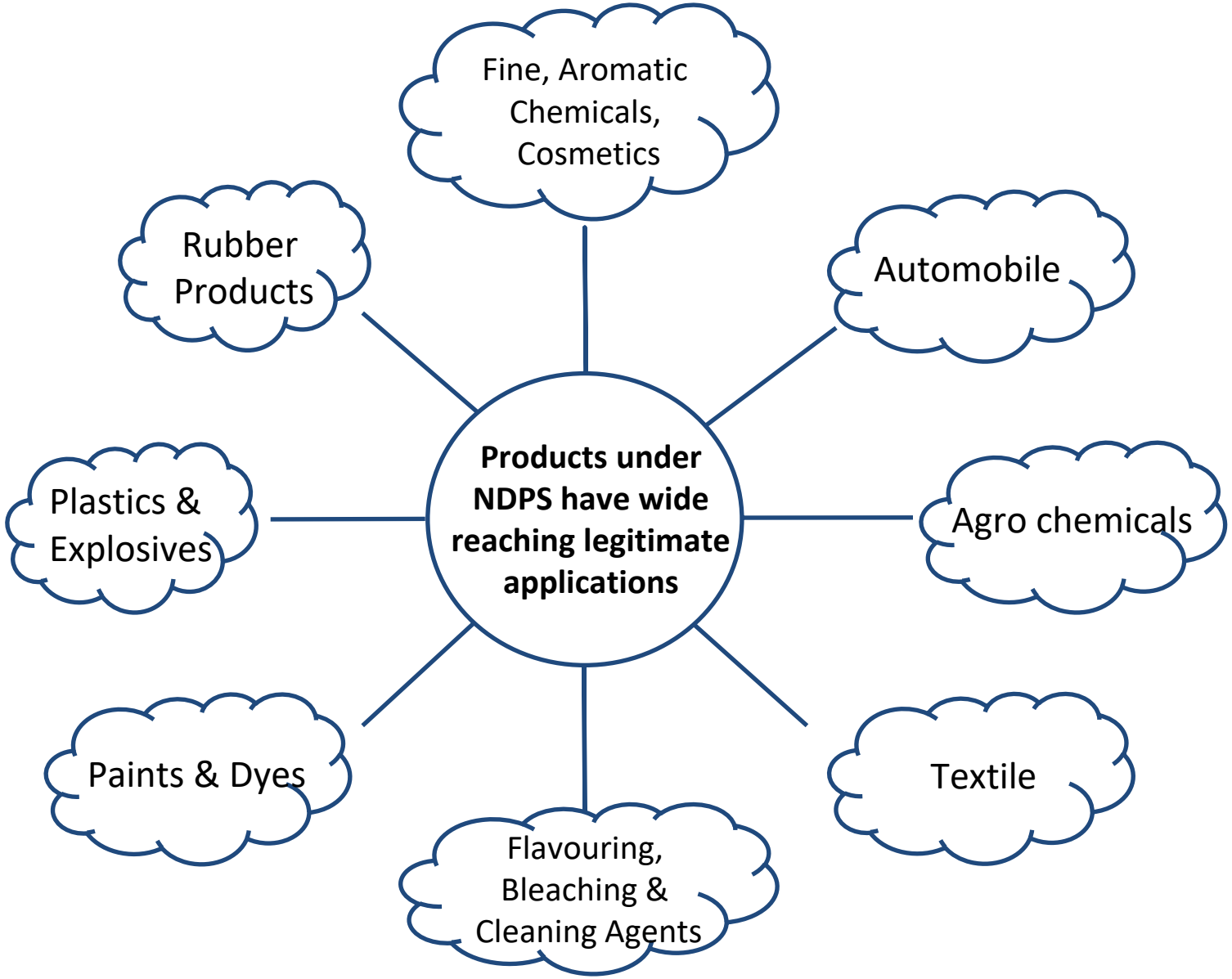
Indian Drug Manufacturers' Association Since 1961

What Should Drug Regulatory Officers Know About NDPS?

