

Minutes of the 203rd (overall) and 71st meeting of the Authority under DPCO, 2013 held on 09.12.2019 at 11:00 AM

The 203rd meeting of the Authority (overall), which is the 71st meeting under the DPCO, 2013, was held on the 09th of December, 2019 at 11:00 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following members of the NPPA were present:

- (i) Ms. Ritu Dhillon, Member Secretary
- (ii) Dr. V. G. Somani, DCGI, Deptt. of Health & Family Welfare
- (iii) Shri B. Bandyopadhyay, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
- (iv) Ms. A. Srija, Economic Advisor, Deptt of Economic Affairs

Shri A.K.Pradhan, Deputy Drug Controller, Deptt. 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 Kalyan Nag, Advisor
- (ii) Shri Amarपाल Singh Sawhney, 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 70th meeting held on 30.10.2019.

1.1 Noted.

1.2 The Authority noted the error in the retail price notification of the formulation Vildagliptin + Metformin Tablet (GLUVILDA M 500 / VIGLUCOZ M 500) for M/s M/s Alkem Healthscience / M/s Alkem Laboratories Ltd whereby the price was notified as Rs. 19.54 per tablet (excluding GST) instead of Rs. 19.64 per tablet (excluding GST). A new notification is to be issued to notify the correct price alongwith the necessary corrigendum in the minutes.

2. Agenda item no. 2 – Action Taken Report on decisions taken by NPPA in its 70th meeting dated 30.10.2019

2.1 Noted.

2.2 The Authority noted the action taken with respect to para 17.2 of the 70th meeting of the Authority and further decided that the matter relating to M/s Unichem Laboratories Ltd (at sl. No 43) of the action taken note may be studied as test case by the Authority Member, Shri B Bandyopadhyay, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure.

2.4 The Authority noted that with respect to retail price stated at sl. no. xii, xiii, xxvii and xxxix of 4.1 of the 70th Minutes, DCGI vide its letter dated 06.12.2019 stated that the four FDCs were considered rational by Kokate Committee and NOC was issued by DCG(I) for continued marketing marketing of the drugs. DCGI also stated that the applications may be considered in the light of the fact that CDSCO has issued letter no: 4-01/2013-DC (Misc. 13-PSC)(P-II) dated 12.12.2019 to all State/ UT Drugs Controllers mentioning pathway for grant of product license by SLAs without seeking NOC from DCG(I) for such FDCs. From, the documents submitted by the companies, the Authority observed that all the four applicants got license from SLAs after 12.12.2018. Accordingly, the Authority decided to notify the retail prices of the four formulations.

3. Agenda item no. 3 – Fixation of Ceiling Price for Human Normal Immunoglobulin 10% solution

3.1 The Authority deliberated upon the matter in detail and approved the ceiling price of Human Normal Immunoglobulin (10% solution) at Rs. 204.41 per ml, excluding GST and decided to notify the same after uploading the draft working sheet on NPPA's website for 10 days.

3.2 The Authority also noted that NPPA had earlier notified the ceiling price of Human Normal Immunoglobulin solution without any strength. Accordingly, Authority decided to re-notify the earlier notified Human Normal Immunoglobulin solution by giving the strength of 5%.

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

4.1 The Authority noted the status of new drugs applications.

4.2 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (ii) to 4(xxix) (total 48 Form I applications) falling under the

