INDIAN DRUG MANUFACTURERS' ASSOCIATION

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PARTNERS IN GLOBAL HEALTHCARE

July 14, 2014

Ms. Rashmi Verma
Additional Secretary
Department of Revenue
Ministry of Finance
Room No. 267- D, North Block
New Delhi 110 001

Sub: Amendment of NDPS Rules for Narcotic drugs - Manufactured drugs and Psychotropic substances.

Dear Madam,

The current rules of manufactured drugs and psychotropic substances need simplification, rationalization and keeping in line with the changes brought in the NDPS (Regulated Controlled Substances) Order, 2013 and the proposed NDPS (Essential Narcotic Drugs) Rules, 2014.

In this regard, we would like to submit a proposal for amendments to NDPS Rules, 1985, with specific reference to manufactured drugs and Psychotropic substances. The table summarizes the amendments proposed and a brief rationale, for the same and proposed amendments, are enclosed, herewith.

We do hope you would consider the Amendments, in the interest of all stakeholders.

Thanking you,

Yours faithfully,

Daara B. Patel
Secretary-General

Encl : as above

CC: 1. Shri. M.L. Meena, Joint Secretary, Department of Revenue, Ministry of Finance, 46/North Block, New Delhi – 110001
2. Shri. Rajesh Srivastava Director Narcotics Control 48-C/North Block New Delhi – 110 001

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SUMMARY OF THE AMENDMENTS PROPOSED TO NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES RULES, 1985

Rule/Sub-rule	Current Provision	Amendment proposed	Rationale
2 (h)	The term "licence" is defined to mean a licence issued under these rules.	For the words "licence issued", the words "licence or loan licence" shall be substituted	Amendment to allow manufacture of manufactured drugs by a loan licensee. Manufacture of APIs and Preparations through a loan license obtained as per the D&C Rules, is a common practice in the Indian and Global pharmaceutical Industry. NDPS Rules, should provide for a definition and manufacture through a loan licensee.
After 2 (h)	New provision introduced.	After sub- rule (h), the following definition is inserted: (hh) "Loan License" shall have the meaning assigned to it in rule 69-A of the Drugs & Cosmetics Rules, 1945	
2 (j)	The term "Schedule" is defined to mean a Schedule annexed to these rules.	The definition is deleted.	Definition of the term "Schedule" in the rules is deleted, consequent to omission of Schedule I, II & III in the rules.
36 (2-A)	Allows manufacture of morphine, codeine, dionine, thebaine etc and their respective salts without prescribing the source of narcotic raw material (NRM) from which these are to be manufactured.	In the rule 36 of the said rules, in sub-rule (2-A), after the words "their respective salts", the words and letters "from opium produced from opium poppy cultivated under a licence issued under rule 8 of these rules" shall be inserted.	Rule 36 sub-rule (2) prohibits manufacture of said narcotic drugs save by Government Opium Factory. However, sub-rule (2-A) which overrides this prohibition and allows manufacture by private entities, is silent as regards the source of the narcotic raw material (NRM) from which said narcotic drugs can be manufactured. The amendment clarifies that if the Central Government determines that such a licence is necessary in public interest and is in consonance with India's obligations under International treaties, conventions or

			protocols, then the said narcotic drugs should be produced only from opium poppy cultivated under a licence issued under Rule 8 of these rules.
36-A (1)	Allows manufacture of poppy straw concentrate from poppy straw without prescribing the source of poppy straw from which these are to be manufactured.	In the rule 36-A of the said rules, in sub-rule (1), after the words "poppy straw", the words "produced from opium poppy cultivated under a licence issued under rule 8 of these rules" shall be inserted.	Rule 36 sub-rule (2) prohibits manufacture of said narcotic drugs save by Government Opium Factory. However, Rule 36-A sub-rule (1) & (2) which overrides this prohibition and allows manufacture of poppy straw concentrate (CPS) and narcotic drugs therefrom, by private entities, is silent as regards the source of the narcotic raw material (NRM). The amendment clarifies that if the Central Government determines that such a licence is necessary in public interest and is in consonance with India's obligations under International treaties, conventions or protocols, then said CPS & narcotic drugs should be produced only from poppy straw produced from opium poppy, cultivated under a licence issued under Rule 8 of these rules.
37 (1)	Prohibits manufacture of manufactured drugs without a licence from Narcotics Commissioner.	In rule 37 sub-rule (1), the letter and brackets "(1)" shall be omitted	Amendment on account of omission of sub-rule (2) providing for licence fee of Rs. 5000/, since similar provision is present in rule 38.
37 (2)	Prescribes a fee of Rs. 5000/- for the licence.	In rule 37 sub-rule (2) shall be omitted.	
38	States that every application for a licence or for renewal thereof under rule 36 or rule 37 or	The rule 38 of the said rules shall be substituted with the	Amendment to ensure consistency with similar provision in the proposed Essential

