Annexure A

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	18.01.17

		with BRAF V600E mutation as detected by an appropriate test.	
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	01.05.2017

		proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.	
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*) The product effectively controls environmental flea population in area to which treated dogs have access.	30.5.2017

		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	20.10.2017

		(MRSA)", sepsis pneumonia	
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

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 patients with arrhythmias of more than 90 days in duration".	10.06.16
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:	15.01.2015

		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.	
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 surgery is not an option or has not been Curative"	18.03.2015
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:	07.05.2015

		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	
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	16.09.15

		for nulliparas) and effacement of ≥50% - a gestational age from 24 until 33 Completed weeks a normal foetal heart rate"	
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) genotype 3 infection"	14.12.2015
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

ANNEXURE B

F. No: 7-5/2017/DCG(I)/MISC(099)
Directorate General of Health Services
Office of Drug Controller General (India)

FDA Bhawan, Kotla Road,
New Delhi-110002.

Dated:- 24 NOV 2017

To,
All State/UT Drugs Controllers

Subject: Amendment in the Drugs and Cosmetics Rules, 1945 vide Notification No. G.S.R 1337(E) dated 27.10.2017 regarding validity of licence & provision for joint inspection of manufacturing premises for grant of licence for manufacture for sale of Drugs and Cosmetics & verification of compliance –Reg.

Sir,

Ministry of Health and Family Welfare, Government of India has amended the Drugs and Cosmetics Rules, 1945 vide Notification No. G.S.R.1337 (E) dated 27.10.2017 providing that manufacturing licence for drugs and cosmetics and approval of drugs/cosmetics testing laboratories shall remain valid if the licencee deposits licence retention fee before the expiry of period of every succeeding five years from the date of issue, unless, it is suspended or cancelled by the licensing authority.

The amendment also provides that before grant of licence in Form 25 or Form 25A or Form 25B or Form 25F or Form 28 or Form 28A or Form 28B or Form 28D or Form 28DA to manufacture for sale or for distribution of Drugs or in Form 32 or Form 32A or Form 33 for manufacture of Cosmetics, the State Licensing Authority shall cause the manufacturing premises to be inspected jointly by the Central and State Drugs Inspectors. Further, the premises licensed shall be inspected jointly to verify the compliance with the conditions of licence and the provisions of the Act and the Rules not less than once in three years or as needed as per risk based approach.

Copy of the notification is enclosed herewith for your information and necessary action.

In this regard, for effective and uniform implementation of the provisions of joint inspection of manufacturing premises, detailed guidelines would be prepared in consultation with the State Drugs Controllers and other stakeholders.

However, in the meantime to ensure smooth processing of applications for grant of manufacturing licenses following modalities may be followed.

i. Applications for the grant of manufacturing licenses complete in all respect as per the provisions of the Drugs and Cosmetics Act, 1940 an Rules, 1945 should be submitted by the manufacturers to the respective State Licensing Authority.
ii. The State Licensing Authority should fix a date for joint inspection of the manufacturing premises, in coordination with the respective Zonal/Sub-Zonal offices of CDSCO at least seven days prior to the date of inspection.

iii. In case drugs inspector of CDSCO Zonal/Sub-Zonal offices is not available on any specific date, drugs inspector from CDSCO (HQ) will be deputed for the joint inspection.

iv. Proper coordination between the State Licensing Authorities, CDSCO HQ and Zonal/Sub-Zonal offices should be ensured for timely inspection and processing of the applications.

v. In case of deficiency in the application in respect of any inspection, the joint inspection team may verify such documents during the inspection and record details of the same in the inspection report.

Your cooperation and valuable feedback or suggestions in this regard will be highly appreciated for further improvement in the implementation of the new rules.

Yours faithfully

24-11-17

Dr. G. N. Singh
Drugs Controller General (India)

Copy to : All Zonal | Sub-Zonal offices, CDSCO.

c.c. PPS to DGHS

" JS(R)

ANNEXURE C

File No. X-11026/163/2017-BD
Directorate General of Health Services
Ministry of Health and Family Welfare
Central Drugs Standard Control organization
Office of Drugs Controller General (India)
(Biological Division)

Dated: 27 NOV 2017

To,

All State/UT Drugs Controllers

It has been reported that the sample of Snake Venom Antiserum I.P., Lyophilized, (Equine Origin) Batch No. A05315062, Mfg. Date: May'2015, Expiry date: April'2019, manufactured by M/s Bharat Serums & Vaccines, Ltd., Ambernath – 421 501, was declared as Not of Standard Quality by CDL, Kasauli with respect to potency test, vide test report no. CDL/2017/GA16 dated 11.10.2017.

In this regard, all the State/UT Drugs Controllers, CDSCO Zonal or Sub-Zonal officers are requested to direct the inspectorate staff under their control to keep strict vigil on the movement of said product (Batch no. A05315062) in the market.

(Dr. G. N. Singh)
Drugs Controller General (India)

Copy for necessary action to:

