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F. No. 8(18)/2014/DP/NPPA-Div. II

कार्यवाहीस. : 150/18/2014/F
Proceeding No : 150/18/2014/F

Minutes of the 150th and 18th meeting of Authority under DPCO, 2013 held on 15th September, 2014 at 11.30 AM

The 150thoverall meeting of the Authority, which is the 18th under the DPCO, 2013 was held on 15th September, 2014 at 11.30 AM under the Chairmanship of Shri Injeti Srinivas, Chairman, NPPA. The following members of the NPPA were present:-

(i) Shri Amit Khare, Member Secretary, NPPA.
(ii) Dr. K.L. Prasad, Member (Ex-Officio), Adviser, Economic Division, Deptt. of Economic Affairs.
(iii) Shri L.M. Kaushal, Director (Cost), Member (Ex-Officio), Deptt. of Expenditure, Ministry of Finance.
(iv) Shri R. Chandrashekar, Deputy Drug Controller, Department of Health.

The following officers also attended the meeting and assisted the Authority in its deliberations:-

(i) Shri A.K. Gautam, Adviser (Cost)
(ii) Shri LalSanglur, Director (Overcharging –II)
(iii) Shri Jagdish Kumar, Director (M&E)
(iv) Shri A.K. Khurana, Director (Pricing &Admn.)
(v) Sh. G. Pradhan, Dy. Director (Cost)
(vi) Smt. Manmohan Kaur, Dy. Director (Cost)
(vii) Shri Rakesh Kakkar, Dy. Director (Cost)
(viii) Shri Naresh Arya, Dy. Director (Cost)
(ix) Shri Suneel Chopra, Dy. Director (Legal)
(x) Smt. Babita Singh, Asstt. Director (Cost)
(xi) Shri T.R. SathishChandran, Asstt. Director (Cost)

Chairman, NPPA welcomed all the members present in the meeting.

1. Agenda Item no. 1:

1.0 Members of the Authority who participated in the 149th and the 17th Meeting under DPCO, 2013 confirmed the minutes of the meeting with the observation that in Agenda item no. 4 of 17th Authority meeting, a line may to be added stating that while working out the ceiling price under DPCO 2013, the ceiling price as fixed under DPCO 1995 has been taken as the base price while fixing ceiling price under the DPCO 2013, and in case the PTR is found to be in excess of the derived PTR as per DPCO 1995 then the same has been restricted to the derived PTR. This has to be included in all agenda items relating to ceiling price fixations of common cases.

2. Agenda Item no. 2: Action Taken Report:

2.0 Noted.

3. Agenda Item no. 3:

3.1 The Chairman briefed the members about the action taken for inclusion of Pharma Trac database under Paragraph 9 of the Drugs (Prices Control) Order (DPCO) 2013 consequent upon the decision taken by the Authority in this regard at the last meeting held on 20.08.2014. He informed that, based on preliminary enquiry, the company has made a 2-month free trial offer, which has been accepted, and accordingly, the Pharma Trac database has also been used in the price fixation calculations made in the proposals put up for the consideration of the Authority at the 150th Authority overall meeting (18th Meeting under DPCO 2013) wherever the IMS Health data on any specific formulation(s) were not available or found deficient or inadequate. He informed that since the Pharma Trac like the IMS Health is a proprietary database, and both together represent the only two comprehensive, reliable and widely accepted pharmaceuticals data bases available in the country, the selection needs to be done on nomination basis keeping IMS Health subscription price as the benchmark for price negotiations; and not through competitive bidding process. He further informed that a committee has been constituted under the chairmanship of the Member Secretary to negotiate and arrive at a mutually acceptable price. The members were specifically informed that the subscription price of the Pharma Trac would

not only include complete access to their entire database for conducting various data analyses for the purposes of price fixation, monitoring price compliance in respect of scheduled drugs, price monitoring in respect of scheduled and non-scheduled drugs, and monitoring of shortagesin respect of scheduled drugs; but also for any related studies concerning price control issues at large. It was also informed that the IMS Health has expressed in writing their inability to furnish monthly maximum retail price (MRP) data whereas Pharma Trac has indicated that it would furnish both price to retailer (PTR) and MRP data in respect of scheduled and non-scheduled drugs on monthly basis. It was clarified that the IMS Health data shall continue to be used as the primary source and the Pharma Trac data will be used as the secondary/supplementary source as indicated in the proposal put up before the Authority. It was also indicated that efforts to have a captive database based on disclosures in Form II, III and V of Schedule-II to the DPCO 2013 were on in full swing.

