मिसिलस.- 8(102)/2022/डी.पी/एनपीपीए-डीवी-II
F. No. 8(102)/2022/DP/NPPA-Div. II

कार्यवाहीस. : 234/102/2022/F
Proceeding No: 234/102/2022/F

Minutes of the 234th(overall) and 102ndmeeting of the Authority under DPCO, 2013 held on 27.09.2022 at 3:00 PM

The 234thmeeting of the Authority (overall), which is the 102ndmeeting under the DPCO, 2013, was held on 27th of September at 3:00 PM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. The following Authority members of NPPA were present during the meeting:

(i) Dr. Vinod Kotwal, Member Secretary, NPPA
(ii) Shri G. Venkatesh, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
(iii) Dr. V. G. Somani, Drug Controller General (India), CDSCO via Video Conferencing

Shri A. K. Pradhan, Jt. Drug Controller, CDSCO, Ministry of Health & Family Welfare also was present and joined through video-conferencing.

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

(i) Shri Manmohan Sachdeva, Advisor (Cost-I)
(ii) Shri Sanjay Kumar, Advisor (Cost-II)
(iii) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
(iv) Shri R. Jegan, Jt. Director (OC & Medical Device)
(v) Shri Prasenjit Das, Deputy Director (Pricing)
(vi) Shri Mahaveer Saini, Deputy Director (Pricing)
(vii) Shri Rajesh Kumar T., Deputy Director (Medical Device, Legal & IT)

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 101st Meeting held on 07.09.2022

1.1 The Authority confirmed the minutes without any change.

2. Agenda item no. 2 – (a) Action Taken Report (ATR) on decisions taken by NPPA in its 101st Meeting held on 07.09.2022

2.1 Noted.

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

3.1 Noted.

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

4.1The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4(xxiv)(total 42 Form I applications containing retail price fixation of 42 new drugs) falling under the purview of Para 2(u) of DPCO, 2013. After deliberations, Authority approved the retail prices of 40(forty) new drugs [except Agenda item no. 4(xxii), 4(xxiv)]under Para 5 and 15 of the DPCO 2013, as detailed below:

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(i)	Calcium Carbonate, Vitamin D3, Methylcobalamin, Methylfolate& Pyridoxal -5-Phosphate tablets	**Each film coated tablet contains:** Calcium carbonate IP 1250mg eq. to Elemental calcium 500mg, Vitamin D3 IP 2000IU, Methylcobalamin IP 1500mcg L Methylfolate Calcium 1mg, Pyridoxal -5-Phosphate 20mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	17.64
4(ii)	Metoprolol Succinate (As Extended Release), Chlorthalidone & Telmisartan Tablets	**Each film coated tablet contains:** Metoprolol Succinate IP 23.75mg eq. to Metoprolol tartrate 25mg (As Extended Release) Chlorthalidone IP 12.50mg Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Ltd.	10.88
4(iii)	Metoprolol Succinate (As Extended Release), Chlorthalidone & Telmisartan Tablets	**Each film coated tablet contains:** Metoprolol Succinate IP 47.50mg eq. to Metoprolol tartrate 50mg (As Extended Release) Chlorthalidone IP 12.50mg Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Ltd.	13.41
4(iv)	Mefenamic	**Each 5ml contains:**	1 ml	M/s Akums Drugs	0.76

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Acid and Paracetamol Oral Suspension	Paracetamol IP 250mg Mefenamic Acid IP 100mg		&Pharmaceuticals Ltd. / M/s Apex Laboratories Pvt. Ltd.	
4(v)	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 Micro Labs Limited	13.83
4(vi)	Clopidogrel & Aspirin Tablets	**Each film coated tablet contains:** Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg Aspirin IP 75mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	4.55
4(vii)	Nebivolol and Telmisartan Tablets	**Each uncoated bilayer tablet contains:** Nebivolol Hydrochloride IP eq. to Nebivolol 5mg, Telmisartan IP 40mg	1 Tablet	M/s Aristo Pharmaceuticals Pvt. Ltd.	14.22
4(viii)	Sodium Alginate, Sodium Bicarbonate & Calcium Carbonate Oral Suspension	**Each 5ml Contains:** Sodium Alginate IP 250mg, Sodium Bicarbonate IP 133.5mg, Calcium Carbonate IP 80mg	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Alembic Pharmaceuticals Ltd.	0.87
4(ix)	Aceclofenac, Paracetamol and Thiocolchicoside tablets	**Each Film Coated Tablet contains:** Aceclofenac IP 100mg Paracetamol IP 325mg Thiocolchicoside IP 4mg	1 Tablet	M/s Theon Pharmaceuticals Limited / M/s Zydus Healthcare Limited	16.35
4(x)	Paracetamol Infusion IP (1%w/v) in 100ml pack	**Each ml contains:** Paracetamol IP 10mg Water for Injection	1 ml	M/s Zydus Healthcare Limited	3.10
4(xi)	Ceftriaxone & Sulbactam Injection	**Each vial contains:** Ceftriaxone Sodium IP (Sterile) eq. to Anhydrous Ceftriaxone 1000mg Sulbactam Sodium IP (Sterile) eq. to Anhydrous Sulbactam 500mg	1 Vial	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Eris Healthcare Pvt. Ltd.	147.20
4(xii)	Paracetamol sustained release Tablets	**Each uncoated bilayered tablet contains:** Paracetamol IP 300mg	1 Tablet	M/s Lincoln Pharmaceuticals Ltd. / M/s Zydus Healthcare Limited	4.10