	under the proviso to rule 35 shall be in such form as may be specified by the Narcotics Commissioner.	following rule:- **"38. Application for licence.-** (1) Every application for a licence or for renewal thereof under rule 36 or rule 37 or under proviso to rule 35 shall be made in **Form-10** to the Narcotics Commissioner. (2) A fee of rupees five thousand shall be payable in advance to the Central Government for each licence issued under this rule or for renewal thereof. (3) The Narcotics Commissioner shall issue a licence in **Form-11** within thirty working days from the date of receipt of an application in **Form-10**. (4) In case the licence is not issued within the stipulated time period of thirty days the Narcotics Commissioner or any other officer authorised by	Narcotic Drug Rules.

		him in this regard shall inform the applicant the reasons thereof."	
39 (1)	"No licence shall be issued under rule 37 or under the proviso to rule 35 unless the applicant therefore has"	In the rule 39 of said rules, in sub rule (1), the words and letters "under rule 37 or" shall be omitted	Amendment to extend the benefit of sub- rule (2) of rule 39 to licences issued under rule 37 i.e. obtaining licence under D & C Act before commencement of manufacture. Also ensures consistency with similar provision in the proposed Essential Narcotic Drug Rules.
39 (2)	Allows issue of licence subject to the condition that the licence under D & C Act shall be obtained before commencement of manufacture.	In the rule 39 of said rules, in sub rule (2), for the words, brackets and letters "sub-rule (2-A) of rule 36 and rule 36-A" the words, brackets and letters "sub-rule (2-A) of rule 36, rule 36-A and rule 37" shall be substituted.	
39 (2)	The word "tender" is wrongly used in the provision.	In the rule 39 of said rules, in sub rule (2), for the word "tender", the word "under" shall be substituted.	Amendment to rectify typographical error.
41	Limits of Manufacture	The rule 41 of the said rules shall be substituted with the following rule:- **"41. Limits of manufacture. –** The issuing authority, while issuing the licence, shall take into account all relevant factors for permitting the quantity of the drug to be manufactured by	Amendment to ensure consistency with similar provision in the proposed Essential Narcotic Drug Rules.

		a licensee including estimated requirements of the country for the relevant year as furnished to the International Narcotics Control Board."	
42	Security arrangements	In rule 42 of the said rules, after the words "issuing authority", the words "in the licence before commencing the manufacture" shall be incorporated.	The current rule is ambiguos regarding the security arrangements to be specified by the licensing authority and the time and manner of communication to the licencee. Hence, it is proposed that the same should be incorporated while issuance of the licence. This ensures better compliance by the licencee and eliminates scope for mis-interpretation.
43	Advance notice for commencement and cessation of manufacture.	The rule 43 of the said rules shall be substituted with the following rule:- "**43. Advance notice for cessation of manufacture.-** The licensee shall give at least fifteen day's notice in writing to the issuing authority before he ceases to manufacture the drug."	Amendment to ensure consistency with similar provision in the proposed Essential Narcotic Drug Rules.
44	Cessation of manufacture.	The rule 44 of the said rules shall be omitted.	Amendment since the same provision is covered in rule 43.
46	Maintenance of accounts and submission of returns.	The rule 46 of the said rules shall be substituted with the following rule:-	There is a need to clarify the procedure for maintenance of accounts and submission of returns in the rules and the amendment

		"46. Maintenance of accounts and submission of returns.- (1) A person who has been issued a licence under these rules shall – (a) maintain daily accounts in **Form-12** and the records of the daily accounts shall be preserved for a minimum period of five years from the date of last entry; and (b) shall file quarterly return in **Form-13** to the Narcotics Commissioner. (2) The return of every quarter shall be filed before the last day of the month following that quarter. *Explanation*.- For the purpose of this rule, the expression "quarter" shall be January to March, April to June, July to September and October to December of every year."	ensures consistency with similar provision in the proposed Essential Narcotic Drug Rules.