3.2 The Authority appreciated the follow-up action taken in this regard, and thereafter deliberated upon the specific proposal made at paragraph 4 of agenda item no. 3 relating to the methodology to be adopted in respect of use of IMS Health and Pharma Trac data in price fixation calculations. After detailed deliberation over the proposal submitted to it, the Authority approved the following methodology under Paragraph 9(2) of the DPCO 2013:-

Step 1– Firstly, IMS Data would be considered in working out the Ceiling/Retail price.

Step 2- In case IMS Data is inadequate/ insufficient i.e. number of manufacturers being less than 5, then the Pharma Trac data would also be considered.

Step 3- The additional data of manufacturers as reported by Pharma Trac, other than IMS Data, would also be considered in the workings.

Step 4- In case there is a difference between the figures reported by IMS and Pharma Trac of common manufacturers appearing in both data bases, then the lowest PTR would be considered in the workings.

Step 5- If data of Pharma Trac is only available then it will be considered while fixing the Ceiling/Retail price.

Step 6- Apart from the above, if data is also available from the other sources viz. companies, SDCs, Internet, etc., that will also be considered while fixing the Ceiling/Retail price as per usual practice.

4. Agenda Item no. 4:

4.1 Initiating the discussion the Chairman stated that, based on the provisions of the DPCO 2013, he wanted to raise certain issues and make some recommendations as detailed below for the consideration of the members:-

(i) The usualpractice followed in the National Pharmaceutical Pricing Authority (NPPA)of carrying out revision in ceiling priceon the basis representation(s) received from one or more manufacturer with reference to working sheets placed on the official website, and subsequent corrections carried out in the price data, based on enquiries made with the IMS Health as well as manufacturers of the said formulation may have to be reviewed, as normallyonce the ceiling priceis notified under paragraph 4, 6, 10, 11 and14 of the DPCO 2013 it should be revised only under paragraph 16(1), which is the annual revision to be carried out on the 1st of April every year, based on increase/decrease in wholesale price index (WPI); under paragraph 18, which is triggered by changes in industry structure; under paragraph 19, which is invoked under extraordinary circumstances for safeguarding public interest for such period as it may be deemed fit; or under paragraph 31 as per directions received from the Government as the Reviewing Authority under the DPCO 2013.

(ii) However,since such price revision is primarily meant for correction of errors in price data, and something that has to be carried out afresh to rectify mistakes in the price fixation done earlier under paragraph 4, 6 and 14, it may be deemed as part of validation exercise made under paragraph 9(1). But with a view to bringing in total consistency and making the entire process more objective and transparent, he suggested that the following internal guidelines may be adopted for this purpose:-

a. It should be first ascertained whether the applicant has already implemented the current price notification; if not, no application should be entertained.

b. No application should be entertained beyond a period of fifteen days of the date of publication of the notification in the Official Gazette;

c. It should be ensured that any manufacturer making a claim about a particular PTR/MRP should have necessarilyreported the same price in the return submitted by them in Form V of Schedule II to the DPCO 2013, to the NPPA, and the onus of providing documentary evidence in this regard shall lie with the applicant(s).

d. Only market based data should be entertained, i.e., the data should be verifiable with the data base of IMS Health and/or Pharma Trac and Form V submitted by the manufacturers concerned, and no other data shall be considered.

e. The case of Applicant whose review petition on the same matter is pending with the Government would be considered after final orders/directions of the Government.

(iii) The proposed guidelines may be adopted with prospective effect covering all pending cases at various levels as on date, including the ones placed before the Authority for consideration in this meeting.

4.2 The Authority deliberated over the issues raised and the proposal made; and decided that the guidelines suggested may be adopted with immediate effect.

4.3 The Authority considered, discussed and approved the prices of two formulation packs for fixing/notifying the ceiling price under Para 4 of DPCO, 2013 based on data furnished by IMS-Health, Pharma Trac and companies.