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		(as Immediate release) Paracetamol IP 700mg (as sustained release)			
4(xiii)	Azithromycin Oral Suspension	**Each 5ml contains:** Azithromycin IP as Dihydrate eq. to Anhydrous Azithromycin 100mg	1 ml	M/s Akums Drugs & Pharmaceuticals Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.	2.16 (Note 5)
4(xiv)	Vitamin D3 Oral Solution	**Each 5ml contains:** Cholecalciferol IP (In nano Droplet form) 60000IU	1 ml	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Micro Labs Ltd.	11.78
4(xv)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	**Each film coated bilayered tablet contains:** Telmisartan IP 40mg, Chlorthalidone IP 12.5mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (as extended release)	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Mankind Pharma Ltd.	10.88
4(xvi)	Trastuzumab for Injection 150mg	**Each Lyophilized vial contains:** (A) Trastuzumab (In House) (150mg) L-Histidine HCl Ph. Eur. (3.36mg) α-α Trehalose dihydrate Ph. Eur. (136.2 mg) Polysorbate-20 IP (0.6mg) L-Histidine Ph. Eur. (2.16mg) (B) Sterile water for Injection IP 10 ml	Per pack	M/s Reliance Life Sciences Pvt. Ltd. / M/s Cadila Pharmaceuticals Limited	15554.49
4(xvii)	Budesonide Nebuliser suspension BP 0.5mg/2ml	**Each 2ml suspension contains:** Budesonide IP 0.5mg Water for injection IP q.s.	Each 2 ml Pack	M/s Ahlcon Parenterals (India) Ltd. / M/s Sun Pharmaceutical Industries Limited	18.01
4(xviii)	Cefixime and Ofloxacin Oral suspension	**Each 5ml reconstituted suspension contains:** Cefixime IP as trihydrate eq. to Anhydrous Cefixime 50mg Ofloxacin IP 50mg	1 ml	M/s Innova Captab Ltd. / M/s Macleods Pharmaceuticals Ltd.	1.77
4(xix)	Aceclofenac	**Each uncoated**	1 Tablet	M/s Zydus	4.64

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	and Paracetamol Tablets	**bilayered tablet contains:** Aceclofenac IP 100mg Paracetamol IP 325mg		Healthcare Ltd.	
4(xx)a	Dapagliflozin and Metformin Hydrochloride (Extended Release) Tablets	**Each film coated tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (as Extended-Release form)	1 Tablet	M/s Macleods Pharmaceuticals Ltd.	9.27 (Note 1)
4(xx)b	Dapagliflozin and metformin Hydrochloride (Extended Release) Tablets	**Each film coated tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (as Extended Release form)	1 Tablet	M/s Macleods Pharmaceuticals Ltd.	10.76 (Note 1)
4(xx)c	Dapagliflozin and metformin Hydrochloride (Extended Release) Tablets	**Each film coated tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Metformin Hydrochloride IP 500mg (as Extended Release form)	1 Tablet	M/s Macleods Pharmaceuticals Ltd.	6.36 (Note 1)
4(xx)d	Dapagliflozin and Metformin Hydrochloride (Extended Release) Tablets	**Each film coated tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Metformin Hydrochloride IP 1000mg (as Extended-Release form)	1 Tablet	M/s Macleods Pharmaceuticals Ltd.	6.55 (Note 1)
4(xx)e	Dapagliflozin and Metformin Hydrochloride (Extended Release) Tablets	**Each film coated tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin	1 Tablet	M/s Exemed Pharmaceuticals / M/s Glenmark Pharmaceuticals Limited	10.76 (Note 1)

