



6 July 2021  
EMA/373584/2021  
Human Medicines Evaluation

## Applications for new human medicines under evaluation by the CHMP

Data extracted 6 July 2021

This list with initial marketing authorisation applications for human medicines currently under evaluation by the Committee for Medicinal Products for Human Use (CHMP), includes the international non-proprietary names (INN) (salt, ester, derivative, etc.) or common name. For generic medicines, it includes active moiety only, with no information on salt, ester or derivative.

This list only includes information for medicines whose applications have been validated and evaluation started at the time the data was extracted. For generics, biosimilar and duplicates where there are several applications with the same substance there is a row per application.

Where the timetable changes from accelerated to standard timetable, the month and year of the switch to standard Time Table is included.

Entries are removed from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website. Information on designated orphan medicines that are being assessed for marketing authorisation is also available in the monthly reports of the Committee for Orphan Medicinal Products (COMP).

International non-proprietary name (INN) (salt, ester, derivative, etc.) / Common Name	Substance type (classification)	Therapeutic area (ATC level 2)	Accelerated Assessment (Art. 14(9) Reg 726/2004)	Revert to standard Time Table (MM/YY)	Orphan Product	Generic or Biosimilar	Start of evaluation
Abrocitinib	Chemicals	Other dermatological medicines	N		N	N	01/10/2020
Adalimumab	Biologicals	Immunosuppressants	N		N	Y	01/10/2020
Adalimumab	Biologicals	Immunosuppressants	N		N	Y	25/05/2021
Adrenalin	Chemicals	Cardiac therapy	N		N	N	26/11/2020
Aducanumab	Biologicals	Other nervous system medicines	N		N	N	29/10/2020
Amifampridine	Chemicals	Other nervous system medicines	N		N	Y	20/05/2021
Amivantamab	Biologicals	Antineoplastic medicines	N		N	N	21/01/2021
Anifrolumab	Biologicals	Immunosuppressants	N		N	N	29/10/2020
Arachis hypogaea extract	Biologicals	Allergens	N		N	N	29/10/2020

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Arimoclomol (citrate)	Chemicals	Other nervous system medicines	N		Y	N	26/11/2020
Artesunate	Chemicals	Antiprotozoals	N		Y	N	01/10/2020
Artesunate	Chemicals	Antiprotozoals	N		Y	N	24/12/2020
Autologous glioma tumor cells, inactivated / autologous glioma tumor cell lysates, inactivated / allogeneic glioma tumor cells, inactivated / allogenei	ATMP	Antineoplastic medicines	N		Y	N	01/10/2020
Avacopan	Chemicals	Immunosuppressants	N		Y	N	29/10/2020
Avalglucosidase alfa	Biologicals	Other alimentary tract and metabolism products	N		Y	N	01/10/2020
Betaine	Chemicals	Other alimentary tract and metabolism products	N		N	Y	24/12/2020
Bevacizumab	Biologicals	Ophthalmologicals	N		N	N	21/05/2020
Bevacizumab	Biologicals	Antineoplastic medicines	N		N	Y	24/12/2020
Birch bark extract	Biologicals	Medicines for wounds and ulcers	N		Y	N	25/03/2021
Budesonide	Chemicals	Antidiarrheals, intestinal antiinflammatory/antiinfective medicines	Y		Y	N	17/06/2021
Capmatinib (dihydrochloride monohydrate)	Chemicals	Antineoplastic medicines	N		N	N	20/05/2021
Ciltacabtagene autoleucel	ATMP	Antineoplastic medicines	Y		Y	N	20/05/2021
Copanlisib (dihydrochloride)	Chemicals	Antineoplastic medicines	N		Y	N	17/06/2021
Dabigatran	Chemicals	Antithrombotic medicines	N		N	Y	16/07/2020
Daridorexant (hydrochloride)	Chemicals	Psycholeptics	N		N	N	25/03/2021
Dasatinib	Chemicals	Antineoplastic medicines	N		N	Y	20/06/2019
Dasatinib	Chemicals	Antineoplastic medicines	N		N	Y	21/06/2019
Dengue tetravalent vaccine (live, attenuated)	Biologicals	Vaccines	N	6/21	N	N	25/03/2021
Difelikefalin (acetate)	Chemicals	Other therapeutic medicines	N		N	N	25/03/2021
Dimethyl fumarate	Chemicals	Immunosuppressants	N		N	Y	17/06/2021
Dimethyl fumarate	Chemicals	Immunosuppressants	N		N	Y	17/06/2021
Diroximel (fumarate)	Chemicals	Immunosuppressants	N		N	N	24/12/2020
Doxorubicin	Chemicals	Antineoplastic medicines	N		N	Y	20/06/2019
Doxorubicin	Chemicals	Antineoplastic medicines	N		N	Y	30/01/2020

