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Information Management Division

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

May 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 4 May 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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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.

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Non-orphan medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Abemaciclib	Antineoplastic medicines
Andexanet alfa	Other therapeutic medicines
Apalutamide	Endocrine therapy
Axalimogene filolisbac	Antineoplastic medicines
Binimetinib	Antineoplastic medicines
Botulinum toxin type A	Muscle relaxants
Brexpiprazole	Psycholeptics
Brigatinib	Antineoplastic medicines
Buprenorphine (hydrochloride)	Other nervous system medicines
Canakinumab	Immunosuppressants
Cemiplimab	Antineoplastic medicines
Ciprofloxacin	Antibacterials for systemic use
Dacomitinib (monohydrate)	Antineoplastic medicines
Dengue tetravalent vaccine (live, attenuated)	Vaccines
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
Glutamine	Other alimentary tract and metabolism products
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 [i]
Lusutrombopag	Antihemorrhagics
Macimorelin (acetate)	Diagnostic medicines
Melatonin	Psycholeptics
Meropenem (trihydrate) /vaborbactam	Antibacterials for systemic use
Naldemedine (tosilate)	Medicines for constipation
Romosozumab	Medicines for bone diseases
Sotagliflozin	Medicines used in diabetes
Tildrakizumab	Immunosuppressants
Ulipristal (acetate) [iii]	Sex hormones and modulators of the genital system
Zanamivir	Antivirals for systemic use

[i] Based on the ATC therapeutic sub-group.
[iii] 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 [i]	Total number of applications
Adalimumab	Immunosuppressants	5
Atazanavir	Antivirals for systemic use	1
Bevacizumab	Antineoplastic medicines	1
Buprenorphine	Other nervous system medicines	1
Deferiprone	Other therapeutic medicines	1
Doxorubicin	Antineoplastic medicines	1
Gefitinib	Antineoplastic medicines	1
Hydroxycarbamide	Antineoplastic medicines	1
Lenalidomide	Immunosuppressants	1
Miglustat	Other alimentary tract and metabolism products	1
Nitisinone	Other alimentary tract and metabolism products	1
Paclitaxel	Antineoplastic medicines	1
Pegfilgrastim	Immunostimulants	8

International non-proprietary name / Common Name	Therapeutic area [i]	Total number of applications
Silodosin	Urologicals	1
Trastuzumab	Antineoplastic medicines	2
Vigabatrin	Antiepileptics	1

[i] Based on the ATC therapeutic sub-group.

Orphan medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Asparaginase	Antineoplastic medicines
Avacopan	Immunosuppressants
Axicabtagene ciloleucel	Antineoplastic medicines
Cannabidiol	Antiepileptics
Caplacizumab	Antithrombotic medicines
Damoctocog alfa pegol	Antihemorrhagics
Daunorubicin (hydrochloride)/ cytarabine [ii]	Antineoplastic medicines
Entolimod	Immunostimulants
Eteplirsen	Other medicines for disorders of the musculo-skeletal system
Inotersen (sodium) [ii]	Other nervous system medicines
Lanadelumab [ii]	Other hematological 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) [ii]	Other nervous system medicines
Pegvaliase	Other alimentary tract and metabolism products
Ropeginterferon alfa-2b	Immunostimulants
Tezacaftor / ivacaftor	Other respiratory system medicines

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Tisagenlecleucel [ii]	Antineoplastic medicines
Treosulfan	Antineoplastic medicines
Trientine (dihydrochloride)	Other alimentary tract and metabolism products
Turoctocog alfa pegol	Antihemorrhagics
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

[i] Based on the ATC therapeutic sub-group.
[ii] Application being reviewed under EMA's accelerated assessment programme.