

ECDD 40

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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Acknowledgments.

This document is an official contribution to the work of the 40th Meeting of the Expert Committee on Drug Dependence of the World Health Organization.

It has been written between May 25th and May 29th, due to the late publishing of the pre and Critical review report documents by the World Health Organization. Some minor errors might have subsisted, due to the extremely limited timeline. We hope that future Meetings will make documentation available on an earlier basis, according to established rules of proceedings.

This contribution has been endorsed by 68 civil society organizations from 29 countries in all continents (see the full list page 30) as of May 30th.

An updated list will be made available on **www.faaat.net**

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Foreword.

The **U** of the ECDD is to issue the **highest standard of evidence-based recommendations**, grounded in science, robust risk-assessment methodologies, and emerging from a broad collection of all available data regarding a product, a plant or a substance. Its **p** is to enable a **science-based 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 the high standards expected and the important consequences of the policy decisions informed by the Committee's discussions, great care should be taken when undertaking such a crucial series of assessments, especially about products so widely used.

Oversight, plagiarism, gross negligences, terminology issues, mistaken references, erroneous translations, mismatched data aggregated, and bias, is evident in 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 omitted or misrelated important pieces of evidence.

This contribution examines, in detail, the bias and oversights that are likely to undermine your work – after presenting a brief historical overview of the previous WHO Expert Committee's influence on the placement of **. U U** in the international Treaty system.

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

- end the review process,
- continue the process despite ethical concerns, bias and over strong objection,
- slowdown to ensure deliberative process, comprehensiveness and thoroughness.

The last option is our preference. Our perspective is that the Expert Committee, whose role is to systematically recommend appropriate international scheduling (which appears to the discipline of **p U o**) would benefit from first updating the description, identification and nomenclature of all the **. U U**-related products and substances so that they match observed realities and the **ppU** scientific research. In other words, as logic suggests, **the Committee should start reviewing the taxonomy² of . U U -related products and substances before addressing systematics.**

¹ The discipline of **i p U o** consists in establishing classification systems and hierarchical arrangement of taxa.

² The word "taxa", plural of "taxon", refers to the discipline of **oU**, which is an exercise of nomenclature and means giving names to different clearly-defined categories, each name being a different taxon.

Part I.

Exploring the history of
Sääää" 15 international control.

01. Historically the first international treaties and arrangements mainly concerned war and commerce. Global health and international law intersected in the drug control system on the occasion of series of war motivated by business issues in the trade of opium, that came up with the adoption of the first drug control treaties (mainly about opium) in the early 1900's³.
02. Initially created only to establish common rules for fairness in the trade of opium, the agreements soon gravitated towards thematics of health – in that time called "hygiene" – and started to acknowledge health outcomes in drug policies.

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

03. The **. U Us** plant was genuinely included in the 1925 International Opium Convention, on the peasant insistence of a small number of countries. The control measures then only required countries to provide some documentation when trading internationally and to pledge to refrain from exporting to countries that had forbidden its use⁴.
04. It has been written that the **League of Nations** (LoN) undertook a review of Cannabis in 1935 but it appears that this was not the case. Contrary to what has been previously written in official WHO documents or in other indispensable research on the origins of international drug policies, the so-called assessment of **. U Us** made in 1935 by League of Nations never took place.
05. The archives have indeed partly disappeared during the second world war (WWII) however something happened at the **x φΥρ U Uú ρ—ó ρΥρ U Ux φ —óó U ρρ xV—**, a **ρρ** international body led by French and Italian Foreign Affairs departments, to which the LoN had delegated a technical and consultative mandate on health issues. In a meeting of their sub-Committee of Experts in Pharmacology held in Bern on 4th and 5th March 1935 (see Images 1 and 2, page 8), they reviewed 5 particular "preparations containing extract or tincture of Indian hemp" in a preparation including other powerful compounds such as strychnine.
06. October of the same year, 1935, the LoN Health Committee noted the review (Image 3) and recommended to countries that preparations partly made with "extracts and tinctures" of **. U Us** be subject to the same control measures as the pure "extracts and tinctures". By then only "extracts and tinctures" were internationally controlled where the "preparations" were not. However, that recommendation was restricted to countries voluntarily applying it, and external and topical preparations were exempted.
07. The **myth of an assessment of . U Us under the LoN** has justified the WHO shirking its responsibilities in the face of draconian measures of control, relying on a supposed previous ruling to avoid making decisions on a difficult subject matter.

