The CRIMSON DIGEST

Volume 2.

Analysis of the 40th and 41st ECDD reviews outcomes and the **INCB's update on *Cannabis*.**

For Alternative Approaches to Addiction
Think & do tank

ISBN 979-10-97087-07-4 EAN 9791097087074

The CRIMSON DIGEST

Volume 2

Analysis of the 40th and 41st ECDD reviews outcomes and the INCB's update on *Cannabis*.

ISBN 979-10-97087-07-4 | EAN 9791097087074

Author: Kenzi Riboulet Zemouli.

Contributors: Martin Díaz Velásquez, Farid Ghehiouèche, Amy Case King and Michael Krawitz.

The authors warmly thank Julie P. Fry for constructive criticism and proofreading.

The authors warmly thank the support received from the teams of the Knowmad Institut (European Institute for Multidisciplinary Studies on Human Rights and Science) in the preparation and edition of this second volume. They are also thankful to Hempoint.cz & Barcelona's Cannabis club La Crème for continuous support.

ISBN 979-10-97087-07-4 | EAN 9791097087074

Suggested citation: Riboulet-Zemouli K (2019), "The Crimson Digest, Volume 2: Analysis of the 40th and 41st ECDD reviews outcomes and the INCB's update on Cannabis." FAAAT think & do tank, Paris, March 2019. Licence: CC BY-NC-SA 3.0 IGO. Available at: faaat.net/publications/979-10-97087-07-4

INDEX

INTRODUCTION

On January 30th, 2019, the Director-General of the World Health Organization issued a letter[1] mentioning the conclusions from the Organization's expert scientific reviews of resin, extracts, tinctures and herbal *Cannabis*, as well as THC and CBD – a process that started in November 2017, rooted in decades of erratic work.

While the Crimson Digest Volume 1 addressed the history of *Cannabis* scheduling in international law and the history and details of the process to changes this status of scheduling, this Volume 2 analyzes the scope of symbolical and reglementary implications of the outcome of the reviews, contained in the Director-General letter, and also scrutinize the concurrently released report of the International Narcotics Control Board on the medical and non-medical uses of *Cannabis*. The last volume, Crimson Digest Volume 3 will review the details of the preparation and assessment process that happened since 2017, and see what lessons can be learned to improve future works of international bodies in relation with *Cannabis*.

The WHO Expert Committee reviews outcome in a nutshell:

- *Cannabis* is legitimate in medicine – new official WHO position
- Experts consider herbal *Cannabis* less dangerous than Schedule I substances
- Countries are encouraged to provide access to a variety of formulations
- Countries have a broad choice and flexibility of policies on preparations
- International policy landscape gets clarified
- Other international legal instruments or tools are called to action

[1] Available at faaat.net/cannabis/who and: who.int/medicines/access/controlled-substances/UNSG_letter_ECDD41_recommendations_cannabis_24Jan19.pdf

Cannabis and cannabis-related substances

#1
- **Cannabis and cannabis resin**
  - To be deleted from Schedule IV of the Single Convention on Narcotic Drugs (1961)

#2
- **Dronabinol (*delta*-9-tetrahydrocannabinol)**
  - To be added to Schedule I of the Single Convention on Narcotic Drugs (1961)

#3
  - To be deleted from Schedule II of the Convention on Psychotropic Substances (1971), subject to the CND's adoption of the recommendation to add dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol) to Schedule I of the Single Convention on Narcotic Drugs (1961)

#4
- **Tetrahydrocannabinol (Isomers of *delta*-9-tetrahydrocannabinol)**
  - To be added to Schedule I of the Single Convention on Narcotic Drugs (1961) subject to the CND's adoption of the recommendation to add dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol) to Schedule I of the Single Convention on Narcotic Drugs (1961)

#5
  - To be deleted from Schedule I of the Convention on Psychotropic Substances (1971), subject to the CND's adoption of the recommendation to add tetrahydrocannabinol to Schedule I of the Single Convention on Narcotic Drugs (1961)

#6
- **Extracts and tinctures**
  - To be deleted from Schedule I of the Single Convention on Narcotic Drugs (1961)

#7
- **Cannabidiol preparations**
  - To give effect to the recommendation of the fortieth meeting of the ECDD that preparations considered to be pure cannabidiol (CBD) should not be scheduled within the International Drug Control Conventions by adding a footnote to the entry for cannabis and cannabis resin in Schedule I of the Single Convention on Narcotic Drugs (1961) to read *"Preparations containing predominantly cannabidiol and not more than 0,2 percent of delta-9-tetrahydrocannabinol are not under international control"*

#8
- **Preparations produced either by chemical synthesis or as preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that delta-9-tetrahydrocannabinol (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health**
  - To be added to Schedule III of the Single Convention on Narcotic Drugs (1961)

Chapter 6. Comparing status.

The first table below shows the current state of scheduling, for purposes of international control, of the different products and molecules of the *Cannabis* plant. The second table reveals what the future status would be if the 53 member countries of the United Nations Commission on Narcotic Drugs (CND) adopts by simple majority[2] the recommendations of the 40th and 41st meetings [WHO, 2018] of the Expert Committee on Drug Dependence (ECDD) of the World Health Organization (WHO).

International scheduling of Cannabis in vigor since october 1991.

1961 Convention		1971 Convention	
Schedule IV	❏ Decarboxylated flowering and fruiting tops of *Cannabis sativa* L. ❏ Resin from the *Cannabis sativa* plant.	Schedule I	❏ Isomer $\Delta^{6a(10a)}$-THC. ❏ Isomer $\Delta^{6a(7)}$-THC. ❏ Isomer Δ^{7}-THC. ❏ Isomer Δ^{8}-THC. ❏ Isomer Δ^{10}-THC. ❏ Isomer $\Delta^{9(11)}$-THC.
Schedule I	❏ Decarboxylated flowering and fruiting tops. ❏ Resin from the *Cannabis sativa* plant. ❏ Preparations made of decarboxylated flowering and fruiting tops or resin.	Schedule II	❏ Isomer Δ^{9}-THC.
Not subject to the régime of control of the Convention's Schedules		❏ CBD.	

Future international scheduling of Cannabis proposed for adoption to the Commission on Narcotic Drugs by the WHO.

1961 Convention	
Schedule I	❏ Decarboxylated flowering and fruiting tops of *Cannabis sativa*. ❏ Resin from the *Cannabis sativa* plant. ❏ Some preparations of decarboxylated flowering and fruiting tops or preparations of resin. ❏ THC (all isomers)
Schedule III	❏ Other preparations of decarboxylated flowering and fruiting tops or of resin.
Not subject to the régime of control of the Convention's Schedules	❏ CBD. ❏ Preparations of decarboxylated flowering and fruiting tops or preparations of resin of *Cannabis sativa* that are almost-only composed of CBD and that contain less than 0.2% of Δ^{9}-THC.

[2] Rule 58 of the Rules of Procedure of the Functional Commissions of ECOSOC.

Chapter 7. 40th and 41st ECDD: What the outcome means.

The recommendations expressed in the WHO Director-General's letter late January, and the review process that precedes them, are legal obligations of the World Health Organization according to two widely ratified Treaties: the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances of 1971 [CND, 2014]. The WHO, through an independent body of qualified experts, is the only entity able to propose a direct modification of the legal obligations binding signatory countries – although it can have its proposal rejected by a vote of a technical sub-commission of the Economic and Social Council of the United Nations: the Commission on narcotic drugs (CND).

7.1 Behind the recommendations & between the lines.

Even before its creation, the WHO was tasked with the external assessment of psychoactive plants, products, and substances. As soon as in November 1946 (two years before the WHO was created), the United Nations General Assembly [UNGA, 1946] amended various Conventions, Agreements, and Protocols related to opium and "other dangerous drugs" (mostly those of The Hague 1912, Geneva 1925 (1 and 2), Geneva 1931, Bangkok 1931 and Geneva 1936). These amendments established a mandate to the future World Health Organization to convene a committee of experts to recommend the placement or withdrawal of certain drugs in these prior international instruments, and within their respective categories of drugs.

One year after its creation, WHO initiated an "Expert Committee on Habit-forming Drugs" (soon to be re-named "Expert Committee on Drugs Liable to Produce Addiction", then "on Addiction-Producing Drugs", then "on Dependence-Producing Drugs" to finally in 1969 take the name of "Expert Committee on Drug Dependence" or ECDD).

Since 1946, the role of this Expert Committee is to analyze all available data (i.e., not only clinical studies, but also epidemiological data or empirical reports) in order to balance the medical benefits of such products/substances in relation to their potential harms and determine the level of control that countries should apply. *De facto*, this public health benefit-risk balance can have direct legal consequences internationally – which makes the exercise particularly delicate, leading the current WHO Assistant-Director-General on medicines to declare that ECDD is "the hard-core part of the WHO's mandate" on drugs.

As early as in 1952, at its third meeting [WHO, 1952], the "justification of the use of cannabis preparations for medical purposes was discussed by the committee. The committee 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." The following year [WHO, 1954a], the same Experts were "pleased to note that the elimination of cannabis preparations had already begun by national action". In 1954 they concluded [WHO, 1954b] with one final sentence, relying on no more information than a report from South Africa. They related "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", among other recently invalidated theories.

An outcome that repeals a 60 years-standing official position

In March 1961 the Single Convention on Narcotic Drugs was adopted. Its goal was to gather in a single Treaty the various provisions contained in the handful of legal instruments in vigor until then.

The WHO expert committee closely monitored the unification of all the different policy provisions under a unique model of four Schedules; in this context, the repeated opinion expressed by the WHO on *Cannabis* as advice to the Convention's authors was 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" [WHO, 1954b page 13]. There was no review of literature at any of the meetings held and meeting documentation mentioned in the minutes are minimal. At that time, Δ^9-THC had still not been identified as the primary compound responsible for the singular psychoactive effects of the *Cannabis* plant.

The 1961 Single Convention placed *Cannabis* in the most restrictive Schedule, at the highest levels of controls – a Scheduling unchallenged until now.

The outcome of the 40th and 41st ECDD meetings on *Cannabis* products and substances is the first time that the WHO has fulfilled its mandate to independently and methodologically assess substances for international control, in the case of *Cannabis*. It is interesting to note, that the WHO has also never reviewed *Erythroxylon coca* (coca leaf) or *Papaver somniferum* (opium poppy), the two other "narcotic plants" from which cocaine and opium are prepared, the two other pillars of the spirit and the letter of the 1961 Single Convention control system.

7.2 Recommendation #1 on "cannabis and cannabis resin" – To what extent is the Experts' outcome biased by political inputs?

The "Experts" gathered at a closed-door meeting, with the WHO civil servants, and some appointed external advisers from other international agencies: United Nations Office on Drugs and Crime (UNODC), International Narcotics Control Board (INCB), and European Monitoring Center on Drugs and Drug Addiction (EMCDDA). Recently, the WHO extended opportunities for civil society to be involved and provide input during short inaugural "open sessions". This gave researchers from FAAAT the opportunity to submit various contributions to the Experts and coordinate many others during the 2-years of the preparation and the review process.

Observers from civil society are not permitted to attend the closed-door sessions where the in-depth discussion happens. It seems apparent that the position and guidance of the WHO staff – under constant pressure – has some influence on the final outcome of the Experts. This influence not only occurs during the one-week Experts meeting, but also downstream in the prism of approach, scope, and method of data collection endeavored by the WHO staff while preparing the Experts Committee documentation.

The outcome has come under scrutiny. Doubts have been expressed among the civil society stakeholders regarding the true recommendations of the Experts. Since the report was delayed for public release for "clearance" reasons by WHO leadership, it is surmised that the Experts might have recommended a lower scheduling (for instance Schedule II instead of Schedule I for herbal cannabis and resin), that would have been rejected because of political interference.

