

गोपनीय: Confidential

मिसिलस - 8(34)/2016/डी.पी./एनपीपीए- डीवी-II

F. No. 8(34)/2016/DP/NPPA-Div. II

कार्यवाहीस. : 166/34/2016/F

Proceeding No : 166/34/2016/F

**Minutes of the 166<sup>th</sup> and 34<sup>th</sup> meeting of Authority under DPCO, 2013 held on 29.7.2016 at 11.00 AM.**

- I. 1. The 166<sup>th</sup> overall meeting of the Authority, which is the 34<sup>th</sup> under the DPCO, 2013 was held on 29<sup>th</sup> July, 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:-

- (i) Shri Kalyan Nag, Adviser (Cost)
- (ii) Smt. Roshni Sohni, Director (M&E/Admn.)
- (iii) Shri A.K. Khurana, Director (Pricing)
- (iv) Shri Baljit Singh, Asstt. Director (Pricing)
- (iv) Shri Presentjit Das, Asstt. Director (Pricing)
- (v) 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 33<sup>rd</sup> Meeting held on 23.6.2016.**

Since no comments were received on the minutes of 165<sup>th</sup> and the 33<sup>rd</sup> Meeting under DPCO, 2013, the Authority confirmed the minutes of the meeting.

**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 24 formulations and approved the ceiling prices in respect of the following 24 formulations.

*Sharmila Mary Joseph K*

S. NO.	UNIQUE NO. AS PER NLEM	NAME OF THE FORMULATION/ COMPOSITIONS	STRENGTH	DESCRIPTION	PACK SIZE	APPROVED CEILING PRICE under NLEM, 2015 (Rs.)
Continan Case						
1	2.3.2	COLCHICINE	0.5 MG	TABLET	Per Tablet	2.88
2	3.3	CHLORPHENIRAMINE	4 MG	TABLET	Per Tablet	0.08514
3	6.2.3.1	CLOFAZIMINE	100 MG	CAPSULE	Per Capsule	2.29
4	6.2.3.1	CLOFAZIMINE	50 MG	CAPSULE	Per Capsule	1.28
5	6.2.4.3	ETHAMBUTOL	800 MG	TABLET	Per Tablet	3.15
6	6.2.4.3	ETHAMBUTOL	400 MG	TABLET	Per Tablet	2.14
7	6.2.4.3	ETHAMBUTOL	200 MG	TABLET	Per Tablet	0.94
8	6.2.4.11	PYRAZINAMIDE	1500 MG	TABLET	Per Tablet	9.29
9	6.3.3	FLUCONAZOLE	100 MG	TABLET	Per Tablet	7.40
10	6.4.3.1.4	LAMIVUDINE + ZIDOVUDINE	150/300 MG	TABLET	Per Tablet	18.61
11	6.4.3.1.5	STAVUDINE + LAMIVUDINE	30/150 MG	TABLET	Per Tablet	8.86
12	6.4.3.1.8	ZIDOVUDINE	300 MG	TABLET	Per Tablet	12.69
13	8.1.11	CHLDRAMBUCIL	2 MG	TABLET	Per Tablet	32.84
14	8.1.13	CYCLOPHOSPHAMIDE	50 MG	TABLET	Per Tablet	3.61
15	8.1.25	MELPHALAN	5 MG	TABLET	Per Tablet	149.73
16	8.1.25	MELPHALAN	2 MG	TABLET	Per Tablet	87.30
17	8.4.10	METOCLOPRAMIDE	10 MG	TABLET	Per Tablet	1.08
18	8.4.4	DIAZEPAM	2 MG	TABLET	Per Tablet	1.39
19	8.4.4	DIAZEPAM	5 MG	TABLET	Per Tablet	1.32
20	12.1.4	GLYCERYL TRINITRATE	0.5 MG	SUBLINGUAL TABLET	Per Tablet	1.68
21	12.3.2	ATENOLOL	100 MG	TABLET	Per Tablet	3.24
22	21.3.1	ETHINYLESTRADIOL	0.01 MG	TABLET	Per Tablet	2.10
23	25.4.1	ACETAZOLAMIDE	250 MG	TABLET	Per Tablet	3.26
New Case						
24	6.2.2.5	DOXYCYCLINE	100 MG	CAPSULE	Per Capsule	2.32

