

मिसिलस.- 8(50)/2017/डी.पी/एनपीपीए-डीवी-II

F. No. 8(50)/2017/DP/NPPA-Div. II

कार्यवाहीस. : 182/50/2017/F

Proceeding No : 182/50/2017/F

Minutes of the 182nd and 50th meeting of Authority under DPCO, 2013 held on 22.11.2017 at 11.00 A.M.

I. The 182nd overall meeting of the Authority, which is the 50th under the DPCO, 2013 was held on 22nd November, 2017 at 11.00 AM under the Chairmanship of Shri Bhupendra Singh, Chairman, NPPA. The following members of the NPPA were present:-

- (i) Shri Rakesh Ranjan, 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 A. K. Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCG(I)).
- (v) Dr. Y.K. Gupta, Head of Department of Pharmacology, AIIMS (Special Invitee)

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) Shri A.P.S. Sawhney, Director (Pricing)
- (iii) Shri Arun Diwan, Dy. Director (O/C)
- (iv) Shri Baljit Singh, Asstt. Director (Pricing)
- (v) Shri Prasenjit Das, Asstt. Director (Pricing)

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 49th Meeting held on 19.9.2017.

1.1 The Authority confirmed the minutes of the overall 181st and the 49th Meeting held on 19.9.2017 under DPCO, 2013.

2. Agenda item no. 2 - Action Taken Report

2.1 Noted.

3.1 Agenda item no. 3(i) - Fixation of Ceiling Prices under NLEM 2015.

3.1.1 The Authority discussed and approved the ceiling prices in respect of following 14 (fourteen) formulations.

S. NO.	NAME OF THE FORMULATION/ COMPOSITIONS	Dosage Form & STRENGTH	Unit for ceiling price	Approved ceiling price under NLEM, 2015 (Rs.)
1	Sevoflurane	Inhalation	1 ml	24.12
2	Acetylsalicylic acid	Tablet 325mg	1 Tablet	0.50
3	Desferrioxamine	Powder for Injection 500mg	Each Pack	145.91
4	Oxaliplatin	Injection 50mg (as licensed)	each pack	2303.01
5	Phytomenadione (Vitamin K1)	Injection 10 mg/ml	1 ML	43.45
6	Glutaraldehyde	Solution 2%	1 ML	0.05868
7	Anti-D immunoglobulin	Injection 300mcg	Each Pack	1936.82
8	BCG vaccine		Each Dose	4.32
9	Oxaliplatin	Injection 100mg (as licensed)	each pack	4055.10
10	Acetylsalicylic acid	Effervescent/ Dispersible/ Enteric coated Tablet 100 mg	1 Tablet	0.1625
11	Japanese encephalitis vaccine	4mcg to 6mcg	Each Pack	632.95
12	Japanese encephalitis vaccine	up to 3mcg	Each Pack	482.22
13	Measles Rubella Vaccine		Each Pack (0.5ml)	80.22
14	Surfactant	Suspension for intratracheal instillation (As licensed)	Per mg of Phosphlipids in the pack	60.69

3.1.2 The draft working sheet of all the above formulations were uploaded on NPPA's website for 10 working days. The following representations were received and considered:

- a) Sevoflurane Inhalation (Sl. No 1): M/s Abbott Ltd filed a representation for sevoflurane Inhalation was considered and the draft ceiling price was revised to Rs. 24.12 from the uploaded draft ceiling price of 23.13.
- b) Desferrioxamine Injection 500mg(Sl. No. 3): M/s Novartis has filed representation against the draft ceiling price as well as the application for upward revision of the Ceiling price citing higher import price for Desferrioxamine Injection 500mg. The committee deliberated on the issue in details and approved the ceiling price at Rs. 145.91 per pack. Their application under para 19 will be considered separately.
- c) Oxaliplatin Injection(Sl. No. 4 & 9): Representation received from some companies for non fixation of price of Oxaliplatin Injection 2mg/ml have been examined and found not tenable. Therefore, there representations have been rejected and prices approved as per draft.
- d) BCG Vaccine (Sl. No. 8): M/s Serum has filed the application for repeat monopoly reduction in the ceiling price of BCG Vaccine and stated that the product will become unviable on reduction. M/s Serum Institute of India Ltd has represented against it. However, as the reduction applied in the draft ceiling price is as per para 6 of the DPCO 2013, the authority decided to notify the uploaded ceiling price of BCG vaccine at Rs. 4.32 per dose. As and when their detail application in para-19 is received, it will considered by the NPPA.
- e) Japanese Encephalitis vaccine (Sl. No. 11 & 12): M/s Biological E Ltd. filed representation asking different price for different strength. The matter was examined in the committee of experts under para 11(3&4) and the committee recommended two categories of strength i.e. Japanese Encephalitis vaccine 4mcg to 6mcg and Japanese Encephalitis vaccine upto 3mcg. The Authority discussed in details and approved the recommendation of the

committee of experts. Accordingly, the ceiling prices for two categories of Japanese Encephalitis vaccine have been fixed.

