

**NEW DRUGS APPROVED LIST FROM SND DIVISION
(FROM 01.01.2022 TO 31.12.2022)**

S. No	Drug Name	Composition	Indication	Date of Approval
1	Ivermectin Tablets 12 mg (Additional Strength)	Each uncoated tablet contains: Ivermectin IP..... 12 mg Excipients.....QS	Treatment of intestinal helminths and suppression of microfilaraemia especially with bancrofti infections	03-01-2022
2	Enzalutamide Tablets 160mg (Additional Dosage form & Strength)	Each film coated tablets contains : Enzalutamide1 60mg	<ul style="list-style-type: none"> • The treatment of adult men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. • The treatment of adults with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after docetaxel therapy <p>"WARNING: To be sold by retail on the prescription of Oncologist only"</p>	04-01-2022
3	Tofacitinib Tablets 10 mg (Additional Strength)	Each tablet contains Tofacitinib Citrate 16.16mg equivalent to Tofacitinib 10mg	1. 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	11-01-2022

			<p>used as monotherapy or in combination with methotrexate or other nonbiologic disease modifying antirheumatic drugs (DMARDs).</p> <p>2. For the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to Methotrexate or other non-biologic disease modifying antirheumatic drugs (DMARDs).</p> <p>The firm should conduct Phase IV study in rheumatoid arthritis and psoriatic arthritis with statistically significant number of patients. Accordingly, firm should submit Phase IV CT protocol within 3 months after approval and study should be completed within 2 years from the approval of the study</p> <p>"WARNING: To be sold by retail on the prescription of a Rheumatologist or Specialist in Internal Medicine only"</p>	
4	<p>Methotrexate Injection 1000mg/10ml</p> <p>(Additional Strength)</p>	<p>Each ml contains: Methotrexate1 00mg</p>	<p>1. Acute lymphocytic leukaemias (ALL): in combination with other cytotoxic medicinal products. 2. Non-Hodgkin's lymphomas: in combination with other cytotoxic medicinal products in adult patients with Non-Hodgkin's lymphomas of intermediate and high degree of malignancy & in</p>	11-01-2022

			<p>combination with other cytotoxic medicinal products in paediatric patients.</p> <p>3. Head and neck cancer: as palliative monotherapy in patients with metastatic or recurrent disease.</p> <p>4. Breast cancer: in combination with other cytotoxic medicinal products in patients for adjuvant treatment after tumour resection or mastectomy and for palliative treatment in advanced disease.</p> <p>5. Choriocarcinoma and similar trophoblastic diseases: as monotherapy in patients with good prognosis (low risk) & in combination with other cytotoxic medicinal products in patients with poor prognosis (high risk).</p> <p>6. Osteosarcoma: in combination with other cytotoxic medicinal products for adjuvant and neoadjuvant therapy.</p> <p>7. Cancer of the bladder: in combination with other cytotoxic medicinal products.</p> <p>"WARNING: To be sold by retail on the prescription of Oncologist only"</p>	
5	<p>Ibrutinib Capsules 140 mg</p> <p>(Additional Indication)</p>	<p>Each Hard Gelatin Capsules Contains: Ibrutinib.....140 mg</p>	<p>For the treatment of patients with Marginal Zone Lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20 based therapy</p> <p>"WARNING: To be sold by retail on the</p>	21-01-2022

			prescription of Oncologist only”	
6	Ibrutinib Capsules 140 mg (Additional Indication)	Each Hard Gelatin Capsules Contains: Ibrutinib.....140 mg	For the treatment of patients with chronic Graft Versus Host Disease (cGVHD) who have received at least one line of systemic therapy "WARNING: To be sold by retail on the prescription of Oncologist only”	21-01-2022
7	Lincomycin Hydrochloride Sustained Release Tablet 1000 mg (Additional Dosage Form)	Each film coated Sustained Release tablets contains: Lincomycin Hydrochloride eq to Lincomycin..... 1000mg	Indicated in the treatment of serious infections due to susceptible strains of streptococci, pneumococci, and staphylococci. Its use should be reserved for penicillin-allergic patient or for whom penicillin is inappropriate The firm should submit safety data of the product to CDSCO every two months for the next one year "WARNING: To be sold by retail on the prescription of Medical specialist only”	21-01-2022
8	Clobazam oral suspension 5mg/5mL & 10mg/5mL (Additional Strength)	Each 5ml contains: Clobazam I.P.....5mg/10 mg Approved colours used	1. Acute and chronic anxiety states. 2. As an adjunctive therapy in patients with refractory epilepsy. "WARNING: To be sold by retail on the prescription of Neurologist/Psychiatrist only”	02-02-2022
9	Rosuvastatin Sprinkle Capsules 10 mg, 20 mg and 40 mg	Each capsule contains: Rosuvastatin calcium equivalent to Rosuvastatin	• As an adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia.	28-02-2022

