गोपनीय: Confidential

मिसिलस.- 8(49)/2017/डी.पी/एनपीपीए-डीवी-II

F. No. 8(49)/2017/DP/NPPA-Div. II

कार्यवाहीस. : 181/49/2017/F
Proceeding No : 181/49/2017/F

Minutes of the 181st and 49th meeting of Authority under DPCO, 2013 held on 19.9.2017 at 11.00 A.M.

I. 1. The 181st overall meeting of the Authority, which is the 49th under the DPCO, 2013 was held on 19th September, 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 A. K. Gautam, Addl. Chief Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
(iii) Shri Arun Kumar, Adviser, Deptt. of Economic Affairs, Ministry of Finance.
(iv) Shri R. Chadrashekhar, 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.)
(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 48th Meeting held on 10.8.2017.

1.1 The Authority confirmed the minutes of the overall 180th and the 48th Meeting held on 10.8.2017 and continued on 14.08.2017 under DPCO, 2013.

2. Agenda item no. 2: Action Taken Report

2.1 Noted.

2.2. The Authority deliberated the section wise list of NLEM 2015 drugs pending for ceiling Price fixation for want of market data and directed as follows:

a. To write letters and make efforts at the level of AIIMS, New Delhi, RML Hospital, New Delhi and Safdarjung Hospital, New Delhi to get procurement/tender rates at

which these Hospitals are procuring medicines from manufacturer / importer alongwith their name.

b. Pricing Division to forward the section wise list of NLEM 2015 drugs pending for ceiling Price fixation for want of market data to Ministry of Health and Family Welfare and DCGI/CDSCO for their comments/inputs regarding the essentiality of these drugs.

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

3.1.1 The Authority discussed and approved the ceiling prices in respect of following 13 (thirteen) formulations.

S. NO.	NAME OF THE FORMULATION/ COMPOSITIONS	Dosage Form & STRENGTH	Unit for ceiling price	Approved ceiling price under NLEM, 2015 (Rs.)
1	Isoniazid	Tablet 100mg	1 Tablet	0.62
2	Actinomycin D	Powder for Injection 0.5mg	Each Pack	287.76
3	Ifosfamide	Powder for Injection 1g	Each Pack	328.33
4	Vinblastine	Injection 1mg/ml	1 ML	18.62
5	Silver sulphadiazine	Cream 1%	1 gm	0.27
6	Measles vaccine	Vaccine	Each Pack (0.5ml)	46.27
7	Rifabutin	Capsule 150mg	1 Capsule	35.99
8	Fluconazole	Oral Liquid 50mg/5ml	1 ML	2.28
9	Sumatriptan	Tablet 25mg	1 Tablet	30.21
10	Sumatriptan	Tablet 50mg	1 Tablet	46.76
11	Iohexol	Injection 300mg iodine/ml	1 ML	15.08
12	Hepatitis B immunoglobulin		Each Pack	4998.20
13	Isoniazid	Tablet 300mg	1 Tablet	1.08

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

Sl No	Formulation with dosage form and strength	Name of manufacturer, who represented	Impact after due consideration of the Representation.
1	Fluconazole Oral Liquid 50mg/5ml	M/s Cipla Ltd.	No Change in price as representation was not relevant.
2	Rifabutin Capsule 150mg	M/s Lupin Ltd.	Price Change from Rs 35.74(draft uploaded) to Rs. 35.99 per capsule.
3	Sumatriptan Tablet 50mg	M/s Sun Pharmaceuticals Ltd.	Price Change from Rs 43.94(draft uploaded) to Rs. 46.76 per tablet.
4	Sumatriptan Tablet 25mg	M/s Sun Pharmaceuticals Ltd.	No Price Change after considering representation.
5	Isoniazid Tablet 300mg	M/s Pfizer Ltd	Representation accepted but no change in the price.
6	Measles vaccine	Ms/ Serum Institute of India Ltd.	Representation of Measles Vaccine is found not relevant and hence not accepted.

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 24(twenty four) formulations which was worked out by adding sixteen percent trade margin on the procurement price of various Government agencies. After detailed discussions and deliberation on the issue, 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. It has been found that institutional prices are substantially higher in comparison to NPPA's ceiling prices in several cases in the past. The Authority approved the ceiling price as detailed below:

