

मिसिल स.- 8(56)/2018/डी.पी/एनपीपीए-डीवी-II

F. No. 8(56)/2018/DP/NPPA-Div. II

कार्यवाहीस. : 188/56/2018/F

Proceeding No : 188/56/2018/F

**Minutes of the 188<sup>th</sup> (overall) and 56<sup>th</sup> meeting of the Authority under DPCO, 2013  
held on 23.04.2018 at 3:00 P.M**

I. The 188<sup>th</sup> overall meeting of the Authority, which is the 56<sup>th</sup> meeting under the DPCO, 2013, was held on 23<sup>rd</sup> April, 2018 at 3:00 PM under the Chairmanship of Dr. Rakesh Kumar Vats, Chairman, NPPA. The following members of the NPPA were present:

- (i) Shri Rakesh Ranjan, Member Secretary
- (ii) Dr. S. Eswara Reddy, DCG(I)
- (iii) Shri Arun Kumar, Adviser, Deptt. of Economic Affairs, Ministry of Finance.
- (iv) Shri B. Bandyopadhyay, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance
- (v) Shri A.K.Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare

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 APS Sawhney, Director(Pricing)
- iii. Shri Rajesh K. Aggarwal, Jt Director (M&E)
- 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 55<sup>th</sup> Meeting held on 26.02.2018.**

1.1 The Authority confirmed the minutes of the overall 187<sup>th</sup> and the 55<sup>th</sup> Meeting held on 26.02.2018.

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

2.1 The Authority noted the action taken report. The Authority noted that information/documents/samples have not been received from M/s Intas Pharmaceuticals



Ltd. in case of implementation of review order of M/s Cipla Ltd and M/s Glenmark Pharmaceuticals Ltd. for Budesonide+Formetral and Tiotrpium Inhalers.

The Authority was informed that, in its las

t meeting, it was decided that the matter of Mythyldopa and M/s Wockhardt Ltd needs to be enquired into in detail and needs to be referred to an appropriate agency of the Government of India dealing with such economic offences. A Committee has been constituted comprising of Shri Kalyan Nag, Adviser, Shri Amarpal Singh Sawhney, Director (Pricing/OC) and Shri Rajesh Aggarwal, Joint Director (M&E) to conduct a preliminary enquiry into the claims of M/s wockhardt Limited that they are not 'existing manufacturer' of Methyldopa 250mg tablet.. The enquiry report will be submitted in the next meeting of the Authority.

### 3. Agenda item no. 3 -Status and implementation of Review orders.

#### 3.1 Agenda item No. 3(i) – Status of Review Orders.

3.1.1. Noted.

3.2 The Authority deliberated the review cases as per Agenda 3(ii) & 3 (iii) and approved revision of ceiling prices of formulations, wherever applicable. Further, the Authority deliberated the review cases as per Agenda 3(iv) & 3 (v) and referred back the cases to the Multi Disciplinary Committee of Expert. The details of the same are as under:

Agenda item no.	Review Order number and date	Petitioner Company	Formulation	Notified ceiling/ retail price	Approved price on the basis of review	Remarks
(1)	(2)	(3)	(4)	(5)	(6)	(7)
3(ii)	31015/87/2017-Pricing dated 21.3.2018	M/s Sun Pharmaceutical Industries Ltd.	Nitrofurantoin 100mg Cpasule.	Rs. 7.13 per capsule	No Change	The company claimed that the product URIFAST CP 100 MG capsule be considered in price fixation. However, the company did not submit the original sample of URIFAST CP 100 MG Capsule manufactured in or before August, 2015. As per Pharmatrac, URIFAST CP 100 MG Capsule 30 was launched in February, 2016 (i.e., subsequent to August 2015, the date used for calculation).
3(iii)	31015/38/2017-Pricing dated 09.02.2018	M/s Abbot Healthcare Pvt. Ltd.	Phenytoin 30mg/5 ml oral liquid.	Rs. 0.28 per ml	Rs. 0.29 per ml (excluding GST)	PTR claimed by the company for "Eptoin 30 mg Suspension 200 ml" is not the highest count. Due to revision in the price of Phenytoin 100 mg tablet, its percentage



					reduction changed from 16.30 to 5.19. As a consequence, average percentage reduction for all strengths changed from 9.38 to 7.53. Authority approved the change of ceiling price on account of this factor as per column 6.
3(iv)	31015/14/2017-Pricing dated 11.01.2018	M/s Cadila Healthcare Ltd	Omeprazole 20 mg tablet	Rs. 4.62 per tablet	Referred back the cases to the Multi Disciplinary Committee of Expert. for re-consideration by the Committee, after co-opting a clinical pharmacologist and therapeutic expert. A list of experts available with DCGI will be shared by DCGI with the convener of the Multi Disciplinary Committee.
3(v)	31015/61/2017-Pricing dated 11.01.2018	M/s Sun Pharmaceutical Industries Ltd	SodiumValproate 200 mg tablet	Rs. 2.91 per tablet	

