CONFEDERATION OF INDIAN PHARMACEUTICAL INDUSTRY (SSI) (Regd.)

(Registered Office : A-3/314, First Floor, Paschim Vihar, New Delhi-110063)

Chairman Office : **BELCO PHARMA** 515, MIE, Bahadurgarh-124507, Haryana E-mail : pkgupta_cipi@yahoo.in Website:www.cipi.in

Chairman :
P. K. Gupta
Cell : 09811106606

Secretary General :
R.K. Jain
Cell : 09927900920

Constituent Members

All India Small Scale Pharmaceutical Mfrs. Association, New Delhi-110054

All India Small Drug Mfrs. Association, Mumbai-400014

Gujarat Pharma Small Scale Industries Association, Vadodara - 390002

Haryana Pharmaceutical Mfrs. Association, Ambala City - 134003

Himachal Drug Mfrs. Association, Baddi -173205

J&K Small Scale Drug Mfrs. Association, Jammu - 180010

Kerala Pharmaceuticals Mfrs. Association, Kerala - 679322

Organisation of Pharmaceutical Mfrs., Hyderabad - 500038 (A.P.)

Ludhiana Drug Mfrs. Association, Ludhiana - 141001

Rajasthan Pharmaceutical Mfrs. Association, Jaipur - 302006

The Pharmaceutical Mfrs. Association of Tamilnadu, Chennai - 600015

Pharmaceutical Mfrs. Association (Kanpur), Kanpur, U.P.

West Bengal Small Scale Pharmaceutical Mfrs. Association, Kolkata - 700033

Baghat Pharmaceutical Mfrs. Association, Solan - 173212

BBN Industries Association, Baddi - 173205

Federation of Pharma Entrepreneurs, Gurgaon - 122015

Association of Pharmaceutical Mfrs., Haridwar - 249403

Devbhoomi Association of Pharmaceutical Mfrs., Dehradun - 248002

Karnataka Drugs & Pharmaceutical Mfrs. Association, Bangalore - 560001

Sirmour Pharma Mfrs. Association, Paonta Sahib - 173025

Ambala Pharmaceutical Mfrs. Association, Ambala City - 134003

Gurgaon Pharmaceuticals Mfrs. Association, Gurgaon - 122001

Bahadurgarh Pharmaceuticals Mfrs. Association, Bahadurgarh-124507

Goa Pharmaceutical Mfrs. Association, Mapusa - 403526

Ref. No.: CIPI/2017/317
27-12-2017

To,

All CIPI Office Bearers, CIPI Members & Pharmaceutical Manufacturers

Dear Members,

Greetings of the Day,

We are please to mention below the latest developments and amendments in the Pharmaceutical Industry done by the Ministry of Health, NPPA and other government agencies.

1. Based on the recent media report Ministry of Health and NPPA has noticed that the doctors and hospitals are charging exorbitant amount for a simple disease like Dengue and even then the patient died. NPPA has issued an office memorandum regarding this which is attached as **Annexure 1.**

2. Government has decided to upgrade and synchronize Schedule M specifications with WHO – GMP compliance standards. The following guidelines have been proposed by DCGI office:-
   - Good manufacturing Practices for Pharmaceutical products
   - Specific requirements for manufacture of sterile products, parenteral preparations(Small Volume Injectables and large volume parenterals) and Sterile Opthalmic preparations
   - Specific requirements for manufacturing of Pharmaceutical Products containing hazardous substances such as sex hormones, steroids (anabolic, androgenic) or cytotoxic substances.
   - Specific requirements for manufacture of Biological products.

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- Specific requirements for radiopharmaceutical products.
- Specific requirements for phytopharmaceuticals.
- Specific requirements for manufacture of Investigational Pharmaceutical products for clinical trials in humans.
- Specific requirements for manufacture of oral solid dosage forms (Tablets and capsules).
- Specific requirements for manufacture of oral liquids (syrups, Elixirs, Emulsions and suspensions)
- Specific requirements for manufacture of topical products i.e. external preparations (Creams, Ointments, Pastes, Emulsions, Lotions, Solutions, Dusting Powders and identical Products)
- Specified requirements for manufacture of Metered – Dose Inhalers (MDI)
- Specific requirements for manufacture of Active Pharmaceutical Ingredients
- Requirements of Plant and Equipment

3. Minutes of the 183rd and 51st meeting of Authority under DPCO, 2013 held on 15.12.2017 at 11.00 am is attached as **Annexure 2**.

4. Minutes of the 183rd and 51st meeting of Authority under DPCO, 2013 held on 20.12.2017 at 11.00 am is attached as **Annexure 3**.

5. NPPA order dated 18th December, 2017 as **Annexure 4.**

6. NPPA order dated 20th December,2017 as **Annexure 5**

7. Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, NPPA has issued office memorandum dated 07/12/2017 attached as **Annexure 6.**

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8. Update on Foreign Trade policy (FTP) 2015-20- For assistance of our member-Exporters attached as **Annexure 7.**

9. List of drugs, medical devices and cosmetics declared as Not of Standard Quality/Spurious/Adulterated/Misbranded for the month of November, 2017 is enclosed as **Annexure 8.**

10. List of new drugs Approved by CDSCO from 01/01/2017 to till date is enclosed as **Annexure 9.**

11. The Indian Pharmacopoeia Commission has extended the date of implementation of Indian Pharmacopoeia 2018 by 3 months i.e. upto 31st March 2018. Now the Indian Pharmacopoeia will be effective from 1st April 2018.

With regards

For Confederation of Indian Pharmaceutical Industry

P.K. Gupta
Chairman

ANNEXURE 1

File No. 27(2)/ 2017-Div-III/NPPA
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

5th/3rd Floor,
YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi-110001
Date: 15 .12.2017

Office Memorandum

Based on a recent media reports on the treatment cost of a deceased patient diagnosed for dengue at Fortis Memorial Research Institute, Gurgaon, NPPA had directed the concerned hospital to submit the requisite information for investigating the overcharging complaint. The information was submitted by the hospital within the prescribed time limit. NPPA has meanwhile received an application under Right to Information Act for providing details of the information provided by the concerned hospital.

2. In conformity with this Government's commitment to absolute transparency and accountability in governance and honouring the people's right to information, all the details are being placed in public domain through the NPPA's website.

3. Information received from the hospital has been analysed and classified into following categories:

A. Scheduled Formulations, based on National List of Essential Medicines, 2015 (Schedule I of DPCO, 2013) and under price control.

B. Non Scheduled Formulations, (Not under price control and out of Schedule 1 of DPCO, 2013)

C. Consumables, neither under price control and nor under Schedule 1 of DPCO, 2013)

4. NPPA shall be taking necessary follow up action as per existing law and within its jurisdiction.

Anand

(Anand Prakash)
Deputy Director

ANNEXURE-2

गोपनीय: Confidential

मिसिलस.- 8(51)/2017/डी.पी/एनपीपीए-डीवी-II

F. No. 8(51)/2017/DP/NPPA-Div. II

कार्यवाहीस. : 183/51/2017/F
Proceeding No : 183/51/2017/F

Minutes of the 183rd and 51st meeting of Authority under DPCO, 2013 held on 15.12.2017 at 11.00 A.M.

I. The 183rd overall meeting of the Authority, which is the 51st under the DPCO, 2013 was held on 15th December, 2017 at 11.00 AM under the Chairmanship of Shri Bhupendra Singh, Chairman, NPPA. The following members of the NPPA were present:-

(i) Shri Rakesh Ranjan, Member Secretary
(ii) Shri Umesh Dongre, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
(iii) Shri Arun Kumar, Adviser, Deptt. of Economic Affairs, Ministry of Finance.
(iv) Shri A. K. Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCG(I)).

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

(i) Shri Kalyan Nag, Adviser (Cost)
(ii) Shri A.P.S. Sawhney, Director (Pricing)
(iii) Shri Arun Diwan, Dy. Director (O/C)
(iv) Shri Baljit Singh, Asstt. Director (Pricing)
(v) Shri Prasenjit Das, Asstt. Director (Pricing)

1.2 Chairman, NPPA welcomed all the members present in the meeting.

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 50th Meeting held on 22.11.2017.

1.1 The Authority confirmed the minutes of the overall 182nd and the 50th Meeting held on 22.11.2017 under DPCO, 2013.

2. Agenda item no. 2 - Action Taken Report

2.1 Noted.

2.2 The Authority discussed the matter in details and approved to issue a fresh notification to partially modify the SO. 3727(E) dated 23.11.2017 to give pre-GST retail price and post GST retail price.

3.1 Agenda item no. 3(i) - Fixation of Ceiling Prices under NLEM 2015.

3.1.1 The Authority discussed and approved the ceiling prices of Phenylephrine 5% drops based on institutional data under para 19 of DPCO, 2013 and Anti-D immunoglobin 150 mcg vial based on para 6 of DPCO, 2013 under monopolistic condition as detailed below:

S. NO.	UNIQUE NO. AS PER NLEM	NAME OF THE FORMULATION/ COMPOSITIONS	STRENGTH & Dosage Form	Unit for ceiling price	Approved ceiling price under NLEM, 2015 (Rs.)
A. Common Formulations					
1	25.5.3	Phenylephrine	Drops 5%	1 ml	3.38
B. New Formulation					
2	22.2.3	Anti-D immunoglobulin	150 mcg	Each vial	1509.69

4.1 Agenda item no. 4(i) - Price fixation of new drug under Para 5 of DPCO 2013

4.1.1 The Authority examined the retail price fixation of the companies in details. With a view to rationalize the prices of new drug, the Authority decided that wherever, the application has been received by NPPA for any new drug for which NPPA has already notified the price, the same price would be extended to subsequent applicants also. Accordingly, the Authority approved the retail price of 59 new drugs on the basis of retail price already notified after giving excise duty effect for post GST rates as detailed below:

Sl. No.	Name of the Scheduled Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
1.	Ferrous Ascorbate + Folic Acid + Cyanocobalamin + Zinc Sulphate Monohydrate tablet (Autrin - XT)	Each film coated tablet contains: Ferrous Ascorbate eq. to Elemental Iron 100mg, Folic Acid IP 1.5mg, Cyanocobalamin IP 15 mcg, Zinc Sulphate Monohydrate IP eq. to Elemental Zinc 22.5mg	1 Tablet	M/s Tirupati Medicare Limited / M/s Pfizer Limited	3.63
2.	Rosuvastatin + Clopidogrel Capsule (Roseday CV 10)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin (As granules) 10mg, Clopidogrel Bisulphate IP eq. to Clopidogrel (As a film coated tablet) 75mg	1 Capsule	M/s Aeon Formulation Pvt. Ltd. / M/s USV Private Limited	13.37
3.	Teneligliptin + Metformin tablet (Ten20 M 1000)	Each uncoated bilayered tablets contains: Teneligliptin Hydrobromide hydrate eq. to Teneligliptin 20mg, Metformin HCL 1000mg (as extended release)	1 Tablet	M/s Glenamark Pharmaceuticals Ltd. / M/s Centaur Pharmaceuticals Pvt. Ltd.	10.87
4.	Clobetasol + Clotrimazole + Neomycin Sulphate Cream	Each gm contains: Clobetasol Propionate IP 0.05%w/w, Clotrimazole IP 1.00% w/w, Neomycin Sulphate IP 0.50%w/w	1 GM	M/s Mankind Pharma Ltd./ M/s Pharma Force Lab.	2.92
5.	Moxifloxacin + Cefixime Tablets (Moximac Plus)	Each Coated Sustained Release tablet contains: Moxifloxacin Hydrochloride BP eq. to Moxifloxacin 400mg, Cefixime IP (as trihydrate) eq. to Ahydrous Cefixime 400mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Macleods Pharmaceuticals Ltd.	33.05
6.	Moxifloxacin + Cefixime Tablets	Each Coated Sustained Release tablet contains: Moxifloxacin	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd.	33.05

	(Macflox Plus)	Hydrochloride BP eq. to Moxifloxacin 400mg, Cefixime IP (as trihydrate) eq. to Ahydrous Cefixime 400mg		/ M/s Macleods Pharmaceuticals Ltd.	
7.	Tramadol + Paracetamol Tablet	Each Film Coated tablet contains: Tramadol Hydrochloride IP 37.5mg, Paracetamol IP 325mg	1 Tablet	M/s Anglo French Drugs & Industries Ltd.	5.57
8.	Rosuvastatin + Aspirin + Clopidogrel Tablet	Each film coated bilayered tablet contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg, Aspirin IP 75mg, Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg	1 Tablet	M/s Safetab Life Science / M/s Intas Pharmaceuticals Limited	9.97
9.	Teneligliptin + Metformin Tablet	Each uncoated bilayered tablets contains: Teneligliptin Hydrobromide hydrate eq. to Teneligliptin 20mg, Metformin HCL 500mg (as extended release)	1 Tablet	M/s Synokam Pharma limited/ M/s Cadila Pharmceuticals Ltd.	9.62
10.	Teneligliptin + Metformin Tablet	Each uncoated bilayered tablets contains: Teneligliptin Hydrobromide hydrate eq. to Teneligliptin 20mg, Metformin HCL 1000mg (as extended release)	1 Tablet	M/s Synokam Pharma limited/ M/s Cadila Pharmceuticals Ltd.	10.87
11.	Paracetamol + Caffeine + Phenylephrine + Diphenhydramine Tablet	Each uncoated tablet contains: Paracetamol IP 500mg, Caffeine (Anhydrous) IP 30mg, Phenylephrine Hydrochloride IP 5mg, Diphenhydramine Hydrochloride IP 25mg	1 Tablet	M/s Biochem Pharmaceutical Industries Ltd.	2.57
12.	Ramipril + Amlodipine Tablet	Each uncoated tablet contains: Ramipril IP 5mg, Amlodipine Besilate IP eq. to Amlodipine 5mg	1 Tablet	M/s Lupin Limited	4.11
13.	Teneliglitptin + Metformin Tablet	Each Film uncoated bilayer tablet contains: Teneliglitptin Hydrobromide Hydrate 20mg eq. to Tenegliptin 20mg, Metformin Hydrochloride IP 1000mg (In Sustained Release form)	1 tablet	M/s Lupin Limited / M/s Unichem Laboratories Ltd.	10.87
14.	Teneliglitptin + Metformin Tablet	Each uncoated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride IP 500mg	1 Tablet	M/s Lupin Limited / M/s Unichem Laboratories Ltd	9.62
15.	Rosuvastatin + Clopidogrel Capsule (Roistar CV 10/75)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Unichem Laboratories Ltd.	13.37
16.	Rosuvastatin + Clopidogrel Capsule (Roistar CV 20/75)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As Pellets), Clopidogrel Bisulphate IP eq. to	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Unichem Laboratories Ltd.	7.80

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		Clopidogrel 75mg (as Pellets)			
17.	Diclofenac Injection	Each ml contains: Diclofenac Sodium IP 75mg Injection	1 ML	M/s Cadila Healthcare Ltd.	13.71
18.	Teneligliptin + Metformin Tablet (EFIGLIN M)	Each uncoated Bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin HCl 500mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s MedoPharm,	9.62
19.	Rosuvastatin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As granules), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as to film coated tablets)	1 Capsule	M/s GKM New Pharma / M/s Cadila Healthcare Ltd.	7.80
20.	Rosuvastatin + Clopidogrel Capsule (Roseday CV 20)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin (As Pellets) 20mg, Clopidogrel Bisulphate IP eq. to Clopidogrel (As Pellets) 75mg	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s USV Pvt. Ltd,	7.80
21.	Teneligliptin + Metformin Tablet	Each uncoated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin HCL 500mg (as sustained release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	9.62
22.	Teneligliptin + Metformin Tablet	Each uncoated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin HCL 1000mg (as sustained release)	1 Tablet	/s Synokem Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	10.87
23.	Metformin + Glimepiride + Voglibose Tablet	Each tablet contains: Metformin HCL 500mg (as sustained release form), Glimepiride 2mg, Voglibose 0.3mg	1 Tablet	M/s Sunglow Pharmaceuticals Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	9.39
24.	Paracetamol Tablet	Each tablet contains: Paracetamol IP (as Immediate Release) 300mg, Paracetamol IP (as Sustained Release) 700mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Strassenburg Pharmaceuticals Ltd.	3.15
25.	Aceclofenac + Paracetamol Tablet	Each Tablet contains: Aceclofenac IP 100mg, Paracetamol IP 325mg	1 Tablet	M/s Rivpra Formulation Pvt. Ltd. / M/s Cadila Pharmaceuticals Ltd.	2.78
26.	Rosuvastatin + Clopidogrel Capsule	Each Hard gelatin capsule contains: Rosuvastatin 10mg, Clopidogrel 75mg	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Ltd.	13.37
27.	Teneligliptin + Metformin Tablet (EFIGLIN M 1000)	Each uncoated Bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride IP 1000mg (as Sustained Release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s MedoPharm	10.87
28.	Olmesartan + Amlodipine Tablet	Each film coated tablet contains: Olmesartan Medoxomil IP 20mg,	1 Tablet	M/s Synokem Pharmaceuticals Ltd.	7.24

