

**Manufacturing and Marketing permission issued from SND Division from January 2017 to December 2017**

S.No.	Drug Name	Indication	Date of Approval
1	Sofosbuvir 400 mg film coated Tablet	In combination with other medicinal products for the treatment of Chronic Hepatitis C (CHC) in adults	16.02.2017
2	Hydralazine tablets BP 25 mg (Additional Strength)	For moderate to severe hypertension (in conjunction with a $\beta$ -adrenoceptor blocking agent or diuretic) and hypertensive crisis.	23.02.2017
3	Hydralazine tablets BP 50 mg (Additional Strength)	For moderate to severe hypertension (in conjunction with a $\beta$ -adrenoceptor blocking agent or diuretic) and hypertensive crisis.	23.02.2017
4	Bendamustine hydrochloride injection 90 mg/mL (Fill volume 0.5 mL in 2 ml capacity vial & 2 mL filled in 2 mL capacity vial)	<ol style="list-style-type: none"> <li>1. For the treatment of patients with chronic lymphocytic leukemia</li> <li>2. For the use in Indolent B-cell Non-Hodgkin's Lymphoma (NHL) that has Progressed During or Within six months of treatment with Rituximab or a Rituximab containing Regimen.</li> </ol>	02.03.2017
5	Eltrombopagolamine 25 mg/50 mg tablets (Additional indication)	For the treatment of thrombocytopenia in paediatric patients 1 year and older with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy. (It should be used only in patients with ITP whose degree of Thrombocytopenia and clinical condition increase the risk for bleeding. It should not be used in an attempt to normalize platelet counts).	02.03.2017
6	Azacitidine for injection 100 mg	For the treatment of adult patients with all sub-types of Myelodysplastic Syndrome <b>With the condition: to be sold by retail on the prescription of Oncologist only</b>	07.03.2017
7	Methylcobalamin 1500 mcg orally disintegrating strips	For the treatment of Diabetic Neuropathy and peripheral Neuropathy	10.03.2017
8	Cefditoren Pivoxil dry powder for suspension 100 mg/5 mL	For the treatment of mild to moderate infections in adults and adolescents (12 years of age or older) which are caused by susceptible strains of the designated microorganisms in the condition listed below <ul style="list-style-type: none"> <li>• Acute Bacterial Exacerbation of Chronic Bronchitis</li> <li>• Community-Acquired pneumonia</li> <li>• Pharyngitis/Tonsillitis</li> </ul>	30.03.2017

		<ul style="list-style-type: none"> <li>• Acute sinusitis</li> <li>• Uncomplicated skin and skin-structure infections.</li> </ul>	
9	Thiotepa Powder for concentrate for solution for infusion 100 mg(Additional strength & indication)	<ol style="list-style-type: none"> <li>1. With or without total body irradiation(TBI), as conditioning treatment prior to allogenic or autologous hematopoietic progenitor cell transplantation (HPCT) in haematological diseases in adult and pediatrics patients;</li> <li>2. When high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumors in adult and pediatrics patients.</li> </ol> <p><b>With the condition: to be sold by retail on the prescription of Hematologist only</b></p>	06.04.2017
10	Thiotepa Powder for concentrate for solution for infusion 15mg (Additional indication)	<ol style="list-style-type: none"> <li>1. With or without total body irradiation(TBI), as conditioning treatment prior to allogenic or autologous hematopoietic progenitor cell transplantation(HPCT) in haematological disease in adult and pediatrics patients;</li> <li>2. When high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumors in adult and pediatrics patients.</li> </ol> <p><b>With the condition: to be sold by retail on the prescription of Hematologist only</b></p>	06.04.2017
11	Bortezomib for Injection (i.v) 1 mg/vial (Additional indication)	For the treatment of patients with mantle cell lymphoma <b>With the condition: to be sold by retail on the prescription of Oncologist only</b>	11.04.2017
12	Bortezomib 3.5 mg/vial Powder for solution for injection (i.v/s.c) (Additional indication)	For the treatment of patients with mantle cell lymphoma <b>With the condition: to be sold by retail on the prescription of Oncologist only</b>	11.04.2017
13	Mesalamine Delayed Release Tablets 800 mg (Additional dosage form)	For the treatment of mild to moderate acute exacerbations of ulcerative colitis and for the maintenance of remission of ulcerative colitis. <b>With the condition: to be sold by retail on the prescription of Specialist/Gastroenterologist only</b>	11.04.2017
14	Teneligliptin Film coated Tablet 20 mg	For the treatment of Type 2 Diabetes Mellitus as a monotherapy adjunct to diet and exercise.	28.04.2017
15	Ticagrelor 60 mg tablets (Additional strength & indication)	Indicated for the prevention of thrombotic events (cardiovascular death, myocardial infarction and stroke) in patients with a history of myocardial infarction (MI occurred at least one year ago) and a high risk of developing a thrombotic event. <b>With the condition: to be sold by retail on the prescription of Cardiologist/Internal Medicine Speciality only</b>	02.05.2017
16	Daclatasvir Tablet 30 mg	“For use with Sofosbuvir for the treatment of patients with chronic hepatitis C virus (HCV)	24.05.2017