S. No.	NAME OF THE FORMULATION/ COMPOSITIONS	Dosage Form & STRENGTH	Unit for ceiling price	Approved Ceiling price
1	Cloxacillin	Powder for Injection250mg	Each Pack	4.03
2	Griseofulvin	Tablet 125mg	1 Tablet	0.74
3	Diloxanide furoate	Tablet 500 mg	1 Tablet	0.96
4	Glycerin	Oral Liquid	1 ML	0.13599
5	Chlorhexidine	Solution 5% (Concentrate for dilution)	1 ML	0.14194
6	Hydrogen peroxide	Solution 6%	1 ML	0.03634
7	Mannitol	Injection 10%	1 ML	0.14626
8	Dicyclomine	Tablet 10mg	1 Tablet	0.09955
9	Anti-tetanus immunoglobulin		Each Pack	748.06
10	Diphtheria antitoxin	10000 IU	Each Pack	1189.22
11	Pyridoxine	Tablet 10mg	1 Tablet	0.10491
12	Vitamin A	Capsule 50000 IU	1 Capsule	0.5
13	Ascorbic acid (Vitamin C)	Tablet 100 mg	1 Tablet	0.17603
14	Artesunate (A) + Sulphadoxine - Pyrimethamine (B)	Tablet 100 mg (A) + 1 Tablet (750 mg + 37.5 mg) (B)	Combi pack	26.77
15	Artesunate (A) + Sulphadoxine - Pyrimethamine (B)	Tablet 150 mg (A) + 2 Tablet (500 mg + 25 mg) (B)	Combi pack	36.34
16	Artesunate (A) + Sulphadoxine - Pyrimethamine (B)	Tablet 200 mg (A) + 2 Tablet (750 mg + 37.5 mg) (B)	Combi pack	33.13
17	Artesunate (A) + Sulphadoxine - Pyrimethamine (B)	Tablet 25 mg (A) + 1 Tablet (250 mg + 12.5 mg) (B)	Combi pack	17.84
18	Acetylsalicylic acid	Tablet 350mg	1 Tablet	0.28
19	Ferrous salt (A) + Folic acid (B)	Oral liqiud 20mg elemental iron (A) + 100mcg (B)/ml	1 ML	0.12074
20	Ferrous salt (A) + Folic acid (B)	Tablet 100 mg elemental iron (A) + 500 mcg (B)	1 Tablet	0.09821
21	Ferrous salt (A) + Folic acid (B)	Tablet 45mg elemental iron (A) + 400 mcg (B)	1 Tablet	0.12755
22	White Petrolatum	Jelly 100%	1 GM	0.0843
23	Dicyclomine	Oral Solution 10mg/5ml	1 ML	0.15089
24	Vitamin A	Oral liquid 100000 IU/ml	1 ML	0.47

4. Agenda Item no. 4 (i): Approval for Retail Price of Rabishield Rabies Human Monoclonal Antibody (rDNA) in 250IU(2.5ml) and 100IU(2.5ml) pack of M/s Serum Institute of India Ltd

The Authority examined the retail price fixation of Rabishield Rabies Human Monoclonal Antibody (rDNA) in 250IU(2.5ml) and 100IU(2.5ml) pack of M/s Serum Institute of India Ltd. After detailed discussion, the Authority decided to approve the retail price at 20% lesser than the therapeutic benchmarked price of Human Rabies Immunoglobin fixed under NLEM, 2015. Accordingly, the approved retail prices are as follows:

a.	Rabisheild (250 IU) i.e 2.5 ml of 100IU/ml	:	Rs. 20139.20 each pack.
b.	Rabisheild (100 IU) i.e 2.5 ml of 40IU/ml	:	Rs. 8055.68 each pack.

5 Discontinuation request of M/s Boston Scientific India Pvt Ltd for (i) Promus PREMIER Everolimus Eluting Coronary Stent and (ii) SYNERGY monorail Everolimus Eluting PtCr Coronary Stent System with Biodegradable Polymer

5.1 The Authority deliberated and decided that NPPA, in any case, shall revisit the pricing of cardiac stents before February 13, 2018. It further noted that the company has submitted two applications one for withdrawal and the other for price revision, both cannot be considered simultaneously. The company may be directed to forward one request by withdrawing the other request and till then both the request may be kept in abeyance.

6 Discontinuation request of M/s Abbott Healthcare Private Limited for Xience Alpine and Absorb

6.1 Discontinuation request of M/s Abbott Healthcare Private Limited for Xience Alpine stent

6.1.1 The Authority, after examining the legal status of the application and taking into account the fact that Department of Pharmaceuticals has not accepted the request of NPPA to exercise Government powers under Para (3) of the DPCO, 2013 and extend the restriction on the stent manufacturers from withdrawing, NPPA is left with no option but to allow formal withdrawal as per the provisions of Para 21(2) of DPCO, 2013.

6.1.2 The Authority, accordingly, examined the whole issue and found that the import cost of Alpine brand is less than the ceiling price and adequate margins are there, so the reason of unviability of sales in India is not understandable. It was also found that these brands have a sizable market share and its withdrawal will create sudden shortage of stents which will not be in the interest of public health safety. Considering all the issues and availability of other brands in the country and in order to ensure adequate supplies of life saving medical device like stent, Authority decided to invoke the public interest clause under Para 21(2) to allow the complete withdrawal of Xience Alpine brand by the applicant company in a period of one year from the date of issue of public notice.

