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www.ema.europa.eu/how-to-find-us
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8 December 2025
EMA/245297/2013 Rev. 139*
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

Good Pharmacovigilance Practice Module on additional monitoring:
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 December 2025 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	Biosimilar Collaborations Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/abevmy-epar-product-information_en.pdf	May 2021
Abecma	idecabtagene vicleucel	New biological, new active substance, PASS[1]	Bristol-Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/abecma-epar-product-information_en.pdf	September 2021
Abrysvo	Respiratory syncytial virus vaccine (bivalent, recombinant)	New active substance and new biological	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/abrysvo-epar-product-information_en.pdf	September 2023
ABSIMKY	Ustekinumab	New biological	Accord Healthcare S.L.U.	https://www.ema.europa.eu/en/documents/product-information/absimky-epar-product-information_en.pdf	January 2025
Acvybra	denosumab	New biological	Reddy Holding GmbH	Not available	November 2025
Adynovi	Rurioctocog alfa pegol	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 *new biological*	Leo Pharma A/S	https://www.ema.europa.eu/en/documents/product-information/adtralza-epar-product-information_en.pdf	June 2021
ADZYNMA	rADAMTS13	New biological, new active substance, authorized under exceptional circumstances	Takeda Manufacturing Austria AG	https://www.ema.europa.eu/en/documents/product-information/adzynma-epar-product-information_en.pdf	September 2024
Afiveg	aflibercept	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/afiveg-epar-product-information_en.pdf	September 2025

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Afqlir	aflibercept	New biological	Sandoz GmbH	https://www.ema.europa.eu/en/documents/product-information/afqlir-epar-product-information_en.pdf	November 2024
AGAMREE	vamorolone	New active substance	Santhera Pharmaceuticals (Deutschland) GmbH	https://www.ema.europa.eu/en/documents/product-information/agamree-epar-product-information_en.pdf	January 2024
Ahzantive	aflibercept	New biological	Formycon AG	https://www.ema.europa.eu/en/documents/product-information/ahzantive-epar-product-information_en.pdf	January 2025
Aklief	trifarotene	New active substance	Galderma Nordic AB	http://mri.cts-mrp.eu/Human/Product/Details/58971	December 2021
Alhemo	concizumab	New active substance, new biological	Novo Nordisk A/S	https://www.ema.europa.eu/en/documents/product-information/alhemo-epar-product-information_en.pdf	January 2025
ALTUVOCT	efanesoctocog alfa	New active substance and new biological	Swedish Orphan Biovitrum AB (publ)	https://www.ema.europa.eu/en/documents/product-information/altuvoct-epar-product-information_en.pdf	June 2024
Alyftrek	deutivacaftor/tezacaftor/vanzacaftor	New active substance	Vertex Pharmaceuticals (Ireland) Limited	https://www.ema.europa.eu/en/documents/product-information/alyftrek-epar-product-information_en.pdf	July 2025
Alymsys	bevacizumab	New biological	Mabxience Research SL	https://www.ema.europa.eu/en/documents/product-information/alymsys-epar-product-information_en.pdf	April 2021
Amvuttra	vutrisiran	New active substance	Alnylam Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/amvuttra-epar-product-information_en.pdf	September 2022
ANDEMBRY	garadacimab	New active substance and new biological	CSL Behring GmbH	https://www.ema.europa.eu/en/documents/product-information/andembry-epar-product-information_en.pdf	February 2025
Anzupgo	delgocitinib	New active substance	LEO Pharma A/S	https://www.ema.europa.eu/en/documents/product-information/anzupgo-epar-product-information_en.pdf	October 2024
Apexxnar	pneumococcal polysaccharide conjugate vaccine (20-valent,	New biological	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/apexxnar-epar-product-information_en.pdf	March 2022
Apretude	cabotegravir	New active substance	ViiV Healthcare BV	https://www.ema.europa.eu/en/documents/product-information/apretude-epar-product-information_en.pdf	September 2023
AQUIPTA	atogepant	New active substance	AbbVie Deutschland GmbH & Co. KG	https://www.ema.europa.eu/en/documents/product-information/aquipta-epar-product-information_en.pdf	September 2023
Arexvy	Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)	New active substance and new biological	GlaxoSmithKline Biologicals S.A.	https://www.ema.europa.eu/en/documents/product-information/arexvy-epar-product-information_en.pdf	June 2023
Artesunate Amivas	artesunate	New active substance	Amivas Ireland Ltd	https://www.ema.europa.eu/en/documents/product-information/artesunate-amivas-epar-product-	December 2021
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 immunglobulin	New biological	Pfizer Pharma GmbH	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdid	March 2022
Atriance	Nelarabine	Authorised under exceptional circumstances	Sandoz Pharmaceuticals d.d.	https://www.ema.europa.eu/en/documents/product-information/atriance-epar-product-information_en.pdf	April 2013
Aucatzyl	obecabtagene autoleucel	New active substance, new biological, conditional marketing authorisation, PASS	Autolus GmbH	https://www.ema.europa.eu/en/documents/product-information/aucatzyl-epar-product-information_en.pdf	July 2025

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
AUGTYRO	repotrectinib	New active substance, conditional marketing authorisation	Bristol Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/augtyro-epar-product-information_en.pdf	January 2025
Awiqli	insulin icodec	New active substance, New biological	Novo Nordisk A/S	https://www.ema.europa.eu/en/documents/product-information/awiqli-epar-product-information_en.pdf	May 2024
AYVAKYT	avapritinib	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
Avtozma	tocilizumab	New biological	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/avtozma-epar-product-information_en.pdf	March 2025
Avzivi	Bevacizumab	New biological	EGK Representative Service GmbH	https://www.ema.europa.eu/en/documents/product-information/avzivi-epar-product-information_en.pdf	Sepetmber 2024
Baiama	aflibercept	New biological	Formycon AG	https://www.ema.europa.eu/en/documents/product-information/baiama-epar-product-information_en.pdf	January 2025
Balversa	erdafitinib	New active substance	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf	September 2024
BEKEMV	eculizumab	New biological	Amgen Technology (Ireland) UC	https://www.ema.europa.eu/en/documents/product-information/bekemv-epar-product-information_en.pdf	April 2023
Benlysta	Belimumab	PASS[1]	Glaxo Group Ltd	https://www.ema.europa.eu/en/documents/product-information/benlysta-epar-product-information_en.pdf	April 2013
Beyfortus	Nirsevimab	New active substance and *new biological*	Sanofi Winthrop Industrie	https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf	November 2022
BEYONTTRA	Lecanemab	New active substance	Bayer AG	https://www.ema.europa.eu/en/documents/product-information/beyonttra-epar-product-information_en.pdf	February 2025
Bildyos	Denosumab	New biological	SciencePharma Sp. z o.o.	https://www.ema.europa.eu/en/documents/product-information/bildyos-epar-product-information_en.pdf	September 2025
Bilprevda	denosumab	New biological	SciencePharma Sp. z o.o.	https://www.ema.europa.eu/en/documents/product-information/bilprevda-epar-product-information_en.pdf	September 2025
BIMERVAX	COVID-19 Vaccine (recombinant, adjuvanted)	New active substance and new biological	Hipra Human Health, S.L.U.	https://www.ema.europa.eu/en/documents/product-information/bimervax-epar-product-information_en.pdf	April 2023
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	September 2021
BLENREP	belantamab mafodotin	New biological	GlaxoSmithKline Trading Services Limited	https://www.ema.europa.eu/en/documents/product-information/blenrep-epar-product-information_en.pdf	July 2025
Blincyto	Blinatumomab	PASS[1]	Amgen Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/blincyto-epar-product-information_en.pdf	December 2015
Bomyntra	denosumab	New biological	Fresenius Kabi Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/bomyntra-epar-product-information_en.pdf	July 2025
Bylvay	Odevixibat	New active substance, authorised under exceptional circumastances	Ipsen Pharma	https://www.ema.europa.eu/en/documents/product-information/bylvay-epar-product-information_en.pdf	July 2021
Byooviz	ranibizumab	New biological	Samsung Bioepis NL B.V.	https://www.ema.europa.eu/en/documents/product-information/byooviz-epar-product-information_en.pdf	April 2024

