



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 March 2016

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 March 2016**.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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 ¹
Abaloparatide	Calcium homeostasis
Alectinib (hydrochloride)	Antineoplastic medicines
Anamorelin (hydrochloride)	Other therapeutic medicines
Baricitinib	Immunosuppressants
Bezlotoxumab	Antidiarrheals, intestinal antiinflammatory/antiinfective medicines
Brodalumab	Immunosuppressants
Cabozantinib (S-malate)	Antineoplastic medicines
Ceftazidime / avibactam	Antibacterials for systemic use
Daclizumab	Immunosuppressants
Dasabuvir (sodium) / ombitasvir / paritaprevir / ritonavir	Antivirals for systemic use
Dimethyl fumarate	Antipsoriatics
Eluxadoline	Antidiarrheals, intestinal antiinflammatory/antiinfective medicines
Empagliflozin / linagliptin	Medicines used in diabetes
Emtricitabine / rilpivirine (hydrochloride) / tenofovir alafenamide (fumarate)	Antivirals for systemic use
Etelcalcetide (hydrochloride)	Calcium homeostasis
Fluciclovine (18F)	Diagnostic radiopharmaceuticals
Follitropin delta	Sex hormones and modulators of the genital system
Glycopyrronium bromide	Medicines for functional gastrointestinal disorders
Grazoprevir / elbasvir	Antivirals for systemic use
Iloperidone	Psycholeptics
Insulin aspart	Medicines used in diabetes
Lenvatinib (mesilate)	Antineoplastic medicines
Lonococog alfa	Antihemorrhagics
Lutetium (177 Lu) chloride	Therapeutic radiopharmaceuticals
Opicapone	Anti-parkinson medicines
Padeliporfin (di-potassium)	Antineoplastic medicines

¹ Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ¹
Palbociclib	Antineoplastic medicines
Pancreas powder	Digestives, incl. enzymes
Pandemic influenza vaccine H5N1 (live attenuated, nasal)	Vaccines
Prasterone	Sex hormones and modulators of the genital system
Reslizumab	Immunosuppressants
Rociletinib (hydrobromide)	Antineoplastic medicines
Sacubitril / valsartan ²	Medicines acting on the renin-angiotensin system
Saxagliptin / dapagliflozin (propanediol monohydrate)	Medicines used in diabetes
Sodium zirconium cyclosilicate	Other therapeutic medicines
Sofosbuvir / velpatasvir	Antivirals for systemic use
Spheroids of human autologous matrix-associated chondrocytes	Other medicines for disorders of the musculo-skeletal system
Tenofovir alafenamide (fumarate)	Antivirals for systemic use

Non-orphan generic and biosimilar medicinal products

International non-proprietary name / Common Name	Therapeutic area ³	Total number of applications
Adalimumab	Immunosuppressants	2
Alendronic acid / colecalciferol	Medicines for bone diseases	1
Atazanavir	Antivirals for systemic use	1
Bortezomib	Antineoplastic medicines	2
Daptomycin	Antibacterials for systemic use	1
Darunavir	Antivirals for systemic use	1
Docetaxel	Antineoplastic medicines	1
Emtricitabine / tenofovir disoproxil	Antivirals for systemic use	3
Enoxaparin sodium	Antithrombotic medicines	2
Ertapenem	Antibacterials for systemic use	1
Etanercept	Immunosuppressants	1

² Submitted according to legal basis: "Informed consent application (Article 10c of Directive No 2001/83/EC)"

³ Based on the ATC therapeutic sub-group.

International non-proprietary name / Common Name	Therapeutic area ³	Total number of applications
Fluticasone / salmeterol	Medicines for obstructive airway diseases	2
Infliximab	Immunosuppressants	1
Insulin glargine	Medicines used in diabetes	1
Ivabradine	Cardiac therapy	3
Methotrexate	Antineoplastic medicines	2
Miglustat	Other alimentary tract and metabolism products	1
Palonosetron	Antiemetics and antinauseants	1
Pegfilgrastim	Immunostimulants	3
Pemetrexed	Antineoplastic medicines	1
Rituximab	Antineoplastic medicines	1
Sildenafil	Urologicals	2
Tadalafil	Urologicals	1
Tenofovir disoproxil	Antivirals for systemic use	2
Teriparatide	Calcium homeostasis	2

Orphan medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ⁴
Aceneuramic acid	Other medicines for disorders of the musculo-skeletal system
Allogeneic t cells genetically modified to express suicide gene	Antineoplastic medicines
Amikacin	Antibacterials for systemic use
Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence	Immunostimulants
Begelomab	Immunosuppressants
Cediranib (maleate)	Antineoplastic medicines
Chenodeoxycholic acid	Bile and liver therapy
Chlormethine	Antineoplastic medicines

⁴ Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ⁴
Daratumumab	Antineoplastic medicines
Dinutuximab beta	Antineoplastic medicines
Drisapersen (sodium)	Other medicines for disorders of the musculo-skeletal system
Edotreotide	Diagnostic radiopharmaceuticals
Eryaspase	Antineoplastic medicines
Irinotecan (hydrochloride trihydrate)	Antineoplastic medicines
Ixazomib (citrate)	Antineoplastic medicines
Mercaptamine (hydrochloride)	Ophthalmologicals
Migalastat (hydrochloride)	Antineoplastic medicines
Nonacog beta pegol	Antihemorrhagics
Obeticholic acid	Bile and liver therapy
Olaratumab	Antineoplastic medicines
Paclitaxel	Antineoplastic medicines
Parathyroid hormone	Calcium homeostasis
Pentosan polysulfate sodium	Urologicals
Sirolimus	Ophthalmologicals
Trientine (tetrahydrochloride)	Other alimentary tract and metabolism products
Venetoclax	Antineoplastic medicines
Vosaroxin	Antineoplastic medicines