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INTERNATIONAL BUT PERSONAL

CANNABIS REGULATION AND CANNABIS DERIVED PRODUCTS

INTRODUCTION

As more jurisdictions around the world move to legalize various forms of cannabis, including hemp and CBD products, recreational marijuana, and medical marijuana, the global cannabis industry continue to blaze forward. But changing and even inconsistent laws and an evolving regulatory environment have created legal uncertainties and tensions in the development of the industry and marketplace. This booklet aims to provide practitioners a summary reference for cannabis laws and regulations in various jurisdictions across the globe. Practitioners should note that because cannabis laws are quickly evolving, through the legislative process, ballot initiatives and regulatory rule implementations and changes, each jurisdiction's most recent cannabis laws and regulations should be reviewed and assessed.

A QUICK PRIMER ON CANNABIS BASICS

Cannabis vs. Marijuana vs. Hemp

Cannabis refers to a genus of plants that has three species – indica, sativa, and redueralis. Marijuana and hemp are both cannabis. Despite popular misconception, marijuana and hemp are not different species of cannabis.

Marijuana, in the common parlance, is cannabis that, when consumed, results in a "high." The "high" in marijuana is produced as a result of high tetrahydrocannabinol or THC content. Hemp, again in common usage, does not cause intoxication because it has low levels of THC.

INTRODUCTION

Some jurisdictions around the world still do not distinguish between marijuana and hemp. For example, for decades, the federal government in the U.S. did not distinguish between hemp and marijuana or the level of THC content in either – both were illegal cannabis and a controlled "Schedule I" drug.

As cannabis laws and policy have changed over the years, now, in the U.S. and, as applicable, in other jurisdictions, the legal difference between marijuana and hemp is often based upon THC content level. In the U.S., again by way of further example, the Agriculture Improvement Act of 2018 defines legal hemp as "Plant Cannabis sativa L. and any part of that plant, including cannabinoids with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." Thus, under federal law in the U.S., cannabis that has no more than 0.3% THC is legal hemp, but cannabis that contains more than 0.3% remains illegal marijuana. Each jurisdictions' definitions for each should, of course, be consulted to determine whether hemp and marijuana are distinguished from one another and where the lines of cannabis legality or illegality are drawn.

THC vs. CBD

THC and CBD are both cannabinoids found in cannabis. A cannabinoid is a naturally occurring compound that reacts with cannabinoid receptors found in our nervous system that are part of our endocannabinoid system, involved in appetite, mood, and sensing pain.

As noted, THC is a psychoactive cannabinoid in marijuana that produces a "high." CBD, or cannabidiol, is a non-psychoactive cannabinoid that may have some health benefits. But more studies are needed. CBD can be derived or extracted from hemp and marijuana. Many CBD products are derived from hemp, containing low levels of THC and higher levels of CBD. Whether CBD or CBD products are legal in any particular jurisdiction will be driven by legal definitions and parameters established by applicable regulatory authorities.

INDIA
DUA ASSOCIATES

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in India?

NDPS Act – With regard to the regulatory framework in India concerning Cannabis, we refer back to the NDPS Act, that prohibits cultivation, production, possession, sale, purchase, trade, import, export, use and consumption of narcotic drugs and psychotropic substances except for medical and scientific purposes in accordance with the law. The Governments' policy has thus been to promote the use of narcotic drugs and psychotropic substances for medical and scientific purposes while preventing their diversion from licit sources and prohibiting illicit traffic and abuse.

The NDPS Act covers three broad classes of substances: (1) narcotic drugs, that is, those covered under the 1961 Convention; (2) psychotropic substances or those covered under the 1971 Convention as well as other psychoactive substances such as ketamine which are not yet classified under international conventions; and (3) "*controlled substances*" that are used to manufacture narcotic drugs or psychotropic substances.

It may be noted that while the NDPS Act is predominantly punitive, it also contains provisions to regulate drugs. In this regard, the NDPS Act empowers both the Central and State governments to frame rules and authorize drug-related activities within the rubric of "medical and scientific purpose", a term which is neither defined nor described in the NDPS Act. While some activities are reserved exclusively for the government, others can be carried out by private entities under a license.

It may also be pointed out that the NDPS Act divides the powers and responsibility of regulation of licit activities. Section 9 of the NDPS Act has listed various activities which the Central Government can, by rules, regulate while Section 10 lists various activities which the State Governments can, by rules, regulate. Thus, we have NDPS Rules of the Central Government and the State NDPS Rules framed by each State Government under the same NDPS Act. These are enforced by the Central or concerned State Government.

The NDPS Act has been amended three times - in 1988, 2001, and most recently in 2014. The 2014 amendment recognizes the need for pain relief as an important obligation of the government. It creates a class of medicines called Essential Narcotic Drugs (ENDs). Power for legislation on ENDs has been shifted from the State Governments to the Central Government so that the whole country now can have a uniform law covering these medicines which are needed for pain relief.

Prohibition, Control and Regulation of Cannabis under the NDPS Act - '*Cannabis (hemp)*' has been defined under Section 2 (*iii*) of the NDPS Act as:

(*a*) *Charas*, that is, the separated resin, in whatever form, whether crude or purified, obtained from the Cannabis plant and also includes concentrated preparation and resin known as hashish oil or liquid hashish;

(*b*) *Ganja*, that is, the flowering or fruiting tops of the Cannabis plant (excluding the seeds and leaves when not accompanied by the tops), by whatever name they may be known or designated; and

(*c*) any mixture, with or without any neutral material, of any of the above forms of Cannabis or any drink prepared therefrom.

General Prohibition: As per Section 8 of the NDPS Act, no person can *inter alia* cultivate any Cannabis plant or produce, manufacture, possess, sell, purchase, transport, warehouse, use, consume, import inter-State, export inter-State, import into India, export from India or tranship any narcotic drug {*Under section 2(xiv) of the NDPS Act the term "narcotic drug" means coca leaf, cannabis (hemp), opium, poppy straw and includes all manufactured drugs*} except for medical or scientific purposes and in the manner and to the extent provided by the provisions of the NDPS Act or the NDPS Rules or orders made thereunder and in a case where any such provision, imposes any requirement by way of license, permit or authorization also in accordance with the terms and conditions of such license, permit or authorization.