For the WHO, **any change in *Cannabis* scheduling brings unnecessary trouble and is complicated to endorse** internally and to defend outside, in particular at the moment of the vote at the CND. The WHO's recent history recounts with the record – present in all minds – of repeated rejections or refusal of vote by the CND on ECDD proposals to lower the scheduling of Δ^9-THC in the 1971 Convention: 1990, 2004, 2005, and twice in 2006 [See Volume 1, see Chapter 5.3].

No doubt that the Experts of the 40th and 41st meetings were briefed extensively on the particular sensibility of countries at the CND regarding the WHO addressing *Cannabis*-related substances and topics – just like their predecessors of the 34th meeting were told about previous recommendations on Δ^9-THC, that at "the CND, most countries, for political reasons, did not like the scientific advise by WHO" [WHO, 2012]. Such a prerogative might have been recalled by the observers from INCB and UNODC present at every ECDD meeting, and whose policies on *Cannabis* are not particularly known for their progressiveness.

Once a meeting finishes, the WHO Medicines Department staff is responsible for editing the notes from the Expert rapporteur from the discussions in the form of a draft outcome report. Then it is transmitted to the office of the Director-General of the WHO for clearance before its release. The WHO has always tended to use this "clearance" interval to amend and sometimes censor the opinions of the Experts and the Experts have always known that their words were passing through the highly politicized filter of WHO Director-General's office.

IV to I or IV to II?

Recommendation #1 from the 41st ECDD	The Committee recommended that Cannabis and Cannabis Resin be deleted from Schedule IV of the 1961 Single Convention on Narcotic Drugs.

Cannabis and resin are recommended for withdrawal from Schedule IV (strictest level of controls, sometimes called "the prohibition Schedule"), which would lead to Cannabis and resin remaining in Schedule 1. This change means downscaling the control provisions applied to these products: The Convention would cease to allow countries to implement "special measures of control" (i.e., exceptional or right-restricting laws) and to "prohibit the production, manufacture, export, and import of, trade in, possession or use" of Cannabis [UN, 1972, see Article 5]. Schedule IV also refers to research as "to be conducted under or subject to the direct supervision and control of the Party" (i.e., government), a provision behind which many countries have been hiding to canalize and orientate research towards the study of abuse and dependence potential rather than the exploration of therapeutic potentials.

Could the Experts have recommended placement in Schedule II of the 1961 Convention? Schedule II does not include any plant material or herbal preparation – and overall has a tiny number of substances (10 as of August 2018). Meanwhile Schedule I – considered the basic core régime of the Convention – includes a substantial number and variety of plants, preparations, and substances (121 at the same date) and in particular *coca* leaf (*Erythroxylon coca*) and its active compounds (cocaine and ecgonine), poppy plant straw (*Papaver somniferum*), opium and their active compounds (morphine, papaverine, and thebaine). Along with *Cannabis*, these two plants and their derivatives play a critical role in the Convention rhetoric and are controlled by specific dispositions separated from the measures of control linked to the Schedules. Compared to any other Scheduled drug, Poppy, *coca* leaf and *Cannabis* policies are ruled by specific provisions in the text of the 1961 Single Convention, in addition to those of the Schedules.

In a Committee where prudence is the watchword, where consensus positions are often sought, and where the CND vote is present as a sword of Damocles, placing Cannabis and its main active compound (Δ^9-THC) in the same Schedule I similar to the other two pillar-plants of the Treaty makes sense. It repeals the 1950's position and gives a strong symbolic signal in favor of increased interest and scrutiny over this plant while following the logic of the spirit of the Convention and aligning with its letter – harmonizing in the core Schedule these three core plant-based drugs.

Declaring that "the Committee did not consider that cannabis is associated with the same level of risk to health of most of the other drugs that have been placed in Schedule I" is, if any, evidence of the Experts'

narrow margin of maneuver within both the structure of the Treaty and political disinclination. It is also true, and may be a door left open for future work of the Committee.

7.3 Recommendations #2, #3, #4 and #5 on "Dronabinol"/"Tetrahydrocannabinol" – A dreamt simplification.

An important double, if not triple-standard, of the current state of international control of *Cannabis* that the ECDD outcome recommendations solve is the status of tetrahydrocannabinol, or THC, the main active compound responsible for the "narcotic effect" of the plant according to the Convention's language.

It is essential to recognize the chemical differences to understand the meaning of the Experts' outcome. We can subdivide "THC" in three levels of chemical category, from wider to narrower:

- THC
- Δ^9-THC
- dronabinol

THC includes all seven molecules found in the *Cannabis* plant that are "tetrahydro derivatives of cannabinol", what the ECDD refer to as "isomers of THC":

- $\Delta^{6a(10a)}$-THC
- $\Delta^{6a(7)}$-THC
- Δ^{7}-THC
- Δ^{8}-THC
- Δ^{9}-THC
- Δ^{10}-THC
- $\Delta^{9(11)}$-THC

Δ^9-THC is only one of these seven molecules, but is the relevant one as the others have shown little benefits *per se* in clinical practice and are not known as being consumed for adult use. Δ^9-THC, as the other seven isomers, consists of four stereochemical variants (that the Experts call "stereoisomers") namely:

- (+)-trans-Δ^9-THC
- (−)-trans-Δ^9-THC (dronabinol)
- (+)-cis-Δ^9-THC
- (−)-cis-Δ^9-THC

Consequently, the Experts call Δ^9-THC "dronabinol and its stereoisomers".

Dronabinol is no more than the International Nonproprietary Name for **(−)-trans-Δ^9-tetrahydrocannabinol**: among the four stereochemical variants of each of the 7 tetra-hydro derivatives of cannabinol, (−)-trans-Δ^9-THC is the one molecule responsible for the particular "narcotic" effect of the Cannabis plant.

Dronabinol, as well as the three other stereochemical variants of Δ^9-THC, refer to both naturally-occurring and synthetically-produced molecules, as (−)-trans-Δ^9-THC obtained from plant material or by synthesis are precisely similar and indistinguishable. Confusion has led many to believe that "dronabinol" referred only to the synthetically-obtained (−)-trans-Δ^9-THC. This was induced in the 1990s by the early marketing of synthetically-produced (−)-trans-Δ^9-THC for medicines traded as Syndros®, Elevat®, Ronabin®, or Marinol®. The communication policies of the pharmaceutical companies marketing these products preferred the word "dronabinol" to anything close to "tetrahydrocannabinol," leading to confusion that still stands today.

Before this 40th and 41st ECDD meetings, THC had already been reviewed by the Expert Committee eight times (at its 17th, 21st, 26th, 27th, 31st, 32nd, 33rd, and 34th meetings [See Volume 1]), but consensus was never found for the name and the scope of the molecules, isomers, and stereochemical variants to be included or not, nor the suitable Schedule(s). International control was first applied to all THC isomers under the name "tetrahydrocannabinols." After a failed attempt to restrict the scheduling only to "dronabinol," the ECDD managed to have the four stereochemical variants of Δ^9 lowered from Schedule I to Schedule II of the 1971 Convention in 1991 [CND, 1991] – but the remaining six isomers did not move from Schedule I.

Recommendation #2 from the 41st ECDD	The Committee recommended that dronabinol and its stereoisomers (delta-9-tetrahydrocannabinol) be added to Schedule I of the 1961 Single Convention on Narcotic Drugs.

Recommendation #3 from the 41st ECDD	The Committee recommended the deletion of dronabinol and its stereoisomers (delta-9-tetrahydrocannabinol) from the 1971 Convention on Psychotropic Substances, Schedule II.

Recommendation #4 from the 41st ECDD	The Committee recommended that tetrahydrocannabinol (understood to refer to the six isomers currently listed in Schedule I of the 1971 Convention on Psychotropic Substances) be added to Schedule I of the 1961 Single Convention on Narcotic Drugs.

Recommendation #5 from the 41st ECDD	The Committee recommended that tetrahydrocannabinol (understood to refer to the six isomers currently listed in Schedule I of the 1971 Convention on Psychotropic Substances) be deleted from the 1971 Convention on Psychotropic Substances.

These are four recommendations and four votes for the CND, all of which interrelated (the outcome requires that each of these recommendations can only be adopted if the previous one has already been adopted). Simply: they schedule all isomers, stereochemical variants – everything that is known as “THC” – alongside *Cannabis* and all its preparations: in the core Schedule I list.

It is not impossible to forecast possible problems at the moment of the vote: Among these four recommendations on the same substance, two votes refer to the 1961 Convention and require a simple majority approval, while the other two refer to the 1971 Convention where a two-thirds majority of votes is mandatory [United Nations, 1971. See Article 2 and Article 17 (2)]. It is hoped that the Chairperson of the Commission on Narcotic Drugs takes the initiative to arrange the agenda in a way that permits the votes referring to the 1971 Convention to happen before those of the 1961 Convention in order to avoid an absurd situation where recommendations #2 and #4 would be accepted while recommendations #3 and #5 be rejected.

7.4 Recommendations #6 and #8 on "preparations" and outcome of the 40th meeting – Clarity, flexibility and variable geometry.

The 1961 Convention explicitly states that "Preparations other than those in Schedule III are subject to the same measures of control as the drugs which they contain" [UN, 1972. See Article 2(3)]. While it seemed unnecessary and duplicative, the authors of the Convention also added "extracts and tinctures of cannabis" in Schedule I without, however, defining what distinguishes "extracts and tinctures" of *Cannabis* from "preparations" of *Cannabis*.

This created yet another double-standard where "preparations of cannabis" (defined as "a mixture, solid or liquid, containing a drug" [UN, 1972. See Article 1(s)]) were virtually in Schedule IV while the undefined "extracts and tinctures of cannabis" were only in Schedule I.

Recommendation #6 from the 41st ECDD	The Committee recommended deleting Extracts and Tinctures of Cannabis from Schedule I of the 1961 Single Convention on Narcotic Drugs.

With this recommendation that simply withdraws the incorrect spelling "extracts and tinctures" to stick to the letter of the Treaty, the Experts act again motivated by harmonization and simplification.

In any of all cases: The products covered by the category "extracts and tinctures" or "preparations" should be understood as being any mixture, solid, or liquid containing part or a totality of decarboxylated flowering and fruiting tops of *Cannabis sativa* L. This excludes preparations containing other parts of the plants, such as the so-called "hemp products" – which are anyway fully exempted from the scope of control of the Convention [UN, 1972. See Article 28(2)].

A partial exemption for some preparations.

In an unexpected move, the ECDD proposes a model of variable geometry designed to fit a needed consensus (at the CND) between countries with different legislation, and different aspirations regarding the ways to ensure compliance with the Preamble of the Convention, which mandates governments "to ensure the availability of narcotic drugs" for the "relief of pain and suffering", "recognizing that the medical use of narcotic drugs continues to be indispensable".

Recommendation #8 from the 41st ECDD	The Committee recommended that preparations containing delta-9-tetrahydrocannabinol (dronabinol), produced either by chemical synthesis or as a preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that delta-9-tetrahydrocannabinol (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health, be added to Schedule III of the 1961 Convention on Narcotic Drugs.

This variable geometry consists in the possibility to consider some preparations as controlled by Schedule III – defined as regrouping "preparations that contain narcotic drugs, but that are intended for medical use and are unlikely to be abused. These preparations are exempt from certain control measures because of their consumption" [CND, 2014]. Notable exemptions for preparations placed in Schedule III include, among others, exceptions on licences, no obligation to closely monitor retail trade stocks, exemption from most government estimates of production and use and other reports to INCB, no obligation of medical prescriptions for the supply or dispensation to individuals, no obligation for pharmacists or retail traders to maintain records of their retail sales of these drugs, unless if they compound or prepare it themselves (with some minor variations and details).

