मिसिल स.- 8(72)/2020/डी.पी/एनपीपीए-डीवी-II
F. No. 8(72)/2020/DP/NPPA-Div. II

कार्यवाहीस. : 204/72/2020/F
Proceeding No : 204/72/2020/F

Minutes of the 204th (overall) and 72nd meeting of the Authority under DPCO, 2013 held on 20.01.2020 at 11:00 AM

The 204th meeting of the Authority (overall), which is the 72nd meeting under the DPCO, 2013, was held on the 20th of January, 2020 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.
Dr. D. Usha Rao, Asstt Controller of Patent and Design, DPIIT attended the meeting as a special invitee for Agenda item no. 8 and 9.

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

(i) Shri Kalyan Nag, Advisor
(ii) Shri Amarpal 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 71st meeting held on 09.12.2019.

1.1 Noted.

2. Agenda item no. 2 – Action Taken Report on decisions taken by NPPA in its 71st meeting dated 09.12.2019

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(xxviii) (total 38 Form I applications) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 38 (thirty eight) cases under para 5 and 15 of the DPCO 2013, as detailed below:

A. Retail price fixed under para 5 of DPCO, 2013

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)	Glimepiride + Metformin Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 1mg Metformin Hydrochloride IP 500mg (as prolonged-release form)	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd. / M/s Apex Laboratories Pvt. Ltd.	4.95
4(ii)	Glimepiride + Metformin Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 2mg Metformin Hydrochloride IP 500mg (as prolonged-release form)	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd. / M/s Apex Laboratories Pvt. Ltd.	7.98
4(iii)	Telmisartan + Chlorthalidone Tablet	Each uncoated bilayered tablet contains: Telmisartan IP 80mg Chlorthalidone IP 12.5mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Mankind Pharma Limited	13.82
4(iv)	Escitalopram Tablet	Each film coated tablet contains: Escitalopram Oxalate eq. to Escitalopram 15mg	1 Tablet	M/s Sun Pharma Laboratories Limited	10.68
4(v)	Aceclofenac + Paracetamol Tablet (Mytigesic Plus)	Each uncoated tablet contains: Aceclofenac IP 100mg Paracetamol IP 325mg	1 Tablet	M/s Themis Pharmaceuticals	3.04
4(vi)	Diclofenac + Paracetamol Tablet (Inflamase Plus)	Each uncoated tablet contains: Diclofenac Sodium IP 50mg (Enteric coated Granules) Paracetamol IP 325mg	1 Tablet	M/s Themis Pharmaceuticals	2.782
4(vii)	Clopidogrel Tablet	Each Film coated tablet contains: Clopidogrel Bisulphate IP eq. to Clopidogrel 150mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Mankind Pharma Limited	6.25
4(viii)	Metoprolol Tablet	Each Film coated extended release tablet contains: Metoprolol Succinate IP 11.875mg eq. to Metoprolol Tartrate 12.5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Mankind Pharma Limited	3.03
4(ix)	Rosuvastatin + Clopidogrel Capsule	Each Hard Gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (as film coated Rosuvastatin tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as two film coated	1 Capsule	M/s Windlas Biotech Pvt. Ltd. / M/s Mankind Pharma Limited	12.95

