



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

Delivered to PS to Secretary, DOP. on
27/3/2014 @ 4:00 PM

PARTNERS IN GLOBAL HEALTHCARE 25th March 2014

Ms. Aradhana Johri, IAS

Secretary to the Government of India,
Department of Pharmaceuticals,
Shastri Bhavan,
New Delhi 110 001.

**Sub: To exempt Innovative Dosage Forms from purview of
DPCO 2013**

Respected Madam,

As you are aware, the Industry has made multiple representations on Innovative Dosage Forms to be excluded from the purview of DPCO 2013, such as the detailed representation dated 13 January 2014 (copy enclosed). You had asked the Industry to give a list of dosage forms that should be excluded from DPCO, 2013, as they are not the regular tablets / capsules and therefore are not part of the NLEM. It is our representation that the following dosage forms should be excluded from DPCO, 2013.

Tablets:

Sustained Release, Controlled Release, Delayed Release, Dispersible, Effervescent, Gelatin Coated, Bi-layered, Chewable, inlay Tablets and Enteric coated.

Capsules:

Soft Gelatin Capsules and Delayed/Sustained/Controlled Release Capsules.

AFFORDABLE MEDICINES FOR ALL

We are in the process of collecting data of such Dosage Forms of Molecules in the NLEM list as per DPCO 2013.

The NPPA has sent Notices to a number of our members regarding prices of these specialized dosage forms. We have made representations for well over a year and were assured by the Department of Pharmaceuticals (DOP) that they agree with the Industry's representation for exempting the innovative dosage forms (copy enclosed). They were only awaiting Ministry of Health's (MOH) response, which we understand was given a few months ago.

We sincerely request you to direct NPPA not to take any action against Companies on these innovative dosage forms till such time as the DOP clarifies/ notifies this issue.

We seek your urgent support on the above matter.

Thanking you,

Yours faithfully,



S V Veerramani
President

Encl: as above.

MOST IMMEDIATE
SPEED POST

No. 31011/17/2012-PI-II
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

Dated, the 19th September, 2013
20th

To

→ Shri M. U. Doshi,
President,
Indian Drug Manufacturers Association (IDMA),
102-B, Poonam Chambers, Dr. A. B. Road,
Worli, Mumbai-400018

Subject: IDMA interactive meeting with Government to discuss DPCO 2013 issues on 7th August, 2013 at Mumbai.

.....

Sir,

I am directed to refer your letter dated 19th August, 2013 on the above subject and to say that the issue of various innovative dosage forms of a scheduled formulation was deliberated in detail in the Department. Prima-facie, as clarified, these innovative dosage forms of the scheduled formulations have been opined not to be kept under price control as per the provisions of DPCO, 2013.

However since NLEM-2011 has been prepared by the Committee under Ministry of Health and Family Welfare, they have been requested to confirm the same.

Yours faithfully

B. Khastgir
(Barnali Khastgir)

Under Secretary to the Govt. of India
Telefax: 23385765