4.4 An Addendum to this agenda item containing two more monopoly cases along with their working sheets were also laid down before the Authority by circulation at the time of meeting. The Authority considered, discussed and approved the prices of fiveformulation packs for fixing/notifying the ceiling price under Para 6 of DPCO, 2013 based on the Monopoly conditions i.e. where data in respect of only one company is available.

4.3 The Authority discussed and thereafter deferred the prices of the six formulation packs based on the representations from the manufacturing/marketing company(ies) so as to confirm whether revisions/corrections are in compliance to the guidelines approved in the current i.e. 18th meeting by the Authority as mentioned above.

4.4 The Table showing the prices approved in respect of each such medicine is given below:

S.No.	Particulars	Approved Revised Price (Price in Rs. including WPI)
A	**Cases based on data of the IMS Health / Pharma Trac / Companies**	
1	Aluminum Hydroxide + Magnesium Hydroxide Suspension	0.24/ml
2	IUD containing Copper	351.41 each
B	**Cases based on Monopoly situations**	
1	Aluminum Hydroxide + Magnesium Hydroxide Tablet	0.49/tablet
2	BCG Vaccine Injection	5.58 per dose
3	Enalpril Maleate/Enalaprilat Injection 1.25mg/ml	185.21 per pack
4	Dextromethorphan Tablet 30 mg	5.77 per tablet
5	Didanosine Tablet 400 mg	32.83 per tablet

5. **Agenda Item no. 5:**

5.1 The Authority discussed and considered the prices of 28 formulation packs which are common in DPCO 2013 as well as in DPCO 1995. The Authority discussed the provisions of Para 10(1) and 10(2) and 16 of DPCO 2013 regarding the fixation/revision of prices of scheduled medicines. It was informed that the Para 10 deals with the pricing of the formulations covered under DPCO 1995 as well as included in the DPCO 2013. The Para 16 deals with the revision of the ceiling prices of scheduled formulations under DPCO 2013 irrespective of their inclusion in DPCO 1995.

5.2 It was observed by the Authority that in case of Chlorpromazine Hcl Tablet 50mg and 100mg there was no reduction in the price. It was informed to the Authority that Para 6 of DPCO 2013 cannot be applied in case of formulations common to both DPCO 1995 and DPCO 2013 as the company is required to follow the ceiling price fixed under DPCO 1995 and the prices have been fixed with reference to Para 10 of DPCO 2013 and the same was noted by the Authority.

5.3 An Addendum to this agenda item containing one more case based on data ofthe IMS Health/Pharma Trac/Companies and one more monopoly case along with their working sheets were also laid down before the Authority by circulation at the time of meeting. The Authority considered, discussed and approved the prices of all the following formulation packs for fixing/notifying the ceiling price under Para 4 and 6 of DPCO, 2013.

5.4 A Table showing the prices approved in respect of each such medicine is given below:

Sl. No.	Medicines	Revised CP (incl. WPI but excl. local taxes) (Rs./unit)
A	**Cases based on data of the IMS Health/Pharma Trac/Companies**	
1	Cefotaxime Injection 250mg	15.19 per pack
2	Cefotaxime Injection 500mg	20.05 per pack
3	Chlorpromazine Hcl Tablet 50 mg	0.41/tablet
4	Chlorpromazine Hcl Tablet 100 mg	0.68/tablet
5	Ciprofloxacin Hcl Tablet 250mg	2.02/Tablet
6	Ciprofloxacin Hcl Tablet 500mg	3.86/Tablet
7	Cloxacillin 500mg capsule	2.21/capsule
8	Rifampicin Tablet 300mg	2.76/Tablet
9	Rifampicin Tablet 450mg	4.06/Tablet
10	Prednisolone Acetate 1% Drop	3.36/ml
B	**Cases based on Monopoly situations**	
1	Acetyl Salicylic Acid 100mg Tablet	0.14/Tablet
2	Acetyl Salicylic Acid 325mg Tablet	0.44/Tablet
3	CarbamezapineSyrup 100mg/5ml	0.14/ml
4	Cloxacillin 250mg Injection	3.72/pack
5	Co-Trimoxazole (Trimethoprism + Sulphamethoxazole tablets) 80mg +400mg	0.58/Tablet
6	FramycetinSulphate cream 0.5%	0.37/gm
7	Frusemide Tablet 40mg	0.33/Tablet