*Dr. Arun Kumar*

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

4.1 The Authority discussed the following 19 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 Retail Price (Rs.)
4(i)	M/s Ajanta Pharma Ltd. (Manufacturer as well as Marketing company) – Teneiglipitin Hydrobromide Hydrate eq. to teneiglipitin 20mg and Metformin HCl 500mg (as extended release) – (Teneiglipitin 20mg +Metformin HCl extended release 500mg tablet).	Rs. 11.14/tablet
4(ii)	M/s Glenmark Pharmaceuticals Ltd. (Manufacturer) and M/s Alkem Lab. Ltd. (Marketing company) – Teneiglipitin Hydrobromide Hydrate eq. to teneiglipitin 20mg and Metformin HCl 500mg (as extended release) – (Olymrpx M 500 tablet).	Rs. 11.14/tablet
4(iii)	M/s Glenmark Pharmaceuticals Ltd. (Manufacturer) and M/s Aristo Pharmaceuticals Ltd. (Marketing company) – Teneiglipitin Hydrobromide Hydrate eq. to teneiglipitin 20mg and Metformin HCl 500mg (as extended release) – (Teneiglipitin 20mg +Metformin HCl extended release 500mg tablet).	Rs. 11.14/tablet
4(iv)	M/s Glenmark Pharmaceuticals Ltd. (Manufacturer) and M/s Panacea Biotec Ltd. (Marketing company) – Teneiglipitin Hydrobromide Hydrate eq. to teneiglipitin 20mg and Metformin HCl 500mg (as extended release) – (Teneipan M500 tablet).	Rs. 11.14/tablet
4(v)	M/s Cadila Healthcare Ltd. (Manufacturer as well as Marketing company) – Teneiglipitin Hydrobromide Hydrate eq. to teneiglipitin 20mg and Metformin HCl 500mg (as extended release) – (Tenglyn M500 tablet).	Rs. 11.14/tablet
4(vi)	M/s Glenmark Pharmaceuticals Ltd. (Manufacturer) and M/s Medley Pharmaceuticals Ltd. (Marketing company) – Teneiglipitin Hydrobromide Hydrate eq. to teneiglipitin 20mg and Metformin HCl 500mg (as extended release) – (Glytrin Met tablet).	Rs. 11.14/tablet
4(vii)	M/s Glenmark Pharmaceuticals Ltd. (Manufacturer) and M/s Cadila Pharmaceuticals Ltd. (Marketing company) – Teneiglipitin Hydrobromide Hydrate eq. to teneiglipitin 20mg and Metformin HCl 500mg (as extended release) – (Teneiglipitin 20mg +Metformin HCl extended release 500mg tablet).	Rs. 11.14/tablet
4(viii)	M/s Cadila Healthcare Ltd. (Manufacturer as well as Marketing company) – Paracetamol 500mg+Caffeine (anhydrous) 30mg+Phenylephrine HCl 5mg and Diphenhydramine HCl 25mg – (Zycold tablet).	Rs. 2.68/tablet
4(ix)	M/s Windias Biotech Ltd. (Manufacturer) and M/s Magnet Labs Pvt. Ltd. (Marketing company) – Paracetamol 500mg+Caffeine (anhydrous) 30mg+Phenylephrine HCl 5mg and Diphenhydramine HCl 25mg – (Nobel-Cold New tablet).	Rs. 2.68/tablet
4(x)	M/s Windias Biotec Ltd. (Manufacturer) and M/s Lifestar Pharma Pvt. Ltd. (Marketing company) – Paracetamol 500mg+Caffeine (anhydrous) 30mg+Phenylephrine HCl 5mg and Diphenhydramine HCl 25mg – (Noblok-New tablet).	Rs. 2.68/tablet
4(xi)	M/s Alkem Lab. Ltd. (Manufacturer as well as Marketing company) - Paracetamol 500mg+Caffeine (anhydrous) 30mg+Phenylephrine HCl 5mg and Diphenhydramine HCl 25mg – (Sumocold tablet).	Rs. 2.68/tablet
4(xii)	M/s Pure & Cure Healthcare Pvt. Ltd. (Manufacturer) and M/s Apex Lab. Pvt. Ltd. (Marketing company) – Pantoprazole sodium eq. to Pantoprazole 40mg – (Pantoprazole tablet).	Rs. 5.56/tablet

