23 November 2020

English only

Commission on Narcotic Drugs Reconvened sixty-third session Vienna, 2–4 December 2020 Item 5 (a) of the provisional agenda* **Implementation of the international drug control treaties: changes in the scope of control of substances**

> Consideration of the notification from the World Health Organization concerning scheduling under the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, and the Convention on Psychotropic Substances of 1971^{**}

Note by the Secretariat

Notification from the World Health Organization concerning cannabis and cannabis-related substances

1. Pursuant to article 3, paragraphs 1 and 3 to 6, of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and article 2, paragraphs 1, 4 and 6, of the Convention on Psychotropic Substances of 1971, the Director-General of the World Health Organization (WHO), in correspondence dated 24 January 2019 (received 28 January 2019), notified the Secretary-General of the outcome of the forty-first meeting of the WHO Expert Committee on Drug Dependence, held in Geneva from 12 to 16 November 2018. At that meeting, the Expert Committee undertook a critical review of cannabis and cannabis-related substances (cannabis plant and cannabis resin, extracts and tinctures of cannabis, *delta*-9-tetrahydrocannabinol (Δ 9-THC; dronabinol) and tetrahydrocannabinol (isomers of THC)) and evaluated their dependence-producing properties and harm to health.

2. In that connection, the Director-General notified the Secretary-General of the scheduling recommendations regarding the review of cannabis and cannabis-related substances, which were as follows (see annex I for the relevant extract of that notification):

(a) To delete cannabis and cannabis resin from Schedule IV of the 1961 Convention;

(b) To add dronabinol and its stereoisomers (*delta-9*-tetrahydrocannabinol) to Schedule I of the 1961 Convention; and to delete it from Schedule II of the





^{*} E/CN.7/2020/1/Add.1.

^{**} This document has not been edited.

1971 Convention, subject to the Commission's adoption of the recommendation to add it to Schedule I of the 1961 Convention;

(c) To add THC (isomers of *delta*-9-tetrahydrocannabinol) to Schedule I of the 1961 Convention, subject to the Commission's adoption of the recommendation to add dronabinol and its stereoisomers to Schedule I of the 1961 Convention; and to delete THC from Schedule I of the 1971 Convention, subject to the adoption of the recommendation to add it to Schedule I of the 1961 Convention;

(d) To delete extracts and tinctures of cannabis from Schedule I of the 1961 Convention;

(e) To add a footnote to the entry for cannabis and cannabis resin in 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";

(f) To add to Schedule III of the 1961 Convention 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 that would constitute a risk to public health.

3. In accordance with the provisions of article 3, paragraph 2, of the 1961 Convention and article 2, paragraph 2, of the 1971 Convention, on 1 February 2019, the Secretary-General transmitted to all Governments a note verbale to which the notification dated 24 January 2019 and the information submitted by WHO in support of those recommendations were annexed. Furthermore, on 29 January 2019, the Secretariat informally circulated the notification and the information submitted by WHO in support of those recommendations to all permanent missions to the United Nations in Vienna.

Sixty-second session of the Commission

4. At its sixty-second session, held from 14 to 22 March 2019, the Commission had before it a note by the Secretariat entitled "Changes in the scope of control of substances: proposed scheduling recommendations by the WHO on cannabis and cannabis-related substances" (E/CN.7/2019/12) for its consideration.

5. In decision 62/14, adopted by consensus at its 9th meeting, on 19 March 2019, the Commission decided to postpone the voting on the WHO scheduling recommendations on cannabis and cannabis-related substances, which had been transmitted to the Secretary-General after the three-month period established pursuant to Commission resolution 2 (S-VII) of 8 February 1982, entitled "*Procedure to be followed by the Commission on Narcotic Drugs in matters of scheduling of narcotic drugs and psychotropic substances*", in order to provide States with more time to consider the recommendations.