purview of para 2(u) of DPCO, 2013 and approved the retail prices in 47 (forty seven) cases under para 5 and 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)
4(ii)	Propranolol Hydrochloride + Flunarizine Tablet	Each uncoated Bilayered Tablet contains: Propranolol Hydrochloride IP 40mg (as Sustained Release), Flunarizine Dihydrochloride eq. to Flunarizine 5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Limited	5.28
4(iii)	Propranolol Hydrochloride + Flunarizine Tablet	Each uncoated Bilayered Tablet contains: Propranolol Hydrochloride IP 40mg (as Sustained Release), Flunarizine Dihydrochloride eq. to Flunarizine 10mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Limited	7.76
4(iv)	Ibuprofen + Paracetamol Suspension	Each 5ml suspension contains: Ibuprofen IP 100mg Paracetamol IP 162.5mg	1 ML	M/s Shiva Biogenetic Pharmaceuticals Pvt. Ltd. / M/s Sun Pharmaceutical Industries Limited	0.35
4(v)	Atorvastatin + Clopidogrel Capsule (Mactor CV 20)	Each Hard Gelatin Capsule contains: Atorvastatin Calcium IP Eq. to Atorvastatin 20mg (As Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Limited / M/s Macleods Pharmaceuticals Limited	14.62
4(vi)	Paracetamol + Thiocolchicoside Tablet	Each film coated tablet contains: Paracetamol IP 325mg Thiocolchicoside IP 4mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Apex Laboratories Pvt. Ltd.	14.00
4(vii)	Metformin + Glimepiride Tablet	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 1000mg, Glimepiride IP 1mg Tablet	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	6.75
4(viii)	Metformin + Glimepiride Tablet	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 1000mg, Glimepiride IP 2mg Tablet	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	9.84
4(ix)	Etoricoxib + Paracetamol Tablet	Each film coated tablet contains: Etoricoxib IP 60mg, Paracetamol IP 325mg	1 Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Lupin Limited	6.01
4(x)	Cefixime + Potassium Clavulanate suspension	Each 5ml of reconstituted suspension contains: Cefixime IP (As Trihydrate) eq. to Anhydrous Cefixime 50mg, Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 31.25mg	1 ML	M/s Brooks Laboratories Ltd. / M/s Intas Pharmaceuticals Limited	2.39

4(xi)	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 500mg	1 Tablet	M/s Cadila Pharmaceuticals Limited	22.77
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 500mg	1 Tablet	M/s Intas Pharmaceuticals Limited	22.77
	Vildagliptin + Metformin Tablet (Vildaphage M)	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Franco-Indian Pharmaceuticals Pvt. Ltd.	22.77
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 500mg	1 Tablet	M/s Eris Lifesciences Limited	22.77
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 500mg	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Lupin Limited	22.77
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 500mg	1 Tablet	M/s Emcure Pharmaceuticals Limited /M/s Zuventus Healthcare Limited	22.77
	Vildagliptin + Metformin Tablet (Vildagard M 500)	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 500mg	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	22.77
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 500mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Alembic Pharmaceuticals Limited	22.77
	4(xii)	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 850mg	1 Tablet	M/s Cadila Pharmaceuticals Limited
Vildagliptin + Metformin Tablet		Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 850mg	1 Tablet	M/s Intas Pharmaceuticals Limited	22.75
Vildagliptin + Metformin Tablet		Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 850mg	1 Tablet	M/s Eris Lifesciences Limited	22.75
Vildagliptin + Metformin		Each film coated tablet contains:	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Lupin	22.72

	Tablet	Vildagliptin 50mg, Metformin Hydrochloride 850mg		Limited	
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 850mg	1 Tablet	M/s Emcure Pharmaceuticals Limited /M/s Zuventus Healthcare Limited	22.72
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 850mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Alembic Pharmaceuticals Limited	22.72
	Vildagliptin + Metformin Tablet (Vildagard M 850)	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 850mg	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	22.72
4(xiii)	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 1000mg	1 Tablet	M/s Cadila Pharmaceuticals Limited	23.40
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 1000mg	1 Tablet	M/s Intas Pharmaceuticals Limited	23.40
	Vildagliptin + Metformin Tablet (Vildaphage M Forte)	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Franco-Indian Pharmaceuticals Pvt. Ltd.	23.40
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 1000mg	1 Tablet	M/s Eris Lifesciences Limited	23.40
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 1000mg	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Lupin Limited	23.40
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 1000mg	1 Tablet	M/s Emcure Pharmaceuticals Limited /M/s Zuventus Healthcare Limited	23.40
	Vildagliptin + Metformin Tablet (Vildagard M 1000)	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride 1000mg	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	23.40
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Alembic	23.40

