

22 July 2022
EMA/245297/2013 Rev. 102*
Human Medicines Division

List of medicinal products under additional monitoring

Related Information:

[Additional monitoring explained:](https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/medicines-under-additional-monitoring)
<https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/medicines-under-additional-monitoring>

[Good Pharmacovigilance Practice Module on additional monitoring:](https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/good-pharmacovigilance-practices)
<https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/good-pharmacovigilance-practices>

For the UK, as from 1st January 2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI

To note: All products added to the list in July 2022 are shown in red font. All products removed from the list are shown with a strikethrough for the period of one month after which they are excluded. For products newly added to the list, EMA will update the 'Product details' section of the medicine page on EMA's corporate website when it publishes the revised summary of product characteristics.

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Abevmy	bevacizumab	New biological	Mylan IRE Healthcare Limited	https://www.ema.europa.eu/en/documents/product-information/abevmy-epar-product-information_en.pdf	May/21
Abecma	idecabtagene vicleucel	New biological, new active substance, conditional marketing authorisation, PASS ¹	Bristol-Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/abecma-epar-product-information_en.pdf	September 2021
Adakveo	crizanlizumab	New biological, new active substance, conditional marketing authorisation	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/adakveo-epar-product-information_en.pdf	November 2020
Adcetris	Brentuximab vedotin	Conditional marketing authorisation	Takeda Pharma A/S	https://www.ema.europa.eu/en/documents/product-information/adcetris-epar-product-information_en.pdf	April 2013
Adynovi	Rurioctocog alfa pegol	New active substance and <i>new biological</i> , PASS ¹	Baxalta Innovations GmbH	https://www.ema.europa.eu/en/documents/product-information/adynovi-epar-product-information_en.pdf	January 2018
Adtralza	tralokinumab	New active substance and <i>new biological</i>	Leo Pharma A/S	https://www.ema.europa.eu/en/documents/product-information/adtralza-epar-product-information_en.pdf	Jun/21
Afluria Tetra	Influenza vaccine (split virion, inactivated)	New biological	Seqirus Netherlands B.V.	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdidentifier=2613962	September 2020
Aimovig	Erenumab	New active substance and <i>new biological</i>	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/aimovig-epar-product-information_en.pdf	September 2018
AJOVY	Fremanezumab	New active substance and new biological	Teva GmbH	https://www.ema.europa.eu/en/documents/product-information/ajovy-epar-product-information_en.pdf	April 2019
Aklief	trifarotene	New active substance	Galderma Nordic AB	http://mri.cts-mrp.eu/Human/Product/Details/58971	December 2021
Alecensa	Alectinib	New active substance	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/alecensa-epar-product-information_en.pdf	March 2017
Alofisel	Darvadstrocel	New active substance and new biological	Takeda Pharma A/S	https://www.ema.europa.eu/en/documents/product-information/alofisel-epar-product-information_en.pdf	April 2018
Alunbrig	Brigatinib	New active substance	Takeda Pharma A/S	https://www.ema.europa.eu/documents/product-information/alunbrig-epar-product-information_en.pdf	December 2018
Alymsys	bevacizumab	New biological	Mabxience Research SL	https://www.ema.europa.eu/en/documents/product-information/alymsys-epar-product-information_en.pdf	Apr/21
Amsparity	Adalimumab	New biological	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/amsparity-epar-product-information_en.pdf	February 2020
Anoro Ellipta	Umeclidinium bromide/vilanterol trifenate	PASS ¹	GlaxoSmithKline (Ireland) Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002751/human_med_001754.jsp&mid=WC0b01ac058001d124	June 2014

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Apexxnar	pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)	New biological	☐ Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/apexxnar-epar-product-information_en.pdf	March 2022
Artesunate Amivas	artesianate	New active substance	Amivas Ireland Ltd	https://www.ema.europa.eu/en/documents/product-information/artesianate-amivas-epar-product-information_en.pdf	Dec/21
Aspaveli	pegcetacoplan	New active substance	☐ Swedish Orphan Biovitrum AB (publ)	https://www.ema.europa.eu/en/documents/product-information/aspaveli-epar-product-information_en.pdf	January 2022
Atgam	anti-human T-lymphocyte immunoglobulin	New biological	Pfizer Pharma GmbH	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdidentifier=2613975	March 2022
Atriance	Nelarabine	Authorised under exceptional circumstances	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000752/human_med_000656.jsp&mid=WC0b01ac058001d124	April 2013
Aybintio	bevacizumab	New biological	Samsung Bioepis NL B.V.	https://www.ema.europa.eu/en/documents/product-information/aybintio-epar-product-information_en.pdf	August 2020
AYVAKYT	avapritinib	New active substance, conditional marketing authorisation	Blueprint Medicines (Netherlands) B.V.	https://www.ema.europa.eu/en/documents/product-information/ayvakyt-epar-product-information_en.pdf	September 2020
Bavencio	Avelumab	New active substance and <i>new biological</i> ,	Merck Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004338/human_med_002157.jsp&mid=WC0b01ac058001d124	September 2017
Benlysta	Belimumab	PASS ¹	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002015/human_med_001466.jsp&mid=WC0b01ac058001d124	April 2013
Beovu	Brolucizumab	New active substance and <i>new biological</i>	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/beovu-epar-product-information_en.pdf	February 2020
Besremi	Ropeginterferon alfa-2b	New active substance and new biological	AOP Orphan Pharmaceuticals AG	https://www.ema.europa.eu/en/documents/product-information/besremi-epar-product-information_en.pdf	February 2019
Biktarvy	Bictegravir / emtricitabine / tenofovir alafenamide	New active substance	Gilead Sciences Ireland UC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004449/human_med_002263.jsp&mid=WC0b01ac058001d124	July 2018
Bimzelx	bimekizumab	New active substance and new biological	UCB Pharma S.A.	https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf	Sep/21
BioThrax (also known as BaciThrax in France)	Anthrax antigen filtrate	New biological	Emergent Sales and Marketing Germany GmbH	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdidentifier=2604178	June 2018
BLNREP	belantamab mafodotin	New active substance, New biological, Conditional marketing authorisation	GlaxoSmithKline (Ireland) Limited	https://www.ema.europa.eu/en/documents/product-information/blnrep-epar-product-information_en.pdf	August 2020
Blinicyto	Blinatumomab	PASS ¹	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003731/human_med_001921.jsp&mid=WC0b01ac058001d124	December 2015
Bylvay	Odevixibat	New active substance, authorised under exceptional circumstances	Albireo AB	https://www.ema.europa.eu/en/documents/product-information/bylvay-epar-product-information_en.pdf	July 2021
Braftovi	Encorafenib	New active substance	Pierre Fabre Medicament	https://www.ema.europa.eu/documents/product-information/braftovi-epar-product-information_en.pdf	October 2018
Bretaris Genuair	Aclidinium bromide	PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002706/human_med_001570.jsp&mid=WC0b01ac058001d124	April 2013
Breyanzi	lisocabtagene maraleucel	New biological, new active substance, PASS ¹	Bristol Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/breyanzi-epar-product-information_en.pdf	Apr/22
Brimica Genuair	Aclidinium bromide/formoterol fumarate dihydrate	PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003969/human_med_001806.jsp&mid=WC0b01ac058001d124	December 2014
Brineura	Cerliponase alfa	authorised under exceptional circumstances, PASS ¹	BioMarin International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004065/human_med_002111.jsp&mid=WC0b01ac058001d124	June 2017
Brukinsa	zanubrutinib	New active substance	BeiGene Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/brukinsa-epar-product-information_en.pdf	Dec/21
Byfavo	remimazolam	New active substance	PAION Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/byfavo-epar-product-information_en.pdf	April 2021
Cablivi	Caplacizumab	New active substance <i>and new biological</i>	Ablynx N.V.	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004426/WC500255071.pdf	September 2018
Calquence	acalabrutinib	New active substance	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/calquence-epar-product-information_en.pdf	November 2020

