मिसिल स.- 8(89)/2021/डी.पी/एनपीपीए-डीवी-II
F. No. 8(89)/2021/DP/NPPA-Div. II

कार्यवाही स. : 221/89/2021/F
Proceeding No: 221/89/2021/F

Minutes of the 221st (overall) and 89th meeting of the Authority under DPCO, 2013 held on 28.06.2021 at 11:30 AM

The 221st meeting of the Authority (overall), which is the 89th meeting under the DPCO, 2013, was held on 28th of June 2021 at 11:30 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following Authority members of the NPPA were present during the meeting:

(i) Dr. Vinod Kotwal, Member Secretary, NPPA
(ii) Ms. A. Srija, Economic Advisor, Department of Economic Affairs
(iii) Shri Amardeep Singh Chowdhary, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
(iv) Dr. V. G. Somani, Drug Controller General of India through Video Conferencing

Shri A. K. Pradhan, Deputy Drug Controller, CDSCO, Ministry of Health & Family Welfare (through Video Conference) was also present during the meeting.

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 (OC and Medical Devices)
(iii) Ms. Rashmi Tahiliani, Jt Director (Pricing)
(iv) Shri Prasenjit Das, Deputy Director (Pricing)
(v) Shri Mahaveer Saini, Deputy Director (Pricing & Monitoring) through Video Conferencing

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 87th Meeting & 88th Meeting held on 27.05.2021 & 03.06.2021.

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 87th Meeting & 88th Meeting held on 27.05.2021 & 03.06.2021.

2.1 The Authority noted that due action has 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 Agenda item no. 4(i) to 4(xx) and 4(xxv)

4.1.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4(xx) and 4(xxv) (total 21 Form I applications containing retail price fixation of 21 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 21 (twenty one) new drugs under Para 5 and 15 of the DPCO 2013, as detailed below:

A. 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(i)	Telmisartan + Nebivolol Tablet	**Each uncoated Bilayered Tablet contains:** Telmisartan IP 40 mg Nebivolol Hydrochloride IP Equivalent to Nebivolol 5 mg	1 Tablet	M/s Eris Lifesciences Limited	13.61 (Note 2)
4(ii)	Glimepiride + Pioglitazone + Metformin HCL (SR) Tablet	**Each uncoated bilayered tablet contains:** Glimepiride IP 2mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg Metformin Hydrochloride IP 1000mg (in sustained release form)	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Eris Lifesciences Limited	12.85
4(iii)	Glimepiride + Pioglitazone + Metformin HCL (SR) Tablet	**Each uncoated bilayered tablet contains:** Glimepiride IP 1mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg Metformin Hydrochloride IP 1000mg (in sustained release form)	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Eris Lifesciences Limited	8.73
4(iv)	Glimepiride + Metformin HCL (SR)	**Each uncoated tablet contains:**	1 Tablet	M/s M/s Agron Remedies	9.44

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Tablet	Glimepiride IP 2mg Metformin Hydrochloride IP 1000mg (in sustained release form)		Private Limited / M/s Cadila Pharmaceuticals Ltd.	
4(v)	Glimepiride + Metformin HCL (SR) Tablet	**Each uncoated tablet contains:** Glimepiride IP 1mg Metformin Hydrochloride IP 1000mg (in sustained release form)	1 Tablet	M/s M/s Agron Remedies Private Limited / M/s Cadila Pharmaceuticals Ltd.	6.86
4(vi)	Dextromethorphan Hydrobromide + Chlorpheniramine Meleate Syrup	**Each 5ml contains:** Dextromethorphan Hydrobromide IP 10mg Chlorpheniramine Meleate IP 2mg	1 ML	M/s East African (India) Overseas / M/s Cadila Pharmaceuticals Ltd.	0.64
4(vii)	Esomeprazole & Domperidone sustained release capsule	**Each hard gelatine capsule contains:** Esomeprazole Magnesium IP eq. to Esomeprazole 40mg (as enteric coated pellets), Domperidone IP 30mg (as sustained release pellets)	1 Capsule	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Jagsonpal Pharmaceuticals Ltd.	10.20
4(viii)	Telmisartan + Amlodipine + Hydrochlorothiazide Tablet	**Each film coated tablet contains:** Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.50 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Ltd.	9.56
4(ix)	Nebivolol Hydrochloride + Telmisartan Tablet	**Each uncoated bilayered tablet contains:** Nebivolol Hydrochloride IP eq. to Nebivolol 5mg Telmisartan IP 40mg	1 Tablet	M/s Windlas Biotech limited / M/s Eris Lifesciences Limited	13.61
4(x)	Vitamin D3 Oral Drops	**Each ml contains:** Cholecalciferol (Vitamin D3) IP 800IU	1 ML	M/s Akums Drugs & Pharmaceuticals Limited / M/s Cipla Limited	5.06
4(xi)	Paracetamol + Methocarbamol + Diclofenac Potassium tablet	**Each Film coated tablet contains:** Paracetamol IP 325mg Methocarbamol IP 500mg Diclofenac Potassium BP 50mg tablet	1 Tablet	M/s Shiv Industries / M/s Profic Organic Limited	7.96 (Note 2)
4(xii)	Dapagliflozin + Metformin Hydrochloride (As	**Each film-coated bilayered tablet contains:** Dapagliflozin Propanediol	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s	7.54 (Note 3)

