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List of new drugs (r-DNA origin) approved for import and marketing in India during Jan, 2020 – Jun, 2024						
S. No.	**Name of the firm**	**Date of Permission**	**Permission No.**	**Name of the Drug**	**Indication**	**Dosage Form & Strength**
1	M/s Bristol-Myers Squibb India Pvt. Ltd.	21-02-2020	IMP/BIO/20/000008	Ipilimumab Injection, 50 mg/10 mL (5 mg/mL), Single use vial	Renal Cell Carcinoma (RCC) Ipilimumab is indicated for treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma, in combination with Nivolumab. Recommended dosage Combination phase: The recommended dose during the combination phase is Ipilimumab 1 mg/kg administered intravenously over a period of 30 minutes every 3 weeks for the first 4 doses in combination with Nivolumab 3 mg/kg administered intravenously over a period of 30 minutes, followed by the single-agent phase. Single-agent phase: The recommended dose of Nivolumab during the single- agent phase is 3 mg/kg every two weeks administered intravenously over a period of 30 minutes.	Dosage Form: concentrate for solution for infusion for intravenous injection Strength: 5 mg/mL
2.	M/s Sandoz Private Limited	15.03.2020	IMP/BIO/19/000001 (Initial approval granted on 18.02.2019)	Ranibizumab Solution for injection in vial 10mg/mL + filter needle	Ranibizumab is indicated in preterm inf ants for: The treatment of retinopathy of prematurity (ROP) with zone I (stage1+, 2+, 3 or 3+), zone II (stage 3+) or AP-ROP (aggressive posterior ROP) disease (Additional Indication)	Solution for injection. Each Vial contains 2.3 mg of Ranibizumab in 0.23 mL solution. Strength: 10 mg/mL,
3	M/s Sandoz Private Limited	26-03-2020	IMP/BIO/20/000026	Crizanlizumab Concentrate for solution for infusion 10 mg/mL (100mg/10mL)	Crizanlizumab is indicated to reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease.	Dosage Form: Concentrate for solution for infusion Strength: 10mg/mL
4	M/s Dr. Reddy's Laboratories	3-04-2020	IMP/BIO/20/000029	Evolocumab Solution for Injection 140mg/ml (r-DNA origin)	1) Homozygous familial hypercholesterolaemia: Evolocumab is indicated in adults and adolescents aged 12 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies. 2) Hypercholesterolaemia and mixed dyslipidaemia: Evolocumab is indicated in adults with primary hypercholesterolaemia (heterozygous familial and	Dosage Form: Solution for Injection. Each single use Prefilled Syringe / Prefilled Autoinjector Strength: Evolocumab Injection 140 mg/mL

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	Ltd				non-familial) or mixed dyslipidaemia, as an adjunct to diet: □ in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or, □ alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated., 3) Evolocumab is indicated in adults with Established atherosclerotic cardiovascular disease (myocardial infarction, stroke or peripheral arterial disease) to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors: □ in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or,	
5	M/s Sandoz Private Limited	1-07-2020	IMP/BIO/20/000056	Brolucizumab solution for injection 120 mg/mL (r-DNA origin)	For the treatment of neovascular (wet) age-related macular degeneration (AMD)	Dosage Form: Solution for Injection (1 Vial + 1 filter needle) Strength: 120 mg/mL
6	M/s Novo Nordisk India Pvt Ltd	16-07-2020	IMP/BIO/20/000059	Catridecacog (recombinant coagulation factor XIII) 2500 IU (Novo Thirteen)	Long term prophylactic treatment of bleeding in patients with congenital factor XIII A subunit deficiency. Novo Thirteen can be used for all age groups	Dosage Form: Lyophilized Powder for solution for injection in vial Strength: 2500 IU
7	M/s Novo Nordisk India Pvt Ltd	27-07-2020	IMP/BIO/20/000060	Semaglutide	Semaglutide is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus • as monotherapy when metformin is considered inappropriate due to intolerance or contraindications; • in combination with other medicinal products for the treatment of diabetes	Dosage Form: Solid oral (tablets). Semaglutide Strength 3 mg Tablets, 7 mg Tablets and 14 mg Tablets
8	M/s Novo Nordisk India Pvt Ltd	5-08-2020	IMP/BIO/20/000063	Nonacog beta pegol	Nonacog beta pegol is indicated for treatment and prophylaxis of bleeding in pretreated patients with haemophilia B (congenital factor IX deficiency	Dosage Form: Lyophilized Powder for solution for injection. Nonacog beta pegol Strength: 500.0 IU/Vial , 1000.0 IU/Vial and 2000.0 IU/Vial

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9	M/s Baxalta Bioscience India Pvt.Ltd	9-09-2020	IMP/BIO/20/000068	Rurioctocog alfa pegol (PEGylated recombinant human FVIII)	Rurioctocog alfa pegol (Adynovate) is a human antihemophilic factor indicated in children and adults with Hemophilia A (congenital factor VIII deficiency) for: □ On-demand treatment and control of bleeding episodes □ Perioperative management □ Routine prophylaxis to reduce the frequency of bleeding episodes	Dosage Form: Lyophilized Powder for solution for injection, Strength: 250 IU/500 IU/750 IU/1000 IU/1500 IU/2000 IU vials
10	M/s Cipla Limited	27-10-2020	IMP/BIO/20/000082 **Note:** Additional Marketing Authorization	Recombinant Human Growth Hormone (Somatropin) Injection 4 IU, (IP)	Long term, treatment of children who have growth failure due to endogenous growth hormone and for treatment of short stature in children with Turner's syndrome confirmed by Chromosomal analysis	Dosage Form: Powder for solution for Injection. Each vial of Recombinant human Growth Hormone (EUTROPIN) contains 4 IU of Recombinant Human Growth Hormone (somatropin). The pack is supplied with 1 mL vial for injection for subcutaneous use
11	M/s Merck Specialities Private Limited	29-10-2020	IMP/BIO/20/000085	Follitropin alfa (r-DNA origin) and Lutropin alfa (r-DNA origin) Injection (Brand Name: Pergoveris)	Pergoveris is indicated for the stimulation of follicular development in adult women with severe LH and FSH deficiency	Dosage Form: Solution for Injection in Prefilled Pen Strength: 1. Pergoveris (300 IU rhFSH + 150 IU r-hLH)/0.48 mL; 2. Pergoveris (450 IU rhFSH + 225 IU r-hLH)/0.72 mL; 3. Pergoveris (900 IU rhFSH + 450 IU r-hLH)/1.44 mL.
12	M/s AstraZeneca Pharma India Limited	16-12-2020	IMP/BIO/20/000097	Benralizumab	Benralizumab is indicated as an add-on maintenance treatment for severe asthma with an eosinophilic phenotype in adult patients. The recommended dose is 30 mg of Benralizumab by subcutaneous injection every 4 weeks for the first 3 doses, and then every 8 weeks thereafter	Dosage Form: Solution for injection in a single dose prefilled syringe (with Needle Safety Guard) for Subcutaneous administration only Strength: 30 mg/mL

