

9 January 2023
EMA/13171/2023
Human Medicines Division

Applications for new human medicines under evaluation by the CHMP

Data extracted 5 January 2023

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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, hybrid or Biosimilar	Start of evaluation
Adagrasib	Chemicals	Antineoplastic medicines	N		N	N	19-05-22
Aflibercept	Biologicals	Ophthalmologicals	N		N	Y	19-05-22
Alpelisib	Chemicals	Antineoplastic medicines	N		Y	N	14-07-22
Aripiprazole	Chemicals	Psycholeptics	N		N	Y	16-06-22
Artesunate	Chemicals	Antiprotozoals	N		Y	N	24-12-20
Atogepant (monohydrate)	Chemicals	Analgesics	N		N	N	14-07-22
Aumolertinib (mesilate)	Chemicals	Antineoplastic medicines	N		N	N	01-12-22
Azacitidine	Chemicals	Antineoplastic medicines	N		N	Y	28-12-22
Bardoxolone (methyl)	Chemicals	Immunosuppressants	N		Y	N	28-10-21
Bevacizumab	Biologicals	Antineoplastic medicines	N		N	Y	24-12-20
Bevacizumab	Biologicals	Ophthalmologicals	N		N	N	28-12-22

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Cabotegravir (sodium)	Chemicals	Antivirals for systemic use	N		N	N	27-10-22
Catumaxomab	Biologicals	Antineoplastic medicines	N		N	N	18-08-22
COVID-19 Vaccine	Biologicals	Vaccines	N		N	N	18-08-22
Crisantaspase	Biologicals	Antineoplastic medicines	N		N	N	16-06-22
Dabigatran etexilate	Chemicals	Antithrombotic medicines	N		N	Y	16-07-20
Dabigatran etexilate	Chemicals	Antithrombotic medicines	N		N	Y	24-02-22
Dabigatran etexilate	Chemicals	Antithrombotic medicines	N		N	Y	24-03-22
Dabrafenib (mesylate)	Chemicals	Antineoplastic medicines	N		Y	N	29-09-22
Dantrolene (sodium hemiheptahydrate)	Chemicals	Muscle relaxants	N		Y	Y	14-07-22
Dapagliflozin	Chemicals	Medicines used in diabetes	N		N	Y	24-02-22
Daprodustat	Chemicals	Antianemic medicines	N		N	N	24-02-22
Decitabine / cedazuridine	Chemicals	Antineoplastic medicines	N		Y	N	18-08-22
Degarelix	Chemicals	Endocrine therapy	N		N	Y	14-07-22
Deucravacitinib	Chemicals	Immunosuppressants	N		N	N	28-10-21
Dopamine	Chemicals	Cardiac therapy	N		N	Y	01-12-22
Eculizumab	Biologicals	Immunosuppressants	N		N	Y	24-03-22
Eculizumab	Biologicals	Immunosuppressants	N		N	Y	14-07-22
Efbemalenograstim alfa	Biologicals	Immunostimulants	N		N	N	30-09-21
Elacestrant (dihydrochloride)	Chemicals	Endocrine therapy	N		N	N	18-08-22
Enalapril	Chemicals	Medicines acting on the renin-angiotensin system	N		N	Y	24-03-22
Eporitamab	Biologicals	Antineoplastic medicines	N		Y	N	27-10-22
Epinephrine	Chemicals	Cardiac therapy	N		N	N	27-10-22
Eribulin	Chemicals	Antineoplastic medicines	N		N	Y	27-10-22
Etrasimod (arginine)	Chemicals	Immunosuppressants	N		N	N	01-12-22
Ferumoxytol	Chemicals	Antianemic medicines	N		N	N	19-05-22
Fezolinetant	Chemicals	Other gynecologicals	N		N	N	29-09-22
Filgrastim	Biologicals	Immunostimulants	N		N	Y	24-02-22
Futibatinib	Chemicals	Antineoplastic medicines	N		Y	N	19-05-22
Gadopicienol	Chemicals	Contrast media	N		N	N	24-02-22
Gadopicienol	Chemicals	Contrast media	N		N	N	15-07-22
Ganaxolone	Chemicals	Antiepileptics	N	1/22	Y	N	28-10-21
Gefapixant	Chemicals	Other nervous system medicines	N		N	N	25-02-21