#### 4. Agenda item no. 4 - Status and Fixation of Retail Price of New Drugs.

##### 4.1 Agenda no. 4(i) - Status of New Drug Cases.

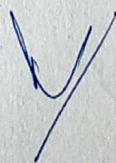
##### 4.1.1. Noted.

4.2 The Authority discussed and cases of retail price fixation of new drugs in Agenda no. 4(ii) to 4(vii) falling under the purview of para 2(u) of DPCO, 2013 as it was clarified by the DCGI that approval of DCGI for the launch of these drugs has not been obtained by the company. Written communication will be received in a couple of days. The Authority discussed the cases of retail price fixation of new drugs in Agenda no. 4(viii) to 4(x) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices of 8(eight) cases under para 5 of the DPCO 2013. The details are as under:

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Remarks/ Approved Retail Price (Rs. Excluding GST)
(1)	(2)	(3)	(4)	(5)	(6)
4(ii)	Chlorthalidone + Amlodipine + Telmisartan Tablet (TRITELSAR 80 HS)	Each film coated tablet contains: Chlorthalidone IP 12.5mg, Amlodipine Besylate IP eq. to Amlodipine 5mg, Telmisartan IP 80mg tablets	1 Tablet	M/s GKM New Pharma. / M/s Unichem Laboratories Limited	Deferred
4(iii)	Olmesartan + Amlodipine + Chlorthalidone tablet (TRIOALSAR)	Each film coated tablet contains: Olmesartan Medoxomil 20mg, Chlorthalidone IP 12.5mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets	1 Tablet	M/s GKM New Pharma. / M/s Unichem Laboratories Limited	Deferred



	20 HS)				
4(iv)	Olmesartan + Amlodipine + Chlorthalidone tablet (TRIOALSAR 40 HS)	Each film coated tablet contains: Olmesartan Medoxomil 40mg, Chlorthalidone IP 12.5mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets	1 Tablet	M/s GKM New Pharma. / M/s Unichem Laboratories Limited	Deferred
4 (v)	Chlorthalidone + Amlodipine + Telmisartan Tablet (TRITELSAR 40)	Each film coated tablet contains: Chlorthalidone IP 6.25mg, Amlodipine Besylate IP eq. to Amlodipine 5mg, Telmisartan IP 40mg tablets	1 Tablet	M/s GKM New Pharma. / M/s Unichem Laboratories Limited	Deferred
4(vi)	Chlorthalidone + Amlodipine + Telmisartan Tablet (TRITELSAR 40 HS)	Each film coated tablet contains: Chlorthalidone IP 12.5mg, Amlodipine Besylate IP eq. to Amlodipine 5mg, Telmisartan IP 40mg tablets	1 Tablet	M/s GKM New Pharma. / M/s Unichem Laboratories Limited	Deferred
4(vii)	Chlorthalidone + Amlodipine + Telmisartan Tablet (TRITELSAR 80)	Each film coated tablet contains: Chlorthalidone IP 6.25mg, Amlodipine Besylate IP eq. to Amlodipine 5mg, Telmisartan IP 80mg tablets	1 Tablet	M/s GKM New Pharma. / M/s Unichem Laboratories Limited	Deferred
4(viii)	Diclofenac + Methyl Salicylate + Menthol (Volini Maxx Spray in 15gm Pack)	contains: Diclofenac Diethylamine BP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w), Methyl Salicylate IP 10% w/w & Menthol IP 5% w/w	15 GM	M/Sun Pharmaceuticals Industries Ltd.	93.75
	Diclofenac + Methyl Salicylate + Menthol (Volini Maxx Spray in 30gm Pack)	contains: Diclofenac Diethylamine BP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w), Methyl Salicylate IP 10% w/w & Menthol IP 5% w/w	30 GM	M/Sun Pharmaceuticals Industries Ltd.	187.50
	Diclofenac + Methyl Salicylate + Menthol (Volini Maxx Spray in 40gm Pack)	contains: Diclofenac Diethylamine BP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w), Methyl Salicylate IP 10% w/w & Menthol IP 5% w/w	40GM	M/Sun Pharmaceuticals Industries Ltd.	231.25
	Diclofenac + Methyl Salicylate + Menthol	contains: Diclofenac Diethylamine BP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w),	60GM	M/Sun Pharmaceuticals Industries Ltd.	318.75





