marijuana is smoked or otherwise heated and also the CRR on cannabis extracts and tinctures section 4.2.4.”</p> <p>The limit of 0,2% THC is in line with the limit of THC in Cannabis Sativa L. in Council Regulation (EC) No. 73/2009 of 19 January 2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers, amending Regulations (EC) No. 1290/2005, (EC) No. 247/2006, (EC) No. 378/2007 and repealing Regulation (EC) No. 1782/2003. But as there are different analytical methods to determine the THC concentrations, which can give confusion/challenges in practice, we suggest to follow the analytic method that was defined in Commission Implementing Regulation (EU) No. 809/2014 of 17 July 2014 laying down rules for the application of Regulation (EU) No. 1306/2013 of the European Parliament and of the Council with regard to the integrated administration and control system, rural development measures and cross compliance. The method is based on the quantitative determination of Δ9-THC by gas chromatography (GC) after extraction with a suitable solvent. This method is a warm method, and reveals the total Δ9THC (sum of THC and the acid which is predominantly present in the plant and is converted to THC under heating). As a consequence a suggestion would be to:</p> <ul style="list-style-type: none"> <li>→ Either refer to a limit of 0,2% total THC (THC + THC-acid);</li> <li>→ Either refer to a limit of 0,2 % THC as determined by gas chromatography.</li> </ul> <p>What is the opinion of the WHO on this matter?</p>
	<p>4) “Enlarge exclusion”  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?</p> <p>Preparations containing predominantly other cannabinoids like Cannabidaverin (CBDV) and not more than 0,2% of delta-9-tetrahydrocannabinol, could be possible in the future and in the same logic they should be excluded. CBDV has no potential of</p>

	<p>abuse either. We suggest reviewing if the reference “containing predominantly CBD” is not too narrow. What is the opinion of the WHO on this matter?</p>
	<p>5) “Relation with cannabis and cultivation of cannabis/hemp plants?”</p> <ul style="list-style-type: none"> <li>- In this case, is the WHO going to recommend that cannabis with less than 0,2% Δ9-THC, obtained from certified seeds of cannabis crops varieties included in the common catalogue of varieties of the European Union, is no longer controlled as substances included in Schedule I of the 1961 Convention are?</li> <li>- Is the strict cultivation regime set out in article 28 of the Single Convention on Narcotic Drugs of 1961 applicable to the production of such cannabidiol preparations? Would the cultivation of the cannabis plant for the purpose of the production of such cannabidiol preparations be in line with article 28 (2) of the Single Convention on Narcotic Drugs of 1961? How else may such products be legally produced?</li> <li>- Depending on the strain of the cannabis plant these preparations for medicinal use would not necessarily, require purification (from THC). Does the recommendation have any implications to the cultivation control measures in article 28? (reference is made to ECDD CRR of CBD section 2, INCB Annual Report 2018 Chapter I, 8. “The treaties set out requirements on States parties as to how they may allow the use of cannabis and its derivatives for medical purposes. For example, articles 23 and 28 of the 1961 Convention as amended require that Governments establish a national cannabis agency to control the production and regulate the supply of cannabinoids for medical use.” and the 1961 Convention commentary (1973) on article 28 points 2 and 9 from the INCB Annual Report 2018: “Cannabis and its derivatives” describe all products derived from the cannabis plant. Cannabis plant products include the flowering tops (marijuana), compressed cannabis resin (hashish), cannabis oils, concentrated cannabis extracts (waxes) and edible preparations (e.g. infusions, cookies and chocolates). Cannabinoids are substances found only in the cannabis plant).</li> </ul>
	<p>6) Since the word “pharmaceutical” is not specifically mentioned, a clarification would be appreciated if the recommendation is applicable to all preparations (consumer products), containing predominantly CBD and with not more than 0,2 % THC? Such preparations would not be restricted to medicinal and scientific use according to the conventions. (Article 4, paragraph (c), of the 1961 Convention as amended limits the use of drugs scheduled under the Convention, including cannabis and its derivatives, to medical and scientific purposes. (Source: INCB Report 2018).</p>
	<p>7) “More evidence on the 0,2% asked”</p> <p>We would welcome further information on the evidence base that informed the recommended percentage of delta-9-tetrahydrocannabinol content permitted within preparations containing predominantly cannabidiol which do not fall under international control.</p> <p>Could the THC traces contained in cannabidiol-based products and their derived forms (including where THC content is lower than 0.2 %) cause medium- / long-term side effects in case of regular and/or heavy use?</p>
	<p>8) Does the term “preparations” refer only to the industrial registered medicinal products or also to the magistral preparations prepared by the pharmacist both under medical prescription? Are “the no-pharmaceutical products for no medical use” included?</p> <p>We wish to clarify what is meant by this type of preparation:</p> <ul style="list-style-type: none"> <li>- does it mean authorised medicines only, such as EPIDIOLEX?</li> <li>- alternatively, does this term encompass all types of product that are available on the market, are extracted from cannabis, claim to contain predominantly CBD and that have a THC content no higher than 0.2 %?</li> </ul>

	<p>9) Cannabidiol (CBD) is not specifically included in the schedules of the UN's International Drug Control Conventions of 1961, 1971 or 1988. Nonetheless, where it is prepared in the form of an extract or tincture of cannabis, it is currently included in Schedule I of the 1961 Single Convention on Narcotic Drugs.</p> <p>The WHO indicates that cannabidiol should not be scheduled on the basis that it 'does not have psychoactive properties and has no potential for abuse and no potential to produce dependence. It does not have significant ill-effects'.</p> <p>According to recent articles by Professor Authier, cannabidiol has psychoactive properties to the extent that it affects the brain, as suggested in particular by its anti-epileptic effects and the side effects indicated in respect of Epidiolex.</p> <p>It is therefore important to clarify that the psychoactive effect of CBD (effect on the brain / CNS) should not be called into question and should be distinguished from the potential for abuse and dependence (which is a psychoactive effect but not the only one).</p> <p>We would therefore like to see the scientific studies on which the WHO is basing these claims.</p> <p>According to the data available, CBD as a substance is unlikely to give rise to abuse or harmful effects of the sort caused by the substances included in the 1961 or 1971 Conventions, such as cannabis or THC, respectively. Thus, the ECDD has recommended that preparations considered to contain pure CBD, and with a THC content no higher than 0.2 %, not be included in the schedules of the international Conventions.</p> <p>We wish to clarify what is meant by this type of preparation:</p> <ul style="list-style-type: none"> <li>- does it mean authorised medicines only, such as EPIDIOLEX?</li> <li>- alternatively, does this term encompass all types of product that are available on the market, are extracted from cannabis, claim to contain predominantly CBD and that have a THC content no higher than 0.2 %?</li> </ul> <p>The ECDD has recommended that preparations considered to contain pure CBD, and with a THC content no higher than 0.2 %, not be included in the schedules of the international Conventions.</p> <p>Could the THC traces contained in cannabidiol-based products and their derived forms (including where THC content is lower than 0.2 %) cause medium- / long-term side effects in case of regular and/or heavy use?</p> <p>Furthermore, it should be noted that, although Member States can put in place more restrictive legislation, we are concerned about the consequences that these changes to the international Conventions would have for health, regulation and control, as well as how the public might perceive the absence of any classification for cannabidiol.</p> <p>Generally, removing cannabis and cannabis resin from Schedule IV (whilst retaining them in Schedule I) has less of an impact on the controls applicable than it does on the message that is sent by reassessing a substance as being less dangerous and having therapeutic potential.</p>
<p><b>Japan</b></p>	<p>Cannabidiol (CBD) can be easily converted to delta-9-THC by acid and heat. Therefore, excluding CBD preparations from the international control raises concerns that those preparations can be used for illicit productions of delta-9-THC. How did WHO assess those concerns?</p> <p>The either of the following options can be a possible solution to minimize those concerns.</p> <ul style="list-style-type: none"> <li>- CBD preparations should be excluded from the international control, only if they are for medical and scientific purposes.</li> </ul>

	<ul style="list-style-type: none"> <li>- CBD preparations should be placed in Schedule III of the 1961 Single Convention on Narcotic Drugs, as the same to other pharmaceutical preparations of cannabis and delta-9-THC.</li> <li>- CBD should be controlled as a precursor of delta-9-THC under the 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.</li> </ul> <p>With regard to the threshold of 0.2% of delta-9-THC, it must be clear whether this threshold counts THCA or not, since THCA can be easily converted to delta-9-THC as mentioned above.</p>
<b>Singapore</b>	1) 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?
	2) We note that Epidiolex, the cannabidiol preparation approved for the treatment of childhood-onset epilepsy, contains not more than 0.15% Δ9-THC by weight and has no effects indicative of potential for abuse or dependence. We also note the Committee’s comment that chemical analysis of Δ9-THC to an accuracy of 0.15% may be difficult for some Member States. However, what is the Committee’s scientific basis for determining the limit of 0.2% by weight of Δ9-THC as the threshold for there to be no effects indicative of potential abuse or dependence? For reference, the chapter on “Tetrahydrocannabinol” from a standard reference book “Disposition of Toxic Drugs and Chemicals in Man” by Randall Baselt, 10th Edition, states, ‘THC is the most psychoactive of the principle constituents of marijuana (Cannabis sativa) and is contained in various parts of the plant in amounts that vary from only traces to as high as 12% by weight. It is administered either orally or by smoking in approximate doses of 5 – 20 mg, which result in sedation, euphoria, hallucinations and temporal distortion.’ Based on the documented dose range, a 10 ml intake of a preparation containing not more than 0.2% of THC will give 20 mg of THC, which could produce effects indicative of potential abuse and dependence.
<b>Turkey</b>	1) Any studies by the WHO on the medical use of CBD and some other chemicals extracted from cannabis.
	2) What is the background of the proposal made by the WHO concerning CBD during the 62. CND? What is the scientific assessment by the WHO on classifying CBD as a precursor?
	3) What is the scientific assessment by the WHO about the information that CBD may convert to THC in the acidic environment of the stomach?
	4) The relevant WHO proposal contains the following text " <i>Preparations containing predominantly cannabidiol and not more than 0.2 percent of delta-9-tetrahydrocannabinol are not under international control.</i> " What are the details and explanations of this proposal? What does the word “preparations” in the text suggest?
<b>United States</b>	1) How was the 0.2% THC threshold determined?
	2) Was the ECDD aware that several states have established low level thresholds of THC, ranging from 1% at the high range, 0.5% in the mid range, 0.3 in the US, and 0.2% in the EU, perhaps to address the concern that there is no "pure" CBD in nature. Is there alternative language that could address the ECDD’s concerns while leaving it up to States to determine what threshold is appropriate to exempt cannabidiol preparations from control?
	3) Can this recommendation be revised to allow countries greater flexibility in interpreting what an allowable low threshold for THC content is?
	4) What does the term "preparation" mean as used by the ECDD in its recommendation? Is it the same definition used in the Single Convention?
	5) Does this recommendation refer to percent by weight or by concentration in a solution?