		Clopidogrel tablet each containing clopidogrel 37.5mg)			
4(x)	Rosuvastatin + Clopidogrel Capsule	Each Hard Gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (as film coated Rosuvastatin tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as two film coated Clopidogrel tablet each containing clopidogrel 37.5mg)	1 Capsule	M/s Windlas Biotech Pvt. Ltd. / M/s Mankind Pharma Limited	16.06
4(xi)	Telmisartan + Cilnidipine Tablet	Each film coated tablet contains: Telmisartan IP 40mg, Cilnidipine IP 10mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Ltd.	8.19
4(xii)	Telmisartan + Cilnidipine Tablet	Each film coated tablet contains: Telmisartan IP 80mg, Cilnidipine IP 10mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Ltd.	13.48
4(xiii)	Paracetamol Tablet	Each uncoated bilayer tablet contains: Paracetamol IP 300mg (As immediate release) Paracetamol IP 700mg (As sustained release)	1 Tablet	M/s Surien Pharmaceuticals (P) Ltd. / M/s Geno Pharmaceuticals Pvt. Ltd.	3.38
4(xiv)	Amoxycillin + Potassium Clavulanate Dry Syrup (Genomox-CV Forte)	Each 5ml of reconstituted suspension contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 400mg, Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 57mg	1 ml	M/s Medicef Pharma / M/s Geno Pharmaceuticals Pvt. Ltd.	3.27
4(xv)	Dextromethorpran Hydrobromide + Chlorpheniramine Maleate Syrup	Each 5ml Syrup contains: Dextromethorpran Hydrobromide IP 10mg Chlorpheniramine Maleate IP 2mg	1 ml	M/s Zydus Healthcare Limited	0.57
4(xvi)	Dextromethorpran Hydrobromide + Chlorpheniramine Maleate Syrup	Each 5ml Syrup contains: Dextromethorpran Hydrobromide IP 10mg Chlorpheniramine Maleate IP 5mg	1 ml	M/s Zydus Healthcare Limited	0.74
4(xvii)	Paracetamol + Phenylephrine HCl + Diphenhydramine HCl + Caffeine Tablet	Each uncoated tablet contains: Paracetamol IP 500mg, Phenylephrine HCl IP 5mg Diphenhydramine HCl IP 25mg, Caffeine (anhydrous) IP 30mg	1 Tablet	M/s Shiv Industries / M/s Profic Organic Limited	3.36
4(xviii)	Paclitaxel + Human Albumin Injection (Paclitaxel Protien Bound Particles for Injectable suspension 100mg)	Paclitaxel Protien Bound Particles for Injectable suspension 100mg Each Lyophilized vial contains: Paclitaxel IP 100mg Human Albumin IP 900mg per 20ml	Each Pack	M/s SPAL Private Limited / M/s Intas Pharmaceuticals Pvt. Ltd.	4795.27
4(xix	Calcium +	Each film coated tablet contains:	1 Tablet	M/s Mascot Health	11.48

)	Vitamin D3 + Methylcobalamin + Pyridoxine + Folic Acid Tablet	Calcium Citrate USP 1000mg, Vitamin D3 200IU, Methylcobalamin IP 500mcg, Pyridoxine HCI IP 10mg, Folic Acid IP 5mg,		Series Pvt. Ltd. / M/s Zydus Healthcare Limited	
4(xx)	Vildagliptin + Metformin Tablet (INSUVIL-M)	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg,	1 Tablet	M/s Pure & Cure Healthcare (P) Ltd. / M/s Anthus Pharmaceuticals Pvt. Ltd.	6.14
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg,	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	6.14
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg,	1 Tablet	M/s Eris Lifesciences Limited / M/s Aprica Healthcare Pvt. Ltd.	6.14
	Vildagliptin + Metformin Tablet (VILDOV M 500)	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg,	1 Tablet	M/s Hetero Labs Limited / M/s Hetero Healthcare Limited	6.14
	Vildagliptin + Metformin Tablet (Valdepain M 500)	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg,	1 Tablet	M/s Innova Captab Ltd. / M/s Galpha Laboratories Limited	6.14
	Vildagliptin + Metformin Tablet (Vilason M 500)	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg,	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	6.07
4(xxi)	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 850mg,	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	6.24
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 850mg,	1 Tablet	M/s Eris Lifesciences Limited / M/s Aprica Healthcare Pvt. Ltd.	6.24
	Vildagliptin + Metformin Tablet (Valdepain M 850)	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 850mg,	1 Tablet	M/s Innova Captab Ltd. / M/s Galpha Laboratories Limited	6.24
4(xxii)	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 1000mg,	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	6.36
	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 1000mg,	1 Tablet	M/s Eris Lifesciences Limited / M/s Aprica Healthcare Pvt. Ltd.	6.36
	Vildagliptin + Metformin Tablet (VILDOV M 1000)	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 1000mg,	1 Tablet	M/s Hetero Labs Limited / M/s Hetero Healthcare Limited	6.36
	Vildagliptin + Metformin Tablet (Valdepain M 1000)	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 1000mg,	1 Tablet	M/s Innova Captab Ltd. / M/s Galpha Laboratories Limited	6.36

