

## National Pharmaceutical Pricing Authority

**Subject: Minutes of the meeting held with Pharma Industry Associations on 30.09.2014 at 02.30 P.M. in 2<sup>nd</sup> Floor Conference Hall of YMCA Cultural Centre Building 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 all participants and thanked them for accepting the invitation and sparing their valuable time for discussion on the agenda circulated for the meeting particularly with reference to specific inputs relating to inclusion / exclusion of medicines from NLEM-2011.

3. In this regard, the Chairman 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 Chairman also 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. In his introductory remarks, Chairman briefed the members on the agenda note circulated for the discussion in the backdrop of NLEM-2011, NPPP-2012, constitution of Core- Committee for revision of NLEM and the role of NPPA as per the direction of the Department of Pharmaceuticals. Chairman pointed out that there is a need to discuss the key issues identified with regard to ensuring that all essential and life saving medicines of mass consumption are included for safe guarding public interest in line with the directive received from the department, which in turn, has to be seen in the light of the directive of the Apex Court, dated 10.03.2003, in SLP no. 3668/2003 (Union of India vs. K. Gopinath & others) wherein it was stated that the criteria adopted for this purpose should ensure that no essential and life saving drug falls out of price control. In this regard, all the participants were requested to provide the inputs during the meeting so as to enable NPPA to make its recommendations to Department of Pharmaceuticals.

4. In addition, Chairman highlighted the problems being faced by the NPPA with regard to lack of information / database, ceiling price fixation of the remaining NLEM medicines, availability / shortage of medicines, un-remunerative pricing of NLEM drugs common in DPCO, 1995 and DPCO, 2013 as pointed out by some of the manufacturers, scope of formulae provided in present DPCO for pricing of medicines with reference to common medicines and other NLEM medicines such as immunoglobulin, Anti-Rabies Vaccines, Anti-Snake Venom, Albumin, Tetanus Vaccine etc. Also, draft internal guidelines dated 21.08.2014 placed on NPPA's website for price revision under para19 of DPCO, 2013 were also mentioned for discussion in the meeting. Chairman also informed that in this regard, NPPA has already completed consultation process with Civil Society Stakeholders and Pharma experts, State Drug Controllers and Trade. Then, the Chairman requested the Industry Representatives to present their view point in reference to agenda circulated for the meeting vide NPPA's letter dated 08.09.2014.

5. Sh. D.G.Shah, General Secretary, Indian Pharmaceutical Alliance (IPA) requested Chairman, NPPA that only the agenda item related to NLEM recommendations may be taken up in the meeting and requested to elaborate NPPA's view point in reference to NLEM revision. IPA also stated that they need more time to discuss other items of agenda for consultation with their constituents. IPA also handed over letter dated 29.09.2014 enclosing a written submission on agenda item no. 2 i.e. inputs on revision of the NLEM 2011 (Annexure I).

6. The President of Indian Drug Manufacturer Association (IDMA) Sh. S.V. Veeramani stated that it is a short period for revision of NLEM / drugs under price revision since the present DPCO was implemented only about a year back in May,2013. He stressed that only "essentiality" should be the criteria and not the turnover / sale volume of the drug for inclusion / exclusion of drugs under price control. He insisted not to enhance the span of price control through NLEM revision.

7. Sh. Sudarshan Jain, Vice President, Organisation of Pharmaceuticals Producers of India (OPPI) mentioned that the Association has earlier requested for extension of time for minimum of one month for industry consultation to study the agenda and submit robust suggestions in this regard. However, realizing the urgency / importance of the NLEM revision, they decided to attend the meeting. He

stressed on stability and predictability of policies and stated that the span of control should not be enhanced and to continue with existing NLEM / price control for the present. OPPI also handed over a copy of representation on NLEM 2011, covering effect of enlarging NLEM (Annexure II).