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Hydrochloride (Extended Release) IP 1000mg			
4(xx)f	Dapagliflozin and Metformin Hydrochloride (Extended Release) Tablets	**Each film coated tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride (Extended Release) IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Glenmark Pharmaceuticals Limited	9.27 (Note 1)
4(xx)g	Dapagliflozin and Metformin Hydrochloride (Extended Release) Tablets	**Each film coated tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride (Extended Release) IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Abbott Healthcare Pvt. Ltd.	9.27 (Note 1)
4(xx)h	Dapagliflozin and Metformin Hydrochloride (Extended Release) Tablets	**Each film coated tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride (Extended Release) IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Abbott Healthcare Pvt. Ltd.	10.76 (Note 1)
4(xxi)a	Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate 62.03mg eq. to Sitagliptin 50mg Metformin Hydrochloride USP/Ph. Eur 1000mg (as Extended Release)	1 Tablet	M/s MSN Laboratories Pvt. Limited	9.73 (Note 2)
4(xxi)b	Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate 124.06mg eq. to Sitagliptin 100mg Metformin Hydrochloride USP/Ph. Eur 1000mg (as Extended Release)	1 Tablet	M/s MSN Laboratories Pvt. Limited	14.19 (Note 2)
4(xxi)c	Sitagliptin and Metformin Hydrochloride (as Extended	**Each film coated tablet contains:** Sitagliptin Phosphate 62.03mg eq. to	1 Tablet	M/s MSN Laboratories Pvt. Limited	9.28 (Note 2)

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Release) Tablets	Sitagliptin 50mg Metformin Hydrochloride USP/Ph. Eur 500mg (as Extended Release)			
4(xxi)d	Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals /M/s Sun pharma Laboratories Limited	20.17 (Note 2)
4(xxi)e	Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Macleods Pharmaceuticals Ltd.	21.56 (Note 2)
4(xxi)f	Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Macleods Pharmaceuticals Ltd.	20.06 (Note 2)
4(xxi)g	Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Macleods Pharmaceuticals Ltd.	20.17 (Note 2)
4(xxi)h	Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Macleods Pharmaceuticals Ltd.	18.67 (Note 2)
4(xxi)i	Sitagliptin and	**Each film coated tablet**	1 Tablet	M/s Macleods	20.02

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Metformin Hydrochloride Tablets	**contains:** Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg		Pharmaceuticals Ltd.	(Note 2)
4(xxi)j	Sitagliptin and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Macleods Pharmaceuticals Ltd.	18.34 (Note 2)
4(xxi)k	Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	**Each bilayered film coated tablet contains:** Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Theon Pharmaceuticals Limited / M/s Wockhardt Limited	11.60 (Note 2)
4(xxi)l	Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	**Each bilayered film coated tablet contains:** Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Theon Pharmaceuticals Limited / M/s Wockhardt Limited	12.50 (Note 2)
4(xxii)	Pantoprazole powder for Oral Suspansion (Sodium Bicarbonate as buffer)	**Each sachet contains:** Pantoprazole Sodium IP eq. to Pantoprazole 40mg (Sodium Bicarbonate as buffer)	1 Sachet	M/s Alkem Laboratories Ltd.	(Note 3)
4(xxiii)	Ibuprofen Solution for Infusion 400mg/100ml	**Each 100 ml contains:** Ibuprofen 400mg water for Injection IP q.s.	Each Pack (100ml)	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Ltd.	122.19
4(xxiv)	Lidocaine Patch 5%	**EachAdhesive Patch contains:** Lidocaine 700mg in an aqueous base (50mg per gm adhesive)	1 Patch	M/s Hetero Healthcare Ltd.	(Note 4)

Note 1.*The Authority deliberated upon the matter in detail and decided to approve the retail price in line with the decision as recorded in Note 5 of Para 4.1 of the Minutes of the 96th Authority meeting dated 24.03.2022*

Note 2.*The Authority deliberated upon the matter in detail and decided to approve the retail price in line with the decision as recorded in Note 7 of Para 4.1 of the Minutes of the 96th Authority meeting dated 24.03.2022.*

Note 3. *The Authority noted that M/s Alkem Laboratories Ltd had made a representation on the retail price recommended by the Multidisciplinary Committee of Experts (MDC) in its 45th meeting held on 13.09.2022. The Authority deliberated upon the matter in detail and decided to refer the matter to the MDC for examination of the representation.*

Note 4*. The Authority noted that M/s Hetero Healthcare Ltd had made a representation on the retail price recommended by the Multidisciplinary Committee of Experts in its 45th meeting held on 13.09.2022. The Authority deliberated upon the matter in detail and decided to refer the matter to the MDC for examination of the representation.*

Note 5. *Drug Controller General of India confirmed that the formulation is approved by CDSCO.*

