

22 June 2026  
EMA/245297/2013 Rev. 145  
Human Medicines Division

## List of medicinal products under additional monitoring

### Related Information:

#### Additional monitoring explained:

<https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/medicines-under-additional-monitoring>

#### Good Pharmacovigilance Practice Module on additional monitoring:

[https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-x-additional-monitoring\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-x-additional-monitoring_en.pdf)

*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 June 2026 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
Abecma	idecabtagene vicleucel Respiratory syncytial virus vaccine (bivalent, recombinant)	New biological, new active substance, PASS <sup>1</sup>	Bristol-Myers Squibb Pharma EEIG	<a href="https://www.ema.europa.eu/en/documents/product-information/abecma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/abecma-epar-product-information_en.pdf</a>	September 2021
Abrysvo	idecabtagene vicleucel Respiratory syncytial virus vaccine (bivalent, recombinant)	New active substance and new biological	Pfizer Europe MA EEIG	<a href="https://www.ema.europa.eu/en/documents/product-information/abrysvo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/abrysvo-epar-product-information_en.pdf</a>	September 2023
Acvybra	denosumab	New biological	Reddy Holding GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/acvybra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/acvybra-epar-product-information_en.pdf</a>	November 2025
<del>ADSTILADRIN</del>	<del>Adofaragene firadenovec</del>	<del>New biological, new active substance and Conditional marketing authorisation</del>	<del>Eerring Pharmaceuticals A/S</del>	<del>Not available</del>	<del>June 2026</del>
Adynovi	Rurioctocog alfa pegol	PASS <sup>1</sup>	Baxalta Innovations GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/adynovi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/adynovi-epar-product-information_en.pdf</a>	January 2018
ADZYNMA	rADAMTS13	New biological, new active substance, authorized under exceptional circumstances	Takeda Manufacturing Austria AG	<a href="https://www.ema.europa.eu/en/documents/product-information/adzynma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/adzynma-epar-product-information_en.pdf</a>	September 2024
Afiveg	aflibercept	New biological	STADA Arzneimittel AG	<a href="https://www.ema.europa.eu/en/documents/product-information/afiveg-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/afiveg-epar-product-information_en.pdf</a>	September 2025
Afqlir	aflibercept	New biological	Sandoz GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/afqlir-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/afqlir-epar-product-information_en.pdf</a>	November 2024

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
AGAMREE	vamorolone	New active substance	Santhera Pharmaceuticals (Deutschland) GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/agamree-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/agamree-epar-product-information_en.pdf</a>	January 2024
Ahzantive	aflibercept	New biological	Formycon AG	<a href="https://www.ema.europa.eu/en/documents/product-information/ahzantive-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ahzantive-epar-product-information_en.pdf</a>	January 2025
Alhemo	concizumab	New active substance, new biological	Novo Nordisk A/S	<a href="https://www.ema.europa.eu/en/documents/product-information/alhemo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/alhemo-epar-product-information_en.pdf</a>	January 2025
Alternaria alternata Prick Test RX	allergen extract from spores of Alternaria alternata	New biological	Roxall Medizin GmbH	<a href="https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.s.html?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdid=entifier=2611886">https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.s.html?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdid=entifier=2611886</a>	June 2026
ALTUVOCT	efanesoctocog alfa	New active substance and new biological	Swedish Orphan Biovitrum AB (publ)	<a href="https://www.ema.europa.eu/en/documents/product-information/altuvoct-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/altuvoct-epar-product-information_en.pdf</a>	June 2024
Alyftrek	deutivacaftor/tezacaftor/vanzacaftor	New active substance	Vertex Pharmaceuticals (Ireland) Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/alyftrek-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/alyftrek-epar-product-information_en.pdf</a>	July 2025
Amvuttra	vutrisiran	New active substance	Alnylam Netherlands B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/amvuttra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/amvuttra-epar-product-information_en.pdf</a>	September 2022
ANDEMBRY	maradacimab	New active substance and new biological	CSL Behring GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/andembry-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/andembry-epar-product-information_en.pdf</a>	February 2025
ANKTIVA	nogapendekin alfa inbakicept	New active substance, new biological and Conditional Marketing Authorisation	ImmunityBio Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/anktiva-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/anktiva-epar-product-information_en.pdf</a>	March 2026
Anzupgo	delgocitinib pneumococcal polysaccharide conjugate vaccine (20-valent,	New active substance	LEO Pharma A/S	<a href="https://www.ema.europa.eu/en/documents/product-information/anzupgo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/anzupgo-epar-product-information_en.pdf</a>	October 2024
Apexxnar	polysaccharide conjugate vaccine (20-valent,	New biological	Pfizer Europe MA EEIG	<a href="https://www.ema.europa.eu/en/documents/product-information/apexxnar-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/apexxnar-epar-product-information_en.pdf</a>	March 2022
Apretude	cabotegravir	New active substance	ViiV Healthcare BV	<a href="https://www.ema.europa.eu/en/documents/product-information/apretude-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/apretude-epar-product-information_en.pdf</a>	September 2023
AQUIPTA	atogepant	New active substance	AbbVie Deutschland GmbH & Co. KG	<a href="https://www.ema.europa.eu/en/documents/product-information/aquipta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/aquipta-epar-product-information_en.pdf</a>	September 2023
Arexvy	Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)	New active substance and new biological	GlaxoSmithKline Biologicals S.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/arexvy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/arexvy-epar-product-information_en.pdf</a>	June 2023
Artesunate Amivas	artesunate	New active substance	Amivas Ireland Ltd	<a href="https://www.ema.europa.eu/en/documents/product-information/artesunate-amivas-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/artesunate-amivas-epar-product-information_en.pdf</a>	December 2021
Aspaveli	pegcetacoplan	New active substance	Swedish Orphan Biovitrum AB (publ)	<a href="https://www.ema.europa.eu/en/documents/product-information/aspaveli-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/aspaveli-epar-product-information_en.pdf</a>	January 2022
Atgam	anti-human T-lymphocyte immunoglobulin	New biological	Pfizer Pharma GmbH	<a href="https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.s.html?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdid=entifier=2613975">https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.s.html?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdid=entifier=2613975</a>	March 2022
Atriance	Nelarabine	Authorised under exceptional circumstances	Sandoz Pharmaceuticals d.d.	<a href="https://www.ema.europa.eu/en/documents/product-information/atriance-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/atriance-epar-product-information_en.pdf</a>	April 2013
Aucatzyl	becabtagene autoleucel	New active substance, new biological, conditional marketing authorisation, PASS	Autolus GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/aucatzyl-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/aucatzyl-epar-product-information_en.pdf</a>	July 2025
AUGTYRO	repotrectinib	New active substance, conditional marketing authorisation	Bristol Myers Squibb Pharma EEIG	<a href="https://www.ema.europa.eu/en/documents/product-information/augtyro-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/augtyro-epar-product-information_en.pdf</a>	January 2025

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
□ Aumseqa	aumolertinib	New active substance	SFL Pharmaceuticals Deutschland GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/aumseqa-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/aumseqa-epar-product-information_en.pdf</a>	February 2026
Awigli	insulin icodec	New active substance, New biological	Novo Nordisk A/S	<a href="https://www.ema.europa.eu/en/documents/product-information/awigli-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/awigli-epar-product-information_en.pdf</a>	May 2024
AYVAKYT	avapritinib	Conditional marketing authorisation	Blueprint Medicines (Netherlands) B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/ayvakyt-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ayvakyt-epar-product-information_en.pdf</a>	September 2020
Avtozma	ecicilzumab	New biological	Celltrion Healthcare Hungary Kft.	<a href="https://www.ema.europa.eu/en/documents/product-information/avtozma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/avtozma-epar-product-information_en.pdf</a>	March 2025
Avzivi	evacizumab	New biological	EGK Representative Service GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/avzivi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/avzivi-epar-product-information_en.pdf</a>	September 2024
Baiama	aflibercept	New biological	Formycon AG	<a href="https://www.ema.europa.eu/en/documents/product-information/baiama-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/baiama-epar-product-information_en.pdf</a>	January 2025
Balversa	erdafitinib	New active substance	Janssen-Cilag International NV	<a href="https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf</a>	September 2024
BEKEMV	eculizumab	New biological	Amgen Technology (Ireland) UC	<a href="https://www.ema.europa.eu/en/documents/product-information/bekemv-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/bekemv-epar-product-information_en.pdf</a>	April 2023
Benlysta	Belimumab	PASS <sup>1</sup>	Glaxo Group Ltd	<a href="https://www.ema.europa.eu/en/documents/product-information/benlysta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/benlysta-epar-product-information_en.pdf</a>	April 2013
Beyfortus	irsevimab	New active substance and <i>new biological</i>	Sanofi Winthrop Industrie	<a href="https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf</a>	November 2022
BEYONTTRA	toramidis	New active substance	Bayer AG	<a href="https://www.ema.europa.eu/en/documents/product-information/beyontra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/beyontra-epar-product-information_en.pdf</a>	February 2025
Bildyos	denosumab	New biological	SciencePharma Sp. z o.o.	<a href="https://www.ema.europa.eu/en/documents/product-information/bildyos-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/bildyos-epar-product-information_en.pdf</a>	September 2025
Bilprevda	denosumab	New biological	SciencePharma Sp. z o.o.	<a href="https://www.ema.europa.eu/en/documents/product-information/bilprevda-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/bilprevda-epar-product-information_en.pdf</a>	September 2025
BIMERVAX	COVID-19 Vaccine (recombinant, adjuvanted)	New active substance and new biological	Eipra Human Health, S.L.U.	<a href="https://www.ema.europa.eu/en/documents/product-information/bimervax-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/bimervax-epar-product-information_en.pdf</a>	April 2023
<b>Bimzelx</b>	<b>bimekizumab</b>	<b>New active substance and new biological</b>	<b>UCB Pharma S.A.</b>	<del><a href="https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf</a></del>	<b>September 2021</b>
BLENREP	belantamab mafodotin	New biological	GlaxoSmithKline Trading Services Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/blenrep-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/blenrep-epar-product-information_en.pdf</a>	July 2025
Blinicyto	Blinatumomab	PASS <sup>1</sup>	Amgen Europe B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/blincyto-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/blincyto-epar-product-information_en.pdf</a>	December 2015
Bomynta	denosumab	New biological	Eresenius Kabi Deutschland GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/bomynta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/bomynta-epar-product-information_en.pdf</a>	July 2025
Bylvay	Odevixibat	Authorised under exceptional circumstances	Ipsen Pharma	<a href="https://www.ema.europa.eu/en/documents/product-information/bylvay-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/bylvay-epar-product-information_en.pdf</a>	July 2021
Byooviz	ranibizumab	New biological	Samsung Bioepis NL B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/byooviz-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/byooviz-epar-product-information_en.pdf</a>	April 2024



