



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 October 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 **2 October 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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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>
<b>Alectinib (hydrochloride)</b>	<b>Antineoplastic medicines</b>
Azd9291 (mesylate)	Antineoplastic medicines
Betulae cortex dry extract (5-10 : 1); extraction solvent: n-heptane 95% (w/w)	Medicines for wounds and ulcers
Brivaracetam	Antiepileptics
Ceftazidime / avibactam	Antibacterials for systemic use
Daclizumab	Immunosuppressants
Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)	Vaccines
Eluxadolone	Antidiarrheals, intestinal antiinflammatory/antiinfective medicines
Emtricitabine / rilpivirine (hydrochloride) / tenofovir alafenamide (fumarate)	Antivirals for systemic use
Emtricitabine / tenofovir alafenamide	Antivirals for systemic use
<b>Etelcalcetide (hydrochloride)</b>	<b>Calcium homeostasis</b>
Ferric maltol	Antianemic medicines
Glycopyrronium bromide	Medicines for functional gastrointestinal disorders
Grazoprevir / elbasvir	Antivirals for systemic use
Human fibrinogen / human thrombin	Antihemorrhagics
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
Pandemic influenza vaccine H5N1 (live attenuated, nasal)	Vaccines
Pegaspargase	Antineoplastic medicines

<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>
Reslizumab	Immunosuppressants
Rociletinib (hydrobromide)	Antineoplastic medicines
Saxagliptin / dapagliflozin (propanediol monohydrate)	Medicines used in diabetes
Spheroids of human autologous matrix-associated chondrocytes	Other medicines for disorders of the musculo-skeletal system
Talimogene laherparepvec	Antineoplastic medicines
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
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	1
Enoxaparin sodium	Antithrombotic medicines	2
Eptifibatide	Antithrombotic medicines	1
Etanercept	Immunosuppressants	1
Fluticasone / salmeterol	Medicines for obstructive airway diseases	2
Infliximab	Immunosuppressants	1
Insulin human	Medicines used in diabetes	1
Lopinavir / ritonavir	Antivirals for systemic use	1
Methotrexate	Antineoplastic medicines	2
Miglustat	Other alimentary tract and metabolism products	1

<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
Palonosetron	Antiemetics and antinauseants	2
Pemetrexed	Antineoplastic medicines	3
Rasagiline	Anti-parkinson medicines	1
Tenofovir disoproxil	Antivirals for systemic use	2
Zonisamide	Antiepileptics	1

## Orphan medicinal products<sup>3</sup>

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>4</sup>
<b>Aceneuramic acid</b>	<b>Other medicines for disorders of the musculo-skeletal system</b>
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
Cediranib (maleate)	Antineoplastic medicines
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
Eftrenonacog alfa	Other alimentary tract and metabolism products
Elotuzumab	Antineoplastic medicines
<b>Eryaspase</b>	<b>Antineoplastic medicines</b>
Factor X	Antihemorrhagics

<sup>3</sup> In line with the Principles for publication of agendas and minutes of EMA scientific committees (EMA/555647/2013), and further to the information in the CHMP Minutes of March 2014 that the invented names of orphan products would no longer be disclosed in the Agendas and Minutes of the CHMP, this document includes (from September 2014 onwards) only the international non-proprietary names (INN) and therapeutic areas for designated orphan medicines under evaluation.

<sup>4</sup> Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>4</sup>
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
Pitolisant (hydrochloride)	Psychoanaleptics
Recombinant L-asparaginase	Antineoplastic medicines
Selexipag	Antithrombotic medicines
Sirolimus	Ophthalmologicals