	6) As a practical matter, how are states to determine the percent in growing plants?
	7) Why is it necessary to specify that a substance is not under international control, rather than simply not listing that substance in the schedules? If the recommendation to delete “extracts and tinctures” from the schedules is accepted by the CND, is this recommendation still necessary?
	8) With respect to the precedent of using a footnote to exempt substances from control, is there precedent for using a footnote to exempt certain preparations (rather than stereoisomers) of a substance from international control?
	9) In lieu of a footnote, are there other ways to clarify that preparations of cannabidiol are not under international control?
	10) Cannabidiol has no potential for abuse or to produce dependence or associated ill-effects, and is only under international control when it is prepared as an extract of cannabis. Article 3, Paragraph 4 of the 1961 Convention specifies that “If the World Health Organization finds that a preparation because of the substances which it contains is not liable to abuse and cannot produce ill effects and that the drug therein is not readily recoverable, the Commission may, in accordance with the recommendation of the World Health Organization, add that preparation to Schedule III.” Do the preparations described in this recommendation meet this definition? Please explain why or why not.

### Answer by WHO

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 & IV) and as an extract or tincture (Schedule I).

Cannabidiol shows no potential for abuse or dependence and any ill-effects are minimal. It is no 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 should not be controlled under the 1961 Convention.

The Committee considered the option of including preparations of cannabidiol 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 preparation of a drug that did not satisfy the criteria for inclusion in the schedules of the 1961 Convention.

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 submitted for approval in other countries), cannabidiol preparations will contain trace amount of THC as well as other cannabinoids and non-cannabinoid plant substances.

The Committee considered that most of the preparation should be CBD, and no more than 0.2% 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.

The value of 0.2% for 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 THC content not greater than 0.15% by weight as a proportion of the total weight of plant material.

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 THC (max. 0.2%) will be below the level that would produce significant effects.

Cannabidiol preparations for medical use include preparations with a pre-marketing authorisation and could also include magistral preparations executed in pharmacies, if authorised in countries.

The Committee was aware that CBD products, such as foods, are being sold in many countries. While CBD does not satisfy the criteria for control under the 1961 or 1971 Conventions, Member States can regulate its availability using their own national legislation.

Both THC and CBD are present in the plant in acid form (THCA and CBDA). The acids of each are converted to THC and CBD, respectively, by heat and/or ultraviolet light. Thus, any product that contained predominantly CBD would not contain significant amount of THCA.

There are no implications for the control of cannabis plants or hemp plants arising from this recommendation.

With regard to other cannabinoids that may be devoid of psychoactive effects e.g. cannabidavarin (CBDV), the Committee considered that each should be considered separately. While there are such substances under investigation for potential therapeutic benefits, this research is in very early stages.

With regard to the conversion of CBD to THC mentioned (Japan), this method was described in a scientific paper over 50 years ago (Gaoni, Y. and R. Mechoulam, Hashish-VII. The isomerization of cannabidiol to tetrahydrocannabinols. Tetrahedron Vol. 22. 1966. 1481-1488) and has been subject of a patent application.

The method is not simple and requires access to a number of chemicals, including certain acids and solvents. The yield is also uncertain, as are the by-products and their side-effects. This would be an expensive and potentially risky method of obtaining THC compared to use of cannabis and hence it is extremely unlikely that it would be implemented.

<b>European Union</b>	<p>Cannabidiol API</p> <p>In countries like the UK and USA, pure Cannabidiol API (white powder) is considered as a narcotic for which import/export authorisations are required. On these import/export authorisations the CBD must be calculated back towards cannabis base substance. This means that:</p> <ul style="list-style-type: none"><li>- other countries' estimates of cannabis are affected by an import of a substance (CBD) which is not scheduled in their drugs legislation.</li><li>- discrepancies in import/export statistics between countries appear.</li></ul> <p>Could this matter be clarified with the INCB? Does the INCB have a clear point of view on this matter?</p>
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### Answer by INCB

The ECDD recommends that cannabidiol preparations not be under international control if they contain no more than 0.2 per cent of  $\Delta 9$ -THC and therefore recommends that a footnote be added to Schedule I of the 1961 Convention to read: "Preparations containing predominantly cannabidiol and not more than 0.2 per cent of  $\Delta 9$ -THC are not under international control".

The main concern of the secretariat of the INCB in regard to this recommendation relates to its practical implementation at the national level. In most countries, chemical analysis down to the required threshold will not

be possible because of lack of access to appropriate identification techniques. In those countries where chemical analysis to the required accuracy of 0.2 per cent of THC is possible, it might not be feasible, or considered to be a good use of resources and may not be employed.

In addition, this recommendation will also give rise to an important question on the control of cannabis that is being cultivated for the extraction of CBD to be used for mentioned CBD preparations.

As a way of reference, the Board has asked countries cultivating opium poppy variety rich in noscapine (an alkaloid not under international control) to report cultivation of that variety because of the presence of morphine content in that variety.

According to article 28 of the 1961 Convention, States parties may permit the cultivation of cannabis for authorized medical and scientific purposes. Parties that permit such cultivation have an obligation to establish control measures in accordance with the Convention. In addition, the 1961 Convention limits the cultivation of cannabis for industrial purposes to fibre and seed.

The cultivation of cannabis for the extraction of CBD will need to be monitored under the provisions of the Single Conventions because it does not meet the definition of article 28 (2) because the cultivation cannot be considered as being done “for industrial purposes” as specified in the Single Convention. Also, cannabis cultivated for the extraction of CBD will have some THC content and this will have to be controlled in accordance with its scheduling.

Romania on behalf of the State Parties also members of the European Union asked about the import and export of Cannabidiol API in various jurisdictions.

If this recommendation is endorsed by the Commission on Narcotic Drugs, the preparations described in the recommendation will not be subject to any international control and it will be up to national Government authorities to establish the criteria for the use and distribution of such preparations. The wording of the recommendation, referring to “preparation”, is also likely to create confusion among competent national authorities.

b) Written answers circulated on 30 July 2019

<b>Canada</b>	Finally, under 5.5, we asked for clarification on the origin of the proposed 0.2% threshold and of ECDD's statement that it had considered leaving the matter of defining a threshold for THC content in CBD preparations to the member states themselves.
<b>Mexico</b>	1) How did the ECDD come to the range of 0.2% of THC for making this recommendation? 2) Could it not be somewhat arbitrarily to set a specific percentage?
<b>Russian Federation</b>	CBD might be easily converted into delta-9 THC (dronabinol) with acid and heat (or light). Has the WHO considered that removal of CBD preparations from the international control might lead to its misuse for the illicit production of dronabinol?

**Answer by WHO**

When produced from the plant, cannabidiol preparations will contain trace amounts of THC as well as other cannabinoids and non-cannabinoid plant substances.

Evidence from clinical trials conducted with a product containing no more than 0.15% delta-9-THC as a proportion of the total mass from the cannabis plant showed that this did not produce characteristics or effects similar to cannabis.

For Member States to control preparations that contain up to 0.15% delta-9-THC as a proportion of the total mass from the cannabis plant, the Expert Committee recognised the difficulty in measurement to this high degree of

accuracy (0.15%) and therefore adopted 0.2% as a more reliable measure that would allow Member States to control.

The value of 9.2% 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.

Epidiolex is the brand name for the cannabidiol preparation that has been approved in the US and contains 0.15% of delta-9-THC, as indicated in the patent, as a total proportion of delta-9-THC relative to the entire plant content and expressed by weight. Therefore, the ECDD's report expressed its threshold of 0.2% delta-9-THC as a proportion of the entire plant content.

It is important to note that the amount of delta-9-THC as a proportion of the total weight of the finished product (w/w of the finished product), will be much lower as a result of the addition of excipients to the cannabis plant extract. However, and in order to prevent confusions, and as other manufacturers may in the future use different amounts or types of excipients, it is important to specify the delta-9-THC content relative to the entire plant content by weight which includes CBD and other cannabis compounds.

With regard to the conversion of CBD to THC mentioned, this method was described in a scientific paper over 50 years ago (Gaoni, Y. and R. Mechoulam, Hashish-VII. The isomerization of cannabidiol to tetrahydrocannabinols. Tetrahedron Vol. 22. 1966. 1481-1488) and has been subject of a patent application. The method is not simple, the yield is uncertain, as are the by-products and their side-effects. There have been no published reports that this method has been used illicitly for the production of THC.

c) Written answers circulated on 4 October 2019

<b>European Union</b>	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?
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**Answer by WHO**

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>European Union</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'.
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**Answer by WHO**

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."

