

मिसिलस . - 8(40)/2016/डी . पी/एनपीपीए-डीवी-II

F. No. 8(40)/2016/DP/NPPA-Div. II

कार्यवाहीस. : 172/40/2016/F  
Proceeding No : 172/40/2016/F

**Minutes of the 172<sup>nd</sup> and 40<sup>th</sup> meeting of Authority under DPCO, 2013 held on 23.01.2017 at 3.00 P.M.**

- I. 1. The 172<sup>nd</sup> overall meeting of the Authority, which is the 40<sup>th</sup> under the DPCO, 2013 was held on 23rd January, 2017 at 3.00 PM under the Chairmanship of Shri Bhupendra Singh, Chairman, NPPA. The following members of the NPPA were present:-

- (i) Dr. Sharmila Mary Joseph K, Member Secretary, NPPA.
- (ii) Shri G.S. Negi, Adviser (Price, Money & Banking Unit), Deptt. of Economic Affairs, Ministry of Finance.
- (iii) Shri Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iv) Shri A.K. Pradhan, 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) Shri Kalyan Nag, Adviser (Cost)
- (ii) Smt. Roshni Sohni, Director (M&E/Admn.)
- (iii) Shri A.K. Khurana, Director (Pricing)
- (v) Shri A.P.S. Sawhney, Director (Overcharging)
- (vi) Shri Baljit Singh, Asstt. Director (Pricing)
- (vii) Shri Prasenjit Das, Asstt. Director (Pricing)
- (viii) 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 40<sup>th</sup> Meeting held on 23.01.2017.**

The Authority confirmed the minutes of the overall 171<sup>st</sup> and the 39<sup>th</sup> Meeting under DPCO, 2013.

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

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 The Authority discussed in detail the data and calculation sheets of 33 formulations at the meeting. The Authority also considered proposal for fixation of ceiling price of Gentamicin

*Sharmila Mary Joseph*

Injection 40mg/ml (in pack sizes of 2ml, 10ml, 20ml and 30ml); Dexamethasone Injection 4mg/ml (in pack size of 2ml, 10ml, 20ml and 30ml); and Tetanus Toxoid Injection (in pack sizes of 5ml and 0.5ml) and Paracetamol Injection (pack size of 2ml) based on recommendations of the meeting of Committee of Experts (constituted to examine proposals under paras 11(3) and 11(4) of DPCO 2013), at its meeting held on 28<sup>th</sup> December 2016. The Committee had recommended separate price based on pack size for these formulations, considering single and multi-dose usages of these formulations. The Authority also observed that data in respect of other pack sizes of Paracetamol Injection (as recommended by Committee of Experts) was not available and hence, ceiling price of other pack sizes of Paracetamol Injection was not worked out. The Authority also examined the representation received in respect of ceiling price calculation of Methylprednisolone Injection 40mg/ml and Cetirizine 10mg capsule and approved the ceiling prices proposed.

3.2 The Authority approved the ceiling prices in respect of all the following 33 formulations:-

S. NO.	UNIQUE NO. AS PER NLEM	NAME OF THE FORMULATION/ COMPOSITIONS	STRENGTH	Dosage Form	Unit for Ceiling Price	Approved ceiling price under NLEM, 2015 (Rs.)
<b>A. Common Formulations</b>						
<b>Section 2–Analgesics, antipyretics, non steroidal anti inflammatory medicines, medicines used to treat gout and disease modifying agents used in rheumatoid disorders.</b>						
<b>2.1– Non-opioid analgesics, antipyretics and nonsteroidal anti-inflammatory medicines</b>						
1	2.1.5	Paracetamol	150mg/ml	Injection	Each Pack (2ml)	5.98
<b>Section 3–Antiallergics and medicines used in anaphylaxis</b>						
2	3.4	Dexamethasone	4mg/ml	Injection	Each Pack (30ml)	32.73
3	3.4	Dexamethasone	4mg/ml	Injection	Each Pack (20ml)	24.49
4	3.4	Dexamethasone	4mg/ml	Injection	Each Pack (10ml)	12.78
5	3.4	Dexamethasone	4mg/ml	Injection	Each Pack (2ml)	5.28
<b>Section 6–Anti infective medicines</b>						
<b>6.1.1–Intestinal anthelmintics</b>						
6	6.1.1.1	Albendazole	200mg/5ml	Oral Liquid	Per ml	1.48
<b>6.2–Antibacterials</b>						
<b>6.2.2–Other antibacterials</b>						
7	6.2.2.6	Gentamicin	40mg/ml	Injection	Each Pack (20ml)	25.27
8	6.2.2.6	Gentamicin	40mg/ml	Injection	Each Pack (10ml)	16.67
9	6.2.2.6	Gentamicin	40mg/ml	Injection	Each Pack (2ml)	4.47
10	6.2.2.6	Gentamicin	40mg/ml	Injection	Each Pack (30ml)	27.65
<b>6.2.4–Antituberculosis medicines</b>						
11	6.2.4.13	Rifampicin	100mg/5ml	Oral Liquid	Per ml	0.34
12	6.2.4.14	Streptomycin	Powder for injection 1Gm	Injection	Each Pack	9.28
<b>6.3–Antifungal medicines</b>						