		1000mg		Pharmaceuticals Limited	
4(xiv)	Pantoprazole + Domperidone Tablet	Each enteric coated tablet contains: Pantoprazole Sodium IP eq. to Pantoprazole 40mg, Domperidone IP 10mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	5.61
4(xv)	Telmisartan + Chlorthalidone Tablet	Each uncoated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.5mg,	1 Tablet	M/s Windlas Biotech Limited / M/s Indoco Remedies Limited	8.20
4(xvi)	Teneligliptin + Metformin Tablet (TENELIGAL-M 500)	Each uncoated bi-layered Tablet contains: Teneligliptin Hydrochloride Hydrate eq. to Teneligliptin 20mg Metformin Hydrochloride (As Sustained-release Form) 500mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Galpha Laboratories Limited	10.24
4(xvii)	Teneligliptin + Metformin Tablet (TENELIGAL-M 1000)	Each uncoated bi-layered Tablet contains: Teneligliptin Hydrochloride Hydrate eq. to Teneligliptin 20mg Metformin Hydrochloride (As Sustained-release Form)1000mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Galpha Laboratories Limited	10.93
4(xviii)	Paclitaxel + Human Albumin Injection	Each Lyophilized vial contains: Paclitaxel IP 100mg Human Albumin IP 900mg per 20ml	1 ML	M/s SPAL Private Limited / M/s Intas Pharmaceuticals Pvt. Ltd.	Deferred (Note 1)
4(xix)	Clarithromycin + Esomeprazole + Amoxicillin Tablet	Competition: Each Strip Contains: A. Clarithromycin IP 2 Tablets Each film coated tablet contains: Clarithromycin IP 500mg, B. Esomeprazole Tablets IP 2 tablet Each enteric coated tablet contains: Esomeprazole Magnesium Trihydrate IP Eq. to Esomeprazole 40mg C. Amoxicillin USP 2 Tablets Each film coated tablet contains: Amoxicillin Trihydrate IP eq. to Amoxycillin 750mg	Each Strip of 6 Tablets	M/s Malik Lifesciences Pvt. Ltd. / M/s Emcure Pharmaceuticals Ltd.	148.32
4(xx)	Glimepiride + Metformin Tablet (Glimiprex MF 3 & Duopil 3)	Each modified release bi-layered Tablet contains: Glimepiride 3mg, Metformin Hydrochloride 500mg (in prolonged release form)	1 Tablet	M/s Anphar Organics Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	7.96
4(xxi)	Glimepiride + Metformin Tablet (Glimiprex MF	Each uncoated bi-layered Tablet contains: Glimepiride 3mg, Metformin Hydrochloride	1 Tablet	M/s Accent Pharma / M/s Aristo Pharmaceuticals Pvt. Ltd.	8.61

	Forte 3 & Duopil 3 Forte)	1000mg (in prolonged release form)			
4(xxii)	Glimepiride + Metformin Tablet (Glimiprex MF 4 & Duopil 4)	Each modified release bi-layered Tablet contains: Glimepiride 4mg, Metformin Hydrochloride 500mg (in prolonged release form)	1 Tablet	M/s Anphar Organics Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	9.30
4(xxiii)	Glimepiride + Metformin Tablet (Glimiprex MF Forte 4 & Duopil 4 Forte)	Each uncoated bi-layered Tablet contains: Glimepiride 4mg, Metformin Hydrochloride 1000mg (in prolonged release form)	1 Tablet	M/s Accent Pharma / M/s Aristo Pharmaceuticals Pvt. Ltd.	9.35

