National Pharmaceutical Pricing Authority

Subject: Minutes of the meeting held with Civil Society Stakeholders and Public Health Experts on 27th August 2014 at 11.00 A.M. in 2nd Floor 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 all participants and thanked them for accepting the invitation and sparing their valuable time to provide suggestions on the criteria to be adopted as also specific inputs relating to inclusion/ exclusion of medicines in the National List of Essential Medicines (NLEM 2011).

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

(i) The current exercise was in pursuance of a direction received from the Department of Pharmaceuticals to provide inputs on the impact of the drugs already covered under the NLEM 2011 and suggest further inclusions that may be required in order to ensure that all essential and lifesaving medicines of mass consumption are included for safeguarding public interest.

(ii) The exercise conducted by the NPPA was entirely from price control angle, as the primary purpose of the Drugs (Prices Control) Order [DPCO] 2013 is to protect public interest and make available all essential and lifesaving medicines to all at affordable prices.

(iii) The need for a separate exercise from pricing angle has arisen due to the fact that the NLEM basically serves as a tool to promote scientific and rational use of medicines and facilitate cost-effective procurement of medicines for the public health system, but does not significantly influence doctors' prescription behaviour, which actually generates demand in the pharmaceutical market.

(iv) The public health system's outreach to outpatient care is limited, and 80% of expenditure on pharmaceuticals in the country is met by the general public by way of out of pocket expenses, and more importantly expenditure on medicines constitutes 70-80% of private health care expenditure, which makes drug price control extremely important.

(v) 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.

2. After making the introductory comments, the Chairman highlighted the salient points of the agenda note circulated for the discussion and requested for the comments/ suggestions/ inputs on issues identified therein.

3. Thereafter, the Chairman requested Dr. Samit Sharma, Formerly, M. D. of Rajasthan Medical Services Corporation and Dr. Shaktivel, Enior Health Economics, Public Health Foundation of India (PHFI) to make their presentations for the benefit of participants. Accordingly, Dr. Samit Sharma made a presentation on "Saving Lives by Making Medicines Affordable in India" and presented the following suggestions to address the issue of affordability:-

(i) As per directives of Honourable Supreme Court, all essential and life saving drugs should be brought under price control as under:

- Drugs Scheduled in the NLEM (all strengths)
- "Me too" drugs of the same group
- Include both Core + Complimentary lists (WHO)
- Uncovered essential non-scheduled drugs
- Essential Patented drugs
- New patented drugs to be granted marketing approval only after price negotiations

(ii) Switch back to Cost based price ceiling with increased MAPE if necessary instead of market based pricing.

(iii) Pharmaceutical sector be protected and promoted to keep the terms of trade favourable for them by:

- Free or concessional land and Tax holiday for new units
- Tax concessions and duty exemptions for existing units
- Promoting export and non tariff barriers for imports

(iv) Other measures suggested by him were:-

- Takeover of Indian pharmaceutical companies through FDI should be regulated
- Domination of market by a few players to be regulated
- Strengthening of PSUs and MSMEs so as to supply to the government sector for medicines for all
- Compulsory Code of conduct for promotion and marketing
- Strengthen Public Health System by introducing centralised procurement and decentralised distribution of quality generic drugs
- National standard guidelines for rational treatment
- Distribution of low cost drugs through Govt. fair price drug counters – *Jan Aushadhi* stores and demand generation for low cost generic drugs
- Public awareness on drug pricing

4. Shri. Sakthivel Selvaraj made a presentation on "Pharmaceutical Price Regulation in India" on behalf of the Public Health Foundation of India, especially covering anomalies in NLEM 2011. The salient points made by him were as under: -

(i) Many life saving and essential medicines have been left out of the NLEM

(ii) All dosages & strengths not covered

(iii) A lot of drugs covered are not relevant for the retail market

(iv) Patented drugs left out

(v) Stae/ region specific concerns not addressed

(vi) Only 17-18% span of control

(vii) Market based pricing not beneficial to patients

(viii) Use of Para 19 to cover essential left-out medicines is a welcome initiative

(ix) Negligible market share coverage in many therapeutic groups; market share not covered is highest in – blood-related (99%), derma 91%), gastro-intestinal (88%), gynec (86%), hepatoprotectives (100%), neuro (84%), HIV (85%), ophthal/ otologicals (95%), pain/ anlagesics (91%), respiratory (95%), stomatologicals (100%), vitamins/ minerals/ nutrients (99%)

(x) Only 8 out of 19 anti-malarials covered under the NLEM (22% of market share covered); the highest selling formulation is Artesunate and only 0.43% of its market is under price control; the prices of second and third highest selling formulations (Arteether & Artemether + Lumefantrine) are left out of the ambit of price control; if at least all strengths and dosages of anti-malarial medicines included under the NLEM are covered it would increase the span of control to 39% (from22%)