	(Volini Maxx Spray in 60gm Pack)	Methyl Salicylate IP 10% w/w & Menthol IP 5% w/w			
4(ix)	Atorvastatin + Aspirin + Clopidogrel capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As granules) Aspirin IP 75mg (As EC tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as two film coated tablets)	1 Capsule	M/s GKM New Pharma / M/s Cadila Healthcare Ltd.	4.12
	Atorvastatin + Aspirin + Clopidogrel capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As granules) Aspirin IP 75mg (As EC tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as two film coated tablets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Eris Lifesciences Limited	4.12
4(x)	Atorvastatin + Aspirin + Clopidogrel capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg (As granules) Aspirin IP 75mg (As EC tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as two film coated tablets)	1 Capsule	M/s GKM New Pharma / M/s Cadila Healthcare Ltd.	5.56
	Atorvastatin + Aspirin + Clopidogrel capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg (As granules) Aspirin IP 75mg (As EC tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as two film coated tablets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Eris Lifesciences Limited	5.56

4.2.1 In respect of Volini Maxx spray [Agenda no. 4(viii)], the Authority noted that the pack sizes in the working sheet are of 15ml and 30ml and, therefore, the pharmpatrac data could be used only for fixing price of Volini Maxx 15mg and 30mg pack size. The authority further decided that in respect of 40gm and 60gm pack sizes, the retail price be fixed on the basis of recommended price of 30mg spray by applying the following formula:

$$P(s) = P^* \times [1 + 0.7 \times \{(s - 30)/30\}]$$

Where: P(s) = price for pack size s

P\* = ceiling price for reference pack size (30mg)

s = pack size for which price is to be fixed (i.e., 40mg or 60mg)

4.3 The Authority discussed the following cases of retail price fixation of new drugs in Agenda no. 4(xi) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices of 27(twenty seven) cases at Sl no. 1, 2, 4 to 13, 15 to 19, 22 to 29, 32 & 33 and deferred cases at Sl. No. 3, 14, 20, 21, 30 & 31 following under para 5 of the DPCO 2013, as under:



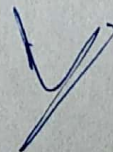
S.No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)/ Remark
(1)	(2)	(3)	(4)	(5)	(6)
1.	Rosuvastatin + Aspirin + Clopidogrel Capsule (R2 Trio 10)	Each hard gelatine capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As film coated tablet) Aspirin IP 75mg (As gastro resistant tab) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As film coated tablet)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	11.70
2.	Rosuvastatin + Aspirin + Clopidogrel Capsule (R2 Trio 20)	Each hard gelatine capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As film coated tablet) Aspirin IP 75mg (As gastro resistant tab) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As film coated tablet)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	18.00
3.	Telmisartan + Cilnidipine Tablet (Telpress LN 40)	Each film coated tablet contains: Telmisartan IP 40mg, Cilnidipine 10mg, tablet	1 Tablet	M/s ACME Generics LLP / M/s Abbott Healthcare Pvt. Ltd.	Deferred
4.	Atorvastatin + Clopidogrel Capsule (Stator CV)	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As film coated tablet) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As 2 film coated 37.5mg each tablet)	1 Capsule	M/s Windlas Biotech Limited / M/s Abbott Healthcare Pvt. Ltd.	8.394
5.	Amoxicillin + Clavulnic Suspension	(a) Each 5ml of constituted suspension contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 400mg, Potassium Clavulante Diluted IP eq. to Clavulnic Acid 57mg (b) One vial of purified water IP Each vial contains: Purified water IP 30ml	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s IPCA Laboratories Limited	2.91
6.	Paclitaxel Injection (Nab-Altaxel 100mg)	Each vial contains: Paclitaxel IP 100mg Human Albumin IPm q.s.	1 Vial	M/s Beta Drugs Limited / M/s Alkem Laboratories Limited	11115.39
7.	Escitalopram + Clonazepam Tablet (Szetalo)	Each film coated tablet contains: Escitalopram Oxalate eq. to Escitalopram 5mg,	1 Tablet	M/s Tristar Formulations Pvt. Ltd. / M/s Abbott	3.83