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Caprelsa	Vandetanib	Conditional authorisation	Genzyme Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002315/human_med_001529.jsp&mid=WC0b01ac058001d124	April 2013
CARVYKTI	ciltacabtagene autoleucl	New active substance, new biological and conditional marketing authorisation	Janssen-Cilag International NV	Not available	June 2022
Cegfila (previously Pegfilgrastim Mundipharma)	Pegfilgrastim	New biological	Mundipharma Corporation (Ireland) Limited	https://www.ema.europa.eu/documents/product-information/cegfila-epar-product-information_en.pdf	January 2020
Ceplene	Histamine dihydrochloride	Authorised under exceptional circumstances	Noventia Pharma Srl	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000796/human_med_000691.jsp&mid=WC0b01ac058001d124	April 2013
Cerdelga	Eliglustat	PASS ¹	Genzyme Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003724/human_med_001840.jsp&mid=WC0b01ac058001d124	February 2015
Chenodeoxycholic acid Leadiant (previously known as Chenodeoxycholic acid sigma-tau)	Chenodeoxycholic acid	Authorised under exceptional circumstances	Leadiant GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004061/human_med_002019.jsp&mid=WC0b01ac058001d124	April 2017
Choriongonadotrophin Genevrier	chorionic gonadotropin	New biological	Laboratoires Génévrier	N/A	January 2022
Cibinqo	abrocitinib	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/cibinqo-epar-product-information_en.pdf	January 2022
Cidofovir 75 mg/ml Concentrate for Solution for Infusion	Cidofovir	PASS ¹	Emcure Pharma UK Limited	http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1466141046287.pdf	May 2016
Cinryze	c1 inhibitor, human	PASS ¹	Takeda Manufacturing Austria AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001207/human_med_001448.jsp&mid=WC0b01ac058001d124	April 2013
Colevance <u>Combined hormonal contraceptives containing chlormadinone (For full list of products see Annex IX)</u>	enoxaparin sodium Chlormadinone Ethinylestradiol, Chlormadinone Acetate Ethinylestradiol	New biological PASS ¹	Venipharm Various (For full list see Annex IX)	N/A http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Combined_hormonal_contraceptives/human_referral_prac_000016.jsp&mid=WC0b01ac05805c516f	January 2022 June 2014
Comirnaty	COVID-19 mRNA Vaccine (nucleoside modified)	Conditional marketing authorisation / New active substance and new biological	BioNTech Manufacturing GmbH	https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf	Jan/21
Copiktra	duvelisib	New active substance	Secura Bio Limited	https://www.ema.europa.eu/en/documents/product-information/copiktra-epar-product-information_en.pdf	Jun/21
COVID-19 Vaccine Janssen COVID-19 Vaccine (inactivated, adjuvanted) Valneva	COVID-19 vaccine (Ad26.COV2-S [recombinant]) COVID-19 vaccine (inactivated, adjuvanted, adsorbed)	Conditional marketing authorisation / New active substance, /new biological New active substance and new biological	Janssen-Cilag International NV Valneva Austria GmbH	https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-inactivated-adjuvanted-valneva-epar-product-information_en.pdf	Mar/21 July 2022
CRYSVITA	Burosumab	New active substance, new biological and conditional authorisation	Kyowa Kirin Holdings B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004275/human_med_002224.jsp&mid=WC0b01ac058001d124	March 2018
Cutaquig <u>Cyproterone acetate and Ethinylestradiol containing medicinal products (For full list of products see Annex I)</u>	Human normal immunoglobulin Cyproterone acetate and Ethinylestradiol	New Biological PASS ¹	Octapharma GmbH Various (For full list see Annex I)	https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdidentifier=2613853 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cyproterone_and_ethinylestradiol-containing_medicines/human_referral_prac_000017.jsp&mid=WC0b01ac05805c516f	March 2019 August 2013
Daurismo	Glasdegib	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/daurismo-epar-product-information_en.pdf	July 2020
Daxas	Roflumilast	PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001179/human_med_001363.jsp&mid=WC0b01ac058001d124	June 2013
Dectova	Zanamivir	Authorised under exceptional circumstances	GlaxoSmithKline Trading Services Limited	https://www.ema.europa.eu/en/documents/product-information/dectova-epar-product-information_en.pdf	May 2019
Defitelio	Defibrotide	Authorised under exceptional circumstances	Gentium S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002393/human_med_001646.jsp&mid=WC0b01ac058001d124	November 2013
Delstrigo	Doravirine / Lamivudine / Tenofovir disoproxil	New active substance	Merck Sharp & Dohme B.V.	https://www.ema.europa.eu/documents/product-information/delstrigo-epar-product-information_en.pdf	December 2018
Deltyba	Delamanid	Conditional authorisation	Otsuka Novel Products GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002552/human_med_001699.jsp&mid=WC0b01ac058001d124	May 2014
Dengvaxia	Dengue tetravalent vaccine (live, attenuated)	New active substance and <i>new biological</i>	Sanofi Pasteur	https://www.ema.europa.eu/documents/product-information/dengvaxia-epar-product-information_en.pdf	January 2019

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Doptelet	Avatrombopag	New active substance	Swedish Orphan Biovitrum AB (publ)	https://www.ema.europa.eu/en/documents/product-information/doptelet-epar-product-information_en.pdf	June 2019
Duaklir Genuair	Acridinium bromide/formoterol fumarate dihydrate	PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003745/human_med_001811.jsp&mid=WC0b01ac058001d124	December 2014
Dupixent	Dupilumab	New active substance and <i>new biological</i>	Sanofi-Aventis groupe	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004390/human_med_002158.jsp&mid=WC0b01ac058001d124	October 2017
Drovelis	drosiprenone/estetrol	New active substance	Gedeon Richter Plc.	https://www.ema.europa.eu/en/documents/product-information/drovelis-epar-product-information_en.pdf	June 2021
Eklira Genuair	Acridinium bromide	PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002211/human_med_001571.jsp&mid=WC0b01ac058001d124	April 2013
Elaprase	Idursulfase	Authorised under exceptional circumstances	Takeda Pharmaceuticals International AG Ireland Branch	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000700/human_med_000757.jsp&mid=WC0b01ac058001d124 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004781/human_med_002182.jsp&mid=WC0b01ac058001d124	April 2013
Elebrato-Eliipta	Fluticasone furoate/umeclidinium/vilanterol	New active substance	GlaxoSmithKline Trading Services Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004781/human_med_002182.jsp&mid=WC0b01ac058001d124	May 2018
Efluelda	Quadrivalent Influenza Vaccine (Split Virion, Inactivated)	New biological	Sanofi Pasteur	https://cima.aemps.es/cima/dochtml/ft/85068/FT_85068.html	February 2021
ELZONRIS	tagraxofusp	New active substance and new biological, Authorised under exceptional circumstances	Stemline Therapeutics B.V.	https://www.ema.europa.eu/en/documents/product-information/elzonris-epar-product-information_en.pdf	January 2021
Emgality	Galcanezumab	New active substance and <i>new biological</i>	Eli Lilly Netherland B.V.	https://www.ema.europa.eu/documents/product-information/emgality-epar-product-information_en.pdf	November 2018
Enhertu	trastuzumab deruxtecan	New biological, new active substance, conditional marketing authorisation	Daiichi Sankyo Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/enhertu-epar-product-information_en.pdf	January 2021
Enspryng Enoxaparin Becat (also known in some EU countries as Losima, Enoxaparin Rovi, Crusia and Arovi)	satralizumab Enoxaparin sodium	New active substance, new biological New biological	Roche Registration GmbH Laboartorios Farmacéuticos Rovi, S.A.	https://www.ema.europa.eu/en/documents/product-information/enspryng-epar-product-information_en.pdf http://mri.cts-mrp.eu/Human/Product/Details/50005	July 2021 November 2018
Erleada	Apalutamide	New active substance	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/erleada-epar-product-information_en.pdf	January 2019
Ervebo	Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)	New active substance, new biological	Merck Sharp & Dohme B.V.	https://www.ema.europa.eu/en/documents/product-information/ervebo-epar-product-information_en.pdf	November 2019
Esperoct	Turoctocog alfa pegol	New active substance, new biological, PASS ¹	Novo Nordisk A/S	https://www.ema.europa.eu/documents/product-information/esperoct-epar-product-information_en.pdf	June 2019
Evkeeza	evinacumab	New active substance, new biological, PASS ¹ , authorised under exceptional circumstances	Ultragenyx Germany GmbH	https://www.ema.europa.eu/en/documents/product-information/evkeeza-epar-product-information_en.pdf	July 2021
Evrenzo	roxadustat	New active substance	Astellas Pharma Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/evrenzo-epar-product-information_en.pdf	September 2021
Evrysdi	risdiplam	New active substance, conditional marketing authorisation	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/evrysdi-epar-product-information_en.pdf	April 2021
Evenity	Romosozumab	New active substance, new biological	UCB Pharma S.A.	https://www.ema.europa.eu/en/documents/product-information/evenity-epar-product-information_en.pdf	January 2020
Evoltra	Clofarabine	Authorised under exceptional circumstances	Genzyme Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000613/human_med_000773.jsp&mid=WC0b01ac058001d124	April 2013
Evusheld	tixagevimab, cilgavimab	New active substance, new biological	☐ AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/evusheld-epar-product-information_en.pdf	March 2022
Exjade	Deferasirox	PASS ¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000670/human_med_000780.jsp&mid=WC0b01ac058001d124	April 2013
Fasenra	Benralizumab	New active substance and <i>new biological</i>	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004433/human_med_002207.jsp&mid=WC0b01ac058001d124	January 2018
Fetcroja	Cefiderocol	New active substance	Shionogi B.V.	https://www.ema.europa.eu/en/documents/product-information/fetcroja-epar-product-information_en.pdf	May 2020
Fintepla	fenfluramine	PASS ¹	Zogenix ROI Limited	https://www.ema.europa.eu/en/documents/product-information/fintepla-epar-product-information_en.pdf	January 2021