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		Amlodipine Besylate IP eq. to Amlodipine 5mg,		/ M/s Zuventus Healthcare Limited	
29.	Telmisartan + Metoprolol Tablet (Xstan-Beta 25mg)	Each film coated tablet contains: Telmisartan IP 40mg, Metoprolol Tartrate IP 25mg (ER)	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	7.62
30.	Telmisartan + Metoprolol Tablet (Xstan-Beta 50mg)	Each film coated tablet contains: Telmisartan IP 40mg, Metoprolol Tartrate IP 50mg (ER)	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	9.16
31.	Voglibose + Glimepride + Metformin Tablet	Each uncoated bilayered tablet contains: Voglibose IP 0.2mg, Glimepride IP 1mg, Metformin HCL IP 500mg (SR)	10 Tablets	M/s Windlas Biotech Pvt. Ltd. / M/s Zuventus Healthcare Limited	68.50
32.	Atorvastatin + Clopidogrel Capsules (Atchol CV 10mg)	Each hard gelatin capsule contains: Atorvastatin Calcium eq. to Atorvastatin (as pellets) 10mg, Clopidogrel (as pellets) 75mg.	10 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	83.94
33.	Voglibose + Glimepride + Metformin Tablet	Each uncoated bilayered tablet contains: Voglibose IP 0.2mg, Glimepride IP 2mg, Metformin Hydrochloride IP 500mg (SR)	1 Tablet	M/s Windlas Biotech Pvt. Ltd. /M/s Zuventus Healthcare Limited	8.68
34.	Teneligliptin + Metformin Tablet (Tenephron M)	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride 500mg (SR)	1 Tablet	M/s Windlas Biotech Limited / M/s Abbott India Limited	9.62
35.	Teneligliptin + Metformin Tablet (Tenephron M Forte)	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin HCl 1000mg (SR)	1 Tablet	M/s Windlas Biotech Limited / M/s Abbott India Limited	10.87
36.	Teneligliptin + Metformin Tablet (TYTIN M)	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride 500mg (as extended release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Wockhardt Ltd.	9.62
37.	Tacrolimus Capsule	Each Hard gelatin capsule contains: Tacrolimus IP 0.25mg	1 Capsule	M/s Emcure Pharmaceuticals Ltd,	10.82
38.	Telmisartan + Amlodipine Tablet	Each uncoated bilayer tablet Contains: Telmisartan IP 80mg, Amlodipine Besilate IP 5mg	10 Tablet	M/s J. K. Print Packs / M/s Mankind Pharma Ltd.	106.05
39.	Telmisartan + Amlodipine Tablet (Tigatel AM 40)	Each film coated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Sun Pharma Laboratories Limited	6.90
40.	Cefixime + Ofloxacin Tablet (Ranixime Plus)	Each film coated tablet contains: Cefixime Trihydrate eq. to Cefixime Anhydrous IP 200mg, Ofloxacin IP 200mg	1 Tablet	M/s Theon Pharmaceuticals Limited / M/s Sun Pharmaceutical Industrial Limited	9.46
41.	Teneligliptin +	Each film coated tablet contains:	1 Tablet	M/s Precise	9.62

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	Metformin Tablet (Glypte M)	Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride 500mg		Chemipharma Pvt. Ltd. / M/s Franco India Pharmaceuticals Private Limited	
42.	Teneligliptin + Metformin Tablet (Glypte M Forte)	Each film coated tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride 1000mg	1 Tablet	M/s Precise Chemipharma Pvt. Ltd. / M/s Franco India Pharmaceuticals Private Limited	10.87
43.	Glemipiride + Metformin Tablet (Ziglim – M1 Forte)	Each uncoated bilayered tablet contains: Glemipiride IP 1mg, Metformin Hydrochlorde IP 1000mg (as SR form)	1 Tablet	M/s Inventia Healthcare Pvt. Ltd. / M/s FDC Limited	5.69
44.	Glemipiride + Metformin Tablet (Ziglim – M2 Forte)	Each uncoated bilayered tablet contains: Glimepiride IP 2mg, Metformin Hydrochlorde IP 1000mg (as SR form)	1 tablet	M/s Inventia Healthcare Pvt. Ltd. / M/s FDC Limited	7.19
45.	Diclofenac Injection	Each ml contains: Diclofenac Sodium IP 75mg/ml	1 ml	M/s Zydus Healthcare Ltd.	13.71
46.	Doxorubicin (Pegylated Liposomal) Injection	Each ml contains: Doxorubicin HCL 2mg (Pegylated Liposomal) water for Injection	1 ml	M/s Natco Pharma Ltd.	694.29
47.	Telmisartan + Indapamide Tablet	Each uncoated bilayered tablet contains: Telmisartan IP 40mg Indapamide IP 1.5mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Mankind Pharma Ltd.	8.48
48.	Paracetamol + Mefenamic Acid Injection (Zydol-P DS)	Each 5ml contains: Paracetamol 250mg Mefenamic Acid 100mg	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Jenburkt Pharmaceuticals Ltd.	0.57
49.	Paracetamol + Phenylephrine + Chlorpheniramine + Sodium Citrate + Menthol Injection	Each 5ml contains: Paracetamol 125mg Phenylephrine Hydr,ochloride IP 5mg, Chlorpheniramine Maleate IP 0.5mg, Sodium Citrate IP 60mg, Menthol IP 1mg	1 ml	M/s Relax Pharmaceuticals Ltd. / M/s Magnet Labs Pvt. Ltd.	0.57
50.	Atorvastatin + Clopidogrel Capsule (Atocor CV)	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As film coated tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As 2 film coated 37.5mg each tablet)	10 Capsule	M/s Windlas Biotech Pvt. Ltd. / M/s Dr. Reddy's Laboratories Ltd.	83.94
51.	Tacrolimus Capsule	Each hard gelatin capsule contains: Tacrolimus premix (20%) eq. to Tacrolimus IP 0.25mg	1 Capsule	M/s Intas Pharmaceuticals Ltd.	10.82
52.	Atorvastatin + Clopidogrel Capsule (Avas 10 Gold)	Each capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As film coated tablet) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As 2 film coated 37.5mg each tablet)	10 Capsule	M/s Micro Lab. Ltd.	83.94
53.	Atorvastatin +	Each capsule contains:	10	M/s Micro Lab. Ltd.	83.94

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	Clopidogrel Capsule (Astin 10 Gold)	Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As film coated tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As 2 film coated 37.5mg each tablet)	Capsule		
54.	Glimepiride + Metformin Tablet (DIAPRIDE M 0.5)	Each uncoated bilayered tablet contains: Glimepiride IP 0.5mg, Metformin Hydrochloride IP 500mg (SR)	1 Tablet	M/s Micro Lab. Ltd.	2.22
55.	Telmisartan + Hydrochlorothiazide Tablet (Tigatel H 40)	Each uncoated tablet contains: Telmisartan IP 40mg, Hydrochlorothiazide IP 12.5mg	1 Tablet	M/Sun Pharma Laboratories Ltd.	7.16
56.	Telmisartan + Hydrochlorothiazide Tablet (Tigatel H 80)	Each uncoated tablet contains: Telmisartan IP 80mg, Hydrochlorothiazide IP 12.5mg	1 Tablet	M/Sun Pharma Laboratories Ltd.	11.12
57.	Telmisartan + Amlodipine Tablet (Tigatel AMH 40)	Each uncoated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP Eq. to Amlodipine 5mg, Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Sun Pharma Laboratories Ltd.	7.48
58.	Telmisartan + Amlodipine Tablet (Tigatel AMH 80)	Each uncoated tablet contains: Telmisartan IP 80mg, Amlodipine Besylate IP Eq. to Amlodipine 5mg, Hydrochlorothiazide IP 12.5mg	10 Tablet	M/s Sun Pharma Laboratories Ltd.	117.83
59.	Sofosbuvir + Velpatasvir Tablet	Each film coated tablet contains: Sofosbuvir 400mg, Velpatasvir 100mg	28 tablets	M/s Hetro Lab Limited / M/s Emcure Pharmaceutical Limited	15625.00

4.2 Agenda item no. 4(ii)- Price fixation of new drug under Para 5 of DPCO 2013 - Methylprednisolone sodium Succinate Injection 1000mg for M/s Claris Injectables Limited.

4.2.1 The Authority examined the matter in details and approved the retail price of Methylprednisolone sodium Succinate Injection 1000mg for M/s Claris Injectables Limited at Rs. 782.78 per vial excluding GST.

4.3 Agenda Item no. 4(iii)- Price fixation of new drug under Para 5 of DPCO 2013 - Methylprednisolone sodium Succinate Injection 500mg for M/s Claris Injectables Limited.

4.3.1 The Authority examined the matter in details and approved the retail price of Methylprednisolone sodium Succinate Injection 500mg for M/s Claris Injectables Limited at Rs. 469.76 per vial excluding GST.

4.4 Agenda item no. 4(iv)- Price fixation of new drug under Para 5 of DPCO 2013 - Methylprednisolone sodium Succinate Injection 125 mg for M/s Claris Injectables Limited.

4.4.1 The Authority examined the matter in details and approved the retail price of Methylprednisolone sodium Succinate Injection 125 mg for M/s Claris Injectables Limited at Rs. 228.44 per vial excluding GST.

4.5 Agenda item no. 4(v)- Price fixation of new drug under Para 5 of DPCO 2013 - BortiRel 3.5mg for M/s Reliance Life Science Pvt. Ltd.

4.5.1 The Authority examined the matter in details and approved the retail price of **BortiRel 3.5mg** for M/s Reliance Life Science Pvt. Ltd at Rs. 12500 per vial excluding GST.

5. Agenda item no. 5 - Status of Monitoring of Prices of Medical Devices.

5.1 Noted. As regards the trade margins involved in medical devices, one RTI application has been received seeking details of trade margin in respect of intra ocular lenses, cochlear implants, balloon catheters and heart valves. The Authority decided to upload in the public domain of NPPA, the details of trade margins of these medical devices whose trade margin analysis have been completed as a part of information dissemination.

6. Agenda item no. 6 - Discontinuation of scheduled formulation Inj NS 0.45% 500ml (Inj. 0.45% Sodium Chloride 500ml) by M/s Baxter (India) Pvt. Ltd. Under para 21 (2) of DPCO, 2013.

6.1 The Authority confirmed the earlier decision to approve the discontinuation request of the Company as the same is not a critical drug and alternatives with somewhat different strength/pack size would be available

7. Agenda item no. 7 – Status of filing in IPDMS by Pharma Companies

7.1 Noted.

8. Agenda item no. 8 – Status regarding launch of drugs Without Price Approval (WPA)

8.1 Noted.

9. Agenda item no. 9 - Status regarding reports on the treatment of Late Miss Adya Singh diagnosed with dengue at Fortis Memorial Research Institute, Gurgaon

9.1 The issue has been deliberated in details and it was decided that the issue will be further discussed and deliberated in the continuation meeting to be held on 20.12.2017 at 11:00 AM in the conference Hall of NPPA.

10. Agenda item no.10 – Request of M/s India Medtronic Pvt Ltd for discontinuation of Endeavor Sprint RX Zotarolimus Eluting Coronary System under para 21(2) of DPCO, 2013

10.1 Noted.

11. The meeting was adjourned with a vote of thanks to the Chair, to meet again on 20.12.2017 at 11:00 AM for Agenda No. 9 and supplementary agenda, if any.

15/12/17

(Rakesh Ranjan)
Member Secretary

ANNEXURE -3

गोपनीय: Confidential

मिसिलस.- 8(51)/2017/डी.पी/एनपीपीए-डीवी-II

F. No. 8(51)/2017/DP/NPPA-Div. II

कार्यवाहीस. : 183/51/2017/F
Proceeding No : 183/51/2017/F

Minutes of the 183rd and 51st meeting (continued) of Authority under DPCO, 2013 held on 20.12.2017 at 11.00 A.M.

I. The 183rd overall meeting of the Authority, which is the 51st under the DPCO, 2013 continued on 20th December, 2017 at 11.00 AM under the Chairmanship of Shri Bhupendra Singh, Chairman, NPPA. The following members of the NPPA were present:-

(i) Shri Rakesh Ranjan, Member Secretary
(ii) Shri Umesh Dongre, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
(iii) Shri Arun Kumar, Adviser, Deptt. of Economic Affairs, Ministry of Finance.
(iv) Shri A. K. Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCG(I)).

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

(i) Shri Kalyan Nag, Adviser (Cost)
(ii) Shri A.P.S. Sawhney, Director (Pricing)
(iii) Shri Baljit Singh, Asstt. Director (Pricing)

1.2 Chairman, NPPA welcomed all the members present in the meeting.

II. Agenda items

1. Agenda item no. 9 – Discussion on the analysis of trade margin regarding reports on the treatment in Fortis Memorial Research Institute, Gurgaon

1.1 After intensive deliberation, the Authority directed NPPA office to analyze the issue of exorbitant trade margins and inflated MRPs in all scheduled and non scheduled drugs and put up options of appropriate action in the next authority meeting.

2. Agenda item No. 11 (Supplementary Agenda) – Fixation of the Retail price for the 'Without Price Approval'(WPA).

2.1 The Authority examined in details, fixation of the Retail price for the 'Without Price Approval' (WPA) cases referred by the M&E Division. With a view to rationalize the prices of new drugs, it has been decided in the Authority Meeting dated 15.12.2017, that wherever NPPA has already notified the price, the same price would be extended to subsequent applicants/ WPA cases also. Accordingly, the Authority approved the retail price of 15 new drugs on the basis of retail price already notified. The Authority also decided that in all such cases where the Pharmaceutical companies have sought approval of retail price for new drug/drugs where the price has already been notified for the same formulation/formulations, NPPA with the approval of the Chairman can extend the same price to subsequent applicants and may bring it to the Authority for information in next authority meeting. The details of retail price approved are as below:

Sl. No.	Name of the Scheduled Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price excluding Local taxes (Pre-GST) (Rs.)	Retail Price excluding Goods and services tax (Post-GST) (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	Glimepiride + Metformin Tablets	Tablet Contains: Glimepiride 1mg & Metformin 500mg.	1 Tablet	M/s Lupin Limited	4.00	3.84
2	Glimepiride + Metformin Tablets	Tablet Contains: Glimepiride 2mg & Metformin 500mg.	1 Tablet	M/s Lupin Limited	4.50	4.32
3	Metoprolol + Chlorthalidone Tablets	Tablet Contains: Metoprolol 25mg & Chlorthalidone 12.5mg.	1 Tablet	M/s Lupin Limited	5.81	5.57
4	Metoprolol + Chlorthalidone Tablets	Tablet Contains: Metoprolol 25mg & Chlorthalidone 12.5mg.	1 Tablet	M/s Lupin Limited	5.81	5.57
5	Metoprolol + Chlorthalidone Tablets	Tablet Contains: Metoprolol 50mg & Chlorthalidone 12.5mg.	1 Tablet	M/s Lupin Limited	7.22	6.92
6	Metoprolol + Chlorthalidone Tablets	Tablet Contains: Metoprolol 50mg & Chlorthalidone 12.5mg.	1 Tablet	M/s Lupin Limited	7.22	6.92
7	Moxifloxacin + Cefixime Tablets	Tablets contains: Moxifloxacin 400mg & Cefixime 400mg	1 Tablet	M/s Lupin Limited	34.46	33.05
8	Gliclazide + Pioglitazone + Metformin Tablets	Tablet containing: Gliclazide 60mg, Pioglitazone 7.5mg & Metformin 500mg.	1 Tablet	M/s Eris Life Sciences Ltd.	6.25	5.99
9	Teneligliptin + Metformin Tablets	Tablet Contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin HCl 1000mg.	1 Tablet	M/s Eris Life Sciences Ltd.	11.33	10.87
10	Teneligliptin + Metformin Tablets	Tablet Contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin HCl 500mg.	1 Tablet	M/s Eris Life Sciences Ltd.	10.03	9.62

11	Glimepiride + Metformin Tablets	Tablet containing: Glimepiride 1mg & Metformin 1000mg.	1 Tablet	M/s Eris Life Sciences Ltd.	5.93	5.69
12	Glimepiride + Metformin Tablets	Tablet containing: Glimepiride 2mg & Metformin 1000mg.	1 Tablet	M/s Eris Life Sciences Ltd.	7.50	7.19
13	Glimepiride + Metformin Tablets	Tablet containing: Glimepiride 3mg & Metformin 1000mg.	1 Tablet	M/s Eris Life Sciences Ltd.	8.73	8.37
14	Metformin + Glimepiride + Pioglitazone Tablets	Tablet containing: Metformin 500mg, Glimepiride 1mg & Pioglitazone 15mg.	1 Tablet	M/s Unison Pharmaceuticals Pvt Ltd.	2.23	2.14
15	Metformin + Glimepiride + Pioglitazone Tablets	Tablet containing: Metformin 500mg, Glimepiride 2mg & Pioglitazone 15mg.	1 Tablet	M/s Unison Pharmaceuticals Pvt Ltd.	2.45	2.35

The Authority also decided that the Status of new drug applications should be updated on NPPA's website fortnightly and in cases where new drug has been launched without price approval, prompt action should be taken to issue show cause notices and do the recoveries as per law.

