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Busting of Clandestine Factories/Lab and Internet Pharmacy engaged in the Illegal Manufacture & Sale and Illegal Export of Narcotic Drugs, Psychotropic Substances and Controlled Substances, by the Empowered Departments/Organizations: An Analysis

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ABSTRACT

Clandestine factory/lab and internet pharmacy operate in the dark and there is no regulatory mechanism to be followed by these unscrupulous units until the same comes to light when busted by the empowered departments/organizations.

The running and functioning of the clandestine factories/labs and the creation of websites and its use in the illicit drug trafficking have taken firm roots in India and are here to stay.

It is only with the latest tools, proper policing, gathering of intelligence or receipt of information that leads to busting of clandestine factory/lab and internet pharmacy.

Clandestine factory/lab and internet pharmacy – a background

1. Clandestine factory/lab and internet pharmacy operate in the dark until it is busted by the empowered departments/organizations like the NCB/DRI/CBN/Police. The running and functioning of the clandestine factories/labs and the creation of websites and its use in the illicit drug trafficking have taken roots in India and it is only with the proper policing, latest tools, gathering of intelligence or receipt of information that leads to busting of clandestine factory/lab and internet pharmacy.

E-pharmacy vs. internet pharmacy

2. At this stage, esteemed readers may not confuse the term “internet pharmacy” with e-commerce pharmacy operating their own websites, like M/s Tata Digital Limited (1mg Technologies Pvt. Ltd), M/s Apollo Pharmacy Pvt. Ltd., M/s Netmeds Marketplace Ltd (Reliance Retail), M/s API Holdings Private Limited (PharmEasy), M/s Practo Technologies Private Ltd. and many more such players, wherein the medicines (except those covered under the NDPS Act, 1985 as per the draft rules on e-pharmacy) are home delivered upon loading the genuine prescription and on payment of value, including GST in the invoice generated. The e-

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commerce pharmacy is a big opportunity as can be seen from the fact that Tata Digital, a subsidiary of the Tata Group, has acquired a majority stake in e-pharmacy 1mg Technologies Pvt. Limited and is helpful in many ways in contrast to visiting the mortar and brick stores. The convenience of the person sitting in his home and ordering for medicines cannot be forgotten at least during the covid pandemic and it has taken firm roots. These activities are legal in nature.

What is internet pharmacy or online pharmacy?

3. In order to understand what an internet pharmacy or an online pharmacy is about, we need to understand the meaning of the terms. *“An online pharmacy, internet pharmacy, or mail-order pharmacy is a pharmacy that operates over the Internet and sends orders to customers through mail, shipping companies, or online pharmacy web portal.”*¹

3.1 In other words *“Internet pharmacy means a pharmacy which does not have a physical location for patrons to visit for retail sales but that receives orders from customers only through the Internet, but does not include the Internet division or operations of pharmacy chains and other retail merchants (such as supermarket chains and discount stores) that dispense prescription drugs and who, as an adjunct to their traditional pharmacy operations also accept prescription orders via the Internet and mail or deliver the Pharmaceutical Products to their customers.”*²

3.2 On a conjoint reading of para 3 and 3.1 above, the following emerges

- (i)** The internet pharmacy is illegitimate but can be legitimate when seen from the e-pharmacy view point.
- (ii)** Legitimate pharmacy does genuine business (except the substances covered under the Act) and obtain orders online and the customers are required to post the valid prescriptions issued by the doctors/hospitals. They are also referred to as e-pharmacy and they were successful during the pandemic in supplying medicines where the general public were not allowed to move out owing to a lockdown. The legitimate internet pharmacy also does not have brick and mortar shop having a physical location for serving its customers unlike the chemist and druggist shops where the persons need to visit with a valid prescription to buy the medicines/drugs.
- (iii)** The internet pharmacy, which generally refers to illegitimate business of dealing in narcotics or psychotropic or controlled substances does not have brick and mortar shop having a physical location for serving its customers

unlike the chemist and druggist shops where the persons need to visit with a valid prescription to buy the medicines/drugs. Here the websites are created for the sake of making money illicitly and they indulge in illicit drug trafficking of narcotic drugs, psychotropic substances or controlled substances and their sole aim is to make illicit profits.

3.3 Be that as it may, the internet pharmacy is basically and largely the creation of series of websites, intertwined and interlinked with one another, for the purpose “dealing” in substances falling under the purview of the Narcotic Drugs and Psychotropic Substances, 1985 (hereinafter referred to as the “Act”). Readers may note that the operation of a website can take place from anywhere while the servers may or may not be located in the same place. To cite an example, a person may be operating a website, albeit illegal, for “dealing” in substances covered under the Act say sitting in Chennai in Tamil Nadu and the servers may be located in Kolkata in West Bengal. The data would be stored in the servers located in Kolkata. The data would certainly contain the transactions for the illicit drug trafficking through primarily export of the substances falling under the Act.

Existence and functioning of clandestine factory/lab

4. Similarly, we find that clandestine factories or labs functioning in different parts of the country, running in remote/inaccessible locations and usually outside the purview of normal policing, pushing especially the psychotropic substances primarily into the domestic market. Running a clandestine drug lab or illegal factory is the direct result of conspiracy entered into by unscrupulous persons to make a living out of the addiction of the persons, especially the misguided youth. It is the money or the monetary benefit solely derived out of the illicit and clandestine activities which drives these unscrupulous persons in joining hands to indulge in illicit manufacturing of narcotic drugs and psychotropic substances. To achieve their goals, foreigners are also roped in as they have the expertise in running clandestine factories/labs. The functioning and running of such factories/labs in India are nothing new, with plenty of illegal factories/labs being busted by the empowered departments. Running a clandestine factory require dedicated personnel, planning, manpower deployment including hiring of labour from faraway places to keep the activities under right wrap, finding the right supply chain, hiring of professionals (chemists and others) to synthesize the chemicals, use of bouncers to guard the activities, sourcing of raw material licitly and illicitly, exploitation of trade facilitation measures put in by the Central Government and State Governments, studying the loopholes in the system and using the systemic loopholes for furtherance of their cause, use of advanced technology/methods/techniques in the illegal/illicit manufacture, deployment of the

right transporter to transport the final products (psychotropic substances or narcotic substances) with and without his knowledge and supply of narcotic drugs and psychotropic substances to the right syndicate for pushing it into the market, etc. All the unscrupulous persons come together for a common goal and with a common intent by deceiving the legal requirements for supplying the illicitly manufactured drugs to persons abroad or to the locals for a monetary consideration using the postal or courier (domestic as well as international) route to persons and hence the illicit market thrives because there is always a ready demand as the abuse of these substances is on the rise. It also thrives because there is consumption and that is the reason there are a set of people who recruit persons to distribute these substances to the youth, initially free, and consequent upon the requirement, charge the person in requirement any amount as it becomes a necessity for him. In contrast, the functioning of an internet pharmacy starts after sourcing the desired narcotic drugs and psychotropic substances. In isolated cases, the illegal/illicit manufacture and internet pharmacy may function together. But it can be safely be concluded that there is a symbiotic relationship between a clandestine factory/lab and internet pharmacy, as the latter sources the required substances from the former.

Compliance of various laws required for pharmaceutical industry

5. India is hailed as “**pharmacy of the world**”³ and is a major exporter of generic drugs to various countries. So, there are any number of pharmaceutical companies - in medium and small scale sector - functioning across the length and breadth of the country. The genuine manufacturers of pharmaceutical products would be exporting both medicines falling and not falling under the provisions of the Act. In addition to the complying with the provisions of the Act, the genuine manufacturers should be compliant with the Drugs and Cosmetics Act, 1940 and the Rules made thereunder, the provisions of Foreign Trade (Development and Regulation) Act, 1992 and the Foreign Trade Policy framed thereunder (presently [FTP 2015-2020](#) is in operation; initially extended up to 31.3.2022⁴ and then up to 30.09.2022⁵). Hence, there is an interplay with the provisions of the Act, the Drugs and Cosmetics Act, 1940 and the Rules made thereunder, the Foreign Trade (Development and Regulation) Act, 1992 and the Foreign Trade Policy framed thereunder. In case the genuine pharma company intends to export, the provisions of the Customs Act, 1962 and the Rules & Regulations made thereunder would also be applicable. Further to it, in case of genuine internet transactions, they have to be compliant in respect of the section 79 of the Information Technology Act, 2000⁶, if one is an intermediary. The benefit of section 79 of the Information Technology Act, 2000 is available only when case falls within the exception carved out therein. On the whole, a host of compliances have been put into place to regulate the functioning of the pharmaceutical companies.

6. The export of narcotic drugs or psychotropic substances are not prohibited under the Act, except as stated under the Act. Subject to the provisions of the Act, there is a legal requirement to obtain an export authorisation from the Narcotics Commissioner, Central Bureau of Narcotics, Gwalior, which falls under the administrative control of the Central Board of Indirect Taxes and Narcotics, New Delhi.

