WHO's first scientific review of medicinal *Cannabis*: from global struggle to patient implications

Kenzi Riboulet-Zemouli and Michael Alan Krawitz

Abstract

Background – *"Cannabis" and "cannabis resin" are derived from the* Cannabis *plant, used as herbal medications, in traditional medicine and as active pharmaceutical ingredients. Since 1961, they have been listed in Schedule IV, the most restrictive category of the single convention on narcotic drugs. The process to scientifically review and reschedule them was launched by the World Health Organisation (WHO) on 2 December 2016; it survived a number of hindrances until finally being submitted to a delayed and* sui generis *vote by the UN Commission on Narcotic Drugs on 2 December 2020, withdrawing "cannabis" and "cannabis resin" from Schedule IV.*

Design/methodology/approach – *To evaluate WHO's scheduling recommendations, the process leading to the Commission vote and subsequent implications at global, national and patient/clinician levels. Narrative account of the four-year proceedings; review of the practical implications of both rejected and accepted recommendations.*

Findings – *The process was historically unprecedented, of political relevance to both medical* Cannabis *and evidence-based scheduling generally. Procedural barriers hampered the appropriate involvement of civil society stakeholders. The landscape resulting from accepted and rejected recommendations allow countries to continue creating decentralised, non-uniform systems for access to and availability of "cannabis" and "cannabis resin" for medical purposes.*

Originality/value – *Perspective of accredited observers; highlight of institutional issues and the lay of the land; contrast of stakeholders' interpretations and engagement.*

Keywords Cannabis*, Medical marijuana, Cannabidiol, Scheduling, United Nations, Commission on narcotic drugs, World Health Organisation, Drug control, Single Convention on narcotic drugs, Convention on psychotropic substances*

Paper type *Research paper*

Kenzi Riboulet-Zemouli is an Independent Researcher, based at Barcelona, Spain and FAAAT think and do tank, Paris, France.
Michael Alan Krawitz is based at Veterans for Medical Cannabis Access, Elliston, Virginia, USA and FAAAT think and do tank, Paris, France.

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Introduction

Cannabis L., an herbaceous plant used in medicine for centuries (Bridgeman and Abazia, 2017; Crocq, 2020; Fankhauser, 2008; Mikuriya, 1969; Pisanti and Bifulco, 2018; Spence, 2020; Zlas *et al.*, 1993), became the subject of international law in 1925 amidst a still relatively new international legal order that was to "shape, and be shaped by, the drugs issue" (McAllister, 2000, p. 44).

Although it was discussed during the First Opium Conference of 1912 (Mills, 2003, pp. 152–187), the *Cannabis* plant only appeared in the "International Convention relating to Dangerous Drugs" (Collins, 2020; Kendell, 2003; McAllister, 2000, p. 44; The *Cannabis* problem, 1962) adopted at the Second Opium Conference in 1925. In parallel, the medicinal products of the plant (the dried tops, its resin or extract and tincture) were briefly considered in 1905 for the First "International Agreement [...] on the Unification of Pharmacopoeial Formulas for Potent Drugs" (Riboulet-Zemouli, 2020, pp. 13-14), but

similarly, only appeared in the Second Pharmacopoeial Agreement, in 1925 (Riboulet-Zemouli, 2020; *Seconde conférence internationale pour l'unification de la formule des médicaments héroïques*, 1925).

This international dichotomy between a "dangerous" drug requiring controls over its chain of supply (as mandated by the 1925 Opium Convention) and a "potent" drug requiring standardisation via pharmacopeial harmonisation (as per the 1925 Pharmacopoeial Agreement) persisted until the adoption of the Single Convention on narcotic drugs in 1961 (C61). This later treaty, superseding all previous international instruments relating to *Cannabis* (Lande, 1962; Mills, 2016), placed the plant under specific controls roughly following the 1925 Opium Convention (Collins, 2020) but, more importantly, it diverted from the Pharmacopoeial Agreement by listing for the first time the medicinal products of *Cannabis* within the schedule of drugs "that are particularly liable to abuse and to produce ill-effects and do not have therapeutic advantages that offset these effects" (WHO, 2019, p. 37): Schedule IV [1]. This opened a parenthesis in the history of medicine where *Cannabis* and its therapeutic derivatives "dwindled to practically nothing" (Mikuriya, 1969, p. 38) on pharmacy shelves and in scientific research agendas (Bewley-Taylor and Jelsma, 2011; Crocq, 2020; Fankhauser, 2008, pp. 10–11; Multidisciplinary Association for Psychedelic Studies, 2020; Nutt, 2019; Nutt *et al.*, 2013).