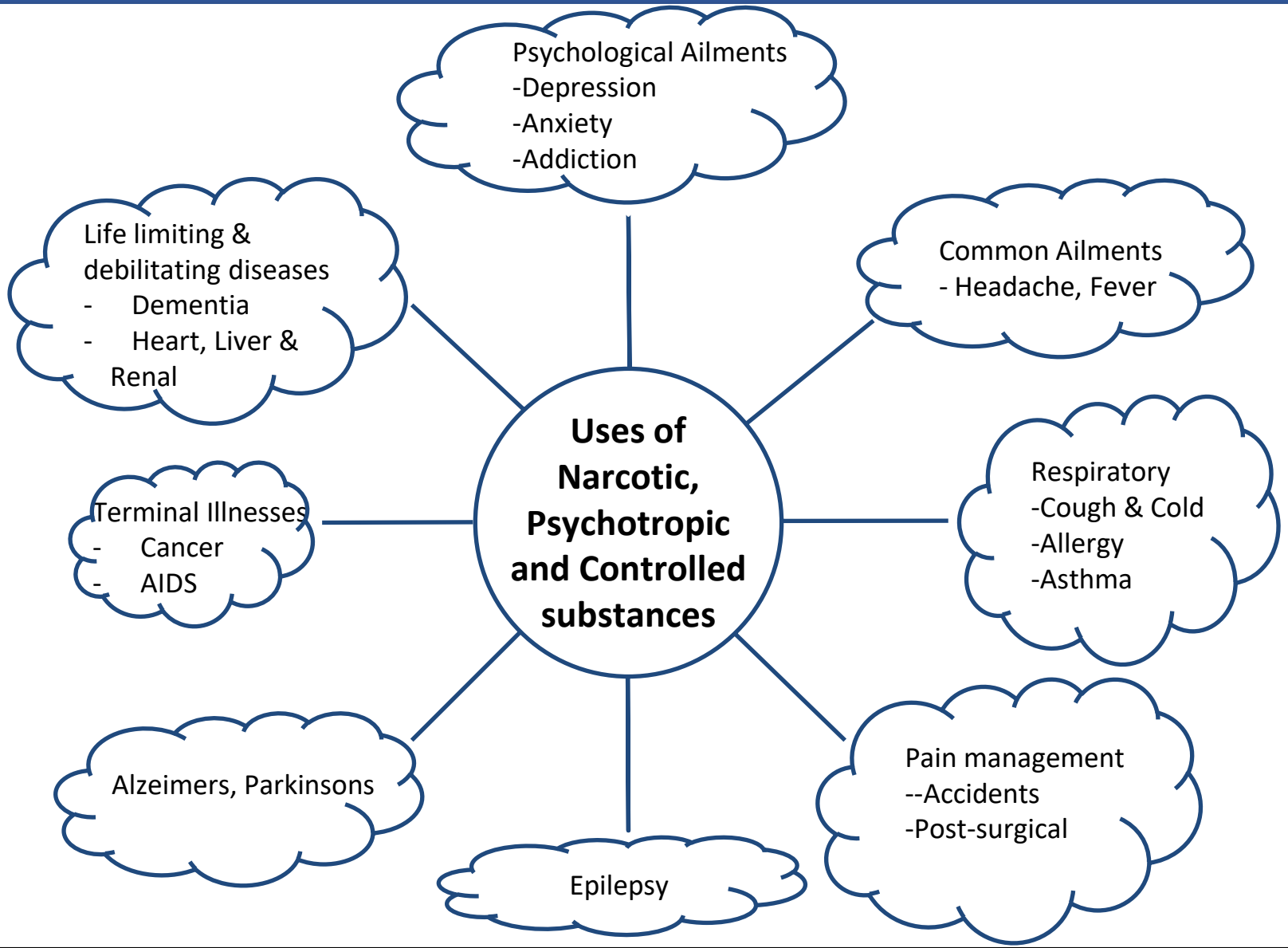
All India Drugs Control Officers Confederation – Training Academy
Live Webinar – By Devesh Malladi, Chairman NDPS Committee, IDMA

27th March, 2021

Legitimate uses of NDPS – Chemical Applications



Legitimate uses of NDPS – Pharmaceutical Applications



Some NDPS are in the National List of Essential Medicines, notified by the Ministry of Health and Family Welfare, Government of India. Access to such medicines is of vital public health importance besides being a matter of an individual's right to health, under the constitution

Principle of Balance

Represents a dual obligation of Governments to :-
(A principle enshrined in the International Drug Conventions)

Establish a system of control that ensures adequate availability of Narcotic Drugs, Psychotropic and controlled substances for medical and scientific purposes

Simultaneously prevent abuse, diversion and trafficking in illicit drugs and mitigate diversion from licit to illicit channels

Source: WHO, Ensuring Balance in National Policies on Controlled Substances

Object of NDPS Act

Central Government shall take all such measures for the purpose of …

Prior to 2014, Section 4, stated as follows:

"Preventing & combating abuse of illicit traffic in Narcotic Drugs, etc…"

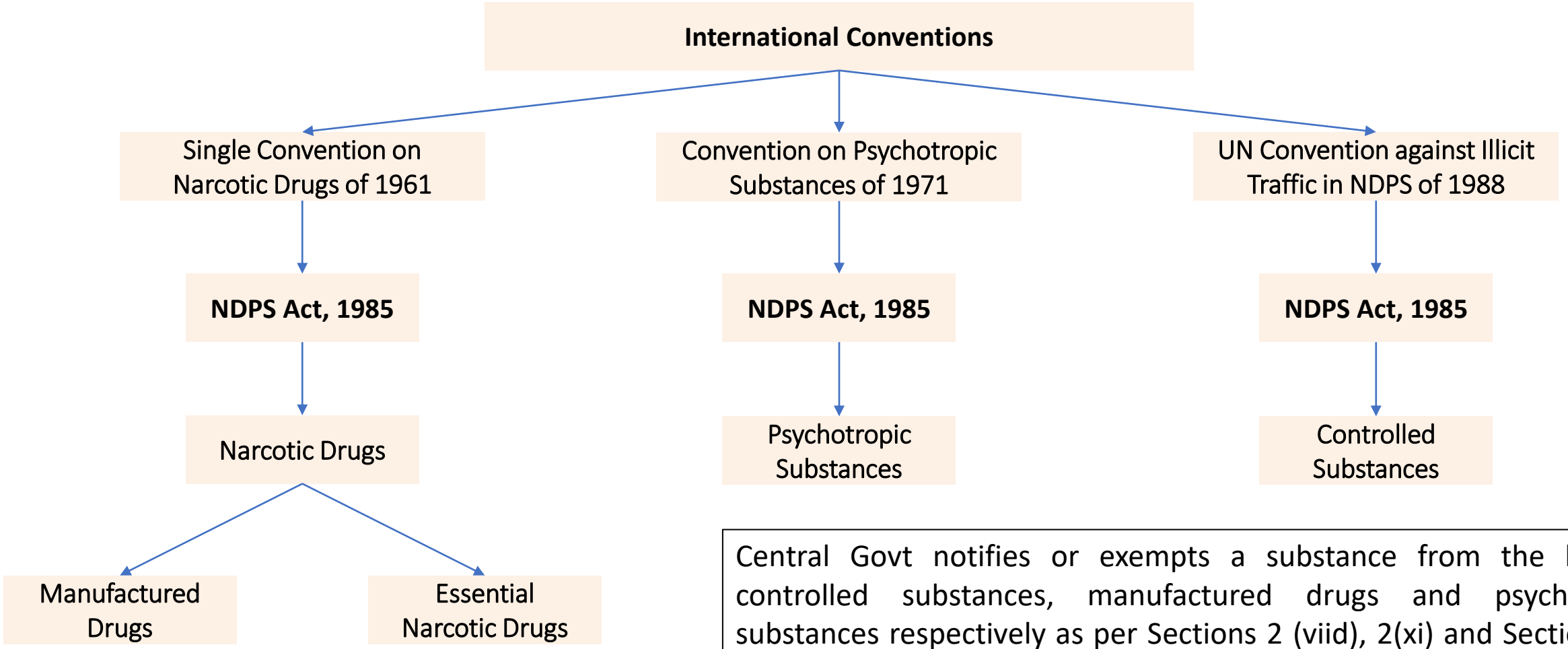
In 2014, Section 4 was amended as follows:

"and for ensuring their medical and scientific use".