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Columvi	glofitamab	New active substance, new biological	Roche Registration GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/columvi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/columvi-epar-product-information_en.pdf</a>	July 2023
Comirnaty	COVID-19 mRNA Vaccine (nucleoside modified)	New active substance and new biological	BioNTech Manufacturing GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf</a>	January 2021
Conexence	denosumab	New biological	Eresenius Kabi Deutschland GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/conexence-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/conexence-epar-product-information_en.pdf</a>	July 2025
Datroway	datopotamab deruxtecan	New active substance, new biological	Daiichi Sankyo Europe GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/datroway-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/datroway-epar-product-information_en.pdf</a>	April 2025
Dazublys	trastuzumab	New biological	<b>CuraTeQ Biologics s.r.o CuraTeQ Biologics (Malta) Limited</b>	<a href="https://www.ema.europa.eu/en/documents/product-information/dazublys-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/dazublys-epar-product-information_en.pdf</a>	July 2025
Dazparda	insulin aspart	New biological	Gan & Lee Pharmaceuticals Europe GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/dazparda-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/dazparda-epar-product-information_en.pdf</a>	May 2026
Dawnzera	Donidalorsen	New active substance	Otsuka Pharmaceutical Netherlands B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/dawnzera-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/dawnzera-epar-product-information_en.pdf</a>	January 2026
Dectova	Zanamivir	Authorised under exceptional circumstances	GlaxoSmithKline Trading Services Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/dectova-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/dectova-epar-product-information_en.pdf</a>	May 2019
Defitelio	Defibrotide	Authorised under exceptional circumstances	Gentium S.p.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/defitelio-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/defitelio-epar-product-information_en.pdf</a>	November 2013
Degevma	denosumab	New biological	Teva GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/degevma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/degevma-epar-product-information_en.pdf</a>	December 2025
Denbrayce	Denosumab	New active substance	Mabxience Research SL	<a href="https://www.ema.europa.eu/en/documents/product-information/denbrayce-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/denbrayce-epar-product-information_en.pdf</a>	July 2025
Denosumab Intas	denosumab	New biological	Intas Third Party Sales 2005, S.L.	<a href="https://www.ema.europa.eu/en/documents/product-information/denosumab-intas-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/denosumab-intas-epar-product-information_en.pdf</a>	November 2025
Deqsig	human normal immunoglobulin	New biological	Takeda Manufacturing Austria AG	<a href="https://www.ema.europa.eu/en/documents/product-information/deqsig-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/deqsig-epar-product-information_en.pdf</a>	May 2025
Dovprela (previously known as Pretomanid FGK)	pretomanid	New active substance	Mylan IRE Healthcare Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/dovprela-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/dovprela-epar-product-information_en.pdf</a>	August 2020
DUVYZAT	givinostat	New active substance, conditional marketing authorisation	Italfarmaco S.p.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/duvyzat-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/duvyzat-epar-product-information_en.pdf</a>	June 2025
Dyrupeg	Pegfilgrastim	New biological	<b>CuraTeQ Biologics s.r.o CuraTeQ Biologics (Malta) Limited</b>	<a href="https://www.ema.europa.eu/en/documents/product-information/dyrupeg-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/dyrupeg-epar-product-information_en.pdf</a>	April 2025
Ebglyss	lebrikizumab	New active substance, new biological	Almirall S.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/ebglyss-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ebglyss-epar-product-information_en.pdf</a>	November 2023
Ebvallo	Tabelecleucel	New active substance and new biological, Authorised under exceptional circumstances	Pierre Fabre Medicament	<a href="https://www.ema.europa.eu/en/documents/product-information/ebvallo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ebvallo-epar-product-information_en.pdf</a>	January 2023
Eladynos	abaloparatide	New active substance	Theramex Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/eladynos-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/eladynos-epar-product-information_en.pdf</a>	January 2023

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Elaprase	Idursulfase	Authorised under exceptional circumstances	Takeda Pharmaceuticals International AG Ireland Branch	<a href="https://www.ema.europa.eu/en/documents/product-information/elaprase-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/elaprase-epar-product-information_en.pdf</a>	April 2013
Elfabrio	pegunigalsidase alfa	New active substance and new biological	Chiesi Farmaceutici S.p.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/elfabrio-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/elfabrio-epar-product-information_en.pdf</a>	May 2023
Elucirem	gadopiclenol	New active substance	Guerbet	<a href="https://www.ema.europa.eu/en/documents/product-information/elucirem-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/elucirem-epar-product-information_en.pdf</a>	January 2024
ELREXFIO	elranatamab	New biological, new active substance, conditional marketing authorisation	Pfizer Europe MA EEIG	<a href="https://www.ema.europa.eu/en/documents/product-information/elrefxio-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/elrefxio-epar-product-information_en.pdf</a>	January 2024
Eiyzey	aflibercept	New biological	Zakłady Farmaceutyczne POLPHARMA S.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/eiyzey-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/eiyzey-epar-product-information_en.pdf</a>	September 2025
Ekterly	betralstat	New active substance	Vista Pharmaceuticals (Ireland) Ltd	<a href="https://www.ema.europa.eu/en/documents/product-information/ekterly-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ekterly-epar-product-information_en.pdf</a>	September 2025
ELAHERE	irvetuximab soravtansine	New biological New active substance and new biological, Authorised under exceptional circumstances	AbbVie Deutschland GmbH & Co. KG	<a href="https://www.ema.europa.eu/en/documents/product-information/elahere-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/elahere-epar-product-information_en.pdf</a>	November 2024
ELZONRIS	tagraxofusp	New biological, new active substance, conditional marketing authorisation	Stemline Therapeutics B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/elzonris-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/elzonris-epar-product-information_en.pdf</a>	January 2021
Enhertu	trastuzumab deruxtecan	New biological, new active substance, conditional marketing authorisation	Daiichi Sankyo Europe GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/enhertu-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/enhertu-epar-product-information_en.pdf</a>	January 2021
Enflonsia	Clesrovimab	New active substance, new biological	Merck Sharp & Dohme B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/enflonsia-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/enflonsia-epar-product-information_en.pdf</a>	01 April 2026
ENOXAPARINE LEDRAXEN	enoxaparin sodium	New biological	VENIPHARM	Not available	September 2022
Enrylaze	isantaspace	New active substance, new biological	Jazz Pharmaceuticals Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/enrylaze-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/enrylaze-epar-product-information_en.pdf</a>	September 2023
Enjaymo	timlimab	New active substance, new biological	Recordati Rare Diseases	<a href="https://www.ema.europa.eu/en/documents/product-information/enjaymo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/enjaymo-epar-product-information_en.pdf</a>	November 2022
Enwylma	enosumab	New biological	Zentiva, k.s.	<a href="https://www.ema.europa.eu/en/documents/product-information/enwylma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/enwylma-epar-product-information_en.pdf</a>	July 2025
Epysqli	culizumab	New biological	Samsung Bioepis NL B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/epysqli-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/epysqli-epar-product-information_en.pdf</a>	June 2023
Esche Prick Test RX	allergen extract from ash tree pollen	New biological	Roxall Medizin GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/esche-prick-test-rx-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/esche-prick-test-rx-epar-product-information_en.pdf</a>	June 2026
Esperoct	Turoctocog alfa pegol	PASS <sup>1</sup>	Novo Nordisk A/S	<a href="https://www.ema.europa.eu/en/documents/product-information/esperoct-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/esperoct-epar-product-information_en.pdf</a>	June 2019
Evfraxy	enosumab	New biological	Biosimilar Collaborations Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/evfraxy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/evfraxy-epar-product-information_en.pdf</a>	July 2025
Evkeeza	evinacumab	PASS <sup>1</sup> , authorised under exceptional circumstances	Ultragenyx Germany GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/evkeeza-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/evkeeza-epar-product-information_en.pdf</a>	July 2021
Evoltra	Clofarabine	Authorised under exceptional circumstances	Genzyme Europe B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/evoltra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/evoltra-epar-product-information_en.pdf</a>	April 2013

