

25 July 2025
EMA/245297/2013 Rev. 135*
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 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-21
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
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 <i>new biological</i>	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
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&mpdid=...	September 2020
Afqlir	aflibercept	New biological	Sandoz GmbH	https://www.ema.europa.eu/en/documents/product-information/afqlir-epar-product-information_en.pdf	November 2024

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Awigli	insulin icodec	New active substance, New biological	N Novo Nordisk A/S	https://www.ema.europa.eu/en/documents/product-information/awigli-epar-product-information_en.pdf	May 2024
AYVAKYT	avapritinib	New active substance, conditional marketing authorisation	Blueprint Medicines (Netherlands) B.V.	https://www.ema.europa.eu/en/documents/product-information/ayvakyat-epar-product-information_en.pdf	September 2020
Avtozma	ācilizumab	New biological	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/avtozma-epar-product-information_en.pdf	March 2025
Avzivi	Ēvacizumab	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	Ĵanssen-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	Ħrsevimab	New active substance and <i>new biological</i>	Sanofi Winthrop Industrie	https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf	November 2022
BEYONTTRA	ācoramidis	New active substance	BridgeBio Europe B.V. Bayer AG	https://www.ema.europa.eu/en/documents/product-information/beyontra-epar-product-information_en.pdf	February 2025
BIMERVAX	COVID-19 Vaccine (recombinant, adjuvanted)	New active substance and new biological	Ĥipra 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	Not available https://www.ema.europa.eu/en/documents/product-information/blincyto-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
Bomynta	denosumab	New biological	Eresenius Kabi Deutschland GmbH	Not availale https://www.ema.europa.eu/en/documents/product-information/bylvay-epar-product-information_en.pdf	July 2025
Bylvay	Odevixibat	New active substance, authorised under exceptional circumstances	Ipsen Pharma	https://www.ema.europa.eu/en/documents/product-information/byooviz-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/breyanzi-epar-product-information_en.pdf	April 2024
Breyanzi	lisocabtagene maraleucel	New biological, new active substance, PASS ¹	Bristol Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/brineura-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/briumvi-epar-product-information_en.pdf	June 2017
Briumvi	Ħblituximab	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

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
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
Byfavo	remimazolam	New active substance	PAION Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/byfavo-epar-product-information_en.pdf	April 2021
Calquence	acalabrutinib	New active substance	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/calquence-epar-product-information_en.pdf	November 2020
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.	Not available	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	Leadiant GmbH	N/A	
			Laboratoires Genévrier	https://www.ema.europa.eu/en/documents/product-information/cibingo-epar-product-information_en.pdf	January 2022
Cibingo	abrocitinib	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/cibingo-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
				N/A	
Colevance	enoxaparin sodium	New biological	Venipharm	https://www.ema.europa.eu/en/documents/product-information/columvi-epar-product-information_en.pdf	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
Conexxence	Enosumab	New biological	Eresenius Kabi Deutschland GmbH	Not available	July 2025
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	Jan-21

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
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
Datroway	datopotamab deruxtecan	New active substance, new biological	Daiichi Sankyo Europe GmbH	Not available	April 2025
Dazublys	trastuzumab	New biological	CuraTeQ Biologics s.r.o	Not availale	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
Denbrayce	Denosumab	New active substance	Mabxience Research SL	Not available	July 2025
Deqsig	human normal immunoglobulin	New biological	Takeda Manufacturing Austria AG	Not available	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.	Not available	June 2025
Dyrupeg	Pegfilgrastim	New biological	CuraTeQ Biologics s.r.o	Not available	April 2025
Ebglyss	Iebrikizumab	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
Eksunbi	ustekinumab	New biological	Samsung Bioepis NL B.V.	https://www.ema.europa.eu/en/documents/product-information/eksunbi-epar-product-information_en.pdf	September 2024
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
□ 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/elrex fio-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	February 2021

