

Delivered to Secretary's office on 17/6/2014



INDIAN DRUG MANUFACTURERS' ASSOCIATION

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PARTNERS IN GLOBAL HEALTHCARE

June 17, 2014

The Secretary
Ministry of Chemicals & Fertilizers,
Department of Pharmaceuticals,
Room No. 340-B, 'A' Wing,
Shastri Bhawan, New Delhi

Respected Madam,

Sub: **Innovative Dosage forms - Differentiation between Hard Gelatin Capsule and Soft Gelatin Capsule formulations - DPCO '13.**

This is further to our multiple representations on the pricing of different dosage forms.

We respectfully submit that the current NLEM list labels both Hard Gelatin Capsules and Soft Gelatin Capsules as "Capsules". As is well known that, both Hard & Soft Gelatin Capsules are two different entities. While in case of hard gelatin capsules, the medicament, in the form of powder / granules is filled in a "ready to use" capsule shell, whereas, in case of Soft Gelatin Capsules, the process starts with Gelatin granules, which are converted into a free flowing liquid and further under strictly controlled, is processed in a way to form Gelatin ribbon in which, the active medicament, which is processed separately in a suitable non-aqueous vehicle, is filled and sealed. In short, production is through "Form-fill & Seal" technology. It is clear that manufacture of Soft Gelatin Capsules is a far more complicated process, involving special machinery and hence large Capital investment. Also, the process is very labour and energy intensive and hence, additional costs.

For this reason, NPPA had under DPCO '95 fixed separate norms for Conversion of both types of capsules. A copy of the Notification No. S.O. 3013

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E issued on 27.12.12 is attached for your ready reference please. May we draw your kind attention to Sr. No. J (i) & (ii). It is, therefore, clear that, Softgel and Hardgel capsules are 2 distinct dosage forms having separate profiles and involving very different type of costs for manufacture.

Presently, in the NLEM, some of the products which are labeled as Capsules, are not differentiated as hard or soft gelatin capsules. Hence, we wish to request you to differentiate the Hard gelatin capsules and Soft gelatin Capsule formulations as had been the case in the past.

Also, labeling requirements under the Drugs & Cosmetics Act mandate to state on the label the type of dosage form i.e., Hard Gelatin Capsule or Soft Gelatin Capsules. This further confirms that the distinction between these two dosage forms is essential to comply with the Drug Regulations.

It is, therefore, humbly submitted that Notification clarifying the issue is released urgently.

Thanking you,

Yours sincerely,

For Indian Drug Manufacturers' Association



S.V. Veerramani

President

- Encl: 1. Copy of S.O. 3013 (E) dated 27.12.12
2. Suggestive list of the Innovative Dosage Forms