

## National Pharmaceutical Pricing Authority

**Subject: Minutes of the meeting held with State Drugs Controllers on 3<sup>rd</sup> September, 2014 at 11.00 A.M. in the Conference Hall of YMCA Cultural Centre at 1 Jai Singh Road, New Delhi.**

Shri Injeti Srinivas, Chairman, NPPA was in Chair. The list of participants is annexed.

2. At the outset the Chairman extended a warm welcome to State Drugs Controllers and Senior Officers of the State Drugs Control Administration and thanked them for accepting the invitation and sparing their valuable time to provide suggestions on price control of essential & life saving drugs on mass consumption, proposed scheme of setting up price monitoring and enforcement units at State / UT level, on-line database management on production , sale, price & availability of scheduled and non-scheduled medicines and other important matters concerning effective implementation of DPCO, 2013.

3. Initiating the discussion, the Chairman, NPPA made the following introductory comments:-

(i) This is the first interactive session organized by the NPPA with all the SDCs, after announcement of DPCO, 2013, in pursuance of a direction received from the Department of Pharmaceuticals to provide input on the impact of the drugs already covered under NLEM- 2011 and suggest further inclusions that may be required in order to ensure that all the life saving drugs of mass consumption are included for safeguarding public interest.

(ii) The primary purpose of the Drugs (Prices Control) Order [DPCO] 2013 is to protect public interest and make available all essential and life saving medicines to all at affordable prices.

(iii) It was also stated that the NLEM- 2011 basically serve as a tool to promote scientific and rational use of medicines and facilitate cost effective procurement of medicines for public health system but does not significantly influence doctor's prescription behavior. The public health system's outreach to outpatient care is limited and majority of the Indian population incur expenditure on health care from their own pocket. Therefore, this necessitates the price control on drugs.

(iv) It was further informed that a high level Core Committee has been constituted under the Chairmanship of Dr. V.M. Katoch, Secretary, Health Research

and DG, ICMR for revision of NLEM-2011, by the Ministry of H&FW. The recommendations of the NPPA would be submitted to the Government / Core Committee for consideration.

4. Thereafter, the Chairman highlighted the salient points of the agenda note and requested the SDCs for presenting their suggestions / comments for discussion.

5. Sh. H. Mahapatra, Drugs Controller, Odisha stated that there is no significant production of Pharmaceutical items in the State which is basically a drugs consuming state. Major drugs consumed in the State are not covered in the NLEM- 2011. In this regard, he pointed out that highly recommended drugs like Lactulose and other antacid combinations with Methyl Poly Siloxane (MPS) used for gastro intestinal are not covered in NLEM-2011. Further, medicines used for region specific diseases are also not covered in NLEM- 2011. He also suggested that there should be separate provision of penalty for minor offences at retail level whereas there is a need for prosecution for major defaults by pharma companies. Sh. Mahapatra also highlighted that Crocin / Calpol Syrup with lower strength of Paracetamol 120mg / 5ml is available in the market at a price that is much higher than the ceiling price notified by the NPPA for Paracetamol Syrup 125 mg/5ml under DPCO, 2013. Accordingly, he suggested that all usual strength and dosage forms available in market should be covered under NLEM / DPCO, 2013.

6. Dr. C.M.Ghosh, Drugs Controller, West Bengal pointed out that there is acute shortage of Anti- Snake Venom in eastern part of the country. He emphasized that there is a need to regulate the prices of all medical devices primarily to control the huge trade margin and sale at very high price by the companies / importers. He suggested that NPPA should organize such meetings at regional level at regular intervals. He also suggested that NPPA may like to include 4 State Drugs Controllers from different states on a rotational basis in the Authority so as to have a vital link with State Drugs Administration.

7. Dr. H.G. Koshia, Commissioner, Gujarat stressed the need to provide incentives to the concerned SDCs to encourage monitoring and enforcement activities in their state. He suggested that a percentage of the overcharged amount recovered on account of their initiatives could be shared with them so that necessary training and motivation programs can be conducted for the Drugs Inspector and Senior Officers in Drugs Control Department of the States. Chairman, NPPA appreciated his point of view and congratulated for valuable input regularly received from the Gujarat, SDC. Commissioner, Gujarat also mentioned that sometimes their reports to NPPA remain unacknowledged and /or they are not informed of the outcome of their reports. Chairman took this matter seriously and directed to issue acknowledgement of the cases and appreciation letter for hard work being done by the SDCs. Chairman also directed NPPA to keep the SDCs informed of the action being taken on their reports.



