

Manufacturing and Marketing permission issued from SND Division from 01.01.2016 to till date.

S.No.	Drug Name	Indication	Date of Approval
1	Amlodipine Orally Disintegrating Strips 2.5mg/5mg/10mg	For the treatment of essential hypertension	07.01.2016
2	Omeprazole Magnesium Delayed Release Granules for oral Suspension 10mg	For the treatment of Gastric ulcer, active duodenal ulcer, gastro esophageal reflux disease (GERD), erosive esophagitis and maintenance of healing erosive esophagitis in adult patients only.	16.02.2016
3	Enoxaparin Sodium Injection 300mg/3ml multidose cartridge (Additional Dosage Form)	1. As a prophylactic in the treatment of thromboembolic disorder during orthopaedic surgery, General surgery and haemodialysis. 2. Treatment of acute ST-segment elevation myocardial infarction including patients to be managed medically or with subsequent percutaneous coronary intervention (PCI)	31.03.2016
4	Mometasone Furoate Monohydrate equivalent to Mometasone Furoate aqueous Nasal Spray 50mcg/actuation (Additional Indication)	For the treatment of the nasal symptoms of seasonal allergic and perennial allergic rhinitis, in adults and children 2 years of age and older	30.04.2015*
5	Darunavir Ethanolate 800mg film coated tablet (Additional Strength)	Darunavir tablet co-administered with Ritonavir (Darunavir/Ritonavir) and other anti-retroviral agents is indicated for the treatment of a human immunodeficiency virus (HIV-1) infection in adult patients only.	04.05.2016
6	Deferasirox film coated tablet 90mg/180mg/360mg (Additional strength)	1. Indicated for the treatment of chronic iron overload due to blood transfusions (Transfusional hemosiderosis) in adult and paediatric patients (aged 2 years and above) 2. For the treatment of chronic iron overload in patients with non-transfusion dependent thalassemia syndromes aged 10 years and older.	05.05.2016
7	Triptorelinembonate equivalent to Triptorelin	For the treatment of locally advanced or metastatic, hormone-	10.05.2016

S.No.	Drug Name	Indication	Date of Approval
	22.5mg Injection (Lyophilized power for suspension for injection, Intramuscular Route) Additional Strength	dependent prostate cancer.	
8	Methadone Hydrochloride tablet 5mg/10mg (additional indication)	For the management of “Chronic refractory moderate to severe pain” With Condition: 1. “Warning: To be sold by retail on the prescription of a Physicians trained and experienced in the management of chronic pain only.” 2. The package insert should have the boxed warning for all serious toxicities of the drug. 3. This drug should be made available/sold as per GSR 359 (E) dated 05-05-2015 of NDPS act, 1985 (Ministry of Finance).	10.05.2016
9	Methadone Hydrochloride Oral Syrup 5mg/10mg per ml (in 150 ml pack) (additional indication)	For the management of “Chronic refractory moderate to severe pain” With Condition: 1. “Warning: To be sold by retail on the prescription of a Physicians trained and experienced in the management of chronic pain only.” 2. The package insert should have the box warning for all serious toxicities of the drug and 1000ml pack size should not be permitted for use in this additional indication. 3. This drug should be made available/sold as per GSR 359 (E) dated 05-05-2015 of NDPS act, 1985 (Ministry of Finance).	10.05.2016

S.No.	Drug Name	Indication	Date of Approval
10	Everolimus tablets 2.5mg. 5mg and 10mg	<p>“Treatments of adults patients with progressive, well differentiated, non-functional neuroendocrinotumors (NET) of gastrointestinal (GT) or lungs origin with unresectable, locally advanced or metastatic disease”</p> <p>With Condition:</p> <ol style="list-style-type: none"> 1. “Warning: To be sold by retail on the prescription of Oncologist only.” 	08.06.2016
11	Povidone Iodine Ointment USP 10% w/w (available Iodine 1% w/w) Water soluble ointment	It is broad spectrum antiseptic for the topical treatment or prevention of infection in minor cuts and abrasions, minor surgical procedures and small area of burns. Treatment of mycotic and bacterial skin infections pyodermas. Treatment of infections in decubitus and stasis ulcers.	15.06.2016
12	Flupenthixol Tablet (FlupenthixolHydrochloride equivalent to Flupenthixol0.5mg/ 1mg)	---	23.07.1981*
13	Travoprost Eye Drops 30mcg/ml with polyquaternium-1 10mcg/ml (Additional Strength)	<p>Decrease of elevated intraocular pressure in adult patients with ocular hypertension or open-angle glaucoma.</p> <p>With Condition:</p> <ol style="list-style-type: none"> 1. “Warning: To be sold by retail on the prescription of Ophthalmologist only.” 2. Phase IV clinical trial in at least 500 Indian subjects be carried out within one year of approval. 	22.07.2016