49 (3)	Appeal – Sub-rule (3) states that every appeal shall be filed in such form and in such manner as may be specified by the Central Government.	In the rule 49 of the said, the sub-rule (3) shall be omitted.	Amendment to ensure consistency with similar provision in proposed Essential Narcotic Drug Rules.
52-A	New provision enabling destruction of drugs.	After rule 52 of the said rules, the following rule shall be inserted:- **"52-A. -Destruction.-** (1) A manufacturer seeking to destroy a manufactured drug shall apply in **Form 14** to the Narcotics Commissioner. (2) The Narcotics Commissioner shall, within a period of thirty days of the receipt of an application in **Form 14**, appoint a Committee comprising a Gazetted Officer of the Central Bureau of Narcotics or Narcotics Control Bureau, Superintendent of Central Excise of the concerned range and an authorised representative of the applicant for supervising the destruction of the manufactured drug and such destruction shall be carried out	Amendment to introduce a provision to allow destruction of manufactured drugs and ensure consistency with similar provision in the proposed Essential Narcotic Drug Rules and NDPS (RCS) Order, 2013.

		within a period of thirty days from the appointment of the Committee."	
53	General Prohibition – Prohibits dealings in narcotic drugs and psychotropic substances in Schedule I to the rules.	The rule 53 of the said rules shall be substituted with the following rule:- "**53. General prohibition –** Subject to the other provisions of this Chapter, no narcotic drug, or psychotropic substances specified in the Schedule to the Act shall be imported into and exported out of India without an import certificate or export authorisation issued under the provision of this Chapter and for the purpose mentioned in Chapter VII-A."	Amendment necessitated on account of omission of Schedule I, II & III of the rules.
53-A	Prohibition of Export – Prohibit export of Schedule II Psychotropic Substances to certain countries and restricts manufacture of Schedule III substances only for exports.	The rule 53-A of the said rules shall be omitted.	Amendment necessitated on account of omission of Schedule I, II & III of the rules.
55 (1)	Application for import certificate.	In rule 55 of the said rules, after sub-rule (1) the following proviso shall be inserted, namely:-	Supply of Narcotic Drugs and Psychotropic Substances needs to be closely monitored, supervised and controlled by the CBN so that excess material is not allowed to be imported, thus plugging potential diversion to illicit

		"Provided that the issuing authority, while issuing the import certificate, shall take into account all relevant factors for permitting the quantity of the narcotic drug, or psychotropic substances to be imported into India including the following:- (a) The estimates for use and consumption of narcotic drugs and psychotropic substances for the country, furnished to the International Narcotics Control Board and quantity of the narcotic drug or psychotropic substances being manufactured in India by licensed manufacturers; (b) The demand of such narcotic drug or psychotropic substances in India;	channels and abuse of these substances. The amendment empowers the Narcotics Commissioner to regulate the availability of Narcotic drugs and Psychotropic Substances based on estimates provided to International agencies and quantum of such drugs & substances produced in the Country. With online registration of Psychotropic substances becoming compulsory and requirement of a license to manufacture Narcotic drugs, these controls can be easily exercised by the Narcotics Commissioner. Similar provisions exist in western countries such as USA, Europe, Japan, Australia etc with regards to Narcotic Drugs & Psychotropic Substances and in absence of such provisions, the concerned narcotic authority would not be in a position to deny an import, if he/she has legitimate reasons to do so.

		(c) Shortage or excess of such narcotic drug or psychotropic substances in India:"	
55 (2)	The current provision does not prescribe a format of application for import certificate.	In rule 55 of the said rules, in the sub-rule (2), for the words "state such details as may be specified by the Narcotics Commissioner", the words "be in **Form 15** appended to these rules", shall be inserted.	Presently there are no forms of application prescribed in the rules. There is a need to clarify the procedure for application of import certificate for simplification and rationalisation.
56	Existing rule lays down obligation on the Narcotics Commissioner to distribute the copies of Import Certificate to various authorities.	The rule 56 of the said rules shall be substituted with the following rule:- **"56. Issue of import certificate. –** (1) The Narcotics Commissioner shall issue or deny the import certificate within a period of twenty one working days from the date of receipt of application and in case the import certificate is not issued within the stipulated time period or denied, the Narcotics Commissioner or any other officer authorised by him in this regard shall inform the applicant the reasons	The current provisions of Rule 56 are complex, lengthy, unrealistic and imposes unnecessary obligations on the issuing authority. There is a need to simply the procedure for issuance of import certificate and the amendment proposed brings consistency with the existing provision in NDPS (RCS) Order, 2013.