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13	M/s Novo Nordisk India Private Limited	02-03-2021	IMP/BIO/21/000001	Turoctocog Alfa Pegol	Turoctocog alfa pegol [antihemophilic factor (recombinant), glycopegylated-exei] is a recombinant DNA-derived coagulation Factor VIII concentrate indicated for use in adults and children with hemophilia A for: □ On-demand treatment and control of bleeding episodes □ Perioperative management of bleeding □ Routine prophylaxis to reduce the frequency of bleeding episodes Limitation of Use: Turoctocog alfa pegol is not indicated for the treatment of von Willebrand disease	Dosage Form: Turoctocog alfa pegol lyophilised powder for reconstitution into a solution for injection for intravenous use Strengths: 500 IU/vial, 1000 IU/vial, 1500 IU/vial, 2000 IU/vial and 3000 IU/vial; single dose vial pack for single use administration
14	M/s Novartis Healthcare Private Limited	12-03-2021	IMP/BIO/21/000004	Ofatumumab	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.	Dosage Form: Solution for injection in pre-filled syringe Strength: Ofatumumab 20 mg/0.4 mL
15	M/s Novartis Healthcare Private Limited	26-03-2021	Import 6200/05 dated 26.10.2005, 12-57/05-DC/Novartis/09. Suppl.Changes-1 dated 01.04.2010, 4-16/Novartis/PAC-R-Omalizumab/14-BD dated 22.10.2014, 4-17/Novartis/PAC-R-Omalizumab/15-BD dated 18.05.2015, 4-160/ Novartis/PAC-R-Omalizumab/15-BD dated 26.10.2015	Omalizumab	**Additional indication -** Omalizuamb is indicated as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with severe Chronic rhinosinusitis with nasal polyps for whom therapy with INC does not provide adequate disease control	(a) Omalizumab powder and solvent for solution for injection 75 mg & 150 mg single-use vial (b) Omalizumab solution for injection in a pre- filled syringe 75 mg/0.5 mL and 150 mg/1.0 mL single-use pre-filled syringe; for subcutaneous administration only
16	M/s Sanofi-synthelabo (India) Pvt. Ltd.	08-04-2021	P-119/2016 dated 02-Aug-2016	Agalsidase Beta	Agalsidase Beta is indicated for long term enzyme replacement therapy in patients with a confirmed diagnosis of Fabry Disease (α- galactosidase A deficiency)	**additional strength** Agalsidase Beta (r-DNA origin) 5 mg Vial,

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						Dosage Form: Powder for Concentrate for Solution for Infusion
17	M/s Roche Products (India) Pvt. Ltd	03-05-2021	IMP/BIO/21/000017	Casirivimab (r-DNA origin) and Imdevimab (r-DNA origin)	Combination of Casirivimab and Imdevimab indicated for restricted use in emergency situation, for the treatment of mild to moderate corona virus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with laboratory confirmed SARS-COV2 infection and who are at high risk of severe COVID-19 and does not require oxygen.	Casirivimab is a sterile, preservative-free, clear to slightly opalescent, color less to pale yellow solution. Imdevimab is a sterile, preservative- free, clear to slightly opalescent, color less to pale yellow solution with a pH of 6.0. Casirivimab and Imdevimab are each supplied in individual single-dose vials. Casirivimab and Imdevimab is approved at combine dose of 1200 mg (600 mg of each drug) administered by intravenous infusion or subcutaneous route.
18	M/s Amgen Technology Private Limited,	04-05-2021	IMP/BIO/21/000018	Romosozumab	Treatment of Postmenopausal Women with Osteoporosis at High Risk for Fracture Romosozumab is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.	Romosozumab (r-DNA origin) Injection 90 mg/mL. 105 mg/1.17mL clear to opalescent, colorless to light yellow solution for injection in a single- use prefilled syringe for Subcutaneous use Strength: 90mg/mL
19	M/s Johnson & Johnson Pvt.				a) In combination with lenalidomide and dexamethasone or with bortezomib, melphalan and prednisone for the treatment of adult	Daratumumab 1800 mg (120 mg/mL). The product is supplied in vial

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	Ltd	01-06-2021	IMP/BIO/21/000027	Daratumumab	patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. b) In combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant. c) For the treatment of patients with multiple myeloma who have received at least one prior therapy. d) For the treatment of patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent.	as a sterile, 120mg/mL liquid for subcutaneous injection. Each vial contains 1800 mg of Daratumumab in a 15mL nominal fill volume and an excess volume of at least 1.3mL. The Drug Product contains no preservatives and is for single use only.
20	M/s Merck Specialities Private Limited	02-06-2021	IMP/BIO/19/000052 (Drug originally approved on 31-Dec-2019	Avelumab	**Additional indication -** 1) Avelumab is indicated as monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) whose disease has not progressed with first-line platinum-based induction chemotherapy. 2) Avelumab in combination with axitinib is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC)	Avelumab concentrate for solution for infusion (Intravenous Infusion) Strength: 20 mg/ml vial
21	M/s Roche Products (India) Pvt. Ltd	09-06-2021	IMP/BIO/21/000030	Satralizumab	Satralizumab is indicated as monotherapy or in combination with immunosuppressants for the treatment of adult and adolescent patients with neuromyelitis optica spectrum disorders (NMOSD).	Satralizumab Injection 120 mg/ml pre-filled syringe (PFS) with needle safety device (NSD) for subcutaneous use for single dose administration
22	M/s Eli Lilly and Company (India) Pvt. Ltd.	06-07-2021	IMP/BIO/21/000038	Insulin Lispro Ultrarapid	Treatment of diabetes mellitus in adults.	Solution for Injection 100 units/ml and 200 units/ml Presentations: 1. Insulin Lispro Ultrarapid Injection 100 units/ml, 3ml cartridge & 3ml prefilled pen 2. Insulin Lispro Ultrarapid

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						Injection 100 units/mL, 10ml vial, multiple dose for Subcutaneous and Intravenous use 3. Insulin lispro Ultrarapid Injection 200 units/ml, 3ml prefilled pen
23	M/s Pfizer Limited	29-09-2021	MP/BIO/21/000080	Infliximab	**Crohn's Disease** • Infliximab is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. Infliximab is indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease. **Pediatric Crohn's Disease** • Infliximab is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy. **Ulcerative Colitis** • Infliximab is indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy. **Pediatric Ulcerative Colitis**	Lyophilized Powder for Concentrate for Solution for Intravenous Infusion; Strength: 100 mg powder per vial

