



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 February 2018

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 5 February 2018.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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
Abemaciclib	Antineoplastic medicines
Andexanet alfa	Other therapeutic medicines
Beclometasone (dipropionate anhydrous) / formoterol (fumarate dihydrate) / glycopyrronium (bromide) <sup>iii</sup>	Medicines for obstructive airway diseases
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
Canakinumab	Immunosuppressants
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
Encorafenib	Antineoplastic medicines
Eravacycline	Antibacterials for systemic use
Erenumab	Analgesics
Fremanezumab	Analgesics
Galcanezumab	Analgesics
Glycopyrronium / formoterol (fumarate dihydrate)	Medicines for obstructive airway diseases
Influenza vaccine surface antigen inactivated prepared in cell cultures	Vaccines
Lesinurad / allopurinol	Antigout medicines
Lorlatinib	Antineoplastic medicines

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>i</sup>
Lusutrombopag	Antihemorrhagics
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
Romosozumab	Medicines for bone diseases
Tildrakizumab	Immunosuppressants
Zanamivir	Antivirals for systemic use

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

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

## Non-orphan generic and biosimilar medicinal products

International non-proprietary name / Common Name	Therapeutic area <sup>i</sup>	Total number of applications
Adalimumab	Immunosuppressants	5
Buprenorphine	Other nervous system medicines	1
Carmustine	Antineoplastic medicines	1
Deferiprone	Other therapeutic medicines	1
Doxorubicin	Antineoplastic medicines	1
Gefitinib	Antineoplastic medicines	1
Infliximab	Immunosuppressants	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

International non-proprietary name / Common Name	Therapeutic area <sup>i</sup>	Total number of applications
Sufentanil	Anesthetics	1
Trastuzumab	Antineoplastic medicines	3
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>
Asparaginase	Antineoplastic medicines
Avacopan	Immunosuppressants
Axicabtagene ciloleucel <sup>ii</sup>	Antineoplastic medicines
Cannabidiol	Antiepileptics
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
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
Patisiran (sodium) <sup>ii</sup>	Other nervous system medicines
Ropeginterferon alfa-2b	Immunostimulants

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>i</sup>
Rucaparib (camsylate)	Antineoplastic medicines
Sodium benzoate	Other alimentary tract and metabolism products
Tezacaftor / ivacaftor	Other respiratory system medicines
Tisagenlecleucel <sup>ii</sup>	Antineoplastic medicines
Treosulfan	Antineoplastic medicines
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.