



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 April 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 8 April 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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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
Alpelisib	Antineoplastic medicines
Angiotensin II (acetate)	Medicines acting on the renin-angiotensin system
Avatrombopag (maleate)	Antihemorrhagics
Bempedoic acid	Lipid modifying medicines
Bempedoic acid / ezetimibe	Lipid modifying medicines
Botulinum toxin type A	Muscle relaxants
Brolucizumab	Ophthalmologicals
Budesonide / glycopyrronium (bromide) / formoterol (fumarate dihydrate)	Medicines for obstructive airway diseases
Bupivacaine / meloxicam	Anesthetics
Buprenorphine (hydrochloride)	Other nervous system medicines
Cefiderocol (sulfate tosilate) ⁱⁱ	Antibacterials for systemic use
Cemiplimab	Antineoplastic medicines
Cholera vaccine, oral, live	Vaccines
Ciprofloxacin	Antibacterials for systemic use
Crisaborole	Other dermatological medicines
Dapagliflozin (propanediol)/saxagliptin/metformin (hydrochloride)	Medicines used in diabetes
Darolutamide	Endocrine therapy
Delafloxacin (meglumine)	Antibacterials for systemic use
Dolutegravir (sodium) / lamivudine	Antivirals for systemic use
Entrectinib	Antineoplastic medicines
Esketamine (hydrochloride)	Anesthetics
Fluticasone furoate /umeclidinium bromide /vilanterol (trifenatate) ⁱⁱⁱ	Medicines for obstructive airway diseases
Fostamatinib (disodium)	Antihemorrhagics
Glucagon	Pancreatic hormones
Hepatitis B surface antigen	Vaccines
Ibalizumab ⁱⁱ	Antivirals for systemic use
Imipenem (monohydrate) /cilastatin (sodium) / relebactam (monohydrate)	Antibacterials for systemic use

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
Levodopa	Anti-parkinson medicines
Lifitegrast	Ophthalmologicals
L-lysine (hydrochloride) / L-arginine (hydrochloride)	Urologicals
Netarsudil (mesilate)	Ophthalmologicals
Omadacycline	Antibacterials for systemic use
Ozanimod (hydrochloride)	Immunosuppressants
Plazomicin (sulfate)	Antibacterials for systemic use
Recombinant vesicular stomatitis virus - zaire ebolavirus vaccine (live) ⁱⁱ	Vaccines
Romosozumab	Medicines for bone diseases
Siponimod (fumaric acid)	Immunosuppressants
Sodium oxybate	Other nervous system medicines
Solriamfetol (hydrochloride)	Other nervous system medicines
Talazoparib	Antineoplastic medicines
Upadacitinib (hemihydrate)	Immunosuppressants

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).

Non-orphan generic and biosimilar medicinal products

International non-proprietary name / Common Name	Therapeutic area ⁱ	Total number of applications
Adalimumab	Immunosuppressants	1
Ambrisentan	Antihypertensives	2
Aripiprazole	Psycholeptics	1
Arsenic trioxide	Antineoplastic medicines	2
Azacitidine	Antineoplastic medicines	3
Bortezomib	Antineoplastic medicines	1
Cabazitaxel	Antineoplastic medicines	1

International non-proprietary name / Common Name	Therapeutic area ⁱ	Total number of applications
Cinacalcet	Calcium homeostasis	1
Clofarabine	Antineoplastic medicines	1
Clopidogrel / Acetylsalicylic acid	Antithrombotic medicines	1
Deferasirox	Other therapeutic medicines	2
Dexmedetomidine	Psycholeptics	1
Erlotinib	Antineoplastic medicines	1
Etanercept	Immunosuppressants	1
Hydroxycarbamide	Antineoplastic medicines	1
Infliximab	Immunosuppressants	1
Ioflupane (123I)	Diagnostic radiopharmaceuticals	1
Methylthioninium chloride	Diagnostic medicines	1
Pegfilgrastim	Immunostimulants	1
Posaconazole	Antimycotics for systemic use	1
Rituximab	Antineoplastic medicines	2
Teriparatide	Calcium homeostasis	1
Tigecycline	Antibacterials for systemic use	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
Cannabidiol	Antiepileptics
Diclofenamide	Ophthalmologicals
Edaravone	Other nervous system medicines
Emapalumab	Immunosuppressants
Enasidenib (mesilate)	Antineoplastic medicines
Fenfluramine ^v	Antiepileptics ^v
Gilteritinib (fumarate) ⁱⁱ	Antineoplastic medicines

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ⁱ
Glutamine	Other alimentary tract and metabolism products
Imlifidase	Immunosuppressants
Ivosidenib	Antineoplastic medicines
Larotrectinib (sulfate) ⁱⁱ	Antineoplastic medicines
Onasemnogene abeparvovec ^{ii, iv}	Other medicines for disorders of the musculo-skeletal system
Osilodrostat (phosphate)	Corticosteroids for systemic use
Pexidartinib (hydrochloride)	Antineoplastic medicines
Polatuzumab vedotin ⁱⁱ	Antineoplastic medicines
Pretomanid	Antimycobacterials
Quizartinib (dihydrochloride) ⁱⁱ	Antineoplastic medicines
Ravulizumab	Immunosuppressants
Selinexor ⁱⁱ	Antineoplastic medicines
Tagraxofusp ⁱⁱ	Antineoplastic medicines
Treprostinil (sodium)	Antithrombotic medicines
Trientine (dihydrochloride)	Other alimentary tract and metabolism products
Turoctocog alfa pegol	Antihemorrhagics
Viable T-cells ^{iv}	Antineoplastic and immunomodulating agents

ⁱ Based on the ATC therapeutic sub-group.

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

ⁱⁱⁱ N/a in this table

^{iv} Medicine classified as advanced therapy medicinal product (ATMP)

^v Fenfluramine was in the March report listed with the substance's previously approved ATC code. This has now been corrected to (N03) Antiepileptics.