4 September 2020
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Human Medicines Division

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

September 2020

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 4 September 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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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]
Arachis hypogaea allergens	Allergens
Autologous human chondrocytes in vitro expanded [iv]	Other medicines for disorders of the musculo-skeletal system
Azacitidine	Antineoplastic medicines
Baloxavir marboxil	Antivirals for systemic use
Bevacizumab	Ophthalmologicals
Bimekizumab	Immunosuppressants
Budesonide / glycopyrronium (bromide) / formoterol (fumarate dihydrate)	Nasal medicines
Bupivacaine	Anesthetics
Cabotegravir (sodium)	Antivirals for systemic use
Cenobamate	Antiepileptics
Dostarlimab	Antineoplastic medicines
Estetrol (monohydrate) / drospirenone	Sex hormones and modulators of the genital system
Fluticasone (propionate) / Salmeterol (xinafoate)	Medicines for obstructive airway diseases
Fostemsavir (trometamol)	Antivirals for systemic use
Hepatitis B surface antigen	Vaccines
Icosapent (ethyl)	Lipid modifying medicines
Inclisiran	Lipid modifying medicines
Influenza quadrivalent vaccine (rDNA)	Vaccines
Istradefylline	Anti-Parkinson medicines
Meningococcal group A, C, W135 and Y conjugate vaccine	Vaccines
Netarsudil (mesilate) / latanoprost	Ophthalmologicals
Obeticholic (acid)	Bile and liver therapy
Ofatumumab	Immunosuppressants
Pertuzumab / trastuzumab	Antineoplastic medicines
Pitolisant (hydrochloride)	Other nervous system medicines
Ponesimod	Immunosuppressants
Pralsetinib	Antineoplastic medicines
Relugolix / estradiol (hemihydrate) / norethisterone (acetate)	Pituitary and hypothalamic hormones and analogues

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Remimazolam (besilate)	Psycholeptics
Rilpivirine	Antivirals for systemic use
Roxadustat	Antianemic medicines
Salmeterol (xinafoate) / fluticasone (propionate)	Medicines for obstructive airway diseases
Selpercatinib	Antineoplastic medicines
Sodium thiosulfate	Other therapeutic medicines
Tanezumab	Analgesics
Tirbanibulin (mesilate)	Antibiotics and chemotherapeutics for dermatological use
Tralokinumab	Other dermatological medicines
Trastuzumab (deruxtecan) [ii]	Antineoplastic medicines
Tucatinib	Antineoplastic medicines
Vericiguat	Cardiac therapy

[i] Based on the ATC therapeutic sub-group.
[ii] Application being reviewed under EMA's accelerated assessment programme.
[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)

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
Bevacizumab	Antineoplastic medicines	4
Dabigatran	Antithrombotic medicines	1
Dasatinib	Antineoplastic medicines	2
Dexamethasone	Corticosteroids for systemic use	1
Doxorubicin	Antineoplastic medicines	2
Glucagon	Pancreatic hormones	1
Icatibant	Other hematological medicines	1

International non-proprietary name / Common Name	Therapeutic area [i]	Total number of applications
Imatinib	Antineoplastic medicines	1
Insulin aspart	Medicines used in diabetes	1
Insulin human (rDNA)	Medicines used in diabetes	1
Ioflupane (123I)	Diagnostic radiopharmaceuticals	1
Lenalidomide	Immunosuppressants	4
Leuprorelin	Endocrine therapy	1
Melphalan	Antineoplastic medicines	1
Pegfilgrastim	Immunostimulants	2
Risperidone	Psycholeptics	1
Rivaroxaban	Antithrombotic medicines	1
Sildenafil	Urologicals	1
Sitagliptin	Medicines used in diabetes	1
Sugammadex	Other therapeutic medicines	1
Sunitinib	Antineoplastic medicines	1
Thiotepa	Antineoplastic medicines	1
Trastuzumab	Antineoplastic medicines	1

[i] Based on the ATC therapeutic sub-group.

Orphan medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex vivo using a lentiviral vector encoding the human arylsulfatase A gene [ii, iv]	Other nervous system medicines
Autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured [ii, iv]	Antineoplastic medicines
Berotralstat (hydrochloride)	Other hematological medicines
Duvelisib	Antineoplastic medicines
Eflornithine (hydrochloride) / sulindac	Antineoplastic medicines
Eladocagene exuparvovec [iv]	Other nervous system medicines

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Fedratinib (dihydrochloride monohydrate)	Antineoplastic medicines
Fenfluramine	Antiepileptics
Glucarpidase	Detoxifying agents for antineoplastic treatment
Hydrocortisone	Corticosteroids for systemic use
Idebenone (titanium dioxide)	Psychoanaleptics
Idecabtagene vicleucel [ii, iv]	Antineoplastic medicines
Ivosidenib	Antineoplastic medicines
Lisocabtagene maraleucel [ii, iv]	Antineoplastic medicines
Lonafarnib	Other alimentary tract and metabolism products
Lumasiran (sodium) [ii]	Other alimentary tract and metabolism products
Moxetumomab pasudotox	Antineoplastic medicines
Obiltoxaximab	Immune sera and immunoglobulins
Pemigatinib	Antineoplastic medicines
Potassium citrate / potassium hydrogen carbonate	Mineral supplements
Risdiplam [ii]	Other medicines for disorders of the musculo-skeletal system
Satralizumab	Immunosuppressants
Selinexor	Antineoplastic medicines
Selumetinib (sulfate)	Antineoplastic medicines
Setmelanotide [ii]	Antiobesity medicines
Somapacitan	Pituitary and hypothalamic hormones and analogues
Tafasitamab	Antineoplastic medicines
Valoctocogene roxaparvovec [ii, iv]	Antihemorrhagics
Vosoritide	Medicines for bone diseases
Zanubrutinib	Antineoplastic medicines

[i] Based on the ATC therapeutic sub-group.
[ii] Application being reviewed under EMA's accelerated assessment programme.
[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