³ E. Rodriguez, 2015. & **ρφ ú ρúó φ ú ρ κφi ρΥρ U Uφi U U x φ U óýó ρW ρ ρU ú U ρρ ρ ρ ρ U Úρ**, Paris, 2010, Université Paris 3 Sorbonne Nouvelle.

⁴ To learn more about the international discussions on **. U Us** prior to the 1925 Convention, see **© ρ ρUú φó ρ W Us · ó 4-ρ ρ ©U ©- ó U Uúq ρρ U° ρW ·**



12. Historically, these three reports constitute a critical tipping point. In those meeting minutes we have been able to identify that members of the Committee clearly acknowledge their ignorance of the mechanisms of action of **. U Us** on the human body (Δ⁹-THC wouldn't be isolated until 1964, and even later the endocannabinoid system). Yet without evidence they issued and reissued outcomes that have gone down in history unchallenged until now.
13. In 1953, the CND created the concept of a Schedule IV which would consist of drugs aimed at being completely prohibited. In 1955⁹ and 1958¹⁰ the Commission finished confirming the inclusion under this new schedule "**. U Us UúU Us p p Us Uú ó p U Us U p óUφ ó U p U Us U Us p ó p pU Us p óp p pU p p Uí U pú p**" No review or scientific assessment was ever mandated prior to that inclusion. However, on the insisting remarks of several countries provision was made in the draft Convention to balance the "**ó p pU p U Us ú** giving exception to **φ U p · · ú p · pú p**"
14. In 1958, the CND "**pú U pM p p Uí p pú U p p p púU U pU p p U Us ú pU Us φ**. However, countries decided to maintain their "**p U pú pAUx s p . p 4 kUs p —úφ·úó U Us ú p p pú U p p p p. φφp p p p U p p pU ú φ U ý p ó γ úU φ U p p p p p p p p U Us úφ ó pú U · p · pU U ú pU U p p φ · U · ó p ó p pú**"
15. Your predecessors in this Committee therefore have directly served as a justification for the strictest possible global policy for medical uses of the **. U Us** plant and its derivatives and thereby have made scientific research into **. U Us** unnecessarily burdensome.
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. **The first-ever assessment for the purpose of international scheduling was exercised for . U Us** , after the United Nations "**pú pÁ úU p x U U pU p U p p p U Us p p Us p ú U ó U pU ó ó p U p p U U Us p —p p U · p p φ U p U ó p ú U p p p; p. p φ p p p U Us p p Us p ú**"¹¹ That year, the Expert Committee met at its 11th Meeting, but although acknowledging promising research on antibiotic properties of **. U Us** , recalled for the third time that "**p p p pú p ú p pU óU pú . U Us Uú pU U p Us U ó p pU ú p p U p · pU p**"¹²

⁹ E/2768/Rev.1

¹⁰ E/3133

¹¹ E/CONF.34/5

¹² WHO Technical Report Series n^o211, 1961.



17. 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 **. O Us** – It is our opinion that this was intended to leave the door open for future identification of the active principles of the plant that would lead to isolating drugs extracted from the Cannabis plant.
18. The 5th and 11th Meeting of the Expert Committee provided direct input to the Single Convention (still in force), considered to be the last and only assessments made of this drug. Because of that, six decades later, robust scientific evidence is still minimal, even for a substance consistently documented as having great therapeutic potential. Schedule IV has effectively stifled gold standard research into **. O Us** and cannabinoids medical applications.
19. The extreme policy that prohibition represents – justified by this Committee – has proven to be an **almost impassable fence for research**, and an **intolerable barrier to medical access**. Hence the emergency for this Committee to:

invoke the **Right to a Remedy and Reparation for Victims of Gross Human Rights Violations**¹³,

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},

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.