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					• Infliximab is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy. **Rheumatoid Arthritis** • Infliximab, in combination with methotrexate, is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. **Ankylosing Spondylitis** • Infliximab is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. **Psoriatic Arthritis** • Infliximab is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis.	
24	M/s Roche Products (India) Pvt. Ltd.	01-10-2021	IMP/BIO/21/00 0082	Pertuzumab-Trastuzumab	**1. Early Breast Cancer (EBC)** Pertuzumab-Trastuzumab Injection is indicated for use in combination with chemotherapy for: ➢ The neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. ➢ The adjuvant treatment of adult patients with HER2- positive early breast cancer at high risk of recurrence. **2. Metastatic Breast Cancer (MBC)**	Solution for subcutaneous injection Strength: 600mg Pertuzumab + 600mg Trastuzumab [10ml/15cc vial] and 1200mg Pertuzumab + 600mg Trastuzumab vial [15ml/20cc vial]

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					Pertuzumab-Trastuzumab Injection is indicated for use in combination with docetaxel for the treatment of adult patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease	
25	M/s Bristol-Myers Squibb India Pvt. Ltd.	09-06-2016	IMP-88/2016	Nivolumab	• **Non-small cell lung cancer (NSCLC):** • Nivolumab as a single agent is indicated for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy (approved on 09.06.2016). • Nivolumab, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 (≥1%) as determined by a validated test, with no EGFR or ALK genomic tumor aberrations (additional indication approved on 09.04.2021). • Nivolumab, in combination with ipilimumab and 2 cycles of platinum- doublet chemotherapy, is indicated for the first- line treatment of adult patients with metastatic or recurrent non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations (additional indication approved on 09.04.2021) **2) Renal cell carcinoma (RCC):** • Nivolumab as a single agent is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) after prior therapy in adults (approved on 09.06.2016). • Ipilimumab is indicated for treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma, in combination with Nivolumab (additional indication approved on 04.06.2020). **3) Squamous Cell Carcinoma of the Head and Neck (SCCHN):**	Nivolumab concentrate for solution for infusion; 40 mg and 100 mg Strength: 10 mg/mL

					Nivolumab as monotherapy is indicated for the treatment of recurrent or metastatic squamous cell carcinoma of the head and neck after platinum based therapy (additional indication approved on 04.10.2017). **4) Melanoma:** • Nivolumab as a single agent is indicated for the treatment of patients with BRAF V600 wild type unresectable or metastatic melanoma (additional indication approved on 12.06.2018) Nivolumab as a single agent is indicated for the treatment of patients with BRAF V600 Mutation positive unresectable or metastatic melanoma (approved on 02.07.2018) • Nivolumab is indicated for the treatment of patients with melanoma with lymph node involvement or metastatic disease who have undergone complete resection, in the adjuvant settings (additional indication approved on 18.04.2019) **5) Classical Hodgkin Lymphoma (cHL) (additional indication approved on 12.06.2018):** Nivolumab is indicated for the treatment of adult patients with classical Hodgkin lymphoma (cHL) that has relapsed or progressed after: • autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin, or • 3 or more lines of systemic therapy that includes autologous HSCT. **6) Urothelial Carcinoma (UC) (additional indication approved on 18.04.2019)-** Nivolumab is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who: • have disease progression during or following platinum- containing chemotherapy. • have disease progression within 12 months of neoadjuvant or adjuvant treatment	

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					with platinum- containing chemotherapy **7) Colorectal Cancer (CRC)** - Nivolumab as monotherapy is indicated for the treatment of adult and pediatric (12 years and older) patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC) that has progressed following treatmentwith a fluoropyrimidine, oxaliplatin, and irinotecan (additional indication approved on 18.04.2019). **8) Esophageal squamous cell carcinoma (ESCC):** Nivolumab is indicated for the treatment of unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine and platinum- based Chemotherapy (additional indication approved on 04.08.2021). **9) Gastric Cancer Gastroesophageal Junction Cancer and Esophageal Adenocarcinoma (Gastric, GEJC or EAC):** Nivolumab in combination with fluoropyrimidine and platinum- containing chemotherapy is indicated for the treatment of patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma (additional indication approved on 30.11.2021). **10) Adjuvant treatment of Resected Junction Cancer (EC or GEJC) Esophageal or Gastroesophageal:** Nivolumab is indicated for the adjuvant treatment of esophageal or completely resected gastroesophageal junction cancer with residual pathologic disease in patients, who have received neoadjuvant chemoradiotherapy (CRT) (additional indication approved on 30.11.2021).	
26	M/s Cipla Limited	14-10-2021	IMP/BIO/21/000085 **Note:** Additional Marketing Authorization	Insulin Lispro I.P.	Diabetes mellitus	Suspension for Injection Strength: 100 IU/mL, Cartridge and prefilled pen and 200U/ml, prefilled pen

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27	M/s Cipla Limited	30-09-2021	IMP/BIO/21/000084 **Note:** Additional Marketing Authorization	Insulin Lispro Biphasic **I** njection I.P. (25% Insulin Lispro and 75% Insulin Lispro Protamine)	Diabetes mellitus	Suspension for Injection in Cartridge and prefilled pen Strength: 100IU/mL
28	M/s Takeda Pharmaceuticals India Pvt. Ltd.	20-10-2021	IMP/BIO/21/000089	Brentuximab Vedotin	Previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with chemotherapy 2. Classical Hodgkin lymphoma (cHL) consolidation 3. Relapsed classical Hodgkin lymphoma(cHL) 4. Previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), in combination with chemotherapy 5. Relapsed systemic anaplastic large cell lymphoma (sALCL) 6. Relapsed primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF)	Powder for concentrate for solution for infusion in vial Strength: 50 mg
29	M/s Cipla Limited	29-11-2021	IMP/BIO/21/000096 **Note:** Additional Marketing Authorization	Recombinant Human Erythropoietin injection I.P.	For treatment of anemia in chronic renal failure patients	Solution for injection Strength: 2000 IU/0.5 ml, 3000 IU/0.3 ml, 4000 IU/0.4 ml, 6000 IU/0.6 ml, 8000 IU/0.8 ml and 10000 IU/1.0ml Solution for injection in pre-filled syringe
30	M/s Cipla Limited	09-12-2021	IMP/BIO/21/000100 **Note:** Additional Marketing Authorization	Insulin Lispro Biphasic Injection I.P. (50% Insulin Lispro and 50% Insulin Lispro Protamine suspension) Injection (r-DNA origin)	For the treatment of patients with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis	Suspension for injection in Cartridge & prefilled pen Strength:100 IU/mL

