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Information Management Division

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

June 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 8 June 2020 (updated with correction 24 June) .

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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]
Abicipar pegol	Ophthalmologicals
Arachis hypogaea allergens	Allergens
Azacitidine	Antineoplastic medicines
Baloxavir marboxil	Antivirals for systemic use
Bevacizumab	Ophthalmologicals
Budesonide / glycopyrronium (bromide) / formoterol (fumarate dihydrate)	Nasal medicines
Bupivacaine	Anesthetics
Bupivacaine / meloxicam	Anesthetics
Cabotegravir (sodium)	Antivirals for systemic use
Cenobamate	Antiepileptics
Dostarlimab [ii]	Antineoplastic medicines
Estetrol (monohydrate) / drospirenone	Sex hormones and modulators of the genital system
Filgotinib (maleate)	Immunosuppressants
Fluticasone (propionate) / Salmeterol (xinafoate)	Medicines for obstructive airway diseases
Fostemsavir (trometamol) [v]	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
Lifitegrast	Ophthalmologicals
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
Plazomicin (sulfate)	Antibacterials for systemic use

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Ponesimod	Immunosuppressants
Pralsetinib	Antineoplastic medicines
Relugolix / estradiol (hemihydrate) / norethisterone (acetate)	Pituitary and hypothalamic hormones and analogues
Remdesivir	Antivirals for systemic use
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
Tucatinib	Antineoplastic medicines

[i] Based on the ATC therapeutic sub-group.
[ii] Application being reviewed under EMA's accelerated assessment programme.
[v] Product no longer being reviewed under EMA's accelerated assessment programme

Non-orphan generic and biosimilar medicinal products

International non-proprietary name / Common Name	Therapeutic area [i]	Total number of applications
Abiraterone	Endocrine therapy	2
Adalimumab	Immunosuppressants	1
Aripiprazole	Psycholeptics	1
Arsenic trioxide	Antineoplastic medicines	1
Azathioprine	Immunosuppressants	1
Bevacizumab	Antineoplastic medicines	6
Caffeine citrate	Psychoanaleptics	1
Dasatinib	Antineoplastic medicines	2
Doxorubicin	Antineoplastic medicines	2
Erlotinib	Antineoplastic medicines	1
Fampridine	Other nervous system medicines	1

International non-proprietary name / Common Name	Therapeutic area [i]	Total number of applications
Glucagon	Pancreatic hormones	1
Insulin aspart	Medicines used in diabetes	1
Insulin human (rDNA)	Medicines used in diabetes	1
Ioflupane (123I)	Diagnostic radiopharmaceuticals	1
Lenalidomide	Immunosuppressants	2
Leuprorelin	Endocrine therapy	1
Melphalan	Antineoplastic medicines	1
Methylthioninium chloride	Diagnostic 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
Teriparatide	Calcium homeostasis	3
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]
Acalabrutinib	Antineoplastic medicines
Amikacin (sulfate)	Antibacterials for systemic use
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
Avapritinib	Antineoplastic medicines
Belantamab mafodotin [ii]	Antineoplastic medicines

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Berotralstat (hydrochloride)	Other hematological medicines
Crizanlizumab	Other hematological medicines
Deferiprone	Other therapeutic medicines
Duvelisib	Antineoplastic medicines
Eladocagene exuparvovec [iv]	Other nervous system medicines
Elexacaftor / tezacaftor / ivacaftor	Other respiratory system medicines
Emapalumab	Immunosuppressants
Fedratinib (dihydrochloride monohydrate)	Antineoplastic medicines
Fenfluramine	Antiepileptics
Hydrocortisone	Corticosteroids for systemic use
Idebenone (titanium dioxide)	Psychoanaleptics
Idecabtagene vicleucel [ii, iv, *note]	Antineoplastic medicines
Imlifidase	Immunosuppressants
Ivosidenib	Antineoplastic medicines
Lonafarnib [ii]	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
Pexidartinib (hydrochloride)	Antineoplastic medicines
Potassium citrate / potassium hydrogen carbonate	Mineral supplements
Satralizumab	Immunosuppressants
Selinexor	Antineoplastic medicines
Selumetinib (sulfate)	Antineoplastic medicines
Somapacitan	Pituitary and hypothalamic hormones and analogues
Tafasitamab	Antineoplastic medicines
Tagraxofusp	Antineoplastic medicines
Valoctocogene roxaparvovec [ii, iv]	Antihemorrhagics

[i] Based on the ATC therapeutic sub-group.
[ii] Application being reviewed under EMA's accelerated assessment programme.
[iv] Medicine classified as advanced therapy medicinal product (ATMP)
[*note] Due to administrative recording issue, this entry was mistakenly omitted in the first version of the June report.