

मिसिलस.- 8(33)/2016/डी.पी./एनपीपीए -डीवी-II

F. No. 8(33)/2016/DP/NPPA-Div. II

कार्यवाहीस. : 165/33/2016/F

Proceeding No : 165/33/2016/F

Minutes of the 165th and 33rd meeting of Authority under DPCO, 2013 held on 23.6.2016 at 11.00 AM.

1. The 165th overall meeting of the Authority, which is the 33rd under the DPCO, 2013 was held on 23 June, 2016 at 11.00 AM 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 Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iii) Shri R.Chandrashekhar, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCGI)

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

- 1) Shri A.P.S. Sawhney, Director (Overcharging/Pricing)
- 2) Smt. Roshni Sohni, Director (M&E/Admn.)
- 3) Shri Presentjit Das, Asstt. Director (Pricing)
- 4) Shri Baljit Singh, Asstt. Director (Pricing)
- 5) 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 32nd Meeting held on 02.6.2016 and 03.06.2016

The Authority confirmed the minutes of the meeting with the following modification.

"The Authority discussed the pack-wise fixation of ceiling price of Gentamicin Injection, Dexamethasone Injection, Paracetamol Injection and Tetanus Toxoid Injection which was deferred from the meeting dated 02-06-2016. After deliberations, the Authority decided not to fix the pack-wise ceiling price for these formulations. Accordingly Agenda Item 3 is not approved"

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 on 42 formulations and approved the ceiling prices in respect of all the following 42 formulations.

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Sl. No.	Section of NLEM No.	Medicines	Dosage form and Strength	Unit for Ceiling Price	Ceiling price NLEM 2015
1	2.2.3	Tramadol	Capsule 50 mg	Per Capsule	4.2
2	2.4.3	Leflunomide	Tablet 10 mg	Per Tablet	9.3
3	2.4.3	Leflunomide	Tablet 20 mg	Per Tablet	18.13
4	2.4.4	Methotrexate	Tablet 10 mg	Per Tablet	10.81
5	2.4.4	Methotrexate	Tablet 7.5 mg	Per Tablet	10.32
6	3.7	Prednisolone	Tablet 20 mg	Per Tablet	1.81
7	5.1	Carbamazepine	Tablet 200 mg	Per Tablet	1.28
8	5.7	Phenobarbitone	Tablet 30 mg	Per Tablet	1.12
9	5.9	Sodium valproate	Tablet 200 mg	Per Tablet	2.75
10	5.9	Sodium valproate	Tablet 500 mg	Per Tablet	6.43
11	6.1.1.1	Albendazole	Tablet 400 mg	Per Tablet	7.15
12	6.1.2.1	Diethylcarbamazine	Tablet 50 mg	Per Tablet	0.5
13	6.2.2.7	Metronidazole	Tablet 200 mg	Per Tablet	0.4
14	6.2.4.11	Pyrazinamide	Tablet 500 mg	Per Tablet	3.77
15	6.2.4.11	Pyrazinamide	Tablet 750 mg	Per Tablet	5.73
16	6.2.4.11	Pyrazinamide	Tablet 1000 mg	Per Tablet	8.39
17	6.2.4.3	Ethambutol	Tablet 800 mg	Per Tablet	3.77
18	6.3.3	Fluconazole	Tablet 200 mg	Per Tablet	17.43
19	6.3.4	Griseofulvin	Tablet 250 mg	Per Tablet	1.48
20	6.4.1.1	Acyclovir	Tablet 200 mg	Per Tablet	6.29
21	6.4.1.1	Acyclovir	Tablet 400 mg	Per Tablet	11.42
22	6.5.3.1.7	Quinine	Tablet 300 mg	Per Tablet	5.09
23	6.5.3.2.1	Mefloquine	Tablet 250 mg	Per Tablet	47.31
24	7.2.2	Propranolol	Tablet 10 mg	Per Tablet	1.07
25	8.1.27	Methotrexate	Tablet 2.5 mg	Per Tablet	4.26
26	8.3.2	Cyclosporine	Capsule 100 mg	Per Capsule	91.21
27	8.3.2	Cyclosporine	Capsule 50 mg	Per Capsule	46.85
28	8.4.13	Ondansetron	Tablet 8 mg	Per Tablet	9.06
29	8.4.2	Amitriptyline	Tablet 25 mg	Per Tablet	2.1
30	8.4.6	Fluoxetine	Capsule 20 mg	Per Capsule	3.38
31	10.2.6	Warfarin	Tablet 5 mg	Per Tablet	2.2
32	12.1.3	Diltiazem	Tablet 30 mg	Per Tablet	2.23
33	12.1.3	Diltiazem	Tablet 60 mg	Per Tablet	4.53
34	12.2.2	Amiodarone	Tablet 100 mg	Per Tablet	5.3
35	12.3.1	Amlodipine	Tablet 2.5 mg	Per Tablet	1.53
36	12.3.2	Atenolol	Tablet 50 mg	Per Tablet	1.66
37	12.3.3	Enalapril	Tablet 2.5 mg	Per Tablet	1.78