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>European Union</b>	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?
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#### Answer by WHO

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.

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>European Union</b>	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?
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#### Answer by WHO

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.

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>European Union</b>	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.
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#### Answer by WHO

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>European Union</b>	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?
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### Answer by WHO

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.

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>European Union</b>	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?
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### Answer by WHO

WHO refers this question to INCB and UNODC

### Answer by UNODC

UNODC is not in the position to define which "low-THC products" would be regulated under the 1961 or the 1971 Conventions. None of those treaties, as they stand, define concentration levels of preparations of cannabis or cannabis resin or of THC, or of any related products (please note that "preparation" is defined as "a mixture, solid or liquid, containing a drug"). Also in the 1971 Convention, there is no reference to a threshold below which THC would not be subject to control measures.

The WHO, within its functions under article 3 of the 1961 Convention and article 2 and 3 of the 1971 Convention, made some recommendations that appear to indicate that the definition of parameters may be positive from a public health perspective. We understand that WHO is the appropriate body to address the question of the health impact of different concentration levels of cannabinoids in different preparations.

From a legal perspective, as explained in our reply to the preceding question, different interpretations have been held by different States parties.

<b>European Union</b>	8) 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
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	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.
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### Answer by UNODC

Art. 28, paragraph 1, of the 1961 Convention addresses the cultivation of the cannabis plant “for the production of cannabis or cannabis resin”. Thus, the interpretation of the provision also depends on the definitions of cannabis and cannabis resin, which are provided in article 1 of the Convention.

If, following the WHO recommendation 5.5., a footnote was added to Schedule I clarifying that preparations of cannabis or cannabis resin containing predominantly CBD and not more than 0.2% of delta-9-tetrahydrocannabinol would be excluded from international control, this would, in consequence, affect the scope of article 2, paragraph 3, when applicable to preparations of cannabis.

The scope of article 28, paragraph 1, of the 1961 Convention would in principle not be modified in relation to the way States parties currently implement that provision. Article 28 would continue to apply to the cultivation of the cannabis plant for the production of cannabis and cannabis resin, as understood today, to the extent that only “preparations” fulfilling the conditions described in the footnote would be excluded from international control.

Some countries hold the interpretation, based on the object and purpose of the treaty provisions, that preparations derived from cannabis that are not psychoactive (i.e. rich in CBD and very poor in THC content), would already now fall outside the scope of control of the Convention. This can also be seen as an analogy to or a consequence of the exclusion of control over cannabis for industrial purposes, where countries in practice limit the THC threshold admissible for cannabis grown for such purposes.

Equally, other countries follow a more literal interpretation and apply control measures to preparations of CBD, no matter how poor they would be in THC content, recognizing that they fall under the definition of preparations of cannabis or cannabis resin under the 1961 Convention. These countries may likely continue adopting the same interpretation irrespective of whether THC would be controlled under the 1961 Convention or continue to be controlled under the 1971 Convention. Recommendation 5.5. would seek to clarify that CBD preparations falling under the scope of the proposed footnote, would be excluded from international control.

The provision of article 28, paragraph 3, of the 1961 Convention, that requires Parties to adopt measures to prevent the misuse of, and illicit traffic in the leaves of the cannabis plant, would continue to apply.

<b>European Union</b>	9) 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?
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### Answer by UNODC

Art. 28, paragraph 1, of the 1961 Convention addresses the cultivation of the cannabis plant “for the production of cannabis or cannabis resin”. Thus, the interpretation of the provision also depends on the definitions of cannabis and cannabis resin, which are provided in article 1 of the Convention.

If, following the WHO recommendation 5.5., a footnote was added to Schedule I clarifying that preparations of cannabis or cannabis resin containing predominantly CBD and not more than 0.2% of delta-9-tetrahydrocannabinol would be excluded from international control, this would, in consequence, affect the scope of article 2, paragraph 3, when applicable to preparations of cannabis.

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cannabis plant for the production of cannabis and cannabis resin, as understood today, to the extent that only “preparations” fulfilling the conditions described in the footnote would be excluded from international control.

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Equally, other countries follow a more literal interpretation and apply control measures to preparations of CBD, no matter how poor they would be in THC content, recognizing that they fall under the definition of preparations of cannabis or cannabis resin under the 1961 Convention. These countries may likely continue adopting the same interpretation irrespective of whether THC would be controlled under the 1961 Convention or continue to be controlled under the 1971 Convention. Recommendation 5.5. would seek to clarify that CBD preparations falling under the scope of the proposed footnote, would be excluded from international control.

The provision of article 28, paragraph 3, of the 1961 Convention, that requires Parties to adopt measures to prevent the misuse of, and illicit traffic in the leaves of the cannabis plant, would continue to apply.

<b>Norway</b>	<p>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.</p> <p>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.</p> <p>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?”</p> <p>Norway therefore propose this wording of the footnote:</p> <p><b><i>“Preparations from cannabis containing not more than 0,2 percent of delta-9-tetrahydrocannabinol, are not under international control”</i></b></p> <p>Will this be in line with WHO's intentions?</p>
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### Answer by WHO

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.



<b>Singapore</b>	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?
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### Answer by WHO

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 & IV) and as an extract or tincture of cannabis (Schedule I).

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.

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.

The option of a footnote was adopted after recognition of the precedents of exclusion of dextromethorphan and dextropropoxyphene 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.

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.

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.

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>United States</b>	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
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	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.
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### Answer by WHO

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.

<b>United States</b>	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?
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### Answer by WHO

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.

<b>United States</b>	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?
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### Answer by WHO

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>United States</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.”
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#### Answer by WHO

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>United States</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?
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#### Answer by WHO

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>United States</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?
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#### Answer by WHO

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>United States</b>	7) In lieu of a footnote, what other methods are available to clarify that preparations predominantly containing cannabidiol are not under international control?
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#### Answer by WHO

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>United States</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?
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#### Answer by WHO

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).

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>United States</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?
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#### Answer by WHO

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.

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.

The option of a footnote was adopted after recognition of the precedents of exclusion of dextromethorphan and dextrophan from control by this means.

<b>United States</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?
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### Answer by WHO

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>United States</b>	11) Is an active pharmaceutical ingredient which may contain trace impurities of a controlled substance considered a preparation of that controlled substance under the Conventions?
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### Answer by UNODC

According to art. 1 (s) of the 1961 Convention, a preparation is “a mixture, solid or liquid, containing a drug”.

According to art. 1 (f) of the 1971 Convention, a preparation is “(i) any solution or mixture, in whatever physical state, containing one or more psychotropic substances or (ii) one or more psychotropic substances in dosage form”.

These definitions may suggest that impurities of a controlled substance could be sufficient to determine the application of the provisions of the Convention for preparations of that controlled substance. The Convention does not contain provisions that would allow for differentiating between ‘impurities’ and ‘ingredients’, or for the determination of specific concentration requirements.

According to an interpretation of the Convention that is based on its object and purpose, the answer to this question would be dependent on the concentration of the “trace impurities”. According to this interpretation, if there would be no possibility of misuse or recovery of the drug component, this could not be considered as a preparation of that drug.

A Party following a more literal interpretation could theoretically consider a preparation containing any level of trace impurities of a drug as a preparation of that drug.

<b>United States</b>	12) 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?
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### Answer by UNODC

In our view, the question does not provide for enough elements for a specific answer. Generally speaking, it is not “necessary” for the Commission to hold any vote. It is up to the Commission to decide on whether to do so. Furthermore, the World Health Organization would not be expected to make a recommendation for the Commission not to schedule a substance that is not yet under international control, in a scheduling proceeding initiated by the WHO itself.

<b>United States</b>	13) 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?
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### Answer by UNODC

The same question was made to the WHO, which is responsible for the recommendation, and we refer to its answer.

<b>United States</b>	14) In lieu of a footnote, what other methods are available to clarify that preparations predominantly containing cannabidiol are not under international control?
	15) 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?
	16) 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?

### Answer by UNODC

We should note that the understanding expressed by the World Health Organization in the context of some of its recommendations, and that of various States parties, is that cannabidiol is a controlled substance, as a preparation of cannabis.

There are different ways to clarify the issue, which would be for the States members of the Commission to determine. One option could be for the CND to make an interpretative decision, under its policy-making authority. Such decision would serve as guidance, but not be binding on the Parties.

Footnotes have been used in schedules in the past. For example, a footnote was used to specifically exclude substances from schedules (example: dextromethorphan and dextrorphan, under the substance levomethorphan, in schedule I of the 1961 Convention); to include isomers, esters and ethers and salts, or stereoisomers in the 1971 Convention; or to exclude salts of hydrochloric acid and sulphuric acid from Table II of the 1988 Convention.

#### e) Written answers circulated on 26 November 2019

<b>China</b>	1) Please provide supplementary experimental data on the non-psychoactive properties of cannabidiol. Since WHO has not yet provided laboratory research data on the non psychoactive properties of cannabidiol, please provide relevant supplementary research and data. Also, since current information indicates that cannabidiol preparations usually contain trace amounts of tetrahydrocannabinol (THC), please
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	provide related research reports or experimental data establishing the dependence potential of cannabidiol preparations containing trace quantities of THC.
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### Answer by WHO

The evidence regarding the lack of psychoactive effects of cannabidiol is summarised in the critical review published as part of the 40th meeting of the ECDD in 2018. In brief, that evidence includes the following: Cannabidiol

- does not bind to CB1 receptors
- does not produce THC-like effects in a range of animal models
- does not produce THC-like effects in humans
- shows no evidence of abuse potential in human studies; for example, in a measure of subjective effects it shows no difference from placebo.