4(xxiii)	Amoxycillin + Potassium Clavulanate Tablet (Panlactic 1000)	Each film coated tablet contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 875mg, Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg,	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Mylan Pharmaceuticals Private Limited	28.00
4(xxi)	Amoxycillin + Potassium Clavulanate Tablet (Panlactic 375)	Each film coated tablet contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 250mg, Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg,	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Mylan Pharmaceuticals Private Limited	15.15

B. Retail price fixed under para 15 of DPCO, 2013

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xxv).	Rabies Human Monoclonal Antibody Injection (Rabishield – 50)	Each ml injectioncontains: Rabies Human Monoclonal Antibody (rDNA) 40IU (50IU/1.25ml)	Each pack of 1.25ml	M/s Serum Institute of India Pvt. Ltd.	856.65
4(xxvi).	Amoxicillin + Cloxacillin + Lactic Acid Bacillus Capsule	Each hard gelatine capsule contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 250mg, Cloxacillin Sodium IP eq. to Cloxacillin 250mg, Lactic Acid Bacillus 2 billion spore	1 Capsule	M/s Skymap Pharmaceuticals Pvt. Ltd.	3.54
4(xxvii).	Metformin Hydrochloride + Evogliptin Tablet (Valera M 1000 Tablet)	Each film coated bilayered Tablet contains: Metformin Hydrochloride IP 1000mg (Sustained Release), Evogliptin Tartrate 6.869mg eq. to Evogliptin 5mg Tablet	1 Tablet	M/s Alkem Healthscience / M/s Alkem Laboratories Ltd.	18.44
4(xxviii).	Paracetamol + Caffeine Tablet (SARBYNA STRONG)	Each uncoated tablets contains: Paracetamol IP 500mg Caffeine Anhydrous IP 50mg	1 Tablet	M/s Rivpra Formulation Pvt. Ltd. / M/s Dabur India Ltd	1.25

C. Agenda item no. 4(xviii) relating to retail price fixation of Paclitaxel Protein bound particles for injectable suspension in which each lyophilized vial contains Paclitaxel IP 100 mg and Human Albumin IP 900mg per 20 ml' for the company M/s Intas Pharmaceuticals Ltd(marketer) and M/s SPAL Pvt. Ltd (manufacturer/importer)

1. M/s Intas Pharmaceuticals Ltd (marketer) and M/s SPAL Pvt. Ltd (manufacturer/importer) submitted application for retail price fixation of 'Paclitaxel Protein bound particles for injectable suspension in which each lyophilized vial contains Paclitaxel IP 100 mg and Human Albumin IP 900mg per 20 ml.' As this is a product which is covered under Trade Margin Rationalization (TMR) of anti cancer drugs vide SO. No.

1041(E) of NPPA dated 27.02.2019, the Authority in 69th meeting dated 08.08.2019 decided as under "…to rework the retail price based on the price to retailer (PTR) and Moving Annual Turnover (MAT) of the period post implementation of the TMR Order. Further, the Authority also directed that a notice may be issued to the companies which have not applied for TMR for revision of MRP."

2. Accordingly, a proposal was prepared for the 72nd meeting dated 20.01.2020 by calculating the retail price, by taking the Price To Retailer (PTR) of the companies as per the Form-V submission made after implementation of SO. 1041(E) dated 27.02.2019 under three options.

3. Show cause notices(SCN) were issued to M/s Fresenius Kabi India Pvt Ltd and M/s Sun Pharmaceutical Industries Ltd for their products "Nanoxel 100 mg injection" and "Bevetex 100 mg injection" for non-compliance of notification no. SO. 1041(E) dated 27.02.2019 relating to Trade Margin Rationalisation (TMR).

4. Both the companies replied that their products are separate from subject formulation namely, 'Paclitaxel Protein bound particles for injectable suspension in which each lyophilized vial contains Paclitaxel IP 100 mg and Human Albumin IP 900mg per 20 ml.' for which clarification was sought from DCGI. DCGI vide its reply dated 15.01.2020 clarified that both these products are separate from 'Paclitaxel Protein bound particles for injectable suspension in which each lyophilized vial contains Paclitaxel IP 100 mg and Human Albumin IP 900mg per 20 ml.'

