

7 February 2024  
EMA/58689/2024  
Human Medicines Division

## Applications for new human medicines under evaluation by the CHMP

### Data extracted 6 February 2024

This list with initial marketing authorisation applications for human medicines currently under evaluation by the Committee for Medicinal Products for Human Use (CHMP), includes the international non-proprietary names (INN) or common name, it includes active moiety only, with no information on salt, ester or derivative.

This list only includes information for medicines whose applications have been validated and evaluation started at the time the data was extracted. For generics, biosimilar and duplicates where there are several applications with the same substance there is a row per application.

Where the timetable changes from accelerated to standard timetable, the month and year of the switch to standard Time Table is included.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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

International non-proprietary name (INN) / Common Name	Substance type (classification)	Therapeutic area (ATC level 2)	Accelerated Assessment (Art. 14(9) Reg 726/2004)	Revert to standard Time Table (MM/YY)	Orphan Product	Generic, hybrid or Biosimilar	Start of evaluation
Acoramidis	Chemicals	Cardiac therapy	N		Y	N	01/02/2024
Aflibercept	Biologicals	Ophthalmologicals	N		N	Y	28/09/2023
Aflibercept	Biologicals	Ophthalmologicals	N		N	Y	23/11/2023
Aflibercept	Biologicals	Ophthalmologicals	N		N	Y	28/12/2023
Aflibercept	Biologicals	Ophthalmologicals	N		N	Y	28/12/2023
Amino acids	Chemicals	Blood substitutes and perfusion solutions	N		Y	N	28/09/2023
Apadamtase alfa / Cinaxadamtase alfa	Biologicals	Other hematological medicines	N		Y	N	18/05/2023
Apremilast	Chemicals	Immunosuppressants	N		N	Y	23/03/2023
Apremilast	Chemicals	Immunosuppressants	N		N	Y	26/10/2023

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Aprocitentan	Chemicals	Antihypertensives	N		N	N	23/02/2023
Aumolertinib	Chemicals	Antineoplastic medicines	N		N	N	01/12/2022
Autologous cartilage-derived articular chondrocytes, in-vitro expanded	ATMP	Other medicines for disorders of the musculo-skeletal system	N		N	N	28/12/2023
Avacincaptad pegol	Chemicals	Ophthalmologicals	N		N	N	17/08/2023
Axitinib	Chemicals	Antineoplastic medicines	N		N	Y	23/03/2023
Aztreonam / Avibactam	Chemicals	Antibacterials for systemic use	Y		N	N	14/09/2023
Belzutifan	Chemicals	Antineoplastic medicines	N		N	N	28/12/2023
Beremagene geperpavec	ATMP	Medicines for wounds and ulcers	N		Y	N	23/11/2023
Bevacizumab	Biologicals	Antineoplastic medicines	N		N	Y	24/12/2020
Bevacizumab	Biologicals	Ophthalmologicals	N		N	N	28/12/2022
Bimatoprost	Chemicals	Ophthalmologicals	N		N	N	23/03/2023
Buprenorphine	Chemicals	Other nervous system medicines	N		N	Y	23/02/2023
Capivasertib	Chemicals	Antineoplastic medicines	N		N	N	18/05/2023
Catumaxomab	Biologicals	Antineoplastic medicines	N		N	N	18/08/2022
Chikungunya vaccine, live, attenuated	Biologicals	Vaccines	Y		N	N	23/11/2023
Ciclosporin	Chemicals	Ophthalmologicals	N		N	N	17/08/2023
Clascoterone	Chemicals	Anti-acne medicines	N		N	N	26/10/2023
Concizumab	Biologicals	Antihemorrhagics	N		N	N	26/01/2023
COVID-19 mRNA vaccine	Chemicals	Vaccines	N		N	N	17/08/2023
Crovalimab	Biologicals	Immunosuppressants	N		N	N	13/07/2023
Dabigatran etexilate	Chemicals	Antithrombotic medicines	N		N	Y	24/03/2022
Danicopan	Chemicals	Immunosuppressants	N		Y	N	23/03/2023
Dantrolene	Chemicals	Muscle relaxants	N		Y	Y	14/07/2022
Dasatinib	Chemicals	Antineoplastic medicines	N		N	Y	18/05/2023
Dasiglucagon	Chemicals	Pancreatic hormones	N		N	N	13/07/2023
Delgocitinib	Chemicals	Other dermatological medicines	N		N	N	17/08/2023
Denosumab	Biologicals	Medicines for bone diseases	N		N	Y	18/05/2023
Denosumab	Biologicals	Medicines for bone diseases	N		N	Y	19/05/2023
Diflunisal	Chemicals	Analgesics	N		Y	N	01/02/2024