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Exblifep	cefepime / enmetazobactam	New active substance	ADVANZ PHARMA Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/exblifep-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/exblifep-epar-product-information_en.pdf</a>	April 2024
EXDENSUR	Depemokimab	New active substance, new biological	GlaxoSmithKline Trading Services Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/exdensur-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/exdensur-epar-product-information_en.pdf</a>	February 2026
Eydenzelt	Aflibercept	New biological	Celltrion Healthcare Hungary Kft.	<a href="https://www.ema.europa.eu/en/documents/product-information/eydenzelt-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/eydenzelt-epar-product-information_en.pdf</a>	February 2025
Eyluxvi	aflibercept	New biological	Biolitec Pharma Limited Zweigniederlassung Jena	<a href="https://www.ema.europa.eu/en/documents/product-information/eyluxvi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/eyluxvi-epar-product-information_en.pdf</a>	September 2025
Ezmekly	mirdametinib	New active substance, conditional marketing authorisation, PASS	Merck Europe B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/ezmekly-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ezmekly-epar-product-information_en.pdf</a>	July 2025
Fabhalta	iptacopan	New active substance	Novartis Europharm Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/fabhalta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/fabhalta-epar-product-information_en.pdf</a>	May 2024
Filspari	Sparsentan	New active substance	Vifor France S.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/filspari-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/filspari-epar-product-information_en.pdf</a>	May 2024
Fintepla	fenfluramine	PASS <sup>1</sup>	UCB Pharma S.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/fintepla-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/fintepla-epar-product-information_en.pdf</a>	January 2021
Firdapse	Amifampridine	Authorised under exceptional circumstances	BioMarin Europe Ltd	<a href="https://www.ema.europa.eu/en/documents/product-information/firdapse-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/firdapse-epar-product-information_en.pdf</a>	April 2013
FRUZAQLA	fruquintinib	New active substance	Takeda Pharmaceuticals International AG Ireland Branch	<a href="https://www.ema.europa.eu/en/documents/product-information/fruzaqla-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/fruzaqla-epar-product-information_en.pdf</a>	July 2024
Fubelv	etanercept	New biological	Biosimilar Collaborations Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/fubelv-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/fubelv-epar-product-information_en.pdf</a>	May 2026
FYLREVY	Estetrol	New active substance	Gedeon Richter Plc.	<a href="https://www.ema.europa.eu/en/documents/product-information/fylrevy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/fylrevy-epar-product-information_en.pdf</a>	April 2026
Fymskina	ustekinumab	New biological	Ermycon AG	<a href="https://www.ema.europa.eu/en/documents/product-information/fymskina-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/fymskina-epar-product-information_en.pdf</a>	October 2024
Garnele Prick Test RX	allergen extract from shrimp	New biological	Roxall Medizin GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/giapreza-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/giapreza-epar-product-information_en.pdf</a>	June 2026
Giapreza	Angiotensin II acetate	New active substance	PAION Pharma GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/giapreza-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/giapreza-epar-product-information_en.pdf</a>	September 2019
Glaskraut Prick Test RX	allergen extract from glass wort pollen	New biological	Roxall Medizin GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/giapreza-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/giapreza-epar-product-information_en.pdf</a>	June 2026
Grassmuno 6000 SU/ml, 2700 SU/ml, 900 SU/ml	allergen extract from 13 types of grass pollen	New biological	Bencard Allergie GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/giapreza-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/giapreza-epar-product-information_en.pdf</a>	June 2026
GOBIVAZ	golimumab	New biological	Advanz Pharma Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/gobivaz-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/gobivaz-epar-product-information_en.pdf</a>	November 2025
Gohibic	vilobelimab	New active substance, new biological, authorised under exceptional circumstances	InflaRx GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/gohibic-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/gohibic-epar-product-information_en.pdf</a>	January 2025
Gonasi Set	Chorionic gonadotrophin	New biological	IBSA Farmaceutici Italia S.r.l.	Not available	May 2024

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Gotenfia	oblimumab	New biological	STADA Arzneimittel AG	<a href="https://www.ema.europa.eu/en/documents/product-information/gotenfia-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/gotenfia-epar-product-information_en.pdf</a>	February 2026
Hemgenix	etranacogene dezaparovec	New biological, new active substance and Conditional Marketing Authorisation, PASS <sup>1</sup>	CSL Behring GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/hemgenix-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/hemgenix-epar-product-information_en.pdf</a>	March 2023
Hepcludex	bulevirtide	new active substance	Gilead Sciences Ireland UC	<a href="https://www.ema.europa.eu/en/documents/product-information/hepcludex-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/hepcludex-epar-product-information_en.pdf</a>	August 2020
Herwenda	trastuzumab	New biological	Sandoz GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/herwenda-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/herwenda-epar-product-information_en.pdf</a>	November 2023
HETRONIFLY	erplumab	New active substance and new biological	Accord Healthcare S.L.U.	<a href="https://www.ema.europa.eu/en/documents/product-information/hetronifly-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/hetronifly-epar-product-information_en.pdf</a>	February 2025
Hukyndra	Adalimumab	New biological	STADA Arzneimittel AG	<a href="https://www.ema.europa.eu/en/documents/product-information/hukyndra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/hukyndra-epar-product-information_en.pdf</a>	November 2021
Hund Prick Test RX	allergen extract from dog epithelia	New biological	Roxall Medizin GmbH	<a href="https://portal.ema.europa.eu/ema/activities/documents/product-information/hund-prick-test-rx-epar-product-information_en.pdf">https://portal.ema.europa.eu/ema/activities/documents/product-information/hund-prick-test-rx-epar-product-information_en.pdf</a>	June 2026
Hympavzi	Marstacimab	New biological, New active substance and PASS	Pfizer Europe MA EEIG	<a href="https://www.ema.europa.eu/en/documents/product-information/hympavzi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/hympavzi-epar-product-information_en.pdf</a>	November 2014
<u>Hydroxyethyl starch (HES)-containing medicinal products (For full list see...)</u>	Hydroxyethyl starch	PASS <sup>1</sup>	Various (For full list see Annex V)	<a href="https://www.ema.europa.eu/en/medicines/human/referrals/hydroxyethyl-starch-solutions-infusion-0">https://www.ema.europa.eu/en/medicines/human/referrals/hydroxyethyl-starch-solutions-infusion-0</a>	January 2014
Idefirix	imlifidase	New biological	Hansa Biopharma AB	<a href="https://www.ema.europa.eu/en/documents/product-information/idefirix-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/idefirix-epar-product-information_en.pdf</a>	September 2020
Imaavy	nipocalimab	New active substance and New biological	Janssen-Cilag International NV	<a href="https://www.ema.europa.eu/en/documents/product-information/imaavy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/imaavy-epar-product-information_en.pdf</a>	December 2025
IMDYLLTRA	tarlatamab	New active substance and New biological	Amgen Europe B.V.	<a href="#">Not available</a>	June 2026
IMJUDO	tremelimumab	New active substance and New biological	AstraZeneca AB	<a href="https://www.ema.europa.eu/en/documents/product-information/imjudo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/imjudo-epar-product-information_en.pdf</a>	March 2023
Imreplys	sargramostim	New biological, Authorised under exceptional circumstances	Partner Therapeutics Ltd.	<a href="https://www.ema.europa.eu/en/documents/product-information/imreplys-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/imreplys-epar-product-information_en.pdf</a>	September 2025
Imuldosa	ustekinumab	New biological	Accord Healthcare S.L.U.	<a href="https://www.ema.europa.eu/en/documents/product-information/imuldosa-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/imuldosa-epar-product-information_en.pdf</a>	January 2025
Imvanex	smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara)	Authorised under exceptional circumstances	Bavarian Nordic A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002596/human_med_001666.jsp&amp;mid=W00b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002596/human_med_001666.jsp&amp;mid=W00b01ac058001d124</a>	September 2013
Inaqovi	decitabine / cedazuridine	New active substance	Otsuka Pharmaceutical Netherlands B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/inaqovi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/inaqovi-epar-product-information_en.pdf</a>	September 2023
Incellipan	Pandemic influenza vaccine (H5N1) (surface antigen, inactivated,	New biological, Conditional Marketing authorisation	Seqirus Netherlands B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/incellipan-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/incellipan-epar-product-information_en.pdf</a>	May 2024
Increlex	Mecasermin	Authorised under exceptional circumstances	Esteve Pharmaceuticals S.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/increlex-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/increlex-epar-product-information_en.pdf</a>	April 2013
Inluriyo	Imlunestrant	New active substance	Eli Lilly Nederland B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/inluriyo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/inluriyo-epar-product-information_en.pdf</a>	January 2026