8	Frusemide Injection 10mg/ml	1.13/ml
9	Pheniramine Maleate Injection 22.75mg/ml	1.03/ml
10	Prednisolone 20mg Injection (as sodium phosphate or succinate)	4.41/ml
11	Rifampicin Tablet 150mg	1.22/Tablet
12	Silver Sulphadiazine cream 1%	0.22/gm
13	Spiranolactone 25mg Tablet	1.22/Tablet
14	Sulphadiazine Tablet 500mg	0.83/Tablet
15	Verapamil Tablet 40mg	0.47/Tablet
16	Verapamil Tablet 80mg	0.90/Tablet
17	Verapamil Injection 2.5mg/ml	0.72/ml
18	Vitamin A Injection 50000IU/ml	1.30/ml
19	Thiamine Tablet 100 mg	4.16/Tablet

6. Agenda Item no. 6:

6.0 The Authority discussed the proposal of price revision in respect of Famotidine tablet 20mg, based on the review order dated 05.08.2014 received from the DOP and approved the revised ceiling price at Rs. 0.29 per tablet (including WPI factor of 6.32%) against the earlier ceiling price of Rs. 0.22 per tablet (including WPI factor of 6.32%), notified vide S.O.2095 (E) dated 20.08.2014.

7. Agenda Item no.7:

7.0 The Authority discussed the cases of retail price fixation of new drug based on Form-I applications received from the following company(ies). The details of approved prices are as under:

S.No	Company name/Product name	Approved Price (Rs.)
7(i)	M/s Theon Pharmaceuticals Ltd (Manufacturer) and M/s IPCA Laboratories Limited. (Marketing company) – CefpodoximeProxetil 200mg & Azithromycin 250mg Tablets (Azibact - CF Tablet) Each film coated tablet contains: CefpodoximeProxetil	17.70/tablet

	Eq. to Cefpodoxime IP 200 mg Azithromycin Dihydrate Eq. to Azithromycin Anhydrous IP 250 mg q.s	
7(ii)	M/s Apex Lab. Ltd. (Manufacturer & Marketing company) – Acetaminophen 325mg and Tramadol 37.5mg (PT-325 tablet) Each film coated tablet contains: Acetaminophen IP 325mg Tramadol HCl IP 37.5mg	4.00/tablet
7(iii)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Apex Labs. Pvt. Ltd. (Marketing company) – Metformin Hcl 1000mg (Scodia SR 1000 Tablet) Each uncoated sustained release tablet contains: Metformin HCL IP 1000mg	3.34/tablet
7(iv)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Apex Labs. Pvt. Ltd. (Marketing company) – Metformin Hcl 750mg (Scodia SR 750 Tablet) Each uncoated sustained release tablet contains: Metformin HCL IP 750mg	1.97/tablet
7(v)	M/s Jagsonpal Pharmaceuticals Ltd (Manufacturer & Marketing company) – Tramadol HCl 50mg, DicyclomineHCl 10mg andAcetaminophen 325mg Each capsule contains: Tramadol HCl IP 50mg Dicyclomine Hydrochloride IP 10mg Acetaminophen 325mg	2.30/capsule
7(vi)	M/s Intas Pharmaceuticals Ltd (Manufacturer & Marketing company) – Glimepiride 0.5mg and Metformin HCl 500mg Each uncoated bilayer tablet contains: Glimepiride IP 0.5mg Metformin HCl 500mg (as extended release form)	2.32/tablet

8. **Agenda Item no. 8:**

8.1 The Authority discussed the agenda note circulated for its consideration in respect of finalization of guidelines regarding discontinuation of schedule formulations under para 21(2) of DPCO, 2013. The Authority after due deliberation, directed to modify the para 4 of the guidelines as under:

"4.0 Taking the above into consideration, the Authority in its 150th meeting held on 15.09.2014 approved the internal guidelines to dispose off Form-IV applications of

discontinuation of production / import of scheduled formulations under 21 (2) of the DPCO, 2013 for issuance of "no objection certificate" by the NPPA without referring the cases to the Authority as per the following:

4.1 No objection for discontinuation may be granted by the NPPA wherever no. of market players are ten or more and the market share of the applicant company is below one percent.

4.2 No objection may be granted by the NPPA for gradual discontinuation and the applicant company may be advised within a period of 60 days from the receipt of Form-IV to continue to manufacture / import and sale the drug during the next six months, wherever number of market players are ten or more and the market share of the applicant company is one percent to three percent.