The amendment to Section 4 of the NDPS Act, 1985 in 2014 makes it obligatory for the Government of India to maintain a balance between controls and ensuring availability for legitimate use

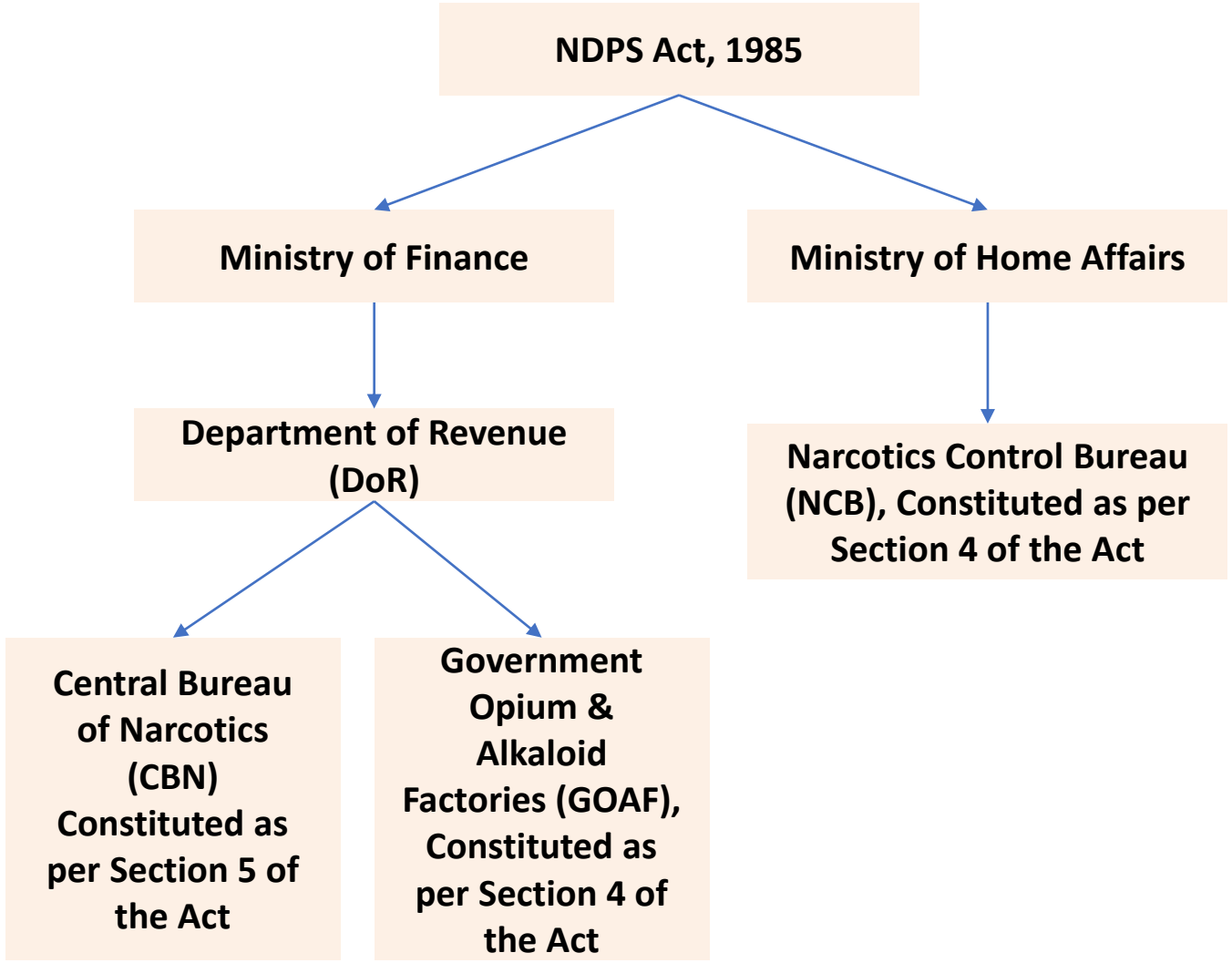
International Conventions & NDPS Act, 1985

The NDPS Act, 1985 has its origin in the three United Nations Conventions which are:-



Central Govt notifies or exempts a substance from the lists of controlled substances, manufactured drugs and psychotropic substances respectively as per Sections 2 (viid), 2(xi) and Section 3 of the NDPS Act

Nodal Agencies Under The NDPS Act, 1985



- CBN's main function is to grant licenses to farmers to cultivate opium poppy, monitor/ surveillance/ law enforcement, collect the opium to be handed over to GOAF, licenses for Narcotics drugs, grant quotas, registrations for Psychotropic substances & grant import/export NOC for NDPS.

- GOAF is responsible for processing opium to manufacture opioids such as morphine, codeine and thebaine and import of the same for any domestic sale in India.

- The NCB is an Indian Federal law enforcement and intelligence agency tasked with combating drug trafficking and the use of illegal substances under the provisions of the NDPS Act, 1985. Registration of Controlled Substances and filing of quarterly returns is done with NCB.