3. Agenda item No. 12 (Supplementary Agenda) – Appreciation of contribution Shri Suneel Chopra, Principal Legal Consultant

3.1 The Authority noted the usual presence of Shri Suneel Chopra, PLC in the meeting and took note of the fact that there are 224 active court cases in the Hon'ble Supreme Court of India and various High Courts and put on record the outstanding services rendered by Shri Suneel Chopra, former Principal Legal Consultant. The Authority also acknowledged the significant contribution made by Shri Chopra in pursuing all court cases efficiently and successfully to obtain a large number of favourable landmark judgments pronounced by Hon'ble Supreme Court and High Courts especially in CA 329/2005 UOI vs. Cipla Ltd & connected cases, CA 5117/2013 UOI vs. Swiss Garnier & mars, CA 1939/2004 Glaxosmithklin vs. UOI, SLP(C) 30089/2016 & WP(C) 2700/2014 filed by IPA vs UOI etc, which helped NPPA in recovery of about Rs.400 crore government dues in the last two years. Further, the authority put on record that Shri Chopra was the only professional in NPPA having legal as well as technical knowledge and well versed with all these cases and therefore, services of Shri Chopra as Principal Legal Consultant should be continued further to properly and effectively safeguard the interest of NPPA/Government in larger public interest. Authority was briefed that the selection committee set up by DoP has chosen Shri Chopra as the only suitable candidate and the file is pending for approval in Govt. for approval of the Competent Authority. Authority asked NPPA to write to DoP again to expedite the approval.

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

(Rakesh Ranjan)
Member Secretary

ANNEXURE 4

(Published in Part II, Section 3, Sub-section (ii) of the Gazette of India, Extraordinary)
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

New Delhi, the 18th December, 2017

ORDER

S. O. In exercise of the powers conferred by paragraphs 5, 11 and 15 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S. O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA), hereby fixes, the price as specified in column (6) of the table herein below as the retail price, exclusive of goods and services tax, if any, in relation to the formulation specified in the corresponding entry in column (2) of the said Table with the strength, unit and name of manufacturer & marketing company, as specified in the corresponding entries in columns (3), (4) and (5) thereof;

Table

Sl. No.	Name of the Scheduled Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
1.	Ferrous Ascorbate + Folic Acid + Cyanocobalamin + Zinc Sulphate Monohydrate tablet (Autrin - XT)	Each film coated tablet contains: Ferrous Ascorbate eq. to Elemental Iron 100mg, Folic Acid IP 1.5mg, Cyanocobalamin IP 15 mcg, Zinc Sulphate Monohydrate IP eq. to Elemental Zinc 22.5mg	1 Tablet	M/s Tirupati Medicare Limited / M/s Pfizer Limited	3.63
2.	Rosuvastatin + Clopidogrel Capsule (Roseday CV 10)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin (As granules) 10mg, Clopidogrel Bisulphate IP eq. to Clopidogrel (As a film coated tablet) 75mg	1 Capsule	M/s Aeon Formulation Pvt. Ltd. / M/s USV Private Limited	13.37
3.	Teneligliptin + Metformin tablet (Ten20 M 1000)	Each uncoated bilayered tablets contains: Teneligliptin Hydrobromide hydrate eq. to Teneligliptin 20mg, Metformin HCL 1000mg (as extended release)	1 Tablet	M/s Glenamark Pharmaceuticals Ltd. / M/s Centaur Pharmaceuticals Pvt. Ltd.	10.87
4.	Clobetasol + Clotrimazole + Neomycin Sulphate Cream	Each gm contains: Clobetasol Propionate IP 0.05%w/w, Clotrimazole IP 1.00% w/w, Neomycin Sulphate IP 0.50%w/w	1 GM	M/s Mankind Pharma Ltd./ M/s Pharma Force Lab.	2.92
5.	Moxifloxacin +	Each Coated Sustained Release	1 Tablet	M/s Akums Drugs	33.05

	Cefixime Tablets (Moximac Plus)	tablet contains: Moxifloxacin Hydrochloride BP eq. to Moxifloxacin 400mg, Cefixime IP (as trihydrate) eq. to Ahydrous Cefixime 400mg		and Pharmaceuticals Ltd. / M/s Macleods Pharmaceuticals Ltd.	
6.	Moxifloxacin + Cefixime Tablets (Macflox Plus)	Each Coated Sustained Release tablet contains: Moxifloxacin Hydrochloride BP eq. to Moxifloxacin 400mg, Cefixime IP (as trihydrate) eq. to Ahydrous Cefixime 400mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Macleods Pharmaceuticals Ltd.	33.05
7.	Tramadol + Paracetamol Tablet	Each Film Coated tablet contains: Tramadol Hydrochloride IP 37.5mg, Paracetamol IP 325mg	1 Tablet	M/s Anglo French Drugs & Industries Ltd.	5.57
8.	Rosuvastatin + Aspirin + Clopidogrel Tablet	Each film coated bilayered tablet contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg, Aspirin IP 75mg, Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg	1 Tablet	M/s Safetab Life Science / M/s Intas Pharmaceuticals Limited	9.97
9.	Teneligliptin + Metformin Tablet	Each uncoated bilayered tablets contains: Teneligliptin Hydrobromide hydrate eq. to Teneligliptin 20mg, Metformin HCL 500mg (as extended release)	1 Tablet	M/s Synokam Pharma limited/ M/s Cadila Pharmceuticals Ltd.	9.62
10.	Teneligliptin + Metformin Tablet	Each uncoated bilayered tablets contains: Teneligliptin Hydrobromide hydrate eq. to Teneligliptin 20mg, Metformin HCL 1000mg (as extended release)	1 Tablet	M/s Synokam Pharma limited/ M/s Cadila Pharmceuticals Ltd.	10.87
11.	Paracetamol + Caffeine + Phenylephrine + Diphenhydramine Tablet	Each uncoated tablet contains: Paracetamol IP 500mg, Caffeine (Anhydrous) IP 30mg, Phenylephrine Hydrochloride IP 5mg, Diphenhydramine Hydrochloride IP 25mg	1 Tablet	M/s Biochem Pharmaceutical Industries Ltd.	2.57
12.	Ramipril + Amlodipine Tablet	Each uncoated tablet contains: Ramipril IP 5mg, Amlodipine Besilate IP eq. to Amlodipine 5mg	1 Tablet	M/s Lupin Limited	4.11
13.	Teneliglitptin + Metformin Tablet	Each Film uncoated bilayer tablet contains: Teneliglitptin Hydrobromide Hydrate 20mg eq. to Tenegliptin 20mg, Metformin Hydrochloride IP 1000mg (In Sustained Release form)	1 tablet	M/s Lupin Limited / M/s Unichem Laboratories Ltd.	10.87
14.	Teneliglitptin +	Each uncoated bilayer tablet	1 Tablet	M/s Lupin Limited /	9.62

	Metformin Tablet	contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride IP 500mg		M/s Unichem Laboratories Ltd	
15.	Rosuvastatin + Clopidogrel Capsule (Roistar CV 10/75)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Unichem Laboratories Ltd.	13.37
16.	Rosuvastatin + Clopidogrel Capsule (Roistar CV 20/75)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Unichem Laboratories Ltd.	7.80
17.	Diclofenac Injection	Each ml contains: Diclofenac Sodium IP 75mg Injection	1 ML	M/s Cadila Healthcare Ltd.	13.71
18.	Teneligliptin + Metformin Tablet (EFIGLIN M)	Each uncoated Bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin HCl 500mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s MedoPharm,	9.62
19.	Rosuvastatin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As granules), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as to film coated tablets)	1 Capsule	M/s GKM New Pharma / M/s Cadila Healthcare Ltd.	7.80
20.	Rosuvastatin + Clopidogrel Capsule (Roseday CV 20)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin (As Pellets) 20mg, Clopidogrel Bisulphate IP eq. to Clopidogrel (As Pellets) 75mg	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s USV Pvt. Ltd,	7.80
21.	Teneligliptin + Metformin Tablet	Each uncoated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin HCL 500mg (as sustained release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	9.62
22.	Teneligliptin + Metformin Tablet	Each uncoated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin HCL 1000mg (as sustained release)	1 Tablet	/s Synokem Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	10.87
23.	Metformin + Glimepiride + Voglibose Tablet	Each tablet contains: Metformin HCL 500mg (as sustained release form), Glimepiride 2mg,	1 Tablet	M/s Sunglow Pharmaceuticals Pvt. Ltd. / M/s Intas Pharmaceuticals	9.39

		Voglibose 0.3mg		Ltd.	
24.	Paracetamol Tablet	Each tablet contains: Paracetamol IP (as Immediate Release) 300mg, Paracetamol IP (as Sustained Release) 700mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Strassenburg Pharmaceuticals Ltd.	3.15
25.	Aceclofenac + Paracetamol Tablet	Each Tablet contains: Aceclofenac IP 100mg, Paracetamol IP 325mg	1 Tablet	M/s Rivpra Formulation Pvt. Ltd. / M/s Cadila Pharmaceuticals Ltd.	2.78
26.	Rosuvastatin + Clopidogrel Capsule	Each Hard gelatin capsule contains: Rosuvastatin 10mg, Clopidogrel 75mg	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Ltd.	13.37
27.	Teneligliptin + Metformin Tablet (EFIGLIN M 1000)	Each uncoated Bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride IP 1000mg (as Sustained Release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s MedoPharm	10.87
28.	Olmesartan + Amlodipine Tablet	Each film coated tablet contains: Olmesartan Medoxomil IP 20mg, Amlodipine Besylate IP eq. to Amlodipine 5mg,	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Zuventus Healthcare Limited	7.24
29.	Telmisartan + Metoprolol Tablet (Xstan-Beta 25mg)	Each film coated tablet contains: Telmisartan IP 40mg, Metoprolol Tartrate IP 25mg (ER)	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	7.62
30.	Telmisartan + Metoprolol Tablet (Xstan-Beta 50mg)	Each film coated tablet contains: Telmisartan IP 40mg, Metoprolol Tartrate IP 50mg (ER)	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	9.16
31.	Voglibose + Glimepride + Metformin Tablet	Each uncoated bilayered tablet contains: Voglibose IP 0.2mg, Glimepride IP 1mg, Metformin HCL IP 500mg (SR)	10 Tablets	M/s Windlas Biotech Pvt. Ltd. / M/s Zuventus Healthcare Limited	68.50
32.	Atorvastatin + Clopidogrel Capsules (Atchol CV 10mg)	Each hard gelatin capsule contains: Atorvastatin Calcium eq. to Atorvastatin (as pellets) 10mg, Clopidogrel (as pellets) 75mg.	10 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	83.94
33.	Voglibose + Glimepride +	Each uncoated bilayered tablet contains:	1 Tablet	M/s Windlas Biotech Pvt. Ltd.	8.68

	Metformin Tablet	Voglibose IP 0.2mg, Glimepride IP 2mg, Metformin Hydrochloride IP 500mg (SR)		/M/s Zuventus Healthcare Limited	
34.	Teneligliptin + Metformin Tablet (Tenephron M)	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride 500mg (SR)	1 Tablet	M/s Windlas Biotech Limited / M/s Abbott India Limited	9.62
35.	Teneligliptin + Metformin Tablet (Tenephron M Forte)	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin HCl 1000mg (SR)	1 Tablet	M/s Windlas Biotech Limited / M/s Abbott India Limited	10.87
36.	Teneligliptin + Metformin Tablet (TYTIN M)	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride 500mg (as extended release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Wockhardt Ltd.	9.62
37.	Tacrolimus Capsule	Each Hard gelatin capsule contains: Tacrolimus IP 0.25mg	1 Capsule	M/s Emcure Pharmaceuticals Ltd,	10.82
38.	Telmisartan + Amlodipine Tablet	Each uncoated bilayer tablet Contains: Telmisartan IP 80mg, Amlodipine Besilate IP 5mg	10 Tablet	M/s J. K. Print Packs / M/s Mankind Pharma Ltd.	106.05
39.	Telmisartan + Amlodipine Tablet (Tigatel AM 40)	Each film coated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Sun Pharma Laboratories Limited	6.90
40.	Cefixime + Ofloxacin Tablet (Ranixime Plus)	Each film coated tablet contains: Cefixime Trihydrate eq. to Cefixime Anhydrous IP 200mg, Ofloxacin IP 200mg	1 Tablet	M/s Theon Pharmaceuticals Limited / M/s Sun Pharmaceutical Industrial Limited	9.46
41.	Teneligliptin + Metformin Tablet (Glypte M)	Each film coated tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride 500mg	1 Tablet	M/s Precise Chemipharma Pvt. Ltd. / M/s Franco India Pharmaceuticals Private Limited	9.62
42.	Teneligliptin + Metformin Tablet (Glypte M Forte)	Each film coated tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride 1000mg	1 Tablet	M/s Precise Chemipharma Pvt. Ltd. / M/s Franco India Pharmaceuticals Private Limited	10.87
43.	Glemipiride + Metformin Tablet (Ziglim – M1 Forte)	Each uncoated bilayered tablet contains: Glemipiride IP 1mg, Metformin Hydrochlorde IP 1000mg (as SR form)	1 Tablet	M/s Inventia Healthcare Pvt. Ltd. / M/s FDC Limited	5.69