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Firdapse	Amifampridine	Authorised under exceptional circumstances	BioMarin Europe Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001032/human_med_001298.jsp&mid=WC0b01ac058001d124	April 2013
Fluad Tetra	Influenza vaccine (surface antigen, inactivated, adjuvanted)	New biological	Seqirus Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/fluad-tetra-epar-product-information_en.pdf	June 2020
Flucelvax Tetra	Influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	New biological	Seqirus Netherlands B.V.	https://www.ema.europa.eu/documents/product-information/flucelvax-tetra-epar-product-information_en.pdf	January 2019
Fotivda	Tivozanib	New active substance	EUSA Pharma (Netherlands) B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004131/human_med_002146.jsp&mid=WC0b01ac058001d124	September 2017
Fulphila	Pegfilgrastim	New biological	Viatriis Limited	https://www.ema.europa.eu/documents/product-information/fulphila-epar-product-information_en.pdf	November 2018
Gavreto	Pralsetinib	New active substance and under conditional marketing authorisation	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/gavreto-epar-product-information_en.pdf	November 2021
Giapreza	Angiotensin II acetate	New active substance	PAION Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/giapreza-epar-product-information_en.pdf	September 2019
Givlaari	Givosiran	New active substance	Alnylam Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/givlaari-epar-product-information_en.pdf	March 2020
Glivec	Imatinib	PASS ¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000406/human_med_000808.jsp&mid=WC0b01ac058001d124	September 2014
Grasustek	Pegfilgrastim	New biological	Juta Pharma GmbH	https://www.ema.europa.eu/en/documents/product-information/grasustek-epar-product-information_en.pdf	July 2019
Halimatoz	Adalimumab	New biological	Sandoz GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004866/human_med_002266.jsp&mid=WC0b01ac058001d124	September 2018
Hefiya	Adalimumab	New biological	Sandoz GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004865/human_med_002267.jsp&mid=WC0b01ac058001d124	September 2018
Hemlibra	Emicizumab	New active substance and <i>new biological</i>	Roche Registration GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004406/human_med_002236.jsp&mid=WC0b01ac058001d124	March 2018
Herzuma	Trastuzumab	New biological	Celltrion Healthcare Hungary Kft.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002575/human_med_002230.jsp&mid=WC0b01ac058001d124	February 2018
Hepaxane	Enoxaparin sodium	New biological	Chemi S.P.A	Not available	November 2018
Hepcludex	bulevirtide	new active substance, conditional MA	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/hepcludex-epar-product-information_en.pdf	August 2020
Hepplisav B	hepatitis B surface antigen	New biological	Dynavax GmbH	https://www.ema.europa.eu/en/documents/assessment-report/heplisav-b-epar-public-assessment-report_en.pdf	March 2021
Holoclar	Ex vivo expanded autologous human corneal epithelial cells containing stem cells	Conditional marketing authorisation	Chiesi Farmaceutici S.P.A., Italy	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002450/human_med_001844.jsp&mid=WC0b01ac058001d124	March 2015
Hukyndra	Adalimumab	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/hukyndra-epar-product-information_en.pdf	November 2021
Hulio	Adalimumab	New biological	Viatriis Limited	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004429/WC500255749.pdf http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Hydroxyethyl_starch-containing_medicines/human_referral_prac_000029.jsp&mid=WC0b01ac05805c516f	September 2018
<u>Hydroxyethyl starch (HES)-containing medicinal products (For full list see Annex V)</u>	Hydroxyethyl starch	PASS ¹	Various (For full list see Annex V)		January 2014
HyQvia	Human normal immunoglobulin	PASS ¹	Baxalta Innovations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002491/human_med_001647.jsp&mid=WC0b01ac058001d124	September 2013
Hyrimoz	Adalimumab	New biological	Sandoz GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004320/human_med_002268.jsp&mid=WC0b01ac058001d124	September 2018
Idacio	Adalimumab	New biological	Fresenius Kabi Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/idacio-epar-product-information_en.pdf	April 2019
Idefirix	imlifidase	New biological	Hansa Biopharma AB	https://www.ema.europa.eu/en/documents/product-information/idefirix-epar-product-information_en.pdf http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004514/smops/Positive/human_smop_001325.jsp&mid=WC0b01ac058001d127&source=homeMedSearch&category=human	Sep/20
Ilumetri	Tildrakizumab	New active substance and <i>new biological</i>	Almirall S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004514/smops/Positive/human_smop_001325.jsp&mid=WC0b01ac058001d127&source=homeMedSearch&category=human	September 2018

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Imcivree	Setmelanotide	New active substance	Rhythm Pharmaceuticals Netherlands B.V	https://www.ema.europa.eu/en/documents/product-information/imcivree-epar-product-information_en.pdf	July 2021
Imfinzi	Durvalumab	New active substance and <i>new biological</i>	AstraZeneca AB	https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/medicines-under-additional-monitoring/list-medicines-under-additional-monitoring	October 2018
Imnovid (formerly Pomalidomide Celgene)	Pomalidomide smallpox vaccine (Live Modified Vaccinia Virus Ankara)	PASS ¹	Celgene Europe Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002682/human_med_001669.jsp&mid=WC0b01ac058001d124	September 2013
Imvanex	smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara)	Authorised under exceptional circumstances	Bavarian Nordic A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002596/human_med_001666.jsp&mid=WC0b01ac058001d124	September 2013
Increlex	Mecasermin	Authorised under exceptional circumstances	Ipsen Pharma	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000704/human_med_000829.jsp&mid=WC0b01ac058001d124	April 2013
Incruse Ellipta	Umeclidinium bromide	PASS ¹	GlaxoSmithKlein (Ireland) Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002809/human_med_001755.jsp&mid=WC0b01ac058001d124	May 2014
Inpremia	insulin human (rDNA)	New biological	Baxter Holding B.V.	https://www.ema.europa.eu/en/documents/product-information/inpremia-epar-product-information_en.pdf	May/22
Inrebic	fedratinib	New active substance	Bristol-Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/inrebic-epar-product-information_en.pdf	February 2021
Insulin aspart Sanofi	Insulin aspart	New biological	Sanofi-Aventis groupe	https://www.ema.europa.eu/en/documents/product-information/insulin-lispro-sanofi-epar-product-information_en.pdf	July 2020
Intrarosa	Prasterone	PASS ¹	Endoceutics Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004138/human_med_002210.jsp&mid=WC0b01ac058001d124	February 2018
Intuniv	Guanfacine	PASS ¹	Takeda Pharmaceuticals International AG Ireland Branch	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003759/human_med_001910.jsp&mid=WC0b01ac058001d124	September 2015
Iqymune	Human normal immunoglobulin	New biological	Laboratoire Francais du Fractionnement et des Biotechnologies	https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdidentifier=2613314	September 2016
Isturisa	Osilodrostat	New active substance	Recordati Rare Diseases	https://www.ema.europa.eu/en/documents/product-information/isturisa-epar-product-information_en.pdf	January 2020
Itulazax	Standardised allergen extract from birch	New biological	ALK-Abelló A/S	https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdidentifier=2613926	September 2019
Jaydess (also known in some EU countries as Fleree)	Levonorgestrel	PASS ¹	Bayer AB	https://docetp.mpa.se/LMF/Jaydess%20intrauterine%20delivery%20system%20ENG%20SmPC.doc	November 2013
JEMPERLI	dostarlimab	New active substance, new biological, conditional marketing authorisation	GlaxoSmithKline (Ireland) Limited	https://www.ema.europa.eu/en/documents/product-information/jemperli-epar-product-information_en.pdf	May 2021
Jinarc	Tolvaptan	PASS ¹	Otsuka Pharmaceutical Europe Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002788/human_med_001857.jsp&mid=WC0b01ac058001d124	June 2015
Jivi	Damoctocog alfa pegol	New active substance, new biological, PASS	Bayer AG	https://www.ema.europa.eu/documents/product-information/jivi-epar-product-information_en.pdf	December 2018
Jyseleca	filgotinib	New active substance	Galapagos NV	https://www.ema.europa.eu/en/documents/product-information/jyseleca-epar-product-information_en.pdf	October 2020
Juluca	Dolutegravir / rilpivirine	New active substance	ViiV Healthcare UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004427/human_med_002254.jsp&mid=WC0b01ac058001d124	May 2018
Kaftrio	ivacaftor / tezacaftor / elexacaftor	New active substance	Vertex Pharmaceuticals (Ireland) Limited	https://www.ema.europa.eu/en/documents/product-information/kaftrio-epar-product-information_en.pdf	August 2020
Kanjinti	Trastuzumab	New biological	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004361/human_med_002255.jsp&mid=WC0b01ac058001d124	May 2018
Kanuma	Sebelipase alfa	PASS ¹	Alexion Europe SAS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004004/human_med_001896.jsp&mid=WC0b01ac058001d124	September 2015
Kapruvia	difelikefalin	New active substance	Vifor Fresenius Medical Care Renal Pharma France	https://www.ema.europa.eu/en/documents/product-information/kapruvia-epar-product-information_en.pdf	May/22
Kerendia	finerenone	New active substance	Bayer AG	https://www.ema.europa.eu/en/documents/product-information/kerendia-epar-product-information_en.pdf	March 2022
Kesimpta	ofatumumab	New biological	Novartis Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/kesimpta-epar-product-information_en.pdf	April 2021