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Eladocagene exuparvovec	ATMP	Other nervous system medicines	N		Y	N	28/01/2020
Enfortumab vedotin	Biologicals	Antineoplastic medicines	Y		N	N	25/03/2021
Eptacog beta (activated)	Biologicals	Antihemorrhagics	N		N	N	25/02/2021
Eptinezumab	Biologicals	Analgesics	N		N	N	24/12/2020
Ertapenem	Chemicals	Antibacterials for systemic use	N		N	Y	25/02/2021
Faricimab	Biologicals	Ophthalmologicals	N		N	N	17/06/2021
Finerenone	Chemicals	Medicines acting on the renin-angiotensin system	N		N	N	26/11/2020
Ganirelix	Chemicals	Pituitary and hypothalamic hormones and analogues	N		N	Y	25/03/2021
Gefapixant	Chemicals	Other nervous system medicines	N		N	N	25/02/2021
Gefapixant	Chemicals	Other nervous system medicines	N		N	N	26/02/2021
Glucarpidase	Biologicals	Other therapeutic medicines	N		Y	N	13/08/2020
Hepatitis B surface antigen	Biologicals	Vaccines	N		N	N	24/12/2020
Imatinib	Chemicals	Antineoplastic medicines	N		N	Y	16/07/2020
Inebilizumab	Biologicals	Immunosuppressants	N		Y	N	24/12/2020
Insulin aspart	Biologicals	Medicines used in diabetes	N		N	Y	20/05/2021
Insulin human (rDNA)	Biologicals	Medicines used in diabetes	N		N	Y	26/03/2020
Istradefylline	Chemicals	Anti-parkinson medicines	N		N	N	02/01/2020
Lasmiditan (succinate)	Chemicals	Analgesics	N		N	N	26/11/2020
Lenadogene nolparvovec	ATMP	Ophthalmologicals	N		Y	N	29/10/2020
Leuprorelin	Chemicals	Endocrine therapy	N		N	Y	26/03/2020
Linzagolix (choline)	Chemicals	Pituitary and hypothalamic hormones and analogues	N		N	N	24/12/2020
Lisocabtagene maraleucel	ATMP	Antineoplastic medicines	N	11/20	Y	N	16/07/2020
Lonafarnib	Chemicals	Other alimentary tract and metabolism products	N	7/20	Y	N	23/04/2020
Lonapegsomatropin	Biologicals	Pituitary and hypothalamic hormones and analogues	N		Y	N	01/10/2020