Criticism of the
Pre-review of **Sääää"15** and
Sääää"15 related products.

social contexts. Similarly, the access to illicit retail of **. 0 06** is more prone to male than to female, in particular young women, thus virtually inflating the data on problematic use of young males. Also factors of genetic predispositions should be balanced according to what modern research has shown²⁹ – including one study referenced in the report, but which conclusions are only partially cited³⁰.

b) Bā5āī15āā'1< '7Z'āā'ā'f'k,Žfi<ā'žt<fZ5D

32. The Pre-review report document on which you, as scientists and independent Experts, will base your discussions is composed of two parts of equal importance:
 - a. A scientific part covering toxicology, chemistry, pharmacology, epidemiology and therapeutic use of the plant or substance under review,
 - b. A country Questionnaire 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 opportunity for Member States to submit comments and feedback, or to highlight country specific situations that systematic reviews might overlook.

33. Significant bias has undermined the ability of countries to provide relevant and accurate data. In particular, this problem concerns the Terms of reference for the data collection, often differing vastly between authors of the **ōp o Ū**, and authors of the **ō '™p Ūp Ū**. Below are highlighted some major differences in the definition and framing of substances about which data has been collected.

34. **Category name:** the Single Convention defines the herbal part of the substance that is placed under control as “cannabis”, and uses the term “cannabis plant” to refer to the plant **. 0 06 Ū ŪL.**, including parts 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. The logic of treaty language would recommend the **use of the term "crude . 0 06 " to designate the dried flowering and fruiting tops of the . 0 06 plant** from which the resin has not been extracted.

35. **Definition:** The terms of reference for countries data collection make absolutely no mention of "Cannabis resin", while for crude **. 0 06**, a weak definition is provided. It is incomprehensible that a **ō Ūp** 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 **. 0 06** resin, the most frequently used product in the illicit market in many countries.

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

²⁸ V. Govender and L. Penn-Kekana, **ŋp oŪp Ūūūo Ū Ūp p ŋ ōp p p Ū pŪ -Ū ū Ūp pŪpū pĀ p Ūūŋp s h ŋp r p pĀux . i oŪ4p p Ū ūp**. 2007.

²⁹ G. Maté, Addiction: Childhood Trauma, Stress and the Biology of Addiction. Journal of Restorative Medicine, 2012.

³⁰ K.J.H. Verweij, B.P. Zietsch, M.T. Lynskey, S.E. Medland, M.C. Neale, N.G. Martin, D.I. Boomsma and J.M. Vink, **ŋp oŪp p Ū p p ō Ū p Ū Ūū o p Ū p Ū Ū Ū ūp**. Society for the Study of Addictions, 2010.



37. 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."
38. WHO records more than 7 million deaths due to tobacco each year³¹, but the morbidity-mortality of . Ū Ū is extraordinarily low – hence the lack of WHO records on . Ū Ū -related deaths.
39. For the ECDD, **not adopting a similar approach for . Ū Ū as the one adopted at its 31st meeting for tobacco would represent an unacceptable double standard for substance scheduling.**

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 <u>plant</u> and Cannabis Resin"	"cannabis <u>plant</u> and cannabis resin"	§34
Definition	<ul style="list-style-type: none"> • <u>Cannabis</u> 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. • <u>Cannabis resin</u> 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"	§35
Examples provided	<p>r pŪ p qū · pŪŪ Ū</p> <p>x · pŪ p · qū · p · hashish</p>	<p>pŪ pŪp qū ō p</p> <p>Ū Ū " · p</p> <p>p · qū p p · pŪ p</p> <p>hashish · p pū pŪ p</p> <p>ō qŪŪ Ū</p>	§36

