Dear Esteemed Members of the 41st Expert Committee,

We are a coalition of Civil Society Organizations that advocate for regulatory, distributive and redistributive public policy reform for cannabis.

Due to the commitments of the 186 state parties of the 1961 Single Convention, cannabis remains classified within many national policies as a drug having no accepted medical value. These policies have disproportionate health, safety and economic impacts on traditional Cannabis farming regions, which are global.

According the United Nations Office on Drugs and Crime (UNODC), Cannabis cultivation was reported by “145 countries (or 85 percent of countries reporting to UNODC) over the period 2010–2016, representing 94 percent of the world’s total population,” (38). Cannabis cultivation was reported through direct indicators such as cultivation or eradication reporting; or indirect indicators including seizures and origin of seizures. North America accounted for roughly 39 percent of the global total of cannabis production. South America, Central America and the Caribbean accounted for nearly 23 percent, whereas Africa, Asia, Europe and Oceania account for roughly 38 percent of cannabis production.

We offer this paper to the ECDD for your consideration of the medical and cultural value of cannabis and geographic indication systems as a mechanism to support national regulation for traditional Cannabis producing regions.

Sincerely,

Michael Krawitz, Speaking for the Coalition of the Following Organizations:

Veterans for Medical Cannabis Access (VMCA)
Mendocino Appellations Project (MAP)
International Cannabis Farmers Association (ICFA)
For Alternative Approaches for Addiction, Think and do tank (FAAAT)

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2 Ibid., 39.
Veterans for Medical Cannabis Access
VMCA advocates for veterans' rights to access medical cannabis for therapeutic purposes. VMCA encourages all legislative bodies to endorse veterans' rights to use medical cannabis therapeutically and responsibly, and is working to end all prohibitions associated with such use. VMCA is working to preserve and protect the long established doctor-patient relationship including the ability to safely discuss medical cannabis use within the V.A. healthcare system without fear of punishment or retribution.

Mendocino Appellations Project
MAP is a non-profit education, research and advocacy organization working to develop legal appellation of origin designations for cannabis. MAP is collaborating with strategic partners to conduct requisite research, develop supporting public policy and support the protection and promotion of the cultural heritage of cannabis throughout the world.

International Cannabis Farmers Association
ICFA is a group of farmers, scientists and stakeholders working together to promote the unique quality and ecological superiority of sun grown Cannabis products while preserving the heritage of traditional farming communities. The association is committed to empowering traditional Cannabis farmers through education, research and advocacy.

For Alternative Approaches to Addiction, Think & do tank
FAAAT is an international advocacy and research organization (non-profit, non-partisan and non-governmental) that addresses the policies of addiction, controlled and illicit drugs, plants, products or substances liable to produce harms or use disorders.
The Importance of Appellations of Origin to the Successful Therapeutic Model of Whole Plant Cannabis, Follow-up on Civil Society Cannabis pre-review input³

N.B. - For this paper ‘whole plant cannabis’ is the term used to describe the medicinal uses of the flowering and fruiting tops, or the inflorescence, of the ‘Cannabis sativa L. plant.’ ‘Whole plant cannabis’ also includes herbal medicine preparations derived from Cannabis inflorescence in its raw botanical form. ‘Cannabis’ is used when referring to the ‘Cannabis sativa L. plant’. Furthermore, ‘cannabis’ is used when referring to the controlled substance or ‘drug’ as it is scheduled under the 1961 Single Convention on Narcotic Drugs (as amended by the 1972 Protocol).

Introduction
In the past decade, a number of global policy initiatives have been introduced that address the contributions to global health offered by traditional medicine, traditional knowledge, related genetic resources, and the use of intellectual property systems to protect these traditions. These initiatives include:

- 2009: World Health Assembly Resolution on Traditional Medicine,⁴
- 2013: WHO Traditional Medicine Strategy: 2014-2023,⁵
- 2017: Mandate of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore,⁶
- 2018: Human Rights Council: Draft United Nations declaration on the rights of peasants and other people working in rural areas⁷

Our coalition of civil society organizations believes it is imperative that such global policy initiatives be applied to protect both the historic and contemporary value of whole plant cannabis and Cannabis-derived products as traditional medicine embedded within traditional knowledge systems throughout the world, while acknowledging the plant’s significant role as an herbal medicine within contemporary complementary medicine.