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31	M/s Cipla Limited	22-12-2021	IMP/BIO/21/000106 **Note:** Additional Marketing Authorization	Recombinant Human Erythropoietin injection I.P.	For treatment of anemia in chronic renal failure patients	Solution for injection in vial Strength:10,000 IU/ 1mL, 20,000 IU/2mL
32	M/s Dr. Reddy's Laboratories Limited	05-01-2022	IMP/BIO/22/000001	Romosozumab	**Treatment of Postmenopausal Women with Osteoporosis at High Risk for Fracture** Romosozumab is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. **Limitations of Use** The anabolic effect of Romosozumab wanes after 12 monthly doses of therapy. Therefore, the duration of Romosozumab use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered. Two 105 mg/1.17 mL single use prefilled syringes are required to administer the recommended 210 mg dose of Romosozumab	Solution for injection in a single-use prefilled syringe for Subcutaneous use. Strength: 90 mg/mL
33	M/s Bristol-Myers Squibb India Pvt. Ltd.	12-01-2022	IMP/BIO/22/000002	Luspatercept	**Myelodysplastic syndromes (MDS):** Luspatercept is indicated for the treatment of adult patients with transfusion-dependent anaemia due to very low, low and intermediate- risk myelodysplastic syndromes (MDS) with ring sideroblasts, who had an unsatisfactory response to or are ineligible for erythropoietin- based therapy. **β-thalassemia:** Luspatercept is indicated for the treatment of adult patients with transfusion-dependent anaemia associated with beta- thalassaemia.	Lyophilized Powder for solution for injection in vial. Strength: 25 mg and 75 mg
34	M/s Cipla Limited	04-02-2022	IMP/BIO/22/000006 **Note:** Additional Marketing Authorization	Dulaglutide	Dulaglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated: 1. as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. 2. to reduce the risk of major adverse cardiovascular events (cardiovascular death,	Dosage Form: Solution for Injection Strength: 0.75 mg/0.5 ml in Prefilled Pen and 1.5 mg/0.5 ml

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					non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.	
35	M/s Johnson & Johnson Pvt. Ltd.,	02-01-2017	IMP-223/2016	Daratumumab	1. In combination with lenalidomide and dexamethasone or with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. 2. For the treatment of patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent. 3. In combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy (indication approved on 08.02.2022). 4. As monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy (indication approved on 08.02.2022).	Concentrate for solution for infusion Strength: 20 mg/mL
36	M/s Eli Lilly and Company (India) Pvt. Ltd.	07-02-2022	IMP/BIO/22/00 0012	Ixekizumab	1. **Psoriatic Arthritis: Ixekizumab,** is indicated for the treatment of adult patients with active psoriatic arthritis., 2. **Plaque Psoriasis: Ixekizumab** is indicated for the treatment of adult patients with moderate-to severe plaque psoriasis who are candidates for systemic therapy or phototherapy	Solution for Injection in Prefilled Autoinjector and Prefilled Syringe Strength: 80 mg/mL

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37	M/s Johnson & Johnson Pvt. Ltd.	08-02-2022	IMP/BIO/22/000013	Amivantamab	Treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal-growth factor receptor (EGFR) Exon 20 insertion mutations whose disease has progressed on or after platinum- based chemo-therapy.	Liquid concentrate for infusion Strength: 50 mg/mL
38	M/s Cipla Limited	07-02-2022	IMP/BIO/22/000011 **Note:** Additional Marketing Authorization	Recombinant Human Follicle stimulating Hormone solution for injection I.P.	Treatment of female infertility	Solution for injection Strengths: 75IU/ 0.15mL, 150 IU/0.3mL, 225 IU/0.45mL, 300 IU/0.6mL Solution for injection in prefilled syringe
39	M/s GlaxoSmithKline Pharmaceuticals Limited	12-06-2018	IMP147/2018	Mepolizumab	**Eosinophilic granulomatosis with polyangiitis (EGPA)** Mepolizumab is indicated as an add-on treatment for adult patients with relapsingremitting or refractory eosinophilic granulomatosis with polyangiitis (EGPA). **Hypereosinophilic syndrome (HES)** Mepolizumab is indicated as an add-on treatment for adult patients with inadequately controlled hypereosinophilic syndrome without an identifiable nonhaematologic secondary cause (additional indication approved on 15.03.2022)	Solution for injection in pre-filled pen (auto-injector) or pre-filled syringe (safety syringe) Strength:100 mg/mL
40	M/s Johnson & Johnson Pvt. Ltd.	10-03-2022	IMP/BIO/22/000020	Ustekinumab	Ustekinumab is indicated for: • Inducing and maintaining clinical response, • Inducing and maintaining clinical remission, • Eliminating corticosteroid use, • Inducing endoscopic healing, • Improving health-related quality of life in adults with moderately to severely active Crohn's disease who: • have failed or were intolerant to immunomodulators or corticosteroids or • were corticosteroid dependent or • have failed or were intolerant to one or more	1. Concentrate solution for IV infusion in single use vial; Strength: 130 mg/ 26 ml, 2. Solution for injection (Sub cutaneous) in pre-filled syringe; Strength: 45 mg/0.5 ml, Strength: 90 mg/ml

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					anti-TNF treatment	
41	M/s Novo Nordisk India Pvt. Ltd.	20-04-2022	IMP/BIO/22/000031	Semaglutide	It is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of • 30 kg/m^2 or greater (obesity) or • 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) Limitations of Use: • It contains semaglutide and should not be co- administered with other semaglutide containing products or with any other GLP-1 receptor agonist. • The safety and effectiveness of semaglutide in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established. • It has not been studied in patients with a history of pancreatitis.	Solution for injection (in prefilled pen (Single dose Pen injector) Strength: Each pre-filled pen contains 1. 0.25 mg Semaglutide in 0.5 mL, 2. 0.5 mg semaglutide in 0.5 mL, 3. 1.0 mg semaglutide in 0.5 mL, 4. 1.7 mg semaglutide in 0.75 mL and, 5. 2.4 mg semaglutide in 0.75 mL
42	M/s Takeda Pharmaceuticals India Pvt. Ltd.	26-07-2022	IMP/BIO/22/000053	Vedolizumab	**Vedolizumab 108mg is indicated as only for maintenance treatment** by subcutaneous route once every 2 weeks, following at least 2 intravenous infusions (Vedolizumab IV 300 mg), for the following indications: **Ulcerative colitis** Vedolizumab is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with lost response to or were intolerant to either conventional therapy or a tumor necrosis factor-alpha (TNFα) antagonist.	Solution for injection in Pre-filled syringe with Needle safety device & Pre-filled syringe with Autoinjector Strength: 108 mg

