



The
CRIMSON
DIGEST

Volume 1.

Briefing on the international
scientific assessment of cannabis:
Processes, stakeholders and history.



*For Alternative
Approaches to Addiction
Think & do tank*

ISBN 979-10-97087-06-7

EAN 9791097087067



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Acknowledgments.

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The authors would like to thank **Arné Verhoef** and **Amy King** for constructive criticism and proofreading.

The authors thank the support from the European Industrial Hemp Association, Hempoint, CBDepot, Harmony Ltd, Don E. Wirtshafter's Cannabis Museum, Revista Cañamo and Sensi Seeds.

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ISBN 979-10-97087-06-7 | EAN 9791097087067

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FAAAT think & do tank is a registered non-profit in Paris Prefecture (France), referenced by Official Gazette (148e année, N°12, 19 mars 2016, N°1540, page 93) with SIREN number 822213013.

INDEX

| | |
|---|-----------|
| FOREWORD | 4 |
| INTRODUCTION | 5 |
| Chapter 1. The Schedules | 10 |
| 1.1 International drug control Conventions | 10 |
| 1.2 An annex to the Conventions: their Schedules | 10 |
| 1.3 Schedules of the 1961 Convention | 12 |
| 1.4 Schedules of the 1971 Convention | 13 |
| 1.5 Treaty obligations. | 14 |
| Chapter 2. The review process | 16 |
| 2.1 Launch | 16 |
| 2.2 Preparation, documentation and data collection process | 17 |
| 2.3 The Expert Committee meetings | 17 |
| 2.4 Assessment criteria | 18 |
| 2.5 Post-review process at WHO | 19 |
| 2.6 Detailed flow chart of the review process | 19 |
| Chapter 3. The Experts | 23 |
| 3.1 Role and mandate of the ECDD | 23 |
| 3.2 History | 23 |
| 3.3 Nomination, rules and functioning | 24 |
| 3.4 Members of the Committee | 25 |
| Chapter 4. After the ECDD: Vote & legal consequences. | 27 |
| 4.1 The voting process | 27 |
| 4.2 53 Countries with right to vote | 28 |
| 4.3 Negotiations within regional groups | 30 |
| 4.4 Sovereignty breach in the European Union | 30 |
| 4.5 Barriers at the Commission on Narcotic Drugs | 32 |
| 4.6 After the vote: entry into force | 32 |
| Chapter 5. Timeline & history of Cannabis in the Schedules | 33 |
| 5.1 From 2016 to 2018 | 34 |
| 5.2 From 1925 to 1961 | 35 |
| 5.3 From 1952 to 2018: detailed timeline. | 37 |

FOREWORD

In 2014, Michael Krawitz, Farid Ghehiouèche and Kenzi Riboulet Zemouli started to cooperate in an effort to diminish the strict controls surrounding cannabis (and sometimes the associated prohibition) imposed to all countries by an international agreement dating back to 1961, with its roots in early 20th Century geopolitical arrangements where moral considerations of the time trumped evidence.

Our focus was the problematic scheduling status of cannabis. The international community had just outrageously broken its own rules to avoid changing the scheduling of THC, but times were changing, and so were the officials and personnel of international institutions. The UNGASS 2016¹ was on the horizon and Uruguay had just demonstrated to the whole world that it is possible to regulate the cannabis market even by voting a downgraded legalization bill.

Our actions were tridirectional: past, present and future. We started a comprehensive review of the archives and historical steps leading to the scheduling status of cannabis; we started mainstreaming the topic among United Nations stakeholders, decision-makers, researchers, civil society and the global cannabis community; and we launched a series of actions to ensure that the start of a process aimed at updating the scheduling status of cannabis would begin as soon as possible.

Part of our work was rendered in documents edited and published online on www.faaat.net/cannabis, in particular, the Crimson papers – A series of information documents on the general functioning of the international drug scheduling processes – and the Crimson fact sheets – briefings detailing the ongoing and expected changes in this domain.

The Crimson Digest that you are reading is an extended and updated collection of these Crimson papers and fact sheets, complemented with materials that were kept restricted at the time.

NB: For the purpose of this document, **cannabis** means the 'drug', the actual substance placed under control and ***Cannabis*** means 'the *Cannabis sativa* L. plant'.

¹ UNGASS 2016 was a Special Session of the United Nations General Assembly dedicated to the "world drug problem", where an important update of the international political consensus on drug policies happened.

INTRODUCTION

In November 2016, the World Health Organization (WHO) launched a process of scientific assessment of the uses (medical or otherwise) and potential harms of the plant *Cannabis sativa* L. and its derivatives. The final outcome of the WHO will be recommendations to place cannabis and its derivatives in the appropriate "Schedules" of the International Drug Control Conventions. These schedules list all controlled drugs by their perceived level of harm and directly impact the international laws and regulations to be applied to the said drug.

Part of the work of the authors consisted of promoting a neutral, comprehensive and independent assessment, one that recognizes and acknowledges both traditional knowledge and contemporary research on *Cannabis* (the plant) and cannabis (the "drug").

Challenging and changing the current position of *Cannabis*/cannabis within the International Conventions' Schedules (which until now bound countries to prohibit its use and eradicate the cultivation thereof) will have profound effects worldwide, increasing room and opportunities for scientific research, but also increasing medical access and supply. More broadly, it will ease off pressure against cannabis policy reforms at the country level, and allow cannabis policies to be integrated into and linked with national policies on health, human rights, education, economy, and rural or sustainable development.

* * *

The international obligations to prohibit cannabis – derived from the drug control Treaties which consider cannabis as one of the drugs with the highest potential of harm and the least medical usefulness – have not evolved since 1961. This undue scheduling was slowly constructed with an obscure process that started in 1925, and ended in 1961 with the inclusion of cannabis and its derivatives at the highest possible level of restrictive State control measures.

Unlike every other drug submitted to international restrictions, cannabis was never scientifically assessed between 1925 and 1961, when it was included at first in the international schedules of the treaties. Neither has it been reassessed after the identification in 1964 of tetrahydrocannabinol (THC), the main active compound of cannabis. Moreover since 1964, even though dozens of new clinical applications were evidenced by research, no further scientific reviews of the plant and its compounds were undertaken.

Since then, almost every single country has followed this scheduling, placing cannabis and cannabis-derived medicines and health products under the strictest of national regulations, blocking availability and denying access for medical patients and researchers, making legal production, trade, or quality certifications almost impossible, whilst de facto creating a near-total prohibition of cannabis, generating countless collateral harms in the process.

While the current classification of cannabis in the Treaties is, almost unbelievably, from an outdated and obscure evidentiary process conducted before 1961, no scientific, evidence-based process has been conducted to assess cannabis and classify it in the appropriate Schedule since that date.

It is essential to recognize the extreme complexity of international drug policy related to plant and substance scheduling, its primary and central role in the prohibition regime, and its impact on day-to-day practices and local policies.

The process of scientific assessment by the Expert Committee on Drug Dependence (ECDD), the only one able to change the status of cannabis within the Treaties schedules, is supposed to be a routine internal

process of the World Health Organization. However, it has been repeatedly blocked since the adoption of the Single Convention on narcotic drugs in 1961, while it could (and should) have happened long ago.

- Until 2014 (Details in Chapter 5)

A review process for THC had been started at the WHO, thought to help secure access to some basic cannabis medicines, but also as a first step to evaluate the response of the countries. The countries brutally stopped this process through the UN Commission on Narcotic Drugs (CND), and the WHO did not react, letting the process come to a stop. It was at this moment that our team started to gather energy for a new start for the WHO assessment process – this time not only for THC but for the whole plant.

- November 2015 - ECDD37

We first started attending the ECDD meetings during their 37th session. On this occasion, we pointed out that one of the experts was, in fact, the same lone witness previously presenting for the United States against rescheduling in the country's federal court, Professor Bertha Madras – an Expert that the WHO had hired on the ECDD. Through an oral statement delivered by Michael Krawitz, we asked the committee to look into possible conflicts of interest due to the relationship of this researcher with the United States government. Although the statement delivered by Krawitz to the ECDD was censored on the WHO website (the part of his statement that dealt with Professor Madras removed), when the ECDD reconvened the following year Professor Bertha Madras was no longer in the committee.

- April 2016 - UNGASS2016

The supreme organ of the United Nations, its General Assembly, held a Special Session focused on drugs (called UNGASS 2016, for United Nations General Assembly Special Session). In the outcome document, the countries agreed on the need for renewing and balancing approaches to the international scheduling system, basing it on scientific evidence, and reaffirmed the role of the WHO. They also resolved to *“[support] scientific evidence-based review and scheduling of the most prevalent, persistent and harmful substances” and called for “informed and coordinated scheduling decisions.”*

- May 2016 - WHA69

Shortly after UNGASS, the 69th World Health Assembly, supreme organ of the WHO, took place in Geneva. FAAAT's goal there was to emphasize the new favourable landscape brought by the UNGASS outcome document, as well as to convince the maximum number of stakeholders to provide increased support, including financially, to the department of WHO in charge of the ECDD and the review process. We also wrote and distributed a “Civil Society Declaration” on behalf of the IMCPC (International Medical Cannabis Patients Coalition) and a “Memo for Member States” recalling the UNGASS outcome as well as the basics of the review process, and the arguments supporting the need to undertake such a review for cannabis and cannabinoids.

This Memo, had been constructed over the previous months, thanks to research and discussions with experts and some Countries' Drug-control authorities. Eventually, these discussions had a supplementary beneficial outcome for the process: one of the countries we had been in discussions with (Czech republic) orally expressed (in a World Health Assembly session) their concerns regarding the lack of a recent review of literature concerning the medical applications of cannabis and cannabinoids on the part of the WHO, and demanded that the WHO undertakes a review process concerning cannabis in order to update knowledge and enlighten countries' decisions on the matter.

Importantly, our stay in Geneva also provided us time for extensive research in the archives and library of the United Nations.

- Fall 2016

We gathered support, evidence and Treaty-binding elements inciting the WHO to start the review, we recalled the direct request by the Czech republic made in May [1], and combined it to previous declarations of the UN Commission on Narcotic Drugs (CND) [2] and the International Narcotics Control Board (INCB) [3] in the same direction. We included all these elements in a letter which was sent to the then Director-General, Dr. Margaret Chan, by hundreds of scientists and political figures from all continents.

Among the signatories of this letter was an NGO “in consultative status with the WHO” [4] which, according to WHO’s rules, is one of the parties that can request a review of a substance by the ECDD.

- November 2016 - ECDD38

On three occasions before the 38th ECDD meeting in November 2016, the WHO eluded the review of cannabis by organizing pointless “update” meetings without procedural value in the scheduling process. In November 2016 however, cornered by the four direct mandates for a review (Country, CND, INCB, consultative NGO - underlined with brackets in the paragraphs above), the WHO finally decided to begin the review process for cannabis, under different components. They announced that the process would start with the Pre-review of cannabidiol (CBD), and convened an extraordinary ECDD meeting specifically to Pre-review all other products of the *Cannabis* plant:

- cannabis (buds) and cannabis resin,
- extracts and tinctures of cannabis,
- Δ^9 THC,
- Isomers of THC.

- November 2017 - ECDD39

At its 39th session, the Committee undertook the Pre-review of CBD. We joined efforts with the European Industrial Hemp Association (EIHA) to present a mutual statement, both orally and in an extended written version (which can be found on faaat.net/publications).

Our conclusion stated that *“CBD is a safe to use substance that is beneficial to human health and public welfare and has numerous applications in industry and nutrition, cosmetics as well as health and wellbeing products, besides its promising benefits in diverse indications such as reducing anxiety or helping people to quit smoking”* and that recommending the scheduling of CBD *“would severely restrict its availability for the non-problematic consumers of CBD and CBD-related products, as well as undermining safe access for many patients who already profit from CBD’s manifold health-related and homeostasis-supporting effects.”* In our understanding and conclusions, *“Cannabidiol did not fit any of the requirements or criteria for inclusion in the international drug control Schedules.”*

We urged the ECDD *“to clearly recommend the exclusion of Cannabidiol from the scope of the international control measures, and reaffirm its unbelonging to the lists of internationally controlled substances.”*

- December 2017 - Outcome of ECDD39

One month after the meeting, the outcome was presented during a CND session. Our call had been heard by the Experts, who recognized that *“CBD is not specifically listed in the Schedules”* and that *“there is no evidence that CBD as a substance is liable to similar abuse and produces similar ill-effects to substances in the 1961 or 1971 Conventions.”* The outcome, however, assimilated CBD-rich extracts of cannabis as “extracts and tinctures of cannabis”, already placed under Schedule I of the 1961 Convention.

- June 2018 - ECDD40

The 40th meeting of the ECDD (this extraordinary reunion, decided in November 2016, and focusing solely on *Cannabis*) pre-reviewed cannabis, cannabis resin, extracts and tinctures of cannabis, THC and the isomers of THC. They also did the Critical-review (final step) of CBD, which in the meantime had been renamed as “pure CBD.” The outcome of the CBD Critical-review was clear enough: “pure CBD should not be scheduled” reaffirming the outcome from the 39th ECDD (See Chapter 5.3).

- November 2018 - ECDD41

The ECDD, at its 41st session, is Critically reviewing cannabis, cannabis resin, extracts and tinctures of cannabis, THC and the isomers of THC. The outcome of this 41st meeting Critical reviews is a definitive and final recommendation proposing the adequate Schedule under which each of these item should be placed.

One of our first tasks has been to clear and highlight the reality of the hidden historical processes and political influences that led to the current international scheduling of cannabis. That process started in 1925 with the inclusion of so-called "Indian hemp" in the by-then "anti-opium" treaties. The WHO and numerous academics have been pretending that a scientific assessment had taken place in 1935, one which supported the inclusion of cannabis in this Treaties – although the minutes were missing.

After extensive research in the archives and history of international cannabis control, the minutes from the 1935 meeting that was alleged to be the scientific basis of the inclusion of cannabis among the other "dangerous drugs", were still impossible to find. Instead, most of the archives have mysteriously disappeared.

