



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Procedure Management and Business Support Division

## Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use February 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 February 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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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>
Alirocumab	Lipid modifying medicines
Atazanavir (sulfate) / cobicistat	Antivirals for systemic use
Betulae cortex dry extract (5-10 : 1); extraction solvent: n-heptane 95% (w/w)	Medicines for wounds and ulcers
Brivaracetam	Antiepileptics
Ceftolozane (sulfate) / tazobactam (sodium)	Antibacterials for systemic use
Ceritinib	Antineoplastic medicines
Cobimetinib (hemifumarate)	Antineoplastic medicines
<b>Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)</b>	<b>Vaccines</b>
Edoxaban (tosylate)	Antithrombotic medicines
Elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide	Antivirals for systemic use
Empagliflozin / metformin (hydrochloride)	Medicines used in diabetes
Evolocumab	Lipid modifying medicines
Fentanyl (hydrochloride)	Analgesics
Ferric citrate coordination complex	Other therapeutic medicines
Ferric maltol	Antianemic medicines
Guanfacine (hydrochloride)	Antihypertensives
Human alpha1-proteinase inhibitor	Antihemorrhagics
Human fibrinogen / human thrombin	Antihemorrhagics
Human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed)	Vaccines
<b>Lesinurad</b>	<b>Antigout medicines</b>
Levodopa /carbidopa (monohydrate)	Anti-parkinson medicines
Lutetium (177 Lu) (chloride)	Diagnostic radiopharmaceuticals
Mepolizumab	Immunosuppressants
Necitumumab	Antineoplastic medicines
Netupitant / palonosetron (hydrochloride)	Antiemetics and anti-nauseants

<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>
Nivolumab	Antineoplastic medicines
Octocog alfa	Antihemorrhagics
Opicapone	Anti-parkinson medicines
Pegaspargase	Antineoplastic medicines
Pegfilgrastim	Immunostimulants
Pembrolizumab	Antineoplastic medicines
Phenylephrine (hydrochloride) / ketorolac (trometamol)	Ophthalmologicals
<b>Sacubitril / valsartan</b>	<b>Cardiovascular system</b>
Sonidegib (phosphate)	Antineoplastic medicines
Spheroids of human autologous matrix-associated chondrocytes	Other medicines for disorders of the musculo-skeletal system
Talimogene laherparepvec	Antineoplastic medicines

## Non-orphan generic and biosimilar medicinal products

International non-proprietary name / Common Name	Therapeutic area <sup>2</sup>	Total number of applications
Aripiprazole	Psycholeptics	5
<b>Atazanavir</b>	<b>Antivirals for systemic use</b>	<b>1</b>
Bortezomib	Antineoplastic medicines	1
<b>Cinacalcet</b>	<b>Calcium homeostasis</b>	<b>1</b>
Docetaxel	Antineoplastic medicines	1
Duloxetine	Psychoanaleptics	3
Eptifibatid	Antithrombotic medicines	1
Etanercept	Immunosuppressants	1
Insulin human	Medicines used in diabetes	1
<b>Lopinavir / ritonavir</b>	<b>Antivirals for systemic use</b>	<b>1</b>

<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
Pemetrexed	Antineoplastic medicines	6
Pregabalin	Antiepileptics	6
Sufentanil	Anesthetics	1
Voriconazole	Antimycotics for systemic use	1

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

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>4</sup>
Allogeneic human heterologous liver cells	Other alimentary tract and metabolism products
Allogeneic T cells genetically modified to express suicide gene	Antineoplastic medicines
Asfotase alfa	Other alimentary tract and metabolism products
Blinatumomab	Antineoplastic medicines
Dasiprotimut-T	Immunostimulants
Dexamethasone (acetate)	Corticosteroids for systemic use
Dinutuximab	Antineoplastic medicines
Efmoroctocog alfa	Antihemorrhagics
Glycerol phenylbutyrate	Other alimentary tract and metabolism products
Idebenone	Other nervous system medicines
Isavuconazole (isavuconazonium sulfate)	Antimycotics for systemic use
Ketoconazole	Other therapeutic medicines
Lenvatinib (mesylate)	Antineoplastic medicines
Lumacaftor / ivacaftor	Other respiratory system medicines
Mercaptamine (hydrochloride)	Ophthalmologicals
Mifepristone	Systemic hormonal preparations, excl. sex hormones and insulins
Panobinostat (lactate anhydrous)	Antineoplastic medicines

<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>
Parathyroid hormone	Calcium homeostasis
Pitolisant (hydrochloride)	Psychoanaleptics
Recombinant L-asparaginase	Antineoplastic medicines
Sebelipase alfa	Other alimentary tract and metabolism products
Selexipag	Antithrombotic medicines
Susoctocog alfa	Antihemorrhagics
Tasimelteon	Psycholeptics
Tolvaptan	Urologicals