This placement of "cannabis and cannabis resin" in Schedule IV of C61 ignored the science and was inconsistent with the uses of the plant in indigenous and Western therapeutics throughout history [2]. It was reversed in 2021 with the entry into force of Decision 63/17 (CND, 2020, p. 5; Commission on Narcotic Drugs, 2021c) of the Commission on Narcotic Drugs (CND) [3]. On 2 December 2020, CND Member States agreed by a simple-majority vote to withdraw "cannabis and cannabis resin" from Schedule IV of the C61 pursuant to one of the World Health Organisation's (WHO) scientific evidence-based recommendations [4]. The discussions leading to that vote revealed unprecedented procedural complexities and a certain amount of drama interspersed with delays and Covid-related disruptions.

On 2 December 2020, four years exactly after WHO announced the launch of the *Cannabis* review (CND, 2016a, p. 8; WHO, 2016c, pp. 7–8), the CND accepted one of the nine *Cannabis*-related recommendations; one did not require a vote, three were rejected and another four were not put on the ballot (Table 1; CND, 2020a, pp. 5–7; CND monitor, 2020). Although only one recommendation was accepted, it represents a landmark for *Cannabis* in (and as a) medicine. It is also an important incremental step towards the much needed "scientific evidence-based review and scheduling of the most prevalent, persistent and harmful substances" called for by the United Nations General Assembly (2016, p. 15; also Ghehiouèche and Riboulet-Zemouli, 2016; Riboulet-Zemouli and Ghehiouèche, 2016; WHO, 2016a, p. 9).

Building upon the detailed reporting of procedural aspects published in Riboulet-Zemouli *et al.* (2021; including detailed dramatis personae pp. 29–33 and comprehensive timeline pp. 34–40), this article provides a brief narrative account and historical review. The authors attended UN and WHO meetings (2015–2021) as observers under the UN-accredited non-governmental organisation DRCNet Foundation, facilitated stakeholder involvement, collected data and evidence to feed into the process – particularly from patients, doctors, academia, government and local communities.

Background

Mainly, the scheduling process sets international control levels for the medical and scientific uses of designated products and substances, with different levels of control governing each of the schedules (UN, 1973, pp. 49–51; Rexed *et al.*, 1984). Separate legal dispositions prevail for "other than medical and scientific purposes," regardless of the

Table 1 Overview of the WHO ECDD's cannabis-related recommendations and outcome of the 2 December 2020 votes at the CND

WHO ECDD recommendation	*Issue date(s)*	*Action taken by the CND*	*Action reflected in CND report*
Recommendation of the 40th ECDD meeting. Preparations considered to be pure cannabidiol (CBD) should not be scheduled within the international drug control conventions	*WHO ECDD meetings*: Pre-review: 6–10 November 2017[a] Critical review: 4–7 June 2018[b] *WHO Director-General communication*: 23 July 2018[c]	***No vote was required***[g]	*idem.*
Recommendation No. 5.1 of the 41st ECDD meeting. Delete cannabis and cannabis resin from Schedule IV of the 1961 Single Convention	*WHO ECDD meetings*: Pre-reviews: 4–7 June 2018[b] Critical reviews: 12–16 November 2018[d] *WHO Director-General communication*: 24 January 2019[e] *WHO Director-General corrections*: 5 August 2020[f]	***Approved*** 27 yes, 25 no, 1 abstention. Decision 63/17[h]	*idem.*
Recommendation No. 5.2.1. of the 41st ECDD meeting. Add *delta-9-THC* to Schedule I of the 1961 Single Convention		***Rejected*** 23 yes, 28 no, 2 abstentions. Decision 63/18[h]	*idem.*
Recommendation No. 5.2.2. of the 41st ECDD meeting. If 5.2.1 is adopted, delete *delta-9-THC* from Schedule II of the 1971 Convention		***Not submitted to a vote*** As per the special procedure adopted in CND Decision 63/16[i]	*idem.*
Recommendation No. 5.3.1. of the 41st ECDD meeting. If 5.2.2 is adopted, add *other isomers of THC* to Schedule I of the 1961 Single Convention		***Not submitted to a vote*** As per the special procedure adopted in Decision 63/16[i]	*idem.*
Recommendation No. 5.3.2. of the 41st ECDD meeting. If 5.3.1 is adopted, delete *other isomers of THC* from Schedule I of the 1971 Convention		***Not submitted to a vote*** As per the special procedure adopted in Decision 63/16[i]	*idem.*
Recommendation No. 5.4. of the 41st ECDD meeting. Delete *extracts and tinctures of cannabis* from Schedule I of the 1961 Single Convention		***Rejected*** 24 yes, 27 no, 2 abstentions. Decision 63/19[j]	*idem.*
Recommendation No. 5.5. of the 41st ECDD meeting. Give effect to the recommendation of the 40th ECDD meeting [. . .] by adding a footnote to the entry for cannabis and cannabis resin in Schedule I of the 1961 Single Convention to read "Preparations containing predominantly CBD and not more than 0.2 per cent of delta-9-THC are not under international control"		***Rejected*** 6 yes, 43 no, 4 abstentions. Decision 63/20[j]	*idem.*
Recommendation No. 5.6. of the 41st ECDD meeting. Add preparations containing delta-9-THC* to Schedule III of the 1961 Single Convention. * *Produced either by chemical synthesis or as preparations of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that delta-9-THC cannot be recovered by readily available means or in a yield which would constitute a risk to public health*		***Not submitted to a vote on 2 December*** As per the special procedure adopted in Decision 63/16[i]	***Rejected by consensus*** As expressed in Decision 63/21[k]

