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Voluntary contribution to INCB Guidelines on Medical Cannabis

– due diligence, good faith, & technical concerns.

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Ceiling of the UN Human Rights and Alliance of Civilizations Room, Geneva.
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Tables and Figures

Introduction

In March 2020, the International Narcotics Control Board (INCB) launched a **"Cannabis Initiative"** with the purpose of issuing **"guidelines/manual of good practices** on the international drug control requirements for the cultivation, manufacture and utilization **of cannabis for medical and scientific purposes"** and to "support Member States in complying with the 1961 Single Convention on Narcotic Drugs as amended by the 1972 Protocol, on requirements for cultivation, manufacture and utilization of cannabis for medical and scientific purposes."[1]

The INCB states:

> "Objective of the Guidelines:
> 1. Improve implementation of the international drug conventions
> 2. Comply with the regulatory control and monitoring requirements of the licit trade
> 3. Monitor cannabis-related activities in national settings
> 4. Meet reporting obligations in accurate and timely manner"

The development of the guidelines has flown under the radar (Chapter 5). A consultant was hired[2], and a series of stakeholders meetings[3] held, during a pandemic. The important discussions on the WHO's recommendations for changes in the scope of control of cannabis and cannabis-related substances eclipsed INCB's work in 2020. In 2021 the agenda of Member States' Vienna delegations will be centered around two major upcoming events (UN Crime Congress in March, and General Assembly special session on corruption, in April[4]).

The draft Guidelines raise a series of questions: they contain a number of issues (Chapter 6) among which an overlap the mandate of the World Health Organization (WHO) and that of State Parties (Chapters 3 & 4) they favour certain formulations against others, they disregard the latest developments in scientific research and clinical applications taking place in Member States, they ignore the hundreds of years of history of use in medicine and the particularities that this entails, compared to other medications (Chapter 2).

The drug control conventions do not operate in a vacuum: They operate within the rule of law that is framed, internationally, by the UN Charter and human rights instruments. **INCB's Guidelines on medical cannabis must acknowledge this** and invite governments to ensure full compliance with international law not only within drug control (Chapter 1).

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[1] United Nations careers. (2020). *Job Opening, Number: 20-United Nations Office on Drugs and Crime-140183-Consultant.* careers.un.org/lbw/jobdetail.aspx?id=140183&Lang=en-US
[2] *Ibid.* See also Chapter 5
[3] INCB. (2021, January 22). *INCB holds Expert Group Meeting on control and monitoring requirements of cannabis and cannabis-related substances* (UNIS/NAR/1430). www.incb.org/incb/en/news/press-releases/2021/incb-holds-expert-group-meeting-on-control-and-monitoring-requirements-of-cannabis-and-cannabis-related-substances.html
[4] UNGA. (2020, June 2). *Resolution 74/276.* www.undocs.org/en/A/RES/74/276

Inter-governmental organizations (IGOs), in performing their mandate, have the duty to **show "due diligence" with respect to the full international legal order, not just the treaty under which they are mandated**. Omission or failure to do so can mislead countries to breach their compliance with other instruments of international law, particularly those which supersede certain dispositions of drug control, such as international human rights law (IHRL).

For *Cannabis sativa*, this is true for fundamental human rights (right to health, to science, to privacy), but also for unforeseen economic, social and cultural rights (related to indigenous peoples and local communities, the environment, the trade in biological, genetic material, and plant resources, the involvement of traditional medical knowledge, etc.) (Chapter 2). **The areas of work the INCB disregards are primarily those that concern developing countries, and in particular indigenous peoples, rural, and other vulnerable communities.**

The INCB should exercise due diligence –just like it has done with regards to death penalty. **The Board should also be open to inputs from civil society and academics, and not only government officials and the largest private sector companies** –similar to the consultations organized by the INCB on a number of other subjects during the previous years.

Acronyms

Δ9-THC	delta-9-tetrahydrocannabinol
API	Active Pharmaceutical Ingredients
CBD	Convention on Biological Diversity*
CEDAW	Convention on the Elimination of All Forms of Discrimination against Women
EMCDDA	European Monitoring Center on Drugs and Drug Addiction
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
HRC	Human Rights Council
ICJ	International Court of Justice
IGO	Inter-governmental organizations
ILC	International Law Commission
IHRL	International Human Rights Law
INCB	International Narcotics Control Board
IPLC	Indigenous Peoples and Local Communities
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICERD	International Convention on the Elimination of All Forms of Racial Discrimination
OHCHR	Office of the United Nations High Commissioner for Human Rights
Plant Treaty	International Treaty on Plant Genetic Resources for Food and Agriculture
T&CM	Traditional & Complementary Medicine
UDHR	Universal Declaration of Human Rights
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples
UNDROP	United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas
UNEP	UN Environment Programme
UNGA	United Nations General Assembly
UNGASS	UNGA Special Session
UNODC	United Nations
UNPFII	United Nations Permanent Forum on Indigenous Issues
WHO	World Health Organization
WIPO	World Intellectual Property Organization

** The acronym "CBD" is not used for "cannabidiol"*

الهيئة الدولية لمراقبة المخدِّرات

"Everyone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized."

– Universal Declaration of Human Rights, Article 28.

国际麻醉品管制局

"The United Nations shall promote [...] universal respect for, and observance of, human rights and fundamental freedoms for all"

– United Nations Charter, Article 55.

ORGANE INTERNATIONAL DE CONTRÔLE DES STUPÉFIANTS

"International organizations [...] are bound by any obligations incumbent upon them under general rules of international law"

– International Court of Justice (Advisory Opinion of 20 December 1980).

МЕЖДУНАРОДНЫЙ КОМИТЕТ ПО КОНТРОЛЮ НАД НАРКОТИКАМИ

"Unnecessary suffering resulting from a lack of appropriate medication due to inaction and excessive administrative requirements is a situation that shames us all"

– International Narcotics Control Board (Preface of the 2015 'availability report').

JUNTA INTERNACIONAL DE FISCALIZACIÓN DE ESTUPEFACIENTES

1. Human rights approach: "more than an added value"

"Placing human rights at the centre of drug control"[5] is broadly recognized as a goal and task of the international community. In 2010, UNODC Executive Director commented:

> "Such an approach represents **more than 'added value'; it is a legal obligation.** [...] That the fight against drugs, crime and terrorism must conform to human rights is clear. The challenge is to **understand how these policies may be pursued in a manner that not only respects and protects human rights, but also contributes towards their positive fulfilment**."[6]

The international community is composed of a series of public stakeholders: the States - parties to the treaties, but also international or inter-governmental organisations (IGOs) as well as non-State actors which include non-governmental organizations, academia and researchers both independent and in publicly or privately supported institutes.

When seeking to pursue human rights-compliant drug policies, not only States, but also IGOs and civil society are subject to the same rule of law in the international order, lying in human rights, development, peace and security. UNODC explains:

> "The normative foundation of the United Nations' work on the rule of law is the Charter of the United Nations and the body of international law, including international human rights law [...]. **Responses to drugs, crime and terrorism that are based on the rule of law must therefore also incorporate human rights law and principles**."[7]

These norms are to be known, considered and implemented by all stakeholders. At the international level this translates into the **need to respect**, or at least not adversely impact areas of work of other IGOs, but also State obligations beyond drug control.

IGOs have legal personalities[8], and can be held accountable. Although IGOs are not *per se* parties to the human rights instruments, this does not allow them to disregard international human rights law (IHRL) in fulfilling their mandate. The International Court of Justice (ICJ) recalls that "there is nothing in the character of international organizations to justify their being considered as some form of 'super-State.' **International organizations are subjects of international law and, as such, are bound by any obligations incumbent upon them under general rules of international law**."[9] This is confirmed by the International Law Commission (ILC),[10] which clearly places **a responsibility over IGOs to ensure they do not induce or encourage a State to commit an act in violation of international law**.

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[5] UNODC. (2010). *Drug control, crime prevention and criminal justice: A Human Rights perspective. Note by the Executive Director* (E/CN.7/2010/CRP.6–E/CN.15/2010/CRP.1). unodc.org/documents/commissions/CND/CND_Sessions/CND_53/CRPs/E-CN7-2010-CRP6_V1051605_E.pdf

[6] *Ibid.* p. 3

[7] UNODC. (n.d.). *UNODC mandates and human rights foundations.* www.unodc.org/unodc/en/Human-rights/unodc-mandates---more.html

[8] ICJ. (1949). *Reparations for Injuries suffered in the Service of the United Nations, Advisory Opinion of 11 April 1949.* www.icj-cij.org/public/files/case-related/4/1837.pdf

[9] ICJ. (1980). *Interpretation of the Agreement of 25 March 1951 between the WHO and Egypt, Advisory Opinion of 20 December 1980.* www.icj-cij.org/public/files/case-related/65/065-19801220-ADV-01-00-BI.pdf

[10] In its *Articles on the responsibility of international organizations*, the ILC included a Chapter on the *"Responsibility of an international organization in connection with the act of a State or another international organization"* which, in particular in its Article 15 on the *"Direction and control exercised over the commission of an internationally wrongful act"* and Article 17. See: ILC. (2011).

Photo: Richard Burlton / unsplash

This is called ***due diligence***.[11,12] The need for due diligence within and among IGOs is an important field of study for academics[13] It has also explicitly been outlined in 2011 by UN Secretary General in its **UN Human Rights Due Diligence Policy**[14] specifically focused on peacekeeping missions. Nonetheless it offers insights for IGO's approach to *due diligence*:

> "This endeavour is congruent with the growing attention that issues of 'shared responsibility' receive today. **Traditionally, the law of international responsibility was focussed very much on the relationships between pairs of two states**—a wrongdoing state and an injured state. Whether and if so how a third state—let alone an [IGO]—would impact on the commission of a wrongful act was considered to be a marginal issue. **This is no longer the case. Especially for states and [IGOs] which proclaim in a solemn manner their attachment to ideals of the international rule of law**, it would fall significantly short of this rhetoric if they pretended that it was none of their business how their support to another actor would be used for the furtherance of wrongful conduct. **This is especially true for the UN.**"[15]

IGOs (including the INCB) have a legal responsibility to show due diligence with respect to the international legal order while performing their treaty mandates. **Omission or failure to do so –negligence– can lead States to breach compliance in other areas of international law** and/or hinder the work of other IGOs.

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[11] Interestingly, the concept of due diligence can be related to that of *bona fide* (good faith) present in the international drug control Conventions. With the difference, as we have seen, that due diligence applies also to IGOs between themselves, and with regard to States.

[12] *"Due diligence comes from Latin diligentia which can be translated as care or circumspection. The opposite of (due) diligence is negligence. [...] Diligence is a qualifier of behaviour as shown in its adverbial use: an actor can behave diligently –or negligently. Due diligence thus is no free-standing obligation but a modality attached to a duty of care for someone or something else (including the duty to prevent and mitigate harm). One might call it an ancillary obligation if one wants to use the language of obligation at all."* Peters A., Krieger H. & Kreuzer L. (2020). Due Diligence in the International Legal Order: Dissecting the Leitmotif of Current Accountability Debates. In: Krieger, H. Peters, A. & Kreuzer, L. *Due Diligence in the International Legal Order* (pp.1–19). Oxford, UK: Oxford University Press. books.google.es/books?hl=es&lr=&id=tmkLEAAAQBAJ

[13] In 2020, a new Chair on *"International Law of Institutions"* opened at the College de France, with its first course titled "Diligence and Negligence in International Law" and addressing specifically the roles and responsibilities of IGOs. See: Collège de France. (2020). *Samantha Besson, International Law of Institutions, 2020-2021 lecture "Diligence and Negligence in International Law"*. www.college-de-france.fr/site/en-samantha-besson/course-2020-2021.htm; see also Samantha Besson. (2020). Due Diligence and Extraterritorial Human Rights Obligations – Mind the Gap! *ESIL Reflections, 9,* 1. hal.archives-ouvertes.fr/hal-02918960/document

[14] United Nations Secretary-General. (2013). *Identical letters dated 25 February 2013 from the Secretary-General addressed to the President of the General Assembly and to the President of the Security Council: "Human rights due diligence policy on United Nations support to non-United Nations security forces" (A/67/775–S/2013/110).* undocs.org/en/A/67/775

[15] Helmut, P. A. (2015). The UN Human Rights Due Diligence Policy: An Effective Mechanism against Complicity of Peacekeeping Forces? *Journal of Conflict and Security Law, 20,* 1, pp.61–73.

