



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 December 2013
EMA/773850/2013
Procedure Management & Business Support Division

Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use December 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 **5 December 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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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
Aclidinium bromide / formoterol (fumarate dihydrate)	Medicines for obstructive airway diseases
Albiglutide	Medicines used in diabetes
Balugrastim	Immunostimulants
Bazedoxifene (acetate) / estrogens conjugated	Sex hormones and modulators of the genital system
Brimonidine (tartrate)	Other dermatological medicines
Brinzolamide / brimonidine (tartrate)	Ophthalmologicals
Canagliflozin / metformin (hydrochloride)	Medicines used in diabetes
Clopidogrel (bisulfate)/acetylsalicylic acid	Antithrombotic medicines
Darunavir (ethanolate)/cobicistat	Antivirals for systemic use
Dolutegravir / abacavir / lamivudine	Antivirals for systemic use
Dulaglutide	Medicines used in diabetes
Empagliflozin	Medicines used in diabetes
Faldaprevir	Antivirals for systemic use
Florbetaben (18F)	Diagnostic radiopharmaceuticals
Flutemetamol (18F)	Diagnostic radiopharmaceuticals
Hepatitis b surface antigen	Vaccines
Human fibrinogen / human thrombin	Antihemorrhagics
Idelalisib	Antineoplastic medicines
Insulin degludec / liraglutide	Medicines used in diabetes
Laquinimod (sodium)	Other nervous system medicines
Lurasidone	Psycholeptics
Mixture of polynuclear iron(III)-oxyhydroxide, sucrose and starches	Other therapeutic medicines
Naloxegol (oxalate)	Medicines for constipation
Naltrexone (hydrochloride) / bupropion (hydrochloride)	Antiobesity medicines
Nintedanib	Antineoplastic medicines

¹ Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ¹
Nonacog gamma	Antihemorrhagics
Ospemifene	Sex hormones and modulators of the genital system
Peginterferon beta-1a	Immunostimulants
Perflubutane	Contrast media
Phenylephrine (hydrochloride) / ketorolac trometamol	Ophthalmologicals
Propranolol (hydrochloride)	Beta blocking medicines
Secukinumab	Immunosuppressants
Serelaxin	Cardiac therapy
Simeprevir	Antivirals for systemic use
Simoctocog alfa	Antihemorrhagics
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
Travoprost	Ophthalmologicals
Umeclidinium bromide	Medicines for obstructive airway diseases
Umeclidinium bromide / vilanterol (trifenatate)	Medicines for obstructive airway diseases
Vedolizumab	Immunosuppressants

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
Busulfan	Antineoplastic medicines	1
Follitropin alfa	Sex hormones and modulators of the genital system	1
Insulin glargine	Medicines used in diabetes	1
Oseltamivir	Antivirals for systemic use	1
Rivastigmine	Psychoanaesthetics	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
Bedaquiline (fumarate)	Sirturo	Janssen-Cilag International N.V.	Antimycobacterials
Cabozantinib ((S)-malate)	Cometriq	TMC Pharma Services Ltd	Antineoplastic medicines
Dexamethasone (acetate)	Neofordex	LABORATOIRES CTRS - BOULOGNE BILLANCOURT	Corticosteroids for systemic use
Eliglustat	Cerdelga	Genzyme Europe BV	Other alimentary tract and metabolism products
Etarfolatide	Folcepri	Endocyte Europe, B.V.	Diagnostic radiopharmaceuticals

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
Ex vivo autologous corneal epithelial cells including stem cells	Holoclax	Chiesi Farmaceutici S.p.A.	Ophthalmologicals
Folic acid	Neocepri	Endocyte Europe, B.V.	Diagnostic medicines
Ibrutinib	Imbruvica	Janssen-Cilag International NV	Antineoplastic medicines
Masitinib (mesylate)	Masiviera	AB Science	Antineoplastic medicines
Mifepristone	Corluxin	FGK Representative Service GmbH	Systemic hormonal preparations, excl. sex hormones and insulins
Nalfurafine (hydrochloride)	Winfuran	Toray Europe Limited	Other therapeutic medicines
Obinutuzumab	Gazyva	Roche Registration Ltd	Antineoplastic medicines
Olaparib	Olaparib astraZeneca ab	AstraZeneca AB	Antineoplastic medicines
Para-aminosalicylic acid	Pas-gr	Lucane Pharma SAS	Antimycobacterials
Ramucirumab	Cyramza	Eli Lilly Nederland B.V.	Antineoplastic medicines
Recombinant human n-acetylgalactosamine-6-sulfatase (rhGalns)	Vimizim	BioMarin Europe Ltd	Other alimentary tract and metabolism products
Riociguat	Adempas	Bayer Pharma AG	Cardiac therapy
Siltuximab	Sylvant	Janssen-Cilag International NV	Antineoplastic medicines
Tobramycin	Vantobra	PARI Pharma GmbH	Antibacterials for systemic use
Vintafolide	Vynfinit	Endocyte Europe, B.V.	Antineoplastic medicines