The ones we could find, however, were hiding key elements that unravel the official story.

It was in fact after the second world war, between 1950 and 1961, that cannabis was placed under a status of exceptionality by the diplomats preparing the draft 1961 Single Convention. They created the concept of lists arranging drugs according to their perceived level of harm, and introduced the **Schedule IV** listing drugs aimed at being completely prohibited – substances considered highly liable to create use disorders and dependence, with particularly dangerous properties, and little or no therapeutic values.

The WHO started to take an interest in the subject in 1952, through its then so-called "Expert Committee on Drugs Liable to Produce Addiction". At its 3rd Meeting, the *"question of justification of the use of cannabis preparations for medical purposes was discussed by the committee. It was of the opinion that cannabis preparations are practically obsolete. So far as it can see, there is no justification for the medical use of cannabis preparations."*² However, no review of the literature was made and preparatory documents of the meeting mentioned in the minutes of the Meeting are minimal. The following year, WHO Experts were *"pleased to note that the elimination of cannabis preparations had already begun by national action"*. In 1954 the Committee delivered its final sentence, relying this time on no more information than "the feeling among the South African police of a relationship between cannabis addiction and crime" and "evidence that, as in other parts of the world, cannabis abuse is likely to be a forerunner of addiction to opiates."

It is apparent that members of the Committee clearly acknowledged their ignorance of the mechanisms of action of cannabis on the human body (Δ^9 -THC wouldn't be isolated until 1964, and even later the endocannabinoid system). Yet without evidence they issued (and reissued) outcomes that have gone unchallenged in history – until now: Their 1954 opinion that *"not only can there be no abatement in control procedures but there should also be extension of the effort towards the abolition of cannabis from all legitimate medical practice"*³ was the last time WHO emitted a statement regarding the uses of Cannabis... until 2018.

² WHO Technical Report Series n°57, 1952.

³ WHO Technical Report Series n°95, 1955.

In 2015, the WHO edited an infographic resuming their Treaty-mandated roles on drug-related matters. It is perhaps the best starting point to this section.

WHO'S ROLE UNDER THE INTERNATIONAL DRUG CONTROL CONVENTIONS

The two major drug control conventions...

1961 Single Convention on Narcotic Drugs

as amended by the 1972 Protocol

1971 Convention on Psychotropic Substances

...recognize the medical use of narcotic drugs and psychotropic substances is indispensable and they should be available for such purposes.

The World Health Organization is responsible for conducting the medical, scientific and public health evaluation of substances.

Evaluations are conducted through:

The WHO Expert Committee on Drug Dependence

The Expert Committee on Drug Dependence (ECDD) evaluates the dependence-producing properties and potential harm to health of psychoactive substances in accordance with the *Guidance on the WHO review of psychoactive substances for international control*.

WHO communicates the ECDD's recommendations on whether or not the substances assessed should be placed under international control. WHO's assessments of psychoactive substances are **"determinative as to medical and scientific matters"**.

The Commission on Narcotic Drugs (CND) considers WHO's recommendation along with other relevant factors (economic, social, legal, administrative). The CND decides whether substances come under international control.

The CND is made up of 53 UN Member States – elected by the UN Economic and Social Council.

- ▶ PLACING A SUBSTANCE UNDER INTERNATIONAL CONTROL REQUIRES COUNTRIES TO APPLY SPECIAL MEASURES TO PREVENT ITS DIVERSION DURING IMPORT, STORAGE, DISTRIBUTION AND USE...
- ▶ CAREFUL CONSIDERATION MUST BE GIVEN TO NATIONAL IMPLEMENTATION TO AVOID RESTRICTING ACCESS TO MEDICINES CONTAINING CONTROLLED SUBSTANCES FOR PATIENTS WHO NEED THEM.



World Health Organization

Chapter 1. The Schedules

As annex to the three international Treaties framing the drug laws and policies that countries can implement (or not), there are a set of lists called **the Schedules**.

They include the whole panoply of products and substances that recent human history has placed "under control", the unduly designated "illegal drugs".

Highly inconsequential and irrelevant in the eyes of any scientist, the Schedules and their methodology of inclusion/withdrawal are like a drill core sample: they actually reflect the layers of an unspoken history of geopolitical struggles that have characterized the 20th Century.

Before 1961, every substance needed its own international multilateral agreement to be placed under control. Each country could choose to endorse it or not.

In 1961 a new Treaty compiled all the previous international agreements on drugs: the Single Convention. It brought an incredible simplification tool, the Schedules, that allow countries to add or withdraw drugs from the scope of international control and to automatically apply the related control measures to all Nations that are signatories to the latter Convention, without the need for renegotiating a Treaty.

However, though the Schedules make the work of governments easier, it is a complex landscape which needs to be debriefed for ordinary people.

1.1 International drug control Conventions

The so-called International Drug Control System relies on three Treaties:

- The 1961 Convention (Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol), which mostly deals with plants or pharmaceutical preparations, but also some molecules. It recovers the many Treaties on opium and other drugs prior to World War II.
- The 1971 Convention (Convention on Psychotropic Substances of 1971). This particular one only addresses psychoactive substances and drugs from a molecular chemical perspective.
- The 1988 Convention (United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988) reinforces the previous two and, as its name eludes, scales-up international cooperation on the repression of traffic (and production/cultivation) of products, substances and plants listed under the 1961 and 1971 Conventions.

It is critical to recall that the reading and implementation of these 3 Conventions is fully framed by general international law, and in particular by the Human, Cultural, Civil, and Political Rights instruments and Treaties, as well as the Charter of the United Nations.

Measures of the drug Treaties that would go against the UN Charter on fundamental rights should be considered null and void.

1.2 An annex to the Conventions: their Schedules

Besides the plants and substances directly placed under control in the Articles of the 1961 Convention (coca leaf, poppy and opium, cannabis and the *Cannabis* plant), and in order to create a **rapid process of legal response** to the eventual appearance or discovery of new substances, the international community created a mechanism that permits the CND (*Commission on Narcotic Drugs of the United Nations*, the

central legislative body on international drug control topics) to add or withdraw substances from the scope of control established by the Convention.

With the notable exception of ethanol and nicotine (the active compounds of alcohol and tobacco, respectively) most psychoactive products or substances are included in the Schedules of the 1961 or 1971 Conventions. Other non-psychoactive products, used as ingredients for the production of synthetic drugs, are scheduled under the 1988 Convention against trafficking in drugs.

Except drugs genuinely included in the Treaties (mostly opium poppy, coca leaf, *Cannabis* and their derivatives) every drug has to be scientifically assessed by independent Experts reporting to the World Health Organization, in order to be placed in, changed, or withdrawn from a Schedule.

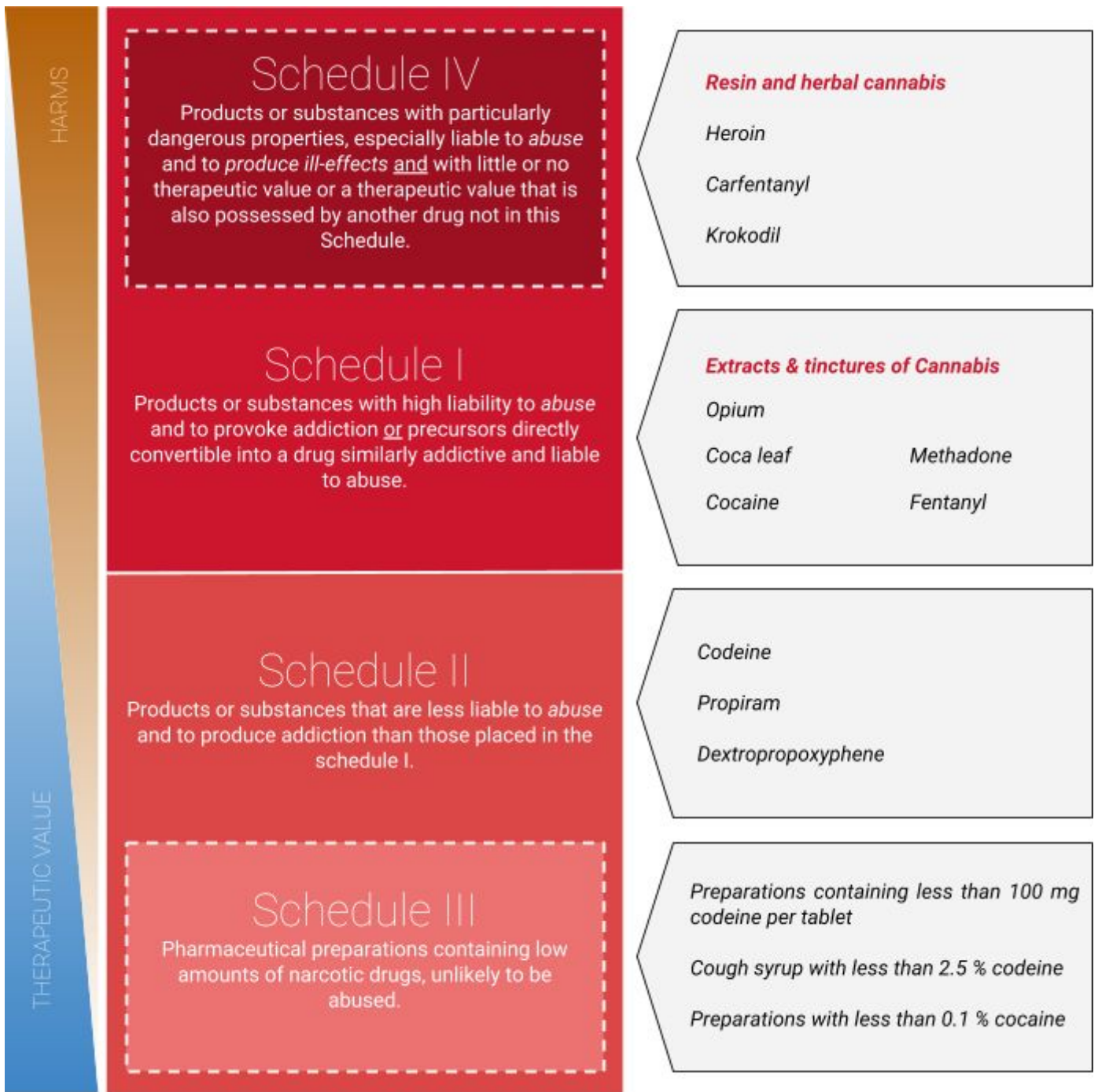
The **1961 Convention on narcotic drugs** created four lists - four Schedules - that are each linked to different, specific control measures. These Schedules list the drugs according to their therapeutic value and their potential for "abuse" and "creating ill-effects".

The 1961 Convention is essentially structured around **Schedule I**, which constitutes the standard regime of the Treaty. Some of the drugs included in Schedule I, considered as the most dangerous, are placed in the complementary **Schedule IV** – also called the Prohibition Schedule.

Plants, drugs or substances placed under **Schedule II of the 1961 Convention** are submitted to the same measures of control as the ones prevailing for schedule I, with some exemptions and a lighter subset of policy obligations. Finally, drugs in **Schedule III** are pharmaceutical preparations containing drugs included in the other schedules of the 1961 Convention, but with a much lighter control régime applied.

The 1961 Convention includes in its schedules pharmaceutical preparations, plants, raw drugs, precursors, as well as chemicals, while the 1971 Convention only includes molecular compounds. However, the **1971 Convention on psychotropic substances** followed this model and created four other (different) Schedules, based on a more rigorous frame.

1.3 Schedules of the 1961 Convention



Schedule III is a lighter subset of the schedules I and II. It exempts from control measures some drug-based preparations that are considered less of a danger than the raw drug they contain (for instance, while codeine is placed under schedule II, medicines containing less than 2.5% of codeine are placed under Schedule III and therefore exempted from control measures applying to Schedule II).

Schedule IV is a stricter subset of schedule I, that specifies extra control measures. Any substance included in Schedule I can also be added to Schedule IV, if it is considered "particularly liable to abuse and to produce ill-effects and if such liability is not offset by substantial therapeutic advantages not possessed by substances other than drugs in Schedule IV".

1.4 Schedules of the 1971 Convention



1.5 Treaty obligations.

Treaties and Conventions establish rules that signee countries commit to respect. In the present case, there are two kinds of rules implied by the Treaties:

- Body rules, general rules specified in the articles of the Conventions,
- Schedule rules, also in the Articles but applying only to substances in a specific Schedule.

To provide a general overview of the obligations derived from the Schedules of the drug-control Conventions, key measures of control imposed by the 1961 Convention have been summarized below.

Of course, beyond the obligations linked to the Schedule in which each substance or product is placed, the Treaties also consider other measures, such as the obligation to eradicate "within 25 years" the cultivation of *Cannabis* and other "narcotic" plants.

The **Schedule IV** or **Prohibition Schedule**, includes plants, drugs, substances or preparations that are considered as having "particularly dangerous properties" in comparison to all other drugs. The worst of the worst. The measures implied by Schedule IV forces countries (although it is not mandatory) to apply stringent regulations, leading up to the complete prohibition.

An open reading of the Convention does not compel mandatory prohibition. It is indeed specified that a country "*shall, if in its opinion the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare, prohibit the production, manufacture, export and import of, trade in, possession or use of any such drug except for amounts which may be necessary for medical and scientific research only.*" A compromise reached during the process of writing of the 1961 Convention, this article indirectly leaves it up to the countries, and their own judgement, whether to enforce prohibition as the means to protect public health or not. Applying prohibition or not, the chosen policy has to be considered sincere and "bona fide" (in good faith). Such a decision made insincerely would be considered a violation of the Treaty.

