

मिसिलस.- 8(47)/2017/डी.पी/एनपीपीए-डीवी-॥

F. No. 8(47)/2017/DP/NPPA-Div. II

कार्यवाहीस. : 179/47/2017/F

Proceeding No : 179/47/2017/F

Minutes of the 179th and 47th meeting of Authority under DPCO, 2013 held on 27.7.2017 at 11.00 A.M.

I. 1. The 179th overall meeting of the Authority, which is the 47th under the DPCO, 2013 was held on 27th July, 2017 at 11.00 AM under the Chairmanship of Shri Bhupendra Singh, Chairman, NPPA. The following members of the NPPA were present:-

- (i) Shri Kalyan Nag, Adviser (Cost) and Member Secretary
- (ii) Shri Umesh Dongre, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iii) Shri Arun Kumar, Adviser, Deptt. of Economic Affairs, Ministry of Finance.
- (iv) Shri R. Chadrashekar, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCG(I)).

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

- (i) Smt. Roshni Sohni, Director (M&E/Admn.)
- (ii) Shri A.P.S. Sawhney, Director (Pricing)
- (iii) Shri Baljit Singh, Asstt. Director (Pricing)
- (iv) Shri Prasenjit Das, Asstt. Director (Pricing)
- (iv) Shri Suneel Chopra, Pr. Legal Consultant

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

II. Agenda Items

1. Agenda Item no. 1: Confirmation of Minutes of the 46th Meeting held on 08.6.2017.

1.1 The Authority confirmed the minutes of the overall 178th and the 46th Meeting held on 08.6.2017 under DPCO, 2013.

2. Agenda Item no. 2: Action Taken Report

2.1 Noted.

3. Agenda Item no. 3: Fixation of Ceiling Prices of Scheduled formulations in the revised Schedule-I of DPCO, 2013 (NLEM, 2015).

3.1 As decided in the 27th Authority Meeting dated 29-March-2016, the ceiling prices under NLEM 2015 were fixed as per NPPA's consistent policy of considering the least option (among the three alternatives for determining 1% market share) in the consumer's interest. The Deptt of Pharmaceuticals in various review order, directed that the medicine/formulations having more

than 1% market share would be considered, since DPCO 2013 does not recognise a company for average PTR, but only medicine/ formulations. Certain review orders also directed to take pack description/SKU having more than 1% market share while re-fixing the ceiling price. Further, even though in certain review orders, it was directed to take pack description/SKU having 1% or more market share for fixation of ceiling prices. There has been apparent inconsistency in the Government's orders and the same was brought to the government's knowledge by NPPA. The Authority deliberated the issue in detail and decided henceforth, the ceiling price/retail price would be fixed by considering the brands having 1% or more market share for fixation of ceiling/ retail price in all cases, as per decision of the government in review cases, since NPPA cannot seek a legal remedy against Government's order.

3.2 The Authority discussed in detail the data and calculation sheets of the following 11 formulations at the meeting. The Authority approved the ceiling prices in respect of all the following formulations as per the decisions taken in para 3.1. (i.e. brands having 1% or more market share).

S. NO.	UNIQUE NO. AS PER NLEM	NAME OF THE FORMULATION/ COMPOSITIONS	Dosage Form & STRENGTH	Unit for ceiling price	Proposed ceiling price under NLEM, 2015 (Rs.)
A. Common Formulations					
Section 8 -Antineoplastic/ immunosuppressives and medicines used in palliative care					
8.1-Antineoplastic medicines					
1	8.1.2	6-Mercaptopurine	Tablet 50mg	1 Tablet	5.86
Section 12-Cardiovascular medicines					
12.2-Antiarrhythmic medicines					
2	12.2.3	Esmolol	Injection 10mg/ml	1 ML	19.65
B. New Formulations					
Section 8 -Antineoplastic/ immunosuppressives and medicines used in palliative care					
1	8.1.5	Arsenic trioxide	Injection 1mg/ml	1 ML	49.28
Section 14-Dermatological medicines (Topical)					
14.3-Anti-inflammatory and antipruritic medicines					
2	14.3.1	Betamethasone	Cream 0.1%	1 GM	0.76
Section 20-Gastrointestinal medicines					
20.6-Medicines used in diarrhoea					
3	20.6.2	Zinc sulphate	Dispersible Tablet 20mg	1 Tablet	2.84
Section 21-Hormones, other endocrine medicines and contraceptives					
21.7-Thyroid and antithyroid medicines					
4	21.7.2	Levothyroxine	Tablet 62.5mcg	1 Tablet	1.27
5	21.7.2	Levothyroxine	Tablet 112mcg	1 Tablet	1.30
Section 25-Ophthalmological Medicines					
25.5-Mydriatics					
6	25.5.3	Phenylephrine	Drop 10%	1 ML	7.34
Section 26-Oxytocics and Antioxytocics					
26.1-Oxytocics and abortifacient					
7	26.1.1	Dinoprostone	Tablet 0.5 mg	1 Tablet	45.42