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Intuniv	Guanfacine	PASS <sup>1</sup>	Takeda Pharmaceuticals International AG Ireland Branch	<a href="https://www.ema.europa.eu/en/documents/product-information/intuniv-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/intuniv-epar-product-information_en.pdf</a>	September 2015
Iqirvo	elafibranor	New active substance, Conditional marketing authorisation	Ipsen Pharma	<a href="https://www.ema.europa.eu/en/documents/product-information/iqirvo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/iqirvo-epar-product-information_en.pdf</a>	October 2024
Itovebi	inavolisib	New active substance	Röche Registration GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/itovebi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/itovebi-epar-product-information_en.pdf</a>	July 2025
Ituxredi	Rituximab	New biological	Reddy Holding GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/ituxredi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ituxredi-epar-product-information_en.pdf</a>	October 2024
IXCHIQ	Chikungunya vaccine (live)	New active substance and New biological	Valneva Austria GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/ixchiq-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ixchiq-epar-product-information_en.pdf</a>	July 2024
Izamby Jaydess (also known in some EU countries as Fleree)	denosumab	New biological	Abxience Research SL	<a href="https://www.ema.europa.eu/en/documents/product-information/izamby-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/izamby-epar-product-information_en.pdf</a>	July 2025
	Levonorgestrel	PASS <sup>1</sup>	Bayer AB	<a href="https://docetp.mpa.se/LMF/Jaydess%20intrauterine%20delivery%20system%20ENG%20SmPC.doc">https://docetp.mpa.se/LMF/Jaydess%20intrauterine%20delivery%20system%20ENG%20SmPC.doc</a>	November 2013
Jaypirca	pirtobrutinib	New active substance, Conditional marketing authorisation	Eli Lilly Nederland B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/jaypirca-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/jaypirca-epar-product-information_en.pdf</a>	November 2023
JEMPERLI	dostarlimab	New active substance, new biological	GlaxoSmithKline Trading Services Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/jemperli-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/jemperli-epar-product-information_en.pdf</a>	May 2021
JERAYGO	aprocitentan	New active substance, PASS <sup>1</sup>	Idorsia Pharmaceuticals Deutschland GmbH	<a href="https://www.ema.europa.eu/en/medicines/human/EPAR/jeraygo/product-info">https://www.ema.europa.eu/en/medicines/human/EPAR/jeraygo/product-info</a>	July 2024
Jubbonti	denosumab	New biological	Sandoz GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/jubbonti-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/jubbonti-epar-product-information_en.pdf</a>	May 2024
Jubereq	denosumab	New biological	Accord Healthcare S.L.U.	<a href="https://www.ema.europa.eu/en/documents/product-information/jubereq-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/jubereq-epar-product-information_en.pdf</a>	June 2025
Junod	denosumab	New biological	Gedeon Richter Plc.	<a href="https://www.ema.europa.eu/en/documents/product-information/junod-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/junod-epar-product-information_en.pdf</a>	July 2025
Joenja	niolisib	New active substance, Authorised under exceptional circumstances	Pharming Technologies B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/joenja-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/joenja-epar-product-information_en.pdf</a>	June 2026
Kabeljau Prick Test RX	allergen extract from cod	New biological	Roxall Medizin GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/kanuma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kanuma-epar-product-information_en.pdf</a>	June 2026
Kanuma	Sebelipase alfa	PASS <sup>1</sup>	Alexion Europe SAS	<a href="https://www.ema.europa.eu/en/documents/product-information/kapruvia-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kapruvia-epar-product-information_en.pdf</a>	September 2015
Kapruvia	difelikefalin	New active substance	Vifor Fresenius Medical Care Renal Pharma France	<a href="https://www.ema.europa.eu/en/documents/product-information/kauliv-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kauliv-epar-product-information_en.pdf</a>	May 2022
Kauliv	teriparatide	New biological	Strides Pharma (Cyprus) Ltd.	<a href="https://www.ema.europa.eu/en/documents/product-information/kavigale-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kavigale-epar-product-information_en.pdf</a>	February 2023
KAVIGALE	Sipavibart	New active substance and new biological	AstraZeneca AB	<a href="https://www.ema.europa.eu/en/documents/product-information/kayfanda-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kayfanda-epar-product-information_en.pdf</a>	February 2025
KAYFANDA	Odevixibat	Authorized under exceptional circumstances	Ipsen Pharma		October 2024

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Kayshild	semaglutide	New biological and Conditional marketing authorisation	Novo Nordisk A/S	<a href="https://www.ema.europa.eu/en/documents/product-information/kayshild-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kayshild-epar-product-information_en.pdf</a>	April 2026
Kefdensis	bezosumab	New biological	STADA Arzneimittel AG	<a href="https://www.ema.europa.eu/en/documents/product-information/kefdensis-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kefdensis-epar-product-information_en.pdf</a>	November 2025
Kerendia	finerenone	New active substance	Bayer AG	<a href="https://www.ema.europa.eu/en/documents/product-information/kerendia-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kerendia-epar-product-information_en.pdf</a>	March 2022
Ketoconazole Esteve (previously Ketoconazole HRA)	Ketoconazole	PASS <sup>1</sup>	Esteve Pharmaceuticals S.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/ketoconazole-hra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ketoconazole-hra-epar-product-information_en.pdf</a>	December 2014
KIMMTRAK	tebentafusp	New active substance and <i>new biological</i>	Immunocore Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/kimmtrak-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kimmtrak-epar-product-information_en.pdf</a>	April 2022
Kisunla	donanemab	New active substance, new biological and PASS	Eli Lilly Nederland B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/kisunla-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kisunla-epar-product-information_en.pdf</a>	October 2025
Klisyri	Tirbanibulin	PASS <sup>1</sup>	Almirall, S.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/klisyri-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/klisyri-epar-product-information_en.pdf</a>	July 2021
Kostaive	rapomeran (siRNA-2105)	New active substance and new biological	Seqirus Netherlands B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/kostaive-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kostaive-epar-product-information_en.pdf</a>	February 2025
Koselugo	selumetinib	Conditional marketing authorisation, PASS <sup>1</sup>	AstraZeneca AB	<a href="https://www.ema.europa.eu/en/documents/product-information/koselugo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/koselugo-epar-product-information_en.pdf</a>	June 2021
Korjuny	catumaxomab	New biological	Atahs Pharma Netherlands B. V.	<a href="https://www.ema.europa.eu/en/documents/product-information/korjuny-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/korjuny-epar-product-information_en.pdf</a>	March 2025
KYGEVVI	doxycitine / doxribtimine	New active substance, authorised under exceptional circumstances	UCB Pharma S.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/kygevvi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kygevvi-epar-product-information_en.pdf</a>	April 2026
Kyinsu	insulin icodec / semaglutide	New active substance, new biological	Novo Nordisk A/S	<a href="https://www.ema.europa.eu/en/documents/product-information/kyinsu-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kyinsu-epar-product-information_en.pdf</a>	December 2025
Kymriah	Tisagenlecleucel	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/kymriah-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kymriah-epar-product-information_en.pdf</a>	September 2018
Krazati	lagrasib	New active substance, Conditional Marketing Authorisation	Bristol Myers Squibb Pharma EEIG	<a href="https://www.ema.europa.eu/en/documents/product-information/krazati-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/krazati-epar-product-information_en.pdf</a>	January 2024
Lamzede	Velmanase alfa	Authorised under exceptional circumstances	Chiesi Farmaceutici S.p.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/lamzede-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lamzede-epar-product-information_en.pdf</a>	April 2018
Latex Prick Test RX	allergen extract from latex	New biological	Roxall Medizin GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/latex-prick-test-rx-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/latex-prick-test-rx-epar-product-information_en.pdf</a>	June 2026
Lazcluze	lazertinib	New active substance	Janssen-Cilag International NV	<a href="https://www.ema.europa.eu/en/documents/product-information/lazcluze-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lazcluze-epar-product-information_en.pdf</a>	February 2025
Lemtrada	Alemtuzumab	PASS <sup>1</sup>	Sanofi Belgium	<a href="https://www.ema.europa.eu/en/documents/product-information/lemtrada-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lemtrada-epar-product-information_en.pdf</a>	January 2020
Leqembi	Lecanemab autologous CD34+ cell enriched population that contains hematopoietic	New active substance, new biological, PASS <sup>1</sup>	Eisai GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/leqembi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/leqembi-epar-product-information_en.pdf</a>	April 2025
Libmeldy		PASS <sup>1</sup>	Orchard Therapeutics (Netherlands) B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/libmeldy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/libmeldy-epar-product-information_en.pdf</a>	January 2021