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
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	April 2022
Brineura	Cerliponase alfa	authorised under exceptional circumstances, PASS[1]	BioMarin International Limited	https://www.ema.europa.eu/en/documents/product-information/brineura-epar-product-information_en.pdf	June 2017
Brinsupri	brensocatib	New active substance and PASS	Insmed Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/brinsupri-epar-product-information_en.pdf	November 2025
Briumvi	ublituximab	New active substance and new biological	Neuraxpharm Pharmaceuticals, S.L.	https://www.ema.europa.eu/en/documents/product-information/briumvi-epar-product-information_en.pdf	June 2023
Brukinsa	zanubrutinib	New active substance	BeiGene Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/brukinsa-epar-product-information_en.pdf	December 2021
CAMZYOS	mavacamten	New active substance	Bristol Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/camzyos-epar-product-information_en.pdf	July 2023
CAPVAXIVE	Pneumococcal polysaccharide conjugate vaccine (21-valent)	New biological and New active substance	Merck Sharp & Dohme B.V.	https://www.ema.europa.eu/en/documents/product-information/capvaxive-epar-product-information_en.pdf	April 2025
CARVYKTI	ciltacabtagene autoleucel	New active substance, new biological	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/carvykti-epar-product-information_en.pdf	June 2022
Casgevy	exagamglogene autotemcel	New active substance, new biological and conditional marketing authorisation, PASS	Vertex Pharmaceuticals (Ireland) Limited	https://www.ema.europa.eu/en/documents/product-information/casgevy-epar-product-information_en.pdf	February 2024
Cejemly	sugemalimab	New active substance and new biological	CStone Pharmaceuticals Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/cejemly-epar-product-information_en.pdf	July 2024
Celldemic	Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated,	New biological	Seqirus Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/celldemic-epar-product-information_en.pdf	May 2024
Ceplene	Histamine dihydrochloride	Authorised under exceptional circumstances	Laboratoires Delbert	https://www.ema.europa.eu/en/documents/product-information/ceplene-epar-product-information_en.pdf	April 2013
Cerdelga	Eliglustat	PASS[1]	Genzyme Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/cerdelga-epar-product-information_en.pdf	February 2015
Cevenfacta	eptacog beta (activated)	New active substance and new biological	Laboratoire français du Fractionnement et des Biotechnologies	https://www.ema.europa.eu/en/documents/product-information/cevenfacta-epar-product-information_en.pdf	September 2022
Chenodeoxycholic acid Leadiant (previously known as	Chenodeoxycholic acid	Authorised under exceptional circumstances	Leadiant GmbH	https://www.ema.europa.eu/en/documents/product-information/cerdelga-epar-product-information_en.pdf	April 2017
Choriongonadotrophin Genevrier	chorionic gonadotropin	New biological	Laboratoires Genévrier	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
Colevance	enoxaparin sodium	New biological	Venipharm	N/A	January 2022
Columvi	glofitamab	New active substance, new biological	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/columvi-epar-product-information_en.pdf	July 2023

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Comirnaty	COVID-19 mRNA Vaccine (nucleoside modified)	New active substance and new biological	BioNTech Manufacturing GmbH	https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf	January 2021
Conexxence	denosumab	New biological	Fresenius Kabi Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/conexxence-epar-product-information_en.pdf	July 2025
Copiktra	duvelisib	New active substance	Secura Bio Limited	https://www.ema.europa.eu/en/documents/product-information/copiktra-epar-product-information_en.pdf	June 2021
Datroway	datopotamab deruxtecan	New active substance, new biological	Daiichi Sankyo Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/datroway-epar-product-information_en.pdf	April 2025
Dazublys	trastuzumab	New biological	CuraTeQ Biologics s.r.o	https://www.ema.europa.eu/en/documents/product-information/dazublys-epar-product-information_en.pdf	July 2025
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.	https://www.ema.europa.eu/en/documents/product-information	November 2013
Deltyba	Delamanid	Conditional authorisation	Otsuka Novel Products GmbH	https://www.ema.europa.eu/en/documents/product-information/deltyba-epar-product-information_en.pdf	May 2014
Degevma	denosumab	New biological	Teva GmbH	Not available	December 2025
Denbrayce	Denosumab	New active substance	Mabxience Research SL	https://www.ema.europa.eu/en/documents/product-information/denbrayce-epar-product-information_en.pdf	July 2025
Denosumab Intas	denosumab	New biological	Intas Third Party Sales 2005, S.L.	https://www.ema.europa.eu/en/documents/product-information/denosumab-intas-epar-product-information_en.pdf	November 2025
Deqsiga	human normal immunoglobulin	New biological	Takeda Manufacturing Austria AG	https://www.ema.europa.eu/en/documents/product-information/deqsiga-epar-product-information_en.pdf	May 2025
Drovelis	drospirenone/estetrol	New active substance	Gedeon Richter Plc.	https://www.ema.europa.eu/en/documents/product-information/drovelis-epar-product-information_en.pdf	June 2021
DUVYZAT	givinostat	New active substance, conditional marketing authorisation	Italfarmaco S.p.A.	https://www.ema.europa.eu/en/documents/product-information/duvyzat-epar-product-information_en.pdf	June 2025
Dyrupeg	Pegfilgrastim	New biological	CuraTeQ Biologics s.r.o	https://www.ema.europa.eu/en/documents/product-information/dyrupeg-epar-product-information_en.pdf	April 2025
Ebglyss	lebrikizumab	New active substance, new biological	Almirall S.A.	https://www.ema.europa.eu/en/documents/product-information/ebglyss-epar-product-information_en.pdf	November 2023
Ebvallo	Tabelecleucel	New active substance and new biological,Authorised under exceptional circumstances	Pierre Fabre Medicament	https://www.ema.europa.eu/en/documents/product-information/ebvallo-epar-product-information_en.pdf	January 2023
Eladynos	abaloparatide	New active substance	Theramex Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/eladynos-epar-product-information_en.pdf	January 2023
Elaprase	Idursulfase	Authorised under exceptional circumstances	Takeda Pharmaceuticals International AG Ireland Branch	https://www.ema.europa.eu/en/documents/product-information/elaprase-epar-product-information_en.pdf	April 2013
Elfabrio	pegunigalsidase alfa	New active substance and new biological	Chiesi Farmaceutici S.p.A.	https://www.ema.europa.eu/en/documents/product-information/elfabrio-epar-product-information_en.pdf	May 2023