1. CDSCO Zonal or Sub-Zonal Offices

ANNEXURE D

List of Drugs, Medical Devices and Cosmetics declared as Not of Standard Quality/Spurious/Adulterated/Misbranded, For the Month of **October, 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.	Oxytocin Injection I.P. 1 ml	B. No.: OX-1616, Mfg dt: 12/2016, Exp dt: 11/2018, Mfd by: M/s. Systochem Laboratories Ltd, B-75, Roop Nagar, Indl Area, Loni – 201 102(U.P)	Description & Particulate Matter	CDSCO, South Zone, Chennai	CDL, Kolkata
2.	Serratiopeptidase Tablets I.P. 10 mg	B. No.: N1604042, Mfg dt: 04/2016, Exp dt: 03/2018, Mfd by: M/s. Talent Healthcare, 66-67, Sector 6A, SIDCUL, IIE, Haridwar 249 403, (Uttarakhand)	Disintegration & Assay	CDSCO, South Zone, Chennai	CDL, Kolkata
3.	Carbimazole Tablets I.P. 5 mg	B. No.: T-12112, Mfg dt: 08/2016, Exp dt: 07/2018, Mfd by: M/s. Jackson Laboratories Pvt. Ltd., 22-24, Majitha Road, Bye Pass, Amritsar 143 001	Description, Identification & Assay	CDSCO, South Zone, Chennai	CDL, Kolkata
4.	Erythromycin Stearate Tablets I.P. 250 mg	B. No.: ES-1602, Mfg dt: 04/2016, Exp dt: 03/2018, Mfd by: M/s. Minopharm Laboratories Pvt. Ltd., Hyderabad 500 073, Works: Opp. I.D.A, Pernamitta - 523002	Dissolution	CDSCO, South Zone, Chennai	CDL, Kolkata
5.	ELPRIL 2.5 (Enalapril Maleate Tablets I.P.)	B. No.: AP6109, Mfg dt: 03/2016, Exp dt: 02/2018, Mfd by: M/s. Affy Parenterals, Village: Gullerwala, P.O. Baddi, Solan 173 205 (H.P.)	Uniformity of Content, Dissolution & Assay	CDSCO, East Zone, Kolkata	CDL, Kolkata
6.	ELPRIL 5 (Enalapril Maleate Tablets I.P.)	B. No.: AP7042, Mfg dt: 02/2017, Exp dt: 01/2019, Mfd by: M/s. Affy Parenterals, Village: Gullerwala, P.O. Baddi, Solan 173 205 (H.P.).	Uniformity of Content, Dissolution & Assay	CDSCO, East Zone, Kolkata	CDL, Kolkata
7.	Oxymac (Oxytocin Injection I.P.)	B. No.: OT-16010, Mfg dt: 03/2016, Exp dt: 02/2018, Mfd by: M/s. Macin Remedies India Ltd, B-21, Ind. Focal Point, Moga-	Description & Particulate Matter	CDSCO, East Zone, Kolkata	CDL, Kolkata

		142001			
8.	Levocetirizine Tablets I.P. 5 mg	B. No.: 9700717, Mfg dt: 05/2017, Exp dt: 04/2020, Mfd by: M/s. Karnataka Antibiotics &Pharmaceuticals Limited, Plot No. 14, II Phase, Peenyar, Bangalore 560 068	Related Substances	CDSCO, East Zone, Kolkata	CDL, Kolkata
9.	Amikacin Sulphate Injection I.P. 250mg/ml	B. No.: P7171, Mfg dt: 04/2017, Exp dt: 03/2019, Mfd by: M/s. Bharat Parenterals Ltd., Vill. Hariupra, Ta. Savli, Dist-Vadodara - 391520, Gujarat.	Description & Particulate Matter	CDSCO, East Zone, Kolkata	CDL, Kolkata
10.	L-BEX-OD (Alpha Lipoic Acid, Pyridoxine Hydrochloride Methylcobalamin, Folic Acid & Vitamin D_3 Tablets)	B. No.: LBDT16003, Mfg dt: 08/2016, Exp dt: 01/2018, Mfd by: M/s. Ravian Life Science Pvt. Ltd., Plot No. 34, Sector-8A, IIE, SIDCUL, Haridwar-249403	Disintegration	CDSCO, East Zone, Kolkata	CDL, Kolkata
11.	Anodex (Dexamethasone Sodium Phosphate Injection I.P. 4mg/ml)	B. No.: FN-231, Mfg dt: 11/2016, Exp dt: 10/2018, Mfd by: M/s. COAX Bioremedies Pvt. Ltd., 83, Sec-28, Industrial Area, Delhi Road, Hisar 125 044	Description, Particulate Matter	CDSCO, East Zone, Kolkata	CDL, Kolkata
12.	Tramicort 40 mg/ml (Triamcinolone Acetonide Injection I.P. 1 ml)	B. No.: VI7074, Mfg dt: 05/2017, Exp dt: 04/2019, Mfd by: M/s. Scott-Edil Pharmacia Limited, 56, E.P.I.P, Phase - I, Jharmajri 173 205	Extractable Volume	CDSCO, Head Quarter, New Delhi	CDL, Kolkata
13.	Becomax Forte (B-Complex with Vitamin C Capsules)	B. No.: HL0099, Mfg dt: 12/2016, Exp dt: 05/2018, Mfd by: M/s. Hindustan Laboratories, Plot No. 5-9, Survey No. 38/2, Aliyali Village, Palghar (W), Dist. Palghar-401404	Assay of Folic Acid	CDSCO, Head Quarter, New Delhi	CDL, Kolkata
14.	Prednisolone Tablets I.P	B. No.: AT17077, Mfg dt: 05/2017, Exp dt: 04/2020, Mfd by: M/s. Arbro Pharmaceuticals Pvt Ltd, 6/14, Kirti Nagar, Industrial	Related Substances	CDSCO, Head Quarter, New Delhi	CDL, Kolkata

		Area, New Delhi-110015			
15.	Gentamicin Injection I.P. 2 ml	B. No.: 5000816, Mfg dt: 05/2016, Exp dt: 04/2018, Mfd by: M/s. Karnataka Antibiotics &Pharmaceuticals Limited , Plot No 14, II Phase, Peenyar, Bangalore-560058	Description, Particulate Matter	CDSCO, North Zone, Ghaziabad	CDL, Kolkata
16.	Amikacin Sulphate Injection I.P. 500 mg - 2 ml	B. No.: 7901616, Mfg dt: 05/2016, Exp dt: 04/2018, Mfd by: M/s. Karnataka Antibiotics &Pharmaceuticals Limited , Plot No 14, II Phase, Peenyar, Bangalore-560058	Description, Particulate Matter	CDSCO, North Zone, Ghaziabad	CDL, Kolkata
17.	Ajanta Brand Rolled Bandages (Non Sterilized) 20 x 14 Superfine	B. No.: B.420, Mfg dt: 05/2017, Exp dt: 04/2020, Mfd by: M/s. Ajanta Surgical Industries, Kanth (Moradabad, U.P).	Threads/dm (Warp/Weft), Wt. in gm/m^2, Length, Foreign Matter, Fluorescence	CDSCO, North Zone, Ghaziabad	CDL, Kolkata
18.	Dexamethasone Sodium Phosphate Injection I.P 2ml	B. No.: HLI612H, Mfg dt: 08/2016, Exp dt: 07/2018, Mfd by: M/s. Himalaya Mediteck Private Ltd., Plot No. 35 & 36, Pharmacity, Selaqui, Industrial Area, Dehradun - 248197	Description, Particulate Matter & Bacterial Endotoxins	CDSCO, North Zone, Ghaziabad	CDL, Kolkata
19.	Dysmeril – Spas (Mefenamic Acid & Dicyclomine HCl Tablets)	B. No.: JBT-2843, Mfg dt: 04/2016, Exp dt: 03/2018, Mfd by: M/s. J. B. Remedies Pvt. Ltd., 11th Mile Stone, Roorkee Road, KH. No. 298, Vill. Kurdi, Manglaur, Roorkee, Haridwar - 247 667 (U.K.).	Disintegration	CDSCO, Hyderabad Zone	CDL, Kolkata
20.	CEZOTUM$^{(R)}$ 1g (Cefoperazone & Sulbactam for Injection) & Sterile Water for Injection I.P.	B. No.: UP16034, Mfg dt: 12/2016, Exp dt: 11/2018, Mfd by: M/s. Unimark Remedies Ltd., At Plot No. 23, EPIP, Phase - II, Thana Baddi -173205, Dist- Solan (H.P.) B. No.: WB6L10, Mfg dt: 12/2016,	Particulate Matter & Clarity of Solution	CDSCO, Hyderabad Zone	CDL, Kolkata