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Libmyris	Adalimumab	New biological	STADA Arzneimittel AG	<a href="https://www.ema.europa.eu/en/documents/product-information/libmyris-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/libmyris-epar-product-information_en.pdf</a>	November 2021
Litfulo	ritlecitinib	New active substance	Pfizer Europe MA EEIG	<a href="https://www.ema.europa.eu/en/documents/product-information/litfulo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/litfulo-epar-product-information_en.pdf</a>	September 2023
Livmarli	maralixibat chloride	New active substance, Authorised under exceptional circumstances	Mirum Pharmaceuticals International B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/livmarli-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/livmarli-epar-product-information_en.pdf</a>	January 2023
LIVTENCITY	maribavir	New active substance	Takeda Pharmaceuticals International AG Ireland Branch	<a href="https://www.ema.europa.eu/en/documents/product-information/livtencity-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/livtencity-epar-product-information_en.pdf</a>	November 2022
Loargys	pegzilarginase	New active substance, New biological, PASS <sup>1</sup>	Inmedica Pharma AB	<a href="https://www.ema.europa.eu/en/documents/product-information/loargys-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/loargys-epar-product-information_en.pdf</a>	January 2024
Locametz	gozetotide	New active substance	Novartis Europharm Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/locametz-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/locametz-epar-product-information_en.pdf</a>	January 2023
Lojuxta	Lomitapide	Authorised under exceptional circumstances	Chiesi Farmaceutici S.p.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/lojuxta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lojuxta-epar-product-information_en.pdf</a>	September 2013
LOQTORZI	toripalimab	New biological and New active substance	Topalliance Biosciences Europe Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/loqtorzi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/loqtorzi-epar-product-information_en.pdf</a>	October 2024
LUMYKRAS	sotorasib	New active substance, Conditional marketing authorisation	Amgen Europe B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/lumykras-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lumykras-epar-product-information_en.pdf</a>	January 2022
Lunsumio	mosunetuzumab	New active substance, new biological and conditional marketing authorisation	Roche Registration GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/lunsumio-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lunsumio-epar-product-information_en.pdf</a>	June 2022
Lupkynis	voclosporin	New active substance	Otsuka Pharmaceutical Netherlands B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/lupkynis-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lupkynis-epar-product-information_en.pdf</a>	September 2022
Luxturna	Voretigene neparvovec	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/luxturna-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/luxturna-epar-product-information_en.pdf</a>	December 2018
Lyfnua	gefapixant	New active substance	Merck Sharp & Dohme B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/lyfnua-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lyfnua-epar-product-information_en.pdf</a>	September 2023
Lynkuet	elinzanetant	New active substance	Bayer AG	<a href="https://www.ema.europa.eu/en/documents/product-information/lynkuet-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lynkuet-epar-product-information_en.pdf</a>	December 2025
LYNOZYFIC	ivoseltamab	New active substance, new biological and conditional marketing authorisation	Regeneron Ireland Designated Activity Company (DAC)	<a href="https://www.ema.europa.eu/en/documents/product-information/lynozyfic-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lynozyfic-epar-product-information_en.pdf</a>	May 2025
Lytenava	bevacizumab gamma	New biological	Outlook Therapeutics NL B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/lytenava-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lytenava-epar-product-information_en.pdf</a>	June 2024
Lytgobi	futibatinib	New active substance, Conditional marketing authorisation	Taiho Pharma Netherlands B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/lytgobi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lytgobi-epar-product-information_en.pdf</a>	July 2023
Maapliv	amino acids	Authorised under exceptional circumstances	Recordati Rare Diseases	<a href="https://www.ema.europa.eu/en/documents/product-information/maapliv-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/maapliv-epar-product-information_en.pdf</a>	September 2025
mCOMBRIAX	Influenza and COVID 19, mRNA vaccine	New biological, new active substance	Moderna Biotech Spain S.L.	<a href="https://www.ema.europa.eu/en/documents/product-information/mcombriax-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/mcombriax-epar-product-information_en.pdf</a>	April 2026
Meerscheinchen Prick Test RX	allergen extract from guinea pig epithelia	New biological	Roxall Medizin GmbH	<a href="https://portal.ema.europa.eu/ema/activities/additionaldocs.s.xhtml?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdid=entifier=2611898">https://portal.ema.europa.eu/ema/activities/additionaldocs.s.xhtml?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdid=entifier=2611898</a>	June 2026

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Mepsevii	Vestronidase alfa	Authorized under exceptional circumstances	Ultragenyx Germany GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/mepsevii-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/mepsevii-epar-product-information_en.pdf</a>	September 2018
Minjuvi	Tafasitamab	New active substance, new biological and conditional marketing authorisation	Incyte Biosciences Distribution B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/minjuvi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/minjuvi-epar-product-information_en.pdf</a>	September 2021
mNEXSPIKE	COVID-19 mRNA vaccine	New active substance, New biological	MODERNA BIOTECH SPAIN, S.L.	<a href="https://www.ema.europa.eu/en/documents/product-information/mnexspike-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/mnexspike-epar-product-information_en.pdf</a>	February 2026
Mounjaro	Tirzepatide	New active substance	Eli Lilly Nederland B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/mounjaro-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/mounjaro-epar-product-information_en.pdf</a>	September 2022
mRESVIA	Single-stranded 5' capped mRNA encoding the respiratory syncytial	New active substance, New biological	MODERNA BIOTECH SPAIN, S.L.	<a href="https://www.ema.europa.eu/en/documents/product-information/mresvia-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/mresvia-epar-product-information_en.pdf</a>	September 2024
Myalepta	Metreleptin	Authorized under exceptional circumstances	Chiesi Farmaceutici S.p.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/myalepta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/myalepta-epar-product-information_en.pdf</a>	September 2018
MYNZEPLI	aflibercept	New biological	Advanz Pharma Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/mynzepli-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/mynzepli-epar-product-information_en.pdf</a>	September 2025
MYQORZO	Baricitinib	New active substance	Cytokinetics (Ireland) Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/myqorzo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/myqorzo-epar-product-information_en.pdf</a>	February 2026
Mysimba	Naltrexone / bupropion	PASS <sup>1</sup>	Orexigen Therapeutics Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/mysimba-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/mysimba-epar-product-information_en.pdf</a>	April 2015
NADROPARINE CALCIQUE ASPEN	nadroparin calcium	New biological	ASPEN PHARMA TRADING LIMITED	Not available	September 2022
Nemluvio	Nemolizumab	New active substance and new biological	Galderma International	<a href="https://www.ema.europa.eu/en/documents/product-information/nemluvio-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/nemluvio-epar-product-information_en.pdf</a>	February 2025
NEXPOVIO	selinexor	New active substance	Karyopharm Europe GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/nexpovio-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/nexpovio-epar-product-information_en.pdf</a>	April 2021
Nexviadyme	avalglucosidase alfa	New active substance and new biological	Genzyme Europe B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/nexviadyme-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/nexviadyme-epar-product-information_en.pdf</a>	July 2022
Ngenla	somatrogon	New active substance and new biological	Pfizer Europe MA EEIG	<a href="https://www.ema.europa.eu/en/documents/product-information/ngenla-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ngenla-epar-product-information_en.pdf</a>	February 2022
NULIBRY	fosdenopterin	New active substance, authorised under exceptional circumstances	MC Pharma (EU) Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/nulibry-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/nulibry-epar-product-information_en.pdf</a>	September 2022
Nuvaxovid	SARS-CoV-2 recombinant spike protein	New active substance and new biological	Sanofi Winthrop Industrie	<a href="https://www.ema.europa.eu/en/documents/product-information/nuvaxovid-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/nuvaxovid-epar-product-information_en.pdf</a>	January 2022
Obizur	Susoctocog alfa	Authorised under exceptional circumstances	Baxalta Innovations GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/obizur-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/obizur-epar-product-information_en.pdf</a>	November 2015
Obgemsa	Vibegron	New active substance	PIERRE FABRE MEDICAMENT	<a href="https://www.ema.europa.eu/en/documents/product-information/obgemsa-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/obgemsa-epar-product-information_en.pdf</a>	July 2024
Obodence	Denosumab	New biological	Samsung Bioepis NL B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/obodence-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/obodence-epar-product-information_en.pdf</a>	February 2025
Ogsiveo	nirogacestat	New active substance	Merck Europe B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/ogsiveo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ogsiveo-epar-product-information_en.pdf</a>	September 2025