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4(xiii)	M/s Alkem Lab. Ltd. (Manufacturer as well as Marketing company) – Paroxetine HCl (as Hemihydrate) eq. to Paroxetine 12.5mg (as extended release form) and Clonazepam 0.5mg - (Depaxil CR Plus 12.5 tablet).	Rs. 11.00/tablet
4(xiv)	M/s Alkem Lab. Ltd. (Manufacturer as well as Marketing company) – Paroxetine HCl (as Hemihydrate) eq. to Paroxetine 25mg (as extended release form) and Clonazepam 0.5mg - (Depaxil CR Plus 25 tablet).	Rs. 15.00/tablet
4(xv)	M/s Akums Drugs & Pharmaceuticals Ltd., (Manufacturer) and M/s Lupin Ltd., (marketing company) – Diclofenac sodium 75mg - (Diponac Inj. 75mg/1ml).	Rs. 14.30/ 1ml Injection
4(xvi)	M/s Inventia Healthcare Pvt. Ltd. (Manufacturer) and M/s Blue Cross Lab. Pvt. Ltd. (Marketing company) – Metformin HCL-8R 500mg , Voglibose 0.2mg and Glimepiride 2mg tablet - (Metformin HCl SR, Voglibose and Glimepiride tablet)	Rs. 90.48 / 10 tablets
4(xvii)	M/s Inventia Healthcare Pvt. Ltd. (Manufacturer) and M/s Blue Cross Lab. Pvt. Ltd. (Marketing company) – Metformin HCL SR 500mg , Voglibose 0.2mg and Glimepiride 1mg tablet - (Metformin HCl SR, Voglibose and Glimepiride tablet)	Rs. 71.43 / 10 tablets
4(xviii)	M/s Lincoln Pharmaceuticals Ltd. (Manufacturer) and M/s Glenmark Pharmaceuticals Ltd. (marketing company) – Ondansetron HCl eq. to Ondansetron 2mg -- (Vomi Spray 15ml).	Rs. 199.00/ 15ml Spray
4(xix)	M/s Safetab Lifescience (Manufacturer) and M/s Lupin Lab. Ltd. (Marketing company) – Rosuvastatin calcium eq. to Rosuvastatin 10mg, Aspirin 75mg and Clopidogrel bisulphate eq. to Clopidogrel 75mg – (Novostat Gold tablet).	Rs. 10.40 per tablet

**5. Agenda Item no. 5: Minutes of the 6<sup>th</sup> meeting of Standing Committee of Experts held on 20.07.2016 under Para 15 of the DPCO 2013.**

5.1 These cases were discussed in detail and the Authority approved all the cases as mentioned below:-

S. No.	Date of Receipt of Application	Manufacturer Company	Marketing Company	Brand Name, If any	Retail Price Claimed (Rs.)
1.	30.5.2016	M/s Ajanta Pharma Ltd.	M/s Ajanta Pharma Ltd.	-	17.61/ Tablet
2.	19.02.2016	M/s Glenmark pharmaceutical Ltd.	M/s Alembic Pharmaceutical Ltd.	-	157.00/10 Tablets
3.	11.3.2016	M/s Glenmark Pharmaceuticals Ltd.	M/s Micro Labs Ltd.	Tenepride M 1000	142.00/10 Tablets
4.	16.3.2016	M/s Glenmark Pharmaceuticals Ltd.	M/s Torrent Pharmaceuticals Ltd.	Afoglip M 1000	142.00/10 Tablets
5.	17.3.2016	M/s Glenmark Pharmaceuticals Ltd.	M/s Unichem Lab. Ltd.	-	135.23/10 Tablets
6.	18.3.2016	M/s Glenmark Pharmaceuticals Ltd.	M/s Wockhardt Ltd.	Inogla M 1000	215.00/10 Tablets
	22.3.2016	M/s Glenmark Pharmaceuticals Ltd.	M/s Indoco Remedies Ltd.,	Zilenta M Forte/J-Ring M Forte	142.00/10 Tablets

8.	22.3.2016	M/s Glenmark Pharmaceuticals Ltd.	M/s Glenmark Pharmaceuticals Ltd.		190.00/10 Tablets
9.	11.4.2016	M/s Glenmark Pharmaceuticals Ltd.	M/s Intas Pharmaceuticals Ltd.		200.00/10 Tablets
10.	03.5.2016	M/s Glenmark Pharmaceuticals Limited	M/s Alkem Laboratories Ltd.	Olymrpax M 1000	220.00/10 Tablet
11.	10.5.2016	M/s Glenmark Pharmaceuticals Ltd.	M/s Cadila Pharmaceuticals Ltd.		160.00/10 Tablets
12.	07.6.2016	M/s Glenmark Pharmaceuticals Ltd.	M/s Panacea Biotec Ltd	Tenepan M 1000	142.00/10 Tablets

5.1.1 The Authority approved all the above 12 cases of Metformin HCl (as extended release tablet) 1000mg and Teneligliptin Hydrobromide 20mg tablet for manufactured/marketed by the companies as mentioned above at Rs. 11.65/tablet, as arrived at under:-

Composition	Basis	Amount (Rs.)
Teneligliptin 20 mg	Price computed as per para 4 of DPCO, 2013	8.27
Metformin 1000mg(CR)	Ceiling Price fixed under NLEM 2015 vide S.O. 1253(E) dated 29.3.2016	3.38
	<b>TOTAL</b>	<b>11.65</b>

5.2 The cases of Digihaler FB 400/200/100 Inhaler MDI 120 delivering Formeterol Fumarate Dihydrate equivalent to anhydrous Formeterol Fumarate (6mcg) + Budesonide (400mcg/200mcg/100mcg) with digital actuator (Dose Counter) manufactured and marketed by Glenmark Pharmaceuticals Ltd, were discussed in detail. The Authority decided to reject the proposals considering the high cost of Digital Actuator.

