ECDD40

Procedural, methodological and terminological bias.

Joint Civil Society Contribution to the
40th Meeting of the WHO
Expert Committee on Drug Dependence.

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Authors.

Farid Ghehiouèche.

Michael Krawitz.

Kenzi Riboulet Zemouli.
Corresponding author: kenzi@faaat.net

Contributing authors.

Boris Baňas, Ing.

Dr. Bernhard Beitzke, ChD

David Borden.

Dr. José-Carlos Bouso, PhD.

Amy L. King.

Dr. Alejandra Outomuro, MD.

Òscar Parés.

Endorsements.

DRCNet Foundation

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About FAAAT think & do tank

FAAAT think & do tank *(For Alternative Approaches to Addiction - Think & do tank)* is a transnational non-governmental, non-partisan and non-profit organization working on the issue of addiction, controlled drugs, and plants, products or substances liable to produce hermful effects.

Based in **Paris** and **Barcelona**, and active in **Geneva**, **New-York** and **Vienna**, FAAAT think & do tank centralizes the collaboration of a global network of experts to provide meaningful inputs in the international processes related to drug policies and strategies.

Genuinely focused on methodologies of substance assessment for international control, our teams have started, since 2014, to follow the processes related to the review of Cannabis and its related substances, both at the United Nations level (Vienna-based UN agencies) and in geneva at the WHO level.

> ***Our vision.*** Transparent and measurable drug policies framed by fundamental rights, grounded on sustainable development, and enforcing empowerment, social justice and health.
>
> ***Our mission.*** Research rigorous and ethical policy alternatives, and take action through social engineering, collective action and advocacy for ground-up democratic reformers at all level.

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Foreword.

The ***goal*** of the ECDD is to issue the **highest standard of evidence-based recommendations**, grounded in excellence, robust risk-assessment methodologies, and emerging from a broad collection of all facets of available data regarding a product, a plant or a substance. The ***purpose*** is to enable a **science-enlightened decision-making process** on a major global health issue: the need to balance the decision of applying restrictive measures of control, with the need to protect and enhance the right of everyone to the enjoyment of Health.

Keeping in mind, on one hand the high standards expected, and on the other hand the important consequences of the policy decisions implied by the Committee's discussions, precaution should be taken when undertaking such a crucial series of assessments, about products so widely used.

Oversight, plagianism, gross negligences, terminology issues, mistaken references, erroneous translations, unaggregable data aggregated, and *in fine* bias, arise from the preparation process of the reviews you are about to undertake. Moreover, some authors of the reports over which you will base your assessment, have obliterated or misrelated important pieces of evidence.

This contribution examines in detail the bias and oversights that are likely to undermine your work – after having presented a brief historical overview of the way previous WHO Expert Committees influenced the placement of *Cannabis* under the current international measures of control.

In light of the bias and errors pointed out in this contribution, 3 possible ways forward appear:

- putting an end to the review process,
- continuing the process on unethical, biased and socially challenged grounds,
- or slowing-down the review process to ensure comprehensiveness and thoroughness.

The latter option obviously seems preferable. In this perspective, the Committee – which role of recommending the appropriate international scheduling apparents to the discipline of *systematics*[1] – would benefit from first updating the description, identification and nomenclature of all the *Cannabis*-related products and substances into different taxa that meet both the observed realities and the *lege artis* scientific research. In other words, as logic suggests, **the Committee should start reviewing the taxonomy[2] of *Cannabis*-related products and substances before addressing systematics**.

[1] The discipline of *Systematics* consists in establishing classification systems and hierarchical arrangement of taxa.
[2] The word "taxa", plural of "taxon", refers to the discipline of *Taxonomy*, which is an exercise of nomenclature and means giving names to different clearly-defined categories, each name being a different taxon.

Part I.

Upgrading knowledge on the history of *Cannabis* international scheduling.

01. Historically – not only for global health, but for the broad international law as well – the international drug control system has played a key role. The first international treaties and arrangements mainly concerned war and commerce. It is on the double occasion of series of war motivated by business issues in the trade of opium, that the first Opium treaties were adopted[3].

02. Initially willing to establish common rules for fairness in the trade of opium, the consequences of previous free commerce on that drug had generated public health outcomes in importing countries, that orientated the next arrangements towards thematics of health – in that time called "hygiene".

Indian Hemp, Public Hygiene and the Dangerous & Habit-Forming Drugs.

03. The ***Cannabis*** **plant was genuinely included in the 1925 International Opium Convention**, on the peasant insistance of a small number of countries. The control measures then only required countries to provide some documentation when trading internationally, while committing to refrain from exporting to countries that had forbidden its use[4].

04. It has been written that the **League of Nations** undertook a review of Cannabis in 1935, although no source was found. The archives have indeed partly disappeared during the second world war. Contrary to what has been previously written in official WHO documents or in otherwise indispensable research, the so-called assessment of *Cannabis* made in 1935 by League of Nations never took place.

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

06. In October of the same year, the LoN Health Committee noted the review (Image 3) and recommended to countries that preparations made with part of "extracts and tinctures" of *Cannabis* be subject to the same control measures as the pure "extracts and tinctures", only one by then controlled under the 1925 International Opium Convention. However, that recommendation was only restricted to countries voluntaries to apply it, and not applicable to external and topical preparations.

07. Interestingly, the **myth of an assessment of *Cannabis* under the LoN** has justified the WHO offloading its responsabilities in the application of draconian measures of control, relying on a supposed previous ruling to avoid taking updated decisions on a difficult subject.

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

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

5° J'en arrive maintenant à une question dont le Comité s'est occupé déjà dans sa dernière session, celle de l'application des dispositions de la Convention de 1925 *aux préparations contenant de l'extrait ou de la teinture de chanvre indien*. Je rappelle que la Convention de Genève de 1925 a mis sous contrôle les seules préparations galéniques de chanvre indien, à savoir l'extrait et la teinture, mais qu'elle ne fait pas mention des préparations pharmaceutiques contenant de l'extrait ou de la teinture de chanvre indien. Or, le Gouvernement égyptien a signalé, en mai 1933, au Secrétariat général de la Société des Nations qu'il existait sur le marché égyptien, en quantité, des préparations à base d'extrait de chanvre indien, susceptibles de produire des effets aussi nuisibles que les substances soumises aux

Liste des préparations à base de chanvre indien indiquées par le Gouvernement égyptien comme employées par des toxicomanes.

1. *Elixir composé de bromure et de chloral* (P. D. et C^ie), autrefois dénommé composé de bromure. Chaque once de liquide représente :

Bromure de potassium	120	grains.
Hydrate de chloral	120	—
Extrait de chanvre indien	1	grain.
Extrait Hyoscyamus	1	—

2. *Pilules sédatives* (P. D. et C^ie) :

Extrait sumbul	1/2	grain.
Extrait Hyoscyamus	1/2	—
Extrait valériane	1/2	—
Extrait chanvre indien	1/10	—

3. *Tablettes de Damiana composées.* N° 154 (P. D. et C^ie) :

Extrait damiana	1 1/2	grain.
Phosphure de zinc	1/10	—
Extrait chanvre indien	1/4	—
Sulfate de strychnine	1/40	—

4. *Tablettes névralgiques* (P. D. et C^ie) C. C. T. 107 :

Phosphure de zinc	1/16	grain.
Strychnine	1/60	—
Extrait chanvre indien	1/8	—
Arséniate de sodium	1/20	—
Aconitine	1/400	—

C.L. 161. 1936. XI.