C. Common Formulations (Explanation to Schedule-I)					
D. New Formulations (Explanation to Schedule-I)					
Section 14-Dermatological medicines (Topical)					
14.3-Anti-inflammatory and antipruritic medicines					
1	14.3.1	Betamethasone	Lotion 0.05%	1 ML	0.48
2	14.3.1	Betamethasone	Lotion 0.1%	1 ML	0.74

4. Agenda Item no. 4: Price fixation of new drug under para 5 of DPCO, 2013.

4.1 The Authority discussed all the 7 cases of retail price fixation of new drugs falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices of the following under para 5 of the DPCO 2013.

S. No.	Company name/Product name	Approved Retail Price (Rs.)
4 (i)	M/s Sirmour Remedies Pvt. Ltd. (Manufacturer) and M/s Lifestar Pharma Pvt. Ltd. (Marketing company) - Fusidic Acid 20mg (2% w/w) + Mometasone Furoate 1mg (0.1% w/w) - (Bactafuz-M Cream).	15.07 per gm
4 (ii)	M/s Torrent Pharmaceuticals Ltd. (Manufacturer and Marketing company) - Rosuvastatin Calcium IP Eq. to Rosuvastatin 20mg (as film coated tablet) + Aspirin IP 75mg (as enteric coated tablet) - (Rozucor Asp 20).	7.80 per Capsule
4 (iii)	M/s Torrent Pharmaceutical Ltd., (Manufacturer as well as Marketing company) - Metformin Hydrochloride IP 1000mg & Voglibose IP 0.2mg - (Voglitor MF Forte 0.2 tablet).	7.46 per Tablet
4 (iv)	M/s Torrent Pharmaceutical Ltd., (Manufacturer as well as Marketing company) - Metformin Hydrochloride IP 1000mg & Voglibose IP 0.3mg - (Voglitor MF Forte 0.3 tablet).	9.32 per Tablet
4 (v)	M/s Torrent Pharma Ltd., (Manufacturer as well as Marketing company) - Metformin HCl 500mg (as sustained release form), Glimepiride 1mg & Voglibose 0.3mg - (TriVoglitor Forte 1 tablet).	9.39 per Tablet
4 (vi)	M/s Torrent Pharma Ltd., (Manufacturer as well as Marketing company) - Metformin HCl 500mg (as sustained release form), Glimepiride 2mg & Voglibose 0.3mg - (TriVoglitor Forte 2 tablet).	11.13 per Tablet
4 (vii)	M/s G.M.H. Organics (Manufacturer company) & M/s Claris Injectable Limited (Marketing company) - Sterile Ceftriaxone Sodium IP eq. to Ceftriaxone 1000mg & Sterile Sulbactam Sodium USP eq. to Sulbactam 500mg.	52.34 per Vial

4(viii) Status of New Drugs

Noted.

5. Agenda Item No: 5: Review Orders on ceiling Prices

Before taking up the agenda for individual review orders, the authority deliberated on the policy adopted by NPPA for fixing the ceiling price and various review orders issued by Department of Pharmaceuticals on the policy for price fixation adopted by NPPA. It was noted that as decided in the 27th Authority Meeting held on 29-March-2016, the ceiling prices under NLEM 2015 were fixed as per NPPA's consistent policy of considering the least option (among the three alternatives for determining 1% market share) in the consumer's interest. The Deptt of Pharmaceuticals in various review orders, directed that the medicine/formulations having more than 1% market share would be considered since DPCO, 2013 does not recognize a company for average PTR but only medicine/

formulations. Certain review orders also directed to take pack description/ SKU having more than 1% market share while re-fixing the ceiling price. The Authority deliberated the issue in detail and stated that there is no provisions in the DPCO, 2013 to consider pack description/ SKU having 1% or more market share and atleast brand do have a mention in the DPCO, 2013. Authority decided that the review orders on the issues would be implemented by considering the brands having 1% or more market share across the board. Accordingly, the review orders as per agenda 5(i) to 5(xiii) are approved based on the above decisions, wherever applicable, which are as follows:

