

Minutes of the 206th (overall) and 74th meeting of the Authority under DPCO, 2013 held on 31.03.2020 at 3:30 PM

The 206th meeting of the Authority (overall), which is the 74th meeting under the DPCO, 2013, was held on the 31st of March, 2020 at 3:30 PM 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 A. K. Saha, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
- (iv) Ms. A. Srijia, 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 S. S. Ojha, Jt. Director (Pricing)
- (ii) Shri Prasenjit Das, Asstt. Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 73rd meeting held on 25.02.2020.

1.1 Noted.

2. Agenda item no. 2 - Action Taken Report on decisions taken by NPPA in its 73rd meeting dated 25.02.2020

2.1 Noted.

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 of DPCO, 2013

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4(xxix) (total 29 Form I applications) falling under the

purview of para 2(u) of DPCO, 2013 and approved the retail prices in 29 (twenty nine) cases under para 5 of 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)	Metoprolol Tablet	Each film coated extended release tablet contains: Metoprolol Succinate IP 95mg eq. to Metoprolol Tartrate 100mg	1 Tablet	M/s Cipla Ltd.	10.34
4(ii)	Vildagliptin + Metformin Tablet (Vildaprim-M 50/500)	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg,	1 Tablet	M/s Swiss Garnier Genexia Sciences Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	6.17
4(iii)	Vildagliptin + Metformin Tablet (Vildaprim-M 50/850)	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 850mg	1 Tablet	M/s Swiss Garnier Genexia Sciences Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	6.24
4(iv)	Vildagliptin + Metformin Tablet (Vildaprim-M 50/1000)	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 1000mg,	1 Tablet	M/s Swiss Garnier Genexia Sciences Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	6.81
4(v)	Trypsin & Chymotrypsin + Paracetamol + Aceclofenac Tablet (Zerodol TC)	Each film coated tablet contains: 50,000 Armour Units Enzymatic Activity Supplied by purified concentrate which has specific Trypsin & Chymotrypsin activity in a ratio of approximately six to One (as enteric coated granules) Paracetamol IP 325mg, Aceclofenac IP 100mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Ipcalaboratories Ltd.	8.29
4(vi)	Emtricitabine + Tenofovir Alafenamide Tablet (TAFNAT-EM)	Each film coated Tablet contains: Emtricitabine IP 200mg, Tenofovir Alafenamide Fumarate eq. to Tenofovir Alafenamide 25mg	1 Tablet	M/s Natco Pharma Limited	51.34
4(vii)	Chlorpheniramine + Phenylephrine Syrup	Each ml syrup contains: Chlorpheniramine Maleate IP 2mg, Phenylephrine Hydrochloride IP 5mg	Per ml	M/s Windlas Biotech Pvt. Ltd. / M/s Zydus Healthcare Limited	0.90
4(viii)	Chlorpheniramine + Phenylephrine Drops	Each ml drops contains: Chlorpheniramine Maleate IP 1mg, Phenylephrine Hydrochloride IP 2.5mg	Per ml	M/s Windlas Biotech Pvt. Ltd. / M/s Zydus Healthcare Limited	3.13
4(ix)	Paracetamol + Chlorpheniramine + Phenylephrine	Each uncoated tablet contains: Paracetamol IP 500mg, Chlorpheniramine Maleate IP	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Zydus Healthcare Limited	3.29