³¹ See **hp Ū · · ŪŪ**, World Health Organization, 2018. www.who.int/news-room/fact-sheets/detail/tobacco



Extracts and tinctures of Cannabis¹⁵

40. Placed under a different control regime (Schedule I) than the plant and resin material of Cannabis (Schedule I & IV), the different types of extractions of the Cannabis plant and the preparations based upon them offer the most complex panorama for a thorough scientific assessment that avoids bias.

a) Cannabis / Cannabis infusa < Cannabis tinctura

41. 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?
42. 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 registry number is too broad, and gives rise to important ambiguities and room for biased interpretation. Indeed, such definition comprises solvent extracts, expressions (pressed 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 number known:
- a. Cannabis seed oil: 8016-24-8,
 - b. Haschish oil: 8001-45-4,
 - c. Cannabis extract: 89958-21-4
43. 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 to "dabbing") or to address important trends in consumption patterns (such as the use of microdosing Cannabis extracts in harm reduction, or in tobacco cessation). Other data that balance the presented research outcomes seem to be missing.
44. 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 absent. Yet the author in her report on "Cannabis plant and cannabis resin", states that the pharmacology of edibles is addressed in the Pharmacology section of "Extracts and tinctures".
45. Finally, 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 shows ample evidence to the contrary^{32,33}.

³² "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

46. Severe points of concern arise from the pre-review report section on **Toxicology**. The first is the strange framing of the different sub-taxa of the category (addressed below in §51–58), which includes "cannabis resin" (yet explicitly excluded from the terms of reference provided to the author), and agglomerates into "concentrates" what other authors divided into up to 5 categories.
47. It is also astonishing to read concerns about "disastrous fires and explosions" 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 home artisanal production of cannabis concentrates are certainly more likely to be associated with the lack of a regulated and standardized legal retail market than the toxicology of **. O U** extracts **p p**
48. The section on **Therapeutic use** has deficiencies too: 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 **. O U** are available on the pharmaceutical market (such as in Germany, Netherlands, Australia, some States of the USA, Malta, Canada...), although often only marketed legally as magistral products in compounding pharmacies.
49. Lastly the section on **Epidemiology** invents 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").
50. The most disconcerting part of 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 §46 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." EMCDDA, **87. 44° qxr xM5° -Uj ° dU U5** **µp d pUu d p p p p p p d U5 o p p µ p Uu p U s p** Brussels, 2008, pp. 255–256.

³³ "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).", **oU**p. 256.



dependence and problematic use. Further this extraordinary focus on burn injuries is a bias that deserves further examination:

- i. Authors indistinctly use the words "legalization", or "medical liberalization", as synonyms, and do not distinguish the huge difference between the terms,
 - ii. There is no mention about the important reporting bias that could explain the increase of burn injuries related to home-made **. U U6** extraction either caused by an unclear retail market liable to bring inexperienced persons to experiment with extraction techniques in inadequate conditions or actual burn accidents mischaracterized because the illegal status as a matter of minimizing legal sanction.
- d. Part 4 proposes 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, " **p o p
w U6 U q p o p U o p U6 p -p p o p U p o p
o p o p U o Y U o u o U o U o p U p U**"³⁴ Experts might have been interested in knowing that this international agency explained that " **p p h u p p U p U U6 p i o p p p
U p p w U6 p p p p U**" and that " **p U p U
p o p p u o p p h u p p**" Much other data is easily available, from highly reliable sources.
- e. Similar to part 4, part 5 ignores the immense amount of information available about the illicit manufacture and traffic of the different extracts or tinctures included. 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 omits oils, concentrates, and other extracts**.

b) P3Ł5<1'ă <ă< 70

51. The category "extracts and tinctures" **encompasses many different products and preparations of the . U U6 plant (gathered according to their manufacturing processes, and not at all according to their chemical composition, pharmacology or toxicological effects** which would be the state of the art) therefore making it tough to frame.
52. The category is known under different names, according to the emitter:
 - a. "Cannabis extracts and tinctures" as per the Single Convention on narcotic drugs;
 - b. "Extracts and tinctures of cannabis" as per the language used by the WHO;
 - c. "Extracts or preparations" of **. U U6** , as per the wording proposed by the 39th ECDD.