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
□ Elucirem	gadopiclenol	New active substance	Guerbet	https://www.ema.europa.eu/en/documents/product-information/elucirem-epar-product-information_en.pdf	January 2024
ELREXFIO	elranatamab	New biological, new active substance, conditional marketing authorisation	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/elrexfio-epar-product-information_en.pdf	January 2024
Efluelda Tetra	Quadrivalent Influenza Vaccine (Split Virion, Inactivated)	New biological	Sanofi Winthrop	https://cima.aemps.es/cima/dochtml/ft/85068/FT_85068.html Efluelda Tetra, suspensie voor injectie in een voorgevulde spuit | Geneesmiddeleninformatiebank | College ter Beoordeling van https://www.geneesmiddeleninformatiebank.nl/ords/f?p=111:3::SEARCH:::P0_DOMAIN,P0_LANG,P3_RVG1:H,NL,133118	February 2021
Efluelda	Trivalent influenza vaccine (split virion, inactivated)	New biological	Sanofi Winthrop		January 2025
Eiyzey	aflibercept	New biological	Zakłady Farmaceutyczne POLPHARMA S.A.	https://www.ema.europa.eu/en/documents/product-information/eiyzey-epar-product-information_en.pdf	September 2025
Ekterly	sebetralstat	New active substance	KalVista Pharmaceuticals (Ireland) Ltd	https://www.ema.europa.eu/en/documents/product-information/ekterly-epar-product-information_en.pdf	September 2025
ELAHERE	mirvetuximab soravtansine	New biological	AbbVie Deutschland GmbH & Co. KG	https://www.ema.europa.eu/en/documents/product-information/elahere-epar-product-information_en.pdf	November 2024
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
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	satralizumab	New active substance, new biological	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/enspryng-epar-product-information_en.pdf	July 2021
ENOXAPARINE LEDRAXEN	enoxaparin sodium	New biological	VENIPHARM	Not available	September 2022
Enrylaze	crisantaspase	New active substance, new biological	Jazz Pharmaceuticals Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/enrylaze-epar-product-information_en.pdf	September 2023
Enjaymo	sutimlimab	New active substance, new biological	Recordati Rare Diseases	https://www.ema.europa.eu/en/documents/product-information/enjaymo-epar-product-information_en.pdf	November 2022
Enwylma	denosumab	New biological	Zentiva, k.s.	https://www.ema.europa.eu/en/documents/product-information/enwylma-epar-product-information_en.pdf	July 2025
Epysqli	eculizumab	New biological	Samsung Bioepis NL B.V.	https://www.ema.europa.eu/en/documents/product-information/epysqli-epar-product-information_en.pdf	June 2023
Esperoct	Turoctocog alfa pegol	PASS[1]	Novo Nordisk A/S	https://www.ema.europa.eu/en/documents/product-information/esperoct-epar-product-information_en.pdf	June 2019
Evfraxy	denosumab	New biological	Biosimilar Collaborations Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/evfraxy-epar-product-information_en.pdf	July 2025
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	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/evrysdi-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
Evoltra	Clofarabine	Authorised under exceptional circumstances	Genzyme Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/evoltra-epar-product-information_en.pdf	April 2013
Exblifep	cefepime / enmetazobactam	New active substance	ADVANZ PHARMA Limited	https://www.ema.europa.eu/en/documents/product-information/exblifep-epar-product-information_en.pdf	April 2024
~~**Exjade**~~	~~**Deferasirox**~~	~~**PASS**[1]~~	~~**Novartis Europharm Limited**~~	~~**https://www.ema.europa.eu/en/documents/product-information/exjade-epar-product-information_en.pdf**~~	~~**April 2013**~~
Eydenzelt	Aflibercept	New biological	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/eydenzelt-epar-product-information_en.pdf	February 2025
Eyluxvi	aflibercept	New biological	Biolitec Pharma Limited Zweigniederlassung Jena	https://www.ema.europa.eu/en/documents/product-information/eyluxvi-epar-product-information_en.pdf	September 2025
Ezmekly	mirdametinib	New active substance, conditional marketing authorisation, PASS	SpringWorks Therapeutics Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/ezmekly-epar-product-information_en.pdf	July 2025
Fabhalta	iptacopan	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/fabhalta-epar-product-information_en.pdf	May 2024
Filspari	Sparsentan	New active substance	Vifor France S.A.	https://www.ema.europa.eu/en/documents/product-information/filspari-epar-product-information_en.pdf	May 2024
Fintepla	fenfluramine	PASS[1]	UCB Pharma S.A.	https://www.ema.europa.eu/en/documents/product-information/fintepla-epar-product-information_en.pdf	January 2021
Firdapse	Amifampridine	Authorised under exceptional circumstances	BioMarin Europe Ltd	https://www.ema.europa.eu/en/documents/product-information/firdapse-epar-product-information_en.pdf	April 2013
FRUZAQLA	fruquintinib	New active substance	Takeda Pharmaceuticals International AG Ireland Branch	https://www.ema.europa.eu/en/documents/product-information/fruzaqla-epar-product-information_en.pdf	July 2024
Fymskina	ustekinumab	New biological	Formycon AG	https://www.ema.europa.eu/en/documents/product-information/fymskina-epar-product-information_en.pdf	October 2024
Giapreza	Angiotensin II acetate	New active substance	PAION Pharma GmbH	https://www.ema.europa.eu/en/documents/product-information/giapreza-epar-product-information_en.pdf	September 2019
GOBIVAZ	golimumab	New biological	Advanz Pharma Limited	https://www.ema.europa.eu/en/documents/product-information/gobivaz-epar-product-information_en.pdf	November 2025
Gohibic	vilobelimab	New active substance, new biological, authorised under exceptional circumstances	InflaRx GmbH	https://www.ema.europa.eu/en/documents/product-information/gohibic-epar-product-information_en.pdf	January 2025
Gonasi Set	Chorionic gonadotrophin	New biological	IBSA Farmaceutici Italia S.r.l.	Not available	May 2024
Hemgenix	etranacogene dezaparvovec	New biological, new active substance and Conditional Marketing Authorisation, PASS[1]	CSL Behring GmbH	https://www.ema.europa.eu/en/documents/product-information/hemgenix-epar-product-information_en.pdf	March 2023
Hepcludex	bulevirtide	new active substance	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/hepcludex-epar-product-information_en.pdf	August 2020
Herwenda	Trastuzumab	New biological	Sandoz GmbH	https://www.ema.europa.eu/en/documents/product-information/herwenda-epar-product-information_en.pdf	November 2023
HETRONIFLY	Serplulimab	New active substance and New biological	Accord Healthcare S.L.U.	https://www.ema.europa.eu/en/documents/product-information/hetronifly-epar-product-information_en.pdf	February 2025

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Hukyndra	Adalimumab	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/hukyndra-epar-product-information_en.pdf	November 2021
Hympavzi	Marstacimab	New biological, New active substance and PASS	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/hympavzi-epar-product-information_en.pdf	November 2014
Hydroxyethyl starch (HES)-containing medicinal	Hydroxyethyl starch	PASS[1]	Various (For full list see Annex V)	https://www.ema.europa.eu/en/medicines/human/referrals/hydroxyethyl-starch-solutions-infusion-0	January 2014
Idefirix	imlifidase	New biological	Hansa Biopharma AB	https://www.ema.europa.eu/en/documents/product-information/idefirix-epar-product-information_en.pdf	September 2020
Imaavy	nipocalimab	New active substance and New biological	Janssen-Cilag International NV	Not available	December 2025
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
IMJUDO	tremelimumab	New active substance and New biological	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/imjudo-epar-product-information_en.pdf	March 2023
Imreplys	sargramostim	New biological, Authorised under exceptional circumstances	Partner Therapeutics Ltd.	https://www.ema.europa.eu/en/documents/product-information/imreplys-epar-product-information_en.pdf	September 2025
Imuldosa	ustekinumab	New biological	Accord Healthcare S.L.U.	https://www.ema.europa.eu/en/documents/product-information/imuldosa-epar-product-information_en.pdf	January 2025
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
Inaqovi	decitabine / cedazuridine	New active substance	Otsuka Pharmaceutical Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/imvanex-epar-product-information_en.pdf	September 2023
Incellipan	Pandemic influenza vaccine (H5N1) (surface antigen, inactivated,	New biological, Conditional Marketing authorisation	Seqirus Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/incellipan-epar-product-information_en.pdf	May 2024
Increlex	Mecasermin	Authorised under exceptional circumstances	Esteve Pharmaceuticals S.A.	https://www.ema.europa.eu/en/documents/product-information/increlex-epar-product-information_en.pdf	April 2013
Insulin aspart Sanofi	Insulin aspart	New biological	Sanofi Winthrop Industrie	https://www.ema.europa.eu/en/documents/product-information/insulin-lispro-sanofi-epar-product-information_en.pdf	July 2020
Intuniv	Guanfacine	PASS[1]	Takeda Pharmaceuticals International AG Ireland Branch	https://www.ema.europa.eu/en/documents/product-information/intuniv-epar-product-information_en.pdf	September 2015
Iqirvo	elafibranor	New active substance, Conditional marketing authorisation	Ipsen Pharma	https://www.ema.europa.eu/en/documents/product-information/iqirvo-epar-product-information_en.pdf	October 2024
Itovebi	inavolisib	New active substance	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/itovebi-epar-product-information_en.pdf	July 2025
Ituxredi	Rituximab	New biological	Teddy Holding GmbH	https://www.ema.europa.eu/en/documents/product-information/ituxredi-epar-product-information_en.pdf	October 2024
IXCHIQ	Chikungunya vaccine (live)	New active substance and New biological	Valneva Austria GmbH	https://www.ema.europa.eu/en/documents/product-information/ixchiq-epar-product-information_en.pdf	July 2024
Izamby	denosumab	New biological	Mabxience Research SL	https://www.ema.europa.eu/en/documents/product-information/izamby-epar-product-information_en.pdf	July 2025