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Efluelda	Trivalent influenza vaccine (split virion, inactivated)	New biological	Sanofi Winthrop	https://www.geneesmiddeleninformatiebank.nl/ords/f?p=111:3::SEARCH:::P0 DOMAIN,P3 RVG1:H,NL,133118	January 2025
ELAHERE	Elirvetuximab 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	Erisantaspase	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	Etimlimab	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	Eenosumab	New biological	Zentiva, k.s.	Not available	July 2025
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
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	Eenosumab	New biological	Biosimilar Collaborations Ireland Limited	Not available	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
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
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
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

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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
Ezmecky	mirdametinib	New active substance, conditional marketing authorisation, PASS	SpringWorks Therapeutics Ireland Limited	Not available	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	Eörmeycon 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
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
Heplisav 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
Herwenda	trastuzumab	New biological	Sandoz GmbH	https://www.ema.europa.eu/en/documents/product-information/herwenda-epar-product-information_en.pdf	November 2023
HETRONIFLY	carplulimab	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
Holoclar	Ex vivo expanded autologous human corneal epithelial cells containing stem cells	Conditional marketing authorisation	Holostem S.r.l.	https://www.ema.europa.eu/en/documents/product-information/holoclar-epar-product-information_en.pdf	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
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
<u>Hydroxyethyl starch (HES)-containing medicinal products</u>	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

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Idefirix	imlifidase	New biological	Hansa Biopharma AB	https://www.ema.europa.eu/en/documents/product-information/idefirix-epar-product-information_en.pdf	Sep-20
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
Imnovid (formerly Pomalidomide Celgene)	Pomalidomide	PASS ¹	Bristol Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/innovid-epar-product-information_en.pdf	September 2013
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 antiaen. 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	Ipsen Pharma	https://www.ema.europa.eu/en/documents/product-information/increlex-epar-product-information_en.pdf	April 2013
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 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	Boehringer Ingelheim GmbH	Not available	July 2025
Ituxredi	Rituximab	New biological	Reddy 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 Jaydess (also known in some EU countries as Fleree)	denosumab	New biological	Abxience Research SL	Not available	July 2025
	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 (Ireland) Limited	https://www.ema.europa.eu/en/documents/product-information/jemperli-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
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
Jinarc	Tolvaptan	PASS ¹	Otsuka Pharmaceutical Europe Ltd.	https://www.ema.europa.eu/en/documents/product-information/jinarc-epar-product-information_en.pdf	June 2015
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.	Not available	June 2025
Junod	denosumab	New biological	Gedeon Richter Plc.	Not available	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-22
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
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 HRA	Ketoconazole	PASS ¹	ERA Pharma Rare Diseases	https://www.ema.europa.eu/en/documents/product-information/ketoconazole-hra-epar-product-information_en.pdf	December 2014
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
Kirsty	Insulin aspart	New biological	Biosimilar Collaborations Ireland 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
Kostaive	zapomeran (miRNA-2105)	New active substance and new biological	Acturus Therapeutics Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/kostaive-epar-product-information_en.pdf	February 2025
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	Atnahts Pharma Netherlands B. V.	https://www.ema.europa.eu/en/documents/product-information/korjuny-epar-product-information_en.pdf	March 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

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Krazati	ādagrasib	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	āzertinib	New active substance	āanssen-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	Not available yet	April 2025
Leqvio	inclisiran autologous CD34+ cell enriched population that contains hematopoietic	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	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
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	āaribavir	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 Skytrofa (Previously known as Lonapegsomatropin)	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
	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
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
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

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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	efapixant	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
LYNOZYFIC	lvoseltamab	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
Medikinet retard 10 / 20 / 30 / 40 / 5 / 50 / 60 mg	Methylphenidate hydrochloride	PASS ¹	Medice Arzneimittel Püttner GmbH Co. KG	Not available	May 2018
MenQuadfi	Meningococcal group A, C, W and Y conjugate vaccine	New biological	Sanofi Winthrop Industrie	https://www.ema.europa.eu/en/documents/product-information/menquadfi-epar-product-information_en.pdf	December 2020
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
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	https://www.ema.europa.eu/en/documents/product-information/natpar-epar-product-information_en.pdf	September 2022
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