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

5.1 Noted.

6. Agenda item no. 6 –Minutes of 45thmeeting of Multidisciplinary Committee of Experts held on 13.09.2022.

6.1 Noted.

7. Agenda item no. 7 - Application by M/s Axa Parenterals Ltd. for separate price under Para 11(3) of DPCO 2013 with respect to (i) Dextrose Injection 25%w/v in 100 ml pack in Non-glass with special feature for in LDPE container with Euro Head (ii) Mannitol injection 20 gm per 100ml in 100 ml pack in Non-glass with special feature for in LDPE container with Euro Head (iii) Metronidazole Injection IP 500mg/100ml in 100ml 100 ml pack in Non-glass with special feature for in LDPE container with Euro Head

7.1 The Authority noted the application filed by M/s Axa Parenterals Ltd for separate price under Para 11(3) of DPCO 2013 with respect to (i) Dextrose Injection 25%w/v in 100 ml pack in Non-glass with special feature for in LDPE container with Euro Head (ii) Mannitol injection 20 gm per 100ml in 100 ml pack in Non-glass with special feature for in LDPE container with Euro Head (iii) Metronidazole Injection IP 500mg/100ml in 100ml 100 ml pack in Non-glass with special feature for in LDPE container with Euro Head. The Authority further noted that the matter was discussed in various meetings

(41st to 45th) of the Multidisciplinary Committee of Experts in which the Committee examined the documents/ literature submitted by the company. The Authority also noted that the request of M/s Axa Parenterals Ltd for withdrawal of application was placed in the 45th meeting of the Multidisciplinary Committee of Experts dated 13.09.2022 in which the Committee recommended "*....to close the application made by M/s Axa Parenterals Ltd. for separate price under Para 11(3) of DPCO 2013 with respect to (i) Dextrose Injection 25%w/v in 100 ml pack in Non-glass with special feature for in LDPE container with Euro Head (ii) Mannitol injection 20 gm per 100ml in 100 ml pack in Non-glass with special feature for in LDPE container with Euro Head (iii) Metronidazole Injection IP 500mg/100ml in 100ml 100 ml pack in Non-glass with special feature for in LDPE container with Euro Head based on the request of the company as requested by the company.*"

7.2 The Authority deliberated upon the matter in detail and accepted the recommendation of the Multidisciplinary Committee of Experts and decided to close the application made by M/s Axa Parenterals Ltd. for separate price under Para 11(3) of DPCO 2013 with respect to the formulation referred in Para 7.1 above.

8. Agenda item no. 8 - Application by M/s Axa Parenterals Ltd. for separate price for Non-Glass with special feature for Ciprofloxacin Injection IP, Compound Sodium lactate Injection IP (Ringer Lactate Solution for injection IP), Dextrose Injection IP (10% w/v), Dextrose Injection (5% w/v) and Fluconazole Injection USP 100 ml in LDPE container with Euro Head

8.1 The Authority noted the application filed by M/s Axa Parenterals Ltd for separate price for Non-Glass with special feature under Para 11(3) of DPCO 2013 for Ciprofloxacin Injection IP 200mg/100ml in 100 ml non glass pack with special features, Compound Sodium lactate Injection IP (Ringer Lactate Solution for injection IP) in 100 ml non glass pack with special features, Dextrose Injection IP (10% w/v) in 100 ml non glass pack with special features, Dextrose Injection (5% w/v) in 100 ml non glass pack with special features and Fluconazole Injection USP 200mg/100 ml in 100 ml non glass pack with special features. The Authority further noted that the matter was discussed in various meetings (41st to 45th) of the Multidisciplinary Committee of Experts in which the Committee examined the documents/ literature submitted by the company. The Authority also noted that the request of M/s Axa Parenterals Ltd for withdrawal of application was placed in the 45th meeting of the Multidisciplinary Committee of Experts dated 13.09.2022 in which the Committee recommended "*...to close the application made by M/s Axa Parenterals Ltd. for separate price for Non-Glass with special feature for (i) Ciprofloxacin Injection IP, Compound Sodium lactate Injection IP (Ringer Lactate Solution for injection IP), Dextrose Injection IP (10% w/v), Dextrose Injection (5% w/v) and Fluconazole Injection USP 100 ml in LDPE container with Euro Head as requested by the company.*"

8.2 The Authority deliberated upon the matter in detail and accepted the recommendation of the Multidisciplinary Committee of Experts and decided to close the

application made by M/s Axa Parenterals Ltd. for separate price under Para 11(3) of DPCO 2013 with respect to the formulations referred in Para 8.1 above.