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13	6.3.2	Clotrimazole	100mg/5ml	Pessary	1 Pessary	8.06
<b>6.4.3-Antiretroviral medicines</b>						
<b>6.4.3.1-Nucleoside reverse transcriptase inhibitors</b>						
14	6.4.3.1.9	Zidovudine (A) + Lamivudine (B) + Nevirapine (C) Tablet	300 mg (A) + 150 mg (B) + 200 mg (C)	Tablet	Per Tablet	18.69
<b>Section 14-Dermatological medicines (Topical)</b>						
<b>14.5-Scabicides and pediculicides</b>						
15	14.5.1	Permethrin	Lotion 1%	Lotion	Per GM	0.84
<b>Section 20-Gastrointestinal medicines</b>						
<b>20.1-Antiulcer medicines</b>						
16	20.1.1	Omeprazole	10mg Capsule	Capsule	Per Capsule	1.96
<b>20.5-Laxatives</b>						
17	20.5.1	Bisacodyl	5mg	Suppository	Per Suppository	7.83
<b>Section 21-Hormones, and other endocrine medicines and contraceptives</b>						
<b>21.1-Adrenal hormones and synthetic substitutes</b>						
18	21.1.4	Methylprednisolone	Injection 40 mg/ml	Injection	Per ML	44.53
<b>Section 22-Immunologicals</b>						
<b>22.3-Vaccines</b>						
<b>22.3.1-For Universal Immunisation</b>						
19	22.3.1.8	Tetanus Toxoid	5ml pack	Injection	Each Pack	24.41
20	22.3.1.8	Tetanus Toxoid	0.5ml pack	Injection	Each Pack	5.53
<b>Section 26-Oxytocics and Antioxytocics 26.1-Oxytocics and abortifacient</b>						
<b>26.1-Oxytocics and abortifacient</b>						
21	26.1.2	Methylergometrine	0.125 mg	Tablet	Per Tablet	7.35
<b>Section 29-Solutions correcting water, electrolyte disturbances and acid based disturbances</b>						
<b>29.3-Miscellaneous</b>						
<b>B. New Formulation</b>						
<b>Section 5-Anticonvulsants/ Antiepileptics</b>						
1	5.8	Phenytoin	Oral Liquid 125mg/5ml	Oral Liquid	Per ML	0.82
<b>Section 14-Dermatological medicines (Topical)</b>						
<b>14.2-Anti-infective medicines</b>						
2	14.2.4	Povidone Iodine	4%	Solution	Per MI	1.62
<b>Section 20-Gastrointestinal medicines</b>						
<b>20.1-Antiulcer medicines</b>						
3	20.1.1	Omeprazole	Powder for oral liquid 20mg	Oral Liquid	Per GM	1.14
<b>C. Common (Explanation to Scheduled-I)</b>						
<b>Section 5-Anticonvulsants/ Antiepileptics</b>						
1	5.8	Phenytoin	100mg	Capsule	Per capsule	1.41
<b>D. New (Explanation to Scheduled-I)</b>						
<b>Section 3-Antiallergics and medicines used in anaphylaxis</b>						
1	3.2	Cetirizine	10mg	Capsule	Per capsule	2.21
<b>Section 5-Anticonvulsants/ Antiepileptics</b>						
2	5.8	Phenytoin	Capsule 300mg	Capsule	Per capsule	3.54
3	5.8	Phenytoin	ER Capsule 300mg	Capsule	Per capsule	3.54