8. Sh. J.P. Paraswani, Representative of Confederation of Indian Industry (CII) expressed that revision of NLEM should be based on unanimous approach considering the scenario of both the domestic as well as international market. Industry is concerned about revision in the NLEM at this stage as that would affect predictability of the market / industry. CII also handed over its suggestions to NPPA in the meeting. (Annexure III).

9. Sh. Umesh Sanghi, Patron of Federation of Pharma Entrepreneurs (FOPE) stated that members of FOPE have decided for discussion/ meeting with the Department of Health and Department of Pharmaceuticals first and thereafter would submit their suggestions in writing to NPPA.

10. Shri. Anil Khaitan, Chairman, Indian Pharma Forum (IPF) was of the view that NPPA should take Industry into confidence before finalization of the NLEM recommendations.

11. Shri. Pankaj Patel, Chairman, Pharma Committee, Federation of Indian Chambers of Commerce and Industry (FICCI) suggested that NLEM list is being handled by Ministry of Health and Family Welfare and therefore it requires open dialogue with Industry in the larger interest. He emphasized that NPPA should give their views / suggestions / recommendations for them to comment upon. FICCI also handed over preliminary inputs on revision of NLEM 2011 during the course of meeting (Annexure IV)

12. Shri. Bharat Kumar Jaiswal, Assistant Director, ASSOCHAM, stated that they endorse the view of industry and ASSOCHAM would submit the consultative views of all the members after few days.

13. Shri. Sudesh Kumar, Confederation of Indian Pharmaceutical Industry (SSI) (CIPI) stated that the core committee for NLEM price revision has already been constituted by the Department of Health. The present DPCO is about one year

old and therefore, industry needs some time to stabilize and implement the DPCO. He also stated that analogue and close substitutes of NLEM should not be part of price control as the experts while preparing the NLEM 2011 must have considered to list out the specified drugs with dosage and strength as mentioned therein from essentialities angles. He also requested that any recommendations in this regard should be circulated to obtain industry feed back before making final submission to the Department. CIPI also raised the issue of registration for online submission of data relating to Form II, Form III and Form V stating that mostly CIPI members are small manufacturers and finding it difficult to complete the job within the period stipulated for the registration. In this regard they suggested that there should be some threshold criteria for exemption from online submission of the data to NPPA. CIPI also stated that Form II and Form V of DPCO,2013 are almost similar. Form II may be abolished and Form V may be modified to accommodate contents of Form II, if required. CIPI also handed over a written submission during the meeting. (Annexure- V)

14. Chairman appreciated the transparent views expressed by the industry relating to NLEM revision and stated that NPPA do realize the importance of the subject matter and the need for stability and predictability for overall growth of the industry. The criteria of essentiality, scientific and rational use of medicine, disease burden profile and the cost effective procurement of drugs for Public Health System and National Health Programmes adopted by Ministry of Health & Family Welfare for the purpose of drawing NLEM list is duly recognised by NPPA. It was also taken on record that preparation / revision of NLEM is the primary responsibility of Ministry of Health & Family Welfare. In this regard, NPPA's role is limited to pricing perspective and to make recommendations thereupon. With regard to the issue of revision of NLEM after one year from the commencement of DPCO,2013, it was duly clarified that the existing NLEM was prepared / notified in the year 2011 and the revision of the same was due as per the procedure adopted by the Ministry of Health and Family Welfare. Further, it was informed that information in Form II is limited to scheduled formulations whereas Form V relates to both schedule and non schedule formulation and both the Forms are included in the DPCO with different purposes. Moreover the issue raised by the CIPI is not the mandate of NPPA.




15. Chairman mentioned that NPPP-2012 again underlined Hon'ble Supreme Court order dated 10.03.2003 in SLP no. 3668/2003 (Union of India & Ors Vs K. Gopinath & Ors.) which directs the Government that the criteria should ensure that, essential and life saving drugs do not fall outside price control. It was however, clarified that while working out the recommendations with regard to addition / deletion of drugs under NLEM / Price Control in Schedule I of DPCO,2013, the filters of scientific and rational use of drugs will be factored in. The dosage form for Pediatric usage may also be separately examined for NLEM point of view. As mass consumption of the drug may also be one of the indicator of the essentiality, volume / value based criteria may be analysed and looked into for this purpose. The issue linked with the analogue and derivatives of NLEM drugs may be examined from usage point of view in order to comply with the directions of the Department of Pharmaceuticals.