Section 20 of the NDPS Act deals with the offences related not only to the consumption but also cultivation, possession, use, sale/purchase, import/export, transportation and warehousing of Cannabis, except for medical or scientific purposes in India. As per the said Section 20 of the NDPS Act whoever, in

contravention of any provision of the NDPS Act or any rule or order made thereunder, or condition of license granted thereunder:

(*a*) cultivates any Cannabis plant is liable to be punished with rigorous imprisonment for a term which may extend to 10 years and shall also be liable to fine which may extend to Rs.100,000.00; or

(*b*) produces, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses Cannabis, is liable to be punished, where such contravention:

(i) involves small quantity, with rigorous imprisonment for a term which may extend to 1 year or with fine which may extend to Rs.10,000.00, or with both.

(*ii*) involves quantity lesser than commercial quantity but greater than small quantity, with rigorous imprisonment for a term which may extend to 10 years and with fine which may extend to Rs.100,000.00.

(*iii*) involves commercial quantity, with rigorous imprisonment for a term which shall not be less than 10 years but which may extend to 20 years and shall also be liable to fine which shall not be less than Rs.100,000.00 but which may extend to Rs.200,000.00.

As per the said Section 20 of the NDPS Act a court may, for reasons to be recorded in the judgment, even impose a fine exceeding Rs.200,000.00.

The only exception to the aforesaid is *Bhang* which is a preparation made from Cannabis leaves consumed in parts of India on some festivals. As it is not made from Cannabis resin or from flowering tops, it is not covered under the NDPS Act. Production and sale of *Bhang* is permitted by many State Governments. Whoever is so licensed to produce *Bhang* is allowed to produce it from the leaves of the wildly growing Cannabis plants only. The use of the flowering tops or the resin produced from the plants to make *Bhang* is not permitted. Anyone found mixing with *Bhang* any part of flowering tops or the resin produced from the Cannabis plants, is liable to be punished under the relevant provisions of the NDPS Act and if such person happens to be a licensee, his license can also be cancelled.

The above being said, although the NDPS Act allows consumption of *Bhang*, various states keeping in line with the fact that the NDPS Act allows State Governments to frame their own rules to regulate various activities in relation to *inter alia* the usage of Cannabis or Cannabis related products have their own laws

banning or restricting its use. For example, in Assam, the Assam Ganja and Bhang Prohibition Act, 1958, prohibits sale, purchase, possession and consumption of *Ganja* and *Bhang*. In Maharashtra, Section 66(1)(b) of the Bombay Prohibition Act, 1949, bans manufacture, possession and consumption of *Bhang* and *Bhang* - containing substances without a license. On February 21, 2017, Gujarat legalized *Bhang* by removing it from the list of "*intoxicating drugs*" covered under Section 23 of the Gujarat Prohibition Act, 1949.

Cultivation of Cannabis for Medical and Scientific purposes: Section 10 of the NDPS Act read with Section 8 of the NDPS Act empowers the State Governments to license cultivation of Cannabis for medical and scientific purposes. Medicinal use of cannabis has so far been extremely limited and confined to alternate medicine such as Homeopathy and Ayurveda. State Governments have actually not been licensing cultivation of Cannabis despite the growing international interest among scientists in exploring possible medical uses of Cannabis of late. As per the extant National Policy on Narcotic Drugs and Psychotropic Substances the cultivation of Cannabis will not be permitted given its limited proven uses for medical purposes. However, the cultivation of Cannabis will be permitted for research including trials of various varieties of Cannabis.

In tune with the aforesaid India has begun its medical research of Cannabis in government authorized research premises. The Indian Institute of Integrative Medicine (IIIM) has taken the legal license to cultivate Cannabis for scientific and medical research purposes to develop products for epilepsy and cancer treatment. Under a tripartite agreement, the Council of Scientific & Industrial Research (CSIR), the India Council of Medical Research (ICMR) and the Department of Biotechnology have agreed to develop the epilepsy and cancer treatment products. In terms of the aforesaid, the CSIR will cultivate various varieties of Cannabis and then carry out clinical work in connection therewith. The ICMR will then administer the clinical trials at the Tata Memorial Centre in Mumbai and All India Institute of Medical Sciences (AIIMS) in New Delhi. In February 2020, the IIIM and CSIR entered into a cross-border agreement with the Canada-based Cannabis research company IndusCann. This research and development collaboration aims to create ample opportunities for developing varied medicines from Cannabis.

Cultivation of Cannabis for Horticultural and Industrial purposes: As per the extant *National Policy on Narcotic Drugs and Psychotropic Substances* the Cannabis

plant can be a source of biomass and fibre for industrial purposes. Cannabis seeds can be used to produce Cannabis seed oil - a high value oil. Some countries license cultivation of Cannabis varieties which have very low content of THC (Tetrahydrocannabinol), the active ingredient which has the intoxicating effect. These varieties of Cannabis are used to produce fibres which are, in turn, used in production of fabrics and for production of biomass.

Section 14 of the NDPS Act empowers the Government to, by general or special order, permit cultivation of Cannabis exclusively for horticultural and industrial purposes. In fact, as per the extant *National Policy on Narcotic Drugs and Psychotropic Substances*, the Central Government is also required to encourage research and trials of cultivars of Cannabis with low THC content. The Central Government, however, is required to follow a cautious, evidence-based approach towards cultivation of Cannabis for horticultural and/or industrial purposes and is required to take decisions based on results of research.