38	12.3.3	Enalapril	Tablet 5 mg	Per Tablet	2.97
39	20.2.1	Domperidone	Tablet 10 mg	Per Tablet	2.24
40	21.6.1	Medroxyprogesteroneacetate	Tablet 10 mg	Per Tablet	4.99
41	26.2.2	Nifedipine	Tablet 10 mg	Per Tablet	1.15
42	28.1.5	Salbutamol	Tablet 4 mg	Per Tablet	0.17

3.2 Further, it was discussed and decided that any earlier order issued regarding retail price(s) or ceiling price(s) for such formulations, if any, will be superseded by the new price order(s) by notification.

4. Agenda Item no. 6: Fixation of retail price in respect of new drugs.

4.1 The Authority discussed the following 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, as under:

S. No.	Company name/Product name	Approved Price (Rs.)
4(i)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Sun Pharmaceuticals Industries Ltd. (Marketing company) – Diclofenac sodium 75mg – (volitra AQ injection).	Rs. 14.30/ml
4(ii)	M/s Swiss Garnier Genexiaa Sciences (Manufacturer) and M/s Indoco Remedies Pvt. Ltd. (marketing company) – Metformin 500mg and Gliclazide 60g – (Glychek M OD 60 tablet).	Rs. 79.80/pack
4(iii)	M/s Samson Lab. Pvt. Ltd. (Manufacturer) and M/s Galpha Lab. Ltd. (Marketing company) – Albendazole 400mg and Ivermectin 6mg – (Zenebend Plus Tablet).	Rs. 15.20/tablet
4(iv)	M/s Malik Lifescience Pvt. Ltd. (Manufacturer) and M/s FDC Ltd. (Marketing company) – Moxifloxacin HCL eq. to Moxifloxacin 400mg and Cefixime (as trihydrate) eq. to anhydrous cefixime 400mg – (Zifi-Max tablet).	Rs. 34.46/tablet
4(v)	M/s Meridian enterprises Pvt. Ltd. (Manufacturer as well as marketing company) – Dicyclomine HCl 20mg – (Dicyclomine HCl 20mg tablet).	Rs. 0.85/tablet
4(vi)	M/s Windlas Biotech Ltd. (Manufacturer) and M/s Intas Phrmaceuticals Ltd. (Marketing company) – Rabeprazole sodium 40mg and Domperidone 30mg – (Rabeprazole sodium 40mg & Domperidone (SR) 30mg capsules).	Rs. 7.19/capsule
4(vii)	M/s Swiss Garnier Genexiaa Sciences (Manufacturer) and M/s Indoco Remedies Pvt. Ltd. (marketing company) – Metformin 500mg and Gliclazide 30g – (Glychek M OD 30 tablet).	Rs. 4.96/tablet
4(viii)	M/s Cadila Phamaceuticals Ltd. (Manufacturer as well as marketing company) – Clindamycin 1% w/v and Hydrous Benzoyl Peroxide 2.5% w/w – (Clindamycin % and Hydrous Benzoyl Peroxide 2.5% Gel)	Rs. 13.31/gm
4(ix)	M/s Sunglow Pharmaceuticals Pvt. Ltd. (Manufacturer) and M/s Indoco Remedices Pvt. Ltd. (marketing company) – Tramadol HCl 50mg and Diclofenac sodium 75mg (SR) –	Rs. 10.08/tablet