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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	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	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
Ocaliva	Obeticholic acid	Conditional authorisation	ADVANZ PHARMA Limited	https://www.ema.europa.eu/en/documents/product-information/ocaliva-epar-product-information_en.pdf	January 2017
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 Allergen extract from house dust mites	New active substance	Biocryst Ireland Limited	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?mpdidentifier=7000377	May 2021
Orylmyte	(Dermatophagoides	New biological	Stallergenes	https://www.ema.europa.eu/en/documents/product-information/orgovyx-epar-product-information_en.pdf	July 2021
Orgovyx	relugolix	New active substance	Myovant Sciences Ireland Limited		May-22

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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.	<u>Not available</u>	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
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
Palforzia Pandemic influenza vaccine H5N1 AstraZeneca	defatted powder of Arachis Pandemic influenza vaccine (H5N1) (live attenuated, nasal)	New biological	Immune Therapeutics Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/palforzia-epar-product-information_en.pdf	November 2022
		Conditional marketing authorisation	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/pandemic-influenza-vaccine-h5n1-astrazeneca-epar-product-information_en.pdf	June 2016
PAVBLU	Aflibercept	New biological	Amgen Technology (Ireland) UC	<u>Not available</u>	April 2025
Paxlovid	ritonavir/ (1R,2S,5S)-N-((1S)-1-Cyano-2-((3S)-2-oxopyrrolidin-3-yl)ethyl)-3-	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/paxlovid-epar-product-information_en.pdf	February 2022
Pegfilgrastim Mundipharma	Pegfilgrastim	New biological	Mundipharma Biologics S.L.	https://www.ema.europa.eu/en/documents/product-information/pegfilgrastim-mundipharma-epar-product-information_en.pdf	January 2020
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	<u>N/A</u>	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
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
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

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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
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/pyrukyn-epar-product-information_en.pdf	November 2022
Pyzchiva Dovprela (previously known as Pretomanid FGK)	ustekinumab	New biological	Samsung Bioepis NL B.V.	https://www.ema.europa.eu/en/documents/product-information/pretomanid-fgk-epar-product-information_en.pdf	May 2024
	pretomanid	New active substance	Mylan IRE Healthcare Limited	https://www.ema.europa.eu/en/documents/product-information/qalsody-epar-product-information_en.pdf	August 2020
Qalsody Qarziba (previously Dinutuximab beta EUSA and Dinutuximab beta	tofersen	New active substance, PASS ¹	Biogen Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/qarziba-epar-product-information_en.pdf	June 2024
	Dinutuximab beta	Authorised under exceptional circumstances	EUSA Pharma (UK) Limited	https://www.ema.europa.eu/en/documents/product-information/qdenga-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/qinlock-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/qoyvolma-epar-product-information_en.pdf	Dec-21
Qoyvolma	ustekinumab	New biological	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/quviviq-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/epruvy-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/ranivisio-epar-product-information_en.pdf	October 2024
Ranivisio	ranibizumab	New biological	Midas Pharma GmbH	https://www.ema.europa.eu/en/documents/product-information/raxone-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/rayvow-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/refixia-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/rekambys-epar-product-information_en.pdf	June 2017
REKAMBYS	rilpivirine	PASS ¹	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/retsevmo-epar-product-information_en.pdf	Jan-21
Retsevmo	selpercatinib	New active substance, Conditional marketing authorisation	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/revestive-epar-product-information_en.pdf	February 2021
Revestive	Teduglutide	PASS ¹	Takeda Pharmaceuticals International AG Ireland Branch		April 2013

