# INDIAN DRUG MANUFACTURERS' ASSOCIATION

102, POONAM CHAMBERS, 'A' WING, DR. A. B. ROAD, WORLI, MUMBAI 400 018, INDIA

Phone : 91- 22 - 24974308
91- 22 - 24944624
Fax : 91- 22 - 24950723

E-mail : idma1@idmaindia.com
accounts@idmaindia.com
Website : www.idma-assn.org


***PARTNERS IN GLOBAL HEALTHCARE***

July 16, 2014

**Mr. Rajesh Nandan Srivastava**
**Director (Narcotics)**
Department of Revenue
Ministry of Finance
Room No. 48-C, North Block
New Delhi 110 001

**Sub:Suggestions to draft NDPS (Essential Narcotic Drugs), 2014 Rules - Regarding**

Dear Sir,

Further to your letter no. F.No.N.11011/1/2014-NC-II dated July 2, 2014, addressed to our Secretary General, Mr. Daara B. Patel seeking our comments on the draft NDPS (Essential Narcotic Drugs) Rules, 2014, we are pleased to forward our suggestions on the same.

We have confirmed vide a separate letter, participation of two nominees in the National workshop on NDPS (Essential Narcotic Drugs) Rules, 2014 to be held on July 28th, 2014 at New Delhi.

Please find enclosed a table summarizing the changes proposed and also the changes to the draft Rules, for your kind perusal.

Thanking you,

Yours faithfully,

Daara B. Patel
Secretary-General

Encl : as above

***AFFORDABLE MEDICINES FOR ALL***


Registered under the Societies Reg. Act XXI of 1860 Reg. No. Bom. 111/1961 G.B.B.S.D.
Registered under the Bombay Public Trust Act, 1950 (Bom. XXIX of 1950) Reg. No. F-1514 (Bom.) Dt. 11-4-67

**SUMMARY OF CHANGES PROPOSEDTO THE DRAFT NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES (ESSENTIAL NARCOTIC DRUGS) RULES, 2014**

| Rule/Sub-rule | Current Provision | Amendment proposed | Rationale |
|---|---|---|---|
| List of Essential Narcotic Drugs | Morphine, Oxycodone, methadone and Fentanyl in bulk form as well as in preparations. | To include Codeine, Dihydrocodeine and Hydrocodone .<br><br>Methyl morphine (commonly known as '**Codeine**') and Ethyl morphine and their salts, all dilutions and preparations except those which are compounded with one or more other ingredients and containing not more than 100 milligrammes of the drug per dosage unit and with a concentration of not more than 2.5 % in undivided preparations and which have been established in Therapeutic practice.<br><br>**Dihydrocodine and Acetyldihydrocodeine**, other derivatives of Dihydrocoedeine and their salts such as, Paracodine and Acetyl Codone and the like) all dilutions and preparations except those which are compounded with one or more other ingredients and containing not more than 100 milligrammes of the drug per dosage unit and with a concentration of not more than 2.5 % in undivided preparations and which have been established in Therapeutic practice.<br><br>Dihydrocodeinone (commonly known as Hydrocodone), its salts (such as Dicodide, | The initial list of Essential Narcotic Drugs should have a balance of mild, moderate and strong/potent analgesics. The current list is devoid of mild, moderate opioids for treatment of pain. The three products viz., Codeine, Dihydrocodeine and Hydrocodone, are commonly used opioids to treat moderate pain world over and a detailed report on each molecule, different dosage strengths available, their legal status in the world and medical references pertaining to their uses in pain management, is attached herewith. Though Codeine is available in India, it is not used for pain management as the preparations for pain management fall under manufactured drug category requiring multiple licences for possession, storage, sale, purchase and transportation. Bringing Codeine under Essential Narcotic Drug would improve access for mild to moderate pain relief and benefit from one uniform licencing system under the NDPS Act, that applies throughout the country. |

| | | | |
|---|---|---|---|
| | | Codinovo, Diconone, Hycodan, Multacodin, Nyodide, Ydroced and the like) and its esters and the salts of its ester and preparation, admixture, extracts or other substances containing any of these drugs. | |
| 2 (g) | 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 Essential NarcoticDrugs 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 for Essential Narcotic Drug, should provide for a definition and manufacture through a loan licensee. |
| After 2 (g) | New provision introduced. | After sub- rule (g), the following definition is inserted:<br>(h) "Loan License" shall have the meaning assigned to it under explanation to rule 69-A of the Drugs & Cosmetics Rules, 1945. | |
| 7 | Security arrangements. | In rule 7 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 ambiguous regarding the security arrangements to be specified by the licensing authority and when and how this is communicated to the licencee. The same should be incorporated while issuance of the licence. This ensures better clarity, compliance by the licencee and eliminates scope for mis-interpretation. |
| 10 (i) | Suspension or cancellation of licence in case the licence is transferred or sub-let. | In the rule 10 of the said rules, in sub-rule (i), after the words "transfer or sub-let", the words and letters "without prior approval of the issuing authority" shall be inserted. | Rule 10 (i) provides suspension or cancellation of licence in case the licence is transferred or sub-let. However, provision for prior approval from the Issuing Authority needs to be provided. For e.g. where there is a change in the entity name. |