LEAGUE OF NATIONS

APPLICATION OF ARTICLE 10 OF THE GENEVA CONVENTION OF 1925 TO PREPARATIONS BASED ON INDIAN HEMP EXTRACT OR TINCTURE

The Secretary-General of the League of Nations has the honour to inform the Government of

that on January 23rd, 1936 (ninetieth session), the Council took note of the following resolution, adopted by the Health Committee at its twenty-second session (October 7th to 14th, 1935), with regard to the request made by the Egyptian Government on May 28th, 1934, that Article 10 of the Geneva Convention of 1925 should be applied to all preparations based on galenic preparations of Indian hemp, or at least to those containing a specified proportion of Indian hemp extract or tincture:

"The Health Committee,

"After noting the report of the Permanent Committee of the Office international d'Hygiène publique:

"Is of opinion that preparations made from tincture or extract of Indian hemp may lead to the same abuses and may produce similar ill-effects to those resulting from use of the tincture or extract of Indian hemp themselves, and consequently decides that these preparations shall be brought within the control of the 1925 Convention."

Image 1
Excerpt from the 1935 review of "preparations containing extract or tincture of Indian hemp" by the Committee of Experts in Pharmacology of the Office International d'Hygiène Publique.

Image 2
List of preparations concerned by the 1935 review.

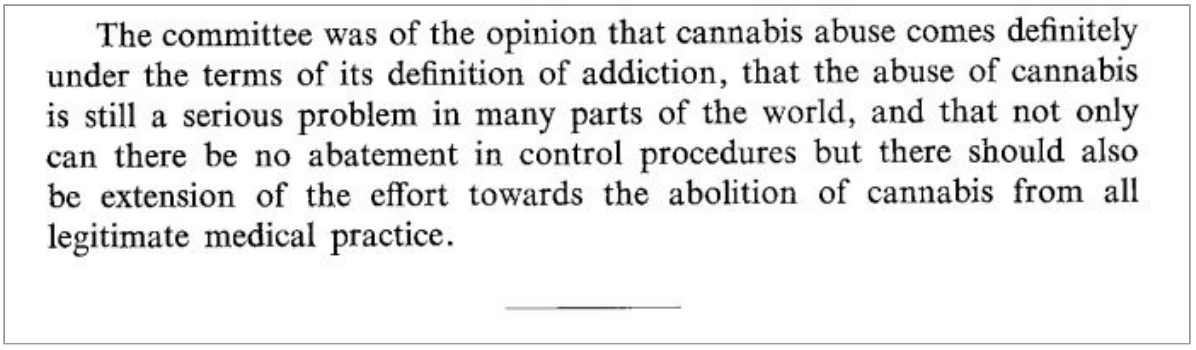
Image 3
Excerpt from the Circular Letter from the Secretary General of the League of Nations acknowledging the outcome of the Experts meeting.

08. Shortly after its creation, the United Nations system initiated a process to **merge all existing international arrangements into one Single Convention** to control the then-called "dangerous drugs", later adopted in 1961 and entered into force in 1964. The first draft of the new Treaty[5], issued in 1950, proposed several options for narrow policy frameworks **allowing medical cannabis use**, while encouraging to discontinue policies that permitted non-medical uses.

09. WHO started to take interest in the subject in 1952, through its then-called Expert Committee on Drugs Liable to Produce Addiction. At its 3rd Meeting, the "*question of justification of the use of cannabis preparations for medical purposes was discussed by the committee. It was of the opinion that* ***cannabis preparations are practically obsolete****. So far as it can see, there is no justification for the medical use of cannabis preparations.*"[6] However, no review of literature was made, and preparatory documents of the meeting mentionned in the minutes of the Meeting are scarce.

10. At its 4th meeting in 1953[7] the Committee "*was pleased to note that the elimination of cannabis preparations had already begun by national action, following the opinion expressed in its [3rd meeting] that* '**there is no justification for the medical use of cannabis preparations**.' *The committee [...] was of the opinion that the definitions for cannabis and its preparations should be revised on the basis of the presence of active principles.*"

11. The year 1954 is the occasion for the Committee to reiterate its allegations, relying this time on no more information than **"feelings" sent by South African police authorities**: "*The committee considered the report of the Inter-Departmental Committee on the Abuse of Dagga, informing it of (1) the existence in the Union of South Africa of widespread addiction to cannabis, always by smoking, (2) the feeling among the South African police of a relationship between cannabis addiction and crime, (3) evidence of permanent deterioration as the result of the addiction, and (4) evidence that, as in other parts of the world, cannabis abuse is very likely to be a forerunner of addiction to opiates. [...] The committee was of the opinion that cannabis abuse comes definitely under the terms of its definition of addiction, that the abuse of cannabis is still a serious problem in many parts of the world, and that not only can there be no abatement in control procedures but there should also be extension of the effort towards the abolition of cannabis from all legitimate medical practice.*"[8]



The committee was of the opinion that cannabis abuse comes definitely under the terms of its definition of addiction, that the abuse of cannabis is still a serious problem in many parts of the world, and that not only can there be no abatement in control procedures but there should also be extension of the effort towards the abolition of cannabis from all legitimate medical practice.

Image 4 *Excerpt from the 5th report of the Expert Committee on Drugs Liable to Produce Addiction.*

[5] E/CN.7/AC.3/3
[6] WHO Technical Report Series n°57, 1952.
[7] WHO Technical Report Series n°76, 1954.
[8] WHO Technical Report Series n°95, 1955.

12. Historically, these three reports constitute a critical tipping point. The majoritarily occidental members of the Committee systematically acknowledge in the minutes of these meetings, their absolute ignorance of the mechanisms of action of *Cannabis* and its related substances on the human body – Δ^9-THC was indeed isolated only in 1964. Yet, they issued and reissued outcomes that have gone down in History without any single base of evidence but have, until today, never been actualized or revoked.

13. **In 1953, the CND created the concept of a Schedule IV** which would comprise drugs aimed at being completely prohibited. In 1955[9] and 1958[10] the Commission finished to confirm the inclusion under this new schedule of "*Cannabis and cannabis resin, extracts and tinctures of cannabis, or any other substances containing the pharmacologically active principle of the cannabis resin (subject to the special regime [for traditional medicine]).*" No review or scientific assessment was ever mandated prior to that inclusion. On the insisting remarks of several countries, however, provision was made in the draft Convention to balance the "*prohibition of the medical use of cannabis drugs"* giving exception to *"certain systems of indigenous medicine.*"

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

15. Your predecessors in this Committee have, thus, directly served as a justification for the global generalization of the strictest possible policy for medical uses of the *Cannabis* plant and its derivatives.

16. In 1960, as the Plenipotentiary Conference was about to begin – to adopt the final text of the Single Convention – the UN premiered what is now a Treaty-mandated role of the ECDD: to assess substances for the purpose of defining the suitable international control to apply. **The first-ever assessment for the purpose of international scheduling was exercised for *Cannabis***, after the United Nations "*invited the World Health Organization to prepare [...] a report on the use of cannabis for the extraction of useful drugs, particularly of the antibiotic type [...] to make this report available to the [...] Plenipotentiary Conference [...] with a view to a* ***possible modification of the provisions of the Single Convention in order to permit the use of cannabis for the extraction of useful drugs.***"[11] That year, the Committee met at its 11th Meeting, but although acknowledging promising researches on antibiotic properties of *Cannabis*, recalled for the third time that "*the opinion expressed in [the 3rd meeting] remains unchanged. Cannabis and its preparations are practically obsolete and there is no justification for their medical use.*"[12]

[9] E/2768/Rev.1
[10] E/3133
[11] E/CONF.34/5
[12] WHO Technical Report Series n°211, 1961.

