



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

5 October 2016  
EMA/655666/2016  
Information Management Division

## Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use October 2016

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 **4 October 2016**.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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 <sup>1</sup>
Abaloparatide	Calcium homeostasis
Alectinib (hydrochloride)	Antineoplastic medicines
Anamorelin (hydrochloride)	Other therapeutic medicines
Andexanet alfa	Other therapeutic medicines
Atezolizumab	Antineoplastic medicines
Baricitinib	Immunosuppressants
Bezlotoxumab	Antidiarrheals, intestinal antiinflammatory/antiinfective medicines
<b>Binimetinib</b>	<b>Antineoplastic medicines</b>
Brodalumab	Immunosuppressants
Cariprazine (hydrochloride)	Psycholeptics
Cladribine	Antineoplastic medicines
<b>Darunavir (ethanolate) / cobicistat / emtricitabine / tenofovir alafenamide (fumarate)</b>	<b>Antivirals for systemic use</b>
D-Biotin	Vitamins
Dengue tetravalent vaccine (live, attenuated)	Vaccines
Dimethyl fumarate	Antipsoriatics
<b>Edoxaban (tosylate)<sup>2</sup></b>	<b>Antithrombotic medicines</b>
<b>Enclomifene (citrate)</b>	<b>Sex hormones and modulators of the genital system</b>
Etirinotecan pegol	Antineoplastic medicines
Fluciclovine (18F)	Diagnostic radiopharmaceuticals
Follitropin delta	Sex hormones and modulators of the genital system
Human IgG1 monoclonal antibody specific for human interleukin-1 alpha	Antineoplastic medicines
Iloperidone	Psycholeptics
Insulin aspart	Medicines used in diabetes
Insulin glargine / lixisenatide	Medicines used in diabetes
Lonococog alfa	Antihemorrhagics
<b>Masitinib</b>	<b>Antineoplastic medicines</b>

<sup>1</sup> Based on the ATC therapeutic sub-group.

<sup>2</sup> Submitted according to legal basis: "Informed consent application (Article 10c of Directive No 2001/83/EC)"

<b>International non-proprietary name (salt, ester, derivative, etc.) / Common Name</b>	<b>Therapeutic area<sup>1</sup></b>
Meningococcal group B vaccine (recombinant, component, adsorbed)	Vaccines
Neratinib	Antineoplastic medicines
Ocrelizumab	Immunosuppressants
Padeliporfin (di-potassium)	Antineoplastic medicines
Patiromer sorbitex calcium	Other therapeutic medicines
Prasterone	Sex hormones and modulators of the genital system
<b>Ribociclib (succinate)</b>	<b>Antineoplastic medicines</b>
Rolapitant	Antiemetics and anti-nauseants
Rurioctocog alfa pegol	Antihemorrhagics
Sarilumab	Immunosuppressants
<b>Sirukumab</b>	<b>Immunosuppressants</b>
Sodium zirconium cyclosilicate	Other therapeutic medicines
Solithromycin	Antibacterials for systemic use
Spheroids of human autologous matrix-associated chondrocytes	Other medicines for disorders of the musculo-skeletal system
Tenofovir alafenamide (fumarate)	Antivirals for systemic use
Tofacitinib (citrate)	Immunosuppressants

## Non-orphan generic and biosimilar medicinal products

<b>International non-proprietary name / Common Name</b>	<b>Therapeutic area<sup>3</sup></b>	<b>Total number of applications</b>
Adalimumab	Immunosuppressants	3
Carglumic acid	Other alimentary tract and metabolism products	1
Carmustine	Antineoplastic medicines	1
Daptomycin	Antibacterials for systemic use	1
Darunavir	Antivirals for systemic use	1
Efavirenz / emtricitabine / tenofovir disoproxil	Antivirals for systemic use	2
Emtricitabine / tenofovir disoproxil	Antivirals for systemic use	2

<sup>3</sup> Based on the ATC therapeutic sub-group.

International non-proprietary name / Common Name	Therapeutic area <sup>3</sup>	Total number of applications
Entecavir	Antivirals for systemic use	2
Etanercept	Immunosuppressants	2
Febuxostat	Antigout medicines	1
Insulin glargine	Medicines used in diabetes	1
<b>Insulin lispro</b>	<b>Medicines used in diabetes</b>	<b>1</b>
Ivabradine	Cardiac therapy	1
<b>Lacosamide</b>	<b>Antiepileptics</b>	<b>1</b>
Methotrexate	Antineoplastic medicines	1
Miglustat	Other alimentary tract and metabolism products	2
Nitisinone	Other alimentary tract and metabolism products	1
Pegfilgrastim	Immunostimulants	4
Pemetrexed	Antineoplastic medicines	2
Pregabalin	Antiepileptics	1
Rituximab	Antineoplastic medicines	2
Tadalafil	Urologicals	1
Tenofovir disoproxil	Antivirals for systemic use	1
Teriparatide	Calcium homeostasis	2
Tigecycline	Antibacterials for systemic use	1
Trastuzumab	Antineoplastic medicines	2

## Orphan medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>4</sup>
Aceneuramic acid	Other medicines for disorders of the musculo-skeletal system
Alpha-1-antitrypsin	Antihemorrhagics
<b>Caffeine (citrate)</b>	<b>Psychoanaleptics</b>

<sup>4</sup> Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>4</sup>
<b>Cerliponase alfa</b>	<b>Other alimentary tract and metabolism products</b>
Chlormethine	Antineoplastic medicines
Dinutuximab beta	Antineoplastic medicines
Edotreotide	Diagnostic radiopharmaceuticals
Eryaspase	Antineoplastic medicines
Expanded human allogeneic mesenchymal adult stem cells extracted from adipose tissue	Immunosuppressants
Inotuzumab ozogamicin	Antineoplastic medicines
Levamisole (hydrochloride)	Anthelmintics
Lutetium (177Lu) dotatate	Therapeutic radiopharmaceuticals
Masitinib (mesylate)	Antineoplastic medicines
Mercaptamine (hydrochloride)	Ophthalmologicals
Midostaurin	Antineoplastic medicines
Nonacog beta pegol	Antihemorrhagics
Obeticholic acid	Bile and liver therapy
Paclitaxel	Antineoplastic medicines
Pacritinib (citrate)	Antineoplastic medicines
Parathyroid hormone	Calcium homeostasis
Pentosan polysulfate sodium	Urologicals
Telotristat (etiprate)	Other alimentary tract and metabolism products
Tivozanib (hydrochloride monohydrate)	Antineoplastic medicines
Trientine (tetrahydrochloride)	Other alimentary tract and metabolism products
<b>Velmanase alfa</b>	<b>Other alimentary tract and metabolism products</b>
Venetoclax	Antineoplastic medicines
Vosaroxin	Antineoplastic medicines