	Tablet	2mg, Phenylephrine Hydrochloride IP 10mg			
4(x)	Atorvastatin + Clopidogrel + Aspirin Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg, Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg, Aspirin IP 75mg (As enteric coated pellets)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	3.90
4(xi)	Atorvastatin + Clopidogrel + Aspirin Capsule	Each hard gelatine capsule contains:Atorvastatin Calcium IP eq. to Atorvastatin 20mg,Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg,Aspirin IP 75mg (As enteric coated pellets)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	5.27
4(xii)	Telmisartan + Cilnidipine + Metoprolol Tablet	Each film coated Bilayered Tablet contains: Telmisartan IP 40mg Cilnidipine IP 10mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (As Extended Release)	1 Tablet	M/s Micro Labs Limited	9.64
4(xiii)	Telmisartan + Cilnidipine + Metoprolol Tablet	Each film coated Bilayered Tablet contains: Telmisartan IP 40mg Cilnidipine IP 10mg, Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (As Extended Release)	1 Tablet	M/s Micro Labs Limited	11.96
4(xiv)	Tranexamic Tablet	Each Film-coated tablet contains: Tranexamic Acid IP 250mg	1 Tablet	M/s Pharma Synth Formulations Ltd/ M/s La Prisine Bioceuticals Pvt. Ltd	15.30
4(xv)	Esomeprazole + Domperidone Capsule	Each hard gelatin capsule contains: Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40mg (as enteric coated pellets) Domperidone IP 30mg (as sustained release pellets)	1 Capsule	M/s East African (India) Overseas / M/s Zydus Healthcare Limited	8.94
4(xvi)	Teneligliptin + Metformin Tablet	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin HCl 500mg (SR)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Apex Laboratories Private Limited	10.45
4(xvii)	Sucralfate + Oxetacaine Suspension	Each 5ml suspension contains: Sucralfate IP 1gm, Oxetacaine BP 10mg	Per ml	M/s Pure & Cure Healthcare Pvt. Ltd. / Dr. Reddy's Laboratories Ltd.	0.95
4(xviii)	Folic Acid + Methylcobalamin Tablet (FDSON-12	Each uncoated tablet contains: Folic Acid IP 5mg, Methylcobalamin IP 750mcg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	2.34

	SL)				
4(xix)	Calcium Carbonate + Cholecalciferol Tablet (Macalvit Forte)	Each film coated Tablet contains: Calcium Carbonate IP 1.250g, eq. to Elemental Calcium 500mg, Cholecalciferol (Stabilized) eq. to Cholecalciferol IP 500IU (Vitamin D3)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Novartis India Limited	10.00
4(xx)	Esomeprazole + Domperidone Capsule	Each hard gelatin capsule contains: Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40mg (as enteric coated pellets) Domperidone IP 30mg (as sustained release pellets)	1 Capsule	M/s Nest Healthcare Pvt. Ltd. / M/s Cadila Pharmaceuticals Limited	8.94
4(xxi)	Temisartan + Metoprolol Tablet	Each film coated bilayered Tablet contains: Temisartan IP 40mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate IP 25mg (As extended Release)	1 Tablet	M/s Sun Pharma Laboratories Limited	10.58
4(xxii)	Temisartan + Metoprolol Tablet	Each film coated bilayered Tablet contains: Temisartan IP 40mg, Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate IP 50mg (As extended Release)	1 Tablet	M/s Sun Pharma Laboratories Limited	12.69
4(xxiii)	Telmisartan + Chlorthalidone Tablet (Tamica-CT 40/6.25)	Each un-coated Bi-Layered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 6.25mg	1 Tablet	M/s Theon Pharmaceuticals Ltd. / M/s Alkem Laboratories Ltd.	7.82
4(xxiv)	Domperidone + Naproxen Sodium Tablet	Each film coated tablet contains: Domperidone Maleate IP eq. to Domperidone 10mg, Naproxen Sodium USP 275mg eq. to Naproxen 250mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Pvt. Ltd.	4.78
4(xxv)	Domperidone + Naproxen Sodium Tablet	Each film coated tablet contains: Domperidone Maleate IP eq. to Domperidone 10mg, Naproxen Sodium USP 550mg eq. to Naproxen 500mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Pvt. Ltd.	5.93
4(xxvi)	Gliclazide + Metformin Hydrochloride Tablet	Each uncoated tablet contains: Gliclazide IP 80mg , Metformin Hydrochloride IP 500mg	1 Tablet	M/s Innova Captab Limited / M/s Abbott Healthcare Pvt. Ltd.	6.86
4(xxvii)	Thiocolchicoside + Aceclofenac + Paracetamol Tablet (Zerodol TH 4 Max)	Each Film Coated Tablet contains: Thiocolchicoside IP 4mg, Aceclofenac IP 100mg, Paracetamol IP 325mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Ipca Laboratories Ltd.	14.04
4(xxvii i)	Thiocolchicoside + Aceclofenac + Paracetamol Tablet	Each Film Coated Tablet contains: Thiocolchicoside IP 8mg,	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Ipca Laboratories	21.40

	(Zerodol TH 8 Max)	Aceclofenac IP 100mg, Paracetamol IP 325mg		Ltd.	
4(xxix)	Linezolid + Dextrose Water for Injection (GAL-LINI I.V.)	Each 100ml contains: Linezolid IP 200mg Dextrose Anhydrous IP 5g Water for Injection	Per 300 ml pack	M/s Aishwarya Lifesciences / M/s Galpha Laboratories Limited	342.08

Note: DCGI clarified that formulations at agenda item nos. 4(v), 4(ix), 4(xviii), 4(xxvii) and 4(xxviii) have been approved by DCGI for continued manufacturing and marketing in India.