More detail as well as references can be found in the critical review available at: ([https://www.who.int/medicines/access/controlled-substances/ecdd\\_40\\_meeting/en/](https://www.who.int/medicines/access/controlled-substances/ecdd_40_meeting/en/)).

In clinical trials of cannabidiol that contain trace amounts of THC there is no evidence of THC effects or of abuse potential. These trials are also discussed in the critical review.

<b>China</b>	2) Whether WHO intends to restrict other cannabis compounds (e.g. cannabinoids other than THC) and non-cannabis substances present in the CBD preparations concerned, and if so, whether such intention should be clearly spelt out (e.g. by making reference to paragraph 3 of Schedule III to the 1961 Convention, which states “provided that such preparations do not contain any substance controlled under the 1971 Convention on Psychotropic Substances”).
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### Answer by WHO

There are no known cannabinoids with sufficient pharmacological activity and that occur at sufficient concentrations in cannabis that would produce effects due to their presence in a cannabis preparation that was predominantly cannabidiol. There is therefore no need to restrict other cannabinoids.

The only other controlled cannabinoids (excluding synthetic compounds) are the isomers of delta-9-THC. These do not occur naturally in the cannabis plant (one may occur at very low concentrations, but this is not yet certain).

<b>European Union</b>	It is not clear why there is need for a more extensive exception for preparations containing predominantly cannabidiol than for any other narcotic substance. Why is a more extensive exception needed, considering that: <ol style="list-style-type: none"> <li>it could have negative implications for the possibility to prosecute personal consumption of cannabis in states parties where this constitutes a criminal offence and</li> <li>the criminalisation of the personal consumption of cannabis is purely a national matter?</li> </ol>
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### Answer by WHO

The recommended exemption from control of cannabidiol is because it does not satisfy the criteria for control under either the 1961 Convention or the 1971 Convention. As it does not satisfy the 1961 criteria it cannot be considered narcotic.

This exemption refers only to international control. Should the recommendation be accepted, its implementation will not prevent any country from controlling cannabidiol or cannabidiol preparations.

<p><b>Japan</b></p>	<p>Is there no possibility for the risk of substance abuse to increase due to exempt all CBD from the Conventions? Technically, as Russian Federation pointed out, CBD has a potential to be easily converted to THC even if there have been no published reports that the method has been used illegally for converting CBD to THC.</p> <p>Therefore, we would like to suggest you to exempt, for example, only medical applications from the restriction in order to minimize the risk of drug abuse.</p> <p>Furthermore, WHO does not seem to consider that the conversion of CBD to THC has a public health risk according to the response to the question from Russian Federation. However, a high-yield method for conversion of CBD to THC is published in 2008 (Webster et al. CONVERSION OF CBD TO Δ8-THC AND Δ9-THC. U.S. Patent 7,399,872 B2). Although the methods are different, doesn't WHO still consider that the CBD conversion to THC has a significant risk of public health?</p>
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**Answer by WHO**

The 1961 Single Convention allows for control of a substance if the substance is convertible into a drug (Article 3 para 3(iii)). The Commentary to the Convention makes it clear that the method of conversion should not just be a theoretical one, but must be such that it can be performed “with relative ease” (paras 10 and 11, pp. 88-89) and that the method “must be of such a kind as to make it, by the ease of the process and by the yield, practicable and profitable for a clandestine manufacturer to transform the substance in question into controlled drugs” (para 13, p. 89).

None of the available methods, including the 2008 patented method, could be considered to convert CBD to THC with relative ease. It is also highly unlikely that this would be considered a practicable method for drug traffickers and nor would it be profitable considering the low costs of producing high THC products from the cannabis plant.

<p><b>Russian Federation</b></p>	<p>Even though CBD does not satisfy criteria for control conditions, it might be relatively easy converted into controlled cannabinoids. Don't you think it might therefore be considered as a sort of precursor?</p>
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**Answer by WHO**

The 1961 Single Convention allows for control of a substance if the substance is convertible into a drug (Article 3 para 3(iii)). The Commentary to the Convention makes it clear that the method of conversion should not just be a theoretical one, but must be such that it can be performed “with relative ease” (paras 10 and 11, pp. 88-89) and that the method “must be of such a kind as to make it, by the ease of the process and by the yield, practicable and profitable for a clandestine manufacturer to transform the substance in question into controlled drugs” (para 13, p. 89).

None of the available methods, including the 2008 patented method, could be considered to convert CBD to THC with relative ease. It is also highly unlikely that this would be considered a practicable method for drug traffickers and nor would it be profitable considering the low costs of producing high THC products from the cannabis plant.



<b>United States</b>	<p>An essential element of recommendation 5.5, as described by the WHO/ECDD during the intersessional meeting, is not reflected in the recommendation text submitted to the Secretary General. Specifically, the text of the recommendation pertaining to cannabidiol preparations does not specify that the 0.2% delta-9-THC threshold is intended to be calculated on a dry weight basis relative to the dried plant material, as has been explained by WHO/ECDD. Pursuant to the Single Convention on Narcotic Drugs, the options available to the Commission in such a case are limited: we can vote to approve the recommendation, vote to reject it, or delay acting until the WHO/ECDD sends the Commission text that accurately reflects the WHO/ECDD intent.</p> <p>1) It has been suggested that the CND can amend the recommendation to fix a technical omission - Could the UNODC Secretariat clarify? Is there any precedent that could be cited?</p>
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### Answer by UNODC

While more information would be needed on the nature of the “technical omission”, the 1961 Single Convention on Narcotic Drugs does not provide for a scenario in which the Commission could amend a recommendation by the WHO. It would be important to ensure that the treaty roles of the WHO and of the Commission are observed. Under article 3 of the 1961 Convention, the Commission “may, in accordance with the recommendation of the World Health Organization”, decide that the substance shall be added to one of the schedules, or that schedules should be amended by transferring a drug between Schedules I and II or by deleting a drug or a preparation from a Schedule. There is no precedent in which the Commission has modified the text of a recommendation by the WHO.

<b>United States</b>	<p>2) If the Commission does not appear to have the authority to correct a WHO/ECDD recommendation submitted to it, could the WHO/ECDD at its next meeting adjust such a recommendation and send it to the CND before the March meeting?</p>
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### Answer by UNODC

It would be possible and up to the WHO to consider whether it would find necessary to modify the text of its recommendations. Until the time that new or modified recommendations on the same subject are made, the Commission would be expected to act on the recommendations that have been communicated to it. Before taking a vote to place a substance under international control or to reschedule a substance, according to recommendations that have been received, the Commission may seek further information from the WHO or from other appropriate sources. With regard to dronabinol, in a proceeding under the 1971 Convention, the Commission has taken in the past decision 50/2, by which it decided not to vote on the recommendation of the WHO and to request the WHO to undertake further review of dronabinol and its stereoisomers when additional information became available. While, differently from the 1971 Convention, the option to seek further information is not explicitly addressed in the text of the 1961 Convention, there would be no element to prevent the Commission from taking that course of action, if it so decided.

<b>United States</b>	<p>3) Alternatively, is there another way to modify the text of the recommendation to remove the ambiguity?</p>
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### Answer by UNODC

Under article 3, paragraphs 3 to 6, of the 1961 Convention, the Commission is required to take decisions on recommendations of the WHO as presented to it. This may include a decision not to vote on a given

recommendation. The Commission does not have a mandate to modify the recommendations by the WHO. However, the Commission may make interpretative decisions, under its policy-making authority, to clarify issues raised in recommendations, or even arising from the interpretation and application of the international drug control conventions. Such decisions would not be scheduling decisions per se, and could serve as non-binding guidance. It is also possible for a State Party to initiate new scheduling proceedings pursuant to article 3(1) of the 1961 Convention.

<p><b>United States</b></p>	<p>The WHO has stated that CBD is not controlled, if the CBD is produced synthetically or if it is derived from cannabis plants produced for industrial or horticultural purposes.</p> <p>4) It is our understanding that synthetically produced CBD will contain some quantity of synthetic THC, currently controlled under the 1971 Convention. By moving THC to the 1961 Convention, does this distinction disappear? Does the INCB agree that synthetically produced CBD is not currently controlled?</p>
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**Answer by WHO**

The amount of THC in synthetically produced cannabidiol will be extremely small. If the recommendation to exclude from control preparations of cannabidiol containing not more than 0.2% of THC is adopted, then these products will be exempt from control. It is not clear how the recommendations relating to the transfer of THC to the schedules of the 1961 Convention would affect this.

**Answer by INCB**

The INCB is not given any formal role under the procedure outline in article 3 of the Single Convention but it must give effects to the decision of the Commission in the performance of its treaty function.

<p><b>United States</b></p>	<p>5) As explained by the WHO/ECDD, the intent of its recommendation to add a footnote was to address the scientific finding and conclusion related to cannabidiol: specifically that CBD does not have psychoactive properties, is not liable to abuse, and does have medical utility. Under these circumstances, we agree that control of CBD under the Single Convention would not appear to be consistent with the aims of the Convention; however, we have questions concerning the WHO/ECDD's interpretation of the Single Convention, as it applies to preparations containing cannabis or cannabis resin. Under the Single Convention, "cannabis" and "cannabis resin" are both a "drug." Furthermore, the Single Convention defines "preparation" as a mixture, solid or liquid, containing a drug, "whether natural or synthetic." Given the definition(s) above, it would appear that preparations containing cannabis or cannabis resin, while not specifically mentioned in the schedules, are in fact subject to the controls of schedule I of the Single Convention. It would be helpful if the INCB could share their view of this provision.</p>
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**Answer by INCB**

Again, the INCB is not given any formal role under the procedure outline in article 3 of the Single Convention but it must give effects to the decision of the Commission in the performance of its treaty function.