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					Crohn's disease Vedolizumab is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with lost response to or were intolerant to either conventional therapy or a tumor necrosis factor-alpha (TNFα) antagonist	
43	M/s Pfizer Products India Private Limited	12-08-2022	IMP/BIO/22/000055	Somatrogon	Indicated for the treatment of children and adolescents from 3 years of age with growth disturbance due to insufficient secretion of growth hormone	Solution for injection Strength: Each Prefilled pen contains: 1. 24mg/mL and. 2. 60mg/1.2mL solution for injection in prefilled pen.
44	M/s Novo Nordisk India Pvt. Ltd.	17-10-2022	IMP/BIO/22/000068	Semaglutide	It is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 1. 30 kg/m^2 or greater (obesity) or 2. 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) **Limitations of Use:** 1. It contains semaglutide and should not be co-administered with other semaglutide containing products or with any other GLP-1 receptor agonist. 2. The safety and effectiveness of semaglutide in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established. 3. It has not been studied in patients with a history of pancreatitis.	Solution for Injection in Prefilled Pen Strength: 0.25mg/0.5mg/1mg/1.7mg/2.4mg
45	M/s Bristol-Myers Squibb India Pvt. Ltd.	02-11-2022	IMP-88/2016	Nivolumab	1. Nivolumab as a single agent is indicated for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. 2. Nivolumab as a single agent is indicated for the	Concentrate for solution for infusion in vial Strength: 240 mg in vial (10 mg/ml)

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					treatment of patients with advanced renal cell carcinoma (RCC) after prior therapy in adults 3. Nivolumab as monotherapy is indicated for the treatment of recurrent or metastatic squamous cell carcinoma of the head and neck after platinum based therapy 4. Nivolumab as a single agent is indicated for the treatment of patients with BRAF V600 wildtype unresectable or metastatic melanoma 5. Nivolumab as a single agent is indicated for the treatment of patients with BRAF V600 mutation positive unresectable or metastatic melanoma 6. Nivolumab is indicated for the treatment of adult patients with classical Hodgkin lymphoma (cHL) that has relapsed or progressed after: • autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin, or • 3 or more lines of systemic therapy that includes autologous HSCT. 7. Nivolumab is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who: • have disease progression during or following platinum containing chemotherapy. • have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum containing chemotherapy 8. Nivolumab as monotherapy is indicated for the treatment of adult and pediatric (12 years and older) pati ents with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan 9. Nivolumab is indicated for the treatment of patients with melanoma with lymph node involvement or metastatic disease who have undergone complete resection, in the adjuvant settings 10. Nivolumab is indicated for treatment of patients with intermediate or poor risk, previously	

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					untreated advanced renal cell carcinoma, in combination with Ipilimumab	
46	M/s MSD Pharmaceuticals Private Limited	25-11-2022	IMP-093/2016	Pembrolizumab	1. **Cervical Cancer:** Pembrolizumab, in combination with chemotherapy with or without Bevacizumab, is indicated for the treatment of persistent, recurrent, or metastatic cervical cancer in adults whose tumours express PD-L1 with a CPS 1. 2. **Esophageal Cancer**: Pembrolizumab, in combination with platinum and Fluoropyrimidine-based chemotherapy, is indicated for the first-line treatment of locally advanced unresectable or metastatic carcinoma of the esophagus or HER-2 negative gastroesophageal junction adenocarcinoma, in adults whose tumours express PD-L1 with a CPS 10	Solution for infusion Strength: 100 mg/4mL (25 mg/ml)
47	M/s Sandoz Private Limited	13-12-2022	IMP/BIO/20/000056	Brolucizumab	Indicated for the treatment of DME (Diabetic Macular Edema)	Solution for injection in vial + filter needle Strength: 120 mg/ml
48	M/s Takeda Biopharmaceuticals India Pvt. Ltd.	31-01-2023	IMP/BIO/23/000001 **Note:** Due to name change MA is re-issued.	Vedolizumab	Vedolizumab is indicated for the treatment of: • Adult patients with moderately to severely active Ulcerative Colitis who have had an inadequate response with, lost response to or were intolerant to either conventional therapy or tumor necrosis factor-alpha (TNF-α) antagonist. • Treatment of adult patients with moderately to severely active Crohn's Disease who have had an inadequate response with, lost response to or were intolerant to either conventional therapy or tumor necrosis factor-alpha (TNF-α) antagonist.	Dosage Form: Powder for concentrate for solution for infusion. Strength: 300 mg
49	M/s Takeda Biopharmaceuticals India Pvt. Ltd.	31-01-2023	IMP/BIO/23/000002 Note: Due to name change MA is re-issued.	Recombinant Antihemophilic Factor VIII (r-AHF-VIII)	For supplementing blood coagulation factor VIII and suppresses bleeding tendency in congenital blood coagulation factor VIII deficient patients (Haemophilia A).	Dosage Form: Lyophilized Powder for Concentrated for Solution for Intravenous Injection

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						Strength: 250IU, 500IU, 1000IU
50	M/s Takeda Biopharmaceuticals India Pvt. Ltd.	31-01-2023	IMP/BIO/23/000003 **Note:** Due to name change MA is re-issued.	Coagulation Factor IX (Recombinant)	Coagulation Factor IX (Recombinant) is an antihemophilic factor indicated for: • Control and prevention of bleeding episodes in adults and children with haemophilia B. • Perioperative management in adults and children with haemophilia B. • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with haemophilia B	Dosage Form: Lyophilized Powder for Solution (for Intravenous use only) Strength: 250 IU/500 IU/1000 IU/2000 IU and 3000 IU
51	M/s Eli Lilly and Company (India) Pvt. Ltd.	06-02-2023	IMP/BIO/23/000005	Galcanezumab	Galcanezumab is indicated for the preventive treatment of migraine in adults.	Dosage Form: Solution for injection as single-dose Prefilled Pen and Prefilled Syringe. Strength: 120 mg/ml
52	M/s AstraZeneca Pharma India Limited.	06-02-2023	IMP/BIO/23/000004	Durvalumab	Durvalumab (IMFINZI) in combination with chemotherapy is indicated for the treatment of patients with locally advanced or metastatic biliary tract cancer (BTC)	Dosage Form: Solution for infusion Strength: 120 mg/2.4 mL and 500 mg/10 mL
53	M/s Takeda Biopharmaceuticals India Pvt. Ltd.	07-02-2023	IMP/BIO/23/000006 **Note:** Due to name change MA is re-issued.	Idursulfase	Idursulfase is indicated for the long-term treatment of patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II)	Dosage Form: Concentrate for Solution for (IV) Infusion. Strength: 2mg/ ml
54	M/s Takeda Biopharmaceuticals India Pvt. Ltd.	08-02-2023	IMP/BIO/23/000007 Note: Due to name change MA is re-issued.	Velaglucerase Alfa	Velaglucerase Alfa is indicated for long-term enzyme replacement therapy (ERT) in patients with type 1 Gaucher disease.	Dosage Form: Powder for Solution for Infusion in single use vial. Strength: 400 units
55	M/s Takeda Biopharmaceuticals India Pvt. Ltd.	13-02-2023	IMP/BIO/23/000009 **Note:** Due to name change MA is re-issued.	Agalsidase alfa	Agalsidase alfa is indicated for long-term enzyme replacement therapy inpatients with a confirmed diagnosis of Fabry Disease (α-galactosidase A deficiency).	Dosage Form: Concentrate solution for intravenous infusion Strength: 1mg/ml

