



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 September 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 3 September 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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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>
Andexanet alfa	Other therapeutic medicines
Angiotensin II (acetate)	Medicines acting on the renin-angiotensin system
Apalutamide	Endocrine therapy
Avatrombopag (maleate)	Antihemorrhagics
Botulinum toxin type A	Muscle relaxants
Brigatinib	Antineoplastic medicines
Buprenorphine (hydrochloride)	Other nervous system medicines
Cemiplimab	Antineoplastic medicines
Ciprofloxacin	Antibacterials for systemic use
Crisaborole	Other dermatological medicines
Dacomitinib (monohydrate)	Antineoplastic medicines
Dapagliflozin (propanediol)/saxagliptin/metformin (hydrochloride)	Medicines used in diabetes
Delafloxacin (meglumine)	Antibacterials for systemic use
Dengue tetravalent vaccine (live, attenuated)	Vaccines
Doravirine	Antivirals for systemic use
Doravirine / lamivudine / tenofovir disoproxil (fumarate)	Antivirals for systemic use
Edaravone	Other nervous system medicines
Fremanezumab	Analgesics
Galcanezumab	Analgesics
Glucagon	Pancreatic hormones
Glycopyrronium / formoterol (fumarate dihydrate)	Medicines for obstructive airway diseases
Influenza vaccine surface antigen inactivated prepared in cell cultures	Vaccines
Levodopa	Anti-parkinson medicines
L-lysine (hydrochloride) / L-arginine (hydrochloride)	Urologicals
Lorlatinib	Antineoplastic medicines
Lusutrombopag	Antihemorrhagics
Macimorelin (acetate)	Diagnostic medicines

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>i</sup>
Meropenem (trihydrate) /vaborbactam	Antibacterials for systemic use
Naldemedine (tosilate)	Medicines for constipation
Paclitaxel	Antineoplastic medicines
Risankizumab	Immunosuppressants
Romosozumab	Medicines for bone diseases
Sodium oxybate <sup>ii</sup>	Other nervous system medicines
Sotagliflozin	Medicines used in diabetes
Talazoparib	Antineoplastic medicines
Zanamivir	Antivirals for systemic use

<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	1
Ambrisentan	Antihypertensives	2
Atazanavir	Antivirals for systemic use	1
Bevacizumab	Antineoplastic medicines	1
Buprenorphine	Other nervous system medicines	1
Cabazitaxel	Antineoplastic medicines	1
Deferasirox	Other therapeutic medicines	1
Doxorubicin	Antineoplastic medicines	1
Erlotinib	Antineoplastic medicines	1
Etanercept	Immunosuppressants	1
Febuxostat	Antigout medicines	1
Hydroxycarbamide	Antineoplastic medicines	1
Ioflupane (123I)	Diagnostic radiopharmaceuticals	1
Miglustat	Other alimentary tract and metabolism products	1
Paclitaxel	Antineoplastic medicines	1

International non-proprietary name / Common Name	Therapeutic area <sup>i</sup>	Total number of applications
Pegfilgrastim	Immunostimulants	6
Posaconazole	Antimycotics for systemic use	1
Rituximab	Antineoplastic medicines	2
Silodosin	Urologicals	1
Tigecycline	Antibacterials for systemic use	1
Tobramycin	Antibacterials for systemic use	1
Trastuzumab	Antineoplastic medicines	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
Cannabidiol	Antiepileptics
Damoctocog alfa pegol	Antihemorrhagics
Emapalumab **	Immunosuppressants
Enasidenib (mesylate)	Antineoplastic medicines
Entolimod	Immunostimulants
Glutamine	Other alimentary tract and metabolism products
Lanadelumab <sup>ii</sup>	Other hematological medicines
Mexiletine (hcl)	Other medicines for disorders of the musculo-skeletal system
Mogamulizumab	Antineoplastic medicines
Pacritinib (citrate)	Antineoplastic medicines
Pegvaliase	Other alimentary tract and metabolism products
Ravulizumab	Immunosuppressants
Ropeginterferon alfa-2b	Immunostimulants
Treosulfan	Antineoplastic medicines
Treprostinil	Antithrombotic medicines
Trientine (dihydrochloride)	Other alimentary tract and metabolism products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>i</sup>
Turoctocog alfa pegol	Antihemorrhagics
Viable T-cells	Antineoplastic and immunomodulating agents
Volanesorsen (sodium)	Lipid modifying medicines
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.

\*\* Correction: Emapalumab was by mistake reported as being reviewed under EMA's accelerated assessment programme in the first version of this September report.