<b>United States</b>	6) Would the INCB agree that based on the above, if preparations containing naturally derived cannabis are already subject to the controls of the Single Convention, it is not necessary to schedule THC separately under the Single Convention for naturally occurring THC to be controlled? This would include preparations such as butane hash oils, where butane is used to extract cannabis resin from the plant.
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#### Answer by INCB

Again, the INCB is not given any formal role under the procedure outline in article 3 of the Single Convention but it must give effects to the decision of the Commission in the performance of its treaty function.

<b>United States</b>	7) The definitions of "cannabis" and "cannabis resin" in the Single Convention are described as either "of" or "obtained from" the cannabis plant, and thus do not include chemical compounds not derived from the cannabis plant. Would the ECDD agree that, notwithstanding usage in the scientific community, the substance controlled under the 1971 Convention is THC not already under control, that is, synthetically occurring THC? Would it be helpful if the Commission issued clarifying guidance to this effect?
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#### Answer by WHO

The entry in Schedule II of the 1971 Convention for dronabinol is as follows:

DRONABINOL	<i>delta</i> -9-tetrahydro-cannabinol and its stereochemical variants	<i>(6aR,10aR)</i> -6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6 <i>H</i> -dibenzo[ <i>b,d</i> ]pyran-1-ol
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The chemically identified substance is present in the cannabis plant and is produced synthetically. The description does not allow identification or differentiation of the source of the substance.

<b>United States</b>	8) Further, does the ECDD agree that based on the above, the same thread applies to CBD, and accordingly, unless the Commission takes specific action to amend the scheduling of cannabis and cannabis resin to reflect the exclusion of non-psychoactive compounds having no liability to abuse, that CBD will remain subject to the same controls as the cannabis from which it is derived?
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#### Answer by WHO

Similar to dronabinol, cannabidiol is identified according to its chemical structure which does not differ between plant and synthetic sources. The exemption for cannabidiol would therefore include the substance obtained from the plant and that which is produced synthetically.

<b>United States</b>	9) The recommendation of the ECDD to remove CBD with .2% THC addresses the issue of THC when present in CBD but does the ECDD agree that this remedy does not expressly remove CBD from control under the Single Convention? An amendment to the schedules noting that the controls do not extend to compounds found by the WHO/ECDD to be non-psychoactive, such as CBD, would not address the problem of CBD containing small amounts of THC. Given that many governments have already identified a threshold for THC content below which a preparation will not be considered as requiring control, and the Conventions acknowledge the principle that the definitions
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	of offenses are to be consistent with the domestic law of each state party, could the intent of the ECDD be achieved by acknowledging that each party may decide whether to establish a threshold, and if it does so, to determine what that threshold should be?
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**Answer by WHO**

The ECDD considered and was advised that the exemption specified in the footnote would exempt cannabidiol preparations from control under the 1961 Convention in a similar way that dextromethorphan and dextrorphan are exempt from control based on their respective footnotes.

The ECDD based its recommendation on evidence concerning the lack of abuse and dependence potential of cannabidiol generally and of cannabidiol preparations containing 0.15% delta-9-THC. Consideration was also given to requests from Member States for guidance on appropriate levels of delta-9-THC allowed in cannabidiol preparations. The specified level relates to that used for international control purposes. Member States may be able to use different control criteria for internal country purposes.

<b>United States</b>	10) Finally, if THC was added to the 1961 schedule, would that not add to the confusion concerning the control of CBD, which, although not listed, would still be subject to controls absent some action by the CND since CBD might contain the threshold amount of THC?
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**Answer by WHO**

Based on the recommendations, a preparation containing predominantly CBD but less than the specified amount of THC is not controlled. If the THC threshold is exceeded then that preparation is controlled, but this does not mean that CBD as a substance is controlled, only those preparations that contain THC above the threshold amount.

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

**Recommendation 5.6:** The Committee recommended that preparations containing delta-9-tetrahydrocannabinol (dronabinol), 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-tetrahydrocannabinol (dronabinol) 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 1961 Convention.

a) Written answers circulated on 2 July 2019

<b>Argentina</b>	<p>1) With respect to the proposal concerning pharmaceutical preparations: are such preparations considered to include preparations used for scientific purposes?</p> <p>2) What is the basis for and purpose of the recommendation relating to pharmaceutical preparations?</p>
<b>Canada</b>	<p>With respect to recommendation 5.6, the committee recommended that preparations containing delta-9-THC (dronabinol) that are compounded as pharmaceutical preparations in such a way that delta-9-THC (dronabinol) 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 1961 Convention on Narcotic Drugs. Canada notes that the 1961 Single Convention on Narcotic Drugs does not distinguish between “pharmaceutical preparations” – understood as substances subject to pre-market review process – and other types of preparations.</p> <p>1) By means of this recommendation, does the committee introduce a distinction between preparations subject to pre-market approval (e.g. SATIVEX and MARINOL) and other types of cannabis-derived preparations?</p> <p>2) Why did the committee specify “pharmaceutical preparations”, as opposed to “preparations compounded in such a way that delta-9-THC (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health”?</p>
<b>China</b>	<p>1) What is the definition of “pharmaceutical preparations”, and what would be the demarcation that distinguishes between pharmaceutical and other preparations</p> <p>2) Elaboration on the evidence which shows that the use of the pharmaceutical preparations containing delta-9-THC mentioned (“Sativex”, “Marinol” and “Syndros”) are not associated with problems of abuse and dependence and they are not diverted for non-medical use</p> <p>3) Whether it is necessary to set objective and quantifiable limits for the amount of delta-9-THC allowed in the preparations concerned, like other substances listed in Schedule III</p> <p>4) Whether there are any objective and scientific standards to determine “readily available means” and “risk to public health”</p> <p>5) Whether it is the intention of WHO to restrict the other substances that may be present in the preparations concerned, and if so, whether such substances could be spelt out in the Recommendation (e.g. by making reference to paragraph 3 of Schedule II which states, “provided that such preparations do not contain any substance controlled under the 1971 Convention on Psychotropic Substances”)</p>
<b>European Union</b>	<p>1) The description is susceptible to different interpretations. All other exempted preparations in Schedule III are linked to minimal concentrations/dosages, which are clear. Can the WHO explain why this description is vague and not related to quantities as it is for other exempted preparations in Schedule III?</p> <p>It is unclear whether cannabis-based drug preparations can be covered by the exception because the active substance does not need to be extracted from the</p>

	<p>product for it to be administered. The proposal to add preparations without concentration limits in Schedule III of the 1961 Convention seems to be new praxis. It is not done for any other substance. Why is a more extensive exception needed? Why aren't concentration limits included in the recommendation?</p> <p>Which would be the quantity limit of <math>\Delta</math>9-THC per unit dose, or <math>\Delta</math>9-THC percentage limit in non-divided presentations, that should contain those preparations according to the pattern already established in preparations currently listed in Schedule III of the 1961 Convention on Narcotic Drugs, such as the codeine, cocaine, opium or morphine preparations?</p>
	<p>2) This kind of preparations can be abused, certainly if patients do not use them in a correct way. Some extracts of the Summarize of Products Characteristics of Sativex (SmPC) state the following: Patients who have a history of substance abuse, may be more prone to abuse Sativex as well (see section 5.1). In a study designed to identify its abuse potential, Sativex at a dose of 4 sprays taken at one time did not differ significantly from placebo. Higher doses of Sativex of 8 to 16 sprays taken at one time did show abuse potential comparable to equivalent doses of dronabinol, a synthetic THC. In a QTc study a dose of Sativex 4 sprays over 20 minutes twice daily was well-tolerated, but a substantially supratherapeutic dose of 18 sprays over 20 minutes twice daily resulted in significant psychoactivity and cognitive impairment. We do not find it appropriate to exempt preparations if their SmPC reveals possible abuse. Can the WHO explain why the information in the SmPC has been ignored?</p>
<b>Japan</b>	<p>The range and scope of "pharmaceutical preparations" to be included in this category is not clear. This can lead to a risk that preparations which produce ill-effects, dependence and abuse potential and/or which do not have enough therapeutic evidences can be included in this category. How did WHO assess that risk?</p> <p>The following actions are necessary to address the risk.</p> <ul style="list-style-type: none"> <li>- A threshold of concentration of delta-9-THC should be applied to "pharmaceutical preparations of cannabis and delta-9-THC" in as the same manner to other preparations currently placed in Schedule III. The appropriate threshold of concentration needs to be proposed by WHO/ECDD after additional study on it.</li> <li>- In order to clarify the definition of "pharmaceutical preparation", the condition such as "pharmaceutical preparations approved by competent authorities" should be added.</li> </ul>
<b>Singapore</b>	<p>1) By what means can it be determined whether <math>\Delta</math>9-THC (dronabinol) can or cannot be recovered by readily available means, or whether the yield would constitute a risk to public health? Are there any international standards or methodologies to enable laboratories or competent authorities make this determination?</p> <p>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?</p> <p>3) Does the Committee intend to recommend a 'per dosage unit' of <math>\Delta</math>9-THC and the 'concentration level' for this preparation, in line with how preparations are currently described in Schedule III of the 1961 Convention?</p> <p>4) Does the Committee intend to recommend the insertion of a definition of the term 'pharmaceutical preparation' to guide Member States' interpretation of the type of <math>\Delta</math>9-THC preparations that would be caught under Schedule III of the 1961 Convention?</p> <p>5) Does the Committee intend to make recommendations as to how Member States may determine if a risk to public health is constituted? If <math>\Delta</math>9-THC is recovered from a preparation in a yield that would constitute a risk to public health, would such a preparation be considered a 'preparation' within the meaning of Article 2, paragraph 4 of the 1961 Convention?</p> <p>6) Could the Committee clarify if the 'preparations' in both Recommendations 5.5 and 5.6 are intended to be confined to preparations for therapeutic (ie, medicinal) use which have been scientifically tested for safety and efficacy?</p>

<b>Thailand</b>	Regarding the article “Preparations produced either by chemical synthesis or as preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that delta-9-tetrahydrocannabinol (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health”, dronabinol will be added to Schedule 3 of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol. Because the article mentions that the pharmaceutical formulations must be made from only substances in Schedule 1, will dronabinol still possibly be used for the formulations?
<b>United States</b>	<p>1) These preparations are already controlled under article 3.2 of the 1971 Convention as preparations containing delta-9-THC. Is this recommendation meant to be contingent on approval of the recommendation to move delta-9-THC to the 1961 Convention?</p> <p>2) If so, can we adjust the language of the recommendations to make that clearer?</p>

### Answer by WHO

Preparations in Schedule II of drugs controlled in Schedule I or Schedule II of the 1961 Convention are exempted from some of the requirements for control of those drugs. However, they are still subject to a significant level of control.