17. Yet, in the spring of 1961, the Plenipotentiary Conference adopted in New-York the Single Convention on Narcotic drugs, with an exemption from Schedule IV for the extracts and tinctures of *Cannabis* – with the aim to leave the door open for future identification of the active principles of the plant that would lead to isolating drugs extracted from the Cannabis plant that would not bear its narcotic effects.

18. Six decades after the 5th and 11th Meeting of the Committee, that have provided direct inputs to the redaction of the still in force Single Convention on Narcotic drugs, and can therefore be considered as the last and only assessments made of this drug, robust scientific evidence is still missing about numerous therapeutical application that, however, are largely documented as being promising.

19. The extreme policy that prohibition represents – justified by this Committee – have proven to be an **almost impassable fence for research**, and an **intolerable barrier to medical access**. Hence the emergency for this Committee to:

    a. invoque the **Right to a Remedy and Reparation for Victims of Gross Human Rights Violations**[13],

    b. by enforcing the **Right of everyone to share in scientific advancement** and its benefits, and the **Right to enjoy the benefits of scientific progress** and its applications[14,15,16,17],

    c. in order to enhance the **Right of everyone to the enjoyment of the highest attainable standard of physical and mental health and wellbeing**[18].

[13] Basic Principles and Guidelines on the Right to a Remedy and Reparation for Victims of Gross Violations of International Human Rights Law and Serious Violations of International Humanitarian Law, included in UNGA Resolution 60/147.
[14] Article 27 of the Universal Declaration of Human Rights.
[15] Article 15 of the International Covenant on Economic, Social and Cultural Rights.
[16] Preamble of the Declaration on Social Progress and Development, included in UNGA Resolution 2542 (XXIV).
[17] 3rd report of the UN Special Rapporteur in the field of cultural rights, included in A/HRC/20/26.
[18] Preamble of the Constitution of the World Health Organization, included in WHO Basic Documents, 45th edition.

Part II.

Pre-reviews of *Cannabis* and *Cannabis*-related products: revoke, don't recur.

Cannabis & cannabis resin.

20. ***Cannabis sativa* L. is the most widely controlled drug used worldwide**. It is virtually cultivated in all the countries of the planet, and is largely present in traditional as well as contemporary cultures on the 5 continents. The history of its documented medical uses dated 3000 B.C, and, beyond its numerous uses under supervised or self medication, the tales about the **state of wellness and pleasure it can provoke**, and the state of mind it induces, are witnessed in all arts, at all times, in all regions.

21. Since the application of global prohibitionist policies, under the impulsion of a post-WWII world community caught in between overflowing optimism and boundless perspectives, it seems that the exact opposite of the initial objectives have been reached. Research, access to quality phytopharmaceutical, galenical or cannabinoids-based medicines, and ceremonial or religious uses are at the lowest. Meanwhile, recreational use has never been so high. Misuse, harms and problematic use have reached historical peaks, illicit trade skyrocks, violence and crime generated by the illicit trade keep increasing, and public expenditure in law enforcement exploded – unlike budgets for prevention, treatment and harm reduction programs.

22. So much can be discussed about that plant, that one might want to first discard from the shackles before moving forward. The suggested *Cannabis and Cannabis resin Pre-Review Report*[19] edited by the NGO Drug Science and provided to the 38th ECDD Meeting, explicits the fact that recommendations made by the Committee at its 3rd, 4th, 5th and 11th meetings (see above, §5-11) are still in force, for not having been revoked or updated.

23. After the adoption of the 1961 Convention, the Committee continued to reiterate its calls for abolishing medical uses of the *Cannabis* plant and its derivatives, although never undertaking any formal step to assess and confirm their claims.

a) Bias arising from the scientific part of the pre-review report.

24. The 1st section on **Chemistry** is extremely interesting, only undermined by the fact that two entire pages of the report (pp. 23-24) are an ***in extenso* reproduction of a report published by the UNODC** in 2010[20]. Even if the content is of high interest, what surprizes is the **lack of quotation marks**, although nothing has been changed compared to the original UNODC document.

25. Further in the document, the interesting part addressing risks of contamination and adulteration in "street marijuana" (unbiased language could have been used) but forgetting to address the widely-spread adulteration of *Cannabis* resin traded in the illicit market, although this information is largely documented by the UNODC (from 1953[21] to present) or by the EMCDDA[22].

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[19] Curran H.V., Wiffen P, Nutt D.J., Scholten W., *Cannabis and Cannabis resin Pre-Review Report, document prepared for the WHO ECDD38*. DrugScience, London, 2016.
[20] United Nations Office on Drugs and Crime, Laboratory and Scientific Section, *Recommended methods for the identification and analysis of cannabis and cannabis products*, 2009, pp. 16-17.
[21] UNODC Bulletin on Narcotic Drugs, *The Surprising Extinction of the Charas Traffic*, New-York, 1953.
[22] European Monitoring Centre for Drugs and Drug Addiction, *EMCDDA INSIGHTS n°12 - Cannabis production and markets in Europe*, Luxembourg, 2012.

26. The adulteration of *Cannabis* resin, mostly due to the legal status and the lack of safety manufacturing standards, is yet a major health issue in terms of related harms, in the countries where the use of haschish is prevalent. A 2015 document[23] commissionned by the EMCDDA stressed that "THC contents are to be considered with caution for it is unclear if a resin showing a 16 % THC content is or is not an end product with half the adulterant amount of a resin showing an 8 % THC content." The author confirmed that "*hashish is very often adulterated with a range of inert or active substances [...] Users and cannabis watchers often mention the presence, sometimes in large quantities, of soil, henna, paraffin wax, bee wax, rosin, glue, flour, liquorice, milk powder, coffee, used motor oil, animal excrement, or even medical drugs.*" The author further details the results of the 2001 British chemical-anthropological Cannabis Resin Impurities Survey Project (CRISP) which found that resin seized "*often showed very high levels of impurities, sometimes up to 80% of the final product.*"

27. The **Pharmacology** section of the report on "*Cannabis* and cannabis resin" is weak when it comes to describing pharmacokinetic and pharmacodynamics of the plant, limited to 2 cannabinoids. The Chemistry section of the report, however, precised that the 120 phytocannabinoids recorded to date, although being minor compared to Δ^9-THC and CBD, "*may affect pharmacology of cannabis via two basic mechanisms: (1) the pure constituent may have pharmacological effects and/or (2) the constituent may interact with Δ^9-THC and alter its effects (e.g. entourage effect)*". Yet, the importance of the substance and its consumption worldwide would have seemed to justify an approach to this section more focused on the multiplicity of cannabinoids, and their "entourage" or cross-cutting pharmacological effects.

28. The section on **Therapeutic use** is interestingly built. This is why its opening sentence addressing non-medical use, as well as some biased language (use of "clients" instead of "patient"), sounds like a wrong note.