Considerations during the fourth and fifth intersessional meeting of the Commission at its sixty-second session

6. During the fourth and fifth intersessional meeting of the Commission at its sixty-second session, held on 24 June 2019 and 23 September 2019, Member States had an opportunity to consult with representatives of WHO and the Expert Committee on Drug Dependence on the WHO scheduling recommendations on cannabis and cannabis-related substances. Representatives of the International Narcotics Control Board (INCB) and the United Nations Office on Drugs and Crime (UNODC) were also present to answer questions within the mandates of their respective organizations.

7. The questions and answers raised prior, during and after the fourth and fifth intersessional meeting have been compiled in conference room paper E/CN.7/2020/CRP.4 that was brought to the attention of the sixty-third session of the Commission.

Reconvened sixty-second session of the Commission

8. As recommended by the Extended Bureau and endorsed by the Commission at its fifth intersessional meeting on 23 September 2019, Member States had an opportunity at the reconvened sixty-second session of the Commission, held on 12 and 13 December 2019, to refer to the recommendations on cannabis and cannabis-related substances in their interventions under agenda item 9, "*Implementation of the international drug control treaties*". A summary of the deliberations is contained in the report on the reconvened sixty-second session (E/2019/28/Add.1-E/CN.7/2019/13/Add.1).

Sixty-third session of the Commission

9. At its sixty-third session, held from 2 to 6 March 2020, the Commission had before it a note by the Secretariat summarizing the consultations on the WHO scheduling recommendations on cannabis and cannabis-related substances conducted during the sixty-second session (E/CN.7/2020/14). Further, the Commission had before it a conference room paper containing comments submitted by States parties to the 1961 and 1971 Convention by 17 January 2020 to be shared with the Commission in response to its note verbale dispatched on 29 November 2019 (E/CN.7/2020/CRP.9).

10. In decision 63/14, adopted by consensus at its 6th meeting, on 4 March 2020, the Commission recalled its mandate to vote on scheduling recommendations as laid out in the international drug control conventions and decided to continue during its current sixty-third session the consideration of the recommendations of the World Health Organization on cannabis and cannabis-related substances, bearing in mind their complexity, in order to clarify the implications and consequences of, as well as the reasoning for, these recommendations, and decided to vote at its reconvened sixty-third session in December 2020, in order to preserve the integrity of the international scheduling system.

Intersessional considerations during the sixty-third session of the Commission

11. On 22 May 2020, the Extended Bureau of the Commission agreed on the conduct of the intersessional considerations during the sixty-third session. It agreed that the Commission would hold three informal closed topical meetings of two days, each focusing on one to three recommendations, followed by an intersessional meeting open to all stakeholders.

12. The first topical meeting was held on 24 and 25 June 2020 and focused on recommendation 5.4 on extracts and tinctures and recommendation 5.5 on cannabidiol preparations. During the second topical meeting on 24 and 25 August 2020, Member States discussed recommendation 5.2 on dronabinol and its stereoisomers, recommendation 5.3 on tetrahydrocannabinol (isomers of *delta*-9-tetrahydrocannabinol) and recommendation 5.6 on preparations of dronabinol. The third topical meeting, held on 6 October, focused on recommendation 5.1 on cannabis and cannabis resin. All topical meetings were conducted virtually to allow for the participation of experts from capital. The meetings were attended by over 600 participants from more than 100 Member States.

13. During the second intersessional meeting on 8 October 2020, Member States had the opportunity to recapitulate relevant arguments and sum up their positions and, in addition, other stakeholders shared their views.

Clarification of the wording of the recommendation 5.6 on dronabinol preparations by WHO

14. On 5 August 2020, WHO clarified via note verbale the wording of recommendation 5.6 (see annex II). WHO specified that the recommendation should read as follows:

Preparations containing delta-9-tetrahydrocannabinol (dronabinol), produced either by chemical synthesis or as a preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a wat that delta-9-tetrhydocannabinol (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health

• To be added to Schedule III of the Single Convention on Narcotic Drugs (1961)

Sixty-third reconvened session of the Commission

15. The Commission is expected to vote on the WHO scheduling recommendations on cannabis and cannabis-related substances during its reconvened sixty-third session. The voting is scheduled for 2 December 2020.