44.	Glemipiride + Metformin Tablet (Ziglim – M2 Forte)	Each uncoated bilayered tablet contains: Glimepiride IP 2mg, Metformin Hydrochlorde IP 1000mg (as SR form)	1 tablet	M/s Inventia Healthcare Pvt. Ltd. / M/s FDC Limited	7.19
45.	Diclofenac Injection	Each ml contains: Diclofenac Sodium IP 75mg/ml	1 ml	M/s Zydus Healthcare Ltd.	13.71
46.	Doxorubicin (Pegylated Liposomal) Injection	Each ml contains: Doxorubicin HCL 2mg (Pegylated Liposomal) water for Injection	1 ml	M/s Natco Pharma Ltd.	694.29
47.	Telmisartan + Indapamide Tablet	Each uncoated bilayered tablet contains: Telmisartan IP 40mg Indapamide IP 1.5mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Mankind Pharma Ltd.	8.48
48.	Paracetamol + Mefenamic Acid Injection (Zydol-P DS)	Each 5ml contains: Paracetamol 250mg Mefenamic Acid 100mg	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Jenburkt Pharmaceuticals Ltd.	0.57
49.	Paracetamol + Phenylephrine + Chlorpheniramine + Sodium Citrate + Menthol Injection	Each 5ml contains: Paracetamol 125mg Phenylephrine Hydr,ochloride IP 5mg, Chlorpheniramine Maleate IP 0.5mg, Sodium Citrate IP 60mg, Menthol IP 1mg	1 ml	M/s Relax Pharmaceuticals Ltd. / M/s Magnet Labs Pvt. Ltd.	0.57
50.	Atorvastatin + Clopidogrel Capsule (Atocor CV)	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As film coated tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As 2 film coated 37.5mg each tablet)	10 Capsule	M/s Windlas Biotech Pvt. Ltd. / M/s Dr. Reddy's Laboratories Ltd.	83.94
51.	Tacrolimus Capsule	Each hard gelatin capsule contains: Tacrolimus premix (20%) eq. to Tacrolimus IP 0.25mg	1 Capsule	M/s Intas Pharmaceuticals Ltd.	10.82
52.	Atorvastatin + Clopidogrel Capsule (Avas 10 Gold)	Each capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As film coated tablet) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As 2 film coated 37.5mg each tablet)	10 Capsule	M/s Micro Lab. Ltd.	83.94
53.	Atorvastatin + Clopidogrel Capsule (Astin 10 Gold)	Each capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As film coated tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As 2 film coated 37.5mg each tablet)	10 Capsule	M/s Micro Lab. Ltd.	83.94

54.	Glimepiride + Metformin Tablet (DIAPRIDE M 0.5)	Each uncoated bilayered tablet contains: Glimepiride IP 0.5mg, Metformin Hydrochloride IP 500mg (SR)	1 Tablet	M/s Micro Lab. Ltd.	2.22
55.	Telmisartan + Hydrochlorothiazide Tablet (Tigatel H 40)	Each uncoated tablet contains: Telmisartan IP 40mg, Hydrochlorothiazide IP 12.5mg	1 Tablet	M/Sun Pharma Laboratories Ltd.	7.16
56.	Telmisartan + Hydrochlorothiazide Tablet (Tigatel H 80)	Each uncoated tablet contains: Telmisartan IP 80mg, Hydrochlorothiazide IP 12.5mg	1 Tablet	M/Sun Pharma Laboratories Ltd.	11.12
57.	Telmisartan + Amlodipine Tablet (Tigatel AMH 40)	Each uncoated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP Eq. to Amlodipine 5mg, Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Sun Pharma Laboratories Ltd.	7.48
58.	Telmisartan + Amlodipine Tablet (Tigatel AMH 80)	Each uncoated tablet contains: Telmisartan IP 80mg, Amlodipine Besylate IP Eq. to Amlodipine 5mg, Hydrochlorothiazide IP 12.5mg	10 Tablet	M/s Sun Pharma Laboratories Ltd.	117.83
59.	Sofosbuvir + Velpatasvir Tablet	Each film coated tablet contains: Sofosbuvir 400mg, Velpatasvir 100mg	28 tablets	M/s Hetro Lab Limited / M/s Emcure Pharmaceutical Limited	15625.00
60.	Methylprednisolone Injection	Each Vial contains: Methylprednisolone Sodium Succinate USP. Eq. to Methylprednisolone 125mg	1 Vial	M/s Aqua Vitoe Laboratories / M/s Claris Injectable Limited,	228.44
61.	Methylprednisolone Injection	Each Vial contains: Methylprednisolone Sodium Succinate USP. Eq. to Methylprednisolone 500mg	1 Vial	M/s Aqua Vitoe Laboratories / M/s Claris Injectable Limited,	469.76
62.	Methylprednisolone Injection	Each Vial contains: Methylprednisolone Sodium Succinate USP. Eq. to Methylprednisolone 1000mg	1 Vial	M/s Aqua Vitoe Laboratories / M/s Claris Injectable Limited,	782.78
63.	Bortezomib Injection (BortiRel)	Each vial contains: Bortezomib IP 3.5mg Injection	1 Vial	M/s Reliance Life Sciences Pvt. Ltd.	12500.00

Note:

(a) The manufacturer of above mentioned formulations i.e. "new drug" under paragraph 2(u) of the DPCO, 2013 shall fix the retail price as specified in column (6) of the table hereinabove.

(b) The manufacturer may add goods and services tax only if they have paid actually or it is payable to the Government on the retail price mentioned in column (6) of the above said table.

(c) The retail price for a pack of the aforesaid formulation shall be arrived at by the concerned manufacturer in accordance with the retail price specified in column (6) of the above table as per provisions contained in paragraph 11 of the DPCO, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(d) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(e) The above mentioned retail price is applicable only to the individual manufacturer / marketeer as mentioned above i.e. who have applied for the same by submitting Form-I for price fixation / revision as stipulated under DPCO, 2013 and subject to fulfilment of all the applicable statutory requirements as laid down by the Govt. under relevant statutes/ rules, including manufacturing license permission from the Competent Authority i.e. the Central/State Licensing Authority, as may be applicable, by the concerned manufacturer/marketing companies.

(f) The concerned manufacturer of above said formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of product in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Manufacturer, in case intending to discontinue above said formulations, shall furnish information to the NPPA, in respect of discontinuation of the production and / or import of above said formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(g) In case the retail price of any of the aforesaid formulations is not complied with, as per instant price notification and notes specified hereinabove, then the concerned manufacturer/marketing company shall be liable to deposit the overcharged amount along with the interest thereon under the provisions of the DPCO, 2013 read with the Essential Commodities Act, 1955.

PN/183/51/2017/F F. No. 8(51)/2017/D.P./NPPA-Div.-II

(BALJIT SINGH)
Assistant Director

(Published in Part II, Section 3, Sub-section (ii) of the Gazette of India, Extraordinary)
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

New Delhi, the 18th December, 2017

ORDER

S.O. _____In exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes the prices as specified in column (5) of the table herein below as ceiling price exclusive of goods and services tax applicable, if any, in respect of the Scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

TABLE

Sl. No.	**Name of the Scheduled Formulation**	**Dosage form & Strength**	Unit	**Ceiling Price (Rs.)**
(1)	**(2)**	**(3)**	(4)	**(5)**
1.	Anti-D Immunoglobulin	Injection 150mcg	Each Vial	1509.69

Note:

(a) All manufacturers of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.

(b) All the existing manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013.

(c) The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.

(d) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(e) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(f) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.

(g) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the

DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(h) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

(i) Consequent to the issue of ceiling price of such formulation as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

PN/183/51/2017/F F. No. 8(51)/2017/D.P./NPPA-Div.-II

(BALJIT SINGH)
Assistant Director

(Published in Part II, Section 3, Sub-section (ii) of the Gazette of India, Extraordinary)
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

New Delhi, the 18th December, 201 7

ORDER

S.O. .....Whereas, the Department of Pharmaceuticals (hereinafter referred as DOP) has amended Schedule I of the Drugs Price Control Order (hereinafter referred as DPCO) 2013 vide S.O. 701(E) dated 10.03.2016 based on revised National List of Essential Medicine (hereinafter referred as NLEM) 2015;

and

02. Whereas on amendment of the list of scheduled formulations, paragraph 17 of the DPCO 2013 requires fixation of the ceiling prices of formulations (i.e. medicines) added in the Schedule I to be fixed as per the provisions of the DPCO, 2013 within a period of sixty days from the date of amendment;

and

03. Whereas the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) initiated the process of the ceiling price fixation in March 2016. In this connection, NPPA vide Office Memorandum (i.e. OM) 19(697)/2016/Div II/NPPA dated 4.4.2016 had uploaded a list of the scheduled formulations for which reference market based data required for price fixation was not available. The said list was subsequently amended and displayed again vide OMs dated 28.4.2016, 13.5.2016, 10.1.2017 and 8.7.2017. Copies of the aforesaid OMs were also sent to Drugs Manufacturers Associations requesting for submission of market based data and whereas NPPA had also suggested the Department of Pharmaceuticals to amend DPCO 2013 so as to facilitate consideration of the State Institutional Procurement Price for such scheduled formulations where market based data are not available to facilitate ceiling price fixation;

and

04. Whereas on the basis of inputs from the manufacturer and official data collection agency viz AIOCD AWACS in respect of certain scheduled formulations where market based prices could be traced, NPPA has fixed the ceiling prices of such scheduled formulations. NPPA has so far fixed the ceiling prices of 821 formulations on the basis of available data. However, even after a number of attempts made to obtain the relevant and reliable market based data, NPPA has not been able to fix the ceiling prices of remaining scheduled formulation for the want of requisite market data;

and

05. Whereas, it is obligatory on the part of the NPPA to revise the ceiling prices of all the drugs notified under the Schedule I of DPCO, 2013 so as to ensure the benefit of fair and reasonable ceiling prices to the consumers of such essential medicines to protect public interest, there is a necessity to adopt alternative methods of price fixation;

and

06. Whereas NPPA also sought information from the various Government Procurement Agencies under Central Government and States and State Medical Services Corporation, as it is necessary to fix ceiling prices of scheduled formulations. Accordingly, in the absence of the relevant market based data in the Pharmatrac report of AIOCD- AWACS, it has been decided in the Authority Meeting held in the NPPA on 19/9/2017 to fix the ceiling prices of remaining scheduled formulations on the basis of procurement prices;

and

07. Now, in exercise of the powers conferred by paragraphs 19 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, which has been upheld by the Honourable High Court and also Hon'ble Supreme court of India and in supersession of the Order of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) No. S. O. 2060(E) and SO 2061(E) dated 30th June, 2017, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes the prices as specified in column (5) of the table herein below as ceiling price exclusive of goods and services tax applicable, if any, in respect of the Scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

TABLE

Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)
(1)	(2)	(3)	(4)	(5)
1.	Phenylephrine	Drops 5%	1 ML	3.38

Note:

(a) All manufacturers of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.

(b) All the existing manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013.

ANNEXURE 5

(Published in Part II, Section 3, Sub-section (ii) of the Gazette of India, Extraordinary)
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

New Delhi, the 20th December, 2017

ORDER

S.O.3946(E) In exercise of the powers conferred by paragraphs 5, 11 and 15 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S. O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA), in supersession of Order No 3727(E) dated 23rd November 2017 (except item of Sl. No. 1 and 2), hereby, fixes the price as specified in column (6) and column(7) of the table herein below as the retail price, exclusive of local taxes and goods and services tax respectively, if any, as applicable, in relation to the formulation specified in the corresponding entry in column (2) of the said Table with the strength, unit and name of manufacturer & marketing company, as specified in the corresponding entries in columns (3), (4) and (5) thereof;

Table

Sl. No.	Name of the Scheduled Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Pre-GST) (Rs.)	Retail Price (Post-GST) (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1.	Voglibose + Metformin	Each tablet contains: Voglibose 0.2mg Metformin 500mg	1 Tablet	M/s Lupin Ltd.	4.84	4.64
2.	Voglibose + Metformin	Each tablet contains: Voglibose 0.3mg Metformin 500mg	1 Tablet	M/s Lupin Ltd.	5.76	5.52
3.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.2mg Metformin 500mg Glimepirid 1mg	1 Tablet	M/s Lupin Ltd.	7.14	6.85
4.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.2mg Metformin 500mg Glimepirid 1mg	1 Tablet	M/s Sanofi India Ltd.	7.14	6.85

5.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.2mg Metformin 500mg Glimepirid 1mg	1 Tablet	M/s Biocon Ltd.	7.14	6.85
6.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.2mg Metformin 500mg Glimepirid 2mg	1 Tablet	M/s Lupin Ltd.	9.05	8.68
7.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.2mg Metformin 500mg Glimepirid 2mg	1 Tablet	M/s Sanofi India Ltd.	9.05	8.68
8.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.2mg Metformin 500mg Glimepirid 2mg	1 Tablet	M/s Biocon Ltd.	9.05	8.68
9.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.3mg Metformin 500mg Glimepirid 1mg	1 Tablet	M/s Lupin Ltd.	8.52	8.17
10.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.3mg Metformin 500mg Glimepirid 1mg	1 Tablet	M/s Alembic Ltd.	8.52	8.17
11.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.3mg Metformin 500mg Glimepirid 2mg	1 Tablet	M/s Lupin Ltd.	10.46	10.03
12.	Diclofenac + Tramadol	Each tablet contains: Diclofenac 75mg Tramadol 50mg	1 Tablet	M/s Alembic Ltd.	9.73	9.33

Note:

(a) The manufacturer of above mentioned formulations i.e. "new drug" under paragraph 2(u) of the DPCO, 2013 shall fix the retail price as specified in column (6) of the table hereinabove.

(b) The manufacturer may add local taxes only if they have paid actually or it is payable to the Government on the retail price mentioned in column (6) of the above said table in respect of period upto 30.6.2017. The manufacturer may add goods and services tax only if they have paid actually or it is payable to the Government on the retail price mentioned in column (7) of the above said table with effect from 1.7.2017.

(c) The retail price for a pack of the aforesaid formulation shall be arrived at by the concerned manufacturer in accordance with the retail price specified in column (6) of the above table as per provisions contained in paragraph 11 of the DPCO, 2013. The manufacturer shall

issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(d) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

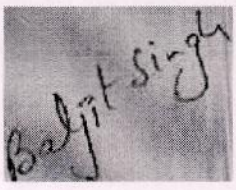
(e) The above mentioned retail prices are applicable only to the manufacturer / marketeer as mentioned above for generic / any brand of the same composition / strength of the subject formulations, subject to fulfillment of all the applicable statutory requirements as laid down by the Govt. under relevant statutes/ rules, including manufacturing license permission from the Competent Authority i.e. the Central/State Licensing Authority, as may be applicable, by the concerned manufacturers/marketing companies.

(f) The concerned manufacturer of above said formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of product in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Manufacturer, in case intending to discontinue above said formulations, shall furnish information to the NPPA, in respect of discontinuation of the production and / or import of above said formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(g) In case the retail price of any of the aforesaid formulations is not complied with, as per instant price notification and notes specified hereinabove, then the concerned manufacturer/marketing company shall be liable to deposit the overcharged amount along with the interest thereon under the provisions of the DPCO, 2013 read with the Essential Commodities Act, 1955.

(h) Consequent to the issue of retail price of the aforesaid formulations as specified in column (2) of the above mentioned table in this notification, the price order(s) if any, issued for concerned manufacturer / marketer prior to the above said date of notification, stand(s) superseded.