While the Experts could very well have decided to include in the recommendation precise formulations, potencies or compounding details, they chose to only specify three criteria that will be left to the discretion of each Member State to make the final choice for the preparations of *Cannabis* to be considered under this Schedule:

1. the presence of Δ^9-THC (without limits other than that there need be the presence of one or more other ingredients),
2. a production process possible either by chemical synthesis or by compounding from herbal material,
3. the need for Δ^9-THC not to be recovered by readily available means or in a yield which would constitute a risk to public health.

As an underlying principle of the Convention, good faith prevails when it comes to choosing at the national level which preparations shall be applied a Schedule I or a Schedule III-type policy framework. Yet, this definition is extremely broad and open to flexible interpretations.

A total exemption for CBD preparations: the Experts strike back.

Regarding cannabidiol (in short, "CBD" and, more precisely, the stereochemical variant (–)-trans-cannabidiol) things are supposed to be much more clear, as cannabidiol is not listed in any of the Schedules of the Conventions [Baňas et al., 2017]. The non-presence of CBD in the Schedules should mean the lack of application of the régime of control they convey. Especially in light of the history of cannabidiol and the Treaties: In the 1960's, during the redaction of the 1971 Convention on Psychotropic Substances, the WHO Experts were again called to advise on how to frame the new Schedules of the future Treaty.

In addition to the four Schedules they suggested, and that became part of the 1971 Convention and are still in vigour today, the Experts made a proposal that was ultimately rejected by the conference of plenipotentiaries in charge of drafting the legal instrument. Reviving a concept foreshadowed in the late 1931 Geneva Convention, the Experts proposed a 5th Schedule that would not directly list "psychotropic" drugs, but only precursor substances (i.e., substances not bearing "psychotropic" effects, but being easily convertible into a Scheduled psychotropic substance).

The Experts knew the difficulty in defining criteria for inclusion and had little faith in the adoption of that recommendation. Still, they decided to review three precursor substances to test their theorem. Among them was CBD, considered by the Experts as "a precursor of the tetrahydrocannabinols used only in their preparation". The conclusion of their assessment advised that CBD should eventually be placed in that 5th Schedule of precursors, in order to have applied similar control measures as those planned for THC [WHO, 1970], which was about to be placed in Schedule I of the new 1971 Treaty [See Volume 1, Chapter 5.3].

Because the proposed 5th Schedule was not approved, CBD was kept out of the Convention. Some countries still consider CBD today at the same level of control as cannabis arguing that a part of a drug should fall under the same régime as the totality of that drug.

Recommendation on CBD from the 40th ECDD	CBD is not specifically listed in the schedules of the [...] Drug Control Conventions. However, if prepared as an extract or tincture, it is controlled under Schedule I of the 1961 Single Convention on Narcotic Drugs. There is no evidence that CBD, as a substance, is liable to similar abuse or leads to similar ill-effects as the substances controlled under the 1961 or 1971 Conventions, such as cannabis or Δ9 -THC, respectively. The Committee recommended that preparations considered to be pure CBD should not be scheduled.

In recent years, interest and demand for products containing CBD – for motives totally unrelated with "narcotic" or "psychotropic" use or abuse – has skyrocketed. The economic development related to that demand, combined with the absence of impairing or euphoric effects of cannabidiol (the 40th ECDD meeting recognized that CBD is "generally well-tolerated and too [has] a good safety profile" and that "there are no case reports of abuse or dependence relating to [its] use"), has lead to very different reactions at the national regulatory level [EMCDDA, 2018].

While a number of countries decided to prohibit the sale of CBD products in retail stores, there is no doubt that the words of the WHO Experts (on the innocuity of the product, the international recognition of the previous unclear ruling, the need to allow reasonable margins of impurity, and the non-recommendation to restrict access to CBD products only to prescription and clinically marketed products) will strengthen the defense of entrepreneurial victims of these suddenly stringent policies on CBD.

Recommendation #7 from the 41st ECDD	The Committee recommended that a footnote be added to Schedule I of the 1961 Single Convention on Narcotic Drugs to read: "Preparations containing predominantly cannabidiol and not more than 0.2 percent of delta-9-tetrahydrocannabinol are not under international control."

In the outcome of their 40th meeting (June 2018), the Experts recognized that CBD should not fall under international control, but was still *de facto* subject to it as part of a Scheduled drug. Such a tenet is questionable, as it could set a precedent and theoretically extend to other constituents of the plant (e.g, other phytocannabinoids, terpenoids, etc.) that would fall *de facto* under international control without even being explicitly listed in the Schedules – therefore requiring individual assessment by the ECDD and specific addition of a footnote as in Recommendation #7 to enjoy Treaty exemption.

Yet, the Experts needed to have their June non-inclusion recommendation turned in a way that could easily be implemented by Member States' administrations. Relying on existing thresholds of the Convention established for the other "core drugs" of the 1961 Treaty (0.2% of morphine allowed in opium and 0.1% of cocaine in coca leaves [INCB, 2018. pp. 9 and 34][3]), the Experts decided to premiere the first-ever threshold

[3] This was confirmed by Pr. Simon Elliot (Member of the 39th, 40th and 41st ECDD) in the informal notes from the 2nd intersessional meeting of the 62nd session of the Commission on Narcotic Drugs, as reported on the CNDblog (these notes do not constitute minutes of the meeting and are only indicative of the content of the debates): cndblog.org/2019/02/cnd-intersessional-meeting-25-february-2019/

policy measure for *Cannabis* in international law – ending, by the way, the 'zero tolerance' era in favour of a pragmatic approach oriented towards policy efficiency.

Experts' considerations oscillated between sticking to the previous zero percent approach, or allowing up to 0.15% of Δ^9-THC (on the basis of limited scientific data on safety of hemp foods in animal models [EFSA, 2011]). The ultimate move to 0.2% echoed the 'simplification' approach underlying all recent ECDD recommendations, in this case, making things simple to overcome the weaknesses of government analytical tools for the measurement of cannabinoids content[4].

Making this 0.2% limit on its own, the Experts believe they acted with generosity. While 0.2 is better than 0.00 or 0.15%, it is evident that this limit might hamper international trade for producers from countries that previously established higher limits of Δ^9-THC in CBD-type products and preparations of the *Cannabis* plant. These countries will need to figure out whether products over 0.2% are applied a Schedule I- or a Schedule III-like model of control (instead of the previous *de facto* inclusion in Schedule I).

Summary of the proposed international scheduling of Cannabis preparations and by-products.

1961 Convention	
Schedule I	❏ *De facto* all preparations of decarboxylated flowering and fruiting tops or preparations of resin.
Schedule III	❏ Some preparations of decarboxylated flowering and fruiting tops or of resin, as decided by every competent jurisdiction.
Not subject to the régime of control of the Convention's Schedules	❏ Preparations of decarboxylated flowering and fruiting tops or preparations of resin of *Cannabis sativa* that are almost-only composed of CBD and that contain less than 0.2 % of Δ^9-THC. ❏ Preparations of other parts of the plant.

[4] Even though the United Nations Office on Drugs and Crime released interesting 'Recommended methods for the identification and analysis of cannabis and cannabis products', that very little countries seem to have followed however. See: unodc.org/unodc/en/scientists/recommended-methods-for-the-identification-and-analysis-of-cannabis-and-cannabis-products.html

Chapter 8. 40th and 41st ECDD: What the outcome brings.

8.1 Changes and incentives for change at the national level.

Cannabis is not freed from the Conventions. Even CBD preparations fully exempted from the Treaties might see International Drug Control law conflict at some point of the cultivation, processing, or marketing – because of the double-régime applied to the plant: Some measures of control go with the level of Scheduling, and others go with the specific Articles of the 1961 Convention addressing specifically *Cannabis sativa*, *Erythroxylon coca*, and *Papaver somniferum* [Jelsma and Armenta, 2015].

Therefore, countries will not be released from their obligation to monitor *Cannabis* cultivation and canalize production through a central agency issuing licences. And the grey zone surrounding adult use will stand. The proposed changes mostly release pressure on administrations and allow for lighter bureaucracy. They also strongly encourage governments to take steps at the national level to release the barriers to access and promote independent research, always with respect to their local trends and social needs.

Direct and indirect impacts.

The United States of America has transcripted the Convention into national law by creating a proper system of five Schedules [Congress of the USA, 1970] and India in a superposition of dozens of different Schedules [Parliament of India, 2011]. However, some countries have directly included the Schedules of the 1961 Convention as part of their national legislative drug control corpus. This is the case, for instance, in Spain, where the 1967 Bill on Narcotics entirely relies on the Convention's Schedules (therefore, also on changes being made at the international level) to define which substances are "narcotic drugs" and fall under the terms of the law[5]. Unlike India or the USA, countries with similar normative framework to Spain's might be forced to undertake regulatory or even legislative steps to react to the changes in the scope of Treaty controls over *Cannabis*.

A broader focus than only mono-molecular formulations.

Restricting access and availability of all *Cannabis*-related products, preparations, and substances to prescription-only clinical trial-approved products is an approach that fails to answer the medical demand for access, but also conflicts with the proposed rules and framework for herbal medicines of the WHO itself [WHO, 2013]. The ECDD held back from such narrow views – unlike the European Parliament that passed a resolution on February 13th calling to "ensure that safe and controlled cannabis used for medicinal purposes can only be in the form of cannabis-derived products that have gone through clinical trials, regulatory assessment, and approval" [European Parliament, 2019] to the detriment of the possible development of herbal or compounded products. WHO Experts preferred to stick to an approach that does not restrict the way the national health systems should implement their recommendations – echoing the WHO's opinion that **"other evaluation methods [than clinical trials] are also valuable" for traditional and complementary medicine** (including herbs), with alternative research methods for these therapies including "outcome and effectiveness studies, as well as comparative effectiveness research, patterns of

[5] "For the purposes of this Law, narcotic substances are [...] substances included in lists I and II of the annexes to the Single Convention of 1961 of the United Nations on Narcotic Drugs and others that acquire such consideration in the international arena" as per Article 2nd, Law 17/1967, of April 8th.

use, and other qualitative methods" and that there is "an opportunity to take advantage of, and sponsor such 'real world experiments' where different research designs and methods are important, valuable and applicable" [WHO, 2013. Page 39].

These are elements that should lead countries to assess the possibility of providing access to botanical formulations of *Cannabis* medicines via their national herbalists or other regular ways of access to phytotherapies.

8.2 A difficult adoption at CND.

ECDD's recommendations do not enter into force by themselves. To be turned into what could be considered as an amendment *de facto* of the Schedules of the Convention, they have to be endorsed by the United Nations through a vote of the functional commission of the UN Economic and Social Council (ECOSOC) for drug-related matters: the Commission on Narcotic Drugs (CND).

The CND functions from March to mid-December, with its one-week main session opening in March and a short reconvened session closing. Results of ECDD meetings are usually presented to Member States during the reconvened CND in December, while voting happens during the main session three months later under an agenda item entitled "Changes in the scope of control of substances"[6]. This process was established to leave at least three months for governments to consult internally, evaluate the impact on their home policies, and consult within regional groups – before voting [CND, 1965].

The WHO announced the results for release on December 7th, 2018 (at the reconvened 61st CND session) and a vote mid-March 2019 (opening of 62nd CND session). But because of now famous "clearance" reasons, they were only transmitted to UN Secretary-General on January 24th and received by governments late-January early-February, less than three months ahead of 62nd session – making likely that the vote will also be delayed. A delay might mean:

- That country members of the CND will take action remotely "by mail or telegram" as planned for "exceptional circumstances" [CND, 1965];
- that the CND will vote on the recommendations on *Cannabis* at its reconvened 62nd session in December 2019, with the risk of having some countries not being present;
- that CND will vote at its 63rd session in March 2020. In this eventuality, the list of voting countries would evolve (see chart below);
- although it is unlikely, there are precedents of the CND deciding not to vote on recommendations of the ECDD. The only time that has happened was in 2014, when "the Commission on Narcotic Drugs decided by consensus [...] 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" [CND, 2007].