Definitions under the NDPS Act, 1985

7. Before proceeding further, it is necessary to extract certain definitions from the Act to understand the issue in proper perspective:

7.1 **Section 2(xiv) defines Narcotic Drug.** “*Narcotic Drug means coca leaf, cannabis (hemp), opium poppy straw and including all manufactured drugs;*”

7.2 We find the term manufactured drug in the definition of narcotic drug. "**Manufactured Drugs**" have been defined under the Act under section 2 (xi) of the Act. Manufactured drug means

“(a) all coca derivatives, medicinal cannabis, opium derivatives and poppy straw concentrate;

(b) any other narcotic substance or preparation which the Central Government may, having regard to the available information as to its nature or to a decision, if any, under any International Convention, by notification in the Official Gazette, declare to be a manufactured drug,

but does not include any narcotic substance or preparation which the Central Government may, having regard to the available information as to its nature or to a decision, if any, under any International Convention, by notification in the Official Gazette, declare not to be a manufactured drug;”

Declaration of certain narcotic drugs and preparations to be manufactured drugs.

7.3 We find that vide S. O. 826(E) dated 14.11.1985⁷, S.O. 40(E) dated 29.01.1993⁸ and S.O. 1431 (E) dated 21.06.2011⁹ and S. O. 2373 (E) dated 12.07.2016¹⁰, the Central Government has declared certain narcotic drugs and preparations to be manufactured drugs. According to these notifications *ibid* preparations, admixtures, extracts or other substances containing any of these drugs also come under the definition of manufactured narcotic drugs. Initially vide S.O. dated 14.11.1985⁷, in exercise of the powers conferred by sub clause (b) of clause (xi) of section 2 of the Act, the Central Government declared 88 narcotic substances and preparations to be manufactured drugs. Subsequently, additions were made to the existing lists

vide S.O. dated 29.01.1993⁸, S.O. dated 21.06.2011⁹, S.O. dated 12.07.2016¹⁰ and S.O. dated 23.03.2021¹¹. The most common narcotic drugs which are being dealt with and/or seized by the empowered officer, *inter alia*, are Oxycodone, Hydrocodone, Buprenorphine, Codeine Phosphate.

7.4 We find the definition of "**Psychotropic Substance**" in section 2(xviii) under the Act. Psychotropic Substances "*means any substance, natural or synthetic, or any natural material or any salt or preparation of such substance or materials included in the list of Psychotropic Substances specified in the Schedule*" (hereinafter to "the Act") and this list has been amended from time to time. Psychotropic substances are substances notified under section 3 read with section 2(xxiii) of the Act which are listed in the Schedule to the Act. Further, vide S.O. 1352(E) dated 13.3.2019¹² and vide S.O. 1275(E) dated 23.3.2021¹³, additions to the existing list of psychotropic substances were made. The most common psychotropic substances which are being dealt with and/or seized by the empowered officers are Alprazolam, Zolpidem Amphetamine, Diazepam, Clonazepam, Lorazepam, Nitrazepam, Tramadol, Ketamine Hydrochloride

7.5 "**Controlled Substance**, as defined under section 2(viid) of the Act "*means any substance which the Central Government may, having regard to the available information as to its possible use in the production or manufacture of narcotic drugs or psychotropic substance or to the provisions of any International Convention, by notification in the official gazette, declare to be a controlled substance.*" The latest additions to the list of controlled substances were made vide Notification G.S.R. 536(E) dated 26.08.2020¹⁴.

Framing of NDPS Rules, 1985

8. In exercise of the powers conferred by section 9 read with section 76 of the Act, the Central Government framed the NDPS Rules, 1985 (hereinafter referred to as the Rules) which stood notified *vide* GSR 837 (E) dated 14.11.1985.¹⁵

Chapter VI of NDPS Rules, 1985

8.1. Chapter VI of the Rules deals with "Import, Export and Transhipment of Narcotic drugs and Psychotropic Substances. Chapter VI contains Rules from Rule 53 to 63. Rule 53 deals with "General Prohibition". In terms of Rule 53, import into and export out of India of narcotic drugs and psychotropic substances is prohibited except with an import certificate or export authorisation issued under the provisions of Chapter VI. The import certificate or export authorisation is issued by the Narcotics Commissioner, Central Bureau of Narcotics, Gwalior. Proviso to Rule 53 states that import into India and export out of India of the narcotic drugs

and psychotropic substances specified in Schedule I of the Rules shall be for the purpose mentioned in Chapter VIIA. Chapter VIIA deals with special provisions regarding manufacture, possession, transport, import-export, purchase and consumption of narcotic drugs and psychotropic substances for medical, scientific and training purposes. Rule 67B falling under Chapter VIIA stood substituted vide GSR 525 (E) dated 25.07.2019¹⁶. At this stage it is required to be noted that the import into and export out of India of any narcotic drugs or psychotropic substances specified in Schedule I is prohibited under the provision of Rule 53 and 64 of the NDPS Rules, 1985.

8.2 The narcotic drugs in Schedule I to Rule 53 are:

1. Coca Leaf,
2. Cannabis (Hemp),
3. (a) Acetorphine, (b) Diacetylmorphine (Heroin), (c) Dihydrodesoxymorphine (Desmorphine), (d) Etorphine, (e) Ketobemidone and their salts, preparations, admixtures, extracts and other substances containing any of these drugs.

8.3 The psychotropic substances included in the Schedule I to Rule 53, as amended from time to time, are 26 in number and the 27th being salts and preparations of the 26 psychotropic substances. Prominent amongst the psychotropic substances are methaqualone, mephedrone, methylone, Catha Edulis (Dry Chatt or Mira Leave Dry Chat Edulis)

8.4 In terms of Rule 54, import of opium, concentrate of poppy straw and morphine, codeine, thebaine, and their salts is prohibited except by the Government Opium Factory. Proviso to Rule 54 states that the above shall not apply to import of morphine, codeine, thebaine, and their salts by manufacturers notified by the Government for use, *inter alia*, in manufacture of products to be exported. Accordingly, we see that the Central Government in exercise of the powers conferred by the proviso to Rule 54 of the Narcotic Drugs and Psychotropic Substances Rules, 1985, notified, *vide* S.O. 3350 (E) dated 17.10.2017¹⁷ has authorised M/s. Cipla Ltd., Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400013 to import morphine, codeine, thebaine and their salts for use in manufacture of products to be exported, after following the procedure specified in rule 55 of the said rules and subject to such conditions as may be specified in the import certificate issued in Form No. 4 A annexed to the aforesaid rules and this Notification was valid till 31.12.2019.

8.5 *Vide* Notification No. S.O. 714(E) dated 14.02.2020¹⁸, in exercise of the powers conferred by the proviso to Rule 54 of the Narcotic Drugs and Psychotropic Substances Rules, 1985, the Central Government notified undermentioned manufacturers to import morphine,

codeine, thebaine and their salts for use in manufacture of products to be exported, after following the procedure specified in Rule 55 of the said rules and subject to such conditions as may be specified in the import certificate issued in Form No. 4A annexed to the aforesaid rules and this Notification is valid till 31.12.2022:

1. M/s. Adcock Ingram Limited, 49-C and D, Bommasandra Industrial Area, Anekal Taluk, Bangalore-560099.

2. M/s. Rusan Pharma Ltd., 58-D, Government Industrial Estate, Charpok, Kandivali (W), Mumbai-400067. 3. M/s. Sanofi India Limited, D-2, Unit No. 5 and 6, 2nd floor, Southern Park, Saket District Centre, New Delhi-110017.

4. M/s. Sun Pharmaceuticals Industries Ltd. Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai-400059.

5. M/s. Verve Human Care Laboratories, Plot No. 15-A, Pharmacy, Selaqui, Dehradun-248011 Uttarakhand.

6. M/s. Wockhardt Limited, Wockhardt Towers, Bandra Kurla Complex, Mumbai-400051.

8.6 Similarly, in terms of Notification No. S.O. 2895(E) dated 26.08.2020¹⁹, M/s. Cipla Limited, Cipla House, Peninsula Business Park, Ganpatrao Kadma Marg, Lower Parel, Mumbai-400013, was permitted to import morphine, codeine, thebaine and their salts for use in manufacture of products to be exported, after following the procedure specified in rule 55 of the said rules and subject to such conditions as may be specified in the import certificate issued in Form No. 4A annexed to the aforesaid rules and this Notification is valid till 31.12.2022.

8.6.1 Readers may note that the permissions granted in the cases referred to above to import morphine, codeine, thebaine and their salts **is for use** in manufacture of products to be **exported** after compliance of the procedure set out.

8.7 Insofar as controlled substances are concerned, the Narcotic Drugs and Psychotropic Substances (Regulation of Controlled Substances) Order, 2013 has been put in place with effect from 26.03.2013, which regulates the controlled substances. There are three Schedules to 2013 Order:

8.7.1 Schedule-A substances are those controlled substances whose manufacture, distribution, sale, purchase, possession, storage and consumption is subject to controls as

specified in this Order. Sub-clause (1) of clause (4) of the 2013 Order was amended *vide* Notification No. GSR 779(E) (E) dated 14.10.2019²⁰, which reads as under:

“No person shall manufacture, distribute, sell, purchase, possess, store, or consume or offer for sale or distribution or mediate in the sale/purchase through website, social media any controlled substance included in Schedule-A - without a unique registration number in Form-A issued by the Zonal Director of NCB.”