5. Accordingly, the Authority considered the matter and approved, the option in which the data of the products "Nanoxel 100 mg injection" and "Bevetex 100 mg injection" of M/s Fresenius Kabi India Pvt Ltd and M/s Sun Pharmaceutical Industries Ltd were not included for calculation of the retail price of 'Paclitaxel Protein bound particles for injectable suspension.' The data of Price To Retailer (PTR) of the companies as per the Form-V submission made after implementation of SO. 1041(E) dated 27.02.2019 was taken for calculating the retail price of lyophilized vial containing 'Paclitaxel IP 100 mg and Human Albumin IP 900mg per 20 ml' for the company M/s Intas Pharmaceuticals Ltd (marketer) and M/s SPAL Pvt. Ltd (manufacturer/importer).

6. The Authority also decided that, henceforth, any applications for retail price fixation of new drugs which are covered under Trade Margin Rationalization (TMR) of anti cancer drugs vide SO. No. 1041(E) of NPPA dated 27.02.2019 shall be fixed by taking the PTR of the companies post implementation of SO. 1041(E) dated 27.02.2019.

7. Further, based on the reply of DCGI, the Authority decided the matter regarding issue of SCNs to M/s Fresenius Kabi India Pvt Ltd and M/s Sun Pharmaceutical Industries Ltd for their products be closed.

D. Agenda item no: 4(xvi) & 4(xix) relating to retail price fixation of 'Dextromethorphan Hydrobromide and Chlorpheniramine Maleate Syrup for M/s Zydus Healthcare Ltd (marketer) and M/s Zydus Healthcare Ltd (manufacturer/ importer)' and 'Calcium citrate, Vitamin D3, Methylcobalamin, Pyridoxine and folic acid tablet for M/s Zydus Healthcare Ltd (marketer) and M/s Mascot Health Series Pvt. Ltd (manufacturer/ importer).

1. DCGI clarified that the formulations covered in its letter no. File No. 4-01/2013-DC (misc. 13-PSC)(Pt-II) dated 12.12.2018 are deemed to be approved by DCGI for continued manufacturing and marketing subject to the conditions mentioned in the letter.
2. Therefore, the formulation as per agenda no. 4(xvi) and 4(xix) are deemed to be approved by DCGI.
3. Henceforth, the Authority decided that the DCGI approval status with respect to the formulations covered in DCGI's letter no. File No. 4-01/2013-DC (misc. 13-PSC)(Pt-II) dated 12.12.2018 shall be seen as per the conditions mentioned in the said letter.

E. Agenda item no: 4(xx), 4(xxi) & 4(xxii) relating to retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildigliptin tablets for various companies

1. The retail price of the Fixed Dose Combinations (FDCs) of Metformin and Vildigliptin tablets were proposed to be calculated as per two options, as follows:
(i) Under para 5 of DPCO 2013 by taking the data of six month prior to the date of application
(ii) By adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for these subject FDCs.
2. The Authority observed that the subject formulations are off-patent items and any fixation of retail prices on the basis of para 5 of DPCO 2013 by taking six month prior data (when the patent was in force) would result in extending the price of patented products to off-patent products. Hence, the benefit of price reduction due to patent expiry would not be made available to the public.

3. The Authority also observed that in its earlier meetings on 30.10.2019 and 09.12.2019, it had approved the fixation of the retail prices of the subject FDCs for various companies under para 5 of DPCO 2013 by taking six month prior data. The companies have since submitted the launch prices. These prices are much lower prices than those approved by the Authority earlier.

4. The Authority deliberated upon the matter in detail and emphasised that benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price as per the Price To Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for these subject FDCs.

5. Accordingly, the Authority decided to fix the retail price of the subject FDCs for the companies as per option 1(ii) in public interest. This is as per the principle followed as per item no. C above relating to anti-cancer drugs.

F. Notification of retail prices after uploading draft working sheet and Minutes of the 15th meeting of Multidisciplinary Committee of Experts for 10 days

1. The retail prices are to be notified after 10 days of uploading the draft working sheet and the minutes of the 15th 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 the Multidisciplinary Committee of Experts in its 15th meeting dated 08.01.2020 could not give any recommendation on the five review orders relating to Ringer Lactate Injection. The Authority directed that the Multidisciplinary Committee of Experts be asked to expedite the same and that its recommendation be placed in the next Authority meeting for deliberation.