	(Dolinsta tablet).	
4(x)	M/s Windlas Biotech Ltd. (Manufacturer) and M/s Glenmark Pharmaceuticals Ltd. (Marketing company) – Telmisartan 40mg and Indapamide 1.5mg tablet - (Telma D tablet).	Rs. 8.84/tablet
4(xi)	M/s Eurolife Healthcare Pvt. Ltd. (Manufacturer) and M/s Lupin Ltd. (marketing company) – Paracetamol 1g – (Paralup IV injection).	Rs. 206.00/100ml injection
4(xii)	M/s Windlas Biotech Ltd. (Manufacturer) and M/s Glenmark Pharmaceuticals Ltd. – Telmisartan 40mg and Nebivolol 5mg) – (Telma NB tablet).	Rs. 11.04/tablet

5. Representation for Price revision of 'Premix Insulin (30:70)', Insulin (Soluble) Injection, Intermediate Acting (NPH), Insulin Injection notified vide S.O. No. 1816(E) dated 18.05.2016.

The Authority discussed the proposal in detail and approved the revised ceiling price as under:

NLEM	Formulation	Ceiling price	Unit for Ceiling Price	CP fixed as per S.O. No. 1816(E) dtd 18.05.2016	Revised CP proposed
21.4.1.5	Premix Insulin (30:70) (Regular : NPH) Injection	Injection 40 IU/ml	Per ml	13.34	13.40
21.4.1.2	Insulin (Soluble) Injection	Injection 40 IU/ml	Per ml	13.34	13.40
21.4.1.3	Intermediate Acting (NPH) Insulin Injection	Injection 40 IU/ml	Per ml	13.34	13.40

The Authority approved the revision of ceiling prices as tabulated above.

6. Agenda note in respect of discontinuation of (i) Herpikind 200 tablet (Acyclovir) and Metrokind PV ointment 5% w/w (Povidone Iodine ointment) under para 21 (2) of DPCO, 2013 by M/s Lifestar Pharma Pvt. Ltd. (A Mankind group co.)

6.1 These two cases were approved. It was decided that the company may be granted no objection for gradual discontinuation under para 21(2) of DPCO, 2013. The company may be advised to continue the manufacture / import and sale of (i) Herpikind 200 tablet and (ii) Metrokind PV ointment 5% w/w during the next one year and then gradually discontinue the same.

7. Agenda for Revision of the ceiling prices fixed for following IV Fluids- Sodium Chloride 0.9%, Glucose 5%, Glucose 5% + Sodium Chloride 0.9% and admissibility of the Ceiling prices for packaging with special features.

7.1 NPPA fixed the Ceiling Prices of Sodium Chloride 0.9%, Glucose 5%, Glucose 5% + Sodium Chloride 0.9% in the Authority Meeting dated 02-06-2016 (continued to 03-06-2016). NPPA fixed these Ceiling Prices based on pack-size and packing material and special features (Glass, PVC and Non-PVC). Accordingly NPPA issued notification S.O.1993(E) dated 03-Jun-2016 based on methodology explained in meetings held on 2nd and 3rd June, 2016.

S. No.	Name of Formulation	Pack Size (ml)	Existing Ceiling Price under DPCO, 2013 (NLEM, 2011) vide SO 644(E) dated 02.3.2016 (Rs.)	Approved Ceiling Price under DPCO, 2013 (NLEM, 2015) (Rs.) (as notified on 3 June, 2016)		
				Glass	PVC	Non-PVC (with special features)
1	Sodium Chloride [Normal Saline (NS)] 0.9%	100	(@ Rs.0.09685/ml) Rs. 8.69	13.06	11.36	31.35
		250	Rs. 21.71	15.18*	17.49	46.28
		500	Rs. 43.43	24.50	20.41	65.55
		1000	Rs. 86.86	32.26*	37.75	73.41
2	Glucose[Dextrose (D5)] 5%	100	(@ Rs. 0.06513/ml) Rs. 6.51	10.84*	12.00*	—
		250	Rs. 16.282	15.33*	18.33	—
		500	Rs. 32.57	25.23	22.45	61.32
		1000	Rs. 65.13	32.25*	38.94	70.88
3	Glucose 5%+ Sodium chloride 0.9% [Dextrose 5% + Normal Saline 0.9%] (DNS)	100	(@ Rs.0.05230/ml) Rs. 6.23	—	9.18*	—
		250	Rs. 15.58	18.47*	17.68	—
		500	Rs. 31.15	24.20	22.79	63.73
		1000	Rs. 62.30	30.76*	38.47	74.49