8.7.2 Schedule B are those controlled substances whose export from India is subject to controls as specified in the 2013 Order.

8.7.3 Schedule- C substances are those controlled substances whose import into India is subject to controls as specified in the 2013 Order.

9. Despite the robust system put in place by the Government, unscrupulous persons operate and find out loopholes to indulge in illicit drug trafficking and the empowered departments, especially the NCB, the CBN, the DRI and the police have been in the forefront in the busting of clandestine factory/lab & internet pharmacies indulging in activities detrimental to interest of the country.

10. Readers may also note that these unscrupulous persons cleverly abuse and mis-use the trade facilitation measures put in by the Government for genuine exporters/importers and many a time get away unnoticed until receipt of the information or gathering of intelligence. The reasons for such activities being detrimental to the interest of the country are that a parallel economy functions and the entire money obtained through illicit drug trafficking is projected as clean money and is used for various activities including narco-terrorism, funding of activities against the interest of the country, purchase of property, non-accountal of money in the system, non-payment of taxes, availment of various incentives of the government, including export and income tax, camouflaging of the activities, etc.

11. The Central Bureau of Narcotics (CBN) is one of the empowered departments under the Act. Acting on a specific intelligence, the joint Preventive team of Central Bureau of Narcotics New Delhi and Gwalior conducted a raid at Plot No. 93, Pocket G, Sector 5, Bawana Industrial Area, New Delhi (one of the prominent industrial hubs in Delhi) and at Sh. Balaji Ayurvedic Store, Janta Bhawan Road, Sirsa (Haryana) on 07.02.2022²¹ and unearthed a clandestine Tramadol manufacturing unit at Bawana Industrial Area, New Delhi, functioning and running in the disguise of Honey processing plant but was found manufacturing Tramadol Tablets, which were branded as Ayurvedic medicine. The search of the said premises resulted into recovery of approximately 52.245 kilograms of Tramadol pills & powder and 1.08

kilograms of substance suspected to be opium. Parallel raid conducted at Sh. Balaji Ayurvedic Store, Janta Bhawan Road, Sirsa (Haryana), used as forefront for diversion of manufactured Tramadol pills in disguise of Ayurvedic Medicines, resulted into recovery of pills containing 1.420 kilograms of Medicinal Opium and pills suspected to be containing 0.495 kilogram of Tramadol.

12 In order to understand the gravity of the situation we are facing, it is essential to point out the extent of penetration by the unscrupulous persons, which can be gauged by the case booked by Chakan Police Station, Pune as Crime No. 1089/2020²² for the offences punishable under Section 8(c), 21(c), 22(c), 27A, 29, 31A of the Act and Section 120B of the Indian Penal Code, 1860. The facts of the case, in brief, are that on 07.10.2020, on a tip off, the police, being an empowered department, intercepted a car bearing MH-12-MN4716 on the Chakan Shikrapur Road, Pune. Five persons were occupying the car - three out of them were sitting on back seat and each had a bag on their laps. They persons were identified as Chetan Dandwate (A-1), Anandeeep Goswai (A-2), Akshay Kale (A-3); Sanjeev Kumar Bansiv Raut (A-4), Tauseef Tasleem (A5). On search of the bags and occupants of the car, 20KG Mephedrone (MD) i.e. commercial quantity worth Rs. 20 Crores and Cash Rs. 23100/- were recovered. During the investigation, **in all 22 accused were arrested**. Their complicity in manufacturing 'Mephedrone' at M/s Sanyog Biotech Plant at Ranjangaon MIDC owned by accused no. 7 – Ashok Sankpal was revealed. Some accused were procuring and making available the raw material i.e. 'Methyle Propiophenone' an essential ingredient for manufacturing M.D. Accused No.3 was found procuring, Acetone; whereas Accused No. 9 Kuldeep Indalkar was found procuring "Methyle Propiophenone" from Bangalore. The accused no. 11 Tushar Kale and Rakesh Khandiwadekar – Accused No. 14, were found manufacturing the drugs with the help of co-accused. The training to manufacture the drugs was imparted by accused nos. 14 and 19. These two accused were found engaged in manufacturing drugs at **Mahad** MIDC at M/s Alchemy Industries and M/s Nimbus Pharma. Accused No. 11 Tushar Kale had taken a rented flat at Mumbai to make the crystals of M.D. Investigation has revealed that Tushar Kale was selling the drugs in the market **through a Nigerian National, Zubi** Accused No. 13. The formula for manufacturing the drugs and the related documents were found and seized from Arvind Kumar - Accused No. 18. The Accused No.11 and 14 had purchased the land and farm house and were planning to commence manufacturing drugs in the farm house.

12.1 Readers may take note of the elaborate exercise that has gone into the illicit manufacture and illicit drug trafficking. The role of a foreigner requires special mention. But

for the specific information, the accused would not have been booked and in all probability enjoyed the ill-gotten wealth by selling within the country or abroad through various means.

12.2 The Hon'ble High Court of Bombay after hearing the rival submissions and while upholding the extension for filing the chargesheet by the prosecution agency observed as under:

“investigation has unfolded complicity of large number of persons involved in manufacturing drugs with systematic and planned approach. Some of them, were found procuring the raw material from various sources; manufacturing drugs in the industrial plants at Ranjangaon MIDC, with the assistance of the experts, selling the drugs in the market across the State and further a sending ill-gotten money across the Country. In consideration of the allegations and evidence surfaced in the investigation, Prosecution has invoked Section 120-B of the IPC. As we know, conspiracies are secretly planned and direct evidence is therefore difficult to produce and therefore in almost all cases, conspiracy is to be inferred from the circumstance pointing out one and only one hypothesis of the existence of conspiracy to commit any unlawful or illegal act.”

12.3 Rejecting the contention of the accused-applicants, the Hon'ble High Court of Bombay held that:

“having regard to magnitude of the offence; complicity of twenty accused, who were from different field and walks of life; complicity of Foreign National; and such other facts surfaced in the investigation, in my view, the Prosecution has indicated and disclosed the progress of investigation and justified for keeping the accused in further custody that is beyond 180 days to enable them to complete the investigation.”

13 To cite another case involving illicit manufacture of Mephedrone, we may refer to the case of **Vegi Srinivasa Rao vs. The Senior Intelligence Officer**²³ wherein the petitioner-accused filed a Criminal Petition before the Hon'ble High Court of Telangana.

13.1 The case of the prosecution is that the petitioner and A-2 were participants in a criminal conspiracy and acted in furtherance of such conspiracy, by illicitly manufacturing, possessing, selling, purchasing, transporting, warehousing and exporting inter-state of Mephedrone, a

psychotropic substance, without having valid licence/permit, thereby violated the provisions of s8 of the Act. The Hon'ble High Court noted that the premises used by the petitioner clearly established that the same was used for manufacture of Mephedrone as it contained raw materials and equipment required for manufacture of Mephedrone, which were seized under the panchanama, dated 10.12.2020. Further, certain raw materials and samples were also seized from the residential premises of the petitioner, under the panchanama, dated 10.12.2020. Furthermore, apart from the consignment of 3156 grams of Mephedrone caught red handed on 10.12.2020, the petitioner-Accused No.1 had manufactured approximately 116 Kgs. of Mephedrone since November, 2019 and handed it over to the persons, who came from Mumbai and he received approximately Rs. 89.00 lakhs as proceeds. The two diaries and other documents recovered from the residential premises of petitioner-Accused No. 1 contained crucial record of transactions pertaining to manufacture of Mephedrone and its sales; record of phone contacts; information pertaining to certain chemical compounds used in the manufacture of Mephedrone; manufacturing process of Mephedrone and records of delivery of raw materials required for manufacture of Mephedrone. These crucial entries were made in the diaries by petitioner-Accused No. 1 and the same were explained by petitioner-Accused No. 1 in his voluntary statement. On the basis of the above, the Hon'ble High Court came to a conclusion and held that petitioner-accused No. 1 having indulged in a serious crime is disentitled to be enlarged on bail in view of the bar contained under s37 of the Act.

14 It is no secret that the illicitly manufactured drugs are for consumption within India and abroad. It is also required to be noted by the esteemed readers at this stage is that the establishment and functioning of such clandestine manufacturing factories for the illicit manufacture of drugs and the sale through internet pharmacies are closely inter-linked. The fact remains that they have to procure it from someone to export the required prohibited substances without following the set out procedure. The primary purpose of setting up of clandestine factories/lab, especially in remote areas or in unused/vacant industrial sheds is to overcome the statutory mechanism put in place and also to make money and there can be no two opinions on that. A large number of clandestine factories/labs have been busted in Alwar²⁴, Hyderabad²⁵, Nashik²⁶, Kala Amb and Panota Sahib²⁷ (Himachal Pradesh) (also see (see para 15 *infra*), Mt. Abu²⁸, Sangli²⁸, Mumbai²⁸, Goa²⁹, Panvel³⁰, Indore, Vadodara³¹, Vapi³², Surat³³, Indore³⁴, Ranjangaon & Mahad (see para 12 *supra*), Dehradun (see para 15 *infra*) to name a few. In most of the cases booked by the empowered agencies, the role of foreigner³¹ (also see para 12 *supra*) has also surfaced.