Recent findings related to the ‘entourage effect’ and the human body’s endocannabinoid system underscore the importance of the continued study of medical and therapeutic applications of

⁴ Sixty-second World Health Assembly, Agenda item 12.4, Traditional medicine, WHA62.13 (22 May 2009)
whole plant cannabis. Due to the international scheduling of cannabis, several member states have developed a patchwork of therapeutic cannabis laws that force regulated Cannabis producers to utilize industrial production methods that often penalize or prohibit traditional farming methods. As such, the global community is at significant risk of reduced genetic diversity within pools of cultivars, creating potential for the loss of under-studied therapeutic applications of whole plant cannabis and its derivatives. Communities of Cannabis farmers, and other people working in rural areas, should be afforded the right to protect their traditional knowledge relevant to plant genetic resources for agriculture through policies and intellectual property laws.(12-13)\(^8\)

Intellectual property systems, such as Protected Designation of Origin (PDO), Denomination of Origin (DO), and Appellation of Origin (AO), offer significant opportunity to protect these valuable traditions and genetic resources for the people of the world. These standards-based regulatory systems soundly codify traditional knowledge, traditional agricultural practices, and protect valuable genetic resources, resulting in the harmonization of respective intellectual property standards, values, and technologies between developed and developing countries engaging in the trade of AO products.

As such, we strongly believe that Appellation of Origin (AO) is the most formidable mechanism by which to protect and regulate the collective intellectual property of a given agricultural region thereby preserving the traditional medicine, traditional knowledge, and related genetic resources associated with the traditional medical use of whole plant cannabis.

We respectfully request that the Expert Committee on Drug Dependency take into consideration the lengthy documented history of the use of whole plant cannabis within traditional medicine systems, complementary medicine systems, and schools of herbalism during its review of the scheduling status of cannabis and Cannabis-derived products, and consider Appellation of Origin systems as a mechanism by which to soundly regulate traditional Cannabis producing regions.

### Cannabis within Traditional Knowledge

The World Intellectual Property Organization (WIPO) was established in 1967 through the WIPO Convention. It is the global forum for intellectual property services, policy, information, and cooperation and is a self-funding agency of the United Nations consisting of 191 member states. The mission of WIPO is to “lead the development of a balanced and effective international intellectual property (IP) system that enables innovation and creativity for the benefit of all.”\(^9\)

WIPO describes ‘Traditional Knowledge’ (TK) as a living body of knowledge, know-how, skills, and practices that are developed, sustained, and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity.\(^10\)

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\(^9\) http://www.wipo.int/about-wipo/en/

\(^10\) http://www.wipo.int/tk/en/tk/
An intense correlation between the traditional and complementary medical use of whole plant cannabis, culture and spiritual identity can be witnessed in many parts of the globe, such as in historic ‘producing’ regions like Nepal, where authors Acharya, Howard, Pant, Mahatma, and Copeland have found that:

Despite being illegal in Nepal, cannabis grows wild, is cultivated, readily available and often consumed during religious festivals, such as those in honour of the Hindu god Shiva. Holy men (sadhus) also consume cannabis to aid meditation, and many are believed to suggest that as a substance favoured by Lord Shiva, and, as such, should be used.**11**

Traditional cultural and spiritual contexts for cannabis consumption mitigates abusive use. In these contexts the cultivation, preparation, and use of whole plant Cannabis medicine is part of a living tradition to be respected, taught, and in some cases carries such stature as to require initiation in order to to engage with cannabis.