PN/183/51/2017/F F. No. 8(51)/2017/D.P./NPPA-Div.-II



(BALJIT SINGH)
Assistant Director

(Published in Part II, Section 3, Sub-section (ii) of the Gazette of India, Extraordinary)
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

New Delhi, the 20th December, 2017

ORDER

S.O.3947(E) In exercise of the powers conferred by paragraphs 5, 11 and 15 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S. O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA), hereby, fixes the price as specified in column (6) and column(7) of the table herein below as the retail price, exclusive of local taxes and goods and services tax respectively, if any, as applicable, in relation to the formulation specified in the corresponding entry in column (2) of the said Table with the strength, unit and name of manufacturer & marketing company, as specified in the corresponding entries in columns (3), (4) and (5) thereof;

Table

Sl. No.	Name of the Scheduled Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Pre-GST) (Rs.)	Retail Price (Post-GST) (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	Glimepiride + Metformin Tablets	Tablet Contains: Glimepiride 1mg & Metformin 500mg.	1 Tablet	M/s Lupin Limited	4.00	3.84
2	Glimepiride + Metformin Tablets	Tablet Contains: Glimepiride 2mg & Metformin 500mg.	1 Tablet	M/s Lupin Limited	4.50	4.32
3	Metoprolol + Chlorthalidone Tablets	Tablet Contains: Metoprolol 25mg & Chlorthalidone 12.5mg.	1 Tablet	M/s Lupin Limited	5.81	5.57
4	Metoprolol + Chlorthalidone Tablets	Tablet Contains: Metoprolol 25mg & Chlorthalidone 12.5mg.	1 Tablet	M/s Lupin Limited	5.81	5.57
5	Metoprolol + Chlorthalidone Tablets	Tablet Contains: Metoprolol 50mg & Chlorthalidone 12.5mg.	1 Tablet	M/s Lupin Limited	7.22	6.92
6	Metoprolol + Chlorthalidone Tablets	Tablet Contains: Metoprolol 50mg & Chlorthalidone 12.5mg.	1 Tablet	M/s Lupin Limited	7.22	6.92
7	Moxifloxacin + Cefixime Tablets	Tablets contains: Moxifloxacin 400mg & Cefixime 400mg	1 Tablet	M/s Lupin Limited	34.46	33.05

8	Gliclazide + Pioglitazone + Metformin Tablets	Tablet containing: Gliclazide 60mg, Pioglitazone 7.5mg & Metformin 500mg.	1 Tablet	M/s Eris Life Sciences Ltd.	6.25	5.99
9	Teneligliptin + Metformin Tablets	Tablet Contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin HCl 1000mg.	1 Tablet	M/s Eris Life Sciences Ltd.	11.33	10.87
10	Teneligliptin + Metformin Tablets	Tablet Contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin HCl 500mg.	1 Tablet	M/s Eris Life Sciences Ltd.	10.03	9.62
11	Glimepiride + Metformin Tablets	Tablet containing: Glimepiride 1mg & Metformin 1000mg.	1 Tablet	M/s Eris Life Sciences Ltd.	5.93	5.69
12	Glimepiride + Metformin Tablets	Tablet containing: Glimepiride 2mg & Metformin 1000mg.	1 Tablet	M/s Eris Life Sciences Ltd.	7.50	7.19
13	Glimepiride + Metformin Tablets	Tablet containing: Glimepiride 3mg & Metformin 1000mg.	1 Tablet	M/s Eris Life Sciences Ltd.	8.73	8.37
14	Metformin + Glimepiride + Pioglitazone Tablets	Tablet containing: Metformin 500mg, Glimepiride 1mg & Pioglitazone 15mg.	1 Tablet	Manufacturer by M/s Jubilant Life Sciences Ltd. and marketer by M/s Hetro Labs Ltd	2.23	2.14
15	Metformin + Glimepiride + Pioglitazone Tablets	Tablet containing: Metformin 500mg, Glimepiride 2mg & Pioglitazone 15mg.	1 Tablet	M/s Biochem Pharmaceuticals Industries Ltd.	2.45	2.35

Note:

(a) The manufacturer of above mentioned formulations i.e. "new drug" under paragraph 2(u) of the DPCO, 2013 shall fix the retail price as specified in column (6) of the table hereinabove.

(b) The manufacturer may add local taxes only if they have paid actually or it is payable to the Government on the retail price mentioned in column (6) of the above said table in respect of period upto 30.6.2017. The manufacturer may add goods and services tax only if they have paid actually or it is payable to the Government on the retail price mentioned in column (7) of the above said table with effect from 1.7.2017.

(c) The retail price for a pack of the aforesaid formulation shall be arrived at by the concerned manufacturer in accordance with the retail price specified in column (6) of the above table as per provisions contained in paragraph 11 of the DPCO, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(d) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of

the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

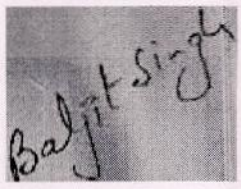
(e) The above mentioned retail prices are applicable only to the manufacturer / marketeer as mentioned above for generic / any brand of the same composition / strength of the subject formulations, subject to fulfillment of all the applicable statutory requirements as laid down by the Govt. under relevant statutes/ rules, including manufacturing license permission from the Competent Authority i.e. the Central/State Licensing Authority, as may be applicable, by the concerned manufacturers/marketing companies.

(f) The concerned manufacturer of above said formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of product in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Manufacturer, in case intending to discontinue above said formulations, shall furnish information to the NPPA, in respect of discontinuation of the production and / or import of above said formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(g) In case the retail price of any of the aforesaid formulations is not complied with, as per instant price notification and notes specified hereinabove, then the concerned manufacturer/marketing company shall be liable to deposit the overcharged amount along with the interest thereon under the provisions of the DPCO, 2013 read with the Essential Commodities Act, 1955.

(h) Consequent to the issue of retail price of the aforesaid formulations as specified in column (2) of the above mentioned table in this notification, the price order(s) if any, issued for concerned manufacturer / marketer prior to the above said date of notification, stand(s) superseded.

PN/183/51/2017/F F. No. 8(51)/2017/D.P./NPPA-Div.-II



(BALJIT SINGH)
Assistant Director

ANNEXURE 6

संख्या / F. No. 19(697)/2016/Div. II/NPPA
भारत सरकार
Government of India
रसायन और उर्वरक मंत्रालय
Ministry of Chemicals & Fertilizers
औषध विभाग
Department of Pharmaceuticals
राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण
National Pharmaceutical Pricing Authority

तीसरी / पांचवी मंजिल 5th / 3rd Floor,
वाई.एम.सी.ए. सांस्कृतिक केन्द्र बिल्डिंग
YMCA Cultural Center Building,
1, जय सिंह रोड, नई दिल्ली-110001
1, Jai Singh Road, N. Delhi - 110001.
दिनांक :- 07.12.2017

OFFICE MEMORANDUM

Subject: NLEM, 2015 formulations under provisions of DPCO, 2013 (Consolidated list as on 30.11.2017).

Reference is invited to OM of even no dated 06.7.2017 on the above subject. As AIOCD (Pharmatrac) is not capturing the PTR & MAT of these formulations, all the concerned manufacturers / marketing companies are requested to furnish the **Price to Retailer (PTR) and Moving Annual Turnover (MAT)** in value terms, duly self attested with proper authorized signature & seal of the authorized officer of the company, for the formulations mentioned in NLEM, 2015 (revised Schedule – I of DPCO , 2013) i.e. **Annexure-I** for the month of **August 2015, by 22.12.2017**, for enabling NPPA to take appropriate action for ceiling price fixation under provisions of DPCO, 2013.

It may be noted that manufacturers/marketing companies have not positively responded to our earlier several OMs. You are once again requested to provide the requisite information positively. In case, manufacturers/marketing companies fail to provide requisite data on or before the deadline, NPPA will have no option but to proceed with price fixation of these formulations based on other available information.

Encl: Annexure - I.

(APS Sawhney)
Director (Pricing)

Copy to:

Apex Pharma Associations i.e. OPPI, IDMA, FICCI, CII, IPA and FOPE for information & necessary action please.

Annexure - I

List of formulation pending for Ceiling price fixation as on 30-11-2017 under NLEM 2015

Sl No	Section of NLEM 2015	Medicines	Dosage form and Strength
1	1.1.4	Nitrous oxide	Inhalation
2	1.1.5	Oxygen	Inhalation (Medicinal gas)
3	1.3.3	Midazolam	Oral liquid 2 mg/ml
4	1.3.3	Midazolam	Tablet 15 mg
5	2.1.1	Acetylsalicylic acid	Effervescent/ Dispersible/ Enteric coated Tablet 300 mg to 500 mg
6	2.1.1	Acetylsalicylic acid	Tablet 300 mg
7	2.1.1	Acetylsalicylic acid	Tablet 300 mg to 500 mg (351mg to 500mg)
8	2.1.1	Acetylsalicylic acid	Tablet 350 mg
9	2.1.4	Mefenamic acid	Capsule 250 mg
10	2.1.4	Mefenamic acid	Capsule 500 mg
11	3.3	Chlorpheniramine	Oral liquid 2 mg/5 ml
12	4.1.1	Activated charcoal	Powder (as licensed)
13	4.2.1	Atropine	Injection 1 mg/ml
14	4.2.4	Dimercaprol	Injection 50 mg/ml
15	4.2.5	Methylthioninium chloride (Methylene blue)	Injection 10 mg/ml
16	4.2.12	Sodium nitrite	Injection 30 mg/ml
17	4.2.13	Sodium thiosulphate	Injection 100 mg/ml
18	5.1	Carbamazepine	Oral liquid 200 mg/5 ml
19	6.1.3.1	Praziquantel	Tablet 600 mg
20	6.2.1.12	Cloxacillin	Oral Liquid 125 mg/5 ml
21	6.2.2.5	Doxycycline	Dry Syrup 50mg/5 ml
22	6.2.3.2	Dapsone	Tablet 25 mg
23	6.2.3.2	Dapsone	Tablet 50 mg
24	6.2.4.2	Cycloserine	Capsule 125 mg
25	6.2.4.4	Ethionamide	Tablet 125 mg
26	6.2.4.5	Isoniazid	Oral liquid 100 mg/5 ml
27	6.2.4.5	Isoniazid	Tablet 50 mg
28	6.2.4.9	Moxifloxacin	Tablet 200 mg
29	6.2.4.10	Para-aminosalicylic acid	Tablet 500 mg
30	6.3.5	Nystatin	Oral Liquid 100, 000 IU/ml
31	6.3.5	Nystatin	Pessary 100,000 IU
32	6.3.5	Nystatin	Tablet 500,000 IU
33	6.4.3.1.1	Abacavir	Tablet 60 mg
34	6.4.3.1.4	Lamivudine (A) + Zidovudine (B)	Tablet 30 mg (A) + 60 mg (B)
35	6.4.3.1.5	Stavudine (A) + Lamivudine (B)	Dispersible Tablet 6 mg (A) + 30 mg (B)
36	6.4.3.1.8	Zidovudine	Oral liquid 50 mg/5 ml
37	6.4.3.1.9	Zidovudine (A) + Lamivudine (B) + Nevirapine (C)	Tablet 60 mg (A) + 30 mg (B) + 50 mg (C)
38	6.4.3.2.1	Efavirenz	Tablet 50 mg
39	6.4.3.2.2	Nevirapine	Dispersible Tablet 50 mg
40	6.4.3.4.3	Lopinavir (A) + Ritonavir (B)	Oral liquid 400 mg (A) + 100 mg (B)/ 5ml
41	6.5.2.2	Miltefosine	Capsule 10 mg
42	6.5.2.2	Miltefosine	Capsule 50 mg
43	6.5.2.3	Paromomycin	Injection 375 mg/ml
44	6.5.4.2	Pentamidine	Powder for Injection 200 mg
45	7.1.3	Sumatriptan	Injection 6 mg/ 0.5 ml
46	8.1.4	All-trans retinoic acid	Capsule 10 mg
47	8.1.8	Calcium folinate	Injection 3 mg/ml

48	8.1.13	Cyclophosphamide	Tablet 200 mg
49	8.1.16	Daunorubicin	Injection 5 mg/ml
50	8.1.19	Etoposide	Capsule 100 mg
51	8.3.2	Cyclosporine	Capsule10 mg
52	8.4.12	Morphine	Tablet 20 mg
53	10.1.2	Ferrous salts	Oral liquid equivalent to 25 mg of elemental iron/ml
54	10.1.2	Ferrous salts	Tablet equivalent to 60 mg of elemental iron
55	10.1.5	Hydroxocobalamin	Injection 1 mg/ml
56	10.2.3	Phytomenadione (Vitamin K1)	Tablet 10mg
57	11.1.1	Fresh frozen plasma	As licensed
58	11.1.2	Platelet rich plasma	As licensed
59	11.1.3	Red blood cel	As licensed
60	11.1.4	Whole blood	As licensed
61	11.3.3	Cryoprecipitate	As licensed
62	14.2.1	Framycetin	Cream 0.5%
63	14.2.3	Methylrosanilinium chloride (Gentian Violet)	Topial preparation 0.25% to 2%
64	14.4.2	Coal tar	Solution 5%
65	14.4.3	Podophyllin resin	Solution 10% to 25%
66	15.1.1	Fluoresceln	Eye drop 1%
67	15.1.2	Lignocaine	Eye drop 4%
68	15.2.1	Barium sulphate	Oral liquid 100% w/v
69	15.2.1	Barium sulphate	Oral liquid 250% w/v
70	15.2.3	Iohexol	Injection 140 to 350 mg iodine/ml (350ml)
71	16.2	Intraperitoneal dialysis solution	As licensed
72	17.1.3	Ethyl alcohol (Denatured)	Solution 70%
73	17.2.1	Bleaching powder	Containing not less than 30% w/w of available chlorine (as per I.P)
74	21.1.3	Hydrocortisone	Injection 100mg/ml
75	21.1.4	Methylprednisolone	Tablet 32 mg
76	21.2.1.2	Ethinylestradiol (A) + Norethisterone	Tablet 0.035 mg (A) + 1 mg (B)
77	21.2.3.1	Condom	As per the standards prescribed in Schedule R of Drugs and Cosmetics rules, 1945
78	21.6.1	Medroxyprogesteroneacetate	Tablet 5 mg
79	22.1.1	Tuberculin, Purified Protein derivative	
80	22.3.1.7	Oral poliomyelitis vaccine	
81	22.3.1.7	Inactivated Polio	
82	25.1.3	Erythromycin	Ointment 0.5%
83	25.1.6	Povidone iodine	Drops 0.6%
84	25.1.6	Povidone iodine	Drops 5%
85	25.2.1	Prednisolone	Drops 0.1%
86	25.5.3	Phenylephrine	Drops 5%
87	27.4.1	Clomipramine	Capsule 10 mg
88	27.4.1	Clomipramine	Capsule 25 mg
89	27.4.1	Clomipramine	Capsule 75 mg
90	29.7	Sodium chloride	Injection 0.45%
91	29.7	Sodium chloride	Injection 3%
92	30.2	Calcium carbonate	Tablet 250 mg
93	30.2	Calcium carbonate	Tablet 500 mg
94	30.5	Nicotinamide	Tablet 50 mg
95	30.6	Pyridoxine	Tablet 50 mg
96	30.7	Riboflavin	Tablet 5 mg
97	30.9	Vitamin A	Capsule 100000 IU
98	30.9	Vitamin A	Capsule 5000 IU
99	30.9	Vitamin A	Injection 50000 IU/ml

ANNEXURE-7

UNIVERSAL CONNECTIONS®
Supporting Export Import Trade
501, Topiwala Centre, 5th Floor, Next to Municipal Market, Goregaon (West), Mumbai - 400 062. India
Tel: 91-22-28721397/28771089 * Fax: 91-22-28771089 * Email: info@universalconnections.in * www.universalconnections.in
KNOWLEDGE • COMPLIANCE • RESULT

Ref No: FTP 2017/Note 1 Date: 12.12.2017

UPDATE ON FOREIGN TRADE POLICY (FTP) – 2015-20

FOR ASSITANCE OF EXPORTER / IMPORTER

Commerce Minister Shri. Suresh Prabhu, announced the much awaited Mid Term Review of the Foreign Trade Policy (FTP) 2015-20 on 5th Dec 2017.