4.3 No objection may be granted by the NPPA for gradual discontinuation and the applicant company may be advised within a period of 60 days from the receipt of Form-IV to continue to manufacture / import and sale the drug during the next twelve months, wherever number of market players are more than five and less than ten and the market share of the applicant company is above three percent but less than five percent. The company intending to discontinue the scheduled formulation from the market shall also issue a public notice.

4.4 In the cases where Form-IV application is received for a formulation which is legally banned and not permissible to manufacture / import / market in India and / or in the country of manufacture from where it is imported, "no objection" shall be issued by the NPPA after being satisfied in this regard.

5. In respect of the Form-IV applications not covered under para 4 above, where number of market players are less than five and the applicant company holds five percent or more of market share, may be processed by the NPPA after due consideration of the feedback received from the respective applicant. In this regard, an

agenda note should be put up of consideration of the Authority within one month of the receipt of Form-IV application. In such cases, "no objection for discontinuation" should be granted only after the approval of the Authority."

8.2 The Authority also directed that the above guideline shall be made available to public at large by putting on NPPA's website.

9. Agenda Item no. 9:

9.1 The Authority deliberated over the matter at length and based on the facts and circumstances of the case as also the analysis/status paper circulated to all the members/representatives present, made the following observations: -

(i) The three separate actions relating to: (a) approval of the internal guidelines by the Authority at its 147th meeting held on 16.05.2014;(b) its subsequent issuance on 29.05.2014,for monitoring inter-brand prices differences and undertaking price fixation in respect of non-scheduled drugs under certain circumstances; and (c) issuance of 50 price notifications/orders on 10.07.2014, under paragraph 19 of the DPCO 2013,were all made by the NPPA in exercise of the powers delegated to it under section 3 and 5 of the Essential Commodities Act 1955.

(ii) As per section 5 of the Essential Commodities Act, the Central Government may, by notified order, direct that the power to make orders or issue notifications under section 3 shall, in relation to such matters and subject to such conditions, if any, as may be specified in the direction be exercisable also by the delegated authority, which in the instant case refers to the NPPA.

(iii) It was noted that while delegating powers to the NPPA the Government did not in any manner circumscribe the same by way of imposition of any condition(s)specified in the delegation order as clearly evident from the Order no. S. O. 1394(E) dated 30.05.2013 issued by the Government in the Department of Pharmaceuticals under the Ministry of Chemicals and Fertilizers.

(iv) Hence, the NPPA acted well within its competence and jurisdiction while notifying the said guidelines as also price notifications.

(v) The decision of the NPPA to cap the MRP in respect of 108 non-scheduled drugs

related to treatment of diabetes and cardiovascular diseases (CVD), both of which have very high incidence in the country, was solely to safeguard public interest from undue financial burden caused by exploitative pricing by some manufacturers, which leads to financial impoverishment of the poor masses.

(vi) The huge and unreasonable price differences across brands in respect of a drug formulation that is identical in pharmaceutical as well as therapeutic terms was considered extraordinary because when viewed in the light of serious market failure/ market imperfections in the form of information asymmetry, where the patient has little role in drug selection, which is largely determined by doctor's prescription behaviour, which in turn is influenced by aggressive promotional strategies of drug manufacturers, negates any role of price competition, especially given the heavy market concentration across formulations in the two therapeutic groups of anti-diabetes and CVD.

(vii) Since those factors/ circumstances hindered access to healthcare or caused undue financial burden, especially for the poor masses, they were considered as extraordinary circumstances and necessary action as deemed fit was taken in order to extend much needed financial relief to affected population, especially the poor masses, for a period of one year.

(viii) The Hon'ble Delhi High Court while refusing to grant stay or restrain the NPPA from issuing further notifications in this regard, at the stage of hearing the writ petition no. W.P. 4809/2014 filed by the OPPI,the Learned Single Judge commented that "extraordinary circumstances" do not necessarily mean "emergent circumstances" only.

(ix) It was noted that the DPCO 2013 does not define "essential" but only defines "NLEM" (National List of Essential Medicines), "Scheduled formulations" and "Non-Scheduled formulations". Hence, to consider all non-scheduled medicines as non-essential medicines wouldbe inappropriate, especially since the NLEM itself is a dynamic list with inclusion and exclusion of drugs taking place at regular intervals based on essentiality as per health needs of the population.