15 Readers may note that some of the manufacturing units having proper licences also

indulge in illicit drug trafficking, as is evident from the following cases.

- (i) In the case booked against **M/s Avon Life Sciences Company, Solapur**³⁵, it is the case of the prosecution (Vartak Nagar Police Station, Thane vide CR. No.II-3056/2016) that:
 - (a) M/s. Avon Organics Ltd. owned by Mr. Manoj Jain (A-6) was granted permission by the Ministry of Health and Family Welfare, Central Drugs Standard Control Organization, Government of India for manufacturing and packing, Pseudoephedrine HCl (BP/USP/EP) and Ephedrine HCl (BP/EP) by its Certificate dated 31.07. 2013 and the said permission was valid till 02.07.2016.
 - (b) Mr. Manoj T. Jain (A-6), Mr. Jay Mulji Mukhi (A-10), Mr. Kishorsing Rathod (A-13) and wanted accused Mr. Vicky Goswami, Smt. Mamta Kulkarni, Dr. Abdulla and his two Associates conducted a meeting in the month of January 2016 at Hotel Bliss, Mombasa, Kenya. It was decided in the said meeting that Mr. Manoj Jain would send Ephedrine powder manufactured at his Avon Life Sciences Company to Kenya and from it Amphetamine (Ice) would be manufactured and sold in the world by wanted accused persons, namely, Mr. Vicky Goswami, Dr. Abdulla and their Associates. As per the conspiracy, Mr. Punit Shringi (A-5) and Jay Mulji Mukhi (A-10) illegally removed 125 kgs. of Ephedrine powder from Avon Life Sciences Company and through Mr. Kishorsing Rathod (A-13), sent it to Narendra D. Kacha (A-8) for processing it. After the said Ephedrine powder was processed and narcotic drug was prepared from it, Mr. Kishorsing Rathod (A-13), Mr. Jay Mulji Mukhi (A-10) and Mr. Bharat Sing Kathia (A-14) handed it over to the agent of wanted accused Mr. Vicky Goswami at Mohammed Ali Road, Mumbai. The wanted accused Vicky Goswami received the said contraband at Kenya and after that, through angadia (courier) via Mr. Jay Mukhi (A-10) sent crores of rupees to Mr. Manoj Jain (A-6).
- (ii) In S.C. No. 7520/2016 (Old No. 06A/15) DRI vs. D.P. Saxena & Ors ³⁶ in the Court of Special Judge (NDPS), Saket Courts, New Delhi, M/s. Daffohills Laboratories Pvt. Ltd, Dehradun was proceeded against for illegal diversion of

controlled substance pseudoephedrine to Delhi by fudging their statutory Central Excise records. Similarly, another unit located in the state of Himachal Pradesh - M/s. G.T. Biopharma (P) Ltd. – was engaged in the diversion in collusion with Accused Yogesh Shah in this case. A complex web of transactions involving Yogesh Shah of Ahmedabad (Gujarat), **M/s. G.T. Biopharma (P) Ltd, Kala Amb in Himachal Pradesh, M/s. Daffohills Laboratories Pvt. Ltd, Dehradun** along with a number of persons viz. accused Rakesh Kr. Bholra (A2), accused Manoj Kumar Nayak (A3), accused Vishal Chaudhary (A4), accused Sanjay Kumar Bhartia (A7) (absconder), accused Sultan Ansari (A8), accused Jai Ballabh (A9) (absconder), accused Inderpal Singh Chawla (A11) of **M/s. Daffohills Laboratories Pvt. Ltd.** (A10) & Accused Prit Pal Singh Chawla (A12) were booked for their respective roles in the offences committed by them under the Act.

- (iii) DRI, Surat³³ received and developed a specific intelligence to the effect that M/s **Ardor Drugs Pvt. Ltd. Songadh-Ukai Road, Songadh, Tapi** is engaged in the business of manufacturing of drugs (medicines) and also engaged in manufacturing and selling Tramadol, a psychotropic substance illicitly and that the aforesaid company through **M/s. Orlando Health Care Ltd, Surat** is in the process of exporting Tramadol tablets by concealing it in containers stuffed with pharma products from Hazira Port. On the basis of the specific intelligence, search was conducted on 06.07.2020, at factory of M/s. Ardor Drugs Pvt. Ltd. and at CFS-Seabird Marine Services Pvt. Ltd, Hazira Port, Surat and during the search, shortages of 1376.443 kgs of Tramadol Hydrochloride; of 174.978 kgs of Ephedrine Hydrochloride IP; and of 137.175 kgs of Pseudoephedrine Hydrochloride were found from the factory premises. On being questioned, Mehulbhai Manubhai Desai and Harshal Prafulbhai Desai, both directors of the company, stated that they have manufactured 60 Lakh tablets of Tramadol Hydrochloride of 225 mg from the aforesaid short found material. Thereafter, it was informed by them that out of the 60 Lakh tablets, 15.21 lakh tablets were lying at CFS Seabird Marine Services Pvt. Ltd., Hazira Port for export vide Shipping Bills Nos. 3594018 & 3614975 dated 03.07.2020 & 04.07.2020, respectively, and the remaining 44.79 Lakh tablets were already exported illicitly. During the searches on 06.07.2020 and 07.07.2020, 15.21 Lakh tablets were seized from two different containers. M/s. Ardor Drugs Pvt. Ltd. had the

permission bearing No. G/25/1623 for manufacturing and export of Tramadol 225 mg. tablets to Cameroon (through M/s. Sanctuary Pharmaceuticals) for only 101000 Tramadol 225 mg tablets. However, in the guise of above mentioned license, they manufactured Tramadol 225 mg. tablets more than the permissible of limit of 101000 Tramadol 225 mg tablets and Harshal Desai got it clandestinely removed from M/s. Ardor Drugs Pvt. Ltd. Further, out of the said tablets 15.21 lakhs tablets were attempted to be exported in the name of M/s. Orlando Healthcare, Surat which is a proprietary concern of Shri Harshal Desai and which did not had any permission to manufacture or export the above said Tramadol 225 mg tablets. On conclusion of the investigation, a complaint against Harshal Prafulbhai Desai & Mehulbhai Manubhai Desai and others for contravention of Sections 8 (c) and 9A punishable under Sections 22, 23, 25, 25(A) and 29 of the Act was filed.

- (iv) The ugly nexus between the Pharmaceutical manufacturing companies and smugglers came to light with the busting of an illegal factory by the Punjab Police. It included Neutec Pharmaceutical Private Limited at Narela in Delhi⁴⁵, which is one of the biggest manufacturers of NRx (Prescription) drugs, such as Clovidol 100 SR, Alprazolam, extensively used as pharma opioids by drug addicts. Father-son duo was involved in the entire operation. The father was already proceeded against in a separate case in the past by the Directorate of Revenue Intelligence functioning under a different name.

16 Internet pharmacies operate on the strength of secrecy and the identity of the kingpins and their associates is difficult to obtain as they are multi-layered in character. By multi-layered, we mean that a person accused of an offence may lead up to the next person without ever meeting the main person behind the entire operation. This is planned in such a way that the main kingpin is kept away from the glare of the empowered departments. This type of shrouded secrecy enables them to survive and create and operate multi-websites. These persons are prone to taking high amount of risk to make deals and hence their true identity is never known to the public/family or their neighbour and they pass on as any good citizen, until law catches them with full force as demonstrated by the following cases:

- (a) In a crackdown on the internet pharmacies, the NCB, Hyderabad, based on an information, searched the house and office premises of the kingpin of the internet pharmacy M/s JR Infinity Pvt. Ltd.³⁷ located at Domalguda on 08.05.2022 for allegedly operating an internet pharmacy that diverts and supplies psychotropic

medicines for recreational use to the U.S. and other countries. M/s JR Infinity was used as a front to use illegal pharmacies and Ashish Jain used to contact customers using Voice over Internet Protocol (VoIP) and email. The drugs being shipped included Oxycodone, Hydrocodone, Alprazolam, Diazepam, Lorazepam, Clonazepam, Zolpidem and Tramadol. It should be noted at this stage, these are psychotropic substances which have been recovered and obviously they have been manufactured in India. It naturally follows that while busting of an internet illegal pharmacy happens, simultaneously, the identification of clandestine factory which manufactured the same should also be identified and busted.

(b) Other major cases booked (with some of them being decided in the recent past) by the empowered departments with reference to internet pharmacies are brought out hereunder for the understanding the *modus operandi* adopted by each of them.

A. Sanjay Kedia³⁸ and internet pharmacy go hand in hand and the case dates back to 2007.

In an elaborate planning and well executed strategy Sanjay Kumar Kedia set up two companies M/s. Xponse Technologies Limited (XTL) and M/s. Xponse IT Services Pvt. Ltd. (XIT) on 22.4.2002 and 08.09.2004 respectively. On 1.2.2007 officers of the Narcotics Control Bureau (NCB) conducted a search at the residence and office premises of the appellant but found nothing incriminating. But subsequently an elaborate investigation conducted by the NCB, as submitted by them to the Hon'ble Supreme Court revealed that:

"The company (Xponse Technologies Ltd. and Xponse IT Services Pvt. Ltd. Headed by Sanjay Kedia) has designed, developed, hosted the pharmaceutical websites and was using these websites, huge quantity of psychotropic substances (Phentermine and Butalbital) have been distributed in USA with the help of his associates. Following are the online pharmacy websites which are owned by Xponse or Sanjay Kedia.