8. Dr. Koshia also shared that due to computerization and effective software, Gujarat, Drugs Control Administration was able to capture large number of cases of price violation. In this regard, Chairman, NPPA desired that the Gujarat model of computerization of SDC's approvals, examination of price violation cases, sampling method etc. may be studied by the NPPA. Dr. Koshia immediately agreed to the same and offered that other SDC's may also study the same if so desire.
9. Sh. Hemant Shrivastva, Asst. Drugs Controller, Chattisgarh stated that there should be an explicit provision in the DPCO, 2013 for administrative action may have to be taken in the case of minor violation / offences and for issuance of show cause notice to retailers also. He also brought to the notice that cardiac stents, lenses, surgical items / dressings are sold to the public at very high price and therefore it requires price regulation. Besides, some companies also have the tendency to sell the same medicine with two or more different brand names at different prices.
10. Sh. Shobit, Drugs Controller, Madhya Pradesh specifically informed the difficulty of displaying the price list of drugs of various companies in the limited space of 110 sq.ft prescribed for running chemist shops under Drugs and Cosmetic Act. He also suggested that NPPA should undertake training programmes for Drugs Inspectors at state level for smooth implementation of DPCO, 2013.
11. Sh. P. Vinay Kumar, Dy Director, Andhra Pradesh requested NPPA to organize such meetings at regional level to increase the interaction and better coordination. He also suggested that taxing a patient with additional burden of taxes to be paid on medicines should be avoided. In addition, charges for processing of blood; prices of surgical items, etc should also be controlled & reduced whereas an appropriate margin should be allowed to make the low cost and low volume drugs easily available in the market.
12. Sh. Lal Sawma Pachuau, Joint Director, Mizoram expressed the problems faced by north- east states with reference to sale and availability of medicines. He requested that the issues relating to logistic and funds availability to SDC may also be addressed to higher authorities in the State such as the Chief Secretary.
13. Mrs. Jyoti Sardessai, Dy. Director, Goa SDC endorsed the views / suggestion of the other SDCs. She also said that State Essential Drug List will be forwarded to NPPA.
14. Sh. Hemant Kumar Sinha, Drugs Controller, Bihar suggested that all the high volume medicines moving in the market should be covered under NLEM / DPCO, 2013 including derivatives, analogues etc. He also emphasised the need of

strengthening the State SDCs particularly to carry out DPCO compliance and requested NPPA for the same.

15. Sh. Bhag Singh, Astt. Drugs Controller, Punjab mentioned that payment of overcharged amount alongwith penalty can not absolve the defaulting companies from prosecution and requested NPPA to look into the matter.

16. Sh. G.L. Singal, Drugs Controller, Haryana requested endorsed the views of ADC Punjab and in this regard broad guidelines should be framed for prosecution.

17. Dr. Buldev Raj Sharma, Drugs Controller, Jammu & Kashmir appreciated the efforts being taken by the NPPA for sensitisation and awareness with regard to matters relating to DPCO,2013. He also pointed out the infrastructural problems faced by the Drug Administration in the State.

18. Mrs. Ritu Sahay, Joint Director (Drugs), Jharkhand showed her concern about the availability and price of different blood products and their coverage under NLEM.

19. Sh. M. Amruth Rao, Dy. Director, FDA, Telangana discussed his point of view with regard to implementation of notified prices under para 19 of DPCO,2013. It was clarified that the notified prices are effective from the date of respective notification. He also suggested that prices of Diagnostic kit should also be monitored by the NPPA under the provisions of DPCO,2013.

20. Sh. R.F. Lotha, Jt. Drugs Controller, Nagaland expressed the difficulties of transportation and making the drugs available in north-east states as per DPCO prices. He explained that strict enforcing the DPCO price, could some times lead to shortage / non availability of drugs in far flung areas. Therefore, the practical problems emerging in the state should also be seen practically under the rule. Chairman, NPPA suggested that in such places, Jan Aushadi outlets may be established to make the drug available at affordable prices to the public at large.


21. After the discussion on issues relating to NLEM as mentioned above, Director (Overcharging), NPPA made a detailed presentation on the agenda item relating to the proposal of creation of Price Monitoring and Enforcement Units (PMEUs) in the States / UTs. By and large the proposal was appreciated by one and all. However, the category of the States / UTs for setting up PMEUs on the basis of concentration of pharma manufacturing units was deliberated in detail and it was considered appropriate to reclassify the States / UTs into different categories on the basis of population. For the purpose of representative sampling of medicines, some criteria and broad guidelines may also be evolved on the basis of market dynamics.

22. Another power point presentation was made by Shri Satinder Singh Bisht, Technical Director, NIC on the Integrated Pharmaceutical Database Management System being developed by the NPPA with the help of NIC / NICSI. Chairman emphasised the need of such database for better functioning of NPPA particularly in the matter of price fixation, overcharging, monitoring and enforcement of DPCO, 2013. Thereafter, Chairman suggested all the SDCs to impress upon all the manufacturing units in their state to register with the system for e -submission of mandatory information / data as per the provisions of DPCO, 2013. Chairman also stated that all SDCs will have access to the database of NPPA.

23. At the end, general discussions were held on the all the points emerging during the session. The broad conclusion that came out were:

- (i) Every SDC to send a fresh list of the drugs to be considered for inclusion / exclusion in the NLEM
- (ii) SDCs also agreed to forward a comparative list of State EDL and NLEM 2011
- (iii) Enforcement of DPCO prices at retail level
- (iv) Suggestions with regard to establishment of PMEU and their consent for further action by the NPPA in this regard
- (v) Training module / workshop / conference at regional level
- (vi) Acknowledgement in all cases of overcharging to be sent invariably by the NPPA
- (vii) NPPA's database reliance on SDCs
- (viii) Providing information to NPPA on new manufacturing approval / products.

24. The meeting ended with the vote of thanks to chair and all participants.

  
(JAGDISH KUMAR)  
DIRECTOR (M&E)  
NPPA