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Information Management Division

## Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use June 2017

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 **1 June 2017**.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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>i</sup>
Abaloparatide	Calcium homeostasis
Andexanet alfa	Other therapeutic medicines
Atezolizumab	Antineoplastic medicines
Benralizumab	Medicines for obstructive airway diseases
Betrixaban	Antithrombotic medicines
Binimetinib	Antineoplastic medicines
Brexpiprazole	Psycholeptics
Brigatinib	Antineoplastic medicines
Ciclosporin	Ophthalmologicals
Cladribine	Antineoplastic medicines
Darunavir (ethanolate) / cobicistat / emtricitabine / tenofovir alafenamide (fumarate)	Antivirals for systemic use
D-biotin	Vitamins
Dengue tetravalent vaccine (live, attenuated)	Vaccines
Dupilumab	Immunosuppressants
Enclomifene (citrate)	Sex hormones and modulators of the genital system
Ertugliflozin (L-pyroglutamic acid)	Medicines used in diabetes
Ertugliflozin (L-pyroglutamic acid) / metformin (hydrochloride)	Medicines used in diabetes
Ertugliflozin (L-pyroglutamic acid) / sitagliptin (phosphate monohydrate)	Medicines used in diabetes
Etirinotecan pegol	Antineoplastic medicines
Fluticasone furoate / umeclidinium (bromide) / vilanterol (trifénatate)	Medicines for obstructive airway diseases
Glecaprevir / pibrentasvir <sup>ii</sup>	Antivirals for systemic use
Guselkumab	Immunosuppressants
Human fibrinogen / human thrombin	Antihemorrhagics
Human herpesvirus 3	Vaccines
Iloperidone	Psycholeptics
<b>Melatonin</b>	<b>Psycholeptics</b>
Naldemedine (tosilate)	Medicines for constipation
Neratinib	Antineoplastic medicines

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>i</sup>
Ocrelizumab	Immunosuppressants
Padeliporfin (di-potassium)	Antineoplastic medicines
Peramivir	Antivirals for systemic use
Prasterone	Sex hormones and modulators of the genital system
Ribociclib (succinate)	Antineoplastic medicines
Ruriococog alfa pegol	Antihemorrhagics
Semaglutide	Medicines used in diabetes
Sirukumab	Immunosuppressants
Sofosbuvir / velpatasvir / voxilaprevir <sup>ii</sup>	Antivirals for systemic use
Tildrakizumab	Immunosuppressants
Tivozanib (hydrochloride monohydrate)	Antineoplastic medicines

<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	4
Anagrelide	Antineoplastic medicines	1
Bevacizumab	Antineoplastic medicines	2
Buprenorphine / naloxone	Other nervous system medicines	1
Carmustine	Antineoplastic medicines	1
Darunavir	Antivirals for systemic use	1
<b>Doxorubicin</b>	<b>Antineoplastic medicines</b>	<b>1</b>
Efavirenz / emtricitabine / tenofovir disoproxil	Antivirals for systemic use	2
Entecavir	Antivirals for systemic use	2
Fulvestrant	Endocrine therapy	1
Hydrocortisone	Corticosteroids for systemic use	1
Imatinib	Antineoplastic medicines	1
<b>Infliximab</b>	<b>Immunosuppressants</b>	<b>1</b>
Insulin glargine	Medicines used in diabetes	1

International non-proprietary name / Common Name	Therapeutic area <sup>i</sup>	Total number of applications
Lacosamide	Antiepileptics	1
Miglustat	Other alimentary tract and metabolism products	1
Naloxone	Other therapeutic medicines	1
Nitisinone	Other alimentary tract and metabolism products	2
Pegfilgrastim	Immunostimulants	3
<b>Prasugrel</b>	<b>Antithrombotic medicines</b>	<b>1</b>
Ritonavir	Antivirals for systemic use	1
Rotigotine	Anti-parkinson medicines	1
Sufentanil	Anesthetics	1
Tacrolimus	Immunosuppressants	1
Tigecycline	Antibacterials for systemic use	1
Trastuzumab	Antineoplastic medicines	4

<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>
Alpha-1-antitrypsin	Antihemorrhagics
Avelumab	Antineoplastic medicines
Burosumab	Medicines for bone diseases
Caplacizumab	Antithrombotic medicines
Ciclosporin <sup>ii</sup>	Ophthalmologicals
Eteplirsen	Other medicines for disorders of the musculo-skeletal system
Expanded human allogeneic mesenchymal adult stem cells extracted from adipose tissue	Immunosuppressants
Gemtuzumab ozogamicin	Antineoplastic medicines
Glibenclamide <sup>ii</sup>	Medicines used in diabetes
Letermovir <sup>ii</sup>	Antivirals for systemic use
Levamisole (hydrochloride)	Anthelmintics
Lutetium (177Lu) dotatate	Therapeutic radiopharmaceuticals
Masitinib (mesylate)	Antineoplastic medicines

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>i</sup>
Metreleptin	Other alimentary tract and metabolism products
Midostaurin	Antineoplastic medicines
NGR-hTNF	Antineoplastic medicines
Niraparib (tosylate monohydrate)	Antineoplastic medicines
Paclitaxel	Antineoplastic medicines
Plitidepsin	Antineoplastic medicines
Ropeginterferon alfa-2b	Immunostimulants
Rucaparib (camsylate)	Antineoplastic medicines
Sodium benzoate	Other alimentary tract and metabolism products
Telotristat (etiprate)	Other alimentary tract and metabolism products
Velmanase alfa	Other alimentary tract and metabolism products
<b>Vestronidase alfa</b>	<b>Other alimentary tract and metabolism products</b>
<b>Viable T-cells</b>	<b>Antineoplastic and immunomodulating agents</b>

<sup>i</sup> Based on the ATC therapeutic sub-group.

<sup>ii</sup> Application being reviewed under EMA's accelerated assessment programme.