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
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
□ Rimmyrah	Enibizumab	New biological	QUILU PHARMA SPAIN S.L.	https://www.ema.europa.eu/en/documents/product-information/rimmyrah-epar-product-information_en.pdf	January 20247
Roclanda	Latanoprost / netarsudil	New active substance New active substance, New biological, Conditional marketing authorisation and	Santen Oy	https://www.ema.europa.eu/en/documents/product-information/roclanda-epar-product-information_en.pdf	January 2021
Roctavian	valoctocogene roxaparvovec	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	Not available	July 2025
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
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
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	Ebzanolixizumab	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	Epiapterin	New active substance	ETC Therapeutics International Limited	Not available	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
Sixmo	Buprenorphine	PASS¹	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
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 Spikevax (previously COVID-19 Vaccine Moderna)	deucravacitinib elasomeran (formally COVID-19 mRNA Vaccine (nucleoside-modified))	New active substance	Bristol Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf	April 2023
STEQEYMA	ustekinumab	New active substance and new biological	MODERNA BIOTECH SPAIN, S.L.	https://www.ema.europa.eu/en/documents/product-information/steqeyma-epar-product-information_en.pdf	January 2021
Stimufend	pegfilgrastim	New biological	Celtrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/stimufend-epar-product-information_en.pdf	September 2024
Strensiq	Pegfilgrastim	New biological	Fresenius Kabi Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/strensiq-epar-product-information_en.pdf	April 2022
Strimvelis	Asfotase alfa Autologous CD34+ enriched cell fraction that contains CD34+ cells	Authorised under exceptional circumstances	Alexion Europe SAS	https://www.ema.europa.eu/en/documents/product-information/strimvelis-epar-product-information_en.pdf	September 2015
Spevigo	Epevosolimab	PASS ¹	Fondazione Telethon ETS	https://www.ema.europa.eu/en/documents/product-information/spevigo-epar-product-information_en.pdf	June 2016
Sublivac Birke	Allergen extract of pollen from Birch	New active substance, new biological and Conditional marketing authorisation	Behringler Ingelheim International GmbH	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdid=...	January 2023
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	Ienacapavir quadrivalent influenza vaccine (recombinant, prepared in cell culture)	New biological	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/sunlenca-epar-product-information_en.pdf	September 2022
Supemtek	Siltuximab	New active substance	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/supemtek-epar-product-information_en.pdf	September 2022
Sylvant	capmatinib	New biological	Sanofi Winthrop Industrie	https://www.ema.europa.eu/en/documents/product-information/sylvant-epar-product-information_en.pdf	November 2020
Tabrecta	Talquetamab	PASS ¹	EUSA Pharma (Netherlands) B.V.	https://www.ema.europa.eu/en/documents/product-information/tabrecta-epar-product-information_en.pdf	June 2014
TALVEY	talquetamab	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/talvey-epar-product-information_en.pdf	June 2022
Tavneos	avacopan	New active substance and new biological	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/tavneos-epar-product-information_en.pdf	September 2023
			Vifor Fresenius Medical Care Renal Pharma France	https://www.ema.europa.eu/en/documents/product-information/tavneos-epar-product-information_en.pdf	January 2022

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Tauvid	Flortaucipir (18F)	New active substance	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	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	January 2021
Tecovirimat SIGA	tecovirimat monohydrate	Authorised under exceptional circumstances	☐ 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/tecwayli-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/tepkiny-epar-product-information_en.pdf	October 2023
☐ 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
TEPEZZA	Teprotumumab	New active substance and new biological	Amgen Europe B.V.	Not available	July 2025
Tevimbra	tebivlizumab	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	Roche Laboratoires Servier	https://www.ema.europa.eu/en/documents/product-information/tivdak-epar-product-information_en.pdf	May 2023
Tivdak	Tivisotumab vedotin	New active substance and new biological	Genmab A/S	https://www.ema.europa.eu/en/documents/product-information/tofidence-epar-product-information_en.pdf	April 2025
Tofidence	tocilizumab	New biological	Biogen Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/translarna-epar-product-information_en.pdf	June 2024
Translarna	Ataluren	Conditional authorisation	PTC Therapeutics Limited	Not available	September 2014
Trivalent Influenza Vaccine	Influenza vaccine (split virion)	New biological	Sanofi Pasteur	https://www.ema.europa.eu/en/documents/product-information/trodelvy-epar-product-information_en.pdf	May 2019
Trodelvy	sacituzumab govitecan	New active substance and new biological	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/trugap-epar-product-information_en.pdf	December 2021
Truqap	capiwasertib	New active substance	AstraZeneca AB	https://www.ema.europa.eu/en/medicines/human/referrals/topiramate	June 2024
Topiramate containing medicinal products in the European Union	topiramate	PASS ¹	Various (for full list see Annex XV)	https://www.ema.europa.eu/en/documents/product-information/tukysa-epar-product-information_en.pdf	May 2024
TUKYSA	tucatinib	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/tuznue-epar-product-information_en.pdf	Feb-21
Tuznue	trastuzumab	New biological	Pfizer Biopharma Belgium BVBA		October 2024