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Extended release form) Tablet	monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 1000mg (As Extended release form)		Mankind Pharma Ltd.	
4(xiii)	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	**Each film-coated bilayered tablet contains:** Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	11.30 (Note 3)
4(xiv)	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	**Each film-coated bilayered tablet contains:** Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	9.78 (Note 3)
4(xv)	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	**Each film-coated bilayered tablet contains:** Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	6.25 (Note 3)
4(xvi)	Dapagliflozin + Metformin Hydrochloride Extended release Tablet	**Each film-coated tablet contains:** Dapagliflozin 10mg, Metformin Hydrochloride USP/IP 1000mg (As Extended release form)	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s J. B. Chemicals & Pharmaceuticls Ltd.	11.30 (Note 3)
4(xvii)	Dapagliflozin + Metformin Hydrochloride Extended release Tablet	**Each film-coated tablet contains:** Dapagliflozin 10mg, Metformin Hydrochloride USP/IP 500mg (As Extended release form)	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s J. B. Chemicals & Pharmaceuticals Ltd.	9.78 (Note 3)
4(xviii)	Dapagliflozin + Metformin Hydrochloride Extended release Tablet	**Each film-coated tablet contains:** Dapagliflozin 5mg, Metformin Hydrochloride USP/ IP 1000mg (As Extended release form)	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s J. B. Chemicals & Pharmaceuticls Ltd.	7.54 (Note 3)

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xix)	Human Coagulation Factor IX Freeze Dried IP 1200IU	**Each pack contains:** Human Coagulation Factor IX Freeze Dried IP 1200IU Sterilized water for injection 10ml (EP/USP)	Each Pack	M/s Baxalta Bioscience India Pvt. Ltd.	20996.50
4(xx)	Trastuzumwb Lyophilized powder for concentrate for solution for infusion vial 375mg with Bacteriostatic water for injection USP 20ml vial	**Combipack of:** A. Each multiple use vial contains: Trastuzumab 375mg B. Bacteriostatic water for injection USP 20ml vial	Each Pack	M/s Intas Pharmaceuticals Limited	17500.00
4(xxv)	Ofloxacin +Metronidazole Tablet	**Each film coated tablet contains:** Ofloxacin USP 200mg Metronidazole IP 500mg	1 Tablet	M/s Unique Pharmaceutical Laboratories (A division of M/s J. B. Chemicals & Pharmaceuticls Ltd) / M/s J. B. Chemicals & Pharmaceuticls Ltd.	6.72

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 DCGI.*

Note 3. *The Authority deliberated upon the matter in detail and decided to approve the retail price in line with the decision as recorded in Note 2 of Para 4.1 of the Minutes of the 82nd Authority meeting dated 23.12.2020, based on the recommendation of Multidisciplinary Committee of Experts.*

4.2 Agenda item no. 4(xxi) to 4(xxiv)

4.2.1 The Authority noted that the retail price application of the new drugs comprising Fixed Dose Combinations (FDCs) of Saxagliptin+ Metformin tablets and also observed the clarification received from Office of the Controller General of Patents, Designs & Trade

Marks, Department for Promotion of Industry and Internal Trade, Ministry of Commerce & Industry that the Patent No. 206543 with respect to the invention titled "A CYCLOPROPYL-FUSED PYRROLIDINE-BASED COMPOUND" which is related to a drug 'Saxagliptin' has expired on 05.03.2021. Accordingly, the Authority noted that the retail price of the Fixed Dose Combinations (FDCs) of Metformin + Saxagliptin tablet, if calculated based on six month prior market data, the price of the patented period would be taken into consideration and hence the benefits of price rationalization due to expiry of the patent would not be passed on to the patients.

