



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 October 2014

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 **3 October 2014**.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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>
Apremilast	Immunosuppressants
Atazanavir (sulfate) / cobicistat	Antivirals for systemic use
Bazedoxifene (acetate) / estrogens conjugated	Sex hormones and modulators of the genital system
Cangrelor	Antithrombotic medicines
Ceftolozane (sulfate) / tazobactam (sodium)	Antibacterials for systemic use
Ceritinib	Antineoplastic medicines
Ciclosporin	Ophthalmologicals
<b>Cobimetinib (hemifumarate)</b>	<b>Antineoplastic medicines</b>
Dalbavancin (hydrochloride)	Antibacterials for systemic use
Dasabuvir (sodium)	Antivirals for systemic use
Duloxetine (hydrochloride)	Psychoanaleptics
Edoxaban (tosylate)	Antithrombotic medicines
Empagliflozin / metformin (hydrochloride)	Medicines used in diabetes
<b>Evolocumab</b>	<b>Lipid modifying medicines</b>
<b>Fentanyl (hydrochloride)</b>	<b>Analgesics</b>
Ferric citrate coordination complex	Other therapeutic 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
Lamivudine (hydrate) / raltegravir (potassium)	Antivirals for systemic use
Liraglutide	Medicines used in diabetes
Lutetium (177 Lu) (chloride)	Diagnostic radiopharmaceuticals
Naltrexone (hydrochloride) / bupropion (hydrochloride)	Antiobesity medicines

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

<b>International non-proprietary name (salt, ester, derivative, etc.) / Common Name</b>	<b>Therapeutic area<sup>1</sup></b>
Netupitant / palonosetron (hydrochloride)	Antiemetics and antinauseants
<b>Nivolumab</b>	<b>Antineoplastic medicines</b>
Nonacog gamma	Antihemorrhagics
Ombitasvir / paritaprevir / ritonavir	Antivirals for systemic use
Oritavancin (diphosphate)	Antibacterials for systemic use
Ospemifene	Sex hormones and modulators of the genital system
Paliperidone (palmitate)	Psycholeptics
Pegaspargase	Antineoplastic medicines
<b>Pegfilgrastim</b>	<b>Immunostimulants</b>
Pembrolizumab	Antineoplastic medicines
Phenylephrine (hydrochloride) / ketorolac (trometamol)	Ophthalmologicals
<b>Rasagiline</b>	<b>Anti-parkinson medicines</b>
Safinamide (methanesulfonate)	Anti-parkinson medicines
Secukinumab	Immunosuppressants
Sevelamer (carbonate)	Other therapeutic medicines
Sevelamer (hydrochloride)	Other therapeutic medicines
Sonidegib (phosphate)	Antineoplastic medicines
Spheroids of human autologous matrix-associated chondrocytes	Other medicines for disorders of the musculo-skeletal system
<b>Talimogene laherparepvec</b>	<b>Antineoplastic medicines</b>
Tedizolid (phosphate)	Antibacterials for systemic use
Vorapaxar	Antithrombotic 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
Bortezomib	Antineoplastic medicines	1
Clopidogrel	Antithrombotic medicines	1
Docetaxel	Antineoplastic medicines	1
<b>Duloxetine</b>	<b>Psychoanaleptics</b>	<b>3</b>
Insulin human	Medicines used in diabetes	1
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>
Afamelanotide	Emollients and protectives
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
Dasiprotimut-T	Immunostimulants
Dinutuximab	Antineoplastic medicines
Eliglustat	Other alimentary tract and metabolism products

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

<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>
Ex vivo autologous corneal epithelial cells including stem cells	Ophthalmologicals
Glycerol phenylbutyrate	Other alimentary tract and metabolism products
Idebenone	Other nervous system medicines
Isavuconazole (isavuconazonium sulfate)	Antimycotics for systemic use
Ketoconazole	Other therapeutic medicines
<b>Lenvatinib (mesylate)</b>	<b>Antineoplastic medicines</b>
Levofloxacin	Antibacterials for systemic use
<b>Mercaptamine (hydrochloride)</b>	<b>Ophthalmologicals</b>
Mifepristone	Systemic hormonal preparations, excl. sex hormones and insulins
Nintedanib	Antineoplastic medicines
Olaparib	Antineoplastic medicines
Panobinostat (lactate anhydrous)	Antineoplastic medicines
Pitolisant (hydrochloride)	Psychoanaleptics
Recombinant L-asparaginase	Antineoplastic medicines
Susoctocog alfa	Antihemorrhagics
Tasimelteon	Psycholeptics
Tolvaptan	Urologicals