29. Lastly, the section on **Epidemiology** presents a balanced and complete panorama of the topic. Minor oversights are to be noted though, such as data relating to self-medication (under part 2.5.3) are in contradiction with data observed in the Netherlands over 13 years, showing the stabilization of use by medical cannabis patients[24]. Interesting studies about the medical conditions of people who use cannabis for medical purposes are also missing[25].

b) *Bias arising from the country part of the pre-review report.*

30. The report document over which the independent scientists members of the ECDD will base their discussions, is composed of two part of equal importance:

    a. A scientific part covering, with the methodology of researchers, the toxicology, chemistry, pharmacology, epidemiology and therapeutic use of the plant or substance under review,

    b. A country Questionaire part, where epidemiological, statistical, empirical and field data is provided by Ministers of Health of all countries, to complement the scientific data presented. This is also the occasion for Member States to submit comments and feedbacks, or to underline specific country-situations that systematic reviews might omit.

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[23] P.A Chouvy, *The supply of hashish to Europe Background paper commissioned by the EMCDDA for the 2016 EU Drug Markets Report*, Lisbon, 2016.
[24] B. de Hoop B, E.R Heerdink & A. Hazekamp, *Medicinal Cannabis on Prescription in The Netherlands: Statistics for 2003-2016*, Cannabis Cannabinoid Research, 2018.
[25] R. Borràs, P. Modamio, C.F. Lastra, & E.L. Mariño, *Medicinal use of Cannabis in Spain*, Alternative Therapies In Health And Medicine, 2011.

31. Important bias have undermined the ability of countries to provide relevant and accurate data. In particular, this problem concerned the Terms of reference for the data collection, often differing importantly between authors of the *scientific part*, and authors of the *country Questionnaire part*. Below are highlighted some major differences in the definition and framing of substances about which data has been collected.

32. **Category name:** the 1961 Convention defines the herbal part of the cannabis drug that is placed under control as "cannabis", and use the term "cannabis plant" to refer to the plant *Cannabis sativa* L., including parts of it that are not placed under control (e.g. leaves, seeds...). Therefore, the use of "cannabis plant" to refer to "cannabis" is in contradiction with the language used internationally since 1961, and adds confusion where clarity should be sought. The logic of treaty language would recommend to **use the term "crude cannabis" to designate the dried flowering and fruiting tops of the *Cannabis* plant** from which the resin has not been extracted.

33. **Definition:** fortunately, the use of, in the terms of reference for authors of the report (see table 1 below), of definitions taken from the Convention makes up the leeway. Unbelievably however, **the terms of reference for countries data collection make absolutely no mention of "Cannabis resin"**, while for crude cannabis, a short and weak definition is provided. It is incomprehensible that a *copy-paste* of the same terms of reference has not been done to avoid the collection of erroneous data. Consequently, it is likely that many countries will not have submitted national data on *Cannabis* resin, however the most frequently used product in the illicit non-medical market, in many countries.

34. Countries are provided at least with some **examples** of terminologies commonly used for cannabis, although some extremely geographically relevant denominations like "ganja" are missing.

Table 1	Terms of reference used to contract authors of the report *(December 2017)*	Terms of reference used to collect data among Countries *(March 2018)*	Comments
Introduction & context	"Cannabis plant and Cannabis Resin"	"cannabis plant and cannabis resin"	§X
Definition	"• Cannabis as defined by the International Drug Control Conventions as "the flowering tops of the cannabis plant from which the resin has not been extracted". The term "cannabis" generally refers to a dried preparation of the flowering tops or other parts of the cannabis plant. • Cannabis resin which is defined as "the separated resin, whether crude or purified, obtained from the cannabis plant". It is normally in solid form and is sometimes known as hashish."	"The dried flower/ leaf of the cannabis sativa plant. Examples: marijuana, weed, pot, hashish, and kief"	§X
Examples provided	*No example provided for herbal cannabis.* *Only 1 example is provided for resin ("*hashish*").*	*4 examples are provided for crude cannabis. Although no definition of resin is provided, there is one example ("*hashish*") merged with examples of crude cannabis.*	§X

c) The case of tobacco: *Double standard of substance scheduling.*

35. Finally, it is to be noted that in 1999, in the outcome of the pre-review of tobacco undertaken at its 31st meeting, the ECDD acknowledged that "smoking tobacco is dependence-producing, causes serious public health problems and has no therapeutic use." But the Experts declared as well that "**existing international drug control measures for narcotic drugs and psychotropic substances appear to be unsuitable for controlling tobacco, a dependence-producing natural substance widely used for non-medical purposes at the time of adoption of the relevant conventions**. Even though new information indicates health risks greater than those previously known, tobacco would not meet the criteria for scheduling under the existing international drug control treaties."

36. WHO records more than 7 million deaths due to tobacco each year[26], but the morbidity-mortality of *Cannabis* is extraordinarily low – hence the lack of WHO records on *Cannabis*-related deaths.

37. For the ECDD, **not adopting a similar approach for *Cannabis* as the one adopted at its 31st meeting for tobacco, would represent an inacceptable double standard for substance scheduling**.

[26] See *Key facts on tobacco*, World Health Organization, 2018. www.who.int/news-room/fact-sheets/detail/tobacco

Extracts and Tinctures of Cannabis.

38. Placed under a different control regime (Schedule I) than the plant and resin material of *Cannabis* (Schedule IV), the different sort of extractions of the *Cannabis* plant, and their preparations, offer the most complex panorama for a thorough scientific assessment that avoids bias.

a) *Bias arising from the scientific part of the pre-review report.*

39. Authors of the **Chemistry** section are misleading the Experts when defining "*Cannabis* extracts" in the footnote 1, on page 7. No systematic overview on the composition of the various products discussed is made and no percentages (max., min., typical values) of the main constituents in the various extracts are provided – except for BHO (the most problematic and least representative of these products). Chemists and experienced readers might wonder: what products are they talking about?

40. Moreover, the Chemical Abstract Service (CAS) registry number provided seems irrelevant for many of the extracts included in this category, that already have separate CAS registry numbers. Defining "cannabis extracts and tinctures" by their CAS is too broad, and gives rise to important ambiguities and important leeway for all kind of biased interpretation. Indeed, such definition comprises solvent extracts, expressions (pressing products), distillation and hydro-distillation, as well as all physically modified derivatives, including purified extracts (e.g. purified by chromatographic techniques). Words to balance such a broad definition would have been desirable, as well as the mention of other CAS registry bumber known:

    a. *Cannabis sativa* seed oil: 8016-24-8,

    b. Haschish oil: 8001-45-4,

    c. *Cannabis sativa* extract: 89958-21-4

41. The **Pharmacology** section of the pre-review report, although being generally thorough, is undermined by a lack of precision when it comes to providing definitions (such as "dabbing") or to address important trends in consumption patterns (such as the use of microdosing *Cannabis* extracts for harm reduction, or in tobacco quitting).

42. Other data that balance the presented research outcomes seem to be missing. Furthermore, although several mentions of "edibles" (ingested preparations made out of *Cannabis* extracts) are made, a definition and a specific description of their pharmacological effects are overseen. Yet, the author precises in her report on "Cannabis plant and cannabis resin" that the pharmacology of edibles is supposed to be addressed in the Pharmacology section of "Extracts and tinctures".

