

ANNEXURE 2

LIST OF APPROVED DRUG

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

Last updated on: 30/10/2017

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 <ul style="list-style-type: none"> • Carfilzomib for injection is indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy. • Carfilzomib for injection is indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy. 	17.01.17
4	Dabrafenib 50mg/75mg Capsules (Dabrafenib Mesylate)	As a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test. In combination with Trametinib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an	18.01.17

		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 <i>Ostertagia ostertagi</i>), lungworm, grubs, sucking and biting lice, chloriopic 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 multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.	01.05.2017
17	Sofosbuvir 400 mg +Velpatasvir 100 mg Tablet	For the treatment of adult patients with -chronic Hepatitis C virus, Genotype 1,2,3,4,5 or 6 infection. -Without cirrhosis or with compensated cirrhosis -With decompensated with chronic for use in combination with Ribavirin.	04.05.2017
18	Velpatasvir Bulk		04.05.2017
19	Osimertinib 40 mg/80 mg Film coated Tablets (Osimertinib Mesylate)	For the treatment of patient with metastatic epidermal growth factor receptor (EGFR) T790 M mutation-positive non-small cell lung cancer (NSCLC), as detected by an appropriate test, whose disease has progressed on or after EGFR TKI therapy	29.05.2017
20	Argatroban Hydrate Bulk & Injection 250 mg/2.5 ml	1) For prophylaxis or treatment of thrombosis in adult patients with Heparin induced thrombocytopenia (HIT). 2) As an anticoagulant in adults patients with or at risk for heparin-induced thrombocytopenia undergoing percutaneous coronary intervention (PCI)	30.05.2017
21	Fluralaner chewable tablets 112.5 mg/250 mg/500mg/1000mg/1400 mg	For the treatment of tick and flea infestations on dogs for 12 weeks. This veterinary medicinal product is a systemic insecticide and acaricide with a long duration of action that provides immediate and persistent tick (adult and juvenile <i>Ixodes ricinus</i> , <i>Ixodes hexagonus</i> , <i>Ixodes scapularis</i> , <i>Ixodes holocyclus</i> , <i>Dermacentor reticulatus</i> , <i>Dermacentor variabilis</i> and <i>Rhipicephalus sanguineus</i>) and flea (<i>Ctenocephalides felis</i> and <i>Ctenocephalides canis</i>) killing activity for 12 weeks.	30.5.2017

		<p>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 (<i>C. felis</i>) and 12 hours of attachment for ticks (<i>I. ricinus</i>)</p> <p>The product effectively controls environmental flea population in area to which treated dogs have access.</p> <p>The product can be used as part of an treatment strategy for the control of Flea Allergy Dermatitis (FAD)</p>	
22	Fluticasone Furoate (100 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 <ul style="list-style-type: none"> • 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 haematopoietic 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 postmenopausal women with the hormone receptor (HR)-Positive, human epidermal growth factor receptor 2 (HER2)-Negative advanced or metastatic breast cancer	27.09.2017
30	Dienogest Bulk & 2mg Tablet	For the management of Pelvic pain associated with Endometriosis	28.09.2017
31	Apremilast bulk & film coated tablets 10 mg/20 mg/30 mg	for treatment of patients with moderate to severe plaque psoriasis who are candidate for phototherapy or systemic therapy	13.10.2017
32	Arbekacin bulk & Injection 200mg/4ml	Treatment of following infections caused by Methicillin resistant Staphylococcus aureus (MRSA)", sepsis pneumonia	20.10.2017

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 flutter of recent onset to sinus rhythm. Patient with atrial arrhythmias of longer duration are less likely to respond to Ibutilide Fumarate Injection. The effectiveness of Ibutilide has 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
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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 10 μ g/20 μ g	For the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in patients who are not controlled on existing therapy: In combination with the following oral antibiotics: -Metformin, a sulphonyl urea, or a combination of these agents. In combination with a basal insulin: alone, in combination with metformin, or in combination with sulphonyl urea.	15.01.2015

4	Dapagliflozin Tablet 5mg/10mg	<p>"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"</p>	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	Empagliflozin 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	<p>"In adult, adolescence and children aged 2 years and older for: 1. contrast enhancement in cranial and spinal magnetic resonance imaging (MRI). 2. Contrast enhancement MRI of other body regions: liver kidneys. 3. Contrast enhancement in Magnetic Resonance Angiography (CE-MRA) 4. For MRI of the breast to assess the presence and extent of malignant breast</p>	07.05.2015
8	Teneligliptin Tablet 20mg	For the treatment of Type 2 Diabetes Mellitus as a Monotherapy adjunct to diet and Exercise	18.05.2015
9	Ceritinib 150 mg Hard Gelatin Capsules	"For the treatment of patients with Anaplastic lymphoma Kinase (ALK)-positive metastatic non- small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib"	13.01.2015

10	Vilazodone Hydrochloride 20mg/40mg and Bulk	"For the treatment of Major depressive disorders in adults"	19.08.15
11	Gemigliptin 50mg tablets	" As an adjunct to the diet & exercise to improve to improve glycemic control in adults with type-2 diabetes mellitus, as an monotherapy or in combination with metformin in patients with inadequate glycemic control on metformin alone"	21.08.15
12	Atosiban Acetate Injection 6.75mg/0.9ml and Bulk	"Indicated to delay imminent pre-term birth in pregnant adult women with: -regular uterine contractions of at least 30 Seconds duration at the rate of ≥ 4 per 30 minutes -a cervical dilation of 1 to 3 cm (0-3 for nulliparas) and effacement of $\geq 50\%$ - a gestational age from 24 until 33 Completed weeks a normal foetal heart rate"	16.09.15
13	Ibrutinib Hard gelatin Capsule 140mg	"For the treatment of adult patients with:- -mantle cell lymphoma (MCL) who have received at least one prior therapy. -Chronic Lymphocytic leukemia (CLL) who have received at least one prior therapy. - Chronic lymphocytic leukemia with 17p deletion"	07.10.2015
14	Ledipasvir (90mg)+ Sofosbuvir (400mg) Tablet	" For the treatment of chronic hepatitis C (CHC) Genotype 1 infection in adults"	08.12.2015
15	Ledipasvir Bulk		08.12.2015

16	Daclatasvir Dihydrochloride bulk & Tablet 30mg/60mg	"For use with Sofosbuvir for the treatment of patient with chronic hepatitis C virus (HCV) 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 progressed on or after Docetaxel therapy	18.12.2015

Start date: 09/02/2015

End date: 01/12/2066