

## **INDIAN DRUG MANUFACTURERS' ASSOCIATION**

### **NOTE ON THE PROPOSED AMENDMENT TO NARCOTIC DRUGS & PSYCHOTROPIC SUBSTANCES (REGULATION OF CONTROLLED SUBSTANCES) ORDER, 2013.**

**Sending of samples outside the factory for analytical testing:-**The current provisions of the NDPS (RCS) Order, 2013 (Clause 4) prohibits manufacture, distribution, sale, purchase, possession, storage or consumption of any Controlled Substance included in Schedule A without a unique registration number (URN). The second proviso to Clause 4 (1) of the Order exempts the following categories for educational, scientific and analytical purposes, from the requirement of URN:-

1. Government institutions.
2. Autonomous institutions.
3. Schools or Colleges or Universities recognised by the Government.
4. Registered Scientific Societies.
5. Hospitals.

Since the above category does not include research institutions and analytical testing laboratories providing services of research, testing and analysis, the express prohibition in Clause 4 of the Order has resulted in refusal by such independent research and analytical laboratories not holding URN, to receive samples of Controlled Substance or preparations for research, analysis and testing. 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 a Controlled substance, as a pre-shipment requirement. Failure to comply with such requirements adversely affects export and sale of such Controlled Substance..

## **INDIAN DRUG MANUFACTURERS' ASSOCIATION**

It is, therefore, suggested that the existing second proviso to Clause 4 (1) of the Order may be replaced with the following:-

“Provide further that the Government or autonomous institutions, Schools or Colleges or Universities recognised by the Government, registered Scientific Societies, Hospital, any research institution and analytical testing laboratory who has a test licence granted under Drug and Cosmetics Act and Rules, 1945, Part VII Rule No. 89 using any controlled substances specified in Schedule A for educational, scientific, research and analytical testing purposes are exempted from the registration. They shall maintain proper accounts and records in relation to the purchase, consumption and use of the controlled substances specified in Schedule A, for a period of two years, from the date of the last entry.”

**Invoice containing all relevant details to be treated as a Consignment Note:-** In the NDPS Rules, 1985, the proviso to sub-rule (4) of Rule 67 waives the requirement of Consignment Note, where the sale of the Psychotropic Substance is accompanied by a sale bill or invoice or cash memo containing all the details of the Consignment Note. A similar provision is also proposed in the NDPS (Essential Narcotic Drugs) Rules, 2014. Such a provision availed for Psychotropic Substance and Essential Narcotic Drugs should be incorporated in the NDPS (RCS) Order, 2013 for Controlled Substance..

It is, therefore, suggested that the following proviso may be inserted after sub-clause (1) to clause 7 of the Order:-

“Provided that consignment note in Form G shall not apply in cases where the sale of the controlled substance is accompanied by a sale bill or invoice or cash memo or any other document duly signed by the consignor or his authorised signatory, which shall include all the information in Form G.”

## **INDIAN DRUG MANUFACTURERS' ASSOCIATION**

Consequently the words “consignment Note” appearing in sub-clauses (2), (5), (6) and (8), to Clause 7 may be replaced with “consignment Note or sale bill or invoice or cash memo”.