Table 1. ***Non-exhaustive list of human rights affected by the modalities of international control over* Cannabis *for medical and scientific purposes.***

Right	*Included in:* Human Rights declarations	International legal instruments	Examples involving *Cannabis*
Right to highest standards of health	UNDRIP Art. 21, 23, 24 UNDROP Art. 4(2), 23(1)	UDHR Art. 25(1) ICESCR Art. 12 ICERD Art. 5(e)(iv)	Lack of access and availability besides ease of cultivation
Right to traditional medicines	UNDRIP Art. 24 UNDROP Art. 23(2)	ICCPR Art. 1, 47 ICESCR Art. 1(2), 11, 15, 25 ICERD Art. 5(e) CBD Art. 8(j), 10, 15 Plant Treaty Art. 9	Access to medicinal plant based products restricted Biopiracy Undue appropriation of traditional medical knowledge, or agricultural know-hows
Right to seeds, plants and genetic resources	UNDRIP Art. 31 UNDROP Art. 19		
Right to prior and informed consent	UNDRIP Art. 11, 19, 28, 29		
Rights to natural and cultural heritage	UNDRIP Art. 8, 11, 29, 31 UNDROP Art. 5, 18, 26		
Right to benefit from science	UNDROP Art. 2(6)(c), 25	ICESCR Art. 15	Findings about medical applications not reflected in broader patient access Research hampered by strict treaty controls
Right to privacy	American Convention on Human Rights Art. 11 Arab Charter on Human Rights Art. 16, 21, 31 ASEAN Human Rights Declaration Art. 21 European Convention on Human Rights Art. 8	UDHR Art. 12 ICCPR Art. 17	Interference with self medication and home cultivation Invasion of private property and consensual transactions
Right to participation in policy-making	UNDRIP Art. 18, 23 UNDROP Art. 2(3), 10, 11, 15(4) Sustainable Development Agenda, Goal 17	UDHR Art. 21 ICCPR Art. 25 ICESCR Art. 8 ICEAR Art. 5(c) CEDAW Art. 7, 8	Only large companies are consulted, and not peasants, IPLC, patients or healthcare workers

Table 1. *Continued.*

Right	*Included in:* Human Rights declarations	International legal instruments	Examples involving *Cannabis*
Right to non-discrimination	UNDRIP Art. 2, 46(3) UNDROP Art. 4 UN Declaration on the Right to Development Art. 6 Sustainable Development Agenda Goal 10	ICCPR Art. 2(1), 26 ICESCR Art. 2(2) ICEAR Arts. 2, 5 CEDAW Art. 2	Persistence of colonial policy and practice w.r.t. pre-colonial plants, products & practices. Access to legal schemes not possible for small stakeholders
Right of religion and belief	UNDRIP Art. 11, 12, 24, 35 UNDROP Art. 8	UDHR Art. 18 ICCPR Art. 18 ICERD Art. 5(d)(vii)	Rastafari (Caribbean), Sadhus (Himalayas), etc.

Scholars[16,17] and IGOs themselves,[18,19] including the INCB[20] agree that an enforcement of international drug control requirements without consideration of other aspects of IHRL can lead to breaches. When considering the cultivation, trade and use of *Cannabis sativa* L. for medical and scientific purposes for its Guidelines **it is quintessentially important for the INCB to consider the package of IHRL that relate to health, well-being and access to medicine and health services.**[21]

It is also important to consider that *Cannabis sativa* is **a plant with environmental, biodiversity, traditional, cultural, and indigenous ties** –all elements constitutive of relevant IHRL dispositions on their own (see Table 1).

Although the role of the INCB is not to comprehensively assess and balance the international obligations of States with regards to *Cannabis*, **the Board should exercise due diligence to ensure, at least, that its Guidelines do not support States in, or promote them to ignore or breach other dispositions of international law that can supercede drug control.**

[16] Piet Hein van Kempen and Masha Fedorova. (2016). *International law and cannabis II. Regulation of cannabis cultivation and trade for recreational use: positive human rights obligations versus UN Narcotic Drugs Conventions [Executive summary]*. Nijmegen: Radboud University. www.ru.nl/publish/pages/797876/internationaal_recht_en_cannabis_ii_-_english_summary.pdf
[17] Piet Hein van Kempen and Masha Fedorova. (2016). *Internationaal recht en cannabis II: Regulering van cannabisteelt en-handel voor recreatief gebruik: positieve mensenrechtenverplichtingen versus VN-drugsverdragen.* Alphen aan den Rijn: Wolters Kluwer. www.ru.nl/publish/pages/797876/internationaal_recht_en_cannabis_ii.pdf
[18] United Nations Development Programme. (2019).
[19] UNODC. (2012). *UNODC and the promotion and protection of human rights; position paper.* unodc.org/documents/justice-and-prison-reform/UNODC_Human_rights_position_paper_2012.pdf
[20] *"There are a number of unintended consequences that can flow from a variety of factors, including the unbalanced implementation of national and international drug control measures."* §38 in INCB. (2016). *Report of the International Narcotics Control Board for 2015* (E/INCB/2015/1).
[21] *See for instance:* OHCHR. (2021). *Claiming Human Rights > Definitions of the right to health* [online]. www.claiminghumanrights.org/health_definition.html

On *Cannabis* and drug policies, the Committee on Economic, Social and Cultural Rights (CESCR) recently provided insights about *Cannabis*,[22] recalling that:

> "given the potential health benefits of these controlled substances, the [drug control] restrictions should also be weighed up in relation to States parties' obligations under article 12 of the Covenant [on Economic, Social and Cultural Rights]."

The CESCR also clarifies the dynamic nature of the "precautionary principle" noting that:

> "The precautionary principle should not hinder and prevent scientific progress, which is beneficial for humanity. Nonetheless, it should be able to address available risks for human health and the environment, inter alia. Thus, in controversial cases, participation and transparency become crucial because the risks and potential of some technical advances or some scientific research should be made public in order to enable society, through informed, transparent and participatory public deliberation, to decide whether or not the risks are acceptable."[23]

These elements should be kept in mind while discussing matters pertaining to the intersection of *Cannabis* control with economic, social and cultural rights.

2. UN-system human rights due diligence and *Cannabis*, in practice

INCB seems to be developing its Guidelines in a vacuum –contrary to UNODC's Human Rights recommendations.[24] This could therefore lead States to, if not direct them towards, breaching their obligations under IHRL. **There are many human rights that can be hindered by wrongful or poorly advised drug control policies** (non-exhaustive list in Table 1).[25]

In the case of **the millenia-old medicinal plant *Cannabis sativa***, a series of supplementary rights are at stake –individual, collective, and nation-wide rights. The most specific and emblematic case is possibly that of indigenous peoples, who have been using *Cannabis* as part of their traditional pharmacopoeia –as **the INCB recognized two decades ago: "Cannabis has been used in traditional medicine in some countries for centuries."**[26]

INCB should exercise due diligence with regards to a number of areas of international law that correlate directly to the international trade in *Cannabis* for medical and scientific purposes. UNODC suggests to assess IGOs' programs in liaison with the Office of the High

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[22] See § 68, in: CESCR. (2020). *General comment No. 25 (2020) on science and economic, social and cultural rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights).* undocs.org/E/C.12/GC/25

[23] *Ibid.* § 57.

[24] *"No treaty, however special its subject-matter, applies in a normative vacuum, as both general international law (including customary international law) and particular concurrent international obligations affect its interpretation and application"* See §9 in: UNODC. (2010). *"Whilst the maintenance of effective working relationships with government counterparts is important, technical assistance cannot be delivered in a vacuum that is divorced from the wider human rights and rule of law context. Protection of human rights need not involve public denunciation of abuses. Rather, through constructive and open dialogue with government counterparts, human rights protection may be achieved alongside the delivery of technical assistance.* ***Indeed, effective support for the rule of law requires both the willingness to partner and the willingness to be clear and bold on international human rights law and standards. From a practical perspective, human rights protection issues are most usually to be addressed in coordination with OHCHR and the UN Resident Coordinator system****."* in: UNODC. (2012).

[25] United Nations Development Programme. (2019). *International Guidelines on Human Rights and Drug Policy.* www.humanrights-drugpolicy.org

[26] See §208, p.34, *in*: INCB. (2002). *Report of the International Narcotics Control Board for 2001* (E/INCB/2001/1). www.incb.org/documents/Publications/AnnualReports/AR2001/AR_01_English.pdf

Commissioner for Human Rights (OHCHR),[27] but the INCB should also seek insights from a number of other IGOs dealing with the issues at stake (see Table 2 below).

Table 2. ***International entities with a mandate related to*** **Cannabis** ***for medical purposes***

	Office of the United Nations High Commissioner for Human Rights – OHCHR *(Geneva, Switzerland)*	
	United Nations Human Rights Bodies including: *Charter-based* (**Human Rights Council**) *Treaty-based* (**Committee on Economic, Social and Cultural Rights**) *Other* (**Expert Mechanism on the Rights of Indigenous Peoples**)	*International Human Rights Law*
	Secretariat of the **United Nations Permanent Forum on Indigenous Issues – UNPFII** *(New York, United States of America)*	
	Secretariat of the **Convention on Biological Diversity – CBD** *(Montreal, Canada)*	*Convention on Biological Diversity* *Nagoya Protocol*
	United Nations Environment Programme – UNEP *(Nairobi, Kenya)*	
	Food and Agriculture Organization of the United Nations – FAO *(Rome, Italy)*	*International Treaty on Plant Genetic Resources for Food and Agriculture*
	Essential medicines and health products section (EMP) of the **World Health Organization – WHO** *(Geneva, Switzerland)*	
	Traditional and Complementary Medicine (T&CM) unit of the **World Health Organization – WHO** *(Geneva, Switzerland)*	*Intellectual Property agreements related to traditional medicine, traditional knowledge and cultural expressions*
	Traditional Knowledge unit of the **World Intellectual Property Organization – WIPO** *(Geneva, Switzerland)*	

[27] UNODC. (2012).

2.1. *Human rights, the environment, and biological diversity*

As early as 1972, the Stockholm Declaration linked the environment to human rights:

> "The protection and improvement of the human environment is a major issue which affects the well-being of peoples and economic development throughout the world [...]. Both aspects of [human]'s environment, the natural and the [human]-made, are **essential to his well-being and to the enjoyment of basic human rights** –even the right to life itself."[28]

The human rights obligations (including non-discrimination obligations) relating to "the enjoyment of a safe, clean, healthy and sustainable environment," have been addressed by the Human Rights Council (HRC) on several occasions.[29,30] Resolution 37/8 recognizes that:

> "unsustainable management and use of natural resources, [...] loss of biodiversity and the decline in services provided by ecosystems may interfere with the enjoyment of a safe, clean, healthy and sustainable environment, and that environmental damage can have negative **implications, both direct and indirect, for the effective enjoyment of all human rights**"[31]

A series of normative instruments relevant to *Cannabis* appeared after the 1992 Rio Earth Conference, strengthening this approach, in particular in what relates to biodiversity. The **Convention on Biological Diversity** and its **Nagoya Protocol on Access and Benefit-sharing of genetic resources** (respectively 193 and 129 States Parties as of February 2021) are good examples of international dispositions on environmental rights directly related to *Cannabis*.