(1) Brother Pharmacy.com and LessRx.com: Brothers pharmacy.com, online pharmacy was identified as a marketing website (front end) for pharmaceutical drugs. LessRx.com has been identified as a "back end" site which was being utilized to process orders for pharmaceutical drugs through Brotherspharmacy.com.

LessRx.com's registrant and administrative contact was listed True Value Pharmacy located at 29B, Rabindra Sarani, Kolkata, India-700073. Telephone No.033-2335-7621 which is the address of Sanjay Kedia. LessRx.com's IP address is 203.86.100.95. The following websites were also utilizing this IP address: ALADIESPHARMACY.com, EXPRESSPHENTERMINE.com, FAMILYYONLINEPHARMACY.com, ONLINEEXPRESSPHARMACY.com, SHIPPEDLIPITOR.com

Domain name Servers for LessRx.com (IP address: 203.86.100.95) were NS.PALCOMONLINE.com and NS2PALCOMLINE.com.

The LessRx.com's website hosting company was identified as Pacom Web Pvt Ltd, C-56/14,1st Floor, Institutional Area, Sector 62, Noida-201301. Sanjay Kedia entrusted the hosting work to Palcom at VSNL, Delhi. These servers have been seized. Voluntary statement of Shri Ashish Chaudhary, Prop. of Palcom Web Pvt Ltd .indicates that he maintained the websites on behalf of Xponse.

According to the bank records, funds have been wired from Brothers pharmacy, Inc's Washington Mutual Bank Account #0971709674 to Xponse IT services Pvt Ltd, ABN AMRO bank account No.1029985, Kolkata.

(2) Deliveredmedicine.com : A review of the Xponse's website-XPONSEIT.com was conducted and observed and advertisement for XPONSERX. That XPONSERX was described as a software platform developed for the purpose of powering online pharmacies. Xponserx was designed to process internet pharmacy orders by allowing customers to order drugs. Drug Enforcement Administration (DEA), USA conducted a "whois" reverse lookup on domain name XPONSERX.COM was at domaintools.Com and it revealed that XPONSERX.COM was registered to Xponse IT Services Pvt Ltd, Sanjay kedia, 29B,Rabindra Sarani, 12E,3rd floor, Kolkata, WB 70073. Telephone no.+91- 9830252828 was also provided for Xponse. Two websites were featured on the XPONSEIT.COM websites as featured clients. And these were DELIVEREDMEDICINE.COM AND TRUEVALUEPRESCRIPTIONS.COM. Review indicated that these two

websites were internet pharmacies. Consequently a "whois" reverse look-up on domain name DELIVEREDMEDICINE.COM at domainstools.com conducted by DEA revealed that it was registered to Xponse Inc., 2760 Park Ave., Santa Clara, CA, USA which is the address of Sanjay Kedia.

(3) Truevalueprescriptions.com: Review of this website indicated that this website was a internet pharmacy. In addition TRUEVALUEPRESCRIPTIONS listed Phentermine as a drug available for sale. It appeared that orders for drugs could be made without a prescription from the TRUEVALUE website, it was noted that orders for drugs could be placed without seeing a doctor. According to the website, a customer can complete an online questionnaire when placing the order for a drug in lieu of a physical exam in a physician's office. Toll free telephone number 800-590-5942 was provided on the TRUEVALUE website for customer Service. DEA, conducted a "whois" reverse look-up on domain name TRUEVALUEPRESCRIPTIONS.COM at domainstools.com and revealed that IP address was 203.86.100.76 and the server that hosts the website was located at Palcom, Delhi which also belongs to Xponse."

Note Behind: Whois", is a widely used Internet record listing that identifies who owns a domain and how to get in contact with them. The Internet Corporation for Assigned Names and Numbers (ICANN) regulates domain name registration and ownership.

B. D. Ramakrishnan & another vs. Intelligence Officer, NCB, SZU³⁹. It is the case of the prosecution that an information was received and further worked upon which indicated that one Seethapathy, President of M/s. Chandra Importers Inc, 160, Home Street, Elmira, New York, was indulging in illegal Internet Pharmacy business and had a branch office at Coimbatore and one D. Ramakrishnan was managing the activities of the said branch at Coimbatore and the said Ramakrishnan procured psychotropic substances such as Alprazolam, Lorazepam, Nitrazepam etc. on daily orders received by him through E-mail from Seethapathy of M/s. Chandra Importers Inc, New York, packed it at his office and effected despatches to various customers abroad. The officers of NCB conducted a

search of the premises M/s Chandra Importers Inc. having a branch at No. 46, R.K. Mills B Colony Road, Coimbatore. 25.01.2008 at about 13.00 hours in the presence of two independent witnesses and D. Ramakrishnan after complying with the necessary formalities under section 50 of the Act. On inquiring about the operations of M/s. Chandra Importers Inc, D. Ramakrishnan informed that he was the Branch Manager of the company and his boss Seethapathy used to inform consolidated requirement of drugs through e-mail which he purchased from local pharmacies, packed and sent to individual customers abroad. He showed the files containing packing slips and receipts for the purchase of drugs. The drugs dealt with by him included psychotropic substances such as Alprazolam, Lorazepam, Nitrazepam, etc. He also informed that he had not obtained any permission from the competent authority i.e. the Narcotics Commissioner, Central Bureau of Narcotics, Gwalior for export of the above scheduled psychotropic substances under the Act. He showed two computers used for the business purpose. The officers seized the mercury make CPU and Wipro make CPU along with mouse and keyboards. The hard disk of CPU mercury make bearing Sl. No. 6PS35DSE and the hard disk of Wipro make bearing Sl. No. 5LAK86PM were detached from the CPU and packed and given markings P1 and P2 respectively. The mouse and the keyboards were packed and given the marking P3. The packages were sealed with NCB seal No. 12. During enquiry, D. Ramakrishnan showed box files containing packing cum despatch slips for despatches to individual customers and other documents regarding establishment and dealings of the company. All these documents, required for investigation, were listed in Annexure A and seized. A panchnama for the entire proceedings was drawn on the spot. In his voluntary statement, D. Ramakrishnan admitted to procurement, possession, using of the residential premises for packing, transportation and illicit export of psychotropic substances out of India to various destinations abroad. Thus, D. Ramakrishnan entered into criminal conspiracy for illicit export of psychotropic substances in contravention of the provisions of section 8(c) read with 22, 23, 25, 27A, 29 and 38 of the Act and Rule 53, 53A and 56 of Narcotics Drugs and Psychotropic Substances Rules, 1985.

C. In the case of Waseem Akram⁴⁰, it is the case of the prosecution that on the basis of a secret information received that one Waseem Akram was illicitly running an internet pharmacy business along with his brother and one Mohammed

Suhail Ahmed in the name of a call centre which starts operating in the night at Thanisandra, Bengaluru through which they are smuggling some controlled substances to foreign countries and making profit. On the basis of this, a team including a Gazetted officer and two panchas reached the house and knocked the door. After mandatory compliance, search of person did not yield anything. Search of the house, led to the recovery of some carton boxes. On search of the said boxes, they found inter alia, 635.25 grams of Alprazolam tablet strips, 24.07 grams of Zolpidem, 129 grams of Amphetamine, 25.27 grams of clonazepam, 13.50 grams of Lorazepam, 16 grams of Phentermine, 2.75 grams of oxycodone, 147 grams of butalbital and 10.2 grams of diazepam tablets strips. The owner of the house i.e., accused No. 1 was not present. Further accused No. 3 admitted that the name of the call center is AM Pharmacy and it was functioning without any valid licence for pharmaceutical business. A panchnama for the proceedings was drawn on the spot and thereafter further proceedings were carried out.

D. Based on a specific information, the NCB, Ahmedabad Zonal Unit, on 24.05.2015 busted a racket of large quantities of psychotropic drugs via courier to earn good returns. Based on the information that a youth, identified as Rishabh Rawal, was sending 24 parcels abroad through a courier company in the walled city he was apprehended and later two others – Mohammad Sayed and Abdul Rauf, both residents of Dariapur Darwaja were caught in connection with the case. A godown owned by Mohammad Sayed, the main person behind the internet pharmacy, on Relief Road was later raided, from which they found the stock of tablets and injections of drugs including Zolpidem, Alprazolam, Diazepam, Lorazepam, Clonazepam, Ketamine Hydrochloride, Acetaminophen, Codeine Phosphate, Oxycodone and Acetaminophen. A team of the Ahmedabad Zonal Unit (AZU) of NCB nabbed four persons – 2 each from two pharmaceutical companies based in Vadodara and Mumbai - in a crackdown on an 'online pharmacy' racket. Based on a specific information that M/s Dolphin Pharmaceuticals in Vadodara⁴¹, was involved in the online distribution of psychotropic drugs in the US and Europe, the officers of NCB, AZU searched the Vasna residence of its director Anil Luhar on 09.08.2016. On finding a stock of psychotropic drugs without proper papers, the firm's warehouse at Gorwa was raided and some 8 lakh alprazolam tablets were seized. Zahid Shaikh, a manager with the company, was also arrested. The illegal online market circumvented the rules of various department viz. Customs Food

and Drugs Control Administration, Gujarat by sending the drugs disguised as vitamins or food supplements via post or courier. During questioning it was gathered that they got the drug from Mumbai-based manufacturer.