43. The last case has to be made for the self-titration of consumption. The author of the pharmacology section notes that "users who smoke or vape products with higher Δ^9-THC contents than their regular product tend to up-titrate, resulting in greater overall exposure." However, more detailed scrutiny into the published literature tends to show the opposite[27,28].

[27] "The concerns that have been expressed about a possible rise in cannabis potency often assume that users will necessarily consume more THC, but the evidence for this is equivocal. If the potency of cannabis products has

44. Furthermore, severe points of concern arise from the pre-review report, particularly in its section on **Toxicology**. The first one is the strange framing of the different sub-taxa of the category (addressed below in §XXXX), which includes "cannabis resin" (yet explicitly excluded from the terms of reference of the author's contract), and agglomerates into "concentrates" what other authors divided into up to 5 categories.

45. It is also astonishing to read concerns about "disastrous fires and explosion" in a report about the toxicology of drugs. Beside the irrelevance of the matter in such a document, it is fair to say that explosions due to personal artisanal production of cannabis concentrates is more likely to be imputable to the lack of a regulated and standardized legal retail production than to the very product.

46. The 4th section on **Therapeutic use** is not immune from surprises, especially about deficiencies: two full parts of the document (namely "Extent of therapeutic use" and "epidemiology of medical use") address only Nabiximols. Yet, other extracts and tinctures of *Cannabis* are available on the pharmaceutical market (such as in Germany, the Netherlands, Australia, some States of the USA, Malta, Canada...), although often only marketed legally as magistral products in compounding pharmacies.

47. Lastly, the 5th section on **Epidemiology** does not makes up the leeway, for instance when inventing the new terminology "BCO" (for "Butane cannabis oil") where common language, and all other authors, use the term "BHO" (for "Butane hash oil" or "Butane honey oil").

48. The most disconcerting, on this last epidemiological section, comes from what is missing:

    a. The part 1 on "industrial use" **only addresses Nabiximols, while other legal industrial uses are well known**, for pharmaceutical (see above §XXXX on toxicology) as well as for other very different purposes (e.g. essential oils and hemp seed oils),

    b. When compared to the report on Therapeutic use (4th Section, part 3.1 "Extent of therapeutic use") **19 countries, where Sativex is marketed, are missing from the list** in the Epidemiology report;

    c. Section 3 is aimed at reviewing thoroughly the "nature and magnitude of public health problems related to misuse, abuse, and dependence." However **it only reports burn injuries** - where one might have expected an update on data concerning the extent of

shown a marked increase, then it might be expected that the typical user would need to consume less on a weight basis to achieve the desired effect. Given a choice, users preferred cigarettes with a higher THC content (Chait and Burke, 1994; Kelly et al., 1997). Ashton (1998) also argued that users would not titrate the dose of THC from cannabis in contrast to tobacco smokers. However, Heishman et al. (1989) found that those smoking cigarettes with a higher THC content tended to have a lower inhalation rate than control subjects. Yet little research has been conducted, particularly in Europe, to answer a crucial question: do those smoking high potency cannabis have higher blood levels of THC? However, even if the strength of some forms of cannabis has increased, and even assuming that, as a consequence, users do have higher blood levels of THC, then it cannot be concluded that this will translate into a greater harm to the individual. Experience with alcohol suggests that the health consequences are not simply related to the alcohol concentration of what is consumed, but rather it is the total quantity of alcohol consumed that is important. As Hall et al. (2001) note, age of onset of use and frequency of use are likely to be more influential than changes in potency in determining consumption levels." *in* EMCDDA, *EMCDDA MONOGRAOPHS - A cannabis reader: global issues and local experiences. Perspectives on cannabis controversies, treatment and regulation in Europe*, Brussels, 2008, pp. 255-256.

[28] "Not only is high-potency cannabis considered suitable as a medicinal product, but an assessment carried out by the Dutch Coordination Centre for the Assessment and Monitoring of New Drugs concluded that (illicit) higher-potency cannabis products did not pose any additional risk than those present for cannabis products as a whole, either to the individual, to society, to public order or criminality (W. Best, personal communication, 2004).", *ibid*, p. 256.

dependence and problematic use. Further this extraordinary focus on burn injuries, important bias deserve to be underlined:

i. Authors indistinctly use the words "legalization", or "medical liberalization", as synonyms, and do not distinguish between the differences in purposes of use,
ii. There is no mention about the important reporting bias that could explain the increase of burn injuries related to home-made cannabis extraction, after that activity has ceased to be illegal. But the major element has been discussed previously, and consists in the unclear retail market, liable to bring inexperienced persons to experiment extractions technique in inadequate conditions;

d. Part 4 pretends that the researchers "did not yield any articles related to licit production, consumptions and international trade of cannabis extracts and tinctures". **A basic search in a web browser, however, shows dozens of results**, such as the 2017 annual report of the UN International Narcotics Control Board stating that globally, "[the] licit use of cannabis has been increasing considerably since 2000. Before 2000, licit use was restricted to scientific research [...] In 2000, total licit production was 1.4 tons; by 2016 it had increased to 211.3 tons"[29]. Experts might have been interested in knowing that this international board explained that "The United Kingdom [where Sativex® is manufactured] continued to be the main exporter of cannabis *(2.1 tons, or 67.7 per cent of the total)*" and that "the large majority of the stocks were held by the United Kingdom *(93.1 tons, or 78.2 per cent).*" Much other data is easily available, from highly reliable sources.

e. Similarly to part 4, part 5 ignores the immense amount of information available about the illicit manufacture and traffic of all the different extracts or tinctures included in the item. The authors only acknowledge the "negligible role" of the "seizures of tinctures" – although it is broadly recognized that seizures are the among least representative metrics of illicit markets – and totally omit to address extracts, oils, concentrates, and other products.

b) *Issues of taxonomy.*

49. The category "extracts and tinctures" encompasses many diferent products and preparations of the *Cannabis* plant – gathered according to their manufacturing processes, and not at all according to their chemical composition, pharmacology or toxicological effects, what would be the state of the art – therefore making it tough to frame. It is known under different names, according to the emitter:

a. "Cannabis extracts and tinctures" as per the 1961 Convention on narcotic drugs;

b. "Extracts and tinctures of cannabis" as per the language used by the WHO;

c. "Extracts or preparations" of *Cannabis*, as per the wording proposed by the 39th ECDD.

50. These extracts or preparations of the *Cannabis* plant gather very different products and substances, according to their manufacturing method, but with no link at all with the

[29] Technical Report of the International Narcotics Control Board for 2017 "Narcotic Drugs Estimated World Requirements for 2018 Statistics for 2016", particularly pp. 43-48. Read online at: www.incb.org/incb/en/narcotic-drugs/Technical_Reports/2017/narcotic-drugs-technical-report-2017.html

pharmacological or toxicological effects of these products on the human body. (what would be state of the art

51. The important variety of products included in this category leads to thinking that **special attention should be focused on the taxonomy of these different products**, before undertaking any analysis of the content.

52. The UN system has developed tools, such as the World Trade Organization's harmonized tariff system, which could be of some help to discuss these issues. WTO already clearly differentiates:

    a. Hemp seed oil (1515.90) among "Other fixed vegetable fats and oils",

    b. Hemp essential oil (3301.90) among "Other Essential oils", and

    c. Cannabis flower/*Cannabis* extract (1302.19) among "Other Vegetable saps and extracts".