During an intersessional meeting on February 25th, Russia, USA and Germany proposed that an informal "Expert Consultation Process" be organized along the year 2019 within the frame of the CND to allow countries to discuss with WHO, UNODC, and INCB and achieve a clearer understanding of the scope of these recommendations. Although preliminary discussions indicate a delay, a final decision will be taken during the March 2019 CND plenary session.

As per the vote itself, the 1961 Convention explains that "assessments [from the World Health Organization] shall be determinative as to medical and scientific matters" but immediately backtracks, giving the CND the possibility to amend WHO recommendations "bearing in mind the economic, social, legal, administrative and other factors it may consider relevant" [UN, 1972, Article 2 (5) and (6)].

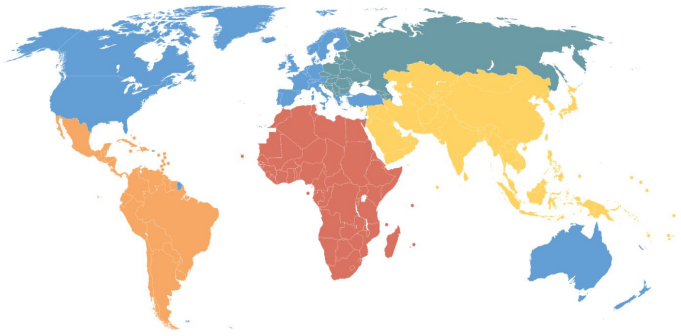
[6] See website of the UNODC, page "Mandate and Functions of the Commission on Narcotic Drugs on Scheduling" at: unodc.org/unodc/fr/commissions/CND/Mandate_Functions/Mandate-and-Functions_Scheduling.html

53 countries with right to vote at CND: differences between 2019 & 2020.

62ND SESSION (**2019**)	63RD SESSION (**2020**)
Afghanistan	Afghanistan
Algeria	Algeria
Argentina	tbc
Australia	Australia
Austria	tbc
Belarus	tbc
Belgium	Belgium
Brazil	Brazil
Burkina Faso	Burkina Faso
Cameroon	tbc
Canada	Canada
Chile	Chile
China	tbc
Colombia	Colombia
Côte d'Ivoire	Côte d'Ivoire
Croatia	Croatia
Cuba	Cuba
Czech Republic	Czech Republic
Dem. Republic of Congo	tbc
Ecuador	tbc
El Salvador	tbc
France	France
Germany	tbc
Guatemala	tbc
Hungary	tbc
India	India
Iran	tbc

(**2019** continued)	(**2020** continued)
Iraq	Iraq
Israel	tbc
Italy	tbc
Japan	tbc
Kenya	tbc
Kyrgyzstan	Kyrgyzstan
Mauritania	tbc
Mexico	tbc
Netherlands	tbc
Norway	tbc
Pakistan	tbc
Peru	tbc
Qatar	tbc
South Korea	tbc
Russia	Russia
Slovak Republic	tbc
South Africa	tbc
Spain	tbc
Sudan	tbc
Switzerland	Switzerland
Thailand	tbc
Togo	Togo
Tur key	tbc
Uganda	tbc
USA	tbc
Uruguay	tbc

Regional groups within the United Nations: a preferred way of negotiation.



AG	Countries members of the **African Group**
APG	Countries members of the **Asia-Pacific Group**
EEG	Countries members of the **Eastern European Group**
WEOG	Countries members of the **Western European and Others Group**
GRULAC	Countries members of the **Latin American and Caribbean Group**
Country	Countries members of the **European Union**

Regional groups are crucial elements of the broad United Nations system: Arrangements and agreements are ordinarily made between countries within these groups first before being discussed with all countries. This also applies to establish the voting positions on Scheduling decisions at the CND. In addition, European Union countries agree on an imperative mandate (they all vote the same way) superseding the discussions within regional groups (as EU Member States divide into WEOG and EEG at the United Nations level).

The 2-years membership turnover of the Commission is responsible for the 33 unknown countries that will compose the CND in 2020. The complete list of countries is decided by the UN Economic and Social Council (ECOSOC), usually during its Spring sessions.

Dr Gilles Forte, Secretary of the ECDD (on screen), discussing the recommendation on Cannabis and Cannabis products with representatives at the Commission on Narcotic Drugs 1st intersessional meeting of the 62nd session, on February 25th, 2019. Photo credits: Secretariat of the Governing Bodies, UNODC, twitter.com/CND_tweets/status/1099969100682592257

8.3 A broader impact on multilateral organizations.

Leaving aside the drug control Conventions, many rules, principles, and tools able to guide and support *Cannabis* policy reforms exist in the international arena. In a way, the status of exceptionality of the plant within international law until now prevented the use of any other international instrument, but the drug control Conventions.

The clear stance of the ECDD – rectifying international *Cannabis* laws and paving the way for a modernization international *Cannabis* policy – binds the WHO to continue moving forward. Other branches of the organization now have the possibility to apply their guidelines and standards to the *Cannabis* plant and its derivatives. It is particularly relevant to the WHO's department on traditional and complementary medicines (T&CM) and its numerous guidelines for safe and efficient research on herbal medicines, agricultural, and processing practices, as well as monitoring and pharmacovigilance methods for herbal materials and botanical preparations.

The documented historical of the use of the *Cannabis* plant in ancient, traditional, and non-conventional medicine systems – acknowledged in the 1961 Convention, although calling for its discontinuation – particularly in specific regions and areas of the world on all continents, invites local communities in Colombia, Jamaica, Morocco, Nepal, Thailand, and so many other regions where peasants have cohabited with *Cannabis* for centuries to consider the mechanisms of legitimate intellectual property protections planned through international law for plant genetics, processing methods, and other traditional cultural expressions related to the *Cannabis* plant and its traditional use in medicine.

The rich and diverse potential of the *Cannabis* plant for medicines relies neither on CBD nor on Δ^9-THC. It relies on what scholars call the "entourage effect"[7], the pharmacological synergy of multiple constituents included in botanical preparations of *Cannabis* (phytocannabinoids, terpenoids, etc.), which explain the empirical recognition of superior efficiency of herbal preparations over conventional medicine, including isolated phytocannabinoids [Blasco-Benito, 2018]. And the diversity of this entourage effect hides in the geographical biodiversity and history of non-conventional medical uses and traditional cultivation.

Increasing the availability and diversity of conventional and traditional medical products from *Cannabis* in contemporary health systems, while scaling-up safety and pharmacovigilance, are now the only legitimate objectives of the international community and in particular, its multilateral cooperation agencies. After a recent common position of all United Nations Agencies on drug policy, adopted by the UN system Chief Executives Board for Coordination [CEB, 2018] early November last year – and that relies on previous work undertaken, in particular, by WHO to endorse more clearly human-based drug policies and non-criminalization of use – the United Nations system should soon be able to issue a similar internal consensus statement to allow the broader "UN family" to work on *Cannabis*-related topics.

[7] Russo describes the entourage effect as a "botanical synergy" related to "the pharmacological contributions of 'minor cannabinoids' and Cannabis terpenoids to the plant's overall pharmacological effect" [Russo, 2019]. In an epistemological approach he introduces phytocannabinoids: "the synergistic contributions of cannabidiol to cannabis pharmacology and analgesia have been scientifically demonstrated. Other phytocannabinoids, including tetrahydrocannabivarin, cannabigerol and cannabichromene, exert additional effects of therapeutic interest" and further mentions the other family of molecules suspected to play a significant role in the so called entourage effect, the terpenoids, that "display unique therapeutic effects that may contribute meaningfully to the entourage effects of cannabis-based medicinal extracts" [Russo, 2018].

Chapter 9. A disoriented INCB.

A few weeks after the WHO Expert Committee outcome was made public, the International Narcotics Control Board (INCB) released its annual report – like every year, ahead of the main CND session. Each year, the report includes an inaugural thematic Chapter, which is this time dedicated to the "use of cannabis and cannabis derivatives for medical and non-medical purposes" [INCB, 2019a]. INCB members witnessed with attention the discussions of ECDD's 39th, 40th and 41st meetings, and convened ahead of the 40th ECDD meeting, their own hearing with Civil Society – a new kind of exercise for the Board[8].

Even though having scrutinized and followed the ECDD meetings, the Board explain in a footnote [INCB 2019b, p. 2] that their report was finalized before the outcome was made public. A cop-out? The INCB report seems indeed to develop a parallel and unrelated reflection to that of the WHO Experts. Not only does the Board's report conflict with ECDD's on many points, but it also disregards key elements of the Treaties and overrules others.

Worst, breaches in the rigor demanded of such an organization intersperse the report. It states, for instance, that "THC and its isomers are included in Schedule I of the [1971 Convention]" [INCB 2019b, §3] – while we know that Δ^9-THC is placed in Schedule II since 1991 [See Volume 1, Chapter 1.4]. They also state that "Under the Convention, cannabinoids may be evaluated in controlled clinical trials" [INCB 2019b, §7], an element which is clearly not included in the Convention and highly dubious when reading the Commentary on the 1961 Convention edited by the United Nations [See UN 1973, and UN 1977].

The Board also repeatedly invokes alleged mandatory measures of the Convention(s) without mentioning them, making it hard to understand what exact provision is referenced. Finally, fallacies of defective inductions and faulty generalization are widely used in the analysis of evidence gathered.

The INCB still has difficulties in recognizing the use of *Cannabis* (in particular herbal formulations) in medicine, but despite everything is clearly mandated by the Convention to address it. For this reason, maybe, the Board takes particular interest in continuing to negate and refuse to address adult use. The threat of "recreational use" is also used by the INCB as a major argument against change in medical availability. This could explain the care taken in not appearing too overzealous supporting countries in implementing a legal way of access to the plant or its preparations [See INCB 2017a]. In 2016, the Board "[reminded] all States that, in recognition of the public health risks associated with its abuse, cannabis has been subjected to the highest levels of control under the international drug control treaties through its inclusion in Schedules I and IV of the 1961 Convention. Schedule IV contains noxious substances that are particularly liable to abuse" [INCB, 2017b. See paragraph 323]. The Board's position will necessarily have to adapt, now that cannabis is recommended for withdrawal from Schedule IV.

This report is a missed opportunity for the INCB to stick to its mandate, and another failed occasion to propose clear and modern international guidance for Governments[9] and affected people[10].

---

[8] "On 7 May 2018 the International Narcotics Control Board (INCB) held a meeting with civil society representatives on the 'the use of cannabis for medical and non-medical purposes'. The meeting brought together a number of representatives of non-governmental organizations (NGOs), selected by the Vienna NGO Committee on Drugs (VNGOC), and members of the Board" in INCB eNewsletter Issue No. 27, Available at: www.incb.org/documents/Newsletter/INCB_eNewsletter_Issue_27.pdf

[9] The INCB has produced numerouds guidelines for use by competent national authorities, compiled on: incb.org/incb/en/publications/guidelines-for-use-by-competent-national-authorities.html

[10] The INCB has also issued information and guidance for patients, for instance in the case of people travelling with medicines containing controlled substances. See: incb.org/incb/en/travellers/index.html and: incb.org/documents/Psychotropics/guidelines/travel-regulations/Intl_guidelines_travell_study/12-57111_ENG_Ebook.pdf

9.1 INCB recommendations on pharmacovigilance, epidemiological research, herbal formulations and approval mechanisms.

Recommendation 1 (a) included in Chapter IV	Governments that wish to establish special access schemes to allow for the medical use of cannabinoids should do so only where there is evidence of efficacy and safety, should limit the use of such preparations to approved medicinal cannabinoids and should monitor their prescription and use to minimize any risk of diversion and abuse.

Recommendation 1 (d) included in Chapter IV	Governments that allow the medicinal use of cannabinoids should monitor and evaluate the medicinal effectiveness as well as any unintended impact of those programmes.