The World Intellectual Property Organization (WIPO) recalls that "traditional medical knowledge, such as the medicinal use of herbs, is often associated with genetic resources [...] subject to access and benefit-sharing regulations under international agreements."[32] In addition, "some genetic resources are linked to traditional knowledge and traditional practices **through their use and conservation by indigenous peoples and local communities, often over generations**."[33]

In this respect, another relevant instrument is FAO's **International Treaty on Plant Genetic Resources for Food and Agriculture** (or "Plant Treaty," 148 State Parties early 2021) that recognizes "farmers' rights."[34] **Local communities, farmers, peasants, and indigenous peoples have used, conserved, bred, maintained, and preserved the biological diversity of *Cannabis* plants within local ecosystems, over generations. This entails rights**: not only to continue preservation but also to moral recognition and to avoid misappropriation of genetic

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[28] UN. (1973). *Report of the United Nations Conference on the Human Environment, Stockholm, 5-16 June 1972.* undocs.org/en/A/CONF.48/14/Rev.1

[29] See resolutions 7/23, 10/4, 16/11, 18/22, 19/10, 28/11, 31/8, 34/20, 37/8, 40/11 (non-exhaustive).

[30] Former Special Rapporteur John Knox expressed more clearly that "the full enjoyment of human rights [...] depends on biodiversity, and the degradation and loss of biodiversity undermine the ability of human beings to enjoy their human rights." See: Human Rights Council. (2017). *Report of the Special Rapporteur on the issue of human rights obligations relating to the enjoyment of a safe, clean, healthy and sustainable environment* (A/HRC/34/49). undocs.org/A/HRC/34/49

[31] UN Human Rights Council. (2018). *Human rights and the environment : resolution adopted by the Human Rights Council on 22 March 2018 at its 37th session (A/HRC/RES/37/8).* ap.ohchr.org/documents/dpage_e.aspx?si=A/HRC/RES/37/8

[32] WIPO. (2015a). *Intellectual Property and Traditional Medical Knowledge (Background Brief No. 6).* www.wipo.int/edocs/pubdocs/en/wipo_pub_tk_6.pdf

[33] WIPO. (2019). *Intellectual Property and Genetic Resources (Background Brief No. 10).* www.wipo.int/edocs/pubdocs/en/wipo_pub_tk_10.pdf

[34] The Treaty's Article 9 recognizes *"the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world."* Food and Agriculture Organization of the UN. (2009). *International Treaty on Plant Genetic Resources for Food and Agriculture.* www.fao.org/3/a-i0510e.pdf

resources protected by and for these communities. This also entails protection from drug control-led eradication programmes.[35]

The Nagoya Protocol includes in its Article 4(3) a call for due diligence, stating that the Protocol "shall be implemented in a **mutually supportive manner with other international instruments**," and calling on IGOs to be "supportive of and do not run counter to the objectives of the Convention and this Protocol."[36]

Plant Treaty and Nagoya Protocol echoe the **World Summit outcome** (General Assembly Resolution 60/1)[37] which called "upon all parts of the United Nations to promote human rights and fundamental freedoms in accordance with their mandates" (§119), supporting "the further **mainstreaming of human rights throughout the United Nations system**" (§126), while "recognizing the need for more efficient environmental activities in the United Nations system, with enhanced coordination, improved policy advice and guidance, [...] better treaty compliance, while respecting the legal autonomy of the treaties" to support a **"stronger system-wide coherence"** (§169).

2.2. *Human rights of indigenous peoples, peasants, and rural communities*

The call for due diligence with regards to human rights contained in the World Summit outcome was reinforced by a mandate to "make **progress in the advancement of the human rights of the world's indigenous peoples** at the local, national, regional and international levels, including through consultation and collaboration with them"[38] (§127).

The **UN Declaration on the Rights of Indigenous People** (UNDRIP) lays out "the minimum standards for the survival, dignity and well-being of the indigenous peoples of the world"[39] (Article 43) and declares that indigenous peoples have, among others:

- the **right to their traditional medicines** and to maintain their health practices, including the conservation of their vital medicinal plants (Art. 24);
- the right not to be subjected to forced **assimilation or destruction of their culture** (Art. 8);
- the right to be actively involved in developing and determining health, housing and other economic and social programmes affecting them and, as far as possible, to administer such programmes through their own institutions (Art. 23);
- the **right to maintain, control, protect and develop** their cultural heritage, traditional knowledge and cultural expressions, and the manifestations of their sciences, technologies and cultures (including **genetic resources, seeds, medicines, knowledge of the properties of fauna and flora**, oral traditions, literatures) and to maintain, control, protect and develop intellectual property over their heritage (Art. 31).

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[35] See also the concerns of the Committee on Economic, Social and Cultural Rights about the use of "aerial spraying of cannabis crops to control the illicit cultivation of cannabis" in CESCE. (2018). *Concluding observations on the initial report of South Africa.* https://undocs.org/E/C.12/ZAF/CO/1

[36] Secretariat of the Convention on Biological Diversity. (2011). *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity : text and annex.* Montreal: Secretariat of the Convention on Biological Diversity. www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

[37] UNGA. (2005). *Resolution 60/1.* undocs.org/A/RES/60/1

[38] *ibid.*

[39] UNGA. (2007, September 13). *Resolution 61/295, United Nations Declaration on the Rights of Indigenous Peoples.* undocs.org/en/A/RES/61/295

The eradication or discontinuation of traditional cultivation and/or medical uses of *Cannabis* –caused by prohibition itself– does not negate the right of indigenous peoples to "practise and revitalize" their cultures, traditions, and customs (Art. 11): this "includes the right to maintain, protect and develop the past, present and future manifestations of their cultures." Interestingly, the **due diligence of IGOs and the UN system is directly called for in UNDRIP**'s Article 41:

> "organs and specialized agencies of the United Nations system and other intergovernmental organizations shall contribute to the full realization of the provisions of this Declaration"

Indigenous peoples and local communities (IPLC) have played an indispensable role in preserving *Cannabis* plant biodiversity over generations. **Without them, in 2021, humans may not be able to explore the hundreds of cultivars** and the different ratios and contents in "diverse phytochemicals in cannabis, including both minor cannabinoids and terpenes," that the US National Institutes of Health say "have shown promise."[40]

Like the UNDRIP suggests, in addition to environmental specificities, INCB Guidelines ought to pay attention to the **IPLC's traditional cultures and knowledge associated with the *Cannabis* plant**, which are often a set of medical skills, practices and know-hows derived from the collective guardianship and conservation of traditional knowledge. Contemporary *Cannabis* medicines are derived from if not built upon this corpus of traditional medical knowledge, which entails intellectual property rights on its own also mapped by a series of international, regional, and other *sui generis* systems.[41,42]

The Nagoya Protocol insists on the "**interrelationship between genetic resources and traditional knowledge, their inseparable nature for indigenous and local communities**" in relation with "the importance of the traditional knowledge for the conservation of biological diversity and the sustainable use of its components, and for the sustainable livelihoods of these communities."

In the case of medicines, the *Global strategy and plan of action on public health, innovation and intellectual property*[43] is a major guideline to diligently address any policy related to access to medicines integrating intellectual property components. The current global strategy of WHO for Traditional and Complementary Medicine confirms that:

> "As T&CM becomes more popular, it is important to balance the need to protect the intellectual property rights of indigenous peoples and local communities and their health care heritage while ensuring access to T&CM and fostering research, development and innovation. Any actions should follow the global strategy and plan of action on public health, innovation and intellectual property."[44]

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[40] National Institutes of Health. (2019). *NIH to investigate minor cannabinoids and terpenes for potential pain-relieving properties* [online]. www.nih.gov/news-events/news-releases/nih-investigate-minor-cannabinoids-terpenes-potential-pain-relieving-properties

[41] WIPO. (2015a).

[42] WIPO. (2015b). *Traditional Knowledge and Intellectual Property (Background Brief No. 1).* www.wipo.int/edocs/pubdocs/en/wipo_pub_tk_1.pdf

[43] WHO. (2011). *Global strategy and plan of action on public health, innovation and intellectual property.* www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf

[44] WHO. (2013). *WHO traditional medicine strategy: 2014-2023.* who.int/medicines/publications/traditional/trm_strategy14_23/en

Cannabis plants in front of Dhaulagiri summit, Nepal.
Photo: Arne Hückelheim / Wikimedia.

Analysing its duties and responsibilities with regards to IHRL, in 2012, UNODC found that:

> "A human rights based approach implies a **conscious and systematic integration of human rights** and human rights principles **in all aspects of programming work**. In particular, a human rights based approach should include a focus in programming on the promotion of **equality and nondiscrimination**, ensuring the participation and inclusion of **disadvantaged groups**, and **strengthening of state accountability** concerning its human rights obligations."[45]

And indeed, beyond indigenous peoples, specially covered by the UNDRIP, other local, rural, but also disadvantaged and marginalized communities have similar ties with the *Cannabis* plant as those of indigenous peoples. These communities are well defined[46] in the **Declaration on the Rights Of Peasants and other people working in rural areas** (UNDROP)[47] adopted in 2018 which recalls in its preamble the right of peoples to exercise "full and complete sovereignty over all their natural wealth and resources." The UNDROP recalls the centrality of human rights in its Article 2(4), and, in its Article 27, echoes UNDRIP's Article 41 by calling on UN system entities and IGOs to contribute to its full realization:

> "Ways and means of **ensuring the participation of peasants and other people working in rural areas on issues affecting them** shall be considered. The United Nations [...] and other intergovernmental organizations [...] shall promote respect for and the full application of the present Declaration and follow up on its effectiveness."

UNDRIP and UNDROP do not create new rights: they explain how fundamental rights included in the core IHRL instruments unfold for these specific populations.[48]

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[45] UNODC. (2012).
[46] A "peasant" is defined as a "person who engages, alone, or in association with others or as a community, in small-scale agricultural production for subsistence and/or for the market, and who relies significantly, though not necessarily exclusively, on family or household labour and other non-monetized ways of organizing labour, and who has a special dependency on and attachment to the land"
[47] UNGA. (2018, December 17). *Resolution 73/165, United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas.* undocs.org/en/A/RES/73/165
[48] As UNPFII explains: "UN Declarations are generally not legally binding; however, they represent the dynamic development of international legal norms and reflect the commitment of states to move in certain directions, abiding by certain principles." See: www.un.org/esa/socdev/unpfii/documents/FAQsindigenousdeclaration.pdf

2.3. INCB and T&CM: an amnesia

Back in 2001, the INCB acknowledged *Cannabis* as a traditional medicine.[49] In its report for 2003[50] and for 2014,[51] the Board addressed "the use of cannabis for medical purposes."

Nonetheless, **more recently, the INCB has stopped referring to "cannabis"** for medical purposes, **preferring the terms** "therapeutic use of cannabinoids"[52] and **"medicinal cannabinoids,"**[53] The bias against herbal and traditional medicines became clear in the report for 2018,[54] where INCB chose to refer "only to cannabinoids that have been extracted from the plant or synthesized" (§4) and declared (§14), with no supporting argument:

> **"attempts to market and promote the medical use of cannabis products as 'herbal medicines' are inconsistent with the classification of cannabis and its derivatives under the 1961 and 1971 Conventions"**

The 2021 draft Guidelines **refers to cannabis medicines as "novel" medicines** [15 February draft, p.11]. But Sativex (commercialized since 2010, UK), delta-9-THC (since 2008, Austria; since 1986, USA), Canasol (since 1987, Jamaica), Bedrocan (since 2003, Netherlands) or Sarpagandha Ghan Vati (ayurveda formulation currently commercialized in India, known for several hundreds years), are all but novel. INCB members should know this.