**6. Agenda Item no. 6: Price Fixation of I.V. Fluids under DPCO, 2013 – Issue of Addendum.**

6.1 This was discussed in detail and the Authority approved the inclusion of (i) Eurohead bottle of M/s Fresenius Kabi India Pvt. Ltd., (ii) Eurohead bottle of M/s Aishwarya Lifesciences, (iii) Viaflex bag of M/s Baxter (India) Pvt. Ltd. and (iv) Eurohead bottle of M/s Claris Otsuka Pvt. Ltd., under the category 'non glass with special features' in Table B of the concerned notification (S.O. 2210(E) dated 24.6.2016) through issue of an addendum.

**7. Agenda Item no. 7: Withdrawl of O.Ms. issued by the NPPA in respect of representation, if any, made by the aggrieved companies.**

7.1 The Authority discussed in detail the directions of DOP regarding uploading of draft working sheets of proposed ceiling/retail price fixation/revision. The Authority decided to withdraw the O.Ms. issued by NPPA on 11.4.2016, 11.5.2016 and 20.5.2016 regarding submission of representations of companies, if any, on prices fixed by NPPA.

**8. Agenda Item no. 8: Additional item.**

8.1 The Authority looked into review orders passed by Dept. of Pharmaceuticals (DOP) on 22.7.2016 in respect of review application of Dr. Reddy's Labs. Ltd. and M/s J.B. Chemicals and Pharmaceuticals Ltd. both dated 15.3.2016, respectively. After deliberations, it was decided to

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write a letter to the DOP requesting the Department to recall the said orders in view of the following reasons:-

(i) OM dated 06.4.2016 is in accordance with DPCO, 2013. Formulations manufactured by the companies were scheduled when price was notified on 26.2.2016 and the same continue to remain scheduled. As per OM dated 19.02.2016 and 02.3.2016, companies were required to make corresponding price reduction on account of reduction in WPI as per para 13(3) proviso and 16(4) of DPCO, 2013. NPPA notified revised prices on 02.3.2016 as per mandate of DPCO, 2013. As per para 20 of DPCO, 2013, companies have to maintain last prices for twelve months before any increase upto ten percent for non-scheduled formulation is allowed. This is also in clear analogy of para 10(4) of the DPCO, 2013 read with para 4(xiv) and para 3(v) of NPPP, 2012 in respect of switchover of scheduled formulations, with the objective to provide benefit of price to the consumers and to protect them against any unwarranted increase of ten percent just on the pretext of scheduled formulations becoming non-scheduled. Moratorium of twelve months is essentially in larger public interest. All medicines whether scheduled and non-scheduled formulations come under the ambit of price control under DPCO, 2013 issued under EC Act, 1955. The essence of the DPCO is to ensure that all essential and lifesaving medicines are available at affordable prices to all, particularly the common man.

(ii) The said OM is in line with the principles laid down by the Hon'ble Supreme Court in the case of Union of India vs. Cynamide India Ltd., reported in (1987) 2 SCC 720, and GlaxoSmithkline vs UOI (2014) 2 SCC 753, as it is intended to provide benefit of price reduction to the public. Further, such action is consistent with and supported by Section 6A of General Clauses Act 1857 in respect of Repeal of Act making textual amendment in Act or Regulation.

(iii) The detailed data showing reduced prices on account of reduction in WPI on 02.3.2016 (vide S. O. 1253 (E) dated 29.3.2016 notification of NPPA) and OM dated 06.4.2016 regarding maintenance of price for twelve months for formulations which were excluded from revised Schedule-I are part of the responses provided to Rajya Sabha Starred Question no. 143 for answer on 06.5.2016 and other unstarred questions also.

(iv) Writ petitions filed by IPA and M/s Wockhardt are pending in the Hon'ble High Court of Bombay and Delhi, respectively. The Department authorized NPPA to deal with the above cases in totality vide letter dated 10.5.2016 and 20.5.2016, respectively. As above matters are still sub-judice, it would be prudent to keep the instant issue in abeyance till it is decided by the Hon'ble High Courts.

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

  
(Dr. Sharmila Mary Joseph K)  
Member Secretary