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Ketoconazole HRA	Ketoconazole	PASS ¹	BRA Pharma Rare Diseases	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003906/human_med_001814.jsp&mid=WC0b01ac058001d124	December 2014
Kinpeygo	budesonide	Conditional marketing authorisation	Calliditas Therapeutics AB	https://www.ema.europa.eu/en/documents/product-information/kinpeygo-epar-product-information_en.pdf	July 2022
KIMMTRAK	tebentafusp	New active substance and <i>new biological</i>	Immunocore Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/kimmtrak-epar-product-information_en.pdf	Apr/22
Kixelle	Insulin aspart	New biological	Mylan IRE Healthcare Limited	https://www.ema.europa.eu/en/documents/product-information/kirsty-epar-product-information_en.pdf	February 2021
Klisyri	Tirbanibulin	New active substance, PASS ¹	Almirall, S.A.	https://www.ema.europa.eu/en/documents/product-information/klisyri-epar-product-information_en.pdf	July 2021
Koselugo	selumetinib	New active substance, conditional marketing authorisation, PASS ¹	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/koselugo-epar-product-information_en.pdf	June 2021
Kymriah	Tisagenlecleucel	New active substance, new biological, PASS	Novartis Europharm Limited	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004090/WC500255529.pdf	September 2018
Lamzede	Velmanase alfa	New active substance, new biological, authorised under exceptional circumstances	Chiesi Farmaceutici S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003922/human_med_002231.jsp&mid=WC0b01ac058001d124	April 2018
Laventair Ellipta	Umeclidinium bromide/vilanterol trifenate	PASS ¹	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003754/human_med_001756.jsp&mid=WC0b01ac058001d124	June 2014
Ledraxen	Enoxaparin sodium	New biological	Venipharm	Not available	February 2019
Lemtrada	Alemtuzumab	PASS ¹	Sanofi Belgium	https://www.ema.europa.eu/en/documents/product-information/lemtrada-epar-product-information_en.pdf	January 2020
Leqvio	inclisiran autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex vivo using a lentiviral vector encoding	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/leqvio-epar-product-information_en.pdf	Jan/21
Libmeldy		New active substance and new biological, PASS ¹	Orchard Therapeutics (Netherlands) B.V.	https://www.ema.europa.eu/en/documents/product-information/libmeldy-epar-product-information_en.pdf	Jan/21
LIBTAYO	Cemiplimab	New active substance, new biological and conditional marketing authorisation	Regeneron Ireland U.C.	https://www.ema.europa.eu/en/documents/product-information/libtayo-epar-product-information_en.pdf	July 2019
LiMAXetin 4 mg/ml Injektionslösung	Methacetin	New active substance	Humedics GmbH	https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?directdisplay=true&mpdidentifier=2196936	May 2020
Libmyris	Adalimumab	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/libmyris-epar-product-information_en.pdf	November 2021
Liumjev	Insulin lispro	New biological	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/liumjev-previously-liumjev-epar-product-information_en.pdf	April 2020
Livogiva	teriparatide	New biological	Theramex Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/livogiva-epar-product-information_en.pdf	Aug/20
Lojuxta	Lomitapide	Authorised under exceptional circumstances	Amryt Pharmaceuticals DAC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002578/human_med_001668.jsp&mid=WC0b01ac058001d124	September 2013
Lokelma	Sodium zirconium cyclosilicate	New active substance	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004029/human_med_002084.jsp&mid=WC0b01ac058001d124	April 2018
Lonapegsomatropin Ascendis Pharma	Lonapegsomatropin	New active substance and new biological	Ascendis Pharma Endocrinology Division A/S	https://www.ema.europa.eu/en/documents/product-information/lonapegsomatropin-ascendis-pharma-epar-product-information_en.pdf	January 2022
Lorviqua	Lorlatinib	New active substance and conditional marketing authorisation	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/lorviqua-epar-product-information_en.pdf	May 2019
Lunsumio	mosunetuzumab	New active substance, new biological and conditional marketing authorisation	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/lunsumio-epar-product-information_en.pdf	June 2022
LUMYKRAS	sotorasib	New active substance, Conditional marketing authorisation	Amgen Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/lumykras-epar-product-information_en.pdf	January 2022
Lutathera	Lutetium (¹⁷⁷Lu)-oxodotreotide	New active substance	Advanced Accelerator Applications	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004123/human_med_002163.jsp&mid=WC0b01ac058001d124	October 2017
Luxturna	Voretigene neparvovec	New active substance, new biological, PASS	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/luxturna-epar-product-information_en.pdf	December 2018

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Lydisilka	drospirenone/estetrol	New active substance	Estetra SRL	https://www.ema.europa.eu/en/documents/product-information/lydisilka-epar-product-information_en.pdf	June 2021
Macimorelin Aeterna Zentaris	Macimorelin	New active substance	Æterna Zentaris GmbH	https://www.ema.europa.eu/en/documents/product-information/macimorelin-aeterna-zentaris-epar-product-information_en.pdf	January 2019
Mayzent	Siponimod	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/mayzent-epar-product-information_en.pdf	January 2020
Medikinet retard 10 / 20 / 30 / 40 / 5 / 50 / 60 mg	Methylphenidate hydrochloride	PASS ¹	Medice Arzneimittel Püttner GmbH Co. KG	Not available	May 2018
Mektovi	Binimetinib	New active substance	Pierre Fabre Medicament	https://www.ema.europa.eu/documents/product-information/mektovi-epar-product-information_en.pdf	October 2018
MenQuadfi	Meningococcal group A, C, W and Y conjugate vaccine	New biological	Sanofi Pasteur	https://www.ema.europa.eu/en/documents/product-information/menquadfi-epar-product-information_en.pdf	December 2020
Mepsevii	Vestronidase alfa	New active substance, <i>new biological</i> , authorized under exceptional circumstances	Ultragenyx Germany GmbH	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004438/WC500254544.pdf	September 2018
Minjuvi	Tafasitamab	New active substance, new biological and conditional marketing authorisation	Incyte Biosciences Distribution B.V.	https://www.ema.europa.eu/en/documents/product-information/minjuvi-epar-product-information_en.pdf	September 2021
Mupleo (previously Lusutrombopag Shionogi)	Lusutrombopag	New active substance	Shionogi B.V.	https://www.ema.europa.eu/en/documents/product-information/mupleo-previously-lusutrombopag-shionogi-epar-product-information_en.pdf	February 2019
Mvabea	Ebola vaccine (MVA-BN-Filo [recombinant])	New active substance, new biological, authorised under exceptional circumstances	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/mvabea-epar-product-information_en.pdf	July 2020
Mvasi	Bevacizumab	New biological	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004728/human_med_002217.jsp&mid=WC0b01ac058001d124	January 2018
Myalepta	Metreleptin	New active substance, new biological, authorized under exceptional circumstances	Amryt Pharmaceuticals DAC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004218/human_med_002251.jsp&mid=WC0b01ac058001d124	September 2018
Mylotarg	Gemtuzumab ozogamicin	New active substance and <i>new biological</i>	Pfizer Europe MA EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004204/human_med_002252.jsp&mid=WC0b01ac058001d124	May 2018
Mysimba	Naltrexone / bupropion	PASS ¹	Orexigen Therapeutics Ireland Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003687/human_med_001845.jsp&mid=WC0b01ac058001d124	April 2015
Natpar	Parathyroid hormone	Conditional authorisation	Shire Pharmaceuticals Ireland Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003861/human_med_002093.jsp&mid=WC0b01ac058001d124	May 2017
Nerlynx	Neratinib	New active substance	Pierre Fabre Médicament	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004030/WC500255241.pdf	September 2018
Nepexto	Etanercept	New biological	Mylan IRE Healthcare Limited	https://www.ema.europa.eu/en/documents/product-information/nepexto-epar-product-information_en.pdf	June 2020
NEXPOVIO	selinexor	New active substance, conditional authorisation	Karyopharm Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/nexpovio-epar-product-information_en.pdf	April 2021
NexoBrid	Concentrate of proteolytic enzymes enriched in bromelain	PASS ¹	MediWound Germany GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002246/human_med_001582.jsp&mid=WC0b01ac058001d124	April 2013
Nexviadyme	avalglucosidase alfa	New active substance and new biological	Genzyme Europe B.V.	Not available	July 2022
Ngenla	somatrogon	New active substance and new biological	□ Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/ngenla-epar-product-information_en.pdf	February 2022
Nilemdo	bempedoic acid	New active substance	Daiichi Sankyo Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/nilemdo-epar-product-information_en.pdf	April 2020
Ninlaro	Ixazomib	New active substance, conditional authorisation	Takeda Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003844/human_med_001998.jsp&mid=WC0b01ac058001d124	November 2016
NUBEQA	darolutamide	New active substance	Bayer AG	https://www.ema.europa.eu/en/documents/product-information/nubeqa-epar-product-information_en.pdf	April 2020
Nuceiva	Botulinum toxin type A	New biological	Evolus Pharma B.V	https://www.ema.europa.eu/en/documents/product-information/nuceiva-epar-product-information_en.pdf	October 2019
Nustendi	bempedoic acid / ezetimibe	New active substance	Daiichi Sankyo Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/nustendi-epar-product-information_en.pdf	April 2020