		Exp dt: 11/2019, Mfd by: M/s. Auraya Healthcare, Plot No. 80E, E.P.I.P. Phase 1, Jharmajri, Baddi, H.P. India			
21.	Blue Valley Shaving Cream	B. No.: B-27, Mfg dt: 07/2017, Exp dt: 06/2020, Mfd by: M/s. Shree Sudarshan Cosmetics DSIDC Indl. Complex Narela, Delhi-110040	Total Microbial Count	Drugs Control Department N.C.T. Delhi	RDTL, Chandigarh
22.	Cefadroxil Oral Suspension IP	B. No.: CLS1701, Mfg dt: 02/2017, Exp dt: 01/2019, Mfd by: M/s. Modern Laboratories 45-47, Sector D-2, Sanwer Road Indore (M.P)-452015.	Assay of Cefadroxil calculated as Anhydrous Cefadroxil	CDSCO, Sub-Zone, Jammu	RDTL, Chandigarh
23.	Diclofenac Potassium, Paracetamol and Serratiopeptidase Tablets (RECOV-SR TABLETS)	B. No.:T-170746 , Mfg dt: 07/2017 Exp dt: 06/2019 Mfd by: M/s. Medirose Drugs & Pharmaceuticals 51, Industrial Area, Phase-III, Sansarpur Terrace, Distt. Kangra, Pin-176501 (H.P)	Disintegration	CDSCO, Sub-Zone, Baddi	RDTL, Chandigarh
24.	Iron, Folic Acid Tablets IP (SAMFER SMALL TABLETS)	B. No.: TX-12052 , Mfg dt: 06/2017 , Exp dt: 05/2019, Mfd by: M/s. Legen Healthcare, Plot No. 20, Sector-5, Parwanoo, Distt. Solan (H.P)-173220	Identification of Folic Acid	CDSCO, Sub-Zone, Baddi	RDTL, Chandigarh
25.	Cefixime and lactic Acid Bacillus Dispersible Tablets (THEOXIME –LB TABLETS)	B. No.: THG160043, Mfg dt: 09/2016 Exp dt: 08/2018 Mfd by: M/s. Theon Pharmaceuticals Ltd., Vill. Saini Majra, Tehsil Nalagarh, Dist. Solan H.P.-174101	Assay of Lactic Acid Bacillus	CDSCO, North Zone, Ghaziabad	RDTL, Chandigarh
26.	Chlorhexidine Mouthwash I.P. 0.2% w/v	B. No.: 616-571, Mfg dt: 03/2016, Exp dt: 02/2018, Mfd by: M/s. Zee Laboratories Ltd., Behind 47, industrial Area, Paonta Sahib-173025	Assay	CDSCO, West Zone, Mumbai	CDTL, Mumbai
27.	Chloroquine (Chloroquine Phosphate Tablet IP. 250mg)	B. No.: M-9504, Mfg dt: 03/2016, Exp dt: 02/2018, Mfd by: M/s. Herb Edge Health Care Pvt. Ltd., 81-82-86-87, Industrial Area, Dewas Road, Ujjain-456010.	Assay	CDSCO, West Zone, Mumbai.	CDTL, Mumbai

28.	Chloroquine Phosphate Tablets IP	B. No.: MPC 6004, Mfg dt: 03/2016 Exp dt: 02/2019 Mfd by: M/s. Halewood Laboratories Pvt. Ltd., 319, Phase-II, G.I.D.C., Vatva, Ahmedabad-382445.	Assay	CDSCO, Sub-Zone, Indore	CDTL, Mumbai
29.	Diazepam Tablets I.P. 5mg	B. No.: DZT409 , Mfg dt: 10/2016 Exp dt: 09/2018 Mfd by: M/s. Unicure India Ltd., C-22 &23, Sector-3, Noida, Uttar Pradesh 201301.	Related Substances & Decomposition Products	CDSCO, Sub Zone/Port Office, Goa	CDTL, Mumbai
30.	Bisacodyl Tablets IP 5mg	B. No.: 603324, Mfg dt: 08/2016, Exp dt: 07/2018, Mfd by: M/s. Ciron Drugs & Pharmaceuticals Pvt. Ltd., Plot No. 35 to 37, 43 to 45, CFC-B, Dewan Udyog Nagar, Aliyali, Palghar, Dist-Thane-401404.	Assay	CDSCO, West Zone, Mumbai	CDTL, Mumbai
31.	Amikacin Sulphate Injection I.P. 100mg	B. No.: AK1611, Mfg dt: 06/2016, Exp dt: 05/2018, Mfd by: M/s. Nandani Medical Laboratories Pvt. Ltd., 221/5, Bicholi Hapsi, Kanadia Road, Indore.	Test for sterility	CDSCO, Sub Zone, Indore	CDTL, Mumbai

ANNEXURE E

542. डेसोक्सीमेटासन

543. डेक्सामेथासोन

544. डिफ्लोरासन डाइएसीटेट

545. फ्लूओसीनोनाइड

546. फ्लूओसिनोलोन एसीटोनाइड

547. हालोबीटासल प्रोपिओनेट

548. हालोमेटासन

549. मिथाइलप्रेड्निसोन

550. प्रेड्निकार्बेट

551. ट्रिअमसिनोलोन एसीटोनाइड"

[फा.सं. एक्स- 11014/14/2017-डीआरएस]

सुधीर कुमार, संयुक्त सचिव

पाद टिप्पण: मूल नियम सरकारी राजपत्र में अधिसूचना सं. एफ.28-10/45-एच(1) दिनांक 21 दिसम्बर, 1945 में प्रकाशित हुए थे और अधिसूचना सं. सा.का.नि.....(अ) दिनांक .... द्वारा अंतिम बार संशोधित किए गए थे।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 1st November, 2017

G.S.R.1357(E).—The following draft of certain rules, which the Central Government proposes to make, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in consultation with the Drugs Technical Advisory Board is hereby published for information of all persons likely to be affected thereby, and notice is hereby given that said draft rules will be taken into consideration on or after the expiry of a period of forty-five days from the date on which copies of the Gazette of India containing these draft rules are made available to the public.