Cannabinoid Drugs: Cannabinoid Drugs are preparations made out of extracts or tincture of Cannabis. If a drug contains cannabinoids which have been synthetically manufactured, they would be regulated as drugs, except for drugs containing THC since THC is regulated as a psychotropic substance in India. Cannabinoid Drugs may be sold in India in accordance with the requirements laid down by law. Cannabinoid Drugs which are an extract or tincture from Cannabis would require a license under the NDPS Act, the NDPS Rules, the Drugs Act and the Drugs and Cosmetics Rules, 1945 (Drugs Rules) for sale in India. In this regard it may be noted that narcotic drugs can be manufactured only after obtaining a license from the Narcotics Commissioner. The Narcotics Commissioner issues a license only if certain prescribed conditions are fulfilled including producing a manufacturing license under the Drugs Act and the rules made thereunder from the State Drugs controller and the licenses to be obtained from the State Government under the State NDPS Rules for possession, use and sale of narcotic drugs.

So far, no cannabinoid drugs have received market approval.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in India?

Regulatory challenges at Policy formulation: Any move towards allowing the medical and recreational use of Cannabis and cannabinoids in India would gather traction at a regulatory level only if the Government/courts, as the case may be, are furnished with satisfactory answers to the following questions supported with cogent and empirical evidence:

1. *Does Cannabis have proven Medicinal benefits?*

While one of the common uses of Cannabis is in the control of nausea and vomiting, however, studies show that there is no statistically significant benefit of Cannabis derivatives over available drugs. Paradoxically, few case reports have described a condition known as cannabinoid hyperemesis (*excessive vomiting*) syndrome in marijuana addicts. With regards to appetite-stimulating actions of Cannabis, we have more effective drugs that are easily available. Cannabis is effective in pain management, but it is weaker and less safe than opiates that are approved. A study did show beneficial effects of Cannabis in a small percentage of extremely rare form of epilepsy and multiple sclerosis. However, most studies are not designed properly to offer any conclusive evidence. In summary, its medicinal benefits are not as strong as presented by the proponents of legalization - safer and effective alternatives are available in the market.

2. *What about health consequences of Cannabis use?*

The severity of the adverse effects of Cannabis depends upon type (*marijuana being the worst*), duration and frequency of use. Adults who smoke marijuana regularly show impaired neural connectivity. Marijuana users are at an increased risk of developing chronic psychotic disorders (*including schizophrenia*). There is an increased incidence of vehicle accidents in those who may be either short-term or long-term users of marijuana. Cannabis smoking is associated with an increased risk of bronchitis, pneumonia and respiratory distress, as also transient ischemic attacks, stroke, myocardial infarctions and Cannabis arteritis. Studies have shown a positive association between marijuana smoking and cancers of the lung, and an increased risk of developing other cancers. Moreover, the interactions between Cannabis and chemotherapy (*or any drug*) are largely unknown.

3. *Does legalization of Cannabis help?*

India has a history of misuse of even prescription drugs that are otherwise beneficial. Weak opiates (*derivatives of opium*) are one of the easily available alternatives to Cannabis for medical conditions. Codeine-based cough syrups are effective for controlling severe cough, but after reports of rampant misuse, the Narcotics Control Bureau asked the Drug Controller General of India to reduce its availability despite proven effectiveness. In Indian context, when prescription drugs are grossly misused, how can we ensure disciplined used of Cannabis is a big question?

4. *Will legalization worsen our overburdened healthcare system?*

India is struggling to control the three addictive substances *viz.*, tobacco, alcohol and areca nut. The younger generation is living in an era of personal liberty and rising affluence which makes them more prone to addiction. Introduction of yet another psychoactive drug will wreak havoc on a population still struggling with tobacco, alcohol and pan masala. It is unlikely to solve the drug menace in Punjab, Rajasthan and other states. Predatory marketing of Cannabis companies will hit the vulnerable population most, such as youth, poor, insecure, illiterate. Once introduced, it will establish a big market that would make subsequent tighter regulations impossible. Following legalization in the West, various newer products with marijuana are available in the market and on online portals, without proper prescription. These include marijuana chewing gums, candies, etc., which youngsters can easily take to.

Regulatory challenges under the NDPS Act: Besides the aforesaid challenges which effectively rule out a policy shift in the drug policy of India for the time being, the following are the regulatory challenges which exist under the currently existing regime which have the effect of rendering the implementation of even the current drug policy of India somewhat difficult:

Uneven co-ordination amongst Government Agencies

Drug policy administration in India is divided not only between the Central and State governments but also between Ministries and Departments at the same level. The distribution of subjects between the Center and State has already been

discussed hereinabove. The division between Ministries and Departments is described in the First Schedule under the Government of India (Allocation of Business) Rules, 1961, which demarcates the scope of work of each agency. As per these rules, the Department of Revenue under the Ministry of Finance (MoF) is entrusted with the administration of the NDPS Act as well as with matters relating to the international conventions on narcotic drugs, psychotropic substances and precursor chemicals, except those managed by the Ministry of Home Affairs (MHA). The Department of Internal Security within the MHA is tasked with handling all matters relating to Narcotics Control Bureau (NCB) {*which coordinates actions by various functionaries (Central and State) under the NDPS Act*} and with the coordination of drug control measures. It also deals with matters relating to the international conventions in respect of illicit traffic in narcotic drugs, psychotropic substances, and precursor chemicals except those allocated to the Department of Revenue, MoF. Matters pertaining to Drug Demand Reduction are handled by the Ministry of Social Justice and Empowerment (MSJE). The MSJE supports various Non-Governmental Organizations (NGOs) involved in Drug Demand Reduction. Ministry of Health, Government of India, which is responsible for all health issues, runs several drug de-addiction centers in the government hospitals across the country.

An inconsistent stand between the MoF and the MHA was seen on the question of the death penalty under the NDPS Act. In May 2012 while the then Finance Minister announced support for making capital punishment discretionary under the NDPS Act, the NCB filed a petition in the Supreme Court to preserve the mandatory death penalty under the NDPS Act. Another example of poor coordination and accountability was apparent in the case concerning human rights abuses against people who use drugs in treatment centers, where neither the Ministry of Health nor the MSJE took responsibility for private, unfunded centers as they ostensibly do not have rule making powers under the NDPS Act. In addition, the MoF said that while it is in charge of making NDPS Rules, it was not responsible for treatment and therefore could not make rules on the subject.

