मिसिल स.- 8(81)/2020/डी.पी/एनपीपीए-डीवी-II
F. No. 8(81)/2020/DP/NPPA-Div. II

कार्यवाहीस. : 213/81/2020/F
Proceeding No : 213/81/2020/F

Minutes of the 213th (overall) and 81st meeting of the Authority under DPCO, 2013 held on 24.11.2020 at 11:30 AM

The 213th meeting of the Authority (overall), which is the 81st meeting under the DPCO, 2013, was held on the 24th of November, 2020 at 11:30 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, and NPPA. The following Authority members of the NPPA were present:

(i) Dr. Vinod Kotwal, Member Secretary
(ii) Shri A. K. Saha, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

Ms. A. Srija, Economic Advisor, Department of Economic Affairs had requested for leave of absence.

Shri Sanjeev Kumar, Deputy Drug Controller, CDSCO, Ministry of Health & Family Welfare was also present.

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

(i) Shri N. I. Chowdhury, Advisor
(ii) Shri S. S. Ojha, Jt. Director (Pricing)
(iii) Shri Prakash Hemani, Asstt. Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 80th meeting held on 26.10.2020.

1.1 The Authority confirmed the minutes without any change.

2. Agenda item no. 2 – Action Taken Report on decisions taken by NPPA in its 80th meeting dated 26.10.2020

2.1 The Authority noted that due actions have been taken.

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

3.1 Noted.

4. Agenda item no. 4 – New Drug application Price fixation under Para 5 and Para 15 of DPCO, 2013

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4(xxvii) (total 27 Form I applications containing retail price fixation of 27 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 22 (twenty two) new drugs [except 5 formulations as per agenda no. 4(xx), 4(xxi), 4(xxii), 4(xxiii) and 4(xxiv)] under Para 5 and 15 of the DPCO 2013, as detailed below:

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

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(i)	Mesalazine Suppositories BP 1g	**Each Suppository contains:** Mesalazine IP 1g	1 Suppository	M/s Bliss GVS Pharma Ltd. / M/s Cipla Limited	97.88
4(ii)	Telmisartan + Chlorthalidone + Amlodipine Tablet	**Each film coated tablet contains:** Telmisartan IP 40mg, Chlorthalidone IP 6.25mg, Amlodipine Besilate IP eq. to Amlodipine 5mg	1 Tablet	M/s Micro Labs Limited	8.39 (Note 2)
4(iii)	Ceftiazone + Sulbactum for Injection (ZIFI SB)	**The combipack contains:** (a) Each vial contains: Ceftiazone Sodium IP eq. to Ceftriaxone 1000mg Sulbactum Sodium IP eq. to Sulbactum 500mg	Per combipack	M/s Zen Pharma (P) Limited / M/s FDC Limited	120.34

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		(b) One ampoule of: Sterile Water for Injections IP 10ml			
4(iv)	Diclofenac + Thiocolchicoside + Linseed Oil + Methyl Salicylate + Menthol Gel	**Composition:** Diclofenac Diethylamine IP 1.16%w/w (eq. to Diclofenac Sodium 1.0%w/w), Thiocolchicoside IP 0.125% w/w, Linseed Oil BP 3% w/w, Methyl Salicylate IP 10%w/w Menthol IP 5%w/w	1 GM	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Zydus Healthcare Limited	5.23 (Note 2)
4(v)	Ciprofloxacin + Dexamethasone Eye Drops	**Composition:** Ciprofloxacin Hydrochloride IP Eq. to Ciprofloxacin 0.3% w/v, Dexamethasone IP 0.1% w/v	1 ML	M/s Skymap Healthcare Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	1.33
4(vi)	Ciprofloxacin + Dexamethasone Eye Drops	**Composition:** Ciprofloxacin Hydrochloride IP Eq. to Ciprofloxacin 0.3% w/v, Dexamethasone IP 0.1% w/v	1 ML	M/s Skymap Healthcare Pvt. Ltd.	1.33
4(vii)	Phenylephrine HCl + Chlorpheniramine Maleate + Sodium Citrate	**Each 5ml contains:** Phenylephrine HCl IP 5mg,	1 ML	M/s Enicar Pharmaceuticals Pvt. Ltd. / M/s Group Pharmaceutical	0.90