Article 2 para 3 of the 1961 Single Convention states:

*Preparations in Schedule III are subject to the same measures of control as preparations containing drugs in Schedule II, except that article 31, paragraphs 1 (b) and 3 to 15 and, as regards their acquisition and retail distribution, article 34, paragraph (b), need not apply, and that for the purpose of estimates (article 19) and statistics (article 20,) the information required shall be restricted to the quantities of drugs used in the manufacture of such preparations.*

This makes clear that the exemption for Schedule II products is for some of the requirements only, and not an exemption from control.

The Committee considered the evidence regarding pharmaceutical preparations, including Sativex®. Based on conventional usage of the term, pharmaceutical preparations are those that are used for defined medical purposes and therefore that are in dosage forms appropriate for such medical use.

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 and as addressed in their national legislation.

The evidence from medical use of these preparations shows that they were not associated with abuse or dependence.

This recommendation is still relevant if the recommendation to move dronabinol (delta-9-THC) to the 1961 Convention is not supported, as the medications may contain dronabinol derived from the cannabis plant and therefore qualify as preparations of cannabis. As they would therefore be subject to control under the 1961 Convention, inclusion of the pharmaceutical preparations in Schedule II is still appropriate.

The pharmaceutical preparations recommended to be placed under Schedule III have dronabinol as the active ingredient and the recommended dosage will vary according to factors such as the conditions being treated and patient history.

### Answer by INCB

The ECDD recommends that preparations containing  $\Delta$ 9-THC (dronabinol), produced either by chemical synthesis or as a preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that delta-9-tetrahydrocannabinol (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health, be added to Schedule III of the 1961 Convention on Narcotic Drugs.

It is not clear to the secretariat to which preparations this would apply. The term “compounded pharmaceutical preparations” is applicable to a large number of preparations. It is not defined what “readily available means”. The convention states that if the drug in the preparations “is not readily recoverable”, the Commission may, in accordance with the recommendation of the World Health Organization, add that preparation to Schedule III.

If this recommendation is endorsed by the Commission on Narcotic Drugs, the inclusion of these drugs in Schedule III will eliminate the need for controls, such as those applicable to the international trade of these preparations but not for the controlled substance contained in the preparations ( $\Delta$ 9-THC). Manufacture of  $\Delta$ 9-THC will need to be monitored and Governments will have to report statistics on its utilization for Schedule III preparations.

The endorsement of the recommendations made under sections V and VI will reduce controls over most preparations containing THC and CBD. Should Member States decide to endorse them, additional guidance would need to be provided to ensure a common understanding and uniform application of the requirements of the conventions by Member States.

b) Written answers circulated on 30 July 2019

<b>Mexico</b>	1) Could you reconfirm that the statement “There is no difference in the therapeutic effects or adverse effects of synthetic $\Delta$ 9-THC compared to $\Delta$ 9-THC from the Cannabis plant”, refers exclusively to the current/known versions of synthetic $\Delta$ 9-THC approved for medical use? Hence, would it be safe to affirm that new versions of synthetic $\Delta$ 9-THC should be addressed on their own?
	2) Could you elaborate further on what would be covered by the term “pharmaceutical preparations of Cannabis” in relation to this recommendation?
<b>Pakistan</b>	1) What is the scientific evidence to prove that benefits of research and utilization of preparations of cannabis are greater than its risks.
	2) what are the areas and aspects which need further research and investigation for enabling the Member States to reach consensus and understanding on the way forward on this issue.

**Answer by WHO**

“Pharmaceutical preparations” refers to substances that are intended for medical use and that are, therefore, in dosage forms appropriate for such medical use.

These pharmaceutical preparations encompass the ones requiring pre-market approval and the ones produced extemporaneously according to a prescription and to agreed food 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.

With respect to the statement referred to above [by Mexico], “There is no difference in the therapeutic effects or adverse effects of synthetic  $\Delta$ 9-THC compared to  $\Delta$ 9-THC from the Cannabis plant”, it should be noted that dronabinol is the international non-proprietary name for (-)- $\Delta$ 9-THC, whether it is found naturally in the cannabis plant or produced synthetically.



Delta-9 THC pharmaceutical preparations are typically consumer through oral administration. Placement of pharmaceutical preparations of cannabis and dronabinol in Schedule III would require that delta-9-THC is not readily recoverable, which means that it cannot be used as a vapor inhalation method or smoking method as other non-medical delta-9 THC preparations described.

With respect to the question on comparing the benefits of research and utilization of preparations of cannabis versus their risks, it is beyond the mandate of the ECDD to make this comparison. However, under section 5.1 in this document, it is said that the ECDD recommended to maintain cannabis and cannabis preparations under Schedule I because of similar abuse potential to cannabis and similar ill effects as other substances under schedule I.

ECDD also acknowledges the recognised scientific evidence for therapeutic use of cannabis preparations in important conditions such as the management of pain and of muscle spasticity in multiple sclerosis.

In all areas of public health, research that is based on robust scientific evidence is needed to ensure better health and wellbeing for people, in particular the most vulnerable. Scientific research on the use of cannabis is no exception and there are currently several hundreds of clinical trial that are being performed to explore efficacy and safety profiles of cannabis for therapeutic use.

c) Written answers circulated on 4 October 2019

<b>European Union</b>	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?
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**Answer by WHO**

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.

There are no implications for the control of "non-medicinal edibles" arising from this recommendation.

<b>European Union</b>	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?
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**Answer by WHO**

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.

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>European Union</b>	3) Why is the text that mentions abuse potential in the summary of product characteristics not considered relevant in making this recommendation?
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#### Answer by WHO

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.

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>European Union</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.
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#### Answer by WHO

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>European Union</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?
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#### Answer by WHO

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>Singapore</b>	<p>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:</p> <p>(a) how can Member States determine whether <math>\Delta</math>9-THC (dronabinol) can or cannot be recovered by “readily available means”, or whether the yield would constitute a risk to public health?</p> <p>(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?</p>
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### Answer by WHO

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>Singapore</b>	<p>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?</p>
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### Answer by WHO

The proposed entry would be as follows:

#### *Dronabinol*

*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.*

<b>Singapore</b>	<p>3) Does the Committee intend to recommend a ‘per dosage unit’ of <math>\Delta</math>9-THC and the ‘concentration level’ for this preparation, in line with how preparations are currently described in Schedule III of the 1961 Convention?</p>
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### Answer by WHO

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.

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.

<b>Singapore</b>	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?
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### Answer by WHO

- (a) 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).

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).

- (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.

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>United States</b>	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?
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### Answer by WHO

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.

<b>United States</b>	2) The recommendation says that preparations containing Delta 9 THC produced either by chemical synthesis or as preparations of cannabis that are compounded as
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	<p>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?</p>
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### Answer by WHO

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.

<b>United States</b>	<p>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.</p>
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### Answer by WHO

Indeed, certain preparations containing predominantly CBD and less than 0.2% delta-9-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. 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>United States</b>	<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>
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### Answer by WHO

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.

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.

The option of a footnote was adopted after recognition of the precedents of exclusion of dextromethorphan and dextropropranolol from control by this means.

d) Written answers circulated on 26 November 2019

<b>China</b>	<p>1) Article 3(4) of the 1961 Convention reads –          “If the World Health Organization finds that a preparation because of the substances which it contains is not liable to abuse and cannot produce ill effects (paragraph 3) and that the drug therein is not readily recoverable, the Commission may, in accordance with the recommendation of the World Health Organization, add that preparation to Schedule III.”</p> <p>It appears that in recommending a substance to be placed in Schedule III, WHO should have found it to have met the criteria in Article 3(4). The current formulation in Recommendation 5.6, with no objective and quantifiable limits of THC, can apply to a large variety and number of preparations beyond “Sativex”, “Marinol” and “Syndros”. WHO may wish to clarify whether such application is possible, and whether the absence of liability to abuse and ill effects of such products has already been established in accordance with Article 3(4).</p>
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**Answer by WHO**

Based on conventional usage of the term, pharmaceutical preparations are those that are used for defined medical purposes and therefore that are in dosage forms appropriate for such medical use. 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. The recommendation applies to pharmaceutical products that can include preparations other than those mentioned in the question. It was considered that individual Member States will have their own criteria for assessing whether a product is for medical use and as addressed in their national legislation.