		thereof. (2) Every importer shall submit the details and documents relating to the import, such as Customs attested invoice and shipping documents relating to the import of the narcotic drug or psychotropic substances which shall contain the details such as name of the narcotic drug or psychotropic substances, quantity, name and address of the exporter and the importer, to the Narcotics Commissioner within a period of seven days of import. (3) An import certificate issued under sub-rule (1) of rule 55 shall be valid for a single consignment only.	
58 (1)	Application for export authorisation – This provision is made subject to Rule 53-A which is proposed for deletion.	In rule 58 of the said rules, in sub-rule (1), the words and letters "and rule 53-A" shall be omitted.	Amendment necessitated on account of omission of Schedule I, II & III of the rules.
58 (2)	The current provisions require submission of original or an authenticated copy of the excise	In rule 58 of the said rules, in sub-rule (2), in clause (a), for	Amendment to simplify and rationalize the procedure for application to obtain export

	permit with the application for export authorisation.	the words "the original or an authenticated copy of the excise permit issued", the words "the attested copy of his licence issued under these rules or" shall be inserted.	authorisation.
58 (3)	The current provision does not prescribe a format of application for export authorisation.	In rule 58 of the said rules, in the sub-rule (3), for the words "state such details as may be specified by the Narcotics Commissioner", the words "be in **Form 16** appended to these rules", shall be inserted.	Presently there are no forms of application prescribed in the rules. There is a need to clarify the procedure for application of export authorisation for simplification and rationalisation.
59 (1)	Existing rule lays down obligation on the Narcotics Commissioner to distribute the copies of Export Authorisation to various authorities.	In the rule 59 of the said rules, the sub-rule (1) shall be substituted with the following sub-rule:- "(1) The Narcotics Commissioner shall issue or deny the export authorisation within a period of twenty one working days from the date of receipt of application and in case the export authorisation is not issued within the stipulated time period or denied, the Narcotics Commissioner or any other officer authorised by	The current provisions of Rule 59 are complex, lengthy, unrealistic and imposes unnecessary obligations on the issuing authority. There is a need to simply the procedure for issuance of export authorisation and the amendment proposed brings consistency with the existing provision in NDPS (RCS) Order, 2013.

		him in this regard shall inform the applicant the reasons thereof. (2) Every exporter shall submit the details and documents relating to the export, such as Customs attested invoice and shipping documents relating to the export of the narcotic drug or psychotropic substances which shall contain the details such as name of the narcotic drug or psychotropic substances, quantity, name and address of the exporter and the importer, to the Narcotics Commissioner within a period of seven days of export. (3) An export authorisation issued under sub-rule (1) of rule 58 shall be valid for a single consignment only."	
60	The current provision uses the term "Customs Collector".	In rule 60 of the said rules, for the word "Collector" the word, Commissioner" shall be substituted.	Amendment on account of change in designation in the Customs department.

61	The current provision uses the term "Customs Collector".	In rule 61 of the said rules, for the word "Collector" the word, Commissioner" shall be substituted.	
62 (1)	The current provision uses the term "Customs Collector".	In rule 62 of the said rules, in sub rule (1), for the word "Collector" the word, Commissioner" shall be substituted	
62 (2) (a)	The current provision uses the term "Customs Collector".	In rule 62 of the said rules, in sub rule (2), clause (a), for the word "Collector" the word, Commissioner" shall be substituted	
62 (2) (b)	The current provision uses the term "Customs Collector".	In rule 62 of the said rules, in sub rule (2), clause (b), for the word "Collector" the word, Commissioner" shall be substituted.	
64	General Prohibition on manufacture, possess etc of Psychotropic Substances in Schedule I.	The rule 64 of the said rules shall be substituted with the following rule:- "**64. General prohibition.-** Subject to the other provisions of this Chapter, no person shall manufacture, possess, sell, purchase, consume or use any of the psychotropic substances	Amendment necessitated on account of omission of Schedule I, II & III of the rules.