The Highlights and Important changes are given below:

A. General Points:

1. E-BRC system of DGFT will be linked to RBI developed a comprehensive IT-based system called Export Data Processing and Monitoring System (EDPMS) for monitoring of export of goods and software and facilitating AD banks to report various returns through a single platform. ***[FTP Para 1.12(e)]***

2. An effective message sending system is in placed with various stake holders like Customs, Banks and EPCs. Now DGFT will also share the data with GSTN and RBI. ***[FTP Para 1.20(e)]***

3. Total of 19 Sea Ports and 17 Air Cargo Complexes are offering 24x7 Custom Clearance. No MOT charges are required to be collected in respect of the services provided by the Customs officers at 24x7 Custom Ports and Airports. ***[FTP Para 1.25]***

4. Provision for exemption of Service Tax on Service received abroad has been deleted. Service Tax is now part of GST and thus GST provisions will apply on the same. ***[FTP Para 1.32]***

5. The FTP acknowledges the aim of ease of doing business and promoting paperless clearance, CBEC has done away with routine print-outs of several documents including GAR 7 Forms/TR6 Challans, TP copy, Exchange Control copy of Bill of Entry and Shipping Bills and Export Promotion copy of Shipping Bill. **However, hard copy of EP copy of shipping Bill/ Bill of Entry may be provided on request only** ***[FTP Para 1.37]***

6. Consequent to India's ratification of the WTO Agreement on Trade Facilitation (TFA) in April 2016, the National Committee on Trade Facilitation (NCTF) has been constituted. The defined objective behind setting up the NCTF is to have national level body that will facilitate domestic co-ordination and implementation of TFA provisions. It will play the lead role in developing the Pan-India road map for trade facilitation. ***[FTP Para 1.38]***

7. Consequent to Implementation of GST, IEC will be equal to PAN (i.e 10 Digit Alpha Numeric No.) and will be separately issued by DGFT based on the application. ***[FTP Para 2.05(I)]***

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8. Details of Prohibition on Trade with the Islamic State in Iraq and the Levant [ISIL, also known as Daesh], Al Nusrah Front [ANF] and other individuals, groups, undertakings and entities associated with Al Qaida has been notified. ***[FTP Para 2.16A]***

9. Direct or Indirect export and import of items whether or not originating from Democratic People's Republic of Korea (DPRK) to/from DPRK is prohibited and will be governed as per details in Appendix – I of FTP. ***[FTP Para 2.17]***

10. Exemption / Remission on Service Tax when exported from DTA and units in EOU/EHTP /STP/BTP have been deleted. Service Tax is now part of GST and thus, provisions of GST will be applicable w.e.f 01.07.2017. ***[FTP Para 2.40]***

11. Imported goods found defective after custom clearance may be re-exported back as per provisions of Customs Act, 1962. ***[FTP Para 2.50(A)]***

12. Permanent IEC Numbers to be used by 13 Non –Commercial PSUs and Categories or Importers / Exporters which were earlier accorded a 10 Digit Numerical IEC No. has been amended to PAN based IEC No. (i.e 10 Digit Alpha Numerical Nos.) These are mainly for Govt. Agencies, Diplomatic Missions, UN Officials, Personal Use, etc... ***[HBP Para 2.07(b)]***

13. Revalidation of Authorisation / Duty Credit Scrip is being allowed without charging any fees for **the period of delay or six months whichever is less** when delay is for following reasons:

    a. If Authorisation/Scrip or any amendment thereof could not be transmitted to Customs Server within fifteen working days from the date of issue/amendment;
    b. If Authorisation/Scrip rejected by Customs server with error Code;
    c. If request for issue of waiver of Bond/EODC was not considered within the period specified under Para 9.10 of HBP, 2015-2020 where complete application was submitted within the validity of the Authorisation. ***[HBP Para 2.20(d)]***

14. Maintenance of Records for every SCOMET Authorisation Holder for period of 5 year from date of export or import is notified. Details of documents to be maintained in electronic or manual format is been prescribed. ***[HBP Para 2.73(c)]***

15. Provisions for Export Authorisation for "Stock and Sale" of SCOMET items and for Spare Parts of SCOMET Items is notified. ***[HBP Para 2.79(A) & 2.79(B)]***

16. Supply of SCOMET items to Military Stores which are referred to as SCOMET Category 6 items, were allowed against No Objection Certificate (NOC) from Department of Defence Production. The same now shall be allowed against **an Authorisation** issued by Department of Defence Production. The Authorisation will be governed by Standard Operating Procedure (SOP). ***[HBP Para 2.81]***

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17. Time line for Comments, views, No Objection from members of IMWG has been reduced to 30 Days from earlier 45 days. ***[HBP Para 2.82]***

18. Free of cost exports for status holders is allowed with annual limit of Rs. 10 Lakhs or 2% of Average Annual Export realisaiton during preceding 3 Years whichever being lower.

    Now for Pharma Exports, the Annual limit would be 2% of Average Annual Export realisaiton during preceding 3 Years.

    For Govt. Supplies, Supplies of vaccines and life saving drugs to health programmes of International Agencies such as UN and WHO-PAHO, the annual limit shall be upto 8% of average annual export realisation during preceding three licensing year.

    Such Free of Cost supplies shall not be entitled to Duty Drawback or any other export incentive under any export promotion scheme.

    [HBP Para 2.84]

19. Procedure of Track and Trace System for export of drug formulations has been notified under the Handbook. Barcode as per GS1 Global Standards at different packaging levels are required to facilitate tracking and tracing of the product. ***[HBP Para 2.90(A)]***

20. A Scheme of Self Certification for certifying the rules of Origin under GSP has been introduced by European Union (EU) w.e.f 01.01.2017. The Registered Exporter System (REX) will help exporter to self certify by a Statement of Origin of their goods being exporter to EU. The details of the scheme are at Annex 1 to Appendix 2C. ***[FTP Para 2.62 & HBP Para 2.104(c)]***

21. Provisions for Application of Policy Interpretation to Policy Interpretation Committee (PRC) have been notified. ***[HBP Para 2.110 & 2.111]***

22. All Provisions related to Board of Industrial and Financial Reconstruction (BIFR)/Rehabilitation Department have been deleted.

B. Chapter 3 – Duty Credit Scrips

23. MEIS incentive scrips were rewared at 2%, 3% and 5%. A Broad increase of 2% in MEIS has been brought about. The increase has been made for exports made w.e.f 01.11.2017 to 30.06.2018 by way of addition of table no. 2 in Appendix 3B. For exact details, HSN wise product details must be verified.
    [Public Notice 44/2015-20 Dated 05.12.2017]

24. Pre – GST Regime Chapter 3 Scrips were allowed to be use for Payment of Customs Duties (BCD), Central Excise Duties, and Service Tax. However, effective of introduction of GST, Chapter 3 Scrips can only be used for

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a. Payment of Basic Customs Duty and Additional Customs Duty specified under sections 3 (1), 3 (3) and 3 (5) of the Customs Tariff Act, 1975 for import of inputs or goods, including capital goods, as per DoR Notification, except items listed in Appendix 3A.

b. Payment of Central excise duties on domestic procurement of inputs or goods, (For Non GST Products only)

c. Payment of Basic Customs Duty and Additional Customs Duty specified under Sections 3 (1), 3 (3) and 3 (5) of the Customs Tariff Act, 1975 and fee as per paragraph 3.18 of this Policy.

[FTP Para 3.02]

25. Ineligible categories for MEIS have been reduced from 20 to only 7. However, MEIS is granted as per 8 digit ITC (HS) with matching of description. Over 8, 000 odd line items have been included in the MEIS benefit. ***[FTP Para 3.04 & 3.06]***

26. The Policy has specifically notified that RA will not ask for Physical Documents namely: EDI shipping bills, Electronic Bank Realisation Certificate (e-BRC) and RCMC except for cases which are under HBP 3.01(h). ***[FTP Para 3.01(c)]***

27. Details of Jurisdiction for Application of MEIS and SEIS have been notified based on various categories of Exporter. This will assist the exporter to confusion of submission.

[FTP Para 3.06 (b) & (c)]

28. As notified earlier vide P.N.33/2015 Dt. 23.10.2015, Scrips under Chapter 3 will be valid for period of **24 Months from the date of issue**. The Scrip must be valid on the date of actual debit of duty is made. ***[FTP Para 3.13]***

29. Regarding procedure of Declaration of Intent on EDI and Non-EDI shipping bills for claiming reward under MEIS had gone changes at various time periods. It is now notified that:
    a. EDI Shipping Bills: Marking/ ticking of "Y' (for Yes) in "Reward" column of shipping bills against each item, **which is mandatory,** would be sufficient to declare intent to claim rewards under the scheme. In case the exporter does not intend to claim the benefit of reward under Chapter 3 of FTP exporter shall tick "N' (for No). Such marking/ticking shall be required even for export shipments under any of the schemes of Chapter 4 (including drawback), Chapter 5 or Chapter 6 of FTP

    b. Non-EDI Shipping Bills: In the case of non-EDI Shipping Bills, Export shipments would need the following declaration on the Shipping Bills in order to be eligible for claiming rewards under MEIS: "We intend to claim rewards under Merchandise Exports from India Scheme (MEIS)". Such declaration shall be required even for export shipments under any of the schemes of Chapter 4 (including drawback), Chapter 5 or Chapter 6 of FTP. ***[FTP Para 3.14(a)]***

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30. SEIS was applicable for export of services made between 01.04.2015 to 31.03.201 7 only as per Note 1 of Appendix 3D. The said note is amended to read that rates as per Public notice will be applicable to exports between 01.04.2017 to 31.03.2018.An increase in 2% across the board is also been made for the benefit under SEIS. ***[Public Notice 45/2015-20 Dated 05.12.2017]***

31. Transfer of Duty Credit Scrips under HSN 4907 attracts "NIL" GST Rate as notified under GST Rules. ***[IGST Notification No. 36/2017 – Integrated Tax(Rate) Dt. 13.10.2017]***

C. Chapter 4 – Advance Authorisation / DFIA

32. Two more categories have been added to Advance Authorisation is issued for inputs in relation to resultant product, they are:
    - (iii) Applicant specific prior fixation of norm by the Norms Committee.
    - (iv) On the basis of Self Ratification Scheme in terms of Para 4.07A of Foreign Trade Policy.

33. Scheme for Special Advance Authorisation for export of Articles of Apparel and Clothing Accessories has been notified in the policy. ***[FTP Para 4.04A]***

34. Advance Authorisation under Self Ratification Scheme currently only for Authorised Economic Operators (AEOs) has been notified. ***[FTP Para 4.07A]***

35. Imports under Advance Authorisation are exempted from payment of Basic Customs Duty, Additional Customs Duty, Education Cess, Anti-dumping Duty, Countervailing Duty, Safeguard Duty, Transition Product Specific Safeguard Duty, wherever applicable. However, imports under Advance Authorisation for **physical exports** are also exempt from whole of the integrated tax and Compensation Cess leviable under sub-section (7) and sub-section (9) respectively, of section 3 of the Customs Tariff Act, 1975 (51 of 1975), as may be provided in the notification issued by Department of Revenue, and **such imports shall be subject to pre-import condition**. Imports against Advance Authorizations for physical exports are exempted from Integrated Tax and Compensation Cess **upto 31.03.2018 only.** ***[FTP Para 4.14]***

36. Validity of Import Authorisation will be as per Handbook of Procedures. It continues to remain at 12 Months from the date of Issue of authorisation. RA may consider grant of One Revalidation for Six Months from expiry date. ***[FTP Para 4.17, HBP Para 4.41,]***

37. DFIA holder will not be eligible for Advance Release Order / Invalidation Facility. ***[FTP Para 4.20(vi)]***

38. Export Obligation under Advance Authorisation will be as Handbook of Procedures. Export Obligation Period as well remains same to 18 Months from date of issue of Authorisation. Export Obligation for items falling in categories of defense, military store, aerospace and nuclear energy shall be 24 Months. ***[FTP Para 4.22 & HBP Para 4.42]***

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39. DFIA will not be available for Import of **Raw Sugar**. ***[FTP Para 4.25(c)]***

40. HRD Diamond Institute Pvt. Ltd, Maharashtra India and International Gemological Institute (India) Pvt. Ltd, BKC, Mumbai has been added along with existing 3 agencies as agencies permitted to import diamonds to their laboratories without any import duty, for the purpose of certification/grading reports with a condition that the same shall be re-exported with the certification/grading report as per the procedure laid down in Handbook of Procedures. ***[FTP Para 4.42]***

41. Subsequent to GST Regime, Jurisdictional Central Excise officer has been changed to Jurisdictional Customs Authority for intimation and endorsement of duty free inputs from one unit to another or to job worker. ***[HBP Para 4.10]***

42. The auto time limit of 4 months from the application date to Norms Committee for acceptance of the fixation of Adhoc Norms has been deleted. ***[HBP Para 4.16(i)]***

43. The Invalidation letter or ARO issued by DGFT will now have GSTIN details of the supplier along with address where input are required to be processed. ***[HBP Para 4.30(d) & 4.32(c)]***

44. Details and procedure for Regularization of Bona fide default in the cases where Authorisation was issued for import of drugs from unregistered sources with pre import condition is been added in the Handbook. ***[HBP Para 4.49(g)]***

D. Chapter -5 Export Promotions Capital Goods Scheme (EPCG)

45. Calculation of Annual Average Export Obligation under EPCG scheme has been notified in Appendix 5E. ***[Public Notice 47 Dt. 6th Dec 2017 – FTP Para 5.04 (b)]***

46. List of Capital Goods not Permitted or Permitted for Import with Specific Conditions under EPCG Scheme are been separated notified in Appendix 5F. ***[Public Notice 47 Dt. 6th Dec 2017 – FTP Para 5.01]***

47. Addition(s)/deletion(s) of import or export items under EPCG will be allowed subject to submission of fresh Nexus Certificate by an Independent Chartered Engineer and giving justification for seeking such amendments. ***[HBP Para 5.03(c) & (d)]***

48. Jurisdiction Custom Authority replaces Jurisdiction Excise Authority in view GST Regime. ***[HBP Para 5.04(a)]***

49. Provision for RA to condone 5% shortfall in specific export obligation has been deleted. ***[HBP Para 5.21]***

Disclaimer:
The above note is compilation of details, notification, guidance notes etc... and our knowledge on the subject; with available resources at our disposal. You are requested to verify and confirm the laws and legal provision duly updated. The aim of the note is to assist and provide clarity for exporters and importers and interpretation of the legal provisions with practical issues. We shall not be responsible for any acts / omissions / decisions; you take on the basis of this information. You will be sole responsible for any act/omissions or decisions

E. Chapter 6 – EOUs.

50. The procurement of goods covered under GST from DTA would be on payment of applicable GST and compensation cess. The refund of GST paid on such supply from DTA to EOU would be available to the supplier subject to such conditions and documentations as specified under GST rules and notifications issued there under. ***[FTP Para 6.01(d)(iii)]***

51. Applications for conversion into an EOU / EHTP / STP / BTP unit from existing DTA units, having an investment of Rs. 50 crores and above in plant and machinery or exporting Rs. 50 crores and above annually, shall be placed before BOA for a decision. ***[FTP Para 6.19(c)]***

F. Chapter 7 - Deemed Exports

52. **"Deemed Exports" for the purpose of this FTP** refer to those transactions in which goods supplied do not leave country, and payment for such supplies is received either in Indian rupees or in free foreign exchange. Supply of goods as specified in Paragraph 7.02 below shall be regarded as "Deemed Exports" provided goods are manufactured in India

    "Deemed Exports" for the purpose of GST would include only the supplies notified under Section 147 of the CGST/SGST Act, on the recommendations of the GST Council. The benefits of GST and conditions applicable for such benefits would be as specified by the GST Council and as per relevant rules and notification.

    [FTP Para 7.01 & Notification 48/2017 – Central Tax Dt. 18.10.2017]

53. Benefits to Supplier / Recipient under FTP For Deemed Exports ***[FTP Para 7.04]***

Categories of supplies as per Para 7.02	Benefits on supplies, as given in Para 7.03 above, whichever is applicable.		
	Para 7.03 (a) Advance Authorisation	Para 7.03 (b) Duty Drawback	Para 7.03 (c) Terminal Excise Duty
(a)	Yes (for inter mediate supplies against an invalidation letter)	Yes (against ARO)	Yes
(b)	Yes	Yes	Yes
(c)	Yes	Yes	NA
(d)	deleted	deleted	deleted
(e)	Yes	Yes	NA
(f)	Yes	Yes	Yes, only for para 7.08(iii)(a)
(g)	Yes	Yes	NA
(h)	Yes	Yes	NA

54. Deemed exports benefits contained in FTP 2015-20 shall be available for supplies effected till 30.06.2017 in terms of FTP 2015-20 provisions as it stood till 30.06.2017. In respect of supply made after 30.6.2017, new provision shall apply. ***[FTP Para 7.12]***

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G. Chapter 9 – Definitions and Miscellaneous Provisions.

55. Following Definitions have been added to the FTP
    a. **"e-commerce"** for the purpose of Merchandise Exports from India Scheme (MEIS) under Foreign Trade Policy (2015-20) (FTP) shall mean the export of goods hosted on a website accessible through the internet to a purchaser. While the dispatch of goods shall be made through courier or postal mode, as specified under the MEIS, the payment for goods purchased on ecommerce platform shall be done through international credit /debit cards and as per the Reserve Bank of India Circular (RBI/2015-16/185) [A.P.(DIR Series) Circular No. 16 dated September 24, 2015.] as amended from time to time. ***[FTP Para 9.17A]***
    b. **"Project Exports"** refers to export of engineering goods on deferred payment terms and execution of turnkey projects and civil construction contracts abroad collectively.