53. As well, the criterion excluding "Cannabis resin" from the scope of this pre-review – although that product is evidently fitting the criteria to be considered as an "extract" – should be discussed.

54. Leaning over the distinct taxonomy proposals made by the authors of the 5 different sections of the pre-review report (see Table 2, below), **the most refined, precise and inclusive categories and taxa should be defined by the Committee**, to enable the possibility of undertaking Critical reviews based on evidence, accordingly.

55. Beyond the core taxonomy issue, demonstrated by the incoherence between the authors of the 5 sections, civil society stakeholders (including affected populations and people who use *Cannabis*, independent and academic researchers, members and former-members of relevant governments administrations and international institutions) have suggested to **extend the taxonomy of this category beyond its current boundaries**. With a view to enabling the Expert Committee to issue final scheduling recommendations that fit the Treaty, match the evidence, and could be acceptable by Countries as well as by civil sectors and non-State actors, the following considerations have been suggested:

    a. **Adopt the taxa used in the Section 1** (Chemistry) of the report, and extend it for the purpose of the assessment, to all disciplines reviewed;

    b. **Include "Cannabis resin" in this category**, under the taxon "Extracts of Cannabis";

    c. Consider creating a taxon that would comprise all **Extracts or preparations of the *Cannabis* plant that bears traditional or indigenous uses**;

    d. Create a sub-taxon under "Extracts of Cannabis", that would comprise all **Extracts or preparations of the *Cannabis* plant with a minor THC profile** (or **Extracts or preparations of the *Cannabis* plant with almost no THC**). Precise quantities and limits could be determined either by the Committee or at the discretion of Countries;

In the report on Chemistry (Section 1) however, the sub-item "Cannabis oils" is controversial, as it includes so-called "Rick Simpson Oil" and "medical cannabis oil", merged with "hemp seed oil" (exempted from the Convention's control measures) and "essential oil", a steam distillate of the freshly-cut *Cannabis* plants which in no way fits any criterion of relevance for international scrutiny.

In 2009, the UN occife on Drugs and Crime (UNODC) wrote that "the essential oil does not contain THC"[30].

e. Products and preparations included under this sub-item should be **reviewed separately one from another**;

f. Essential oils and *Cannabis sativa* Semen Oleum should be completely excluded from further reviews in thgis category, and might be considered for inclusion under a newly created sub-taxon "Extracts and preparations *Cannabis* with a minor THC profile" that would keep the door open for **continuing the exemption from the Treaty's control measures**, exemption presently into force for these products.

56. Such an update in the taxonomy of this category appears as a mandatory preliminary step prior to any further step in the assessment process.

c) *Bias arising from the country part of the pre-review report.*

57. Besides the taxonomical considerations, important concerns must be raised concerning the preparation process for this meeting, which should rely on a comprehensive data collection among the scientific community, and countries. The table 3 (below) illustrates important differences between the Terms of reference provided to the scientific community (through the core authors of the report) on one side, and to Countries (through the questionnaires sent to all Ministers of Health) on the other.

58. While the assessment has to be made on the basis of all existing data, including non-medical use and so-called "recreational" use, the Questionnaire sent to countries obviously obliterates that part, requesting only concerning "approved medical uses". This is directly contrary to the *Guidance* document, which rules the ECDD proceedings and states that **all possible uses and all data must be included in the review reports**, either regarding **medical, scientific, recreational or religious** uses.

59. In the "definition", the difference between the substances and products about which information is requested, to authors and to countries, is tremendous. A main consideration is the inclusion under this category of products made out of *Cannabis*, but that are clearly exempted from the scope of the international drug control system[31]. This concerns in particular:

a. the aqueous extract Bhang, legally commercialized in some countries, and prepared using the leaves (exempted from international control) of the *Cannabis* plant,

b. *Cannabis sativa* Semen Oleum, the so-called "hemp seed oil", sometimes also called "hemp oil", made out of the seeds/achenes of the *Cannabis* plant, exempted from international control, and that contain an insignificant amount of intoxicating substances (namely Δ^9-THC);

60. Finally, although Countries are provided with 10 more examples of products and names to be included, some examples such as "Hemp seed oil" have inexplicably disappeared in the terms of reference headed to Ministers of Health.

[30] United Nations Office on Drugs and Crime, Laboratory and Scientific Section, *Recommended methods for the identification and analysis of cannabis and cannabis products*, 2009, page 19.
[31] See Article 28 (2) of the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol.

61. Seen the wide diversity of products and uses included in the category "extracts and tinctures", feedbacks from countries, and their national health data collection services, appears to be indispensable in complement of the scientific part, to ensure thoroughness of the data corpus.

Table 2

Differences of taxonomy between the 5 sections of the pre-review report on "Extracts and tinctures of cannabis"

Section 1, CHEMISTRY	Section 2, PHARMACOLOGY	Section 3, TOXICOLOGY	Section 4, THERAPEUTIC USE	Section 5, EPIDEMIOLOGY
Cannabis tinctures	Cannabis tinctures	"Cannabis extracts, tinctures, oils and tea."	"Cannabis Sativa Extract."	Extracts and tinctures
Cannabis extracts	Cannabis oils			
Cannabis oils				
Aqueous extracts	Aqueous extracts			
	Hemp seed oil		"Hemp seed, Evening Primrose Oils."	
"Nabiximols / CBD in preparation with other cannabis-related ingredients."	Nabiximols	Nabiximols	Nabiximols	Nabiximols
			"Oral-mucosal cannabinoid extract"	
		Cannabis resin		

Table 3	Terms of reference used to contract authors of the report *(December 2017)*	Terms of reference used to collect data among Countries *(March 2018)*	Comments
Introduction & context	/	"approved medical use of extracts and tinctures"	§X
Definition	"• Cannabis extracts: this term refers to a plant extract mixture from the leaves and flowers of Cannabis sativa • Cannabis tinctures: this term refers to specific alcohol extractions of the flowering tops or other parts of Cannabis sativa. • Cannabis oils e.g. Butane Hash Oil, Hemp Seed Oil • Aqueous extracts e.g. marijuana tea • Nabiximols (e.g. Sativex®)"	"The term 'extracts and tinctures' refers to substances that have been extracted from the Cannabis sativa plant. This term does not include synthetic preparations. Examples: • Liquid concentrate (e.g. hash oil, hemp oil, butane honey oil, etc) • CBD oil • Solid concentrate (e.g. shatter, budder) • Edibles (e.g. prepared food products) • Liquids (e.g. marijuana tea;) • Tinctures (e.g. concentrated amounts ingested orally or taken under the tongue) • Topical ointments (lotions, salves, balms, etc) • Nabiximols (e.g. Sativex®) • Epidiolex • Arvisol"	§X
Examples provided	*4 examples provided for so-called oils ("*Butane Hash Oil, Hemp Seed Oil*"), aqueous extracts ("*marijuana tea*"), and for one pharmaceutical preparation ("*Nabiximols*").*	*14 examples provided in the definition.*	§X

Delta-9-tetrahydrocannabinol.

62. **Δ⁹-THC is the key active compound** responsible for the international scrutiny and control over the whole *Cannabis* plant. Crude cannabis, resin, extracts, tinctures and other preparations, systematically refer to Δ⁹-THC – hence the importance of **thoroughness and comprehensiveness of its assessment**.

