



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 June 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 June 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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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 (dimalate)	Antineoplastic medicines
Albiglutide	Medicines used in diabetes
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 peripheral blood mononuclear cells, including autologous cd54+ cells activated with pap-gm-csf	Immunostimulants
Bazedoxifene (acetate) / estrogens conjugated	Sex hormones and modulators of the genital system
Brimonidine (tartrate)	Other dermatological medicines
Canagliflozin	Medicines used in diabetes
Canagliflozin / metformin (hydrochloride)	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
Dolutegravir	Antivirals for systemic use
Elvitegravir	Antivirals for systemic use
Empagliflozin	Medicines used in diabetes
Fenofibrate / simvastatine	Lipid modifying medicines
Florbetaben (18F)	Diagnostic radiopharmaceuticals
Flutemetamol (18F)	Diagnostic radiopharmaceuticals
Fluticasone furoate / vilanterol (trifenatate)	Medicines for obstructive airway diseases
Hepatitis b surface antigen	Vaccines

¹ Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area¹
Human fibrinogen / human thrombin	Antihemorrhagics
Indacaterol (maleate) / glycopyrronium bromide	Medicines for obstructive airway diseases
Influenza vaccine (tetravalent live attenuated, nasal)	Vaccines
Laquinimod (sodium)	Other nervous system medicines
Levodopa / carbidopa (monohydrate)/ entacapone	Anti-Parkinson medicines
Lidocaine / prilocaine	Anesthetics
Lurasidone	Psycholeptics
Mixture of polynuclear iron(III)-oxyhydroxide, sucrose and starches	Other therapeutic medicines
Nonacog gamma	Antihemorrhagics
Ospemifene	Sex hormones and modulators of the genital system
Peginesatide	Antianemic medicines
Perflubutane	Contrast media
Propranolol	Beta blocking medicines
Radium-223 (chloride)	Therapeutic radiopharmaceuticals
Regorafenib	Antineoplastic medicines
Serelaxin	Cardiac therapy
Simeprevir	Antivirals for systemic use
Sofosbuvir	Antivirals for systemic use
Spheroids of human autologous matrix-associated chondrocytes	Other medicines for disorders of the musculo-skeletal system
Strontium ranelate / colecalciferol	Medicines for bone diseases
Tilmanocept	Diagnostic radiopharmaceuticals
Trametinib	Antineoplastic medicines
Trastuzumab emtansine	Antineoplastic medicines
Travoprost	Ophthalmologicals
Turoctocog alfa	Antihemorrhagics
Umeclidinium bromide	Medicines for obstructive airway diseases
Umeclidinium bromide / Vilanterol (trifenatate)	Medicines for obstructive airway diseases
Vedolizumab	Immunosuppressants

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ¹
Vismodegib	Antineoplastic medicines
Vortioxetine (hydrobromide)	Psychoanaleptics
Vortioxetine (dl-lactate)	

Non-orphan generic and biosimilar medicinal products

International non-proprietary name / Common Name	Therapeutic area ²	Total number of applications
Budesonide / formoterol	Medicines for obstructive airway diseases	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	1
Infliximab	Immunosuppressants	2
Levetiracetam	Antiepileptics	1
Memantine	Psychoanaleptics	1
Oseltamivir	Antivirals for systemic use	1
Tacrolimus	Immunosuppressants	1
Zoledronic acid	Medicines for bone diseases	1

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

² Based on the ATC therapeutic sub-group.

³ Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Product name	Marketing authorisation applicant	Therapeutic area³
Bedaquiline (fumarate)	SIRTURO	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
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
Ex vivo autologous corneal epithelial cells including stem cells	Holoclar	Chiesi Farmaceutici S.p.A.	Ophthalmologicals
Folic acid	Neocepri	Endocyte Europe, B.V.	Diagnostic medicines
Macitentan	Opsumit	Actelion Registration Ltd.	Antihypertensives
Masitinib (mesylate)	Masican	AB Science	Antineoplastic medicines
Masitinib (mesylate)	KINACTION	AB Science	Antineoplastic medicines
Mercaptamine (bitartrate)	Procsybi	Raptor Pharmaceuticals Europe BV	Other alimentary tract and metabolism products
Nalfurafine (hydrochloride)	Winfuran	Toray Europe Limited	Other therapeutic medicines
Obinutuzumab	Gazyva	Roche Registration Ltd	Antineoplastic medicines
Para-aminosalicylic acid	PAS-GR	Lucane Pharma SAS	Antimycobacterials
Recombinant human n-acetylgalactosamine-6-sulfatase (rhGalns)	Vimizim	BioMarin Europe Ltd	Other alimentary tract and metabolism products
Riociguat	Adempas	Bayer Pharma AG	Cardiac therapy
Tobramycin	VANTOBRA	PARI Pharma GmbH	Antibacterials for systemic use
Vintafolide	Vynfinit	Endocyte Europe, B.V.	Antineoplastic medicines