E. The NCB, DZU busted an illegal Gurugram-based online pharmacy⁴² that was shipping psychotropic medicinal tablets to the USA and some European countries under the garb of 'herbal medicine'. The agency had intercepted 44 packets of such psychotropic substances bound for the US, the UK and Hungary at the Foreign Post Office New Delhi on 02.08.2018. The packets bore authentication stamps of various regulatory departments and the consignment was declared and concealed as "herbal medicines". Raid on various premises linked to the firms and their owner in Gurgaon, Haryana led to recovery of 22,410 tablets of psychotropic medicines like Diazepam, Zolpidem, Clonazepam, Alprazolam, Nitrazepam, Tramadol and others. In order to conduct the internet pharmacy business, 57 websites were floated. A total of 79 fake seals of various government agencies like the Postal Department, Customs, insurance companies, banks, hospitals and pharma companies were also seized during the raids

F. An illegal internet pharmacy, based in West Patel Nagar, New Delhi⁴³ sending drugs, under the garb of auto parts and religious items, to foreign destinations like the USA and Canada was busted by the NCB. Search of the premises resulted in the seizure of over 41,000 psychotropic tablet strips on 19.08.2018. Four people were booked under the provisions of the Act.

G. The **interplay of darknet and internet pharmacy and the legal pharma** manufacturing unit **cannot be understated**. The interplay was busted by the NCB⁴⁴. The illicit drug trafficking syndicate was operating over the darknet also operated using internet pharmacy with nine websites registered at various locations including Delhi, UP & Uttarakhand in India and having its extended arms in the USA, the UK, Canada, and the Philippines. A **Haridwar based pharmaceutical manufacturing** company was also found involved and working for this syndicate.

17 The internet pharmacies have been busted in the past too especially by NCB. But it is a fact on record that internet pharmacies, using the available loopholes, obtaining the illegally manufactured narcotic drugs and psychotropic substances have used the courier (both domestic and international) and Foreign Post Office route to transport the drugs - primary reason being

the sheer number of courier bags and postal articles being cleared on day to day basis. Despite the huge work load, the alert and dedicated Customs officer manning the courier and FPO routes have booked cases primarily pertaining to psychotropic substances.

18 Another widely abused, misused substance is cough syrup of different brands manufactured by major pharmaceutical companies in India and many cases have been booked by various empowered departments. It has been contention that “dealing” in cough syrup falls outside the provisions of the Act.

18.1 The leading case on the subject is Mohd. Sahabuddin⁴⁶ in which it was mainly contented by the appellant as under:

“7.The contentions of the appellants were fourfold. In the first place, it was contended that the cough syrups Phensedyl and Recodex are pharmaceutical products covered under the provisions of the Drugs and Cosmetics Act, that the Rules prescribe the measure of dosage as 5 ml and that under Rules 65 and 97 of the Drugs and Cosmetics Rules, it is lawfully permissible to sell such cough syrups in the open market, which can also be transported, kept in stock and sold in the pharmaceutical shops as a prescribed drug under Schedule H at Serial No. 132. According to the appellants, such prescribed drugs under the Rules can contain codeine to the extent permissible. While referring to Rule 97, it was contended that Schedule H drugs containing permissible extent of narcotic substance could be sold in retail on the prescription of registered medical practitioner. The learned counsel, therefore, contended that each of the 100 ml bottles, seized from the appellants, satisfy the requirement prescribed under the aboveresferred to two Rules 65 and 97 and in the circumstances there was no question of proceeding against the appellants under the NDPS Act.”

Upon hearing the rival submissions, the Hon’ble Supreme Court held as under:

11. The submission of the learned counsel for the appellants was that the content of the codeine phosphate in each 100 ml bottle if related to the permissible dosage, namely, 5 ml would only result in less than 10 mg of codeine phosphate thereby would fall within the permissible limit as stipulated in the Notifications dated 14-11-1985 and 29-1-1993. As rightly held by the High Court, the said contention should have satisfied the twin conditions, namely, that the contents of the narcotic substance should not be more than 100 mg of codeine, per dose unit and with a concentration of not more than 2.5% in undivided preparation apart from the other

condition, namely, that it should be only for therapeutic practice. Therapeutic practice as per dictionary meaning means “contributing to cure of disease”. In other words, the assessment of codeine content on dosage basis can only be made only when the cough syrup is definitely kept or transported which is exclusively meant for its usage for curing a disease and as an action of remedial agent.

12. As pointed out by us earlier, since the appellants had no documents in their possession to disclose as to for what purpose such a huge quantity of Schedule H drug containing narcotic substance was being transported and that too stealthily, it cannot be simply presumed that such transportation was for therapeutic practice as mentioned in the Notifications dated 14-11-1985 and 29-1-1993. Therefore, if the said requirement meant for therapeutic practice is not satisfied then in the event of the entire 100 ml content of the cough syrup containing the prohibited quantity of codeine phosphate is meant for human consumption, the same would certainly fall within the penal provisions of the NDPS Act calling for appropriate punishment to be inflicted upon the appellants. Therefore, the appellants' failure to establish the specific conditions required to be satisfied under the aboveresferred to notifications, the application of the exemption provided under the said notifications in order to consider the appellants' application for bail by the courts below does not arise.

Emphasis applied

18.2 It is essential at this juncture to discuss the interplay between the provisions of the Act and those of the Drug and Cosmetics Act, 1940 and the issue stood finally settled by the Larger Bench of the Hon'ble Supreme Court in the case Sanjeev V Deshpande⁴⁷ where the Larger Bench of the Hon'ble Supreme Court, on the inter play between the provisions of the Act and the Drugs and Cosmetics Act, 1940, held as under:

“35. In view of our conclusion, the complete analysis of the implications of Section 80 [“80. Application of the Drugs and Cosmetics Act, 1940 not barred].—The provisions of this Act or the Rules made thereunder shall be in addition to, and not in derogation of, the Drugs and Cosmetics Act, 1940 (23 of 1940) or the Rules made thereunder.”] of the Act is not really called for in the instant case. It is only required to be stated that essentially the Drugs and Cosmetics Act, 1940 deals with various operations of manufacture, sale, purchase, etc. of drugs generally whereas the Narcotic Drugs and Psychotropic Substances Act, 1985 deals with a more specific class of drugs and, therefore, a special law on the subject. Further the provisions of

the Act operate in addition to the provisions of the 1940 Act.”

18.3 Some cases decided in the recent past require special mention. A careful perusal of the same reveals that there is divergence of opinion as to whether the cough syrup falls under the ambit of the Act or not. These are discussed herein

(a). In *Vibhor Rana and Bittu Kumar*⁴⁸, the common question decided was as to whether Phensedyl New Cough Linctus Syrup is a Narcotic Drug and falls within the purview of the Act. The Hon’ble High Court after going through the definitions of “manufactured drug,” “narcotic drug”, “opium”, “opium derivative” under section 2(xi), (xiv), (xv) & (xvi) respectively and section 8 of the Act, held in para 21 as under:

“21. The position which emerges from a combined reading of the above quoted definitions is that as per Section 2 (xvi) (c) of the Act, codeine and its salts are "opium derivatives". As per Section 2 (xi) (a), opium derivatives are included in "manufactured drugs" and as per Section 2 (xiv) all manufactured drugs are included in the definition of "narcotic drugs", unless the same falls within the exception appended to Section 2 (xi) providing that "but does not include any narcotic substance or preparation which the Central Government may, having regard to the available information as to a decision, if any, under any International Convention, by notification in the Official Gazette, declare not to be a manufactured drug".

Moving further, the Hon’ble High Court observed in para 23 to 25 as under:

‘23. Thus, as per the aforesaid Notification, if any drug contains not more than 100 milligrams of Methyl Morphine, which is commonly known as Codeine, per dosage unit, and in that drug Codeine is compounded with one or more other ingredients and if in the drug the concentration of Codeine is not more than 2.5% in undivided preparations and the drug has been established in Therapeutic practice, will not be a "Manufactured Drug" and, therefore, it will not be a "Narcotic Drug".

24. The prohibition contained in Section 8 of the Act is applicable to "Narcotic Drugs" and since Phensedyl New Cough Linctus contains Codeine compounded with one other ingredient, namely Chlorpheniramine Maleate and since Phensedyl New Cough Linctus contains merely 10 milligrams per dosage unit of 5 ml, which is not more than 100 milligrams of the drug per dosage unit in undivided preparations and the concentration of Codeine in Phensedyl New Cough Linctus is merely 0.2%, which obviously is not more than 2.5% and which has been established in

Therapeutic practice, it is not a "Manufactured Drug" and, therefore, it is not a "Narcotic Drug", the prohibition contained in Section 8 of the Act does not apply to it.

