National Pharmaceutical Pricing Authority
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Inviting Comments of All Stakeholders on Draft Proposal for Display of Distinguishing Mark and Ceiling Price/ Unit in respect of Scheduled Drugs under DPCO 2013

The National Pharmaceutical Pricing Authority (NPPA), which is the implementing authority of the Drugs (Prices Control) Order (DPCO) 2013, in collaboration with the Ministry of Consumer Affairs, Food and Public Distribution is making efforts to promote consumer awareness and protect consumer interest in the use of medicines.

2. Although drugs are covered under the Essential Commodities Act 1955 (10 of 1955), and the DPCO 2013 specifically aims at ensuring the availability and affordability of lifesaving and essential drugs for all, there is very little consumer awareness in this regard, including that of price fixation under the DPCO. Equally, there is a great degree of ignorance about the National List of Essential Medicines (NLEM) 2011 notified by the Ministry of Health and Family Welfare to promote scientific and rational use of medicines that is both clinically and cost effective, which forms part of the First Schedule to the DPCO 2013.

3. One of the biggest challenges being faced by the NPPA today is to monitor ceiling/ retail price compliance in respect of scheduled drugs/ "new drugs". With over 600 scheduled formulations, which translate into more than 6000 packs (different brands) sold at over 6 lakh retail outlets spread across the length and breadth of the country the task of ensuring comprehensive oversight on price compliance by manufacturers, importers, marketers, distributors, retailers of pharmaceutical products is a very challenging task to accomplish in the absence widespread consumer awareness regarding ceiling/ retail prices of scheduled drugs/"new drugs" notified by the NPPA as well as a greater degree of self-regulation and accountability among the pharmaceutical industry & trade. There are thousands of overcharging cases booked against erring manufacturers by the NPPA, which involve recovery of nearly Rs. 4,000/- crore. But on account of a number of cases being locked up in litigation the NPPA has so far been successful in recovering less than 10% of the total dues.

4. The problem has got further accentuated because many small and tiny manufacturers, which usually work as contract manufacturers for large companies, are also largely ignorant about

scheduled drugs as well as the ceiling/ retail prices of those scheduled/ "new drugs" as notified by the NPPA, which must not be breached by manufacturer/ marketer/ importer/ distributer/ retailer.

5. At present the NPPA does random procurement of samples to detect cases of overcharging and book cases under the Essential Commodities Act 1955 for recovery of overcharged amount along with interest and/ or penalty as may be applicable. But given that the NPPA has no field offices of its own in states, the current efforts are not commensurate with the magnitude of the problem. Although a few states do make efforts to enforce the DPCO, including monitoring of price compliance, majority of them are not much involved in this task. Separately, the NPPA has proposed a central scheme entitled "Price Monitoring and Resource Units" (PMRU) to build capacity at state level to enforce the DPCO, but even that by itself would not be sufficient unless it is backed by greater consumer awareness and vigilance as also greater accountability on the part of the pharmaceutical industry and trade.

6. In view of the abovementioned considerations, it is considered necessary to make all consumers aware of which all drugs are scheduled as well as their ceiling/ retail price as notified by the NPPA from time to time. This measure will not only enhance consumer awareness and vigilance, but also enhance accountability and self-regulation among the pharmaceutical industry and trade. The proposal under consideration is to make it mandatory to display a scheduled drug by way of a distinguishing mark (may be a bold red strip with the words "DPCO Scheduled Drug" printed on it in black ink) and also to mention its ceiling price per unit. Based on discussion with the Ministry of Consumer Affairs, Food and Public Distribution, it is proposed to examine the feasibility of making the abovementioned disclosures mandatory by way of a suitable notification under the Legal Metrology Act 2009 and the Legal Metrology (Packaged Commodities) Rules 2011, both of which are meant to protect consumer interest.

7. However, with a view to taking all stakeholders, especially the pharmaceutical industry and industry on board, comments of all stakeholders, including pharmaceutical industry and trade associations, consumer organisations and state drug controllers are invited on the abovementioned proposal. Comments, in this regard, if any, may be submitted within two weeks positively.

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