



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 August 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 **29 July 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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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
Albiglutide	Medicines used in diabetes
Aripiprazole (monohydrate)	Psycholeptics
Bazedoxifene (acetate) / estrogens conjugated	Sex hormones and modulators of the genital system
Brimonidine (tartrate)	Other dermatological medicines
Brinzolamide / brimonidine (tartrate)	Ophthalmologicals
Canagliflozin	Medicines used in diabetes
Canagliflozin / metformin (hydrochloride)	Medicines used in diabetes
Dapagliflozin (propanediol monohydrate) /metformin (hydrochloride)	Medicines used in diabetes
Dolutegravir	Antivirals for systemic use
Elvitegravir	Antivirals for systemic use
Empagliflozin	Medicines used in diabetes
Florbetaben (18F)	Diagnostic radiopharmaceuticals
Flutemetamol (18F)	Diagnostic radiopharmaceuticals
Fluticasone furoate / vilanterol (trifenatate)	Medicines for obstructive airway diseases
Hepatitis b surface antigen	Vaccines
Influenza vaccine (tetraivalent live attenuated, nasal)	Vaccines
Insulin degludec / liraglutide	Medicines used in diabetes
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
Ospemifene	Sex hormones and modulators of the genital system
Peginesatide	Antianemic medicines

¹ Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ¹
Peginterferon beta-1a	Immunostimulants
Perflubutane	Contrast media
Propranolol	Beta blocking medicines
Radium-223 (chloride)	Therapeutic radiopharmaceuticals
Serelaxin	Cardiac therapy
Simeprevir	Antivirals for systemic use
Simoctocog alfa	Antihemorrhagics
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
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
Follitropin alfa	Sex hormones and modulators of the genital system	1
Imatinib	Antineoplastic medicines	1
Insulin glargine	Medicines used in diabetes	1
Levetiracetam	Antiepileptics	1
Memantine	Psychoanaleptics	1
Oseltamivir	Antivirals for systemic use	1
Tacrolimus	Immunosuppressants	1
Zoledronic acid	Medicines for bone diseases	2

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)	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

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
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)	Masiviera	AB Science	Antineoplastic medicines
Masitinib (mesylate)	Masican	AB Science	Antineoplastic medicines
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