Owing to the aforesaid the implementation of the drug policy of India has sometimes seen a confusing overlap and, at times, an abdication of responsibility.

Lack of consultation in Policymaking

The lack of policy co-ordination is compounded by the non-application of consultative mechanisms provided in the NDPS Act and the NDPS Consultative Committee Rules, 1988 ("Committee Rules").

The NDPS Act allows the Central Government to establish a 20-member NDPS Consultative Committee ("Committee") as a policy-advisory body with a broad mandate. The Committee Rules allow the Committee to review the NDPS Act and the NDPS Rules, advise the government on policy matters, and consider any other issue requested by the government. The Committee may prepare a special report on any topic of importance for the government's consideration. The Committee may delegate specific policy matters to sub-committees, including sub-committees that review policy enforcement and treatment, rehabilitation, social reintegration and other connected matters. The Committee can draw upon experts and civil society representatives to review and recommend changes in nearly all areas of drug policy. Sadly, these provisions have not yet been invoked.

In 2008, the government announced the setting up of a National Consultative Committee on De-Addiction and Rehabilitation (NCCDR) under the Chairmanship of the MSJE to advise the Central and State governments on drug demand reduction, especially education/awareness building, deaddiction and rehabilitation. The composition of the NCCDR does not appear to be in accordance with the law. Not much is known about its role and functioning.

In 1961, driven by Western nations, the UN sponsored an international treaty to prohibit the production and supply of drugs including Cannabis. India resisted and negotiated exceptions, loopholes, and deferrals. It is ironic that the West is now legalizing Cannabis and other drugs. Given that some in India are clamouring for the same, India should carefully consider all the risks associated with Cannabis use and consider alternatives. One possible way of dealing with the situation could be the decriminalization of Cannabis coupled with the forbidding of the commercialization thereof. Alternately, if India were to liberalize its policy on Cannabis altogether, it should at the same time ensure that there are enough protections for children, the young, and those with severe mental illnesses, who are most vulnerable to its effects. Finally, before any of the aforesaid steps are considered treatments for those who become addicted to Cannabis should be in place.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in India?

In order to determine what regulatory framework would be relevant for the medicinal and recreational Cannabis products cultivation, manufacture and supply in India it would be relevant to take note of the following emerging trends towards regulation of Cannabis in India:

Trends in the Legal Sphere: The Indian Cannabis market has gathered significant attention recently, with various activists/NGOs filing court petitions demanding legalization of Cannabis. They argue that the medicinal benefits of Cannabis are hard to ignore, and the ideal climatic conditions for Cannabis cultivation have the potential to boost the Indian economy and create millions of jobs. One of these NGOs is the Great Legalization Movement India (GLM), which is working to legalize the use of Cannabis for medical and industrial purposes in India. In the summer of 2019, the Delhi High Court admitted a writ petition filed by GLM seeking decriminalization of Cannabis under the NDPS Act. The public interest litigation argues that the grouping of Cannabis with other chemical drugs under the NDPS Act is "arbitrary, unscientific and unreasonable" Although originally planned to be heard in February 2020, the hearing has been pushed back.

Trends in the Political Sphere: There is also traction among some government officials for the legalization of Cannabis. Officials including Maneka Gandhi and Tathagata Satpathy have spoken in favour of Cannabis decriminalization. In November 2019, Madhya Pradesh, the second largest state in India, decided to legalize the cultivation of Cannabis for medicinal and industrial purposes. Even more recently, it was announced in February 2020 that the Bhartiya Janata Party (BJP) government in Manipur is also considering the legalization of Cannabis for medical and industrial purposes.

Ayurveda, Unani, Siddhi and Homeopathy (AYSUH) system of Medicines: AYUSH experts as recently in August 2019 pitched for the legalization of medicinal use of Cannabis, saying that India can revolutionize pain management with Cannabis by using ayurvedic knowledge. The experts were speaking at the third edition of Oja Festival organized in August 2019 by NirogStreet (*India's first technology-led*

Ayurveda platform) in association with the AYUSH Ministry and co-organized by CSIR-IIIM Technology Business Incubator.

A statement said that renowned ayurvedic experts, researchers and practitioners voiced their opinion on critical issues related to Ayurveda and its relevance in the modern healthcare system. "*The government is working very hard as medicinal marijuana or cannabis will be legalized soon. Scientists are aggressively working to find out the active components of cannabis*." Dr Saurabh Saran, CSIR-IIM Technology Business Incubator, Jammu said.

Trends in the Commercial/Industrial Sphere: A number of promising Indian Cannabis start-ups have arisen in recent years, some of whom are collaborating in order to grow in the domestic market. These start-ups are generally focusing on medicines, cosmetics, textiles, accessories and foods. One of the most promising is Boheco (*the Bombay Hemp Company*), which is backed by high-profile investors including Google India's Managing Director Mr. Rajan Anandan, and Mr. Ratan Tata of Tata Sons. The company is agro-based and intends to reimagine the future of Indian agriculture and sustainable living with hemp. It is also a major supplier of raw material to fellow start-ups, Hempster and B.E. Hemp.

In February 2020, the India-based healthcare start-up HempStreet (*which concentrates on the use of cannabis in Ayurvedic medicine*) raised USD $1 million in pre-series A funding. The company will use the funding to support its technology growth, research development and to launch a new set of cannabis-based products. Abhishek Mohan, HempStreet's co-founder said they intend to set new milestones for the medicinal Cannabis sector in the country. They are also building blockchain technology to track the Cannabis from seed to sale, eliminating the risk that the Cannabis they grow will add to the substance abuse problem.

Despite being a trusted ingredient in the treatment of various ailments for thousands of years, the use of Cannabis in modern medicine is restricted by India's outdated Cannabis laws. Although legalization is still some way off, the rising number of cannabis and hemp start-up companies, and the growing popular support for the plant's legalization, is encouraging. Considering the medical and economic reasons in favor of legalizing

cannabis, it may not be long before the Indian Government unlocks the full potential that legalization of Cannabis would bring.