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
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
Jaypirca	pirtobrutinib	New active substance, Conditional marketing authorisation	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/jaypirca-epar-product-information_en.pdf	November 2023
JEMPERLI	dostarlimab	New active substance, new biological	GlaxoSmithKline Trading Services Limited	https://www.ema.europa.eu/en/documents/product-information/jemperli-epar-product-information_en.pdf	May 2021
JERAYGO	aprocitentan	New active substance, PASS[1]	Idorsia Pharmaceuticals Deutschland GmbH	https://www.ema.europa.eu/en/medicines/human/EPAR/jeraygo#product-info	July 2024
Jubbonti	denosumab	New biological	Sandoz GmbH	https://www.ema.europa.eu/en/documents/product-information/jubbonti-epar-product-information_en.pdf	May 2024
Jubereq	denosumab	New biological	Accord Healthcare S.L.U.	https://www.ema.europa.eu/en/documents/product-information/jubereq-epar-product-information_en.pdf	June 2025
Junod	denosumab	New biological	Gedeon Richter Plc.	https://www.ema.europa.eu/en/documents/product-information/junod-epar-product-information_en.pdf	July 2025
Kanuma	Sebelipase alfa	PASS[1]	Alexion Europe SAS	https://www.ema.europa.eu/en/documents/product-information/kanuma-epar-product-information_en.pdf	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 2022
Kauliv	teriparatide	New biological	Strides Pharma (Cyprus) Ltd.	https://www.ema.europa.eu/en/documents/product-information/kauliv-epar-product-information_en.pdf	February 2023
KAVIGALE	Sipavibart	New active substance and new biological	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/kavigale-epar-product-information_en.pdf	February 2025
KAYFANDA	Odevixibat	Authorized under exceptional circumstances	Ipsen Pharma	https://www.ema.europa.eu/en/documents/product-information/kayfanda-epar-product-information_en.pdf	October 2024
Kefdensis	denosumab	New biological	STADA Arzneimittel AG	Not available	November 2025
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 Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/kesimpta-epar-product-information_en.pdf	April 2021
Ketoconazole Esteve (previously Ketoconazole HRA)	Ketoconazole	PASS[1]	Esteve Pharmaceuticals S.A.	https://www.ema.europa.eu/en/documents/product-information/ketoconazole-hra-epar-product-information_en.pdf	December 2014
KIMMTRAK	tebentafusp	New active substance and *new biological*	Immunocore Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/kimmtrak-epar-product-information_en.pdf	April 2022
Kisunla	donanemab	New active substance, new biological and PASS	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/kisunla-epar-product-information_en.pdf	October 2025
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
Kostaive	Zapomeran (mRNA-2105)	New active substance and new biological	Arcturus Therapeutics Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/kostaive-epar-product-information_en.pdf	February 2025

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
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
Korjuny	catumaxomab	New biological	Atnahs Pharma Netherlands B. V.	https://www.ema.europa.eu/en/documents/product-information/korjuny-epar-product-information_en.pdf	March 2025
Kyinsu	insulin icodec / semaglutide	New active substance, new biological	Novo Nordisk A/S	Not available	December 2025
Kymriah	Tisagenlecleucel	PASS[1]	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/kymriah-epar-product-information_en.pdf	September 2018
Krazati	Adagrasib	New active substance, Conditional Marketing Authorisation	Bristol Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/krazati-epar-product-information_en.pdf	January 2024
Lamzede	Velmanase alfa	authorised under exceptional circumstances	Chiesi Farmaceutici S.p.A.	https://www.ema.europa.eu/en/documents/product-information/lamzede-epar-product-information_en.pdf	April 2018
Lazcluze	Lazertinib	New active substance	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/lazcluze-epar-product-information_en.pdf	February 2025
Lemtrada	Alemtuzumab	PASS[1]	Sanofi Belgium	https://www.ema.europa.eu/en/documents/product-information/lemtrada-epar-product-information_en.pdf	January 2020
Leqembi	Lecanemab	New active substance, new biological, PASS[1]	Eisai GmbH	https://www.ema.europa.eu/en/documents/product-information/leqembi-epar-product-information_en.pdf	April 2025
Libmeldy	autologous CD34+ cell enriched population that contains hematopoietic	~~**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	January 2021
LIBTAYO	Cemiplimab	New active substance, new biological	Regeneron Ireland U.C.	https://www.ema.europa.eu/en/documents/product-information/libtayo-epar-product-information_en.pdf	July 2019
Libmyris	Adalimumab	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/libmyris-epar-product-information_en.pdf	November 2021
Litfulo	ritlecitinib	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/litfulo-epar-product-information_en.pdf	September 2023
Livmarli	maralixibat chloride	New active substance, Authorised under exceptional circumstances	Mirum Pharmaceuticals International B.V.	https://www.ema.europa.eu/en/documents/product-information/livmarli-epar-product-information_en.pdf	January 2023
LIVTENCITY	maribavir	New active substance	Takeda Pharmaceuticals International AG Ireland Branch	https://www.ema.europa.eu/en/documents/product-information/livtencity-epar-product-information_en.pdf	November 2022
Loargys	pegzilarginase	New active substance, New biological, PASS[1]	Immedica Pharma AB	https://www.ema.europa.eu/en/documents/product-information/loargys-epar-product-information_en.pdf	January 2024
Locametz	gozetotide	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/locametz-epar-product-information_en.pdf	January 2023
Lojuxta	Lomitapide	Authorised under exceptional circumstances	Chiesi Farmaceutici S.p.A.	https://www.ema.europa.eu/en/documents/product-information/lojuxta-epar-product-information_en.pdf	September 2013
Skytrofa (Previuosly known as Lonapegsomatropin	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-	January 2022
LOQTORZI	toripalimab	New biological and New active substance	Topalliance Biosciences Europe Limited	https://www.ema.europa.eu/en/documents/product-information/loqtorzi-epar-product-information_en.pdf	October 2024

