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Information Management Division

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

December 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 December 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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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]
Andexanet alfa	Other therapeutic medicines
Angiotensin II (acetate)	Medicines acting on the renin-angiotensin system
Avatrombopag (maleate)	Antihemorrhagics
Botulinum toxin type A	Muscle relaxants
Buprenorphine (hydrochloride)	Other nervous system medicines
Canakinumab	Immunosuppressants
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
Dolutegravir (sodium) / lamivudine	Antivirals for systemic use
Esketamine (hydrochloride)	Anesthetics
Fostamatinib (disodium)	Antihemorrhagics
Fremanezumab	Analgesics
Glucagon	Pancreatic hormones
Ibalizumab [ii]	Antivirals for systemic use
Imipenem (monohydrate) /cilastatin (sodium) / relebactam (monohydrate)	Antibacterials for systemic use
Levodopa	Anti-parkinson medicines
L-lysine (hydrochloride) / L-arginine (hydrochloride)	Urologicals
Lorlatinib	Antineoplastic medicines
Lusutrombopag	Antihemorrhagics
Naldemedine (tosilate)	Medicines for constipation
Netarsudil (mesilate)	Ophthalmologicals
Omadacycline	Antibacterials for systemic use
Plazomicin (sulfate)	Antibacterials for systemic use

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Risankizumab	Immunosuppressants
Romosozumab	Medicines for bone diseases
Siponimod (fumaric acid)	Immunosuppressants
Sodium oxybate [ii]	Other nervous system medicines
Solriamfetol (hydrochloride)	Other nervous system medicines
Sotagliflozin	Medicines used in diabetes
Talazoparib	Antineoplastic medicines
Zanamivir	Antivirals for systemic use

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

Non-orphan generic and biosimilar medicinal products

International non-proprietary name / Common Name	Therapeutic area [i]	Total number of applications
Adalimumab	Immunosuppressants	4
Ambrisentan	Antihypertensives	2
Atazanavir	Antivirals for systemic use	1
Bevacizumab	Antineoplastic medicines	1
Bortezomib	Antineoplastic medicines	1
Cabazitaxel	Antineoplastic medicines	1
Clofarabine	Antineoplastic medicines	1
Clopidogrel / Acetylsalicylic acid	Antithrombotic medicines	1
Deferasirox	Other therapeutic medicines	2
Doxorubicin	Antineoplastic medicines	1
Erlotinib	Antineoplastic medicines	1
Etanercept	Immunosuppressants	1
Febuxostat	Antigout medicines	1
Hydroxycarbamide	Antineoplastic medicines	1
Ioflupane (123I)	Diagnostic radiopharmaceuticals	1

International non-proprietary name / Common Name	Therapeutic area [i]	Total number of applications
Miglustat	Other alimentary tract and metabolism products	1
Paclitaxel	Antineoplastic medicines	1
Pegfilgrastim	Immunostimulants	3
Posaconazole	Antimycotics for systemic use	1
Rituximab	Antineoplastic medicines	2
Tigecycline	Antibacterials for systemic use	1
Tobramycin	Antibacterials for systemic use	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]
Autologous cd34+ cell enriched population that contains hematopoietic stem cells transduced with lentiglobin bb305 lentiviral vector encoding the beta-a-t87q-globin gene [ii]	Other hematological medicines
Avacopan	Immunosuppressants
Cannabidiol	Antiepileptics
Edaravone	Other nervous system medicines
Emapalumab	Immunosuppressants
Enasidenib (mesilate)	Antineoplastic medicines
Glutamine	Other alimentary tract and metabolism products
Larotrectinib (sulfate) [ii]	Antineoplastic medicines
Onasemnogene abeparvovec [ii]	Other medicines for disorders of the musculo-skeletal system
Osilodrostat (phosphate)	Corticosteroids for systemic use
Pacritinib (citrate)	Antineoplastic medicines
Pegvaliase	Other alimentary tract and metabolism products
Quizartinib (dihydrochloride) [ii]	Antineoplastic medicines
Ravulizumab	Immunosuppressants
Ropeginterferon alfa-2b	Immunostimulants

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Treosulfan	Antineoplastic medicines
Trientine (dihydrochloride)	Other alimentary tract and metabolism products
Turoctocog alfa pegol	Antihemorrhagics
Viable T-cells	Antineoplastic and immunomodulating agents
Volanesorsen (sodium)	Lipid modifying medicines

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