* Ceiling Price calculated in monopoly conditions by applying the average reduction in the other pack sizes of the same packaging material of the same formulation (i.e. D5, NS or DNS, as the case may be).

Subsequently, on 9th June 2016, a corrigendum Notification S.O. 2062(E) read with SO 1993(E) dated 03-Jun-2016 was issued which read as follows:

"The manufacturer intending to avail the ceiling prices for such Non-PVC packaging shall approach NPPA alongwith documents supporting such features, demonstrate and take approval for admissibility of prices for Non-PVC packaging."

Therefore the Note (e) shall be read as follows:

"(e) For formulation in Non-PVC packaging, ceiling price mentioned in column (5) of the above said table shall be admissible provided such packs are (i) self collapsible;(ii) not having air-vent; and (iii) there is no chance of contamination at manufacturing as well as admixing levels. The manufacturer intending to avail the ceiling prices for such Non-PVC packaging shall approach NPPA along with documents supporting such features, demonstrate and take approval for admissibility of prices for Non-PVC packaging. Otherwise the ceiling price for PVC packs shall be applicable for such Non-PVC packaging also."

7.2 Consequent to the above notification, a special sitting of the Authority was held on 21.6.2016 for deciding on admissibility of ceiling prices for manufacturers who wished to avail of ceiling prices for IV fluids (non-PVC) with special features. The manufacturers appeared before the Special Sitting of the Authority and conducted demo of their products and submitted documents in support thereof.

7.3 The Authority also examined various representations received in this regard.

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7.4 The Special sitting of the Authority took note of the fact that many manufacturers had shifted from PVC to Non-PVC in the recent past with a view to avail Non-PVC higher prices with or without adequate level of precision, sophistication and health security parameters as special features as conceived by the Authority and that a few of these manufacturers also managed certifications for the same from respective State Drug Licensing Authority. The glass and PVC manufacturers also represented that 2016 prices as notified by the NPPA again increased the distortion in pricing of IV Fluids, as in the case of prices of IV Fluids in glass bottles of 500ml and 1000ml. Further prices of IV Fluids in PVC packing also suffered because of the increased difference between the PVC and Non-PVC (with special Feature) as per their representation. The Authority found some substance in the contentions made by the manufacturers and realised the need for review of its earlier notification both in terms of pricing for the sake of removing price distortions and also for fine-tuning the features to be considered as special features in the interest of public health security.

7.5 The Authority took note of the fact that the powers under paragraph 11(3) and 11(4) of the DPCO'2013 are non-obstinate in nature, which empowers fixing of separate ceiling prices of scheduled formulations having special features considering type of packaging, pack-size, delivery methods and patient health security etc. The Authority also realised the fact that due to non-availability of sufficient market data, it is constrained to follow any one method of the existing provisions of price fixation and will be required to look beyond the general provisions of ceiling price fixation.

7.6 The Authority also took note that the major cost involved in the production of IV Fluid is the cost of packaging; and that the type of packaging plays an important role in the therapeutic benefits and compliance. Within this context the Authority endeavoured to fix a reasonable and competitive price regime for all forms of IV Fluids manufacturers having different packing material with or without special features. This involved removing the existing price distortion for all manufacturers based on unit volume price fixation leaving lower volumes non remunerative and higher volumes with extra pricing for manufacturers. Authority also realised its responsibility to ensure adequate production and availability of IV Fluids in all different types of packaging which depends on a well balanced pricing regime where the price differentiation between different types of packaging and features is not unreasonable and distorted. The Authority also kept in mind the various references from DIPP and DOP to recognise the significance of innovative packaging, need for technological upgradation for better patient health security and also the need for further growth and investment in the sector.