The Committee considered that it was not necessary to recommend a maximum content of dronabinol, 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>China</b>	<p>2) Whether it is the intention of WHO to restrict the other substances that may be present in the preparations concerned, and if so, whether such substances could be spelt out in the Recommendation (e.g. by making reference to paragraph 3 of Schedule III which states, “provided that such preparations do not contain any substance controlled under the 1971 Convention on Psychotropic Substances”).</p>
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**Answer by WHO**

The only other controlled cannabinoids (excluding the synthetic cannabinoids controlled under Schedule II of the 1971 Convention such as AB-CHMINACA and 5F-APINACA) are the isomers of THC that are controlled under Schedule I of the 1971 Convention. These do not occur naturally in the cannabis plant (one may occur at very low concentrations, but this is not yet certain).

<b>European Union</b>	The recommendation of WHO to move pharmaceutical preparations of cannabis and dronabinol to Schedule III of 1961 convention can be justified with limited availability of crucial medicines. Is there evidence that there is availability issues of pharmaceutical preparations of cannabis and dronabinol? Is there evidence for extensive use of pharmaceutical preparations of cannabis and dronabinol for the therapeutic indications marked on the marketing authorisation of currently available medicines or is increasing of prescribing these products for aforementioned indications foreseen?
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### **Answer by WHO**

In reaching its recommendation, the Committee applied the criteria for control of preparations under Schedule III of the 1961 Convention as set out in Article 3 para 4. Neither the availability of a medicine nor the amount of its use form part of the criteria that should be used to determine the suitability of a preparation for inclusion in Schedule III and were therefore not considered by the ECDD.

## Annex 1 – TABLE OF CONTROL MEASURES – LICIT ACTIVITIES

The table below provides an overview of specific control measures as provided for in the international drug control conventions. It is illustrative, and it indicates applicable provisions in the Conventions, to facilitate reference, search and comparison.

The table also indicates the level of obligation attached to a particular control measure, i.e., whether they are of a “mandatory” or “optional” nature. In this context, “optional” would mean that Parties may exercise discretion as to whether or not to apply the particular measure of control to the specified drugs. This is indicated in the first column of the table below. In a number of cases, the Conventions require that a particular control measure be implemented as mandatory with regard to a particular schedule while leaving the application of the same measure to other schedules at the discretion of the Party. In such cases, the column indicates a “mandatory/optional” nature.

Level of obligation	Control measures	Article(s) in the 1961 Convention as amended	Article(s) in the 1971 Convention	Article(s) in the 1988 Convention
<b>General</b>				
Mandatory	Obligation to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs	Art. 4(c)	Art. 5(2) and 7(1)	
Mandatory	Establish and maintain a special administration for the purpose of applying the provisions of the Convention	Art. 17	Art. 6	
Mandatory	Periodic returns of estimates of drug requirements; annual statistical reports/returns	Arts. 19 and 20	Art. 16 (4)	Art. 12 (12)
<b>Cultivation</b>				
Mandatory Optional for specific provisions	Limitation of cultivation	Arts. 22, 23, 25 (1), 26 , 27 and 28.		
<b>Manufacture</b>				
Mandatory	Licensing of enterprises	Art. 29(1)	Arts. 7(b) and 8(1)	Art. 12(8)(a), (b)(i)
Mandatory	Licensing of premises	Art. 29(2) (b)	Art. 8(2)(b)	Art, 12 (8)(b)(ii)
Mandatory Optional for narcotic drugs preparations	Periodical permits for manufacture	Art. 29(2)(c)		



Level of obligation	Control measures	Article(s) in the 1961 Convention as amended	Article(s) in the 1971 Convention	Article(s) in the 1988 Convention
Mandatory	Prevent the accumulation of quantities of drugs and poppy straw in excess of those required	Art. 29(3)		
Mandatory	Recording of operations	Art. 34(b)	Art 11	
<b>Wholesale<sup>1</sup></b>				
Mandatory  Optional ("may") for precursors	Trade in and distribution of drugs be under licence except where such is carried out by a State enterprise	Art. 30(1)(a)	Arts.7(a-d) and 8 (1) and (2)(a)	Art. 12(8)(b)(i)
Mandatory  Optional ("may") for precursors	Licensing of premises	Art. 30(1)(b),	Art. 8(2)(b)	Art, 12 (8) (b)(ii)
Mandatory for narcotic drugs  Optional ("may") for precursors	Limitation on stocks/ quantities	Art. 30(2)(a)		Art. 12(8)(b)(iv)
Mandatory	Recording of operations	Art. 34 (b)	Art. 11	
Optional (at the discretion of the Party)	Special labelling/ packaging (red band)	Art. 30(4)		

<sup>1</sup> The term wholesale is used in Article 23 of the 1961 Convention and in Articles 11 and 15 of the 1971 Convention (in relation to wholesale distribution). In the 1988 Convention, the term wholesale is used in Article 12, on monitoring international trade.

Level of obligation	Control measures	Article(s) in the 1961 Convention as amended	Article(s) in the 1971 Convention	Article(s) in the 1988 Convention
<b>Retail distribution</b>				
Mandatory	Licensing of distribution	Art. 30(1)	Art. 8 (1), 8(2)(a)	
Mandatory/optional	Licensing of premises	Art. 30.1(b)	Art. 8(2b)	
Mandatory	Limitation of stocks /quantities	Art. 30(2)(a)	Art. 5(2)	
Mandatory/optional	Medical prescription for supply or dispensation	Art. 30(2)(b)	Art. 9(1)	
Optional	Prescription written on official forms issued in the form of counterfoil books	Art. 30(2)(b)(ii)		
Optional /mandatory	Labelling indications	Art.30(3), (4) and (5)	Art. 10(1)	
Optional ("it is desirable")/ Mandatory ("shall" with due regard to constitutional provisions")	Advertising	Art.30(3-5)	Art. 10(2)	
<b>International Trade</b> (see section below for provisions on precursors)				
Mandatory	Import and export licensing	Art. 31 (3)	Art. 8(1)	
Mandatory	Import and export authorization and certificate	Art. 31(4-7) and (10)	Art. 12(1), (2) and (3)(d)	
Mandatory	Prohibition on consignments addressed to post office box or to bank account of someone other than person named in authorization	Art. 31(8)	Art. 12(3)(b)	
Mandatory	Limits on exports of consignments to a bonded warehouse	Art. 31(9)	Art. 12(3)(c)	
Mandatory	Transit: export authorization produced to country or region of transit	Art 31(11)	Art. 12(3)(e-h)	
<b>Special provisions</b>				
Mandatory	Carriage of drugs in first-aid kits of ships or aircraft engaged in	Art. 32	Art. 14	Arts. 15, 17

Level of obligation	Control measures	Article(s) in the 1961 Convention as amended	Article(s) in the 1971 Convention	Article(s) in the 1988 Convention
	international traffic/international travellers			
Mandatory Optional ("may") for precursors	Measures of supervision and inspection	Arts. 29(a), 34	Arts. 8(2)(a), 15	Art. 12(8)(b)(i)
Optional	Destruction of damaged and expired drugs	-	-	
<b>Precursors</b>				
Mandatory	System to monitor the international trade in precursors			Art. 12(9)(a)
Mandatory	Provide for the seizure of any substances suspected to be for use in the illicit manufacture of narcotic drugs or psychotropic substances			Art. 12(9)(b)
Mandatory	Requirement for proper labelling of imports and exports and maintenance of documents			Art. 12(9)(d) and (e)
Mandatory	Requirement for pre-export notification and information to be supplied to importing country			Art. 12(10)
Mandatory (if required by the Party furnishing information)	Information on trade, business, commercial or professional secret or trade process kept confidential			Art. 12(11)
<b>Other provisions</b>				
Mandatory	Extradition	Art. 36(2)(b)	Art. 22(b)	Art. 6
Mandatory	Widest measure of mutual legal assistance in investigations, prosecutions and judicial proceedings in relation to criminal offences; other forms of law enforcement cooperation			Arts. 7 and 9
Mandatory	Cooperate to the fullest extent possible to suppress illicit traffic by sea			Art. 17

Level of obligation	Control measures	Article(s) in the 1961 Convention as amended	Article(s) in the 1971 Convention	Article(s) in the 1988 Convention
Mandatory	Take all practicable measures for the prevention of abuse of narcotic drugs and psychotropic substances and for the early identification, treatment, education, after-care, rehabilitation and social reintegration of the persons involved, and shall coordinate their efforts to these ends	Art. 38	Art. 20	

## Annex 2 – TABLE OF CONTROL MEASURES – PENAL PROVISIONS

The table below, which has illustrative purposes, lists conduct that Parties are required to establish as criminal offences.