9. Agenda item no. 9 - Application for extension of ceiling price of Sodium Chloride Injection 0.9% in 500 ml with packaging in non glass with special feature in line with S.O.1500(E) dated 30.03.2022

9.1 The Authority noted that the application made by M/s Puerto life Sciences Private Limited for extension of ceiling price of Sodium Chloride Injection 0.9% in 500 ml with packaging in non glass with special feature in line with S.O. 1500(E) dated 30.03.2022 since their products have the features like (i) self collapsibility (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels. The Authority further noted that the matter was discussed in various meetings (42nd to 45th) of the Multidisciplinary Committee of Experts in which the Committee examined the documents/ literature submitted by the company. The Authority further noted that in the 45th meeting of the Multidisciplinary Committee of Experts held on 13.09.2022, the Multidisciplinary Committee recommended *"...to extend the ceiling prices and the formulations mentioned in SO. 1500(E) dated 30.03.2022 to M/s Puerto Life Sciences Pvt. Ltd for the formulation 'Sodium Chloride Injection 0.9% in 500 ml with packaging in non glass with special feature."*

9.2 The Authority deliberated upon the matter in detail and accepted the recommendation of Multidisciplinary Committee of Experts and decided to extend the ceiling prices mentioned in SO. 1500(E) dated 30.03.2022 to M/s Puerto Life Sciences Pvt. Ltd for the formulation 'Sodium Chloride Injection 0.9% in 500 ml with packaging in non glass with special feature under Para 11(3) of DPCO 2013.

10. Agenda item no. 10 - Application for extension of ceiling price of (i) Glucose Injection 5% in 500ml Non Glass With special features with Euro Head and (ii) Glucose (A) + Sodium Chloride (B) Injection 5% (A) + 0.9% (B) in 500ml Non Glass With special features with Euro Head in line with S.O.1500(E) dated 30.03.2022.

10.1 The Authority noted that the application made by M/s Puerto life Sciences Private Limited for extension of ceiling price of (i) Glucose Injection 5% in 500ml Non Glass with special features with Euro Head and (ii) Glucose (A) + Sodium Chloride (B) Injection 5% (A) + 0.9% (B) in 500ml Non Glass with special features with Euro Head in line with S.O.1500(E) dated 30.03.2022 since their products have the features like (i) self collapsibility (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels. The Authority further noted that the matter was placed in the 45th meeting of the Multidisciplinary Committee of Experts held on 13.09.2022 in which the Committee recommended *"...to extend the ceiling prices and the formulations mentioned in SO. 1500(E) dated 30.03.2022 to M/s Puerto Life Sciences Pvt. Ltd for the formulations (i) Glucose Injection 5% in 500ml Non Glass With*

special features with Euro Head and (ii) Glucose (A) + Sodium Chloride (B) Injection 5% (A) + 0.9% (B) in 500ml Non Glass With special features with Euro Head."

10.2 The Authority deliberated upon the matter in detail and accepted the recommendation of Multidisciplinary Committee of Experts and decided to extend the ceiling prices mentioned in SO. 1500(E) dated 30.03.2022 to M/s Puerto Life Sciences Pvt. Ltd for the formulations (i) Glucose Injection 5% in 500ml Non Glass With special features with Euro Head and (ii) Glucose (A) + Sodium Chloride (B) Injection 5% (A) + 0.9% (B) in 500ml Non Glass With special features with Euro Head under Para 11(3) of DPCO 2013.

11. Agenda item no. 11 - Application for extension of ceiling price of Ringer lactate injection with packaging in non glass with special feature in line with S.O. 1501(E) dated 30.03.2022

11.1 The Authority noted that the application made by M/s Puerto life Sciences Private Limited for extension of ceiling price of Ringer lactate injection with packaging in non glass with special feature in line with S.O. 1501(E) dated 30.03.2022 since their products have the features like (i) self-collapsibility (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels. The Authority further noted that the matter was placed in the 45th meeting of the Multidisciplinary Committee of Experts held on 13.09.2022 in which the Committee recommended *"...to extend the ceiling prices and the formulations mentioned in SO. 1501(E) dated 30.03.2022 to M/s Puerto Life Sciences Pvt. Ltd for the formulation Ringer lactate injection in 500 ml pack with packaging in non glass with special feature."*

11.2 The Authority deliberated upon the matter in detail and accepted the recommendation of Multidisciplinary Committee of Experts and decided to extend the ceiling prices mentioned in SO. 1501(E) dated 30.03.2022 to M/s Puerto Life Sciences Pvt. Ltd for the formulation Ringer lactate injection in 500 ml pack with packaging in non glass with special feature under Para 11(3) of DPCO 2013.