6.1.3 The Authority decided that the company be also directed to continue to maintain uninterrupted supply of Xience Alpine stent for a period of first six months at the level of average of total imports in the last three months (June to August, 2017) from the date of issue of the public notice. From the seventh month, however, the manufacturer may start reducing supplies of stents of this brand @ 15% every month for another five months and at the end of twelfth month, it can withdraw the same by hundred per cent.

6.2 Discontinuation request of M/s Abbott Helathcare Private Limited for Absorb and Absorb GT1 brands of Bioresorbable Vascular Scaffold

6.2.1 The Authority took note of the company's assertion that it is stopping the manufacturing and doing global withdrawal of these brands based on "low commercial uptake". This was being reflected in the sale figures of these brands in India.

6.2.2 The Authority, however, taking more specific note of the issue of global safety concerns of enhanced adverse cardiac activity including increased level of thrombosis' already raised by USFDA, EU, TGA-Government of Australia and also in India decided to approve and allow immediate withdrawal of Absorb and Absorb GT1 brands of coronary stents of the company under exceptional circumstances and by relaxing the mandatory period of six months prior intimation under Para 21(2) of DPCO, 2013 in public interest. The Authority took note of the fact that the safety concern is the prime reason behind low commercial global sales of these brands.

6.2.3 The Authority, however, decided to direct Abbott to continue to follow up implanted patients in existing Absorb clinical trials and attend to all follow up issues arising in the cases under trial as well as others who have got the device implanted in India in the same manner as it has been asked to do by the US and European Federal Drug Regulators apart from instructions by DCGI.

7. Agenda No. 7. Status of review Orders issued by DOP for implementation by NPPA

7.1 Noted.

8. Agenda No. 8 Status of pending Form-I application of New Drug

8.1 The Authority examined the issue in details and directed as follows:

a) The 39 Form-I application as per Annexure-I which are pending due to incomplete documents/ information be rejected and uploaded on NPPA's website. The original application to be returned to companies.
b) The status of 92 form I applications as per annexure II may also be uploaded on NPPA website.
c) All the form I application received after 19.07.2017 as per Annexure III shall be examined in 15 working days time and wherever the applications are incomplete due to documents/information shall be rejected and returned in original to respective companies.
d) All the form I application received henceforth would be examined in the next 10 working days and wherever the form I applications are incomplete, the application will be sent back to the applicant company with the check list clearly bringing out the documents/information not provided.
e) The compliance of IPDMS filing shall be strictly enforced.
f) Complete application with IPDMS compliance shall be approved within 60 days as far as possible.

9. Agenda No. 9. Pendency Status of requests for withdrawal of drugs as on 15.9.2017

9.1 Noted.

10 Agenda No. 10. Agenda note in respect of proposed change in provision of Guidelines for discontinuation of scheduled formulations and O.M. dated 01.02.2017 (regarding IPDMS compliance) to exclude the 100% compliance requirement of Form-II submission in IPDMS for processing Applications (Form-IV) for discontinuation of Scheduled formulations

10.1 The issue of discontinuation of scheduled formulations was deliberated in detail. It was noted that large number of Form-IV applications for discontinuation of scheduled formulations are pending / withheld due to non-compliance of IPDMS or pending Overcharging cases against the applicant Companies as provided in the para 4.7 & 4.8 of the existing Guidelines dated 23.01.2017 and O.M. dated 1.2.2017.

10.2 It was decided, after detailed deliberation on the utility vs futility of the provision, to delink IPDMS compliance and Overcharging cases for processing / approval of Form-IV applications of Companies for discontinuation of scheduled formulations. The authority further decided that Form-IV applications would be processed as per other provisions in the existing Guidelines on market share etc.

11 Agenda No. 11. Status of non-availability of drugs cases and the actions taken in these cases

11.1 Noted.

12.1 Agenda No 12A. Launching of new drugs without price approval

12.1.1 The authority deliberated on the issue and it was brought to the notice of the Authority that in many WPA cases, it was observed that these formulations may not have been approved by DCG(I) as per the list available in DCG(I) website. The Authority directed the matter to be taken up on priority with MoHFW and DCG(I) for examination at their end as it appears that these FDCs are launched without required FDC approvals/manufacturing permission from DCG(I).

12.2 Agenda No. 12B. IPDMS Status

12.2.1 Noted.

13 Agenda No. 13. Calculation of interest in processing of overcharging cases

13.1 The Authority deliberated and decided that NPPA shall continue with the policy of charging interest from the date of overcharging.

14. Agenda No. 14 Status of overcharging cases

14.1 Noted.

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

(Rakesh Ranjan)
Member Secretary