Relevant Sections of the NDPS Act, 1985

Section 8:

- Prohibition of certain operations of any Narcotic or Psychotropic Substances (including cultivation of Cannabis), except:
  - for medical or scientific purposes and in the manner and to the extent provided by the provisions of the Act or rules or orders made thereunder and in a case where any such provision imposes any requirement by way of license, permit or authorisation in accordance with terms & conditions of such license, permit or authorisation.

Section 9:

- Power of the Central Government to permit, control and regulate

Section 10:

- Power of the State Government to permit, control and regulate

Section 70:

- Section 70 of the NDPS Act, directs Central & State Governments to have regard to international conventions while making rules.

Section 80:

- As per section 80 of the act, the provisions or rules of the NDPS Act are in addition to the provisions and rules of the Drugs & Cosmetics Act, 1940 and not in derogation of it

Different Categories of Substances Under the NDPS Act

Sr. No	Category	No. of Substances	Examples
1	Narcotic Drugs		
a)	Manufactured Drugs	124 Substances	Thebaine, Diphenoxylate, Dextropropoxyphene, etc.
b)	Essential Narcotic Drugs	6 Substances	List of ENDs: Morphine, Codeine, Oxycodone, Hydrocodone, Methadone, Fentanyl
2	Psychotropic Substances	149 Substances	Alprazolam, Pentazocine, Clonazepam, Phenobarbital Buprenorphine, etc.
3	Controlled Substances	23 Substances	Acetic Anhydride, Ephedrine, Pseudoephedrine

Authorities Empowered Under the NDPS Act

Sr. No	Drug Category	Rule - Making Authority	Licensing authority
1	Manufactured drugs (excluding ENDs)	Central & State Government	CBN for API's & State authorities for preparations as stipulated under state NDPS rules
2	Essential Narcotic Drugs	Central Government	State Drug Controllers
3	Psychotropic substances	Central Government	- Drug license granted under the Drugs & Cosmetics Rules, 1945 - Compulsory registration for manufacturers & submission of returns to Narcotics Commissioner
4	Controlled substance	Central Government	Registration of Schedule A substances with NCB

Misconceptions & Misinterpretation of the Act

Narcotic Drugs

Psychotropic Substances

नशीली दवा

Controlled Substances

NDPS Categories

Misconception: There is lack of understanding of the different categories under NDPS by some drug regulatory officers and the reasons why they are placed in a particular category

- Narcotic Drugs, refers to a category of perception altering or sensory dulling drugs which are addictive
- Psychotropic Substances are Psychoactive stimulants and Psychedelics which are habit forming
- Controlled Substances are precursor chemicals which are raw materials for manufacture of substance of abuse

Codeine Cough Syrup

Misconception: Codeine Cough Syrup is under the purview of NDPS Act

- As per Section 2(xi); The Central Government by notification in the Official Gazette, can declare not to be a manufactured drug. Exemption for codeine preparations is also provided in the list of manufactured drugs at entry no. 35
- Rule 52-A of the NDPS Act, 1985 specifies that codeine preparations containing not more than 100mg of the drug per dosage unit and with a concentration of not more than 2.5% in undivided preparations is outside the purview of the NDPS Act.

Ephedrine & Pseudoephedrine

Misconception: Ephedrine & Pseudoephedrine should be banned because of their misuse as a नशीली दवा

- EPH & PSE are precursor chemicals for manufacture of Methamphetamine (substance of abuse) and by itself do not have addictive, psychoactive or habit forming properties. It is the most effective and popular nasal decongestant in combination with anti-allergy drugs in the world
- Ephedrine/Pseudoephedrine formulations are outside the purview of the NDPS Act, except in the case of import & export, where NOC is required from CBN.

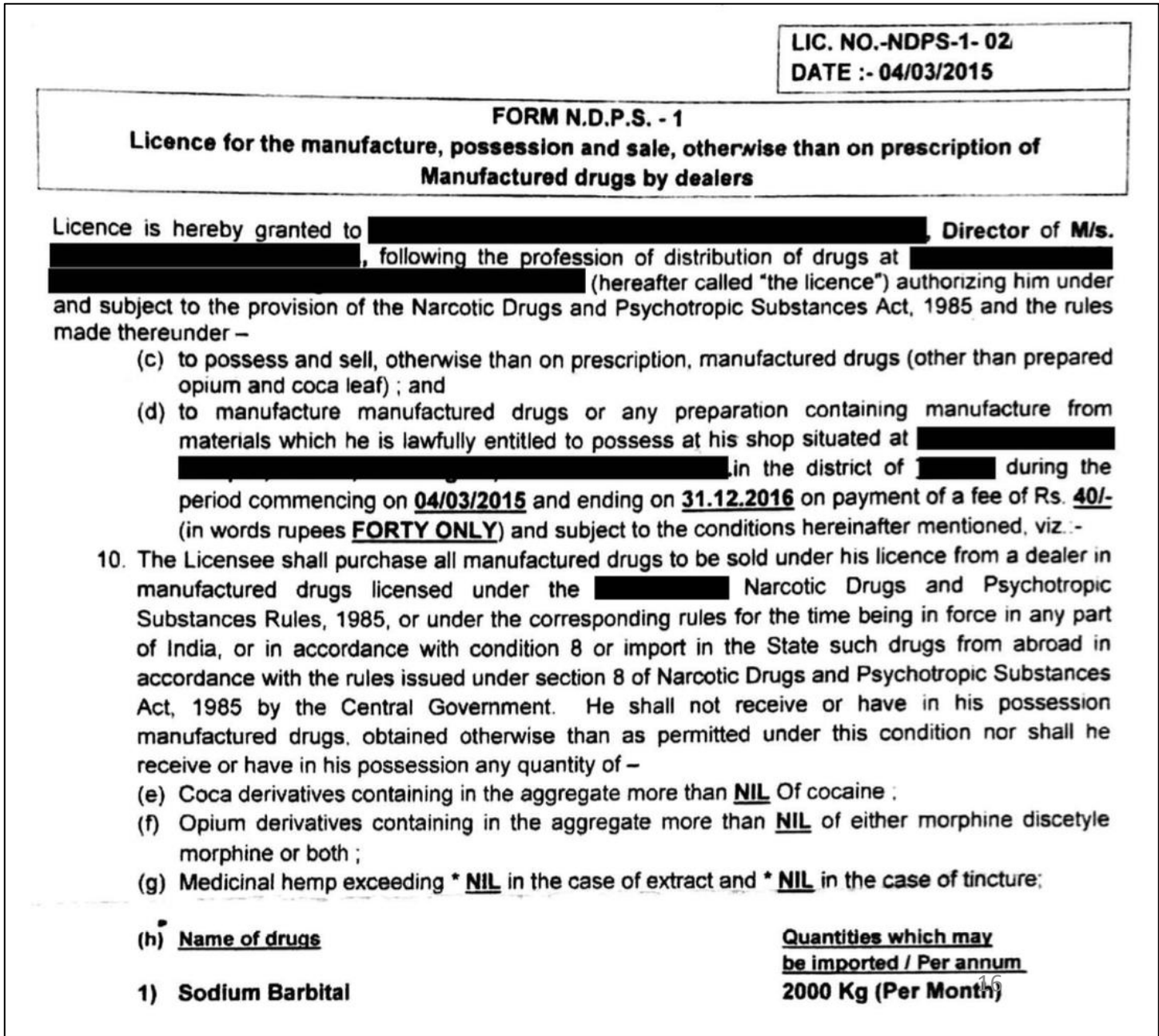
Isomers & Derivatives of Psychotropic and Controlled Substances