63. The substance has previously been reviewed by the Expert Committee at its 17th, 21st, 26th, 27th, 31st, 32nd, 33rd and 34th meetings. Consensus has never been found on the name and the scope of the molecules, isomers and stereochemical variants to be included or not in the present category. International control was first applied to Δ⁹-THC and its 6 isomers under the name "tetrahydrocannabinols", later on addressed as "dronabinol", a sole-stereochemical variant of the molecule, and finally until today, open to the 4 stereochemical variants of Δ⁹-THC.

64. As up to 8 meetings of the ECDD have reviewed the substance (among which three were Critical reviews), previous Critical review meeting documents and outcomes would have been expected to be more central in this new review working document.

65. The Section 2 on **Pharmacology** misses a more refined acknowledgement of the numerous scientific discoveries about cannabinoids and the endocannabinoid system. The **absolute lack of information concerning the endocannabinoid system** (two lines in total) surprises particularly. No mention is made of the mechanisms of anandamide and 2-AG as well as of FAAH and monoacylglycerol lipase. No more mention is made in the references of key researchers such as Prof. Mechoulam. Beyond these details, the broad approach seems lightweight as the document cites very little references from the period 1988-present, while the Pharmacology section of the 2006 Critical review document edited for the 34th ECDD meeting provided for much more evidence[32].

66. The same document from 2006 presents numerous elements whose inclusion in the present Section would have been welcomed, such as the figure in Image 5, below.

67. Again in the Pharmacology section of the report ignores important emerging evidence indicating that the two-cannabinoid receptor theory might be incorrect. Beyond CB1 and CB2, the activation of some other receptors (e.g. GPR55) by cannabinoids suggests that they may have a role in the wide ranging neuro-modulatory effects of the endocannabinoid system[33].

68. Cannabinoids, and Δ⁹-THC in particular, not only have important brain-related activity, they also have notable gastrointestinal activity. Not mentionned in the Pharmacology section.

69. Much more complete is the section of the report on **Therapeutic use**. However, it underestimates important pre-clinical research, as well as preliminary and anecdotal evidence of the therapeutic potential of Δ⁹-THC (e.g. ongoing studies related to the anti-tumor activity of Δ⁹-THC in several cancer models).

[32] WHO ECDD34, Assessment of dronabinol and its stereo-isomers. Available on: www.who.int/medicines/areas/quality_safety/4.2DronabinolCritReview.pdf
[33] Reviewed in Pertwee et al., 2010; Stella, 2010

70. Finally, the **Epidemiology** section leaves without voice, as parts 2, 3, 4 and 5 are scarce, if not empty. To follow on the comparaison, the 2006 review document prepared for the 34th ECDD meeting, presented more than ½ page of information about both parts 3 (nature and magnitude of the public health problems) and 4 (licit production, consumption and international trade).

71. Contrarily to the other products and substances under review, the **preparation process for the assessment of** Δ^9-THC has less bias. It is to regret, however, that the definition provided to countries is shorter and more synoptic. Again, copying and pasting the same terms of reference should have been considered (see table 4 below).

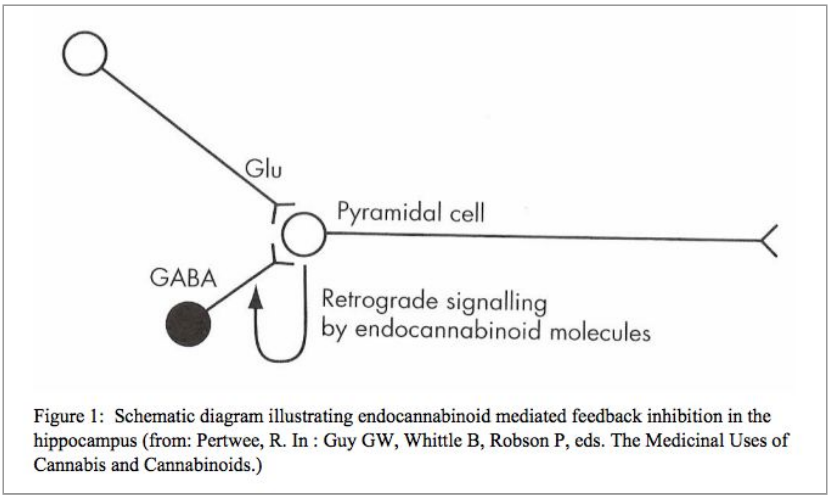

Figure 1: Schematic diagram illustrating endocannabinoid mediated feedback inhibition in the hippocampus (from: Pertwee, R. In : Guy GW, Whittle B, Robson P, eds. The Medicinal Uses of Cannabis and Cannabinoids.)

Image 5 *Excerpt from the 2006 Critical review document on Dronabinol.*

Table 4	Terms of reference used to contract authors of the report *(December 2017)*	Terms of reference used to collect data among Countries *(March 2018)*	Comments
Introduction & context	Delta-9- tetrahydrocannabinol (THC)	Delta-9- tetrahydrocannabinol (THC)	§X
Definition	• Pure delta-9-tetrahydrocannabinol that is obtained either directly from the cannabis plant or synthesised. • The stereochemical variants of delta-9-tetrahydrocannabinol: - (-)-trans-delta-9-tetrahydrocannabinol *(also known as dronabinol)*, - (+)-trans-delta-9-tetrahydrocannabinol, - (-)-cis-delta-9-tetrahydrocannabinol, - (+)-cis-delta-9-tetrahydrocannabinol.	Pure delta-9-tetrahydrocannabinol that is obtained either directly from the cannabis plant or synthesised. This definition also includes the following stereochemical variants of THC: -dronabinol (Marinol; Syndros)	§X
Examples provided	*No example provided.*	*2 examples provided in the definition ("*Marinol; Syndros*")*	§X

Part III.

The critical case of cannabidiol.

The Critical review of cannabidiol: Irrelevant assessment, inexistent methodology, but biding outcome.

72. The numerous bias referred to in Part II of this contribution seriously undermine the ability of the Committee to issue serious pre-review outcomes for *Cannabis*, resin, extracts, tinctures, THC and its isomers. However, the pre-review being a preliminary step, these can always be corrected or caught up. When it comes to Critical review however, the process has a much broader impact: Critical review outcomes are biding recommendation for international scheduling, ultimately notified to all countries by a *Note Verbale* of the UN Secretary-General.

73. Decisions made in a Critical review meeting therefore have direct and permanent consequences on the broad international drug control system, and through it on millions of people.

a) General comments on cannabidiol and the relevance of a review.

74. A Critical review of "**Extracts or preparations containing <u>almost exclusively</u> cannabidiol**" was convened by decision of the Experts of the 39th ECDD, in November 2017.

75. A first confusion emerges from the indistinct use of the terms "extracts", "tinctures" and "preparations", associated together as if they were synonyms. An interesting approach would be to take inspiration in the WTO Harmonized Tariff System, where "Vegetable saps and extracts" are up to 80% purified (HS 1302.19), being considered as "chemical mono-constituent" over this percentage of purification (HS 2907.29).