- f) Measles Rubella vaccine (Sl. No. 13): M/s Serum Institute filed a representation against the draft ceiling price of Rs. 52.75 for MR Vaccine. It was found that the product considered for the same was wrong i.e Rubella only instead of Measles + Rubella. The representation has been accepted based on the document submitted by the company and revised price of Rs.80.22 was approved.
- g) Surfactant (Sl. No. 14): The draft ceiling price of the surfactant was uploaded on the website of the NPPA on the per ml. M/s Paviour filed a representation stating the concentration. The matter was referred to the committee of experts and it was recommended to fix the ceiling on per mg of phospholipids in the pack. Further representation of M/s Abbot and M/s Paviour have also been examined on the revised draft ceiling price and found contradictory and not tenable. The Authority discussed the matter in details and decided to approve the recommendation of the expert committee to fix the ceiling price based on the per mg content of phospholipids in the pack. Accordingly, the ceiling price of Surfactant suspension for intratracheal instillation is fixed at Rs. 60.69 per mg of phospholipids.

3.2 Agenda item no. 3(ii) - Fixation of ceiling Prices on the basis of the Market based data from the alternative sources

3.2.1 The Authority examined the draft ceiling price fixation of 14(fourteen) formulations which was worked out by adding sixteen percent trade margin on the procurement price of various Government agencies. After detailed discussions and keeping in mind the extraordinary situation of non-availability of market data and the essentiality of these drugs to be made affordable in public interest, the Authority decided to fix state institutional procurement price as ceiling price without adding any further trade margin as institutional procurement price is inclusive of all margins by invoking the government jurisdiction under Para 19 of the DPCO 2013. The Authority approved the ceiling price as detailed below:

S. NO.	NAME OF THE FORMULATION/ COMPOSITIONS	Dosage Form & STRENGTH	Unit for ceiling price	Proposed ceiling price under NLEM, 2015 (Rs.)
1	Lignocaine (A) + Adrenaline (B)	Injection 1% (A) + 1:200000 (5 mcg/ml) (B)	1 ML	0.41
2	Calcium gluconate	Injection 100 mg/ml	1 ML	0.50
3	Dextran-40	Injection 10%	1 ML	0.38
4	Coagulation factor IX	Powder for Injection 600 IU	Each Pack	11180.00
5	Digoxin	Oral liquid 0.05 mg/ml	1ML	0.29
6	Potassium permanganate	Crystals for topical solution	1 gm	0.40
7	Pilocarpine	Drops 4%	1 ML	10.6
8	Morphine	SR Tablet 30 mg	1 Tablet	4.94
9	Alteplase	Powder for Injection 20 mg	Each pack	17235
10	Alteplase	Powder for Injection 50 mg	Each pack	35985
11	Gadobenate	Injection 529 mg/ml	1 ML	98.90
12	Haemodialysis fluid	As license	1 ML	0.03695
13	Furosemide	Oral liquid 10 mg/ml	1 ML	0.29
14	Glucose	Injection 50%	1 ML	0.44

3.2.2. The draft working sheet of all the above formulations were uploaded on NPPA's website for 10 working days. The following representations were received and considered:

- a) Dextron 40 Injection 10% (Sl. No. 3): The draft ceiling price of the Dextran-40 Injection 10% was fixed on the basis of the Institutional prices. M/s Otsuka filed a representation stating the high PTR. However, the company failed to provide the supporting documents, therefore, their representation was rejected.

- b) Coagulation factor IX (Sl. No. 4): The draft ceiling price of the Coagulation factor IX was uploaded on the website of the NPPA based on Institutional price of Rs. 11,180. M/s Baxalta filed representation that they have high PTR of Rs. 12,400. However, complete documents were not submitted. The ceiling price based on the Institutional prices was approved.
- c) The Authority deliberated on the ceiling price of potassium permanganate (sl. no 6) in details and decided to restrict the ceiling price presently available at Rs. 0.40 per gm.

