



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management Division

Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use December 2019

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 2 December 2019.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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



Non-orphan medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ⁱ
Abicipar pegol	Ophthalmologicals
Alpelisib	Antineoplastic medicines
Arachis hypogaea allergens	Allergens
Baloxavir marboxil	Antivirals for systemic use
Bempedoic acid	Lipid modifying medicines
Bempedoic acid / ezetimibe	Lipid modifying medicines
Brolucizumab	Ophthalmologicals
Budesonide / glycopyrronium (bromide) / formoterol (fumarate dihydrate)	Medicines for obstructive airway diseases
Bupivacaine	Anesthetics
Bupivacaine / meloxicam	Anesthetics
Cabotegravir (sodium)	Antivirals for systemic use
Cefiderocol (sulfate tosilate)	Antibacterials for systemic use
Cholera vaccine, oral, live	Vaccines
Crisaborole	Other dermatological medicines
Darolutamide	Endocrine therapy
Ebola vaccine (rDNA, replication-incompetent) ⁱⁱ	Vaccines
Entrectinib	Antineoplastic medicines
Filgotinib (maleate)	Immunosuppressants
Fluticasone (propionate) / Salmeterol (xinafoate)	Medicines for obstructive airway diseases
Hepatitis B surface antigen	Vaccines
Icosapent (ethyl)	Lipid modifying medicines
Imipenem (monohydrate) / cilastatin (sodium) / relebactam (monohydrate)	Antibacterials for systemic use
Indacaterol (acetate) / glycopyrronium (bromide) / mometasone (furoate)	Medicines for obstructive airway diseases
Indacaterol (acetate) / mometasone (furoate)	Medicines for obstructive airway diseases
Influenza quadrivalent vaccine (rDNA)	Vaccines

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ⁱ
Influenza vaccine (surface antigen, inactivated)	Vaccines
Insulin lispro	Medicines used in diabetes
Lefamulin (acetate)	Antibacterials for systemic use
Lifitegrast	Ophthalmologicals
Meningococcal group A, C, W135 and Y conjugate vaccine	Vaccines
Ozanimod (hydrochloride)	Immunosuppressants
Plazomicin (sulfate)	Antibacterials for systemic use
Rilpivirine	Antivirals for systemic use
Semaglutide	Medicines used in diabetes

ⁱ Based on the ATC therapeutic sub-group.

ⁱⁱ Application being reviewed under EMA's accelerated assessment programme.

NB: From Dec 2019, footnote ^v will only be applied in the first report after reverting to a standard timetable

^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	1
Adalimumab	Immunosuppressants	1
Apixaban	Antithrombotic medicines	1
Aripiprazole	Psycholeptics	1
Arsenic trioxide	Antineoplastic medicines	2
Azacitidine	Antineoplastic medicines	3
Bevacizumab	Antineoplastic medicines	2
Budesonide / formoterol	Medicines for obstructive airway diseases	1
Cabazitaxel	Antineoplastic medicines	1
Caffeine citrate	Psychoanaleptics	1
Cinacalcet	Calcium homeostasis	1
Dasatinib	Antineoplastic medicines	2

International non-proprietary name / Common Name	Therapeutic area ⁱ	Total number of applications
Dexmedetomidine	Psycholeptics	1
Doxorubicin	Antineoplastic medicines	2
Erlotinib	Antineoplastic medicines	1
Etanercept	Immunosuppressants	1
Fampridine	Other nervous system medicines	1
Fingolimod	Immunosuppressants	2
Insulin aspart	Medicines used in diabetes	2
Ioflupane (123I)	Diagnostic radiopharmaceuticals	1
Lenalidomide	Immunosuppressants	1
Melphalan	Antineoplastic medicines	1
Methylthioninium chloride	Diagnostic medicines	1
Pegfilgrastim	Immunostimulants	1
Rituximab	Antineoplastic medicines	3
Rivaroxaban	Antithrombotic medicines	1
Sunitinib	Antineoplastic medicines	1
Teriparatide	Calcium homeostasis	3
Tigecycline	Antibacterials for systemic use	1
Trastuzumab	Antineoplastic medicines	2

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
Avapritinib	Antineoplastic medicines

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ⁱ
Bulevirtide (acetate) ⁱⁱ	Antivirals for systemic use
Crizanlizumab	Other hematological medicines
Deferiprone	Other therapeutic medicines
Elexacaftor / tezacaftor / ivacaftor ⁱⁱ	Other respiratory system medicines
Emapalumab	Immunosuppressants
Enasidenib (mesilate)	Antineoplastic medicines
Fenfluramine	Antiepileptics
Givosiran (sodium) ⁱⁱ	Other alimentary tract and metabolism products
Glasdegib (maleate)	Antineoplastic medicines
Idebenone (titanium dioxide)	Psychoanaleptics
Imlifidase	Immunosuppressants
Isatuximab	Antineoplastic medicines
Ivosidenib	Antineoplastic medicines
Luspatercept	Antianemic medicines
Obiltoxaximab	Immune sera and immunoglobulins
Onasemnogene abeparvovec ^{iv}	Other medicines for disorders of the musculo-skeletal system
Pexidartinib (hydrochloride)	Antineoplastic medicines
Potassium citrate/potassium hydrogen carbonate	Mineral supplements
Pretomanid	Antimycobacterials
Satralizumab ⁱⁱ	Immunosuppressants
Selinexor	Antineoplastic medicines
Somapacitan	Pituitary and hypothalamic hormones and analogues
Tagraxofusp	Antineoplastic medicines
Treprostinil (sodium)	Antithrombotic medicines

ⁱ Based on the ATC therapeutic sub-group.

ⁱⁱ Application being reviewed under EMA's accelerated assessment programme.

ⁱⁱⁱ N/A (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)

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^v Product no longer being reviewed under EMA's accelerated assessment programme