Thematic Recommendation included in paragraph **74**	Governments that allow the medicinal use of cannabinoids should monitor and evaluate the effects of the programmes. Such monitoring should include collecting data on the number of patients who use cannabinoids, the medical conditions for which they use them, patient and clinician assessments of their benefits, and rates of adverse events. Governments should also monitor the extent of diversion of cannabinoids to non-medical use, and in particular their diversion for use by minors.

Although the Board is right in stating that "Governments allowing the medical use of cannabis must ensure that cannabis is prescribed by competent medical practitioners according to sound medical practice and based on sound scientific evidence" [§10], the Treaty in no moment restricts its scope to mono-molecular preparations or the need of clinical trials. To the contrary: there is a **voluntarily broad definition of medical practice**, which derives from the geopolitical struggles for the respect of different historical medical practices and systems. The Commentary [UN, 1973, p. 111] mentions that "The term 'medical purposes' has not been uniformly interpreted by Governments" and specifies that the scope of medical practice "does not necessarily have exactly the same meaning at all time and under all circumstances. Its interpretation must depend on the stage of medical science at the particular time in question; and **not only modern medicine, sometimes also referred to as 'western medicine', but also legitimate systems of indigenous medicine such as those which exist in China, India and Pakistan, may be taken into account** in this connexion."

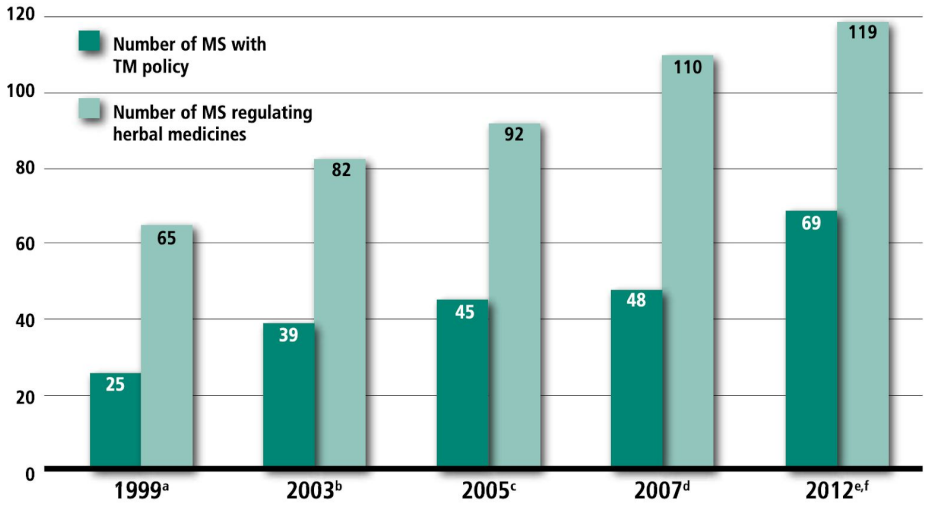
Trying to restrict the scope of its analysis only to "medicinal cannabinoids", leaving aside the uses of other types of preparations and formulations, is a clear bias taken by the Board. Not addressing the use and access to raw botanicals and herbal preparations is an abandon by the Board of part of its mandate. Although the Board might wish to express a preference for mono-molecular preparations over herbal medicines, they certainly cannot erase or withdraw the mere existence of the use of botanical formulations of *Cannabis*, used for centuries, covered by the Convention's obligation to provide access, and even more reinforced in their legitimacy in medical practice after the ECDD outcome.

The Conventions allow for the use of botanical and herbal formulations of scheduled medicines.

The 1961 Convention is in no point focused on "western" medicine or "mono-molecular" medicines. It is more than that, the WHO actively works at supporting countries in establishing or strengthening traditional and complementary medicine systems in their national legislations.

The WHO includes herbal medicines in its category of **Traditional and Complementary Medicine (T&CM)** defined as "encompassing products, practices and practitioners"[11]. Absolute legitimacy is given to herbal medicines by the World Health Organization, regardless of its formulation. This category of drugs is defined as including "include herbs, herbal materials, herbal preparations and finished herbal products that contain parts of plants, other plant materials or combinations thereof as active ingredients." [WHO, 2013, p. 31].

The Alma-Ata International Conference on Primary Health Care in 1978 recommended to accommodate traditional medicines in national drug policies and regulatory measures [WHO, 1996, p. 179]. Since then, the WHO has published numerous guidances and guidelines for safe and efficient use of herbal medicines covering a broad variety of issues like pharmacovigilance, specific methodologies for research, assessment and approval, but also good agricultural, harvesting, processing and manufacturing practices[12] . There has also been an effort to scale-up the quality and comprehensiveness of pre-existing national policies relating to traditional or herbal medical products and practices, but also to assist those countries that relied only on "modern medicine" in creating legislations that regulate T&CM. The table below shows the monitoring of policy modernization in the field of T&CM among the 194 Member States (MS) of the WHO:



Source: World Health Organization, "Monitoring changes in country progress indicators defined by the WHO Traditional Medicine Strategy" in "WHO Traditional Medicine Strategy 2014-2023" page 21.

[11] The WHO defines Traditional medicine as "the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness" and "Complementary medicine" or "alternative medicine" as "a broad set of health care practices that are not part of that country's own tradition or conventional medicine and are not fully integrated into the dominant health-care system. They are used interchangeably with traditional medicine in some countries." WHO precises that "Traditional and complementary medicine (T&CM) merges the terms TM and CM, encompassing products, practices and practitioners." [WHO, 2013, p. 15]

[12] See all WHO publications on the topic of T&CM at "Essential Medicines and Health Products Information Portal. Traditional Medicine" apps.who.int/medicinedocs/permalinks/open/traditional-medicines-subjects
See also a selection of key resolutions and decisions by the WHO Assembly and Executive Board on Traditional medicines: who.int/traditional-complementary-integrative-medicine/about/en/

Therefore, the statement made by INCB [§14] that "attempts to market and promote the medical use of cannabis products as 'herbal medicines' are inconsistent with the classification of cannabis and its derivatives under the 1961 and 1971 Conventions" is wrong in light of the text of the Convention (which recognizes herbal and traditional medicines). Additionally, this determination opposes the existence of legitimate and recognized sound policies on herbal medicines – contemplated in the Convention and framed by WHO. Reliant on the placement of raw herbal *Cannabis* in Schedule IV of the 1961 Convention, the INCB statement also loses value in light of the ECDD's recognition that herbal *Cannabis* should be withdrawn from Schedule IV, and also that "the Committee did not consider that cannabis is associated with the same level of risk to health of most of the other drugs that have been placed in Schedule I".

Policies granting access to raw herbal *Cannabis* and its botanical preparations for medical purposes are not only allowed under international law, including the 1961 Convention: they are also needed. Monitoring and pharmacovigilance are key. While the INCB's help would certainly be welcome to help monitor and assess availability of the different forms of medical *Cannabis* and cannabinoid preparations in all countries, the Board oversteps its mandate when recommending to Member States the restriction of access to mono-molecular formulations. Assessing countries in the implementation of their health systems regulatory frameworks are fully incumbent upon WHO, and the INCB should refer countries to that Organization's numerous guidance and guideline documents that precisely tackle all the concerns of the INCB, such as:

- Traditional Medicine and Health Care Coverage (1983);
- WHO/DANIDA Training Course: the **Selection and Use of Traditional Remedies** in Primary Health Care (1986);
- WHO/DANIDA Intercountry Course on the Appropriate **Methodology** for the Selection and Use of Traditional Remedies in National Health Care Programme (1991);
- Natural Resources and Human Health: Plants of Medicinal and Nutritional Value *in* Proceedings of WHO Symposium on Plants and Health for All (1992);
- **Research Guidelines** for Evaluating the Safety and Efficacy of Herbal Medicines (1993);
- WHO/IUCN/WWF Guidelines on the **Conservation** of Medicinal Plants (1993);
- Guidelines for Training Traditional Health Practitioners in **Primary Health Care** (1995);
- **Traditional Practitioners** as Primary Health Care Workers (1995);
- Guidelines for the **Assessment** of Herbal Medicines, *in* WHO Expert Committee on Specifications for Pharmaceutical Preparations, 34th Report (1996);
- Guidelines for the **Appropriate use** of Herbal Medicines (1998);
- Basic **Tests** for Drugs - Pharmaceutical Substances, Medicinal Plant Materials and Dosage Forms (1998);
- General Guidelines for **Methodologies on Research** and Evaluation of Traditional Medicine (2000);
- Guidelines on Good Agricultural and Collection Practices (**GACP**) for Medicinal Plants (2003);
- Guidelines on Developing **Consumer Information** on Proper Use of Traditional, Complementary and Alternative Medicine (2004);
- Clinical Trials on Treatment Using a Combination of Traditional Chinese Medicine and Western Medicine (2004);
- Guidelines on Safety Monitoring of Herbal Medicines in **Pharmacovigilance** Systems (2004);
- Guidelines on good manufacturing Practices (**GMP**) for Herbal Medicines (2007);
- Guidelines for Assessing Quality of Herbal Medicines with Reference to **Contaminants** and Residues (2007);
- **Quality Control** Methods for Herbal Materials (2011);
- WHO Traditional Medicine Strategy: 2014-2023 (2013).

In *Cannabis*, like in other botanical medicines, "the plant preparation as a whole is therapeutically effective" according to WHO [WHO, 1994], and "clinical investigation of the therapeutic activity of such crude preparations may be useful, because that activity may depend not only on a single substance but may be influenced by a large number of other components in the herbal medicine."

The Conventions do not request for clinical trials or any mandatory approval process.

When the Board declares [§71] that "Governments [...] should limit the use of such preparations to approved medicinal cannabinoids", it is clearly opposing the Convention's mandate to ensure access and availability to all controlled drugs, regardless of their status of Scheduling, regardless of their use in first-line or last resort treatment, and regardless of their methods of intake or formulations. In all situations, access and availability should be granted – according to the provisions of the Convention that specify the policy frame to give to this imperative of availability. The role of the INCB is to oversee the smooth running of the system, in no way the Board can emit opinions on the preferred formulations or preparations to provide access to, or on the assessment or approval processes needed by countries.

In the three international drug control Convention, the only mention of "clinical trials" is present in Article 5(b) of the 1961 Treaty referring to the substances placed in Schedule IV – mentioned in no way as an obligation for countries to use clinical trials as the only mandatory safety assessment process. Also, this position might even soon be irrelevant, as the withdrawal of *Cannabis* from Schedule IV is around the corner.

Safety assessment and proper evaluation processes must be sought – to scale-up knowledge and facilitate an efficient use by medical practitioners, not as a genuine requisite. However, specific approval and marketability processes are needed. In its *Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines* [WHO, 1994], the WHO declares that "herbal medicines have been recognized as a valuable and readily available resource for primary health care, and WHO has endorsed their safe and effective use" and "supports the appropriate use of herbal medicines and encourages the use of remedies that have been proven to be safe and effective [...] Most herbal medicines still need to be studied scientifically, although the experience obtained from their traditional use over the years should not be ignored."

Because specific assessment and approval methodologies are needed, the "requirement of evidence as to the safety and efficacy of herbal medicines and the method of research chosen should be adjusted to the original purpose of the research." Countries should therefore rather try to consult the ways to ensure the safety of herbal *Cannabis* and botanical formulations of the plant with national institutions in charge of herbalist or phytotherapeutic systems and enforce measures for *Cannabis* that mimic those in place for other commonly used herbal medicines.

