NATIONAL PHARMACEUTICAL PRICING AUTHORITY

File No. 16(1)/2013/Div-III/NPPA

12 February 2015

Subject: Consumer Awareness about Scheduled Drugs and their Ceiling Prices notified in the Gazette of India Extraordinary

National Pharmaceutical Pricing Authority (NPPA) vide Public Notice No.16(1)/2013-Div.III/NPPA dated 14.11.2014 invited comments from all stakeholders on a draft proposal made by it for display of distinguishing mark as well as ceiling price per unit on the label of every scheduled medicine under the Drugs (Prices Control) Order, (DPCO) 2013. The primary objective of the proposal was to ensure effective implementation of the DPCO with a view to empowering the consumer and protecting consumer interest.

2. By distinguishing scheduled drugs under DPCO, 2013 the basic objective was to firstly make the consumer aware of medicines that form part of the National List of Essential Medicines (NLEM), 2011 notified by the Ministry of Health & Family Welfare, which aims at promoting scientific and rational use of medicines that is both clinically effective and cost effective; and secondly to make the consumer less vulnerable to the possibility of overpricing of scheduled medicines with reference to their ceiling prices as notified by NPPA in the Gazette of India Extraordinary. It would also enable the industry to ensure compliance with the notified ceiling price by way of self-regulation, which could to a very large extent eliminate the fear of overpricing of scheduled medicines.

3. It was noted that monitoring of price compliance in respect of Scheduled drugs by NPPA alone was a humongous task given the number of stock-keeping units (SKUs) falling under NLEM, which is incorporated in the First Schedule of DPCO, 2013 for the purpose of price control. Typically for every drug formulation of mass consumption there are scores of brands, which makes it all the more difficult for NPPA to monitor price compliance through random checks. As per the available database, there are around 12,000 SKUs related to NLEM or Scheduled Drugs under DPCO, 2013. Non-Scheduled drugs SKUs are well over 150,000. Given the numerous brands of medicines available for each drug formulation it becomes extremely difficult for the drug price regulator to effectively monitor price compliance by manufacturers, marketers, distributors, dealers and retailers. The same applies to monitoring of permissible annual price revision with respect to scheduled (to be reported in Form II) and non-scheduled drugs.

4. It was also noted that many times when overpricing is detected and recovery proceedings are initiated against the manufacturer under the Public Demand Recovery Act, the manufacturer claims that he is only a contract manufacturer who has produced the drug as per the order placed on him by the marketer, and the brand name, trademark, MRP, etc., affixed on the medicine label is as per the directions given to him by the marketer who has outsourced the production to him. Similarly, many times the marketer contends that it is the retailer who is responsible for overcharging and not him because he has duly issued the price list in Form V to all concerned, including the retailer in accordance with DPCO, 2013, and hence the retailer should be made accountable for overcharging. On the other hand, the

typical complaint of retailers is that most pharma companies are not issuing to them the price list in Form V on several occasions and hence they are unable to keep a check. In other words, the typical tendency is to pass the blame to someone else, which makes enforcement all the more difficult although as per law they are all individually and severally responsible for the offence committed.

5. The DPCO, 2013 requires every retailer to display the current price list and supplementary price list, if any, of both scheduled and non-scheduled formulations based on price list issued to him in Form V by the manufacturers, but it is observed that most of the retail outlets are not complying with this requirement on the ground of space constraint, as the number of SKUs they deal in may run into several thousand. As a result, the consumer is generally unaware about the medicines that are scheduled under DPCO, 2013 and whose prices are controlled by the Government and are, therefore, vulnerable to the possibility of being overcharged.

6. In view of the above, the primary objective of prescribing special marking was to make the consumer automatically aware of a scheduled medicine and its ceiling price so that in case of overpricing he can lodge a complaint against the manufacturer. It was, therefore, suggested to make it mandatory to display on the label of a scheduled medicine under DPCO, 2013 a distinguishing mark, may be a bold red line with the words 'DPCO Scheduled Drug' (printed on it in black ink) and the ceiling price per unit. The proposal was to examine the feasibility of implementing the above mentioned measure through the Ministry of Consumer Affairs, Food and Public Distribution (Department of Consumer Affairs) 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. In response to the public notice dated 14.11.2014 issued by NPPA a number of suggestions were received from individual companies as well as industry associations, namely, Federation of Pharma Entrepreneurs (FOPE), Federation of Indian Chambers of Commerce and Industry (FICCI), Indian Drugs Manufacturers' Association (IDMA), Organisation of Pharmaceutical Producers of India (OPPI), Karnataka Drugs & Pharmaceuticals Manufacturers' Association (KDPMA), GlaxoSmithKline Asia Private Ltd., (GSK), Sun Pharmaceutical Industries Limited, Cadila Healthcare Limited, Confederation of Indian Pharmaceutical Industry (CIPI), and one chemist.