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	+ Menthol Syrup	Chlorpheniramine Maleate IP 1mg Sodium Citrate IP 60mg, Menthol IP 1mg		s Ltd.	
4(viii)	Omeprazole for Injection	**Each vial contains:** Omeprazole IP (Sterile) 40mg (As Sodium Suitably buffered) Water for Injection IP q. s.	Per Pack	M/s Skymap Healthcare Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	34.86
4(ix)	Metoprolol Injection	**Each ml contains:** Metoprolol Tartrate IP 1mg Water for injection IP q. s.	Per Pack	M/s Skymap Healthcare Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	13.53
4(x)	Norethisterone Acetate Controlled Release Tablet	**Each film coated controlled released tablet contains:** Norethisterone Acetate BP 10mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Limited	15.09
4(xi)	Ibuprofen + Paracetamol Tablet	**Each uncoated tablet contains:** Ibuprofen IP 400mg Paracetamol IP 325mg	1 Tablet	M/s Vapi Care Pharma Pvt. Ltd. /M/s Alembic Pharmaceutical Limited	1.11
4(xii)	Moxifloxacin Hydrochloride + Dexamethason	**Each ml contains:** Moxifloxacin Hydrochloride IP	1 ml	M/s Skymap Healthcare Pvt. Ltd. / M/s Glensmith Labs	19.07

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	e Phosphate Eye Drops	eq. to Moxifloxacin 0.5% w/v Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 0.1% w/v		Pvt. Ltd.	
4(xxv)	Ofloxacin + Dexamethasone Sodium Phosphate Eye /Ear Drops	**Composition:** Ofloxacin IP 0.3% w/v, Dexamethasone Sodium Phosphate IP 0.1% w/v	1 ml	M/s Skymap Healthcare Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	4.25 (Note 2)
4(xxvi)	Ofloxacin + Dexamethasone Sodium Phosphate Eye /Ear Drops	**Composition:** Ofloxacin IP 0.3% w/v, Dexamethasone Sodium Phosphate IP 0.1% w/v,	1 ml	M/s Skymap Healthcare Pvt. Ltd.	4.25 (Note 2)
4(xxvii)	Ascorbic Acid (Vitamin C) + Zinc Chewable Tablet	**Each uncoated Chewable Tablet C contains:** Ascorbic Acid IP 100mg, Sodium Ascorbate IP 450mg eq. to Ascorbic Acid 400mg, Zinc Citrate USP eq. to Elemental Zinc 5mg.	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	3.82 (Note 2)

B. Retail price fixed under Para 5 and 15 of DPCO, 2013

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xiii)	Povidone-Iodine Gargle 0.5% w/v	Composition: Povidone-Iodine IP 0.5% w/v (available Iodine 0.06% w/v)	1 ml	M/s Windlas Biotech Pvt. Ltd. / M/s Mankind Pharma Limited	0.79
4(xiv)	Trihexyphenidyl Hydrochloride Tablet	Each uncoated tablet contains: Trihexyphenidyl Hydrochloride IP 1mg	1 Tablet	M/s D. D. Pharmaceuticals Pvt. Ltd.	0.73
4(xv)	Azelnidipine + Telmisartan Tablet	Each film coated bi-layered tablet contains: Azelnidipine IP 8mg Telmisartan IP 40mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Torrent Pharmaceuticals Ltd.	12.45
4(xvi)	Azelnidipine + Telmisartan Tablet	Each film coated bi-layered tablet contains: Azelnidipine IP 8mg Telmisartan IP 80mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Torrent Pharmaceuticals Ltd.	14.20
4(xvii)	Vildagliptin + Metformin Hydrochloride (as sustained release) Tablet	Each uncoated bilayered tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP (As sustained release) 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Life Sciences Limited	6.58 (Note 3)
4(xviii)	Vildagliptin + Metformin Hydrochloride (as sustained release) Tablet	Each uncoated bilayered tablet contains: Vildagliptin 50mg, Metformin	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Life Sciences Limited	7.07 (Note 3)

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Hydrochloride IP (As sustained release) 1000mg			
4(xix)	Povidone Iodine Topical Solution 1%w/v	Each 100ml contains: Povidone Iodine IP 1.0g (Available Iodine 0.1g) 2-Propanol IP 50g In an aqueous base	Per 200ml Pack	M/s G.S. Pharmbutor Pvt. Ltd./M/s Win-Medicare Pvt. Ltd.	92.00

Note 1. *The retail prices are to be notified after 10 working days from uploading of draft working sheet/Minutes of the Multidisciplinary Committee of Experts/ Minutes of the Authority Meeting on NPPA's website, as applicable.*

Note 2. *The representative of DCGI present in the meeting confirmed that the formulations are approved by CDSCO.*