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414 A, D Wing, Nirman Bhavan, New Delhi – 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (.....Amendment) Rules, 2017.
   (2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in Schedule H, after serial number 537 and entries relating thereto, the following serial numbers and entries shall be inserted, namely,-

"538. Alclometasone

539. Beclomethasone

540. Betamethasone

541. Desonide

542. Desoximetasone

543. Dexamethasone

544. Diflorasone diacetate

545. Fluocinonide

546. Fluocinolone acetonide

547. Halobetasol propionate

548. Halometasone

549. Methylprednisone

550. Prednicarbate

551. Triamcinolone acetonide"

[F. No. X-11014/14/2017-DRS]

SUDHIR KUMAR, Jt. Secy.

Foot note: The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number G.S.R. .....(E) dated.....

RAKESH SUKUL Digitally signed by RAKESH SUKUL Date: 2017.11.02 22:30:41 +05'30'

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ANNEXURE - F

• Soon, the expiry dates printed on the packaging are likely to be based on the test results MINT FILE

Regulator set to make stress tests mandatory for all drugs in India

Teena Thacker
• teena.t@livemint.com

NEW DELHI: India's drug regulator is set to propose amendments to the existing Drugs and Cosmetics Rules, 1945, to make "stability testing" mandatory for all drugs sold in the country before they are deemed suitable for use by patients. "Stability testing will be made compulsory for all drugs. An advisory letter has already been sent to the state drug controllers and a notification amending the rules is likely to come soon," said GN Singh, drug controller general of India (DCGI).

Once the rules take effect, pharma firms will have to subject their products to quality tests to make sure that drugs do not lose their potency and the expiry dates printed on the packaging are based on the test results.

"We will also get random checks done from the samples picked up from the market and if any discrepancies are found, the companies will have to shell out fines and may lose their licence," added Singh.

Mandated globally, stability testing is the process of subjecting drugs to different tests in varying degrees of temperature and sunlight. In India, such tests are mandatory only for patented and proprietary drugs.

The Central Drugs Standards Control Organisation (CDSCO) has proposed making stability tests compulsory for all drugs, including active pharmaceutical ingredients (APIs), the raw materials used in a drug that give it a therapeutic effect.

The pharmaceutical industry is unhappy about the proposal to widen the ambit of the stability tests.

"As of now the stability tests are carried out on formulations. If they widen the ambit and include all drugs, this will mean adding APIs and capsules too. It takes at least 6-9 months to carry out stability tests. There will be practical problems to get this done and we have been requesting the CDSCO to not include all the drugs into it," a pharma lobby group representative said on condition of anonymity.

CDSCO officials say they are unlikely to yield.

ANNEXURE-G

भारत में बिकने वाली हर 10 में से 1 दवा फर्जी: WHO की रिपोर्ट

नई दिल्ली (प्रेस ट्रस्ट ऑफ इंडिया) वर्ल्ड हेल्थ ऑर्गेनाइजेशन (डब्ल्यूएचओ) ने गरीब और विकासशील देशों में बिकने वाली दवाओं को लेकर एक बड़ा खुलासा किया है। डब्ल्यूएचओ की 25 नवंबर को जारी की गई रिपोर्ट में बताया गया है कि कैसे फर्जी या घटिया क्वालिटी की दवाओं की शिकायत को नजरअंदाज कर दिया जाता है। रिपोर्ट में बताया गया है कि भारत जैसे विकासशील देशों में जो दवाएं बेची जाती हैं, उनमें 10 में से एक दवा फर्जी है। रिपोर्ट के अनुसार 2007 से 2016 के दौरान 48,218 अस्पतालों के 100 अध्ययनों के विश्लेषण में करीब 10.5 फीसदी दवाएं नकली व घटिया पाई गई हैं। डब्ल्यूएचओ के अनुसार 2013 के बाद से नकली और घटिया दवाओं की 1500 रिपोर्ट मिली हैं। इनमें एंटीमलेरिया और एंटीबायोटिक दवाएं शामिल थीं। यह रिपोर्ट आने के बाद यह माना जा सकता है कि लोग ऐसी दवाएं इस्तेमाल कर रहे हैं जिससे उनके जीवन में बचाव और इलाज संभव नहीं है। यहां से न सिर्फ लोगों के पैसे का दुरुपयोग किया जा रहा है, बल्कि उनके जान पर भी गंभीर बीमारियों का खतरा बना रहता है।

डब्ल्यूएचओ ने माना कि ये फर्जी और खराब दवाओं से लोगों की जान पर बहुत ही बुरा प्रभाव पड़ता है। यह रिपोर्ट प्रभावित देशों में कहती है कि फर्जी और घटिया दवाओं की समस्या दुनिया के लिए एक गंभीर खतरा है। हर साल आबादी के समान गरीब और कमजोर हिस्से को ही इसकी मार झेलनी पड़ती है। डॉक्टर अलग-अलग तरह के इलाज आजमाते रहते हैं, जबकि जरूरत उन्हीं दवाओं की पर्याप्त डोज से सुनिश्चित करने की होती है। मरीज कभी पर्याप्त दवा न मिलने की वजह से तो कभी खराब क्वालिटी के प्रोडक्ट के चलते जान गंवा बैठते हैं। रिपोर्ट में इस समस्या का बड़ा कारण ग्लोबलाइजेशन को बताया गया है। उन्होंने कहा कि फर्जी दवाओं का उत्पादन कहीं और होता है और पैकेजिंग किसी और देश में होती है और फिर किसी अलग देश में इसका वितरण होता है, इसलिए इसकी बिक्री पर रोक लगाना मुश्किल होता जा रहा है।