Annex I

Extract of the notification dated 24 January 2019 from the Director-General of the World Health Organization to the Secretary-General on cannabis and cannabis-related substances, containing scheduling recommendations on substances controlled under the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, and the Convention on Psychotropic Substances of 1971, including the relevant extract from the report on the forty-first meeting of the Expert Committee on Drug Dependence

With reference to article 3, paragraphs 1, 3, 5 and 6, of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, and article 2, paragraphs 1, 4 and 6, of the Convention on Psychotropic Substances of 1971, I am pleased to submit recommendations of the Expert Committee on Drug Dependence at its forty-first meeting regarding the review of cannabis and cannabis-related substances, as follows:

Cannabis and cannabis-related substances

Cannabis and cannabis resin

• To be deleted from Schedule IV of the 1961 Convention

Dronabinol (delta-9-tetrahydrocannabinol)

- To be added to Schedule I of the 1961 Convention
- To be deleted from Schedule II of the 1971 Convention, subject to the adoption by the Commission on Narcotic Drugs of the recommendation to add dronabinol and its stereoisomers (*delta-9*-tetrahydrocannabinol) to Schedule I of the 1961 Convention

Tetrahydrocannabinol (isomers of delta-9-tetrahydrocannabinol)

- To be added to Schedule I of the 1961 Convention, subject to the adoption by the Commission of the recommendation to add dronabinol and its stereoisomers (*delta-9*-tetrahydrocannabinol) to Schedule I of the 1961 Convention
- To be deleted from Schedule I of the 1971 Convention, subject to the adoption by the Commission of the recommendation to add tetrahydrocannabinol to Schedule I of the 1961 Convention

Extracts and tinctures

• To be deleted from Schedule I of the 1961 Convention

Cannabidiol preparations

• To give effect to the recommendation of the Expert Committee on Drug Dependence at its fortieth meeting that preparations considered to be pure cannabidiol (CBD) should not be scheduled within the international drug control conventions, by adding a footnote to the entry for cannabis and cannabis resin in 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."

Preparations 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

• To be added to Schedule III of the 1961 Convention

The assessments and findings on which they are based are set out in detail in the report on the forty-first meeting of the Expert Committee on Drug Dependence.

Extract from the report on the forty-first meeting of the Expert Committee on Drug Dependence

5. Cannabis and cannabis-related substances

5.1 Cannabis and cannabis-resin

In the 1961 Convention, cannabis and cannabis resin are described, respectively, as the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, and as the separated resin, whether crude or purified, obtained from the cannabis plant. References to cannabis below will be taken to also include cannabis resin. Of the many compounds in cannabis, *delta*-9-tetrahydrocannabinol (Δ^9 -THC) is the principal psychoactive constituent of cannabis, while CBD is also present but is not psychoactive.

Following consumption of cannabis, the adverse effects experienced include dizziness and impairment of motor control and cognitive function. As a result of the effects on movement and cognition, cannabis use can impair driving. There are particular risks of cannabis use reported for children, such as respiratory depression, tachycardia and coma. The adverse effects of cannabis consumption are similar to those produced by Δ^9 -THC alone.

There are also a number of adverse effects associated with long-term cannabis use, particularly increased risk of mental health disorders such as anxiety, depression and psychotic illness. Chronic regular cannabis use is particularly problematic for young people because of its effects on the developing brain.

Cannabis can cause physical dependence in people who use the drug daily or near-daily. This is evidenced by the onset of cannabis withdrawal symptoms that occur upon abstinence; these symptoms include gastrointestinal disturbance, appetite changes, irritability, restlessness and sleep impairment. Clinical diagnostic guidelines such as DSM-5 and ICD-10 recognize cannabis dependence and other disorders related to cannabis use.

The Committee considered information regarding the therapeutic indications of cannabis and ongoing research into its possible medical applications. A number of countries permit the use of cannabis for the treatment of medical conditions such as chemotherapy-induced nausea and vomiting, pain, sleep disorders and spasticity associated with multiple sclerosis. The Committee recognized the limited robust scientific evidence on the therapeutic use of cannabis. However, some oral pharmaceutical preparations of cannabis have therapeutic advantages for treatment of conditions such as certain forms of pain and epilepsy. Preparations of cannabis are defined as a mixture, solid or liquid containing cannabis and are generally subject to the same measures of control as cannabis and cannabis resin as per article 2, paragraph 3, of the 1961 Convention.