76. Secondly, and most importantly, the WHO has reformulated the terminology of the review. All the preparation process was undertaken in the perspective of a Critical review of CBD instead of products "**containing <u>almost exclusively</u>**" CBD. Requests for data sent to Ministers of Health, beside not reproducing the terminology recommended by the ECDD, vary importantly between languages:

    a. *"**Extracts and tinctures containing cannabidiol** (CBD)"* (English version),

    b. *"**Cannabidiol** (CBD)"* (French version: "Les questions ont trait au cannabidiol (CBD)"),

    c. *"**Extracts and preparations that contain cannabidiol** (CBD)"* (Spanish version: "Extractos y preparaciones que contienen cannabidiol (CBD)").

77. The ECDD explicitly called for a Critical review, not of CBD, but of these among the extracts of *Cannabis* that are rich in CBD. **The difference is extremely substantial**. "CBD", in fact **Pure Cannabidiol** (whether produced synthetically or by isolation from *Cannabis* plant) **has been clearly excluded from the scope of control of the Conventions**, excluding any narcotic-related harms or effects.

78. In parallel, it is admitted that almost all extract or tinctures of *Cannabis* will contain some CBD. Therefore, the **"extracts or tinctures containing CBD" corresponds to almost all of the extracts from**

the *Cannabis* plant. But these extracts are already under review under a different category ("Extracts and tinctures of cannabis", see above). The terminological precision made by the 39th ECDD was also meant to avoid a data collection that would aggregate all sorts of extracts of the *Cannabis* plant, regardless of the fact that preparations may contain other cannabinoids that importantly modify the effect of CBD.

79. Pure CBD has never been agreed by the Experts to be critically reviewed during the 40th ECDD. The no respect by WHO administration of the request of the Experts to collect data on "Extracts or preparations **containing almost exclusively cannabidiol**" will have a direct impact on the ability of the meeting to result in an assessment and outcome based on evidence. Such an error constitutes an unacceptable bypass of the work and decisions of the Experts, but also a violation of their independence.

80. For recall, pure Cannabidiol is legally used in an important number of industrial products (e.g. cosmetics ingredient), particularly in EU. The broad scope of the category under Critical review could have important and unexpected effects on such products.

81. The Experts of the 40th ECDD should refrain from undertaking a Critical review of "pure CBD" in such conditions. The Experts might prefer wording that sets precise boundaries to include and exclude in a clear manner certain products irrelevant to the 1961 and 1971 Conventions.

82. CBD should be clearly and definitely excluded from the scope of the ECDD's mandate. Moreover, for procedural, practical and clarification reasons, the Experts could consider creating a sub-taxon of "extracts and tinctures with almost no THC" that should be exempted from the scope of the Treaty's control measures (thus solving as well the problem of "hemp seed oil" and "essential oil" included under tha category "Extracts and tinctures of cannabis", see above §XXX).

Table 5	Terms of reference used to contract authors of the report *(December 2017)*	Terms of reference used to collect data among Countries *(March 2018)*	Comments
Introduction & context	"Extracts or preparations containing almost exclusively CBD (cannabidiol; (1'R,2'R)-5'-Methyl-4-pentyl-2'-(prop-1-en-2-yl)-1',2',3',4'- tetrahydro-[1,1'-biphenyl]-2,6-diol)".	*In the English version:* "Extracts and tinctures containing cannabidiol (CBD)" *In the French version:* "Cannabidiol (CBD)"	§X
Definition	*CBD is defined as "*cannabidiol*" and as "*(1'R,2'R)-5'-Methyl-4-pentyl-2'-(prop-1-en-2-yl)-1',2',3',4'- tetrahydro-[1,1'-biphenyl]-2,6-diol*".*	*No definition provided.*	§X

Concluding words.

Adopted two weeks ago, the 13th general programme of work for 2019–2023 addresses (at least in its §37, 43 and 62) and the Report by the Director-General titled "Addressing the global shortage of, and access to, medicines and vaccines", join the concerns expressed by the UNGASS 2016 about the lack of availability and access to medicines[34], which undermines the goal "1 billion more people enjoying better health and well-being".

In May 2016, a report of the WHO Secretariat presented during the 69th World Health Assembly (WHA)[35] "highlighted the **importance of moving towards a more balanced and comprehensive approach in global drug policies** that highlights public health and development outcomes, **consistent with the original purpose of the three international drug control conventions to promote the health and welfare of humankind**". It was also recalled that "the enjoyment of the highest attainable standard of health is a fundamental right of every human being [...] and that WHO is the directing and coordinating authority for health within the United Nations system", noting that "WHO is one of [the] four treaty bodies [of the drug control conventions]."

One month before, the United Nations in a special General Assembly (UNGASS) dedicated to drug policies, reaffirmed the same desire to refocus global drug policies around health outcomes, in up to six occasions[36], and especially made **a call for "informed and coordinated scheduling decisions"**[37], while recalling the need for "scientific evidence-based review and scheduling of the most prevalent, persistent and harmful substances"[38] with the aim to clear existing debate for the purpose of focus on the rapid emergence of new psychoactive substances (NPS).

In the same UNGASS outcome document, a deep concern is expressed regarding the "low or non-existent" availability of internationally controlled drugs for medical purposes[39] as well as a "strong commitment to improving access" to those substances[40]. The link between the scheduling status of medicines, and their lack of availability, is not a coincidence.

In light of these elements, a renewed and more accurate scheduling of substances appears as an essential issue towards a comprehensive availability of scheduled substances for medical purposes[41]. And mandate is given to the ECDD to start issuing scheduling recommendations headed at public health, more than moral, considerations.

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[34] WHO/A71/4, General programme of work 2019–2023, "Promote health, keep the world safe, serve the vulnerable".
[35] WHO/A69/12
[36] General Assembly resolution A/S-30/1, annex "*Our joint commitment to effectively addressing and countering the world drug problem*", 2016. 6th and 19th paragraphs of the introduction, preliminar paragraph and paragraph 1 (d) of item 1, 2nd preliminar paragraph and paragraph (y) of item 5.
[37] A/S-30/1, annex, item 2, paragraph (g).
[38] A/S-30/1, annex, item 5, 2nd preliminar paragraph.
[39] A/S-30/1, annex, introduction, 5th paragraph.
[40] A/S-30/1, annex, item 2, preliminar paragraph.
[41] To learn more, check the contribution to the post-UNGASS process by the NGO FAAAT think & do tank "*One proposed reading of the UNGASS 2016 outcome document: reassessing substances*", available on www.unodc.org/postungass2016/en/contributions/ngos/faat-think-and-do-tank.html

Abbreviations

CAS	Chemical Abstract Service
CBD	Cannabidiol
CND	Commission on Narcotic Drugs
CRISP	Cannabis Resin Impurities Survey Project
EMP	WHO Essential Medicines and health Products department
ECDD	Expert Committee on Drug Dependence
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
Guidance	Guidance on the WHO review of psychoactive substances for international control
HCV	Hepatitis C Virus
HIV	Humane Immunodeficiency Virus
INCB	International Narcotics Control Board
INNs	International Non-proprietary Names
LoN	League of Nations
NGO	Non-Governmental Organizations
NPS	New Psychoactive Substances
OIHP	Office International d'Hygiène Publique (International Office of Public Hygiene)
THC	Tetrahydrocannabinol
UN	United Nations
UNGA	United Nations General Assembly
UNGASS	United Nations General Assembly Special Session
UNODC	United Nations Office on Drugs and Crime
UN-SG	United Nations Secretary-General
WHA	World Health Assembly
WHO	World Health Organization
WHO-DG	Director-General of the World Health Organization
WTO	World Trade Organization