List of new drugs (r-DNA origin) approved for import and marketing in India for the Year 2020						
S. No.	**Name of the firm**	**Date of Permission**	**Permission No.**	**Name of the Drug**	**Indication**	**Dosage Form & Strength**
1	Bristol-Myers Squibb India Pvt. Ltd.	21-Feb-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.	5 mg/mL concentrate for solution for infusion for intravenous injection
2	Sandoz Private Limited	26-Mar-2020	IMP/BIO/20/000026	Crizanlizumab Concentrate for solution for infusion 10 mg/mL (100 mg/10 mL)	Crizanlizumab is indicated to reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease.	Concentrate for solution for infusion
3	Dr. Reddy's Laboratories Ltd	3-Apr-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 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,	Solution for Injection. Each single use Prefilled Syringe / Prefilled Autoinjector contains: Evolocumab Injection 140 mg/mL
4	Sandoz Private Limited	1-Jul-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)	Solution for Injection (1 Vial + 1 filter needle)
5	Novo Nordisk India Pvt Ltd	16-Jul-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	Lyophilized Powder for solution for injection in vial (2500 IU)
6	Novo Nordisk India Pvt Ltd	27-Jul-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	Solid oral (tablets). Semaglutide 3 mg Tablets, 7 mg Tablets and 14 mg Tablets
7	Novo Nordisk India Pvt Ltd	5-Aug-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	Lyophilized Powder for solution for injection. Nonacog beta pegol 500.0 IU/Vial , 1000.0 IU/Vial and 2000.0 IU/Vial
8	Baxalta Bioscience India Pvt.Ltd	9-Sep-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	Lyophilized Powder for solution for injection, 250 IU/500 IU/ 750 IU/1000 IU/ 1500 IU/2000 IU vials
9	Cipla Limited	27-Oct-2020	IMP/BIO/20/000082	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	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

10	Merck Specialities Private Limited	29-Oct-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	Solution for Injection in Prefilled Pen 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.