B. Retail price fixed under para 15 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)
4(xxiv)	Bictegravir + Emtricitabine + Tenofovir Tablet (TAFVIC)	Each film coated tablet contains: Bictegravir Sodium eq. to Bictegravir 50mg, Emtricitabine IP 200mg, Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25mg	1 Tablet	M/s Hetero Labs Ltd. / M/s Hetero Healthcare Ltd.	130.61
4(xxv)	Clobazam Tablet	Each uncoated tablet contains: Clobazam IP 7.5mg	1 Tablet	M/s Sun Pharma Laboratories Limited	7.04
4(xxvi)	Clobazam Tablet	Each uncoated tablet contains: Clobazam IP 2.5mg	1 Tablet	M/s Sun Pharma Laboratories Limited	3.02
4(xxvii)	Ranitidine Hydrochloride + Dicyclomine Hydrochloride +, Simethicone Tablet	Each film coated tablet contains: Ranitidine Hydrochloride IP eq. to Ranitidine 150mg, Dicyclomine Hydrochloride IP 10mg, Simethicone IP 20mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Mankind Pharma Limited	4.86
4(xxviii)	Darunavir + Ritonavir Tablet (DAREIT R)	Each film coated tablet contains: Darunavir 600mg, Ritonavir 100mg	1 Tablet	M/s Emcure Pharma Limited / M/s Aurobindo Pharma Limited	160.71
4(xxix)	Cefotaxime Sodium Injection	Each vial contains: Cefotaxime Sodium IP eq. to Cefotaxime 2g	Each Pack (2gm)	M/s Alkem Healthscience / M/s Alkem Laboratories Ltd.	57.10

Explanatory Notes:

Note 1 : **Sl. No. 4(xviii)** The Authority directed that clarification be obtained from DCGI on the categorisation of the products “Nanoxel 100 mg injection” of M/s Fresenius Kabi India Pvt Ltd and ‘Bevetex 100 mg injection” of M/s Sun Pharmaceutical Industries Ltd.

Note 2 : The retail prices at Agenda item no. 4 (xiv to xxiii) are to be notified after 10 days of uploading the draft working sheet on NPPA’s website.

Note 3. The retail prices fixed based on the recommendations of the Multidisciplinary Committee of Experts are to be notified after 10 days of the uploading of the minutes of the 14th meeting of the Multidisciplinary Committee on NPPA’s website.

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

5.1 It was noted that no review order was pending at NPPA.

6. Agenda item no. 6 - Intimation of Minutes of 14th meeting of Multidisciplinary Committee of Experts held on 04.12.2019

6.1 Noted.

7. Agenda item no. 7 - Representation from M/s Emcure Pharmaceuticals Ltd regarding retail price fixation under Para 5 of DPCO, 2013 of Emtricitabine 200 mg plus Tenofovir Alafenamide 10 mg tablets for M/s Emcure Pharmaceuticals Ltd (marketer) and M/s Hetero Labs Ltd (manufacturer/importer).

7.1 The Authority deliberated upon the representation received from M/s Emcure Pharmaceuticals Ltd with a request for revision of retail price of Emtricitabine IP 200 mg + Tenofovir Alafenamide Hemifumarate eq to Tenofovir Alafenamide 10 mg tablet based on Wholesale Price Index (WPI) in line with the review orders no. 31015/10/2019-Pricing of M/s Cipla Ltd dated 30.08.2019 and the subsequent Authority decision in its 70th meeting dated 30.10.2019 and decided to extend the retail price of Emtricitabine IP 200 mg + Tenofovir Alafenamide Hemifumarate eq to Tenofovir Alafenamide 10 mg tablet for M/s Emcure Pharmaceuticals Ltd (marketer) and M/s Hetero Labs Ltd (manufacturer/importer) at Rs. 32.49 per tablet (excluding GST).