The text of the Convention already shapes a policy framework for each drug (in this case, prohibition). However, as there is an exception for "medical and scientific research only", some minor production, trade and use of the drug can be conducted. This is why there are complementary measures of control related to the Schedules.

| Mandatory control measures of the 1961 Convention | Schedules to which the measure applies | | | |
|--|--|---|----|-----|
| Limitation to medical and scientific purposes The production, manufacture, export, import, distribution of, trade, use and possession have to be limited exclusively to medical and scientific purposes. | IV | I | II | III |
| System of licences Governmental licensing is required for participation in any phase of the trade (manufacture, trade, distribution). Licensed persons and enterprises as well as all the modalities of the business are controlled. | IV | I | II | III |
| System of authorisations for import/export A governmental authorisations is required for each individual international transaction (import and export). | IV | I | II | |
| Exceptions on licences Governmental licensing is required for manufacturers of these preparations: a periodical permit specifies the kinds | | | | III |

| | | | | |
|--|----|---|----|-----|
| and amounts of drugs which they are allowed to manufacture. Governmental licensing is required for the establishments and premises in which trade or distribution takes place. | | | | |
| Control and inspection Governments must quite generally control all persons and enterprises carrying on, or engaged in the manufacture, trade or distribution. | IV | I | II | III |
| Estimates for the International Narcotics Control Board (INCB) Governments have to provide to INCB estimates of: - the quantities of drugs to be consumed for medical and scientific purposes; - quantities of drugs to be utilized for the manufacture of other drugs, of preparations in Schedule III, and of substances not covered by this Convention; - stocks of drugs to which the estimates relate; - quantities of drugs necessary for addition to special stocks; - the number of industrial establishments which will manufacture synthetic drugs and the quantities of synthetic drugs to be manufactured by each of these establishments; Afterwards, quantities in manufacture and importation, trade and distribution are limited in accordance with the estimates. | IV | I | II | III |
| Exception on retail trade stocks No obligation to prevent the accumulation of drugs in the possession of retail trade distributors, including in excess of the quantities required for the normal conduct of business. | | | II | III |
| Exception on estimates Estimates are not directly required for drugs in this Schedule, although indirectly, the general estimates of the drug requirements (see above) must include information about the quantities of drugs to be utilized for the compounding of these Schedule III preparations. | | | | III |
| Reports to the INCB Governments have to provide to INCB annual statistical returns on: - production or manufacture of drugs; - utilization of drugs for the manufacture of other drugs or preparations; - consumption of drugs; - seizures of drugs; - stocks of drugs; - area of cultivation; - imports and exports of drugs (quarterly reports). | IV | I | II | |
| Medical prescription A medical prescription is required for the supply or dispensation of drugs to individuals. Does not apply to such drugs that certain individuals may lawfully obtain, use, dispense or administer in connexion with their duly authorized therapeutic functions. Only authorized persons engaged in the drug trade and distribution, (such as manufacturers, wholesale and retail traders, medical practitioners and scientists) are entitled to acquire the drugs necessary for the performance of their legal business functions, professions or occupations. | IV | I | | |
| Exception on medical prescriptions No obligation of medical prescriptions for the supply or dispensation to individuals No obligation to use the official prescription forms in the shape of counterfoil books issued by authorities. The label under which these drugs are offered for sale in the retail trade must not show the exact content by weight or percentage. | | | II | III |
| Records All participants in the trade have to keep detailed records of any transaction done. The obligation however does not applies for medical practitioners (physicians, surgeons, veterinarians and dentists). | IV | I | II | III |
| Exception on records Pharmacists (retail traders) are not obligated to maintain records of their retail sales of these drugs, unless if they compound or prepare it themselves (with some minor variations). | | | II | III |

Chapter 2. The review process

The World Health Organization (WHO) is mandated by international law to review, assess and recommend appropriate levels of control to apply to each drug already included in the lists of the international Conventions, or those susceptible to enter. The process to generate such a public health benefit-risk assessment of drugs, plants, products or substances liable to produce harms or dependence, is called "scientific assessment" or "**review of substances for international control**". Officially, the purpose of this "**abuse liability assessment**" is to "evaluate substances for international control" and "provide scheduling advice".

The WHO defines its role regarding the three drug control Conventions as follows: *"WHO is the only treaty body with a mandate to carry out medical and scientific assessment of substances. According to the Convention on Psychotropic Substances (Article 2, paragraph 5), the CND, taking into account the information received from WHO "whose assessment shall be determinative as to medical and scientific matters, and bearing in mind the economic, social, legal, administrative and other factors it may consider relevant" makes a scheduling decision with regard to the substance.*

The role of the WHO, through the Expert Committee on Drug Dependence (ECDD), is to evaluate the impact of psychoactive substances on public health by evaluating their dependence producing properties and potential harm to health, as well as considering their potential medical benefits and therapeutic applications. The ECDD then makes recommendations for the scheduling (or de-scheduling) of substances according to international drug conventions. These recommendations are communicated to the Secretary-General of the United Nations, and are subject to a vote by the United Nations Commission on Narcotic Drugs (CND)."

The ECDD assessment process is precisely defined by the rules and procedures of the WHO – known for being complex and with room for interpretation. The mechanism goes through all the existing data and knowledge about a medicine (a product with known or supposed therapeutical properties, may it be a plant, a substance or a complex preparation) determining the due policies and regulations that should apply to it.

The WHO entrusts this work to a group of independent Experts specially called for the occasion. This group, the Expert Committee on Drug Dependence (or ECDD), analyzes the information submitted to them by different stakeholders (see flow-chart of the evaluation procedure under Chapter 2.5), and assesses the therapeutic effects, health-related or social harms that can be associated with the particular product.

The outcome of this global public health risk-benefit balance, is a recommendation to the United Nations to concretely amend the Treaties' Schedules and include, withdraw or move drugs amongst these.

2.1 Launch

A proposal to review a drug, plant or substance, already present in the Schedules of the 1961 or 1971 Conventions or not, can come from different stakeholders, namely:

- One or several of the Experts of the ECDD themselves,
- WHO officials,
- The United Nations Office on Drugs and Crime (UNODC),
- The International Narcotics Control Board (INCB),
- Observers (necessarily NGOs in an official status of relations with the WHO),
- The UN Commission on Narcotic Drugs (CND),
- The government of any member country of the Conventions (called "Party to the Convention").

Once one of these stakeholders presents a request for a review, the WHO should start collecting data and add the suggested drug to the agenda of the next meeting.

2.2 Preparation, documentation and data collection process

The preparation process consists of gathering all relevant data concerning the plant, product or substance under review. It is prepared by civil servants of the WHO, employing three methods of data collection:

- Routine data collection by the Secretariat,
- Questionnaires sent to countries to collect field information and data from national drug agencies,
- Sub-contraction of an Expert or advisor to write a scientific report

Along the review process, several different documents are edited – and not always published. Only the last of these, in the list below, proposes the definitive views on the product reviewed.

- **Pre-review report**, presented to ECDD [*Uploaded in PDF version on who.int*],
- Outcome report of the pre-review meeting [*Edited and published in the WHO Technical Report Series*],
- Working-report on the questionnaires [*Confidential*],
- Working-report on the scientific data part [*Confidential*],
- Preliminary critical-review report for peer-review [*Confidential*],
- **Critical-review report**, presented to ECDD [*Uploaded in PDF version on who.int*],
- Outcome report of the critical-review meeting, including the final Scheduling recommendations [*Edited and published in the WHO Technical Report Series*].

2.3 The Expert Committee meetings

The review process is composed of two meetings of the Experts. Each of these reviews has its own preparation process.

- **Pre-review.** The purpose of this review is for the Experts to determine whether the data submitted to them justifies that attention should be increased on the substance, and that a thorough evaluation (Critical review) should be made on the basis of comprehensive data.
- **Critical review.** It is the central duty of the Experts. The outcome is definitive and has legal consequences globally: if the United Nation adopts these recommendations, they become an amendment of the Treaty's schedules.

The closed-doors meetings gather all the Experts, plus some external advisers usually appointed among experts of relevant international institutions (often the UNODC, the INCB and the European monitoring center on drug addiction).

At every meeting, the WHO tries to better the possibility of involvement and inputs from civil society: there is now an opening session where civil society representatives and researchers can present their views and directly address the Experts.

2.4 Assessment criteria

The criteria for the Experts to recommend a "change in the scope of drug control" (i.e the placement under control of a drug, plant or substance, its change of Schedule, or its withdrawal from the lists) follows a strict and formal, although illogical, assessment index, simplified in the chart below.

Essentially, these criteria can be summarized to the following:

- Similarity to substances already controlled under either the 1961 or 1971 Convention, or both;
- Degree of therapeutic usefulness;
- "Extent of abuse" or "degree of likelihood to abuse", or its liability to provoke addiction;
- Possible broader impact on public health and on creating social problems.

| TREATY PRINCIPLE | ASSESSMENT CRITERION |
|--|---|
| If the substance, plant or preparation under review is either... | |
| 1 | <p>SIMILARITY</p> <p>"liable to similar abuse, and productive of similar ill-effects as the substances in Schedules I or II" of the 1961 Convention</p> |
| OR | |
| 2 | <p>"convertible into a substance already in Schedules I or II" of the 1961 Convention</p> |
| OR | |
| 3 | <p>"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",</p> |
| ...if it is, then it should be scheduled under the 1961 Convention. | |
| ...if it is not, but there is "sufficient evidence that the substance is being or is likely to be abused so as to constitute a public health and social problem", and the substance has... | |
| 4 | <p>a "capacity to produce a state of dependence"</p> <p style="text-align: center;">AND</p> <p>capacity to produce a "central nervous system stimulation or depression, resulting in hallucinations"</p> <p style="text-align: center;">OR</p> <p>capacity to produce a "disturbances" in "motor function" / "thinking" / "behaviour" / "perception" / "mood"</p> |
| OR | |
| 5 | <p>SIMILARITY</p> <p>if found that substance has no capacity to produce dependence nor a stimulation or depression of the central nervous system, but "has the capacity to produce similar abuse and similar ill-effects as a substance in Schedule I, II, III or IV" of the 1971 Convention</p> |
| ...then it should be scheduled under the 1971 Convention. | |

Luckily enough, the WHO has issued internal guidelines precising these elements. However, besides efforts made to strengthen the procedure, the last Guidance for the Experts to recommend a level of control for drugs dates back to 2010⁴. They would benefit from an in-depth revision, and should take advantage of a civil society consultation where different academic proposals and methodologies could be shared.

2.5 Post-review process at WHO

Once a meeting has finished, the ECDD Secretariat takes care of editing the outcome of the discussions, to shape it in the form of an outcome report. It is then cleared by the internal WHO administration and ultimately endorsed by the Director-General of the WHO. The WHO has had a tendency to use this period between the end of the Experts meeting and the release of the report to amend and sometimes undermine opinions from the Experts.

The WHO DG takes then two steps:

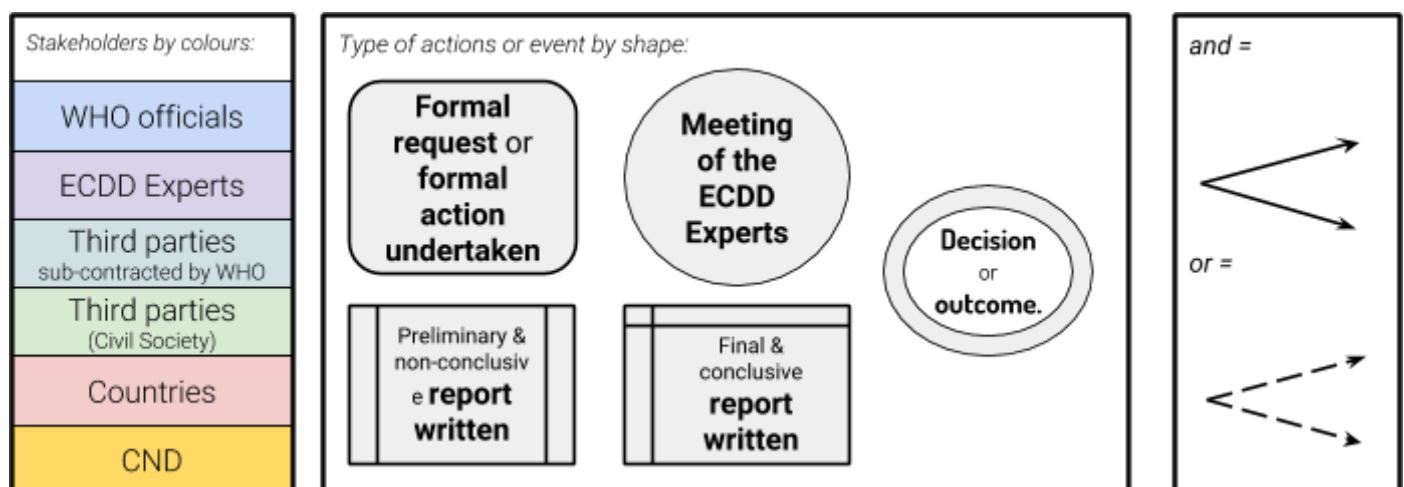
- Transmission of the content of the recommendations to the Secretary-General of the United Nations, for the emission of a Note Verbale to all countries, an official letter announcing the result of the ECDD meeting and announcing the votes to come at the CND.
- Transmission of the report to the Executive Board of WHO for adoption and final publication in press by the WHO Technical Report Series.

Every year in March, the CND meets and discusses the recommendations of the Expert Committee on Drug Dependence. The Commission has a 2-years rotating membership of 53 countries. It is these countries that have the right to vote on the scheduling recommendations of the ECDD.