In the article Ganja in Jamaica, Tim Boekhout van Solinge writes:

Although there are various Rastafarian groups, the majority of Rastafarians do not belong to a group; being a Rastafarian is - above all else - a personal perception. There are, however, a number of rules. Rastafarians eat ‘Ital’, which means that only natural, vegetarian food without salt is consumed. The most eye-catching aspect is the hairdo of the Rasta, the dreadlocks. One of the most famous ‘rules’ is smoking the holy herb. To Rastafarians, ganja is not only a mere stimulant, it is the holy herb mentioned in the bible. Sometimes it is also claimed that the holy herb grew on the grave of King Salomon. The use of ganja is supposed to lead to a deeper faith, which explains the fact why ganja is smoked at religious Rastafarian ceremonies.

Cannabis lovers in the West with an overly romanticised image of Jamaica and the Rastafarian movement may occasionally get the impression that Rastafarians spend a good part of their day smoking ‘peace pipes’ filled with ganja. True, Rastafarians usually do smoke regularly and more frequently than non-Rastafarians, yet it is still a matter of moderate and integrated use, like the consumption of ganja in Jamaica in general. In the streets of Jamaica you will seldom come across people heavily intoxicated from smoking ganja. Larger amounts of ganja are only consumed at special occasions like religious ceremonies or during an afternoon or evening in the circle of friends. [sic]**12**

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The History of Cannabis in Traditional Medicine
The World Health Organization (WHO) has defined ‘Traditional Medicine’ (TM) 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.\(^{13}\)

Cannabis’ long-standing historic use as a traditional medicine by many cultures throughout the world continues to this day. Traditional medicinal uses of cannabis are even acknowledged in Commentary on Article 28 of the 1961 Single Convention on Narcotic Drugs, where it is noted that the Convention does not exclude “use in such non-Western medical systems as the Ayurvedic, Unani and Tibbi systems of India and Pakistan from the scope of medical use.” (314)\(^{14}\)

Historical and contemporary traditional medicinal uses of cannabis are found in China, Bangladesh, Iran, India, Nepal, Pakistan, Tibet, and beyond. Textual studies of Pre-modern Chinese materia medica texts, Chinese ‘bencao’ literature, find numerous mentions of cannabis herbal preparations or uses for relieving pain or for applications for “mental effects or mental illness”. In their study of Chinese medical texts, Brand and Zhao found that “all parts of the cannabis plant were recorded in ‘bencao’ texts”.\(^{15}\) Presently, Cannabis achenes, or seeds, are used in Traditional Chinese Medicine preparations.

In India, cannabis continues to have medicinal applications in both the Ayurvedic Traditional Medicine system as well as within tribal communities’ systems of traditional knowledge regarding the use of medicinal plants. Recent studies in ethnobiology, ethnobotany, ethnopharmacology, and ethnomedicine have continued to document use of whole plant cannabis in traditional medicine in Nepal, Bangladesh, Pakistan, and Tibet.\(^{16}\)

The WHO has not only acknowledged the continued and growing demand and interest in traditional medicine across the globe, in developed and developing nations alike, but also its

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growing economic importance and the significant role it stands to play in economic development. Additionally, WHO Director-General, Dr. Margaret Chan, stated in 2013 that:

> traditional medicines, of proven quality, safety, and efficacy, contribute to the goal of ensuring that all people have access to care. For many millions of people, herbal medicines, traditional treatments, and traditional practitioners are the main source of health care, and sometimes the only source of care. This is care that is close to homes, accessible and affordable. It is also culturally acceptable and trusted by large numbers of people. The affordability of most traditional medicines makes them all the more attractive at a time of soaring health-care costs and nearly universal austerity. Traditional medicine also stands out as a way of coping with the relentless rise of chronic non-communicable diseases.