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
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
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
Lupkynis	voclosporin	New active substance	Otsuka Pharmaceutical Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/lupkynis-epar-product-information_en.pdf	September 2022
Luxturna	Voretigene neparvovec	PASS[1]	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/luxturna-epar-product-information_en.pdf	December 2018
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
Lyfnua	lefapixant	New active substance	Merck Sharp & Dohme B.V.	https://www.ema.europa.eu/en/documents/product-information/lyfnua-epar-product-information_en.pdf	September 2023
Lynkuet	elinzanetant	New active subtance	Bayer AG	Not available	December 2025
LYNOZYFIC	linvoseltamab	New active substance, new biological and conditional marketing authorisation	Regeneron Ireland Designated Activity Company (DAC)	https://www.ema.europa.eu/en/documents/product-information/lynozyfic-epar-product-information_en.pdf	May 2025
Lytenava	bevacizumab gamma	New biological	Outlook Therapeutics Limited	https://www.ema.europa.eu/en/documents/product-information/lytenava-epar-product-information_en.pdf	June 2024
Lytgobi	futibatinib	New active substance, Conditional marketing authorisation	Taiho Pharma Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/lytgobi-epar-product-information_en.pdf	July 2023
Maapliv	amino acids	Authorised under exceptional circumstances	Recordati Rare Diseases	https://www.ema.europa.eu/en/documents/product-information/maapliv-epar-product-information_en.pdf	September 2025
Mepsevii	Vestronidase alfa	Authorized under exceptional circumstances	Ultragenyx Germany GmbH	https://www.ema.europa.eu/en/documents/product-information/mepsevii-epar-product-information_en.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
Mounjaro	tirzepatide	New active substance	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/mounjaro-epar-product-information_en.pdf	September 2022
mRESVIA	Single-stranded 5' capped mRNA encoding the respiratory syncytial	New active substance, New biological	MODERNA BIOTECH SPAIN, S.L.	https://www.ema.europa.eu/en/documents/product-information/mresvia-epar-product-information_en.pdf	September 2024
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
Myalepta	Metreleptin	Authorized under exceptional circumstances	Chiesi Farmaceutici S.p.A.	https://www.ema.europa.eu/en/documents/product-information/myalepta-epar-product-information_en.pdf	September 2018
MYNZEPLI	aflibercept	New biological	Advanz Pharma Limited	https://www.ema.europa.eu/en/documents/product-information/mynzepli-epar-product-information_en.pdf	September 2025
Mysimba	Naltrexone / bupropion	PASS[1]	Orexigen Therapeutics Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/mysimba-epar-product-information_en.pdf	April 2015
NADROPARINE CALCIQUE ASPEN	nadroparin calcium	New biological	ASPEN PHARMA TRADING LIMITED	Not available	September 2022

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Natpar	Parathyroid hormone	Conditional authorisation	Shire Pharmaceuticals Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/natpar-epar-product-information_en.pdf	May 2017
Nemluvio	Nemolizumab	New active substance and new biological	Galderma International	https://www.ema.europa.eu/en/documents/product-information/nemluvio-epar-product-information_en.pdf	February 2025
NEXPOVIO	selinexor	New active substance	Karyopharm Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/nexpovio-epar-product-information_en.pdf	April 2021
Nexviadyme	avalglucosidase alfa	New active substance and new biological	Genzyme Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/nexviadyme-epar-product-information_en.pdf	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
NULIBRY	fosdenopterin	New active substance, authorised under exceptional circumstances	MC Pharma (EU) Limited	https://www.ema.europa.eu/en/documents/product-information/nulibry-epar-product-information_en.pdf	September 2022
Nuvaxovid	SARS-CoV-2 recombinant spike protein	New active substance and new biological	Sanofi Winthrop Industrie	https://www.ema.europa.eu/en/documents/product-information/nuvaxovid-epar-product-information_en.pdf	January 2022
Obizur	Susoctocog alfa	Authorised under exceptional circumstances	Baxalta Innovations GmbH	https://www.ema.europa.eu/en/documents/product-information/obizur-epar-product-information_en.pdf	November 2015
Obgemsa	Vibegron	New active substance	PIERRE FABRE MEDICAMENT	https://www.ema.europa.eu/en/documents/product-information/obgemsa-epar-product-information_en.pdf	July 2024
Obodence	Denosumab	New biological	Samsung Bioepis NL B.V.	https://www.ema.europa.eu/en/documents/product-information/obodence-epar-product-information_en.pdf	February 2025
Ogsiveo	nirogacestat	New active substance	SpringWorks Therapeutics Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/ogsiveo-epar-product-information_en.pdf	September 2025
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
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
Omjjara	momelotinib	New active substance	GlaxoSmithKline Trading Services Limited	https://www.ema.europa.eu/en/documents/product-information/omjjara-epar-product-information_en.pdf	February 2024
Omlyclo	Omalizumab	New biological	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/omlyclo-epar-product-information_en.pdf	June 2024
Omvoh	mirikizumab	New active substance, new biological	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/omvoh-epar-product-information_en.pdf	June 2023
Opdualag	nivolumab/relatlimab	New active substance, new biological	Bristol Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/opdualag-epar-product-information_en.pdf	September 2022
Opuviz	Aflibercept	New biological	Samsung Bioepis NL B.V.	https://www.ema.europa.eu/en/documents/product-information/opuviz-epar-product-information_en.pdf	November 2024
Ordspono	odronextamab	New active substance, new biological and Conditional Marketing authorisation	Regeneron Ireland Designated Activity Company (DAC)	https://www.ema.europa.eu/en/documents/product-information/ordspono-epar-product-information_en.pdf	September 2024
Orladeyo	berotralstat	New active substance	Biocryst Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/orladeyo-epar-product-information_en.pdf	May 2021

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Orylmyte	Allergen extract from house dust mites (Dermatophagoides	New biological	Stallergenes	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?mpdidentifier=7000377	July 2021
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 2022
Orphacol	Cholic acid	Authorised under exceptional circumstances	Laboratoires CTRS	https://www.ema.europa.eu/en/documents/product-information/orphacol-epar-product-information_en.pdf	October 2013
ORSERDU	elacestrant	New active substance	Stemline Therapeutics B.V.	https://www.ema.europa.eu/en/documents/product-information/orserdu-epar-product-information_en.pdf	September 2023
Osenvelt	Denosumab	New biological	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/osenvelt-epar-product-information_en.pdf	February 2025
Osvyrti	denosumab	New biological	Accord Healthcare S.L.U.	https://www.ema.europa.eu/en/documents/product-information/osvyrti-epar-product-information_en.pdf	June 2025
Oxbryta	Voxelotor	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/oxbryta-epar-product-information_en.pdf	February 2022
Otulfi	ustekinumab	New biological	Fresenius Kabi Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/otulfi-epar-product-information_en.pdf	October 2024
Oyavas	bevacizumab	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/oyavas-epar-product-information_en.pdf	April 2021
Padcev	enfortumab vedotin	New active substance and *new biological*	Astellas Pharma Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/padcev-epar-product-information_en.pdf	April 2022
Palforzia	defatted powder of Arachis	New biological	Immune Therapeutics Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/palforzia-epar-product-information_en.pdf	November 2022
Pandemic influenza vaccine H5N1 AstraZeneca	Pandemic influenza vaccine (H5N1) (live attenuated, nasal)	Conditional marketing authorisation	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/pandemic-influenza-vaccine-h5n1-astrazeneca-epar-	June 2016
PAVBLU	Aflibercept	New biological	Amgen Technology (Ireland) UC	https://www.ema.europa.eu/en/documents/product-information/pavblu-epar-product-information_en.pdf	April 2025
Paxlovid	nirmatrelvir	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/paxlovid-epar-product-information_en.pdf	February 2022
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	April 2021
Percolozin	enoxaparin sodium	New biological	Venipharm	N/A	January 2022
Piasky	crovalimab	New active substance, new biological	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/piasky-epar-product-information_en.pdf	September 2024
Pluvicto	lutetium (177Lu) vipivotide tetraxetan	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/pluvicto-epar-product-information_en.pdf	January 2023
Ponlimsi	Denosumab	New biological	Teva GmbH	Not available	December 2025
Ponvory	ponesimod	New active substance	LABORATOIRES JUVISE PHARMACEUTICALS	https://www.ema.europa.eu/en/documents/product-information/ponvory-epar-product-information_en.pdf	June 2021