| | | | |
|---|---|---|---|
| 16 (9) | Possession of essential narcotic drug - New sub-rule enabling testing of Essential Narcotic Drugs at independent testing laboratory. | A Government or autonomous institutions or research institutions, , Schools or Colleges or Universities recognised by the Government, , registered Scientific Societies and any research institution or analytical laboratories who has a licence granted under Drug and Cosmetics Rules,1945 may possess a reasonable quantity of essential narcotic drug as may be necessary for their genuine educational, scientific, research or analytical requirements.<br><br>Provided the Government or autonomous institution, School or College or University recognised by the Government, registered Scientific Society and research institution or analytical laboratories shall maintain proper accounts and records in relation to the purchase, use and consumption of essential narcotic drug, for a period of two years. | Certain tests require specialized analytical instruments which are not available with the manufacturer, but are mandatorily required to be carried out in accordance with the provisions of Drugs & Cosmetics Act, 1945, the rules and executive instructions thereunder. These tests are also essential for complying with the FDA requirements of United States, European Union and other Countries. The tests may also be required by a customer, from an independent analytical laboratory to confirm quality of an Essential Narcotic Drug, as a pre-shipment requirement. Failure to comply with such requirements adversely affects manufacturers of such Essential Narcotic Drugs. |
| 18 | Transport of essential narcotic drugs – Amendment enabling transport of essential narcotic drug without mentioning license number in the Consignment Note. | The Explanation appearing at the end of rule 18 may be replaced with the following:-<br><br>*Explanation.-Where the consignee is a person to whom such drug has been sold or dispensed for his personal use, a Government* | |

| | | | |
|---|---|---|---|
| | | *or autonomous institution or research institution, School or College or University recognised by the Government, registered Scientific Society registered medical practitioner, hospital, dispensary and analytical laboratories, the requirement of incorporating licence number of the consignee shall not be applicable*. | |
| 28 | New provision enabling destruction of Essential Narcotic Drugs for certain class of persons such as licensed dealer, licensed chemist, approved medical practitioner or recognized medical institutions. | After rule 27 of the said rules, the following rule shall be inserted:-<br><br>"28. -Destruction.- (1) Any person seeking to destroy a Essential Narcotic Drug shall apply in Form 5 to the Narcotics Commissioner.<br><br>(2) The Narcotics Commissioner shall, within a period of thirty days of the receipt of an application in Form 5, 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 Essential Narcotic Drugand such destruction shall be carried out within a period of thirty days from the appointment of the Committee." | Amendment to introduce a provision to allow destruction of Essential Narcotic Drug and ensure consistency with similar provision for manufacturers in proposed NDPS (Essential Narcotic Drugs) Rules and NDPS (RCS) Order, 2013. |
| 30 (4) | The proposed provision states that in case of change in designated medical practitioner or the over-all in charge, the RMI shall inform the | (4) Whenever there is a change in the designated medical practitioner or the over-all in charge, as the case may be, the recognized medical institution shall inform the Controller | The period seven days for intimating change of designated medical practitioner or the over-all in charge, permitted to the RMI is too short. Hence, a reasonable period of thirty days should |

| | | | |
|---|---|---|---|
| | Controller of Drugs above such change within seven days. | of Drugs within thirty days from date of such change for appropriate endorsement on the Certificate of Recognition. | be allowed to intimate such a change. |
| Form 1<br>Form 2 | The proposed formats are tailor made for issue of licence only to a manufacturer and not to a loan licence manufacturer. | New Format of Form 1 attached<br>New Format of Form 2 attached | Common form of application and licence proposed for licencee and loan licencee. |
| 21 & 30 (1) | As per Rule 30(1) there is a requirement of hands-on training in pain relief and palliative care for a period of 10 days for an approved Medical Practitioner, designated by a RMI | Consistency to be brought between Rule 21 & 30(1). The Institute or Recognition for training needs to be specified in the rules. | The training Institute granting a certificate for training needs to be specified in the rules to remove any ambiguity. Also the training needs to be applicable for an independent approved Medical Practitioner as per Rule 21, as much as the requirement for a designated approved Medical Practitioner attached to a RMI. Alternatively, the need for training may be omitted from Rule 30(1). |