रिपोर्ट के अनुसार स्वास्थ्यकर्मी चिकित्सक उपचारों से बचने के लिए समय बर्बाद कर रहे हैं जबकि वास्तव में उसी उपचार के लिए आम्हें विकल्प मौजूद हैं। इस रिपोर्ट में सबसे खराब बात यह है कि बीमारी का इलाज न होने से लाखों की बड़ी संख्या में मृत्यु हो रही है। रिपोर्ट में यह बात भी सामने आई है कि अगर किसी बीमारी के इलाज में सही दवाई का इस्तेमाल नहीं किया जाता तो शरीर में मौजूद रोगाणु (बीमारी से लड़ने वाले रोगाणु) बुरी तरह से नष्ट हो जाते हैं। रिपोर्ट में यह भी कहा गया है कि करीब 15 साल पहले [illegible] दवाओं के स्तर पर गिरावट [illegible] थी। अब दोबारा से इसमें [illegible] आई है। [illegible] भारत में [illegible] गई है।

ANNEXURE H

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 3rd November, 2017

S.O. 1369(E).—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by sections 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published as required by sub-section (1) of the section 33 of the said Act for information of all persons likely to be affected thereby; and notice is hereby given that said draft rules will be taken into consideration on or after the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing these draft rules are made available to the public;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414 A, D Wing, Nirman Bhavan, New Delhi - 110011 or e-mailed at drugsdiv-mohfw@nic.in;

Objections and suggestions which may be received from any person within the aforesaid period will be considered by the Central Government.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (_____Amendment) Rules, 2017.

   (2) They shall come into force after their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in rule 96, in sub-rule (1), in clause (xi), for the portion beginning with the words "In addition to the" and ending with the words "in the above list:", the following shall be substituted, namely:-

   "In addition to the other particulars which are required to be printed or written under these rules, the label of inner most container of the following categories of drugs and every other covering in which the container is packed shall bear caution/ warning in legible black coloured font size in completely red rectangular box without disturbing other conditions printed on the label under these rules, namely:-

   Narcotic analgesics, hypnotics, sedatives, tranquillisers, corticosteroids, hormones, hypoglycemic, antimicrobials, antiepileptics, antidepressants, anticoagulants, anti-cancer drugs and all other drugs falling under Schedules G, H, H1 and Schedule X whether covered or not in the above list:".

3. In the said rules, in rule 97, in sub-rule (1),

   (i) for clause (a), the following shall be substituted, namely:—

   "(a) if it contains a drug substance specified in Schedule G, be labeled with following words in legible black coloured font size in completely red rectangular box:

SCHEDULE G PRESCRIPTION DRUG – CAUTION
It is dangerous to take this preparation except under medical supervision.

"

   (ii) for clause (b), the following shall be substituted, namely:—

   "(b) if it contains a drug substance specified in Schedule H, be labeled with symbol Rx and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE H PRESCRIPTION DRUG – CAUTION
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

"

(iii) for clause (c), the following shall be substituted, namely:—

"(c) if it contains a drug substance specified in Schedule H and comes within the purview of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) be labeled with symbol NRx which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE H PRESCRIPTION DRUG – WARNING To be sold by retail on the prescription of a Registered Medical Practitioner only.

"

(iv) for clause (d), the following shall be substituted, namely:—

"(d) if it contains a drug substance specified in Schedule X, be labeled with symbol XRx which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE X PRESCRIPTION DRUG – WARNING To be sold by retail on the prescription of a Registered Medical Practitioner only.

"

(v) for clause (e), the following shall be substituted, namely:—

"(e) if it contains a drug substance specified in Schedule H1, be labeled with symbol Rx which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION – It is dangerous to take this preparation except in accordance with the medical advice. – Not to be sold by retail without the prescription of a Registered Medical Practitioner.

"

(vi) after clause (e), the following clause shall be inserted, namely:—

"(f) if it contains a drug substance specified in Schedule H1 and comes within the purview of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) be labeled with symbol NRx which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION – It is dangerous to take this preparation except in accordance with the medical advice. – Not to be sold by retail without the prescription of a Registered Medical Practitioner.

4. In the said rules, in Schedule H, after Note 3 appended to the said Schedule, the following Note shall be inserted, namely:-

"4. The salts, esters, derivatives and preparations containing steroids for topical or external use are also covered by this Schedule."

5. In the said rules, in Schedule K, against serial number 27, for the entries under the column 'class of drugs' the following shall be substituted, namely:—

"Oral Rehydration Salts (Manufactured as per the following formula):-Composition of the formulation in terms of the amount in g, to be dissolved in sufficient water to produce 1000 ml.

- Sodium Chloride 2.6
- Dextrose (anhydrous) or 13.5
- Dextrose mono-hydrate 14.85
- Potassium chloride 1.5
- Sodium Citrate 2.9."

[F. No. X. 11014/06/2016-DFQC]

SUDHIR KUMAR, Jt. Secy.

Note : The principal rules were published in the Gazette of India *vide* notification No. F.28-10/45-H (1) dated 21st December, 1945 and last amended *vide* notification number G.S.R. (E) dated .

RAKESH SUKUL

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ANNEXURE I

(To be 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 23rd November, 2017

ORDER

S.O. _____In exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 15, 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.	Oxaliplatin	Injection 100mg (as licensed)	Each Pack	4055.10
2.	Acetylsalicylic acid	Effervescent/ Dispersible/ Enteric coated Tablet 100 mg	1 Tablet	0.1625
3.	Japanese Encephalitis Vaccine	4mcg to 6mcg	Each Pack	632.95
4.	Japanese Encephalitis Vaccine	up to 3mcg	Each Pack	482.22
5.	Measles Rubbela Vaccine		Each Pack (0.5ml)	80.22
6.	Surfactant	Suspension for intratracheal instillation (As liensed)	Per mg of Phospholipids in the pack	60.69

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/182/50/2017/F F. No. 8(50)/2017/D.P./NPPA-Div.-II

(BALJIT SINGH)
Assistant Director

(To be 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 23rd November, 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, and in supersession of the Order of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) No. SO 2060(E) & S.O. 2061(E) dated 30th June, 2017 respectively in so far as it relates to formulation packs mentioned in the table below, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby fixes the price 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 from & 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.	Sevoflurane	Inhalation	1 ml	24.12
2.	Acetylsalicylic acid	Tablet 325mg	1 Tablet	0.50
3.	Desferrioxamine	Powder for Injection 500mg	Each pack	145.91
4.	Oxaliplatin	Injection 50mg (as licensed)	Each Pack	2303.01
5.	Phytomenadione (Vitamin K1)	Injection 10mg/ml	1 ML	43.45
6.	Glutaraldehyde	Solution 2%	1 ML	0.05868
7.	Anti-D immunoglobulin	Injection 300mcg	Each Pack	1936.82
8.	BCG vaccine		Each Dose	4.32