12. Agenda item no. 12 - Approval for ceiling price of different dosage forms and strength of I.V Fluids with packaging in non-glass with special features "SAFE PORT" dated 09.05.2022 being filed byM/s Sachin Parenteral Pvt. Ltd.

12.1 The Authority noted that the application made by M/s Sachin Parenteral Pvt. Ltd for separate ceiling price for the formulations (i) Dextrose(Glucose) Injection5% w/v in 500 ml pack with packaging in non glass with special features with brand 'safe port' (ii) Sodium Chloride Injection 0.9% w/v in 100 ml pack with packaging in non glass with special features with brand 'safe port' (iii) Sodium Chloride Injection 0.9% w/v in 250 ml pack with packaging in non glass with special features with brand 'safe port' (iv) Sodium Chloride Injection 0.9% w/v in 500 ml pack with packaging in non glass with special features with brand 'safe port' (v) Glucose 5% + Sodium Chloride 0.9 % Injection

m/v in 500 ml pack with packaging in non glass with special features with brand 'safe port' (vi) Ringer lactate injection in 500 ml pack with packaging in non glass with special feature with brand 'safe port'. The Authority further noted that the matter was placed in the 45th meeting of the Multidisciplinary Committee of Experts held on 13.09.2022 in which the Committee recommended "*...to extend the ceiling prices and the formulations mentioned in SO. 1500(E) dated 30.03.2022 to M/s Sachin Parenterals Pvt. Ltdfor the formulations (i) Dextrose(Glucose) Injection5% w/v in 500 ml pack with packaging in non glass with special features with brand 'safe port' (ii) Sodium Chloride Injection 0.9% w/v in 100 ml pack with packaging in non glass with special features with brand 'safe port' (iii) Sodium Chloride Injection 0.9% w/v in 250 ml pack with packaging in non glass with special features with brand 'safe port' (iv) Sodium Chloride Injection 0.9% w/v in 500 ml pack with packaging in non glass with special features with brand 'safe port' (v) Glucose 5% + Sodium Chloride 0.9 % Injection m/v in 500 ml pack with packaging in non glass with special features with brand 'safe port'. The Committee also decided to extend the ceiling prices and the formulations mentioned in SO. 1501(E) dated 30.03.2022 to M/s Sachin Parenterals Pvt. Ltd for the formulations Ringer lactate injection in 500 ml pack with packaging in non glass with special feature with brand 'safe port'.*"

12.2 The Authority deliberated upon the matter in detail and accepted the recommendation of Multidisciplinary Committee of Experts and decided to extend the ceiling prices mentioned in SO. 1500(E) dated 30.03.2022 to M/s Sachin Parenteral Pvt. Ltd for the formulations (i) Dextrose(Glucose) Injection5% w/v in 500 ml pack with packaging in non glass with special features with brand 'safe port' (ii) Sodium Chloride Injection 0.9% w/v in 100 ml pack with packaging in non glass with special features with brand 'safe port' (iii) Sodium Chloride Injection 0.9% w/v in 250 ml pack with packaging in non glass with special features with brand 'safe port' (iv) Sodium Chloride Injection 0.9% w/v in 500 ml pack with packaging in non glass with special features with brand 'safe port' (v) Glucose 5% + Sodium Chloride 0.9 % Injection m/v in 500 ml pack with packaging in non glass with special features with brand 'safe port' under Para 11(3) of DPCO 2013. The Authority also decided to extend the ceiling prices and the formulations mentioned in SO. 1501(E) dated 30.03.2022 to M/s Sachin Parenteral Pvt. Ltd for the formulations Ringer lactate injection in 500 ml pack with packaging in non glass with special feature with brand 'safe port' under Para 11(3) of DPCO 2013.

13. Agenda item no. 13 - Application for Price approval of Dextrose Injection IP (5% w/v) 250ml, Dextrose Injection IP (25% w/v) in 100ml, Glucose 5% with sodium chloride 0.9% w/v 250ml, Metronidazole Injection IP 100ml, Mannitol Injection IP (20% w/v) 100ml non-glass having special features- Euro Head bottle dated. 16.05.2022.

