मिसिल स.- 8(82)/2020/डी.पी/एनपीपीए-डीवी-II
F. No. 8(82)/2020/DP/NPPA-Div. II

कार्यवाहीस. : 214/82/2020/F
Proceeding No : 214/82/2020/F

Minutes of the 214th (overall) and 82nd meeting of the Authority under DPCO, 2013 held on 23.12.2020 at 11:30 AM

The 214th meeting of the Authority (overall), which is the 82nd meeting under the DPCO, 2013, was held on 23rd of December, 2020 at 11:30 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, 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
(iii) Ms. A. Srija, Economic Advisor, Department of Economic Affairs

Shri A. K. Pradhan, 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 Prasenjit Das, Asstt. Director (Pricing)
(iv) Shri Prakash Hemani, Asstt. Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 81st meeting held on 24.11.2020.

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 81st meeting dated 24.11.2020

2.1 The Authority noted that due actions have been taken.

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

3.1 Noted.

3.2 The Authority noted that the most of the retail price applications of new drugs mainly consist of Fixed Dose Combinations (FDCs) of two or more drugs. In this context, it was observed by the Authority that rationality of their use is important as information asymmetry exists in this area leading to concerns of consumer affordability and over medication. This is not desirable in the overall public interest and welfare. The Authority also noted that based on the deliberation in the matter in its 80th meeting dated 26.10.2020, the matter has already been highlighted to Indian Council of Medical research (ICMR), New Delhi. It was further noted by the Authority that a number of Public Grievances are on the irrational pack size wherein a consumer is forced to buy more than his/her need. Thus, looking at the pervasive nature of the issue that may also impact the public health system; it was agreed that these issues may be raised with Ministry of Health and Family Welfare, Government of India.

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(xxii) (total 22 Form I applications containing retail price fixation of 22 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 19 (nineteen) new drugs [except 3 formulations as per agenda no. 4(v), 4(vi), and 4(viii)] 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)	Dapagliflozin + Metformin Hydrochloride Extended-	**Each film-coated tablet contains:** Dapagliflozin 10mg, Metformin Hydrochloride IP	1 Tablet	M/s Torrent Pharmaceuticals Limited	10.60 (Note 2)

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Release Tablet	(In Extended release form) 500mg			
4(ii)	Dapagliflozin + Metformin Hydrochloride Extended-Release Tablet	**Each film-coated tablet contains:** Dapagliflozin 10mg, Metformin Hydrochloride IP (In Extended release form) 1000mg	1 Tablet	M/s Torrent Pharmaceuticals Limited	12.26 (Note 2)
4(iii)	Gentamicin Sulphate + Dexamethasone Sodium Phosphate Eye Drop	**Each ml contains:** Gentamicin Sulphate IP eq. to Gentamicin base 0.3% w/v Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 0.1% w/v	1 ml	M/s Skymap Healthcare Pvt. Ltd.	1.47 (Note 3) (Note 4)
4(iv)	Gentamicin Sulphate + Dexamethasone Sodium Phosphate Eye Drop	**Each ml contains:** Gentamicin Sulphate IP eq. to Gentamicin base 0.3% w/v Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 0.1% w/v	1 ml	M/s Skymap Healthcare Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	1.47 (Note 3) (Note 4)
4(v)	Rosuvastatin + Aspirin Capsule	**Each Capsule contains:** Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg Aspirin IP 75mg	1 Capsule	M/s Sun Pharma Laboratories Limited	Deferred (Note 5)
4(vi)	Rosuvastatin + Aspirin Capsule	**Each Capsule contains:** Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg Aspirin IP 150mg	1 Capsule	M/s Sun Pharma Laboratories Limited	Deferred (Note 5)
4(vii)	Cefixime Tablet	**Each film coated tablet contains:** Cefixime IP as Trihydrate eq. to Anhydrous Cefixime 100mg	1 Tablet	M/s Hema Laboratories Pvt. Limited /M/s Sun Pharmaceutical Industries Limited	6.16
4(viii)	Ciprofloxacin + Dexamethason	**Each ml Contains:** Ciprofloxacin Hydrochloride	1 ml	M/s AXA Parenterals Ltd. /	Closed (Note 6)