4.2.2 The Authority observed that MRP of FDCs of 'Vildagliptin+Metformin' tablet which was in the range of Rs. 25.00-Rs. 27.00 per tablet during the patented period of Vildagliptin came down to Rs. 7.00-9.00 per tablet after the expiry of the patent. Similarly, the MRP of FDCs of 'Dapagliflozin + Metformin' tablet which was in the range of Rs. 56.00-Rs. 57.00 per tablet during the patent period of drug Dapagliflozin came down to Rs. 11.00-Rs.12.00 per tablet after the expiry of the patent. Thus, considerable reduction in the price of FDCs after the expiry of the patent was observed. Further, it was clarified by the representative of Drug Controller General of India (DCGI) that drug Saxagliptin falls in the same class of '...gliptin' drugs like Vildagliptin, Dapagliptin, Sitagliptin etc. and mechanisms of their action are similar. *The Authority also observed the wide variation in the prices of drugs due to patent regime from the recent market based data wherein the Maximum Retail Price (MRP) of Saxagliptin 2.5 mg tablet in 14's pack is Rs. 546.00 whereas the MRP of Saxagliptin 5 mg tablet in 14's pack is Rs. 605.00.*

4.2.3 The Authority further noted that that the issues relating to retail price fixation of Fixed Dose Combinations (FDCs) of Saxagliptin+ Metformin tablets was deliberated in the 33rd meeting of the Multidisciplinary Committee of Experts held on 21.06.2021 in which the Committee applying the principles of Pharmacoeconomics recommended to fix the retail price after allowing a reduction of 50% on the patented component of the FDCs i.e Saxagliptin, on lines of price movement observed in other off-patented '...gliptins' and leaving sufficient room for further price discovery through market dynamics.

4.2.4 The Authority observed the representation dated 25.06.2021 received from M/s Zydus Group on the recommendation of retail price by the Multidisciplinary Committee of Experts in its meeting held on 21.06.2021 with respect to the FDC of Saxagliptin+ Metformin tablets for M/s Morepen Laboratories Ltd and noted that Para 9(2) of DPCO 2013 states that *"the Government may in the due course of time come out with other appropriate mechanism of collecting or obtaining the market based data related to drugs and the decision of Government with respect to collection or obtaining of data shall be final"*. The Form-V filed by companies to NPPA in the Integrated Pharmaceutical Database Management System (IPDMS) is the primary and accurate database maintained by NPPA. Laying recourse to this database under Para 9(2) comes under the powers delegated by the Government to NPPA. Accordingly, it was noted by the Authority that the fixation of retail

price based on Form-V data, issued by the company to the distributor, State Drug Controller and the Government as per the provisions of DPCO 2013, is well within its mandate.

4.2.5 The Authority deliberated upon the matter in detail and accepted recommendation of the Multidisciplinary Committee of Experts regarding allowing a reduction of 50% on the patented component of the FDCs i.e Saxagliptin while fixing the retail price of Fixed Dose Combinations (FDCs) of Saxagliptin+ Metformin tablets and approved the retail prices of 4 (four) new drugs under Para 5 and 15 of the DPCO 2013, as detailed below:

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xxi)	Saxagliptin + Metformin Hydrochloride (ER) Tablet	**Each film coated tablet contains:** Saxagliptin Hydrochloride eq. to Saxagliptin 2.5mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Morepen Laboratories Limited	17.70
4(xxii)	Saxagliptin + Metformin Hydrochloride (ER) Tablet	**Each film coated tablet contains:** Saxagliptin Hydrochloride eq. to Saxagliptin 2.5mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Morepen Laboratories Limited	19.09
4(xxiii)	Saxagliptin + Metformin Hydrochloride (ER) Tablet	**Each film coated tablet contains:** Saxagliptin Hydrochloride eq. to Saxagliptin 5mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Morepen Laboratories Limited	19.45
4(xxiv)	Saxagliptin + Metformin Hydrochloride (ER) Tablet	**Each film coated tablet contains:** Saxagliptin Hydrochloride eq. to Saxagliptin 5mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Morepen Laboratories Limited	20.84