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Pombiliti	cipaglucosidase alfa	New active substance, new biological	Amicus Therapeutics Europe Limited	https://www.ema.europa.eu/en/documents/product-information/pombiliti-epar-product-information_en.pdf	April 2023
Pylclari	piflufolastat (18F)	New active substance	CURIUM PET France	https://www.ema.europa.eu/en/documents/product-information/pylclari-epar-product-information_en.pdf	September 2023
Pyrukynd	mitapivat	New active substance	Agios Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/pyrukynd-epar-product-information_en.pdf	November 2022
Pyzchiva	ustekinumab	New biological	Samsung Bioepis NL B.V.	https://www.ema.europa.eu/en/documents/product-information/pyzchiva-epar-product-information_en.pdf	May 2024
Dovprela (previuosly known as Pretomanid FGK)	pretomanid	New active substance	Mylan IRE Healthcare Limited	https://www.ema.europa.eu/en/documents/product-information/pretomanid-fgk-epar-product-information_en.pdf	August 2020
Qalsody	tofersen	New active substance, PASS[1]	Biogen Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/qalsody-epar-product-information_en.pdf	June 2024
Qarziba (previously Dinutuximab beta EUSA and Dinutuximab beta	Dinutuximab beta	Authorised under exceptional circumstances	EUSA Pharma (UK) Limited	https://www.ema.europa.eu/en/documents/product-information/qarziba-epar-product-information_en.pdf	May 2017
Qdenga	dengue tetravalent vaccine (live, attenuated)	New biological	Takeda GmbH	https://www.ema.europa.eu/en/documents/product-information/qdenga-epar-product-information_en.pdf	December 2022
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	December 2021
Qoyvolma	ustekinumab	New biological	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/qoyvolma-epar-product-information_en.pdf	June 2025
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
Epruvy (previously Ranibizumab Midas)	ranibizumab	New biological	Midas Pharma GmbH	https://www.ema.europa.eu/en/documents/product-information/epruvy-epar-product-information_en.pdf	October 2024
Ranivisio	ranibizumab	New biological	Midas Pharma GmbH	https://www.ema.europa.eu/en/documents/product-information/ranivisio-epar-product-information_en.pdf	September 2022
Raxone	Idebenone	Authorised under exceptional circumstances	Chiesi Farmaceutici S.p.A.	https://www.ema.europa.eu/en/documents/product-information/raxone-epar-product-information_en.pdf	September 2015
RAYVOW	lasmiditan	New active substance	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/rayvow-epar-product-information_en.pdf	September 2022
Refixia	Nonacog beta pegol	PASS[1]	Novo Nordisk A/S	https://www.ema.europa.eu/en/documents/product-information/refixia-epar-product-information_en.pdf	June 2017
Relfydess	Clostridium botulinum neurotoxin type A	New biological	Ipsen Pharma	Relfydess 100 E/ml injektionsvätska, lösning | Läkemedelsverket	November 2025
REKAMBYS	rilpivirine	PASS[1]	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/rekambys-epar-product-information_en.pdf	January 2021
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	https://www.ema.europa.eu/en/documents/product-information/revestive-epar-product-information_en.pdf	April 2013

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Revlimid	Lenalidomide	PASS[1]	Bristol-Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/revlimid-epar-product-information_en.pdf	June 2014
Rezzayo	Rezafungin	New active substance	Mundipharma GmbH	https://www.ema.europa.eu/en/documents/product-information/rezzayo-epar-product-information_en.pdf	January 2024
Rezdiffra	Resmetirom	New active substance, Conditional marketing authorisation	Madrigal Pharmaceuticals EU Limited	https://www.ema.europa.eu/en/documents/product-information/rezdiffra-epar-product-information_en.pdf	September 2025
Rimmyrah	Ranibizumab	New biological	QILU PHARMA SPAIN S.L.	https://www.ema.europa.eu/en/documents/product-information/rimmyrah-epar-product-information_en.pdf	January 20247
Roctavian	valoctocogene roxaparvovec	New active substance, New biological, Conditional marketing authorisation and PASS[1]	BioMarin International Limited	https://www.ema.europa.eu/en/documents/product-information/roctavian-epar-product-information_en.pdf	September 2022
Rolcya	denosumab	New biological	Sandoz GmbH	https://www.ema.europa.eu/en/documents/product-information/rolcya-epar-product-information_en.pdf	July 2025
ROMVIMZA	vimseltinib	New active substance	Deciphera Pharmaceuticals (Netherlands) B.V.	https://www.ema.europa.eu/en/documents/product-information/romvimza-epar-product-information_en.pdf	October 2025
Ronapreve	Casirivimab/imdevimab	New active substance and *new biological*	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/ronapreve-epar-product-information_en.pdf	November 2021
Rozlytrek	entrectinib	Conditional marketing authorisation	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/rozlytrek-epar-product-information_en.pdf	August 2020
~~**Rukobia**~~	~~**fostemsavir**~~	~~**New active substance**~~	~~**ViiV Healthcare BV**~~	~~**https://www.ema.europa.eu/en/documents/product-information/rukobia-epar-product-information_en.pdf**~~	~~**February 2021**~~
Rybrevant	Amivantamab	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
Rystiggo	Rozanolixizumab	New active substance, New biological	UCB Pharma S.A.	https://www.ema.europa.eu/en/documents/product-information/rystiggo-epar-product-information_en.pdf	January 2024
Rytelo	imetelstat	New active substance	Geron Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/rytelo-epar-product-information_en.pdf	March 2025
Ryzneuta	efbemalenograstim alfa	New active substance and new biological	Evive Biotechnology Ireland LTD	https://www.ema.europa.eu/en/documents/product-information/ryzneuta-epar-product-information_en.pdf	April 2024
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
Scemblix	asciminib	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/scemblix-epar-product-information_en.pdf	September 2022
Scenesse	Afamelanotide	Authorised under exceptional circumstances	Clinuvel UK Limited	https://www.ema.europa.eu/en/documents/product-information/scenesse-epar-product-information_en.pdf	January 2015
Seladelpar Gilead	seladelpar	New active substance, Conditional marketing authorisation	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/seladelpar-gilead-epar-product-information_en.pdf	March 2025
Sephience	Sepiapterin	New active substance	PTC Therapeutics International Limited	https://www.ema.europa.eu/en/documents/product-information/sephience-epar-product-information_en.pdf	July 2025