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Gefapixant	Chemicals	Other nervous system medicines	N		N	N	26-02-21
Germanium (68Ge) chloride / gallium (68Ga) chloride	Radiopharmaceuticals	Diagnostic radiopharmaceuticals	N		N	N	19-08-21
Germanium (68Ge) chloride / gallium (68Ga) chloride	Radiopharmaceuticals	Diagnostic radiopharmaceuticals	N		N	N	28-12-22
Glofitamab	Biologicals	Antineoplastic medicines	N		Y	N	19-05-22
Ibuprofen	Chemicals	Cardiac therapy	N		N	Y	01-12-22
Ivosidenib	Chemicals	Antineoplastic medicines	N		Y	N	24-03-22
Ivosidenib	Chemicals	Antineoplastic medicines	N		Y	N	19-07-22
Lacosamide	Chemicals	Antiepileptics	N		N	Y	19-05-22
Latanoprost	Chemicals	Ophthalmologicals	N		N	Y	29-09-22
Lebrikizumab	Biologicals	Immunosuppressants	N		N	N	27-10-22
Lenadogene nolpharvec	ATMP	Ophthalmologicals	N		Y	N	29-10-20
Leniolisib (phosphate)	Chemicals	Antineoplastic medicines	Y		Y	N	27-10-22
Leriglitzone	Chemicals	Other nervous system medicines	N		Y	N	18-08-22
Masitinib (mesilate)	Chemicals	Antineoplastic medicines	N		Y	N	18-08-22
Mavacamten	Chemicals	Cardiac therapy	N		N	N	30-09-21
Miglustat	Chemicals	Other alimentary tract and metabolism products	N		Y	Y	25-11-21
Mirikizumab	Biologicals	Immunosuppressants	N		N	N	19-05-22
Molnupiravir	Chemicals	Antivirals for systemic use	N		N	N	23-11-21
Momelotinib (dihydrochloride monohydrate)	Chemicals	Antineoplastic medicines	N		Y	N	01-12-22
Natalizumab	Biologicals	Immunosuppressants	N		N	Y	14-07-22
Nintedanib	Chemicals	Antineoplastic medicines	N		N	Y	28-12-22
Niraparib /abriterone	Chemicals	Antineoplastic medicines	N		N	N	19-05-22
Omaveloxolone	Chemicals	Other nervous system medicines	N		Y	N	28-12-22
Omecamtiv mecarbil (dihydrochloride hydrate)	Chemicals	Cardiac therapy	N		N	N	28-12-22
Oteseconazole	Chemicals	Antimycotics for systemic use	N		N	N	19-05-22
Paclitaxel	Chemicals	Antineoplastic medicines	N		N	Y	20-01-22
Palopegteriparatide	Chemicals	Calcium homeostasis	N		Y	N	01-12-22

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Palovarotene	Chemicals	Other medicines for disorders of the musculo-skeletal system	N		Y	N	20-05-21
Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	Biologicals	Vaccines	N		N	N	28-12-22
Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	Biologicals	Vaccines	N		N	N	28-12-22
Pegfilgrastim	Biologicals	Immunostimulants	N		N	Y	30-09-21
Pegfilgrastim	Biologicals	Immunostimulants	N		N	Y	28-10-21
Pegunigalsidase alfa	Biologicals	Other alimentary tract and metabolism products	N		Y	N	24-02-22
Pegzilarginase	Biologicals	Other alimentary tract and metabolism products	N		Y	N	18-08-22
Piflufolastat (18F)	Radiopharmaceuticals	Diagnostic radiopharmaceuticals	N		N	N	14-07-22
Pirtobrutinib	Chemicals	Antineoplastic medicines	N		Y	N	16-06-22
Polihexanide	Chemicals	Antiseptics and disinfectants	N		Y	N	19-05-22
Quizartinib (dihydrochloride)	Chemicals	Antineoplastic medicines	N		Y	N	18-08-22
Raltegravir	Chemicals	Antivirals for systemic use	N		N	Y	24-03-22
Ranibizumab	Biologicals	Ophthalmologicals	N		N	N	20-05-21
Ranibizumab	Biologicals	Ophthalmologicals	N		N	Y	27-10-22
Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E	Biologicals	Vaccines	Y		N	N	27-10-22
Rezafungin (acetate)	Chemicals	Antimycotics for systemic use	N		Y	N	18-08-22
Ritlecitinib (tosilate)	Chemicals	Immunosuppressants	N		N	N	18-08-22
Rozanolixizumab	Biologicals	Antineoplastic medicines	N		Y	N	01-12-22
Ruxolitinib (phosphate)	Chemicals	Other dermatological medicines	N		N	N	28-10-21
Sirolimus	Chemicals	Immunosuppressants	N		Y	Y	24-12-21
Sitagliptin/metformin	Chemicals	Medicines used in diabetes	N		N	Y	24-02-22
Sodium phenylbutyrate / ursodoxicoltaurine	Chemicals	Other nervous system medicines	N		Y	N	24-02-22

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Sodium thiosulfate	Chemicals	Other therapeutic medicines	N		N	N	27-02-20
Sparsentan	Chemicals	Other therapeutic medicines	N		Y	N	18-08-22
Spirolactone	Chemicals	Diuretics	N		N	Y	25-11-21
Sugammadex	Chemicals	Other therapeutic medicines	N		N	Y	19-05-22
Sugammadex	Chemicals	Other therapeutic medicines	N		N	Y	18-08-22
Sugammadex	Chemicals	Other therapeutic medicines	N		N	Y	18-08-22
Tislelizumab	Biologicals	Antineoplastic medicines	N		N	N	24-03-22
Tislelizumab	Biologicals	Antineoplastic medicines	N		Y	N	24-03-22
Tocilizumab	Biologicals	Immunosuppressants	N		N	Y	18-08-22
Tocilizumab	Biologicals	Immunosuppressants	N		N	Y	29-09-22
Tocilizumab	Biologicals	Immunosuppressants	N		N	Y	14-12-22
Tofersen	Chemicals	Other nervous system medicines	N		Y	N	01-12-22
Tolvaptan	Chemicals	Diuretics	N		N	Y	24-12-21
Toripalimab	Biologicals	Antineoplastic medicines	N		N	N	01-12-22
Trametinib (dimethyl sulfoxide)	Chemicals	Antineoplastic medicines	N		Y	N	29-09-22
Trastuzumab	Biologicals	Antineoplastic medicines	N		N	Y	20-01-22
Trastuzumab duocarmazine	Biologicals	Antineoplastic medicines	N		N	N	14-07-22
Ublituximab	Biologicals	Immunosuppressants	N		N	N	24-12-21
Ustekinumab	Biologicals	Immunosuppressants	N		N	Y	01-12-22
Vadadustat	Chemicals	Antianemic medicines	N		N	N	25-11-21
Vamorolone	Chemicals	Other medicines for disorders of the musculo-skeletal system	N		Y	N	27-10-22
Zilucoplan	Chemicals	Immunosuppressants	N		Y	N	29-09-22