7.7 The Authority also took note that prices notified in Dec 2014(which was based on Sep 2013 data) were set-aside by the DoP vide Review Order dated 22-March 2016 under Para 31 of the DPCO 2013. As per provision of the DPCO 2013, price revision under para 31 has to be worked out on same base data with suitable modification as per review order. The base data is now nearly three years old. In these three years, manufacturers adopted technological innovation like FFS, BFS which was limited to few players only earlier.

7.8 The present market prices are capped on the basis of ceiling prices fixed on 10-Dec-2014. The pharma industry is aggrieved because of the obvious fallacies in the per ml based pricing which did not take into account packaging material or technology used in packaging.

7.9 The Authority, based on the representation and feedback of various glass and non-glass manufactures and also on the basis of other feedbacks from experts in the field, decided to modify the previous categorisation of different types of packaging as (a) glass (b) non glass and (c) non glass with special features, The special features were reconfigured as: (i) self-

collapsibility and self-seal ability (ii) not having air-vent; and (iii) having no chance of contamination during manufacture/ infusion/ admixing levels. The Authority decided to re-fix price of aforesaid formulations under modified categories i.e. glass, non glass and separate ceiling prices for specific manufacturers of non glass with special features as given in Table I, and Table II below.

(a) In the case of glass and non-glass formulations the Authority after detailed deliberations and exploring several alternatives to price fixation decided to fix the prices based on DPCO 1995 price with adjustment of excise duty and WPI on account of the following:

- (i) The DPCO base data for glass and non glass packs was fixed in 2011 based on DPCO, 1995 prices. These prices adjusted with WPI and excise duty appeared to be reasonable and remunerative to the glass and non-glass industry, and at the same time, was affordable from the consumer perspective.

Table I

Sl. No.	Name of the Scheduled Formulation	Strength	Unit/ Packaging	Ceiling Price (Rs.)
(1)	(2)	(3)	(4)	(5)
1	Glucose Injection	Glucose-5%	100ml Glass	16.73
2	Glucose Injection	Glucose-5%	250ml Glass	23.11
3	Glucose Injection	Glucose-5%	500ml Glass	32.80
4	Glucose Injection	Glucose-5%	1000ml Glass	59.60
5	Glucose Injection	Glucose-5%	100ml Non-Glass	15.14
6	Glucose Injection	Glucose-5%	250ml Non-Glass	20.88
7	Glucose Injection	Glucose-5%	500ml Non-Glass	28.31
8	Glucose Injection	Glucose-5%	1000ml Non-Glass	48.09
9	Sodium Chloride Injection	Sodium Chloride-0.9%	100ml Glass	16.29
10	Sodium Chloride Injection	Sodium Chloride-0.9%	250ml Glass	21.96
11	Sodium Chloride Injection	Sodium Chloride-0.9%	500ml Glass	30.52
12	Sodium Chloride Injection	Sodium Chloride-0.9%	1000ml Glass	55.06
13	Sodium Chloride Injection	Sodium Chloride-0.9%	100ml Non-Glass	14.67
14	Sodium Chloride Injection	Sodium Chloride-0.9%	250ml Non-Glass	19.72
15	Sodium Chloride Injection	Sodium Chloride-0.9%	500ml Non-Glass	26.00
16	Sodium Chloride Injection	Sodium Chloride-0.9%	1000ml Non-Glass	43.43
17	Glucose+ Sodium Chloride Injection	Glucose-5% Sodium Chloride-0.9%	100ml Glass	16.78
17	Glucose+ Sodium Chloride Injection	Glucose-5% Sodium Chloride-0.9%	250ml Glass	23.21
18	Glucose+ Sodium Chloride Injection	Glucose-5% Sodium Chloride-0.9%	500ml Glass	32.97
19	Glucose+ Sodium Chloride Injection	Glucose-5% Sodium Chloride-0.9%	1000ml Glass	59.97
20	Glucose+ Sodium Chloride Injection	Glucose-5% Sodium Chloride-0.9%	100ml Non-Glass	15.16
21	Glucose+ Sodium Chloride Injection	Glucose-5% Sodium Chloride-0.9%	250ml Non-Glass	20.97
22	Glucose+ Sodium Chloride Injection	Glucose-5% Sodium Chloride-0.9%	500ml Non-Glass	28.48
23	Glucose+ Sodium Chloride Injection	Glucose-5% Sodium Chloride-0.9%	1000ml Non-Glass	48.46