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
SIILTIBCY	rdESAT-6 and rCFP-10	New active substance, new biological	Serum Life Science Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/siiltibcy-epar-product-information_en.pdf	January 2025
Skyclarys	omaveloxolone	New active substance	Biogen Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/skyclarys-epar-product-information_en.pdf	February 2024
~~**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**~~	~~**April 2021**~~
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
SOTYKTU	deucravacitinib	New active substance	Bristol Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/sotyktu-epar-product-information_en.pdf	April 2023
Spikevax (previously COVID-19 Vaccine Moderna)	elasomeran (formally COVID-19 mRNA Vaccine (nucleoside-modified))	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	January 2021
STEQEYMA	ustekinumab	New biological	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/steqeyma-epar-product-information_en.pdf	September 2024
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	Authorised under exceptional circumstances	Alexion Europe SAS	https://www.ema.europa.eu/en/documents/product-information/strensiq-epar-product-information_en.pdf	September 2015
Strimvelis	Autologous CD34+ enriched cell fraction that contains CD34+ cells	PASS[1]	Fondazione Telethon ETS	https://www.ema.europa.eu/en/documents/product-information/strimvelis-epar-product-information_en.pdf	June 2016
Spevigo	Spesolimab	New active substance, new biological and Conditional marketing authorisation	Boehringer Ingelheim International GmbH	https://www.ema.europa.eu/en/documents/product-information/spevigo-epar-product-information_en.pdf	January 2023
Sublivac Birke	Allergen extract of pollen from Birch	New biological	HAL Allergie GmbH	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdid	September 2018
Sublivac Bäume	Allergen extract of pollen from Birch, Alder and Hazel	New biological	HAL Allergie GmbH	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdid	September 2018
Sunlenca	lenacapavir	New active substance	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/sunlenca-epar-product-information_en.pdf	September 2022
Sylvant	Siltuximab	PASS[1]	EUSA Pharma (Netherlands) B.V.	https://www.ema.europa.eu/en/documents/product-information/sylvant-epar-product-information_en.pdf	June 2014
Tabrecta	capmatinib	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/tabrecta-epar-product-information_en.pdf	June 2022
TALVEY	talquetamab	New active substance, new biological and Conditional marketing authorisation	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/talvey-epar-product-information_en.pdf	Septermber 2023
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
Tauvid	Flortaucipir (18F)	New active substance Conditional marketing authorisation /	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/tauvid-epar-product-information_en.pdf	September 2024
Tecartus	autologous anti-CD19-transduced CD3+ cells	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	January 2021

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Tecovirimat SIGA	tecovirimat monohydrate	Authorised under exceptional circumstanc	SIGA Technologies Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/tecovirimat-siga-epar-product-information_en.pdf	January 2022
TECVAYLI	teclistamab	New active substance, new biological and	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/tecvayli-epar-product-information_en.pdf	September 2022
Tepkinly	epcoritamab	New active substance, new biological and conditional marketing authorisation	AbbVie Deutschland GmbH & Co. KG	https://www.ema.europa.eu/en/documents/product-information/tepkinly-epar-product-information_en.pdf	October 2023
Tepmetko	Tepotinib hydrochloride mo	New active substance	Merck Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/tepmetko-epar-product-information_en.pdf	March 2022
TEPEZZA	Teprotumumab	New active substance and new biological	Amgen Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/tepezza-epar-product-information_en.pdf	July 2025
Tevimbra	tislelizumab	New biological	BeiGene Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/tevimbra-epar-product-information_en.pdf	September 2023
Tezspire	tezepelumab	New active substance and new biological	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/tezspire-epar-product-information_en.pdf	September 2022
Thiosix	Tioguanin	Authorised under exceptional circumstances	Teva Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/tibsovo-epar-product-information_en.pdf http://db.cbg-meb.nl/IB-teksten/h114681.pdf	May 2015
Tibsovo	ivosidenib	New active substance	Les Laboratoires Servier		May 2023
Tivdak	tisotumab vedotin	New active substance and new biological	Genmab A/S	https://www.ema.europa.eu/en/documents/product-information/tivdak-epar-product-information_en.pdf	April 2025
Tofidence	tocilizumab	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/tofidence-epar-product-information_en.pdf	June 2024
Trivalent Influenza Vaccine	Influenza vaccine (split viric	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
Truqap	capivasertib	New active substance	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/truqap-epar-product-information_en.pdf	June 2024
Tryngolza	olezarsen	New active substance	Swedish Orphan Biovitrum AB (publ)	https://www.ema.europa.eu/en/documents/product-information/tryngolza-epar-product-information_en.pdf	September 2025
Topiramate containing medicinal products in the	topiramate	PASS[1]	Variuos (for full list see Annex XV)	https://www.ema.europa.eu/en/medicines/human/referrals/topiramate	May 2024
Tuznue	trastuzumab	New biological	Prestige Biopharma Belgium BVBA	https://www.ema.europa.eu/en/documents/product-information/tuznue-epar-product-information_en.pdf	October 2024
Tyenne	tocilizumab	New biological	Fresenius Kabi Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/tyenne-epar-product-information_en.pdf	September 2023
Tyruko	natalizumab	New biological	Sandoz GmbH	https://www.ema.europa.eu/en/documents/product-information/tyruko-epar-product-information_en.pdf	October 2023

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Uplizna	inebilizumab	New active substance, new biological	Amgen Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/uplizna-epar-product-information_en.pdf	May 2022
Upstaza	Eladocagene exuparvovec	New active substance, new biological, authorised under exceptional circumstances	PTC Therapeutics International Limited	https://www.ema.europa.eu/en/documents/product-information/upstaza-epar-product-information_en-0.pdf	July 2022
Usgena	ustekinumab	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/usgena-epar-product-information_en.pdf	November 2025
Usrenty	ustekinumab	New biological	Biosimilar Collaborations Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/usrenty-epar-product-information_en.pdf	October 2025
Usymro	ustekinumab	New biological	Gedeon Richter Plc.	https://www.ema.europa.eu/en/documents/product-information/usymro-epar-product-information_en.pdf	September 2025
Uzpruvo	ustekinumab	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/uzpruvo-epar-product-information_en.pdf	January 2024
Vabysmo	Faricimab	New active substance, new biological	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/vabysmo-epar-product-information_en.pdf	September 2022
Valproate and related substances (sodium valproate, valproic acid,	Sodium valproate, valproic acid, valproate semisodium, valpromide	PASS[1]	Various (For full list see Annex XIII)	https://www.ema.europa.eu/en/medicines/human/referrals/valproate-related-substances	January 2015
Vafseo	Vadadustat	New active substance	AKEBIA EUROPE Limited	https://www.ema.europa.eu/en/documents/product-information/vafseo-epar-product-information_en.pdf	May 2023
VANFLYTA	quizartinib	New active substance	Daiichi Sankyo Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/vanflyta-epar-product-information_en.pdf	November 2023
Vaxneuvance	pneumococcal polysaccharide	New active substance, new biological	Merck Sharp & Dohme B.V.	https://www.ema.europa.eu/en/documents/product-information/vaxneuvance-epar-product-information_en.pdf	January 2022
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	March 2021
Vedrop	Tocofersolan d-alpha tocopheryl polyethylene glycol succinate	Authorised under exceptional circumstances	Recordati Rare Diseases	https://www.ema.europa.eu/en/documents/product-information/vedrop-epar-product-information_en.pdf	April 2013
VEGZELMA	bevacizumab	New biological	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/vegzelma-epar-product-information_en.pdf	September 2022
Velsipity	etrasimod	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/velsipity-epar-product-information_en.pdf	February 2024
Verquvo	Vericiguat	New active substance	Bayer AG	https://www.ema.europa.eu/en/documents/product-information/verquvo-epar-product-information_en.pdf	July 2021
Veoza	fezolinetant	New active substance	Astellas Pharma Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/veoza-epar-product-information_en.pdf	January 2024
Vevzuo	denosumab	New biological	Biosimilar Collaborations Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/vevzuo-epar-product-information_en.pdf	July 2025
Vgenfli	aflibercept	New bilogical	Zakłady Farmaceutyczne POLPHARMA S.A.	https://www.ema.europa.eu/en/documents/product-information/vgenfli-epar-product-information_en.pdf	September 2025
Vimizim	Elosulfase alfa	PASS[1]	BioMarin International Limited	https://www.ema.europa.eu/en/documents/product-information/vimizim-epar-product-information_en.pdf	June 2014