*Abraham Joseph*

6.2-Antibacterials						
6.2.1-Beta lactam medicines						
4	6.2.1.8	Cefixime	Capsule 200mg	Capsule	Per Capsule	13.39
6.4.3-Antiretroviral medicines						
6.4.3.1-Nucleoside reverse transcriptase inhibitors						
5	6.4.3.1.8	Zidovudine	Capsule 300mg	Capsule	Per Capsule	1.84
Section 8 -Antineoplastic/ Immunosuppressives and medicines used in palliative care						
8.1-Antineoplastic medicines						
6	8.1.30	Procarbazine	50mg tablet	Tablet	Per Tablet	41.91
Section 14-Dermatological medicines (Topical)						
14.3-AntiInflammatory and antipruritic medicines						
7	14.3.1	Betamethasone	Gel 0.05%	Gel	Per GM	0.49
Section 20-Gastrointestinal medicines						
20.1-Antiulcer medicines						
8	20.1.1	Omeprazole	10mg	Tablet	Per Tablet	4.11

#### 4. Agenda Item no. 4: Fixation of retail price in respect of new drugs.

4.1 The Authority discussed the following 15 cases of retail price fixation of new drugs falling under the purview of para 2(u) of DPCO, 2013 and in principle approved the retail prices of the following under para 5 of the DPCO 2013, subject to the verification that the companies concerned have filed all the mandatory forms viz. Form II/III/IV for all their products in Integrated Pharmaceutical Database Management System (IPDMS). Price notifications to be issued after ensuring compliance.

S. No.	Company name/Product name	Approved Retail Price (Rs.)
4(i)	M/s Anglo French Drugs & Ind. Ltd. (Manufacturer as well as Marketing company) - Paracetamol 325mg and Tramadol HCl 37.5mg tablet - (Tramadol HCl & Paracetamol Tablet).	Rs. 6.37 per tablet
4(ii)	M/s Pharma Force Lab. (Manufacturer) and M/s Mankind Pharma Ltd. (Marketing company) - Clobetasol Propionate 0.05% w/w, Clotrimazole 1% w/w and Neomycin Sulphate 0.50% w/w and Chlorocresol (as preservative) 0.10% w/w - (Clobetasol + Neomycin + Clotrimazole Cream).	Rs. 3.04 per gm
4(iii)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s IPCA Lab. Ltd. (Marketing company) - Paracetamol 1000mg infusion - (Pacimol 10mg/ml Infusion).	Rs. 2.06 per ml
4(iv)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s IPCA Lab. Ltd. (Marketing company) - Mefenamic acid 500mg and Paracetamol 325mg - (Pacimol MF Tablet).	Rs. 26.46 per 10 tablets
4(v)	M/s Sirmour Remedies Pvt. Ltd. (Manufacturer) and M/s Lifestar Pharma Pvt. Ltd. (Marketing company) - Fusidic Acid 20mg (2% w/w) and Mometasone Furoate 1mg (0.1% w/w) - (Bactafuz-M Cream).	Rs. 13.95 per gm
4(vi)	M/s Aristo Lab. Pvt. Ltd. (Manufacturer) and M/s Aristo Pharmaceuticals Pvt. Ltd. (Marketing company) - Ceftriaxone sodium 125mg and Sulbactam sodium 62.5mg - (Monocef-SB 125mg Injection).	Rs. 32.28 per vial
4(vii)	M/s Abbott Healthcare Pvt. Ltd. (Manufacturer as well as Marketing company) - Propranolol HCl 20mg - (Inderal 20mg Tablet).	Rs. 2.03 per tablet
4(viii)	M/s Synokem Pharmaceuticals Ltd. (Manufacturer) and M/s Torrent Pharmaceuticals Ltd. (Marketing company) - Rosuvastatin 10mg and Clopidogrel 75mg - (Rozuplatt 10	Rs. 13.94 per capsule

