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 10, 2014

To,
Shri. Rajesh NandanSrivastava,
Director (Narcotics)
48-C/North Block,
New Delhi – 110 001

Sub: **Voluntary Code of Conduct and proposed amendments to NDPS (Regulation of Controlled Substances) Order, 2013**

Dear Sir,

Further to the office memorandum dated June 30, 2014 vide reference no. F.No. 11021/3/2010-NC-II, and meeting held in North Block, New Delhi on 4th March 2014, as per your request, we are enclosing herewith Voluntary Code of Conduct (VCC), for your kind perusal.

Thanking you,

Yours faithfully,

Daara B. Patel
Secretary-General

Encl: Note on proposed amendments to NDPS (Regulation of Controlled Substances) Order, 2013

AFFORDABLE MEDICINES FOR ALL

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INDIAN DRUG MANUFACTURERS ASSOCIATION

PROPOSED VOLUNTARY CODE OF CONDUCT FOR MANUFACTURERS, C&F AGENTS/DISTRIBUTORS AND STOCKISTS FOR DEALING WITH THE FINISHED FORMULATIONS OF EPHEDRINE AND PSEUDOEPHEDRINE

ARTICLE 1

OBJECTIVE

The purpose of the VCC is to enable all manufacturers and distributors of **the finished formulations of Ephedrine and Pseudoephedrine** follow a common system in accounting Production, Storage & Handling, Dispatches, Sales& Marketing and Financial transactions.

The major objective is to prevent the diversion of the finished formulations of Ephedrine and Pseudoephedrine without hampering, normal legitimate transactions.

ARTICLE 2

SCOPE

This model VCC will apply to the following categories of industry and trade:

- Manufacturers of finished formulations of Ephedrine and Pseudoephedrine
- C&F Agents, Stockists and Distributors

ARTICLE 3

MAINTENANCE OF RECORDS

Personnel concerned with the categories mentioned in Article 2 above and dealing with the said finished formulations are required to maintain statutory records as prescribed under the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945, as applicable and follow the minimum procedures recommended below relating to the following:

a) Production (wherever applicable).
b) Storage and Handling.
c) Dispatches.
d) Sales &Marketing.
e) Financial Transactions.

The records so maintained are required to be preserved for a minimum period of TWO years.

ARTICLE 4

PRODUCTION

The manufacturers should produce/manufacture the finished formulations in batches and each such finished formulation should be clearly labelled with batch numbers and other details of the batch.

The manufacturers should maintain and keep a daily record, for the said finished formulations, which must include the following information:

a) Opening stock.
b) Quantity produced/ manufactured.
c) Quantity sold /dispatched.
d) Quantity lost, destroyed or reduced by damages and other causes such as accidents, pilferage, manufacturing losses, etc.
e) Closing stock.

The quantity of the said finished formulations must be recorded in prescribed measures such as number of tablets / capsules /milliliters etc.

The quantity of finished formulations produced/manufactured must be recorded separately for each batch.

The said record must be duly authenticated on a daily basis by the Head/ Authorized officer of the Company.

ARTICLE 5

STORAGE AND HANDLING

The categories mentioned in Article 2 above are required to store the finished formulations in a secured area, in such a manner that physical checks and verification of the stock can be undertaken easily. A person should be appointed as in-charge of the storage area.

Records must be maintained relating to storage, issue and receipt.

Any loss of the said finished formulations while handling or due to environmental conditions such as temperature variations etc. must be recorded.

ARTICLE 6

DISPATCHES

Dispatch of the said finished formulations by the categories mentioned in Article 2 above must be made only on receipt of authorized dispatch advice or delivery order duly signed by the designated/ authorized officer.

It should be ensured that no large or abnormal quantities of finished formulations should be sold to a particular distributor without sufficient reason.

Supply of the same must be made only against written purchase order from the purchaser.

Documentation must be maintained in regard to the dispatch by way of preparation of invoice/ delivery challan which will include the following minimum information:

a) Date of transaction.
b) Consignor and consignee name and address with telephone, facsimile numbers.
c) Description and quantity of the said finished formulations including batch numbers.
d) No. of boxes/ bottles/ cartons.
e) Means of transportation.

ARTICLE 7

SALES & MARKETING

The categories mentioned in Article 2 while marketing the said finished formulations, must follow the "KNOW YOUR CUSTOMER" (KYC) principle and obtain the following minimum information and verify it before delivery of the first consignment.

a) Detail of the name, address, contact telephone and facsimile numbers, email ID of the purchaser.
b) The intended use and place of distribution.
c) Details of the Drug Licence of the purchaser including a copy thereof.
d) Letter of undertaking to the effect that they will comply with the rules and regulation/ law in the country as well as with the VCC.
e) Reasons for requirement of additional quantities of finished formulations than routine requirements.

ARTICLE 8

FINANCIAL TRANSACTIONS

The following shall be the norms:

- No cash transactions.
- Receipt of payments by cheques/demand drafts or through normal banking channels only.
- Payments to be received directly from the purchaser and not through commission agents or intermediaries, if these are not authorized prior to the sale.

ARTICLE 9

REPORTING OF IRREGULAR TRANSACTIONS

The categories mentioned in Article 2 engaged in the manufacture, preparation, processing, storage, distribution, marketing and transportation of the said finished formulations shall immediately report to the respective Zonal offices of Narcotic Control Bureau of any transaction or proposed transactions, when they have reasonable grounds to suspect that such finished formulations may be used in the production, manufacture, preparation or extraction of illicit narcotic drugs or psychotropic substances. Reasonable grounds of suspicion are as follows:

1. Purchasers who are not willing to give all the required information and declarations.
2. Purchasers who offer to pay much higher price for immediate supply.
3. Purchasers who insist making payment by cash only.
4. Purchasers who place orders for unusually large quantities.
5. Purchasers who request for delivery at a place other than the consignee address mentioned in delivery documents.

The industry and trade, whenever they come across a transaction involving one or more of the grounds referred to above, must immediately bring to the notice of the respective Zonal office of Narcotic Control Bureau, of such instances without any delay and also cooperate and assist in the follow up investigation.

ARTICLE 10

DISPOSAL OF THE FINISHED FORMULATIONS

The industry and trade must destroy or dispose off the expired / damaged finished formulations, as per the Drugs & Cosmetic Rules, 1945.