9.2 INCB recommendations on Treaty compliance and the use of *Cannabis* and cannabinoids as last resort medicines.

Recommendation 1 (c) included in Chapter IV	Medical use of cannabinoids should be regulated and supervised in a manner that meets the requirements set out in the drug control treaties. The integrity of the pharmaceutical regulatory system must be maintained, in particular by ensuring that cannabinoids are used in medical practice only where there is evidence of their equal or superior effectiveness relative to other medicinal products, and evidence of their safety.
Thematic Recommendation included in paragraph **67**	The medical use of cannabinoids is allowed under the international drug control treaties only if States comply with the treaty requirements that are designed to prevent diversion to non-medical use. The treaties require that States license and control cannabis production for medical use, provide estimates of the national requirements for cannabis for medical purposes and ensure that medicinal cannabinoids are used in accordance with evidence on their safety and effectiveness and under medical supervision. Taking those measures should also contribute to maintaining the integrity of the pharmaceutical regulatory system.
Thematic Recommendation included in paragraph **68**	Recent reviews of the evidence from clinical trials indicate that: (a) there is weak evidence that dronabinol may be useful in treating nausea and vomiting in cancer patients; (b) there is moderate evidence that nabiximols may be useful in treating neuropathic pain and muscle spasticity in patients with multiple sclerosis; and (c) there is moderate evidence that CBD may reduce seizure frequency in some genetic intractable childhood epilepsy syndromes. Cannabinoids are not a first-line treatment for any of those conditions.
Thematic Recommendation included in paragraph **72**	Under medical cannabis programmes implemented in Canada and possibly in some other States, and in some states in the United States, the medical use of cannabinoids is poorly regulated. Those programmes are inconsistent with the international drug control treaties in failing to control cannabis production and supply. They fail to ensure that good-quality medicines are provided under medical supervision and they enable cannabis and its derivatives to be diverted to non-medical use.

It is undeniable that international law should be respected – by the way, all international law, also considering international legal instruments beyond the drug-related treaties.

Moreover, it is also true that some regulations of the production and dispensation of *Cannabis* for medical purposes in the United States are "inconsistent with the international drug control treaties" in what concerns the concrete measures of control. For instance, the Board recalls in this years' report (§8) that a governmental agency must "licence producers, purchase and take possession of stocks and maintain monopoly on the wholesale trading and stocks." Growers of medical grade *Cannabis* in US States that regulated its use are indeed not licenced by a federal agency, as it is, for instance, the case in Jamaica, Switzerland or Canada (among the dozens of countries where it was regulated [Aguilar et al., 2018]). However, none of the above-mentioned countries, not more than Australia, Chile, Croatia, Czech Republic, Germany, Israel, Mexico, the Netherlands, New Zealand, Uruguay or the many other jurisdictions which provide legal access, do comply with the obligation to take possession of all stocks and provide a monopoly on wholesale trading.

Consistency is a delicate matter, especially when different obligations conflict between each other. This is the case of the preambular part of the 1961 Convention, which recognizes "that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes". This, in addition to the "right to the enjoyment of the highest attainable standard of physical and mental health" (OHCHR 2008), conflicts with the overly restrictive provisions of the 1961 Convention *de facto* acting as barriers to medical access.

The way to resolve normative conflict within and between Treaty/ies is clear, having been explained by the International Law Commission (ILC): a resolution that balances the two sets of obligations in conflict must always be preferred. In the case of the 1961 Convention, this means accommodating the spirit of the Treaty with its letter, calling for what Richard Lines[13] calls as "a good faith reading of the text in light of its object and purpose." The ILC, however, recalls that "some rules of international law are more important than other rules and for this reason enjoy a superior position or special status in the international legal system. This is sometimes expressed by the designation of some norms as 'fundamental' or as expressive of 'elementary considerations of humanity' or 'intransgressible principles of international law'" [ILC 2006, p. 419].

In this case, it seems that non-compliance to a specific part of the Convention enables compliance to the whole – by fulfilling the purpose of the text and complying with the fundamental right to health. In that sense, many medical *Cannabis* policies openly violate some technical provisions of the 1961 Convention, having balanced their relevance with elementary considerations of humanity: providing effective and safe access to those in need.

When recalling the need for "universal and full implementation of the treaties" (§61 and §851), the INCB might start assessing if its goal is to protest specific provisions of the text or protect and promote the overall goal, object, and purpose of the international law they guard.

[13] See Richard Lines' intervention at the "Academic forum on Legal Regulations. Human Rights and the Drug Control System: hierarchy of norms & flexibility for Member States" youtube.com/watch?v=ujalZSUv7k0

The INCB recognizes in §20 that "Physicians may use approved drugs off-label, that is, to treat medical conditions other than those for which the drugs have been approved."

In the next paragraph (§21), the Board exposes the special case of "compassionate use", stating that "Many national pharmaceutical regulatory systems have established special-access schemes that enable patients with serious illnesses (such as cancer) to access unapproved medicines. This requires evidence that the patient has failed to respond to conventional treatment and patients must give informed consent for the use of an unapproved medicine. Medicines obtained in this way may have been approved for medical use in other countries but are not available in the country where a patient lives". This is indeed a true case where last-resort is mandatory, and even is fundamental in the definition of the concept of "compassionate use". The countries that allow for the prescription of *Cannabis* or cannabinoids only as last-resort medicines do not do it on the basis of a lower efficiency of these treatments over conventional ones, but only because of the policy restrictions imposed by the character of exceptionality surrounding *Cannabis* that only allow for effective access via provisions of "compassionate" use.

Generally, the Board seems to recommend the use of *Cannabis* and cannabinoid medicines as a last-resort treatment only, in all cases. While the INCB is right in noting that "Cannabinoids are not a first-line treatment" for the three medical conditions cited as examples (nausea and vomiting in cancer patients, neuropathic pain and muscle spasticity in patients with multiple sclerosis, and some genetic intractable childhood epilepsy syndromes), this does not mean that cannabinoids are a last-line treatment either. *Cannabis* and cannabinoids for the treatment of severe medical conditions create additional therapeutic value from being used in adjunct or supporting conventional treatment, in a rational and patient-focused approach. No more a first-line than a last-resort medicine: a tool more in the doctor's toolkit.

It would be a faulty generalization to conclude to the necessity of *Cannabis* and cannabinoids only in "late-resort" therapeutic interventions, either by extension of the aspect of compassionate use to all medicinal uses or by opposition to the non-first-line aspect. None are a serious justification for such an approach, and physicians should be granted the possibility of prescribing and administering *Cannabis* and cannabinoids at all stages of treatments.

9.3 INCB recommendations on smoked *Cannabis* in medicine.

Thematic Recommendation included in paragraph 69	The evidence that cannabinoids can relieve symptoms of some medical illnesses does not justify the "medical use" of cannabis by smoking. Smoking a crude plant product is not a safe or reliable way to obtain standardized doses of cannabinoids.

It is heartening that the Board recognizes "The evidence that cannabinoids can relieve symptoms of some medical illnesses" in such clear words, and it is even more satisfying to see the INCB express its correct understanding of methods of administration as a key cause of harms – rather than the substance itself.

Not only is combustion (the chemical process involved in "smoking" botanical tops of *Cannabis*) "not a safe or reliable way to obtain standardized doses of cannabinoids" in the case of medicinal uses, but it can also be a harmful way of using *Cannabis* in the case of non-medical uses.

An efficient harm-reducing method of intake which relies on the same route of administration than smoking (i.e., broncho-pulmonary inhalation, an interesting route of intake allowing a rapid onset of action and patient control over the effect) is vaporization, a method whereby the botanical material is heated at a temperature lower than the combustion point, that has proven efficiency in medical practice and lack of harms to others like second-hand smoke exposure [Solowij et al., 2018]. In medical practice, when rapid onset of action is not desired, routes of administration other than broncho-pulmonary inhalation should be sought.

However, the use of smoked herbal *Cannabis* or resin can also find its room in the physician's toolkit, in particular for patients with prior non-medical use. The use of low-THC chemovars of *Cannabis* in substitution or dishabituation therapies for people with *Cannabis* or tobacco use disorders can also be contemplated, and is currently being studied in several countries as a promising tool in tobacco cessation strategies [See Riboulet-Zemouli et al., 2019, p. 39].

The composition of smoke from *Cannabis* cigarettes, however, varies from that of tobacco cigarettes, and should, therefore, call for a specific evidence-based approach rather than a generalization based on knowledge derived from tobacco smoke studies. Pletscher et al [2012] note that "Marijuana smoke contains many of the same constituents as tobacco smoke, but it is unclear whether smoking marijuana causes pulmonary damage similar to that caused by tobacco" and finds that "occasional and low cumulative marijuana use was not associated with adverse effects on pulmonary function." In addition, a thirty year longitudinal study found that "the accumulated weight of evidence implies far lower risks for pulmonary complications of even regular heavy use of marijuana compared with the grave pulmonary consequences of tobacco" [Taskin, 2013].

Although it is evident that physicians should prefer vaporization over combustion, conclusions should not be drawn too rapidly regarding the non-viability of smoked *Cannabis* as a route of administration.

9.4 INCB recommendations on adult use: addressing diversion and incentives to policy reforms.

Recommendation 1 (b) included in Chapter IV	Governments should ensure that such programmes do not result in the de facto legalization of cannabis for non-medical purposes.
Thematic Recommendation included in paragraph 70	Poorly controlled programmes for the medicinal use of cannabinoids can potentially have adverse effects on public health. They may increase non-medical cannabis use among adults and contribute to the legalization of non-medical cannabis use by weakening public perceptions of the risks of using cannabis and reducing public concern about legalizing non-medical (so-called "recreational") cannabis use, which is contrary to the international drug control treaties.
Thematic Recommendation included in paragraph 71	Governments that have created special-access schemes to allow the medical use of cannabis should ensure that those programmes are not used to de facto legalize cannabis for non-medical use. Governments should limit the indications for medical use to those for which there is evidence of efficacy, restrict use to medicinal cannabinoids, and monitor the prescription and use of cannabinoids to minimize their diversion and abuse.
Thematic Recommendation included in paragraph 73	"Medical cannabis" programmes may also have been used by advocates of the legalization of cannabis use to facilitate the legalization of non-medical cannabis use, which is contrary to the international drug control treaties. Such programmes have used very broad definitions of "medical use" and allowed commercial businesses to supply illicitly produced cannabis. In the United States, those programmes also appear to have reduced public perceptions of the risks of using cannabis and have weakened public concern about cannabis legalization.
Recommendation 2 included in Chapter IV	Recalling the limitation of use of narcotic drugs and psychotropic substances to medical and scientific purposes as well as the health and welfare objectives of the treaties, the Board reiterates that the three international drug control treaties limit the use of cannabis exclusively to medical and scientific purposes. The Board calls upon the Governments of countries in which the use of cannabis or cannabis derivatives for non-medical, "recreational" purposes has been permitted to take steps to bring the entirety of their territories back into compliance with the international drug control conventions and their obligations thereunder.

The International Narcotics Control Board has always had views opposed to any room for recreational or adult use [Bewley-Taylor et al., 2014] and in particular, since the inaugural chapter of its report for 1992 titled "View of the Board on the question of legalization of the non-medical use of drugs". In that piece, the Board was "[drawing] the attention of industrialized countries to the fact that in 1961 they initiated the introduction of the international control of cannabis at a period when serious cannabis abuse problems did not exist in their countries [...] If cannabis were to be legalized, the responsibility of industrialized countries would be enormous: they would be obliged to justify, at the same time, their 1961 decision to prohibit cannabis and their new decision to add cannabis to other legalized substances like alcohol and tobacco" [INCB, 1992. See part I. A. §22.].

It is indeed arguable, as the current President of INCB recently declared[14], that "any measure that permits the use of cannabis for non-medical purposes is contrary to the international drug control conventions" and that the "policies pursued in Uruguay, some jurisdictions in the United States and now in Canada are contrary to the [...] undertakings those countries made [...] to promote health and wellbeing".

Addressing abuse.