(xi) In Anti-TB medications, only 5 out of 21 medicines are under price control covering only 22% of the market share for anti-TB medicines; the 3 highest selling formulations (Rifampicin + Isoniazide + Pyrazinamide,Rifampicin + Isoniazide, and Rifampicin + Isoniazide + Ethambutol are outside price control; if at least all strengths and dosages of those included are covered it would increase the market share coverage to 26% (from 22%)

(xii) In respiratory medicines, NLEM covers only Rs. 202 crore out of Rs 5,709 crore respiratory medicines market, resulting in a measly span of control of 3%

(xiii) The Indian Pharmaceutical market is highly concentrated at the formulation level; 2,230 out of 2,583 (86%) common use formulations have high concentration accounting for nearly 50% of the entire pharmaceutical market.

5. Dr. Anant Phadke, Senior Advisor, Sathi-Cehat, stressed on the Supreme Court directive of "ensuring that essential and lifesaving drugs not to fall out of price control". He suggested a step-by-step approach: (i) NLEM 2014 may be prepared by suitable modification (inclusions & exclusions) of NLEM 2011; (ii) prepare list of lifesaving medicines of mass consumption; (iii) prepare a comprehensive list of analogues of essential & lifesaving medicines; and (iv) work out the comprehensive list of NLEM and others. He also pointed out deficiencies in NLEM 2011 in terms of important essential medicines that have been left out, namely anti-anaemic (combination of ferrous sulphate and folic acid); TB (FDCs recommended in WHO model list may be included); all drugs for use in MDR-TB; drugs for treatment of severe faliciparum malaria; and more anti-diabetic to be included (gliclazide and glimepiride).

6. Shri. S. Srinivasan Managing Trustee, LOCOST suggested that all drugs included in state essential drug lists, all national disease programmes, all drugs related to chronic diseases, and all drugs used in life-threatening diseases must be covered under price control. He added that drugs of the same therapeutic class, their chemical analogues, esters, isomers and derivatives must be included, besides combinations containing one or more scheduled formulation(s).

7. Dr Seema Gulia, Assistant Professor of Medical Oncology, Tata Memorial Centre, Mumbai made a detailed presentation on inclusions and exclusions in medicines related to Oncology, which is in the form of official recommendation of the Department of Atomic Energy. Drugs recommended for deletion include Busulphan, Raloxifene and Danazol. Drugs recommended for inclusion are All Trans Retinoic Acid, Bendamustine, Rituximab, Lenalidomide, Trastuzumab, Capecitabine, Temozolomide, Irinotecan,Erlotinib, Zoledronic acid, Megesterol acetate, and Letrozole.

8. Dr. C. M. Gulhati, Editor Monthly Index of Medical Specialities (MMIS) could not attend the meeting but submitted a paper, which was circulated to all participants. He has questioned the adequacy of the NLEM, and stated that it would be totally erroneous to consider all medicines outside the NLEM as clinically unessential. He has also pointed out that many clinically lifesaving drugs have been left out of price control. For example, in hypertensives while enalapril has been brought under price control other widely used *"prils"* such as captopril, fosinnopril, imidapril, Lisinopril, perindopril, quinapril, Ramipril and trandolapril are not covered. In the case of Angiotension II receptor blockers (ARBS), prices of all agents including losartan, candesartan, irbesartan, telmisatran, valsartan and olmesartan are not price regulated. Among drugs included in Asthma except salbutamol and the little used ipratropium, all other agents in high usage such as terbutaline, salmeterol, formeterol, bambuterol, theophylline, doxofylline, montelukast and zafirlukast are not under price control. Similarly, even within the NLEM two-third formulations of the 348 bulk drugs are not under price control. For example, only 625 mg tablet of fixed drug combination (FDC) of amoxicillin + clavulanic acid is under price control and 375 mg and 1000 mg are outside, thereby incentivising manufacturers to migrate to non-controlled drugs. He has also argued in favour of including all rational FDCs. He has concluded by stating that the NLEM is not really meant for price control, hence restricting price control to NLEM is not proper; it has been suggested that a separate list of all essential and lifesaving drugs may be prepared for price control, and pending that Paragraph 19 of the DPCO

2013 should be implemented in letter and spirit in all therapeutic groups to help patients and prevent profiteering.

9. Dr Mira Shiva, Co-Convenor, All India Drug Action Network (AIDAN) by and large endorsed the recommendations made by Dr. Anant Phadke. She added that irrational FDCs must be discouraged. She emphasised on higher coverage of diseases such as breast cancer, anaemia, etc., that have higher incidence among women.

10. Dr. Rakesh Lodha, Additional Professor, AIIMS recommended that all formulations of scheduled molecules and their FDCs must be covered. He, however, added that price control is only one of the means of achieving access to medicines and other equally important measures like enlargement of public health system, etc., must be taken.

11. Dr. S. P. Kalantri, Professor of Medicine, MGIMS, Sewagram, Wardha stressed the need to control margins in the distribution channel.