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Tyenne	efocilizumab	New biological	Eresenius Kabi Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/tyenne-epar-product-information_en.pdf https://www.ema.europa.eu/en/documents/product-information/tyruko-epar-product-information_en.pdf	September 2023
Tyruko	natalizumab	New biological	Sandoz GmbH	https://www.ema.europa.eu/en/documents/product-information/uplizna-epar-product-information_en.pdf	October 2023
Uplizna	inebilizumab	New active substance, new biological	Amgen Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/upstaza-epar-product-information_en-0.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/uzpruvo-epar-product-information_en.pdf	July 2022
Uzpruvo	ustekinumab	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/vabysmo-epar-product-information_en.pdf	January 2024
Vabysmo <u>Valproate and related substances (sodium valproate, valproic acid, valproate semisodium, valpromide)</u>	Faricimab Sodium valproate, valproic acid, valproate semisodium, valpromide	New active substance, new biological	Roche Registration GmbH	https://www.ema.europa.eu/en/medicines/human/referrals/valproate-related-substances	September 2022
				https://www.ema.europa.eu/en/documents/product-information/vafseo-epar-product-information_en.pdf	January 2015
				https://www.ema.europa.eu/en/documents/product-information/vanflyta-epar-product-information_en.pdf	
Vafseo	Vadadustat	New active substance	AKEBIA EUROPE Limited	https://www.ema.europa.eu/en/documents/product-information/vaxneuvance-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/vazkepa-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/vedrop-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/vegzelma-epar-product-information_en.pdf	Mar-21
Vedrop	Tocofersolan d-alpha tocopheryl polyethylene glycol succinate	Authorised under exceptional circumstances	Recordati Rare Diseases	https://www.ema.europa.eu/en/documents/product-information/veklury-epar-product-information_en.pdf	April 2013
VEGZELMA	bevacizumab	New biological	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/velsipity-epar-product-information_en.pdf	September 2022
Veklury	Remdesivir	New active substance	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/verquvo-epar-product-information_en.pdf	July 2020
Velsipity	etrasimod	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/veoza-epar-product-information_en.pdf	February 2024
Verquvo	Vericiguat	New active substance	Bayer AG		July 2021
Veozza	fazolinetant	New active substance	Astellas Pharma Europe B.V.		January 2024
Vevzuo	fenosumab	New biological	Biosimilar Collaborations Ireland Limited	Not available	July 2025
Vimizim	Elosulfase alfa	PASS ¹	BioMarin International Limited	https://www.ema.europa.eu/en/documents/product-information/vimkunya-epar-product-information_en.pdf	June 2014
VIMKUNYA	Chikungunya vaccine (recombinant, adsorbed) (EXVX0317)	New biological, new active substance,	Bavarian Nordic A/S		March 2025

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
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
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
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-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
Vyjuvek	Bremagene geperpavec	New active substance, new biological, PASS ¹	Krystal Biotech Netherlands B.V.	Not available	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
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	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
WELIREG	Elzutifan	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
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.	Not available	February 2025

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
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&mpdid=1	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	Etanercept	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
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
Yaxwer	denosumab	New biological	Gedeon Richter Plc.	Not available	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/ipadocdisplay.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/yselfty-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.	not available	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
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
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	Enidatamab	New active substance, New biological and Conditional marketing authorisation	Jazz 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

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
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	ganaxolone	New active substance	Immedica Pharma AB	https://www.ema.europa.eu/en/documents/product-information/ztalmy-epar-product-information_en.pdf	September 2023
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	Imcyte 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.