		specified in Schedule to the Act except in accordance with the Drugs and Cosmetics Rules, 1945.	
65 (1)	Manufacture of Psychotropic Substance - The current provision requires manufacture under a licence obtained under D & C Rules.	In rule 65 of the said rules, in sub rule (1), for the words "other than those specified in Schedule I", the words "specified in Schedule to the Act" shall be inserted.	Amendment necessitated on account of omission of Schedule I, II & III of the rules.
65 (1)	Proviso to Rule 65 (1) states that Psychotropic Substances in Schedule III can only be exported.	In rule 65 of the said rules, in sub rule (1), the proviso shall be omitted.	
65 (3)	First and Second Proviso to Rule 65 (3) concerns Schedule I & III Psychotropic Substances.	In rule 65 of the said rules, in sub-rule (3), the first and second proviso shall be omitted.	
65-A	Current provision provides for sale, purchase, consumption or use of Psychotropic Substance only in accordance with D & C Rules.	The rule 65-A of the said rules shall be omitted.	Omission necessitated on account of merging of rule 65-A with rule 66.
66	Current provisions prohibits possession of any Psychotropic Substances unless under the D & C Rules and also allows legal possession to certain categories of persons.	The rule 66 of the said rules shall be substituted with the following rule:- **"66. Sale, purchase, consumption, possession or use of psychotropic substances.-** (1) No person shall sell, purchase, consume,	Amendment to simplify and rationalize the current rule and the class of persons who are exempted from the prohibition in sub-rule (1). Also to allow possession, use and consumption of Psychotropic Substance by certain class of persons without a license under Drugs & Cosmetics Rules, 1945.

		possess or use any psychotropic substance except in accordance with the Drugs & Cosmetics Rules, 1945. (2) Notwithstanding anything contained in sub-rule (1), any Government or autonomous institutions or research institutions, Schools or Colleges or Universities recognised by the Government, registered Scientific Societies, registered medical practitioner, hospital, dispensary or any person may possess, use or consume psychotropic substances specified in Schedule to the Act, as may be necessary for their genuine educational, scientific, medical, research or analytical requirements: Provided that where such psychotropic substance is in possession of an individual for his personal medical use, the quantity thereof shall not	

		exceed one hundred dosage units at a time: Provided further that an individual may possess the quantity exceeding one hundred dosage units at a time but not exceeding three hundred dosage units at a time for his personal long term medical use if specifically prescribed by a Registered Medical Practitioner. (3) The Government or autonomous institution or research institution, School or College or University recognised by the Government, registered Scientific Society, registered medical practitioner, hospital and dispensary shall maintain proper accounts and records in relation to the purchase, use and consumption of psychotropic substance, for a period of two years."	
67 (1)	Transport of Psychotropic Substance.	In rule 67 of the said rules, in sub-rule (1) after the words	Amendment necessitated on account of omission of Schedule I, II & III of the rules.

		"psychotropic substances", the words "specified in Schedule to the Act" shall be inserted.	
67 (2)	Transport of Psychotropic Substance.	In rule 67 of the said rules, in sub-rule (2) after the words "psychotropic substances", the words "specified in Schedule to the Act" shall be inserted.	
67 (3)	Transport of Psychotropic Substance.	In rule 67 of the said rules, in sub-rule (1) after the words "psychotropic substances", the sub-rule (3) shall be omitted.	There is a need to simply the procedure of making necessary entries on the triplicate copy of the consignment note and the amendment proposed brings consistency with the existing provision in NDPS (RCS) Order, 2013.
67 (4)	Transport of Psychotropic Substance.	In rule 67 of the said rules, in the first proviso to sub-rule (4) after the words "psychotropic substances", the words "specified in Schedule to the Act" shall be inserted.	Amendment necessitated on account of omission of Schedule I, II & III of the rules.
67 (5)	Exempts mentioning of license number in Consignment Note for transport of Psychotropic Substance.	In rule 67 of the said rules, in the explanation appearing sub-rule (4), for the words " research institution, registered medical practitioner, hospital or dispensary" the words "Government or autonomous institution or research	Amendment to provide exemption from mentioning licence number in the consignment note when supplied to certain class of persons.