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 prices of such formulations 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/182/50/2017/F F. No. 8(50)/2017/D.P./NPPA-Div.-II

(BALJIT SINGH)
Assistant Director

(To be 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 23rd November, 2017

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 falling in therapeutic category of cardiovascular, blood products and plasma substitutes etc. 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, 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.	Morphine	SR Tablet 30 mg	1 Tablet	4.94
2.	Alteplase	Powder for Injection 20 mg	Each Pack	17235.00
3.	Alteplase	Powder for Injection 50 mg	Each Pack	35985.00
4.	Gadobenate	Injection 529 mg/ml	1 ML	98.90
5.	Haemodialysis fluid	As license	1 ML	0.03695
6.	Furosemide	Oral liquid 10 mg/ml	1 ML	0.29
7.	Glucose	Injection 50%	1 ml	0.44

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/182/50/2017/F F. No. 8(50)/2017/D.P./NPPA-Div.-II

(BALJIT SINGH)
Assistant Director

(To be 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 23rd November, 2017

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 falling in therapeutic category of cardiovascular, blood products and plasma substitutes etc. 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.	Lignocaine (A) + Adrenaline (B)	Injection 1% (A) + 1:200000 (5 mcg/ml) (B)	1 ML	0.41
2.	Calcium gluconate	Injection 100 mg/ml	1 ML	0.50
3.	Dextran-40	Injection 10%	1 ML	0.38 0.80
4.	Coagulation factor IX	Powder for Injection 600 IU	Each Pack	11,180.00
5.	Digoxin	Oral liquid 0.05 mg/ml	1 ML	0.29
6.	Potassium permanganate	Crystals for topical solution	1 gm	0.40
7.	Pilocarpine	Drops 4%	1 ML	10.60

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 prices of such formulations 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/182/50/2017/F F. No. 8(50)/2017/D.P./NPPA-Div.-II

(BALJIT SINGH)
Assistant Director

(To be 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 23rd November, 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)	(2)	(3)	(4)	(5)	(6)
1.	Sofosbuvir & Velpatasvir	Each film coated tablet contains: Sofosbuvir 400mg, Velpatasvir 100mg	28 Tablets	M/s Hetero Labs Ltd. / M/s Abbott India Ltd.	15625.00
2.	Sofosbuvir & Velpatasvir	Each film coated tablet contains: Sofosbuvir 400mg, Velpatasvir 100mg	28 Tablets	M/s Hetero Labs Ltd. / M/s Cadila Healthcare Ltd.	15625.00
3.	Sofosbuvir & Velpatasvir	Each film coated tablet contains: Sofosbuvir 400mg, Velpatasvir 100mg	28 Tablets	M/s Natco Pharma Ltd. /M/s Sun Pharmaceuticals Industries Ltd.	15625.00
4.	Sofosbuvir & Velpatasvir	Each film coated tablet contains: Sofosbuvir 400mg, Velpatasvir 100mg	28 Tablets	M/s Natco Pharma Ltd. / M/s Cipla Ltd.	15625.00
5.	Sofosbuvir & Velpatasvir	Each film coated tablet contains: Sofosbuvir 400mg, Velpatasvir 100mg	28 Tablets	M/s Natco Pharma Ltd.	15625.00

6.	Sofosbuvir & Velpatasvir	Each film coated tablet contains: Sofosbuvir 400mg, Velpatasvir 100mg	28 Tablets	M/s Natco Pharma Ltd. / M/s Mylan Pharmaceuticals Pvt. Ltd.	15625.00

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/182/50/2017/F F. No. 8(50)/2017/D.P./NPPA-Div.-II

(BALJIT SINGH)
Assistant Director

(To be 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 23rd November, 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)	(2)	(3)	(4)	(5)	(6)
1.	Sofosbuvir & Velpatasvir	Each tablet contains: Sofosbuvir 400mg, Velpatasvir 100mg	28 Tablets	M/s Dr. Reddy's Limited	15,625.00
2	Sofosbuvir & Velpatasvir	Each tablet contains: Sofosbuvir 400mg, Velpatasvir 100mg	28 Tablets	M/s Hetro Labs Ltd.	15,625.00
3.	Voglibose + Metformin	Each tablet contains: Voglibose 0.2mg Metformin 500mg	1 Tablet	M/s Lupin Ltd.	4.84
4.	Voglibose + Metformin	Each tablet contains: Voglibose 0.3mg Metformin 500mg	1 Tablet	M/s Lupin Ltd.	5.76
5.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.2mg Metformin 500mg Glimepirid 1mg	1 Tablet	M/s Lupin Ltd.	7.14
6.	Voglibose + Metformin + Glimepirid	Each tablet contains: Voglibose 0.2mg Metformin 500mg Glimepirid 1mg	1 Tablet	M/s Sanofi India Ltd.	7.14

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

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 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/182/50/2017/F F. No. 8(50)/2017/D.P./NPPA-Div.-II

(BALJIT SINGH)
Assistant Director

(To be 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 23rd November, 2017

ORDER

S. O. In implementation of directions given in line with review orders issued by the Department of Pharmaceuticals (DOP) vide order(s) specified in column (6) of the table herein below passed by the Department of Pharmaceuticals under para 31 of Drugs (Prices Control) Order, 2013 and 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, and in supersession of the Order(s) of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) specified in the Column (7) of the table, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA), hereby fixes, the price as specified in column (5) 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 (8) thereof;

Table

Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)	Review Order number and date	Existing SO number and date	Manufacturer & Marketing Company respectively
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1.	Trypsin, Bromelain, Rutoside Trihydrate, & Diclofenac Sodium (Volitra Enzo) tablet	Each enteric coated tablet contains: Trypsin 48mg Bromelain 90mg Rutoside Trihydrate 100mg Diclofenac Sodium 50mg	1 Tablet	13.91	31015/09/2017 -Pricing dated 27.08.2017	4131(E) dated 22.12.2016 (at Sl. No. 5)	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Sun Pharmaceuticals Ind. Ltd.

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 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.