	(Additional Dosage Form)10 mg / 20 mg / 40 mg Excipients q.s.	<ul style="list-style-type: none"> • As an adjunct to diet for the treatment of adult patients with primary dysbetalipoproteinemia (Type III Hypolipoproteinemia). • As adjunctive therapy to other lipid lowering treatments (e.g., LDL apheresis) or alone if such treatments are unavailable to reduce LDLC, Total-C, and ApoB in adult patients with homozygous familial hypercholesterolemia. 	
10	Minocycline Hydrochloride Topical Gel 4% (Additional Dosage Form & Additional Indication)	Each gram of gel contains: 40 mg of Minocycline equivalent to 43 mg of Minocycline Hydrochloride Ph. Eur.	<p>Indicated for the topical treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and pediatric patients 9 years of age and older</p> <p>The firm should conduct Phase IV Clinical trial</p>	28-02-2022
11	Lenalidomide Capsules 5mg/10mg/15mg (Additional Indication)	Each hard gelatin capsule contains: Lenalidomide..... 5mg/10mg/15mg	<ul style="list-style-type: none"> • Follicular Lymphoma: Lenalidomide in combination with a Rituximab product, is indicated for the treatment of adult patients with previously treated follicular lymphoma (FL). • Marginal Zone Lymphoma: Lenalidomide in combination with a Rituximab product, is indicated for the treatment of adult patients with previously treated marginal zone lymphoma (MZL) <p>"WARNING: To be sold by retail on the</p>	02-03-2022

			prescription of oncologist only”	
12	Thymosin Alpha-1 for injection 1.6 mg (Additional Indication)	Each Vial Contains: Thymosin Alpha 1 for Injection... 1.6 mg Excipients...q. s.	As add-on therapy for the treatment of moderate to severe Covid patients requiring ventilator support (NIV as well as Mechanical ventilation) The firm should conduct active PMS study for which protocol should be submitted for further review by the committee “WARNING: To be sold by retail on the prescription of Medical specialists only”	02-03-2022
13	Cholecalciferol (Vitamin D3) Oral Solution 6000IU	Each 5ml syrup contains: Cholecalciferol.... . 60000IU In a Flavoured baseq.s.	For the Treatment of Vitamin D3 Deficiency. “WARNING: To be sold by retail on the prescription of a RMP only”	02.03.2022
14	Glutathione for Injection 600 mg / vial (Additional Indication)	Each Vial Contains: Glutathione BP..... 600 mg Excipients... q. s.	As an add-on to the standard of care in moderate COVID-19 patients “WARNING: To be sold by retail on the prescription of Medical specialists only”	11-03-2022
15	Levosalbutamol tartrate Inhalation Aerosol (Levosalbutamol 45mcg/actuation)	Each actuation delivers (ex-actuator): Levosalbutamol Tartrate 59 mcg equivalent to Levosalbutamol45mcg Ethanol anhydrous Ph Eur ...4.7% w/w Excipients – Oleic	Indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older with reversible obstructive airway disease	14-03-2022

