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Product Data Management

## Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use December 2012

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 **22 November 2012**.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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 / conjugated estrogens	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
Dextromethorphan (hydrobromide)/quinidine (sulfate)	Other nervous system medicines
Dimethyl fumarate	Other nervous system medicines
Diphtheria, tetanus, pertussis (acellular, component), hepatitis b (rdna), poliomyelitis (inactivated) and haemophilus influenzae type b conjugate vaccine (adsorbed)	Vaccines
Elvitegravir	Antivirals for systemic use
Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil	Antivirals for systemic use
Enzalutamide	Antineoplastic medicines
Fenofibrate/simvastatin	Lipid modifying 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>
Fibrinogen human/ thrombin human	Antihemorrhagics
Fluticasone (furoate) / vilanterol (trifénatate)	Medicines for obstructive airway diseases
Hepatitis b, surface antigen	Vaccines
Human coagulation factor VIII / von Willebrand factor	Antihemorrhagics
Human normal immunoglobulin/recombinant human hyaluronidase	Immune sera and immunoglobulins
Iloperidone	Psycholeptics
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
Loxapine	Psycholeptics
Lurasidone	Psycholeptics
Mipomersen	Lipid modifying medicines
Modified vaccinia ankara virus	Vaccines
Nalmefene	Other nervous system medicines
Ocriplasmin	Ophthalmologicals
Peginesatide	Antianemic medicines
Perflubutane	Contrast media
Pertuzumab	Antineoplastic medicines
Regorafenib	Antineoplastic medicines
Somatropin	Pituitary and hypothalamic hormones and analogues
Strontium ranelate / cholecalciferol	Medicines for bone diseases
Teriflunomide	Immunosuppressants
Tofacitinib (citrate)	Immunosuppressants

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>1</sup>
Trastuzumab emtansine	Antineoplastic medicines
Trenonacog alfa	Antihemorrhagics
<b>Turoctocog alfa</b>	<b>Antihemorrhagics</b>
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	1
Imatinib	Antineoplastic medicines	3
Infliximab	Immunosuppressants	2
Insulin human	Medicines used in diabetes	3
Memantine	Psychoanaleptics	7
<b>Rhfsh, follitropin alfa</b>	<b>Sex hormones and modulators of the genital system</b>	<b>1</b>
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
<b>Ataluren</b>	<b>Translarna</b>	<b>PTC Therapeutics Ltd</b>	<b>Other medicines for disorders of the musculo-skeletal system</b>
Bedaquiline	Bedaquiline	Janssen-Cilag International N V	Antimycobacterials
Bosutinib	Bosulif	Pfizer Ltd.	Antineoplastic medicines
<b>Cabozantinib</b>	<b>Cometriq</b>	<b>TMC Pharma Services Ltd.</b>	<b>Antineoplastic medicines</b>
Cholic acid	Cholic acid fgk	FGK Representative Service GmbH	Bile and liver therapy
Cysteamine bitartrate	Cysteamine bitartrate	Raptor Pharmaceuticals Europe B.V.	Other alimentary tract and metabolism products
Defibrotide	Defitelio	Gentium SpA	Antithrombotic medicines
Delamanid	Delamanid	Otsuka Novel Products GmbH	Antimycobacterials
<b>Etarfolatide</b>	<b>Folcepri</b>	<b>Endocyte Europe, B.V.</b>	<b>Diagnostic radiopharmaceuticals</b>
<b>Folic acid</b>	<b>Neocepri</b>	<b>Endocyte Europe, B.V.</b>	<b>Diagnostic medicines</b>
Idebenone	Raxone	Santhera Pharmaceuticals (Deutschland) GmbH	Psychoanaleptics
<b>Macitentan</b>	<b>Opsumit</b>	<b>Actelion Registration Ltd.</b>	<b>Antihypertensives</b>
Masitinib (mesylate)	Kinaction	AB Science S.A.	Antineoplastic medicines
Masitinib (mesylate)	Masican	AB Science S.A.	Antineoplastic medicines
Mercaptopurine	Loulla	Only For Children Pharmaceuticals	Antineoplastic medicines
Nalfurafine (hydrochloride)	Winfuran	Toray International U.K. Limited	Other therapeutic medicines
Para-aminosalicylic acid	Pas-gr	Lucane Pharma SA	Antimycobacterials
Pomalidomide	Pomalidomide celgene	Celgene Europe Ltd.	Immunosuppressants
Ponatinib	Lclusig	ARIAD Pharma Ltd.,	Antineoplastic medicines

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

International non-proprietary name / Common Name	Product name	Marketing authorisation applicant	Therapeutic area <sup>3</sup>
Ridaforolimus	Jenzyl	Merck Sharp & Dohme Ltd.	Antineoplastic medicines
Sodium 4-phenylbutyrate	Pheburane	LUCANE PHARMA	Other alimentary tract and metabolism products
Tobramycin	Vantobra	PARI Pharma GmbH	Antibacterials for systemic use
<b>Vintafolide</b>	<b>Vynfinit</b>	<b>Endocyte Europe, B.V.</b>	<b>Antineoplastic medicines</b>