Misconception: Isomers & derivatives of psychotropic and controlled substances are included in NDPS Act and its schedules

Definition of a Psychotropic Substance under Section 2(xxiii), Section 3 and The Schedule to the Act (Psychotropic substances) at entry no. 111, specifies 'Salts and preparations of the above' and Schedule A, B, C of the RCS order, 2013 clearly specifies Salts and preparations for certain substances only. Example: d-ephedrine is an isomer of ephedrine and Paracetamol/Aspirin is a derivative of acetic anhydride

Incorrect Categorization of Psychotropic Substances as a Manufactured Drug

State FDA authority wrongly interprets a psychotropic substance as a manufactured drug



LIC. NO.-NDPS-1- 02
DATE :- 04/03/2015

FORM N.D.P.S. - 1

Licence for the manufacture, possession and sale, otherwise than on prescription of Manufactured drugs by dealers

Licence is hereby granted to [redacted], **Director** of **M/s.** [redacted], following the profession of distribution of drugs at [redacted] (hereafter called "the licence") authorizing him under and subject to the provision of the Narcotic Drugs and Psychotropic Substances Act, 1985 and the rules made thereunder –

(c) to possess and sell, otherwise than on prescription, manufactured drugs (other than prepared opium and coca leaf) ; and

(d) to manufacture manufactured drugs or any preparation containing manufacture from materials which he is lawfully entitled to possess at his shop situated at [redacted] in the district of [redacted] during the period commencing on **04/03/2015** and ending on **31.12.2016** on payment of a fee of Rs. **40/-** (in words rupees **FORTY ONLY**) and subject to the conditions hereinafter mentioned, viz.:-

10. The Licensee shall purchase all manufactured drugs to be sold under his licence from a dealer in manufactured drugs licensed under the [redacted] Narcotic Drugs and Psychotropic Substances Rules, 1985, or under the corresponding rules for the time being in force in any part of India, or in accordance with condition 8 or import in the State such drugs from abroad in accordance with the rules issued under section 8 of Narcotic Drugs and Psychotropic Substances Act, 1985 by the Central Government. He shall not receive or have in his possession manufactured drugs, obtained otherwise than as permitted under this condition nor shall he receive or have in his possession any quantity of –

(e) Coca derivatives containing in the aggregate more than **NIL** Of cocaine ;

(f) Opium derivatives containing in the aggregate more than **NIL** of either morphine discetyle morphine or both ;

(g) Medicinal hemp exceeding * **NIL** in the case of extract and * **NIL** in the case of tincture;

(h) **Name of drugs**	**Quantities which may be imported / Per annum**
1) **Sodium Barbital**	**2000 Kg (Per Month)**

Prohibition of Cannabis

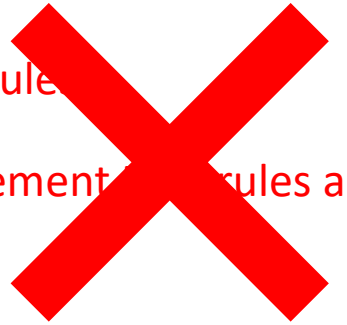
Misconception: Cultivation of Cannabis is prohibited and illegal under the NDPS Act

- Section 8 read with Section 10 (1)(a)(iii) of the NDPS Act, 1985 permits cultivation of cannabis for medical and scientific purposes
- Section 14 permits cultivation for industrial purposes for obtaining fibre or seed for horticultural purposes

Essential Narcotic Drugs

Misconceptions –

- ENDs are under the purview of State NDPS Rule
- Need 'go-ahead' from chief minister to implement rules as per chapter V-A, NDPS rules
- State NDPS Rules need Amendment