6. Agenda item no. 6 - Intimation of Minutes of 15th meeting of Multidisciplinary Committee of Experts held on 08.01.2020.

6.1 Noted.

7. Agenda item no. 7 - Fixation of Ceiling Price of Calcium Carbonate 500mg Tablets under para 19 of DPCO, 2013 based on Institutional Data received from Hospitals.

7.1 The Authority deliberated upon the matter in detail and decided that the working sheet for the proposed ceiling price of Calcium carbonate 500 mg tablet at Rs. 1.36 per

tablet excluding GST under para 19 of DPCO 2013 based on institutional data collected from various hospitals and central government agencies as per Department of Pharmaceuticals letter no. F. No. 31026/31/2016 dated 05.02.2019 is to be uploaded on NPPA's website for 10 days and be submitted to the Authority in its next meeting for decision.

8. Agenda item no. 8 – 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)

8.1 The Authority noted that in its 71st meeting dated 09.12.2019 it deliberated as under "…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 Scafford 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).'

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."

8.2 The reply was received from M/s Meril Life Sciences Pvt. Ltd which was forwarded to Office of the Controller General of Patents, Designs & Trademarks for its clarification.

8.3 Office of the Controller General of Patents, Designs & Trademarks, Deptt for Promotion Industry and Internal Trade, Ministry of Commerce and Industry, Government of India, vide letter dated 15.01.2020, inter-alia, stated that "…..DCGI license is for Eluting bioresorbable Vascular Scaffold system (cardiac stent). Thus, whether the above disclosure in Patent specification and granted claims of Patent No. 296768 are covered in the DCGI's license product or not can be examined and clarified by an expert or a group of experts in the field of the said technology."

8.4 The Authority noted that the reply received from Office of the Controller General of Patents, Designs & Trademarks (CGP), Deptt for Promotion Industry and Internal Trade, Ministry of Commerce and Industry, Government of India, is unclear. Therefore, the

Authority directed the representative of Office of the CGP present in the meeting to ensure that a clear reply is given to the Authority on the said issue being the subject expert in the matter having issued the Patent under discussion.

9. Agenda item no. 9 – Application of M/s s Gilead Sciences India Pvt Ltd for exemption from fixation ceiling price in respect of Tenofovir Alafenamide tablets for the treatment of chronic Hepatitis B (registered Trade/ Brand name Vemlidy) under paragraph 32 of Drug (Prices Control) Order, 2013 read with Drugs (Prices Control) Amendment Order, 2019.

9.1 The Authority deliberated upon the matter in detail and noted that the issue for exemption under para 32(i) of DPCO, 2013 is multilayered as enumerated below:

9.1.1 (i) The application for exemption has been filed by M/s Gilead Sciences Inc, which is a US based company.

(ii) Office of the Controller General of Patents, Designs & Trademarks, Deptt of Industrial Policy and Promotion, Ministry of Commerce and Industry, Government of India has granted a patent to M/s Gilead Sciences Inc, a US company for "Methoxy Phosphonate Nucleotide Prodrug" vide patent number 241597 dated 14.07.2010.

(iii) Central Drugs Standard Control Organisation (CDSCO) has granted a permission to import finished formulation of a new drug "Tenofovir Alafenamide 25 mg tablet" to M/s Gilead Sciences India Pvt. Ltd, an Indian Company.

(iv) The new drug "Tenofovir Alafenamide 25 mg tablet" is to be manufactured by M/s Gilead Sciences Ltd, Ireland.

9.1.1.1 Accordingly, the Authority directed as follows:

(i) To obtain information from the company about the relationship among the three entities namely, Gilead Sciences, Inc (the Patent holder), M/s Gilead Sciences India Pvt. Ltd (to whom the import licence for new drug has been granted) and M/s Gilead Sciences Ltd, Ireland (manufacturer).

(ii) After receipt of details of relationship status from the company, further necessary examination would be undertaken regarding eligibility for exemption under para 32(i) of DPCO 2013.