Notes: [a]WHO (2018c, [b]2018d); [c]Adhanom Ghebreyesus (2018); [d]WHO (2019); [e]Adhanom Ghebreyesus (2019); [f]CND (2020c, pp. 11–12); [g]CND (2019a, p. 3); [h]CND (2020b, p. 5, [i]pp. 3–4, [j]p. 6, [k]p. 7). CBD: cannabidiol; CND: Commission on Narcotic Drugs of the United Nations; delta-9-THC: delta-9-tetrahydrocannabinol; ECDD: Expert Committee on Drug Dependence; WHO: World Health Organization

Schedule in which the *drug* is placed (UN, 1973, pp. 110–114, 402–403). Hence, the status of scheduling (and any amendments) primarily affect medicine and research: prescription requirements, supply parameters, licensing of pharmacists, of producers, etc. (detailed in Rexed *et al.*, 1984, pp. 33–50; also UNODC, 2020b, pp. 8–13).

The international legal regime currently in force for *Cannabis*-related controlled drugs (CCDs) was established by the C61 with the placement of "cannabis" (dried tops, also known as *ganja*, *marijuana* or *dagga*) and "cannabis resin" (oleoresinous exudate from the plant's glandular trichomes, also called *charas*, *kief* or *hashish*) in Schedule I and IV and of "extracts and tinctures of cannabis" (galenic preparations of the former) only in Schedule I (Collins, 2020; Curran *et al.*, 2016). The legal panorama of CCDs was completed in 1971 with the placement of all the isomers of tetrahydrocannabinol (THC) in Schedule I of the 1971 Convention on psychotropic substances (C71). Other *Cannabis*-derived or *Cannabis*-related medicines, such as cannabidiol (CBD, marketed in a number of countries; WHO, 2018d, pp. 13–17) and *Cannabis* seeds (present in the Japanese and Chinese pharmacopoeias; Riboulet-Zemouli, 2020, pp. 8, 14, 16) have never been listed in the Schedules of the C61 or C71 and are, therefore, not CCDs.

In April 1991, two decades after C71 was adopted, the scheduling status of *Cannabis* and cannabinoids first changed with CND Decision 2(XXXIV), down-scheduling the isomer delta-9 of THC (also known by the international non-proprietary name *dronabinol*) to C71's Schedule II as per WHO's evidence-based recommendations (CND, 1991; Riboulet-Zemouli, 2018, pp. 40–41; WHO, 2018d, p. 39). Although that decision applies to both plant-derived and laboratory-made dronabinol (the Conventions control compounds regardless of their source), it concerns only *pure* dronabinol, having no effect on the control of whole-plant botanical *Cannabis* medicines under the C61.

WHO's *Cannabis*-related recommendations issued in 2018 (Adhanom Ghebreyesus, 2018) and 2019 (Adhanom Ghebreyesus, 2019; CND, 2020b, pp. 11–12) and the scientific evidence-based and methodology-reliant reviews that underpinned them (Mayor, 2019; WHO, 2018d; 2019, pp. 34–55) were historically unprecedented (Curran *et al.*, 2016; Danenberg *et al.*, 2013; Krawitz *et al.*, 2018; Riboulet-Zemouli, 2018): despite treaty requirements, herbal CCDs had never been submitted to a formal review (Danenberg *et al.*, 2013; WHO, 2010; 2016a). Stakeholders, including the UN Committee on Economic, Social and Cultural Rights (2020, p. 13), emphasised that the placement of "cannabis and cannabis resin" in C61's Schedule IV had not been validated by any sort of scientific assessment. Observers (Clarke, 2018; Curran *et al.*, 2016; Krawitz *et al.*, 2018, pp. 9–10; Mills, 2016, pp. 100–101; Multidisciplinary Association for Psychedelic Studies, 2020; Riboulet-Zemouli, 2018, pp. 36–37) had also pointed out that WHO's 1954 recommendation encouraging "efforts towards the abolition of *Cannabis* from all legitimate medical practice" (WHO, 1955; also FAAAT, 2019), reiterated throughout the 1950s, relied on "personal views, experiences or anecdotes" (Danenberg *et al.*, 2013, p. 180), used biased sources (such as reports from the South African Apartheid regime's police; Clarke, 2018; WHO, 1955, pp. 12–13), scant medical data and lacked any real methodology.