Cannabis and cannabis resin are included in Schedule I and Schedule IV of the 1961 Convention. Substances that are included in both these Schedules are particularly liable to abuse and to produce ill-effects and have little or no therapeutic use. Other substances that are included in both Schedules I and IV are fentanyl analogues, heroin and other opioids that are considered especially dangerous. Use of all these substances is associated with a significant risk of death, whereas cannabis use is not associated with such risk.

The evidence presented to the 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 Convention. In addition, preparations of cannabis have shown therapeutic potential for treatment of pain and other medical conditions, such as epilepsy and spasticity associated with multiple sclerosis. In line with the above, 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 preparations for medical use.

The Committee concluded that the inclusion of cannabis and cannabis resin in Schedule IV is not consistent with the criteria for a drug to be placed in Schedule IV.

The Committee then considered whether cannabis and cannabis resin were better placed in Schedule I or Schedule II of the 1961 Convention. While the Committee did not consider that cannabis is associated with the same level of risk to health as most of the other drugs that have been placed in Schedule I, it noted the high rates of public health problems arising from cannabis use and the global extent of such problems, and for these reasons recommended that cannabis and cannabis resin continue to be included in Schedule I of the 1961 Convention:

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

5.2 Dronabinol (*delta*-9-tetrahydrocannabinol; Δ^9 -THC)

The main psychoactive substance in the cannabis plant is one of the four stereoisomers of *delta*-9-tetrahydrocannabinol (Δ^9 -THC). This substance has therapeutic uses and is sometimes known by its international non-proprietary name, dronabinol. It is currently placed in Schedule II of the 1971 Convention.

At the time of the adoption of the 1961 Convention, scientific research had not identified Δ^9 -THC as the main psychoactive compound in cannabis. Subsequently, Δ^9 -THC was included in the 1971 Convention at its inception. In previous reviews by the Expert Committee on Drug Dependence, the active and naturally occurring stereoisomer of Δ^9 -THC known as dronabinol had been considered in a synthetic form as a pharmaceutical preparation. Following a recommendation from the Expert Committee on Drug Dependence at its twenty-seventh meeting, dronabinol was placed in Schedule II of the 1971 Convention. The Commission on Narcotic Drugs, however, did not adopt a subsequent recommendation to place dronabinol in Schedule III of the 1971 Convention.

The Committee noted that, whereas in these previous reviews by the Expert Committee on Drug Dependence, Δ^9 -THC, and especially its active stereoisomer dronabinol, had been considered in a synthetic form as a pharmaceutical preparation, Δ^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 Δ^9 -THC at concentrations as high as 90 per cent. Butane hash oil is an example of a high-purity Δ^9 -THC illicit cannabis-derived product that has recently emerged and is being used by heating and inhalation of the vapour. In such high-purity, illicitly-derived forms, Δ^9 -THC produces ill-effects, dependence and abuse potential that is at least as great as for cannabis, which is placed in Schedule I of the 1961 Convention.

A substance liable to similar abuse and productive of similar ill-effects as that of a substance already scheduled within the 1961 Convention would normally be scheduled in the same way as that substance. As Δ^9 -THC is liable to similar abuse as cannabis and has similar ill-effects, it meets the criteria for inclusion in Schedule I of the 1961 Convention. It was further recognized that cocaine, the principal active compound in coca, is contained along with coca leaf in Schedule I of the 1961 Convention, and morphine, the principal active compound in opium, is placed with opium in the same schedule. Placing Δ^9 -THC, the principal active compound in cannabis, in the same schedule as cannabis would be consistent with this approach.

Based on requests received from Member States and information received from other United Nations agencies, the Committee understood that placing Δ^9 -THC under the same Convention and in the same Schedule as cannabis, Schedule I of the 1961 Convention, would greatly facilitate the implementation of the control measures of the Conventions in Member States. Accordingly:

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.