4. Which body is responsible for legislative controls relating to CBD?

As discussed above, the Central Government, in the year 1985, brought into force the NDPS Act, which is the central legislation that provides for a regulatory framework under which narcotic drugs and other psychotropic substances are regulated in India. It is to be noted that the legislative framework in India governs and regulates the use of Cannabis, in its entirety, and that there are no specific legislations, as such, which separately govern CBD as a substance. It may, however, be noted that THC is separately categorized as a psychotropic substance in the NDPS Act. It is therefore understood that the bodies that are responsible for legislative controls relating to a Cannabis plant, as a whole, would also be responsible for the regulation of CBD. It would also be important to note that Cannabis is defined in such a manner in the NDPS, such that it specifically excludes the seeds of the Cannabis plant and the leaves, as long as they are without the flowering and fruiting tops.

The NDPS Act, which governs Cannabis, as a narcotic drug, extends to the entire territory of India, and requires the constitution of certain bodies for enabling the implementation and for ensuring the strict enforcement of the NDPS Act. As has also been discussed above, the NDPS Act segregates the powers and responsibilities of regulation of activities between the Central and State Governments.

In terms of the NDPS Act and the NDPS Rules, the Central Government is vested with certain powers, such as to permit and regulate the manufacture, possession, transport, import, sale, etc., of 'essential narcotic drugs'[1] , while the State Governments are vested with certain powers to permit specific activities related to 'Cannabis' within the jurisdiction of each respective state. It must be noted that Cannabis, as on date, has not been classified as an 'essential narcotic drug'. The State Governments are therefore required to formulate rules for the purposes of regulation of the cultivation, manufacture and use of Cannabis.

[1] Section 9, The Narcotic Drugs and Psychotropic Substances Act, 1985.

Notwithstanding the above, the Central Government has categorically stated in the NDPS Act that Cannabis can be cultivated, manufactured and used only for: (i) industrial uses; and (ii) medicinal and scientific purposes.

Several states in India, such as the states of Kerala, Rajasthan, Uttar Pradesh, etc., have enacted their own NDPS rules, in order to regulate the cultivation, manufacture and use of Cannabis. These rules relate to permitting and regulating the cultivation of any Cannabis plant, the production, manufacture, possession, transport, inter-state import and export, sale, purchase, consumption and use of Cannabis.

The legislative controls therefore in relation to Cannabis lie with both, the Central Government and the State Governments.

The nodal organization under the Central Government that is responsible for introducing reforms/amendments to the existing legislative framework is the Department of Revenue under the MoF[2] . The Department of Revenue has the responsibility to frame rules to regulate the various activities as set out in the NDPS Act[3] , and is also responsible for activities such as the administration of the NDPS Act, and the examination of proposals for the amendment of the NDPS Act and the rules made thereunder. The Department of Revenue ensures compliance with its duties and responsibilities through bodies such as the Central Bureau of Narcotics, and other bodies under the Narcotics Department.

The enforcement of the provisions of the NDPS Act and the NDPS Rules have been allocated to multiple departments of the Government and to various bodies. The allocation is on the basis of the Government of India (Allocation of Business) Rules, 1961, which provides for separate ministries, departments, and/ or bodies to enforce the NDPS Act. Accordingly, under the Central Government, certain bodies such as the Narcotics Control Bureau, the Central Bureau of Narcotics, the Central Economic Intelligence Bureau, the Directorate General of Revenue Intelligence, the Customs Department, the Indian Coast Guard, etc., have been vested with specific and separate powers to ensure the enforcement of the NDPS Act and the NDPS Rules.

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[2] The National Policy on Narcotic Drugs and Psychotropic Substances.

[3] The List of Subjects Allocated to the Department of Revenue (Revenue Headquarters), The Government of India (Allocation of Business) Rules, 1961.

At the state level, the State Governments broadly require its police departments and its excise officers to ensure compliance with the NDPS Act, the NDPS Rules and the relevant state NDPS Rules in the particular State.

Parallelly, the MHA has also been given certain responsibilities in terms of the administration of the NDPS Act, such as the examination of drug related agreements, and is also vested with certain administrative functions such as overseeing the budget and carrying on the financial monitoring of the Narcotics Control Bureau, which has been established by the Ministry[4]. The MHA undertakes and implements its duties and obligations through the Narcotics Control Bureau, which is the body that is engaged in discharging various functions[5], including coordinating with various central and state agencies that are engaged in the enforcement of drug laws.

While the central legislative framework empowers the States to frame rules for the issue of licenses to cultivate Cannabis, in practice, the mechanism of issuing licenses is still evolving at the state level. At present, few states in India, such as Uttarakhand and Uttar Pradesh, have been able to formulate a mechanism for issuing such licenses. Such licenses are issued, subject to certain conditions which are to be strictly followed by the license holders. While the legislative framework is silent on the specifications for the cultivation of Cannabis, the conditions attached to the licenses set out requirements such as area of the land, the specific level of CBD/THC that should be present, the purpose for use, etc.

While the use of Cannabis and Cannabis related products are primarily governed by the NDPS Act, the NDPS Rules, and the relevant State rules, the use of Cannabis in drugs and cosmetics is also governed by the Drugs Act. In terms of the Drugs Rules, the Central Drugs Standard Control Organization (CDSCO), headed by the Drug Controller General, is the Central Drug Authority for discharging functions assigned to the Central Government under the Rules[6]. While the Drugs Act and the rules thereunder were introduced by the Ministry of Health and Family Welfare, the CDSCO is responsible for making any amendments to the Drugs Act and the relevant rules.

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[4] S.O. 96 (E), dated March 17, 1986, issued by the Department of Revenue, Ministry of Finance.

[5] Office Memorandum No.50/71/86-Ad.I, dated February 2,1987, issued by the Department of Revenue, Ministry of Finance.