It is not impossible for INCB to express a preference for certain types of preparations (even if it is doubtful that it is part of their mandate). Yet, they should not do so by ignoring or disqualifying the mere existence of *Cannabis* botanical formulations. Among many surprising statements in the report for 2018, the INCB explains (§21):

> "A large variety of preparations containing cannabinoids are used in various regions of the world to provide different dosage forms and concentrations of active and psychoactive ingredients by different routes of administration. They are used in the belief that they will alleviate a wide range of symptoms, often in the absence of high-quality evidence that they are safe and effective. In many cases, it is unclear what cannabinoids these products contain (active principles and dosage), what the best route of administration is or what their adverse side effects may be."

This kind of statement is surprising, since it seems to **correspond to the definition of "traditional medicine" provided by the WHO**:

> "the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness"[55]

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[49] See §208, in: INCB. (2002).
[50] See p. 24 in: INCB. (2004). *Report of the International Narcotics Control Board for 2003* (E/INCB/2003/1). www.incb.org/documents/Publications/AnnualReports/AR2003/AR_03_English.pdf
[51] See pp. 35–36 in: INCB. (2015).
[52] See pp. 49-50 in: INCB. (2018). *Report of the International Narcotics Control Board for 2017* (E/INCB/2017/1).
[53] INCB. (2019). *Report of the International Narcotics Control Board for 2018* (E/INCB/2018/1). www.incb.org/documents/Publications/AnnualReports/AR2018/Annual_Report/Annual_Report_2018_E_.pdf
[54] *ibid.*
[55] WHO. (2013).

The European Monitoring Center on Drugs and Drug Addiction (EMCDDA) rightly notes in this regard:

> "The preference among some patients for **the medical use of herbal preparations of the whole cannabis plant** rather than pharmaceutical products **has strong similarities to the reasons people give for using traditional herbal medicines**."[56]

INCB's bias is reflected in the **draft Guidelines, which introduce an artificial distinction between formulations**: the draft has been developed on the basis that "cannabis and cannabis resin [...] are described as raw materials" [15 February draft, p.6] while "Cannabis extracts and tinctures [...] are described as Active Pharmaceutical Ingredients (API)" [p.7]. It is only suggested that "in some circumstances, cannabis is also considered an API when it is directly administered for medical purposes" [p.7].

However, this notion is not present in the Conventions where, like in real life, **"cannabis" and "cannabis resin" are both a starting material and an API** –not only "in some circumstances."

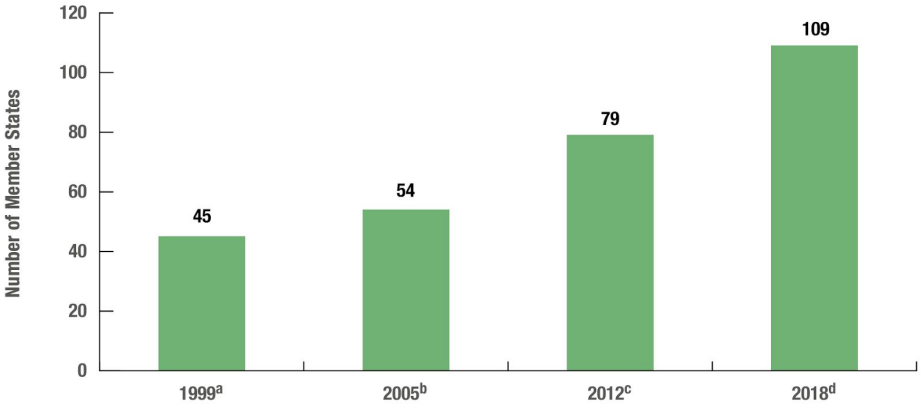
The draft also insists on the need for "cannabis" herbal material to be comminuted (*i.e.* cut, powdered, or granulated) although no such requirement exists in the Convention.

The drug control Conventions do not restrict their scope to certain formulations of *Cannabis*. To the contrary: there is a voluntarily broad definition of medical practice. The Commentary[57] on the Single Convention (p. 111) mentions that "the term 'medical purposes' has not been uniformly interpreted by Governments" and specifies that "medicine":

> "does not necessarily have exactly the same meaning at all time and under all circumstances. Its interpretation must depend on the stage of medical science at the particular time in question; and not only modern medicine, sometimes also referred to as 'western medicine', but also legitimate systems of indigenous medicine such as those which exist in China, India and Pakistan, may be taken into account in this connexion."

Far from being *ancient* or *something of the past*, T&CM are increasingly incorporated into national health systems and regulations, as shown in the figures below.

[56] EMCDDA. (2018). *Medical use of cannabis and cannabinoids: Questions and answers for policymaking.* www.emcdda.europa.eu/system/files/publications/10171/20185584_TD0618186ENN_PDF.pdf
[57] UN. (1973). *Commentary on the Single Convention on Narcotic Drugs, 1961.*



Sources:

[a] WHO Traditional Medicine Strategy 2002–2005.

[b] National policy on traditiona-l medicine and regulation of herbal medicines – Report of a WHO global survey (N=141).

[c] Includes Member States who 1) responded "Yes" to the second survey on T&CM, and 2) responded "Yes" to the first survey but did not respond to the second survey (N=170; i.e. 141 +29, the 29 being respondents exclusive to the second survey).

[d] Includes 1) 2012 data and 2) additional Member States who responded "Yes" to the update survey, but either replied "No" or did not reply to the first and second surveys or responded "Yes" through additional data sources (e.g. regional reports and data verification during 2016–2018).

Figure 1. ***Growth in the number of Member States with national or state level laws or regulations for T&CM, 1999–2018.***

Source: *WHO, 2019 (p.18).*[58]

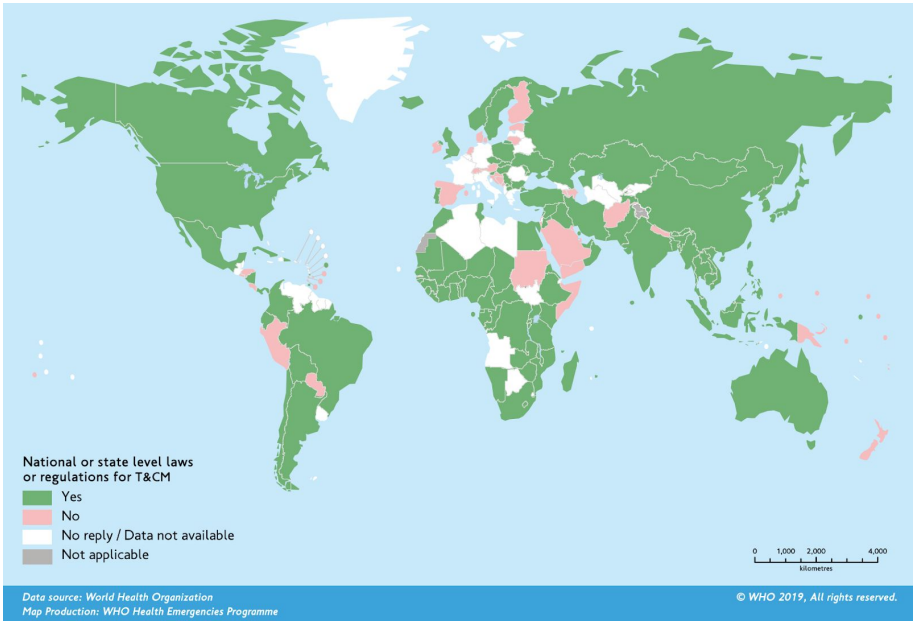


Figure 2. ***WHO Member States with national or state level laws or regulations for T&CM, 2018.***

Source: *WHO, 2019 (p.19).*[59]

[58] WHO. (2019). *WHO global report on traditional and complementary medicine 2019.* www.who.int/traditional-complementary-integrative-medicine/WhoGlobalReportOnTraditionalAndComplementaryMedicine2019.pdf

[59] *ibid.*

2.4. Freedom of religion and belief

There are also concerns regarding the need for INCB to balance drug control with human rights particularly towards the **well-established religious and spiritual uses of the *Cannabis* plant** throughout the world –most famously by Sadhus in the Himalayan region, or people of Rastafarian faith in the Caribbean and among the Caribbean diaspora.

Frontally attacking the **freedom of religion and belief** of people of Rastafari belief, the Board stated that "regulatory developments in Jamaica are not in accordance with the 1961 Convention, which limits the use of cannabis to medical and scientific purposes,"[60] and encouraged Jamaican authorities to revisit the piece of legislation allowing for the use of *Cannabis* products by rastafari peoples.[61]

The World Summit outcome (§119) called "upon all parts of the United Nations to promote human rights and fundamental freedoms" –including freedom of religion and belief[62]– and recalled (§130) that "the promotion and protection of the rights of persons belonging to national or ethnic, religious and linguistic minorities **contribute to political and social stability and peace and enrich the cultural diversity and heritage of society**."[63]

3. Home cultivation and self-medication

The Board "repeatedly stated that personal cultivation of cannabis for medical purposes is inconsistent with the 1961 Convention as amended because, inter alia, it heightens the risk of diversion."[64] The arguments of the Board are that:

> "Personal cultivation of cannabis to be used for medical purposes does not allow Governments to exercise the supervision required by the 1961 Convention over the production, manufacture, export, import and distribution of, trade in and use and possession of cannabis, the establishment of estimates of medical usage, the furnishing of related statistical returns or the implementation of the provisions of article 28 of that Convention. In addition to the risks of diversion, allowing private individuals to cultivate cannabis for personal medical consumption may present additional health risks, in that the dosages and levels of THC consumed may be different from those medically prescribed. The production of very high THC concentrates and extracts for 'medical use' heightens the Board's concerns about the risks of diversion for non-medical use."[65]

This opposition of the Board to activities that relate to privacy is significative of the **tendency to "overemphasise the importance of preventing non-medical use, while not paying attention**

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[60] INCB. (2017). *Report of the International Narcotics Control Board for 2016* (E/INCB/2016/1). www.incb.org/documents/Publications/AnnualReports/AR2016/English/AR2016_E_ebook.pdf
[61] Klein, Axel, and Hanson, Vicki J. (2020). *Ganja Licensing in Jamaica: Learning lessons and setting standards.* http://iccresearch.org/sites/default/files/Ganja%20Licensing%20in%20Jamaica%20-%20April2020.pdf
[62] *"Freedom of religion or belief is guaranteed by article 18 of the Universal Declaration of Human Rights, article 18 of the International Covenant on Civil and Political Rights and the Declaration on the Elimination of All Forms of Intolerance and of Discrimination Based on Religion or Belief"* see: www.ohchr.org/en/issues/freedomreligion/pages/standards.aspx
[63] UNGA. (2005).
[64] See § 12 in: INCB. (2019).
[65] See § 12 in: INCB. (2019).

to the importance of medical use" in a context where "the burden of disease from pain is at least 37 times larger than the burden of disease from substance use disorder."[66]

It should not be within the prerogative of INCB to comment on, and even less condemn, personal, home-bound private activities such as the cultivation of *Cannabis* for one's personal medical use. Worth noting, this right might extend to self medication, as Jessica Flanigan explains in *Pharmaceutical Freedom: Why Patients Have a Right to Self-Medicate* published at Oxford University in 2017.[67]

In case the Board wishes to express an opinion on activities that relate to the private sphere it should diligently explain the existence of conflicting obligations and **propose alternative solutions short of a prohibition of these activities.**

This is particularly true since **there are "flexibilities in the UN drug control conventions** to decriminalise the possession, purchase, or cultivation of controlled substances for personal consumption."[68] And it became even clearer after a series of groundbreaking cases in the highest courts of South Africa,[69] Georgia,[70] Mexico,[71] and Italy[72,73] which confirmed that "under international law, States must give priority to their human rights obligations over and above any conflicting obligations under the UN Drugs Conventions."[74] The EMCDDA issued a press release on "Cannabis control and the right to privacy,"[75] explaining:

> "In 2018 the highest courts in countries across three continents have asserted that state intervention in the private life of their citizens who wish to (grow and) use cannabis is not always justified. [...]
>
> The Georgian court noted the increasing application of human rights law in modern legal standards, and the South African court ruled that such state interference is not justified 'in open and democratic societies'.
>
> In the **1988 UN Convention against trafficking, Article 3(2) states that a country should criminalise possession and cultivation for personal use 'subject to its constitutional principles'.** The court in Mexico stated that it upheld the constitutional principle of free development of personality and considered it was still in line with the Convention."