5.3 Tetrahydrocannabinol (isomers of *delta*-9-tetrahydrocannabinol)

There are currently six isomers of tetrahydrocannabinol (THC) listed in Schedule I of the 1971 Convention. These six isomers are chemically similar to *delta*-9-tetrahydrocannabinol (Δ^9 -THC), which is currently listed in Schedule II of the 1971 Convention, but which the Committee has recommended deleting from this Schedule and including in Schedule I of the 1961 Convention.

While these six isomers are chemically similar to Δ^9 -THC, there is very limited to no evidence concerning the abuse potential and acute intoxicating effects of these isomers. There are no reports that the THC isomers listed in Schedule I of the 1971 Convention induce physical dependence or that they are being abused or are likely to be abused so as to constitute a public health or social problem. There are no reported medical or veterinary uses of these isomers.

While the Committee recognized that available evidence has not demonstrated abuse and ill-effects of these isomers similar to those associated with Δ^9 -THC, it noted that, due to the chemical similarity of each of the six isomers to Δ^9 -THC, it is very difficult to differentiate any of these six isomers from Δ^9 -THC using standard methods of chemical analysis. The Committee understood that placing these six isomers under the same Convention and in the same Schedule as Δ^9 -THC would facilitate the implementation of international control of Δ^9 -THC, as well as assist Member States in the implementation of control measures at the country level. Accordingly:

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.

5.4 Extracts and tinctures of cannabis

Extracts and tinctures of cannabis are preparations that are produced by application of solvents to cannabis and that are currently placed in Schedule I of the 1961 Convention. These include both medical preparations such as that containing an approximately equal mixture of *delta*-9-tetrahydrocannabinol (dronabinol; Δ^9 -THC) and CBD and non-medical preparations with high concentrations of Δ^9 -THC such as butane hash oil. While the medical extracts and tinctures are administered orally, those produced and used illicitly are normally inhaled following heating and vaporization.

The Committee recognized that the term "extracts and tinctures of cannabis", as cited in the 1961 Convention, encompasses these diverse preparations that have psychoactive properties as well as those that do not. The Committee also recognized that the variability in psychoactive properties of these preparations is due principally to varying concentrations of Δ^9 -THC, which is currently scheduled in the 1971 Convention, and that some extracts and tinctures of cannabis without psychoactive properties and including predominantly CBD have promising therapeutic applications. The fact that diverse preparations with a variable concentration of Δ^9 -THC are controlled within the same entry, "Extracts and tinctures", and the same Schedule, is a challenge for responsible authorities that implement control measures in countries.

As per the 1961 Convention, preparations are defined as mixtures, solids or liquids containing a substance in Schedule I or II and are generally subject to the same measures of control as that substance. The Committee noted that, by this definition, the 1961 Convention 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 Convention was followed, as "preparations" of dronabinol and its stereoisomers. Accordingly:

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

5.5 Cannabidiol preparations

At its fortieth meeting, the Expert Committee on Drug Dependence considered a critical review of CBD and recommended that preparations considered to be pure CBD should not be scheduled within the international drug control conventions. CBD is found in cannabis and cannabis resin but does not have psychoactive properties and has no potential for abuse and no potential to produce dependence. It does not have significant ill-effects. CBD has been shown to be effective in the management of certain treatment-resistant, childhood-onset epilepsy disorders. It was approved for this use in the United States of America in 2018 and is currently under consideration for approval by the European Union.

CBD can be chemically synthesized or it can be prepared from the cannabis plant. The approved medication (Epidiolex) is a preparation of the cannabis plant. The Committee noted that medicines without psychoactive effects that are produced as preparations of the cannabis plant will contain trace amounts of *delta*-9-tetrahydrocannabinol (Δ^9 -THC; dronabinol). The CBD preparation approved for the treatment of childhood-onset epilepsy, Epidiolex, contains not more than 0.15 per cent Δ^9 -THC by weight and has no effects indicative of potential for abuse or dependence. In keeping with the recommendation that preparations considered pure CBD not be controlled, and recognizing that trace levels of Δ^9 -THC may be found in such preparations, such as the concentration of 0.15 per cent in Epidiolex, while acknowledging that chemical analysis of Δ^9 -THC to an accuracy of 0.15 per cent may be difficult for some Member States:

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."

