



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 July 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 **2 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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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 |
|--|--|
| Afatinib (dimaleate) | Antineoplastic medicines |
| Albiglutide | Medicines used in diabetes |
| 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 |
| 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 |
| 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 |
| Indacaterol (maleate) / glycopyrronium bromide | Medicines for obstructive airway diseases |
| Influenza vaccine (tetraivalent live attenuated, nasal) | Vaccines |
| Insulin degludec / liraglutide | Medicines used in diabetes |
| Laquinimod (sodium) | Other nervous system medicines |

¹ Based on the ATC therapeutic sub-group.

| International non-proprietary name (salt, ester, derivative, etc.) / Common Name | Therapeutic area ¹ |
|--|--|
| 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 |
| 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 |
| Filgrastim | Immunostimulants | 1 |
| Follitropin alfa | Sex hormones and modulators of the genital system | 2 |
| 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 |
| Delamanid | Delamanid | Otsuka Novel Products GmbH | Antimycobacterials |

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 area ³ |
|--|--------------|--|--|
| 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 |
| 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 |