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56	M/s Takeda Biopharmaceuticals India Pvt. Ltd	13-02-2023	IMP/BIO/23/000010 **Note:** Due to name change MA is re-issued.	Vedolizumab	Vedolizumab 108mg is indicated as only for maintenance treatment by subcutaneous route once every 2 weeks, following at least 2 intravenous infusions (Vedolizumab IV 300 mg), for the following indications: **Ulcerative colitis** Vedolizumab is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with lost response to or were intolerant to either conventional therapy or a tumor necrosis factor-alpha (TNFα) antagonist. **Crohn's disease** Vedolizumab is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with lost response to or were intolerant to either conventional therapy or a tumor necrosis factor-alpha (TNFα) antagonist	Dosage Form: Solution for injection in Pre-filled syringe with Needle safety device & Pre-filled syringe with Autoinjector Strength: 108mg
57	M/s Takeda Biopharmaceuticals India Pvt. Ltd	13-02-2023	IMP/BIO/23/000011 **Note:** Due to name change MA is re-issued.	Rurioctocog alfa pegol	Rurioctocog alfa pegol (Adynovate) is a human antihemophilic factor indicated in children and adults with Hemophilia A (congenital factor VIII deficiency) for: • On-demand treatment and control of bleeding episodes. • Perioperative management. • Routine prophylaxis to reduce the frequency of bleeding episodes.	Dosage Form: Lyophilized Powder for solution for injection Strength: 250IU/vial, 500IU/vial, 750IU/vial, 1000IU/vial, 1500IU/vial in 2ml, 2000IU/vial in 5ml
58	M/s Sanofi Healthcare India Private Limited	21-02-2023	IMP/BIO/23/000016	Insulin Glargine + Lixisenatide	For treatment of adults patients with Obesity with insufficiently controlled type 2 diabetes mellitus to improve glycemic control as an adjunct to diet and exercise in addition to metformin with or without SGLT2 inhibitors, when this has not been provided by metformin alone or metformin combined with another oral glucose lowering medicinal product (sulfonylurea, glinide, DPP-4 inhibitors or gliptins, and Sodium-glucose co-transporter 2 (SGLT2) inhibitors or gliflozins) or with basal insulin or with glucagon-like peptide-1 (GLP-1) receptor agonist	Dosage Form: Solution for Subcutaneous injection in prefilled pen Strength: 100 U/ml + 33 mcg/ml and 100 U/ml + 50 mcg/ml

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59	M/s Takeda Biopharmaceuticals India Pvt. Ltd	22-03-2023	IMP/BIO/23/000025 **Note:** Due to name change MA is re-issued.	Coagulation Factor VIII (Recombinant) rFVIII	Treatment and prophylaxis of bleeding in patients with Haemophilia A (Congenital factor VIII deficiency) in all age groups.	Dosage Form: Powder and Solvent for Solution for Injection along with Baxjact II reconstitution device Strength: 250 IU/ 500IU/ 1000 IU/1500 IU/2000 IU/3000 IU
60	M/s Takeda Biopharmaceuticals India Pvt. Ltd	24-03-2023	IMP/BIO/23/000029 **Note:** Due to name change MA is re-issued.	Brentuximab Vedotin	• Previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with chemotherapy. • Classical Hodgkin lymphoma (cHL) consolidation. • Relapsed classical Hodgkin lymphoma(cHL). • Previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), in combination with chemotherapy. • Relapsed systemic anaplastic large cell lymphoma (sALCL). • Relapsed primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF).	Dosage Form: Powder for concentrate for solution for infusion in vial Strength: 50 mg
61	M/s Roche Products (india) Private Limited	24-03-2023	IMP/BIO/23/000032	Faricimab	Indicated for the treatment of: • Neovascular(wet) age-related macular degeneration (nAMD) • Diabetic macular edema (DME)	Dosage Form: Intravitreal solution for injection Strength: 6 mg/0.05 mL (120mg/mL)
62	M/s Roche Products (India) Private Limited	24-03-2023	IMP/BIO/23/000028	Ocrelizumab	Ocrelizumab is indicated for the treatment of: 1. Relapsing forms of Multiple Sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. 2. Primary Progressive MS, in adults.	Dosage Form: single-dose vial. Strength: 30 mg/ml
63	M/s Boehringer Ingelheim India Private Limited	24-03-2023	IMP/BIO/23/000031	Spesolimab	Spesolimab is indicated for the treatment of flares in adult patients with Generalized Pustular Psoriasis	Dosage Form: Concentrate for solution for infusion 450 mg/7.5 ml (60 mg/ml) in 10 ml vial administered through intravenous (IV) route Strength: 60 mg/ml

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64	M/s GSK Pharma India Private Limited	26-04-2023	IMP/BIO/23/000048	Dostarlimab	Dostarlimab is indicated as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen.	Dosage Form: Concentrate for solution for infusion (sterile concentrate) Strength: 500 mg/ 10 mL
65	M/s Cipla Limited	26-04-2023	IMP/BIO/23/000049 **Note:** Additional Marketing Authorization	Insulin Lispro Ultrarapid (UR) Injection	Treatment of diabetes mellitus in adults.	Dosage Form: Solution for Injection Strength: 100 Units/mL in 3 ml cartridge and prefilled pen
66	M/s AstraZeneca Pharma India Limited	01-05-2023	IMP/BIO/23/000054	Trastuzumab deruxtecan	Trastuzumab deruxtecan is indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen	Dosage Form: Single use sterile, lyophilized powder for concentrate for solution for infusion Strength: 100 mg/ 5 ml
67	M/s Sanofi India Limited	16-05-2023	IMP/BIO/23/000058	Biphasic Insulin Aspart Injection IP	Biphasic Insulin Aspart Injection I.P. is indicated for treatment of diabetes mellitus in adults, adolescents and children aged 10 years and above.	Dosage Form: 30% Soluble insulin aspart IP and 70 % protamine-crystallised insulin aspart IP; suspension for injection. Strength: 100 IU/mL in 3 mL cartridge and 3 mL cartridge in pen injector.
68	M/s AstraZeneca Pharma India Limited	26-05-2023	IMP/BIO/23/000061	Tremelimumab	Tremelimumab in combination with durvalumab is indicated for the treatment of patients with unresectable hepatocellular carcinoma (uHCC)	Dosage Form: 25mg/ 1.25mL and 300 mg/ 15mL Solution for infusion in single dose vial Strength: 20 mg/mL
69	M/s MSD Pharmaceutical Private Limited	31-05-2023	IMP/BIO/23/000063	Pembrolizumab Injection	1. Pembrolizumab, in combination with axitinib, is indicated for the first-line treatment of advanced renal cell carcinoma in adults. 2. Pembrolizumab, as monotherapy, is indicated for the adjuvant treatment of adults with renal cell carcinoma at increased risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.	Dosage Form: Solution in single vial Strength: 25 mg/mL