Most State Parties include the right to privacy among their "constitutional principles," also present, inter alia, in Article 12 of the Universal Declaration on Human Rights and Article 17 of the International Covenant on Civil and Political Rights, as well as a number of regional instruments (see Table 1). **Due diligence would be welcome, in this domain too.**

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[66] Scholten, W. (2020). Access to Controlled Medications: Barriers, Measuring Adequacy of Consumption, and Current Developments. *Journal of Illicit Economies and Development.* jied.lse.ac.uk/articles/10.31389/jied.59
[67] See also: Roberts. (2020). *How to Regulate the Right to Self-Medicate.* doi.org/10.1007/s10730-020-09415-7
[68] p. 14 in: United Nations Development Programme. (2019).
[69] Constitutional Court of South Africa. (2018). *Case CCT 108/17*. www.saflii.org.za/za/cases/ZACC/2018/30.pdf
[70] Constitutional Court of Georgia. (2018). *Judgement №1/3/1282 dated July 30, 2018 on the case of "Citizens of Georgia – Zurab Japaridze and Vakhtang Megrelishvili v. the Parliament of Georgia"* www.constcourt.ge/uploads/documents/5e6111b70798e.pdf and www.constcourt.ge/en/judicial-acts?legal=1949
[71] Suprema Corte de Justicia de la Nación. (2018). *Comunicado de prensa: Reitera primera sala inconstitucionalidad de la prohibición absoluta del consumo recreativo de marihuana e integra jurisprudencia.* www.internet2.scjn.gob.mx/red2/comunicados/noticia.asp?id=5785
[72] Corte Cassazione Penale, Sezioni Unite. (2019). *Informazione Provvisoria n. 27.* www.giurisprudenzapenale.com/2019/12/27/la-decisione-delle-sezioni-unite-sulla-rilevanza-penale-della-coltivazione-modiche-quantita-cannabis-informazione-provvisoria/
[73] The New York Times. (2019). *Growing a Little Marijuana at Home Is Not a Crime, Italy's Top Court Says.* www.nytimes.com/2019/12/27/world/europe/italy-marijuana-growing-cannabis.html
[74] Piet Hein van Kempen and Masha Fedorova. (2016).
[75] EMCDDA. (2019). *Press release: Cannabis control and the right to privacy.* www.emcdda.europa.eu/news/2019/cannabis-control-and-the-right-to-privacy_en

4. Cannabidiol: from stance to insistence

The phytocannabinoid compound cannabidiol[76] is a molecule which was not, is not, and will not be listed *per se* in the Schedules of the international drug control Conventions. Since **drugs under international control are defined as the substances being listed in the Schedules**, cannabidiol should not be considered internationally controlled. Indeed, some governments consider cannabidiol this way, and do not require narcotic or psychotropic drug control requirements for this substance.

This should be clearly explained to State Parties by the **INCB, whose role is only to monitor substances listed in the Schedules**.

Nonetheless, it is true that cannabidiol products are complex. Some governments are concerned that these products are not always composed only of the "pure" cannabidiol molecule, and can also contain minor amounts of Δ^9-THC, which is a controlled substance (listed in the Schedules). This leads these governments to consider cannabidiol products under control, because of their trace-amounts of Δ^9-THC.

Other governments may consider cannabidiol products under control, viewing it as "cannabis resin," a substance which is also *per se* under international control (listed in the Schedules).

For instance, European Union (EU) Member States follow a recent judgment of the EU Court of Justice which "concluded that **cannabidiol is not a 'drug' within the meaning of the United Nations Single Convention** on Narcotic Drugs"[77] and the United States have declared that "it is not our position that cannabidiol should be or is under the control of the international drug conventions."[78]

There are broad divergences.

In addition to these diverging views about the substance itself, actual cannabidiol products are produced, marketed, and **used for a series of different motives and purposes**. Not all of these purposes can be assimilated to medical uses. This leads some governments to consider that cannabidiol products are "industrial hemp" products, therefore exempt from international drug control requirements.[79,80]

Figure 3, next page, shows how a cannabidiol product might be viewed as falling under international control, or not, depending on the particular interpretation adopted. The red dots indicate the opportunities to choose different interpretations.

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[76] Note: in this document, the acronym "CBD" is only used to refer to the "Convention on Biological Diversity," and not to refer to the molecule "cannabidiol"

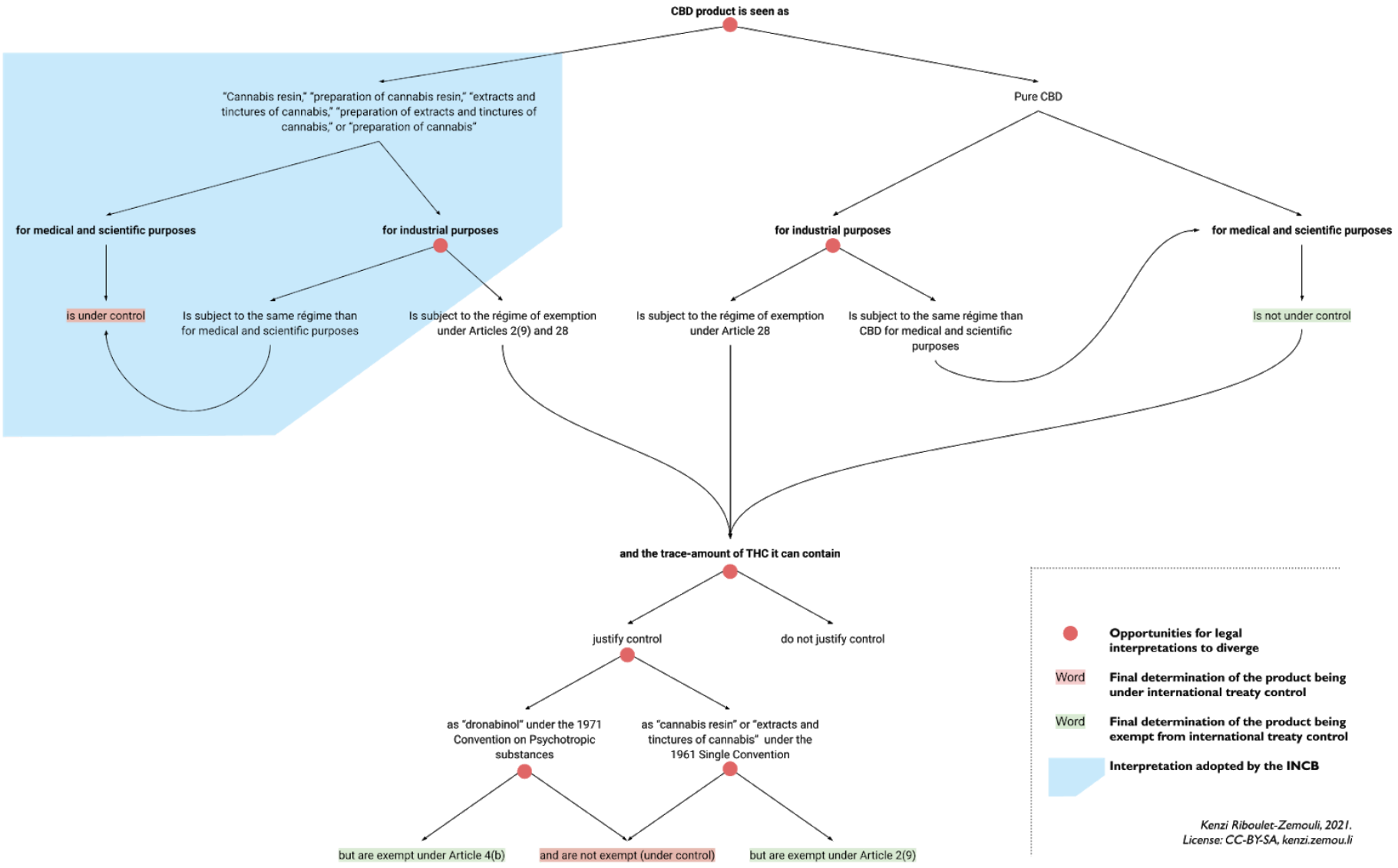
[77] Delegation of the European Union to the United Nations (Vienna). (2020). *Conference Room Paper: Judgment of the Court of Justice of the European Union in case C-663/18 ("Commercialisation du cannabidiol (CBD)") (ECLI:EU:C:2020:938)*. unodc.org/documents/commissions/CND_CCPCJ_joint/2020_Reconvened_Statements/ECN72020_CRP23_V2007192.pdf

[78] Secretariat to the Commission on Narcotic Drugs. (2020). *Statements following the voting on the WHO scheduling recommendations on cannabis and cannabis-related substances* (E/CN.7/2020/CRP.24). unodc.org/documents/commissions/CND/CND_Sessions/CND_63Reconvened/ECN72020_CRP24_V2007524.pdf

[79] Riboulet-Zemouli, K. (2019). *Scope and definition of the exemption covering "hemp" in the international drug control Conventions. A total exemption – by purpose* [online] www.researchgate.net/publication/336617754

[80] Riboulet-Zemouli, K. (2020). *CBD as a 'narcotic'? Food for thought.* Barcelona: FAAAT editions. www.researchgate.net/publication/343768923_CBD_as_a_'narcotic'_Food_for_thought

Figure 3. ***Are cannabidiol and cannabidiol products under international treaty control? Flexibilities and options for legal interpretation.***



The INCB has long held one of **the most restrictive interpretations of the treaty in relation to cannabidiol: considering it systematically under control**. However, it is but one of numerous points of view.

In this case, there is no direct breach of IHRL involved but it undermines the sovereignty and freedom of States to interpret the treaties according to their needs and priorities.

Just like for the preference of the INCB for "medical cannabinoids" over all *Cannabis*-based and *Cannabis*-related medicines, their particular interpretation of international control over cannabidiol is not *per se* problematic. What is concerning is the insistence of the Board on this particular interpretation with no reservation or contextualization. It would rather be expected for **the Board, *in good faith*,** to **present the array of possible choices offered to Member States**, while explaining its favoured interpretation.

For State Parties to take efficient and justified decisions in good faith they need to receive honest, unbiased advice. **The Board should not withhold information about the flexible interpretative options regarding the status of cannabidiol under international law**. It should not present the most restrictive reading of the treaties as the norm.

5. (Lack of) civil society participation

In previous works and reports, the INCB has organized consultations with civil society stakeholders, in particular relying on the two worldwide NGO Committees on Drugs.[81]

Following UNODC, the INCB should **recognize "the need to promote strong partnerships with civil society organizations** in dealing with the complex issues of drug abuse" and "the active involvement of [...] NGOs, community groups, labour unions, indigenous groups, charitable organizations, faith-based organizations, professional associations and foundations."[82]

The right to participate in public life and in policy-making is enshrined in core IHRL treaties (see Table 1) and more specifically in the UNDROP (Article Art. 2(3), 10, 11, 15(4)) and UNDRIP (Art. 18, 23). **However, for its Guidelines, the INCB consulted almost entirely large companies –but no peasants, IPLC, patients, or healthcare workers were involved or even consulted for these guidelines.**

There is a huge disparity in the efforts put forward to prevent "diversion and abuse" of *Cannabis* medicines compared to efforts to promote access to these substances for therapeutic uses and for the science of drugs, drug use and dependence. Often it has been the role of non governmental organizations to champion these important facets.

By having a process **without the benefit of civil society participation** –and not only the private sector, but also NGOs, researchers, affected populations, IPLC, etc.– **the INCB deprives itself of first hand information** not easily accessible to large companies or governments: an *on the ground* perspective of how *Cannabis* is being cultivated and used right now as a medicine, of how that use relates to a rich botanical and cultural history, of how and when human rights are at stake.