Sl. No.	Review Order No. and date	Petitioner Company	Formulation	CP after Review order with GST Impact	Remarks
5(i)	31015/96/2016-PI.I 04.05.2017	J.B. Chemicals	Ranitidine 25mg/ml injection	Rs.1.47/ml	
5(ii)	31015/91/2016-PI.I 06.03.2017	Sun Pharmaceutical Industries	Nitrofurantoin 100 mg capsule	Rs.7.13/capsule	
5(iii)	31015/65/2016-PI.I 10.1.2017	Micro Labs	Amlodipine 5 mg tablet	Rs.2.37/tablet	
5(iv)	31015/2/2017-PI.I 18.4.2017	Cipla Ltd	Azithromycin Powder for Injection 500 mg	Rs.174.45/pack	
			Lamivudine150mg+Nevirapine200mg+ Stavudine30mg Tablet	Rs.14.16/tablet	refer Agenda item number 7
5(v)	31015/103/2016-PI.I 05.04.2017	Sun Pharma Laboratories	Carboxymethylcellulose 1% drops	Rs.16.07/ml	No change
5(vi)	31015/46/2016-PI.I 18.4.2017	Cipla Ltd	Cefixime 200mg tablet	Rs.8.71/tablet	
			Amoxicillin1g+Clavulanic acid 200mg Powder for Injection	Rs.113.95/pack	
			Amoxicillin 500mg+ Clavulanic Acid 125 mg tablet	Rs.16.30/tablet	
			Amoxicillin 500 mg capsule	Rs.5.86/capsule	
5(vii)	31015/23/2016-PI.I 06.10.2016	Lupin Ltd	Levofloxacin 500 mg tablet	Rs.7.32/tablet	
5(viii)	31015/76/2016-PI.I 05.4.2017	IPCA Laboratories	Methotrexate 2.5 mg tablet	Rs.4.34/tablet	No change
			Methotrexate 7.5 mg tablet	Rs.10.52/tablet	No change
			Methotrexate 10 mg tablet	Rs.11.02/tablet	No change
5(ix)	31015/59/2016-PI.I 18.4.2017	Cipla Ltd	Ondansetron 4 mg tablet	Rs.4.26/tablet	No change
			Ondansetron 2mg/ml injection	Rs.5.31/ml	No change
5(x)	31015/98/2016-PI.I 05.4.2017	Wockhardt Ltd	Povidone Iodine 5% solution	Rs.0.35/ml	
5(xi)	31015/40/2015-PI.I 29.11.2016	Sun Pharmaceuticals Industries	Ciprofloxacin 250 mg tablet	Rs.1.89/ tablet	
			Ciprofloxacin 500 mg tablet	Rs.3.31/ tablet	
5(xii)	31015/45/2016-PI.I 18.4.2017	Cipla Ltd*	Azithromycin 250mg tablet	Rs.9.58/tablet	
			Azithromycin 500mg tablet	Rs.19.33/tablet	
5(xiii)	31015/9/2015-PI.I 05.5.2016	Various Pharma Companies	Ringer Lactate Injection (100ml pack)	Rs.18.95/pack	
			Ringer Lactate Injection (250ml pack)	Rs.32.31/pack	
			Ringer Lactate Injection (500ml pack)	Rs.41.17/pack	
			Ringer Lactate Injection (1000ml pack)	Rs.72.38/pack	

*Review order of Cipla Ltd. at 5(xii) for Ciprofloxacin 250mg tablet, Ciprofloxacin 500mg tablet and Amlodipine 5 mg tablet) are dealt along-with Review Order mentioned at 5(i) and 5(xi).