		Acid USP NF Norflorane Ph. Eur.(Propellant HFA 134a).....q.s		
16	Trametinib 0.5 mg and 2 mg tablets (Additional Indication)	Each film coated tablet contains: Trametinib dimethyl sulfoxide equivalent to Trametinib..... 0.5mg/2mg	Trametinib is indicated, in combination with dabrafenib, for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations as detected by an appropriate test and involvement of lymph node(s), following complete resection “WARNING: To be sold by retail on the prescription of Oncologist only”	17-03-2022
17	Trametinib 0.5 mg and 2 mg tablets (Additional Indication)	Each film coated tablet contains: Trametinib dimethyl sulfoxide equivalent to Trametinib..... 0.5mg/2mg	Trametinib is indicated, in combination with dabrafenib, for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAFV600E mutation and with no satisfactory locoregional treatment Options “WARNING: To be sold by retail on the prescription of Oncologist only”	17-03-2022
18	Dabrafenib Capsules 50mg and 75mg (Additional Indication)	Each hard gelatin capsule contains: Dabrafenib Mesylate equivalent to Dabrafenib 50mg/75mg	Dabrafenib in combination with trametinib for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an appropriate test, and involvement of lymph node(s), following complete resection	17-03-2022

			“WARNING: To be sold by retail on the prescription of Oncologist only”	
19	Dabrafenib Capsules 50mg and 75mg (Additional Indication)	Each hard gelatin capsule contains: Dabrafenib Mesylate equivalent to Dabrafenib50mg/75mg	Dabrafenib in combination with trametinib for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAFV600E mutation and with no satisfactory locoregional treatment options “WARNING: To be sold by retail on the prescription of Oncologist only”	17-03-2022
20	Tacrolimus Hard Gelatin Capsules 0.75mg (Additional Strength)	Each Hard Gelatin Capsules contains: Tacrolimus Monohydrate equivalent to Tacrolimus ... 0.75mg	For the prophylaxis of organ rejection in patients receiving allogeneic liver or kidney transplants "WARNING: To be sold by retail on the prescription of a Nephrologist only"	05-04-2022
21	Estriol Cream BP 1mg/gm (Additional Dosage Form)	Each gram contains: Estriol BP.....1mg Chlorhexidine Hydrochloride BP (as preservative)0 .1 mg	For vaginal symptoms due to Estrogen deficiency in menopause	11-04-2022
22	Betahistine dihydrochloride Orodispersible film 8mg/16mg/24mg (Additional Strength)	Each Orodispersible Contains: Betahistine dihydrochloride ...8mg/16mg/24mg	indicated in the treatment of Menier’s syndrome, characterized by unilateral or bilateral tinnitus, vertigo, sensorineural hearing loss	12-04-2022
23	Linezolid Sustained	Each film coated sustained release	For the treatment of complicated/uncomplicat	12-04-2022

	<p>Release Tablets 1200 mg</p> <p>(Additional Dosage Form & Strength)</p>	<p>tablet contains: Linezolid IP.....1200mg</p>	<p>ed skin & skin structure infection, community acquired pneumonia & osteomyelitis in adults</p> <p>You are required to conduct PMS study in adequate number of patients. Accordingly, submit protocol to this office within six months of launch of product in Indian market</p>	
24	<p>Empagliflozin Tablets 10/25mg</p> <p>(Additional Indication)</p>	<p>Each Film coated tablets contains: Empagliflozin 10/25mg</p>	<p>To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure subject to condition that the drug should be prescribed only to the patients with eGFR more than 30ml/min/1.73m²</p>	05-05-2022
25	<p>Tofacitinib Extended Release Tablets 11mg</p> <p>(Additional Strength)</p>	<p>Each film-coated extended release tablets contains: Tofacitinib Citrate equivalent to Tofacitinib.....11 mg</p>	<p>Rheumatoid Arthritis: Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more TNF blockers. Psoriatic Arthritis: Indicated for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more TNF blockers. Ulcerative Colitis: Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC), who have an inadequate response or intolerance to one or more TNF blockers</p> <p>The firm should conduct the Active PMS Study. Accordingly, the firm</p>	09-05-2022