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Nuvaxovid	SARS-CoV-2 recombinant spike protein	Conditional marketing authorisation, new active substance and new biological	Novavax CZ, a.s	https://www.ema.europa.eu/en/documents/product-information/nuvaxovid-epar-product-information_en.pdf	January 2022
Nyvepria	pegfilgrastim	New biological	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/nyvepria-epar-product-information_en.pdf	December 2020
Obizur	Susoctocog alfa	New active substance, authorised under exceptional circumstances	Baxalta Innovations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002792/human_med_001918.jsp&mid=WC0b01ac058001d124	November 2015
Obiltoximab SFL	obiltoximab	New active substance, new biological, authorised under exceptional circumstances	SFL Pharmaceuticals Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/obiltoximab-sfl-epar-product-information_en.pdf	December 2020
Ocaliva	Obeticholic acid	New active substance, conditional authorisation	Intercept Pharma Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004093/human_med_002043.jsp&mid=WC0b01ac058001d124	January 2017
Ocrevus	Ocrelizumab	New active substance and <i>new biological</i>	Roche Registration GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004043/human_med_002187.jsp&mid=WC0b01ac058001d124	January 2018
Ondexxya	Andexanet alfa	New active substance, new biological and conditional marketing authorisation	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/ondexxya-epar-product-information_en.pdf	May 2019
Onbevzi	bevacizumab	New biological	Samsung Bioepis NL B.V.	https://www.ema.europa.eu/en/documents/product-information/onbevzi-epar-product-information_en.pdf	January 2021
Ogivri	Trastuzumab	New biological	Viartis Limited	https://www.ema.europa.eu/documents/product-information/ogivri-epar-product-information_en.pdf	January 2019
Ontruzant	Trastuzumab	New biological	Samsung Bioepis UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004323/human_med_002188.jsp&mid=WC0b01ac058001d124	November 2017
Onpattro	Patisiran	New active substance	Alnylam Netherlands B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004699/smops/Positive/human_smop_001335.jsp&mid=WC0b01ac058001d127	September 2018
Ontozry	cenobamate	New active substance	Angelini Pharma S.p.A	https://www.ema.europa.eu/en/documents/product-information/ontozry-epar-product-information_en.pdf	April 2021
Orladeyo	berotralstat Allergen extract from house dust mites (Dermatophagoides pteronyssinus and Dermatophagoides farinae)	New active substance	Biocryst Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/orladeyo-epar-product-information_en.pdf	May 2021
Orylmyte		New biological	Stallergenes	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdidentifier=7000390	July 2021
Orkambi	Lumacaftor/Ivacaftor	PASS ¹	Vertex Pharmaceuticals (Ireland) Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003954/human_med_001935.jsp&mid=WC0b01ac058001d124	December 2015
Orgovyx	relugolix	New active substance	Myovant Sciences Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/orgovyx-epar-product-information_en.pdf	May/22
Orphacol	Cholic acid	Authorised under exceptional circumstances	Laboratoires CTRS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001250/human_med_001419.jsp&mid=WC0b01ac058001d124	October 2013
Oxbryta	Voxelotor	New active substance	☐ Global Blood Therapeutics Netherland	https://www.ema.europa.eu/en/documents/product-information/oxbryta-epar-product-information_en.pdf	February 2022
Oyavas	bevacizumab	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/oyavas-epar-product-information_en.pdf	April 2021
Ozanex (also known in some EU countries as	Ozenoxacin	New active substance	Ferrer Internacional S.A.	https://cima.aemps.es/cima/dochtml/ft/82357/FichaTecnica_82357.html	November 2017
Ozempic	Semaglutide	New active substance and <i>new biological</i>	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004174/human_med_002211.jsp&mid=WC0b01ac058001d124	February 2018
Oxlumo	lumasiran	New active substance	Alnylam Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/oxlumo-epar-product-information_en.pdf	December 2020
Padcev	enfortumab vedotin	New active substance and <i>new biological</i>	Astellas Pharma Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/padcev-epar-product-information_en.pdf	April 2022
Palylnziq	Pegvaliase	New active substance and <i>new biological</i>	BioMarin International Limited	https://www.ema.europa.eu/en/documents/product-information/palylnziq-epar-product-information_en.pdf	May 2019
Pandemic influenza vaccine H5N1 AstraZeneca	Pandemic influenza vaccine (H5N1) (live attenuated, nasal)	New active substance and <i>new biological</i> , conditional marketing authorisation	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003963/human_med_001984.jsp&mid=WC0b01ac058001d124	June 2016
Paxlovid	ritonavir/ (1R,2S,5S)-N-((1S)-1-Cyano-2-((3S)-2-oxopyrrolidin-3-yl)ethyl)-3-((2S)-3,3-dimethyl-2-	New active substance, conditional marketing authorisation	☐ Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/paxlovid-epar-product-information_en.pdf	February 2022

