



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 June 2014
EMA/349630/2014
Procedure Management and Business Support Division

Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use June 2014

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 **6 June 2014**.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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
Apremilast	Immunosuppressants
Balugrastim	Immunostimulants
Bazedoxifene (acetate)/estrogens conjugated	Sex hormones and modulators of the genital system
Cangrelor	Antithrombotic medicines
Ceritinib	Antineoplastic medicines
Ciclosporin	Ophthalmologicals
Clopidogrel (bisulfate)/acetylsalicylic acid	Antithrombotic medicines
Daclatasvir (dihydrochloride)	Antivirals for systemic use
Dalbavancin (hydrochloride)	Antibacterials for systemic use
Darunavir (ethanolate)/cobicistat	Antivirals for systemic use
Dasabuvir (sodium)	Antivirals for systemic use
Dolutegravir/abacavir/lamivudine	Antivirals for systemic use
Dulaglutide	Medicines used in diabetes
Duloxetine (hydrochloride)	Psychoanaesthetics
Edoxaban (tosylate)	Antithrombotic medicines
Faldaprevir	Antivirals for systemic use
Ferric citrate coordination complex	Other therapeutic medicines
Flutemetamol (18F)	Diagnostic radiopharmaceuticals
Guanfacine (hydrochloride)	Antihypertensives
Human alpha1-proteinase inhibitor	Antihemorrhagics
Human fibrinogen/human thrombin	Antihemorrhagics
Human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed)	Vaccines
Idelalisib	Antineoplastic medicines
Insulin degludec/liraglutide	Medicines used in diabetes
Lamivudine (hydrate)/raltegravir (potassium)	Antivirals for systemic use
Liraglutide	Medicines used in diabetes
Lutetium (177 Lu) (chloride)	Diagnostic radiopharmaceuticals

¹ Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area¹
Mixture of polynuclear iron(III)-oxyhydroxide, sucrose and starches	Other therapeutic medicines
Naloxegol (oxalate)	Medicines for constipation
Naltrexone (hydrochloride)/bupropion (hydrochloride)	Antiobesity medicines
Netupitant/palonosetron (hydrochloride)	Antiemetics and antinauseants
Nintedanib	Antineoplastic medicines
Nonacog gamma	Antihemorrhagics
Ombitasvir/paritaprevir/ritonavir	Antivirals for systemic use
Oritavancin (diphosphate)	Antibacterials for systemic use
Ospemifene	Sex hormones and modulators of the genital system
Perflubutane	Contrast media
Phenylephrine (hydrochloride)/ketorolac (trometamol)	Ophthalmologicals
Safinamide (methanesulfonate)	Anti-parkinson medicines
Secukinumab	Immunosuppressants
Sofosbuvir/ledipasvir	Antivirals for systemic use
Sonidegib (phosphate)	Antineoplastic medicines
Spheroids of human autologous matrix-associated chondrocytes	Other medicines for disorders of the musculo-skeletal system
Tedizolid (phosphate)	Antibacterials for systemic use
Tilmanocept	Diagnostic radiopharmaceuticals
Vorapaxar	Antithrombotic medicines

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	3
Busulfan	Antineoplastic medicines	1
Filgrastim	Immunostimulants	1
Insulin glargine	Medicines used in diabetes	1
Tadalafil	Urologicals	1
Voriconazole	Antimycotics for systemic use	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
Allogeneic T cells genetically modified to express suicide gene	Zalmoxis	Molmed Spa	Antineoplastic medicines
Allogenic human heterologous liver cells	Heparesc	Cytonet Gmbh&Co KG	Other alimentary tract and metabolism products
Dasiprotimut-T	Dasiprotimut-T Biovest	Biovest Europe Ltd	Immunostimulants
Dexamethasone (acetate)	Neofordex	Laboratoires Ctrs - Boulogne Billancourt	Corticosteroids for systemic use
Dinutuximab	Unituxin	United Therapeutics Europe Ltd	Antineoplastic medicines
Eliglustat	Cerdelga	Genzyme Europe Bv	Other alimentary tract and metabolism products
Ex vivo autologous corneal epithelial cells including stem cells	Holoclar	Chiesi Farmaceutici S.P.A.	Ophthalmologicals
Ibrutinib	Imbruvica	Janssen-Cilag International Nv	Antineoplastic medicines

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
Idebenone	Raxone	Santhera Pharmaceuticals (Deutschland) Gmbh	Other nervous system medicines
Ketoconazole	Ketoconazole Lab Hra Pharma	Laboratoire Hra Pharma	Antimycotics for systemic use
Ketoconazole	Ketoconazole Aid-Scfm	Agenzia Industrie Difesa-Stabilimento Chimico Farmaceutico Militare	Other therapeutic medicines
Levofloxacin	Levofloxacin – Aptalis	Aptalis Pharma Sas	Antibacterials for systemic use
Mifepristone	Corluxin	FGK Representative Service Gmbh	Systemic hormonal preparations, excl. sex hormones and insulins
Nintedanib	Ofev	Boehringer Ingelheim International Gmbh	Antineoplastic medicines
Olaparib	Olaparib Astrazeneca AB	Astrazeneca AB	Antineoplastic medicines
Panobinostat (lactate anhydrous)	Farydak	Novartis Pharmaceuticals UK Limited	Antineoplastic medicines
Pitolisant (hydrochloride)	Wakix	Bioprojet Pharma	Psychoanaleptics
Ramucirumab	Cyramza	Eli Lilly Nederland B.V.	Antineoplastic medicines
Recombinant l-asparaginase	Spectrila	Medac Gesellschaft Fuer Klinische Spezialpraeparate Mbh	Antineoplastic medicines
Tasimelteon	Hetlioz	Vanda Pharmaceuticals Ltd.	Psycholeptics
Tobramycin	Vantobra	PARI Pharma Gmbh	Antibacterials for systemic use
Tolvaptan	Jinarc	Otsuka Pharmaceutical Europe Ltd	Urologicals