25. Phensedyl New Cough Linctus contains Codeine which is mentioned at Serial Number 20 in Schedule H1 appended to the Drugs Rules, 1945 and a note appended to Schedule H1 provides that "Preparations containing the above drug substances and their sales excluding those intended for topical or external use (except ophthalmic and ear or nose preparations) containing above substances are also covered by this Schedule". Therefore, Phensedyl New Cough Linctus is a drug covered by the Drugs and Cosmetics Act, 1940."

The respondent-NCB submitted that for falling within the exception carved out in entry 35 of the Notification dated 14.11.1985, the drug in question must fulfil two conditions:-

- (a) Methyl morphine (commonly known as 'Codeine') and Ethyl morphine and their salts (including Dionine), all dilutions and preparations except those which are compounded with one or more other ingredients and containing not more than 100 milligrams of the drug per dosage unit and with a concentration of not more than 2.5% in undivided preparations **and**
- (b) It should have been established in Therapeutic practice."

It was further submitted that although there is no dispute that the drug in question fulfils the condition no. 1 above, yet the same does not fulfil the condition no. 2 above, *viz.* **having been established in therapeutic practice.** It was further submitted that the drug in question is being illegally diverted for non-therapeutic uses, and, therefore, it does not fall within the exception to item No. 35 of the Notification dated 14.11.1985 issued and it would be subject to the provisions of the Act. The expression "**established in therapeutic practice**" has neither been defined under the Act nor has been interpreted in any of the decisions rendered on the issue. Hon'ble High Court, while explaining the expression "**established in therapeutic practice**" observed and held as under:

*"38. The expression "established in therapeutic practice" has not been interpreted in any previous decision. **It is a basic rule of interpretation that the words used in the statute should be given their simple and natural meaning and neither any word should be added nor should any word be ignored while interpreting any provision.** When the Government has used the expression "established in therapeutic practice" these words cannot be altered so as to read it as "used for therapeutic purposes". The*

phrase **“established in therapeutic practice” apparently means that the compound in question has been established to be a drug in accordance with the therapeutic practices followed for establishment of new drugs.** Therefore, the submission **that the drug in question does not fulfil the condition no. (2) of having been “established in therapeutic practice”, is without any force.**

Addressing the issue of misuse of the impugned syrup by the end consumer, the Hon’ble High Court observed as under:

‘‘39. Moreover, use or misuse of a drug by the end user or consumer of the same would not have any affect on the law governing the drug. Phensedyl is a drug covered by the exception contained in Article 35 of the Notification dated 14.11.1985 issued by the Central Government and it is not a narcotic drug and hence not covered by the provisions of the NDPS Act and **merely because some persons may be misusing it for other than therapeutic purposes, it would not come within the purview of the NDPS Act. NDPS Act has been enacted with a specific object and the Authorities under the Act can exercise jurisdiction strictly in accordance with the provisions of the Act.** The Authorities under the Act do not have sweeping powers to take action upon suspicion of any illegality or irregularity of any sort committed at any place in respect of any substance. It is settled law that penal statutes have to be interpreted in a strict manner. ‘‘

On account of the conclusion arrived at to the effect that Phensedyl New Cough Linctus fell outside the purview of the Act, the Hon’ble High Court held that the officers of the respondent could not have exercised the power under s42 of the Act as there was no reasons to believe and hence the jurisdiction. Accordingly, both the Writ Petitions were allowed. The proceedings of the aforesaid complaint in Case No. NCB/LZU/CR No. 04 of 2021 under Sections 8, 21 (c), 22, 25, 29 and 60 (3) of the NDPS Act pending in the Court of Special Judge, NDPS Act, Jaunpur and the investigation against the petitioners in relation to the aforesaid complaint were quashed.

(b) In the case of Hemant Kumar Saini & in the case of Yogita Nand Yadav⁴⁹, a prayer was made to quash the notice/summons issued against petitioners in both the writ petitions as well as the FIR as prayed in Writ Petition MISC. BENCH No. - 11190 of 2021 in the case of Hemant Kumar Saini. The facts of the case were that a specific information was received that huge quantity of codeine based syrup have illegally been stored in the shop/godown No.09 and Shop No.31 of Gyan Mondal Plaza @ Imam Mondal Plaza @

Aaj Press Building, Sant Kabir Marg near Maidagin Chauraha, Police Station Kotwali, Varanasi, by one Sunil Jaiswal. The information was reduced in writing and submitted to superior officer, i.e. Superintendent, N.C.B., Lucknow on 03.04.2021. A team was constituted for further action. The aforesaid team reached Varanasi along with necessary articles and met the S.H.O., Kotwali Varanasi and shared the information to procure police party. The information was also communicated to Drug Inspector, Varanasi. The N.C.B. team along with police personnel and Drug Inspector, Varanasi reached at the suspected shops on 05.04.2021. The shops in question, i.e. Shop Nos. 09 and 31 were found locked. The team tried to contact to Sunil Jaiswal but after repeated calls and long waiting, said Sunil Jaiswal did not appear before the team to open the shops. The team inquired about Sunil Kumar Jaiswal through his brother's shop also but Sunil Jaiswal could not be contacted. Then the team arranged a local key maker, Abhishek Jaiswal, who opened the lock of both the premises in presence of independent witnesses. The Shops were found fully packed with the cough syrup. All the legal formalities were completed by the team without causing any damage to any person or property. Both the shops were locked by the new locks purchased by the N.C.B. team. Based on the above, panchnama proceedings were carried out.

(c) In the case of Sandeep Kumar @ Sandeep Kumar Diwakar⁵⁰, the case of the prosecution is that the petitioner was in illegal possession of Chlorpheniramine Maleate and codeine phosphate syrup Onerex-100 ml-11 pieces and kufedeine-100 ml-5 pieces as well as wine and liquor. The Hon'ble High Court, after hearing the rival submissions and while rejecting the bail held as under:

“In view of the settled principle of law as discussed above as held by the Hon'ble Supreme Court of India in the case of Md. Sahabuddin & Anr. Vs. State of Assam (supra) in order to get exemption from the application of section 21 of the Narcotic Drugs and Psychotropic Substances Act, 1985 twin conditions are to be fulfilled; the first one is that the contents of the narcotic substance should not be more than 100mg. of codeine per does unit and with a concentration of not more than 2.5% in undivided preparation; and the second is it should be only for therapeutic practice. In the absence of any documents in possession of the petitioner to disclose as to for what purpose such a huge quantity of Schedule 'H' drug containing narcotic substance was being transported, this court is of the considered view that the petitioner has failed to satisfy the said 2nd condition that the said Chlorpheniramine Maleate and codeine phosphate syrup Onerex-100 ml-11 bottles and kufedeine-100 ml-5 bottles were

carried by the petitioner for therapeutic use, thus this court has no hesitation in holding that inter alia the offence punishable under section 22 (c) of the Narcotic Drugs and Psychotropic Substances Act, 1985 is attracted in this case.”

(d) In the case of Iqbal Singh⁵¹, the facts of the case are that on the basis of specific information that one boy, proficient in Punjabi Language, will board a train to Punjab from Sakur Basti Railway Station, Delhi and may be carrying huge quantity of drugs, the said information was reduced to writing and put up to the Superintendent, NCB who directed to take the necessary action. Accordingly, a team was constituted and at 0915 hours and they proceeded to the said Railway Station and arrived there at 0950 hours. At their request, a team of Railway Police Force (RPF) also joined the proceedings. At 10.30 A.M., they noticed three persons. One of them (the petitioner herein) was holding a white coloured plastic bag (plastic katta). The NCB team suspected the said persons and they were stopped and were informed of their rights. The NCB searched them in the presence of the Gazetted Officer. Nothing incriminating was found on either of them. However, the search of the white coloured bag carried by the Iqbal Singh yielded two black polythenes containing 57 bottles of "Onerex Cough Syrup" of 100 ml each, one of the ingredient being codeine phosphate. The Hon'ble High Court, after hearing the rival submissions, held as under:

“25. Plainly, the quantity of the mixture of a manufactured drug and a neutral substance would require to be considered for the purposes of determining whether the quantity is a commercial quantity or a small quantity for the purposes of the NDPS Act. However, a drug which is manufactured but falls outside the scope of the definition of a 'manufactured drug' under the NDPS Act on account of the component of offending material being below the prescribed threshold, cannot be construed as a manufactured drug by dissecting its ingredients and considering them in isolation.

26. In the present case, it cannot be NCB's case that 99.83% (that is, 100% minus 0.17%) of the components of the formulation are neutral substances masking 0.17% of the illicit substance. On the contrary, it is apparent that the cough syrup is a medicinal product.

27. At this stage, this Court is not required to examine the matter in any further detail. Suffice it to state that the petitioner has presented reasonable grounds for being acquitted in the present case. There is no allegation that the petitioner is involved in any other case.