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					3. Pembrolizumab, in combination with chemotherapy, is indicated for the treatment of locally recurrent unresectable or metastatic triple-negative breast cancer in adults whose tumours express PD-L1 with a CPS ≥ 10 and who have not received prior chemotherapy for metastatic disease. 4. Pembrolizumab, in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery, is indicated for the treatment of adults with locally advanced, or early-stage triple- negative breast cancer at high risk of recurrence.	
70	M/s Sanofi Healthcare India Private Limited	14-06-2023	IMP/BIO/23/000066	Avalglucosidase Alfa	Avalglucosidase Alfa is indicated for the treatment of long-term enzyme replacement therapy for the treatment of patients with Pompe disease (acid -glucosidase deficiency)	Dosage Form: Powder for concentrate for solution for infusion Strength: 100 mg/Vial
71	M/s Cipla Limited	01-08-2023	IMP/BIO/23/000076 **Note:** Additional Marketing Authorization	Insulin Glargine IP	Insulin Glargine is indicated for the treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.	Dosage Form: Solution for injection Strength: 100 Units/mL in 3 ml cartridge and 3 ml pre-filled pen
72	M/s Bristol-Mayer Squibb India Pvt. Ltd.	01-09-2023	IMP/BIO/23/000083	Nivolumab	**Additional Indication:** Renal Cell Carcinoma (RCC) Nivolumab in combination with cabozantinib, is indicated for the first line treatment of patients with advanced Renal Cell Carcinoma (RCC).	Dosage Form: concentrate for solution for infusion. Strength: 10 mg/ml
73	M/s Roche Products (India) Private Limited	04-09-2023	IMP/BIO/23/000087	Polatuzumab Vedotin	Polatuzumab vedotin in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (R-CHP) is indicated for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL)	Dosage Form: Powder for concentrate for solution for infusion Strength: 30 mg/Vial and 140 mg/Vial
74	M/s Johnson & Johnson Pvt. Ltd.	11-09-2023	IMP/BIO/23/000090	Teclistamab	Teclistamab is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.	Dosage Form: Powder for concentrate for solution for infusion. Strength: 10 mg/mL

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75	M/s AstraZeneca Pharma India Limited	25-09-2023	IMP/BIO/23/000092	Palivizumab	Palivizumab is indicated for the prevention of serious lower respiratory tract disease requiring hospitalization caused by respiratory syncytial virus (RSV) in children at high risk for RSV disease: • Infants born at 35 weeks of gestation or less and less than 6 months of age at the onset of the RSV season. • Children less than 2 years of age and requiring treatment for bronchopulmonary dysplasia (BPD) within the last 6 months. • Children less than 2 years of age and with haemodynamically significant congenital heart disease (CHD).	Dosage Form: single dose vials administered through intramuscular route. Strength: 100 mg/mL
76	M/s Novo Nordisk India Pvt. Ltd.	22-11-2023	IMP/BIO/23/000104	Somapacitan	Somapacitan is indicated for the replacement of endogenous growth hormone (GH) in children and adolescents with growth failure due to growth hormone deficiency (paediatric GHD (GHD)) and in adults with growth hormone deficiency (adult GHD (AGHD))	Dosage Form: Solution for Injection in pre-filled pen Strength: 10 mg/1.5ml; 15 mg/1.5ml
77	M/s Pfizer Products (India) Private Limited	28-11-2023	IMP/BIO/23/000105 **Note:** This product was initially approved on 05.09.2018. Based on the application, the modification of approved indication is approved.	Nonacog Alfa (Recombinant human coagulation factor IX)	**Revised Therapeutic Indication:** Nonacog alfa (recombinant coagulation factor IX) is a recombinant human blood coagulation factor IX indicated for adults and children with hemophilia B (congenital factor IX deficiency or Christmas disease) for: • On-demand treatment and control of bleeding episodes. • Perioperative management of bleeding. • Routine prophylaxis to reduce the frequency of bleeding episodes. **Limitations of Use:** Nonacog alfa (recombinant coagulation factor IX) is not indicated for induction of immune tolerance in patients with hemophilia B	Dosage Form: powder and solvent for solution for injection Strength: 250IU, 500IU, 1000IU, 2000IU and 3000 IU
78	M/s Sanofi Healthcare India Private Limited	22-12-2023	IMP/BIO/23/000110	Olipudase alfa	Olipudase alfa is indicated as enzyme replacement therapy for long-term treatment of non-central nervous system (CNS) manifestations of acid sphingomyelinase deficiency (ASMD) in pediatric and adult patients.	Dosage Form: Powder for concentrate for solution for infusion. Strength: 21.2 mg/ Vial

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79	M/s Astellas Pharma India Pvt. Ltd.	08-01-2024	IMP/BIO/24/000001	Enfortumab vedotin	Enfortumab vedotin as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a programmed death receptor 1 or programmed death ligand 1 inhibitor	Dosage Form: Powder for concentrate for solution for infusion. Strength: 20 mg/vial & 30mg/vial After reconstitution, each mL of solution contains 10mg of Enfortumab vedotin
80	M/s Bristol-Myers Squibb India Pvt. Ltd.	17-01-2024	IMP/BIO/24/000006 **Note:** Approval of Additional Indication.	Nivolumab	**Additional Indication:** 1. Nivolumab, in combination with fluoropyrimidine- and platinum-containing chemotherapy is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC). 2. Nivolumab for the adjuvant treatment of adult patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC]	Dosage Form: concentrate for solution for infusion. Strength: 10 mg/mL
81	M/s Novo Nordisk India Private Limited	17-01-2024	IMP/BIO/24/000005 **Note:** This product was initially approved on 27.07.2020. Based on the application, the modification of approved indication is approved	Semaglutide tablets	**Revised Therapeutic Indication:** RYBELSUS is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use 1. RYBELSUS has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis. 2. RYBELSUS is not indicated for use in patients with type 1 diabetes mellitus.	Dosage Form: Tablets. Strength: 3mg. 7mg & 14mg.
82	M/s AstraZeneca Pharma India Limited	19-01-2024	IMP/BIO/24/000004	Andexanet alfa	Andexanet alfa is indicated for patients treated with FXa inhibitors (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.	Dosage Form: Powder for solution for infusion. Strength: 200mg/ 20mL Vial
83	M/s. Lupin Limited	19-01-2024	IMP/BIO/24/000009 **Note:** Additional Marketing Authorization	Biphasic Isophane Insulin Injection I.P. (30% Soluble insulin and 70% Isophane insulin)	For the treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis.	Dosage Form: Suspension for injection in cartridge administered through subcutaneous route.

