



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 March 2013
EMA/192989/2013
Product Data Management

Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use March 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 **13 March 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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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 ¹
Afatinib (dimaleate)	Antineoplastic medicines
Alemtuzumab	Immunosuppressants
Alogliptin (benzoate)	Medicines used in diabetes
Alogliptin (benzoate) / metformin (hydrochloride)	Medicines used in diabetes
Alogliptin (benzoate) / pioglitazone (hydrochloride)	Medicines used in diabetes
Aripiprazole (monohydrate)	Psycholeptics
Autologous cultured chondrocytes	Other medicines for disorders of the musculo-skeletal system
Autologous oral mucosal epithelial cells	Ophthalmologicals
Autologous peripheral blood mononuclear cells, including autologous cd54+ cells activated with pap-gm-csf	Immunostimulants
Avanafil	Urologicals
Bazedoxifene (acetate) / estrogens conjugated	Sex hormones and modulators of the genital system
Bosentan (monohydrate)	Antihypertensives
Brimonidine (tartrate)	Other dermatological medicines
Budesonide / salmeterol (xinafoate)	Medicines for obstructive airway diseases
Canagliflozin	Medicines used in diabetes
Cobicistat (on silicon dioxide)	Antivirals for systemic use
Cultured autologous chondrocytes on hyaluronan based scaffold	Other medicines for disorders of the musculo-skeletal system
Dabrafenib (mesilate)	Antineoplastic medicines
Dapagliflozin (propanediol monohydrate) /metformin (hydrochloride)	Medicines used in diabetes
Dextromethorphan (hydrobromide)/quinidine (sulfate)	Other nervous system medicines
Dimethyl fumarate	Other nervous system medicines
Dolutegravir	Antivirals for systemic use
Elvitegravir	Antivirals for systemic use

¹ Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ¹
Elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil	Antivirals for systemic use
Enzalutamide	Antineoplastic medicines
Fenofibrate / simvastatin	Diagnostic radiopharmaceuticals
Florbetaben (18F)	Diagnostic radiopharmaceuticals
Flutemetamol (18F)	Diagnostic radiopharmaceuticals
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
Indacaterol (maleate) / glycopyrronium bromide	Throat medicines
Influenza vaccine (tetraivalent 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
Mixture of polynuclear iron(III)-oxyhydroxide, sucrose and starches	Other therapeutic medicines
Modified vaccinia ankara virus	Vaccines
Nonacog gamma	Antihemorrhagics
Peginesatide	Antianemic medicines
Perflubutane	Contrast media
Radium-223 (chloride)	Therapeutic radiopharmaceuticals
Regorafenib	Antineoplastic medicines
Serelaxin	Cardiac therapy
Somatropin	Pituitary and hypothalamic hormones and analogues
Spheroids of human autologous matrix-associated chondrocytes	Other medicines for disorders of the musculo-skeletal system

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ¹
Strontium ranelate / colecalciferol	Medicines for bone diseases
Teriflunomide	Immunosuppressants
Tilmanocept	Diagnostic radiopharmaceuticals
Tofacitinib (citrate)	Immunosuppressants
Trametinib	Antineoplastic medicines
Trastuzumab emtansine	Antineoplastic medicines
Travoprost	Ophthalmologicals
Turoctocog alfa	Antihemorrhagics
Umeclidinium bromide / Vilanterol (trifenatate)	Medicines for obstructive airway diseases
Vismodegib	Antineoplastic medicines
Vortioxetine (hydrobromide)	Psychoanaleptics
Vortioxetine (dl-lactate)	Psychoanaleptics

Non-orphan generic and biosimilar medicinal products

International non-proprietary name / Common Name	Therapeutic area²	Total number of applications
Atosiban	Other gynecologicals	1
Capecitabine	Antineoplastic medicines	1
Esomeprazole	Medicines for acid related disorders	1
Filgrastim	Throat medicines	1
Follitropin alfa	Sex hormones and modulators of the genital system	2
Imatinib	Antineoplastic medicines	2
Infliximab	Immunosuppressants	2
Levetiracetam	Antiepileptics	1
Memantine	Psychoanaleptics	2
Voriconazole	Antimycotics for systemic use	1
Zoledronic acid	Medicines for bone diseases	1

² Based on the ATC therapeutic sub-group.

Orphan medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Product name	Marketing authorisation applicant	Therapeutic area ³
Afamelanotide	Scenesse	Clinuvel (UK) Limited	Emollients and protectives
Ataluren	Translarna	PTC Therapeutics Limited	Other medicines for disorders of the musculo-skeletal system
Bedaquiline (fumarate)	Bedaquiline	Janssen-Cilag International N.V.	Antimycobacterials
Cabozantinib ((S)-malate)	Cometriq	TMC Pharma Services Ltd	Antineoplastic medicines
Cholic acid	Cholic acid fgk	FGK Representative Service GmbH	Bile and liver therapy
Defibrotide	Defitelio	Gentium S.p.A.	Antithrombotic medicines
Delamanid	Delamanid	Otsuka Novel Products GmbH	Antimycobacterials
Dexamethasone (acetate)	Neofordex	LABORATOIRES CTRS - BOULOGNE BILLANCOURT	Corticosteroids for systemic use
Etarfolatide	Folcepri	Endocyte Europe, B.V.	Diagnostic radiopharmaceuticals
Folic acid	Neocepri	Endocyte Europe, B.V.	Diagnostic medicines
Macitentan	Opsumit	Actelion Registration Ltd.	Antihypertensives
Masitinib (mesylate)	Kinaction	AB Science	Antineoplastic medicines
Masitinib (mesylate)	Masican	AB Science	Antineoplastic medicines
Mercaptamine (bitartrate)	Cysteamine bitartrate	Raptor Pharmaceuticals Europe BV	Other alimentary tract and metabolism products
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 (hydrochloride)	Iclusig	ARIAD Pharma Ltd	Antineoplastic medicines
Riociguat	Adempas	Bayer Pharma AG	Cardiac therapy
Tobramycin	Vantobra	PARI Pharma GmbH	Antibacterials for systemic use
Vintafolide	Vynfinit	Endocyte Europe, B.V.	Antineoplastic medicines

³ Based on the ATC therapeutic sub-group.