       Project Exports would encompass (i) Civil construction contracts; (ii) Turnkey Engineering contracts including supply of Capital Goods on deferred payment terms; (iii) Process and Engineering Consultancy Services; and (iv) Project Construction items (excluding Steel and Cement). ***[FTP Para 9.42A]***

56. ***Contact@DGFT*** service Complaint Resolution has been activated on DGFT website with an aim to provide single window contact for all the issues for exporters and importers with respect to foreign trade related issues.

    Exporters can raise they query on the DGFT Website under this option and can tack the status of the query through the assigned reference number.

57. Three New Divisions Namely: Logistics Division, Service Division and State-of-Art Trade Analytics division are being set up.

    The Logistics Division will aim to develop and co-ordinate implementation of action plan for integrated development of logistic sector.

    The Service Division will examine EXIM policies and procedures from the point of view of "Services"

    The Analytics Division will provide DGFT trade information from various national and international data bases to identify specific actions to address export interest in various markets and products.

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(For Private Circulation Only.)

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ANNEXURE 8.

List of Drugs, Medical Devices and Cosmetics declared as Not of Standard Quality/Spurious/Adulterated/Misbranded. For the Month of November, 2017

Sl. No.	Name of Drugs/medical device/cosmetics	Batch No./Date of Manufacture/Date of Expiry/Manufactured By	Reason for failure	Drawn By	From
1.	MOXILIUM® PLUS (Amoxycillin & Dicloxacillin Capsules)	B. No.: BC16085, Mfg dt: 11/2016, Exp dt: 10/2018, Mfd by: M/s. Skymap Pharmaceuticals Pvt Ltd., B3, Dev Bhoomi Industrial Estate, Pohana Iqbalpur Road, Roorkee 247667	Assay of Dicloxacillin	CDSCO (HQ), New Delhi	CDL, Kolkata
2.	Tadalafil Tablets 20mg (TADARISE – 20)	B. No.: 121517, Mfg dt: 05/2017, Exp dt: 04/2020, Mfd by: M/s. Sunrise Remedies Pvt Ltd. (Address is not stated on the sample label)	Dissolution	CDSCO (HQ), New Delhi	CDL, Kolkata
3.	Tadalafil Tablets 40mg (TADARISE – 40)	B. No.: 141517, Mfg dt: 05/2017, Exp dt: 04/2020, Mfd by: M/s. Sunrise Remedies Pvt. Ltd. (Address is not stated on the sample label)	Dissolution	CDSCO (HQ), New Delhi	CDL, Kolkata
4.	CAMCLOX-LB (Amoxycillin & Cloxacillin with Lactic Acid Bacillus Capsules)	B. No.: C-1032, Mfg dt: 05/2017, Exp dt: 10/2018, Mfd by: M/s. Kuemen Laboratories P. Ltd., 2nd Mile Stone, Basai Road, Gurgaon 122001	Assay of Cloxacillin	CDSCO (HQ), New Delhi	CDL, Kolkata
5.	Methylergometrine Injection I.P.	B. No.: I-10203, Mfg dt: 11/2015, Exp dt: 10/2017, Mfd by: M/s. Jackson Laboratories Pvt. Ltd., Bye-Pass, Majhitha Road, Amritsar - 143001	Identification	CDSCO, South Zone, Chennai	CDL, Kolkata
6.	Gentamicin Injection I.P. 80 mg/2 ml,	B. No.: GM-1701, Mfg dt: 01/2017, Exp dt: 12/2018, Mfd by: M/s. Systochem Laboratories Ltd., B-75, Roop Nagar Ind. Area, Loni 201 102, (U.P.).	Description & Particulate Matter	CDSCO, East Zone, Kolkata	CDL, Kolkata
7.	Vitamin B-Complex Tablets with Vitamin B12 & C (BEPLEX PLUS)	B. No.: 12603P, Mfg dt: 12/2016, Exp dt: 05/2019, Mfd by: M/s. Anglo-French Drugs & Industries Limited, Plot No. 4, Phase-II, Peenya Industrial Area, Peenya, Bangalore 560 058	Assay of Cyanocobalamin & Folic Acid	CDSCO, East Zone, Kolkata	CDL, Kolkata

8.	Antemox- P (Dispersible Amoxycillin Tablets I.P.).	B. No.: T-13576, Mfg dt: 02/2017, Exp dt: 01/2019, Mfd by: M/s. Jackson Laboratories Pvt. Ltd., Bypass, Majitha Road, Amritsar - 143004, B.O., 32-33, CBD, Belapur, New Mumbai.	Disintegration & Uniformity of dispersion	CDSCO, East Zone, Kolkata	CDL, Kolkata
9.	Bandage Than (Non Sterile)	B. No.: 20, Mfg dt: 02/2017, Exp dt: 01/2020, Mfd by: M/s. Iris Surgical, Naikuri., West Bengal.	"Threads/dm (Warp/Weft)" "Weight in gm/m^2" "Length & Width", "Foreign Matter" and "Fluorescence"	CDSCO, East Zone, Kolkata	CDL, Kolkata
10.	DULAX (Bisacodyl Tablets I.P.)	B. No.: T7060302, Mfg dt: 06/2017, Exp dt: 05/2019, Mfd by: M/s. ION Healthcare Pvt. Ltd., Baddi, Barotiwala Road, Baddi, Distt. Solan (H.P.) – 173 205.	Related substances & Assay	CDSCO, East Zone, Kolkata	CDL, Kolkata
11.	Geragen (Gentamicin Injection I.P. 2 ml)	B. No.: V10967, Mfg dt: 06/2017, Exp dt: 05/2019, Mfd by: M/s. B.M. Pharmaceuticals, 47-48, Industrial Area, Phase - II, Chandigarh 160 002.	Description & Particulate Matter	CDSCO, Sub Zone, Baddi	CDL, Kolkata
12.	Salif 250 mg (Ceftazidime for Injection I.P.)	B. No.: I-11468, Mfg dt: 05/2016, Exp dt: 04/2018, Mfd by: M/s. Jackson Laboratories Pvt. Ltd., Bye Pass, Majitha Road, Khanna Nagar, P.O. Amritsar, Punjab	Particulate Matter & Clarity of Solution	CDSCO, Sub Zone, Baddi	CDL, Kolkata
13.	Theophylline and Etofylline Injection	B. No.: TE170201, Mfg dt: 02/2017, Exp dt: 01/2019, Mfd by: M/s. Sara Pharmaceuticals, No. 4 & 15 Industrial Estate, Nagercoil, Tamilnadu	Description & Particulate Matter	CDSCO, Sub-Zone/Port office Goa	CDL, Kolkata
14.	TYFY-300 TABLETS (Paracetamol Tablets IP 300 mg)	B. No.:CTQ-01, Mfg dt: 03/2017, Exp dt: 02/2020, Mfd by: M/s. Coastal Medicare Pvt. Ltd., RS No. 9/2, 5, Ramchandrapuram, Surampalli, Krishna Dist-521212, AP	Dissolution	CDSCO, Zonal Office, Hyderabad	CDTL, Chennai
15.	ACICLOVIR DISPERSIBLE TABLETS IP	B. No.: T-14181, Mfg dt: 05/2017, Exp dt: 04/2019,	Disintegration	CDSCO, South-Zone, Chennai	CDTL, Chennai

	200 mg	Mfd by: M/s. Jackson Laboratories Pvt. Ltd., 22-24, Majitha Road, Bye Pass, Amritsar-143001 (India)			
16.	Paracetamol Tablets IP 500 mg	B. No.: B70328, Mfg dt: 05/2017, Exp dt: 04/2019, Mfd by: M/s. Bochem Healthcare Pvt. Ltd., 83-84, Industrial Area, Dewas Road, Nagziri, Ujjain-456010(MP). India	Dissolution	CDSCO, South-Zone, Chennai	CDTL, Chennai
17.	IMIPRAMINE TABLETS IP 25 mg	B. No.: T-14170, Mfg dt: 05/2017, Exp dt: 04/2019, Mfd by: M/s. Jackson Laboratories Pvt. Ltd., 22-24, Bye Pass, Majitha Road, Amritsar-143001	Assay	CDSCO, South-Zone, Chennai	CDTL, Chennai
18.	PANTOPIN – 40 TABLETS	B. No.: T1128, Mfg dt: 04/2017, Exp dt: 03/2019, Mfd by: M/s. India Life Bio Science, B. No. 1185/A-1, Sotnej, Dist. Gandhinagar-382721	Dissolution	Drugs Control Department, Assam	RDTL, Guwahati
19.	Paracetamol Tablets	B. No.: CT70162, Mfg dt: 06/2017, Exp dt: 05/2019, Mfd by: M/s. Omega Biotech Ltd., 7th Mile Stone, Dehradun Road, Roorkee, Uttarakhand-247667	Dissolution	Drugs Control Department, Assam.	RDTL, Guwahati
20.	Paracetamol Tablets	B. No.: GT 60377, Mfg dt: 10/2016, Exp dt: 09/2018, Mfd by: M/s. Omega Biotech Ltd., 7th Mile Stone, Dehradun Road, Roorkee, Uttarakhand-247667	Dissolution	Drugs Control Department, Assam.	RDTL, Guwahati
21.	Paracetamol Tablets	B. No.: CT70153, Mfg dt: 06/2017, Exp dt: 05/2019, Mfd by: M/s. Omega Biotech Ltd., 7th Mile Stone, Dehradun Road, Roorkee, Uttarakhand-247667	Dissolution	Drugs Control Department, Assam	RDTL, Guwahati
22.	Amoxycillin for Oral Suspensions	B. No.: B70317, Mfg dt: 03/2017, Exp dt: 02/2019, Mfd by: M/s. Vysali Pharmaceuticals Limited, IX/639 Edathala, Emakulam-683561	Assay	Drugs Control Department, Assam.	RDTL, Guwahati

23.	Azithromycin Oral Suspensions	B. No.: L-1624702, Mfg dt: 12/2016, Exp dt: 11/2018, Mfd by: M/s. Hanuchem Laboratories, VPO Manpura, Tehsil Baddi, Dist-Solan, H.P.-173205	Assay	Drugs Control Department, Arunachal Pradesh.	RDTL, Guwahati
24.	Azithromycin Tablets	B. No.: AZ50-142, Mfg dt: 12/2016, Exp dt: 11/2018, Mfd by: M/s. Overseas Health Care Pvt. Ltd., 335 km. Milestone, National Highway No. 1, P.O. Box No. 25, Phillaur-144410	Dissolution	Drugs Control Department, Arunachal Pradesh.	RDTL, Guwahati
25.	Pantoprazole Sodium for Injections	B. No.:ADG-135, Mfg dt: 03/2017, Exp dt: 02/2019, Mfd by: M/s. Alliance Biotech, Vill-katha, Baddi, Dist-Solan, H.P.-173205	Particulate Contamination	Drugs Control Department, Arunachal Pradesh.	RDTL, Guwahati
26.	Target 100 Tablets	B. No.: T-1705704, Mfg dt: 05/2017, Exp dt: 04/2019, Mfd by: Not Mentioned.	Misbranded	Drugs Control Department, Tripura.	RDTL, Guwahati
27.	Target 100 Tablets	B. No.: T-1605705, Mfg dt: 12/2016, Exp dt: 11/2018, Mfd by: Not Mentioned.	Misbranded	Drugs Control Department, Tripura.	RDTL, Guwahati
28.	Target 100 Tablets	B. No.: T-1705702, Mfg dt: 04/2017, Exp dt: 03/2019, Mfd by: Not Mentioned.	Misbranded	Drugs Control Department, Tripura.	RDTL, Guwahati
29.	DOTOV – 80 TABLETS	B. No.: ULT-10271, Mfg dt:06/2016, Exp dt: 05/2018, Mfd by: M/s. Ultratech Pharmaceuticals, Vill-Tipra, P.O. Barotiwala, Dist-Solan, H.P.	Misbranded	Drugs Control Department, Mizoram	RDTL, Guwahati
30.	Nor+Metro (Metronidazole and Norfloxacin Tablets)	B. No.: 7001, Mfg dt: 03/2017, Exp dt: 02/2020, Mfd by: M/s. Lesanto Laboratories, Plot No.9,10,11 & 20, Survey No. 53, Palghar (East) 401404	Assay of Metronidazole	CDSCO, West Zone, Mumbai	CDTL, Mumbai
31.	Paracetamol Tablets I.P.	B. No.:APC6036AL, Mfg dt:09/2016, Exp dt:08/2019, Mfd by: M/s. Hindustan Laboratories, Plot No. 5-9,Survey No. 38/2, Aliyali, Palghar (W) 401404 (M.S.)	Dissolution	CDSCO, West Zone, Mumbai	CDTL, Mumbai

32.	Calcitas-D (Calcium with Vitamin D_3 Tablets)	B. No.: IOL-161004, Mfg dt: 10/2016, Exp dt: 09/2018, Mfd by: M/s. Oasis Pharma & Phytomolecules Pvt. Ltd., Village Lodhimajra Road, Nalagarh, Distt. Solan (H.P.)	Assay of Vitamin D3	CDSCO, West Zone, Mumbai	CDTL, Mumbai
33.	Herry Herbal Conditioner Shampoo	B. No.:121, Mfg dt: 02/2017, Exp dt: 07/2018, Mfd by: M/s. Herbs India Products, Post Box No.8426, Delhi-110052	The Foam height for two percent solution & Total Microbial Count	Drugs Control Department, NCT of Delhi	RDTL, Chandigarh
34.	Isosorbide dinitrate Tablets IP	B. No.: ET17002, Mfg dt: 03/2017, Exp dt: 02/2019, Mfd by: M/s. Ortin Laboratories Ltd., 275 &278 (Part), I.D.A. Pashamilaram-502307 Medak, Dist T.S.,India	Assay of Diluted Isosorbide Dinitrate Calculated as Isosorbide Dinitrate	CDSCO, North-Zone, Ghaziabad	RDTL, Chandigarh
35.	Rebeprazole Tablets IP (RABE ROB TABLETS)	B. No.: KR-2503, Mfg dt: 06/2017, Exp dt: 05/2019, Mfd by: M/s. Park Pharmaceuticals, 272, Indl. Area-II, Panchkula-134113	Dissolution (In Acidic medium), (In Buffer Medium) and the Assay of Rebeprazole Sodium	CDSCO, Sub-Zone, Baddi	RDTL, Chandigarh
36.	Metoprolol Succinate Extended Release Tablets USP (UMETLOL-XR-25 TABLETS)	B. No.: UM XT-09, Mfg dt: 02/2017, Exp dt: 01/2019, Mfd by: M/s. Unison Pharmaceuticals, Plot No. 124, E.P.I.P. Ind Area Phase-1, Jharmajri, Baddi (H.P.)	Dissolution (Metoprolol Succinate)	CDSCO, Sub-Zone, Baddi	RDTL, Chandigarh
37.	Stanozolol 10 mg Tablets (STANO-10 TABLETS)	B. No.: 10525, Mfg dt: 02/2017, Exp dt: 02/2020, Mfd by: M/s. Meditech Human Pharmaceuticals Lorachstr, 238, Ingoldheim, Germany.	Uniformity of dosage units, Assay & Dissolution	Drugs Control Department, NCT Delhi	RDTL, Chandigarh

ANNEXURE 9

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

DIRECTOR GENERAL OF HEALTH SERVICES,
MINISTRY OF HEALTH AND FAMILY WELFARE,
GOVERNMENT OF INDIA

CDSCO

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Approval

LIST OF APPROVED DRUG

LIST OF NEW DRUG APPROVED FROM 01-01-2017 to TILL DATE BY NEW DRUGS DIVISION

S.No	Name of drug	Indication	Date of issue
1	Hydrocortisone Aceponate 0.584mg/ml Cutaneous Spray Solution (Vet.)	For symptomatic treatment of inflammatory and pruritic dermatosis in dogs.	06.01.17
2	Dexlansoprazole Delayed Release Capsule 30/60mg & Bulk	For the treatment of i) Healing of all grades of erosive esophagitis (EE). ii) Maintaining healing of EE and relief of heartburn. iii) Treating heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD).	16.01.17
3	Carfilzomib Sterile Lyophilized Powder for Injection 60mg/vial (50ml vial)	Relapsed or refractory multiple myeloma • Carfilzomib for injection is indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy. • Carfilzomib for injection is indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.	17.01.17
4	Dabrafenib 50mg/75mg Capsules (Dabrafenib Mesylate)	As a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test. In combination with Trametinib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test.	18.01.17
5	Trametinib 0.5mg/2mg Tablets (Trametinib Dimethyl Sulfoxide)	As a monotherapy and in combination with Dabrafenib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test.	18.01.17
6	Alectinib 150mg Capsules (Alectinib Hydrochloride)	For the treatment of patients with anaplastic lymphoma kinase (ALK)-Positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Crizotinib.	23.01.17