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Maralixibat (chloride)	Chemicals	Bile and liver therapy	N		Y	N	26/11/2020
Maribavir	Chemicals	Antivirals for systemic use	N		Y	N	17/06/2021
Melphalan (flufenamide hydrochloride)	Chemicals	Antineoplastic medicines	N		Y	N	20/05/2021
Metformin / sitagliptin	Chemicals	Medicines used in diabetes	N		N	Y	26/11/2020
Obeticholic (acid)	Chemicals	Bile and liver therapy	N		N	N	30/01/2020
Omburtamab I-131	Biologicals	Therapeutic radiopharmaceuticals	N		Y	N	20/05/2021
Opicapone	Chemicals	Anti-parkinson medicines	N		N	N	24/05/2021
Oportuzumab monatox	Biologicals	Antineoplastic medicines	N		N	N	25/03/2021
Palovarotene	Chemicals	Other medicines for disorders of the musculo-skeletal system	N		Y	N	20/05/2021
Pegcetacoplan	Chemicals	Immunosuppressants	N		Y	N	01/10/2020
Pegfilgrastim	Biologicals	Immunostimulants	N		N	Y	21/05/2020
Pirfenidone	Chemicals	Immunosuppressants	N		N	Y	20/05/2021
Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)	Biologicals	Vaccines	N		N	N	25/03/2021
Pneumococcal polysaccharide conjugate vaccine (adsorbed)	Biologicals	Vaccines	N		N	N	24/12/2020
Pralsetinib	Chemicals	Antineoplastic medicines	N		N	N	21/05/2020
Ranibizumab	Biologicals	Ophthalmologicals	N		N	N	20/05/2021
Relugolix	Chemicals	Endocrine therapy	N		N	N	25/03/2021
Retifanlimab	Biologicals	Antineoplastic medicines	N		Y	N	25/02/2021
Rimegepant	Chemicals	Analgesics	N		N	N	25/02/2021
Ripretinib	Chemicals	Antineoplastic medicines	N		Y	N	01/10/2020
Risperidone	Chemicals	Psycholeptics	N		N	Y	30/01/2020
Rivaroxaban	Chemicals	Antithrombotic medicines	N		N	Y	01/10/2020
Sacituzumab govitecan	Biologicals	Antineoplastic medicines	Y		N	N	25/03/2021
Sapropterin	Chemicals	Other alimentary tract and metabolism products	N		N	Y	21/01/2021
Semaglutide	Biologicals	Antiobesity medicines	N		N	N	21/01/2021
Sildenafil	Chemicals	Urologicals	N		N	Y	27/02/2020
Sitagliptin	Chemicals	Medicines used in diabetes	N		N	Y	21/05/2020

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Sitagliptin	Chemicals	Medicines used in diabetes	N		N	Y	26/11/2020
Sitagliptin / metformin	Chemicals	Medicines used in diabetes	N		N	Y	20/05/2021
Sodium thiosulfate	Chemicals	Other therapeutic medicines	N		N	N	27/02/2020
Somatrogon	Biologicals	Pituitary and hypothalamic hormones and analogues	N		Y	N	25/02/2021
Sotorasib	Chemicals	Antineoplastic medicines	N		N	N	21/01/2021
Sugammadex	Chemicals	Other therapeutic medicines	N		N	Y	21/05/2020
Sugammadex	Chemicals	Other therapeutic medicines	N		N	Y	25/03/2021
Tanezumab	Biologicals	Analgesics	N		N	N	26/03/2020
Tecovirimat	Chemicals	Antivirals for systemic use	N		N	N	29/10/2020
Tepotinib (hydrochloride monohydrate)	Chemicals	Antineoplastic medicines	N		N	N	26/11/2020
Teriparatide	Biologicals	Calcium homeostasis	N		N	Y	01/10/2020
Teriparatide	Biologicals	Calcium homeostasis	N		N	Y	26/11/2020
Teriparatide	Chemicals	Calcium homeostasis	N		N	Y	21/01/2021
Teriparatide	Biologicals	Calcium homeostasis	N		N	Y	25/03/2021
Tezepelumab	Biologicals	Medicines for obstructive airway diseases	N		N	N	17/06/2021
Thalidomide	Chemicals	Immunosuppressants	N		N	Y	20/05/2021
Trastuzumab	Biologicals	Antineoplastic medicines	N		N	Y	23/05/2019
Trastuzumab	Biologicals	Antineoplastic medicines	N		N	Y	25/02/2021
Vildagliptin / metformin	Chemicals	Medicines used in diabetes	N		N	Y	24/12/2020
Voxelotor	Chemicals	Other hematological medicines	N		Y	N	21/01/2021
Zanubrutinib	Chemicals	Antineoplastic medicines	N		Y	N	18/06/2020
Voxelotor	Chemicals	Other hematological medicines	N		Y	N	21/01/2021
Zanubrutinib	Chemicals	Antineoplastic medicines	N		Y	N	18/06/2020