



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 May 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 **10 May 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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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
Cariprazine (hydrochloride)	Psycholeptics
Dasabuvir (sodium) / ombitasvir / paritaprevir / ritonavir	Antivirals for systemic use
Dengue tetravalent vaccine (live, attenuated)	Vaccines
Dimethyl fumarate	Antipsoriatics
Eluxadoline	Antidiarrheals, intestinal antiinflammatory/antiinfective medicines
Empagliflozin / linagliptin	Medicines used in diabetes
Etelcalcetide (hydrochloride)	Calcium homeostasis
Fluciclovine (18F)	Diagnostic radiopharmaceuticals
Follitropin delta	Sex hormones and modulators of the genital system
Grazoprevir / elbasvir	Antivirals for systemic use
Human IgG1 monoclonal antibody specific for human interleukin-1 alpha	Antineoplastic medicines
Iloperidone	Psycholeptics
Insulin aspart	Medicines used in diabetes
Insulin glargine / lixisenatide	Medicines used in diabetes
Lenvatinib (mesilate)	Antineoplastic medicines
Lonococog alfa	Antihemorrhagics
Padeliporfin (di-potassium)	Antineoplastic medicines
Palbociclib	Antineoplastic medicines
Prasterone	Sex hormones and modulators of the genital system

¹ Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ¹
Reslizumab	Medicines for obstructive airway diseases
Rociletinib (hydrobromide)	Antineoplastic medicines
Rolapitant	Antiemetics and antinauseants
Rurioctocog alfa pegol	Antihemorrhagics
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
Tofacitinib (citrate)	Immunosuppressants

Non-orphan generic and biosimilar medicinal products

International non-proprietary name / Common Name	Therapeutic area ²	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
Fluticasone / salmeterol	Medicines for obstructive airway diseases	2
Insulin glargine	Medicines used in diabetes	1

² Based on the ATC therapeutic sub-group.

International non-proprietary name / Common Name	Therapeutic area ²	Total number of applications
Ivabradine	Cardiac therapy	3
Methotrexate	Antineoplastic medicines	2
Miglustat	Other alimentary tract and metabolism products	1
Nitisinone	Other alimentary tract and metabolism products	1
Pegfilgrastim	Immunostimulants	3
Pemetrexed	Antineoplastic medicines	2
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 ³
Aceneuramic acid	Other medicines for disorders of the musculo-skeletal system
Allogeneic T cells genetically modified to express suicide gene	Antineoplastic medicines
Alpha-1-antitrypsin	Antihemorrhagics
Amikacin	Antibacterials for systemic use
Begelomab	Immunosuppressants
Cediranib (maleate)	Antineoplastic medicines
Chenodeoxycholic acid	Bile and liver therapy
Chlormethine	Antineoplastic medicines
Dinutuximab beta	Antineoplastic medicines
Drisapersen (sodium)	Other medicines for disorders of the musculo-skeletal system
Edotreotide	Diagnostic radiopharmaceuticals

³ Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ³
Eryaspase	Antineoplastic medicines
Expanded human allogeneic mesenchymal adult stem cells extracted from adipose tissue	Immunosuppressants
Irinotecan (hydrochloride trihydrate)	Antineoplastic medicines
Ixazomib (citrate)	Antineoplastic medicines
Mercaptamine (hydrochloride)	Ophthalmologicals
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
Tivozanib (hydrochloride monohydrate)	Antineoplastic medicines
Trientine (tetrahydrochloride)	Other alimentary tract and metabolism products
Venetoclax	Antineoplastic medicines
Vosaroxin	Antineoplastic medicines