			<p>should submit Active PMS Study protocol within 03 months after approval of the product</p> <p>"WARNING: To be sold by retail on the prescription of a Rheumatologist, Gastroenterologist, Hepatologist or Specialist in Internal Medicine only"</p>	
26	<p>Clozapine Extended Release Capsules 12.5mg/25mg/50mg/100mg/200mg</p> <p>(Additional Dosage Form)</p>	<p>Each Extended Release Capsules contains: Clozapine 12.5mg/25mg/50mg/100mg/200mg</p>	<p>Indicated in the management of schizophrenic patients</p> <p>"WARNING: To be sold by retail on the prescription of Psychiatrist only"</p>	09-05-2022
27	<p>Magnesium Sulphate Intravenous Infusion 4% w/v</p> <p>(Additional Strength)</p>	<p>Each 100 ml contains: Magnesium Sulphate Heptahydrate..... 4g (equivalent to 32.5 mEq of Magnesium) Excipients..... ...qs Water for injection.....qs to 100ml</p>	<p>Indicated for the prevention and control of seizures in pre-eclampsia and eclampsia, respectively</p> <p>"WARNING: To be sold by retail on the prescription of a Gynecologist only"</p>	11-05-2022
28	<p>Sacubitril Valsartan Tablet</p> <p>(Additional Indication)</p>	<p>Each Film Coated Tablet Contains: 1. Sacubitril + Valsartan.....50 mg (24mg+26mg) (as sodium salt complex) 2. Sacubitril + Valsartan.....100 mg (49mg+51mg) (as sodium salt complex) 3. Sacubitril + Valsartan.....200 mg</p>	<p>To reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with Left Ventricular Ejection Fraction (LVEF) below normal. LVEF is a variable measure, so use clinical judgment in deciding whom to treat</p>	11-05-2022

		(97mg+103mg) (as sodium salt complex)		
29	Metformin Hydrochloride Sustained Release Tablets 500/850/1000mg (Additional Indication)	Each Sustained Release Tablets contains: Metformin Hydrochloride ...500/850/1000mg	<ul style="list-style-type: none"> • Reduction in the risk or delay of the onset of type 2 diabetes mellitus in adult, overweight patients with Impaired Glucose Tolerance and/or Impaired Fasting Glucose, and/or increased HbA1C who are: <ul style="list-style-type: none"> o At high risk for developing overt type 2 diabetes mellitus and o Still progressing towards type-2 diabetes mellitus despite implementation of intensive lifestyle change for 3 to 6 months. • Treatment with metformin SR must be based on a risk score incorporating appropriate measures of glycaemic control and including evidence of high cardiovascular risk. • Lifestyle modifications should be continued when metformin is initiated, unless the patient is unable to do so because of medical reasons. 	17-05-2022
30	Vardenafil Oral Jelly 20mg/5g Sachet (Pineapple Flavour) (Additional Dosage Form)	Each sachet (5g) contains: Vardenafil Hydrochloride Trihydrate equivalent to Vardenafil.....20 mg	For the treatment of erectile dysfunction "WARNING: To be sold by retail on the prescription of a Urologist/Endocrinologist/Psychiatrist/Cardiologist only"	17-05-2022
31	Sodium Dichloroisocyanurate / Sodium Troclosene / NaDCC Tablets 0.5 gm, 2.5 gm and 5.0 gm	Each uncoated effervescent disinfectant Tablets contains: Sodium Dichloroisocyanurate / Sodium	Cleaning , Cleaning of work surfaces, Cleaning of Hospital Surfaces	17-05-2022

	(Additional Strength & Indication)	Troclosene / NaDCC0.5 gm/ 2.5 gm/ 5.0gm Excipients:.....qs		
32	Levothyroxine Sodium Tablets 125mcg/137mcg/150mcg (Additional Strength)	Each uncoated tablet contains: Thyroxine Sodium Eq. to anhydrous Thyroxine sodium125mcg/137mcg/150mcg	For the treatment of hypothyroidism	18-05-2022
33	Thyroxine Sodium Tablets 62.5mcg (Additional Strength)	Each uncoated tablet contains: Thyroxine Sodium Eq. to anhydrous Thyroxine sodium62.5mcg	For the treatment of hypothyroidism	18-05-2022
34	Ropivacaine Solution for Infusion 2 mg/ml (250ml) in Administration System (Additional Dosage Form)	1ml solution for infusion contains ropivacaine hydrochloride monohydrate, equivalent to 2 mg ropivacaine hydrochloride. 1 dispensing device (Ropivacaine 2 mg/ml Solution for Infusion in Administration System) contains 250ml ropivacaine hydrochloride monohydrate solution for infusion, equivalent to 500mg ropivacaine hydrochloride	For acute, postoperative pain management in adults. It is used to maintain a continuous peripheral nerve block via a continuous infusion and for continuous wound infiltration “ WARNING: To be sold by retail on the prescription of Anesthesiologist only ”	18-05-2022
35	Liposomal Amphotericin B	Each vial contains:	• Febrile Neutropenia in cancer patients.	02-06-2022