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

5.1 Noted.

6. Agenda item no. 6 – Application of M/s Torrent Pharmaceutical Limited for exemption from DPCO under Para 32(i) of DPCO, 2013 for formulation "Tapentadol Nasal Spray 225mg/ml" in which each spray (0.1ml) contains Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative)

6.1 The Authority noted the application filed by M/s Torrent Pharmaceuticals Ltd for exemption under para 32(i) of DPCO 2013 for the formulation "Tapentadol Nasal Spray 225mg/ml" in which each spray (0.1ml) contains Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative).

6.2 The Authority further noted the document submitted by the applicant company is as follows:

a. Patent No. 355890 granted on 15.01.2021 to M/s Torrent Pharmaceuticals Ltd for invention entitled "Pharmaceutical invention of Tapentadol" for the term of 20 years from 19th July, 2012, issued by the Patent Office, Government of India.

b. New drug approval granted to M/s Torrent Pharmaceuticals Ltd on 02.09.2020 from Central Drugs Standard Control Organisation (CDSCO), in form CT-23, to manufacture the new drug 'Tapentadol Hydrochloride Nasal Spray 225mg/ml Nasal Spray' in which "Each spray (0.1ml) containing Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative).

6.3 The Authority also noted that CDSCO vide its email dated 26.05.2021 stated that "... the new drug approval granted to M/s Torrent Pharma for Tapentadol Nasal spray is covered under the Patent granted by the Patent Office vide Patent No. 355890."

6.4 The Authority deliberated upon the matter in detail and observed that M/s Torrent Pharmaceuticals Ltd fulfills the conditions as per para 32(i) of DPCO 2013 with respect to the formulation "Tapentadol Nasal Spray 225mg/ml" in which each spray (0.1ml) contains Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative).

6.5 Accordingly, the Authority decided that exemption be granted to M/s Torrent Pharmaceuticals Ltd under Para 32(i) of DPCO 2013 for their formulation "Tapentadol Nasal Spray 225mg/ml" in which each spray (0.1ml) contains Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative) 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.

6.6 The Authority further directed that M/s Torrent Pharmaceutical Ltd be requested to intimate the date of commercial marketing of formulation "Tapentadol Nasal Spray 225mg/ml" in which each spray (0.1ml) contains Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative) in the country and the launch price of the product.

6.7 The Authority recalled the decision taken in its 84th meeting dated 10.03.2021 and also directed M/s Torrent Pharmaceuticals Ltd to seek retail price approval, if applicable, three month before the expiry of the exemption granted under Para 32(i) of DPCO 2013.

7. Agenda item no. 7 - Intimation of Minutes of 33rd meeting of Multidisciplinary Committee of Experts held on 21.06.2021.

7.1 Noted.

8. Agenda item no. 8 – (A) Form-IV Intimation of M/s Cipla Limited for discontinuation of 5 scheduled formulations viz., (i) Abamune L Tablets (ii) Abamune Tablets (iii) Efavir 200 Capsules (iv) Hepcvir 28 Tablets and (v) Tenvir L Tablets
(B) Form-IV Intimation of M/s Neon Laboratories Limited for discontinuation of scheduled formulation viz., Lox 5% Ointment (Lidocaine 5%)

8.1 The Agenda item was deferred.

9. Agenda item no. 9 - Issues relating to pricing of Amphotericin B (Emulsion) 50mg /10 ml injection

9.1 The Authority noted that the formulation Amphotericin-B Powder for injection 50 mg in its three variants i.e. conventional, lipid and liposomal are scheduled formulations under DPCO 2013 and their ceiling prices are notified.