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Pegfilgrastim Mundipharma	Pegfilgrastim	New biological	Mundipharma Biologics S.L.	https://www.ema.europa.eu/en/documents/product-information/pegfilgrastim-mundi	January 2020
Pelgraz	Pegfilgratim	New biological	Accord Healthcare Limited	https://www.ema.europa.eu/documents/product-information/pelgraz-epar-product-information_en.pdf	October 2018
Pelmeg	Pegfilgrastim	New biological	Mundipharma Biologics S.L.	https://www.ema.europa.eu/documents/product-information/pelmeg-epar-product-information_en.pdf	December 2018
Pemazyre	pemigatinib	New active substance, conditional marketing authorisation	Incyte Biosciences Distribution B.V.	https://www.ema.europa.eu/en/documents/product-information/pemazyre-epar-product-information_en.pdf	Apr/21
Percolozin	enoxaparin sodium	New biological	Venipharm	N/A	January 2022
Phesgo	pertuzumab / trastuzumab	New biological	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/phesgo-epar-product-information_en.pdf	Jan/21
Pifeltro	Doravirine	New active substance	Merck Sharp & Dohme B.V.	https://www.ema.europa.eu/documents/product-information/pifeltro-epar-product-information_en.pdf	December 2018
Piqray	Alpelisib	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information_en.pdf	August 2020
Polivy	Polatuzumab vedotin	New active substance, new biological	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/polivy-epar-product-information_en.pdf	January 2020
Ponvory	ponesimod	New active substance	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/ponvory-epar-product-information_en.pdf	June 2021
Portrazza	Necitumumab	New active substance and <i>new biological</i>	Eli Lilly Nederland B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003886/human_med_001953.jsp&mid=WC0b01ac058001d124	March 2016
Poteligeo	Mogamulizumab	New active substance and <i>new biological</i>	Kyowa Kirin Holdings B.V.	https://www.ema.europa.eu/documents/product-information/poteligeo-epar-product-information_en.pdf	December 2018
PreHevbri	Hepatitis B vaccine (recombinant, adsorbed)	New biological	VBI Vaccines B.V.	https://www.ema.europa.eu/en/documents/product-information/prehevri-epar-product-information_en.pdf	May/22
Prevmis	Letermovir	New active substance	Merck Sharp & Dohme B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004536/human_med_002200.jsp&mid=WC0b01ac058001d124	January 2018
Dovprela (previously known as Pretomanid FGK)	pretomanid	new active substance, conditional MA	Mylan IRE Healthcare Limited	https://www.ema.europa.eu/en/documents/product-information/pretomanid-fgk-epar-product-information_en.pdf	August 2020
Qarziba (previously Dinutuximab beta EUSA and Dinutuximab beta Apeiron)	Dinutuximab beta	Authorised under exceptional circumstances	EUSA Pharma (UK) Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003918/human_med_002104.jsp&mid=WC0b01ac058001d124	May 2017
QINLOCK	ripretinib	New active substance	Deciphera Pharmaceuticals (Netherlands) B.V.	https://www.ema.europa.eu/en/documents/product-information/qinlock-epar-product-information_en.pdf	Dec/21
Quinsair	Levofloxacin	PASS ¹	Chiesi Farmaceutici S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002789/human_med_001846.jsp&mid=WC0b01ac058001d124	April 2015
Quofenix	Delafloxacin	New active substance	Menarini - Industrie Farmaceutiche Riunite - s.r.l.	https://www.ema.europa.eu/en/documents/product-information/quofenix-epar-product-information_en.pdf	January 2020
QUVIVIQ	daridorexant	New active substance	Idorsia Pharmaceuticals Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/quviviq-epar-product-information_en.pdf	May 2022
Ragwizax	Standardised allergen extract of pollen from Short Ragweed (<i>Ambrosia artemisiifolia</i>)	New biological	ALK-Abelló A/S	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdidentifier=2613788	April 2018
Raxone	Idebenone	Authorised under exceptional circumstances	Santhera Pharmaceuticals (Deutschland) GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003834/human_med_001900.jsp&mid=WC0b01ac058001d124	September 2015
Reblozyl	Luspatercept	New active substance	Celgene Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/reblozyl-epar-product-information_en.pdf	July 2020
Recarbrio	Imipenem / cilastatin / relebactam	New active substance	Merck Sharp & Dohme B.V.	https://www.ema.europa.eu/en/documents/product-information/recarbrio-epar-product-information_en.pdf	February 2020
Refixia	Nonacog beta pegol	PASS ¹	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004178/human_med_002107.jsp&mid=WC0b01ac058001d124	June 2017
Regkirona	Regdanvimab	New active substance and <i>new biological</i>	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/regkirona-epar-product-information_en.pdf	November 2021

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REKAMBYS	rilpivirine	PASS ¹	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/rekambys-epar-product-information_en.pdf	Jan/21
<u>Retinoid-containing medicinal products and related substances (acitretin, alitretinoin and isotretinoin)</u>	Acitretin, Alitretinoin, Isotretinoin	PASS ¹	Various for full list see Annex XIV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Retinoids_containing_medicinal_products/human_referral_prac_000061.jsp&mid=WC0b01ac05805c516f	September 2018
Retsevmo	selpercatinib	New active substance, Conditional marketing authorisation	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/retsevmo-epar-product-information_en.pdf	February 2021
Revestive	Teduglutide	PASS ¹	Takeda Pharmaceuticals International AG Ireland Branch	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002345/human_med_001583.jsp&mid=WC0b01ac058001d124	April 2013
Revlimid	Lenalidomide	PASS ¹	Bristol-Myers Squibb Pharma EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000717/human_med_001034.jsp&mid=WC0b01ac058001d124	June 2014
Rhokiinsa	Netarsudil	New active substance	Santen Oy	https://www.ema.europa.eu/en/documents/product-information/rhokiinsa-epar-product-information_en.pdf	December 2019
Rinvoq	Upadacitinib	New active substance	AbbVie Deutschland GmbH & Co. KG	https://www.ema.europa.eu/en/documents/product-information/rinvoq-epar-product-information_en.pdf	January 2020
Ritemvia	Rituximab	New biological	Celltrion Healthcare Hungary Kft.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004725/human_med_002137.jsp&mid=WC0b01ac058001d124	July 2017
Rizmoic	Naldemedine	New active substance	Shionogi B.V.	https://www.ema.europa.eu/en/documents/product-information/rizmoic-epar-product-information_en.pdf	February 2019
Roclanda	Latanoprost / netarsudil	New active substance	Santen Oy	https://www.ema.europa.eu/en/documents/product-information/roclanda-epar-product-information_en.pdf	January 2021
Rolufta Ellipta (previously Rolufta)	Umeclidinium	PASS ¹	GlaxoSmithKline Trading Services Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004654/human_med_002085.jsp&mid=WC0b01ac058001d124	March 2017
Ronapreve	Casirivimab/imdevimab	New active substance and <i>new biological</i>	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/ronapreve-epar-product-information_en.pdf	November 2021
Rozlytrek	entrectinib	new active substance, conditional MA	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/rozlytrek-epar-product-information_en.pdf	August 2020
Rubraca	Rucaparib	New active substance, conditional marketing authorisation	Clovis Oncology UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004272/human_med_002215.jsp&mid=WC0b01ac058001d124	June 2018
Rukobia	fostemsavir	New active substance	ViiV Healthcare BV	https://www.ema.europa.eu/en/documents/product-information/rukobia-epar-product-information_en.pdf	Feb/21
Ruxience	Rituximab	New biological	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/ruxience-epar-product-information_en.pdf	April 2020
Rxulti	Brexpiprazole	New active substance	Otsuka Pharmaceutical Europe Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003841/smops/Positive/human_smop_001298.jsp&mid=WC0b01ac058001d127	September 2018
Rybelsus	Semaglutide	New biological	Novo Nordisk A/S	https://www.ema.europa.eu/en/medicines/human/EPAR/rybelsus	April 2020
Rybrevant	Amivantamab	Conditional marketing authorisation, new active substance, new biological	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/rybrevant-epar-product-information_en.pdf	January 2022
Ryeqo	relugolix / estradiol / norethisterone acetate	New active substance	Gedeon Richter Plc.	https://www.ema.europa.eu/en/documents/product-information/ryeqo-epar-product-information_en.pdf	September 2021
Rymphysis	alfa 1 antitrysin	New biological	Takeda Austria GmbH	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdidentifier=7005138	June 2022
Saphnelo	anifrolumab	New active substance and new biological	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/saphnelo-epar-product-information_en.pdf	February 2022
Sarclisa	Isatuximab	New active substance and <i>new biological</i>	Sanofi-Aventis groupe	https://www.ema.europa.eu/en/documents/product-information/sarclisa-epar-product-information_en.pdf	June 2020
Scenesse	Afamelanotide	Authorised under exceptional circumstances	Clinuvel UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002548/human_med_001826.jsp&mid=WC0b01ac058001d124	January 2015
Segluromet	Ertugliflozin / metformin hydrochloride	New active substance	Merck Sharp & Dohme Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004314/human_med_002238.jsp&mid=WC0b01ac058001d124	April 2018
Semglee	Insulin glargine	New biological	Viatriis Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004280/human_med_002239.jsp&mid=WC0b01ac058001d124	April 2018