(x) Non-NLEM drugs are not non-essential drugs also because the NLEM is more a tool for promoting scientific and rational use of medicines, and facilitating cost-effective

procurement of drugs for the public health system than that for price control of drugs.

(xi) Further, in the absence of mandatory standard treatment guidelines, the NLEM is unable to significantly influence the doctor's prescription behaviour, which is still largely influenced by aggressive promotional strategies of drug manufacturers. Added to that, the public health care system also has a very limited outreach to outpatient care. Hence, the span of price control under the NLEM, which is around 15-17% in value terms and 18-20% in volume terms, is not sufficient for having adequate impact in making essential and lifesaving medicines more affordable to the common man. It therefore, becomes necessary to look beyond the NLEM whenever warranted by circumstances endangering public interest.

(xii) The action taken by the NPPA under Paragraph 19 of the DPCO 2013 was not intended as a general measure of price fixation, but as something to be used whenever public interest was endangered by extraordinary circumstances. In the instant case the action was confined to only 50 molecules where unreasonable price differences were noticed. In terms of packs, only 120 out of 568 packs verified in anti-diabetes group, and 247 out of 1410 packs verified in CVD group were affected. In terms of formulations, 9 out of 11 in anti-diabetes group and 43 out of 127 in CVD group were affected. Hence, it has not been taken as a general measure but as something specifically resorted to only in cases where unreasonable price differences were seen to undermine public interest.

(xiii) 25 out of the 50 molecules covered under Paragraph 19 of the DPCO 2013 are in the Top-300 molecules in terms of moving annual turnover (MAT) Volume, out of over 2800 molecules, which shows that these cannot be considered as non-essential medicines because they are being heavily prescribed by doctors for treatment of the two chronic and life-threatening diseases, namely, diabetes and CVD, which have large incidence in the country. India is commonly referred to as the Diabetes capital of the world with 60 to 70 million people suffering from the disease, which is likely to cross 100 million by 2030. Similarly, around 25% of the deaths in the age group of 25-69 are caused by CVD.

(xiv) Out of these 25 molecules figuring in the Top-300 molecules, in 21 the top-5 companies have a market share of more than 50%, and within that in several cases

exceeding 75%, which shows the extent of market concentration that exists in these two therapeutic groups.

(xv) The market leaders are also in the higher price band, which is indicative of counter-intuitive demand behaviour caused due to information asymmetry and market concentration.

(xvi) The price notifications have impacted only 58 manufacturer as per available information with the NPPA: 19 manufacturers, one molecule each; 6 manufacturers, two molecules each; 8 manufacturers, three molecules each; 7 manufacturers, four molecules each; 6 manufactures, five molecules each; 3 manufacturers, seven molecules each; 2manufacturer, eight molecules each; 1 manufacturers, nine molecules; 2 manufacturers, ten molecules each; 1 manufacturer, eleven molecules; 1 manufacturer,twelve molecules; 1 manufacturer, thirteen molecules; and 1 manufacturer, 14 molecules.

(xvii) 29 out of 39 companies that are affected in 2 or more molecules are amongst the Top-50 companies; in other words, mainly large companies have been affected, which should be able to easily absorb the price reduction.

(xviii) Out of the 50 molecules covered having a market share of Rs. 5, 936 crore, 25 are major molecules accounting for 91.30% of that market share; and the remaining 25% account for only 8.7% of that market share.

(xix) In major molecules, in 14 molecules the majority of the players have complied; in 3 molecules all players have complied; in 5 molecules partial compliance has been there; and only in 3 molecules there is no compliance. In minor molecules, in 9 molecules there is 100% compliance (32% market share); in 8 molecules majority compliance (38% market share); and in 8 non-compliance (30% market share).

(xx) Overall in terms of market share the compliance is over 70%.

(xxi) Hence, the price benefit has started to accrue to the common man, which is estimated to be close to Rs. 350 crore per annum once fully implemented.

(xxii) The observations communicated by the Department of Pharmaceuticals are post-facto in nature, i.e., after issuance and implementation of the guidelines in question, and appear to have been made without full appreciation of the facts; and more importantly, they are not in the form of Government directions issued under section 5

of the Essential Commodities Act 1955 and, therefore, cannot override action already exercised in good faith under delegated power by the subordinate entity, i.e., the NPPA.