9.2 The Authority further noted that M/s Lyka Labs Ltd had filed application for retail price fixation of the formulation Amphotericin B (Emulsion) 50mg /10 ml injection. The matter was placed before the Multidisciplinary Committee of Experts in its 33rd meeting dated 21.06.2021 in which the Committee recommended decided that *"...clarification be obtained from Central Drugs Standard Control Organisation (CDSCO) as to whether Emulsion form of Amphotericin B has major difference from Lipid form to consider a separate price for it or ceiling price notified for Amphotericin B (Lipid) may also be extended to Amphotericin B (Emulsion)." Accordingly, clarification was sought from CDSCO.*

9.3 CDSCO vide its e-mail dated 23.06.2021 stated that *"....Drugs Delivery system of Amphotericin-B includes liposomal encapsulation of Amphotericin-B or incorporation of the drug in lipid complex/emulsion. Liposomal or Lipid incorporated formulations of Amphotericin B may vary from one another in the chemical composition and physical form of the lipid components. However, broadly the Amphotericin-B lipid complex/ emulsion may be considered as one group which is different from liposomal Amphotericin-B & Conventional Amphotericin-B."*

9.4 Drug Controller General of India (DCGI), also the Authority member clarified that the emulsion version of Amphotericin B is a sub category of a broader category of lipid variants. DCGI also mentioned that the emulsion and other lipid variants of Amphotericin B injection have same/ similar level of efficacy and toxicity.

9.5 The Authority deliberated upon the matter in detail and decided that ceiling price as applicable for Amphotericin B (Lipid) Powder for Injection 50 mg is also applicable for Amphotericin B (Emulsion) injection having the same dosage form and strength. The Authority further decided to issue a clarification in this regard. The Authority also decided to close the retail price application of M/s Lyka Labs Ltd.

10. Agenda item no. 10 - Revision of Ceiling Price of select Scheduled formulations under Para 19 of DPCO, 2013

10.1 Record of discussion for members being circulated separately.

10.2 The Authority noted that NPPA has been receiving applications for upward price revision under para 19 of DPCO, 2013 for more than two years citing various reasons like drug being under repeated price regulation; increase in cost of production; exchange rate volatility etc. resulting in their unviability in sustainable production and marketing of these drugs.

10.3 The Authority further noted that the issue relating to application for upward price revision under Para 19 of DPCO 2013 was referred 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. SCAMHP in its 2nd meeting held on 07.11.2019 authorized NPPA to examine formulations/ molecules experiencing issues of manufacturing unviability due to low prices and apply price revision by allowing 50% increase from the ceiling price.

10.4 The case of upward price revision of 13 drugs comprising 27 formulations under Para 19 of DPCO 2013 was deliberated upon by the Authority. Based on deliberation, the Authority rejected the case of 6 drugs comprising 11 formulations and deferred the case of 4 drugs comprising 7 formulations for further examination. The Authority noted that the remaining 3 drugs comprising 9 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. 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.

10.5 The Authority further noted that the Inter-Ministerial Committee constituted for examination of cases under Para 19 of DPCO 2013 also observed that those 3 drugs are essential medicines for public health management and pricing of these shouldn't be reason for shortage, discontinuation and unavailability of these medicines and accordingly recommended for upward revision of price under Para 19 of DPCO 2013.

10.6 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 extra ordinary powers in public interest under Para 19 of DPCO 2013 for upward revision of the ceiling prices of 3 drugs by giving one time increase of 50% from the present ceiling price as detailed below:

S. No.	Medicines	Dosage form and Strength	Unit	Approved ceiling (excluding GST) (Rs.)
1	Carbamazepine	Tablet 100 mg	1 tablet	1.02
		CR Tablet 200 mg	1 tablet	2.34
		CR Tablet 400 mg	1 tablet	4.61
		Oral Liquid 100 mg/5ml	1 ml	0.29
2	Ranitidine	Oral Liquid 75 mg/5ml	1 ml	1.08
		Tablet 150 mg	1 tablet	1.10
		Injection 25mg/ml	1 ml	2.43
3	Ibuprofen	Tablet 200 mg	1 tablet	0.59
		Tablet 400 mg	1 tablet	1.04

10.7 Further, the provisions of para 13(2) of DPCO 2013 would not be applicable on the revised ceiling price of the formulations mentioned in para 10.6 above.

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

The meeting ended with a vote of thanks to the Chair and all the participants in the meeting.

Kotwal

(Dr. Vinod Kotwal)
Member Secretary