8. Agenda item no. 8 – Upward revision of Ceiling Price of select Scheduled formulations under para 19 of DPCO, 2013

8.1 The Authority noted that NPPA has been receiving applications for upward price revision under para 19 of DPCO, 2013 since last two years citing various reasons like increase in API cost, increase in cost of production, exchange rates etc. resulting in unviability in sustainable production and marketing of the drugs.

8.2 The Authority further noted that in its 62nd meeting dated 21.01.2019, the Authority deliberated upon 49 such applications consisting of 72 formulations, received from manufacturers/marketers seeking upward revision of ceiling price under paragraph 19 of DPCO, 2013 and shortlisted 19 formulations for further examination.

8.3 The Authority also noted that in its 65th meeting held on 27th March, 2019, the Authority constituted a committee comprising Adviser (Cost), Adviser DGHS and Deputy Drug Controller, DCGI under the convenorship of Director (Pricing), NPPA for further examination of 19 such formulations based on parameters of essentiality, market share of the applicant company and available alternatives etc. This Committee in its 2nd meeting held on 23.05.2019 recommended that these 19 formulations could be considered for an upward price revision under para 19 of DPCO, 2013 to ensure availability of these medicines and these recommendations were presented to the Authority in its 68th meeting of 25th June, 2019.

8.4 Further, it was noted that the Authority in its 68th meeting held on 25.06.2019 examined the summary sheets prepared for these 19 formulations and after deliberating upon the matter at length took a view that the revision of ceiling prices under para 19 of DPCO 2013 should be undertaken only in exceptional circumstances as there is neither a precedent nor any formula prescribed for upward revision of ceiling prices under para 19 of DPCO, 2013. Further, the Authority in its 68th meeting held on 25.06.2019 stated that it was cognizant that any upward revision of ceiling price under para 19 of DPCO 2013 may be used as precedent for more applications of a similar nature for upward revision of ceiling prices in future and therefore, based on the analysis, the Authority further in this meeting shortlisted only 12 formulations and referred the issue to the Standing Committee on Affordable Medicines and Health Products (SCAMHP), Niti Aayog, Government of India for guidance on the modalities/ methodology to be followed for such cases.

8.5 SCAMHP in its 2nd meeting held on 07.11.2019 recommended that there was a need to revisit the prices of the 12 formulations presented to it for upward price revision under

para 19 of DPCO 2013 by allowing one-time 50% increase from the present ceiling price. It was also recommended that NPPA may examine any other additional formulations/ molecules for upward price revision and present to the Authority.

8.6 Accordingly, the Committee constituted for examination of cases under Para 19 in its 3rd meeting dated 26th November, 2019 examined the 9 formulations (including 7, earlier deferred by Authority, and additional 2 formulations Clofazimine 50mg & 100mg capsules) for upward price revision under para 19 of DPCO 2013. The committee reiterated that the seven scheduled formulations recommended earlier are essential and pricing of these shouldn't be reason for shortage or unavailability of these medicines. Further, regarding Clofazimine capsules the committee noted that these formulations are included in National Program as first line treatment of leprosy and are essential. Accordingly, the committee recommended that these 9 formulations can be considered for revision of ceiling price under para 19 of DPCO, 2013 in addition to the 12 formulations already being considered.

8.7 Thus, the case of upward price revision of 21 formulations under para 19 of DPCO 2013 was deliberated upon by the Authority. The Authority noted that the twenty one scheduled formulations being considered for upward price revision under para 19 of DPCO 2013 are low priced drugs and have been under repeated price control. Most of these drugs are used as first line of treatment and are crucial to the public health program of the country. Many companies have applied for discontinuation of the product on account of unviability.

8.8 The mandate of NPPA is to ensure availability of drugs at affordable prices. It was noted that while ensuring affordability, access cannot be jeopardized and the life saving essential drugs must remain available to the general public at all times. Therefore, the Authority is of the considered view that unviability of these formulations should not lead to a situation, where these drugs become unavailable in the market and the public is forced to switch to costly alternatives.