2.6 Detailed flow chart of the review process

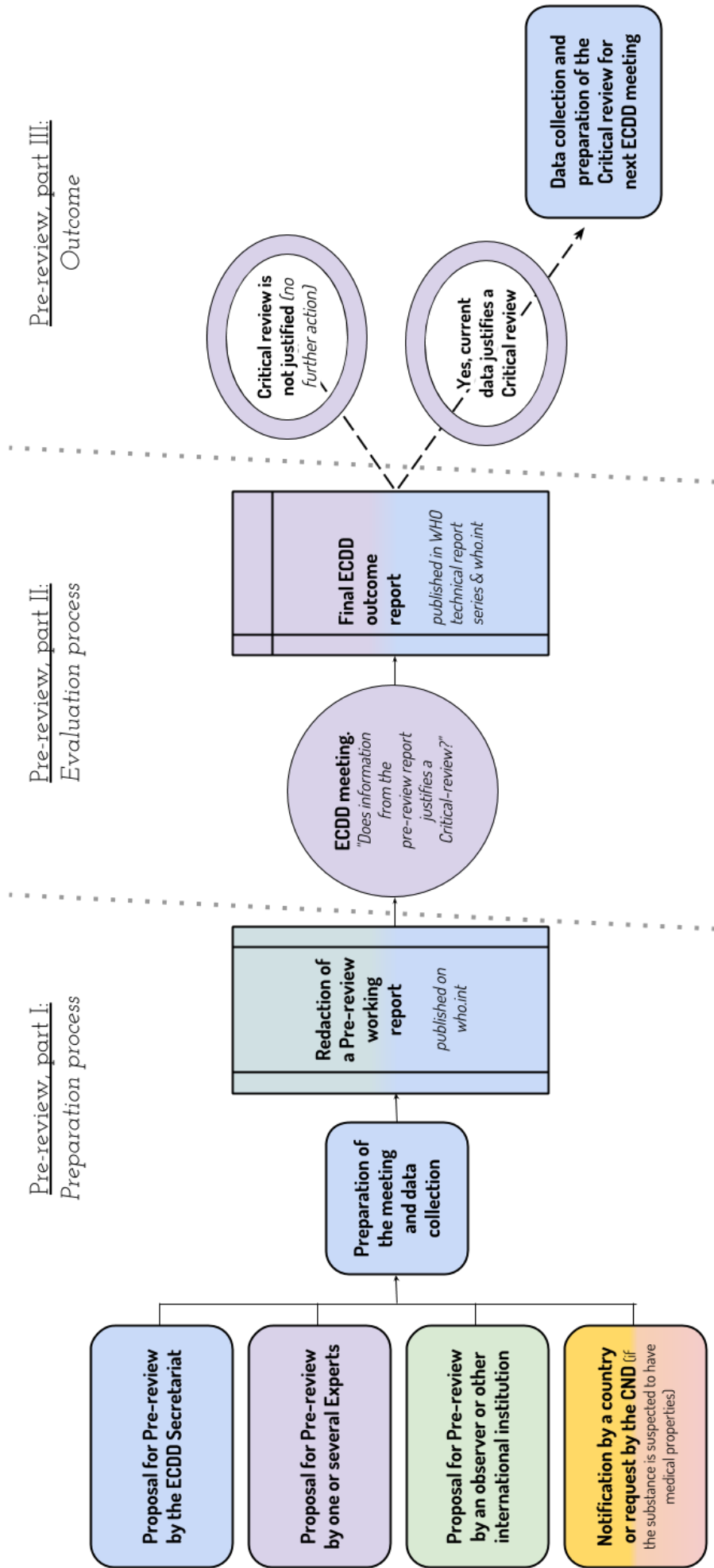
The next pages present a detailed flow-chart of the Pre-review and Critical review processes.

The opportunities for involvement of different stakeholders (Countries, UN agencies, civil society) has been underlined, and the legend below can guide this lecture:

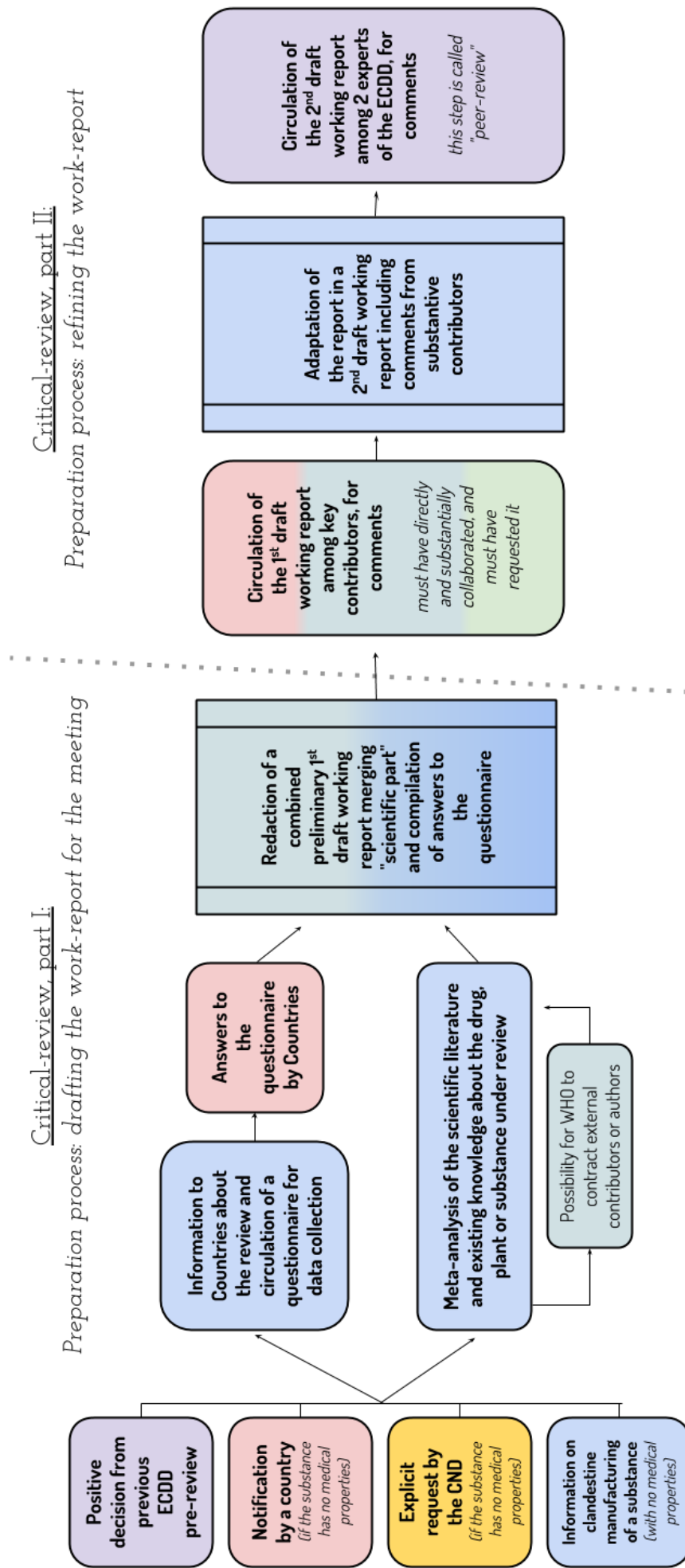


⁴ Guidance on the WHO review of psychoactive substances for international control, WHO, Geneva, 2010. http://www.who.int/medicines/areas/quality_safety/GLS_WHORev_PsychoactSubst_IntC_2010.pdf

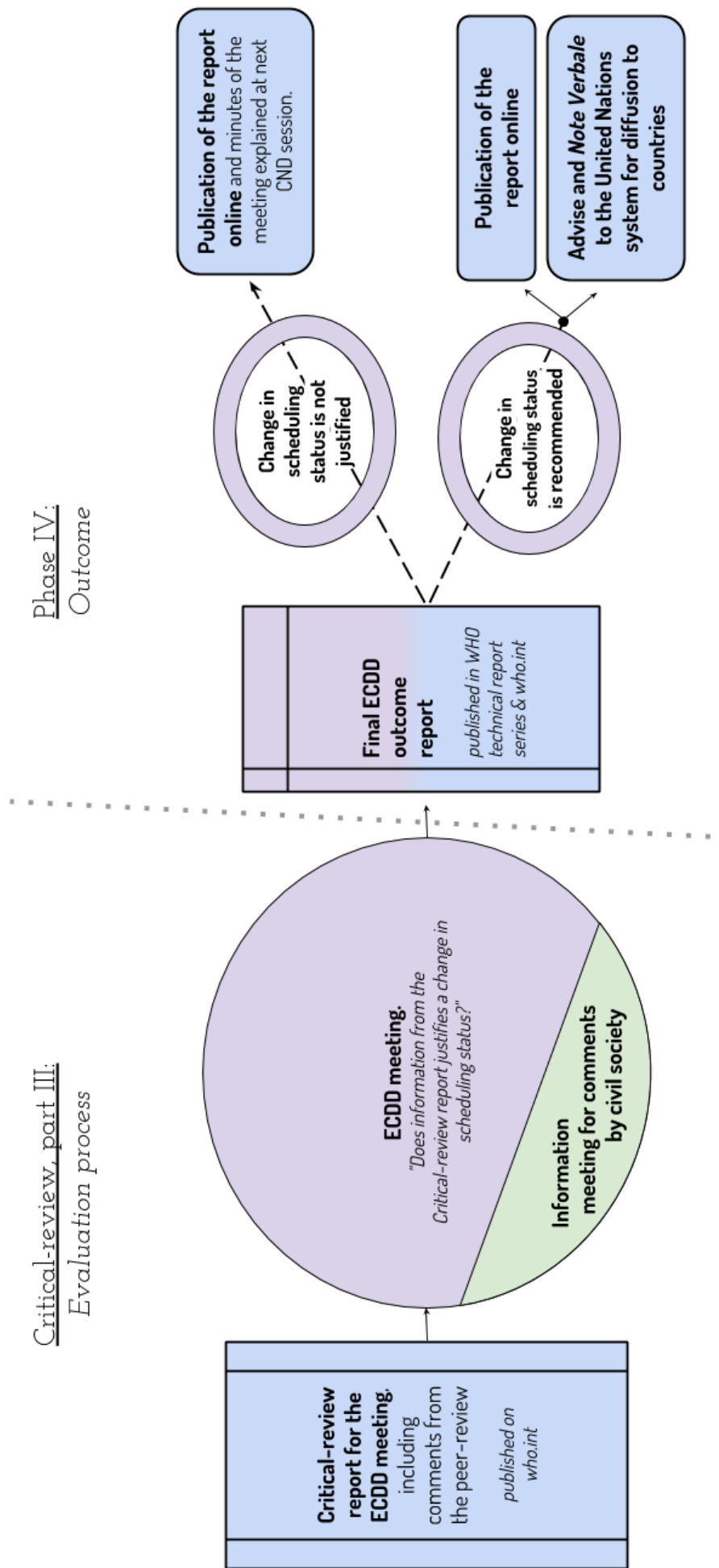
Pre-review



Critical review



Critical review (continued)



Chapter 3. The Experts

3.1 Role and mandate of the ECDD

The ECDD (Expert Committee on Drug Dependence) of the World Health Organization is the only international body responsible for conducting scientific and medical evaluations of all dependence-producing plants or substances.

The ECDD releases recommendations concerning the level of international control to be applied, under the 1961 or the 1971 international Conventions on drugs, and submits it to the Commission on Narcotic Drugs (CND) of the United Nations, the central legislative organ on drugs at international level.

The ECDD is a technical body, aimed at being independent from countries and political pressure.

The CND, one of the sub-commissions of the UN ECOSOC (Economic and Social Council), is a legislative body where Parties to the international Conventions (member countries) gather to vote on the recommendations of the ECDD.

Theoretically, no psychoactive substance can be scheduled internationally without first being evaluated by this expert committee. All decisions from the CND to add or withdraw a drug from the schedules needs to be backed by such a recommendation.

The review procedure, or abuse liability assessment, consists of a pre-review and a critical review ⇒ Read the Crimson Paper #3 to learn more about the pre & critical review.

Although they have no obligation to follow the ECDD recommendations, the treaties clearly imply that the recommendations shall be followed by votes from the CND.

Outcomes from the ECDD meetings are issued in a report, published by the World Health Organization in its Technical Report Series collection.

3.2 History

Although the name of the ECDD hasn't changed since 1969, it has previously had different names:

- 1966-1969: Expert Committee on Dependence-Producing Drugs.
- 1964-1966: Expert Committee on Addiction-Producing Drugs.
- 1950-1964: Expert Committee on Drugs Liable to Produce Addiction.
- 1949: Expert Committee on Habit-Forming Drugs established.

Before the second world war, the League of Nations used a so-called "Committee of experts in pharmacology", the ancestor of the ECDD. Caught in a struggle between two concurrent ancestors of the WHO (the Health Committee of the League of Nations, and the International Office for Public Hygiene), this committee was issuing pseudo-scientific reviews of substances and recommendations for the consideration of the League of Nations' General Assembly to place several substances under control. At that time the Schedules were non-existent, each new substance required a specific multilateral agreement to be ratified by every country individually, in order to fall under the international controls of the existing Treaties.

3.3 Nomination, rules and functioning

The ECDD is composed of independent experts, academics and researchers from all over the planet, following the general rules of procedure of the WHO for the choice of independent experts working groups (WHO's Regulations on Expert Advisory Panels and Committees):

Each meeting of the ECDD requires a renewal of its members, chosen by the WHO among a list of eminent specialists in medicine, pharmacology, behavioural or biological disciplines, but also members of public health administrations, etc. Mechanisms exist to prevent conflicts of interest.

The WHO, under its department of "Essential Medicines and Health Products", convenes, prepares, organizes and monitors the meetings of the Experts. The so-called "ECDD Secretariat" is in charge of this work. The Secretariat also compiles data and provides it to the Experts.

After years of absence of clear formal procedures, the WHO adopted in 2010 a document titled "Guidance on the WHO Review of Psychoactive Substances for International Control"⁵ that precises the procedures to be followed by the ECDD members to undertake the abuse liability evaluation within a clearer and more accurately defined evidence-based process, centered around matters of public health.

However, previously to the very Experts' review, the process and criterion followed by the Secretariat for the choice and selection of the relevance of data to be presented to the ECDD keeps following an undefined procedure. That can possibly represent an important way of undermining the independence of the work of the ECDD, by impeding access to parts of the collected data.

