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

November 4, 2014

To,
The Chief Controller of Explosives
'A' Block, CGO Complex,
5th Floor, Seminary Hills,
Nagpur – 440006
Maharashtra

Sub: Prohibition of possession, sale and use of Nitro-glycerin based explosives / Directions to stock manufacture of diluted Nitroglycerin solution

Dear Sir,

We are submitting this representation to bring to your kind notice difficulties faced by our members due to directions issued by Petroleum and Explosives Safety Organization (PESO) to stop the production of Diluted Nitroglycerine Solution (having more than 1% w/v nitroglycerine in Alcohol or Propyline Glycol). It appears that the said directions have been issued as it falls in the category of explosive class 1.1D and in view of Gazette Notification no. GSR 59(E) dated 21st January, 2004, issued by the Department of Industrial Policy & Promotion – Ministry of Commerce & Industry under which possession, sale and use of Nitro-glycerin based explosives has been prohibited. The said prohibition has come into effect from 1st April, 2004.

These directions have compelled the manufacturers of Nitroglycerin formulations to discontinue manufacturing of Nitroglycerin formulations as they are unable to procure diluted Nitroglycerin [more than 1% w/v]. In this regard, we wish to bring following facts for your kind consideration:-

1. Nitroglycerin and Nitroglycerin formulations are considered drugs as defined under Section 3(b) of the Drugs and Cosmetics Act, 1940.

2. Nitroglycerin was first used for medical indication in the year 1878. It is used as a medicine for angina pectoris (ischemic heart disease). It is available in different dosage forms such in tablets, ointment, solution for intravenous use, transdermal patches, or sprays administered sublingually.

3. From time to time, the Drugs Controller General (India) has also approved various dosage forms of Nitroglycerin as below:-

   - Nitroglycerine Sustained Release tablet 2.6 mg was approved in March, 1975
   - Nitroglycerin ointment was approved in January, 1982
   - Nitroglycerin Injection was approved in June, 1986
   - Nitroglycerin patch 25/50 mg was approved in June, 1993

4. In India, many pharmaceuticals companies such as Neon Laboratories ltd., Swiss Pharma pvt. Ltd. Troikaa Pharmaceuticals ltd., VHB Sciences ltd., Sun Pharmaceuticals ltd., Samarth Pharma Pvt. Ltd. etc. are manufacturing different formulations which contain Nitroglycerin.

5. The directions issued by PESO has resulted in non-availability of Active Pharmaceutical Ingredient namely - Diluted Nitroglycerin (more than 1% w/v) required by the manufacturers of Nitroglycerin formulations.

6. Non availability of the aforesaid Active Pharmaceutical Ingredient will compel the manufacturers to make changes in the formulation and for this purpose such manufacturers will have to switch to either 1% w/v in Alcohol/ Propyline Glycol or else 10% in Lactose.

7. The switch from existing formulation to the changed formulation cannot happen overnight. The process involves number of steps and the manufacturers will have to take care of prerequisites such as process validation, analytical method validation and stability study. The manufacturers will have to also obtain regulatory approval for the changed formulation. **This entire activity normally takes 1 to 2 years**.

8. Abrupt non-availability of this particular concentration of nitroglycerin will create shortage of this life saving drugs leading to life threatening situations in certain cases

In the circumstances, it is necessary to give a timeframe of at least two years to the manufacturers for effecting changes in the formulation, complete the processes listed above and obtain regulatory approval. We therefore request you that the aforesaid directions issued by PESO may kindly be stayed for at least two years so that the manufacturers can continue manufacturing with existing formulation and simultaneously complete the process to switch over to the modified formulation.

We shall be grateful if our request is considered favourably in the interest of public health.

Thanking you,

Yours sincerely,

Daara B. Patel
Secretary-General

Cc: **Dr. G.N. Singh**
Drugs Controller General (India)
Central Drugs Standard Control Organisation
Directorate General of Health Services
FDA Bhavan, Kotla Road,
New Delhi – 110 002

Office of the Drugs Controller General (India)-DGHS New Delhi
Received
11/7

Shri Lov Verma, IAS
Secretary to the Government of India,
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi 110 011

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