National Pharmaceutical Pricing Authority

Subject: Minutes of the meetings held on 17.09.2014 with Trade Associations and Representatives of CII & FICCI.

1. Consultation meetings were held on 17.09.2014 with Trade Associations namely AIOCD and AICDF at 10:30 AM and 3:00 PM respectively. A joint meeting with Medical Technology Division of CII and FICCI was also held on 17.09.2014 at 4:00 PM. The list of the participants, meeting wise is annexed.

Meeting with All Indian Origin Chemists & Distributors (AIOCD):

2. The Chairman, NPPA welcomed the members of AIOCD present in the meeting. The Chairman, NPPA briefed about the agenda circulated and highlighted the issues relevant to trade in the backdrop of NLEM-2011, NPPP-2012 and present DPCO, 2013 issued under Essential Commodities Act, 1955.

3. President, AIOCD pointed out that the retailer's margin has been affected / reduced under DPCO,2013 and explained the implication of 16% margin on Price to Retailer (PTR) specified under DPCO,2013 to the retailers. He also mentioned that for the safety and efficacy of the medicines, the retailers are required to spend more money for providing cold chain cover to the medicines, besides the increased burden of minimum wages to be paid by them.

4. In spite of the difficulties faced by them, he has assured the availability of medicines to the common people. The members of AIOCD also stated that they will continue to help the common people even if the number of drugs in the price control category are increased. They however, requested that the margin to retailer should be increased from 16% to 20% if the basis is on PTR instead of MRP as was in practice in DPCO,1995 regime. Further, in order to bring out clarity in the trade, the wholesalers margin may be defined in DPCO,2013 to the minimum of 10% in respect of scheduled category of drugs.

5. As regards the withdrawal of the product from the market in case of downward revision in the notified prices of medicines, AIOCD was clear that it should happen within a period of 45 days but in practice it is not happening so due to (i) large number of retailers say about 7 lakhs across the country (ii) unwillingness of the manufacturers / marketers / importers to withdraw pre-notification stock (iii) tendency to earn the higher margin (iv) logistic difficulties etc.

6. With regard to above, the Chairman, NPPA clarified that there cannot be two ceiling prices at any one point in time and ceiling price notified by the NPPA carries force of law from the date of notification itself. The period of 45 days is to facilitate recalling the stock, stickering, re-labeling etc. In this regard, the decision of the Supreme Court in Glaxosmithkline case was also referred to. The AIOCD, however stated traders point of view that (i) the information dissemination takes time, (ii) the availability of medicines should not suffer and (iii) reluctance on the part of manufacturer (iv) absence of any specified system of withdrawal (v) Form V are by and large not provided to the retailers in time. It was further pointed out that stickering / re-labelling is the primary responsibility of the manufacturer under the law as per Packaging & Commodity Act, Excise Act, VAT rules, etc. However, to overcome these difficulties / problems, they informed that AIOCD compiles the information including ceiling price notified by the NPPA and make it available to their member units within the minimum possible time. The Chairman, NPPA appreciated their efforts and requested the AIOCD to work on other alternatives formulate an alternate system of the implementation of the prices notified by the NPPA as per provisions of DPCO,2013 and submit a feasible proposal to pass on the benefit to the consumer at large which they have agreed.

7. At the end, Chairman, NPPA apprised the AIOCD members about the Integrated Pharmaceutical Database Management System (IPDMS) being developed by the NPPA which will help all in the matter of pricing, monitoring, enforcement of the DPCO provisions. The registration by the companies under IPDMS is opening shortly. In the mean time, he requested that AIOCD may submit the market price data in respect of the NLEM / scheduled

formulations for which ceiling prices are yet to be fixed by the NPPA. In this regard, AIOCD agreed to forward the available data to the NPPA within a months time

8. The members of AIOCD appreciated the initiative taken by NPPA and the meeting ended with the vote of thanks to Chair.

Meeting with All India Chemists and Distributors Federation (AICDF):

9. The Chairman, NPPA welcomed the members of AICDF and briefly mentioned enlighten the issues concerning trades and distributions of drug and requested for support in the matter of implementation of notified prices of medicines and related provisions of DPCO, 2013. While the AICDF assured co-operation in this regard, they pointed out wide price difference between the two brands of the same drug / molecule exist in the market which needs correction in the interest of poor consumer. The other major issues flagged by the AICDF were (i) non-issuance of Form-V / Price list by the manufacturers, (ii) reduction in span of price control in respect of NLEM / scheduled drugs, (iii) shifting of drugs from price control to decontrolled category, (iv) delay in withdrawal / replacement of old / pre-manufactured stock of higher price, (v) lower margin of 16% on PTR to retailers after announcement of DPCO, 2013, (vi) prevalence of lower strength of a drug at higher price with reference to NLEM drugs in the market, (vii) no specific penalty clause in the DPCO, 2013, (vii) refusal of supply of drugs by some of the manufacturer.

