



INDIAN DRUG MANUFACTURERS' ASSOCIATION

B-4/115 (2nd floor), Safdarjung Enclave, New Delhi 110 029

Phone : 91-11 - 26171367
91-11 - 41650726
Fax : 91-11 - 26171369

E mail : idmadelhi@gmail.com
akmadan.idma@gmail.com
Website : www.idma-assn.org

PARTNERS IN GLOBAL HEALTHCARE 21 August 2014

Dr. G.N. Singh,
Drugs Controller General (I)
Central Drugs Standards Control Organization,
FDA Bhavan, Kotla Road,
New Delhi 110 002.

Dear Sir,

Sub: 'Reward Scheme for whistleblowers in the fight against the menace of spurious or fake drugs, cosmetics and medical devices'

We appreciate the 'Reward Scheme for whistleblowers in the fight against the menace of spurious or fake drugs, cosmetics and medical devices' devised by the Government to fight the menace of spurious or fake drugs, cosmetics and medical devices. Though the purpose of the scheme, to encourage people to provide information on manufacture, sale and distribution of spurious drugs is to be lauded, the inclusion of the words 'misbranded, adulterated or not of standard quality drugs' in the scheme is inconsistent with the objective of the scheme and could potentially create confusion and unnecessary harassment to licensed manufacturers. We request that the scope of the scheme should be only for spurious drugs, as otherwise, it could certainly be misused against routine mistakes on labeling etc.

For example, if a product is not labelled in the prescribed manner then it would be covered under the scheme. We apprehend that such inclusions could be misused against routine mistakes on labeling etc. Also genuine licensed manufacturers could be victimised and harassed by unscrupulous persons even for misbranded products. Again, for instance, if the generic name on the label is not prominent, then the products can be declared misbranded, and this may lead to seizure of the goods as the reward scheme also provides for "giving handsome rewards to the informers who provide specific information to the designated authorities leading to the seizures of spurious, adulterated, misbranded and not of standard quality drugs, cosmetics and medical devices".



AFFORDABLE MEDICINES FOR ALL

Head office: 102-B, Poonam Chambers, 'A' WING, Dr. A.B Road, Worli, Mumbai - 400 018 (India)
Ph: 022 - 24944624, 24974308 Fax: 022 - 24950723 E mail: idma1@idmaindia.com
Registered under the Societies Reg. Act XXI of 1860 Reg. No. Bom. 111/1961 G.B.S.D
Registered under the Bombay Public Trust Act, 1950 (Bom. XXIX of 1950) Reg. No. F-1514 (Bom.) Dt. 11-4-67

INDIAN DRUG MANUFACTURERS' ASSOCIATION

The Government needs to discuss this scheme thoroughly with the industry as a committed stakeholder, as it will be another avenue of harassment of genuine manufacturers, as any individual can approach the officials and there can potentially be many prosecutions for unintentional misbranding, such as even a misprint or mistake on label, as the monetary reward is to be given on filing of the case in the court of law.

We seek your indulgence and look forward to your prompt action to avoid confusion amongst the manufacturers, the public and the Government authorities.

Thanking you,

Yours sincerely,



S V Veerramani
President

CC: Shri Sudipta Dey, Deputy Drugs Controller (India)