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	e Eye/Ear Drops	IP Eq. to Ciprofloxacin 0.3% w/v, Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 0.1% w/v		M/s Sun Pharmaceutical Industries Limited	
4(ix)	Ibuprofen with Paracetamol Suspension	**Each 5ml contains:** Ibuprofen IP 100mg Paracetamol IP 162.5mg	1 ml	M/s Vivimed Labs Ltd. /M/s Alembic Pharmaceuticals Limited	0.36
4(x)	Lidocaine Spray 10% w/v	**Each ml contains:** Lidocaine USP 100mg Ethanol IP 30.4% v/v	1 ml	M/s Zydus Healthcare Limited	8.51
4(xi)	Remogliflozin Etabonate + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Remogliflozin Etabonate 100mg, Metformin Hydrochloride IP 500mg	1 Tablet	M/s Glenmark Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	11.44 (Note 7)
4(xii)	Remogliflozin Etabonate + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Remogliflozin Etabonate 100mg, Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Glenmark Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	13.18 (Note 7)
4(xiii)	Aceclofenac + Paracetamol Tablet	**Each film coated tablet contains:** Aceclofenac IP 100mg Paracetamol IP 325mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.	4.23
4(xiv)	Atorvastatin + Aspirin Capsule	**Each Hard Gelatin Capsule Contains:** Atorvastatin Calcium IP eq to Atorvastatin 10mg (As Film coated tablet form) Aspirin IP 75mg (As Enteric Coated tablet form)	1 Capsule	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s FDC Limited	2.59
4(xv)	Thiocolchicoside + Aceclofenac + Paracetamol Tablet	**Each film coated tablet contains:** Thiocolchicoside IP 4mg Aceclofenac IP 100mg Paracetamol IP 325mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	14.99

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(xvi)	Metformin Hydrochloride (As sustained release) and Vildagliptin Tablets	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP (As sustained release) 500mg, Vildagliptin 50mg,	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	6.58 (Note 8) (Note 9)
4(xvii)	Metformin Hydrochloride (As sustained release) and Vildagliptin Tablets	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP (As sustained release) 1000mg, Vildagliptin 50mg,	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	7.07 (Note 8) (Note 9)
4(xviii)	Metformin Hydrochloride (As sustained release) and Vildagliptin Tablets	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP (As sustained release) 500mg, Vildagliptin 50mg,	1 Tablet	M/s Exemed Pharmaceuticals / M/s Lupin Limited	6.58 (Note 8)
4(xix)	Metformin Hydrochloride (As sustained release) and Vildagliptin Tablets	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP (As sustained release) 1000mg, Vildagliptin 50mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Lupin Limited	7.07 (Note 8)
4(xx)	Metronidazole and Dextrose Injection	**Each 100ml contains:** Metronidazole IP 0.2gm Dextrose IP (as anhydrous) 5.0gm	Per 500ml Pack	M/s Aculife Healthcare Pvt. Ltd.	79.29

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Water for injection IP			
4(xxi)	Dapagliflozin + Metformin Hydrochloride Extended-Release Tablet	**Each film-coated tablet contains:** Dapagliflozin 5mg, Metformin Hydrochloride IP (In Extended release form) 500mg	1 Tablet	M/s Torrent Pharmaceuticals Limited	6.97 (Note 10)
4(xxii)	Dapagliflozin + Metformin Hydrochloride Extended-Release Tablet	**Each film-coated tablet contains:** Dapagliflozin 5mg, Metformin Hydrochloride IP (In Extended release form) 1000mg	1 Tablet	M/s Torrent Pharmaceuticals Limited	8.35 (Note 10)

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. *(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.

(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets.

(iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet by adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers.