(b) In the case of 'non-glass formulations with special features' the Authority had the following observations:

- (i) In the Special Sitting of the Authority held on 21.6.2016, 8 companies could demonstrate that their products satisfied the criteria for admissibility of special price for non-glass with special features. The Authority found that the claims of these companies were in accordance with the criteria fixed for the same and that they had submitted adequate documentary support and practical demonstration. The claim of other manufacturers was accordingly rejected with the observation that some of these companies might go for modernization and in future come out with products which could be considered for separate prices.
- (ii) The market based data of Sept. 2013 captured the data of only few companies having non-glass packs with special features which was taken as the base for calculating a reasonable price level. In the Special Sitting the Authority found that 8 companies mentioned in Table III fulfilled the criteria for 'Non-Glass with special features'.
- (iii) *The data for PVC packs with special features have also been considered in revision in computing the ceiling price of 'Non-Glass with special features' due to re-categorization of the packs from Non-PVC to Non-Glass which takes into account the special features to be the main criterion for separate pricing ignoring the material based distinction between PVC and non-PVC .*
- (iv) The Authority took note of the fact that in due course of time competition may help to bring the MRP down.

Table II

Sl. No.	Name of the Scheduled Formulation	Strength	Unit/ Packaging	Ceiling Price (Rs.)
(1)	(2)	(3)	(4)	(5)
1	Glucose Injection	Glucose-5%	500ml Non Glass with special features	54.43
2	Glucose Injection	Glucose-5%	1000ml Non Glass with special features	70.88
3	Sodium Chloride Injection	Sodium Chloride-0.9%	100ml Non Glass with special features	22.23
4	Sodium Chloride Injection	Sodium Chloride-0.9%	250ml Non Glass with special features	46.28
5	Sodium Chloride Injection	Sodium Chloride-0.9%	500ml Non Glass with special features	59.93
6	Sodium Chloride Injection	Sodium Chloride-0.9%	1000ml Non Glass with special features	69.33
7	Glucose+ Sodium Chloride Injection	Glucose-5% Sodium Chloride-0.9%	500ml Non Glass with special features	55.95
8	Glucose+ Sodium Chloride Injection	Glucose-5% Sodium Chloride-0.9%	1000ml Non Glass with special features	74.49

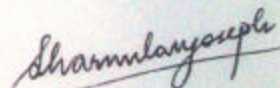
Table III

SL No.	Name of Manufacturer	Product /Brand Name
1	M/s B.Braun Medical (I) Pvt Ltd.	Ecofiac Plus bottle with Eurohead
2	M/s Amanta Healthcare Ltd.	Steriport bottle
3	M/s Aculife Healthcare Pvt Ltd.	Aculife bottle with Eurohead
4	M/s Albert David Limited	Albert David bottle with Eurohead
5	M/s Denis Chem Limited	Aquapulse with Eurohead
6	M/s Claris Life Sciences Limited	Claris bottle with Eurohead
7	M/s Fresenius Kabi India Pvt Limited	Freeflex bags
8	M/s Claris Otsuka Private Limited	Unibag

7.10 The separate ceiling price as mentioned in Table II will be valid for one year or until revised under Paragraph 16 and 18 of DPCO, 2013, as the case may be.

7.11 For any other special features claimed or any other pack size manufactured, the manufacturer shall approach NPPA for specific price approval for its formulations.

8. The meeting ended with vote of thanks to the Chair.



(Dr. Sharmila Mary Joseph K)
Member Secretary