

5. Cannabis and cannabis-related substances

5.1 Cannabis and cannabis resin

In the 1961 Single Convention on Narcotic Drugs, 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. Reference 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 *cannabidiol* (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 recognised 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 2.3 of the 1961 Single Convention on Narcotic Drugs.

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Cannabis and cannabis resin are included in Schedule I and Schedule IV of the 1961 Single Convention on Narcotic Drugs. 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 Single Convention on Narcotic Drugs. 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 preparation 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 Single Convention on Narcotic Drugs. While 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 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 Single Convention on Narcotic Drugs.

- ***Recommendation 5.1:*** The Committee recommended that Cannabis and Cannabis Resin be deleted from Schedule IV of the 1961 Single Convention on Narcotic Drugs.

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 on Psychotropic Substances.

At the time of the adoption of the 1961 Single Convention on Narcotic Drugs, scientific research had

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not identified Δ^9 -THC as the main psychoactive compound in cannabis. Subsequently, Δ^9 -THC was included in the 1971 Convention on Psychotropic Substances at its inception. In previous ECDD reviews, 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 27th ECDD, dronabinol was placed in Schedule II of the 1971 Convention on Psychotropic Substances. The Commission on Narcotic Drugs however 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 reviews 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%. 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 Single Convention on Narcotic Drugs.

A substance liable to similar abuse and productive of similar ill-effects as that of a substance already scheduled within the 1961 Single Convention on Narcotic Drugs 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 Single Convention on Narcotic Drugs. It was further recognised that cocaine, the principal active compound in coca is placed along with coca leaf in Schedule I of the 1961 Single Convention on Narcotic Drugs 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 UN 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 Single Convention on Narcotic Drugs, 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 Single Convention on Narcotic Drugs

As indicated in the “Guidance on the WHO review of psychoactive substances for international

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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 on Psychotropic Substances, Schedule II, subject to the Commission’s adoption of the recommendation to add dronabinol and its stereoisomers (*delta*-9- tetrahydrocannabinol) to Schedule I of the 1961 Single Convention on Narcotic Drugs

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

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

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 recognised 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 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 on Psychotropic Substances) be added to Schedule I of the 1961 Single Convention on Narcotic Drugs, subject to the Commission’s adoption of the recommendation to add dronabinol (*delta*-9-tetrahydrocannabinol) to the 1961 Single Convention on Narcotic Drugs in Schedule I.

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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 on Psychotropic Substances) be deleted from the 1971 Convention on Psychotropic Substances, subject to the Commission’s adoption of the recommendation to add tetrahydrocannabinol to Schedule I of the 1961 Single Convention on Narcotic Drugs.

5.4 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 Single Convention on Narcotic Drugs. These include both medical preparations such as that containing an approximately equal mixture of *delta*-9-tetrahydrocannabinol (dronabinol; Δ^9 -THC) and cannabidiol 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 vaporisation.

The Committee recognised that the term Extracts and Tinctures of Cannabis as cited in the 1961 Single Convention on Narcotic Drugs encompasses these diverse preparations that have psychoactive properties as well as those that do not. The Committee also recognised 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 on Psychotropic Substances, and that some extracts and tinctures of cannabis without psychoactive properties and including predominantly cannabidiol have promising therapeutic applications. 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.

As per the 1961 Single Convention on Narcotic Drugs, preparations are defined as mixtures, solid, or liquid 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 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. Accordingly:

- **Recommendation 5.4:** The Committee recommended deleting Extracts and Tinctures of

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Cannabis from Schedule I of the 1961 Single Convention on Narcotic Drugs.

5.5 Cannabidiol preparations

At its 40th Meeting the ECDD considered a critical review of cannabidiol and recommended that preparations considered to be pure cannabidiol should not be scheduled within the International Drug Control Conventions. Cannabidiol 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. Cannabidiol 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 in 2018 and is currently under consideration for approval by the EU.

Cannabidiol 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 cannabidiol preparation approved for the treatment of childhood-onset epilepsy, Epidiolex, contains not more than 0.15% 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 cannabidiol not be controlled and recognising that trace levels of Δ 9-THC may be found in such preparations, such as the concentration of 0.15% in Epidiolex, while acknowledging that chemical analysis of Δ 9-THC to an accuracy of 0.15% may be difficult for some Member States:

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

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* ($\Delta 9$ -THC; dronabinol).

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

A second type contains only $\Delta 9$ -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 antiemetic treatments.

Currently approved medicines with $\Delta 9$ -THC as the only active compound use synthetically produced $\Delta 9$ -THC, e.g. Marinol, Syndros, although it is possible in the future that medicines with equivalent amounts of $\Delta 9$ -THC could be prepared from cannabis. 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.

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

The evidence concerning the use of these $\Delta 9$ -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 recognised 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 Single Convention on Narcotic Drugs for cannabis based preparations such as Sativex and the level of control associated with Schedule II of the 1971 Convention on Psychotropic Substances, 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 3.4 of the 1961 Single Convention on Narcotic Drugs

- ***Recommendation 5.6:*** 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

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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.