Note 3. *The Authority deliberated upon the matter in detail and decided to approve the retail price in line with the decision taken in its 80th meeting dated 26.10.2020 as recorded in Note 6 of Para 4.1 of the Minutes of the 80th Authority meeting dated 26.10.2020.*

4.2 **Agenda item no. 4(xx), 4(xxi), 4(xxii), 4(xxiii)**: The Authority noted that DCGI vide its e-mail 20.11.2020 has informed that Central Drugs Standard Control Organisation (CDSCO) has not given permission to M/s Savi Health Sciences with respect to the formulations FDC of Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/10mg/5mg/10mg+ Metformin HCl IP (as extended release) 500mg/500mg/1000mg/1000mg tablets. The Authority deliberated upon the matter in detail and decided to reject the applications listed as per agenda items no. 4(xx), 4(xxi), 4(xxii), 4(xxiii). The Authority also directed to write to DCGI to take necessary action in the matter.

4.3 **Agenda item no. 4(xxiv):** The Authority noted that DCGI vide letter dated 23.11.2020 has stated that Central Drugs Standard Control Organisation (CDSCO) has approved Doxycycline formulation (capsule and syrup) in December 1967. Thus, Doxycycline is an old drug, available in the market since many years. However, no specific information about approval status of Doxycycline Injection USP 100mg is available in CDSCO. Accordingly, the Authority directed to reject the application as per agenda item no. 4(xxiv).

5. Agenda item no. 5 – Status of implementation of Review cases

5.1 Noted.

6.1 Agenda item no. 6 – Review order no. 31015/12/2019-Pricing dated 24.07.2020 relating to application filed by M/s Sun Pharma Laboratories Ltd for ceiling price fixation of Diltiazem 90 mg capsule vide SO. 1687(E) dated 09.05.2016

6.1 The Authority deliberated upon the matter in detail and noted the representation of M/s Sun Pharma Laboratories Ltd based on the decision taken in its 78th meeting held on 14.09.2020.

6.2 The Authority observed that based on ceiling price notification for the formulation Diltiazem 90 mg capsule vide S.O. 1687(E) dated 09.05.2016, M/s Sun Pharma Laboratories Ltd could have sought clarification as to whether the same is also applicable for Diltiazem SR 90 mg capsule. This is in view of the fact that the ceiling price of Diltiazem 90 mg capsule has been fixed based on the data of SR variants only including M/s Sun Pharma formulations and the working/ calculation sheet had been uploaded on NPPA website.

6.3 The Authority further observed note (c) of notification SO. 1039(E) dated 01.04.2017 relating to revised ceiling price of Scheduled formulations based on Wholesale Price Index (WPI) in which it was mentioned that in respect of any scheduled formulation for which ceiling price is not mentioned, the manufacturer shall approach NPPA for specific price approval for its formulation. Notes on the same line have also been issued in notification relating to revised ceiling price of Scheduled formulations based on Wholesale Price Index (WPI) during 2018, 2019 and 2020. Accordingly, it was incumbent on M/s Sun Pharma Laboratories Ltd to seek clarification as to whether the same is also applicable for Diltiazem SR 90 mg capsule.

6.4 In view of the above, the Authority reiterated its earlier decision taken in the 78th meeting held on 14.09.2020 and decided that the review order no. 31015/12/2019-Pricing dated 24.07.2020 be treated as closed. The Authority further noted that demand notice has been issued to M/s Sun Pharma Laboratories Ltd for violation of ceiling price fixed for Diltiazem 90 mg capsule and directed that further necessary action be taken for the violation as per the provisions of DPCO 2013.

7.1 Agenda item no. 7 - Intimation of Minutes of 24th meeting of Multidisciplinary Committee of Experts held on 11.11.2020.

7.1 Noted.

8. Agenda item no. 8 - Fixation of Ceiling Price of scheduled formulations under DPCO 2013 (NLEM 2015)

8.1 The Authority deliberated upon the matter in detail and approved the ceiling price of 2 (two) scheduled formulations as detailed below:

S. No.	Formulation	Dosage and Strength	Unit	Approved ceiling price (ex. GST) (Rs.)
1	Methylrosanilinium chloride (Gentian Violet)	Paint 1%	Per ml	0.08503
2	Oral poliomyelitis vaccine		Per ml	102.24

8.2 The Authority further noted the representation received from M/s Zydus Healthcare Ltd and observed that as per provisions of DPCO 2013, the revision of ceiling prices shall be carried out as and when the National List of Essential Medicines (NLEM)is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order, whichever is earlier. Since the ceiling price of the two formulations namely, Oral poliomyelitis vaccine and Methylrosanilinium chloride (Gentian Violet) paint 1% is being fixed for the first time under amended Schedule I of DPCO 2013, it is in accordance with the provisions of DPCO 2013. Hence, the representation has no merit and be treated as closed.