***Note 3**. The representative of DCGI present in the meeting confirmed that the formulations are approved by DCGI*

***Note 4.** The Authority noted that as per DCGI's letter dated 12.12.2018, the formulation has been mentioned as eye drop whereas the State Drug Licensing Authority has given the permission for the formulation for eye/ ear drop. The Authority deliberated upon the matter in detail and decided to approve the formulation as eye drop as per the license.*

***Note 5.** The Authority noted that representation has been received from M/s Sun Pharma Laboratories Ltd. Accordingly, the Authority decided to examine the same.*

***Note 6.** The Authority noted that M/s Sun Pharmaceutical Industries Ltd has applied for withdrawal of Form-I application. Accordingly, the Authority decided to close the application of M/s Sun Pharmaceutical Industries Ltd.*

***Note 7.** The Authority noted that M/s Intas Pharmaceuticals Ltd and M/s Mankind Pharma Ltd have also launched the formulation without price approval for which explanation has been issued for non-compliance. The Authority deliberated upon the matter in detail and decided to issue Show Cause Notice (SCN) to M/s Intas Pharmaceuticals Ltd and M/s Mankind Pharma Ltd for the same.*

***Note 8.** The Authority deliberated upon the matter in detail and decided to approve the retail price in line with the decision as recorded in Note 6 of Para 4.1 of the Minutes of the 80th Authority meeting dated 26.10.2020, based on the recommendation of Multidisciplinary Committee of Experts.*

***Note 9**. The Authority noted the representation of M/s Zydus Healthcare Ltd regarding retail price fixation of Metformin 500 mg (sustained release) + Vildagliptin 50 mg tablet and Metformin 1000 mg (sustained release) + Vildagliptin 50 mg tablet for M/s Zydus healthcare Ltd (Agenda item no. 4(xvi) and 4(xvii). Authority was of the view if the present methodology of retail price fixation is not followed then it will deprive the benefit of passing price reduction due to medicine going off-patent to consumers, which is not in public interest. Accordingly, the Authority decided not to consider the representation of M/s Zydus Healthcare Ltd and the same be treated as closed.*

***Note 10.** (i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin was expired on 02.10.2020 making it an off-patent drug.*

(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.

(iii) The Authority further noted that the retail price of Dapagliflozin 10mg + Metformin (ER) 500/1000 mg tablet has been fixed earlier for M/s Micro Labs Limited and the company has launched the formulation and has submitted the Form-V data. However, no retail price of the formulation Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 500/ 1000 mg tablet

(iv) The Authority also noted that the matter has been referred to the Multidisciplinary Committee of Experts which in its 25th meeting dated 16.12.2020 in which it recommended the retail price as per the following methodology:

> *a. To derive the price of Dapagliflozin 5 mg tablet by applying the recommendation of Pronab Sen Committee on the retail price arrived at for FDC of Dapagliflozin 10mg + Metformin (ER) 500 mg tablet in line with the decision taken in the 72nd Authority meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets.*

b. To derive the retail price of Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 500/ 1000 mg tablet by adding the derived price of Dapagliflozin 5 mg, as mentioned in (a) above, with the present ceiling price of Metformin ER 500/ 1000 mg tablet, as applicable, after applying the recommendations of Pronad Sen Committee.

(v) The Authority deliberated upon the matter in detail and observed that the benefit of price reduction due to medicines going off-patent needs to be passed on to the consumers. Accordingly, the Authority accepted the recommendations of the Multidisciplinary Committee of Experts and approved the retail price of Dapagliflozin 5mg + Metformin Hydrochloride IP (In Extended release form) 500mg and Dapagliflozin 5mg + Metformin Hydrochloride IP (In Extended release form) 1000mg at Rs. 6.97 per tablet (excluding GST) and Rs. 8.35 per tablet (excluding GST) respectively.

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

5.1 The Authority noted that no review case was pending at NPPA.

6. Agenda item no. 6 – Intimation of Minutes of 25th meeting of Multidisciplinary Committee of Experts held on 16.12.2020.