- Proviso u/s 9(1)(a)(va) of the NDPS Act is clear- 'Provided that where, in respect of an END, the State Govt has granted license or permit under the provisions of section 10 prior to the commencement of the NDPS (Amendment) Act, 2014, such license or permit shall continue to be valid till the date of its expiry or for a period of twelve months from such commencement, whichever is earlier;'
- Section 10 (1) and (v)- 'the possession, transport, purchase, sale, import inter-State, export inter-State, use or consumption of manufactured drugs (other than prepared opium and Essential Narcotic Drugs) and of coca leaf and any preparation containing any manufactured drug'

Definition of Narcotic Drugs As Per the NDPS Act, 1985

Narcotic Drugs as defined vide Section 2 (viiia), (xi) & (xiv) of NDPS Act, 1985 include:

- Coca Leaf
- Cannabis (Hemp)
- Opium Poppy Straw
- All Manufactured Drugs
- All Essential Narcotic Drugs

Essential Narcotic Drugs (ENDs)

Keeping in line with the 2014 amendment, the object of the Act (Section 4), was amended to ensure the availability of Narcotic Drugs and Psychotropic Substances for medical and scientific purposes. A new category defined under Section 2 (viiia) - 'Essential Narcotic Drug' was carved out from list of Manufactured Drugs to ensure its easy availability for palliative care.

List of ENDs:

1. Morphine
2. Codeine
3. Oxycodone
4. Hydrocodone
5. Methadone
6. Fentanyl

Central Govt can notify any drug as END under section 2(viiia) of the NDPS Act. So far, 6 substances have been notified but in future, there may be more.

Rules Governing ENDs

Old Procedure

- Multiple licenses required
- Multiple agencies involved
- Different validity periods
- Different rules in different states (State NDPS Rules)
- Need for transport permit (State NDPS Rules)

New procedure

- Rules pertaining to possession, transport, import inter-State, export inter-State, sale, purchase, consumption and use of ENDs simplified under Chapter V-A
- Uniform rules for all States and UTs
- Single licensing authority i.e., State Drug Controller
- Simplified rules for 'Recognized Medical Institution' (RMI) for possessing, dispensing and selling ENDs
- RMI certificate valid for 3 years and can be renewed
- Consignment note under rule 52 – D (as per sub-rule 2) or Sale bill or invoice or cash memo with details as specified under rule 52 – D (as per sub-rule 3)

Manufactured Drugs - Manufacture, Possession, Transport, Sale & Filing of Returns

Sr. No	Manufactured Drug	Relevant Rule under NDPS	Licensing Authority
1	License for: 1. Manufacture – API 2. Manufacture - Preparations 3. Possession, Transport, Sale	1. Rule 36, 36-A & 37 2. Rule 37 3. State NDPS Rules	1. NC, CBN 2. State NDPS Rules 3. State NDPS Rules
2	Record Keeping & Filing of Returns: 1. Manufacturer – API 2. Manufacturer - Preparations 3. Distributor/ Chemist	1. Rule 46 2. State NDPS Rules 3. State NDPS Rules	1. NC, CBN 2. State NDPS Rules 3. State NDPS Rules
3	Destruction: 1. Manufacturer – API 2. Manufacturer - Preparations 3. Distributor/ Chemist	1. Rule 45-A 2. State NDPS Rules 3. State NDPS Rules	1. NC, CBN 2. State NDPS Rules 3. State NDPS Rules

END - Manufacture, Possession, Transport, Sale & Filing of Returns

Sr. No	END	Relevant Rule under NDPS	Licensing Authority
1	License for: 1. Manufacture – API 2. Manufacture - Preparations 3. Possession, Transport, Sale	1. Rule 36, 36-A & 37 2. Rule 37 3. Rule 52-A, 52-B, 52-F	1. NC, CBN 2. State NDPS Rules 3. No license required
2	Record Keeping & Filing of Returns: 1. Manufacturer – API 2. Manufacturer - Preparations 3. Distributor/ Chemist	1. Rule 46 2. State NDPS Rules 3. Rule 52-B	1. NC, CBN 2. State NDPS Rules 3. State NDPS Rules
3	Destruction: 1. Manufacturer – API 2. Manufacturer - Preparations 3. Distributor/ Chemist	1. Rule 45-A 2. State NDPS Rules 3. Rule 52-B	1. NC, CBN 2. State NDPS Rules 3. State NDPS Rules

Psychotropic Substances - Manufacture, Registration & Filing of Returns

Sr. No	Psychotropic Substances	Relevant Rule under NDPS	Licensing Authority
1	License for: 1. Manufacture- API & Preparations 2. Sale, Possession, Transport	1. Rule 64 2. 65-A, 66, 67	1. As stipulated under D&C Rules, 1945 2. As stipulated under D&C Rules, 1945
2	Registration & Filing of Returns	Rule 65	NC, CBN
3	Destruction	-	As stipulated under D&C rules, 1945

Controlled Substances – Registration, Transport, Sale & Filing of Returns

Sr. No	Controlled Substances	Relevant Clause Under NDPS (RCS) Order, 2013	Licensing Authority
1	Unique Registration Number for Schedule - A substances	Clause 4	Zonal Director, NCB
2	1. Transport & Sale for Schedule - A substances 2. Export & Import of Schedule – A, B & C Substances	1. Clause 7 & 8 2. Clause 10 & 11	1. No license required 2. CBN
3	Destruction	Clause 9	Zonal Director, NCB

Cannabis (Marijuana)

Cannabis - As Defined Under the NDPS Act

- Under Section 2 (iii) of the Act, Cannabis (hemp) is defined as the following:

    a. Charas – This is the separated resin (crude or purified) obtained from the cannabis plant, also including concentrated preparations and resin known as hashish oil or liquid hashish.
    b. Ganja – This is the flowering of fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops)
    c. Any mixture with or without any neutral material of any of the above forms of cannabis or any drink prepared therefrom