The Therapeutic Potentials of Whole Plant Cannabis and the ‘Entourage Effect’

In this paper, ‘whole plant cannabis’ is the terminology used to describe the medicinal uses of the flowering and fruiting tops, or the inflorescence, of the *Cannabis* plant. ‘Whole plant cannabis’ also includes herbal medicine preparations derived from *Cannabis* inflorescence in its raw botanical form. The term ‘whole plant cannabis’ corresponds indistinctly to the forms of *Cannabis* referenced in the 1961 Convention as ‘cannabis’, ‘cannabis resin’, ‘extracts of cannabis’ and ‘tinctures of cannabis’. Whole plant cannabis offers complex therapeutic benefits through what is termed as the ‘entourage effect’.

Introduced in 1999 by researchers Raphael Mechoulam and S. Ben-Shabat, ‘entourage effect’ has become widely used to describe their findings that suggest endogenous cannabinoids produced in the body actually work by means of such ‘entourage effect.’ For example, when the endocannabinoid 2-AG (2-arachidonoylglycerol), was administered along with two related compounds, 2-AG more readily bound to the cannabinoid receptors, resulting in an increased behavioral effect being observed in the test subject. Mechoulam and Ben-Shabat have found that:

> Biochemically active natural products, from either plant or animal origin, are in many instances accompanied by chemically related though biologically inactive constituents. Very seldom is the biological activity of the active constituent assayed together with inactive ‘entourage’ compounds. Investigations of the effect of the active component in the presence of its ‘entourage’ compounds may lead to results that differ from those observed with the active component only.

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18 Ibid., 16.
21 Ibid., 136.
A further study, published in 2008 by Ethan B. Russo and John M. McPartland, found that:

A central tenet underlying the use of botanical remedies is that herbs contain many active ingredients. Primary active ingredients may be enhanced by secondary compounds, which act in beneficial synergy. Other herbal constituents may mitigate the side effects of dominant active ingredients. We reviewed the literature concerning medical cannabis and its primary active ingredient, Δ9-tetrahydrocannabinol (THC). Good evidence shows that secondary compounds in cannabis may enhance the beneficial effects of THC. Other cannabinoid and non-cannabinoid compounds in herbal cannabis or its extracts may reduce THC-induced anxiety, cholinergic deficits, and immunosuppression. Cannabis terpenoids and flavonoids may also increase cerebral blood flow, enhance cortical activity, kill respiratory pathogens, and provide anti-inflammatory activity.

These findings suggest that the therapeutic value of cannabis, as used by many cultures throughout the world for hundreds of years, has long capitalised on the ‘entourage effect’ offered by whole plant cannabis and herbal cannabis preparations. These works also reflect the need for continued scientific study of the endocannabinoid system and whole plant cannabis specifically to illuminate the medicinal and therapeutic values and uses of cannabis.

The Significance of Cannabis in Complementary Medicine

Complementary medicine is a term often used to describe a treatment that is given to, or undertaken by, a patient in addition to Western or conventional medical treatment.

The term ‘Complementary Medicine’ (CM) is defined by the WHO as:

a broad set of health care practices that are not part of that country’s own tradition or conventional medicine and are not fully integrated into the dominant health-care system. They are used interchangeably with traditional medicine in some countries.

In developed countries, whole plant cannabis has seen a significant increase in use within complementary medicine, to such extent and efficacy that this use is driving widespread global cannabis policy reform. In the United States some of the more notable applied uses of cannabis include demographics impacted by the AIDS/HIV epidemic, military personnel suffering from Post Traumatic Stress Disorder (PTSD), and within harm reduction strategies for treatment of people navigating substance addiction. Interestingly, in the treatment of patients with HIV/AIDS and veterans with PTSD, the prescription of Dronabinol (a single-compound formulation of (−)-trans-Δ⁹THC) has been authorized for decades – and although theoretically preferred by physicians and patients for its commodity of dosage and intake, as well as its supposed absence of side-effects – the legally prescribed single compound did not replace nor challenge the use of whole plant cannabis by those patients.

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Historically and increasingly in recent decades, whole plant cannabis has been used as a food. Nutrition is foundational to health and wellness and food, along with herbal medicine, is commonly regarded as ‘The People’s Medicine’.