6.1 Noted.

7. Agenda item no. 7 - Application for exemption under para 32 of DPCO 2013 being filed M/s Sun Pharmaceutical Industries Limited for Fixed Dose Combination (FDC) of Silver Sulfadiazine (Nanonized) 0.5% w/w and Chlorhexidine Gluconate 0.2% w/w topical cream

7.1 The Authority noted that M/s Sun Pharmaceutical Industries Ltd has applied for exemption under para 32(i) of DPCO 2013 for Fixed Dose Combination (FDC) of Silver Sulfadiazine (Nanonized) 0.5% w/w and Chlorhexidine Gluconate 0.2% w/w topical cream vide letter dated 20.10.2020. The company had submitted the following documents as detailed below:

a. A copy of the Patent Certificate granted by the Patent Office, Government of India to M/s Sun Pharmaceutical Industries Ltd having Patent No 349599 (date of filing: 27.07.2016, date of grant : 20.10.2020) for the invention entitled A STABLE TOPICAL PHARMACEUTICAL COMPOSITION COMPRISING NANONIZED SILVER SULFADIAZINE

b. A copy of the New Drug approval dated 06.07.2017 received from CDSCO for the formulation 'Fixed Dose Combination (FDC) of Silver Sulfadiazine and Chlorhexidine Gluconate Cream (0.5% w/w + 0.2% w/w' having the dosage form "topical cream" and composition Silver Sulfadiazine IP (nanonized) 0.5% w/w and Chlorhexidine Gluconate Solution IP eq to Chlorhexidine Gluconate 0.2% w/w.

c. A copy of the approval for manufacturing of the product issued by State Drug Licensing Authority together with the confirmation from the company that the product would be manufactured in India.

7.2 The Authority further noted the letter dated 23.11.2020 received from Central Drugs Standard Control Organisation (CDSCO), Directorate General of Health Sciences, Ministry of Health and Family Welfare, Government of India and the letter dated 22.12.2020 received from the Office of Controller General of Patents, Design & Trade Marks, Department for Promotion of Industry and Internal Trade, Ministry of Commerce & Industry, Government of India.

7.3 The Authority also noted that Department of Pharmaceuticals vide its letter dated 22.01.2020 stated that the exemption granted under para 32(i) and para 32(ii) of DPCO 2013 for a period of 5 years is co-terminus with the duration of Indian Patent.

7.4 The Authority deliberated upon the matter in detail and observed that M/s Sun Pharmaceutical Industries Ltd fulfills the conditions as per para 32(i) of DPCO 2013 with respect to its product 'Fixed Dose Combination (FDC) of Silver Sulfadiazine (Nanonized) 0.5% w/w and Chlorhexidine Gluconate 0.2% w/w topical cream'.

7.5 Accordingly, the Authority decided that exemption be granted to M/s Sun Pharmaceutical Industries Ltd under para 32(i) of DPCO, 2013 for their product 'Fixed Dose Combination (FDC) of Silver Sulfadiazine (Nanonized) 0.5% w/w and Chlorhexidine Gluconate 0.2% w/w topical cream' for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country subject to it being co-terminus with the duration of Indian Patent.

7.6 The Authority further directed that M/s Sun Pharmaceutical Industries Ltd be requested to intimate the date of commercial marketing of 'Fixed Dose Combination (FDC) of Silver Sulfadiazine (Nanonized) 0.5% w/w and Chlorhexidine Gluconate 0.2% w/w topical cream' in the country and the launch price of the product.

7.7 The Authority also observed that NPPA may maintain data in respect of the Drugs to which exemption has been granted under Para 32 of DPCO 2013 regarding date of launch of the product (marketing) and the price. Such status report be placed before the Authority in its next meeting.

8. Agenda item no. 8 - Violation of order regarding Trade Margin Rationalisation for Anti-Cancer Medicines.

8.1 Noted.

9. Agenda item no. 9 - Submission of Form-IV by M/s Intas Pharmaceuticals Limited in respect of scheduled formulation Atro Eye Drops 5ml (Atropine Sulphate Ophthalmic Solution USP 1% w/v) under para 21(2) of DPCO, 2013-reg

9.1 Noted.

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

Sd/-
(Dr. Vinod Kotwal)
Member Secretary