6. Agenda Item no. 6: Status of Review orders issued by DOP for implementation by NPPA.

6.1 Noted.

7. Agenda Item no. 7: Revision of ceiling price due to representation in respect of GST impact.

7.1 The matter was discussed and it was decided to notify the ceiling price as proposed in the agenda as follows:

Sl No	Name of Schedule formulation	Dosage form and strength	Unit	Proposed ceiling price (Rs.)
1	Atropine	Injection 0.6 mg/ml	1 ml	3.80
2	Atropine	Ointment 1%	1 gm	3.43
3	Atropine	Drops 1%	1 ml	3.11
4	Coagulation factor VIII	Powder for Injection 250 IU	Each pack	3,389.14
5	Coagulation factor VIII	Powder for Injection 500 IU	Each Pack	8,316.70
6	Ethambutol	Tablet 800 mg	1 Tablet	3.84
7	Ethambutol	Tablet 600 mg	1 Tablet	3.21
8	Ethambutol	Tablet 400 mg	1 Tablet	2.18
9	Ethambutol	Tablet 200 mg	1 Tablet	0.96
10	Homatropine	Drops 2%	1 ml	5.64
11	Human Normal Immunoglobulin		1 ml	139.98
12	Antitetanus Human immunoglobulin	Injection 250 IU	Each Pack	1,034.87
13	Antitetanus Human immunoglobulin	Injection 500 IU	Each Pack	1,725.16
14	Vinblastine Sulphate	Injection 10mg	Each Pack	312.07
15	Abacavir (A) + Lamivudine (B)	Tablet 600 mg (A)+ 300 mg (B)	1 Tablet	82.69
16	Abacavir (A) + Lamivudine (B)	Tablet 60 mg (A) + 30 mg (B)	1 Tablet	18.22
17	Atazanavir (A) + Ritonavir (B)	Tablet 300 mg (A) + 100 mg (B)	1 Tablet	89.58
18	Capecitabine	Tablet 500 mg	1 Tablet	114.68
19	Lamivudine (A) + Nevirapine (B) + Stavudine (C)	Tablet 150 mg (A) + 200 mg (B) + 30 mg(C)	1 Tablet	14.16
20	Lamivudine (A) + Zidovudine (B)	Tablet 150 mg (A) + 300 mg (B)	1 Tablet	18.20
21	Lamivudine (A)+ Nevirapine (B) + Stavudine (C)	Dispersible Tablet 30 mg (A) + 50 mg (B) + 6 mg (C)	1 Tablet	4.49
22	Lopinavir (A) + Ritonavir (B)	Tablet 200 mg (A) + 50 mg (B)	1 Tablet	41.35
23	Lopinavir (A) + Ritonavir (B)	Tablet 100 mg (A) + 25 mg (B)	1 Tablet	21.34
24	Methylprednisolone	Tablet 16 mg	1 Tablet	8.09
25	Methylprednisolone	Tablet 8 mg	1 Tablet	4.63
26	Methylprednisolone	Injection 40 mg/ml	1 ml	43.55
27	Nevirapine	Tablet 200 mg	1 Tablet	12.99
28	Nevirapine	Oral Liquid 50 mg/5ml	1 ml	0.76
29	Rituximab	Injection 10 mg/ml	1 ml	688.24

30	Stavudine (A) + Lamivudine (B)	Tablet 30 mg (A) +150 mg (B)	1 Tablet	8.66
31	Zidovudine (A) + Lamivudine (B) + Nevirapine (C)	Tablet 300 mg (A) + 150 mg (B) + 200 mg(C)	1 Tablet	18.28

8. Agenda Item no. 8: Representation received from companies under Para 19 for increase in ceiling price.

8.1 The Authority discussed and directed to seek the yearwise change in price of API also from the respective companies.

9. Agenda Item no. 9: Status of Overcharging Cases.

9.1 Noted.

10. Allegations regarding unethical innovative trade practices adopted by certain Companies to bypass the order of NPPA regarding restricted trade margins.

10.1 The Authority deliberated the matter in details. Accordingly, the Authority directed to obtain the Registration Certificate issued by DCG(I) in form 41(for obtaining the import Licence) from the importing company.

11. Agenda Item no. 11: Price methodology of new drugs in the light of review orders.

11.1 As decided in 3.1 above in the case of retail price fixation of new drug, the same methodology would be followed.

12. Agenda Item no. 12: Status of filing of various forms in IPDMS by Pharma companies.

12.1 The Authority noted that 90 pharmaceutical companies have submitted at least one Form-V for all their products registered in IPDMS

12.2 Authority instructed that the list of those companies who have submitted at least one form V for product registered in IPDMS and not having any demand note pending against them may be uploaded on the website of NPPA.

13. Agenda Item no. 13: Agenda for Authority meeting on 27.7.2017 on status of OM issued by NPPA on 17.5.2017, regarding launch of new drugs by pharmaceutical companies without obtaining prior price approval from NPPA.

13.1 Authority observed that out of 67 companies (201 formulations), 39 companies (123 formulations) have not yet submitted their replies to the Show Cause Notice for launch of new drugs without obtaining prior price approval as per provisions of DPCO 2013. Authority instructed that reminder may be issued to these companies for submitting the replies within 7 working days.

14. Agenda Item no. 14: Status of non-availability of drugs cases and the action taken in these cases.

14.1 Noted.

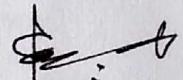
15. Agenda Item no. 15: Pendency Status of requests for withdrawal of drugs as on 25.7.2017.

15.1 Noted.

16. Agenda Item no. 16: Minutes of the 5th meeting of Committee of Experts under para 11(3 & 4) held on 21.7.2017 at 11:00 AM in NPPA.

16.1 Noted.

17. The meeting ended with a vote of thanks to the Chair.



(Kalyan Nag)

Adviser (Cost) & Member Secretary