[6] Rule 2(b), The Drugs and Cosmetics Rules, 1945.

In addition to the above, the manufacture and consumption of any food substance, in India, is governed by the Food Safety and Standards Act, 2006 (FSS Act). While there are certain countries which have recognized the use of certain parts of the Cannabis plant as well as CBD in food products, India has not, as on date, recognized Cannabis or CBD as a food product. possibility of the regulation of the use of Cannabis or CBD in a food product, the same will be regulated by the FSS Act whereunder the Food Safety and Standards Authority of India (FSSAI) has been established and is the regulating authority who would have the powers to legislate on this subject.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in India?

As an introduction, it is understood that while CBD is primarily extracted from the seeds and leaves of the Cannabis plant, it is also found and can be extracted from the other strains of the plant. As discussed above, the definition of the term 'Cannabis (hemp)' for the purposes of the NDPS Act and its categorization as a narcotic drug, excludes the seeds and the leaves, as long as the leaves do not have the flowering and fruiting tops with them. It is therefore understood that CBD, when extracted from the seeds and leaves, may not be classifiable, as a narcotic drug, but when extracted from the other strains of the plant, could be categorized as narcotic drug, as all such other parts are so categorized.

Novel Food Approval:

'Food' means any substance which is intended for human consumption, however, does not include any drugs, medicinal products, cosmetics or 'narcotic or psychotropic substances'[7]. In terms of the FSS Act, food has been broadly categorized as standardized foods, novel foods, nutraceuticals, health supplements, foods for special medical purposes, proprietary foods, novel foods, other non-specified foods, etc. Each of these categories are governed by separate provisions, and the products made available to consumers are required to conform with all the mandatory requirements stipulated in the regulations governing them.

[7] Section 2(j), The Food Safety and Standards Act, 2006.

In India, in order for a person to commence or carry on any food business[8] , a compulsory license or a registration is required to be obtained by the food business operator[9] from the FSSAI. As most of the categories of food products are regulated in terms of the FSS Act and the regulations thereunder, such categories are not required to obtain a separate approval from the FSSAI, other than obtaining the license/registration which is a permission to manufacture, etc. For example, for the manufacture of a standardized food product, i.e., foods for which specific standards have been set out in the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, the food business operator does not require a separate product approval, as the product would be required to comply with the standards that have been set out for the same, however, the required licenses/registrations would have to be obtained.

The use of Cannabis or CBD as a food product or food ingredient in the Indian market has not been recognized or standardized as yet, by the relevant government authorities. The reason behind this may be the consideration of certain parts of the Cannabis plant as a 'narcotic drug', in terms of the NDPS Act, and the fact that the definition of the term 'food' specifically excludes 'narcotic or psychotropic substances'. The FSSAI has, as a matter of fact, in the year 2017, issued a letter[10] to various food business operators, stating that 'hemp' is a product for which no standard has been prescribed due to the lack of certain data and information and any hemp product that is marketed using a FSSAI license is an illegal and unauthorized act.

At this juncture, while categories of 'non-specified foods' and 'novel foods' exist in terms of the FSS Act, and these categories mandatorily require an approval from the FSSAI for its manufacture, the question that remains is whether Cannabis or any part of it can be used as a food or a food ingredient, as the same being a 'narcotic drug/substance', is excluded from the definition of the term 'food'.

In relation to the above, there could be a possibility of drawing a distinction between a 'narcotic CBD' and 'non-narcotic CBD', for the reasons, as set out

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[8] Section 2(n), The Food Safety and Standards Act, 2006.

[9] Section 2(o), The Food Safety and Standards Act, 2006.

[10] File No. 4(37) 2017/States/RCD/FSSAI (Vol. 1), dated October 17, 2017, issued by the Food Safety and Standards Authority of India.

above, and it could be possibly interpreted that CBD, which is extracted from the seeds and leaves of the Cannabis plant, may be used as an ingredient in food as the same may not be a narcotic drug, which is categorically excluded from the definition of the term 'food'. This is, however, only a possible argument and at present there is no regulation or discussion on this subject under the FSS Act.

It may, however, be noted that even if there could be a distinction created between narcotic CBD and non-narcotic CBD, under the FSS Act, a food business operator would not be permitted to simply use the non-narcotic CBD as an ingredient in any food product. The use of this, whether as a food or an ingredient, would require a specific approval from the FSSAI, either as a 'novel food/ ingredient' or as a 'non-specified food/ingredient'[11].

Medicinal Product Marketing Authorization:

The Drugs Act and the Drugs Rules are the legislations which govern the licensing of drugs and cosmetics in India. The legislation has been framed in a manner such that there are several categories of drugs, cosmetics and ayurvedic drugs and each category is separately governed by the Drugs Act and the Drugs Rules. In addition, the Drugs Act and the Drugs Rules also lay down the concepts of 'new drugs' and 'patent or proprietary medicines' which may not necessarily be categorized under any of the Schedules under the Drugs Act and the Drugs Rules, however, they may have certain other specific criteria and standards that have to be complied with.

Every person intending to manufacture a drug or a cosmetic, is required to submit an application in terms of the Drugs Act, for the proper licenses, permissions, authorizations, etc., on the basis of the Schedule under which the drug falls. Schedule H to the Drugs Rules contains a list of drugs which are 'prescription drugs' and which can be sold only by a registered pharmacist[12]. This Schedule expressly lists down all the 'narcotics drugs' as listed in the NDPS Act, as prescription drugs. This would therefore mean that a drug or a medicine, being a narcotic drug, or which contains narcotic drugs as an ingredient, can only be sold as a prescription drug by a registered pharmacist. The licenses that have to be

[11] Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017.

[12] Rule 65, The Drugs and Cosmetics Rules, 1945.

obtained for the manufacture of Schedule H drugs/medicines are the licenses to manufacture for sale or for distribution. At present, it must be noted that there is no separate marketing authorization, as such, that would be required for the marketing and advertising of these products, other than the license for the sale of the product. It is however understood that the conditions that would be set out when such licenses are issued and which the licenses would be subject to, would clearly and properly set out conditions in relation to the marketing of these drugs.