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Ojemda	tovorafenib	New active substance, Conditional marketing authorisation	Ip̄sen Pharma	<a href="https://www.ema.europa.eu/en/documents/product-information/ojemda-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ojemda-epar-product-information_en.pdf</a>	April 2026
Olivenbaum Prick Test RX	allergen extract from olive tree pollen	New biological	Roxall Medizin GmbH	<a href="https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdid=entifier=2611864">https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdid=entifier=2611864</a>	June 2026
Ondexxya	Andexanet alfa	New active substance, new biological and conditional marketing authorisation	AstraZeneca AB	<a href="https://www.ema.europa.eu/en/documents/product-information/ondexxya-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ondexxya-epar-product-information_en.pdf</a>	May 2019
Ondibta	Insulin glargine	New biological	Gan & Lee Pharmaceuticals Europe GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/ondibta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ondibta-epar-product-information_en.pdf</a>	January 2026
Ontozry	cenobamate	New active substance	Angelini Pharma S.p.A	<a href="https://www.ema.europa.eu/en/documents/product-information/ontozry-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ontozry-epar-product-information_en.pdf</a>	April 2021
Omjjara	momelotinib	New active substance	GlaxoSmithKline Trading Services Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/omjjara-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/omjjara-epar-product-information_en.pdf</a>	February 2024
Omlyclo	Omalizumab	New biological	Celltrion Healthcare Hungary Kft.	<a href="https://www.ema.europa.eu/en/documents/product-information/omlyclo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/omlyclo-epar-product-information_en.pdf</a>	June 2024
OmvoH	mirikizumab	New active substance, new biological	Eli Lilly Nederland B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/omvoh-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/omvoh-epar-product-information_en.pdf</a>	June 2023
Opdualag	nivolumab/relatlimab	New active substance, new biological	Bristol Myers Squibb Pharma EEIG	<a href="https://www.ema.europa.eu/en/documents/product-information/opdualag-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/opdualag-epar-product-information_en.pdf</a>	September 2022
Opuviz	Aflibercept	New biological	Samsung Bioepis NL B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/opuviz-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/opuviz-epar-product-information_en.pdf</a>	November 2024
Ordspono	odronextamab	New active substance, new biological and Conditional Marketing authorisation	Regeneron Ireland Designated Activity Company (DAC)	<a href="https://www.ema.europa.eu/en/documents/product-information/ordspono-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ordspono-epar-product-information_en.pdf</a>	September 2024
Orylmyte	Allergen extract from house dust mites (Dermatophagoides)	New biological	Stallergenes	<a href="https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?mpdid=7000377">https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?mpdid=7000377</a>	July 2021
Orgovyx	relugolix	New active substance	Myovant Sciences Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/orgovyx-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/orgovyx-epar-product-information_en.pdf</a>	May 2022
Orphacol	Cholic acid	Authorised under exceptional circumstances	Laboratoires CTRS	<a href="https://www.ema.europa.eu/en/documents/product-information/orphacol-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/orphacol-epar-product-information_en.pdf</a>	October 2013
ORSERDU	elacestrant	New active substance	Stemline Therapeutics B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/orserdu-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/orserdu-epar-product-information_en.pdf</a>	September 2023
Osenvelt	Denosumab	New biological	Celltrion Healthcare Hungary Kft.	<a href="https://www.ema.europa.eu/en/documents/product-information/osenvelt-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/osenvelt-epar-product-information_en.pdf</a>	February 2025
Osvyrti	denosumab	New biological	Accord Healthcare S.L.U.	<a href="https://www.ema.europa.eu/en/documents/product-information/osvyrti-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/osvyrti-epar-product-information_en.pdf</a>	June 2025
Osqay	denosumab	New biological	Theramex Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/osqay-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/osqay-epar-product-information_en.pdf</a>	January 2026
Oxbryta	Voxelotor	New active substance	Pfizer Europe MA EEIG	<a href="https://www.ema.europa.eu/en/documents/product-information/oxbryta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/oxbryta-epar-product-information_en.pdf</a>	February 2022
Otulfi	ustekinumab	New biological	Fresenius Kabi Deutschland GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/otulfi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/otulfi-epar-product-information_en.pdf</a>	October 2024

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Padcev	enfortumab vedotin	New active substance and <i>new biological</i>	Astellas Pharma Europe B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/padcev-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/padcev-epar-product-information_en.pdf</a>	April 2022
Palforzia	defatted powder of Arachis	New biological	Immune Therapeutics Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/palforzia-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/palforzia-epar-product-information_en.pdf</a>	November 2022
Palsonify	palivizumab	New active substance, PASS <sup>1</sup>	Crinetics Pharmaceuticals Europe GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/palsonify-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/palsonify-epar-product-information_en.pdf</a>	May 2026
Pandemic influenza vaccine H5N1 AstraZeneca	Pandemic influenza vaccine (H5N1) (live attenuated, nasal)	Conditional marketing authorisation	AstraZeneca AB	<a href="https://www.ema.europa.eu/en/documents/product-information/pandemic-influenza-vaccine-h5n1-astrazeneca-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pandemic-influenza-vaccine-h5n1-astrazeneca-epar-product-information_en.pdf</a>	June 2016
PAVBLU	paliperidone	New biological	Amgen Technology (Ireland) UC	<a href="https://www.ema.europa.eu/en/documents/product-information/pavblu-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pavblu-epar-product-information_en.pdf</a>	April 2025
Paxlovid	nirmatrelvir	New active substance	Pfizer Europe MA EEIG	<a href="https://www.ema.europa.eu/en/documents/product-information/paxlovid-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/paxlovid-epar-product-information_en.pdf</a>	February 2022
Pemazyre	pemigatinib	New active substance, conditional marketing authorisation	Incyte Biosciences Distribution B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/pemazyre-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pemazyre-epar-product-information_en.pdf</a>	April 2021
Percolozin	enoxaparin sodium	New biological	Venipharm	N/A	January 2022
Pferd Prick Test RX	allergen extract from horse epithelia	New biological	Roxall Medizin GmbH	<a href="https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdid=entifier=2611900">https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdid=entifier=2611900</a>	June 2026
Piasky	crovalimab	New active substance, new biological	Boehringer Ingelheim GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/piasky-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/piasky-epar-product-information_en.pdf</a>	September 2024
Platane Prick Test RX	allergen extract from plane tree pollen	New biological	Roxall Medizin GmbH	<a href="https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdid=entifier=2611866">https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdid=entifier=2611866</a>	June 2026
Pluvicto	lutetium (177Lu) vipivotide tetraxetan	New active substance	Novartis Europharm Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/pluvicto-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pluvicto-epar-product-information_en.pdf</a>	January 2023
Poherdy	pertuzumab	New biological	N.V. Organon	<a href="https://www.ema.europa.eu/en/documents/product-information/poherdy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/poherdy-epar-product-information_en.pdf</a>	May 2026
Ponlimsi	paliperidone	New biological	Teva GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/ponlimsi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ponlimsi-epar-product-information_en.pdf</a>	December 2025
Pombiliti	cipaglucosidase alfa	New active substance, new biological	Amicus Therapeutics Europe Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/pombiliti-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pombiliti-epar-product-information_en.pdf</a>	April 2023
Prufibry	Human fibrinogen	New biological	Biotest Pharma GmbH	<a href="https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?mpdid=entifier=7020399">https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?mpdid=entifier=7020399</a>	January 2026
Pyllclari	piflufolastat (18F)	New active substance	CURIUM PET France	<a href="https://www.ema.europa.eu/en/documents/product-information/pyllclari-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pyllclari-epar-product-information_en.pdf</a>	September 2023
Pyrukynd	mitapivat	New active substance	Agios Netherlands B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/pyrukynd-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pyrukynd-epar-product-information_en.pdf</a>	November 2022
Pyzchiva	ustekinumab	New biological	Samsung Bioepis NL B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/pyzchiva-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pyzchiva-epar-product-information_en.pdf</a>	May 2024



Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Rezzayo	Rezafungin	New active substance	Mundipharma GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/rezzayo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rezzayo-epar-product-information_en.pdf</a>	January 2024
Rezdiffra	Resmetirom	New active substance, Conditional marketing authorisation	Madrigal Pharmaceuticals EU Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/rezdiffra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rezdiffra-epar-product-information_en.pdf</a>	September 2025
Rhapsido	remibrutinib	New active substance	Novartis Europharm Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/rhapsido-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rhapsido-epar-product-information_en.pdf</a>	May 2026
□ Rimmyrah	Eanibizumab	New biological	QILU PHARMA SPAIN S.L.	<a href="https://www.ema.europa.eu/en/documents/product-information/rimmyrah-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rimmyrah-epar-product-information_en.pdf</a>	January 20247
Rolcya	denosumab	New biological	Sandoz GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/rolcya-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rolcya-epar-product-information_en.pdf</a>	July 2025
ROMVIMZA	vimseltinib	New active substance	Deciphera Pharmaceuticals (Netherlands) B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/romvimza-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/romvimza-epar-product-information_en.pdf</a>	October 2025
Rozlytrek	entrectinib	Conditional marketing authorisation	Roche Registration GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/rozlytrek-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rozlytrek-epar-product-information_en.pdf</a>	August 2020
Rybrevant	Amivantamab	New active substance, new biological	Janssen-Cilag International NV	<a href="https://www.ema.europa.eu/en/documents/product-information/rybrevant-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rybrevant-epar-product-information_en.pdf</a>	January 2022
Rystiggo	Ebzanolixizumab	New active substance, New biological	CCB Pharma S.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/rystiggo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rystiggo-epar-product-information_en.pdf</a>	January 2024
Rytelo	imetelstat	New active substance	Geron Netherlands B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/rytelo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rytelo-epar-product-information_en.pdf</a>	March 2025
Ryzneuta	efbemalenograstim alfa	New active substance and new biological	Evive Biotechnology Ireland LTD	<a href="https://www.ema.europa.eu/en/documents/product-information/ryzneuta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ryzneuta-epar-product-information_en.pdf</a>	April 2024
Saphnelo	anifrolumab	New active substance and new biological	□ AstraZeneca AB	<a href="https://www.ema.europa.eu/en/documents/product-information/saphnelo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/saphnelo-epar-product-information_en.pdf</a>	February 2022
Scemblix	asciminib	New active substance	Novartis Europharm Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/scemblix-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/scemblix-epar-product-information_en.pdf</a>	September 2022
Scenesse	Afamelanotide	Authorised under exceptional circumstances	Clinuvel UK Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/scenesse-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/scenesse-epar-product-information_en.pdf</a>	January 2015
Seladelpar Gilead	seladelpar	New active substance, Conditional marketing authorisation	Gilead Sciences Ireland UC	<a href="https://www.ema.europa.eu/en/documents/product-information/seladelpar-gilead-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/seladelpar-gilead-epar-product-information_en.pdf</a>	March 2025
Sephience	Eapiapterin	New active substance	PTC Therapeutics International Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/sephience-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/sephience-epar-product-information_en.pdf</a>	July 2025
SIILTIBCY	rdESAT-6 and rCFP-10	New active substance, new biological	Serum Life Science Europe GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/siiltibcy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/siiltibcy-epar-product-information_en.pdf</a>	January 2025
Skyclarys Skytrofa (previously known as Lonapegsomatropin Ascendis Pharma)	omaveloxolone	New active substance	Biogen Netherlands B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/skyclarys-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/skyclarys-epar-product-information_en.pdf</a>	February 2024
	Lonapegsomatropin	New active substance and new biological	□ Ascendis Pharma Endocrinology Division A/S	<a href="https://www.ema.europa.eu/en/documents/product-information/skytrofa-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/skytrofa-epar-product-information_en.pdf</a>	January 2022

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Sondelbay	teriparatide	New biological	Accord Healthcare S.L.U.	<a href="https://www.ema.europa.eu/en/documents/product-information/sondelbay-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/sondelbay-epar-product-information_en.pdf</a>	April 2022
SOTYKTU	deucravacitinib	New active substance	Bristol Myers Squibb Pharma EEIG	<a href="https://www.ema.europa.eu/en/documents/product-information/sotyktu-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/sotyktu-epar-product-information_en.pdf</a>	April 2023
Spevigo	epesolimab	New active substance, new biological and Conditional marketing authorisation	LEO Pharma A/S	<a href="https://www.ema.europa.eu/en/documents/product-information/spevigo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/spevigo-epar-product-information_en.pdf</a>	January 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.	<a href="https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf</a>	January 2021
Spitzwegerich Prick Test RX	allergen extract from english plantain	New biological	Roxall Medizin GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/spitzwegerich-prick-test-rx-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/spitzwegerich-prick-test-rx-epar-product-information_en.pdf</a>	June 2026
STEQEYMA	ustekinumab	New biological	Celltrion Healthcare Hungary Kft.	<a href="https://www.ema.europa.eu/en/documents/product-information/steqeyma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/steqeyma-epar-product-information_en.pdf</a>	September 2024
Stimufend	Pegfilgrastim	New biological	Fresenius Kabi Deutschland GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/stimufend-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/stimufend-epar-product-information_en.pdf</a>	April 2022
Strensiq	Asfotase alfa Autologous CD34+ enriched cell fraction that contains CD34+ cells	Authorised under exceptional circumstances	Alexion Europe SAS	<a href="https://www.ema.europa.eu/en/documents/product-information/strensiq-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/strensiq-epar-product-information_en.pdf</a>	September 2015
Strimvelis		PASS <sup>1</sup>	Fondazione Telethon ETS	<a href="https://www.ema.europa.eu/en/documents/product-information/strimvelis-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/strimvelis-epar-product-information_en.pdf</a>	June 2016
Sunlenca	lenacapavir	New active substance	Gilead Sciences Ireland UC	<a href="https://www.ema.europa.eu/en/documents/product-information/sunlenca-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/sunlenca-epar-product-information_en.pdf</a>	September 2022
Sylvant	Siltuximab	PASS <sup>1</sup>	EUSA Pharma (Netherlands) B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/sylvant-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/sylvant-epar-product-information_en.pdf</a>	June 2014
Tabrecta	capmatinib	New active substance	Novartis Europharm Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/tabrecta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tabrecta-epar-product-information_en.pdf</a>	June 2022
TALVEY	talquetamab	New active substance, new biological and Conditional marketing authorisation	Janssen-Cilag International NV	<a href="https://www.ema.europa.eu/en/documents/product-information/talvey-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/talvey-epar-product-information_en.pdf</a>	September 2023
Tavneos	avacopan	New active substance	Vifor Fresenius Medical Care Renal Pharma France	<a href="https://www.ema.europa.eu/en/documents/product-information/tavneos-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tavneos-epar-product-information_en.pdf</a>	January 2022
Tauvid	Flortaucipir (18F)	New active substance	Eli Lilly Nederland B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/tauvid-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tauvid-epar-product-information_en.pdf</a>	September 2024
Tecartus	autologous anti-CD19-transduced CD3+ cells	Conditional marketing authorisation / New active substance and new biological/ PASS <sup>1</sup>	Kite Pharma EU B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/tecartus-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tecartus-epar-product-information_en.pdf</a>	January 2021
Tecovirimat SIGA	tecovirimat monohydrate	Authorised under exceptional circumstances and	SIGA Technologies Netherlands B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/tecovirimat-siga-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tecovirimat-siga-epar-product-information_en.pdf</a>	January 2022
TECVAYLI	teclistamab	New active substance, new biological and	Janssen-Cilag International NV	<a href="https://www.ema.europa.eu/en/documents/product-information/tecvayli-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tecvayli-epar-product-information_en.pdf</a>	September 2022
Teizeild	Teplizumab	New active substance and new biological	Sanofi Winthrop Industrie	<a href="https://www.ema.europa.eu/en/documents/product-information/teizeild-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/teizeild-epar-product-information_en.pdf</a>	January 2026
Tepkinly	epcoritamab	New active substance, new biological and conditional marketing authorisation	AbbVie Deutschland GmbH & Co. KG	<a href="https://www.ema.europa.eu/en/documents/product-information/tepkinky-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tepkinky-epar-product-information_en.pdf</a>	October 2023