S.No.	Drug Name	Indication	Date of Approval
14	Paclitaxel Lipid Suspension for Injection 30mg/vial and 60mg/vial (Additional Dosage Form)	<ol style="list-style-type: none"> 1. Paclitaxel is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or replace with 6months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated. 2. Paclitaxel is indicated for the adjuvant treatment of node positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy. 3. Paclitaxel is indicated as first line and subsequent therapy for the treatment of advanced carcinoma of the ovary. As first line therapy, it is indicated in combination with cisplatin. 4. Paclitaxel, in combination with cisplatin, is indicated for the first line treatment of non small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy. 5. Paclitaxel is indicated for the second line treatment of AIDS related Kaposi's sarcoma. <p>With Condition:</p> <ol style="list-style-type: none"> 1. "Warning: To be sold by retail on the prescription of Oncologist only." 	02.08.2016

S.No.	Drug Name	Indication	Date of Approval
15	Liposomal Amphotericin B Injection 50mg/vial (Additional Dosage Form)	For the treatment of invasive fungal infection in patients who are refractory to or intolerant of conventional Amphotericin B therapy. With Condition: 3. "Warning: To be sold by retail on the prescription of RMP only." 4. You should conduct active post marketing surveillance studies in at least 250 patients with in 2 years.	02.08.2016
16	Azacitidine Lyophilized powder for Injection 100mg/vial (Intravenous or Subcutaneous)	For the treatment of adult patients with a subtypes of Myelodysplastic Syndrome. With Condition: 1. To be sold by retail on the prescription of a "Oncologists" only 2. A Phase IV study should be conducted in patients in the country. Accordingly, the firm should submit the protocol etc., to the office of DCG(I) within 3 months of approval	04.08.2016
17	Abiraterone Acetate Tablet 250 mg (Additional Indication)	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. With Condition: 1. To be sold by retail on the prescription of a "Oncologists" only	12.08.2016
18	Medoxyprogesterone Acetate Suspension for Injection 104mg/0.65ml Subcutaneous Route. (Additional Indication)	For long-term female contraception.	12.08.2016

S.No.	Drug Name	Indication	Date of Approval
19	Minocycline Hydrochloride Extended Release Tablets 45mg/65mg (Additional Strength)	Indicated to treat only inflammatory lesion on non-nodular moderate to severe acne vulgaris in patients 12years of age and older With Condition: 1. To be sold by retail on the prescription of RMP only 2. Prescribing information should highlight all the adverse events (AE's) in bold letters.	29.08.2016
20	PEG L-Asparaginase (Pegaspargase) Injection 750IU/mL, iv/im (Pack size 5mL/vial)	Indicated as a component of multi agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukaemia who are hypertensive to Asparaginase. With Condition: 1. To be sold by retail on the prescription of Oncologist only. 2. Phase IV study is required to be initiated within 6 months from the date of approval of the drug. Accordingly, protocol and all the other required documents should be submitted to this directorate for approval.	29.08.2016
21	Eplerenone Tablets 25mg/50mg (Additional Indication)	Indicated as an adjunct to standard to standard therapy, to reduce the risk of CV mortality and morbidity in adult patients with New York Heart Association (NYHA) class II (chronic) heart failure and left ventricular systolic dysfunction (LVED \leq 30%) With Condition: 1. To be sold by retail on the prescription of Specialist only.	14.09.2016
22	EltrmbopagOlamine 25mg and 50mg (Additional Indication)	Indicated for the treatment of patients with Severe Aplastic Anaemia (SAA) who have had an insufficient response to immunosuppressive therapy. With Condition: 1. To be sold by retail on the	14.09.2016

S.No.	Drug Name	Indication	Date of Approval
		prescription of Hematologist only.	
23	Afatinib Tablets 20mg/30mg/40mg/50mg (Free base) corresponding to Afatinibdimaleate 29.56mg/44.34mg/59.12mg/73.9mg (Additional Indication)	Indicated for the treatment of locally advanced or metastatic, NSCLC of squamous histology progressing on or after platinum based chemotherapy. With Condition: 1. To be sold by retail on the prescription of Oncologist only.	27.09.2016
24	EribulinMesylate solution for injection 0.5mg/mL (2mL/vial; intravenous route)	For the treatment of adult patients with unresectableliposarcoma who have received anthracycline containing therapy (unless unsuitable) for advanced metastatic disease	27-10-2016
25	RebamipideOphthalmic suspension 2% w/v Each mL contains : Rebamipide 20mg Benzalkonium Chloride IP 0.01% w/v (as preservative)	Indicated for the treatment of dry eye signs and symptoms With Condition: To be sold by retail on the prescription of Oncologist only.	11-11-2016
26	Tilmicosin 300mg/mL solution for injection (For Veterinary use only)	For the treatment of Pasteurella infection in cattle only With Condition: To be sold by retail on the prescription of Registered Veterinary Practitioners only (withdrawal period shall be mentioned on the labels).	22-12-2016
27	Bendamustine Hydrochloride 100mg/vial powder for concentrate for solution for infusion	For the treatment of Front line treatment of multiple myeloma (Durie-Salmon stage II with progress or stage III) in combination with prednisone for patients older than 65 years who are not eligible for autologous stem cell transplantation and who have clinical neuropathy at time of diagnosis precluding the use of thalidomide or bortezomib containing treatment. With Condition: To be sold by retail on the prescription of Oncologist only.	23-12-2016

