



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

8 September 2014  
EMA/545907/2014  
Procedure Management and Business Support Division

## Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use September 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 **5 September 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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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>
Aclidinium (bromide) / formoterol fumarate (dihydrate)	Medicines for obstructive airway diseases
Apremilast	Immunosuppressants
Atazanavir (sulfate) / cobicistat	Antivirals for systemic use
Balugrastim	Immunostimulants
Bazedoxifene (acetate) / estrogens conjugated	Sex hormones and modulators of the genital system
Cangrelor	Antithrombotic medicines
<b>Ceftolozane (sulfate) / tazobactam (sodium)</b>	<b>Antibacterials for systemic use</b>
Ceritinib	Antineoplastic medicines
Ciclosporin	Ophthalmologicals
Dalbavancin (hydrochloride)	Antibacterials for systemic use
Darunavir (ethanolate) / cobicistat	Antivirals for systemic use
Dasabuvir (sodium)	Antivirals for systemic use
Dulaglutide	Medicines used in diabetes
Duloxetine (hydrochloride)	Psychoanaleptics
Edoxaban (tosylate)	Antithrombotic medicines
Empagliflozin / metformin (hydrochloride)	Medicines used in diabetes
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
Naloxegol (oxalate)	Medicines for constipation
Naltrexone (hydrochloride) / bupropion (hydrochloride)	Antiobesity 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>
Nintedanib	Antineoplastic medicines
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
<b>Paliperidone (palmitate)</b>	<b>Psycholeptics</b>
Pegaspargase	Antineoplastic medicines
Pembrolizumab	Antineoplastic medicines
Phenylephrine (hydrochloride) / ketorolac (trometamol)	Ophthalmologicals
Safinamide (methanesulfonate)	Anti-parkinson medicines
Secukinumab	Immunosuppressants
Sevelamer (carbonate)	Other therapeutic medicines
Sevelamer (hydrochloride)	Other therapeutic medicines
Sofosbuvir / ledipasvir	Antivirals for systemic use
Sonidegib (phosphate)	Antineoplastic medicines
Spheroids of human autologous matrix-associated chondrocytes	Other medicines for disorders of the musculo-skeletal system
Tedizolid (phosphate)	Antibacterials for systemic use
Tilmanocept	Diagnostic radiopharmaceuticals
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
Budesonide / formoterol	Medicines for obstructive airway diseases	3
Clopidogrel	Antithrombotic medicines	1
Docetaxel	Antineoplastic medicines	1
Insulin human	Medicines used in diabetes	1
<b>Pregabalin</b>	<b>Antiepileptics</b>	<b>6</b>
Sufentanil	Anesthetics	1
Tadalafil	Urologicals	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.

<b>International non-proprietary name (salt, ester, derivative, etc.) / Common Name</b>	<b>Therapeutic area<sup>4</sup></b>
Ex vivo autologous corneal epithelial cells including stem cells	Ophthalmologicals
Glycerol phenylbutyrate	Other alimentary tract and metabolism products
Idebenone	Other nervous system medicines
<b>Isavuconazole (isavuconazonium sulfate)</b>	<b>Antimycotics for systemic use</b>
Ketoconazole	Antimycotics for systemic use
Ketoconazole	Other therapeutic medicines
Levofloxacin	Antibacterials for systemic use
Mifepristone	Systemic hormonal preparations, excl. sex hormones and insulins
Nintedanib	Antineoplastic medicines
Olaparib	Antineoplastic medicines
Panobinostat (lactate anhydrous)	Antineoplastic medicines
Pitolisant (hydrochloride)	Psychoanaleptics
Ramucirumab	Antineoplastic medicines
Recombinant L-asparaginase	Antineoplastic medicines
Susoctocog alfa	Antihemorrhagics
Tasimelteon	Psycholeptics
Tolvaptan	Urologicals