As, however, stated above, there could be a possible distinction between narcotic CBD and non-narcotic CBD, and it could possibly be interpreted that Schedule H to the Drugs Rules would be applicable to narcotic CBD and use of the same as a drug/medicine, as a whole, or as an ingredient in a drug/medicine.

In view of the above understanding, the use of the non-narcotic CBD, if not governed by Schedule H to the Drugs Rules, could possibly be governed by such other relevant Schedule under which the drug/medicine, in which non-narcotic CBD is used, would be classified. Further, while there is no express or separate authorization required for the marketing or advertising of these other drugs/ medicine, other than the license required for the sale of the drugs/medicines, it is understood that the conditions attached to the licenses that would be issued would properly and adequately set out conditions in relation to marketing and advertising products containing non-narcotic CBD.

The Drugs Act also regulates the manufacture of Ayurvedic, Siddha or Unani drugs (ASU Drugs), and the ingredients and formulae used for the manufacture of ASU Drugs should be exclusively in accordance with the formulae prescribed in the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine[13]. While there is no express reference to CBD in the Drugs Act and Drugs Rules, a reference to '*bhaang*', '*ganja*' and '*çharas*', being forms in which Cannabis can be consumed, is present in the Drugs Rules and the same have been listed as poisonous substances[14] in relation to ASU Drugs. It has been clarified that if the substances of '*bhaang*', '*ganja*' and '*çharas*' are used in ASU Drugs, for internal uses, the label of such product should clearly set out the words "Caution: to be

[13] Section 3(a), The Drugs and Cosmetics Act, 1940.

[14] Schedule E-(I), The Drugs and Cosmetics Rules, 1945.

taken under medical supervision", in both the Hindi and English languages[15]. There is, however, no provision as such, which requires a separate marketing authorization for the marketing and sale of such products, other than the license required for the sale of the products and as stated above, the conditions of license should more than adequately provide for the compliances/restrictions in relation to the advertising of the products which contain any form of Cannabis, including CBD, if so permitted.

The Drugs Act similarly also regulates the manufacture of cosmetics and there are certain standards set out for varied kinds of products such as ointments, ophthalmic preparations, and the like. The Drugs Act also specifically sets out that there are other cosmetic items, such as, attars, perfumes, etc., for which standards have not been set out in the Schedules laid down therein. The Drugs Act however, in relation to cosmetics as well, has not set out any provisions which relate to CBD (whether narcotic or non-narcotic) being used as an ingredient and if being so used, whether a separate marketing authorization is required to be obtained. In a similar manner, as set out above, it could be understood that the Licensing Authorities will set out specific conditions in relation to the marketing and advertising of products that contain CBD in them while issuing the required licenses for the manufacture and sale of cosmetics.

While the Drugs Act and the Drugs Rules do not discuss the requirement of obtaining a separate marketing authorization for the advertising and promotion of drugs, ASU drugs or cosmetics, which may contain CBD or any other form of Cannabis in them, there are rules as well guidelines which set out principles of advertising for all kinds of drugs and cosmetics. In particular, the Drugs Rules prohibit the manufacturers of ASU Drugs from advertising any ASU drug which claims to be used for the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder, syndrome or conditions[16]. In addition, the other principles have been framed to ensure that all advertisements in relation to drugs are truthful and not misleading in any manner for the safety of consumers[17].

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[15] Rule 161(2), The Drugs and Cosmetics Rules, 1945.

[16] Rule 170, The Drugs and Cosmetics Rules, 1945.

[17] These principles are laid down in the provisions of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, the Advertising Standards Council of India Code, the Uniform Code for Pharmaceutical Marketing Practices, Organization of Pharmaceutical Producers of India Code of Pharmaceutical Practice, the International Federation of Pharmaceutical Manufacturers and Associations Code and such other codes.

6. What are the testing specifications in India for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

The United Nations Office on Drugs and Crime has released a document on the recommended methods for the identification and analysis of Cannabis and Cannabis products, which acts as a manual to be used by the drug analysis laboratories across the world. The purpose of the manual is to deal with the identification and analysis of drugs, and it has therefore made an attempt to harmonize and establish certain recommended methods of analysis to be followed by laboratories around the world, in addition to specific legal requirements. The manual particularly specifies that on an international level, the THC levels in 'industrial hemp' should be recognized to be 0.2% (zero point two percent).

Considering that the current legislative framework for the manufacture, sale and use of Cannabis in India is still in the nascent stage, it appears that there is no specific and separate legislation which regulates CBD in particular and which sets out any standards, that CBD is required to comply with. Further, there also appear to be no specifications or testing methods to analyze the level of any controlled substance in CBD or the level of purity of CBD in the legislative framework. As stated above, the State Governments have been empowered to issue the licenses for the manufacture, sale, etc., of Cannabis under the NDPS Act, and it appears that such State Governments through the conditions attached to the licenses being issued, are regulating the level of CBD and THC in Cannabis. For instance, the State of Uttarakhand has allowed the cultivation of 'industrial hemp', only if the level of THC is less than 0.3% (zero point three percent), however, there have been no testing methodologies or specifications that have been set out in the legislative framework in relation to the same.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

The cultivation and production of hemp falls under the State list of the Constitution of India, therefore, the proliferation of entrepreneurial activities in the hemp industry comes under the purview of the State governments.

Cannabis grows mainly in North India, particularly in the States of Uttarakhand, Uttar Pradesh, Himachal Pradesh and Jammu & Kashmir[18], however today only the State of Jammu and Kashmir and the State of Uttarakhand have formulated hemp – related cultivation policies.

Regarding the State of Himachal Pradesh[19] policies seem to be still in the making on the lines of the neighbouring State of Uttarakhand to legalize the cultivation of Cannabis for the production of life-saving medicines and some other limited number of industrial products. With Uttarakhand taking the lead[20], States like Uttar Pradesh and Jharkhand are also coming forward to disrupt the prevailing policies and to pave a path for skilled entrepreneurs of India to grow, prosper, and strengthen Indian economy[21].