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				(Note: The permission is granted to the firm additionally to the original MA holder M/s Eli Lilly)		Strength: 100IU/mL (3mL Cartridge)
84	M/s. Lupin Limited	19-01-2024	IMP/BIO/24/000008 **Note:** Additional Marketing Authorization	Isophane Insulin Injection I.P. (Note: The permission is granted to the firm additionally to the original MA holder M/s Eli Lilly)	For the treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis	Dosage Form: Suspension for injection in cartridge administered through subcutaneous route. Strength: 100IU/mL (3mL Cartridge)
85	M/s Johnson and Johnson Private Limited	15-02-2024	IMP/BIO/24/000018	Guselkumab	Guselkumab is indicated for the treatment of adult patients with active psoriatic arthritis	Dosage Form: Single-use pre-filled syringe & single-use pre-filled pen for subcutaneous administration. Strength: 100 mg/mL
86	M/s MSD Pharmaceuticals Private Limited	06-03-2024	IMP/BIO/24/000025 **Note:** Approval of Additional Indication.	Pembrolizumab	**Additional Indication:** 1. Pembrolizumab as a monotherapy is indicated for the adjuvant treatment of adults with Stage III melanoma and lymph node involvement who have undergone complete resection. 2. Pembrolizumab as a monotherapy is indicated for the first-line treatment of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (MMR) colorectal cancer in adults. 3. Pembrolizumab as a monotherapy is indicated for the treatment of adult with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option.	Dosage Form: Solution in single vial Strength: 25mg/mL
87	M/s Astrazeneca Pharma India Limited	26-03-2024	IMP/BIO/24/000035 **Note:** Approval of Additional Indication.	Trastuzumab deruxtecan	**Additional Indication:** Locally Advanced or Metastatic Gastric Cancer Trastuzumab deruxtecan is indicated for the treatment of adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma	Dosage Form: Single use sterile, lyophilized powder for concentrate for solution for infusion Strength: 100mg/5mL

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					who have received a prior trastuzumab based regimen.	
88	M/s Astrazeneca Pharma India Limited	26-03-2024	IMP/BIO/24/000036 **Note:** Approval of Additional Indication.	Trastuzumab deruxtecan	**Additional Indication:** HER2-Low Metastatic Breast Cancer Trastuzumab deruxtecan is indicated for the treatment of adult patients with unresectable or metastatic HER2-Low (IHC 1+ or IHC 2+/ISH-) breast cancer who have received a prior chemo therapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.	Dosage Form: Single use sterile, lyophilized powder for concentrate for solution for infusion Strength: 100mg/5mL
89	M/s Novartis Healthcare Private Limited	26-03-2024	IMP/BIO/24/000032	Erenumab	Prophylaxis of migraine	Dosage Form: Solution for injection. Strength: 70mg/mL
90	M/s. Lupin Limited	08-04-2024	IMP/BIO/24/000040 **Note:** Additional Marketing Authorization	Dulaglutide	Dulaglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated: • As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. • To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors	Dosage Form: Solution for Injection in a single use prefilled pen. Strength: 0.75 mg/0.5 ml in Prefilled Pen and 1.5 mg/0.5 ml
91	M/s. Lupin Limited	08-04-2024	IMP/BIO/24/000038 **Note:** Additional Marketing Authorization	Insulin Lispro Injection I.P.	Treatment of patients with Diabetes Mellitus	Dosage Form: 3mL Cartridge and 3mL Prefilled Pen.
92	M/s. Lupin Limited	09-04-2024	IMP/BIO/24/000039 **Note:** Additional Marketing Authorization	Insulin Lispro Biphasic Injection I.P. (25% Insulin Lispro and 75% Insulin Lispro Protamine suspension)	Treatment of patients with Diabetes Mellitus.	Dosage Form: Suspension for injection in 3mL Cartridge & in 3mL prefilled pen Strength: 100 IU/mL

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93	M/s. Lupin Limited	09-04-2024	IMP/BIO/24/000037 **Note:** Additional Marketing Authorization	Insulin Lispro Biphasic Injection I.P. (50% Insulin Lispro and 50% Insulin Lispro Protamine suspension)	Indicated for treatment of patients with Diabetes Mellitus.	Dosage Form: Suspension for injection in 3mL Cartridge & in 3mL prefilled pen. Strength: 100 IU/mL
94	M/s. Lupin Limited	09-04-2024	IMP/BIO/24/000041 **Note:** Additional Marketing Authorization	Insulin Human I.P.	Indicated for treatment of patients with Diabetes Mellitus.	Dosage Form: Concentrate solution for IV infusion in single use vial Solution for injection (Sub cutaneous) in pre-filled syringe. Strength: 100 IU/mL
95	M/s Johnson & Johnson Pvt. Ltd.	16-04-2024	BIO/IMP/20/000067 **Note:** Approval of Additional Indication	Ustekinumab	Ustekinumab is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis	Dosage Form: Suspension for injection in 3mL Cartridge. Strength: 130 mg/ 26 ml in vial 45 mg/0.5 ml, 90 mg/ml in PFS
96	M/s Dr. Reddy's Laboratories Limited,	10.05.2024	IMP/BIO/24/000049	Toripalimab	1. Toripalimab is indicated, in combination with cisplatin and gemcitabine, for first line treatment of adults with metastatic or with recurrent, locally advanced nasopharyngeal carcinoma (NPC). 2. Toripalimab is indicated, as a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.	Dosage Form: Intravenous Solution for Infusion in 6mL vial. Strength: 240mg/6mL
97	M/s Bristol-Myers Squibb India Pvt. Ltd.	22.05.2024	IMP/BIO/24/000051 **Note:** Approval of Additional Indication	Nivolumab	Non-Small Cell Lung Cancer (NSCLC) - Nivolumab, in combination with platinum-doublet chemotherapy, is indicated as neoadjuvant treatment of adult patients with resectable (tumours ≥ 4cm or node positive) non-small cell lung cancer (NSCLC)	Dosage Form: concentrate for solution for infusion. Strength: 10 mg/ml
98	M/s Sanofi India Limited	10.06.2024	IMP/BIO/24/000058	Nirsevimab	Nirsevimab Indicated for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in: • Neonates and infants born during or entering their first RSV season.	Dosage Form: Solution for injection in pre-filled syringe Strength: 50mg/PFS and

Annexure 'A'

					• Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.	100mg/PFS