28. *In the given circumstances, this Court considers it apposite to allow the present petition. The petitioner shall be released on bail on his furnishing a Personal Bond in the sum of 20,000/- to the satisfaction of the Trial Court/Duty Magistrate.....”*

(e) In the case of Mohd Ahsan⁵², the facts of the case are that the investigation revealed that each bottle weighing 100 grams and each of the bottle had Codeine concentration of 0.17% which translates to about 18.7 grams of concentrated codeine in total 110 bottles. The Hon’ble High Court, after hearing the rival submissions, held as under:

“16. A reading of the judgment in Iqbal Singh (supra) therefore shows that this Court has created a distinction between illicit substances which are sold in mixtures containing neutral substances or which may have the effect of enhancing the effect of the offending substance or facilitate its abuse and a non offending substance or preparation with bifacial qualities which may have the miniscule quantities of a substance which are also used for medicinal purposes and are available in medical shops across country.

17. Codeine is a Schedule H-1 Drug, under the Drugs and Cosmetics Act, 1940, and is not to be sold without a valid prescription. Any Codeine based cough syrup ideally should not be available without a prescription. The reality however is different. This Court can take judicial notice of the fact that any person desirous of obtaining a Codeine based cough syrup can do so without much difficulty.

18. If the argument of the prosecution based on Hira Singh (supra) is accepted, any person who purchases or obtains a bottle of cough syrup without a valid prescription from a doctor would be in possession of an intermediate quantity of Codeine as he would be in possession of 100 grams of a manufactured drug and would face punishment under Section 21 (b) of the NDPS Act. A dealer of ganja caught with a quantity less than 20 kilograms, would face the same punishment as a person possessing a single bottle of Codeine based cough syrup.

19. A person who is in habit of dealing ganja and is caught with slightly less than 1 kg of ganja (which obviously cannot be for self use) will face significantly lesser punishment.

20. Even if the person is using a codeine cough syrup for illicit reasons, of obtaining a 'high', possessing a single bottle of codeine cough syrup will ensure that such user is treated on par with a person who possesses even 19 kilograms of

ganja. Hypothetically, a family where there are a number of people having chronic cough problem procures 10 bottles of cough syrup before embarking on a trip to ensure adequate supply of the cough syrup, would be deemed to be in possession of a commercial quantity of Codeine, and would face a minimum of 10 years imprisonment. This obviously was not and could not be the intention of the legislature or the true meaning of the judgment of the Supreme Court in Hira Singh's case.

21. *Be that as it may, para 8.4 and para 10(II) of the judgment of the Supreme Court in Hira Singh V. Union of India - (2020) SCC OnLine SC 382 does not make any distinction between manufactured drugs with a miniscule percentage of narcotic substance and other mixture of narcotic drugs or psychotropic substance out of a neutral substance. The judgment of Iqbal Singh (supra) is therefore contrary to a plain reading of the judgment of the Supreme Court. Since cases of this nature are common there is a strong possibility that different Single Judge Benches of this Court may take different opinions while deciding as to whether the rigour of Section 37 would be attracted or not in such cases. It would therefore be in the interest of justice that an authoritative and final pronouncement is made by a larger Bench of this Court*

22. *The following questions therefore are required to be considered by a larger Bench of this Court:*

a) *whether in cases specifically related to manufactured drug with a miniscule percentage of a narcotic substance, the weight of the neutral substance ought to be ignored while determining the nature of the quantity seized i.e. small, commercial or in between?*

b) *whether Note 4 of the S.O. 1055 (E) dated 19th October, 2001 published in the Gazette of India, Extra., Pt.II, Sec3 (ii) dated 19th October 2001, as amended on 18.11.2009, should be held inapplicable to manufactured drug which contain a miniscule percentage of a narcotic drug?*

c) *whether Note 4 of the S.O. 1055 (E) dated 19th October, 2001 published in the Gazette of India, Extra., Pt.II, Sec3 (ii) dated 19th October 2001, as amended on 18.11.2009, should be made applicable to cough syrups containing miniscule percentage of Codeine since it has medicinal value and is also easily available?''*

19 The cases listed herein are only illustrative in nature. The fact of the matter is that on

the basis of cases booked by various empowered departments/organization, in some cases, there is licit manufacturing (especially codeine syrups) and there is proper documentation and payment of taxes at the end of the original manufacturer but thereafter there is a chain of activities, including diversion without valid documents have come to the fore. The illegal diversion and storage thereof, without a valid licence and transport documents in godowns close to the borders are not new to the empowered departments. Even if a valid licence is produced, the quantity stored is excess of the quantity recorded in the records or allowed to be stored under the Drugs Licence. It is primarily meant for illegal export to Bangladesh using the porous border and the transactions may not take place through internet pharmacy because of the proximity to the border but the transactions of these kind are similar in nature to the transactions using illegal internet pharmacy.

Summary of cases/issues

20 Be that as it may, the internet pharmacies engage primarily in export of the substances listed under the Act. The methodology adopted varies from time to time and during the course of busting of various internet pharmacies, it can be summarized as under:

- (i) They have exported (where substances have left for the destination and the counterpart agencies have informed the empowered departments, including NCB/DRI/Police) or attempted to export (where the psychotropic substances have been caught/seized before being exported) the psychotropic medicines in the garb of herbal medicines
- (ii) Clandestine and unregistered call centre that used to sell psychotropic substances and other prescription drugs through the internet to the USA, Australia and various European countries.
- (iii) Sending the drugs disguised as vitamins or food supplements *via post* or courier.
- (iv) Daily orders received through E-mail and despatch through courier.
- (v) Sending these drugs under the garb of auto parts and religious items.
- (vi) Illicit diversion and transportation to Bangladesh of huge quantities of a cough syrup made and sold by a multinational pharmaceutical giant.
- (vi) Involvement of foreign operatives has been noticed in setting up clandestine laboratories that make drugs and this indicates that India is being used by international

criminal networks for the illicit manufacture of amphetamine-type stimulants and methamphetamine.

(vii) Diversion into the domestic market if overseas buyers not found

Analysis of the cases booked – a cause of concern for the Nation

Analysis of cases

21 An analysis of the cases booked by various empowered departments/organization categorically reveal that unscrupulous persons join hands together for a common cause i.e. to earn profit for which the services of foreign national are also pressed into service. The illegal/clandestine factory, until busted, have been found using the export route to route their finished products mainly psychotropic substances disguised as herbal medicines, food supplements, vitamin powder, or concealed in auto parts or religious books, etc. The *modus operandi* changes with the times and it cannot be stated with certainty that only a particular method would be adopted for illegal export. These psychotropic substances have been attempted to be exported by way of concealment and it is no surprise that the *modus operandi* adopted in imports is put in to use at the time of exports, though the transactions may relate to unconnected persons. The syndicates effectively keep a track of the latest *modus operandi* and keep on changing the mode of concealment and there is always a mastermind behind the entire operation and it is too difficult to reach this mastermind/kingpin until a full-fledged and proper investigation is carried out. The veil of secrecy put into service by mastermind/kingpin is to remain clean and unnoticed and be far away from the empowered agencies. In cases where the export abroad is not a possible solution, these very persons have diverted drugs into the open market and the empowered departments have booked a number of cases on this front too.

Busting of clandestine factory/lab or internet pharmacy does not translate into conviction

22 The busting of clandestine factories/labs or internet pharmacies, *ipso facto*, does not result in the conviction. The compliances that are required to be followed in normal cases are equally applicable while busting illegal internet pharmacies. The empowered officers should note that there is mandatory compliance i.e. information received is reduced into writing and put up to the next senior officer and comply with the directions of the superior officer. Non-compliance of mandatory compliances vitiates the trial (see D. Ramakrishna & Wasim Akram for further details).

Conclusion

23. The empowered officers are also to take note of the fact that the guilt of the accused should be proved beyond reasonable doubt and should not sit on the laurels that illegal internet pharmacies have been busted. The evidences should be such that there should be linkages and interlinkages amongst the *dramatis personae* and the charge sheet should be filed after corroborating the statements and evidences should be of sterling quality (see Sanjay Kedia for further details).

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6. section 79 of Information Technology Act, 2000 Exemption from liability of intermediary in certain cases. -

(1) Notwithstanding anything contained in any law for the time being in force but subject to the provisions of sub-sections (2) and (3), an intermediary shall not be liable for any third party information, data, or communication link made available or hosted by him.

(2) The provisions of sub-section (1) shall apply if-

(a) the function of the intermediary is limited to providing access to a communication system over which information made available by third parties is transmitted or temporarily stored or hosted; or

(b) the intermediary does not-

(i) initiate the transmission,

(ii) select the receiver of the transmission, and

(iii) select or modify the information contained in the transmission;

(c) the intermediary observes due diligence while discharging his duties under this Act and also observes such other guidelines as the Central Government may prescribe in this behalf.

(3) The provisions of sub-section (1) shall not apply if-

(a) the intermediary has conspired or abetted or aided or induced, whether by threats or promise or otherwise in the commission of the unlawful act;

(b) upon receiving actual knowledge, or on being notified by the appropriate Government or its agency that any information, data or communication link residing in or connected to a computer resource, controlled by the intermediary is being used

to commit the unlawful act, the intermediary fails to expeditiously remove or disable access to that material on that resource without vitiating the evidence in any manner.

Explanation. -For the purpose of this section, the expression "third party information" means any information dealt with by an intermediary in his capacity as an intermediary.

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