(xxiii) It is observed that the Indian Pharmaceutical Alliance (IPA) are trying to take improper advantage of the difference in views between the Department of Pharmaceuticals and the NPPA on the scope of Paragraph 19 of the DPCO 2013, as evident from a recent notice No. KD/ 0982 dated 12.09.2014 received by the NPPA from the Advocates of the IPA. It is seen as a direct attempt made by the IPA to undermine the versatility and efficacy of Paragraph 19 of the DPCO 2013 as a tool to protect public interest as and when it is endangered by extraordinary circumstances.

(xxiv) Since the entire matter is sub-judice in the Hon'ble High Courts of Bombay and Delhi, therefore, the Authority is of the unanimous and considered view that it would be appropriate to await resolution of the entire matter relating to the scope of Paragraph 19 by way of Court judgment or statutory directions from the Government.

(xxv) Pending the above, all pending proposals for price fixation under paragraph 19 of the DPCO 2013 shall remain deferred until further review in this regard.

10. Agenda Item no. 10:

10.1 It was noted that India is the highest TB burden country, accounting for one-fourth of global incidence. In 2012, out of estimated 8.7 million TB cases, 2.4 were estimated to have occurred in India. In this context, it was noted that the impact of the proposed capping of MRP in respect of non-scheduled anti-TB drugs was minimal; only Rs. 19 lakh annually. It was also noted that only 5 out of 21anti-TB formulations were at present under price control covering only 22% of the market share for anti-TB medicines. The the 3 highest selling formulations, namely, Rifampicin + Isoniazide + Pyrazinamide; Rifampicin + Isoniazide; and Rifampicin + Isoniazide + Ethambutol,were outside price control. Even if all strengths and dosages of those drugs included in the NLEM 2011 are covered, it would increase the market share coverage to only 26% (from 22%). It was noted that even under DOTS-TB Control programme, availability of some drugs was sometimes a big problem.

10.2 Hence, it was recommended that in view of the decision taken in respect of agenda no. 9,

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the essential anti-TB medicines, including fixed drug combinations (FDCs) mentioned above, may be recommended for coverage under the revised NLEM barring irrational combinations, if any.

11. Agenda Item no. 11:

11.0 The Authority noted the position with regard to short supply in respect of Albumin, Anti-Snake Venom, Rabies Vaccine, Rabies Immunoglobin and Anti- malarial combination of Sulfadoxine + Pyrimethamine Tablets and granted its ex post-facto approval on the notification issued vide S.O. 2292(E) dated 09.09.2014.

Other matters:

12. NLEM Study:

12.1 The Chairman briefed the members that the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers has requested the NPPA to undertake a detailed study of the drugs already included in NLEM 2011 and also identify drugs that require inclusion with a view to ensuring that all lifesaving and essential drugs of mass consumption are included in the revised NLEM for safeguarding public interest.

12.2 He informed that the NPPA has already held meetings in this regard with the civil society and public health experts on 27.08.2014, and state drug controllers (SDC) on 03.09.2014, and obtained their feedback, views, suggestions and recommendations. A meeting with the industry and trade is scheduled to be held on 17.09,2014, which will complete the on going consultation process in this regard.

12.3 The broad suggestions that came out of meeting with the civil society and public health experts 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. It was suggested that in addition to NLEM drugs, a list of commonly used price sensitive drugs may be drawn up, including FDCs approved

by the DCGI, high volume-value drugs, etc., for inclusion in Schedule I.

12.4 The broad conclusion that came out from the meeting with the SDCs were (i) each SDC will send a list of the drugs to be considered for inclusion/ exclusion in the NLEM; and (ii) SDCs to forward a list of medicines included in the State essential drugs list (EDL) but not covered under NLEM 2011, for the purpose of inclusion in the revised NLEM. Some of the specific inclusions suggested by SDCs were medical devices falling under the category of drugs, blood related items, surgery items, etc.

