



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use February 2020

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 **date 7 February 2020**.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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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 |
| Baloxavir marboxil | Antivirals for systemic use |
| Budesonide / glycopyrronium (bromide) / formoterol (fumarate dihydrate) | Medicines for obstructive airway diseases |
| Bupivacaine | Anesthetics |
| Bupivacaine / meloxicam | Anesthetics |
| Cabotegravir (sodium) | Antivirals for systemic use |
| Cefiderocol (sulfate tosilate) | Antibacterials for systemic use |
| Ebola vaccine (rDNA, replication-incompetent) ⁱⁱ | Vaccines |
| Entrectinib | Antineoplastic medicines |
| Filgotinib (maleate) | Immunosuppressants |
| Fluticasone (propionate) / Salmeterol (xinafoate) | Medicines for obstructive airway diseases |
| Fostemsavir ⁱⁱ | Antivirals for systemic use |
| Hepatitis B surface antigen | Vaccines |
| Icosapent (ethyl) | Lipid modifying medicines |
| Inclisiran | Lipid modifying medicines |
| Indacaterol (acetate) / glycopyrronium (bromide) / mometasone (furoate) | Medicines for obstructive airway diseases |
| Indacaterol (acetate) / mometasone (furoate) | Medicines for obstructive airway diseases |
| Influenza quadrivalent vaccine (rdna) | Vaccines |
| Influenza vaccine (surface antigen, inactivated) | Vaccines |
| Istradefylline | Anti-parkinson medicines |
| Lefamulin (acetate) | Antibacterials for systemic use |
| Lifitegrast | Ophthalmologicals |
| Meningococcal group A, C, W135 and Y conjugate vaccine | Vaccines |
| Netarsudil (mesilate) / latanoprost | Ophthalmologicals |
| Ofatumumab | Immunosuppressants |
| Ozanimod (hydrochloride) | Immunosuppressants |

| International non-proprietary name (salt, ester, derivative, etc.) / Common Name | Therapeutic area ⁱ |
|----------------------------------------------------------------------------------|---------------------------------|
| Pertuzumab / trastuzumab | Antineoplastic medicines |
| Plazomicin (sulfate) | Antibacterials for systemic use |
| Remimazolam (besilate) | Psycholeptics |
| Rilpivirine | Antivirals for systemic use |
| Selpercatinib | Antineoplastic medicines |
| Tucatinib | Antineoplastic medicines |

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 |
|--------------------------------------------------|---------------------------------|------------------------------|
| Abiraterone | Endocrine therapy | 1 |
| Apixaban | Antithrombotic medicines | 1 |
| Aripiprazole | Psycholeptics | 1 |
| Arsenic trioxide | Antineoplastic medicines | 1 |
| Azathioprine | Immunosuppressants | 1 |
| Bevacizumab | Antineoplastic medicines | 3 |
| Cabazitaxel | Antineoplastic medicines | 1 |
| Caffeine citrate | Psychoanaleptics | 1 |
| Dasatinib | Antineoplastic medicines | 2 |
| Doxorubicin | Antineoplastic medicines | 3 |
| Erlotinib | Antineoplastic medicines | 1 |
| Etanercept | Immunosuppressants | 1 |
| Fampridine | Other nervous system medicines | 1 |
| Fingolimod | Immunosuppressants | 2 |
| Glucagon | Pancreatic hormones | 1 |
| Insulin aspart | Medicines used in diabetes | 2 |
| Ioflupane (123I) | Diagnostic radiopharmaceuticals | 1 |

| International non-proprietary name / Common Name | Therapeutic area ⁱ | Total number of applications |
|--------------------------------------------------|---------------------------------|------------------------------|
| Lenalidomide | Immunosuppressants | 2 |
| Melphalan | Antineoplastic medicines | 1 |
| Methylthioninium chloride | Diagnostic medicines | 1 |
| Pegfilgrastim | Immunostimulants | 1 |
| Risperidone | Psycholeptics | 1 |
| Rituximab | Antineoplastic medicines | 2 |
| Rivaroxaban | Antithrombotic medicines | 1 |
| Sunitinib | Antineoplastic medicines | 1 |
| Teriparatide | Calcium homeostasis | 3 |
| Tigecycline | Antibacterials for systemic use | 1 |
| Trastuzumab | Antineoplastic medicines | 2 |

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} Medicine classified as advanced therapy medicinal product (ATMP)

^v Product no longer being reviewed under EMA's accelerated assessment programme

Orphan medicinal products

| International non-proprietary name (salt, ester, derivative, etc.) / Common Name | Therapeutic area ⁱ |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Acalabrutinib | Antineoplastic medicines |
| Amikacin (sulfate) | Antibacterials for systemic use |
| Autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex vivo using a lentiviral vector encoding the human arylsulfatase a gene ^{ii, iv} | Other nervous system medicines |
| Autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured ^{ii, iv} | Antineoplastic medicines |
| Avapritinib | Antineoplastic medicines |
| Belantamab mafodotin ⁱⁱ | Antineoplastic medicines |
| Bulevirtide (acetate) ⁱⁱ | Antivirals for systemic use |

| International non-proprietary name (salt, ester, derivative, etc.) / Common Name | Therapeutic area ⁱ |
|----------------------------------------------------------------------------------|--------------------------------------------------------------|
| Crizanlizumab | Other hematological medicines |
| Deferiprone | Other therapeutic medicines |
| Duvelisib | Antineoplastic medicines |
| Eladocagene exuparvec | Other nervous system medicines |
| Elexacaftor / tezacaftor / ivacaftor ^v | Other respiratory system medicines |
| Emapalumab | Immunosuppressants |
| Fedratinib | Antineoplastic medicines |
| Fenfluramine | Antiepileptics |
| Glasdegib (maleate) | Antineoplastic medicines |
| Idebenone (titanium dioxide) | Psychoanaleptics |
| Imlifidase | Immunosuppressants |
| Isatuximab | Antineoplastic medicines |
| Ivosidenib | Antineoplastic medicines |
| Luspatercept | Antianemic medicines |
| Moxetumomab pasudotox | Antineoplastic medicines |
| Obiltoxaximab | Immune sera and immunoglobulins |
| Onasemnogene abeparvec ^{iv} | Other medicines for disorders of the musculo-skeletal system |
| Pemigatinib | Antineoplastic medicines |
| Pexidartinib (hydrochloride) | Antineoplastic medicines |
| Potassium citrate / potassium hydrogen carbonate | Mineral supplements |
| Pretomanid | Antimycobacterials |
| Satralizumab | Immunosuppressants |
| Selinexor | Antineoplastic medicines |
| Somapacitan | Pituitary and hypothalamic hormones and analogues |
| Tagraxofusp | Antineoplastic medicines |
| Valoctocogene roxaparvec ^{ii, iv} | Antihemorrhagics |

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)

^v Product no longer being reviewed under EMA's accelerated assessment programme