Apart from an introductory "open session" in which duly accredited observers can have short formal exchanges with the Experts, all meetings and deliberations of the ECDD are confidential, and indeed made public only after a clearing from the hierarchy of the WHO – another possible way of undermining the voice of the Experts.

For more detailed information, we recommend the reading of a very complete article⁶ detailing the history, process and details about the ECDD, as well as a NGO paper from 2014⁷.

⁵ See footnote 4, page 18

⁶ E. Danenberg, W.K. Scholten et al., Drug and alcohol dependence (#13, 2013, pp. 175–181)

⁷ C. Hallam, D. Bewley-Taylor and M. Jelsma, TNI-IDPC series No. 25, 2014

3.4 Members of the Committee

| 37th ECDD Nov. 2015 <i>UPDATE</i> | 38th ECDD Nov. 2016 <i>UPDATE</i> | 39th ECDD Nov. 2017 <i>P-R CBD</i> | 40th ECDD June 2018 <i>C-R CBD</i> <i>P-R CANNABIS</i> | 41st ECDD November 2018 <i>C-R CANNABIS</i> | |
|---|---|--|---|---|---------------|
| | | | | Junishi Kitanaka | ♂ JAPAN |
| | | | | Sutisa Nudmamud Thanoi | ♀ THAILAND |
| | | | | Katie Gysling | ♀ CHILE |
| | | | Lin Lu | | ♂ CHINA |
| | | Sandra Comer | | | ♀ USA |
| | Hye Jin Cha | | | | ♀ SOUTH KOREA |
| Simon Elliott | | | | | ♂ UK |
| Raka Jain | | | | | ♀ INDIA |
| Pamela Kaduri | | | | | ♀ TANZANIA |
| Jason White | | | | | ♂ AUSTRALIA |
| Afarin Rahimi-Movaghar | | | | | ♀ IRAN |
| Ifeoma Toyin Ekwere | | | | | ♀ NIGERIA |
| Patrick M. Beardsley | | | | | ♂ USA |
| Bruna Brands | | | | | ♀ CANADA |
| Bertha Madras | | | | | ♀ USA |

| | | |
|------------------------|--|--|
| Junishi Kitanaka | Pharmacology / Molecular neurobiology. Specialist of methamphetamine use and addiction. | Ex-NIDA advisor. Currently Associate Professor, Hyogo College of Medicine |
| Sutisa Nudmamud Thanoi | Psychiatry + Pharmacy + Medical & Cognitive Neurosciences + Medicinal Plants and Herbs + Depression | Department of Anatomy, Naresuan University |
| Katie Gysling | Biochemistry + Pharmacology + Interaction between stress & addiction | Pontificia Universidad Católica de Chile |
| Lin Lu | Neurobiological mechanisms + clinical intervention measures of psychiatric disorders | National Institute of Drug Dependence of Beijing University |
| Sandra Comer | Neurobiology + Psychiatry | Columbia University + New York State Psychiatric Institute |
| Hye Jin Cha | Government official + Specialist of New psychoactive substances and Synthetic cannabinoids | National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety |
| Simon Elliott | Biochemistry + Forensic Toxicologist + Biochemical Toxicology | Consultant + Managing Director of Forensics Ltd (Alere Forensics) + Advisor of EMCDDA and WHO on NPS |
| Raka Jain | Chemistry + Toxicology + Neuro-psycho-pharmacology (Behavioral, Biochemical, Molecular studies) + Abuse liability & abuse patterns + tobacco cessation | National Drug Dependence Treatment Centre + Department of Psychiatry, All-India Institute of Medical Sciences + In Charge of De-addiction centres. |
| Pamela Kaduri | Addiction Psychiatrist | (MD, Mmed, MscCH) Addiction Psychiatrist at the Department of Psychiatry and Mental Health |
| Jason White | Pharmacology + Neurosciences + Behaviour analysis & management of alcohol and drug problems | |
| Afarin Rahimi-Movaghar | Psychiatry + policy-making on substance use & mental health | Head of the Iranian National Centre for Addiction Studies + Tehran University of Medical Sciences + regular advisor for WHO & UNODC |
| Ifeoma Toyin Ekwere | Pain medicine + Anaesthesia + Intensive care | Senior Consultant Anaesthesiologist |
| Patrick M. Beardsley | Pharmacology + Toxicology | Researcher, Virginia Commonwealth University |
| Bruna Brands | Pharmacology | Office of Drug Science & Surveillance (Health Canada) + Director of the Collaborative Program in Addiction Studies (Univ. Toronto) |

Chapter 4. After the ECDD: Vote & legal consequences.

The recommendations of the WHO do not enter into force by themselves. To be turned into a Treaty amendment, they have to be endorsed by the United Nations, through its functional commission for drug-related matters: the Commission on Narcotic Drugs (CND).

The United Nations Office on Drugs and Crime (UNODC) gives a clear overview of the “scheduling procedures” on its website⁸. *“The CND exercises its mandated treaty-based scheduling functions under agenda item entitled “Implementation of the international drug control treaties: Changes in the scope of control of substances”. Under that agenda item the Commission considers proposals to add substances to the schedules/tables or to transfer or delete substances from the schedules/tables.”*

4.1 The voting process

“In the case of changes in the scope of control of substances under the 1961 and the 1971 Conventions, the Commission decides whether a substance is to be placed under international control. Under the 1961 Convention, it can either accept the recommendation of the WHO concerning changes in the scope of control of substances or abstain from extending control at all. The CND cannot decide to add a substance or preparation to a schedule of the 1961 Convention if WHO has not recommended to do it.”

“Under the 1971 Convention, the Commission has more discretion. It may decide - contrary to a recommendation of WHO - to add a substance to a schedule of the 1971 Convention or refuse to do so, to add a substance to a different schedule than recommended, or to remove a substance from the schedule in which it is listed or refuse to do so. However, the CND has to take into account the assessment from the WHO, which shall be determinative as to medical and scientific matters, and to bear in mind the economic, social, legal, administrative and other factors communicated to it by the Parties. The Commission may also decide to seek further information from the WHO or from other appropriate sources.”


















































































The voting processes are very similar for the 1961 and 1971 Conventions. The only difference is in the quorum for the vote:

- In the case of the **1961 Convention**, **“a single majority** of the members of the Commission present and voting is sufficient for decisions to add, transfer or delete substances to or from the schedules annexed to the 1961 Convention”
- Under the **1971 Convention however**, **“a two-thirds majority** of the members of the Commission is required for such decisions”.

Although this is contested, it has already happened that the **Commission decided by consensus not to vote on recommendations** concerning scheduling changes. This is what happened in 2014 with THC (see historical timeline below).

⁸ See [unodc.org/unodc/fr/commissions/CND/Mandate_Functions/Mandate-and-Functions_Scheduling.html](https://www.unodc.org/unodc/fr/commissions/CND/Mandate_Functions/Mandate-and-Functions_Scheduling.html)

4.2 53 Countries with right to vote

| | |
|------------------------------|---|
| Afghanistan | |
| Algeria | |
| Argentina |     |
| Australia |     |
| Austria |   |
| Belarus | |
| Belgium |  |
| Brazil |     |
| Burkina Faso | |
| Cameroon | |
| Canada |     |
| Chile |     |
| China |  |
| Colombia |   |
| Côte d'Ivoire | |
| Croatia |     |
| Cuba | |
| Czech Republic |     |
| Democratic Republic of Congo | |
| Ecuador |  |
| El Salvador | |
| France |   |
| Germany |     |
| Guatemala |  |
| Hungary |  |
| India |  |
| Iraq | |
| Iran | |
| Israel |     |
| Italy |     |
| Japan |  |
| Kenya | |
| Kyrgyzstan | |
| Mauritania | |
| Mexico |   |
| Netherlands |     |
| Norway |    |
| Pakistan | |
| Peru |  |
| Qatar | |
| South Korea |  |
| Russia | |
| Slovak Republic |  |
| South Africa |  |
| Spain |   |
| Sudan | |
| Switzerland |    |
| Thailand |  |
| Togo | |
| Turkey |  |
| Uganda | |
| USA |     |
| Uruguay |     |

(Legend next page)



Access to **prescription** cannabis in its **phytopharmaceutical form** is possible, in all or part of the territory.



Access to **prescription** cannabis in the form of **extracts or tinctures** is possible, in all or part of the territory.



Access to **prescription** CBD preparations or **CBD-rich extracts** is possible, in all or part of the territory.



Access to **non-medical CBD preparations** or CBD-rich extracts is possible, in all or part of the territory.



Countries members of the **European Union**



Countries members of the **Organization of American States.**



Countries members of the **African Group**



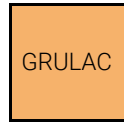
Countries members of the **Asia-Pacific Group**



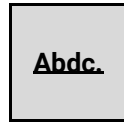
Countries members of the **Eastern European Group**



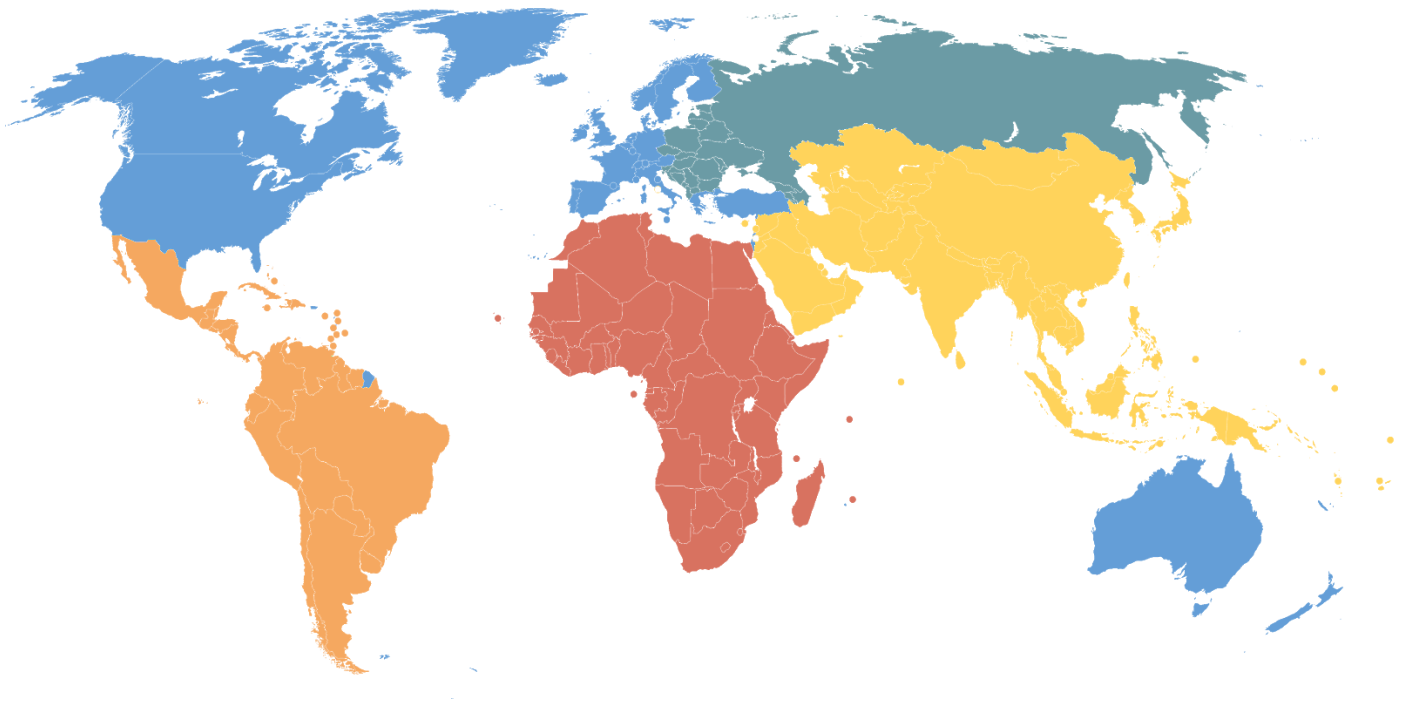
Countries members of the **Western European and Others Group**



Countries members of the **Latin American and Caribbean Group**



Countries where some non-illicit access to recreational cannabis is regulated.



Map of the five regional groups of Countries within the United Nations.

4.3 Negotiations within regional groups

As we can see in the chart above, countries are identified by their regional groups. As the regional groups are pivotal elements of the broad United Nations system, arrangements and agreements are ordinarily made between countries of these groups. Therefore, other considerations or negotiations, unrelated to the topic of substance scheduling, can influence the decision of countries of the different regional groups to align with the common position or not.

It is an important element to consider in the voting process that should be explicitly addressed by civil society stakeholders, to avoid their country's decision on the vote being a *negotiation tool* for other topics within the regional groups.

4.4 Sovereignty breach in the European Union

During the last few decades, member countries of the European Union have been previously agreeing on common approaches to adopt during the discussions and negotiations at CND. A joint position was always sought for substance scheduling issues (and the vote that goes with it - as all other decisions at CND are taken by consensus). In early March 2017, the European Commission and the Council of the European Union decided that, on voting matters, the joint position of EU member states should be mandatory, and that the vote of EU Member States on substance scheduling at CND should be previously authorized by the Council.

Obviously, this “imperative mandate” to vote jointly interferes with the fact that some member states belong to the UN regional group WEOG, and others to the regional group EEG (see above p. 28, under 4.2).

The Horizontal Working Party on Drugs of the European Union, much better known as **Horizontal Drug Group** (HDG) is a preparatory body of the Council of the European Union, established in 1997 to coordinate EU Member States' internal action on drug-related matters, and their position in the international landscape.

The HDG, integrated by top public servants from national drug-control agencies, meets on a monthly basis in Brussels to prepare all relevant legislation and political documents adopted by the Council (EU drugs strategies, action plans, or EU common statements on drug-related aspects for international fora, such as the CND). They are also in charge of the cooperation with EMCDDA (European Monitoring Centre on Drugs and Drug Addiction), Europol (European Law Enforcement Agency), with international organisations, and with non-EU countries.