		genotype 3 infection”. With the condition: to be sold by retail on the prescription of Hepatologist only	
17	Daclatasvir Tablet 60 mg	“For use with Sofosbuvir for the treatment of patients with chronic hepatitis C virus (HCV) genotype 3 infection”. <b>With the condition: to be sold by retail on the prescription of Hepatologist only</b>	24.05.2017
18	Rosuvastatin Tablets 15 mg	<ul style="list-style-type: none"> <li>a. Treatment of patients with primary hypercholesterolemia or mixed dyslipidemia, homozygous familial hypercholesterolemia as an adjunct to diet,when response to diet and exercise is inadequate</li> <li>b. As an adjunctive therapy to diet for the treatment of adult patients with hypertriglycerdemia.</li> <li>c. As an adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower total C and LDL-C to target levels.</li> <li>d. Risk reduction of Myocardial Infarction stroke and arterial revascularization procedure in patients without clinically evident CHD but with multiple risk factors.</li> <li>e. As an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (type-III hyperlipoproteinemia).</li> <li>f. As adjunct to diet to reduce total-C,LDL-C and ApoB levels in adolescent boys and girls,who are atleast one year post-menarche,10-17 years of age with heterozygous familial hypercholesterolemia if after and adequate trial of diet therapy the following findings are present:LDL-C &gt;190 mg/dL or &gt; 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more CVD risk factors.</li> </ul>	30.05.2017
19	Rosuvastatin film coated Tablets 30 mg	<ul style="list-style-type: none"> <li>a. Treatment of patients with primary hypercholesterolemia or mixed dyslipidemia, homozygous familial hypercholesterolemia as an adjunct to diet,when response to diet and exercise is inadequate</li> <li>b. As an adjunctive therapy to diet for the treatment of adult patients with hypertriglycerdemia.</li> <li>c. As an adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower total C and LDL-C to target levels.</li> <li>d. Risk reduction of Myocardial Infarction stroke and arterial revascularization procedure in patients without clinically</li> </ul>	30.05.2017

		<p>evident CHD but with multiple risk factors.</p> <p>e. As an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (type-III hyperlipoproteinemia).</p> <p>f. As adjunct to diet to reduce total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post-menarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after and adequate trial of diet therapy the following findings are present: LDL-C &gt;190 mg/dL or &gt; 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more CVD risk factors.</p>	
20	Abiraterone Acetate Tablet 500 mg	<p>1. In combination with prednisone for the treatment of patients with metastatic castration resistant prostate cancer who have received prior chemotherapy containing docetaxel</p> <p>2. For the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated with prednisone or prednisolone.</p> <p><b>With the condition: to be sold by retail on the prescription of Oncologist only</b></p>	12.07.2017
21	Enzalutamide hard Gelatin Capsules 40 mg	<p>For the treatment of adults with metastatic castration resistant prostate cancer whose disease has progressed on or after Docetaxel therapy.</p> <p><b>With the condition: to be sold by retail on the prescription of Oncologist only</b></p>	12.07.2017
22	Rizatriptan Benzoate Orally Disintegrating Strips 5mg	Anti-Migraine	19.07.2017
23	Rizatriptan Benzoate Orally Disintegrating Strips 10mg	Anti-Migraine	19.07.2017
24	Vitamin D3 (Cholecalciferol) 60000 IU Orally disintegrating Strips	For the treatment of Vitamin D3 deficiency	25.08.2017
25	Empagliflozin 10mg, 25mg Tablet	To reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.	22.09.2017

