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Human Medicines Division

Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use

January 2021

This document lists information on applications for centralised marketing authorisation for human medicines that the European Medicines Agency has received for evaluation. It includes the international non-proprietary names (INN) and therapeutic areas for all new innovative medicines under evaluation by the Committee for Medicinal Products for Human Use (CHMP). For generic and biosimilar medicines, it includes the INN (active moiety only, with no information on salt, ester or derivative) and therapeutic area.

This list only includes information for medicines whose applications have been validated at the time the report was compiled. The information in this report was compiled on 6 January 2020.

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).

Information in bold corresponds to new entries in the monthly list.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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 CHMP opinions is also published in the monthly CHMP highlights.

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Non-orphan medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Abrocitinib	Other dermatological medicines
Adrenalin	Cardiac therapy
Aducanumab	Other nervous system medicines
Anifrolumab	Immunosuppressants
Arachis hypogaea extract	Allergens
Azacitidine	Antineoplastic medicines
Bevacizumab	Ophthalmologicals
Bimekizumab	Immunosuppressants
Cenobamate	Antiepileptics
Diroximel (fumarate)	Immunosuppressants
Dostarlimab	Antineoplastic medicines
Eptinezumab	Analgesics
Estetrol (monohydrate) / drospirenone	Sex hormones and modulators of the genital system
Evinacumab [ii]	Lipid modifying medicines
Finerenone	Medicines acting on the renin-angiotensin system
Fluticasone (propionate) / Salmeterol (xinafoate)	Medicines for obstructive airway diseases
Hepatitis B surface antigen	Vaccines
Icosapent (ethyl)	Lipid modifying medicines
Istradefylline	Anti-parkinson medicines
Lasmiditan (succinate)	Analgesics
Linzagolix (choline)	Pituitary and hypothalamic hormones and analogues
Obeticholic (acid)	Bile and liver therapy
Ofatumumab	Immunosuppressants
Pitolisant (hydrochloride)	Other nervous system medicines
Ponesimod	Immunosuppressants

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Pralsetinib	Antineoplastic medicines
Relugolix / estradiol (hemihydrate) / norethisterone (acetate)	Pituitary and hypothalamic hormones and analogues
Remimazolam (besilate)	Psycholeptics
Roxadustat	Antianemic medicines
Salmeterol (xinafoate) / fluticasone (propionate)	Medicines for obstructive airway diseases
Sodium thiosulfate	Other therapeutic medicines
Tanezumab	Analgesics
Tecovirimat	Antivirals for systemic use
Tepotinib (hydrochloride monohydrate)	Antineoplastic medicines
Tirbanibulin (mesilate)	Antibiotics and chemotherapeutics for dermatological use
Tralokinumab	Other dermatological medicines
Vericiguat	Cardiac therapy

[i] Based on the ATC therapeutic sub-group.
[ii] Under EMA's accelerated assessment programme cf. Article 14(9) of Regulation (EC) No 726/2004.

Non-orphan generic and biosimilar medicinal products

International non-proprietary name / Common Name	Therapeutic area [i]	Total number of applications
Abiraterone	Endocrine therapy	3
Adalimumab	Immunosuppressants	1
Azathioprine	Immunosuppressants	1
Betaine	Other alimentary tract and metabolism products	1
Bevacizumab	Antineoplastic medicines	5
Dabigatran	Antithrombotic medicines	1
Dasatinib	Antineoplastic medicines	2
Dexamethasone [vi]	Corticosteroids for systemic use	1

International non-proprietary name / Common Name	Therapeutic area [i]	Total number of applications
Doxorubicin	Antineoplastic medicines	2
Fingolimod	Immunosuppressants	1
Icatibant	Other hematological medicines	1
Imatinib	Antineoplastic medicines	1
Insulin human (rDNA)	Medicines used in diabetes	1
Ioflupane (123I)	Diagnostic radiopharmaceuticals	1
Leuprorelin	Endocrine therapy	1
Metformin / sitagliptin	Medicines used in diabetes	1
Pegfilgrastim	Immunostimulants	1
Ranibizumab	Ophthalmologicals	1
Risperidone	Psycholeptics	1
Rivaroxaban	Antithrombotic medicines	1
Sildenafil	Urologicals	1
Sitagliptin	Medicines used in diabetes	2
Sugammadex	Other therapeutic medicines	1
Teriparatide	Calcium homeostasis	2
Thiotepa	Antineoplastic medicines	1
Trastuzumab	Antineoplastic medicines	1
Vildagliptin / metformin	Medicines used in diabetes	1

[i] Based on the ATC therapeutic sub-group.
[ii] Under EMA's accelerated assessment programme cf. Article 14(9) of Regulation (EC) No 726/2004.
[iii] Submitted according to legal basis: Informed consent application (Article 10c of Directive No 2001/83/EC).
[iv] Medicine classified as advanced therapy medicinal product (ATMP).
[v] Product no longer being reviewed under EMA's accelerated assessment programme.
[vi] Accelerated timetable for COVID-19 related medicine.

Orphan medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Arimoclomol (citrate)	Other nervous system medicines
Artesunate	Antiprotozoals
Autologous glioma tumor cells, inactivated / autologous glioma tumor cell lysates, inactivated / allogeneic glioma tumor cells, inactivated / allogeneic glioma tumor cell lysates, inactivated [iv]	Antineoplastic medicines
Avacopan	Immunosuppressants
Avalglucosidase alfa	Other alimentary tract and metabolism products
Berotralstat (hydrochloride)	Other hematological medicines
Duvelisib	Antineoplastic medicines
Eflornithine (hydrochloride) / sulindac	Antineoplastic medicines
Eladocagene exuparvovec [iv]	Other nervous system medicines
Elivaldogene autotemcel [ii, iv]	Other nervous system medicines
Glucarpidase	Other therapeutic medicines
Hydrocortisone	Corticosteroids for systemic use
Idecabtagene vicleucel [ii, iv]	Antineoplastic medicines
Inebilizumab	Immunosuppressants
Lenadogene nolparvovec [iv]	Ophthalmologicals
Lisocabtagene maraleucel [iv]	Antineoplastic medicines
Lonafarnib	Other alimentary tract and metabolism products
Lonapegsomatropin	Pituitary and hypothalamic hormones and analogues
Maralixibat (chloride)	Bile and liver therapy
Odevixibat (sesquihydrate) [ii]	Bile and liver therapy
Pegcetacoplan	Immunosuppressants
Pemigatinib	Antineoplastic medicines
Ripretinib	Antineoplastic medicines

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Risdiplam [ii]	Other medicines for disorders of the musculo-skeletal system
Satralizumab	Immunosuppressants
Selinexor	Antineoplastic medicines
Selumetinib (sulfate)	Antineoplastic medicines
Setmelanotide	Antiobesity medicines
Somapacitan	Pituitary and hypothalamic hormones and analogues
Tafasitamab	Antineoplastic medicines
Vosoritide	Medicines for bone diseases
Zanubrutinib	Antineoplastic medicines

[i] Based on the ATC therapeutic sub-group.
[ii] Under EMA's accelerated assessment programme cf. Article 14(9) of Regulation (EC) No 726/2004.
[iii] Submitted according to legal basis: Informed consent application (Article 10c of Directive No 2001/83/EC).
[iv] Medicine classified as advanced therapy medicinal product (ATMP).