



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Product Data Management

## Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use January 2013

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 **7 January 2013**.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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>
Afatinib (dimaleate)	Antineoplastic medicines
Alemtuzumab	Immunosuppressants
Alogliptin	Medicines used in diabetes
Alogliptin / metformin	Medicines used in diabetes
Alogliptin / pioglitazone	Medicines used in diabetes
Autologous cultured chondrocytes	Other medicines for disorders of the musculo-skeletal system
Autologous oral mucosal epithelial cells	Ophthalmologicals
Autologous peripheral blood mononuclear cells activated with PAP-GM-CSF	Immunostimulants
Avanafil	Urologicals
Bazedoxifene / estrogens conjugated	Sex hormones and modulators of the genital system
Bosentan (monohydrate)	Antihypertensives
Budesonide / salmeterol	Medicines for obstructive airway diseases
Canagliflozin	Medicines used in diabetes
Cobicistat	Antivirals for systemic use
Cultured autologous chondrocytes on hyaluronan based scaffold	Other medicines for disorders of the musculo-skeletal system
Dabrafenib	Antineoplastic medicines
<b>Dapagliflozin / metformin</b>	<b>Medicines used in diabetes</b>
Dextromethorphan (hydrobromide) / quinidine (sulphate)	Other nervous system medicines
Dimethyl fumarate	Other nervous system medicines
Diphtheria (d), tetanus (t), pertussis (acellular, component) (pa), hepatitis b (rdna) (hbv), poliomyelitis (inactivated) (ipv) and haemophilus influenzae type b (hib) conjugate vaccine (adsorbed)	Vaccines
Elvitegravir	Antivirals for systemic use
Elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil	Antivirals for systemic use
Enzalutamide	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>
Fenofibrate / simvastatin	Lipid modifying medicines
<b>Flutemetamol (18F)</b>	<b>Diagnostic radiopharmaceuticals</b>
Fluticasone (furoate) / vilanterol (trifenatate)	Medicines for obstructive airway diseases
Hepatitis b surface antigen	Vaccines
Human coagulation factor VIII / human von Willebrand factor	Antihemorrhagics
Human fibrinogen / human thrombin	Antihemorrhagics
Hyaluronidase (human recombinant) / human normal immunoglobulin	Immune sera and immunoglobulins
Imatinib (mesilate)	Antineoplastic medicines
Indacaterol (maleate) / glycopyrronium (bromide)	Medicines for obstructive airway diseases
Influenza vaccine (tetravalent live attenuated, nasal)	Vaccines
Laquinimod (sodium)	Other nervous system medicines
Lidocaine / prilocaine	Anesthetics
Lipegfilgrastim	Immunostimulants
Lomitapide	Lipid modifying medicines
Lorcaserin (hydrochloride)	Antiobesity medicines
Lurasidone	Psycholeptics
Mipomersen	Lipid modifying medicines
Modified vaccinia ankara virus	Vaccines
Nalmefene	Other nervous system medicines
Ocriplasmin	Ophthalmologicals
Peginesatide	Antianemic medicines
Perflubutane	Contrast media
Regorafenib	Antineoplastic medicines
Somatropin	Pituitary and hypothalamic hormones and analogues
<b>Spheroids of human autologous matrix-associated chondrocytes</b>	<b>Other medicines for disorders of the musculo-skeletal system</b>
Strontium ranelate / colecalciferol	Medicines for bone diseases
Teriflunomide	Immunosuppressants
Tofacitinib (citrate)	Immunosuppressants
Trastuzumab emtansine	Antineoplastic medicines

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>1</sup>
Trenonacog alfa	Antihemorrhagics
Turoctocog alfa	Antihemorrhagics
Vismodegib	Antineoplastic medicines
Vortioxetine	Psychoanaleptics

## Non-orphan generic and biosimilar medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>2</sup>	Total number of applications
Atosiban	Other gynecologicals	1
Capecitabine	Antineoplastic medicines	1
Esomeprazole	Medicines for acid related disorders	1
Filgrastim	Immunostimulants	1
Follitropin alfa	Sex hormones and modulators of the genital system	2
Imatinib	Antineoplastic medicines	3
Infliximab	Immunosuppressants	2
<b>Levetiracetam</b>	<b>Antiepileptics</b>	<b>1</b>
Memantine	Psychoanaleptics	6
Telmisartan	Medicines acting on the renin-angiotensin system	1
Telmisartan / hydrochlorothiazide	Medicines acting on the renin-angiotensin system	1
Voriconazole	Antimycotics for systemic use	1
Zoledronic acid	Medicines for bone diseases	1

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

## Orphan medicinal products

International non-proprietary name / Common Name	Product name	Marketing Authorisation Applicant	Therapeutic area <sup>3</sup>
Afamelanotide	Scenesse	Clinuvel (UK) Limited	Emollients and protectives
Ataluren	Translarna	PTC Therapeutics Limited	Other medicines for disorders of the musculo-skeletal system
Bedaquiline	Bedaquiline	Janssen-Cilag International N.V.	Antimycobacterials
Bosutinib	Bosulif	Pfizer Limited	Antineoplastic medicines
Cabozantinib	Cometriq	TMC Pharma Services Ltd	Antineoplastic medicines
Cholic acid	Cholic acid fgk	FGK Representative Service GmbH	Bile and liver therapy
Cysteamine (bitartrate)	Cysteamine bitartrate	Raptor Pharmaceuticals Europe BV	Other alimentary tract and metabolism products
Defibrotide	Defitelio	Gentium S.p.A.	Antithrombotic medicines
Delamanid	Delamanid	Otsuka Novel Products GmbH	Antimycobacterials
Etarfolatide	Folcepri	Endocyte Europe, B.V.	Diagnostic radiopharmaceuticals
Folic acid	Neocepri	Endocyte Europe, B.V.	Diagnostic medicines
Idebenone	Raxone	Santhera Pharmaceuticals (Deutschland) GmbH	Psychoanaleptics
Macitentan	Opsumit	Actelion Registration Ltd.	Antihypertensives
Masitinib (mesylate)	Kinaction	AB Science	Antineoplastic medicines
Masitinib (mesylate)	Masican	AB Science	Antineoplastic medicines
Mercaptopurine	Loulla	Only for children pharmaceuticals	Antineoplastic medicines
Nalfurafine (hydrochloride)	Winfuran	Toray Europe Limited	Other therapeutic medicines
Para-aminosalicylic acid	Pas-gr	Lucane Pharma SAS	Antimycobacterials
Pomalidomide	Pomalidomide celgene	CELGENE EUROPE LIMITED	Immunosuppressants
Ponatinib	Lclusig	ARIAD Pharma Ltd	Antineoplastic medicines
Ridaforolimus	Jenzyl	Merck Sharp & Dohme Limited	Antineoplastic medicines
Sodium 4-phenylbutyrate	Pheburane	Lucane Pharma	Other alimentary tract and metabolism products

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

<b>International non-proprietary name / Common Name</b>	<b>Product name</b>	<b>Marketing Authorisation Applicant</b>	<b>Therapeutic area<sup>3</sup></b>
Tobramycin	Vantobra	PARI Pharma GmbH	Antibacterials for systemic use
Vintafolide	Vynfinit	Endocyte Europe, B.V.	Antineoplastic medicines