3.2.3. The Committee has directed pricing division to provide the copy of list of 99 pending formulation to Ministry of Health and family welfare, for which the ceiling price cannot be fixed due to non availability of data from Pharma Trac as well institutional data in order to find out the way to fix the ceiling price and the essentiality of these drugs. Authority also decided, if no more essential, NPPA should request Ministry of Health and Family welfare to replace these formulations with other drugs suggested by the NPPA with exorbitant trade margins.

4.1 Agenda item no. 4 (i) - Status of New Drug application

4.1 Noted.

4.2 Agenda item no. 4 (ii) - Retail Price fixation of formulation containing Sofosbuvir 400mg and Velpatasvir 100mg for price fixation

4.2.1 The Authority examined the retail price fixation of the companies in details and approved the recommendations of the expert committee as detailed below:

SOFOSBUVIR + VELPATASVIR 400mg+100mg		28 tablet pack		
Name of the applicant/Marketer (M/s)	Manufactures (M/s)	Price claimed/ MRP	Less GST @ 12%	Price approved (excluding GST)
Abbott India Ltd	Hetero Labs Ltd	17500	15625	15625
Cadila Healthcare Ltd	Hetero Labs Ltd	18500	16518	15625
Natco Pharma Ltd	Sun Pharmaceuticals Industries Ltd	18500	16518	15625
Natco Pharma Ltd	Cipla Ltd	18500	16518	15625
Natco Pharma Ltd	Natco Pharma Ltd	18500	16518	15625
Natco Pharma Ltd	Mylan Pharmaceuticals Pvt.Ltd.	18500	16518	15625
Herto Labs Ltd	Hetero Labs Ltd. (suo motto)	17619	15731	15625
Dr. Reddy Limited	Dr. Reddy Limited (suo motto)	18500	16518	15625

4.3 Agenda item no. 4.3 - Fixation of the Retail price for the 'Without Price Approval' (WPA) referred by the M&E Division.

4.3.1 The Authority examined the fixation of retail price for the Without Price Approval' (WPA) referred by the M&E Division in details and approved the retail price as detailed below:

Sl. No.	Name of the Scheduled Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Voglibose + Metformin	Each tablet contains: Voglibose 0.2mg	1 Tablet	M/s Lupin Ltd.	4.84

		Metformin 500mg			
2.	Voglibose + Metformin	Each tablet contains: Voglibose 0.3mg Metformin 500mg	1 Tablet	M/s Lupin Ltd.	5.76
3.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.2mg Metformin 500mg Glimepirid 1mg	1 Tablet	M/s Lupin Ltd.	7.14
4.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.2mg Metformin 500mg Glimepirid 1mg	1 Tablet	M/s Sanofi India Ltd.	7.14
5.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.2mg Metformin 500mg Glimepirid 1mg	1 Tablet	M/s Biocon Ltd.	7.14
6.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.2mg Metformin 500mg Glimepirid 2mg	1 Tablet	M/s Lupin Ltd.	9.05
7.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.2mg Metformin 500mg Glimepirid 2mg	1 Tablet	M/s Sanofi India Ltd.	9.05
8.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.2mg Metformin 500mg Glimepirid 2mg	1 Tablet	M/s Biocon Ltd.	9.05
9.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.3mg Metformin 500mg Glimepirid 1mg	1 Tablet	M/s Lupin Ltd.	8.52
10.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.3mg Metformin 500mg Glimepirid 1mg	1 Tablet	M/s Alembic Ltd.	8.52
11.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.3mg Metformin 500mg Glimepirid 2mg	1 Tablet	M/s Lupin Ltd.	10.46
12.	Diclofenac + Tramadol	Each tablet contains: Diclofenac 75mg Tramadol 50mg	1 Tablet	M/s Alembic Ltd.	9.73

5. Agenda item no. 5 - Summary of implementation of review orders put up for the consideration of the Authority.

5.1 The Authority examined the review orders in details and implemented the review orders as detailed below:

Sl. No.	Review order no. and date	Petitioner Company	Formulation	Presently notified ceiling/re tail price	Approved ceiling/retail price on the basis of review order
1	31015/59/2017- Pricing dated 10.10.2017	Alkem Laboratories Ltd	Ceftriaxone PFI 1gm.	Rs. 46.74 per pack	Rs. 48.92 per pack
2	31015/32/2017-	IPCA	Chloroquine 150 mg	Rs. 0.60	Rs. 0.72 per tablet