Although the idea to ban *Cannabis* from the realm of therapeutics was promoted earlier by some Member States (Kozma, 2011; McAllister, 2000; Mills, 2003, 2016), followed by the office of UN Secretary-General Trygve Lie (Economic and Social Council, 1951; Lande, 1962; Mills, 2016), and its incorporation into the C61 was made credible by and justified through, the repeated WHO recommendations of the 1950s. These recommendations seem to have been based upon the erroneous notion that there was a previous international scientific assessment in 1935, which there was not (Krawitz *et al.*, 2018, pp. 7-9).

Since the rescheduling of dronabinol in 1991, CCDs had been included as minor, non-review agenda items (Ghehiouèche and Riboulet-Zemouli, 2016, pp. 42–43) in several meetings of the WHO expert committee on drug dependence (ECDD, the internal WHO working group mandated with the evidentiary evaluation of substances), but never submitted to a formal review. Nevertheless, as contemporary evidence accumulated, the need for a sound assessment became pressing (O'Grady, 2020; Pisanti and Bifulco, 2017, 2018; WHO, 2018c, 2018d). The binding request (WHO, 2010, pp. 10–13) for a review of delta-9-THC in 2007 (CND Resolution 50/2, UNODC, 2019, p. 4, 17) was followed by six subsequent requests to review "cannabis and cannabis resin" (Krawitz and Riboulet-Zemouli, 2019, p. 4):

- CND (2009; also WHO, 2016d, p. 32);
- International Narcotics Control Board (INCB, 2014, pp. 93–94);
- ECDD in 2015 (WHO, 2016d, p. 32);
- the Czech Republic in 2016 (WHO, 2016b, p. 248);
- the International Association for Hospice and Palliative Care in 2016 (Ghehiouèche and Riboulet-Zemouli, 2016); and
- the Caribbean Community in 2018 (Antoine and Douglas, 2018).

Review process

On 2 December 2016, WHO finally announced the launch of the official *Cannabis* review process (CND, 2016a, p. 8; WHO, 2016c, pp. 7–8). Compared with the 1950s' meetings and subsequent reports hastily drawn up *on the back of an envelope*, the methodology, quality of work and mechanisms for the review of substances considered for international control have evolved substantially (WHO, 2010), although there is still room for improvement (Danenberg *et al.*, 2013; Hallam *et al.*, 2014).

The official assessment process began with a call for "authorship of Pre-Review reports on *Cannabis*-related substances" (United Nations Global Marketplace, 2017; WHO, 2016e), hiring of a dedicated technical officer and establishment of a questionnaire to collect data from Member States (WHO, 2018e). Particular to this review was that the ECDD dedicated an entire meeting to *Cannabis* and its products (WHO, 2018d) relying on upgraded data collection and analysis (WHO, 2018c, pp. 10–11). As WHO (2020b) explains:

> These recommendations are the outcome of a multi-year review process conducted by the [ECDD], an independent scientific advisory body to the WHO. Based on scientific assessment, potential health risk and therapeutic benefit, the ECDD recommends the appropriate scheduling of psychoactive substances within the international drug conventions. [. . .] Formal reviews [. . .] considered both the best available scientific evidence and data from Member States provided through the annual WHO ECDD Member State questionnaire. In addition, Member States, members of the public, civil society groups, pharmaceutical industry representatives, and other relevant groups were also able to comment on the ECDD assessments and recommendations through Open Sessions at all ECDD meetings.

The open sessions that preceded ECDD meetings facilitated the participation of a broad range of stakeholders (WHO, 2017, 2018a, 2019, pp. 2–3; detail in Riboulet-Zemouli *et al.*, 2021, pp. 22–39). Many patients and clinicians provided input. A speaker played audio of gunfire which, she commented, results from a "war on drugs" that has scheduling at its core, inviting the ECDD to balance the harms of substances under review with such *[un]intended negative consequences* of drug control (Bretteville-Jensen *et al.*, 2017, pp. 23–44). Ahead of the 40th ECDD meeting, a joint contribution of hundreds of civil society organisations (Krawitz *et al.*, 2018) pointed out bias and inconsistencies in the initial Pre-review documentation; all criticisms were acknowledged by the authors – except for the pharmacology section – and addressed in the revised 41st meeting's critical-review documents.