Additionally, in the United States cannabis is often used as a therapy of last resort for the poor, terminal patients, patients with conditions that are unresponsive to conventional therapies, or for whom the side effects of conventional therapies are too much to bear. This helps to contextualize access to whole plant cannabis as an issue of social justice, human rights and human dignity.

The Importance of ‘T&CM’
In its 2014-2023 Strategy, the WHO merges the terms ‘Traditional Medicine’ (TM) and ‘Complementary Medicine’ (CM), into ‘T&CM’, which encompasses related products, practices and practitioners. The Strategy goes on to say, “T&CM is an important and often underestimated part of health care”, and that, “TM of proven quality, safety, and efficacy, contributes to the goal of ensuring that all people have access to care.”

The WHO Traditional Medicine Strategy: 2014-2023 outlines three strategic objectives:

1. To build the knowledge base for active management of T&CM through appropriate national policies,
2. To strengthen the quality assurance, safety, proper use and effectiveness of T&CM by regulating products, practices and practitioners,
3. To promote universal health coverage by integrating T&CM services into health care service delivery and self-health care.

The neologism ‘T&CM’ signifies the acknowledgment by the WHO of the inherent connection between the categories of traditional and complementary medicines. We posit that cannabis belongs to both.

We respectfully request that the WHO strategic objectives related to T&CM public policy, standards, and patient access be extended to whole plant cannabis therapies as a fundamental tenet of global health and with these essential considerations in mind, encourage international policies that prioritize sensible regulation over eradication.

Cannabis as a Genetic and Cultural Resource
In 2015, Prashant Reddy and Malathi Lakshmikumaran described traditional knowledge (TK) as containing two categories:

TK can be divided into two broad categories. The first category, traditional cultural expressions (TCEs), covers artistic works, musical works, symbols, etc., of indigenous people. The second category is biological resource–related TK, which covers areas like

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25 Ibid., 7.
26 Ibid., 7.
traditional medicine that have been created through the ability of indigenous communities to identify the medicinal properties of various biological resources within their geographical boundaries.\(^{27}\)

In the case of Cannabis, foremost amongst the biological resources and diversity to be protected are the cultivars themselves, as well as the ecologies of the traditional farming regions. Intrinsically linked to this are the protection of these regions’ cultural resources, including the continued preservation and sustainable innovation of the farming practices which have stewarded this living body of knowledge and repository of genetics over the generations. The self-determination and economic health of traditional farming communities is paramount to the success of these preservation goals.

Cannabis, an annual plant, readily and rapidly adapts to environmental and human influence, evidenced in the resulting plant structure, growth cycles, and chemical expression. Human needs and preferences for cannabis use, and resulting Cannabis breeding and cultivation practices over centuries, have resulted in a vast and diverse global repository of Cannabis cultivars. Cannabis cultivars referred to as ‘hemp’ - one of the most dramatic examples - are the result of selective breeding for fiber and seed. Cultivars referred to as ‘drug type’ are a result of selection for the production of chemical constituents, such as THC. Michael Pollan, Ignacio Chapela, Cathy Gallagher, and Patricia Unterman have written that:

> The THC molecule, one of the active ingredients in marijuana, is a very complicated molecule, and it takes some expense, metabolic expense, for the plant to produce it. These colors, these scents, all these are expensive propositions. Well, the main reason plants need to do all this, to gratify our desires, is that they can’t move. The single great existential fact of plant life is... well, they can’t locomote. They can move with the wind and water, but they can’t pick themselves up and go. So what they’ve worked on, what they have, are chemicals instead of legs. Cannabis works on our minds in order to borrow our feet...\(^{28}\)

There is immeasurable value stewarded within the world’s regional repositories of Cannabis genetics, the diversity and innovation of which are intimately connected to these bioregions, but perhaps even more significantly, owed to the practices of the cultures within these bioregions.