		institution, School or College or University recognised by the Government, registered Scientific Society, registered medical practitioner, hospital, dispensary or any person using or consuming any psychotropic substances specified in Schedule to the Act for educational, scientific, medical, research or analytical purposes" shall be inserted.	
Omission of Schedule I, II & III	The current provisions classify Psychotropic Substances in Schedule I, II & III of the rules. Schedule I substances are absolutely prohibited, Schedule II cannot be exported to certain countries and Schedule III can be manufactured only for the purpose of export.		In Section 8 of the NDPS Act, 1985 there is an express prohibition on production, manufacture, possession, sale, consumption or use of Narcotic Drugs & Psychotropic Substances except for medical or scientific purposes and in the manner and to the extent provided by the provisions of this Act. This implies that such dealings in respect of Narcotic Drugs & Psychotropic Substances for medical or scientific purposes, should be as per the procedure laid down in the rules failing with the penal provisions of the act would be attracted. While such a provision exist in the Act, to have a separate category of Narcotic Drug & Psychotropic Substances in Schedule I and to impose absolute restriction

			on such drugs or substances, is unnecessary. Absolute bar exists in Section 8 of the Act, which states that express prohibition exists, if not used for scientific or medical purposes and would be a violation in the manner and extent provided in the act or rules. Schedule I Narcotic Drugs includes 1. Coca Leaf, 2. Cannabis (Hemp), 3. Acetorphine, Diactgeylmorphine (Heroin), Dihydrodesoxymorphine (Desomorphine), Etorphine, Ketobemidone and their salts, preparations, admixtures, extracts and other substances containing any of these drugs The manufacture of Narcotic Drug (manufactured drugs) for medical and scientific use is permitted only in Rule 36, 36-A & 37 of the rules. The name of the drugs illustrated therein does not include those listed in Schedule I to the rules. Hence, to clamp absolute prohibition on export or import of such drugs which are not even allowed to be manufactured in India by including such drugs in Schedule I, can only be termed as redundant provision. Psychotropic Substances covered in Schedule

			I are:- 1. Etryptamine 2. Methaqualone 3. Methcathinone And the salts the preparations thereof. All these Psychotropic Substances are also covered in Schedule to the Act and as per the provisions of Section 8 of the Act, there is an absolute prohibition thereon, except for scientific or medical use and to be carried out in the manner and extent of the provisions of the act or rules. As per the existing Rule 53 of the Narcotic Drugs & Psychotropic Substances Rules, 1985, there is an absolute bar on import or export of the Narcotic Drugs & Psychotropic Substances listed in Schedule I to the NDPS Rules, 1985. The classification of these Narcotic Drugs & Psychotropic Substances in Schedule I is irrelevant, since as per the existing proviso to Rule 53, the Narcotic Drugs or Psychotropic Substances can only be imported or exported under an import permit or export authorisation from Narcotics Commissioner. Hence, to have a different category of Narcotic Drugs & Psychotropic Substance in Schedule I which are absolutely

			barred by import or export, is irrelevant and unnecessary. The manufacture, possession, transport, import inter-state, export inter-state, purchase, consumption etc of the Psychotropic Substances listed in Schedule I to the rule are also prohibited as per existing Rule 64 of the NDPS Rule, 1985. However, the Psychotropic Substances which are listed in the Schedule to the Act are allowed to be manufactured in accordance with a licence under Drugs & Cosmetics Rules, 1945 as per Rule 65 of the rules. The Rules 64 imposes an absolute prohibition and the Rule 65 prescribes a conditional prohibition, which on failure to comply with the condition, would impose an absolute prohibition. Hence, to classify same Psychotropic Substances both in Schedule to the Act and Schedule I to the rules, only complicates the implementation of the provision with no resultant benefit to promote the object of the NDPS provisions. Schedule II substances are prohibited for export to certain countries only and Schedule III substances for the purpose of export only. These lists are redundant and not upto date with the current provisions of the respective

			countries. Even otherwise, export of any Psychotropic Substance is only under an Export Authorisation issued by the Narcotics Commissioner, relying on a valid import permit issued by the respective importing Country. Prior to issue of Export Authorisation, the Narcotics Commissioner validates the import permit through Pre-Export Notification (PEN). Hence, Schedule II & III needs to be omitted.