10. During the course of the discussion, AICDF also mentioned that in the state of West Bengal, there is a tendency of printing MRP at much higher price by the small / local companies as compared to that of equivalent major brands of different companies and sell with huge discount to the consumer. They emphasized that this kind of practice leads to market distortion and creates confusion about the quality of drug in the public mind and therefore, huge price variation needs to be checked upon.

11. Chairman, NPPA appreciated the above important issues raised by the AICDF related to Pharma Industry and sale / distribution of drugs in the country. Chairman, NPPA also informed that the Integrated Pharmaceutical Database Management System (IPDMS) being developed by the NPPA, will help all in the matter of pricing, monitoring, enforcement of the DPCO provisions. The registration by the companies under IPDMS is opening shortly. In respect of NLEM / scheduled formulations for which ceiling prices are yet to be fixed by the NPPA, AICDF was requested to submit the market price data for enabling NPPA to fix their prices under DPCO, 2013. AICDF agreed to forward the available market price data for such drugs alongwith a detailed report in respect of major issues incorporated in para 9 & 10 above to the NPPA within a months time

12. The members of AICDF appreciated the initiative taken by NPPA and the meeting ended with the vote of thanks to Chair.

Joint Meeting with Medical Device Committees of the CII and FICCI:

13. Chairman, NPPA welcomed the members of both the organizations and expressed concern about the high prices of medical devices such as stents. Chairman, NPPA also informed the participants that the specific agenda related to medical devices was not prepared in view of the fact that the medical devices notified as drugs under Drugs and Cosmetics Act are treated as drugs and therefore, needs to be regulated as per provisions of DPCO, 2013 issued under Essential Commodities Act. Two medical devices have already been included in the NLEM-2011 / Schedule- I of DPCO, 2013 and the ceiling prices have already been notified for these two devices as drugs under provision of the said order.

14. The Chairman, NPPA then informed that a high level Core Committee has been constituted under the Chairmanship of Dr. V.M. Katoch for revision of NLEM-2011, by the Ministry of H&FW. In this regard, Chairman, NPPA informed that Department of Pharmaceutical, Ministry of C&F has separately requested NPPA to undertake a detailed study of the drugs already included in NLEM-2011 and to identify drugs that requires inclusion so as to

ensure that all life saving and essential drugs of mass consumption are included for safeguarding the public interest.

15. The members of CII and FICCI informed that a separate bill for amendment under Drugs and Cosmetics Act is under consideration of the Government to treat the medical device separately from drugs. Further, Parliamentary Standing Committee of Ministry of Health and Family Welfare has also endorsed the same. In this regard, they impressed upon the fact that the sale and distribution of market devices is little complicated and is not the same as for drugs channelized through chemists / retailers. Most of the medical devices are sold in different variants and patent issues are also involved in respect of certain medical devices. Taking the above into consideration, they requested that medical devices require different methodology of capturing the price data and needs for factoring in the distribution system. They further emphasized that not providing the separate treatment to medical device may obviate investment in the sector and would affect market availability and affordability.

16. Chairman, NPPA noted their concern and stated that there are challenges which need to be discussed thoroughly to make the medical devices affordable to public at large. Manufacturer and importer of the medical device may consider to sale with fixed margin over and above the production cost / import price of medical device, as the common man often ends up paying 2 to 3 times. The medical devices being looked at include drug eluting stents, base metal stents, orthopedic implants, and surgical devices / needles etc. At the end, Chairman stated that it needs to be discussed in a more consultative manner and requested the members of both the organization to submit a detailed and comprehensive note for taking further action in the matter with in a period of 15 days.

17. Both the organizations agreed to the above and also offered to submit a separate note on the details of action taken by them so far to bring down the prices of medical devices.