Level of obligation	Control measures	Article(s) in the Conventions
<b>Offences</b>		
1. Mandatory SCLLSDL*	A series of related actions constituting offences, if committed in different countries, shall each be considered as distinct offences	Art. 36(1)(a) and (2)(a)(i), 1961 Convention and art. 22(1)(a) and (2)(a)(i), 1971 Convention
2. Mandatory	Production, manufacture, extraction, preparation, offering, offering for sale, distribution, sale, delivery on any terms whatsoever, brokerage, dispatch, dispatch in transit, transport, importation or exportation of any narcotic drug or any psychotropic substance contrary to the provisions of the 1961 Convention, the 1961 Convention as amended, or the 1971 Convention	Art. 3(1)(a)(i), 1988 Convention
3. Mandatory	Possession or purchase of any narcotic drug or psychotropic substance for the purpose of any of the activities enumerated in (2) above	Art. 3(1)(a)(iii), 1988 Convention
4. Mandatory	Cultivation of opium poppy, coca bush or cannabis plant for the purpose of the production of narcotic drugs contrary to the provisions of the 1961 Convention and the 1961 Convention as amended	Art. 3(1)(a)(ii), 1988 Convention
5. Mandatory	Manufacture, transport or distribution of equipment, materials or precursors knowing that they are to be used in or for the illicit cultivation, production or manufacture of narcotic drugs or psychotropic substances	Art. 3(1)(a)(iv), 1988 Convention
6. Mandatory	Organization, management or financing of any of the offences listed in (2, 3, 4 or 5) above	Art. 3(1)(a)(v), 1988 Convention
7. Mandatory	Conversion or transfer of property, knowing that it is derived from any offence or offences established in (2, 3, 4, 5 or 6), or from an act of participation in such offence or offences, for the purpose of concealing or disguising the illicit origin of the property or of assisting any person who is involved in the commission of such an offence or offences to evade legal consequences	Art. 3(1)(b)(i), 1988 Convention

Level of obligation	Control measures	Article(s) in the Conventions
8. Mandatory	Concealment or disguise of the true nature, source, location, disposition, movement, rights with respect to, or ownership of property, knowing that such property is derived from an offence established in accordance with (2, 3, 4, 5 or 6) above or from an act of participation in such an offence	Art. 3(1)(b)(ii), 1988 Convention
9. Mandatory SBCLS**	Acquisition, possession or use of property, knowing, at the time of receipt, that such property was derived from an offence derived from (2, 3, 4, 5 or 6) above	Art. 3(1)(c)(i), 1988 Convention
10. Mandatory SBCLS**	Possession of equipment or material or substances listed in Table I and Table II, knowing that they are being or are to be used in or for the illicit cultivation, production or manufacture of narcotic drugs or psychotropic substances	Art. 3(1)(c)(ii), 1988 Convention
11. Mandatory	Publicly inciting or inducing others, by any means, to commit any of the offences established in accordance with (2-12) or to use narcotic drugs or psychotropic substances illicitly	Art. 3(1)(c)(iii), 1988 Convention
12. Mandatory SBCLS**	Possession, purchase, or cultivation of narcotic drugs or psychotropic substances for personal consumption contrary to the provisions of the 1961 Convention, the 1961 Convention as amended, or the 1971 Convention.	Art. 3(2), 1988 Convention
13. Mandatory SCLLSDL*	Intentional participation in, conspiracy to commit and attempts to commit, any of such offences, and preparatory acts and financial operations in connexion with the offences as provided, shall be punishable offences	Art. 36(2)(a)(ii), 1961 Convention and art. 22(2)(a)(ii), 1971 Convention
14. Mandatory SBCLS**	Participation in, association or conspiracy to commit, attempts to commit, aiding, abetting, facilitating and counselling for the commission of any of the offences established in accordance with (2 through 12) above	Art. 3(1)(c)(iv), 1988 Convention
<b>Jurisdiction</b>		
15. Mandatory	Offences committed within its territory and on-board its vessels and aircrafts	Art. 36(2)(a)(iv), 1961 Convention, art. 22(2)(a)(iv) 1971 Convention, art. 4(1)(a) 1988 Convention

Level of obligation	Control measures	Article(s) in the Conventions
16. Optional	May take such measures as may be necessary to establish jurisdiction over the offences it has established when committed by one of its nationals or a by a person who has his habitual residence in its territory; the offence is committed on board a vessel concerning which that Party has been authorized to take appropriate action pursuant to the Article on illicit traffic by sea...and the offence in accordance with (14) above is committed outside its territory with a view to the commission, within its territory, of an offence established in accordance with (2-11, 13-14) above	Art. 4(1)(b), 1988 Convention
17. Optional	May establish jurisdiction over offences when the alleged offender is present in its territory and does not extradite him to another Party	Art. 4(2)(a-b), 1988 Convention
<b>Sanctions and other measures</b>		
18. Mandatory (subject to the constitutional limitations of the Party)	Serious offences shall be liable to adequate punishment particularly by imprisonment or other penalties of deprivation of liberty	Art. 36(1)(a), 1961 Convention, art. 22(1)(a), 1971 Convention
19. Mandatory	Make the commission of the offences...liable to sanctions which take into account the grave nature of these offences, such as imprisonment or other forms of deprivation of liberty, pecuniary sanctions and confiscation	Art. 3(4)(a), 1988 Convention
20. Optional	For offences in accordance with (1) above: drug abusers shall undergo measures of treatment, education, after-care, /rehabilitation and social reintegration either as an alternative or in addition to conviction or punishment	Art. 36(1)(b), 1961 Convention and art. 22(1)(b), 1971 Convention
21. Optional	For offences in accordance with (2-11) above: the offender shall undergo measures such as treatment, education, aftercare, rehabilitation or social reintegration in addition to conviction or punishment	Art. 3(4)(b), 1988 Convention

Level of obligation	Control measures	Article(s) in the Conventions
22. Optional	In appropriate cases of a minor nature, the Parties may provide, as alternatives to conviction or punishment, measures such as education, rehabilitation or social reintegration, as well as, when the offender is a drug abuser, treatment and aftercare	Art. 3(4)(c), 1988 Convention
23. Optional	For offences in accordance with (2-11) above: the offender shall undergo measures such as treatment, education, aftercare, rehabilitation or social reintegration in addition to conviction or punishment	Art. 3(4)(d), 1988 Convention
<b>Aggravating circumstances</b>		
24. Mandatory <i>SCLLSDL*</i>	Foreign convictions shall be taken into account for the purpose of establishing recidivism	Art. 36(2)(a)(iii), 1961 Convention and art. 22(2)(a)(iii), 1971 Convention
25. Mandatory	Ensure that their courts and other competent authorities having jurisdiction can take into account factual circumstances which make the commission of the offences particularly serious, such as: Prior conviction, particularly for similar offences, whether foreign or domestic, to the extent permitted under the domestic law of a Party	Art. 3(5)(h), 1988 Convention
26. Mandatory	Ensure that their courts and other competent authorities having jurisdiction can take into account factual circumstances which make the commission of the offences particularly serious, such as: - involvement in the offence of an organized criminal group to which the offender belongs; - involvement of the offender in other international organized criminal activities; - involvement in other illegal activities facilitated by commission of the offence; - use of violence or arms by the offender; - the fact that the offender holds a public office and that the offence is connected with the office in question; - victimization or use of minors; - the offence is committed in a penal or in an educational institution or social service facility or in their immediate vicinity or in other places	Art. 3(5), 1988 Convention



Level of obligation	Control measures	Article(s) in the Conventions
	to which school children and students resort for educational, sports and social activities	
<b>Confiscation/seizures</b>		
27. Mandatory	Any drugs, substances <sup>2</sup> and equipment used in or intended for the commission of any of the above-mentioned offences, shall be liable to seizure and confiscation	Art. 37, 1961 Convention, art. 22(3), 1971 Convention, and art. 5(2) of the 1988 Convention
28. Mandatory	Adopt such measures as may be necessary to enable confiscation of: <i>[not an exhaustive list of items in Art. 5]</i> - proceeds derived from offences or property of corresponding value; - drugs, materials and equipment used in or intended for use in offences; And shall - empower its authorities to order financial records be available or seized; - confiscation of intermingled property; <i>and may consider</i> - reversion of the onus of proof regarding the lawful origin of alleged proceeds or other property liable to confiscation	Art. 5(1), 1988 Convention
29. Mandatory	Seizure of any precursors if there is sufficient evidence that it is for use in the illicit manufacture of a drug	Art. 12(9)(b), 1988 Convention
30. Optional	Necessary measures for early destruction or lawful disposal of drugs and precursors which have been seized or confiscated and for the admissibility as evidence of duly certified necessary quantities of such substances	Art. 14(5), 1988 Convention
<b>Criminal procedure</b>		
31. Mandatory / optional	Endeavour to ensure that any discretionary legal powers under their domestic law relating to the prosecution of persons ... are exercised to maximize the effectiveness of law enforcement measures ... and ... to deter the commission of such offences	Art. 3(6), 1988 Convention

<sup>2</sup> Article 22(3) of the 1971 Convention refers to “any psychotropic substance or other substance”.

Level of obligation	Control measures	Article(s) in the Conventions
32. Mandatory	Ensure that authorities bear in mind the serious nature of the offences and the circumstances when considering early release or parole for (2-11, 13 and 14) above	Art. 3(7), 1988 Convention
33. Mandatory (consistent with the legal system of the Party)	Ensure presence at the criminal proceedings of a person charged with or convicted of an offence ..., who is found within its territory	Art. 3(9), 1988 Convention
34. Mandatory	Long statute of limitations period for offences in (2-11, 13 and 14), and a longer period where the alleged offender has evaded the administration of justice	Art. 3(8), 1988 Convention
35. Mandatory	Knowledge, intent or purpose required as an element of an offence may be inferred from objective factual circumstances	Art. 3(3), 1988 Convention
36. Mandatory	Tracing and seizing of proceeds	Art. 5(2), 1988 Convention
37. Mandatory	Availability of bank and financial records	Art. 5(3), 1988 Convention
38. Mandatory (if permitted by the basic principles of the legal system of the Party)	Appropriate use of controlled delivery at the international level ... to identify persons involved in offences ... and take legal action against them	Art. 11, 1988 Convention
39. Mandatory	Measures to suppress the use of the mails for illicit traffic / investigative and control techniques designed to detect illicit consignment of drugs and precursors in mails	Art. 19, 1988 Convention
* <b>SCLLSDL</b> : Subject to the constitutional limitations of the Party, its legal system and domestic law		
** <b>SBCLS</b> : Subject to the constitutional principles of the Party and the basic concepts of its legal system		