



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 2015

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 December 2015**.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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 <sup>1</sup>
Alectinib (hydrochloride)	Antineoplastic medicines
Anamorelin (hydrochloride)	Other therapeutic medicines
Azd9291 (mesylate)	Antineoplastic medicines
<b>Bezlotoxumab</b>	<b>Antidiarrheals, intestinal antiinflammatory/antiinfective medicines</b>
<b>Brodalumab</b>	<b>Immunosuppressants</b>
Ceftazidime / avibactam	Antibacterials for systemic use
Daclizumab	Immunosuppressants
Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)	Vaccines
Eluxadoline	Antidiarrheals, intestinal antiinflammatory/antiinfective medicines
Empagliflozin / linagliptin	Medicines used in diabetes
Emtricitabine / rilpivirine (hydrochloride) / tenofovir alafenamide (fumarate)	Antivirals for systemic use
Emtricitabine / tenofovir alafenamide	Antivirals for systemic use
Etelcalcetide (hydrochloride)	Calcium homeostasis
Ferric maltol	Antianemic medicines
Follitropin delta	Sex hormones and modulators of the genital system
Glycopyrronium bromide	Medicines for functional gastrointestinal disorders
Grazoprevir / elbasvir	Antivirals for systemic use
Ixekizumab	Immunosuppressants
Lesinurad	Antigout medicines
Lutetium (177 Lu) chloride	Therapeutic radiopharmaceuticals
Necitumumab	Antineoplastic medicines
Octocog alfa	Antihemorrhagics
Opicapone	Anti-parkinson medicines
Palbociclib	Antineoplastic medicines
Pancreas powder	Digestives, incl. enzymes

<sup>1</sup> Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>1</sup>
Pandemic influenza vaccine H5N1 (live attenuated, nasal)	Vaccines
Reslizumab	Immunosuppressants
Rociletinib (hydrobromide)	Antineoplastic medicines
Saxagliptin / dapagliflozin (propanediol monohydrate)	Medicines used in diabetes
<b>Sofosbuvir / velpatasvir</b>	<b>Antivirals for systemic use</b>
Spheroids of human autologous matrix-associated chondrocytes	Other medicines for disorders of the musculo-skeletal system
Trifluridine / tipiracil (hydrochloride)	Antineoplastic medicines

## Non-orphan generic and biosimilar medicinal products

International non-proprietary name / Common Name	Therapeutic area <sup>2</sup>	Total number of applications
Alendronic acid / colecalciferol	Medicines for bone diseases	1
Amlodipine / valsartan	Medicines acting on the renin-angiotensin system	1
Aripiprazole	Psycholeptics	1
Atazanavir	Antivirals for systemic use	1
Bortezomib	Antineoplastic medicines	2
Caspofungin	Antimycotics for systemic use	1
Darunavir	Antivirals for systemic use	1
Docetaxel	Antineoplastic medicines	1
Emtricitabine / tenofovir disoproxil	Antivirals for systemic use	2
Enoxaparin sodium	Antithrombotic medicines	2
Ertapenem	Antibacterials for systemic use	1
<b>Etanercept</b>	<b>Immunosuppressants</b>	<b>1</b>
Fluticasone / salmeterol	Medicines for obstructive airway diseases	2
Infliximab	Immunosuppressants	1
<b>Ivabradine</b>	<b>Cardiac therapy</b>	<b>1</b>
Methotrexate	Antineoplastic medicines	2

<sup>2</sup> Based on the ATC therapeutic sub-group.

International non-proprietary name / Common Name	Therapeutic area <sup>2</sup>	Total number of applications
Miglustat	Other alimentary tract and metabolism products	1
Palonosetron	Antiemetics and antinauseants	2
<b>Pegfilgrastim</b>	<b>Immunostimulants</b>	<b>2</b>
Pemetrexed	Antineoplastic medicines	1
Rasagiline	Anti-parkinson medicines	1
Rituximab	Antineoplastic medicines	1
Tenofovir disoproxil	Antivirals for systemic use	2
Zonisamide	Antiepileptics	1

## Orphan medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>3</sup>
Aceneuramic acid	Other medicines for disorders of the musculo-skeletal system
Albutrepenonacog alfa	Antihemorrhagics
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
Daratumumab	Antineoplastic medicines
Dexamethasone (acetate)	Corticosteroids for systemic use
Dinutuximab beta	Antineoplastic medicines
Drisapersen (sodium)	Other medicines for disorders of the musculo-skeletal system
Edotreotide	Diagnostic radiopharmaceuticals

<sup>3</sup> Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>3</sup>
Eftrenonacog alfa	Other alimentary tract and metabolism products
Elotuzumab	Antineoplastic medicines
Eryaspase	Antineoplastic medicines
Factor X	Antihemorrhagics
Irinotecan (hydrochloride trihydrate)	Antineoplastic medicines
Ixazomib (citrate)	Antineoplastic medicines
Mercaptamine (hydrochloride)	Ophthalmologicals
Migalastat (hydrochloride)	Other alimentary tract and metabolism products
Obeticholic acid	Bile and liver therapy
Parathyroid hormone	Calcium homeostasis
Selexipag	Antithrombotic medicines
Sirolimus	Ophthalmologicals
<b>Venetoclax</b>	<b>Antineoplastic medicines</b>