8.9 The Authority is cognizant that as per prevailing policy, cost based pricing is not feasible. To address the situation arising due to repeated price control, one time price increase of 50% from the present ceiling price is being considered in public interest as an exceptional measure as advised by SCAMHP. Accordingly, the Authority invoked extraordinary powers in public interest under para 19 of DPCO 2013 for upward revision of the

ceiling prices of twenty one scheduled formulations of 12 drugs by giving one time increase of 50% from the present ceiling price as detailed below:

Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Main Usage	Unit	Approved Ceiling Price (excluding GST) (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	BCG vaccine		Vaccine	Each Dose	8.75
2.	Benzathine benzylpenicillin	Powder for Injection 12 lac units	Anti-biotic	Each Pack	17.84
3.	Benzathine benzylpenicillin	Powder for Injection 6 lac units	Anti-biotic	Each Pack	11.81
4.	Benzyl penicillin	Powder for Injection 10 Lac Units	Anti-biotic	Each Pack	7.64
5.	Chloroquine	Tablet 150mg	Anti-malarial	1 Tablet	1.16
6.	Dapsone	Tablet 100 mg	Leprosy	1 Tablet	0.35
7.	Furosemide	Tablet 40 mg	Diuretic/ Anti Hypertensive	1 Tablet	0.74
8.	Furosemide	Injection 10mg/ml	Diuretic/ Anti Hypertensive	1 ml	2.43
9.	Metronidazole	Oral Liquid 200 mg/5ml	Anti-biotic/ anti-protozoal	1 ml	0.44
10.	Metronidazole	Tablet 200 mg	Anti-biotic/ anti-protozoal	1 Tablet	0.68
11.	Metronidazole	Tablet 400 mg	Anti-biotic/ anti-protozoal	1 Tablet	1.25
12.	Metronidazole	Injection 500mg/100ml	Anti-biotic/ anti-protozoal	1 ml	0.20
13.	Ascorbic Acid (Vitamin C)	Tablet 500 mg	Vitamin	1 Tablet	1.34
14.	Co-trimoxazole (Sulphamethoxazole (A)+Trimethoprim (B)]	Tablet 400 mg(A)+80 mg(B)	Anti-biotic	1 Tablet	0.77
15.	Co-trimoxazole (Sulphamethoxazole (A)+Trimethoprim (B)]	Tablet 800 mg(A)+160 mg(B)	Anti-biotic	1 Tablet	1.98
16.	Co-trimoxazole (Sulphamethoxazole (A)+Trimethoprim (B)]	Oral Liquid 200 mg(A)+40 mg(B)/5ml	Anti-biotic	1 ml	0.32
17.	Pheniramine	Injection 22.75 mg/ml(10ml)	Anti-allergy	1 ml	1.67
18.	Pheniramine	Injection 22.75	Anti-allergy	1 ml	2.24

		mg/ml (2ml)			
19.	Prednisolone	Drops 1%	Anti-allergy	1 ml	4.92
20.	Clofazimine	Capsule 50 mg	Leprosy	1 Capsule	2.13
21.	Clofazimine	Capsule 100 mg	Leprosy	1 Capsule	3.63

8.10 Further, the provisions of para 13(2) of DPCO 2013 would not be applicable on the revised ceiling price of the twenty one scheduled formulations mentioned in para 8.9 above.

8.11 The Authority also decided that these twenty one formulations, being scheduled formulations, the annual price increase would be as per Wholesale price Index (WPI).

9. Agenda item no. 9 – Application of M/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)

9.1 The Authority deliberated upon the matter in detail. The Authority noted that M/s Meril Life Sciences Pvt. Ltd has applied for price exemption under Para 32(ii) of DPCO 2013 with respect to its product cardiac stent named “MeRes-100 – Sirolimus Eluting **Bioresorbable** Vascular Scaffold System” in which Patent Registration No. 296768 dated 14.05.2018 was mentioned. However, from the documents of Patent office submitted by the company it was observed that the patent is for “Annealing process for a **bioabsorbable** stent”. The Authority further noted that the DCGI license submitted by M/s Meril Life Science Pvt Ltd, is for “Sirolimus Eluting **bioresorbable** Vascular Scaffold system (cardiac stent).