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[81] Vienna NGO Committee (vngoc.org) and New-York NGO Committee (nyngoc.org). See also: Fordham, A. (2020). The Meaningful Participation of 'Stakeholders' in Global Drug Policy Debates—A Policy Comment. *International Development Policy, 12.* https://journals.openedition.org/poldev/3861

[82] UNODC. (2021). *UNODC Engagement with Civil Society on Drugs and Crime* [online] www.unodc.org/unodc/en/ngos/cst.html

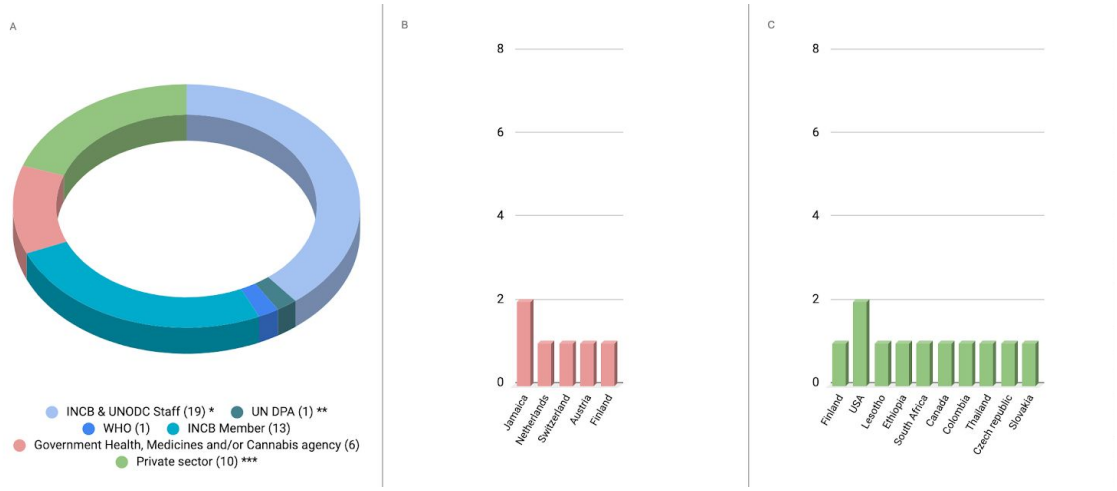
Table 3. ***Tentative timeline of the INCB Cannabis Initiative.***

Date	Event	Purpose	Stakeholders
November 2019	**Informal Consultation on the Supply of Cannabis raw materials and Demand for cannabinoids**	*Identification of knowledge gaps.*	Governments ("Competent national authorities") "Private industry of major cultivators and producers of cannabis"
March 2020	**Initiation of the activities of the INCB Cannabis Initiative**	*Launch of the project with Member States*	INCB Board Members. INCB Staff. Governments.
20 August 2020	**Job Opening for a Consultant to prepare guidelines/manual of good practices on the international drug control requirements for Cannabis**	*"The consultant is expected to deliver the following outputs: Outline of the guidelines; Annotated draft; First draft"*	INCB Board Members. INCB Staff.
Fall 2020	**Outline for the Guidelines and annotated draft**	*Delivered by the Consultant*	Consultant.
2 December 2020	**Reconvened 63rd Commission on narcotic Drugs**	*Majority vote in favour of removing "cannabis and cannabis resin" from 1961 Convention, Schedule IV*	Governments (diplomatic embassies in Vienna)
December 2020	**1st Draft Guidelines**	*Delivered by the Consultant*	Consultant.
From 18 to 21 January 2021	**1st Expert Group Meeting "on the Control and Monitoring Requirements of Cannabis and Cannabis-related"**	*Consultations with selected stakeholders (private sector stakeholders with profile of analysts, former or current drug authority members, former INCB staff, etc.)*	INCB Board Members & Staff. Consultant. A selection by INCB of ± 16 government and private sector stakeholders*
January-February 2021	**2nd Draft Guidelines**	*Revision of the Draft*	INCB Board Members & Staff. Consultant.
23 February 2021	**2nd Expert Group Meeting (part 1)**	*Joint Consultations with Competent National Authorities and the Private Sector*	INCB Board Members & Staff. Consultant. ± 80 government and private sector stakeholders selected by Governments**
24 and 25 February 2021	**2nd Expert Group Meeting (part 2)**	*Consultations Competent National Authorities*	INCB Board Members & Staff. Consultant. ± 70 Government stakeholders**
February-March 2021	**3rd Draft Guidelines**	*Revision of the Draft*	INCB Board Members & Staff. Consultant.
24 March 2021	**Intergovernmental Meeting with Permanent Missions**	*"Gathering knowledge and exchanging information"*	Governments (diplomatic embassies in Vienna)
Between 12 and 16 April 2021	**64th Commission on Narcotic Drugs, Side event "Way Forward in the Control and Monitoring of Cannabis and Cannabis-related Substances"**	*Expose the development of INCB Guidelines on the International Drug control Requirements on Cannabis for Medical and Scientific Purposes*	Public
November 2021 (estimation)	**132th Session of the Board**	*Approval of Draft Guidelines by INCB Board Members*	INCB Board Members & Staff.
March 2021 (estimation)	**65th Commission on Narcotic Drugs**	*Acknowledgement or acceptance of the Guidelines by the Commission*	Governments (diplomatic embassies in Vienna)

** See detail in figure 4. ** See detail in figure 5.*

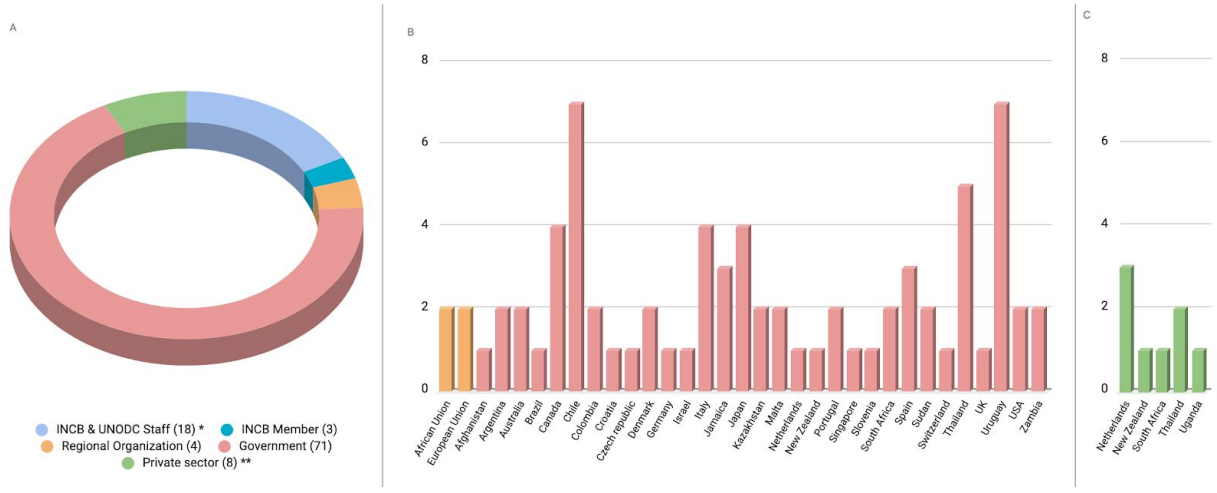
There are also concerns regarding the participants to the two series of meetings, since a number of them have been identified as having **potential conflicts of interests**. For instance, the consultant hired for the redaction of the draft Guidelines (national of New-Zealand) is well known for its work for, and professional relation with, an important Dutch cannabis pharmaceutical company. Several attendees to the two "informal consultations"/"Expert Group Meetings" are also listed as **patent holders, or holders of plant variety protection** rights, in direct relation (and therefore potential conflict) with the topics discussed.

Figure 4. ***Participation in the 1st Expert Group Meeting, INCB Cannabis Initiative.***



A: Approximate composition of the meeting (n=51). B: Geographic distribution of participants from Governments (private sector and IGOs excluded) (n=10). C: Geographic distribution of participants from the private sector (Governments and IGOs excluded) (n=6). **The Consultant from the private sector hired by INCB is included among "INCB & UNODC Staff." **Department of Political Affairs. ***Majoritarily includes representatives from "cannabis companies" with profiles of analysts, former or current drug authority members, former INCB staff, etc.*

Figure 5. ***Participation in the 2nd Expert Group Meeting, INCB Cannabis Initiative.***



A: Approximate composition of the meeting (n=104). B: Geographic distribution of participants from Governments and Regional Organizations (private sector and INCB/UNODC excluded) (n=75). C: Geographic distribution of participants from the private sector (Governments and IGOs excluded) (n=8). **The Consultant from the private sector hired by INCB is included among "INCB & UNODC Staff." **Government-owned enterprises which unfold in the legal market in competition with other companies have been listed among "private sector."*

6. Other technical issues

In addition to the important concerns expressed in this document, the draft Guidelines includes **a series of technical issues that will need to be addressed**.

The first problem is a **tendency to simplify the complexity of the *Cannabis* plant** –starting with the oversimplifying comparison with poppy and opium [15 February draft, p.4]. The differences between opioids and cannabinoids, in terms of potential harms and clinical approaches, are also fundamental –but not captured in the draft. The INCB plants to harmonize control requirements for *Cannabis* on the basis of opium, poppy, poppy straw, and concentrate of poppy straw, although these are very different from *Cannabis* products: botanically, pharmaceutically, and in terms of drug control.

The Guidelines **describe "the plant, *Cannabis sativa* L." as a "substance under control"** [p.6]. Although some provisions of the Convention do apply to the plants, they are not, and cannot be considered "under control" insofar as the *Cannabis* plant is not listed in the Schedules.

The Guidelines attempt to **introduce terms of questionable appropriateness**. This is for instance the case with the word "utilisation for medical and scientific purposes" that INCB uses as a synonym of "use." If there are several instances where the word "utilisation" is used in international law, its meaning does not always correlate to the "use" understood as "consumption." For instance, "utilisation" is defined as "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology" in the Nagoya Protocol, and similarly in other instruments. Such definitions do not include "use" as present in the drug control treaties.

The INCB presents as universal a standard that is only limited to a small number of jurisdictions, namely that "'hemp' [is] currently defined as cultivars containing < **0.2% THC** w/w" [15 February draft, p.9]. Many jurisdictions rely on different definitions or thresholds.