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Senshio	Ospemifene	PASS ¹	Shionogi Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002780/human_med_001837.jsp&mid=WC0b01ac058001d124	February 2015
Shingrix	Herpes zoster vaccine (recombinant, adjuvanted)	New active substance and <i>new biological</i>	GlaxoSmithKline Biologicals S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004336/human_med_002240.jsp&mid=WC0b01ac058001d124	April 2018
Sirturo	Bedaquiline	Conditional authorisation	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002614/human_med_001730.jsp&mid=WC0b01ac058001d124	March 2014
Sixmo	Buprenorphine	New biological, PASS ¹	L. Molteni & C. dei F.lli Alitti Soc.Es.S.p.A	https://www.ema.europa.eu/en/documents/product-information/sixmo-epar-product-information_en.pdf	July 2019
Skyrizi	Risankizumab	New active substance and <i>new biological</i>	AbbVie Deutschland GmbH & Co. KG	https://www.ema.europa.eu/en/documents/product-information/skyrizi-epar-product-information_en.pdf	May 2019
Sogroya	somapacitan	New active substance and new biological	Novo Nordisk A/S	https://www.ema.europa.eu/en/documents/product-information/sogroya-epar-product-information_en.pdf	Apr/21
Sondelbay	teriparatide	New biological	Accord Healthcare S.L.U.	https://www.ema.europa.eu/en/documents/product-information/sondelbay-epar-product-information_en.pdf	April 2022
Spikevax (previously COVID-19 Vaccine Moderna)	elasomeran (formally COVID-19 mRNA Vaccine (nucleoside-modified))	Conditional marketing authorisation / New active substance and new biological	MODERNA BIOTECH SPAIN, S.L.	https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf	Jan/21
Spravato	Esketamine	Restrictions with regards to the safe and effective use of the medicinal product	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/spravato-epar-product-information_en.pdf	January 2020
Steglatro	Ertugliflozin	New active substance	Merck Sharp & Dohme Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004315/human_med_002241.jsp&mid=WC0b01ac058001d124	April 2018
Steglujan	Ertugliflozin / sitagliptin	New active substance	Merck Sharp & Dohme B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004313/human_med_002242.jsp&mid=WC0b01ac058001d124	April 2018
Stimufend	Pegfilgrastim	New biological	Fresenius Kabi Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/stimufend-epar-product-information_en.pdf	April 2022
Strensiq	Asfotase alfa Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence	Authorised under exceptional circumstances	Alexion Europe SAS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003794/human_med_001901.jsp&mid=WC0b01ac058001d124	September 2015
Strimvelis	encodes for the human ADA cDNA sequence	PASS ¹	Orchard Therapeutics (Netherlands) B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003854/human_med_001985.jsp&mid=WC0b01ac058001d124	June 2016
Striverdi Respimat (also known in some EU countries as Infortispir Respimat)	Olodaterol	PASS ¹	Boehringer Ingelheim International GmbH	http://db.cbq-meb.nl/IB-teksten/h112058.pdf	February 2015
Sublivac Birke	Allergen extract of pollen from Birch	New biological	HAL Allergie GmbH	https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdidentifier=2613841	September 2018
Sublivac Bäume	Allergen extract of pollen from Birch, Alder and Hazel	New biological	HAL Allergie GmbH	https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdidentifier=2613842	September 2018
Sulovas	Sulodexide	New biological	Aflofarm Farmacja Polska Sp. z o.o.	http://pub.rejestrnymedyczne.csioz.gov.pl/ProduktSzczegoly.aspx?id=38063	December 2018
Sunosi	Solriamfetol	New active substance	Jazz Pharmaceuticals Ireland Ltd	https://www.ema.europa.eu/en/documents/product-information/sunosi-epar-product-information_en.pdf	January 2020
Supemtek	quadrivalent influenza vaccine (recombinant, prepared in cell culture)	New biological	Sanofi Pasteur	https://www.ema.europa.eu/en/documents/product-information/supemtek-epar-product-information_en.pdf	November 2020
Sylvant	Siltuximab	PASS ¹	EUSA Pharma (Netherlands) B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003708/human_med_001769.jsp&mid=WC0b01ac058001d124	June 2014
Symkevi	Tezacaftor/ivacaftor	New active substance	Vertex Pharmaceuticals (Ireland) Limited	https://www.ema.europa.eu/documents/product-information/symkevi-epar-product-information_en.pdf	November 2018
Tabrecta	capmatinib	New active substance	Novartis Europharm Limited	Not available	June 2022
TAKUDEX (also known in some EU countries as Dextra)	Framadol hydrochloride/ dextketoprofen	PASS¹	GUIDOTTI FARMA	https://cima.aemps.es/cima/docthtml/ft/80802/FT_80802.html	April 2018
Takhzyro	Lanadelumab	New active substance, new biological	Takeda Pharmaceuticals International AG Ireland Branch	https://www.ema.europa.eu/documents/product-information/takhzyro-epar-product-information_en.pdf	December 2018
Talzenna	Talazoparib	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/talzenna-epar-product-information_en.pdf	June 2019

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TAVLESSE	Fostamatinib	New active substance	Instituto Grifols S.A. ☐	https://www.ema.europa.eu/en/documents/product-information/tavlesse-epar-product-information_en.pdf	January 2020
Tavneos	avacopan	New active substance	Vifor Fresenius Medical Care Renal Pharma France	https://www.ema.europa.eu/en/documents/product-information/tavneos-epar-product-information_en.pdf	January 2022
Tecartus	autologous anti-CD19-transduced CD3+ cells	Conditional marketing authorisation / New active substance an new biological/ PASS ¹	Kite Pharma EU B.V. ☐	https://www.ema.europa.eu/en/documents/product-information/tecartus-epar-product-information_en.pdf	Jan/21
Tecovirimat SIGA	tecovirimat monohydrate	Authorised under exceptional circumstances and new act	SIGA Technologies Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/tecovirimat-siga-epar-product-information_en.pdf	January 2022
Tegsedi	Inotersen	New active substance	Akcea Therapeutics Ireland Ltd	https://www.ema.europa.eu/documents/product-information/tegsedi-epar-product-information_en.pdf	July 2018
Temybric Ellipta	Fluticasone furoate / umeclidinium / vilanterol	New active substance	GlaxoSmithKline Trading Services	https://www.ema.europa.eu/en/documents/product-information/temybric-ellipta-epar-product-information_en.pdf	July 2019
☐ Tepmetko	Tepotinib hydrochloride monohydrate	New active substance	☐ Merck Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/tepmetko-epar-product-information_en.pdf	March 2022
Thiosix	Tioguanin	Authorised under exceptional circumstances	Teva Nederland B.V.	http://db.cbq-meb.nl/IB-teksten/h114681.pdf	May 2015
Tookad	Padeliporfin	New active substance	Steba Biotech S.A	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004182/human_med_002190.jsp&mid=WC0b01ac058001d124	November 2017
Translarna	Ataluren	Conditional authorisation	PTC Therapeutics Limited	https://www.ema.europa.eu/en/documents/product-information/translarna-epar-product-information_en.pdf	September 2014
Trazimera	Trastuzumab	New biological	Pfizer Europa MA EEG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004463/human_med_002282.jsp&mid=WC0b01ac058001d124	September 2018
Trelegy Ellipta	Fluticasone furoate/umeclidinium/vilanterol	New active substance	GlaxoSmithKline Trading Services Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004363/human_med_002191.jsp&mid=WC0b01ac058001d124 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004271/human_med_002183.jsp&mid=WC0b01ac058001d124	November 2017
Tremfya	Guselkumab	New active substance and new biological	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004271/human_med_002183.jsp&mid=WC0b01ac058001d124	November 2017
Trivalent Influenza Vaccine	Influenza vaccine (split virion, inactivated)	New biological	Sanofi Pasteur	Not available	May 2019
Trodelvy	sacituzumab govitecan	New active substance and new biological	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/trodelvy-epar-product-information_en.pdf	December 2021
Trogarzo	Ibalizumab	New active substance and new biological	Theratechnologies Europe Limited	https://www.ema.europa.eu/en/documents/product-information/trogarzo-epar-product-information_en.pdf	October 2019
Truvelog Mix	insulin aspart	New biological	Sanofi-Aventis groupe	https://www.ema.europa.eu/en/documents/product-information/truvelog-mix-30-epar-product-information_en.pdf	May 2022
TUKYSA	tucatinib	New active substance	Seagen B.V.	https://www.ema.europa.eu/en/documents/product-information/tukysa-epar-product-information_en.pdf	Feb/21
Ultomiris	Ravulizumab	New active substance, new biological	Alexion Europe SAS	https://www.ema.europa.eu/en/documents/product-information/ultomiris-epar-product-information_en.pdf	July 2019
Uplizna	inebilizumab	New active substance, new biological	Viela Bio B.V.	https://www.ema.europa.eu/en/documents/product-information/uplizna-epar-product-information_en.pdf	May 2022
Upstaza	Eladocogene exuparovec	New active substance, new biological, authorised under exceptional circumstances	PTC Therapeutics International Limited	Not available	July 2022
Vaborem (previously Vabomere) <u>Valproate and related substances (sodium valproate, valproic acid, valproate semisodium, valpromide-containing)</u>	Meropenem/vaborbactam Sodium valproate, valproic acid, valproate semisodium, valpromide	New active substance PASS ¹	Menarini International Operations Luxembourg S.A. Various (For full list see Annex XIII)	https://www.ema.europa.eu/documents/product-information/vabomere-epar-product-information_en.pdf http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/V_alproate_and_related_substances/human_referral_prac_000032.jsp&mid=WC0b01ac05805c516f	December 2018 January 2015
Vaxchora	Cholera vaccine (recombinant, live, oral)	New active substance, new biological	Emergent Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/vaxchora-epar-product-information_en.pdf	May 2020
Vaxneuvance Vaxigrip Tetra (also known in some EU countries as quadrivalent influenza vaccine (split virion, inactivated))	pneumococcal polysaccharide Influenza vaccine (split virion, inactivated)	New active substance, new biological New biological	Merck Sharp & Dohme B.V. Sanofi Pasteur Europe	https://www.ema.europa.eu/en/documents/product-information/vaxneuvance-epar-product-information_en.pdf https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdidentifier=2613948	January 2022 September 2016