9.2 Accordingly, the Authority directed that the company may be asked to explain the reasons for submission of these discrepant documents for seeking price exemption under Para 32 of DPCO 2013.

10. Agenda item no. 10 – Application of M/s Glenmark Pharmaceuticals Ltd for separate price of “Budesonite+ Formeterol MDI Digital Inhalation under the brand “Digihaler”.

10.1 The Authority deliberated upon the matter in detail. NPPA supports incremental innovations that could increase the therapeutic value and effectiveness of a drug. It was noted with satisfaction that two Pharmacoeconomics experts had been co-opted in the Multidisciplinary Committee of Experts. The Authority accepted the recommendation of

Multidisciplinary Committee of experts under para 11(3&4) of DPCO 2013 that in case the incremental innovation is not supported by a published journal, well designed study, adequate trial, conclusive clinical data, then an incremental price increase upto 15% be allowed and in case, the incremental innovation is supported by published journal, well designed study, adequate trial, conclusive clinical data, then an incremental price increase upto 20% be allowed.

10.2 The Authority deliberated upon the matter in detail.

10.3 Accordingly, the Authority approved the price for the digital dose counter brand 'digihaler' of M/s Glenmark Pharmaceuticals Ltd at Rs. 44.70 (excluding GST) on the ceiling price of the MDI Digital Inhalation (Inhalation having digital dose counter) having the formulation (a) Budesonide 100mcg+ Formeterol 6mcg per dose Inhaler 120 MDI (b) Budesonide 200mcg+ Formeterol 6mcg per dose Inhaler 120 MDI (c) Budesonide 400mcg+ Formeterol 6mcg per dose Inhaler 120 MDI, based on the recommendations of the Multidisciplinary Committee of Experts.

10.4 The Authority also decided that the additional price of Rs. 44.70 (excluding GST) on the applicable ceiling price of the MDI Digital Inhalation (Inhalation having digital dose counter) brand "Digihaler" of M/s Glenmark Pharmaceuticals Ltd would remain fixed irrespective of the subsequent change in ceiling prices of the Inhalation having the formulation (a) Budesonide 100mcg+ Formeterol 6mcg per dose Inhaler 120 MDI (b) Budesonide 200mcg+ Formeterol 6mcg per dose Inhaler 120 MDI (c) Budesonide 400mcg+ Formeterol 6mcg per dose Inhaler 120 MDI.

11. Agenda item No. 11 - Application for grant of separate price/ special price for "Synchrobreathe inhaler device" under the provision of Para 11(3) or para 32(3) of DPCO 2013

11.1 The Authority deliberated the applications of M/s Cipla Ltd regarding separate/ special price for 'Synchrobreathe inhaler device' and approved the additional price for 'Synchrobreathe inhaler device' of M/s Cipla Ltd at Rs. 67.20 (excluding GST) on the ceiling price of the Inhalation having the formulation (a) Budesonide 200mcg+ Formeterol 6mcg per dose Inhaler 120 MDI and (b) Budesonide 400mcg+ Formeterol 6mcg per dose Inhaler 120 MDI, based on the recommendations of the Multidisciplinary Committee of Experts.

11.2 The Authority also decided that the additional price of Rs. 67.20 (excluding GST) of 'Synchrobreathe inhaler device' of M/s Cipla Ltd on the applicable ceiling price of the Inhalation having the formulation (a) Budesonide 200mcg+ Formeterol 6mcg per dose Inhaler 120 MDI and (b) Budesonide 400mcg+ Formeterol 6mcg per dose Inhaler 120 MDI would remain fixed irrespective of the subsequent change in ceiling price of the Inhalation.

