



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 April 2012

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.

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.



Non-orphan medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ¹
Acclidinium (bromide)	Medicines for obstructive airway diseases
Aflibercept	Antineoplastic medicines Ophthalmologicals
Autologous cultured chondrocytes	Other medicines for disorders of the musculo-skeletal system
Autologous oral mucosal epithelial cells	Ophthalmologicals
Autologous peripheral blood mononuclear cells activated with PAP-GM-CSF	Immunostimulants
Budesonide/salmeterol	Medicines for obstructive airway diseases
Ceftaroline fosamil	Antibacterials for systemic use
Colestilan	Other therapeutic medicines
Copper (64 Cu) (chloride)	Various (radiolabelling)
Crizotinib	Antineoplastic medicines
Dapagliflozin	Medicines used in diabetes
Dextromethorphan (hydrobromide)/quinidine (sulfate)	Other nervous system medicines
Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil	Antivirals for systemic use
Fenofibrate/simvastatin	Lipid modifying medicines
Ferumoxytol	Antianaemic medicines
Florbetapir (18F)	Diagnostic radiopharmaceuticals
Glycopyrronium (bromide)	Medicines for obstructive airway diseases
Human coagulation factor VIII / von Willebrand factor	Antihemorrhagics
Human normal immunoglobulin/recombinant human hyaluronidase	Immune sera and immunoglobulins
Iloperidone	Psycholeptics
Influenza vaccine (surface antigen, inactivated)	Vaccines

¹ Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ¹
Ingenol (mebutate)	Immunostimulants
Insulin degludec	Medicines used in diabetes
Insulin degludec/insulin aspart	Medicines used in diabetes
Linaclotide	Medicines for functional gastrointestinal disorders
Linagliptin/metformin (hydrochloride)	Medicines used in diabetes
Lipegfilgrastim	Immunostimulants
Lixisenatide	Medicines used in diabetes
Loxapine	Psycholeptics
Memantine (hydrochloride)/donepezil (hydrochloride)	Psychoanaleptics
Meningococcal group B vaccine (rDNA, adsorbed)	Vaccines
Mipomersen	Lipid modifying medicines
Mirabegron	Urologicals
Nalmefene	Other nervous system medicines
Nonacog gamma	Antihemorrhagics
Ocriplasmin	Ophthalmologicals
Peginesatide	Antianemic medicines
Pegloticase	Antigout medicines
Perampanel	Antiepileptics
Pertuzumab	Antineoplastic medicines
Phentermine/topiramate	Antiobesity medicines
Semuloparin (sodium)	Antithrombotic medicines
Somatropin	Pituitary and hypothalamic hormones and analogues
Teriflunomide	Immunosuppressants
Tesamorelin	Pituitary and hypothalamic hormones and analogues
Tofacitinib (citrate)	Immunosuppressants
Vismodegib	Antineoplastic medicines

Non-orphan generic and biosimilar medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area ²	Total number of applications
Capecitabine	Antineoplastic medicines	1
Follitropin alfa	Sex hormones and modulators of the genital system	1
Ibandronic acid	Medicines for bone diseases	1
Imatinib	Antineoplastic medicines	2
Imiquimod	Antibiotics and chemotherapeutics for dermatological use	1
Infliximab	Immunosuppressants	1
Insulin human	Medicines used in diabetes	3
Megestrol	Endocrine therapy	1
Zoledronic acid	Medicines for bone diseases	5

Orphan medicinal products

International non-proprietary name / Common Name	Product name	Marketing authorisation applicant	Therapeutic area ³
Afamelanotide	Scenesse	Clinuvel (UK) Limited	Emollients and protectives
Axitinib	Inlyta	Pfizer Ltd.	Antineoplastic medicines
Bosutinib	Bosulif	Pfizer Ltd.	Antineoplastic medicines
Brentuximab vedotin	Adcetris	Takeda Global Research and Development Centre (Europe) Ltd.	Antineoplastic medicines
Bromelain enriched proteolytic enzyme preparation from <i>Ananas comosus</i>	NexoBrid	Teva Pharma GmbH	Medicines for wounds and ulcers
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.

* Cholic Acid has been added.

International non-proprietary name / Common Name	Product name	Marketing authorisation applicant	Therapeutic area ³
Decitabine	Dacogen	Janssen-Cilag International N.V.	Antineoplastic medicines
Defibrotide	Defitelio	Gentium SpA	Antithrombotic medicines
Delamanid	Delamanid	Otsuka Novel Medicines GmbH	Antimycobacterials
Idebenone	SAN idebenone	Santhera Pharmaceuticals (Deutschland) GmbH	Psychoanaleptics
Ivacaftor	Kalydeco	Vertex Pharmaceuticals (U.K.) Ltd.	Other respiratory system medicines
Mercaptopurine	Loulla	Only For Children Pharmaceuticals	Antineoplastic medicines
Ridaforolimus	Jenzyl	Merck Sharp & Dohme Ltd.	Antineoplastic medicines
Romidepsin	Istodax	Celgene Europe Ltd.	Antineoplastic medicines
Ruxolitinib	Jakavi	Novartis Europharm Ltd.	Antineoplastic medicines
Taliglucerase alfa	Elelyso	Pfizer Ltd.	Other alimentary tract and metabolism medicines
Teduglutide	Revestive	Nycomed Danmark APS.	Other alimentary tract and metabolism medicines