



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Information Management Division

## Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use December 2017

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 28 November 2017.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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>i</sup>
Abaloparatide	Calcium homeostasis
Abemaciclib	Antineoplastic medicines
Andexanet alfa	Other therapeutic medicines
Betrixaban	Antithrombotic medicines
Bictegravir / emtricitabine / tenofovir alafenamide (fumarate)	Antivirals for systemic use
Binimetinib	Antineoplastic medicines
Botulinum toxin type A	Muscle relaxants
Brexpirazole	Psycholeptics
Brigatinib	Antineoplastic medicines
Buprenorphine (hydrochloride)	Other nervous system medicines
Ciclosporin	Ophthalmologicals
Dengue tetravalent vaccine (live, attenuated)	Vaccines
Dolutegravir (sodium) /rilpivirine (hydrochloride)	Antivirals for systemic use
Doravirine	Antivirals for systemic use
Doravirine / lamivudine / tenofovir disoproxil (fumarate)	Antivirals for systemic use
Durvalumab	Antineoplastic medicines
Emicizumab <sup>ii</sup>	Antihemorrhagics
Enclomifene (citrate)	Sex hormones and modulators of the genital system
Encorafenib	Antineoplastic medicines
Eravacycline	Antibacterials for systemic use
Erenumab	Analgesics
Ertugliflozin (L-pyroglutamic acid)	Medicines used in diabetes
Ertugliflozin (L-pyroglutamic acid) / metformin (hydrochloride)	Medicines used in diabetes

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>i</sup>
Ertugliflozin (L-pyroglutamic acid) / sitagliptin (phosphate monohydrate)	Medicines used in diabetes
Galcanezumab	Analgesics
Glycopyrronium / formoterol (fumarate dihydrate)	Medicines for obstructive airway diseases
Human herpesvirus 3	Vaccines
Influenza vaccine surface antigen inactivated prepared in cell cultures	Vaccines
Lesinurad / allopurinol	Antigout medicines
Macimorelin (acetate)	Diagnostic medicines
Melatonin	Psycholeptics
Meropenem (trihydrate) /vaborbactam,	Antibacterials for systemic use
Naldemedine (tosilate)	Medicines for constipation
Neratinib	Antineoplastic medicines
Peramivir	Antivirals for systemic use
Semaglutide	Medicines used in diabetes
Tildrakizumab	Immunosuppressants

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

<sup>ii</sup> Application being reviewed under EMA's accelerated assessment programme.

## Non-orphan generic and biosimilar medicinal products

International non-proprietary name / Common Name	Therapeutic area <sup>i</sup>	Total number of applications
Adalimumab	Immunosuppressants	3
Anagrelide	Antineoplastic medicines	1
Buprenorphine	Other nervous system medicines	1
Carmustine	Antineoplastic medicines	1
Deferiprone	Other therapeutic medicines	1
Doxorubicin	Antineoplastic medicines	1
Efavirenz / emtricitabine / tenofovir	Antivirals for systemic use	1

International non-proprietary name / Common Name	Therapeutic area <sup>i</sup>	Total number of applications
disoproxil		
Gefitinib	Antineoplastic medicines	1
Hydrocortisone	Corticosteroids for systemic use	1
Infliximab	Immunosuppressants	1
Insulin glargine	Medicines used in diabetes	1
Lenalidomide	Immunosuppressants	1
Nitisinone	Other alimentary tract and metabolism products	1
Paclitaxel	Antineoplastic medicines	1
Pegfilgrastim	Immunostimulants	6
Pemetrexed	Antineoplastic medicines	1
Prasugrel	Antithrombotic medicines	1
Rotigotine	Anti-parkinson medicines	1
Sufentanil	Anesthetics	1
<b>Trastuzumab</b>	<b>Antineoplastic medicines</b>	<b>4</b>
Vigabatrin	Antiepileptics	1

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

## Orphan medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>i</sup>
Axicabtagene ciloleucel <sup>ii</sup>	Antineoplastic medicines
Burosumab	Medicines for bone diseases
Caplacizumab	Antithrombotic medicines
Damoctocog alfa pegol	Antihemorrhagics
Daunorubicin (hydrochloride) / cytarabine <sup>ii</sup>	Antineoplastic medicines
Entolimod	Immunostimulants
Eteplirsen	Other medicines for disorders of the musculo-skeletal system
Expanded human allogeneic mesenchymal adult stem cells extracted from adipose tissue	Immunosuppressants

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>i</sup>
Gemtuzumab ozogamicin	Antineoplastic medicines
Glibenclamide	Medicines used in diabetes
Inotersen (sodium) <sup>ii</sup>	Other nervous system medicines
Masitinib (mesylate)	Antineoplastic medicines
Metreleptin	Other alimentary tract and metabolism products
Mexiletine hcl	Other medicines for disorders of the musculo-skeletal system
Mogamulizumab	Antineoplastic medicines
Paclitaxel	Antineoplastic medicines
Pacritinib (citrate)	Antineoplastic medicines
Plitidepsin	Antineoplastic medicines
Ropeginterferon alfa-2b	Immunostimulants
Rucaparib (camsylate)	Antineoplastic medicines
Sodium benzoate	Other alimentary tract and metabolism products
Tezacaftor / ivacaftor	Other respiratory system medicines
Tisagenlecleucel <sup>ii</sup>	Antineoplastic medicines
Velmanase alfa	Other alimentary tract and metabolism products
Vestronidase alfa	Other alimentary tract and metabolism products
Viable T-cells	Antineoplastic and immunomodulating agents
Volanesorsen (sodium)	Lipid modifying medicines
Vonicog alfa	Antihemorrhagics
Voretigene neparvovec	Ophthalmologicals

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

<sup>ii</sup> Application being reviewed under EMA's accelerated assessment programme.