12. Agenda item No. 12 - Launch of formulations under para 32 of DPCO 2013

12.1 The Authority noted that provisions of para 32 of DPCO 2013 stipulates that the exemption under para 32 of DPCO 2013 would be applicable *only when* the companies seeking exemption under para 32 of DPCO 2013 produce requisite documents before the Government.

12.2 The Authority noted that M/s Glenmark Pharmaceuticals Ltd had earlier applied for retail price fixation for the products "RemoM" and "RemoZenM" tablets containing Remogliflozin Etabonate 100 mg + Metformin Hydrochloride 500 mg which was withdrawn by the company before retail price was fixed.

12.3 Later M/s Glenmark Pharmaceuticals Ltd had launched the products "RemoM" and "RemoZenM" tablets containing Remogliflozin Etabonate 100 mg + Metformin Hydrochloride 500 mg in the market without seeking exemption from NPPA under para 32 of DPCO 2013

12.4 It further informed NPPA that M/s Lupin Ltd and Boehringer Ingelheim had launched 'Empagliflozin + Metformin' combination tablets and M/s Sun Pharma Laboratories Ltd and M/s Astrazeneca had also launched 'Dapagliflozin + Metformin' combination tablets without seeking prior approval of NPPA.

12.5 Based on representation of M/s Glenmark Pharmaceuticals Ltd, NPPA analysed Pharmatrac data and it was observed M/s Abbott Healthcare Pvt. Ltd had also launched Dapagliflozin + Metformin' combination tablet without obtaining approval from NPPA. Accordingly, NPPA issued Show Cause notice to M/s Glenmark Pharmaceuticals Ltd, M/s Lupin Ltd, M/s Sun Pharma Laboratories Ltd and M/s Abbott Healthcare Pvt. Ltd.

12.6 In response to Show Cause Notices, the companies stated that the formulations are patented products which are within the purview of Para 32 of DPCO, 2013 and are therefore exempted from applicability of provisions of DPCO, 2013.

12.7 The Authority took a serious view of this issue as this amounts to self invocation of para 32 of DPCO 2013 by the companies which is a wilful violation of DPCO 2013. The

due procedure for grant of such exemption requires the submission of all documents by the company for a considered view to be taken by the Authority after due diligence has been done on the submissions made. This has been the procedure that has been adopted by the Authority in all the four exemptions given so far under para 32 of DPCO 2013. Besides, the cases of M/s Sun Pharmaceutical Industries Ltd and M/s Meril Life Sciences Pvt Ltd have been in the public domain and have been widely reported in the media since the past one year. The Authority has approved price exemption to M/s Sun Pharmaceutical Industries Ltd for ready to use Gemcitabine bags only in its 70th meeting dated 30.10.2019. Therefore, the Authority found there to be no room to assume ignorance of the procedure being adopted for all such cases.

12.8 An exemption under para 32 of DPCO 2013 is not a one time measure but also subsequent exemption from provisions relating to annual price increase. Therefore, self invocation of para 32 of DPCO 2013 needs careful examination to safeguard public interest to obviate any possibility of misuse. The Authority noted that the self invocation of para 32 of DPCO 2013 is thus an audacious move challenging the price regulation framework of the Government. Self invoking of para 32 of DPCO 2013 would tantamount to bypassing the regulatory framework and lead to chaos in product pricing, grievously impacting choices before the hapless consumers. Such attempts needs to be checked forcefully in order to safeguard public health and safety.

12.9 The Authority directed for exemplary action to be taken against the wilful defaulters. They may be directed to provide all data of manufacturing/import and sales of the said formulation since its launch to date under Para 29 of DPCO, 2013. The NPPA shall take further necessary action as applicable.

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

Sd/-
(Ritu Dhillon)
Member Secretary