9.1.2 The Authority further directed to seek clarification from Department of Pharmaceuticals as to whether the foreign company, the applicant, the Patent holder and

the manufacturer can be treated as the same entity for the purpose of granting exemption under para 32(i) of DPCO 2013.

9.1.3 The Authority observed that the Patent No. 241597 dated 14.07.2010 has been granted for a term of 20 years from 20th July 2001. However, the company is seeking exemption from price control under DPCO 2013 for 5 years from the date of commencement of its commercial marketing by the company which would be a case of evergreening of Patent. The clarification sought from Department of Pharmaceuticals in the matter is awaited.

9.1.4 The Authority further observed that the application is for exemption from price fixation of Tenofovir Alafenamide tablet under para 32(i) of DPCO, 2013 whereas the patent has been granted for "Methoxy Phosphonate Nucleotide Prodrug". The Authority noted that a clarification sought from the Office of the Controller General of Patents, Designs & Trademarks (CGP), Deptt of Industrial Policy and Promotion, Ministry of Commerce and Industry, Government of India is still awaited. Accordingly, the Authority directed the representative from the Office of the CGP to expedite the same.

9.2 The Authority also observed that the company has given voluntary license to many companies for manufacturing/ marketing the products "Tenofovir Alafenamide 25 mg tablet" in India. Accordingly, the Authority directed obtain the details of the companies and the terms and conditions at which the voluntary licenses were given by M/s Gilead Sciences Inc for manufacturing/ marketing the products "Tenofovir Alafenamide 25 mg tablet" in India. The Authority further directed to confirm that the exemption, if granted, would not be applicable to the manufacturing/ marketing companies to whom voluntary licenses has been given by M/s Gilead Sciences Inc for manufacturing/ marketing the products "Tenofovir Alafenamide 25 mg tablet" in India.

10. Agenda item no. 10 – Price fixation as per Pharmaceuticals Purchase Policy (PPP) for products of Pharma Central Public Sector Enterprises (CPSEs) and their subsidiaries.

10.1 The Authority deliberated upon the matter in detail and noted that based on Department of Pharmaceuticals'(DoP) OM dated 10.12.2013 regarding Pharmaceutical Pricing Policy(PPP) , NPPA worked out the price of 154 formulations pack (of 103 medicines) for consideration of DoP. Further, NPPA vide its letter dated 24.07.2017 communicated the revised price of these 154 formulations by giving WPI impact and GST implementation which were authenticated by DoP vide letter dated 08.08.2017.

10.2 PPP was in vogue till December 2018 and was extended on the same terms and conditions with the inclusion of one additional product namely, Alcoholic Hand Disinfectant (AHD) till the final closure/ strategic disinvestment of Pharma CPSUs, as communicated vide DoP's letter dated 04.12.2019.

10.3 Therefore, a meeting with the five central Pharma CPSUs was held on 12.12.2019 regarding price fixation of these formulations. The Pharma CPSUs submitted that of the 154 formulations (pack of 103 medicines) for which the price had been fixed earlier under the PPP, the price of 94 formulations could be considered to be revised as per the Annual Wholesale Price Index (WPI) and that in respect of the remaining 61 formulations (including AHD), the price could be considered to be re-fixed based on the data submitted by the CPSUs.

10.4 The Authority deliberated upon the matter in detail and decided that out of 94 formulations, the price of 92 formulations [except Gentamycin IP 2 ml (eq to 40 mg) and Ranitidine IP 25mg/ml (2ml ampoule)] may be revised by giving WPI increase for the year 2018 and 2019 on the price prevailing as on 01.07.2017, as per Pharmaceutical Purchase Policy (PPP) and the same be recommended to the Department of Pharmaceuticals for consideration.

11. Agenda item No. 11 - Issues relating to Overcharging cases under DPCO, 2013

11.1 The Authority was appraised of the issues emerging from examination of some cases out of the 228 cases of DPCO 2013, carried out so far. It was recommended that in cases where companies had not submitted data even after issuance of Show Cause Notices (SCN) as were required by guidelines, the SCN may be converted into a demand notice and the company given a final opportunity to submit data failing which the case be referred to the collector.