Originally, at the end of 2016, the Legal Service of the European Commission⁹ announced that the Treaties allowed for an imperative mandate of all EU Member States for the votes on substance scheduling at the CND – meaning that all the countries will agree to vote the same way prior to the actual vote, and be obliged by such agreement to vote the same as the rest. This imperative mandate decided in the HDG has already been functioning without a problem for decisions concerning the scheduling of ‘precursors’ under the 1988 Convention (a very different process not addressed in this report).

⁹ Proposal for a Council Decision on the position to be adopted, on behalf of the European Union, in the sixtieth session of the Commission on Narcotic Drugs on the scheduling of substances under the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the Convention on Psychotropic Substances of 1971. Explanatory Memorandum by the Commission. Brussels, 6th February 2017, included in 2017/0026 (NLE) <http://data.consilium.europa.eu/doc/document/ST-5912-2017-INIT/en/pdf>

"It is necessary that Member States prepare the meeting of the CND when it is called to decide on the scheduling of substances by reaching a common position in the Council. Such position, due to the limitations intrinsic to the observer status of the Union should be expressed by the Member States that are currently members of the CND, acting jointly in the interest in the Union within the CND. The Union, who is not a party to the 1961 UN Convention and to the 1971 UN Convention would not vote in the CND. To this end, the Commission is proposing a position to be adopted, on behalf of the European Union..."

"The legal basis for this proposal is Article 83(1) in conjunction with Article 218(9) of the Treaty on the Functioning of the European Union (TFEU).

"Article 83(1) TFEU identifies illicit drug trafficking as one of the crimes with a particular cross-border dimension and empowers the European Parliament and the Council to establish minimum rules concerning the definition of offences and sanctions in the area of illicit drug trafficking.

Article 218(9) TFEU applies regardless of whether the Union is a member of the body or a party to the agreement at issue. The CND is "a body set up by an agreement" within the meaning of this Article, given that it is body that has been given specific tasks under the 1961 UN Convention and the 1971 UN Convention.

The CND's scheduling-decisions are "acts having legal effects" within the meaning of Article 218(9) TFEU. According to the 1961 UN Convention and the 1971 UN Convention, decisions of the CND automatically become binding, unless a party has submitted the decision for review to ECOSOC within the applicable time-limit. The decisions of ECOSOC on the matter are final. The CND's scheduling decisions also have legal effects in the EU legal order by virtue of Union law, namely Framework Decision 2004/757/JHA. Changes to the schedules of the 1961 UN Convention and the 1971 UN Convention have direct repercussions for the scope of application of this EU legal instrument."

This imperative mandate, however, already did not apply to the United Kingdom due to technical details linked to the adoption of the Lisbon Treaty, with no link to their status of negotiation to leave the European Union.

The HDG discussed that decision, *"delegations expressed their views"* – and disagreed with it.

"A number of delegations questioned the possibility/necessity to adopt a Council decision on this matter in preparation for the forthcoming 60th CND session. Delegations questioned the EU competence in this area, the appropriateness of the proposed procedure as well as the short timeframe for the procedure"

It was decided to refer to the COREPER II (2nd Committee of the Permanent Representatives of the Governments of the EU Member States), a preparatory and advisory body of the Council that clears the claims or disputes. The COREPER and the Council's Legal Service, however, backed the proposal of the Commission:

*"The Union's competence is exclusive in so far as it relates strictly to the scheduling of substances, and therefore **Member States are only able to exercise their voting prerogative at the CND once it has been authorised by the Union, through a Council decision based on Article 218(9) TFEU.**"*

It is worth noting at this point that both HDG and COREPER take their decisions with a 2/3 majority of the votes.

Finally, the dispute was resolved a few days before the beginning of the CND session, with a precision that the imperative mandate was concerned only with the decision to vote on substance scheduling, and not the general position of Countries within the CND discussions.

The HDG therefore agreed to expand for narcotic drugs (1961 Convention) and psychotropic substances (1971 Convention) the imperative mandate voting process that was already in force for their precursors (1988 Convention).

As the EU Commission and Council noted themselves, the European Union is not a member of the Conventions - just an observer entity. Therefore, the EU does not have right to vote. Even though, as it is

explained in the Commission's explanatory memorandum, the CND scheduling decisions automatically apply to the EU, the decisions on substance scheduling are fully part of the sovereignty of States that have individually ratified the Treaties.

This is however highly questionable, and seems to hamper the sovereignty of EU Member States on the topic of substance scheduling.

4.5 Barriers at the Commission on Narcotic Drugs

As we have seen earlier, the CND can eventually decide not to vote on the recommendations. Such a step is extraordinary, and happened to date only for THC (dronabinol) in 2014, after the WHO has recommended on several occasions lowering the scheduling of this substance.

"At its 1277th meeting, on 14 March 2007, the Commission on Narcotic Drugs decided by consensus:

(a) Not to vote on the recommendation of the World Health Organization to transfer dronabinol and its stereoisomers from Schedule II to Schedule III of the Convention on Psychotropic Substances of 1971;

(b) To request the World Health Organization, in consultation with the International Narcotics Control Board, as appropriate, to undertake, for consideration by the Commission, a review of dronabinol and its stereoisomers when additional information became available."

The decision by consensus (with all countries present) bypasses the limited mandate of only 53 countries to vote on the recommendations, and is a way for countries that are not *voting members* of the CND to overlap the mandate of "the 53" planned in the Treaty.

Another possible barrier at the CND level is its secretariat, that could eventually tend to diminish the importance of the voting process (by scheduling it at the end of the meeting agenda, for instance).

4.6 After the vote: entry into force

It is possible for a Country to formally object to the UN Economic and Social Council (ECOSOC) about a vote made at the CND. In this case (which is quite unlikely to happen) the ECOSOC can confirm, alter or reverse the decision of the CND, and *"the decision of the Council shall be final"*.

If no objection is made, decisions become effective immediately (or after 180 days in the case of the 1971 Convention).

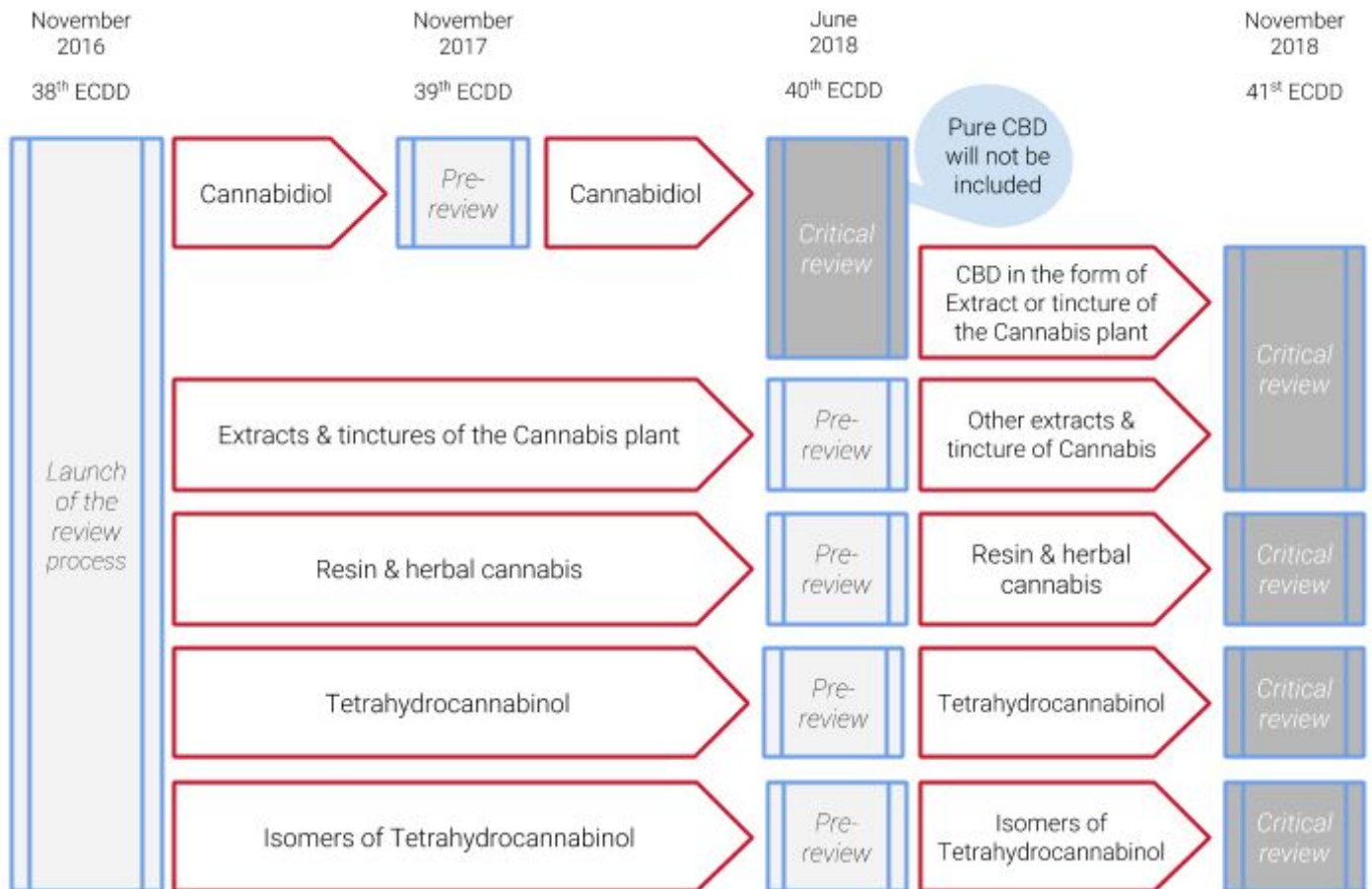
Chapter 5. Timeline & history of Cannabis in the Schedules

Basically, nothing has changed since 1961 for Cannabis, and since 1991 for THC. Before that however, the uncertainty of the global community regarding the controls to apply was palpable:

| 1925 Geneva Treaty | 1961 Convention | 1971 Convention | | | | |
|---|-----------------|-----------------|---|--|--|-------------|
| THE WHO TAKES OVER THE LEAGUE OF NATIONS' MANDATE OF THE PRE-2nd WORLD WAR DRUG TREATIES. | | | 1947 | | | |
| Indian hemp | | | 1948 | | | |
| | | | --- | | | |
| Extracts of Indian hemp | | | 1960 | | | |
| | | | --- | | | |
| ADOPTION OF THE 1961 SINGLE CONVENTION | | | 1961 | | | |
| Herbal Cannabis Schedule I Schedule IV | | | 1962 | | | |
| | | | --- | | | |
| | | | 1970 | | | |
| | | | ADOPTION OF THE 1971 CONVENTION | | | 1971 |
| | | | Cannabis resin Schedule I Schedule IV | | | 1972 |
| | | | | | | --- |
| | | | Extracts of Cannabis Schedule I | | | 1977 |
| | | | | | | --- |
| | | | Tinctures of Cannabis Schedule I | | | 1978 |
| | | | | | | --- |
| 1990 | | | | | | |
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| | | | 1991 | | | |
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| | | | 2018 | | | |

5.1 From 2016 to 2018

Since 2016 however, and the launch of the review process, things are moving:



However, to better understand how this review process is now possible - and why it took so long to start it, it is necessary to have a look at history. The journey between the inclusion in the lists and the reviews has been a long, as shown in the chart above.

Interestingly enough, the Experts of the ECDD have proposed, on several occasions, to undertake scientific assessments of tobacco or alcohol, noting that the harms generated by the use of these substances made relevant their consideration for inclusion in the schedules.

In both cases, either the Experts or the WHO officials noted that the current legal framework - basically any other legal framework than the one of the Treaties - would better address the public health problems related to these substances, instead of an actual inclusion in the lists of narcotic or psychotropic drugs.

5.2 From 1925 to 1961

Historically the first international treaties and arrangements mainly concerned war and commerce. Global health and international law intersected in the drug control system on the occasion of a series of wars motivated by business issues in the trade of opium, that came up with the adoption of the first drug control treaties (mainly about opium) in the early 1900's¹⁰.

Initially created only to establish common rules for fairness in the trade of opium, the agreements soon gravitated towards thematics of health – in that time called "hygiene" – and started to acknowledge health outcomes in drug policies.

The **Cannabis plant was genuinely included in the 1925 International Opium Convention**, on the pedant insistence of a small number of countries. The control measures then only required countries to provide some documentation when trading internationally and to pledge to refrain from exporting to countries that had forbidden its use¹¹.

It has been written that the **League of Nations (LoN)** undertook a review of Cannabis in 1935 but it appears that this was not the case. Contrary to what has been previously written in official WHO documents or in other indispensable research on the origins of international drug policies, **the so-called assessment of Cannabis made in 1935 by League of Nations never took place.**

The archives have indeed partly disappeared during the second world war (WWII) however something happened at the *Office International d'Hygiène Publique (International Office of Public Hygiene, OIHP)*, a *sui generis* international body led by French and Italian Foreign Affairs departments, to which the LoN had delegated a technical and consultative mandate on health issues. In a meeting of their sub-Committee of Experts in Pharmacology held in Bern on 4th and 5th March 1935 (see Images 1 and 2, page 8), they **reviewed 5 particular "preparations containing extract or tincture of Indian hemp"**, in preparations that included other powerful compounds such as strychnine.

October of the same year, 1935, the LoN Health Committee noted the review (Image 3) and recommended to countries that preparations partly made with "extracts and tinctures" of *Cannabis* be subject to the same control measures as the pure "extracts and tinctures". By then only "extracts and tinctures" were internationally controlled where the "preparations" were not. However, that recommendation was restricted to countries voluntarily applying it, and external and topical preparations were exempted.