PN/182/50/2017/F F. No. 8(50)/2017/D.P./NPPA-Div.-II

(BALJIT SINGH)
Assistant Director

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Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

New Delhi, 23rd November, 2017

ORDER

S.O._____ In implementation of directions given in line with review orders issued by the Department of Pharmaceuticals (DOP) vide order(s) specified in column (6) of the table herein below passed by the Department of Pharmaceuticals under para 31 of Drugs (Prices Control) Order, 2013 and in exercise of the powers conferred by paragraphs 4, 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, and in supersession of the Order(s) of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) specified in the Column (7) of the table regarding formulation specified in mentioned in the table in so far as it relates to formulation pack mentioned in the table below, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby fixes/revises the price 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 formulation(s) 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.)	Review Order number and date	Existing SO number and date
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1.	Ceftriaxone	Powder for Injection 1gm	Each Pack	48.92 46.74	31015/59/2017-Pricing dated 10.10.2017	2058(E) dated 30.6.2017 (at Sl. No. 120)
2.	Chloroquine	Tablet 150mg	1 Tablet	0.72 0.60	31015/32/2017-Pricing dated 24.8.2017	2059(E) dated 30.6.2017 (at Sl. No. 23)

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 prices of such formulations 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/182/50/2017/F F. No. 8(50)/2017/D.P./NPPA-Div.-II

(BALJIT SINGH)
Assistant Director

ANNEXURE J

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

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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

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Bahadurgarh Pharmaceuticals Mfrs. Association, Bahadurgarh-124507

Goa Pharmaceutical Mfrs. Association, Mapusa - 403526

Ref: CIPI/2017/307
Date: 26/11/2017

Shri Arun Jaitely, Finance Minister
Shri Shiv Pratap Shukla, Minister of State (Finance)
Shri Nripendra Misra, Principal Secretary to PM
Dr. Rajiv Kumar, Vice Chairman
Dr. Hasmukh Adhia, Revenue Secretary to GST Council
Shri Udai Singh, Kumawat, Joint Secretary to Revenue Department
Dr. G.N. Singh, Drug Controller General (India)
Shri Yanamala Ramakrishnudu Minister of Finance, Andhra Pradesh
Shri Chowna Mein, Deputy Chief Minister, Arunachal Pradesh
Shri Dr. Himanta Biswa Sarma, Finance Minister, Assam
Shri Sushil Kumar Modi, Deputy Chief Minister, Bihar
Shri Amar Agrawal, Minister, Commercial Taxes, Chhattisgarh
Shri Manish Sisodia, Deputy Chief Minister, Delhi
Shri Mauvin Godinho, Minster, Panchayat, Goa
Shri Nitin Patel, Deputy Chief Minister, Gujarat
Shri Cap. Abhimanyu, Minister, Excise & Taxation
Shri Prakash Chaudhry, Minister, Excise & Taxation
Dr. Haseeb A Drabu, Finance Minister
Shri Manpreet Singh Badal, Finance Minster
Shri Rajpal Singh Shekhawat, Minister for Industries
Shri Ram Vilas Paswan, Minister of consumer Affairs
Shri Giriraj Singh, Minister of MSME

Hon'ble Sir,

Greeting of the day!

SUB: GSTR 2- REMOVAL OF TABLE NO. 4B, 7 & 13

We are really appreciated for the implementation of GST in the country. All difficulties of paper work have become so short that easily even small scale sector can implemented.

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Recently, we hold our Executive Meeting and deeply study GST chapter and decided to send our comments on Form GSTR-2, which are as follows:

1. In GSTR 2 return under **Table No: 7(details of supplies received from composition taxable person and other exempt/Nil rate/Non GST suppliers received)** the details of the exempted expenditure item are expected to be given by each assesse on the monthly basis. In addition, another **Table No: 13 (HSN Summary of inward supplies)** the HSN-code wise quantity summary of all inward supplies (all expenses and purchases) is to be filled.

2. The example exempted expenditure are :
   a. Electrical Energy,
   b. Court fee,
   c. Postal items ,
   d. Newspapers, journals and periodicals,
   e. Railways tickets,
   f. Bus tickets,
   g. Metered cabs / auto rickshaws (including e-rickshaws),
   - the above list is only illustrative and not exhaustive.

3. The Units below the limits of GST Act and Units opting for compounding scheme under GST Actboth should be deemed to be considered as exempted as they can neither take input credit nor give invoices for input credit.

4. It is also relevant that, to help the small traders the compounding limits have been increased and a large number

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of units now come under the compounding schemes the limits are also likely to be increased in due course.

5. It is also relevant that for many assesses who employ staff for selling their products which will involve expenditure incurred while in travelling through
   a) Bus,
   b) Railways,
   c) Jeeps,
   d) Share Auto/Taxi,
   e) Waterways

   the above list is only illustrative and not exhaustive and all these are grouped under travelling and showing those details is an accounting nightmare.

6. **ACCOUNTING NIGHTMARE:** - As far as expenses for exempted category, complete details have to be given and the quantum of expenditure is very low and maintaining a detailed account is beyond the scope for many of the Small, Medium and even for large industries. The same applies and details are to be given under the **Table No: 7 of GSTR 2.**

7. Units give invoice for which Input Tax Credit can be taken; they are maintained separately and are shown in **Table No: 3(details of inward supplies received from a registered person other than the supplies attracting reverse charge)**and there is no difficulty as Input Tax Credit is taken.

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8. In respect of Table no.13 of GSTR2, it is important to note that relaxation has been given to provide HSN code in the invoice as per the below table –

Sl no	Turnover Limit	HSN Digits to be shown
1	Upto INR 1.50 Crores	Nil
2	INR 1 to 5 Crores	2
3	More than 5 Crores	4

That being the case, it is virtually impossible to ascertain HSN codes for inward supplies (particularly expenses and purchases from SME enterprises).

Hence, requirement to maintain such detailed records in order to provide HSN summary is impossible to comply with.

9. **REVERSE CHARGE**: - Under section 9(4) of GST Act (as originally stated) the Goods and Service used by a registered person from an unregistered person reverse charge was payable.

10. An exemption was given with a limit of Rs. 5000/- per day under the Section 9(4) of GST Act and subsequently the entire Section of 9(4) has been suspended till March 2018.

11. It is unfortunate and sad that when the Reverse Charge section has been amended and consequent action has not been taken in deleting the requirement of the exempted expenditure in **GSTR 2 (Table No. 7)**.

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12. The above details need not been given under Income Tax Act and Companies Act.