	Injection 50 mg/vial (Lyophilized) (Additional Indication)	Amphotericin B.....50 mg (intercalated into Liposomal Membrane)	<ul style="list-style-type: none"> • For the treatment of invasive fungal infection in patients who are refractory to or intolerant of conventional amphotericin-B therapy. • For the treatment of visceral leishmaniasis <p>The Firm should conduct active post marketing surveillance studies in at least 250 patients. Accordingly, you should submit the protocol for approval. The data of safety monitoring shall be submitted on monthly basis</p>	
36	Pantoprazole Powder for Oral Suspension (Sodium Bicarbonate as Buffer) 40mg per sachet (Additional Dosage Form)	Each sachet contains: Pantoprazole sodium IP Equivalent to Pantoprazole.....40mg (sodium Bicarbonate as buffer)	For the treatment of gastric ulcer, duodenal ulcer, Zollinger Ellison Syndrome and Gastro-Esophageal reflux disease	14-06-2022
37	Dexamethasone Intravitreal Implant 0.7mg (Additional Indication)	Each Intravitreal Implant contains: Dexamethasone0.7mg (in solid polymer drug delivery system)	For the treatment of diabetic macular edema The firm should conduct active post marketing surveillance study in 500 patients with follow up period of six months. The protocol for active post marketing surveillance study should be submitted to CDSCO within three months of approval of the drug	15-06-2022

			“WARNING: To be sold by retail on the prescription of Ophthalmologist only”	
38	Carbetocin injection 100 mcg/ml (Pre Filled Syringes)	Each ml of solution for injection in vial contains: Carbetocin.....100mcg Excipients..... ...q.s. Water for injections.....q .s. to 1.0ml	Prevention of postpartum haemorrhage due to uterine atony Firm should submit the Phase IV clinical trial protocol within 3 months of approval of the product “WARNING: To be sold by retail on the prescription of a Gynecologist and obstetrician only”	17-06-2022
39	Colchicine Tablets USP 0.6mg (Additional Strength)	Each tablets contains: Colchicine.....0.6 mg	For treatment and prophylaxis of acute gout. It is also indicated for the treatment of familial Mediterranean fever	17-06-2022
40	Gabapentin Oral solution 250mg/5ml (Additional Dosage Form)	Each Oral solution contains: Gabapentin250mg/5ml	For the treatment of neuropathic pain and as adjunctive therapy in the treatment of partial seizures with or without secondary generalization in adults	27-06-2022
41	Cisatracurium Besylate Injection 20mg/10ml (Additional Indication)	Each ml contains: Cisatracurium Besylate USP Equivalent to Cisatracurium...2 mg Benzyl Alcohol IP 0.09% (As Preservative) Water for Injection IP.....qs	Indicated for in-patients as an adjunct to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation in the ICU The firm should conduct Phase IV clinical trial for the indication to provide skeletal muscle relaxation during mechanical ventilation in the ICU. Accordingly, you should submit the Phase IV clinical trial	25-07-2022

			<p>within 3 months after approval for further review</p> <p>"WARNING: To be sold by retail on the prescription of Specialist only"</p>	
42	<p>Fosfomycin Sodium for Injection 4 gm (Powder for solution for infusion)</p> <p>(Additional Dosage Form)</p>	<p>Each vial contains:</p> <p>Fosfomycin Sodium EP equivalent to Fosfomycin.....</p> <p>.....4gm</p> <p>Excipients.....</p> <p>.....q.s</p>	<p>For the treatment of uncomplicated urinary tract infections (acute cystitis) in women due to susceptible strains of E. Coli and Enterococcus faecalis</p>	26-07-2022
43	<p>Olaparib film coated Tablets 100mg and 150mg</p> <p>(Additional Indication)</p>	<p>Each film-coated tablets contains:</p> <p>Olaparib.....</p> <p>..... 100mg / 150mg</p>	<p>As monotherapy for the adjuvant treatment of adult patients with BRCA-mutated HER2-negative high risk early breast cancer who have previously been treated with neoadjuvant or adjuvant chemotherapy</p> <p>"WARNING: To be sold by retail on the prescription of Oncologist only"</p>	17-08-2022
44	<p>Rifapentine film-coated tablets 300mg</p> <p>(Additional Strength)</p>	<p>Each film-coated tablets contains:</p> <p>Rifapentine</p> <p>.....</p> <p>300mg</p>	<p>For the treatment of latent tuberculosis infection caused by Mycobacterium tuberculosis in adults and children 2 years and older who are at high risk of progression to tuberculosis disease (including those in close contact with active tuberculosis patients, recent conversion to a positive tuberculin skin</p>	18-08-2022

