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Information Management Division

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

August 2019

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 7 August 2019.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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]
Abicipar pegol	Ophthalmologicals
Alpelisib	Antineoplastic medicines
Arachis hypogaea allergens	Allergens
Bempedoic acid	Lipid modifying medicines
Bempedoic acid / ezetimibe	Lipid modifying medicines
Brolucizumab	Ophthalmologicals
Budesonide / glycopyrronium (bromide) / formoterol (fumarate dihydrate)	Medicines for obstructive airway diseases
Bupivacaine	Anesthetics
Bupivacaine / meloxicam	Anesthetics
Cefiderocol (sulfate tosilate) [v]	Antibacterials for systemic use
Cholera vaccine, oral, live	Vaccines
Ciprofloxacin	Antibacterials for systemic use
Crisaborole	Other dermatological medicines
Dapagliflozin (propanediol)/saxagliptin/metformin (hydrochloride)	Medicines used in diabetes
Darolutamide	Endocrine therapy
Delafloxacin (meglumine)	Antibacterials for systemic use
Entrectinib	Antineoplastic medicines
Esketamine (hydrochloride)	Anesthetics
Fostamatinib (disodium)	Antihemorrhagics
Glucagon	Pancreatic hormones
Hepatitis B surface antigen	Vaccines
Imipenem (monohydrate) /cilastatin (sodium) / relebactam (monohydrate)	Antibacterials for systemic use
Indacaterol (acetate) / glycopyrronium (bromide) / mometasone (furoate)	Medicines for obstructive airway diseases
Indacaterol (acetate) / mometasone (furoate)	Medicines for obstructive airway diseases
Influenza vaccine (surface antigen, inactivated)	Vaccines
Insulin lispro	Medicines used in diabetes
Lefamulin (acetate)	Antibacterials for systemic use
Lidocaine / prilocaine [iii]	Anesthetics

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Lifitegrast	Ophthalmologicals
Netarsudil (mesilate)	Ophthalmologicals
Omadacycline	Antibacterials for systemic use
Ozanimod (hydrochloride)	Immunosuppressants
Plazomicin (sulfate)	Antibacterials for systemic use
Recombinant vesicular stomatitis virus - zaire ebolavirus vaccine (live) [ii]	Vaccines
Semaglutide	Medicines used in diabetes
Siponimod (fumaric acid)	Immunosuppressants
Sodium oxybate	Other nervous system medicines
Solriamfetol (hydrochloride)	Other nervous system medicines
Upadacitinib (hemihydrate)	Immunosuppressants

[i] Based on the ATC therapeutic sub-group.
[ii] Application being reviewed under EMA's accelerated assessment programme.
[iii] Submitted according to legal basis: Informed consent application (Article 10c of Directive No 2001/83/EC).
[iv] N/A (Medicine classified as advanced therapy medicinal product (ATMP))
[v] Product no longer being reviewed under EMA's accelerated assessment programme
* Avapritinib – corrected to be reported in the orphan table

Non-orphan generic and biosimilar medicinal products

International non-proprietary name / Common Name	Therapeutic area [i]	Total number of applications
Adalimumab	Immunosuppressants	1
Apixaban	Antithrombotic medicines	1
Aripiprazole	Psycholeptics	1
Arsenic trioxide	Antineoplastic medicines	2
Azacitidine	Antineoplastic medicines	3
Bevacizumab	Antineoplastic medicines	1
Bortezomib	Antineoplastic medicines	1
Cabazitaxel	Antineoplastic medicines	1
Cinacalcet	Calcium homeostasis	1
Clofarabine	Antineoplastic medicines	1
Clopidogrel / Acetylsalicylic acid	Antithrombotic medicines	1

International non-proprietary name / Common Name	Therapeutic area [i]	Total number of applications
Dasatinib	Antineoplastic medicines	1
Deferasirox	Other therapeutic medicines	1
Dexmedetomidine	Psycholeptics	1
Doxorubicin	Antineoplastic medicines	2
Erlotinib	Antineoplastic medicines	1
Etanercept	Immunosuppressants	1
Fingolimod	Immunosuppressants	2
Insulin aspart	Medicines used in diabetes	1
Ioflupane (123I)	Diagnostic radiopharmaceuticals	1
Melphalan	Antineoplastic medicines	1
Methylthioninium chloride	Diagnostic medicines	1
Rituximab	Antineoplastic medicines	3
Teriparatide	Calcium homeostasis	3
Tigecycline	Antibacterials for systemic use	1
Trastuzumab	Antineoplastic medicines	2

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

Orphan medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Amikacin (sulfate)	Antibacterials for systemic use
Avapritinib*	Antineoplastic medicines
Crizanlizumab	Other hematological medicines
Deferiprone	Other therapeutic medicines
Diclofenamide	Ophthalmologicals
Emapalumab	Immunosuppressants
Enasidenib (mesilate)	Antineoplastic medicines
Fenfluramine	Antiepileptics

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area [i]
Gilteritinib (fumarate) [ii]	Antineoplastic medicines
Givosiran (sodium) [ii]	Other alimentary tract and metabolism products
Glasdegib (maleate)	Antineoplastic medicines
Idebenone (titanium dioxide)	Psychoanaleptics
Imlifidase	Immunosuppressants
Isatuximab	Antineoplastic medicines
Ivosidenib	Antineoplastic medicines
Luspatercept	Antianemic medicines
Obiltoxaximab	Immune sera and immunoglobulins
Onasemnogene abeparvovec [iv, v]	Other medicines for disorders of the musculo-skeletal system
Osilodrostat (phosphate)	Corticosteroids for systemic use
Pexidartinib (hydrochloride)	Antineoplastic medicines
Polatuzumab vedotin [ii]	Antineoplastic medicines
Pretomanid	Antimycobacterials
Quizartinib (dihydrochloride) [v]	Antineoplastic medicines
Selinexor [v]	Antineoplastic medicines
Tagraxofusp [v]	Antineoplastic medicines
Treprostinil (sodium)	Antithrombotic medicines
Viable T-cells [iv]	Antineoplastic and immunomodulating agents

[i] Based on the ATC therapeutic sub-group.
[ii] Application being reviewed under EMA's accelerated assessment programme.
[iii] N/A (Submitted according to legal basis: Informed consent application (Article 10c of Directive No 2001/83/EC)).
[iv] Medicine classified as advanced therapy medicinal product (ATMP)
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