	Plus 5)	Clonazepam IP 0.5mg		Healthcare Pvt. Ltd.	
8.	Teneligliptin + Metformin Tablet (Terostil M)	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin HCl 500mg (SR)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Anthem BioPharma Pvt. Ltd.	9.62
9.	Glimepride + Metformin Tablet (Glimison-M2 Forte)	Each uncoated Bilayered tablet contains: Glimepride IP 2mg, Metformin Hydrochloride (SR) 1000mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	3.88
10.	Glimepride + Metformin Tablet (Glimison-M1 Forte)	Each uncoated Bilayered tablet contains: Glimepride IP 1mg, Metformin Hydrochloride (SR) 1000mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	3.53
11.	Metoprolol + Amlodipine Tablet (MPROL-AM 25/5)	Each film coated bilayered tablet contains: Metoprolol Succinate ER 25mg Amlodipine Besylate 5mg bilayered Tablets	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	1.96
12.	Telmisartan + Chlorthalidone Tablet (Telmiride - CH 6.25)	Each uncoated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 6.25mg Tablets	1 Tablet	M/s Windlabs Biotech Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt. Ltd.	2.68
13.	Telmisartan + Chlorthalidone Tablet	Telmiride - CH 12.50 Tablet Each uncoated bilayered tablet contains: Telmisartan IP 40mg + Chlorthalidone IP 12.50mg Tablets	1 Tablet	M/s Windlabs Biotech Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt. Ltd.	3.21
14.	Telmisartan + Cilnidipine Tablets (Telmiride - LN)	Each film coated tablets contains: Telmisartan IP 40mg, Cilnidipine 10mg	1 Tablet	M/s Windlabs Biotech Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt. Ltd.	Deferred
15.	Ferrous + Folic Acid + Elemental Tablet (Tonofolic - XT)	Each film coated tablets contains: Ferrous Ascorbate eq. to elemental Iron 100mg + Folic Acid 1.5mg + Elemental Zinc 22.5mg Tablets	1 Tablet	M/s Ravenbhel Healthcare Pvt. ltd. / M/s Unison Pharmaceuticals Pvt. Ltd.	3.52
16.	Voglibose + Glimepride + Metformin Tablet (Voglyson GM1)	Each uncoated bilayered tablet contains: Voglibose 0.2mg, Glimepride 1mg & Metformin Hydrochloride 500mg Tablets	1 Tablet	M/s Windlabs Biotech Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt. Ltd.	3.21
17.	Voglibose + Glimepride + Metformin	Each uncoated bilayered tablet contains: Voglibose 0.2mg,	1 Tablet	M/s Windlabs Biotech Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt.	3.57