³⁴ 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



53. The vast variety of products included in this category implies that **special attention should be focused on the taxonomy of these different products**, before undertaking any analysis of the content.
54. 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/. **0 05** extract (1302.19) among "Other Vegetable saps and extracts".
55. As well, the criterion excluding "Cannabis resin" from the scope of this pre-review – although that product is obviously fitting the criteria to be considered as an "extract" – should be discussed.
56. Taking advantage of 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 Expert Committee itself** to enable the possibility of undertaking Critical reviews based on evidence accordingly.
57. 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 **. 0 05** , 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 best fits the Treaty, correlates with 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 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 . 0 05 plant known to be part of traditional or indigenous uses**;
 - d. Create a sub-taxon under "Extracts of Cannabis", that would comprise all **Extracts or preparations of the . 0 05 plant with a minimal THC profile** (or **Extracts or preparations of the . 0 05 plant with almost no THC**). Precise quantities and limits could be determined either by the Committee or at the discretion of Countries;

Note: 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" (the latter is directly exempted from the Convention's control measures) and "essential oil", a steam distillate of the freshly-cut **. 0 05** plants which in no way fits any criterion that would justify international scrutiny. In 2009, the UN Office on Drugs and Crime (UNODC) wrote that " **þþ þ 0 úþ· ð 0 0u** ".³⁵

³⁵ United Nations Office on Drugs and Crime, Laboratory and Scientific Section, **šþ þ þú þ ú þ þ þ 0 0500 · 0 05 050 05 · úð**, 2009, page 19.



- e. Products and preparations included under this sub-item should be **reviewed separately one from another**;
- f. Essential oils and **. O U S O U**Semen Oleum should be completely excluded from further reviews in this category, and might be considered for inclusion under a newly created sub-taxon "Extracts and preparations **. O U S** 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.

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

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59. Besides, there are concerns about the comprehensiveness of data collection: table 3 (below) illustrates **important differences between the Terms of reference provided** to the scientific community (through the core authors of the report) versus to Countries (through the questionnaires sent to all Ministers of Health). This is a inconsistency with serious implications.

60. 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 is incomplete, requesting only "approved medical uses". This is directly contrary to the **M O P** document, which governs 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.

61. 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 **. O U S**, but that are clearly exempted from the scope of the international drug control system³⁶. This concerns in particular:

- a. the aqueous extract **Bhang**, or "**hemp teas**", legally commercialized in some countries, and prepared using the leaves (**exempted from international control**) of the **. O U S** plant,
- b. **. O U S O U**Semen Oleum, the so-called "**hemp seed oil**", sometimes also called "hemp oil", made out of the seeds/achenes of the **. O U S** plant, **exempted from international control**, and that contains an insignificant amount of Δ⁹-THC.

62. 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.

63. Given the wide diversity of products and uses included in the category "extracts and tinctures", feedback from countries especially including their national health data collection services appears to be indispensable as a complement to the scientific part to ensure thoroughness of the data corpus.

³⁶ See Article 28 (2) of the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol.