			<p>test, HIV-infected patients, or those with pulmonary fibrosis on radiograph). Active tuberculosis disease should be ruled out before initiating treatment for latent tuberculosis infection. Rifapentine Tablets must always be used in combination with isoniazid as a 12 week once weekly regimen for the treatment of latent tuberculosis infection</p> <p>This drug should be available only through National Tuberculosis elimination Programme (NTEP) in the treatment of LTBI</p> <p>Phase IV clinical trial shall be conducted by the firm through the programme, for which protocol should be developed in consultation with the programme expert & submitted to CDSCO</p> <p>"WARNING: for the use in revised National Tuberculosis elimination Programme (NTEP) only"</p>	
45	<p>Ruxolitinib tablets 5mg, 10mg, 15mg and 20mg (Additional Indication)</p>	<p>Each tablet contains: Ruxolitinib.....5mg/10mg/15mg/20mg</p>	<p>Ruxolitinib is indicated for the treatment of patients aged 12 years and older with acute graft versus host disease or chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies</p>	18-08-2022

			“WARNING: To be sold by retail on the prescription of Oncologist only”	
46	Ozenoxacin Lotion 2% w/v (New Dosage Form)	Ozenoxacin2 % w/v	For the treatment of superficial skin infections and Acne “WARNING: To be sold by retail on the prescription of a Medical Specialist only”	01-09-2022
47	Perampanel Tablet 2mg/4mg/6mg/ 8mg/10mg/12mg (Additional Indication)	Each film coated tablet Contains: Perampanel.....2mg/4mg/6mg/8mg/10mg/12mg	Perampanel is indicated for the treatment of partialonset seizures with or without secondarily generalized seizures in patients with epilepsy 12 years of age and older The firm should submit cognitive effects of the drug products in Indian Population (specially School going Children) within one year of the issuance of marketing approval of the applied drug product for proposed additional indication “WARNING: To be sold by retail on the prescription of Neurologist only”	14-09-2022
48	Paracetamol Injection (Intramuscular), 2ml (Additional Route & Additional Strength)	Each ml contains: Paracetamol...250mg Absolute Alcohol IP.....30%v/v Water for injection	For the short term treatment of moderate pain especially following surgery and for the short term treatment of fever, when administration by parenteral route is clinically justified	16-09-2022

		IP.....q.s.	Package Insert (PI) of the product should clearly mention the Warning that the product is for Intramuscular use only and not for Intravenous use	
49	Tranexamic acid spray 10% w/v (New Dosage Form)	Each ml Contains: Tranexamic Acid IP.....100mg	To reduce or prevent hemorrhage and reduce the need of replacement therapy during accidental and domestic injury	19-09-2022
50	Tofacitinib Sustained Release Tablets 22mg (Additional Strength)	Each film-coated sustained release tablets contains: Tofacitinib Citrate equivalent to Tofacitinib.....22mg g	Indicated for the treatment of adult patients with moderately to severely active Ulcerative Colitis (UC), who have an inadequate response or intolerance to one or more TNF blockers "WARNING: To be sold by retail on the prescription of a Gastroenterologist, Hepatologist or Specialist in Internal Medicine only"	26-09-2022
51	Sildenafil Citrate Oro-Dispersible Granules 50 mg and 100mg (Additional Dosage Form)	Sildenafil Citrate Oro-Dispersible Granules 50 mg and 100mg Each Stick Pack Contains: Sildenafil citrate IP equivalent to Sildenafil50mg/100mg Excipients..... ...q.s.	For the treatment of Erectile Dysfunction "WARNING: To be sold by retail on the prescription of an Urologist, Psychiatrist and Endocrinologist only"	07-10-2022
52	Abemaciclib Tablets 50 mg, 100mg 150mg & 200mg	Each film coated tablet Contains: Abemaciclib	Early Breast Cancer: In combination with endocrine therapy is indicated for the adjuvant treatment of adult patients with hormone	11-10-2022