However, the prohibition of "recreational use" is hard to defend on the sole basis of the Treaties. The word "recreational" is never present, and there is no terminology specifically addressing adult use. The 1961 Convention, to be exact, mentions these different types of possible purposes:

- Medical use
- Research
- Industrial use
- Use for manufacture of preparations of drugs
- Quasi-medical use (in the case of opium) and use of cannabis "for non-medical purposes"[15]
- Abuse

It is commonly accepted that – besides the already-obsolete "use of cannabis for non-medical purposes", which is present in Article 49 as being potentially authorized in a country for a transitional period of 25 years after entry into force of the Convention in that country (after which any "use of cannabis for non-medical purposes" should be discontinued) – the recreational use of *Cannabis* and other drugs is covered by the word "abuse". However, "abuse" is never defined in the Treaty, and could also be understood in its vernacular meaning (i.e. "to use something for the wrong purpose in a way that is harmful or morally wrong", "to use something in the wrong way", "a situation in which a person uses something in a bad or wrong way, especially for their own advantage or pleasure"[16]) or in its public health meaning (defined for instance by the DSM or ICD).

Many argue that "drug abuse" refers to a "patterned use of a drug in which the user consumes the substance in amounts or with methods which are harmful to themselves or others, and is a form of substance-related disorder"[17], in other words, leading to an abusive use by a person of a prescribed or recommended medication. In clear contemporary words, abuse refers to what the 5th Diagnostic and Statistical Manual of Mental Disorders (DSM-5) calls "substance use disorder". Previous versions of the DSM separated "substance abuse disorder" (close to the Treaty terminology "abuse", and conditioned by "recurrent substance-related legal problems") and "substance dependence disorder" (closer to the accepted definition of problematic use of psychoactive substances, regardless of their legal status), but the last version (DSM-5) recognizes a single "substance use disorder" unrelated to the legal status of the

[14] See the statement of Dr. Viroj Sumyai, President of the INCB, to the ECOSOC Coordination and Management Meeting, July 2nd, 2018, at: incb.org/documents/Speeches/Speeches2018/ECOSOC_CMM_2018_for_webposting.pdf
[15] Included in Article 49.
[16] See: Cambridge Dictionary, "Meaning of abuse in English" at: dictionary.cambridge.org/dictionary/english/abuse
[17] See wikipedia "Substance abuse" at: en.wikipedia.org/wiki/Substance_abuse

substance, or the way of obtention (prescribed of for non-medical uses) [Substance Abuse and Mental Health Services Administration, 2016. See Chapter 2].

In 2019, an international law, the purpose and objective of which is to protect public health from adverse effects of scheduled drugs and ensure availability for medical purposes, must stop considering as "abuse" all the uses other than "medical", "scientific", and "industrial" and focus on addressing the real cause of adverse public health consequences: substance use disorders.

It is nowadays widely accepted that "there are also substances that can be abused that have no mood-altering or intoxication properties, such as anabolic steroids. The use of anabolic steroids to enhance performance or develop muscles and strength is abusive because of the negative side effects of their use, which can range from merely annoying to life-threatening in some cases. [...] Theoretically, almost any substance can be abused."[18] In the XXI[st] Century, the term "abuse" refers to the actual excessive or disproportionate use of a substance, compared with the initially desired use – regardless of the purpose of that use, may it be medical, recreational, or non-related to any mood alteration or "narcotic-like" effect.

The UNODC recognizes, in what refers to *Cannabis*, that between 165 and 234 million people use it yearly worldwide [UNODC, 2018]. Among these, *Cannabis* use disorders are estimated to affect about 10% of adult people who use herbal *Cannabis* during their lifetime [Hall and Pacula, 2010; Anthony, 2006].

In the paragraph 7 of this year's report, the INCB declares that "Article 4, paragraph (c), of the 1961 Convention as amended limits the use of drugs scheduled under the Convention, including cannabis and its derivatives, to medical and scientific purposes" but forgets to mention that the same article specifies that this is "Subject to the provisions of this Convention".

An important provision, which is not subject to the limitations to medical and scientific use, is the clear exemption of all "industrial uses" from the scope of the Treaty introduced by Article 2(9): "Parties are not required to apply the provisions of this Convention to drugs which are commonly used in industry for other than medical or scientific purposes." It is further detailed in Article 28(2) that "This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes."

The Commentary of the 1961 Convention explains clearly [UN 1973, p. 312] that this provision has to be read in parallel with the preceding paragraph of Article 28 binding countries to apply the provisions of Article 23 (i.e, national agency, control over stocks etc.) to the "cultivation of the cannabis plant for the production of cannabis and cannabis resin" (understood as the drugs scheduled in the Convention, for medical or scientific purposes – the purposes that the Convention addresses). Consequently, "Cultivation of the plant for any other purpose, and not only the purposes mentioned in paragraph 2 [i.e. industrial, horticultural, fibre and seed[19]], is consequently exempted from the control régime provided in article 23." The Commentary makes it even more clear saying that "A Party permitting the cultivation of the plant for the drugs, but also permitting the cultivation elsewhere exclusively for other purposes, must apply Article 23 to the former, but not to the latter" [UN 1973, p. 314]. What is exempted here is neither "hemp" nor only "fibres and seeds". Any part of the plant is exempted, because the exemption relies on the purpose of use, which must not be scientific or medical (abuse being understood as an abusive medical use).

This interpretation directly conflicts with that of the INCB according to which, "The cultivation of the cannabis plant for industrial purposes other than those explicitly indicated in article 28, paragraph 2, should not be considered licit." Such interpretation of the Convention differs so much from that of the Commentary, prepared by the United Nations Secretary-General, that it puts into question the knowledge that the Board has of this Commentary, otherwise considered the gold standard for interpreting the Treaty.

[18] See: Buddy T and Fogoros R N, MD (2018), "An Overview of Substance Use", at: verywellmind.com/substance-use-4014640

[19] Comments inter brackets added by the author.

If we trust the Commentary more than the current INCB, the result is that Article 23 does not apply to the cultivation of *Cannabis* for industrial purposes, and that the "use in industry" of *Cannabis* is totally exempted from the Convention by Article 2. In such situation, "recreational use" does not fall under "medical and scientific" purposes controlled by the Treaty, and does not equal "abuse" which is a particular type of medical use. Yet, "recreational use" does not conflict with the possibility of falling under the definition of use related to "industrial" purposes. **Countries can definitely implement a compliant regulation for the non-medical and non-scientific cultivation of *Cannabis* for "industrial purposes", relying on Article 2(9) and Article 28(2) of the Convention.**

If the production and the use for industrial purposes, by the industry, can be implemented in the margins of the Convention while complying with it, it is also the case for "non-medical and non-scientific" adult use. The Commentary of Article 4(c) explains that "the 'use' of drugs is not specifically listed in Article 36 paragraph 1, among the actions which [...] a Party must treat as punishable offenses." [UN 1973, p. 111] and explains that countries Party to the Convention must "make possession of drugs contrary to the provisions of the Single Convention a punishable offence." But, because possession in industrial contexts is exempted, and no reference at all is made to adult use, the possession for those purposes is not contrary to the Convention [ibid., p. 112; See also commentaries on Article 33, pp. 404-405; and commentaries on Article 36(1), pp. 425-429].

Countries can definitely make entirely legal the use and possession of *Cannabis* produced for industrial purposes, for non-medical and non-scientific purposes, relying on Articles 4(c), 33 and 36(1) of the Convention.

This allows **regulation of the adult use of *Cannabis* to be in full compliance** with the Convention and international Human Rights law. The way to remain compliant is to continue meeting the goals of the Treaty, specifically global health and wellbeing, access and availability for medical and research purposes, and prevention of harmful or adverse health hazards related to *Cannabis*.

A first condition is the respect of the general principle of *bona fide* – i.e. a sincere "good faith" toward the text and spirit of the Treaty and convincing actuation of "good faith" *vis-a-vis* other countries, an underlying spin of the application of the Convention by countries, which must always guide national policies. Then, the researchers Piet Hein Van Kempen and Masha Fedorova explain in their *International law and cannabis II* (Van Kempen et al., 2017) that five essential conditions are needed to keep compliant with international law, arising from the balanced analysis of drug-control Convention and international Human Rights texts. These are:

1. A relevant human rights-based interest in the reform (the reform must be based on a desire to increase and enhance human rights);
2. Substantiation of the claim of a more effective human rights protection (the regulation implemented must result in a more effective protection of human rights);
3. National democratic decision-making and support of the reform (policies chosen must have public support and be decided through regular nationwide democratic processes);
4. No disadvantage for other states: a closed system (the regulation must be in a closed system so that neighbor and other foreign countries are not affected or disadvantaged in any way);
5. Obligatory policy of "discouragement" to use (the country is required to scale-up its approaches aimed at discouraging the use of *Cannabis* and reducing its prevalence via public policies).

The scholars conclude that "If a state is able to satisfy these conditions, under current international law it can legitimately prioritize the human rights obligations over and above any conflicting obligations arising from the UN Narcotic Drugs Conventions", and "it can be possible for states to regulate cannabis cultivation and trade for recreational use by legalization in accordance with international law".

The solution is and has always been here. **The lack of reflexion from the part of INCB on adult use can only lead to poor international credibility, while an increasing number of jurisdictions take the steps toward "legalization" in a public health-oriented manner.**

Addressing "diversion".

Another topic raised by the Board is that of the "diversion" of *Cannabis* from medical to non-medical settings, i.e. the misdirection of *Cannabis* destined to medical systems toward recreational use.

A way to avoid diversion and misuse of medical *Cannabis*, however, would be the close separation of that field with that of non-medical use. Answering the demand in non-medical *Cannabis* via separate settings, separate policies, and separate supply systems seems an efficient way to avoid the diversion of medical products and preparations to the "recreational" use market, assuming that this diversion is driven by a demand for other than medical use.

The exact opposite is also true: if only non-medical *Cannabis* is available, patients (or physicians) might divert the ways of access to that *Cannabis* and make medical use of it. It is this case, for instance, in Spain where (i) there is no legal access to herbal *Cannabis* for medical purposes, and (ii) people self-organized to create a quasi-legal way of access to herbal *Cannabis* for adult use (the so-called "Cannabis social clubs"). There, it is estimated that about 6% of the members registered in the Cannabis social clubs make therapeutic use of the plant. This is another example of diversion resulting from a lack of proper separated supply systems for medical use and adult use.

Just like connected vessels: diversion from one side only makes sense when there is an unanswered demand on the other side. **The only way to prevent diversion and safeguard the integrity of medical and pharmaceutical systems is to provide for simultaneous regulations and specific settings for all types of uses.**

References.

Notice:

CEB - Chief Executives Board for Coordination
CND - Commission on Narcotic Drugs
DSM - Diagnostic and Statistical Manual of Mental Disorders
EFSA - European Food Safety Authority
EMCDDA - European Monitoring Centre for Drugs and Drug Addiction
ILC - International Law Commission
INCB - International Narcotics Control Board
OHCHR - Office of the United Nations High Commissioner for Human Rights
UNGA - United Nations General Assembly
UNODC - United Nations Office on Drugs and Crime
WHO - World Health Organization

Aguilar S, Gutiérrez V, Sánchez L and Nougier M (2018), "Medicinal cannabis policies and practices around the world" IDPC and MUCD, April 2018.
Available at: fileserver.idpc.net/library/Medicinal%20cannabis%20briefing_ENG_FINAL.PDF

Anthony J C (2006), "The epidemiology of cannabis dependence." In: Roffman RA, Stephens RS, editors. Cannabis dependence: its nature, consequences and treatment. Cambridge University Press: 58–105.