In some instances, the Guidelines suggest as a standard the installation of "high fences and secondary perimeter of control" to "limit the risks of intrusion with double controls for entering the facilities." These sort of measures, besides their onerous cost, are not required under the Convention and might not be needed in all circumstances. Furthermore, it has been suggested that over-protection and **disproportional security measures** over licit *Cannabis* crops in economies transitioning away from prohibition can **disrupt local security or even generate violence and criminality**. As a report on Jamaican security requirements mentions:

> "farmers are struggling to meet the requirements imposed. What they would question further is if the particular circumstances of their situation should not be taken into account. Could for instance community cohesion or geographical isolation not be listed as security factors in lieu of standardised requirements for hard fences and security cameras?"[83]

Many other "good practices" are pushed for without it being related to drug control requirements. The overall feeling is that **the draft Guidelines are *de facto* increasing control measures and reporting requirements over *Cannabis* and its derivatives –a move that seems in direct opposition to the decision of the international community to lower the status of control of "cannabis and cannabis resin"** on 2 December 2020.[84]

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[83] Klein and Hanson. (2020).
[84] FAAAT. (2020). *Press release — History made today: UN recognizes medical cannabis.* https://faaat.net/blog/press-release-united-nations-recognize-medical-cannabis-december-2020/

Conclusion

The INCB regularly proclaims that "due respect for universal human rights, human duties and the rule of law is important for effective implementation of the international drug control conventions."[85] It stressed on several occasions that "it is clear that the human rights conventions form an important cluster of binding international legislation that needs to be taken into consideration while implementing any international treaty."[86]

It is therefore positive to note that, following the 2016 UNGASS, the INCB has already exerted due diligence with regards to IHRL[87] for example by encouraging Member States "to consider the abolition of the death penalty for drug-related offences," even though this "remains the prerogative of States parties." In doing so, the INCB recalled "relevant international conventions and protocols and resolutions of the General Assembly, the Economic and Social Council and other United Nations bodies on the application of the death penalty."[88]

There is no reason why the INCB would not act in a similar fashion with respect to the series of rights outlined in this contribution, particularly those protected in the "nine core human rights conventions."[89] It would fall short if the INCB pretended to ignore their omission to mention overlapping provisions of international law can be used for the furtherance of wrongful conduct against indigenous peoples, farmers, peasants, but also patients, and their rights. These are **topics of primary concern for developing countries.**

When recommending traceability systems on seeds and reproductive materials, labeling, cultivation practices, documentation regarding the seeds and starting material, restrictive licensing schemes, and so many other elements contained in its Draft guidelines 15 February, **the Board is entering into fields that require an effort of due diligence.**

Back in September 2020, the authors of this document shared their concerns with the members of the Board (see Annex). This document now adds that the issues raised are not peripheral, ceremonial, or facultative: they entail diligent scrutiny and accountability.

We call on the INCB to have its actions follow its words, according to the motto of its 2015 report on access to controlled medicines: **"indispensable, adequately available and not unduly restricted"** and suggest adding ***and human rights compliant.***

Failure of the Board to take appropriate steps, even though they are "the prerogative of States parties," could be qualified as negligence since it might be seen as "**the [direction] of a State [...] in the commission of an internationally wrongful act**,"[90] something which could eventually "[incurs] international responsibility"[91] if the IGO "does so with knowledge of the circumstances of the internationally wrongful act."

[85] See §35 in INCB. (2008). *Report of the International Narcotics Control Board for 2007* (E/INCB/2007/1). www.incb.org/documents/Publications/AnnualReports/AR2007/AR_07_English.pdf
[86] See §35 in INCB. (2015). *Report of the International Narcotics Control Board for 2014* (E/INCB/2014/1). www.incb.org/documents/Publications/AnnualReports/AR2014/English/AR_2014.pdf
[87] See §34 in: Fordham, A. (2020).
[88] See §315 in INCB. (2017). *Report of the International Narcotics Control Board for 2016* (E/INCB/2016/1). www.incb.org/documents/Publications/AnnualReports/AR2016/English/AR2016_E_ebook.pdf
[89] §37 in INCB. (2015).
[90] ILC. (2011). Draft articles on the responsibility of international organizations. *Yearbook of the International Law Commission, vol. II*, Part Two. legal.un.org/ilc/texts/instruments/english/draft_articles/9_11_2011.pdf
[91] *Ibid.* Article 17

Annex: Copy of the **Letter addressed to INCB Board Members, September 2020**

From:

Michael KRAWITZ,

Kenzi RIBOULET-ZEMOULI

To:

Members of the INCB

International Narcotics Control Board,

Vienna International Centre,

P.O. Box 500, A-1400 Vienna, Austria.

Barcelona, September 21st, 2020

Dear INCB member,

We hope this letter finds you well amidst particularly difficult times.

The INCB is preparing a "guidelines/manual of good practices on the international drug control requirements for the cultivation, manufacture and utilization of cannabis for medical and scientific purposes" that "will support Member States in complying with the 1961 Single Convention."[92]

Since the establishment of such guidelines/manual represents a giant step on a topic rarely addressed so in-depth in the 52 years of activity of the Board, we volunteer to provide insight into critical elements that such guidelines/manual should provide.

Cannabis sativa L.-based medicines are diverse, numerous, and complex. This is however not necessarily problematic since these medicines correspond to pre-existing legal and regulatory pharmaceutical and clinical systems which apply to most situations. The diversity and complexity of these medicines are also reflected in a range of regulatory models, the three main lanes of which being:

1. Standard regulations for pharmaceutical medicines (*e.g.*, dronabinol, cannabidiol[93], nabiximols),
2. Standard regulations for phytopharmaceutical (herbal) medicines,
3. *Sui generis* regulations/protections for traditional pharmaceutical and non-pharmaceutical medicines.

WHO finds that 82% of the world's population uses some form of "lane 2." herbal drugs and/or "lane 3." traditional drugs.[94,95]

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[92] See UN Careers, cache page for the Job Opening "20 - United Nations Office on Drugs and Crime - 140183 - Consultant" careers.un.org/lbw/jobdetail.aspx?id=140183&Lang=en-US

[93] The medication identified with International Nonproprietary Name "cannabidiol / cannabidiolum" is not an internationally controlled medicine.

[94] Morris W, Gomes S & Allen M (2012), International Classification of Traditional Medicine. *Global Advances in Health and Medicine* 2012;1(4):38–41.

[95] See: World Health Assembly Resolutions on traditional & complementary medicine n°56.31 (2003), n°62.13 (2009), n°67.18 (2014), and n°69.39 (2016), as well as WHO Executive Board report EB120/36 (2006).

* * *

Countries always have a system in place for "lane 1.", and either have coexisting lanes 2. and 3., or only one of each (see WHO global report on traditional and complementary medicine 2019).

These are echoed, mainly, by these two clinical approaches and regulations:

A. Standard clinical healthcare regulations,
B. *Sui generis* regulations for traditional healers or practitioners.

On "lane 1.": It is likely that the Board will provide comprehensive guidelines regarding the lanes 1. and A., however, these only concern a handful of medical products subject to international control (e.g., dronabinol, nabiximols, other pharmaceutical compound-based medications).

* * *

On "lane 2.": Medical products available such as Bedrocan® or Bedrobinol® in the Netherlands and many similar products in other countries provide access to medicines consisting of prepared *Cannabis* flowering and fruiting tops (*e.g.*, Germany, Israel, many States of the USA). These are sometimes present in Pharmacopeias as such (*e.g.*, German and Swiss Pharmacopeia, American Herbal Pharmacopeia) as "*Cannabis sativa flos*."

Other corresponding products present or likely to be presented in Pharmacopeias as herbal drugs[96] are *Cannabis sativa oleoresinæ* or *plantarum medicinalium extracta* (see Ph.Eur. monograph nº0765; corresponds in the Single Convention to "preparation of cannabis resin" or "preparation of dronabinol" in the event WHO recommendations are adopted), but also *tincturæ*, teas and instant teas (*plantæ ad ptisanam*, see Ph.Eur. monographs nº1435 and nº2620), etc.

It would be unfortunate if these products should be forcibly controlled and ruled under inappropriate laws and regulations. They correspond to the "lane 2." stated above of "standard phytopharmaceutical medicines regulations" and should be regulated accordingly. This implies a change in the focus of pre-conceived notions of the pharmaceutical system that do not encompass the well-established specificities of herbal drugs. Europe's drug agency (EMCDDA) explains[97] that, even beyond Europe:

> "most pharmaceutical regulatory systems allow the use of herbal medicines that do not meet the same requirements as those for pharmaceutical medicines [...] For example, manufacturers of traditional herbal medicines with well-established uses are not usually required to provide evidence of efficacy and safety from clinical trials. Instead, they are required only to show evidence of product quality and consistency to ensure that consumers receive standardised doses of herbal products that are free from contaminants or adulterants."

In its *General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine*[98], WHO explains:

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[96] The concept of "herbal drugs" or "medicinal plants" is largely encompassed in Pharmacopeias worldwide (Brazilian, British, Chinese, European, French, German, Indian, Japanese, Swiss, Pharmacopeia). They sometimes merge single compound-based medicines and herbal medical products, but most often provide for a separate volume for such medications.

[97] See p. 21 in: EMCDDA (2018), Medical use of cannabis and cannabinoids: Questions and answers for policymaking. Lisbon: EMCDDA.
www.emcdda.europa.eu/system/files/publications/10171/20185584_TD0618186ENN_PDF.pdf

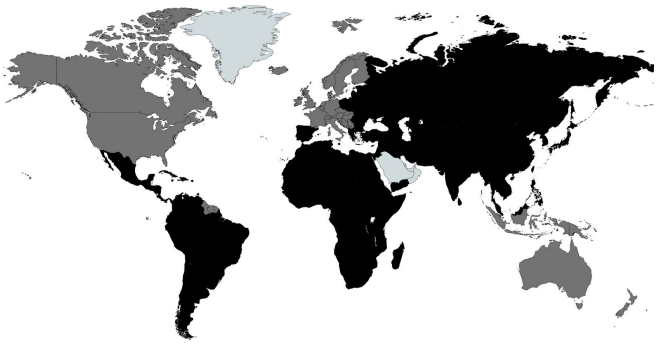
[98] WHO (2000), *General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine*. Document WHO/EDM/TRM/2000.1
apps.who.int/iris/bitstream/handle/10665/66783/WHO_EDM_TRM_2000.1.pdf

> "methods such as randomization and use of a placebo may not always be possible as they may involve ethical issues as well as technical problems. For example, it may be not possible to have a placebo control if the herbal medicine has a strong or prominent smell or taste, as is the case for products containing certain essential oils. In addition, patients who have been treated previously with the herbal medicine under investigation that has a characteristic organoleptic property, cannot be randomized into control groups."

There is no justification for the INCB guidelines to overly restrict the model of assessment, certification, and acceptance for herbal medicines, or to expand that of single compounds to herbal drugs. INCB should refer Member States to applicable guidelines and manuals, such as:

- 2000: General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine[7],
- 2011: Quality control for herbal materials[99],
- 2018: WHO Expert Committee on Specifications for Pharmaceutical Preparations, 52nd report[100], containing:
  - Guidelines on good herbal processing (Annex 1),
  - Guidelines on good manufacturing practices for herbal drugs (Annex 2),
  - Good pharmacopoeial practices for herbal drugs monographs (Annex 7).

Natural biodiversity *Cannabis sativa* and associated traditional knowledge

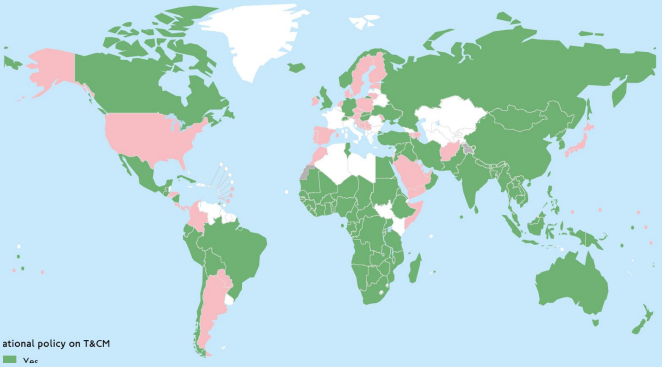


Countries with endemic varieties of *Cannabis sativa*, and documented traditional knowledge, traditional cultural expressions & folklore, before 1961.

Countries with documented traditional knowledge, traditional cultural expressions & folklore, before 1961.

No data available.

National policies on traditional & complementary medicine



Yes

No

No data available

n/a

Source: WHO global report on traditional and complementary medicine 2019. © World Health Organization 2019, All rights reserved.