	(Additional Indication)	50mg/100mg/150 mg/200mg	receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative, node positive early breast cancer at high risk of recurrence. In pre or postmenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinizing hormone releasing hormone agonist “WARNING: To be sold by retail on the prescription of oncologist only”	
53	Tofacitinib Tablets (Additional Indication)	Each film coated tablet contains: Tofacitinib citrate equivalent to Tofacitinib..... 5mg	Treatment of adult patients with active ankylosing spondylitis (AS) who have responded inadequately to conventional therapy The firm should conduct Phase IV clinical trial for the proposed indication. Accordingly, the firm should submit Phase IV clinical trial protocol before marketing. “WARNING: To be sold by retail on the prescription of a Rheumatologist or Specialist in Internal Medicine only”	17-10-2022
54	Nimesulide Granules for oral suspension 100mg (Additional Dosage Form)	Each Sachet Contains: Nimesulide100mg	For short-term treatment of inflammatory conditions including joint disorders such as rheumatoid arthritis, post-traumatic and postoperative painful conditions and fever	25-10-2022

			<p>Label should contain “Not for children below 12 years” The drug product should be available only under prescription of a Registered Medical Practitioner. The prescription should contain clearly displayed Medical Council Registration No. of the Physician</p> <p>The firm should conduct Phase IV clinical trial. Accordingly, the firm should submit phase IV clinical trial protocol to CDSCO within 3 months of approval of the product “WARNING: To be sold by retail on the prescription of a Medical Specialist only”</p>	
55	<p>Capecitabine Dispersible Tablets 150mg/500mg/1000mg</p> <p>(Additional Dosage Form & Additional Strength)</p>	<p>Each Dispersible Tablets Contains: Capecitabine 150mg/500mg/1000mg</p>	<p>1. For the treatment of patients with metastatic colorectal cancer. 2. For the treatment of metastatic breast cancer after failure of paclitaxel and anthracycline containing chemotherapy regimen</p>	25-10-2022
56	<p>Biapenem for Injection 300mg and Sodium Chloride Injection IP 0.9% w/v 100ml-Dual Chamber bag</p> <p>(Additional Packing (Dual Chamber Bag))</p>	<p>Each Dual Chamber Bag contains: (A) Biapenem for Injection 300mg Each Bag Contains: Biapenem IP (Sterile).....300mg (B) Sodium Chloride Injection IP 0.9% w/v 100ml Each ml contains:</p>	<p>Complicated urinary tract infections (cUTI)</p> <p>“WARNING: to be sold by retail on the prescription of Specialist only”</p>	02-11-2022

		Sodium Chloride IP 0.9% w/v Water for Injection IP.q.s. to 100ml		
57	Sterile dehydrated Human Amnion Chorion Membrane	Each unit contains: Sterile dehydrated Human Amnion Chorion Membrane (Patch size 5 x 5 cm ²)	Indicated for the treatment of acute and chronic non-healing wounds	15-11-2022
58	Sterile dehydrated Human Amnion Chorion Membrane with Polyhexamethy lene Biguanide 0.5%	Each unit contains: Sterile dehydrated Human Amnion Chorion Membrane with Polyhexamethy lene Biguanide (PHMB)0.5% (Patch size 12 x 6 cm ²)	Indicated for the treatment of acute and chronic non-healing wounds	15-11-2022
59	Loratadine Orally Disintegrating Tablets USP 10mg (Additional Dosage Form)	Each Orally Disintegrating Tablets Contains: Loratadine10m g	Indicated for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria in adults and children	22-11-2022
60	Desidustat Tablets 100mg (Additional Strength)	Each uncoated tablet contains: Desidustat100mg Excipients..... q.s	Treatment of Anemia in Adult Patients with Chronic Kidney Disease (CKD) not on Dialysis and on Dialysis "WARNING: To be sold by retail on the prescription of a Nephrologist/ Internal Medicine specialist"	23-11-2022
61	Dapagliflozin tablets 10mg	Each film- coated tablets contains:	To reduce the risk of sustained eGFR and kidney disease,	23-11-2022