The **myth of an assessment of Cannabis under the LoN** has justified the WHO shirking its responsibilities in the face of draconian measures of control, relying on a supposed previous ruling to avoid making decisions on a difficult subject matter.

Shortly after its creation the United Nations system initiated a process to **merge all existing international arrangements into a Single Convention** to control the then-so-called "dangerous drugs". The Single Convention on Narcotic drugs would be adopted in 1961 and enter into force in 1964. The first draft of this new Treaty¹², issued in 1950, proposed several options for narrow policy frameworks **allowing medical cannabis use**, while seeking to discontinue policies that allowed non-medical uses.

WHO started to take interest in the subject in 1952, through its then-so-called **Expert Committee on Drugs Liable to Produce Addiction**. At its 3rd Meeting, the *"question of justification of the use of cannabis preparations for medical purposes was discussed by the committee. It was of the opinion that **cannabis preparations are practically obsolete**. So far as it can see, there is no justification for the medical use of*

¹⁰ E. Rodriguez, 2015. *À l'origine des lois d'interdiction des drogues : Le Sommet International de Shanghai 1909 Ou l'irruption de la société civile dans les relations diplomatiques et les politiques internationales*, Paris, 2010, Université Paris 3 Sorbonne Nouvelle.

¹¹ To learn more about the international discussions on *Cannabis* prior to the 1925 Convention, see *The rise and decline of cannabis prohibition*, D. Bewley-Taylor, T. Blickman and M. Jelsma, Amsterdam, 2014.

¹² E/CN.7/AC.3/3

cannabis preparations.¹³ However, no review of literature was made, and preparatory documents of the meeting mentioned in the minutes of the Meeting are minimal.

At its 4th meeting in 1953¹⁴ the Committee "was pleased to note that the elimination of cannabis preparations had already begun by national action, following the opinion expressed in its [3rd meeting] that **there is no justification for the medical use of cannabis preparations.**' The committee [...] was of the opinion that the definitions for cannabis and its preparations should be revised on the basis of the presence of active principles."

The year 1954 is the occasion for the Committee to reiterate its allegations, relying this time on no more information than "**feelings**" sent by South African police authorities: "The committee considered the report of the Inter-Departmental Committee on the Abuse of Dagga, informing it of (1) the existence in the Union of South Africa of widespread addiction to cannabis, always by smoking, (2) the feeling among the South African police of a relationship between cannabis addiction and crime, (3) evidence of permanent deterioration as the result of the addiction, and (4) evidence that, as in other parts of the world, cannabis abuse is very likely to be a forerunner of addiction to opiates. [...] The committee was of the opinion that cannabis abuse comes definitely under the terms of its definition of addiction, that the abuse of cannabis is still a serious problem in many parts of the world, and that not only can there be no abatement in control procedures but there should also be extension of the effort towards the abolition of cannabis from all legitimate medical practice."¹⁵

Historically, these three reports constitute a critical tipping point. In those meeting minutes we have been able to identify that members of the Committee clearly acknowledge their ignorance of the mechanisms of action of Cannabis on the human body (Δ^9 -THC wouldn't be isolated until 1964, and even later the endocannabinoid system). Yet without evidence they issued and reissued outcomes that have gone down in history unchallenged until now.

In 1953, the CND created the concept of a Schedule IV which would consist of drugs aimed at being completely prohibited. In 1955¹⁶ and 1958¹⁷ the Commission finished confirming the inclusion under this new schedule "Cannabis and cannabis resin, extracts and tinctures of cannabis, or any other substances containing the pharmacologically active principle of the cannabis resin (subject to the special regime [for traditional medicine])." No review or scientific assessment was ever mandated prior to that inclusion. However, on the insisting remarks of several countries provision was made in the draft Convention to balance the "prohibition of the medical use of cannabis drugs" giving exception to "certain systems of indigenous medicine."

In 1958, the CND "noted that some Governments had reported that there still existed an appreciable use of cannabis drugs in medical practice". However, countries decided to maintain their "view [...] shared by the WHO Expert Committee on Drugs Liable to Produce Addiction that cannabis drugs no longer served any useful purpose. The Commission decided, therefore, that **the new treaty [...] should provide for a régime of prohibition.** It should also be made clear in the new treaty that **the use of cannabis would be prohibited for all purposes, medical and non-medical alike,** except that of scientific research."

Therefore the predecessors of the ECDD have directly served as a justification for the strictest possible global policy for medical uses of the Cannabis plant and its derivatives and thereby have made scientific research into Cannabis unnecessarily burdensome.

In 1960, as the Plenipotentiary Conference was about to begin – to adopt the final text of the Single Convention – the UN premiered what is now a Treaty-mandated role of the ECDD: to assess substances for the purpose of defining the suitable international control. **The first-ever assessment for the purpose of international scheduling was exercised for Cannabis,** after the United Nations "invited the World Health

¹³ WHO Technical Report Series n°57, 1952.

¹⁴ WHO Technical Report Series n°76, 1954.

¹⁵ WHO Technical Report Series n°95, 1955.

¹⁶ E/2768/Rev.1

¹⁷ E/3133

Organization to prepare [...] a report on the use of cannabis for the extraction of useful drugs, particularly of the antibiotic type [...] to make this report available to the [...] Plenipotentiary Conference [...] with a view to a possible modification of the provisions of the Single Convention in order to permit the use of cannabis for the extraction of useful drugs."¹⁸ That year, the Expert Committee met at its 11th Meeting, but although acknowledging promising research on antibiotic properties of Cannabis, recalled for the third time that "the opinion expressed in [the 3rd meeting] remains unchanged. Cannabis and its preparations are practically obsolete and there is no justification for their medical use."¹⁹

In the spring of 1961 the Plenipotentiary Conference adopted, in New-York, the Single Convention on Narcotic drugs with an exemption from Schedule IV for the extracts and tinctures of Cannabis – It is our opinion that this was intended to leave the door open for future identification of the active principles of the plant that would lead to isolating drugs extracted from the Cannabis plant.

The 5th and 11th Meeting of the Expert Committee repeatedly provided direct input to the Single Convention on cannabis (still in force), considered to be the **last and only assessments made of this drug**. Because of that, six decades later, robust scientific evidence is still minimal, even for a substance consistently documented as having an important therapeutic potential. **Schedule IV has effectively stifled gold standard research into Cannabis and cannabinoids medical applications.**

5.3 From 1952 to 2018: detailed timeline.

| Date | Body Reference | Action taken related to Cannabis |
|------|--|--|
| 1952 | 3 rd ECDD: ECDD03 TRS_57 | Update of Cannabis as "<u>Cannabis sativa L.</u>" <i>"The question of justification of the use of cannabis preparations for medical purposes was discussed by the committee. It was of the opinion that cannabis preparations are practically obsolete. So far as it can see, there is no justification for the medical use of cannabis preparations."</i> |
| 1953 | ECDD04 TRS_76 | Update of Cannabis as "<u>Cannabis sativa L.</u>" <i>"The committee was pleased to note that the elimination of cannabis preparations had already begun by national action, following the opinion expressed in its [ECDD03] report that 'there is no justification for the medical use of cannabis preparations.' The committee expressed its agreement with the action taken by the Commission on Narcotic Drugs at its eighth session to the effect that the term 'Indian hemp' should be replaced by the term 'cannabis', as proposed by the representative of the World Health Organization. Furthermore, it was of the opinion that the definitions for cannabis and its preparations should be revised on the basis of the presence of active principles."</i> |
| 1954 | ECDD05 TRS_95 | Update of Cannabis under the item "<u>Situation concerning Cannabis sativa</u>" <i>"The committee considered the report of the Inter-Departmental Committee on the Abuse of Dagga, informing it of (1) the existence in the Union of South Africa of widespread addiction to cannabis, always by smoking, (2) the feeling among the South African police of a relationship between cannabis addiction and crime, (3) evidence of permanent deterioration as the result of the addiction, and (4) evidence that, as in other parts of the world, cannabis abuse is very likely to be a</i> |

¹⁸ E/CONF.34/5

¹⁹ WHO Technical Report Series n^o211, 1961.

forerunner of addiction to opiates.

The committee was pleased to note the steps taken by the Government of the Union of South Africa to assess and control the cannabis situation in the Union. The committee was also pleased to note information on improvement in the cannabis situation in India. Evidence from India, however, confirmed the development of permanent deterioration as the result of the abuse of cannabis. The committee was of the opinion that cannabis abuse comes definitely under the terms of its definition of addiction, that the abuse of cannabis is still a serious problem in many parts of the world, and that not only can there be no abatement in control procedures but there should also be extension of the effort towards the abolition of cannabis from all legitimate medical practice."

1959 ECDD 10
[TRS 188](#) Opinion about Schedule IV: Total prohibition should not be mandatory, and Treaty should impose the less restrictions as possible to physicians.

Update about "**Antibiotic Substances from Cannabis**"

"The Committee considered the information available regarding substances with antibacterial activity which can be extracted from Cannabis sativa. The Committee concluded that at present the case has not been proved in favour of making cannabis available for the extraction of useful drugs, particularly of the antibiotic type.

1960 ECDD11
[TRS 211](#) As regards the question of the therapeutic usefulness of cannabis, the opinion expressed in [ECDD03] remains unchanged. Cannabis and its preparations are practically obsolete and there is no justification for their medical use. This conclusion does not affect the Committee's opinion as expressed in its tenth report.² The prohibition or restriction of the medical use of a drug representing a particularly high danger to the community should continue to be recommended by the international organs concerned, but should not be mandatory."

1961 Pleni-
potentiaries
Conference
[Treaty](#) **Adoption of the 1961 Convention on narcotic drugs.**
The WHO's ECDD receives a more direct mandate from the Convention to recommend scheduling of narcotic drugs.

Definition of the "**drug-dependence of cannabis type**"

"Drug dependence of cannabis type is described as a state arising from repeated administration of cannabis or cannabis substances, which in some areas is almost exclusively periodic, in others more continuous. Its characteristics include:

1964 ECDD13
[TRS 273](#) (1) a desire (or need) for repeated administration of the drug on account of its subjective effects, including the feeling of enhanced capabilities;
(2) little or no tendency to increase the dose, since there is little or no development of tolerance;
(3) a psychic dependence on the effects of the drug related to subjective and individual appreciation of those effects;
(4) absence of physical dependence so that there is no definite and characteristic abstinence syndrome when the drug is discontinued."

Update of "**Cannabis**"

1965 ECDD14
[TRS 312](#) "As pointed out previously, medical need for cannabis as such no longer exists. It is becoming increasingly apparent that tetrahydrocannabinol is its most important constituent from the point of view of pharmacodynamic effects, and tetrahydrocannabinol or related substances, whether naturally or synthetically produced, may eventually be shown to have medical applications. Research on cannabis will be facilitated if all investigators will calibrate their methods and results using the same uniform sample. Such a sample has been prepared by the Narcotics Laboratory of the United Nations."

Update of "**Cannabis***"

With the precision "Ganja, hashish, kif, maconha, marihuana and 'pot' are but a few of the names commonly used in referring to cannabis."

"As pointed out by previous WHO Expert Committees concerned with drug dependence, medical need for cannabis as such no longer exists.

However, the non-medical use of this substance persists and has been increasing in a number of countries. In some countries, there are considerable differences of opinion about questions of dependence liability, the acute and chronic effects on the individual user and the community, and the type and nature of the controls to be applied.

This Committee strongly reaffirms the opinions expressed in previous reports 1 that cannabis is a drug of dependence, producing public health and social problems, and that its control must be continued.

It was generally recognized that more basic data on the acute and chronic effects of cannabis on the individual and society are needed to permit accurate assessment of the degree of hazard to public health. It was also noted that tetrahydrocannabinols, which are important constituents of cannabis, have been isolated in pure form and completely synthesized. The availability of these compounds will make it possible to intensify basic research into such matters as tolerance, dependence potential, abuse liability, and specific acute and chronic toxic effects."

1968

ECDD16
[TRS_407](#)

Recommendation to schedule "**tetrahydrocannabinols**"

Tasked with drafting the future 1971 Convention, the ECDD recommended to place under control "*tetrahydrocannabinols, all isomers*" in the "*Group (a)*", the strictest schedule (later adopted by Member States as Schedule I of the 1971 Convention), without even the possibility of medical prescription.

Inherited from the 1931 Convention "*Group 1*" Schedule, the ECDD proposed "*Group (a)*" was aiming to reunite "*drugs recommended for control because their liability to abuse constitutes an especially serious risk to public health and because they have very limited, if any, therapeutic usefulness.*"

Recommendation to schedule "**cannabidiol**" as a precursor.

Parallely, ECDD proposes a supplementary 5th Schedule for the 1971 Convention, that would list the substances precursor (easily convertible into scheduled drugs), a concept foreshadowed in the 1931 Convention. Although they assumed the difficulty to define criteria for inclusion would not allow them to create such a *Schedule of precursors*, they still decided to review the case of 3 substances, among which "*cannabidiol, a precursor of the tetrahydrocannabinols used only in their preparation*". The ECDD recommended that CBD should fall under similar control measures as those planned for THC:

"The Committee recommended that [cannabidiol] be controlled and suggested that the broad controls be the same as those suggested for drugs in group (a), except that (1) they should be available to licensed persons only on the basis of a non-refillable order, and

(2) records should be kept of all transactions from the production or manufacture of the precursors up to and including the initial disposal of any non-controlled products resulting from their transformation."

1970

ECDD17
[TRS_437](#)

1971

Pleni-
potentiaries
Conference
[Treaty](#)

Adoption of the 1971 Convention on psychotropic substances.

The WHO's ECDD receives a more direct mandate from the Convention to recommend scheduling of psychotropic substances.

1973

ECDD20
[TRS_551](#)

An extensive report discussing a wide range of topics concerning problems related to the non-medical use of psychoactive substances.