13.1 The Authority noted that the application made by M/s SachinParenterals Pvt. Ltd for separate ceiling price for the formulations (i) Dextrose Injection IP (5% w/v) 250ml (ii) Dextrose Injection IP (25% w/v) in 100ml (iii) Glucose 5% with sodium chloride 0.9% w/v 250ml (iv) Metronidazole Injection IP 100ml (v) Mannitol Injection IP (20% w/v) 100ml non-glass having special features. The Authority further noted that the

matter was placed in the 45th meeting of the Multidisciplinary Committee of Experts held on 13.09.2022 in which the Committee recommended as follows:

".....to extend to M/s Sachin Parenteral Pvt. Ltd, the ceiling prices and the formulations mentioned in (i) SO. 1504(E) dated 30.03.2022 for the formulation Metronidazole Injection (0.5%w/v) 500mg/100ml in100 ml pack for packages in non-glass container in plastic bottle with euro head having special features, (ii) SO. 1505(E) dated 30.03.2022 for the formulation Mannitol Injection 20% in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features and (iii) SO. 1506(E) dated 30.03.2022 for the formulation Dextrose(Glucose) Injection(25%w/v) in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features."

"... The Committee further noted that the separate ceiling price of the formulation (i) Dextrose (Glucose) Injection5% w/v in 250 ml pack with packages in non glass pack having special features and (ii) Glucose 5% + Sodium Chloride 0.9 % Injection w/v in 250 ml pack with packaging in non glass with special feature has not been fixed earlier. The Committee deliberated upon the matter in detail and decided to provide the separate ceiling price for these formulations by allowing 15 percent over the present applicable ceiling price of the formulations (i) Glucose Injection % in 250 ml non-glass pack and (ii) Glucose 5% + Sodium Chloride 0.9 % Injection in 250 ml non-glass pack respectively...."

13.2 The Authority deliberated upon the matter in detail and accepted the recommendation of Multidisciplinary Committee of Experts and decided to extend to M/s Sachin Parenteral Pvt. Ltd, the ceiling prices mentioned in (i) SO. 1504(E) dated 30.03.2022 for the formulations Metronidazole Injection (0.5%w/v) 500mg/100ml in100 ml pack for packages in non-glass container in plastic bottle with euro head having special features, (ii) SO. 1505(E) dated 30.03.2022 for the formulation Mannitol Injection 20% in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features and (iii) SO. 1506(E) dated 30.03.2022 for the formulation Dextrose (Glucose) Injection(25%w/v) in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features under Para 11(3) of DPCO 2013.

13.3 The Authority also noted the recommendation of the Multidisciplinary Committee of Experts on the separate ceiling price under Para 11(3) of DPCO 2013 for the formulations (i) Dextrose (Glucose) Injection 5% w/v in 250 ml pack with packages in non glass pack having special features at Rs. 28.74 per pack excluding GST and (ii) Glucose 5% + Sodium Chloride 0.9 % Injection w/v in 250 ml pack with packaging in non glass with special feature at Rs. 28.84 per pack excluding GST. The Authority deliberated upon the matter in detail and observed that the separate price as recommended by the Committee is not in line with the special ceiling price as provided to other strength/ pack size of IV fluids having features as specified in SO. 1500(E) dated 30.03.2022. Accordingly, the Authority decided that the matter may be referred back to the Committee for re-examination.

14. Agenda item no. 14 - Application for "Special Feature rate" for scheduled products (i) Tazofic Injection 2.25 gm containing Piperacillin 2gm+Tazobactum 250mg and (ii) Tazofic Injection 4.5 gm containing Piperacillin 4gm+Tazobactum 500 mg under Para 11(3) of DPCO 2013

14.1 The Authority noted that the application made by M/s Gufic Biosciences Limitedfor special price of the formulations (i) Tazofic Injection 2.25 gm containing Piperacillin 2gm+Tazobactum 250mg and (ii) Tazofic Injection 4.5 gm containing Piperacillin 4gm+Tazobactum 500 mg under Para 11(3) of DPCO 2013as formulation will be manufactured under 'New Drug Delivery System' namely packing in DCB (Dual Chamber Bags). The Authority further noted that these formulations are scheduled formulations under DPCO 2013. The Authority also noted that the matter was placed in 42nd to 45th meeting of the Multidisciplinary Committee of Experts. The Committee in its 45th meeting held on 13.09.2022 recommended "*...to provide addition 15 percent price over the present applicable ceiling price of these formulations, as specified in Sl. No. 675 and 676 of SO. 1499(E) dated 30.03.2022, for incremental innovation of the packaging. Accordingly, the Committee decided to provide the ceiling price of (i) Tazofic Injection 2.25 gm containing Piperacillin 2gm+Tazobactum 250mg at Rs. 267.03 per pack excluding GST and (ii) Tazofic Injection 4.5 gm containing Piperacillin 4gm+Tazobactum 500 mg at Rs. 560.92 per pack excluding GST under para 11(3) of DPCO 2013.*" The Authority observed that M/s Gufic Biosciences Ltd made representation vide letter no. GBSL/58/2022 dated 23.09.2022 on the price recommended by the Multidisciplinary Committee of Experts in its 45th meeting dated 13.09.2022.