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

5.1 It was noted that there is no review case pending with NPPA.

6. Agenda item no. 6 - Revision of ceiling price of Paclitaxel Injection 100mg / 16.7 ml and 30mg / 5 ml.

6.1 The Authority deliberated upon the matter in detail and decided to approve the revised ceiling price of 'Paclitaxel Injection 100mg/16.7 ml injection' and 'Paclitaxel 30mg/5 ml injection' at Rs. 205.04 per ml excluding GST.

7. Agenda item no. 7 - Price Fixation of Human Normal Immunoglobulin 16.5% Solution for infusion.

7.1 The Authority deliberated upon the matter in detail and approved the ceiling price of Human Normal Immunoglobulin 16.5% solution for infusion at Rs. 379.83 per ml excluding GST.

8. Agenda item no. 8 - Revision of ceiling price of scheduled formulations based on Wholesale Price Index (WPI) as per para16 of DPCO 2013 to be effective from 01.04.2020.

8.1 The Authority deliberated on the issue and approved the WPI @ 1.88468% to be applicable on scheduled formulations w.e.f 01.04.2020. The Authority also approved the revised ceiling price of the scheduled formulations based on WPI @ 1.88468% to be effective from 01.04.2020.

9. Agenda item no. 9 - Price fixation as per Pharmaceuticals Purchase Policy (PPP) for products of Pharma Central Public Sector Enterprises (CPSEs) and their subsidiaries.

9.1 Record note of discussion.

10. Agenda item no. 10 - Intimation of Minutes of 17th meeting of Multidisciplinary Committee of Experts held on 19.03.2020.

10.1 The agenda item was deferred.

11. Agenda item no. 11 - Implications of Notification S.O 648(E) dated 11th February, 2020 of MoH&FW declaring all Medical Devices as 'Drugs' under the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945

11.1 The comments received from the Authority members relating to Agenda item no. 11 were examined and it was noted that as per para 2(2) of DPCO 2013 any item that is defined as Drugs under para 3(b)(iv) of Drugs and Cosmetics Act 1940 shall be covered under para 2(2) of DPCO 2013. It was noted that NPPA was monitoring only 24 out of 5000 categories of medical devices under Medical Rules 2017.

11.2 However, Ministry of Health and Family Welfare, Government of India vide SO. 648(E) dated 11.02.2020 notified that the medical devices as mentioned in the notification will be considered as drugs under Drugs and Cosmetics Act 1940 w.e.f 01.04.2020 bringing all medical devices under regulation from 1st April in a phased manner. Hence, it is incumbent that these additional medical devices, being defined as drugs from 01.04.2020, would also come under the ambit of DCPO 2013. These medical devices would be considered as non-scheduled formulations under DPCO 2013 and would be regulated and monitored as per the provisions applicable for non-scheduled formulations.

11.3 Further, it was also noted that after coming into the ambit of DPCO 2013, the manufacturer/ marketer of medical devices are required to submit information as per the provisions of DPCO 2013 and hence amendment to DPCO 2013 is required for inclusion of Form-V for medical Devices. Earlier too, NPPA had requested Department of Pharmaceuticals for amendment of DPCO 2013 to revise Form-V where upon Department of Pharmaceuticals directed to sent a comprehensive proposal for amendment of DPCO 2013 rather than piecemeal requests.

11.4. The Authority further noted that a comprehensive proposal for amendment of DPCO would require time and hence decided that the proposal for amendment of DPCO 2013 by inclusion of new Form-V relating to medical devices and related enabling provisions may

be sent to Department of Pharmaceuticals for consideration on a priority basis since the medical devices would come under the ambit of DPCO 2013 from 01.04.2020.

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

Sd/-
(Ritu Dhillon)
Member Secretary