12.5 The final recommendations to be placed before the Authority will be based on the stakeholder consultations and internal analyses of molecules/ formulations across various therapeutic groups, particularly those with high incidence in the country. A detailed analysis of Top-300 molecules in terms of MAT volume and MAT value and other studies are being carried out for this purpose. The various issues being looked at include: strengths and dosage forms not covered under the NLEM 2011; analogues of scheduled formulations; close substitutes in the same therapeutic class; paediatric dosages; high-volume use rational fixed drug combinations (FDCs), especially in certain therapeutic groups such as respiratory, ant-diabetic, derma, anti-malarial, anti-TB/ MDR-TB; preparation of a separate list of lifesaving drugs based on existing lifesaving drugs list of government agencies like the CGHS; region-specific needs as reflected in states' essential drugs lists; essential and lifesaving patented drugs; and inclusion of some medical devices which are already covered under the definition of drugs under the Drugs and Cosmetics Act 1940. The recommendations approved by the Authority will be submitted to the Department of Pharmaceuticals and the Core Committee on NLEM for consideration.

12.6 The Authority deliberated over the matter. It was noted that the list of scheduled formulations need not be restricted to the NLEM alone for the following reasons:-

(i) The NLEM is primarily meant to promote scientific and rational use of medicines in the public health system at primary, secondary and tertiary facilities, and is not essentially a drug price control tool.

(ii) The public health system caters to the medicinal requirement of not more than 20 percent of the population; the remaining 80 percent meet their medicinal requirements on

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their own from the retail market by way of out-of-pocket expenses.

(iii) Due to the absence of mandatory standard treatment guidelines that promote scientific and rational use of medicines in the country, the NLEM marginally impacts the prescription behaviour of doctors, which is still largely influenced by aggressive promotional strategies of drug manufacturers.

(iv) Amongst the top-100 molecules in volume terms, only 40 are included in the NLEM; and amongst the top-100 molecules in value terms, only 33 are included in the NLEM. Further, as not all salts, esters, isomers, analogues and derivatives of molecules covered and not all strengths and dosage forms of their formulations covered are included in the NLEM, the overall span of control of the NLEM is only around 15-17 per cent in value terms and 18-20 per cent in volume terms; which shows that the impact of DPCO 2013 on the common man is quite limited, as a number of top- selling medicines are not covered under the NLEM/ price control.

(v) The percentage of FDCs in total sales of medicines is close to 40 per cent (in some therapeutic groups like respiratory, gastro-intestinal and anti-diabetic it is more than 50 per cent) but their coverage under NLEM is negligible. In antidiabetics, for antidiabetics, for example, Glimepride+ Metformin occupies 6th rank in volume (out of 2800+ molecules) and 2nd rank in value (Rs. 1188 crore) but is not under price control.

(vi) Lifesaving drugs are not specifically defined in the NLEM and their coverage is fairly limited under the present essentiality criteria.

(viii) As of now, patented drugs do not find place in the NLEM. There is no restriction on inclusion of patented drugs in the Schedule I except that those covered under Para 32 (i) and (ii) are exempted from the application of DPCO for a period of 5 years from the date of commencement of commercial production.

12.7 Accordingly, apart from making specific recommendations for plugging deficiencies in the NLEM, the Authority felt that a separate list of medicines that may not be part of the NLEM should also be incorporated in Schedule as a 'complementary list of essential and lifesaving medicines' or 'NLEM Plus List' just as we have a 'core list' and 'complementary list' in the

WHO 'Model List'. The drugs included in the complementary/ NLEM Plus list would be those that are absent from the NLEM but are ranked high in MAT volume as well as value, excluding irrational combinations.

12.8 The broad principles that have been worked out are as follows: -

(i) Name of the main molecule should be mentioned so that it automatically includes its salts, esters, isomers, analogues and derivatives.

(ii) Broad classification of dosage forms may be indicated such as "oral solid", "oral liquid", "topical preparations", etc., so as to make it more inclusive.

(iii) Inclusion of all strengths or at least "usual strengths", which would mean commonly used strengths.

(iv) Inclusion of pediatric dosages.

(v) Inclusion of lifesaving drugs.

(vi) Inclusion of essential and lifesaving patented drugs.

(vii) Inclusion of region-specific needs as reflected in State Essential Drug Lists.

(viii) Retail market pricing aspect to be duly factored; hence cost-effectiveness needs broader

12.9 The Authority approved the broad principles with the addition of medical devices covered under the definition of drugs.

13. This issues with the approval of Chairman, NPPA.

15.9.04

(Amit Khare)
Member Secretary