	No. Deve Nove Detection Detection				
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 β -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 β -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)	 For the treatment of patients with chronic lymphocytic leukemia 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. 	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 With the condition: to be sold by retail on the prescription of Oncologist only	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 Acute Bacterial Exacerbation of Chronic Bronchitis Community-Acquired pneumonia Pharyngitis/Tonsillitis 	30.03.2017		

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		 Acute sinusitis Uncomplicated skin and skin-structure infections. 	
9	Thiotepa Powder for concentrate for solution for infusion 100 mg(Additional strength & indication)	 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; When high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumors in adult and pediatrics patients. With the condition: to be sold by retail on the prescription of Hematologist only 	06.04.2017
10	Thiotepa Powder for concentrate for solution for infusion 15mg (Additional indication)	 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; When high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumors in adult and pediatrics patients. With the condition: to be sold by retail on the prescription of Hematologist only 	06.04.2017
11	Bortezomib for Injection (i.v) 1 mg/vial (Additional indication)	For the treatment of patients with mantle cell lymphoma With the condition: to be sold by retail on the prescription of Oncologist only	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 With the condition: to be sold by retail on the prescription of Oncologist only	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. With the condition: to be sold by retail on the prescription of Specialist/Gastroenterologist only	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. With the condition: to be sold by retail on the	02.05.2017

		prescription of Cardiologist/Internal	
		Medicine Speciality only	
16	Daclatasvir Tablet 30	"For use with Sofosbuvir for the treatment of	24.05.2017
	mg	patients with chronic hepatitis C virus (HCV)	
		genotype 3 infection".	
		With the condition: to be sold by retail on the	
		prescription of Hepatologist only	
17	Daclatasvir Tablet 60	"For use with Sofosbuvir for the treatment of	24.05.2017
	mg	patients with chronic hepatitis C virus (HCV)	
		genotype 3 infection".	
		With the condition: to be sold by retail on the	
		prescription of Hepatologist only	
18	Rosuvastatin Tablets 15	a. Treatment of patients with primary	30.05.2017
	mg	hypercholesterolemia or mixed	
		dyslipedemia, homozygous familial	
		hyper cholesterolemia as an adjutant to	
		diet, when response to diet and excercise	
		is inadequate	
		b. As an adjunctive therapy to diet for the	
		treatment of adult patients with	
		hypertriglycerdemia.	
		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.	
		d. Risk reduction of Myocardial Infarction	
		stroke and arterial revascularization	
		procedure in patients without clinically	
		evident CHD but with multiple risk	
		factors.	
		e. As an adjunct to diet for the treatment	
		of patients with primary	
		dysbetalipoproteinemia (type-III	
		hyperlipoprotenemia).	
		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	
		>190 mg/dL or > 160 mg/dL and there	
		is a positive family history of premature	
		cardiovascular disease (CVD) or two or	
		more CVD risk factors.	
19	Rosuvastatin film	a. Treatment of patients with primary	30.05.2017
	coated Tablets 30 mg	hyper cholesterolemia or mixed	
		dyslipedemia, homozygous familial	
		hyper cholesterolemia as an adjutant to	
		diet, when response to diet and excercise	
		is inadequate	
		b. As an adjunctive therapy to diet for the	

		With the condition: to be sold by retail on the prescription of Oncologist only	
		therapy.	
	Gelatin Capsules 40 mg	castration resistant prostate cancer whose disease has progressed on or after Docetaxel	
21	Enzalutamide hard	For the treatment of adults with metastatic	12.07.2017
		prescription of Oncologist only	
		With the condition: to be sold by retail on the	
		or prednisolone.	
		whom chemotherapy is not yet clinically indicated with prednisone	
		of androgen deprivation therapy in	
		or mildly symptomatic after failure	
		in adult men who are asymptomatic	
		castration resistant prostate cancer	
		docetaxel 2. For the treatment of metastatic	
		prior chemotherapy containing	
		prostate cancer who have received	
	-	metastatic castration resistant	
	Tablet 500 mg	the treatment of patients with	
20	Abiraterone Acetate	1. In combination with prednisone for	12.07.2017
		more CVD risk factors.	
		is a positive family history of premature cardiovascular disease (CVD) or two or	
		>190 mg/dL or > 160 mg/dL and there	
		following findings are present: LDL-C	
		adequate trial of diet therapy the	
		hypercholesterolemia if after and	
		heterozygous familial	
		boys and girls, who are atleast one year post-menarche, 10-17 years of age with	
		LDL-C and ApoB levels in adolescent	
		f. As adjunct to diet to reduce total-C,	
		hyperlipoprotenemia).	
		dysbetalipoproteinemia (type-III	
		of patients with primary	
l		e. As an adjunct to diet for the treatment	
		factors.	
		evident CHD but with multiple risk	
l		procedure in patients without clinically	
		d. Risk reduction of Myocardial Infarction stroke and arterial revascularization	
		target levels.	
1		strategy to lower total C and LDL-C to	
		adult patients as part of a treatment	
		the progression of atherosclerosis in	
		c. As an adjunctive therapy to diet to slow	
ł		treatment of adult patients with hypertriglycerdemia.	