Ahead of the meetings, the experts had recalled "that unpublished data, although considered low-quality evidence, can be informative during the meeting proceedings" (WHO, 2018c, pp. 10–11). This is a crucial element because the knowledge of traditional medicinal plants is sometimes maintained orally. WHO claims to have incorporated "Scientific published and unpublished data, hundreds of publications reviewed and referenced" in addition to "Member States' data, UNODC [UN Office on Drugs and Crime] and INCB" as well as a number of national and regional health monitoring centres

(Forte, 2020). The two-year ECDD review process seems to have effectively collected opinions, information and science in a balanced and independent manner.

Recommendations

The final ECDD *Cannabis*-related recommendations were made public in June 2018 and January 2019 (Adhanom Ghebreyesus, 2018, 2019). The WHO Experts' recommendations not only called for withdrawing "cannabis and cannabis resin" from Schedule IV (recommendation 5.1), but also proposed important changes to the scope of controls of the different CCDs under both C61 and C71 (Table 1), to "reflect the emerging therapeutic role of cannabis-based medicines whilst continuing to prevent diversion, misuse, and other public health-related harms that may arise from cannabis use" (WHO, 2020a).

Had all recommendations been adopted, the scheduling status of CCDs would have been dramatically simplified: recommendations 5.2 and 5.3 would have placed all CCDs in a single Schedule of one Convention – instead of the current three schedules in two Conventions (Table 2, fourth column). Recommendation 5.4 would have deleted redundant treaty language without affecting controls. Recommendations 5.5 and 5.6 would have increased Member States' options by facilitating access to a broad array of medicines, with different tiers for dronabinol- or cannabidiol-dominant CCDs (Riboulet-Zemouli *et al.*, 2021, pp. 12–15). The full set of recommendations sketched a simplified, three-tiered control architecture:

1. *Cannabis*, *Cannabis* resin and all the isomers of THC would remain in Schedule I of C61;
2. governments could decide, on domestic criteria, to subject any CCD medicines with more than 0.2% dronabinol to the least-restrictive regime of Schedule III (dispensing over the counter when relevant); and
3. CBD medicines (with less than 0.2% dronabinol) would be clearly defined as outside of the scope of international control, similar to seeds, "pure CBD," and other non-scheduled cannabinoids.

For most observers, recommendation 5.1 (withdrawal from Schedule IV) represented a symbolic yet very strong statement: the logical outcome of the *de facto* repeal of the position expressed in the 1950s by WHO. If before 2019, WHO's Expert opinion on "medical cannabis" tended towards its abolition from legitimate medical practice, it follows that today's position supports the reintroduction of *Cannabis* into legitimate medical practice.

Although veiled in complexity, especially due to the voting process, other sets of recommendations (5.2 through 5.6, none accepted by CND) would have presented a cohesive and well-reasoned system of access to CCDs in medical care while preserving Member States' sovereignty on if and how to reform nationally. These rejected recommendations would have *levelled the playing field* between synthetic and plant-derived medicines. Currently, only pure THC medicines enjoy a reduced level of control; ECDD recommendations would have provided for the same regime for both forms of medicines, allowing countries to also apply a Schedule III regime to both synthetic (essentially Marinol® and Syndros®) and herbal *Cannabis* medicines (e.g., Asmasol®, Bediol®, Cannador®, Sativex®, etc., but also non-proprietary medicines such as pharmacy-compounded drugs or Ayurvedic formulations; Aggarwal and Gupta, 2019).

Other observers, however, expressed disappointment with the recommendations. Many did not understand the purpose of recommendations 5.2 through 5.6. Some even accused ECDD of making a "political decision" (Drugreporter, 2020) for not recommending to remove "cannabis and cannabis resin" from Schedule I, mentioning a "questionable rationale" (Smith, 2020). The ECDD indeed "did not consider that cannabis is associated

Table 2 Comparison of the international scheduling status of cannabis-related controlled drugs before and after the 1991 and 2021 changes, with the WHO's recommended changes