13. **HARASSMENT AND UNETHICAL PRACTICE:** - If there are any error and non-submission of expenses & HSN code and if the same is found out on scrutiny or audit or which ever means, negotiations will start for taking non – cognizance for the explanation given and if the negotiations are not satisfactory or incomplete, cognizance will be taken and said procedure like issue of show - cause notice, hearing, placing orders, appeals etc., would follow.

14. The state which takes pride in claiming that all its transaction are open that there is no negotiation and operation are carried out open and transparent it want to introduce section that will lead to this type of unethical behavior which will logically follow if details under exemption category are not given even by error.

15. As pointed out earlier if GST is involved, Input Tax Credit can be taken with the details of account which is being maintained separately and it is only in the case of exempted expenditure whose quantum are small but larger in number and there arises the difficulty with the problem of harassment and unethical practices.

16. In light of the fact that the Reverse Charge under section 9(4) has been suspended and the requirement of filling **Table No : 4B (details of inward supplies received from an**

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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

unregistered supplier on which tax is to be paid on reverse charge) of GSTR 2 can be omitted to give relief to the assesse from harassment etc.,

17. **OPENING FLOOD GATE:-** Government which is taking pride in stating that all operation is transparent and no negotiation takes place does it want to opens the flood gate for unethical practice by asking for the above details to be filled in GSTR 2 which opens the flood gate for unethical practices.

18. **TAX IMPICATION:** - By asking the above information there is no tax loss or tax gain as explained, the Reverse Charger under section 9(4) has been suspended and there will be no loss of revenue. To avoid harassment and to stop the unethical practice referred above the **Table No: 4B, 7 & 13 of GSTR2** can be eliminated.

19. In light of what we have said the details to be given under **Table No: 4B, 7 & 13 of GSTR2** can be deleted as there is no loss of revenue to the government and will prevent the harassment and unethical practice.

Regards
For Confederation of Indian Pharmaceutical Industry (CIPI)

P.K.Gupta
Chairman

ANNEXURE K

F. No.37 (1)/2016/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: 24.11.2017

Office Memorandum

Sub: Guidelines for examination of cases of launch of 'New Drugs' by Pharma companies without obtaining prior price approval as required under the DPCO 2013

The undersigned is directed to refer to Office Memorandum of even no. dated 17.05.2017 and 26.05.2017 issued by this office communicating identification of formulation (new drug) launched by Pharma companies on the basis of market data (Pharmatrac) without following the provisions contained in the Drugs (Prices Control) Order, 2013 (DPCO 2013).

2. During the course of examination of replies submitted by various companies, it has been observed that the pharma companies have not submitted the requisite document(s) to support their contention. In order to bring clarity in the examination of cases of launch of new drugs "without prior price approvals" (WPA cases) and standardisation of documents to be submitted by the companies, it has been decided to follow a standard and uniform procedure, as mentioned in the paragraphs given hereunder, in respect of cases of launch of new drugs without prior price approval (WPA):

3. WPA cases will be dropped in the following cases and the Company will be duly informed.

(a) The Company produces evidence (licence issued by State Drugs Controller (SDC)/ Drugs Controller General (India) (DCG(I)) and invoices and samples prior to 15th May 2013, certified by Chartered Accountant (CA) / Cost Accountant (CMA) in support of the claim that the formulation was launched before the DPCO 2013 came into effect;

(b) If AIOCD-Pharmatrac data confirm that the formulation was launched prior to 15th May 2013.

(c) If the company claims and produces sufficient evidence to support the claim that the formulation does not come under the definition of a "new drug" under paragraphs 2 (u) of the DPCO,2013, i.e.,

(i) either the Company is not an "existing manufacturer" of the scheduled formulation; or

(ii) none of the components of the formulation is under Schedule I of the DPCO,2013 as amended from time to time.

(d) The Company claims are duly supported with sufficient evidence i.e. samples and invoices that the formulation is a scheduled formulation and the ceiling price is complied therewith and followed in accordance with provisions of the DPCO, 2013

(e) The Company's claim that the formulation was never manufactured/ marketed by it is confirmed by AIOCD-Pharmatrac.

(f) The Company has changed only the pack size and launched the new pack size (i) at a price equal to or less than the pro rata price of the previous pack size, or (ii) the increase in pro rata price if any taken by the company is in conformity with the provisions of paragraphs 20 (1) of DPCO,2013.

The Company will be required to submit evidence (licence issued by SDC/ DCG(I), invoice and sample, duly certified by CA/CMA regarding the previous and the existing pack size of concerned formulation manufactured / marketed by it.

(g) The Company has launched the new brand having same composition as in earlier brand with a different brand name (i) at the price equal to or less than that of the earlier brand, or (ii) the increase in price taken by the company is in conformity with the provisions of paragraph 20 (1) of DPCO 2013.

The Company will be required to submit evidence (licence issued by SDC/DCG(I) and invoice and sample, duly certified by CA/CMA regarding the previous and the existing brand of concerned formulation manufactured / marketed by it.

(h) In cases where the brand has been procured/re-launched under a different name by another Company post-DPCO 2013, keeping the same composition of the formulation concerned as in the earlier brand (i) at the price equal to or less than that of the earlier brand, or (ii) the increase in price taken by the company is in conformity with the provisions of paragraph 20 (1) of DPCO 2013.

The Company will be required to submit evidence (licence issued by SDC/DCG(I) and invoice/sample, certified by CA/CMA) regarding the previous and the existing brand manufactured / marketed by it.

4. Any WPA case not coming under any of the above said categories will be referred for price fixation and, after fixing the price concerned companies shall be liable to deposit overcharged amount alongwith interest from the date of overcharge, in addition to penalty, as per provisions of paragraph 15 of the DPCO, 2013.

5. The companies are instructed to submit the complete and requisite documents as stipulated in paragraph 3 herein above. Companies are once again advised to check 'new drugs', if any, has been launched by them and obtain requisite price approval after complying with IPDMS requirements by submitting Form I prescribed in Schedule-II of DPCO, 2013, along with the documents as required by NPPA vide O.M. No. 19(78)/2014/Div.II/NPPA dated 07.02.2017 and OM No. 19(78)/2014/DP/NPPA/Div.II dated 01.05.2017, if not done earlier.

24/11/17

(Rakesh Ranjan)
Member Secretary, NPPA

Copy to:

a) All Pharma Companies
b) IDMA, OPPI, IPA and other Pharma Associations
c) Department of Pharmaceuticals