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				
	Hemp seed oil			
"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	/	" <u>approved medical</u> use of extracts and tinctures"	§60
Definition	<ul style="list-style-type: none"> • 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, <u>Hemp Seed Oil</u> • Aqueous extracts e.g. marijuana tea • Nabiximols (e.g. Sativex®)" 	<p>"The term 'extracts and tinctures' refers to substances that have been extracted from the Cannabis sativa plant. This term does not include synthetic preparations.</p> <p>Examples:</p> <ul style="list-style-type: none"> • Liquid concentrate (e.g. hash oil, <u>hemp oil</u>, butane honey oil, etc) • CBD oil • Solid concentrate (e.g. shatter, budder) • Edibles (e.g. prepared food products) • <u>Liquids</u> (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" 	§61
Examples provided	<p>ᐃᐅ ᐃᐅ ᐃᐅ ᐃᐅ • Butane Hash Oil, Hemp Seed Oil ᐃᐅ ᐃᐅ ᐃᐅ • marijuana tea ᐃᐅ ᐃᐅ ᐃᐅ • Nabiximols</p>	<p>ᐃᐅ ᐃᐅ ᐃᐅ ᐃᐅ</p>	§62



Delta-9-tetrahydrocannabinol.

64. Δ^9 -THC is the key active compound justifying the international scrutiny and control over the whole **. U B** plant. Crude cannabis, resin, extracts, tinctures and other preparations, systematically refer to Δ^9 -THC – hence the importance of **thoroughness and comprehensiveness of its assessment**.
65. 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 Δ^9 -THC and its 6 isomers under the name "tetrahydrocannabinols", later addressed as "dronabinol", a sole-stereochemical variant of the molecule, and finally until today, open to the 4 stereochemical variants of Δ^9 -THC.
66. Since as many as 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.
67. The Section 2 on **Pharmacology** misses a more refined acknowledgement of the numerous scientific discoveries about cannabinoids and the endocannabinoid system (ECS). The **absolute lack of information concerning the endocannabinoid system** (two lines in total) is particularly surprising. No mention is made of the mechanism of action of anandamide and 2-AG as well as of FAAH and monoacylglycerol lipase. No mention is made in the references of key researchers such as Prof. Raphael Mechoulam leading the team that isolated Δ^9 -THC and premiered ECS research. Beyond these details the document also cites very few references, especially recent, while the Pharmacology section of the 2006 Critical review document edited for the 34th ECDD meeting provided far more evidence³⁷.
68. The same pre-review document from 2006 presents numerous elements whose inclusion in the present Section would have been welcomed such as, inter alia, the figure in Image 6 below.
69. 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 system³⁸.
70. Cannabinoids, and Δ^9 -THC in particular, not only have important brain-related activity, they also have notable gastrointestinal activity. Not mentioned in the Pharmacology section.
71. 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 Δ^9 -THC (e.g. ongoing studies related to the anti-tumor activity of Δ^9 -THC in several cancer models).

³⁷ WHO ECDD₃₄, Assessment of dronabinol and its stereo-isomers. Available on: www.who.int/medicines/areas/quality_safety/4.2DronabinolCritReview.pdf

³⁸ Reviewed in Pertwee et al., 2010; Stella, 2010

72. Finally, the **Epidemiology** section is sparse, as parts 2, 3, 4 and 5 are almost non-existent. To follow on the comparison, 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).
73. Contrarily to the other products and substances under review, the **preparation process for the assessment of Δ⁹-THC** has less bias. It is regrettable 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).