Until 1991	*1991–2021*	*After 21 April 2021*	*If all of WHO's recommendations had been accepted*
Régimes of control according to Schedule placement, Single Convention on narcotic drugs of 1961			
Schedule I and Schedule IV Cannabis, cannabis resin	Schedule I and Schedule IV Cannabis, cannabis resin	Schedule I and Schedule IV –	Schedule I and Schedule IV –
Schedule I extracts and tinctures of cannabis	Schedule I extracts and tinctures of cannabis	Schedule I Cannabis, cannabis resin, extracts and tinctures of cannabis	Schedule I Cannabis, cannabis resin, extracts and tinctures of cannabis, and all THC isomers
Schedule II –	Schedule II –	Schedule II –	Schedule II –
Schedule I and Schedule III –	Schedule I and Schedule III –	Schedule I and Schedule III –	Schedule I and Schedule III Preparations containing delta-9-THC (produced either by chemical synthesis or as preparations of cannabis) that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that delta-9-THC cannot be recovered by readily available means or in a yield which would constitute a risk to public health
Schedules, Convention on psychotropic substances of 1971			
Schedule I Delta-6a(10a)-THC delta-6a(7)-THC delta-7-THC delta-8-THC delta-9-THC delta-10-THC delta-9(11)-THC	Schedule I Delta-6a(10a)-THC delta-6a(7)-THC delta-7-THC delta-8-THC delta-10-THC delta-9(11)-THC	Schedule I Delta-6a(10a)-THC delta-6a(7)-THC delta-7-THC delta-8-THC delta-10-THC delta-9(11)-THC	Schedule I –
Schedule II –	Schedule II delta-9-THC	Schedule II delta-9-THC	Schedule II –
Schedule III –	Schedule III –	Schedule III –	Schedule III –
Schedule IV –	Schedule IV –	Schedule IV –	Schedule IV –
Not in the Schedules of neither the Single Convention on narcotic drugs of 1961 nor the Convention on psychotropic substances of 1971			
Cannabidiol, cannabinol, cannabigerol and many other phytocannabinoids; terpenes, terpenoids and phenols; chlorophyll; other phytoconstituents of the *Cannabis* plant	Cannabidiol, cannabinol, cannabigerol and many other phytocannabinoids; terpenes, terpenoids and phenols; chlorophyll; other phytoconstituents of the *Cannabis* plant	Cannabidiol, cannabinol, cannabigerol and many other phytocannabinoids; terpenes, terpenoids and phenols; chlorophyll; other phytoconstituents of the *Cannabis* plant	Cannabidiol, cannabinol, cannabigerol and many other phytocannabinoids; terpenes, terpenoids and phenols; chlorophyll; other phytoconstituents of the *Cannabis* plant and preparations of delta-9-THC, of cannabis or of cannabis resin, containing predominantly CBD, and not more than 0.2% of delta-9-THC

Note: Changes in the scope of scheduling are underlined

with the same level of risk to health as [. . .] other drugs placed in Schedule I" (WHO, 2019, p. 41). However, these positions failed to acknowledge that ECDD remains captive to the treaty provisions framing its work (Danenberg *et al.*, 2013; WHO, 2010), besides all the progress made by WHO in strengthening the role of science in scheduling assessments.

C61 stipulates (in Article 2[6]) that "in addition to the measures of control applicable to all drugs in Schedule I, [. . .] cannabis [is subject to the provisions of] article 28." This submits CCDs to the

regimes of both Schedule I and Article 28. Unless Article 2(6) is modified, a removal of CCDs from Schedule I by the CND would have no effect (Boister, 2001, pp. 549–553; UN, 1976, p. 39). The opportunity and relevance of an ECDD recommendation to move CCDs out of Schedule I are therefore questionable in light of such treaty constraints.

On top of that, the treaties' criteria for substance scheduling, under which the ECDD has to frame its reviews, are anything but scientifically sound: they base the addition of new drugs to the Schedules on their similarity to CCDs (Danenberg *et al.*, 2013; Hallam *et al.*, 2014; Lohman and Barrett, 2020; Riboulet-Zemouli, 2018, pp. 18–19). By moving CCDs out of Schedule I, what would the consequences be for substances placed in Schedule I as per their similarity to "cannabis"? This context suggests that, within the limitations inherent to the construct of the legal regime framing its work, the ECDD went *as far as it could* to facilitate medicinal access.

Vote

Traditionally, votes on ECDD recommendations are held at the next available CND session following their issuance. But this particular voting was subject to repeated delays, not only due to the complexity and interconnectedness of the recommendations, but also to organisational problems at WHO leadership and burdensome governmental discussions organised by the successive CND Chairs (Ambassadors of Sudan and Pakistan) assisted by the UNODC, which manages CND Secretariat (Riboulet-Zemouli *et al.*, 2021, pp. 16–18, 38–39). These two-years of "topical meeting" discussions in Vienna were held with an exclusive focus on governments, leaving little room for participation by civil society or substantive input from affected populations (detail in Riboulet-Zemouli *et al.*, 2021, pp. 16–18, 38–39). Of particular concern was the *sui generis* (i.e. of its own kind, unique, unprecedented) voting procedure (Decision 63/16; CND, 2020a, p. 23) that resulted in some recommendations not even getting voted on, and the rejection of others without a vote (Table 1; details in Riboulet-Zemouli *et al.*, 2021, p. 17).

