



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 May 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 **2<sup>nd</sup> May 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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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>
Acclidinium (bromide)	Medicines for obstructive airway diseases
Aflibercept	Antineoplastic medicines Ophthalmologicals
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
<b>Avanafil</b>	<b>Urologicals</b>
Budesonide/salmeterol	Medicines for obstructive airway diseases
Ceftaroline fosamil	Antibacterials for systemic use
Colestilan	Other therapeutic medicines
Copper (64 Cu) (chloride)	Various (radiolabelling)
Crizotinib	Antineoplastic medicines
<b>Cultured autologous chondrocytes on hyaluronan based scaffold</b>	<b>Other medicines for disorders of the musculo-skeletal system</b>
Dextromethorphan (hydrobromide)/quinidine (sulfate)	Other nervous system medicines
<b>Dimethyl fumarate</b>	<b>Other nervous system medicines</b>
Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil	Antivirals for systemic use
Fenofibrate/simvastatin	Lipid modifying medicines
<b>Fibrinogen human/thrombin human</b>	<b>Antihemorrhagics</b>
Florbetapir (18F)	Diagnostic radiopharmaceuticals
Glycopyrronium (bromide)	Medicines for obstructive airway diseases
Human coagulation factor VIII / von Willebrand factor	Antihemorrhagics
Human normal immunoglobulin/recombinant human hyaluronidase	Immune sera and immunoglobulins

<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>
Iloperidone	Psycholeptics
<b>Imatinib (mesilate)</b>	<b>Antineoplastic medicines</b>
Ingenol (mebutate)	Immunostimulants
Insulin degludec	Medicines used in diabetes
Insulin degludec/insulin aspart	Medicines used in diabetes
Linaclotide	Medicines for functional gastrointestinal disorders
Linagliptin/metformin (hydrochloride)	Medicines used in diabetes
Lipegfilgrastim	Immunostimulants
Lixisenatide	Medicines used in diabetes
<b>Lomitapide</b>	<b>Lipid modifying medicines</b>
<b>Lorcaserin (hydrochloride)</b>	<b>Antiobesity medicines</b>
Loxapine	Psycholeptics
Memantine (hydrochloride)/donepezil (hydrochloride)	Psychoanaleptics
Meningococcal group B vaccine (rDNA, adsorbed)	Vaccines
Mipomersen	Lipid modifying medicines
Mirabegron	Urologicals
<b>Modified vaccinia Ankara virus</b>	<b>Vaccines</b>
Nalmefene	Other nervous system medicines
Nonacog gamma	Antihemorrhagics
Ocriplasmin	Ophthalmologicals
Peginesatide	Antianemic medicines
Pegloticase	Antigout medicines
Perampanel	Antiepileptics
Pertuzumab	Antineoplastic medicines
Phentermine/topiramate	Antiobesity medicines
<b>Secretin human</b>	<b>Diagnostic medicines</b>
Semuloparin (sodium)	Antithrombotic medicines

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>1</sup>
Somatropin	Pituitary and hypothalamic hormones and analogues
Teriflunomide	Immunosuppressants
Tesamorelin	Pituitary and hypothalamic hormones and analogues
Tofacitinib (citrate)	Immunosuppressants
Vismodegib	Antineoplastic medicines

## 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
Capecitabine	Antineoplastic medicines	1
Follitropin alfa	Sex hormones and modulators of the genital system	1
Ibandronic acid	Medicines for bone diseases	1
Imatinib	Antineoplastic medicines	2
Imiquimod	Antibiotics and chemotherapeutics for dermatological use	1
Infliximab	Immunosuppressants	1
Insulin human	Medicines used in diabetes	3
Megestrol	Endocrine therapy	1
Zoledronic acid	Medicines for bone diseases	3

## 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

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

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

\* Cholic Acid has been added.

International non-proprietary name / Common Name	Product name	Marketing authorisation applicant	Therapeutic area <sup>3</sup>
Axitinib	Inlyta	Pfizer Ltd.	Antineoplastic medicines
Bosutinib	Bosulif	Pfizer Ltd.	Antineoplastic medicines
Brentuximab vedotin	Adcetris	Takeda Global Research and Development Centre (Europe) Ltd.	Antineoplastic medicines
Bromelain enriched proteolytic enzyme preparation from <i>Ananas comosus</i>	NexoBrid	Teva Pharma GmbH	Medicines for wounds and ulcers
Cholic Acid*	Cholic Acid FGK	FGK Representative Service GmbH	Bile and liver therapy
<b>Cysteamine</b>	<b>Cysteamine bitartrate</b>	<b>Raptor Pharmaceuticals Europe B.V.</b>	<b>Other alimentary tract and metabolism products</b>
Decitabine	Dacogen	Janssen-Cilag International N.V.	Antineoplastic medicines
Defibrotide	Defitelio	Gentium SpA	Antithrombotic medicines
Delamanid	Delamanid	Otsuka Novel Medicines GmbH	Antimycobacterials
Idebenone	SAN idebenone	Santhera Pharmaceuticals (Deutschland) GmbH	Psychoanaleptics
Ivacaftor	Kalydeco	Vertex Pharmaceuticals (U.K.) Ltd.	Other respiratory system medicines
Mercaptopurine	Loulla	Only For Children Pharmaceuticals	Antineoplastic medicines
<b>Para-aminosalicylic acid</b>	<b>PAS-GR</b>	<b>Lucane Pharma SA</b>	<b>Antimycobacterials</b>
Ridaforolimus	Jenzyl	Merck Sharp & Dohme Ltd.	Antineoplastic medicines
Romidepsin	Istodax	Celgene Europe Ltd.	Antineoplastic medicines
<b>Sodium 4-phenylbutyrate</b>	<b>Pheburane</b>	<b>Lucane Pharma</b>	<b>Other alimentary tract and metabolism products</b>
Taliglucerase alfa	Elelyso	Pfizer Ltd.	Other alimentary tract and metabolism medicines
Teduglutide	Revestive	Nycomed Danmark APS.	Other alimentary tract and metabolism medicines