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Vaxzevria (previously COVID-19 Vaccine AstraZeneca)	COVID-19 Vaccine (ChAdOx1-S [recombinant])	Conditional marketing authorisation / New active substance and new biological	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-product-information_en.pdf	Feb/21
Vazkepa	Icosapent ethyl	New active substance	Amarin Pharmaceuticals Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/vazkepa-epar-product-information_en.pdf	Mar/21
Vedrop	Tocofersolan d-alpha tocopheryl polyethylene glycol succinate	Authorised under exceptional circumstances	Recordati Rare Diseases	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000920/human_med_001129.jsp&mid=WC0b01ac058001d124	April 2013
Veklury	Remdesivir	New active substance and conditional marketing authorisation	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/veklury-epar-product-information_en.pdf	July 2020
Venclyxto	Venetoclax	New active substance	AbbVie Deutschland GmbH & Co. KG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004106/human_med_002045.jsp&mid=WC0b01ac058001d124	December 2016
VeraSeal	Human fibrinogen / human thrombin	New biological	Instituto Grifols, S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004446/human_med_002197.jsp&mid=WC0b01ac058001d124	November 2017
Verquvo	Vericiguat	New active substance	Bayer AG	https://www.ema.europa.eu/en/documents/product-information/verquvo-epar-product-information_en.pdf	July 2021
Verzenio	Abemaciclib	New active substance	Eli Lilly Netherland B.V.	https://www.ema.europa.eu/documents/product-information/verzenio-epar-product-information_en.pdf	October 2018
Veyvondi	Vonicog alfa	New active substance and <i>new biological</i>	Baxalta Innovations GmbH	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004454/WC500255622.pdf	September 2018
Vimizim	Elosulfase alfa	PASS ¹	BioMarin International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002779/human_med_001759.jsp&mid=WC0b01ac058001d124	June 2014
VITRAKVI	Larotrectinib	Conditional authorisation, new active substance	Bayer AG	https://www.ema.europa.eu/documents/product-information/vitrakvi-epar-product-information_en.pdf	October 2019
Vizimpro	Dacomitinib	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/vizimpro-epar-product-information_en.pdf	April 2019
Vocabria	cabotegravir	New active substance, PASS ¹	ViiV Healthcare BV	https://www.ema.europa.eu/en/documents/product-information/vocabria-epar-product-information_en.pdf	Jan/21
Voraxaze	glucarpidase	Authorised under exceptional circumstances, new active substance and new biological	SERB SAS	https://www.ema.europa.eu/en/documents/product-information/voraxaze-epar-product-information_en.pdf	January 2022
Voxzogo	vosoritide	New active substance and new biological	BioMarin International Limited	https://www.ema.europa.eu/en/documents/product-information/voxzogo-epar-product-information_en.pdf	Sep/21
Vydura	rimegepant	New active substance	Biohaven Pharmaceutical Ireland DAC	https://www.ema.europa.eu/en/documents/product-information/vydura-epar-product-information_en.pdf	May/22
Vyepti	eptinezumab	New biological	H. Lundbeck A/S	https://www.ema.europa.eu/en/documents/product-information/vyepti-epar-product-information_en.pdf	February 2022
Vyndaqel	Tafamidis	Authorised under exceptional circumstances	Pfizer Europa MA EEG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002294/human_med_001498.jsp&mid=WC0b01ac058001d124	April 2013
Wakix	Pitolisant hydrochloride	PASS ¹	Bioprojet Pharma	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002616/human_med_001955.jsp&mid=WC0b01ac058001d124	April 2016
Waylivra	Volanesorsen	New active substance and conditional marketing authorisation	Akcea Therapeutics Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/waylivra-epar-product-information_en.pdf	May 2019
Wegovy	semaglutide	New biological	Novo Nordisk A/S	https://www.ema.europa.eu/en/documents/product-information/wegovy-epar-product-information_en.pdf	January 2022
Xarelto	Rivaroxaban	PASS ¹	Bayer Pharma AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000944/human_med_001155.jsp&mid=WC0b01ac058001d124	July 2013
Xeljanz	Tofacitinib	New active substance	Pfizer Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004214/human_med_001662.jsp&mid=WC0b01ac058001d124	April 2017
Xembify	human normal Immunoglobulin	New biological	Instituto Grifols S.A.	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdidentifier=7001176	March 2022
Xenleta	lefamulin	New active substance	Nabriva Therapeutics Ireland DAC	https://www.ema.europa.eu/en/documents/product-information/xenleta-epar-product-information_en.pdf	August 2020
Xenpozyme	olipudase alfa	New active substance, new biological	Genzyme Europe B.V.	Not available	July 2022

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Xerava	Eravacycline	New active substance	PAION Deutschland GmbH	https://www.ema.europa.eu/documents/product-information/xerava-epar-product-information_en.pdf	October 2018
Xermelo	Telotristat	New active substance	Ipsen Pharma	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003937/human_med_002168.jsp&mid=WC0b01ac058001d124	September 2017
Xevudy	Sotrovimab	New active substance, new biological	GlaxoSmithKline Trading Services Limited	https://www.ema.europa.eu/en/documents/product-information/xevudy-epar-product-information_en.pdf	January 2022
Xofigo	Radium Ra 223 dichloride	PASS ¹	Bayer AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002653/human_med_001692.jsp&mid=WC0b01ac058001d124	December 2013
Xofluza	baloxavir marboxil	New active substance	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/xofluza-epar-product-information_en.pdf	January 2021
Xospata	Gilteritinib	New active substance	Astellas Pharma Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/xospata-epar-product-information_en.pdf	November 2019
Yescarta	Axicabtagene ciloleuce	New active substance, <i>new biological</i> , PASS ¹	Kite Pharma EU B.V.	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004480/WC500254958.pdf	September 2018
Yselty	linzagolix choline	New active substance	ObsEva Ireland Ltd.	https://www.ema.europa.eu/en/documents/product-information/yselty-epar-product-information_en.pdf	June 2022
Yuflyma	adalimumab	New biological	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/yuflyma-epar-product-information_en.pdf	March 2021
Zabdeno	Ebola vaccine (Ad26.ZEBOV-GP [recombinant])	New active substance, new biological Authorised under exceptional circumstances	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/zabdeno-epar-product-information_en.pdf	July 2020
Zejula	Niraparib	New active substance	GlaxoSmithKline (Ireland) Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004249/human_med_002192.jsp&mid=WC0b01ac058001d124	November 2017
Zercepac	trastuzumab	New Biological, New active substance	Accord Healthcare S.L.U.	https://www.ema.europa.eu/en/documents/product-information/zercepac-epar-product-information_en.pdf	August 2020
Zeposia	Ozanimod	New active substance	Bristol-Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/zeposia-epar-product-information_en.pdf	June 2020
Zessly	Infliximab	New biological	Sandoz GmbH	https://www.ema.europa.eu/en/documents/product-information/zessly-epar-product-information_en.pdf	June 2018
Ziextenzo	Pegfilgrastim	New biological	Sandoz GmbH	https://www.ema.europa.eu/documents/product-information/ziextenzo-epar-product-information_en.pdf	December 2018
Zirabev	Bevacizumab	New biological	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/zirabev-epar-product-information_en.pdf	February 2019
Zokinvy	Lonafarnib	New active substance, authorised under exceptional circumstances	EigerBio Europe Limited	Not available yet	July 2022
Zolgensma	Onasemnogene abeparvovec	New active substance, new biological	AveXis EU Limited	https://www.ema.europa.eu/en/documents/product-information/zolgensma-epar-product-information_en.pdf	May 2020

¹ PASS: Post-authorisation safety study. A PASS is defined in Article 1(15) of Directive 2001/83/EC as any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.

* This list was previously amended on 24 June 2022.