16. With reference to above, all the industry associations were of the view that NLEM revision should be entirely left to the core committee constituted for this purpose under the chairmanship of Dr. Katoch, by the Ministry of Health and Family Welfare and NPPA need not make separate recommendations in this regard. The Chairman explained that both the Department of Pharmaceuticals and NPPA were represented on the Committee and accordingly would provide necessary inputs after due consultation with all stakeholders, particularly industry and consumer organizations. In this regard, Chairman requested all the Industry Associations to make their submission in writing, para-wise, in reference NPPA's letter dated 08.09.2014 at the earliest, which they agreed to.

17. In the end, Chairman requested the Industry Association to impress upon their member units for registration under IPDMS for online submission of mandatory Form II, Form III & Form V of DPCO,2013 to prepare an authentic database on the basis of actual feedback from the individual manufacturer / marketier / importer in the overall interest of Industry and the NPPA at large. The meeting ended with the vote of thanks to Chair.

Enclosures: Written submissions submitted by (i) IPA, (ii) OPPI, (iii) CII, (iv) FICCI and (v) CIPI

  
(Jagdish Kumar)  
Director (H&E)  
NPPA

**List of Participants for Consultation with Pharma Industry Associations**

**1. ASSOCHAM**

- (i) Shri. Bharat Kumar Jaiswal
- (ii) Shri. Amitabh Baxi
- (iii) Shri. Khomba Singh

**2. BDMA**

- (iv) Shri. Anand Khullar

**3. CII**

- (v) Shri. J.P. Paraswani
- (vi) Shri. Agnideep Mukherjee
- (vii) Shri. Shirish Goge
- (viii) Dr. D. Sengupta

**4. CIPI**

- (ix) Shri. Puneet Singh
- (x) Shri. Surender Sareen
- (xi) Shri. Sudesh Kumar

**5. FICCI**

- (xii) Shri. Pankaj Patel
- (xiii) Shri. Manoj Kamra
- (xiv) Shri. Kanwaljeet Singh

**6. FOPE**

- (xv) Shri. Umesh Sanghi
- (xvi) Shri. J.S. Chauhan
- (xvii) Shri. R.K. Rustagi

**7. IPF**

- (xviii) Shri. Anil Khaitan

**8. IPA**

- (xix) Dr. Satish Reddy
- (xx) Shri. Dilip Shangvi
- (xxi) Shri. Sudhir Mehta
- (xxii) Shri. D.G. Shah
- (xxiii) Shri. Chetan Gupta
- (xxiv) Shri. Vinod Khanna

**9. IDMA**

- (xxv) Shri. S.V. Veeramani
- (xxvi) Shri. B.G. Barve
- (xxvii) Shri. C. Venkatraman
- (xxviii) Shri. Ashok Kr. Madan

**10. OPPI**

- (xxix) Shri. Sudarshan Jain
- (xxx) Shri. Aijaz Tobaccowalla
- (xxxii) Ms. Ranjana Smetacek
- (xxxii) Shri. Tabrez Ahmad

**11. Officers from NPPA**

- (i) Shri. Amit Khare, Member Secretary
- (ii) Shri. Lal Sanglur, Director
- (iii) Shri. Jagdish Kumar, Director
- (iv) Smt. Manmohan Kaur, Deputy Director
- (v) Shri. G. Pradhan, Deputy Director
- (vi) Shri. Naresh Arya, Deputy Director
- (vii) Shri. Rakesh Kakkar, Deputy Director
- (viii) Shri. Suneel Chopra, Deputy Director
- (ix) Smt. Babita Singh, Assistant Director
- (x) Shri. T.R. Satish Chandran, Assistant Director