	Pricing dated 24.8.2017	Laboratories Ltd	tablet	per tablet	
3	31015/09/2017- Pricing dated 27.08.2017	Sun Pharmaceutical Industries Ltd	Trypsin48 mg + Bromelain 90 mg + Rutoside Trihydrate BP 100 mg + Diclofenac Sodium IP 50mg tablet	Rs. 14.44 per tablet including GST	Rs.13.91 excluding GST
4	31015/13/2017- Pricing dated 24.8.2017	Sun Pharma Laboratories Ltd	Methylprednisolone 40mg/ml injection	Rs. 43.55 per ml	Rs. 43.55 per ml
	31015/11/2017- Pricing dated 28.9.2017	Neon Laboratories Ltd			
5	31015/102/2016- P.I.I dated 24.8.2017	Sun Pharma Laboratories Ltd	Propranolol 40mg capsules	Rs. 3.45 per capsule	No change

5.2 The Authority deliberated in details on the review orders issued by the Department of Pharmaceuticals relating to retail price fixation principles followed by the Authority and decided to implement the review orders as per the directions given by the reviewing authority.

6. Agenda item no. 6 - Price fixation of Condom

6.1 The Committee deliberated the issue in details and decided that the ceiling price of condoms will be fixed in two broad categories i.e. ordinary condoms and condoms with special features.

7. Agenda item no. 7 - Status of the para 19 application for upward price revision

7.1 The Authority directed Pricing Division to place the applications received for price revision under para 19 after examination in the next Authority Meeting.

8. Agenda item no. 8 - Agenda note in respect of discontinuation of 6 formulations by M/s FDC Limited [1.Synplatt 75 Tablets (Clopidogrel - 75 mg), 2. Vasomet XL 25 Tablet (Metoprolol 25 mg), 3. Vasomet XL 50 Tablet (Metoprolol 50 mg), 4. Vorast -2 Injection (Ondansetron 2 mg), 5. Vorast - 4MD Tablet (Ondansetron 4 mg), 6.Vorast Syrup 30 ml (Ondansetron 2 mg)] Under para 21 (2) of DPCO, 2013.

8.1 Approved.

9. Agenda item no. 9 - Agenda note in respect of proposed addition in the Guidelines for discontinuation of scheduled formulations

9.1 After detailed deliberations, Authority decided to approve addition of following Para to the guidelines :

“Exemption from any condition prescribed in the Guidelines for allowing discontinuation of scheduled formulations may be required in cases of unforeseen situation which is beyond the control of manufacturers/importers e.g., cases in which import license gets expired or marketing/distribution agreement between the manufacturer/importer and marketing company gets terminated prior to period of six/nine/twelve months (under Para 4.1 / 4.2 / 4.3 respectively) for which Company is asked to continue production/import from the intended date of discontinuation. Such exemption may be approved by the Authority for

cases falling under Para 4.3 / 4.4 of the Guidelines and by Chairman, NPPA for cases falling under Para 4.1 / 4.2 of the Guidelines.”

10. Agenda item no. 10 - Pendency Status of requests for withdrawal of drugs as on 20.11.2017.

10.1 Noted

11. Agenda item no. 11 - Status of non-availability of drugs cases and the action taken in these cases.

11.1 Noted.

12. Agenda item no. 12 Agenda note in respect of discontinuation of 4 formulations by M/s Baxter (India) Pvt. Ltd. [1. Glucose 5% 500 ml (Dextrose 5% 500 ml), 2. Dextrose 5% with NS 0.9% 500 ml (Dextrose with NS/DNS Infusion 500 ml), 3. Inj. Ringer Lactate 500 ml, 4. Inj NS 0.45% 500ml (Inj. 0.45% Sodium Chloride 500ml)] under para 21 (2) of DPCO, 2013.

12.1 After detailed deliberations, Authority decided to approve the request for discontinuation of 4 formulations subject to the condition that company will issue a public notice in atleast two national newspapers in the specified format, continue to manufacture/import and sell the drug for a period of twelve months from the intended date of discontinuation or date of public notice (whichever is later) and will not reduce the level of production by more than 25% of last year's production in each quarter.

13. Agenda item no. 13 - Agenda on status of IPDMS

13.1 Noted.

14. Agenda item no. 14 - Agenda on status regarding launch of drugs without price approval (WPA)

14.1 Authority suggested monitoring and enforcement division to issue clear guidelines for disposing off these WPA cases and put it in public domain.

15. Agenda item no . 15 - Agenda on status of overcharging as on 31.10.2017

15.1 Noted.

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


(Rakesh Ranjan)
Member Secretary