5.6 Pharmaceutical preparations of cannabis and dronabinol (*delta*-9-tetrahydrocannabinol)

There are currently two main types of registered medicines that contain *delta*-9-tetrahydrocannabinol (Δ^9 -THC; dronabinol).

One type is a preparation of cannabis that contains both the psychoactive Δ^9 -THC and the non-psychoactive CBD in approximately equal concentrations, e.g., Sativex. This is used for the treatment of spasticity due to multiple sclerosis.

A second type contains only Δ^9 -THC as the active compound and is used for the treatment of anorexia associated with weight loss in patients with acquired immune deficiency syndrome (AIDS) and for nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional anti-emetic treatments.

Currently approved medicines with Δ^9 -THC as the only active compound use synthetically produced Δ^9 -THC, e.g., Marinol and Syndros, although it is possible in the future that medicines with equivalent amounts of Δ^9 -THC could be prepared from cannabis. There is no difference in the therapeutic effects or adverse effects of synthetic Δ^9 -THC compared to Δ^9 -THC from the cannabis plant.

These medicines are all taken orally and are approved for use in a number of countries.

The evidence concerning the use of these Δ^9 -THC-containing medicines is that they are not associated with problems of abuse and dependence and they are not diverted for the purpose of non-medical use.

The Committee recognized that such preparations are formulated in a way that they are not likely to be abused and there is no evidence of actual abuse or ill-effects to an extent that would justify the current level of control associated with Schedule I of the 1961 Convention for cannabis-based preparations such as Sativex and the level of control associated with Schedule II of the 1971 Convention, for preparations using synthetic *delta-*9-THC, e.g., Marinol and Syndros.

In order not to impede access to these medicines, and in reference to article 3, paragraph 4, of the 1961 Convention:

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.

Annex II



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The Office of the Secretary-General of the United Nations New York, NY 10017 Etats-Unis d'Amérique

The World Health Organization (WHO) presents its compliments to the Office of the Secretary-General of the United Nations and refers to the WHO Director-General's letter of 24 January 2019 (attached), submitting the recommendations of the Forty-first meeting of the WHO Expert Committee on Drug Dependence (ECDD) on the review of cannabis and cannabisrelated substances, convened from 12 to 16 November 2018 at WHO headquarters in Geneva, Switzerland.

The recommendation on pharmaceutical preparations of cannabis and dronabinol (*delta*-9-tetrahydrocannabinol) is formulated as follows in the said letter:

"Preparations produced either by chemical synthesis or as a preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that *delta*-9-tetrahydrocannabinol (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health

• To be added to Schedule III of the Single Convention on Narcotic Drugs (1961)"

The World Health Organization wishes to hereby confirm that this recommendation should be read as formulated in the ECDD's Forty-first report, an extract of which is annexed to the Director-General's letter itself, i.e. as follows:

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

ENCL: (1)

cc: United Nations Office on Drugs and Crime (UNODC), Vienna

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Accordingly, the phrase "containing *delta*-9-tetrahydrocannabinol (dronabinol)" should be regarded as part of the text of the recommendation on pharmaceutical preparations of cannabis and dronabinol (*delta*-9-tetrahydrocannabinol) submitted to the Commission on Narcotic Drugs for consideration.

The World Health Organization would be grateful if this communication could be circulated to the States Parties to the 1961 Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances as well as to the Commission on Narcotic Drugs.

The World Health Organization trusts this clarification will facilitate the Commission on Narcotic Drugs' consideration of the recommendations on cannabis and cannabis-related substances at its reconvened Sixty-third session.

The World Health Organization avails itself of this opportunity to renew to the Office of the Secretary-General of the United Nations the assurances of its highest consideration.



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