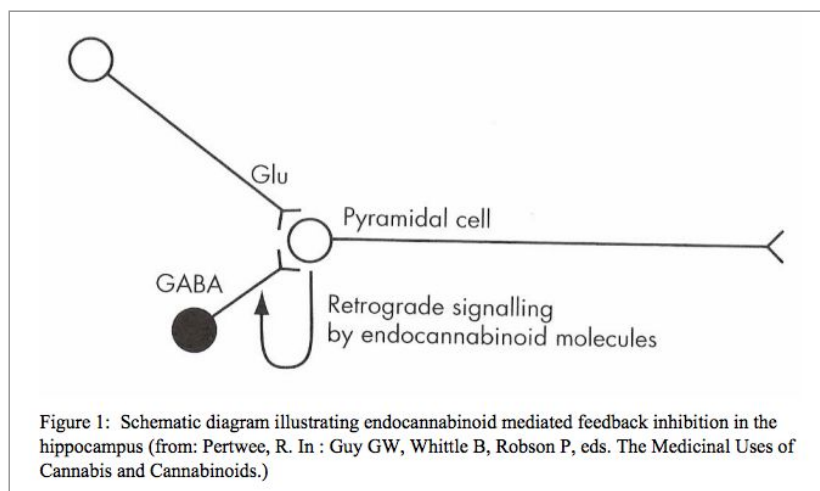


Image 6 **Δ⁹-THC** **Δ⁹-tetrahydrocannabinol**

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)
Introduction & context	Delta-9- tetrahydrocannabinol (THC)	Delta-9- tetrahydrocannabinol (THC)
Definition	<ul style="list-style-type: none"> • Pure delta-9-tetrahydrocannabinol that is obtained either directly from the cannabis plant or synthesised. • The stereochemical variants of delta-9-tetrahydrocannabinol: <ul style="list-style-type: none"> - (-)-trans-delta-9-tetrahydrocannabinol Δ⁹-THC - (+)-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)
Examples provided	Δ⁹-THC	Δ⁹-THC Marinol; Syndros

Part III.

Getting critical on cannabidiol.

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

74. 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 **. U Ub**, 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 binding recommendation for international scheduling, ultimately notified to all countries by a **r pApUp** of the UN Secretary-General.
75. Decisions made in a Critical Review meeting therefore **have direct and permanent consequences** on the broad international drug control system, and through it affect millions of people.

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76. A Critical review of "**Extracts or preparations containing almost exclusively cannabidiol**" was convened by decision of the Experts of the 39th ECDD, in November 2017.
77. 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).
78. 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 almost exclusively**" CBD. Requests for data sent to Ministers of Health, besides not reproducing the terminology recommended by the ECDD, vary importantly between languages:
- s Ub Uú o p o U w Ubú .-4** (English version),
 - . U Ubú .-4** (French version: "Les questions ont trait au cannabidiol (CBD)"),
 - s Ub Uú pUU U o U w Ubú .-4** (Spanish version: "Extractos y preparaciones que contienen cannabidiol (CBD)").
79. The ECDD explicitly called for a Critical review, not of CBD, but of these among the extracts of **. U Ub** that are rich in CBD. **The difference is extremely substantial.** "CBD", in clear terms **Pure Cannabidiol** (whether produced synthetically or by isolation from **. U Ub** plant), **has been clearly excluded from the scope of control of the Conventions**, excluding any narcotic-related harms or effects.
80. In parallel, it is admitted that almost all extract or tinctures of **. U Ub** will contain some CBD. Therefore, the "**extracts or tinctures containing CBD**" corresponds to **almost all of the extracts from**

the **. 0 06** 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 **. 0 06** plant, regardless of the fact that preparations may contain other cannabinoids that importantly modify the effect of CBD.

81. Pure CBD has never been agreed by the Experts to be critically reviewed during the 40th ECDD. The lack of respect by WHO administration exemplified by 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.
82. Please note, 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.
83. 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.
84. Based upon the wishes of the 39th ECDD, CBD should be clearly and definitely excluded from the scope of the 40th 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 the category "Extracts and tinctures of cannabis", see above §57).

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)".	γ · β8 · β "Extracts and tinctures containing cannabidiol (CBD)" γ · βL β δ · β " Cannabidiol (CBD)"	§77-80
Definition	. -4' ip μU cannabidiol 0 uU (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	r ip · φu	

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 medicines³⁹, 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)⁴⁰ "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 occasions⁴¹, and especially made a **call for "informed and coordinated scheduling decisions"**⁴², while recalling the need for "scientific evidence-based review and scheduling of the most prevalent, persistent and harmful substances"⁴³ 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 purposes⁴⁴ as well as a "strong commitment to improving access" to those substances⁴⁵. 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 not only as an **essential issue towards a comprehensive availability of scheduled substances for medical purposes**⁴⁶, but also as a **mandate given to the WHO ECDD by the international community to start issuing scheduling recommendations driven by public health, more than moral, considerations**.