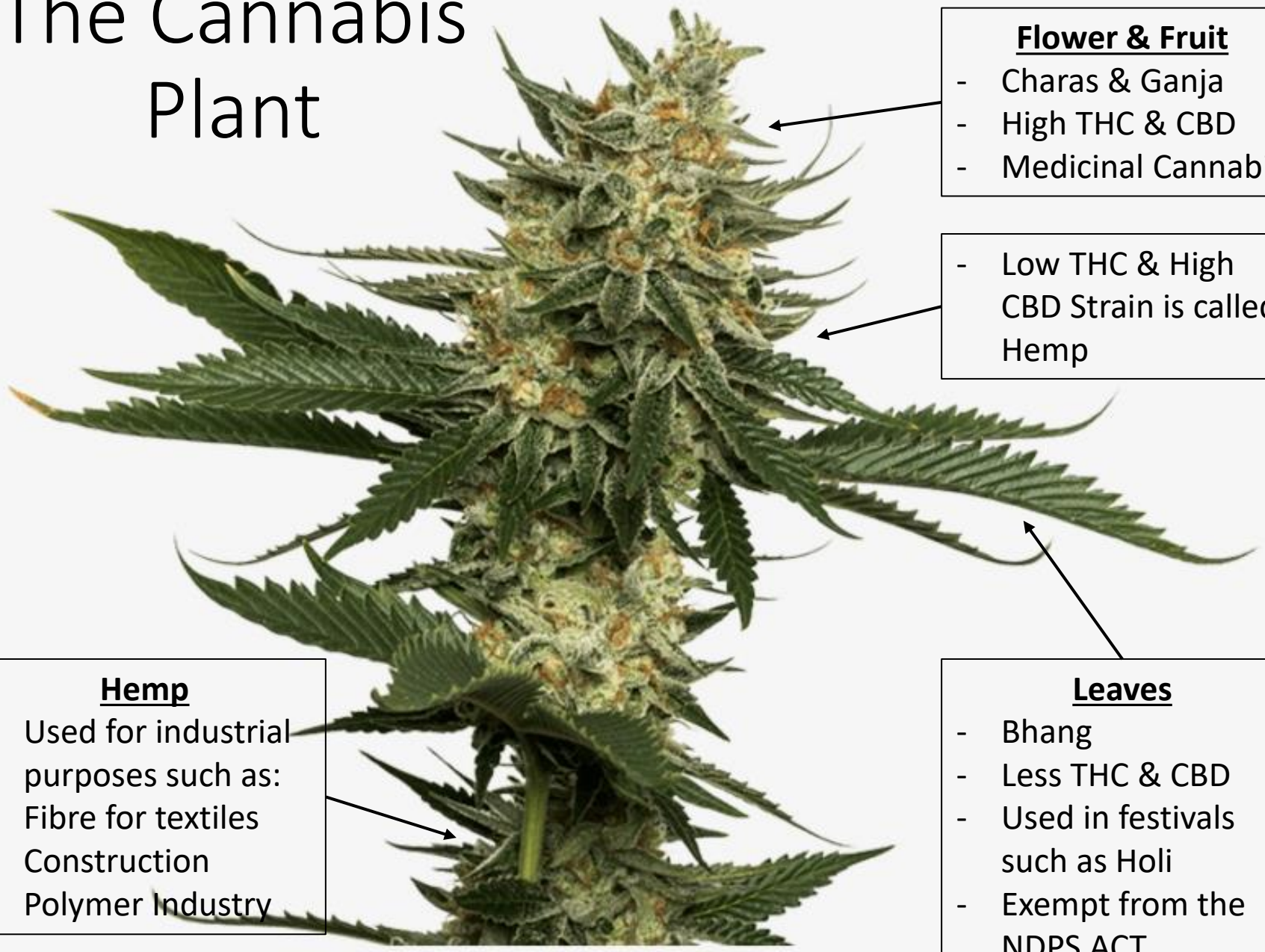
- Under Section 2 (iv) of the Act, 'Cannabis plant' means any plant of the genus Cannabis

- Under Section 2 (xii) of the Act, 'Medicinal Cannabis' that is, medicinal hemp, means any extract or tincture of Cannabis (hemp)

- Section 10 of the act empowers State Governments to permit and regulate the cultivation, production, manufacture, possession, transport, import inter-State, export inter-State, sale inter-State, purchase, consumption or use of cannabis (excluding charas), provided that the cultivators deliver all product to the State Government.

- Section 14 of the act permits the cultivation of cannabis plant for industrial purposes only of obtaining fibre or seed for horticultural purposes.

The Cannabis Plant



Flower & Fruit
- Charas & Ganja
- High THC & CBD
- Medicinal Cannabis

- Low THC & High CBD Strain is called Hemp

Hemp
- Used for industrial purposes such as:
- Fibre for textiles
- Construction
- Polymer Industry

Leaves
- Bhang
- Less THC & CBD
- Used in festivals such as Holi
- Exempt from the NDPS ACT

Medicinal Cannabis

Medicinal Cannabis is the flower of the Cannabis plant to treat diseases or conditions as approved by a country's drug regulatory authority. The Flower in measured quantities is allowed to be prescribed in many countries such as USA, Canada, Germany, Netherlands, Thailand, Australia, Czech Republic, Denmark, Finland, Israel, Italy, Switzerland, Turkey, New Zealand, South Africa, United Kingdom and Uruguay.