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
VIMKUNYA	Chikungunya vaccine (recombinant, adsorbed) (PXVX0317)	New biological, new active substance,	Bavarian Nordic A/S	https://www.ema.europa.eu/en/documents/product-information/vimkunya-epar-product-information_en.pdf	March 2025
VITRAKVI	Larotrectinib	Conditional authorisation	Bayer AG	https://www.ema.europa.eu/documents/product-information/vitrakvi-epar-product-information_en.pdf	October 2019
Vocabria	cabotegravir	PASS[1]	ViiV Healthcare BV	https://www.ema.europa.eu/en/documents/product-information/vocabria-epar-product-information_en.pdf	January 2021
Voranigo	vorasidenib	New active substance	Les Laboratoires Servier	https://www.ema.europa.eu/en/documents/product-information/voranigo-epar-product-information_en.pdf	September 2025
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	September 2021
Voydeya	danicopan	New active substance	Alexion Europe SAS	https://www.ema.europa.eu/en/documents/product-information/voydeya-epar-product-information_en.pdf	May 2024
Vueway	gadopiclenol	New active substance	Bracco Imaging SPA	https://www.ema.europa.eu/en/documents/product-information/vueway-epar-product-information_en.pdf	January 2024
Vydura	rimegepant	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/vydura-epar-product-information_en.pdf	May 2022
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
Vyjuvek	beremagene geperpavec	New active substance, new biological, PASS[1]	Krystal Biotech Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/vyjuvek-epar-product-information_en.pdf	May 2025
Vyloy	zolbetuximab	New biological	Astellas Pharma Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/vyloy-epar-product-information_en.pdf	October 2024
Vyndaqel	Tafamidis	Authorised under exceptional circumstances	Pfizer Europa MA EEG	https://www.ema.europa.eu/en/documents/product-information/vyndaqel-epar-product-information_en.pdf	April 2013
Vyvgart	efgartigimod alfa	New active substance and new biological	argenx BV	https://www.ema.europa.eu/en/documents/product-information/vyvgart-epar-product-information_en.pdf	September 2022
Wainzua	eplontersen	New active substance	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/wainzua-epar-product-information_en.pdf	March 2025
Wakix	Pitolisant hydrochloride	PASS[1]	Bioprojet Pharma	https://www.ema.europa.eu/en/documents/product-information/wakix-epar-product-information_en.pdf	April 2016
Waylivra	Volanesorsen	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
WELIREG	belzutifan	New active substance and conditional marketing authorisation	Merck Sharp & Dohme B.V.	https://www.ema.europa.eu/en/documents/product-information/welireg-epar-product-information_en.pdf	February 2025
Wezenla	Ustekinumab	New biological	Amgen Technology (Ireland) UC	https://www.ema.europa.eu/en/documents/product-information/wezenla-epar-product-information_en.pdf	July 2024

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Winlevi	Clascoterone	New active substance	Cassiopea S.p.A.	Not available	October 2025
Winrevair	sotatercept	New active substance, new biological	Merck Sharp & Dohme B.V.	https://www.ema.europa.eu/en/documents/product-information/winrevair-epar-product-information_en.pdf	September 2024
Wyost	denosumab	New biological	Sandoz GmbH	https://www.ema.europa.eu/en/documents/product-information/wyost-epar-product-information_en.pdf	May 2024
Xbryk	Denosumab	New biological	Samsung Bioepis NL B.V.	https://www.ema.europa.eu/en/documents/product-information/xbryk-epar-product-information_en.pdf	February 2025
Xbonzy	denosumab	New biological	Reddy Holding GmbH	Not available	November 2025
Xembify	Human normal Immunoglot	New biological	Instituto Grifols S.A.	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdid	March 2022
Xenpozyme	olipudase alfa	New active substance, new biological	Genzyme Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/xenpozyme-epar-product-information_en.pdf	July 2022
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
Ximluci	Faricimab	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/ximluci-epar-product-information_en.pdf	November 2022
Xofigo	Radium Ra 223 dichloride	PASS[1]	Bayer AG	https://www.ema.europa.eu/en/documents/product-information/xofigo-epar-product-information_en.pdf	December 2013
Yaxwer	denosumab	New biological	Gedeon Richter Plc.	https://www.ema.europa.eu/en/documents/product-information/yaxwer-epar-product-information_en.pdf	July 2025
Yesafili	aflibercept	New biological	Biosimilar Collaborations Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/yesafili-epar-product-information_en.pdf	September 2023
Yescarta	Axicabtagene ciloleucel	PASS[1]	Kite Pharma EU B.V.	https://www.ema.europa.eu/en/documents/product-information/yescarta-epar-product-information_en.pdf	September 2018
Yesintek	Ustekinumab	New biological	Biosimilar Collaborations Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/yesintek-epar-product-information_en.pdf	February 2025
Yimmugo	Human normal Immunoglobulin	New biological	Biotest Pharma GmbH	https://portal.dimdi.de/amguifree/am/docoutput/jpadocdisplay.xhtml?globalDocId=E9C019E2F641455FBDB3AF3C8E60006F&directdisplay=true&docid=1	November 2022
Yorvipath	palopegteriparatide	New active substance	Ascendis Pharma Bone Diseases A/S	https://www.ema.europa.eu/en/documents/product-information/yorvipath-epar-product-information_en.pdf	November 2023
Yselty	linzagolix choline	New active substance	Theramex Ireland Limited	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
ZADENVI	denosumab	New biological	Zentiva k.s.	https://www.ema.europa.eu/en/documents/product-information/zadenvi-epar-product-information_en.pdf	July 2025
Zefylti	Filgrastim	New biological	CuraTeQ Biologics s.r.o	https://www.ema.europa.eu/en/documents/product-information/zefylti-epar-product-information_en.pdf	February 2025

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Zegalogue	Dasiglucagon	New active substance	Novo Nordisk A/S	https://www.ema.europa.eu/en/documents/product-information/zegalogue-epar-product-information_en.pdf	July 2024
Zemcelpro	Ddrocubicel / allogeneic umbilical cord-derived CD34- cells, non-expanded	New active substance, New biological and Conditional marketing authorisation	CCordex Biologics International Limited	https://www.ema.europa.eu/en/documents/product-information/zemcelpro-epar-product-information_en.pdf	September 2025
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
Zilbrysq	zilucoplan	New active substance	UCB Pharma S.A.	https://www.ema.europa.eu/en/documents/product-information/zilbrysq-epar-product-information_en.pdf	December 2023
Ziihera	zZanidatamab	New active substance, New biological and Conditional marketing authorisation	JJazz Pharmaceuticals Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/ziihera-epar-product-information_en.pdf	July 2025
Zokinvy	Lonafarnib	New active substance, authorised under exceptional circumstances	TMC Pharma (EU) Limited	https://www.ema.europa.eu/en/documents/product-information/zokinvy-epar-product-information_en.pdf	July 2022
Zolgensma	Onasemnogene abeparvovec	New active substance, new biological	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/zolgensma-epar-product-information_en.pdf	May 2020
ZTALMY	Gganaxolone	New active substance	Immedica Pharma AB	https://www.ema.europa.eu/en/documents/product-information/ztalmy-epar-product-information_en.pdf	September 2023
Zurzuvae	Zuranolone	New active substance	Biogen Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/zurzuvae-epar-product-information_en.pdf	October 2025
Zvogra	DDenosumab	New biological	STADA Arzneimittel AG	Not available	November 2025
Zynlonta	loncastuximab tesirine	New active substance, new biological and Conditional marketing authorisation	ADC Therapeutics (NL) B.V.	https://www.ema.europa.eu/en/documents/product-information/zynlonta-epar-product-information_en.pdf	January 2023
ZYNYZ	retifanlimab	New active substance, New biological	IIncyte Biosciences Distribution B.V.	https://www.ema.europa.eu/en/documents/product-information/zynyz-epar-product-information_en.pdf	May 2024

[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 26 July 2024.

[2] Product currently suspended following a referral procedure under Article 20 of Regulation (EC) 726/2004.