We are confident that the Experts will correct this situation and undertake the necessary steps to fully appreciate the substantially increased scientific . U Us -related knowledge-base.

³⁹ WHO/A71/4, General programme of work 2019–2023, "Promote health, keep the world safe, serve the vulnerable".

⁴⁰ WHO/A69/12

⁴¹ General Assembly resolution A/S-30/1, annex "x · ö þ · þ þ þ Uúþ Uúö þ · þ úú · óþ", 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.

⁴² A/S-30/1, annex, item 2, paragraph (g).

⁴³ A/S-30/1, annex, item 5, 2nd preliminar paragraph.

⁴⁴ A/S-30/1, annex, introduction, 5th paragraph.

⁴⁵ A/S-30/1, annex, item 2, preliminar paragraph.

⁴⁶ To learn more, check the contribution to the post-UNGASS process by the NGO FAAAT think & do tank "x þ þú þú · þerMi · ö þúö þ þúþ · ó Uφ", 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
ECS	Endocannabinoid System
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)
Single Convention	1961 Convention
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
Vienna Convention	1971 Convention
WHA	World Health Assembly
WHO	World Health Organization
WHO-DG	Director-General of the World Health Organization
WTO	World Trade Organization
WWII	II nd World War
1961 Convention	1961 Single Convention on Narcotic drugs, as amended buy the 1972 Protocol
1971 Convention	1971 Convention on Psychotropic Substances
Δ ⁹ -THC	Delta-9-tetrahydrocannabinol

Endorsements.

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 Ale Yarok **Yš**,
 Americans for Safe Access **@i°**,
 Asociación Civil Rosarina de Estudios Culturales **°šM**
 Australian Medical Cannabis Council **°@i°**,
 Austrian Cannabis Network **f@**,
 Auto Support des Usager.e.s de Drogues **Lš°**,
 Canadian Students for Sensible Drug Policy **.°r**,
 Cannabis Sans Frontières **°Lš°**,
 Cannabis War is Over campaign **.Ñ**,
 Caribbean Collective for Justice **°@@**,
 Caribbean Drug & Alcohol Research Institute **k°**,
 Center of Excellence in Harm Reduction and Dependency **°LM**
 Collectif Thémis **°Lš°**,
 Criminal Justice Policy Foundation **@i°**,
 Dosemociones **°i—**,
 DRCNet Foundation **°@i°**,
 DrugScience **@h**,
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 Federation of Cannabis Users Associations of Aragón **°i—**,
 Federation of Cannabis Users Associations of Euskadi **°i—**,
 Fields of Green for All **ÑL**,
 Foundation of Cannabis Unified Standards **@i°**,
 Fundación Renovatio **°i—**,
 Groupement Romand d'Étude des Addictions **.U**,
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 Help Not Harm **šk**,
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 Knowmad Institute **4&@**,

KOPAC **.Ñ**,
 Latino America Reforma **.Uk**,
 La María Guanaca **°iKÁ**,
 Legalizače **.Ñ**,
 Legalize **rk**,
 Madawa Addiction and Health Care Organisation **°LM**
 MamaCoca **.xk**,
 Multidisciplinary Association for Psychedelic Research **@i°**,
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 NORML France **°Lš°**,
 Patients Out of Time **°@i°**,
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 Verbond voor Opheffing van het Cannabisverbod **rk**,
 Veterans Ending The Stigma **@i°**,
 Veterans for Medical Cannabis Access **@i°**,
 Virginians Against Drug Violence **@i°**,
 Zimbabwe Civil Liberties & Drug Network **Ñ&S**.

About FAAAT think & do tank

FAAAT think & do tank **L°pU p° šp °w@ @ úU** 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 harmful 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.

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