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Dimethyl fumarate	Chemicals	Immunosuppressants	N		N	Y	23/11/2023
Dimethyl fumarate	Chemicals	Immunosuppressants	N		N	Y	22/01/2024
Dimethyl fumarate	Chemicals	Immunosuppressants	N		N	Y	22/01/2024
Donanemab	Biologicals	Psychoanaleptics	N		N	N	17/08/2023
Dopamine	Chemicals	Cardiac therapy	N		N	Y	01/12/2022
Efanesoctocog alfa	Biologicals	Antihemorrhagics	N		Y	N	18/05/2023
Elafibranor	Chemicals	Bile and liver therapy	N		Y	N	26/10/2023
Eltrombopag	Chemicals	Antihemorrhagics	N		N	Y	28/12/2023
Enzalutamide	Chemicals	Endocrine therapy	N		N	Y	17/08/2023
Epinephrine	Chemicals	Cardiac therapy	N		N	N	27/10/2022
Eplontersen	Chemicals	Other nervous system medicines	N		Y	N	26/10/2023
Erdafitinib	Chemicals	Antineoplastic medicines	N		N	N	28/09/2023
Eribulin	Chemicals	Antineoplastic medicines	N		N	Y	18/05/2023
Fidanacogene elaparvovec	ATMP	Antihemorrhagics	N		N	N	18/05/2023
Filgrastim	Biologicals	Immunostimulants	N		N	Y	28/12/2023
Flortaucipir (18F)	Radiopharmaceuticals	Diagnostic radiopharmaceuticals	N		N	N	23/03/2023
Fruquintinib	Chemicals	Antineoplastic medicines	N		N	N	15/06/2023
Garadacimab	Biologicals	Other hematological medicines	N		Y	N	23/11/2023
Germanium (68Ge) chloride / Gallium (68Ga) chloride	Radiopharmaceuticals	Diagnostic radiopharmaceuticals	N		N	N	19/08/2021
Germanium (68Ge) chloride / Gallium (68Ga) chloride	Radiopharmaceuticals	Diagnostic radiopharmaceuticals	N		N	N	28/12/2022
Givinostat	Chemicals	Other medicines for disorders of the musculo-skeletal system	N		Y	N	17/08/2023
Govorestat	Chemicals	Other alimentary tract and metabolism products	N		Y	N	28/12/2023
Guanfacine	Chemicals	Antihypertensives	N		N	Y	26/10/2023
Imetelstat	Chemicals	Antineoplastic medicines	N		Y	N	28/09/2023
Insulin aspart	Biologicals	Medicines used in diabetes	N		N	Y	28/09/2023
Insulin glargine	Biologicals	Medicines used in diabetes	N		N	Y	17/08/2023
Insulin human	Biologicals	Medicines used in diabetes	N		N	Y	26/01/2023
Insulin icodex	Biologicals	Medicines used in diabetes	N		N	N	18/05/2023

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Insulin lispro	Biologicals	Medicines used in diabetes	N		N	Y	28/09/2023
Iptacopan	Chemicals	Immunosuppressants	N		Y	N	18/05/2023
Lazertinib	Chemicals	Antineoplastic medicines	N		N	N	01/02/2024
Lecanemab	Biologicals	Psychoanaleptics	N		N	N	26/01/2023
Leniolisib	Chemicals	Antineoplastic medicines	N	1/23	Y	N	27/10/2022
Levetiracetam	Chemicals	Antiepileptics	N		N	Y	13/07/2023
Linvoseltamab	Biologicals	Antineoplastic medicines	N		N	N	01/02/2024
Liquid ethanolic extract 30 per cent (W/W) of Allium cepa fresh bulb and Citrus limon fresh fruit / Dry aqueous extract of paullinia cupana seed / Dry	Biologicals	Other dermatological medicines	N		N	N	15/06/2023
Lutetium (177Lu) chloride	Radiopharmaceuticals	Therapeutic radiopharmaceuticals	N		N	N	17/08/2023
Macitentan / Tadalafil	Chemicals	Antihypertensives	N		N	N	13/07/2023
Marstacimab	Biologicals	Antihemorrhagics	N		Y	N	26/10/2023
Masitinib	Chemicals	Antineoplastic medicines	N		Y	N	18/08/2022
Meningococcal groups A, B, C, W and Y vaccine	Biologicals	Vaccines	N		N	N	15/06/2023
Methylphenidate	Chemicals	Psychoanaleptics	N		N	Y	23/02/2023
Mirvetuximab soravtansine	Biologicals	Antineoplastic medicines	N		Y	N	26/10/2023
Nemolizumab	Biologicals	Other dermatological medicines	N		N	N	01/02/2024
Nilotinib	Chemicals	Antineoplastic medicines	N		N	Y	13/07/2023
Nintedanib	Chemicals	Antineoplastic medicines	N		N	Y	28/12/2022
Odevixibat	Chemicals	Bile and liver therapy	N		N	N	28/12/2023
Odronextamab	Biologicals	Antineoplastic medicines	N		Y	N	17/08/2023
Omalizumab	Biologicals	Medicines for obstructive airway diseases	N		N	Y	18/05/2023
Omecamtiv mecarbil	Chemicals	Cardiac therapy	N		N	N	28/12/2022
Paclitaxel	Chemicals	Antineoplastic medicines	N		N	Y	20/01/2022
Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	Biologicals	Vaccines	N		N	N	28/12/2022
Pegfilgrastim	Biologicals	Immunostimulants	N		N	Y	01/02/2024
Polihexanide	Chemicals	Ophthalmologicals	N		Y	N	19/05/2022