11.2 Shri B. Bandyopadhyay, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure discussed the case examined as test case and the Authority decided to accept the observations/ recommendations made by the member. Further, it was decided to examine these observations/ recommendations and undertake necessary changes in the existing guidelines. It was also decided that CA audited data may be certified by the Statutory Auditor of the Company and countersigned by the Company Secretary. Further,

where possible, data submitted by the company may be validated with reference to Excise/GST records and returns (ER-1/GST-R-1) filed by the Company under the statutes.

12. Agenda item No. 12 – Representations of M/s Emcure Pharmaceuticals Ltd regarding retail price fixation of Darunavir 800 mg + Ritonavir 100 mg tablet

12.1 The Authority deliberated upon the matter in detail and noted that the retail price of Darunavir 800 mg + Ritonavir 100 mg tablet for M/s Emcure Pharmaceuticals Ltd at Rs. 197.55 per tablet excluding GST was approved by the Authority in its 70th meeting dated 30.10.2019 and notified vide SO. 4062(E) dated 08.11.2019 based on the recommendations of the Multidisciplinary Committee of Experts in its 13th meeting dated 24.09.2019.

12.2 The Authority further observed that the Committee recommended the retail price of Rs. 197.55 per tablet excluding GST based on the data as per Form-V submitted by M/s Hetero Healthcare Ltd, for whom the retail price for the same formulation was approved by the Authority in its 60th meeting dated 29.10.2018 and notified vide SO. 5638(E) dated 02.11.2018 at Rs. 212.91 per tablet.

12.3 Since M/s Hetero Healthcare Ltd had launched the formulation at a price lower than the retail price approved, as per the Form-V submitted, the Authority reiterated that the benefit of lower price is to be extended to the public and decided to reject the representation of M/s Emcure Pharmaceuticals Ltd in public interest.

13. Agenda item No. 13 - Representation of M/s Biological E. Ltd. for separate pricing of vaccines having new drug delivery system- Pre filled Syringe (PFS) packs

13.1 The Authority deliberated the upon matter in detail and noted that based on the application of M/s Biological E. Ltd for separate price of Pre-filled syringe (PFS) for its products (i) Liquid Pentavalent vaccine and (ii) Inactivated Japanese Encephalitis vaccine, the matter was referred to the 10th meeting of the Multidisciplinary Committee of Experts held on 21.05.2019 in which it recommended that no separate price may be given for PFS since PFS is a minor modification which will ease the drugs administration but has no significant clinical advantage.

13.2 The recommendations of the Multidisciplinary Committee of Experts in its 10th meeting was discussed in the 67th Authority meeting held on 29.05.2019 in which it was

decided that the matter may be examined to see whether PFS qualifies as a fit case for an incremental innovation and hence separate price.

13.3 Accordingly, the matter was again referred to the Multidisciplinary Committee of Experts in its 15th meeting dated 08.01.2020 in which it again reiterated in its previous stand and recommended that no separate price may be given for PFS.

13.4 The Authority deliberated upon the matter in detail and decided not to give separate price for Pre-filled syringe (PFS) based on the recommendation of the Multidisciplinary Committee of Experts in its 15th meeting 08.01.2020.

14. Agenda item No. 14 – Price fixation of Human Immunoglobin 10% solution

14.1 The Authority deliberated upon the matter in detail and noted that the Authority in its 71st meeting dated 09.12.2019 approved the ceiling price of Human Normal Immunoglobin (10% solution for infusion) 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. Based on the draft upload, M/s Paviour Pharmaceuticals Pvt. Ltd made a representation. The representation of M/s Paviour Pharmaceuticals Pvt. Ltd was placed before the Multidisciplinary Committee of Experts in its 15th meeting dated 08.01.2020 in which the Committee recommended to reject the representation of M/s Paviour Pharmaceuticals Pvt. Ltd being devoid of merit.

14.2 The Authority deliberated upon the matter in detail and decided to reject the representation of M/s Paviour Pharmaceuticals Pvt. Ltd based on the recommendation of the Multidisciplinary Committee of Experts in its 15th meeting 08.01.2020. Accordingly, the Authority approved the ceiling price of Human Normal Immunoglobin (10% solution for infusion) at Rs. 204.41 per ml, excluding GST.

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

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

Sd/-
(Ritu Dhillon)
Member Secretary