Although the NDPS Act allows the State governments to grant permissions/licenses for the cultivation of hemp for specific purposes, the actual process of obtaining these permissions/licenses is far from easy. This is because of the absence of a standardized

[18] Available at https://www.forbesindia.com/article/sustainability-special/on-the-hemp-trail-bohecos-attempt-to-build-a-new-narrative-around-cannabis/50349/1

[19] Available at https://himachalwatcher.com/2019/10/29/cannabis-legalization-in-himachal-pradesh/

[20] A few salient features of the Uttarakhand State Policy, notified on 5 December 2016, are stated hereunder:

(a) Any person, institution or entity may cultivate industrial hemp subject to prior license granted by the collector. The cultivation shall only be for the purposes of obtaining seeds and/or fibres. The license granted shall not be transferable from one person/entity to another;

(b) Any land owner or any entity in collaboration with the land owners may apply to the collector for the license to cultivate in the prescribed format annexed to the State Policy and provide such details as are mandated;

(c) The licensee shall be required to provide a character certificate along with the application for the license;

(d) The license may be granted or rejected by the collector upon scrutiny. In the event the application is rejected, the collector shall be required to provide cogent reasons for the same and the licensee shall have the right to appeal to the Excise Commissioner within 30 (thirty) days from the rejection of the application;

(e) The license for cultivation and storage shall be submitted before the collector along with a fee of INR 1000.00 per hectare per year and the license shall be issued in the prescribed format after scrutiny;

(f) The licensee shall be permitted to only cultivate industrial hemp with THC count under 0.3. Licensee shall have to present the seeds before the licensing authority along with a certificate stating the THC count to be under 0.3. The seeds shall be verified by the licensing authority and confirmed for use for cultivation;

(g) The licensee shall also be required to intimate the collector for carrying out measurement of THC count prior to undertaking harvesting. The harvesting shall be undertaken subject to the permission of the appropriate authority. Such confirmation shall be provided by the concerned authorities within 7 (seven) days. The crop may be destroyed in the event the THC count is over 0.3;

(h) The Excise Superintendent of the Excise Department and the Nayab-Tehsildars from the Revenue Department shall have the right to investigate into the existing licenses and the licensees shall be required to maintain registers as may be prescribed.

[21] Available at https://www.entrepreneur.com/article/331292

government route. For instance, there is no clarity on which State government departments are responsible for the granting of permissions to cultivate hemp[22]. This affects the ease of doing business and creates unnecessary barriers to entry for firms interested in the industrial/medical/scientific use of hemp.

- *Purchase*

  The NDPS Act[23] mandates that sale, purchase, consumption or use of a psychotropic substance such as Cannabis shall be only for medical and scientific purposes. The Jammu & Kashmir Excise Act, 1958 does not regulate the purchase of hemp, it limits the regulation to the import, export, transport, manufacture, sale and possession of intoxicating drugs including hemp in the State of Jammu & Kashmir.

  The Uttarakhand State Policy in respect of intoxicated Hemp Abolition and Cultivation of Industrial Hemp for Commercial and Horticulture purposes under Section 14 of the said Act, enables the purchase on the following conditions: the units of hemp not used for the cultivation, can be used for purchase, use and storage of the fibers and seeds of the plants of industrial hemp from the licensed farmer prior purchase license application before the Collector of the concerned area, in the prescribed proforma[24]. However, the licensee is not authorized to get any kind of psychotropic substances from the plant of industrial hemp and to do the purchase-sale, use and storage for himself, except the industrial and horticulture use may be made as per the Rules[25]. It is mandatory to maintain the details of the purchase in the required registers by the licensee, that might be submitted for inspection on demand by any competent authority[26]. Presently, the Indian startup HempCann Solutions has launched its first research-based Cannabis clinic in Bangalore that can prescribe Cannabis infused tablets produced by Vedi

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22 Available at https://www.ikigailaw.com/hemp-high-time-for-legalisation/

23 See Rule 65 A of the Act "Sale, purchase, consumption or use of psychotropic substances. No person shall sell, purchase, consume or use any psychotropic substance except in accordance with the Drugs and Cosmetics Rules, 1945:

Provided that sale, purchase, consumption or use of a psychotropic substance specified in Schedule I shall be only for the purposes mentioned in Chapter VIIA".

24 See Rule 3, available at http://uttrakhandexcise.org.in/Docs/bhang.pdf

25 See Rule 7 and 11, available at http://uttrakhandexcise.org.in/Docs/bhang.pdf

26 See Rule 9, available at http://uttrakhandexcise.org.in/Docs/bhang.pdf

Herbals. HempCann has received a pan-India license to distribute these medicines on a prescription basis, which can be given by any Ayurvedic doctor or through an online consultation[27].

- *Import*

Import into India of the narcotic drugs and psychotropic substances is prohibited except with an import certificate from the Narcotic Commissioner for each consignment, issued under the provision of Chapter VI of the NDPS Act.

The NDPS Act does not lay down proper procedures for hemp cultivation, procurement, use and does not provide any limits on the quantity of CBD that can be imported, unlike that in the case of legal opium[28].

The Jammu & Kashmir Excise Act states that no intoxicating drugs shall be imported into Jammu & Kashmir except (a) after payment of any duty to which it may be liable under this Act, or execution of a bond for such payment, and (b) in compliance with such conditions as the Government may impose[29].

The Uttarakhand State policy does not regulate the import of hemp.

[27] Available at https://www.vice.com/en_in/article/qjdv9p/indias-first-medical-cannabis-marijuana-clinic-is-finally-here

[28] Opium regulation available at http://cbn.nic.in/html/GN-OP-19-20.pdf

[29] See Section 5 of the Act, substituted by Act XIV of 1966, available at http://jkexcise.nic.in/documents/eact.pdf

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