14.2 The Authority deliberated upon the matter in detail and decided that the representation of M/s Gufic Biosciences Ltd be referred to Multidisciplinary Committee of Experts for examination.

15. Agenda item no. 15 - Extension of revised price of Medical Oxygen

15.1 The Authority noted that the price fixed for Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) in cylinder vide SO. 3322(E) dated 25.09.2020 applicable up to 31.03.2021 were extended upto 30.09.2021 vide SO. 1335(E) dated 25.03.2021, and then upto 31.12.2021 vide SO. 3936(E) dated 23.09.2021, and then again upto 31.03.2022 vide SO. 5424(E) dated 28.12.2021, again upto 30.06.2022 vide SO. 1508(E) dated 30.03.2022 and then further extended upto 30.09.2022 or until further orders, whichever is earlier, vide SO. 2982(E) dated 30.06.2022.

15.2 In this context, comments/inputs were sought from Department for Promotion of Industry and Internal Trade (DPIIT) for further extension of prices for Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) in cylinder beyond 30.09.2022 vide letter dated 31.08.2022 and e-mail dated 13.09.2022. The matter was deliberated in the meeting of EG-4 in DPIIT on 27.09.2022, which was attended by Advisor, NPPA

wherein it has been decided that prices of Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) in cylinder be further extended for 3 month i.e. 31.12.2022.

15.3 The Authority deliberated upon the matter in detail and considering the continuing COVID pandemic decided that the revised price of Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) in cylinder fixed vide SO. 3322(E) dated 25.09.2020 and extended vide SO. 1335(E) dated 25.03.2021, SO. 3936(E) dated 23.09.2021, SO. 5424(E) dated 28.12.2021, SO. 1508(E) dated 30.03.2022 and SO. 2982(E) dated 30.06.2022 be further extended up to 31.12.2022 or until further orders, whichever is earlier, in public interest.

16. Agenda item no. 16 – Price fixation as per Pharmaceuticals Purchase Policy (PPP) for products of Pharma Central Public Sector Enterprises (CPSEs) and their subsidiaries

Record of discussion to be circulated separately to the members.

17. Agenda item no. 17 - Extension of revised ceiling price of Heparin Injection 1000IU/ml and 5000IU/ml

17.1 8.1 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 were applicable up to 31.12.2020 and the same were extended up to 31.03.2021 vide SO. 4333(E) dated 03.12.2020, then upto 30.09.2021 vide SO. 1236(E) dated 17.03.2021, and then upto 31.03.2022 vide SO. 3935(E) dated 23.09.2021 and again upto 30.09.2022 or until further orders, whichever is earlier, vide SO. 1507(E) dated 30.03.2022. The Authority further noted that since the matter regarding nomination of new Chairman of the Committee to monitor export/import trends of APIs is under consideration, the import data of Heparin API from the port offices of Central Drugs Standard Control Organisation (CDSCO) during the period from March 2022 to August 2022 was obtained from CDSCO and examined by NPPA.

17.2 The Authority observed the import prices of Heparin API during the period March 2022 to August 2022 were in the similar range as that of the earlier period based on which the revised ceiling price was earlier extended.

17.3 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, essential for COVID-19 pandemic, since the COVID-19 pandemic is not fully subdued. Accordingly, the Authority decided that the revised ceiling price of Heparin Injection 5000IU/ml and 1000 IU/ml fixed vide SO. 2151(E) dated 30.06.2020 and extended vide SO. 4333(E) dated 03.12.2020, SO. 1236(E) dated 17.03.2021, SO. 3935(E) dated 23.09.2021 and again vide SO. 1507(E) dated 30.03.2022 to be further extended upto 31.12.2022 or until further orders, whichever is earlier, in public interest.

17.4 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 31.12.2022 or until further order, whichever is earlier.

18. Agenda item no. 18 - Clarification regarding Trade Margin in Pricing of Coronary Stents

18.1 The Authority was apprised of the Notifications on coronary stents and the provisions pertaining to trade margin from the year 2017 to 2022. The Authority observed that Coronary stents are scheduled medical devices and other than coronary stents, in no other scheduled drug, there is the requirement of maintaining trade margin.

18.2. The Authority deliberated the above in detail and with reference to the clarification sought by the companies on trade margin, decided that henceforth, the Notes mentioned in S.O. No 1502 dated 30th March 2022 shall only be applicable; without any change in the notified ceiling prices, till further orders.

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

वि.कोत्वाल
28/9/2022
(Dr. Vinod Kotwal)
Member Secretary