

**Minutes of the 195<sup>th</sup> (overall) and 63<sup>rd</sup> meeting of the Authority under DPCO, 2013 held on 21.02.2019 at 11 AM**

The 195<sup>th</sup> meeting of the Authority (overall), which is the 63<sup>rd</sup> meeting under the DPCO, 2013, was held on the 21<sup>st</sup> of February, 2019 at 11 AM under the Chairpersonship of Ms. Shubhra Singh, Chairperson, NPPA. The following members of the NPPA were present:

- (i) Ms. Ritu Dhillon, Member Secretary
- (ii) Dr. S. Eswara Reddy, Drugs Controller General (India)
- (iii) Shri Arun Kumar, Advisor, Dept of Economic Affairs, Ministry of Finance
- (iv) Shri B. Bandyopadhyay, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

Shri A.K.Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare also attended.

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

Shri Amarpal Singh Sawhney, Director (Pricing)

Shri Rajesh K. Agarwal, Director (M&E)

Shri Arun Kumar Diwan, Dy. Director (M&E)

Shri Prasenjit Das, Asstt. Director (Pricing)

Shri Prakash Hemani, Asstt. Director

Chairperson, NPPA welcomed all present in the meeting.

**II. Agenda items**

**1. Agenda item no. 1 - Confirmation of Minutes of the 62nd Meeting held on 21.01.2019.**

1.1 The Authority confirmed the minutes of the 194<sup>th</sup> (overall) and the 62<sup>nd</sup> Meeting under DPCO 2013 held on 21.01.2019.

**2. Agenda item no. 2 – Action Taken Report**

2.1 Noted.

**3. Agenda item no. 3 – Status of New Drug application**

3.1 The Authority noted that the pendency of applications has come down sharply and 410 retail prices of new drugs were approved since January 2018 (including 23 cases in the 63<sup>rd</sup> Authority meeting). Therefore, the clearances are now concurrent to the receipt of new applications.

**4. Agenda item no. 4 – New Drug applications**

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4(xxvi) (total 38 Form I applications) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 23(twenty three) cases [except cases at sl no (xiv), (xv), (xviii), (xxiii) and (xxiv)], under para 5 and para 15 of the DPCO 2013, as detailed below:

A. Retail price fixed under para 5 of DPCO, 2013

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
(i)	Escitalopram + Clonazepam Tablet (Andefre-LS)	Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 5mg, Clonazepam IP 0.25mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Neomac Pharmaceuticals Pvt. Ltd.	5.88
(ii).	Paracetamol + Aceclofenac Tablet	Each uncoated tablet contains: Paracetamol IP 325mg, Aceclofenac IP 100mg.	1 Tablet	M/s Caplet India Private Limited	3.35
(iii)	Misoprostol Tablet	Each uncoated tablets contains: Misoprostol 25mcg	1 Tablet	M/s Acme Formulation Pvt. Ltd. / M/s Zydus Healthcare Limited	4.37
(iv)	Mefenamic Acid + Paracetamol Tablet	Each uncoated tablets contains: Mefenamic Acid IP 500mg, Paracetamol IP 325mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	2.76
(v)	Trastuzumab Injection	Each Lyophilized Vial contains: Trastuzumab 150mg	1 Vial	M/s Cadila Healthcare Limited / M/s Glenmark Pharmaceuticals Limited	18400.89
(vi)	Cilnidipine + Telmisartan + Chlorthalidone Tablet	Each film coated tablet contains: Cilnidipine IP 10mg, Telmisartan IP 40mg Chlorthalidone IP 6.25mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. /M/s Emcure Pharmaceuticals Limited	10.43
(vii)	Metformin + Gliclazide Tablet	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500mg (in extended release form) Gliclazide IP 80mg	1 Tablet	M/s Anphar Organics Pvt. Ltd. / M/s Lupin Limited	6.31
(viii)	Metformin + Gliclazide Tablet	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500mg (in extended release form) Gliclazide IP 60mg (as modified release form)	1 Tablet	M/s Anphar Organics Pvt. Ltd. / M/s Lupin Limited	8.64
(ix)	Telmisartan + Metoprolol Tablet (TELMELIFE – M25)	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Neomac Pharmaceuticals (P) Ltd.	9.43

