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

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PARTNERS IN GLOBAL HEALTHCARE

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The Chairman,
National Pharmaceutical Pricing Authority,
Department of Pharmaceuticals,
Ministry of Chemicals & Fertilizers,
1, Jai Singh Marg, New Delhi.

RE: SUGGESTIONS FOR CORRECTING SOME OF THE ANOMALIES IN DPCO 2013

Respected Sir,

At the outset we thank you for the time spared to us at our meeting on 16th July 2014 and patiently listening to our issues. We would like to place our views on the captioned subject as under:-

1. **PRICE LIST:** DPCO 2013 lists two Forms for providing price lists, namely Form II & Form V. There are not many differences in both the forms except Form II includes effective batch number and date. Since both the Forms need to be given by the manufacturers, we request that Form V may be discontinued to avoid confusion as to which form need to be submitted. Para 16 indicates that the manufacturers have to file Form II. However for issuance of price list to state drug authorities, distributors, the manufacturers have to issue Form V. Hence Govt. may do away with Form V so that manufacturers have to issue only one Form, i.e., Form II which is more detailed.

2. **Para 16 (2)** indicates that the manufacturers may increase the MRP of Scheduled formulations once a year in the month of April. Suppose, the manufacturer does not manufacture any batch for 2-3 months, and plans to manufacture in July, can the manufacturer increase the MRP in July? Or as a business strategy, the manufacturer may want to take increase only in July. The provisions make it compulsory for all manufacturers to increase the price in April. Hence we suggest that the manufacturers should be allowed price increase once in a financial year (April to March) as per WPI of the previous calendar year.

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3. **Shortfall in IMS data:** It is observed that in many cases NPPA has not fixed the prices for new drugs for lack of data from IMS. Our suggestion is that NPPA may use AWACS data if IMS data is not available. Further, DPCO 2013 should specify clearly that if the prices are not notified within 60 days from the date of application, then the manufacturers will be free to manufacture & market as per the price applied for.

4. **Price increase in case of extraordinary circumstances**: At present DPCO 2013, does not provide for any provision for increase in the ceiling price, if the raw material cost increases substantially nor provides any methodology for revising the price in case of substantial increase in input cost to ensure availability of essential medicines.

If on any ground, the manufacturers are denied the legitimate price increase due to certain factors, the anomalies should be corrected invoking the provisions under Para 19, so that availability of essential drugs to the patients are not jeopardized.

5. With respect to application for prices from companies, there has been a delay from NPPA in approving the same. This may be given clearance within 30 days on receipt of applications.

6. **IMPLEMENTATION OF CEILING PRICE:** At present the manufacturers have to implement the ceiling price if there is a reduction within 45 days from the date of notification at the retailer's level. Sir, this provision was challenged by the industry as it is impossible for a manufacturer to ensure that the lower price is implemented at the retailer's level. Sir, Department of Pharmaceuticals & NPPA being expert body of Pharma Industry are fully aware about the logistics related issues of the Industry. It is humanly impossible to ensure implementation of price across 7 lacs retailers in the country. Further GMP and D&C Act do not allow changing the label outside manufacturing premises etc. However as requested by the erstwhile Secretary, DOP to Pharma companies to co-operate in implementing the DPCO 2013, Pharma companies agreed to do the best. We would request your office to take a re-look at the policy considering GMP requirements / Excise regulations etc.

Thanking you,

S V Veerramani
President