Update of Δ^9 -THC as "**Tetrahydrocannabinols**"

"The Expert Committee accepted that expediency had prompted reference in Schedule I of the Convention to 'all isomers' of the tetrahydrocannabinols but, for the reasons [of broad definition of the word 'isomer'], considered that this description was too imprecise because it could include alternative cyclic structures or positional isomerism of functions other than hydrogen. On the assumption that the original intention had been to control the tetrahydro derivatives of cannabinol, the Committee recommended that control should be restricted to seven specific double-bond tetrahydrocannabinol isomers, namely $\Delta^{6a(10a)}$, $\Delta^{6a(7)}$, Δ^7 , Δ^8 , Δ^9 , Δ^{10} , $\Delta^{9(11)}$, and their stereochemical variants. If the recommendation is adopted by the Commission it should no longer be necessary to retain the specific chemical designation of one isomer, Δ^8 -tetrahydrocannabinol, in the schedule."

1978

ECDD21
[TRS_618](#)

In an annex, they precise that "The main evidence of abuse potential is for the (–)-trans- Δ^8 and (–)-trans- Δ^9 isomers of tetrahydrocannabinol. The $\Delta^{6a(10a)}$, Δ^7 , and $\Delta^{9(11)}$ isomers have distinctly lower psychotropic potency. [...]"

An extensive series of natural substances has been extracted from cannabis, and there is a considerable literature on their biological properties. [...]"

An increasing number of cannabinoid substances show promise as therapeutic agents but not many of them have yet been shown to possess hallucinogenic activity [underlined by the authors]."

The wording of that last sentence almost betrays a pre-judgement, and their impossibility to conceive that cannabis could be something else than a harmful drug.

Critical review of (–)-trans- Δ^9 -THC as "**dronabinol**"

"On 1 December 1987, the Government of the United States of America sent a notification [...] requesting the transfer of delta-9- tetrahydrocannabinol (delta-9-THC) from Schedule I to Schedule II of the Convention. [...]"

The generic term delta-9-THC in the Convention refers to two racemates and four stereoisomers. However, both the data presented by the United States of America together with its notification and the material presented in the Critical Review concern a single stereochemical variant of delta-9-THC, namely dronabinol. Since little or no data exist on the racemates and other stereoisomers, and since the pharmaceutical preparation marketed in the USA contains only this particular stereochemical variant, the Expert Committee reviewed only dronabinol, and it is to this substance alone that the recommendation given below thus refers. [...]"

[The] Committee recommended rescheduling of the drug from Schedule 1 to Schedule 2 of the Convention on Psychotropic Substances, 1971".

For the first time, there is a recognition of a therapeutic potential of (–)-trans- Δ^9 -THC, as an "antiemetic adjuvant to cancer chemotherapy in selected cases."

A footnote refers to discrepancies from two Experts that "considered that the recommendations might be misinterpreted and promote the abuse of cannabis and its extracts."

1989

ECDD26
[TRS_787](#)

1990

CND-S11
11th Special
session

Negative vote on rescheduling (–)-trans- Δ^9 -THC.

The Commission on Narcotic Drugs rejects the ECDD recommendation to reschedule dronabinol from Schedule I to Schedule II of the 1971 Convention.

1990

ECDD27
[TRS_808](#)

Critical review of " **Δ^9 -THC**"

"Although the data on the therapeutic usefulness and dependence liability relate only to one stereochemical variant of delta-9-THC (namely, dronabinol), it was noted that making a distinction between this single isomer and the others contained in the group may create legal and forensic analytical problems in some countries. For this reason, it is recommended that delta-9-THC and its stereochemical variants be rescheduled together. [...]

It is recommended that delta-9-tetrahydrocannabinol and its stereo-chemical variants be rescheduled from Schedule 1 to Schedule 2 of the Convention on Psychotropic Substances, 1971."

| | | |
|------|---|--|
| | | Positive vote on rescheduling Δ9-THC. |
| 1991 | CND34 Decision 2 (XXXIV) | "At its 1045 th meeting [...] the Commission on Narcotic Drugs [...] decided that delta-9-tetrahydrocannabinol (also referred to as delta-9-THC) and its stereochemical variants should be transferred from Schedule I to Schedule II of [the 1971] Convention." |
| 1995 | ECDD29 TRS 856 | Call for a Pre-review of nicotine-based products (such as chewing gums, patches, etc). |
| 1998 | ECDD30 TRS 873 | Nicotine Pre-review outcome is a call for the pre-review of tobacco. |
| | | The ECDD call for another pre-review of Dronabinol. |
| 1999 | ECDD31 TRS 887 | Tobacco Pre-review outcome: "Smoking tobacco is dependence-producing, causes serious public health problems and has no therapeutic use. However, judging from the control measures provided for, the scheduling criteria specified and the substances already under control, existing international drug control measures for narcotic drugs and psychotropic substances appear to be unsuitable for controlling tobacco, a dependence-producing natural substance widely used for non-medical purposes at the time of adoption of the relevant conventions. Even though new information indicates health risks greater than those previously known, tobacco would not meet the criteria for scheduling under the existing international drug control treaties. Furthermore, once scheduled, total prohibition would be the only control measure applicable to tobacco, since the regulated supply of controlled substances is not allowed for non-medical and non-scientific purposes." |
| | | Pre-review of (–)-trans-Δ9-THC as "dronabinol" |
| 2001 | ECDD32 TRS 903 | Expansion of the recognition of therapeutical use for "anorexia associated with weight loss in patients with AIDS." Recommandation to undertake Critical review of the whole Δ9-THC. |
| | | Critical review of "delta-9-tetrahydrocannabinol" |
| 2003 | ECDD33 TRS 915 | The ECDD recommends to place all stereoisomers of Δ9-THC in the schedule IV, with the lowest control measures. "The abuse liability of Dronabinol is expected to remain very low [and] does not constitute a substantial risk to public health and society. [...] To avoid placing different stereochemical variants of the same substance under different control systems, the Committee recommended that all stereochemical variants of delta-9-tetrahydrocannabinol be moved to Schedule IV of the 1971 Convention." |
| 2004 | CND47 | Absence of vote on rescheduling Δ9-THC. |
| 2005 | CND48 | |
| 2006 | CND49 | |
| 2006 | ECDD34 TRS 942 | At ECDD33, "the Committee considered that dronabinol should be rescheduled to Schedule IV of the 1971 Convention. However, no further procedural steps were taken. Therefore, the existing critical review report was updated, including information from recent scientific publications" |

"The committee reconsidered the recommendation of the 33th ECDD [and] concluded that Dronabinol constitutes a substantial risk to public health. However this risk is different from those related to cannabis - controlled under the 1961 Convention. [...] the Committee recommended that dronabinol and its stereoisomers should be rescheduled from Schedule II to Schedule III of the 1971 Convention [and they] indicated that the recommendation pertains to all stereoisomeric forms of delta-9-THC"

| | |
|--|--|
| <p>2006</p> <p>CND50 Decis 50/2</p> | <p>Decision not to vote on rescheduling Δ9-THC.</p> <p>"The Commission on Narcotic Drugs, decided by consensus: (a) Not to vote on the recommendation of the WHO to transfer dronabinol and its stereoisomers from Schedule II to Schedule III of the 1971 Convention; (b) To request the WHO [to undertake] a review of dronabinol and its stereoisomers when additional information became available."</p> |
| <p>2009</p> <p>CND52 Res 52/5</p> | <p>1st Request for a review of Cannabis.</p> <p>"The Commission [...] requests the United Nations Office on Drugs and Crime to share information regarding the health risks posed by cannabis with the [ECDD], and, in that regard, looks forward to an updated report on cannabis by the Expert Committee"</p> |
| <p>2012</p> <p>ECDD35 TRS 973</p> | <p>The ECDD notes the request by the CND to review Cannabis, they prepare a preliminary document for the next meeting. The ECDD reconducts its recommendation to move Δ9-THC from Schedule II to Schedule III of the 1971 Convention. To be noted also: "There was a brief discussion as to whether ethanol (ethyl alcohol) should be considered for pre-review. The Secretariat informed the Expert Committee that WHO Secretariat and Member States are in the process of implementing the WHO Global Strategy to Reduce the Harmful Use of Alcohol [...] Noting this, the Expert Committee referred the matter for consideration at a future Expert Committee meeting." Since then, the topic has never been addressed again by the ECDD.</p> |
| <p>2013</p> <p>CND56</p> | <p>Decision not to vote on rescheduling Δ9-THC.</p> |
| <p>2014</p> <p>CND57 Report of the session</p> | <p>Negative vote on rescheduling Δ9-THC.</p> <p>The Dutch embassy brought back the topic in the CND, introducing a draft decision and noting "that it was based on a medical and scientific recommendation made by the WHO Expert Committee stating that dronabinol had proven medical usefulness, that there was no risk of abuse and that it was appropriate for the substance to be rescheduled." Having received 9 votes in favour, 20 votes against and 12 abstentions, dronabinol was not moved from Schedule II to Schedule III of the 1971 Convention, and the CND referred back to the ECDD for further assessment.</p> |
| <p>2014</p> <p>ECDD36 TRS 991 Info doc</p> | <p>Update of "Cannabis and cannabis resin"</p> <p>An information document on cannabis and cannabis resin was presented to the ECDD for consideration (no further action).</p> |
| <p>2015</p> <p>INCB Report for 2014</p> | <p>2nd Request for a review of Cannabis.</p> <p>The INCB invited the ECDD "to evaluate the potential medical utility of cannabis and the extent to which cannabis poses a risk to human health."</p> |
| <p>2015</p> <p>ECDD37 TRS 998 Info doc</p> | <p>Update of "Cannabis and cannabis resin"</p> <p>An update document on cannabis and cannabis resin is presented to the ECDD. After deliberating, the ECDD requested "the Secretariat to begin collecting data towards a pre-review of cannabis, cannabis resin, extracts and tinctures of cannabis at a future meeting. Furthermore, it specifically requested the Secretariat to place emphasis on any therapeutic advantages that they may have relative to other existing therapeutics."</p> |

Update of "**Cannabis and cannabis resin**"

On its website, the WHO announced that "WHO has provided updates on Cannabis in 2014, 2015 and will again share updated evidence in 2016 at the [ECDD meeting]. So far, material to formally review the status of Cannabis as a scheduled substance is either insufficient or inconclusive. WHO will continue to review all available scientific evidence to determine whether the current scheduling status should change."

"The Committee noted that the current Schedule I of the Single Convention on Narcotic Drugs of 1961 groups together cannabis and cannabis resin, extracts and tinctures of cannabis. Cannabis plant and cannabis resin are also in Schedule IV of the 1961 Convention. The Committee further noted that there are natural and synthetic cannabinoids in Schedule I and Schedule II of the Convention on Psychotropic Substances of 1971.

ECDD38

The Committee recognized:

- (a) an increase in the use of cannabis and its components for medical purposes;
- (b) the emergence of new cannabis-related pharmaceutical preparations for therapeutic use;
- (c) that cannabis has never been subject to a formal pre-review or critical review by the ECDD.

The Committee requested that the Secretariat prepare relevant documentation [...] in order to conduct pre-reviews for the following substances:

- (a) cannabis plant and cannabis resin
- (b) extracts and tinctures of cannabis
- (c) delta-9-tetrahydrocannabinol (THC)
- (d) cannabidiol (CBD)
- (e) stereoisomers of THC

The Committee recommended that these pre-reviews be evaluated at a specific ECDD meeting dedicated to cannabis and its component substances to be held within 18 months of the thirty-eighth meeting."

2016

[TRS_1005](#)

[Info doc 1](#)

[Info doc 2](#)

Pre-review of "**cannabidiol**"

"There is no evidence that CBD as a substance is liable to similar abuse and produces similar ill effects to substances in the 1961 or 1971 Conventions (including cannabis and dronabinol (THC), respectively). [...] As CBD is not currently a scheduled substance in its own right (only as a component of cannabis extracts), current information does not justify a change in this scheduling status nor does it justify scheduling of the substance. However, where CBD is produced for pharmaceutical purposes as an extract of cannabis, cannabis extracts and tinctures are included in the 1961 Convention. The pre-review of cannabis extracts and tinctures will take place at the fortieth ECDD meeting in May 2018. Therefore it is also recommended that extracts or preparations containing almost exclusively CBD [...] be subject to critical review at that meeting."

2017

ECDD39

[TRS_1009](#)

Pre-review of "**cannabis and cannabis resin**"

"The evidence presented to the Committee did not indicate that cannabis plant and cannabis resin were liable to produce ill-effects similar to these other substances that are in Schedule IV of the 1961 Convention on Narcotic Drugs. The inclusion of cannabis and cannabis resin in Schedule IV may not appear to be consistent with the criteria for Schedule IV"

2018

ECDD40

[Note verbale](#)

"The Committee concluded that there is sufficient evidence to [...] explore further the appropriateness of their current scheduling within the 1961 Convention."

Pre-review of "**extracts and tinctures of cannabis**"

"The Committee noted that the category 'extracts and tinctures of cannabis' encompasses a variety of very diverse formulations with varying ratios of cannabis components, in particular THC, and with or without psychoactive properties"

"The Committee [...] concluded that there is sufficient information [...] to address the necessity of continuing to include the nomenclature 'extracts and tinctures of cannabis' in the 1961 Convention."

Pre-review of "[Δ9-THC](#)"

"Δ9-THC [...] produces similar ill-effects, dependence and abuse potential to cannabis which is placed under the 1961 Single Convention. A substance liable to produce 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. The Committee concluded that there is sufficient information [...] to address the appropriateness of its placement within the Conventions."

Critical review of "[cannabidiol](#)"

"The Committee recommended that preparations considered to be pure CBD should not be scheduled within the International Drug Control Conventions"

| | | |
|------|-----------------------------------|--|
| 2018 | ECDD41 Website | Critical review of "<u>cannabis and cannabis resin</u>", "<u>extracts and tinctures of cannabis</u>", "<u>Δ9-THC</u>" and "<u>Isomers of THC</u>" |
| 2019 | CND62 | Vote on ECDD41 outcome recommendations. |