		form) 25mg			
(x)	Telmisartan + Metoprolol Tablet (TELMELIFE – M50)	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Metoprolol Succinate IP 47.5mg eq. to Metoprolol Tartrate (as extended release form) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Neomac Pharmaceuticals (P) Ltd.	11.72
(xi)	Propranolol + Flunarizine Capsule	Each hard gelatine capsule contains: Propranolol Hydrochloride IP 40mg (as SR pellets), Flunarizine Dihydrochloride BP eq. to Flunarizine 5mg (as pellets)	1 Capsule	M/s Innova Captab Ltd. / M/s Cipla Limited	6.72
(xii)	Propranolol + Flunarizine Capsule	Each hard gelatine capsule contains: Propranolol Hydrochloride IP 40mg (as SR pellets), Flunarizine Dihydrochloride BP eq. to Flunarizine 10mg (as pellets)	1 Capsule	M/s Innova Captab Ltd. / M/s Cipla Limited	9.20
(xiii)	Levonorgestrel Tablet	Each uncoated tablet contains: Levonorgestrel IP 1.5mg	1 Tablet	M/s Mylan Laboratories Limited / M/s Mylan Pharmaceutical Private Limited	92.80
(xiv)	Ceftriaxone + Sulbactam Injection (Taxone SB 1000mg)	Each vial contains: Ceftriaxone Sodium IP eq. to Ceftriaxone 1000mg Sulbactam Sodium USP eq. to Sulbactam 500mg	1 vial	M/s Mapra Laboratories Pvt. Ltd.	Deferred
(xv)	Ceftriaxone + Sulbactam Injection (Taxone SB 250mg )	Each vial contains: Ceftriaxone Sodium IP eq. to Ceftriaxone 250gm Sulbactam Sodium USP eq. to Sulbactam 125mg	1 vial	M/s Mapra Laboratories Pvt. Ltd.	
(xvi)	Formoterol + Budesonide Respirator suspension (Budetrol 0.5)	Each ml respule contains: Formoterol Fumarate Dihydrate IP eq. to Formoteraol Fumarate 20mcg, Budesonide IP 0.5mg	Each 2 ml pack	M/s Axa Parenterals Ltd. / M/s Macleods Pharmaceutical Limited	36.04
(xvii)	Formoterol + Budesonide Respirator suspension (Budetrol 1)	Each ml respule contains: Formoterol Fumarate Dihydrate IP eq. to Formoteraol Fumarate 20mcg, Budesonide IP 1mg	Each 2 ml pack	M/s Axa Parenterals Ltd. / M/s Macleods Pharmaceutical Limited	42.12
(xviii)	Ceftriaxone + Sulbactam Injection (Taxone SB 500mg )	Each vial contains: Ceftriaxone Sodium IP eq. to Ceftriaxone 500gm Sulbactam Sodium USP eq. to Sulbactam 250mg	1 vial	M/s Mapra Laboratories Pvt. Ltd.	Deferred
(xix)	Metformin + Glimepiride Tablet (Geminor 0.5)	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500mg (as prolonged release	1 Tablet	M/s Macleods Pharmaceutical Limited	3.57

		form) Glimepiride IP 0.5mg			
--	--	-------------------------------	--	--	--

B. Retail price fixed under para 5 and 15 of DPCO, 2013 (Pharmaeconomics cases)

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
(xx)	Clobazam suspension	Each ml suspension contains: Clobazam IP 2.5mg,	1 ML	M/s Intas Pharmaceutical Limited	2.54
(xxi)	Diclofenac + Chlorzoxazone Tablet (MYOSPAS-F)	Each film coated tablet contains: Diclofenac Potassium BP 50mg Chlorzoxazone USP 500mg	1 Tablet	M/s G. S. Pharmbutor Pvt. Ltd. /M/s Win-Medicare Pvt. Ltd.	9.28
(xxii)	Clonazepam Orally disintegrating Strips (Melzap ODS 0.5)	Each Orally disintegrating Strips contains: Clonazepam IP 0.5mg	1 Orally disintegrating Strip	M/s ZIM Laboratories Limited / M/s Alkem Laboratories Ltd.	5.33
	Clonazepam Orally disintegrating Strips (Melzap ODS 1)	Each Orally disintegrating Strips contains: Clonazepam IP 1mg	1 Orally disintegrating Strip	M/s ZIM Laboratories Limited / M/s Alkem Laboratories Ltd.	7.25
	Clonazepam Orally disintegrating Strips (Melzap ODS 2)	Each Orally disintegrating Strips contains: Clonazepam IP 2mg	1 Orally disintegrating Strip	M/s ZIM Laboratories Limited / M/s Alkem Laboratories Ltd.	13.05
(xxiii)	Emtricitabine + Tenofovir tablet (Tafmune - EM)	Each film coated tablet contains: Emtricitabine IP 200 mg Tenofovir Alafenamide Hemifumarate eq to Tenofovir Alafenamide 25 mg	1 Tablet	M/s Hetero Labs Ltd. / M/s Cipla Ltd.	The cases have been referred back to Multidisciplinary Committee of Experts to seek inputs from representative of O/o the DG, NaCO in the matter.
	Tenofovir + Emtricitabine Tablet (TAFICITA)	Each film coated contains: Tenofovir Alafenamide 25mg, Emtricitabine 200mg	1 Tablet	M/s Mylan Laboratories Ltd. / M/s Mylan Pharmaceuticals Pvt. Ltd.	
(xxiv)	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/s Mylan Laboratories Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	The cases have been referred back to Multidisciplinary Committee of Experts to seek inputs from

Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/s Hetero Labs Ltd./ M/s Cipla Ltd.	representative of O/o the DG, NaCO in the matter.
Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/s Hetero Labs Ltd./ M/s Cadila Healthcare Ltd.	
Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/s Hetero Labs Ltd./ M/s Emcure Pharmaceuticals Ltd.	
Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/ Natco Pharma Ltd. / M/s Sun Pharma Laboratories Ltd.	
Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/ Natco Pharma Ltd. / M/s Abbott India Ltd.	
Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/ Natco Pharma Ltd.	
Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/ Natco Pharma Ltd. / M/s Cadila Healthcare Ltd.	
Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/ Natco Pharma Ltd. / M/s Dr. Reddy's Laboratories Ltd.	
Tenofovir Alafenamide Tablet	Each film coated tablet contains:	1 Tablet	M/ Natco Pharma Ltd. / M/s	

		Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg		Aprazer Healthcare Pvt. Ltd.	
(xxv)	Alpha Lipoic Acid + Methylcobalamin + Vitamin B6 IP + Folic Acid IP + Benfotiamine + Biotin USP + Chromium Picolinate Capsule (Jubinerv)	Each hard gelatine capsule contains: Alpha Lipoic Acid USP 100mg, Methylcobalamin 1500mcg, Vitamin B6 IP 3mg, Folic Acid IP 1.5mg, Benfotiamine 50mg, Biotin USP 5mg, Chromium Picolinate USP eq. to Chromium 200mcg	1 Capsule	M/s Theon Pharmaceutical Ltd. / M/s Jubilant Life Sciences Limited	11.34
(xxvi)	Alpha Lipoic Acid + Methylcobalamin + Vitamin + Folic Acid + Benfotiamine + Biotin Capsule	Each hard gelatine capsule contains: Alpha Lipoic Acid USP 200mg, Methylcobalamin 1500mcg, Vitamin B6 IP 3mg, Folic Acid IP 1.5mg, Benfotiamine 50mg, Biotin USP 5mg,	1 Capsule	M/s KonTest Chemicals Limited	11.51

Note: The retail prices for agenda item no. (xxv) & (xxvi) to be notified after 10 days of uploading the draft working sheet.

## 5. Agenda item no. 5 - Implementation of review orders

### 5.1 Agenda item no. 5(i) - Review order in respect of M/s Sun Pharma Laboratories Ltd for retail price fixation of Baclofen Oral Solution containing Baclofen 5 mg/ 5 ml.

5.1.1 The Authority deliberated upon and decided to revise the ceiling price of Baclofen Oral Solution containing Baclofen 5 mg/ 5 ml to Rs. 1.44 per ml excluding GST.

### 5.2 Agenda item no. 5(ii) – Review order in respect of M/s Cadila Healthcare Ltd and M/s Wockhardt Ltd for ceiling price fixation of Dexamethasone 4mg/ml injection in 2 ml pack.