Throughout 2019 and 2020, during the discussions organised in Vienna (headquarters of CND, INCB and UNODC) some Member States expressed anxiety that WHO's recommendations could be "viewed as a shift and support for legalisation of the recreational use of cannabis" ("Nigeria" in CND monitor, 2020; CND, 2020c, pp. 2, 5–6). A few days after the vote, on 5 December 2020, the Ambassador of the Russian Federation in Vienna tweeted his concerns that "'#UN News' misinterpreted the decision of #CND and claimed that #cannabis is no longer considered to be a risky drug. This assertion doesn't correspond to reality" (Ulyanov, 2020). Subsequently, the UN News press release title "UN commission reclassifies cannabis" was changed from "no longer considered risky narcotic" (Archive.org, 2020a) to "[. . .] yet still considered harmful" (Archive.org, 2020b). Other edits included the deletion of "long-heralded" in reference to *Cannabis*' "medicinal properties."

In addition to these biased interpretations, the Member States opposing the decision used the occasion for diverting CND from its primary concern. The purpose of scheduling, it should be recalled, is to regulate international controls for medical and scientific purposes only. Nonetheless, some Member States chose knowingly to blur those boundaries:

> We are not under any illusion that the Recommendations are a receipt for legalization of cannabis, but we understand how the perception of our actions may influence public attitude to non-medical use of cannabis and related substances (Permanent mission of Nigeria to international organizations in Vienna, 2020).

Such excessive focus on non-medical uses deviated CND discussions from the questions of medical purposes, treatments and health care.

This lack of interest in the core of the question is reflected in deficient accounts of the topic in CND reports. For example, the December 2016 session's report (CND, 2016b, pp. 14–15) made no mention of the announcement by WHO of the launch and announced a timeline for the *Cannabis* review process (WHO, 2016c, p. 8). The report on 2 December

2020 makes no mention of the explanations of votes (CND, 2020a, 2020d), and that of the April 2021 CND session (CND, 2021a, 2021b) mentions Decision 63/17 only once and refers to it in relation to "the wider use of cannabis," without any mention to medical uses. It partially relates the discussion by mentioning only countries that opposed the vote (CND, 2021b, p. 6) but none of the voices in support (Australian Embassy in Vienna and Permanent Mission to the UN, 2021; Mission interministérielle de lutte contre les drogues et les conduites addictives, 2021; New Zealand Embassy to Austria and Permanent Mission to the United Nations, 2021; Permanent Mission of Jamaica to the United Nations – Geneva, 2021; Permanent Mission of Uruguay to the United Nations Office, Vienna, 2021; Secretaría Nacional Antidrogas, 2021; South African Embassy and Permanent Mission in Vienna, 2021a, 2021b; UNODC, 2021).

Implications

Schedule IV does not obligate countries to ban medical uses but does provide legal cover for such an exceptional policy. The placement of "cannabis and cannabis resin" in Schedule IV in 1961 was the direct heir of initial attempts for a generalised, worldwide prohibition (Economic and Social Council, 1951; Lande, 1962; Mills, 2016). In that sense, the removal of "cannabis and cannabis resin" from Schedule IV of C61, although it "will remove some international procedural barriers to research and development of cannabis-based medical products according to national regulatory frameworks" (WHO, 2020b), is, most importantly, an emblematic correction of the historical record (Bannister, 2021; FAAAT, 2020) and a reversal of WHO medical opinion now supporting the reintroduction of CCDs into the common realm of healthcare like that of many other Schedule I medications widely prescribed and used in appropriate medical settings today.

It is a ying-yang. On the one hand, a "long-heralded medicinal plant" is, again, legitimate medicine closing a 57-year parenthesis since the C61 entered into force in 1964. On the other hand, because WHO's eight other proposals were declined the world is left without the regulatory guidance scheduling usually provides for healthcare systems, physicians, pharmacists, patients or traditional healers.

However, even without a detailed international policy framework, a myriad of local "medical cannabis access" programs exist throughout the world. Under a Schedule IV regime, there were already *Cannabis* plants legally grown, processed, traded, controlled for quality, prescribed and used by patients – including in countries where the Judicial power had granted citizens the right to grow at home for self-medication. This has been possible under an approach described as "respect [for] the conventions; flexible interpretation; tolerance for national policies" (Brownfield, 2014; Bewley-Taylor, 2003; Collins, 2018).

By refusing ECDD's policy suggestions, the CND, instead of hampering the development of "medical cannabis programs" on the ground, might actually be perpetuating the model initiated in the US state of California in 1996 and followed by dozens of other jurisdictions: that of *sui generis*, locally-oriented access programs, reliant on small- and medium-scale businesses and compound botanical medicines. As WHO (2006, p. 2) explains about coca leaf, another herbal medicine now subject to the exact same control as *Cannabis*, Schedule I of the C61:

> There is no international uniform standard for regulatory evaluation of safety, efficacy and quality of medicines, particularly traditional medicines, which can be specified only by relevant national regulatory authorities. [. . .] If any plant or part of a plant, including [. . .] coca leaf, is to be used as a medicine or traditional medicine, its safety, efficacy and quality need to meet the national regulatory requirements, and only national authorities have the right to decide on the basis of national legal provisions.