	Tablet (Voglyson GM2)	Glimepiride 2mg & Metformin Hydrochloride 500mg ablets		Ltd.	
18.	Doxorubicin Injection	Each ml contains: Doxorubicin Hydrochloride 2mg (Pegylated Liposomal) Water for Injection	1 ML	M/s Natco Pharma Limited / M/s RPG Life Sciences Ltd.	694.29
19.	Glimiepiride + Metformin Tablet (GLYCOMET GP 3 Forte)	Each film coated tablet contains: Glimiepiride IP 3mg, Metformin Hydrochloride IP 1000mg (SR)	1 Tablet	M/s Accent Pharma / M/s USV Private Limited	8.37
20.	Telmisartan + Cilnidipine Tablet (ZITELMI -CL)	Each film coated tablet contains: Telmisartan IP 40mg Cilnidipine IP 10mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Limited / M/s FDC Limited	Deferred
21.	Telmisartan + Cilnidipine Tablet (NEXOVA S T)	Each film coated tablet contains: Telmisartan IP 40mg Cilnidipine IP 10mg	1 Tablet	M/s Macleods Pharmaceuticals Limited	Deferred
22.	Rosuvastation + Aspirin + Clopidogrel Capsule (Rxtor Gold 10)	Each hard gelatine capsule contains: Rosuvastation Calcium IP 10mg (As pellets), Aspirin 75mg (as enteric coated pellets) & Clopidogrel Bisulphate IP 75mg (as pellets)	1 Capsule	M/s Synokem Pharmaceuticals Limited / M/s IPCA Laboratories Limited	11.70
23.	Rosuvastation + Aspirin + Clopidogrel Capsule (Rxtor Gold 20)	Each hard gelatine capsule contains: Rosuvastation Calcium IP 20mg (As pellets), Aspirin 75mg (as enteric coated pellets) & Clopidogrel Bisulphate IP 75mg (as pellets)	1 Capsule	M/s Synokem Pharmaceuticals Limited / M/s IPCA Laboratories Limited	18.00
24.	Paclitaxel (Protein bound Particles) for Injectable Suspension	Each vial contains: Paclitaxel IP 100mg Human Albumin IP 900mg	1 Vial	M/s Emcure Pharmaceuticals Ltd.	11115.39
25.	Glimepiride + Metformin Tablet (Glimy M 0.5mg)	Each uncoated bilayered Tablet contains: Glimepiride IP 0.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Dr. Reddy's Laboratories Limited	2.22
26.	Gliclazide + Metformin Tablet (Glizest M)	Each uncoated tablet contains: Gliclazide IP 80mg, Metformin Hydrochloride IP 500mg	1 Tablet	M/s Pharmafabikon	4.88
27.	Doxorubicin Hydrochloride liposomal Injection. (2mg/ml)(20m g/vial) 10ml	contains: Doxorubicin Hydrochloride IP 2mg (As pegylated liposomal) Water for Injection	1 ML	M/s Natco Pharma Limited / M/s Zydus Cadila Healthcare Limited	694.29
28.	Teneligliptin +	Each uncoated bilayered tablet	1 Tablet	M/s Glenmark	10.87





	Metformin Tablet	contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin HCl 1000mg (ER)		Pharmaceuticals Ltd. / M/s Koye Pharmaceuticals Private Limited	
29.	Rosuvastatin + Aspirin Capsules (Roseday A 20)	Each hard gelatine capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As pellets), Aspirin IP 75mg (As Enteric Coated pellets IP),	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s USV Private Limited	7.80
30.	Telmisartan + Amlodipine + Chlorthalidone Tablets (Telvas 3D CT 80)	Each film coated tablet contains: Telmisartan 80mg, Amlodipine 5mg & Chlorthalidone 12.5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	Deferred
31.	Telmisartan + Amlodipine + Chlorthalidone Tablets (Telvas 3D CT 40)	Each film coated tablet contains: Telmisartan 40mg, Amlodipine 5mg & Chlorthalidone 12.5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	Deferred
32.	Metformin + Glimepiride Tablet (Glucoryl - M 0.5)	Each uncoated bilayer tablet contains: Metformin Hydrochloride IP 500mg (As prolonged Release form), Glimepiride IP 0.5mg	1 Tablet	M/s Alkem Laboratories Ltd.	2.22
33.	Amoxicillin + Clavulanic Dry Syrup (Trimox CV Forte)	Each 5ml of re-constituted Suspension contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 400mg, Potassium Clavulanic Diluted IP eq. to Clavulanic Acid 57mg	1 ML	M/s Malik Life Sciences Pvt. Ltd. / M/s Mapra Laboratories Pvt. Ltd.	2.91

## 5. Agenda item no. 5 - Update of Overcharging

5.1 Noted.

## 6. Agenda item no. 6 - Withdrawal Proposals

**6.1 Request of M/s Magnet Pvt. Ltd for discontinuation of five scheduled formulations (1) Cope MD Tablet (2) Napilex CR 200 tablet (3) Napilax CR 500 tablet (4) Tryal tablet (5) Eptokind 100 tablet and request of M/s Mankind Pvt. Ltd of scheduled formulation Clindatime 150 capsule under para 21(2) of DPCO, 2013.**

6.1.1 Authority approved the withdrawal proposal of M/s Magnet Pvt. Ltd and M/s Mankind Pvt. Ltd



**6.2 Discontinuation of Xience Alpine brand of Coronary stent under Para 21(2) of DPCO, 2013 by M/s Abbott Healthcare Private Limited.**

6.1.1 The Authority approved the change in date of withdrawal of Xience Alpine brand of coronary stents as proposed by M/s Abbott Healthcare Private Limited