8. FOPE stated that the proposal does not appear to be practical, as drug labels already over-congested with too much information, and the proposal of NPPA would also involve a huge cost for the industry. It further stated that medicines selling at a price much below the ceiling price may be perceived to be of low quality or sub-standard. This issue of possible negative perception cannot be accepted because DPCO 2013 follows a market-based and not cost-based pricing methodology. Moreover, as per the DPCO, all existing manufacturers (including importers and marketers) of a drug formulation who are selling it below the ceiling price are required to maintain their existing MRP. The market-based pricing methodology under DPCO 2013 enables the consumer to choose between different prices at which a medicine is available, which is what price competition is all about. Hence, it is very important for the consumer to know that the same formulation sells at different prices. FICCI stated that

the Drugs and Cosmetics Act (DCA), 1940 and Rules already prescribe the use of a red vertical line for certain types of drugs and as such it would not be feasible to again use red line for marking of price controlled drugs. It also stated that printing of ceiling price in addition to MRP may confuse the consumer and labelling requirements under the DCA, 1940 were more than adequate. IDMA also made similar observations as FICCI and stated that special marking of scheduled drugs may not be a feasible proposition. OPPI, while welcoming NPPA's gesture of inviting suggestions on the draft proposal, sought more clarity on certain issues. It also underlined the need to strike a balance between ease of implementation for the industry and consumer education. KDPMA suggested that it may be better for NPPA to develop a mobile application for consumer education and reiterated the implementation problems highlighted by other industry associations. Although the suggestion to develop an App is a good one, the problem is that at present there is no official database on pharmaceutical products and prices. The NPPA is developing an Integrated Pharmaceutical Database Management System (IPDMS), but given the large number of manufacturers (over 10,000) and large number of products (nearly 200,000 SKUs), it will take some time before IPDMS is fully populated and stabilised. GSK pointed out that the requirement of special marking would be burdensome on industry because they already have to comply with a lot of mandatory labelling requirements. Sun Pharmaceutical Industries Limited highlighted the problems of over congestion of labels and the possibility of creating confusion for the consumer by indicating both the ceiling price and MRP. They also highlighted the additional cost burden. Cadila Healthcare Ltd. stated that there may be no purpose served by the proposal, as the common man may not be interested in knowing whether a medicine is price controlled or not. Such a contention, however, cannot be accepted because consumer awareness in this regard is essetial for protection of consumer interest. CIPI observed that implementation of the proposal may require amendment to Drugs and Cosmetic Rules. However, they broadly endorsed the idea of promoting consumer awareness about NLEM and price controlled drugs. Shri Raj Vaidya, a pharmacist stated that even retailers do not have adequate knowledge of the Scheduled Drugs and given the huge number of drugs and fixed dosage combinations (FDCs) in the market it is very difficult to keep a track. He suggested that there should be some sort of provision for reporting price violation to NPPA in a user-friendly manner. It may be stated here that NPPA has already developed an online consumer grievance redressal system for complaints related to price and availability of drugs, which would be launched very soon.

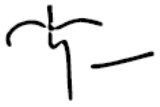
9. A meeting with the industry representatives was held in this regard today (12.02.2015) wherein the same concerns regarding special marking and additional labelling requirements were reiterated. Based on the deliberations, two broad options were identified, which are as under:-

i) The special distinguishing marking requirement may be reduced to the minimum. For example, there can be an underlying light coloured stripe without any text or price information on the label so as to not add to the existing labelling requirement. The other suggestions that came out from discussion were to have a coloured dot, like the green and red dots that are used in Vegetarian and Non-Vegetarian dietary supplements.

ii) The second option was to design a method which does not involve any additional labelling requirement.

10. The first option was discussed in detail, but there was a lot of reluctance on the part of industry to take any additional labelling burden for this purpose, and the industry representatives reiterated the written comments already submitted by them. In view of the above, it was considered desirable to try and achieve the same objective through the second option. Accordingly, it is now proposed to make use of the existing reporting obligations of manufacturers as well as existing price list display obligations of dealers (including retailers) under the DPCO, 2013 for this purpose. Under DPCO, 2013 every manufacturer is required to issue a price list in Form V to all dealers (including retailers) dealing with their product(s), state drug controllers and the Government/ NPPA in respect of both scheduled and non-scheduled drug formulations, both own-manufacturered and those purchased or imported from others, along with medicine composition, pack size, price to the retailers (PTR including excise duty) and MRP (which is inclusive of local taxes). Therefore, the same information can be used at the retail level while issuing invoice to the consumer. In this regard, it is suggested that, apart from mentioning the name of the medicine, pack size and price, the invoice should also mention whether it is a scheduled or non-scheduled medicine under DPCO 2013 (this information is to be disclosed in the price list in Form V), and if it is a scheduled medicine, it should also mention the current notified ceiling price per unit (which is exclusive of local taxes). This would enable the consumer to know whether the medicine purchased by him is a scheduled medicine or non-scheduled medicine and in case it is a scheduled medicine he can see verify whether the MRP is within or exceeding the ceiling price plus applicable local taxes; and in case of the latter, he can file a complaint with NPPA for initiating necessary action against all concerned under DPCO 2013 and the Essential Commodities Act, 1955. The consumer will also know that it is under NLEM, which covers medicines that are clinically-effective as well as cost-effective.

11. NPPA shall, therefore, pursue the above mentioned option in place of the earlier proposed option of special marking, and will hold a meeting with the Pharmaceutical trade associations for finalising the modalities for its early implementation. It is sincerely believed that this approach would not only strike a balance between ease of implementation for the industry and consumer education, but also help in effective implementation of DPCO, 2013, empower the consumer, and protect consumer interest through a robust information dissemination mechanism duly supported by an online consumer grievance redressal system for complaints relating to price and availability of medicines.



(Injeti Srinivas)
Chairman