	(Additional indication)		
26	Ketamine Injection 50mg/ml (5ml & 10ml vial)  Veterinary use only	Ketamine Injection may be used in cats for restraint or as the sole anesthetic agent for diagnostic or minor, brief, surgical procedures that do not require skeletal muscle relaxation. It may be used in subhuman primates for restraint. <b>Warning:-to be sold by retail on the prescription of a “Veterinary Doctor” only</b>	03.10.2017
27	Tacrolimus Prolonged Release Hard Gelatin Capsules 3 mg	1. Prophylaxis of transplant rejection in adult kidney or liver allograft recipients. 2. Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients. <b>Warning:-to be sold on the prescription of physicians experienced in immunosuppressive therapy and management of organ transplant only</b>	13.10.2017
28	Clonazepam IP Orally Disintegrating Strips 0.5 mg	In the treatment of petitmal, its variant, akinetic & myoclonic seizures. <b>Warning:-to be sold by retail on the prescription of a “Neurologist &amp; Psychiatrist” only</b>	23.10.2017
29	Clonazepam IP Orally Disintegrating Strips 1mg.	In the treatment of petitmal, its variant, akinetic & myoclonic seizures. <b>Warning:-to be sold by retail on the prescription of a “Neurologist &amp; Psychiatrist” only</b>	23.10.2017
30	Clonazepam IP Orally Disintegrating Strips 2mg.	In the treatment of petitmal, its variant, akinetic & myoclonic seizures. <b>Warning:-to be sold by retail on the prescription of a “Neurologist &amp; Psychiatrist” only</b>	23.10.2017
31	Diclofenac Diethylamine Gel 2.32 % w/w	For the local symptomatic treatment of post-traumatic inflammation of the tendons, ligaments, muscles and joints. Localized forms of rheumatism & soft-tissue rheumatism.	23.10.2017
32	Ibuprofen 100mg/ml Intravenous injection (8ml vial)	Caldolor is an NSAID indicated in adults for the: 1. Management of mild to moderate pain. 2. Management of moderate to severe pain as an adjunct to opioid analgesics. 3. Reduction of fever.	02.11.2017
33	Crizotinib Hard Gelatin Capsules 200 mg  (Additional indication)	Crizotinib is a kinase inhibitor indicated for the treatment of patients with metastatic NSCLC whose tumors are ROS1-positive. <b>Warning:-to be sold by retail on the prescription of a “Oncologist” only.</b>	03.11.2017
34	Crizotinib Hard Gelatin Capsules 250 mg  (Additional indication)	Crizotinib is a kinase inhibitor indicated for the treatment of patients with metastatic NSCLC whose tumors are ROS1-positive. <b>Warning:-to be sold by retail on the prescription of a “Oncologist” only</b>	03.11.2017
35	Progesterone Sustained Release Tablet 200mg, 300mg, 400mg	For the treatment of secondary amenorrhea associated with normal estrogen level in women	03.11.2017

	(Micronised)		
36	Sodium Hyaluronate Ophthalmic Solution 0.2%	Symptomatic use in the treatment of dry eyes (Dry Eye Sundrome) including severe cases and after surgical interventions. <b>With the condition: "To be sold by retail on the prescription of Ophthalmologist only."</b>	07-11-2017
37	Raltegravir Tablet 400 mg (Additional Indication)	Raltegravir is indicated in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients.	17-11-2017
38	Diosmin Tablet 900 mg	For the treatments of Hemorrhoids	24-11-2017
39	Clostridium Botulinum Type-A toxin Haemagglutinin complex injection 300 units/vial	Dysport® is Indicated in adults for symptomatic treatment of the temporary improvement in the appearance of moderate to severe glabellar lines (vertical lines between the eyebrows) seen at frown, in adult patients under 65 years, when the severity of these lines has an important psychological impact on the patient. <b>With the condition: To be sold by retail on the prescription of specialist like Dermatologist, Plastic Surgeons, Anaesthesiologist, Ophthalmologist, Neurologist and ENT Surgeons.</b>	13-12-2017
40	Nonoxynol-9 (1.0971g) vaginal Contraceptive Sponge	Contraception	18-12-2017
41	Ceritinib Capsules 150 mg	As monotherapy is indicated for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK) – positive advanced non-small cell lung cancer (NSCLC). <b>With the condition: to be sold by retail on the prescription of Oncologist only.</b>	28-12-2017
42	Palbociclib Capsules 75mg/100mg/125mg (Additional Indication)	“Palbociclib is a kinase inhibitor indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-Negative advanced or metastatic breast cancer in combination with: fulvestrant in women with disease progression following endocrine therapy”. <b>With the condition: to be sold by retail on the prescription of Oncologist only.</b>	30-12-2017