5.2.1 The Authority deliberated upon and noted that the Reviewing Authority while examining this case has stated as under:

“...that this injectable fluid were in NLEM, 2011 and the ceiling price was already in existence for them, when the NLEM was revised in 2016. After revision of Schedule I of DPCO, due to revision in NLEM, the price caps of injectable fluids were re-fixed, this time, by segregating the

pack sizes on the basis of recommendation of Expert Committee. Since while fixing the ceiling price of subject formulation on 28.04.2014, the segregation of market based data on the basis of pack size was not done, this resulted in depressing the prices of smaller pack sizes. This lower base was taken while fixing the ceiling price of 2ml pack again on 24.1.2017, which resulted in further depressing the ceiling price of 2ml pack. This anomalous situation needs to be rectified in the interest of the long term sustained availability of Dexamethasone 2ml injection in the market. This could be justifiably rectified if the segregated market data of September, 2013 is used to arrive at a ceiling price along with giving effect to WPI for subsequent years.”

Accordingly, the Authority decided to revise the ceiling price of Dexamethasone 4mg/ml injection in 2 ml pack to Rs. 8.75 per 2 ml pack, excluding GST, on the basis of data for the month of September 2013.

**5.3 Agenda item no. 5(iii) - Review order no. 31015/27/2016-PI.I dated 14.09.2016 of M/s Cipla Ltd., no. 31015/52/2017-Pricing dated 30.10.2017 of M/s Glenmark Ltd. and no. 31015/54/2017-Pricing dated 26.06.2018 of M/s Lupin Ltd. and WP(C) 3632/2017 of M/s Cipla Ltd., WP(C) 4975/2017 of M/s Glenmark Pharmaceuticals Ltd., WP(C)/2017 of M/s Zydus Cadila Ltd. and WP 3912/2018 of M/s Lupin Ltd. in respect of fixation of ceiling price of Budesonide, Budesonide + Foremetrol & Tiotropium Inhalers.**

5.3.1 Based on the recommendation of the Multidisciplinary committee of experts, the Authority approved the ceiling prices for different formulations as under:

S. No.	Dosage form	MDI Only	DPI Only
		Revised Price as per Correction of PTR (with WPI) (MDI only)(Rs. excluding GST)	Revised Price as per Correction of PTR ((with WPI) (DPI only) (Rs. Excluding GST)
1	2	4	5
	<u>UNIT</u>	Per metered dose	Per dose
	<u>Budesonide</u>	(b)	(c)
1	Inhalation (MDI/DPI) 100 mcg/dose	1.19	1.87
2	Inhalation (MDI/DPI) 200 mcg/dose	1.48	2.71
	<u>Budesonide (A)+ Formoterol (B)</u>		
3	Inhalation (MDI/DPI) 100 mcg (A) + 6 mcg (B)	1.77	3.56
4	Inhalation (MDI/DPI) 200 mcg (A) + 6 mcg (B)	2.51	4.73
5	Inhalation (MDI/DPI) 400 mcg (A) + 6 mcg (B)	2.86	6.04
	<u>Tiotropium</u>		
6	Inhalation (MDI/DPI) 9 mcg/dose	2.08	
7	Inhalation (MDI/DPI) 18 mcg/dose		8.72

**5.4 Agenda item no. 5(iv) – Review order in respect of M/s Abbott Healthcare Pvt. Ltd for ceiling price fixation of Gentamicin 40mg/ml injection in 2 ml pack.**

5.4.1 The Authority deliberated upon and noted that the Reviewing Authority while examining this case has stated as under:

“...that this injectable fluid were in NLEM, 2011 and the ceiling price was already in existence for them, when the NLEM was revised in 2016. After revision of Schedule I of DPCO, due to revision in NLEM, the price caps of injectable fluids were re-fixed, this time, by segregating the pack sizes on the basis of recommendation of Expert Committee. Since while fixing the ceiling price of subject formulation on 28.04.2014, the segregation of market based data on the basis of pack size was not done, this resulted in depressing the prices of smaller pack sizes. This lower base was taken while fixing the ceiling price of 2ml pack again on 24.1.2017, which resulted in further depressing the ceiling price of 2ml pack. This anomalous situation needs to be rectified in the interest of the long term sustained availability of Gentamicin 2ml injection in the market. This could be justifiably rectified if the segregated market data of September, 2013 is used to arrive at a ceiling price along with giving effect to WPI for subsequent years.”

Accordingly, the Authority decided to revise the ceiling price of Gentamicin 40mg/ml injection in 2 ml pack to Rs. 7.89 per 2 ml pack, excluding GST, on the basis of data for the month of September 2013.