	(Additional Indication)	Dapagliflozin propanediol monohydrate equivalent to Dapagliflozin...10 mg	cardiovascular death, and hospitalization for heart failure in adult with chronic kidney disease at risk of progression” with condition that: - It is indicated in adults for the treatment of patients of chronic Kidney disease (CKD) upto eGFR of greater than or equal to 25 ml/min/1.73m2 .Below this, initiation of the treatment is not recommended, however the patients may continue 10 mg orally once daily to reduce the risk of eGFR decline, ESKD, CV death and hHF “WARNING: To be sold by retail on the prescription of Nephrologist only”	
62	Naproxen Sodium Tablets USP 275mg & 550mg (Additional strength for new indication)	Each Uncoated Tablet Contains: Naproxen Sodium USP 275mg/550mg	In Adult: Rheumatoid arthritis, osteoarthritis (degenerative arthritis), ankylosing spondylitis, acute musculoskeletal disorders, dysmenorrhea and acute gout. In Children: Juvenile rheumatoid arthritis	29-11-2022
63	Paracetamol Oral Solution (Taste Masked) 125mg/5ml (Additional Dosage Form)	Each 5ml contains: Paracetamol IP.....125mg In a flavoured vehicle base.....q.s.	For symptomatic relief of Pain and fever	06-12-2022
64	Paracetamol Oral Solution (Taste Masked) 250mg/5ml	Each 5ml contains: Paracetamol IP.....250mg In a	For symptomatic relief of Pain and fever	06-12-2022

	(Additional Dosage Form)	flavoured vehicle base.....q.s.		
65	Nicotine Transdermal Patch 14.5 mg (7mg/24 hr), 29 mg (14 mg/24 hr) and 43.5 mg (21mg/24 hr) (Additional Dosage form)	1. Nicotine Transdermal patch Each transdermal Patch contains Nicotine USP.....14.5mg (7mg/24hr) Excipients.....q.s 2. Nicotine Transdermal patch Nicotine USP.....29 mg (14mg/24hr) Excipients.....q.s 3. Nicotine Transdermal patch Nicotine USP.....43.5mg (21mg/24hr) Excipients.....q.s	To relieve and/or prevent cravings and nicotine withdrawal symptoms associated with tobacco dependence	09-12-2022
66	Brivaracetam Sustained Release Tablets 200mg (Modified Dosage Form)	Each Film Coated Sustained Release Tablets Contains: Brivaracetam200mg	As adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy Firm should conduct active PMS study after marketing of the drug product	12-12-2022
67	Inosine Pranobex Tablets 1000mg (Additional Strength)	Each uncoated Tablet Contains: Inosine Pranobex 1000mg	A. As add-on therapy for treatment of Mild Covid-19 patients with Co-Morbidities and Moderate Covid-19 Patients. B. Mucocutaneous infections due to herpes simplex virus (Type1 and/or Type II), Genital warts and adjunctive therapy to podophyllin or carbon dioxide laser, Subacute sclerosing panencephalitis, Influenza and other acute respiratory viral infections	12-12-2022

			<p>The firm should conduct active PMS study with minimum of 100 subjects and submit study data to CDSCO after marketing the drug product</p> <p>"WARNING: To be sold by retail only under prescription of Medical Specialists"</p>	
68	<p>Loteprednol etabonate ophthalmic suspension 1%</p> <p>(Additional Strength)</p>	<p>Each ml Contains: Loteprednol Etabonate..... 1.0% w/v Benzalkonium chloride IP....0.01% w/v (As Preservative) Sterile Aqueous Vehicle.....q.s</p>	<p>It is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery</p> <p>"WARNING: to be sold by retail on the prescription of Ophthalmologists only"</p>	12-12-2022
69	<p>Esomeprazole Dual-Release Gastro-Resistant Tablets 80mg</p> <p>(Additional Dosage Form)</p>	<p>Each Dual-Release Gastro-Resistant Tablets Contains: Esomeprazole80mg</p>	<p>Indicated for the treatment of moderate to severe refractory gastro-esophageal reflux disease (GERD) for 4 weeks only</p>	16-12-2022