Re-legitimizing *Cannabis* and its derivatives in medicine (and as medicines), whereas refusing to fully mainstream them within a uniform global pharmaceutical sector, might

represent a unique opportunity for public health authorities to experiment with adapted regulatory schemes that are more socially responsive and culturally sensible. It could contribute to needed economic revitalisation locally while preventing larger, profit-driven pharmaceutical companies from distorting public health objectives; it could also facilitate the tailoring of conservation strategies of biological diversity when endangered plant varieties or traditional medical knowledge (often linked) are at risk.

Conclusion

Beyond *Cannabis*, this paper points at *normative deficits* that have curtailed WHO's assessments (lack of a robust science-based framework for the work of the ECDD experts) and the important *democratic deficit* that the *Cannabis* scheduling process faced during subsequent CND discussions (Lohman and Barrett, 2020). The latter calls for an articulation of political voluntarism with efficient diplomacy. The former presses the need for a renewed methodological approach to the assessment of substances for international control – as urged by Danenberg *et al.* (2013) – which could benefit from proposals such as the multi-criteria decision analysis (Nutt *et al.*, 2007) in the context of an ongoing effort to follow the evidence and to understand the intricate realities of drug use. However, such a change in approach requires treaty modifications.

Indeed the fundamental bias in relation to CCDs and to other traditional herbal medicines lacking scientific assessment (coca leaf and opium poppy), which serve as a criterion for the placement of other drugs under international control (under Article 2[6], like *Cannabis*), suggests that a broader reform of the framework provided by the conventions might be the next step towards an approach responsive to cultural and social realities as well as public health and "scientific evidence-based review and scheduling of the most prevalent, persistent and harmful substances" (United Nations General Assembly, 2016, p. 15) beyond *Cannabis*. This may become even more evident as traditional herbal medicines – from coca leaf to kratom – continue to appear in ECDD meetings agendas (WHO, 2021, p. 8).

Not without difficulties, the *Cannabis* (de)scheduling process has enabled CND and WHO, for the first time since their inception in 1946, to admit to a historical mistake and take action, rely on evidence and correct it. Something that many patients (European coalition for just and effective drug policies, 2020) and health care professionals (Multidisciplinary Association for Psychedelic Studies, 2020; Spence, 2020; Vienna NGO Committee on Drugs, 2020) celebrate. Regardless of the outcome of the UN vote(s), the WHO's expert body's approval of the legitimacy of *Cannabis* medicines will enable the worldwide community of doctors, nurses and other health care professionals to herald a new era of CCDs in – and as – medicine.

Notes

1. Schedule I, main regime of the Single Convention, contains drugs considered "highly addictive and highly liable to abuse." Schedule II contains drugs "less addictive and less liable to abuse than those in Schedule I." Additionally, Schedules III and IV are *complimentary* layers: they respectively remove restrictions for "preparations [. . .] unlikely to be abused," and add restrictions to "certain drugs listed in Schedule I that are [. . .] highly liable to abuse and rarely used in medical practice" (UNODC, 2020a, pp. 8–9; also Riboulet-Zemouli *et al.*, 2018).
2. A large variety of medical uses are supported by anecdotal evidence, cultural practise, observational studies and an extensive global pharmacy-shelf history. Yet, prospective, randomised, double-blind, placebo-controlled clinical trial evidence is limited, in part due to the complex phytochemical formulation of *Cannabis* derivatives and associated methodological difficulties (National Academies of Sciences [. . .], 2017, pp. 385–389), as well as strict scheduling status representing barriers to research at several levels (Campbell, 2015, p. 191; also Cooper *et al.*, 2021, p. 115; Howard *et al.*, 2021; National Academies of Sciences [. . .], 2017, pp. 378–384). See the details of the therapeutic uses of *Cannabis* assessed by WHO in Riboulet-Zemouli *et al.* (2021, pp. 34–40) and WHO (2018c; 2018d; 2019).

3. CND is the "policymaking body of the UN with prime responsibility for drug control matters" (UN General Assembly, 2016, pp. 3, 21), and the only body with the mandate to amend the 1961 Convention's schedules.
4. WHO is the "only treaty body with a mandate to carry out medical and scientific assessment of substances" (WHO, 2018b) and the only body able to trigger changes in scheduling at the CND, on the basis of such an assessment (WHO, 2010, pp. 7–10; 2016). Decision 63/17 on "cannabis and cannabis resin" entered into force on 21 January and became definitively into force on 21 April, 90 days after the reception of the notification (UNODC, 2020a, p. 7; United Nations Secretariat, 2021).

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Corresponding author

Kenzi Riboulet-Zemouli can be contacted at: kenzi@zemou.li