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Pomalidomide	Chemicals	Immunosuppressants	N		N	Y	28/09/2023
Pomalidomide	Chemicals	Immunosuppressants	N		N	Y	28/09/2023
Pomalidomide	Chemicals	Immunosuppressants	N		N	Y	28/09/2023
Pomalidomide	Chemicals	Immunosuppressants	N		N	Y	28/09/2023
RdESAT-6 / rCFP-10	Biologicals	Diagnostic medicines	N		N	N	23/02/2023
Repotrectinib	Chemicals	Antineoplastic medicines	N		N	N	28/12/2023
Respiratory syncytial virus mRNA vaccine (nucleoside modified)	Biologicals	Vaccines	N		N	N	13/07/2023
Retifanlimab	Biologicals	Antineoplastic medicines	N		Y	N	23/03/2023
Rituximab	Biologicals	Antineoplastic medicines	N		N	Y	18/05/2023
Serplulimab	Biologicals	Antineoplastic medicines	N		Y	N	23/03/2023
Sotatercept	Biologicals	Cardiac therapy	N	1/24	Y	N	26/10/2023
Sparsentan	Chemicals	Other therapeutic medicines	N		Y	N	18/08/2022
Sugemalimab	Biologicals	Antineoplastic medicines	N		N	N	23/02/2023
Temozolomide	Chemicals	Antineoplastic medicines	N		Y	Y	17/08/2023
Teriparatide	Biologicals	Calcium homeostasis	N		N	Y	13/07/2023
Tiratricol	Chemicals	Thyroid therapy	N		Y	Y	26/10/2023
Tislelizumab	Biologicals	Antineoplastic medicines	N		N	N	24/03/2022
Tisotumab vedotin	Biologicals	Antineoplastic medicines	N		N	N	01/02/2024
Tocilizumab	Biologicals	Immunosuppressants	N		N	Y	29/09/2022
Tofersen	Chemicals	Other nervous system medicines	N		Y	N	01/12/2022
Toripalimab	Biologicals	Antineoplastic medicines	N		N	N	01/12/2022
Trabectedin	Chemicals	Antineoplastic medicines	N		N	Y	01/02/2024
Trastuzumab	Biologicals	Antineoplastic medicines	N		N	Y	17/08/2023
Trastuzumab	Biologicals	Antineoplastic medicines	N		N	Y	01/02/2024
Troriluzole	Chemicals	Other nervous system medicines	N		Y	N	26/10/2023
Ustekinumab	Biologicals	Immunosuppressants	N		N	Y	18/05/2023
Ustekinumab	Biologicals	Immunosuppressants	N		N	Y	18/05/2023
Ustekinumab	Biologicals	Immunosuppressants	N		N	Y	15/06/2023
Ustekinumab	Biologicals	Immunosuppressants	N		N	Y	13/07/2023
Ustekinumab	Biologicals	Immunosuppressants	N		N	Y	15/08/2023

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Ustekinumab	Biologicals	Immunosuppressants	N		N	Y	28/09/2023
Vibegron	Chemicals	Urologicals	N		N	N	18/05/2023
Vilobelimab	Biologicals	Immunosuppressants	N		N	N	17/08/2023
Vorasidenib	Chemicals	Antineoplastic medicines	Y		Y	N	25/01/2024
Zolbetuximab	Biologicals	Antineoplastic medicines	N		Y	N	13/07/2023
Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted,	Biologicals	Vaccines	N		N	N	28/12/2022