8.3 The Authority also noted the representation received from M/s Zydus Healthcare Ltd and observed that the major procurement of Oral poliomyelitis vaccine is done by Ministry of Health and Family Welfare (MoH&FW) and its data has been considered while fixing the ceiling price based on institutional procurement. Accordingly, the Authority is of the view that the representation of M/s Zydus Healthcare Ltd has no merit and decided to treat the same as closed.

9. Agenda item no. 9 - Application by M/s Torrent Pharmaceuticals Ltd for exemption under Para 32(i) of DPCO 2013 for the formulations:

a. Remoglifozin Etabonate 100 mg + Metformin Hydrochloride 500 mg tablet
b. Remoglifozin Etabonate 100 mg + Metformin Hydrochloride 1000 mg tablet

9.1 The Authority noted that the new drug approval for the formulations (a) Remoglifozin Etabonate 100 mg + Metformin Hydrochloride 500 mg tablet and (b) Remoglifozin Etabonate 100 mg + Metformin Hydrochloride 1000 mg tablet has been granted by Central Drugs Standard Control Organisation (CDSCO) to M/s Glenmark Pharmaceuticals Ltd.

Further, the manufacturing license for these formulations has been granted by State Licensing Authority to M/s Glenmark Pharmaceuticals Ltd.

9.2 The Authority further noted that M/s Torrent Pharmaceuticals Ltd does not have new drug approval for the formulations (a) Remoglifozin Etabonate 100 mg + Metformin Hydrochloride 500 mg tablet and (b) Remoglifozin Etabonate 100 mg + Metformin Hydrochloride 1000 mg tablet from Central Drugs Standard Control Organisation (CDSCO). M/s Torrent Pharmaceuticals Ltd has only entered into an agreement with M/s Glenmark Pharmaceuticals Ltd as a sub-license partner for marketing the formulation in India. M/s Torrent Pharmaceuticals Ltd also does not hold the patent in its name.

9.3 The Authority deliberated upon the matter in detail and observed that provisions of para 32 of DPCO 2013 do not provide for exemption to sub-license partner and hence M/s Torrent Pharmaceuticals Ltd has no *locus standi* to apply for exemption under para 32 of DPCO 2013. Accordingly, the Authority decided to reject the applications of M/s Torrent Pharmaceuticals Ltd for exemption under para 32 of DPCO 2013 for the formulations (a) Remoglifozin Etabonate 100 mg + Metformin Hydrochloride 500 mg tablet and (b) Remoglifozin Etabonate 100 mg + Metformin Hydrochloride 1000 mg tablet.

10. Agenda item no. 10 - Revised Ceiling price of Heparin Injection 1000IU/ml and 5000IU/ml.

10.1 The Authority noted that the revised ceiling price of Heparin Injection 5000IU/ml and 1000 IU/ml fixed vide SO. 2151(E) dated 30.06.2020 are applicable upto 31.12.2020. The Authority further noted the opinion of the Committee headed by Dr. S. Eswara Reddy, Jt Drug Controller, CDSCO communicated through letter dated 19th November, 2020. The Committee opined that "NPPA may continue with the increased ceiling price for Heparin Injection 5000IU/ml, to ensure continuous availability of this essential drug. Further, recent spurt in the number of cases in some states may also lead to higher demand of the drug. The ceiling price of Heparin may be reviewed after the Covid-19 situation become normal or earlier as deemed fit."

10.2 The Authority deliberated upon the matter in detail and considered the aspect of availability of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml, a scheduled formulation, especially during the pandemic situation of COVID-19 and opined that any situation of non-availability due to increase in the price of API needs to be seen from a public interest perspective. Therefore, due to extra-ordinary situation, the Authority

decided to extend the revised ceiling price of Heparin Injection 5000IU/ml and 1000 IU/ml fixed vide SO. 2151(E) dated 30.06.2020 up to 31.03.2021, in public interest.

10.3 The Authority further directed that the provisions of para 13(2) of DPCO 2013 would not be applicable on the revised ceiling price of Heparin 1000IU/ml Injection and Heparin 5000IU/ml Injection up to 31st March 2021.

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

Sd/-
(Dr. Vinod Kotwal)
Member Secretary