**7. Agenda Item No. 7 - Proposal under Para 19.**

**7.1 Agenda no. 7(i) - Bochem Healthcare Pvt Ltd. in respect (i) Ferrous Salt (A) + Folic acid (B) - 100mg(A) + 500mcg(B) Tablet and (ii) Ferrous salt (A)+ Folic acid (B) - 45mg(A) + 400mcg(B) Tablet fixed vide SO 3091(E) dated 20.9.2017.**

7.1.1 The Authority noted that

- (i) In the Authority meeting dated 19.9.2017, it was decided to fix the ceiling prices based on the institutional procurement prices where market data are not available. Accordingly, NPPA notified the ceiling price vide SO 3091(E) dated 20.9.2017 as follows:

Formulation	Notified ceiling price	Revised Ceiling price wef 1.4.2018
Ferrous Salt(A) + Folic acid (B) - (100mg + 500mcg) Tablet	0.09821 per Tablet	0.10159 per Tablet
Ferrous salt (A)+ Folic acid (B) - (45mg + 400mcg) Tablet	0.12755 per Tablet	0.13194 per Tablet

- (ii) M/s Bochem Healthcare Pvt Ltd. vide its letter dated 10th Jan 2018 has given a representation stating the prices are not viable. They also claimed that almost 98% of the supply is for NRHM.

7.1.2. The Authority considered the following factors to decide the matter:

- (i) The Hon'ble High court of Madhya Pradesh having principal bench at Jabalpur vide its order dated 19.03.2018 in WP 1550/2018 in the matter of BOCHEM HEALTH CARE PVT. LTD. Vs UNION OF INDIA has given direction: "let decision be taken reviewing the notification dated ~~12.9.2017~~ 20.09.2017 within two weeks on or before 9.4.2018."
- (ii) The petitioner company M/s BOCHEM HEALTH CARE PVT. LTD. Vs UNION OF INDIA, in its submission in the court, stated that the grievance does not relate to 45mg tablet as it is competitively placed.
- (iii) It is also noticed that the ceiling price of lower strength is more than the ceiling price of higher strength.

7.1.3. Considering all the above factors, the Authority decided to withdraw the ceiling price of (i) Ferrous Salt (A) + Folic acid (B) - 100mg(A) + 500mcg(B) Tablet and refix it at a later stage when the relevant market data are available.



**7.2 Agenda no. 7(ii) – Application for upward revision of the ceiling price of BCG vaccine under DPCO, 2013 by M/s Serum Institute of India.**

7.2.1 The Authority discussed the matter in detail.

7.2.2 Price of the formulation was fixed in the meeting of the Authority held on 22.11.2017. Before that the worksheet of draft price calculation was uploaded on the website of NPPA. M/s Serum Institute of India had submitted its representations dated 31.10.2017 and 20.11.2017 wherein it had claimed that

(i) the reduction under para 6 has been carried out to the extent of 45.64% in 2014 and further downward reduction of 20.024% in price would only render manufacturing of BCG vaccine unviable; and

(ii) the reduction is not applicable in this case as each vaccine has distinct therapeutic usage and criteria of reduction based on sub-therapeutic group cannot be applied to vaccines.

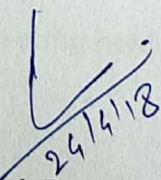
7.2.3 The matter was discussed in the Authority meeting dated 22.11.2017, whereby the authority noted “M/s Serum has filed the application for repeat monopoly reduction in the ceiling price of BCG Vaccine and stated that the product will become unviable on reduction. M/s Serum Institute of India Ltd has represented against it. However, as the reduction applied in the draft ceiling price as per para 6 of the DPCO 2013, 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.” Vide its letter dated 13<sup>th</sup> February 2018, M/s Serum Institute of India has submitted its application under para-19 of DPCO for revising the price upward.

7.2.4 In view of the above, the Authority decided that the ceiling price may be fixed/revised under para 19 without applying reduction under monopolistic condition to address the genuine grievance of the applicant as well as to ensure sufficient availability of the drug in the market. It therefore approved the ceiling price without monopolistic reduction at Rs. 5.59/ dose against the present ceiling price of Rs. 4.47/ dose.

**8. Agenda item no. 8 - Ceiling Price Revision under para 16(2) in respect of WPI.**

8.1 Noted.

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

  
(Rakesh Ranjan)  
Member Secretary