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	Capsule).	
4(ix)	M/s Synkem Pharmaceuticals Ltd. (Manufacturer) and M/s FDC Ltd. (Marketing company) – Teneligliptin Hydrobromide 20mg and Metformin HCl 500mg – (TenDC M 500 Tablet).	Rs. 10.03 per tablet
4(x)	M/s Synkem Pharmaceuticals Ltd. (Manufacturer) and M/s FDC Ltd. (Marketing company) – Teneligliptin Hydrobromide 20mg and Metformin HCl 1000mg – (TenDC M 1000 Tablet).	Rs. 11.33 per tablet
4(xi)	M/s Glenmark Pharmaceuticals Ltd. (Manufacturer) and M/s Centaur Pharmaceuticals (Marketing company) – Teneligliptin Hydrobromide 20mg and Metformin HCl 1000mg – (Ten20 M 1000 Tablet).	Rs. 11.33 per tablet
4(xii)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Blue Cross Lab. Pvt. Ltd. (Marketing company) – Pantoprazole 40mg and Levosulpiride 75mg - (P-PPI-L Capsule).	Rs. 8.00 per capsule
4(xiii)	M/s Safetab Life Science (Manufacturer) and M/s Intas Pharmaceuticals Ltd. (Marketing company) – Rosuvastatin 10mg and Clopidogrel 75mg and Aspirin 75mg – (Rosuvastatin + Aspirin + Clopidogrel Tablet).	Rs. 10.40 per tablet
4(xvi)	M/s Mankind Pharma Ltd. (Manufacturer as well as Marketing company) – Ceftriaxone 500mg and Tazobactam 62.5mg - (Ceftriaxone sodium & Tazobactam sodium Injection).	Rs. 79.96 per 10ml clear glass vial with 5ml WFI
4(xv)	M/s Lincoln Pharmaceuticals Ltd. (Manufacturer) and M/s Cadila Healthcare Ltd. (Marketing company) – Paracetamol 300mg (as immediate release) and Paracetamol 700mg (as sustained release) – (Paracetamol sustained release 1000mg tablet).	Rs. 3.28 per tablet

4.2 Taking a concerned view on status of compliance in Integrated Pharmaceuticals DataBase Management System (IPDMS), the Authority emphasized the need for coercive action and directed that in all the pending cases of Form-I applications and in case of other applications, proposals for fixation of Retail Price under Para 2(u) will be taken up only after the companies concerned filed all the mandatory forms viz. Form II/III/IV for all their products in IPDMS.

4.3 The Authority also decided that the prior representation on provisional ceiling prices should also be accompanied with IPDMS compliance status report and representations, not supported by IPDMS should not be considered.

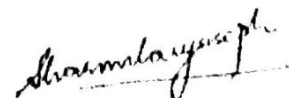
**Additional agenda items circulated during the meeting:-**

**5. Agenda Item no. 5: Minutes of 3<sup>rd</sup> meeting of Committee of Experts under Para 11(3&4) of DPCO 2013 held on 28.12.2016 at 11:00 AM in NPPA.**

5.1 The Authority took note of the minutes of the meeting of Committee of Experts under Para 11(3&4) of DPCO 2013 held on 28.12.2016 at 11:00 AM in NPPA. The Authority advised to include the names of Sh. P.K. Abdul Kareem, Addl. Economic Adviser, Deptt. of Economic Affairs and Sh. Rakesh Pandey, Deputy Director, O/o Chief Adviser Cost (who are already members of Committee of Experts under Para 15 of DPCO 2013) also by co-opting as special members of the Committee of Experts under Para 11(3&4) of DPCO 2013.

**6. Agenda Item no. 6: Price fixation of Coronary Stents under DPCO 2013.**

6.1 The Authority noted the draft calculations which have already been uploaded on the website of NPPA. The Authority further directed to explore various other options too based on the data made available by the different companies and data collected from various Government



agencies. After preliminary discussions on various related issues, the Authority deferred the issue to be discussed in the next meeting of the Authority.

**7. Status of Review orders issued by DOP, which are pending, with NPPA for implementation.**

7.1 The Authority, in order to quickly dispose off the compliance of DOP review orders approved the proposal for notifying the revised ceiling/retail prices in case of review orders, on weekly/fortnightly basis or the period as considered from time to time, after taking the approval of Chairman, NPPA and to place such proposals before the next scheduled Authority meeting for post facto approval.

**Miscellaneous:-**

8. The Authority also directed that a proposal for fixation for ceiling prices of scheduled formulations based on institutional data (wherever market based data is not available) may be put up in the next Authority meeting for consideration and further directions.

9. Moreover, the Authority examined the matter relating to shortage of Penicillamine based formulations and the request of the M/s Panacea Biotech Ltd. for an upward price revision under para 19 of DPCO, 2013 in detail. The Authority observed that the shortage of the formulation occurred due to non-receipt of adequate import quantity of API of Pencillamine mainly from China due to import restrictions. The Authority observed that the shortage was not due to the ceiling price fixation by NPPA under NLEM, 2015, as the price fixation has resulted in minimal reduction of 5.1% only (w.r.t. highest PTR). The Authority also decided to take up with Department of Commerce as well as Ministry of Health and Family Welfare for considering export restrictions in respect of export of API/formulations of Penicillamine, till the shortage of the formulation is sorted out.

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

  
(Dr. Sharmila Mary Joseph K)  
Member Secretary