INDIAN DRUG MANUFACTURERS' ASSOCIATION

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PARTNERS IN GLOBAL HEALTHCARE

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Recvd
21/7/14

The Chairman,
National Pharmaceutical Pricing Authority,
Department of Pharmaceuticals,
Government of India,
1, Jai Singh Marg, New Delhi.

RE: DIFFERENTIATED/MODIFIED DOSAGE FORMS OUT THE AMBIT OF PRICE CONTROL&ENCOURAGING INNOVATION IN HEALTHCARE INDUSTRY

Respected Sir,

At the outset we thank you for the time spared to us and listen to the issues relating to pharma sector. We would like to place our views on the captioned subject as under:-

1. You will agree that Pharmaceutical industry is a differentiated/modified technology driven industry, wherein new technology is introduced for administration of drugs to the patient, with an objective of providing patient friendly dosages along with therapeutic dosage compliance, anti-counterfeiting measures to provide patients with a genuine product, better therapeutic value, superior quality dosage forms combined with benefit of better safety profile. In this differentiated/modified dosage forms like SR / CR, gelatin coated tablets/gelatin enrobed tablets, effervescent/dispersible/soluble tablets, soft gelatin capsules (softgels) etc formulations are developed by companies investing large sum in R&D, plant, specialized equipments, intellectual property and development of processes and technologies.

2. We also understand that the Dept. of Pharmaceuticals had informed NPPA to keep the differentiated/modified dosage forms outside price control in order to encourage innovation reference to inter letter dated 19th/20th September 2013 (Annexure –I).

3. Differentiated/modified dosage forms as stated above are patient friendly and involve huge investment in R&D to develop the formulations. The manufacturing process is also different compared to normal dosage forms. The materials used in manufacture of such dosage forms are also often distinct. Thus considering the superiority of the differentiated/modified dosage forms, same should not be clubbed with normal dosage forms for arriving at the Ceiling price.

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4. DPCO 1995 recognized different formulations and prices were fixed according to the technical category (list of the categories is attached in Annexure II). However, since DPCO 2013 does not recognize cost, the ceiling price fixed under DPCO 1995 for a certain formulation on actual cost basis, has got reduced substantially due to averaging out the prices.

Sir, Looking at the facts referred to above, we feel that the differentiated/modified dosage forms are outside the ambit of price control. Notwithstanding this, we have seen that in a number of cases, the differentiated dosage forms have been included in the list of products while calculating the average prices for setting ceiling prices for molecules in the basic dosage forms. Even if it is the department thought that the differentiated dosage forms should have been under price control, these products are different to the conventional dosage forms and even if averaging was to be done, it should have been done separately for each molecule in each specific dosage form separately. However, it is our submission that these products should be kept outside the ambit of price control and this should be applicable for all the differentiated dosage forms as enclosed herewith in Annexure II.

Sir, as many of these products are in the market for a number of years and we do not want the patients/consumers to be deprived of such products. We would be like to request your office to keep all the issued notices to our members on hold without any actions and also kindly request not to issue fresh notices to our members with reference to products which are in the **"differentiated/modified dosage forms" as per the enclosure.**

Sir, Industry has serious concerns for all the stake holders and the issue of differentiated/modified dosage forms pricing needs to be resolved immediately as otherwise it will result in non-availability of product to patients/consumers who are already on the product thereby impacting their health/lives, lay-offs of workers and will kill the innovation dependent upon such differentiated/modified technologies and will also lead to significant losses for business operations leading to closure of operations.

Trust our request would be acceded to at the earliest.

Thanking you,

Yours sincerely,

S.V. Veerramani
President