12. Dr. Santanu Tripathi, Professor of Pharmacology & Head, Calcutta School of Tropical Medicine stated that all existing government formulary lists may be used for identifying essential and lifesaving drugs to be included under price control. He shared the CGHS formulary list, which has around 2,200 medicines (1447 in generic name and 660 brand name medicines). He also agreed to identify close substitutes in different therapeutic classes that need to be included in the list of essential medicines.

13. Dr. Narendra Gupta of Prayas, Chittogarh suggested that medicines made available under government reimbursement schemes can be treated as essential after weeding out irrational medicines, if any.

14. Dr. Amit Sengupta, Convenor, Jan Swasthya Abhiyan suggested that for different strengths of the same medicine a pro-rata pricing methodology would be more appropriate.

15. Shri. Amitava Guha, General Secretary, FMRAI People's Health Movement stated that the deficiencies of the DPCO 2013 need to be addressed.

16. Ms. Kajal Bharadwaj of Third World Network India stressed on the need to include patented drugs that are essential.

17. Ms. Malini Aisola volunteered to work on the expansion list and additional or NLEM plus list.

18. Dr. Sangeeta Dabhade endorsed the general recommendations that came up and the need to have a larger coverage under price control.

19. Dr. Yogesh Jain, Managing Truste Jan Swasthya Sahyog, Bilaspur also stressed on the need to include all strengths and dosage forms of scheduled drugs and rational FDCs.

20. Shri. Dinesh Abrol, Fellow, ISID endorsed the need to expand the NLEM to include left-out essential medicines.

21. Thereafter, general discussion was held on all points. The broad suggestions that came out were: (i) all strengths and dosages of scheduled formulations to be considered for inclusion; (ii) High volume drugs left out of NLEM to be considered for inclusion; (iii) analogues of scheduled formulations to be considered for inclusion; (iv) lifesaving drugs list should be prepared, as the NLEM does not cover it adequately; and (v) rational FDCs which are having high volume sales to be considered for inclusion, especially in therapeutic groups such as anti-diabetes, respiratory, anti-TB/ MDR-TB, etc.

22. Apart from the revised NLEM list, a separate add-on list to be prepared which could consist of high consumption medicines that may not find place in the revised NLEM. In order to make the essential drugs affordable to all, it was suggested that in addition to NLEM drugs, a list of price sensitive drugs may be drawn which may cover popularly prescribed drugs, FDCs approved by the DCGI, high volume-value drugs, etc. During the course of discussion it was also felt that there is a need to bring out a "code of marketing and distribution of medicines" to maintain some kind of discipline and system in this regard.

23. With reference to suggestions made by the participants in respect of inclusion/ exclusion of drugs from NLEM-2011 and Schedule-I of DPCO 2013, Chairman, NPPA requested the participants to compile and forward a list of such drugs along with specific reasons/ justifications to NPPA for scrutiny and an appropriate action in the matter.

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

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(JAGDISH KUMAR)
DIRECTOR (M&E)
NPPA

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List of Participants for Consultation with Civil Society Stakeholders and Public Health Experts

1. Dr. Anant Phadke, anant.phadke@gmail.com, cell 9423531478, Advisor, SATHI-CEHAT, Pune and Senior activist and public health researcher.
2. Dr. S.P. Kalantri, M.D., MPH, sp.kalantri@gmail.com, cell 9421057740, 07152-2841344, Professor of Medicine, MGIMS, Sewagram, Wardha.
3. Dr. Sangeeta Dabhade, MD(Pharmacology), cell 982340872, sangeetadr99@gmail.com, Professor, BJ Medical College, Pune.
4. Dr. Yogesh Jain, MD (Paediatrics), jethuram@gmail.com, Mng. Trustee, Jan Sawasthaya, Sahayog (JSS), Bilaspur, cell 9425530357.
5. Dr. C.M. Gulhati, MD, indianmims@yahoo.co.in, Editor, MIMS India, New Delhi, cell 9350225986, 011-26234875. (could not attend but submitted written recommendations)
6. Dr. Santanu Tripathi, tripathi.santanu@gmail.com, Professor of Pharmacology and Head, Calcutta School of Tropical Medicine, Kolkata, cell 9230566771.
7. Dr. Mira Shiva, miracmc68@gmail.com, MD, (Medicine), Coordinator, Initiative for Health & Equity in Society, A-60, Hauz Khas, New Delhi-110016 Tel: 91-11-26512385, Mob: 91-9810582028, 26856795
8. Dr. Amit Sengupta, amit37064@yahoo.com, cell 09810611245, Convener, Jan Swasthaya Abhyan(JSA).
9. Dr. Samit Sharma, MD(Paed), IAS, Formerly, MD, Rajasthan Medical Services Corporation drsamitsharma@yahoo.co.in, cell 9828596446.