Medicinal Cannabis is Approved for the following Disease Indications

Chronic pain – mainly pain associated with the nervous system, for example pain caused by damaged nerves, phantom pain, facial neuralgia, or shingles

Multiple sclerosis – pain and muscle spasms or cramps associated with multiple sclerosis (MS) or spinal cord damage

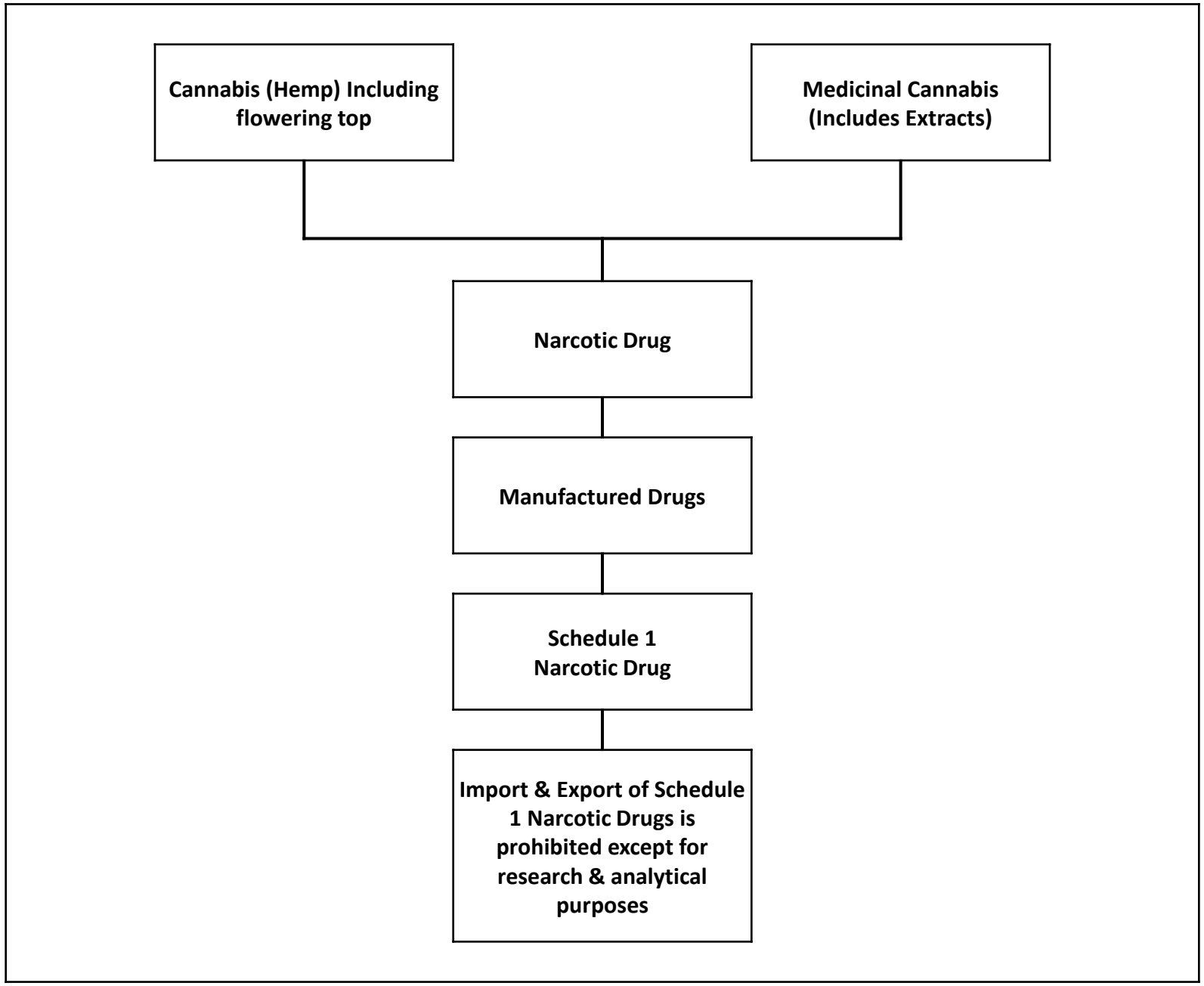
Nausea, vomiting and appetite – associated with chemotherapy or radiotherapy used in the treatment of cancer. Appetite and weight loss and debilitation due to hepatitis C, cancer or HIV infection and AIDS

Gilles de la Tourette syndrome – inability to control the making of repeated, quick movements or sounds

Glaucoma – uncontrolled eye pressure with therapy-resistant glaucoma

Other indications – cancer, epilepsy, inflammatory bowel diseases, Parkinson's disease and Psychiatric disorders

Legal Status of Cannabis in India



Legal Status of Cannabis in India

Cultivation of Cannabis plant for medicinal purposes

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State governments are empowered to permit & regulate cultivation

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Out of 29 states & 7 Union Territories only 3 states have framed rules for cultivation of cannabis- Uttarakhand, Himachal & Haryana

↓

However, cultivation of Cannabis for medicinal purposes is currently permitted by certain states for research and analytical purposes.

Cultivation of Cannabis plant for industrial purposes

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Allowed for seed, fibre, & horticulture purposes only

Note: The leaves (bhang) & seeds of the cannabis plant are outside the purview of the NDPS Act, 1985

Legal Status of Cannabis in India – Continued…

- A number of States – Andhra, Maharashtra, Rajasthan, Orissa and Haryana have specific chapters on Cannabis in their respective NDPS Rules, which permits registered medical practitioners and patients to possess, use & consume Ganja for medical purposes. Other states provide for a general reference to manufactured drugs, which includes by definition medicinal Cannabis under Section 2 (xi)(a).

- Cannabis or its products like Bhang and Ganja are included in schedule E(I) of the DCR (Ayurvedic - Bhang, Siddha - Ganja(excluding seeds) and Unani medicines – Charas (Excluding Seeds).

- Entry no. 346 under Schedule-H states ‘Narcotic drugs listed in NDPS Act, 1985’. Cannabis or its extracts is a narcotic drug and hence is permitted for medicinal purposes under the DCR Rules, 1945.

Remarkable Effect of Cannabis in Treatment of Parkinsons

https://www.youtube.com/watch?v=aETBzlCO1Qs

Thank You

Devesh Malladi, Chairman NDPS Committee, IDMA

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27th March, 2021