**5.5 Agenda item no. 5(iv) – Status of implementation of review order.**

5.5.1 The Authority noted that pendency of the implementation of the review order has reduced to a considerable extent. 79 review orders were implemented since January 2018 (including 7 cases in the 63<sup>rd</sup> Authority meeting). Thus, only 7 review cases are now pending, the details of which are given below:

- (i) 5 cases – Based on the recommendation of Multidisciplinary Committee of Experts, data/information is being requisitioned from the companies. The data is yet to be received from the companies.
- (ii) 1 case- The matter is pending due to internal inquiry.
- (iii) 1 case- The matter will be examined after receipt of further orders from Department of Pharmaceuticals.

**6.1 Agenda item no. 6 (i) - Application of M/s s Meril Life Sciences Pvt. Ltd. for Exemption under para 32(ii) of DPCO, 2013 for their product Sirolimus Eluting BioResorbable vascular scaffold system (MeRes100).**



**6.2 Agenda item no. 6 (ii) - Application of M/s Sun Pharmaceutical Industries Ltd for Exemption under para 32 of DPCO, 2013 for their product Gemcitabine hydrochloride injection 10mg/ml (Ready to use infusion bags 1200mg/120ml, 1400mg/140ml and 1600mg/160ml).**

6.3 The Authority deliberated on para 6.1. and para 6.2 above and noted that in public health, choice of consumer is impeded by information asymmetry and lack of knowledge regarding quality and efficacy of drugs/ medical devices. Often, high priced items are prescribed/ preferred on the premise of improved quality. It is, therefore, important that pricing policy is not operated in silos. Any decision to exempt drugs from price regulation has to be taken in holistic perspective.

6.4 With respect to para 6.1 and 6.2, the Authority noted that the expert Committee had not applied itself fully to the important agenda pertaining to public interest as stated above. It was decided to refer both applications to 'Standing National Committee on Medicines for revision of NLEM' with a request to examine the products from the perspective of any significant therapeutic advantage and increased efficacy that may merit exemption under para 32 of DPCO, 2013.

**7.1 Agenda item no. 7 – Submission of Form IV application by M/s GlaxoSmithKline Pharmaceuticals Ltd. (GSK) for discontinuation of scheduled formulation Cetzine 5mg/5ml Syrup (Cetirizine5mg/5ml) under para 21 (2) of DPCO, 2013.**

**7.2 Agenda item no. 8 - Submission of Form IV application by M/s. GlaxoSmithKline Pharmaceuticals Ltd. (GSK) for discontinuation of scheduled formulation Cetzine 10 mg tablet (Cetirizine 10 mg tablet) under para 21 (2) of DPCO, 2013.**

7.3 The Authority deliberated on the issues at 7.1 & 7.2 above and noted that the license agreement of GSK with Farchem, S.A. (A USB group Company) for the said product terminated in December 2017 and GSK had one year to complete the formalities to effect the transfer and assignment of trade mark, which expired in December 2018. Further, Dr Reddy's Laboratories, which has entered into license agreement with Farchem, S.A. (A USB group Company) has informed that they will manufacture and market the said product from March, 2019. The Authority also noted that the company had given 6 month notice for discontinuation, as prescribed, and that there are many other companies in the market for the said product. In view of the above, it was decided to grant no objection for discontinuation of the said formulation without the condition to manufacture/sell the product for a period of twelve months from the intended date of discontinuation. However, the Company will be directed to issue public notice that GSK is discontinuing manufacturing/ marketing of the said product and the same would henceforth be manufactured/ marketed by Dr. Reddy's Laboratories.

**8. Agenda item no. 9 - Deliberation in respect of ceiling price notified by the NPPA for Oxygen Gas is being supplied to the various Hospitals through composite contract**

8.1 The Authority deliberated in the matter and noted that the issue needs further examination. Accordingly, the Authority decided that the Multidisciplinary Committee of Experts may re-examine the matter after co-opting subject experts and after obtaining the views of the representatives of various stakeholders in the trade.

**9. Agenda item no. 10 - Deliberation in respect of overcharging cases regarding pre-manufactured stocks (batches manufactured before the date of ceiling price notification and available in the market at pre-notified price after the date of notification).**

9.1 The Authority deliberated on the issue. It was observed that since DPCO 2013 provided the implementation framework to the Authority, the Authority will act as per the extant provisions till an amendment of DPCO, 2013 takes place in this matter.

**10. Agenda item no. 11 - Minutes of the 7th meeting of Multidisciplinary Committee of Experts held on 07.02.2019.**

10.1 Noted.

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

(Ritu Dhillon)  
Member Secretary