7	Eliglustat 84mg Capsules (Eliglustat Tartrate or Hemitartrate Salt)	For the long term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an appropriate test.	31.01.17
8	Pasireotide long-acting release 20/40/60mg powder for suspension for injection (Additional Indication) (Pasireotide pamoate)	For the treatment of patients with acromegaly who have had an inadequate response to surgery and/ or for whom surgery is not an option.	14.02.2017
9	Etonogestrel 68 mg implant	For use by women to prevent pregnancy.	15.02.2017
10	Bepotastine Besilate 1.5 %w/v Ophthalmic solution	For the treatment of itching associated with allergic conjunctivitis	22.02.2017
11	Dienogest 2mg Tablets	For the management of Pelvic pain associated with Endometriosis	09.03.2017
12	Eprinomectin 0.5% for beef and dairy cattle (vet.)	It is indicated for the treatment and control of gastrointestinal roundworm (including inhibited Ostertagia ostertagi), lungworm, grubs, sucking and biting lice, chlorioptic and sarcoptic-mange mites, and horn flies in beef and dairy cattle of all ages, including lactating dairy cattle.	14.03.2017
13	Bepotastine Besilate 10 mg Tablets	For the treatment of allergic rhinitis	27.03.2017
14	Prucalopride 1mg/2mg Tablet & Bulk (Prucalopride Succinate)	For the treatment of chronic idiopathic constipation in adults in whom laxatives fail to provide adequate relief	13.04.2017
15	Teriflunomide 14 mg tablets	For the treatment of patients with relapsing form of multiple sclerosis	13.04.2017
16	Pomalidomide 1mg/2mg/3mg/4mg Capsules & Bulk	In combination with dexamethasone, for patient with patient multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.	01.05.2017
17	Sofosbuvir 400 mg +Velpatasvir 100 mg Tablet	For the treatment of adult patients with -chronic Hepatitis C virus, Genotype 1,2,3,4,5 or 6 infection. -Without cirrhosis or with compensated cirrhosis -With decompensated with chronic for use in combination with Ribavirin.	04.05.2017
18	Velpatasvir Bulk		04.05.2017
19	Osimertinib 40 mg/80 mg Film coated Tablets (Osimertinib Mesylate)	For the treatment of patient with metastatic epidermal growth factor receptor (EGFR) T790 M mutation-positive non-small cell lung cancer (NSCLC), as detected by an appropriate test, whose disease has progressed on or after EGFR TKI therapy	29.05.2017
20	Argatroban Hydrate Bulk & Injection 250 mg/2.5 ml	1) For prophylaxis or treatment of thrombosis in adult patients with Heparin induced thrombocytopenia (HIT). 2) As an anticoagulant in adults patients with or at risk for heparin-induced thrombocytopenia undergoing percutaneous coronary intervention (PCI)	30.05.2017
21	Fluralaner chewable tablets 112.5 mg/250 mg/500mg/1000mg/1400 mg	For the treatment of tick and flea infestations on dogs for 12 weeks. This veterinary medicinal product is a systemic insecticide and acaricide with a long duration of action that provides immediate and persistent tick (adult and juvenile Ixodes ricinus, *Ixodes hexagonus, Ixodes scapularis, Ixodes holocyclus, Dermacentor reticulates, Dermacentor variabilis and Rhipicephalus sanguineus)* and flea *(Ctenocephalides felis and Ctenocephalides canis*) killing activity for 12 weeks. Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance. the onset of effect is within 8 hours of attachment for fleas (*C. felis*) and 12 hours of attachment for ticks *(I. ricinus*)	30.5.2017

		The product effectively controls environmental flea population in area to which treated dogs have access. The product can be used as part of an treatment strategy for the control of Flea Allergy Dermatitis (FAD)	
22	Fluticasone Furoate (100 mg mcg) and Vilanterol Trifenatate (25 mcg) powder for inhalation	Indicated for the maintenance treatment of the airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/ or emphysema and to reduce exacerbation of COPD in patients with an exacerbation history.	29.06.2017
23	Mirabegron Prolonged Release Tablet 25 mg /50 mg	Symptomatic treatment of urgency, increased micturition frequency and / or urgency incontinence as may occur in patients with over active bladder (OAB) Syndrome	12.07.2017
24	Delamanid 50 mg tablet	For the use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability	02.08.2017
25	Mirabegron Prolonged Release Tablet 25 mg /50 mg & Bulk	Symptomatic treatment of urgency, increased micturition frequency and / or urgency incontinence as may occur in patients with over active bladder (OAB) Syndrome	18.08.2017
26	Efonidipine Hydrochloride Ethanolate Bulk & Tablets 10 mg/20mg/40mg	Indicated for the management of • Hypertension • Renal parenchymal hypertension • Angina	28.08.2017
27	Brivaracetam Film Coated Tablets 50mg/75mg/100mg	As adjunctive therapy in the treatment of partial -onset seizures in patients 16 years of age and older with epilepsy	07.09.2017
28	Treosulfan Bulk & injection 5g/vial	For the conditioning treatment prior to haematopoetic stem-cell transplantation	26.09.2017
29	Ribociclib 200 mg Film coated Tablets	In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of post menopausal women with the hormone receptor (HR)-Positive, human epidermal growth factor receptor 2 (HER2)-Negative advanced or metastatic breast cancer	27.09.2017
30	Dienogest Bulk & 2mg Tablet	For the management of Pelvic pain associated with Endometriosis	28.09.2017
31	Apremilast bulk & film coated tablets 10 mg/20 mg/30 mg	for treatment of patients with moderate to severe plaque psoriasis who are candidate for phototherapy or systemic therapy	13.10.2017
32	Arbekacin bulk & Injection 200mg/4ml	Treatment of following infections caused by Methicillin resistant Staphylococcus aureus (MRSA)", sepsis pneumonia	20.10.2017
33	Benestermycin Intra-mammary suspension (vet.)	For the treatment of subclinical mastitis at drying off, and the prevention of new bacterial infections of the udder during the dry period in dairy cows, caused by bacteria susceptible to penicillin and framycetin	03.11.2017
34	Midostaurin 25 mg Capsules	• In combination with standard induction and consolidation chemotherapy followed by single agent in maintenance of therapy for adult patients with newly diagnosed with acute myeloid leukemia (AML) who are FLT-3 Mutation positive. • For the treatment of adult patients with advanced systemic mastocycosis (Advanced SM)	09.11.2017
35	Tenofovir Alafenamide Fumarate bulk & 25 mg capsules	For the treatment of chronic Hepatitis B virus infection in adults with compensated liver disease	10.11.2017
36	Arteolane Maleate and Piperaquine phosphate Dispersible tablets (37.5 mg +187.5 mg	Indicated in children aged 6 months to 12 years for the treatment of : - Acute uncomplicated Plasmodium falciparum malaria infection - Acute uncomplicated Plasmodium Vivax malaria infection	24.11.2017
37	Macitentan Bulk and Tablets 10 mg	Macitentan is an endothelin receptor antagonist (ERA)l indicated for the treatment of Pulmonary arterial hypertension (PAH, WHO group I) to delay disease progression	07.12.2017

LIST OF NEW DRUG APPROVED FROM 01-01-2016 to TILL DATE BY NEW DRUGS DIVISION

S.No	Name Of Drug	Indication	Date of issue
1	Nintedanib soft Gelatin Capsule 100/150mg (Nintedanib ethanesulfonate)	For the treatment of Idiopathic Pulmonary Fibrosis (IPF).	11.03.16
2	Cisatracurium Besylate Bulk & 2mg/ml injection	As an adjunct to general anaesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery.	14.03.16
3	Fomepizole Bulk & Fomepizole Injection 1.5gm/Ampoule	As an antidote for Ethylene glycol or Methanol used poisoning or for use in suspected Ethylene glycol or Methanol ingestion, either alone or in combination with hemodialysis.	14.03.16
4	Tofacitinib Tablets 5 mg(Tofacitinib Citrate)	"For the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to Methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs)".	01.04.16
5	Nintedanib Soft Gelatin Capsule 100/150mg (Nintedanib ethanesulfonate)	"In combination with docetaxel for the treatment of adult patients with locally advanced, metastatic or recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumor histology after line chemotherapy".	01.04.16
6	Ceftaroline Fosamil Injection 600 mg/Vial	"For the treatment of adult (≥ 18 years of age patients with community-acquired pneumonia".	09.05.2016
7	Panobinostat Hard Gelatin Capsules 10mg/15mg/20mg (Panobinostat lactate)	"In combination with bortezomib and dexamethasone, is indicated for the treatment of patients with multiple myeloma, who have received at least 1 prior therapy"	27.05.2016
8	Bepotastine Besilate Bulk & Bepotastine Besilate 1.5 %w/v Ophthalmic solution	"For the treatment of itching associated with allergic conjunctivitis"	08.06.16
9	Ibutilide Bulk & Ibutilide Fumarate Injection 0.1mg/ml	"For the rapid conversion of atrial fibrillation or atrial flutterof recent onset to sinus rhythm. Patient with atrial arrhythmias of longer duration are less likely to respond to Ibutilide Fumarate Injection. The effectiveness of Ibutilidehas not been determined in	10.06.16

		patients with arrhythmias of more than 90 days in duration".	
10	Acotiamide Hydrochloride Bulk & Tablet 100mg	"For the treatment of bloating after meals, epigastric bloating and early satiety in functional dyspepsia".	06.07.2016
11	Sacubutril+ Valsartan film coated tablets 50mg/100 mg/200mg	"To reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction".	14.07.2016
12	Lurasidone Hydrochloride Bulk & Lurasidone Hydrochloride Tablets 40mg/80mg	"For the treatment of Patients with Schizophrenia"	18.07. 16
13	Fenticonazole Nitrate Vaginal Capsule 600 mg	"For the treatment of vulvovaginal candidiasis"	10.08.2016
14	Palbociclib Capsules 75mg/100mg/125 mg	"Palbociclib is a kinase inhibitor indicated in combination with Letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-Positive, human epidermal growth factor receptor 2 (HER2)-Negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease".	11.08.2016
15	Midodrine Hydrochloride 2.5 mg Tablet	"For the treatment of symptomatic orthostatic hypotension"	02.09.2016
16	Phospholipids Fraction from Bovine Lung (surfactant) 50 mg/vial	"Preventive use in premature neonates with a high risk of respiratory Distress Syndrome"	12.09.2016
17	Dolutegravir 50 mg Tablet & Bulk (Dolutegravir Sodium)	"Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults weighing more than 40 kg"	07.11.2016
18	Alcaftadine Eye Drops 0.25% w/v & Bulk	"For the prevention of itching associated with allergic conjunctivitis in patients between the age group 10 to 60 years"	21.11.2016
19	Bepotastine Besilate Bulk		23.11.2016
20	Lenvatinib 4mg/10mg Hard Gelatin Capsules (Lenvatinib Mesylate)	"For the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer"	02.12.2016

21	Perampanel 2mg/4mg/6mg/8mg/10mg/12mg Tablets	"The adjunctive treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older"	02.12.2016
22	Azilsartan Medoxomil Bulk & 40mg/80mg Tablets	"Indicated for the treatment of hypertension in adults patients, either alone or in combination with other antihypertensive agents"	09.12.2016

LIST OF APPROVED DRUG FROM 01-01-2015 to 31-01-2015

S.No	Name Of Drug	Indication	Date of issue
1	Sofosbuvir Tablet 400 mg	"In combination with other medicinal products for the treatment of chronic Hepatitis C (CHC) in adults".	13.01.2015
2	Bedaquiline Tablet 100 mg	"In adults (≥ 18 years), as part of Combination therapy of pulmonary tuberculosis due to multi-drug resistant Mycobacterium tuberculosis when an effective treatment regimen cannot Otherwise be provided".	14.01.2015
3	**Lixisenatide** pre-filled solution for injection 10µg/20 µg	For the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in patients who are not controlled on existing therapy: In combination with the following oral antibiotics: -Metformin, a sulphonyl urea, or a combination of these agents. In combination with a basal insulin: alone, in combination with metformin, or in combination with sulphonyl urea.	15.01.2015
4	Dapagliflozin Tablet 5mg/10mg	"In adult aged 18 years and older with Type-II diabetic mellitus to improve glycemic control: As mono-therapy when diet and exercise alone do not provide adequate glycemic control in patients for whom use of metformin is considered inappropriate due to intolerance. As add-on combination therapy in combination therapy in combination with other glucose- lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycemic control"	25.02.2015
5	Pasireotide solution for injection 0.3mg/0.6mg/0.9mg	"For the treatment of adult patients with Cushing's disease for whom pituitary	18.03.2015

		surgery is not an option or has not been Curative"	
6	Emphagliflozin Tablet 10mg/25mg	"As an adjunct to diet and exercise to improve glycemic Control in adults with Type 2 diabetes Mellitus."	07.05.2015
7	Gadobutrol solution for injection	"In adult, adolescence and children aged 2 years and older for: 1.contrast enhancement in cranial and spinal magnetic resonance imaging (MRI). 2. Contrast enhancement MRI of other body regions: liver kidneys. 3. Contrast enhancement in Magnetic Resonance Angiograpy (CE-MRA) 4.For MRI of the breast to assess the presence and extent of malignant breast	07.05.2015
8	Teneligliptin Tablet 20mg	For the treatment of Type 2 Diabetes Mellitus as a Monotherapy adjunct to diet and Exercise	18.05.2015
9	Ceritinib 150 mg Hard Gelatin Capsules	"For the treatment of patients with Anaplastic lymphoma Kinase (ALK)-positive metastatic non- small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib"	13.01.2015
10	Vilazodone Hydrochloride 20mg/40mg and Bulk	"For the treatment of Major depressive disorders in adults"	19.08.15
11	Gemigliptin 50mg tablets	" As an adjunct to the diet & exercise to improve to improve glycemic control in adults with type-2 diabetes mellitus, as an monotherapy or in combination with metformin in patients with inadequate glycemic control on metformin alone"	21.08.15
12	Atosiban Acetate Injection 6.75mg/0.9ml and Bulk	"Indicated to delay imminent pre-term birth in pregnant adult women with: -regular uterine contractions of at least 30 Seconds duration at the rate of ≥ 4 per 30 minutes -a cervical dilation of 1 to 3 cm (0-3 for nulliparas) and effacement of ≥50% - a gestational age from 24 until 33 Completed weeks a normal foetal heart rate"	16.09.15
13	Ibrutinib Hard gelatin Capsule 140mg	"For the treatment of adult patients with:- -mantle cell lymphoma (MCL) who have received at least one prior therapy. -Chronic Lymphocytic leukemia (CLL) who have received at least one prior therapy. - Chronic lymphocytic leukemia with 17p deletion"	07.10.2015
14	Ledipasvir (90mg)+ Sofosbuvir (400mg) Tablet	" For the treatment of chronic hepatitis C (CHC) Genotype 1 infection in adults"	08.12.2015
15	Ledipasvir Bulk		08.12.2015
16	Daclatasvir Dihydrochloride bulk & Tablet 30mg/60mg	"For use with Sofosbuvir for the treatment of patient with chronic hepatitis C virus (HCV)	14.12.2015

		genotype 3 infection"	
17	Enzalutamide 40 mg soft Capsule	"For the treatment of adults with metastatic castration resistant prostate cancer whose disease has progessed on or after Docetaxel therapy	18. 12 .2015

Start date: 09/02/2015

End date: 01/12/2066