[99] apps.who.int/iris/handle/10665/44479

[100] apps.who.int/iris/bitstream/handle/10665/272452/9789241210195-eng.pdf

On "lane 3.": Traditional and complementary medicine (according to the terminology used by WHO [101]) or indigenous systems of medicine (according to the words of the Commentary[11]) are fully legitimate under the Single Convention **at the same level as "lane 1."**[102] In practice, the INCB recalls in its report for 2001 (§208) a widely-documented and researched fact: "Cannabis has been used in traditional medicine in some countries for centuries" and explains that "Countries where traditional use of cannabis existed were allowed a 25-year moratorium to phase out the use of cannabis for purposes other than medical and scientific purposes, in accordance with 1961 Conv. Art. 49." The "traditional use" mentioned does not concern traditional medicine, which is a subset of medical purposes (thus allowed by, and controlled and regulated under, the Single Convention)

Additionally, the United Nations Declaration on the Rights of Indigenous People[103] (UNDRIP) lays out "the minimum standards for the survival, dignity and well-being of the indigenous peoples of the world" (Article 43). The UNDRIP is clear in that "Indigenous peoples have the right to their traditional medicines and to maintain their health practices, including the conservation of their vital medicinal plants" (Article 24), and that "indigenous peoples have the right to be actively involved in developing and determining health, housing and other economic and social programmes affecting them and, as far as possible, to administer such programmes through their own institutions" (Article 23).

Article 8's "Indigenous peoples and individuals have the right not to be subjected to forced assimilation or destruction of their culture" suggests traditional medical systems should not be assimilated within the conventional medicine system (*e.g.*, "lane 1." or "lane 2."), and specific policies and measures should be sought for that purpose.

In practice, this implies that expensive, overly-restrictive, and burdensome regulations or administrative red tape should be avoided, simplified or adapted to allow indigenous peoples to develop and sustain their traditional medical systems in countries where conventional medical use is allowed.

The discontinuation of the traditional use of *Cannabis* in medicine, in some countries, is not an excuse to ignore these issues. Indeed, "Indigenous peoples have the right to practise and **revitalize** their cultural traditions and customs. This includes the right to maintain, protect and develop the **past**, present and future manifestations of their cultures" (Article 11-1).

* * *

Link between "lane 1." and "lane 3.": Finally, the UNDRIP also specifies that "Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures [...] They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions."

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[101] WHO defines traditional and complementary medicine as "the sum total of the knowledge, skill and practices based on the theories, beliefs and experiences indigenous to different cultures (whether explicable or not) used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness." See also the recent WHO global report on traditional and complementary medicine published in 2019: apps.who.int/iris/handle/10665/312342

[102] "'medical purposes' does not necessarily have the same meaning at all times and under all circumstances [...] not only 'western medicine', but also legitimate systems of indigenous medicine such as those which exist in China, India and Pakistan, may be taken into account in this connexion." (Commentary on the Single Convention, p.111, §12).

[103] UNDRIP undocs.org/en/A/RES/61/295

This triggers **critical legal questions** that the INCB should, at least, suggest Member States pay attention to especially those Member States representing developing countries. Contemporary *Cannabis* medicines are developed from two sensitive materials:

- natural and genetic resources (the plants, derived from traditional varieties), without which the development of *Cannabis* pharmaceuticals is **impossible**, and
- the traditional medical knowledge over these resources (including oral knowledge or ancient texts) which serves as a quintessential indication for pharmaceutical research and development.

Both are subject to international laws and norms in particular the Convention on Biological Diversity and its Nagoya Protocol[104] (of prime relevance), FAO's "Plant Treaty"[105], the Paris Convention on the Protection of Industrial Property, the WTO TRIPS Agreement[106] as well as a series of other treaties administered by the World Intellectual Property Organization. Non-compliance with these instruments constitute gross violation of international law and of the rights of indigenous peoples and local communities to which *Cannabis* is a traditional and complementary medicine. INCB should consider including these elements not only as considerations for traditional medical knowledge or plant genetics holders but also for the Western pharmaceutical research and development sector.

"Indigenous peoples have the right to the recognition, observance and enforcement of treaties, agreements and other constructive arrangements concluded with States or their successors and to have States honour and respect such treaties, agreements and other constructive arrangements" (UNDRIP, Article 37-1)

The UNDRIP calls on the INCB: "The organs and specialized agencies of the United Nations system and other **intergovernmental organizations shall contribute to the full realization** of the provisions **of this Declaration** through the mobilization, inter alia, of financial cooperation and technical assistance. **Ways and means of ensuring participation of indigenous peoples on issues affecting them shall be established.**" (Article 41).

* * *

Porosity between "lane 1." and "lane 3.": There is a porosity between "Western" herbal drug medicine and other traditional medicines, and Cannabis bridges both "lanes" because of its formulations and because of the way it is used and perceived by patients and physicians. "The preference among some patients for the medical use of herbal preparations of the whole cannabis plant rather than pharmaceutical products has strong similarities to the reasons people give for using traditional herbal medicines"[107]. Moreover, "the fact that field-based academic research in cannabis-producing countries has most often been limited in time, scope, and depth, explains why a large number academics and journalists alike write rather inaccurately not only about the Cannabis plant but also about the many traditional [...] cannabis end products"[108].

* * *

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[104] *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.* Signed in 2010, entered into force in 2014, see: www.cbd.int/abs/

[105] *International Treaty on Plant Genetic Resources for Food and Agriculture.* Signed in 2001, entered into force in 2004, see: www.fao.org/plant-treaty/en/

[106] *Agreement on Trade-Related Aspects of Intellectual Property Rights.* www.wto.org/trips

[107] Joseph Brand & Zhao (2017), *Cannabis in Chinese Medicine: Are Some Traditional Indications Referenced in Ancient Literature Related to Cannabinoids?* Front Pharmacol. 2017;8:108. DOI:10.3389/fphar.2017.00108 www.ncbi.nlm.nih.gov/pmc/articles/PMC5345167/

[108] Chouvy (2019), *Cannabis cultivation in the world: heritages, trends and challenges*, EchoGeo 2019;48. DOI:10.4000/echogeo.17591 journals.openedition.org/echogeo/17591

On personal cultivation: INCB declares that "personal cultivation of cannabis for medical purposes is inconsistent with the 1961 Convention for several reasons: it heightens the risk of diversion and it presents health risks."[109] However, self-cultivation of cannabis for medical purposes is only dependent on the Conventions, it is also dependent on international human rights law in particular the right to privacy.

Countries that authorize self-cultivation do it under their constitutional principles (reflected in international human rights law) of right to privacy and right to the free development of personality. It is clearly established (see 1988 Convention and UN Charter) that constitutional, fundamental rights are above and supersede the requirements of the Conventions in case of conflict. Even refusing to incorporate the elements laid out in the 1988 Convention legal analysis of international law[110] echoes this superiority of human rights principles (in this case, the human rights contained in constitutional texts) above and over any conflicting provision mandated under the drug control Conventions.

Constitutional human rights protect the right of people to cultivate cannabis for their personal use in a private context. This principle is not exclusive of medical use hence whatever the purpose is of the self-cultivation (and regardless of the status of control of such purpose under the Conventions) conventional obligations are not relevant in the case of self-cultivation.

* * *

On security requirements: INCB has repeatedly requested governments to scale-up minimum security requirements for licensed cannabis production or manufacturing facilities. While the need for safe workspace makes no doubt, the controls required under the Conventions are those of monitoring, licensing, tracking, and scrutinizing the production. An analysis of the licensing system in one Member State that implemented medical cannabis access policies noted that overly-restrictive security requirements constitute a barrier to access to legally-regulated settings for small-scale traditional farmers:

> "farmers have been asked to set up a high perimeter fences and to install security cameras for continuous monitoring. The costs for acquiring these are forbidding, the installation requires significant inputs of labour, will then impede the free movement of farmers across the terrain not to speak of blighting the landscape. Community members were caustic in their criticism of this requirement, which they did not see as being needed given the circumstances of their location. [These farmers] are situated in locations that are not easy to access among tight knit communities with a long history of ganja cultivation. Strong community support, the difficulty of access to the growing areas, and a severe approach to criminal justice mitigate the risks of praedial larceny [=theft of agricultural produce] and diversion to criminal markets."[111]

The Conventions do not impose specific security requirements, but an *a priori* and *a posteriori* oversight of the national agency in charge of cannabis licensing and regulations. The details of security requirements should be left up to Member States, depending on the particular conditions of their territories and populations.

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[109] www.incb.org/documents/Publications/AnnualReports/AR2018/LAUNCH/Highlights.pdf

[110] English summary of *International law and cannabis II. Regulation of cannabis cultivation and trade for recreational use: positive human rights obligations versus UN Narcotic Drugs Conventions*: www.ru.nl/publish/pages/797876/internationaal_recht_en_cannabis_ii_-_english_summary.pdf

[111] Klein A & Hanson VJ (2020), *Ganja Licensing in Jamaica Learning lessons and setting standards*. University of the West Indies/Interdisciplinary Centre for Cannabis Research. iccresearch.org/sites/default/files/Ganja%20Licensing%20in%20Jamaica%20-%20April2020.pdf

Conclusion: In recent reports the Board has recalled that international drug control is fully part of international law and therefore falls under the Charter of the United Nations and the general principles of international law beyond the three drug control legal instruments. Therefore, **the "international drug control requirements for the cultivation, manufacture and utilization of cannabis for medical and scientific purposes" are not only those of the Single Convention** but also those of the international Human Rights instruments, the Convention on Biological Diversity and its protocols, the FAO Plant Treaty, etc. Addressing only the requirements of the drug control treaties with no mention of other key obligations of Member States would not constitute "guidelines" but fundamental research, which is interesting, but not the role of INCB.

Member States have obligations to respect, protect, promote, and progressively unfold the "right to the enjoyment of the highest attainable standard of physical and mental health" which includes the right for patients to access the medicines that both patient and caregiver agree to use (a right expressly recognized by the Single Convention for the case of cannabis and other controlled medicines). **Any external injunction hampering the freedom of patients and medical caregivers to select, access, prescribe, and use the medicine they deem useful for therapy constitutes a violation of the right to health** as contemplated in Article 25 of the Universal Declaration of Human Rights and Article 12 of the International Covenant on Economic, Social and Cultural Rights. This should be central to these proposed guidelines.

To achieve this, the guidelines should avoid recommending the creation of new layers of *sui generis* regulations for cannabis medicines, but rather rely on the different existing "lanes."

The INCB should also remember its own words:

> "civil society organizations have diverse perspectives on the means and modalities for the implementation of the drug control conventions in their local communities. Nonetheless, without the assistance of dedicated organizations, the aims of the conventions to prevent substance abuse and provide treatment and rehabilitation will be hard to achieve. The Board therefore wishes to reaffirm in this Alert the important role of civil society, as outlined in the outcome document of the UN General Assembly Special Session (UNGASS) in 2016 and the 2019 Ministerial Declaration. The INCB clarified at the time of UNGASS that the principle of a balanced approach to elaborating drug policy means facilitating greater participation and cooperation between all relevant stakeholders, including civil society groups"[112]

* * *

[112] INCB (2019), *The role of civil society in the development and implementation of drug policies on prevention, treatment and social reintegration.* Document NºE/INCB/2019/Alert.16. www.incb.org/documents/News/Alerts/Alert16_CES_Essay_civil_society_Dec_2019.pdf

We suggest the INCB revise the process for the edition of the planned guidelines, and:

- **Extend the deadline**, to take into account the pandemic and the following elements,
- Include references to **existing guidelines for herbal & traditional medicines**,
- Involve **other UN agencies** (at least WHO, Secretariat of the Convention on Biological Diversity, WIPO & FAO),
- Engage in **open-ended dialogues**, and **consult with civil society** (patients, doctors, scientists, indigenous peoples and other communities concerned),
- Share the above information with the Consultant in charge of drafting the report,
- Submit the draft report to a transparent and open process of "Public Comments."

We remain at your disposal to assist in this direction. Our unequivocal commitment to human rights, our strong not-for-profit approach, our commitment to multilateralism, and our absence of conflicts of interest with either side of the debate can help the Board ensure the ultimate delivery of guidelines that strengthen access and availability of medicine while efficiently countering the potential risks associated with the inappropriate prescription and misuse of controlled drugs.

Sincerely,

Michael Krawitz,

Kenzi Riboulet-Zemouli