The international community must act decisively and quickly to protect these vulnerable global resources, as the tumult of policy reforms and a global commodification of cannabis unfolds. The biodiversity of Cannabis cultivars is rapidly shrinking as traditional Cannabis farming communities succumb to sweeping changes. The impacts are severe - among them are the reduced genetic diversity of Cannabis and the associated loss of phytochemical compounds of medicinal value and our ability to research these genetic resources.


\(^{28}\) Pollen, Michael and Ignacio Chapela, Cathy Gallagher, Patricia Unterman, Cannabis, Forgetting, and the The Botany of Desire, (Doreen B. Townsend Center Occasional Papers, 27), 4.
WIPO’s Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) is negotiating international legal instrument(s) on intellectual property (IP), genetic resources (GRs), traditional knowledge (TK) and traditional cultural expression (TCEs). We appeal to the ECDD and the IGC to consider Cannabis within these frameworks, and to protect it as biological resource–related TK.

Conclusion: Appellations of Origin, a Sui Generis System of Protection for Cannabis Resources

‘Sui Generis’ is a Latin term meaning “for of its own kind, and used to describe a form of legal protection that exists outside typical legal protections -- that is, something that is unique or different. In intellectual property law, for example, ship hull designs have achieved a unique category of protection and are ‘sui generis’ within copyright law.”

In WIPO’s introductory publication on Geographic Indications, sui generis is discussed:

In certain jurisdictions, GIs may be protected through a system that applies specifically and exclusively to them – a sui generis system of protection. Such systems establish a specific right, a sui generis right, over GIs, separate from a trademark right or any other IP right. A sui generis protection system exists in the EU with regard to GIs for wines and spirits, agricultural products and foodstuffs. Many other jurisdictions throughout the world, such as India, Switzerland, the Andean Community countries and the African Intellectual Property Organization (OAPI), among others, also have sui generis systems of protection.

WIPO speaks to the Sui Generis System for the protection of traditional knowledge:

Some countries have adopted special sui generis laws and measures, specifically to protect traditional medical knowledge. For example, Thailand’s Act on Protection and Promotion of Traditional Thai Medicinal Intelligence protects ‘formulas’ of traditional Thai drugs and “texts on traditional Thai medicine”. Only those who have registered their IP rights can research, develop and produce drugs using traditional medical knowledge. At the international level, the international legal instrument on the protection of traditional knowledge negotiated by the WIPO IGC (Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore) would embody a sui generis approach.

Within geographic indication systems, Appellation of Origin (AO) is regarded as a sui generis system that defines and protects the unique Intellectual Property (IP), Genetic Resources (GRs), Traditional Knowledge (TK) and Traditional Cultural Expression (TCE) unique to a given region. AO codifies traditional practices into regulated production standards, protects

29 http://www.wipo.int/tk/en/igc/
30 https://www.law.cornell.edu/wex/sui_generis
32 World Intellectual Property Organization, Intellectual Property and Traditional Medical Knowledge, (WIPO, Background Brief No 6), 3.
traditional producing regions and assures safe public access to, and administration of, whole plant medicines.

As local and global public policy for cannabis evolves, the historic and contemporary value of cannabis as a traditional and complementary medicine becomes increasingly more apparent through emerging research and regulated use. Rapidly, these cultures and ecologies are changing - increasingly they are becoming endangered.

The Appellation of Origin system is profound, the rarest of economic and regulatory tools embodying not just the capacity to preserve and protect our world’s agricultural and medicinal traditions, but to also harmonize the social, economic, and environmental imbalances of a global economy impacted by the sweeping commodification of our natural and cultural resources over the last century. In this respect, we believe that AO and cannabis share a fundamental therapeutic action - that of regulating systemic balance and stimulating progenerative adaptation. We believe that AO cannabis models a way for traditional Cannabis producing regions to move forward as integrated cultural-biological systems that will not only survive the global commodification of cannabis, but also inform a balanced future for global agriculture.