18. The meeting ended with the vote of thanks to Chair.

(JAGDISH KUMAR)
DIRECTOR (M&E)
NPPA

Inputs received from Shri. Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry (AIMED)

19. AIMED has acknowledged the receipt of NPPA's invite sent to them and has sent the following response:

"Pricing is a sensitive topic and your letter deals with a very complex and daunting Regulatory Mechanism for Pharmaceuticals which is as yet unfamiliar to us from the Consumer Engineering Business. We need to collate opinion of nearly 300 Members with divergent views and drive a consensus to present as AIMED's views and our stand to Govt. / Public on this issue, so please bear with us.

Manufacturers are concerned about this issue but are grappling how to address it as we are all Consumers 1st and Manufacturers 2nd and it is also the 3rd most important factor stunting the growth of our Domestic Industry.

Some of our Products go through 2 Stages before reaching Consumers and some even through 5 Stages. Distribution and warehousing Costs ,Margins, Freight and Interim Taxes are added at each Stage. Varying Margins are needed to compensate Costs which vary from Metropolitan Cities to Rural Areas as well as varying payment terms. Cost of Traders get inflated at times by an unreasonably high rental / lease agreements with Corporate Hospitals and high rentals in Malls & Premium Shopping Complexes. Another factor to be considered is volume of sale and turnaround of stocks and shelf life of slow moving items which may take years to sell compared to fast moving items. Consumers in Rural areas have to bear with same MRP as for high cost Urban areas. Over 70% of India is in Rural / Small Towns and forced to bear same cost as 30% Urban as Manufacturers need to satisfy the need of Retailers on highest cost factor.

MRP was introduced under License Raj at time of shortages of Suppliers and Traders / Retailers used to overcharge Clients. Govt. had put the Onus on Manufacturer whom they thought to be more ethical than Retailers.

Now there are no more shortages and due to Competition Ex Factory Prices has been going down and Consumers (Doctors) at Institution and Clinic level

have gained from this but individual Consumers are not gaining as Max Retail Prices are going up, in recent years – Artificial Inflation.

In most other Countries Max Retail Prices is not printed on consumer goods. Some Countries use a Maximum Suggested Price but in most case Retailers sells at a Price Discounted and far less then these , MSP's.

In most Countries Onus of printing Prices is on the Retailer and not on Manufacturer and is limited to the Retailers Operational Costs and Over Heads and his profit expectations and his retail competition . Consumers can buy at more expensive Shops in their locality or drive to Discount Stores located at a distance where Real Estate Costs are lower. The onus of putting MRP on Manufactures should be reviewed and shifted to Retailers as is usual practice by all market driven Economies.

In India , for Medical Devices the problem was compounded as Imports did not carry Retail Price on Unit Pack but only on Shelf Box giving a Blank Cheque to Corporate Hospitals and Chemists Shops permitting them to sell at any Price they wished. Domestic Manufacturers always had a catch up game to play to go on increasing their printed Prices to retain their Market Share. AIMED had brought this issue to the notice of Ministry of Consumer Affairs and 2 years ago the Packaging Rules were amended to ensure Maximum Retail Price is printed also on Unit Pack, however enforcement is weak and varies from State to State. AIMED has been lobbying for stringent enforcement at Ports of Imports as is done by Drugs (CDSCO). It is easier to control this at few Ports then at 1000's of Hospitals & Retail Outlets.

Thereafter we recommend that Govt. (Ministry of Consumer Affairs & Ministry of Finance) should consider bringing in a disincentive Mechanism that discourages Retail Price to be increased by way of a Tax Mechanism and encourages lowering it by the Manufacturer on voluntary basis to arrive at a self leveling point.

We have also recommended to Government to plug the loop hole in Packaging Rules being used by Importers of not putting MRP on Unit Packs on pretext of Institutional supplies and not for Retail over the Counter Sale.

We also think that as Medical Devices are not Drugs – so NPPA and DPCO should not be applicable but Dept of Consumer Affairs and Dept of Revenue should drive this initiative of safeguarding all Consumers. There are 14+8 Medical Devices being incorrectly and incompletely regulated as Drugs and

once new Law or Amendments to regulate Medical Devices differently from Drugs are passed these 14+8 Devices will not be regulated as Drugs in any case."