Baňas B, Beitzke B, Cannazza G, Carus M, Gabrielová H, Ghehiouèche G, Iffl K, Krawitz M, Kruse D, Pirich E and Riboulet-Zemouli K (2017), "Joint EIHA – FAAAT contribution to the 39th ECDD evaluation of Cannabidiol." EIHA, Geneva (Switzerland), November 6th, 2017.
Available at: faaat.net/wp-content/uploads/EIHA-FAAAT_WHO_CBD_submission_2017.pdf

Bewley-Taylor D, Blickman T and Jelsma M (2014), "The INCB and cannabis: from description to condemnation", in "The Rise and Decline of Cannabis Prohibition, the History of cannabis in the UN drug control system and options for reform." Transnational Institute, 2012.
Available at: tni.org/files/download/rise_and_decline_ch2.pdf

Blasco-Benito S et al. (2018), "Appraising the "entourage effect": Antitumor action of a pure cannabinoid versus a botanical drug preparation in preclinical models of breast cancer." Biochem Pharmacol. 2018 Nov; 157:285-293.
Available at: ncbi.nlm.nih.gov/pubmed/29940172

Chief Executives Board for Coordination (2018), "Summary of deliberations of the Second regular session of 2018" included in CEB/2018/2.

Commission on Narcotic Drugs (1965), "Resolution 1(XX). The control of new narcotic substances."
Available at: unodc.org/documents/commissions/CND/Drug_Resolutions/1960-1969/1965/CND_Resolution-1_XX.pdf

Commission on Narcotic Drugs (1991), "34th Session, Decision 2 (XXXIV)."
Available at: unodc.org/documents/commissions/CND/Drug_Resolutions/1990-1999/1991/CND_Decision-34-2_XXXIV.pdf

Commission on Narcotic Drugs (2007), "Decision 50/2. Review of dronabinol and its stereoisomers."
Available at: unodc.org/documents/commissions/CND/Drug_Resolutions/2000-2009/2007/CND_Decision-50-2.pdf

Commission on Narcotic Drugs (2014), E/CN.7/2014/10 - Challenges and future work in the review of substances for possible scheduling recommendations. Note by the Secretariat.
Available at: undocs.org/en/E/CN.7/2014/10

Congress of the United States of America (1970), "Comprehensive Drug Abuse Prevention and Control Act of 1970." Public Law 91-513, October 27th, 1970. Washington D.C, USA.
Available at: govinfo.gov/content/pkg/STATUTE-84/pdf/STATUTE-84-Pg1236.pdf

Drug Enforcement Administration (2018), "Press release: FDA-approved drug Epidiolex placed in schedule V of Controlled Substance Act." Washington D.C, USA. September 27, 2018.
Available at:
dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act

European Food Safety Authority (2011), Scientific Opinion on the safety of hemp (*Cannabis genus*) for use as animal feed, EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP). European Food Safety Authority (EFSA), Parma, Italy.
Available at:
efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2011

European Monitoring Centre for Drugs and Drug Addiction (2018), Cannabis drug policy news item: Low-THC cannabis products being sold in the EU – key legal issues.
Available at:
emcdda.europa.eu/news/2018/low-thc-cannabis-products-being-sold-in-the-EU–key-legal-issues_en

European Monitoring Centre for Drugs and Drug Addiction (2018), Cannabis legislation in Europe: an overview, Publications Office of the European Union, Luxembourg.
Available at:
www.emcdda.europa.eu/system/files/publications/4135/TD0217210ENN.pdf

European Parliament (2019), European Parliament Resolution of 13 February 2019 on use of cannabis for medicinal purposes (2018/2775(RSP)).
Available at:
europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2019-0113+0+DOC+XML+V0//EN

Hall WD, Pacula RL (2010), "Cannabis use and dependence: public health and public policy (reissue of first edition 2003)." Cambridge University Press, 2010.

International Law Commission (2006), "Fragmentation Of International Law: Difficulties Arising From The Diversification And Expansion Of International Law" in "Report on the work of the fifty-eighth session"
Available at:
legal.un.org/docs/?symbol=A/61/10

International Narcotics Control Board (1992), "Report of the International Narcotics Control Board for 1992." United Nations, New-York, 1992.
Available at:
incb.org/documents/Publications/AnnualReports/AR1992/1992_ANNUAL_report_eng.pdf

International Narcotics Control Board (2009), "Report of the International Narcotics Control Board for 2008."
Available at:
incb.org/documents/Publications/AnnualReports/AR2008/AR_08_English.pdf

International Narcotics Control Board (2017a), Alert on Control of Narcotic Drugs, June 2017. The therapeutic use of cannabis.
Available at:
incb.org/documents/News/Alerts/Alert_on_Control_of_Narcotic_Drugs_June_2017.pdf

International Narcotics Control Board (2017b), Report of the International Narcotics Control Board for 2016.
Available at:
incb.org/documents/Publications/AnnualReports/AR2016/English/AR2016_RegulationOfTheUseOfCannabisForNonMedicalPurposes.pdf

International Narcotics Control Board (2018), List of Narcotic Drugs Under International Control (Yellow List), in accordance with the Single Convention on Narcotic Drugs, 1961, and the Protocol of 25 March 1972 amending the Single Convention on Narcotic Drugs, 1961.
Available at:
incb.org/documents/Narcotic-Drugs/Yellow_List/57th_edition/57th_edition_YL_ENG.pdf

International Narcotics Control Board (2019a), Press release, INCB concludes 124th session, meets with Member States on past year drug control developments.
Available at:
incb.org/incb/en/news/press-releases/2019/incb-concludes-124th-session--meets-with-member-states-on-past-year-drug-control-developments.html

International Narcotics Control Board (2019b), Report of the International Narcotics Control Board for 2018.
Available at:
incb.org/incb/en/publications/annual-reports/annual-report-2018.html

Jelsma M and Armenta A (2015), The UN Drug Control Conventions, A primer.
Available at:
tni.org/files/publication-downloads/primer_unconventions_24102015.pdf

Office of the United Nations High Commissioner for Human Rights (2008), “The Right to Health. Fact Sheet No. 31” United Nations, Geneva, June 2008.
Available at: ohchr.org/Documents/Publications/Factsheet31.pdf

Parliament of the Republic of India (2011), The Narcotic Drugs and Psychotropic Substances Act, 1985, and other texts, with Short Notes. Universal Law Publishing Co. Pvt. Ltd., New Delhi.
Available at: www.cbn.nic.in/html/ndpsact1985.pdf

Pletcher M J, Vittinghoff E, Kalhan R, et al. (2012), “Association Between Marijuana Exposure and Pulmonary Function Over 20 Years.” JAMA. 2012;307(2):173–181. doi:10.1001/jama.2011.1961

Riboulet-Zemouli K, Krawitz M and Ghehiouèche F (2018), “The Crimson Digest, volume 1. Briefing on the international scientific assessment of cannabis: Processes, stakeholders and history.” FAAAT think & do tank, Geneva, November 2018.
Available at: faaat.net/cannabis/who#digest1

Riboulet-Zemouli K, Anderfuhren-Biget S, Díaz Velásquez M and Krawitz M (2019), “Cannabis & Sustainable Development. Paving the way for the next decade in Cannabis and hemp policies.” FAAAT think & do tank, Vienna, March 2019.
Available at: faaat.net/publications

Russo E B (2018), “Taming THC: potential cannabis synergy and phytocannabinoid-terpenoid entourage effects.” Br J Pharmacol. 2011 Aug; 163(7): 1344–1364.
Available at: ncbi.nlm.nih.gov/pmc/articles/PMC3165946/

Russo E B (2019), “The Case for the Entourage Effect and Conventional Breeding of Clinical Cannabis: No “Strain,” No Gain.” Front. Plant Sci., 09 January 2019
Available at: doi.org/10.3389/fpls.2018.01969

Solowij N, Galettis P, Broyd S J, de Krey P and Martin J H (2018), "Second-Hand Exposure of Staff Administering VaporisedCannabinoid Products to Patients in a Hospital Setting." Drugs in R&D. 18. 10.1007/s40268-017-0225-5.

Substance Abuse and Mental Health Services Administration (2016), "Impact of the DSM-IV to DSM-5 Changes on the National Survey on Drug Use and Health CBHSQ Methodology Report" Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2016 Jun.
Available at: ncbi.nlm.nih.gov/books/NBK519697/

Tashkin D P (2013), "Effects of marijuana smoking on the lung." Ann Am Thorac Soc. 2013 Jun;10(3):239-47. doi: 10.1513/AnnalsATS.201212-127FR.
Available at: ncbi.nlm.nih.gov/pubmed/23802821

United Nations (1971), “Convention on Psychotropic Substances, 1971.”
Available at: unodc.org/pdf/convention_1971_en.pdf

United Nations (1972), “Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961.”
Available at: unodc.org/pdf/convention_1961_en.pdf

United Nations (1973), “Commentary on the Single Convention on Narcotic Drugs, 1961. Prepared by Secretary-General in accordance with paragraph 1 of Economic and Social Council resolution 914 D (XXXIV) of 3 August 1962.” Sales No. E.73.XI.1

United Nations (1977), “Commentary on the Protocol Amending the Single Convention on Narcotic Drugs, 1961.” E/CN.7/588. Sales No. E.76.XI.6

United Nations General Assembly (1946), “Protocol on narcotic drugs : protocol amending the agreements, conventions and protocols on narcotic drugs concluded at The Hague on 23 January 1912, at Geneva on 11 February 1925 and 19 February 1925 and 13 July 1931, at Bangkok on 27 November 1931 and at Geneva on 26 June 1936.” Included in General Assembly Resolution 54 (I) in A/64/Add.1
Available at: undocs.org/A/64/Add.1

United Nations Office on Drugs and Crime (2018), “World Drug Report 2018.”
Available at: unodc.org/wdr2018

Van Kempen P H P H M C and Fedorova M I (2016), "International law and cannabis II. Regulation of cannabis cultivation and trade for recreational use: positive human rights obligations versus UN Narcotic Drugs Conventions" Wolters Kluwer, December 2016.
See: ru.nl/english/news-agenda/news/vm/law-0/law/2016/international-law-allows-legalisation-cannabis/

World Health Organization (1952), “Expert Committee on on Drugs Liable to produce Addiction, Third Report.” Technical Report Series No 57.
Available at: apps.who.int/iris/bitstream/handle/10665/40195/WHO_TRS_57.pdf

World Health Organization (1954a), "Expert Committee on on Drugs Liable to produce Addiction, Fourth Report." Technical Report Series No 76.
Available at: apps.who.int/iris/bitstream/handle/10665/40233/WHO_TRS_76.pdf

World Health Organization (1954b), "Expert Committee on on Drugs Liable to produce Addiction, Fifth Report." Technical Report Series No 95.
Available at: apps.who.int/iris/bitstream/handle/10665/40262/WHO_TRS_95.pdf

World Health Organization (1970), "Expert Committee on Drug Dependence, Seventeenth Report." Technical Report Series No 437.
Available at: apps.who.int/iris/bitstream/handle/10665/40766/WHO_TRS_437.pdf?sequence=1

World Health Organization (1994), "Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines." World Health Organization Regional Office for the Western Pacific Manila 1993
Available at: apps.who.int/medicinedocs/en/d/Jh2946e/#Jh2946e

World Health Organization (1996), "Report of the 34th WHO Expert Committee on Specifications for Pharmaceutical Preparations." Technical Report Series No 863.
Available at: apps.who.int/medicinedocs/pdf/s5516e/s5516e.pdf

World Health Organization (2012), "Documentation of the 35th ECDD, Agenda item 3.2: Work of international bodies concerned with controlled substances."
Available at: who.int/medicines/areas/quality_safety/3.2information.pdf?ua=1

World Health Organization (2013), "WHO traditional medicine strategy: 2014-2023." WHO Press, Geneva, Switzerland.
Available at: apps.who.int/medicinedocs/documents/s21201en/s21201en.pdf

World Health Organization (2018), "Expert Committee on Drug Dependence, Fortieth Report." Technical Report Series No 1013.
Available at: apps.who.int/iris/bitstream/handle/10665/279948/9789241210225-eng.pdf