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
□ Tepmetko	Tepotinib hydrochloride mo	New active substance	□ Merck Europe B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/tepmetko-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tepmetko-epar-product-information_en.pdf</a>	March 2022
TEPEZZA	Teprotumumab	New active substance and new biological	Amgen Europe B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/tepezza-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tepezza-epar-product-information_en.pdf</a>	July 2025
Tevimbra	tebivelimab	New biological	BeiGene Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/tevimbra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tevimbra-epar-product-information_en.pdf</a>	September 2023
Tezspire	tezepelumab	New active substance and new biological	AstraZeneca AB	<a href="https://www.ema.europa.eu/en/documents/product-information/tezspire-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tezspire-epar-product-information_en.pdf</a>	September 2022
Thiosix	Tioguanin	Authorised under exceptional circumstances	Teva Nederland B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/tibsovo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tibsovo-epar-product-information_en.pdf</a>	May 2015
Thunfisch Prick Test RX	allergen extract from tuna	New biological	Roxall Medizin GmbH	<a href="https://per.tandfonline.com/doi/full/10.1080/14639868.2023.2241123.s.html?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdid=entifier=2611923">https://per.tandfonline.com/doi/full/10.1080/14639868.2023.2241123.s.html?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdid=entifier=2611923</a> <a href="http://db.cbg-meb.nl/IB-teksten/h114681.pdf">http://db.cbg-meb.nl/IB-teksten/h114681.pdf</a>	June 2026
Tibsovo	ivosidenib	New active substance	Les Laboratoires Servier	<a href="https://www.ema.europa.eu/en/documents/product-information/tivdak-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tivdak-epar-product-information_en.pdf</a>	May 2023
Tivdak	risotumab vedotin	New active substance and new biological	Genmab A/S	<a href="https://www.ema.europa.eu/en/documents/product-information/tofidence-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tofidence-epar-product-information_en.pdf</a>	April 2025
Tofidence	tocilizumab	New biological	STADA Arzneimittel AG	<a href="https://www.ema.europa.eu/en/documents/product-information/trozdelvy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/trozdelvy-epar-product-information_en.pdf</a>	June 2024
Trivalent Influenza Vaccine	Influenza vaccine (split viric	New biological	Sanofi Pasteur	Not available <a href="https://www.ema.europa.eu/en/documents/product-information/trozdelvy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/trozdelvy-epar-product-information_en.pdf</a>	May 2019
Trodelvy	sacituzumab govitecan	New active substance and new biological	Gilead Sciences Ireland UC	<a href="https://www.ema.europa.eu/en/documents/product-information/truqap-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/truqap-epar-product-information_en.pdf</a>	December 2021
Truqap	capivasertib	New active substance	AstraZeneca AB	<a href="https://www.ema.europa.eu/en/documents/product-information/tryngolza-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tryngolza-epar-product-information_en.pdf</a>	June 2024
Tryngolza	olezarsen	New active substance	Swedish Orphan Biovitrum AB (publ)	<a href="https://www.ema.europa.eu/en/medicines/human/referrals/topiramate">https://www.ema.europa.eu/en/medicines/human/referrals/topiramate</a>	September 2025
<u>Topiramate containing medicinal products in the European Union (EMA)</u>	topiramate	PASS <sup>1</sup>	<u>Various ( for full list see Annex XV)</u>		May 2024
Tuznue	trastuzumab	New biological	Prestige Biopharma Belgium BVBA	<a href="https://www.ema.europa.eu/en/documents/product-information/tuznue-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tuznue-epar-product-information_en.pdf</a>	October 2024
Tuyory	tocilizumab	New biological	Gedeon Richter Plc.	<a href="https://www.ema.europa.eu/en/documents/product-information/tuyory-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tuyory-epar-product-information_en.pdf</a>	May 2026
Tyenne	tebivelimab	New biological	Eresenius Kabi Deutschland GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/tyruko-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tyruko-epar-product-information_en.pdf</a>	September 2023
Tyruko	natalizumab	New biological	Sandoz GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/uplizna-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/uplizna-epar-product-information_en.pdf</a>	October 2023
Uplizna	inebilizumab	New active substance, new biological	Amgen Europe B.V.		May 2022

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Upstaza	Eladocagene exuparvec	New active substance, new biological, authorised under exceptional circumstances	PTC Therapeutics International Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/upstaza-epar-product-information_en-0.pdf">https://www.ema.europa.eu/en/documents/product-information/upstaza-epar-product-information_en-0.pdf</a>	July 2022
Usgena	ustekinumab	New biological	STADA Arzneimittel AG	<a href="https://www.ema.europa.eu/en/documents/product-information/usgena-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/usgena-epar-product-information_en.pdf</a>	November 2025
Usrenty	ustekinumab	New biological	Biosimilar Collaborations Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/usrenty-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/usrenty-epar-product-information_en.pdf</a>	October 2025
Usymro	ustekinumab	New biological	Gedeon Richter Plc.	<a href="https://www.ema.europa.eu/en/documents/product-information/usymro-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/usymro-epar-product-information_en.pdf</a>	September 2025
Uzpruvo	ustekinumab	New biological	STADA Arzneimittel AG	<a href="https://www.ema.europa.eu/en/documents/product-information/uzpruvo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/uzpruvo-epar-product-information_en.pdf</a>	January 2024
Vabysmo	Faricimab	New active substance, new biological	Röche Registration GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/vabysmo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vabysmo-epar-product-information_en.pdf</a>	September 2022
VacPertagen	Filamentous haemagglutinin	New active substance and new biological	BioNet Europe	<a href="https://www.ema.europa.eu/en/documents/product-information/vacpertagen-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vacpertagen-epar-product-information_en.pdf</a>	January 2026
Valproate and related substances (sodium valproate, valproic acid, valproate semisodium, valpromide-containing medicinal products) (For full list of products see Annex XIII)	Sodium valproate, valproic acid, valproate semisodium, valpromide	PASS <sup>1</sup>	Various (For full list see Annex XIII)	<a href="https://www.ema.europa.eu/en/medicines/human/referrals/valproate-related-substances">https://www.ema.europa.eu/en/medicines/human/referrals/valproate-related-substances</a>	January 2015
Vafseo	Vadadustat	New active substance	AKEBIA EUROPE Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/vafseo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vafseo-epar-product-information_en.pdf</a>	May 2023
VANFLYTA	quizartinib	New active substance	Daiichi Sankyo Europe GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/vanflyta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vanflyta-epar-product-information_en.pdf</a>	November 2023
Vaxneuvance	pneumococcal polysaccharide Tocoferolan d-alpha tocopheryl polyethylene glycol succinate	New active substance, new biological	Merck Sharp & Dohme B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/vaxneuvance-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vaxneuvance-epar-product-information_en.pdf</a>	January 2022
Vedrop		Authorised under exceptional circumstances	Recordati Rare Diseases	<a href="https://www.ema.europa.eu/en/documents/product-information/vedrop-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vedrop-epar-product-information_en.pdf</a>	April 2013
VEGZELMA	bevacizumab	New biological	Celltrion Healthcare Hungary Kft.	<a href="https://www.ema.europa.eu/en/documents/product-information/vegzelma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vegzelma-epar-product-information_en.pdf</a>	September 2022
Velsipity	etrasimod	New active substance	Pfizer Europe MA EEIG	<a href="https://www.ema.europa.eu/en/documents/product-information/velsipity-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/velsipity-epar-product-information_en.pdf</a>	February 2024
Verquvo	Vericiguat	New active substance	Bayer AG	<a href="https://www.ema.europa.eu/en/documents/product-information/verquvo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/verquvo-epar-product-information_en.pdf</a>	July 2021
Veozza	fzolinetant	New active substance	Astellas Pharma Europe B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/veozza-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/veozza-epar-product-information_en.pdf</a>	January 2024
Vevzuo	enosumab	New biological	Biosimilar Collaborations Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/vevzuo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vevzuo-epar-product-information_en.pdf</a>	July 2025

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Vgenfli	āflibercept	New biological	Zakłady Farmaceutyczne POLPHARMA S.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/vgenfli-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vgenfli-epar-product-information_en.pdf</a>	September 2025
Vimizim	Elosulfase alfa Chikungunya vaccine (recombinant, adsorbed)	PASS <sup>1</sup>	BioMarin International Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/vimizim-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vimizim-epar-product-information_en.pdf</a>	June 2014
VIMKUNYA	(PKVX0317)	New biological, new active substance,	Bavarian Nordic A/S	<a href="https://www.ema.europa.eu/en/documents/product-information/vimkunya-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vimkunya-epar-product-information_en.pdf</a>	March 2025
VITRAKVI	Larotrectinib	Conditional authorisation	Bayer AG	<a href="https://www.ema.europa.eu/documents/product-information/vitrakvi-epar-product-information_en.pdf">https://www.ema.europa.eu/documents/product-information/vitrakvi-epar-product-information_en.pdf</a>	October 2019
Vocabria	cabotegravir	PASS <sup>1</sup>	ViiV Healthcare BV	<a href="https://www.ema.europa.eu/en/documents/product-information/vocabria-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vocabria-epar-product-information_en.pdf</a>	January 2021
Voranigo	vorasidenib	New active substance	Lés Laboratoires Servier	<a href="https://www.ema.europa.eu/en/documents/product-information/voranigo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/voranigo-epar-product-information_en.pdf</a>	September 2025
Voraxaze	glucarpidase	Authorised under exceptional circumstances, new active substance and new biological	SERB SAS	<a href="https://www.ema.europa.eu/en/documents/product-information/voraxaze-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/voraxaze-epar-product-information_en.pdf</a>	January 2022
Voxzogo	vosoritide	New active substance and new biological	BioMarin International Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/voxzogo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/voxzogo-epar-product-information_en.pdf</a>	September 2021
Voydeya	danicopan	New active substance	Alexion Europe SAS	<a href="https://www.ema.europa.eu/en/documents/product-information/voydeya-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/voydeya-epar-product-information_en.pdf</a>	May 2024
Vueway	gadopiclenol	New active substance	Bracco Imaging SPA	<a href="https://www.ema.europa.eu/en/documents/product-information/vueway-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vueway-epar-product-information_en.pdf</a>	January 2024
Vydura	rimegepant	New active substance	Pfizer Europe MA EEIG	<a href="https://www.ema.europa.eu/en/documents/product-information/vydura-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vydura-epar-product-information_en.pdf</a>	May 2022
Vyepti	eptinezumab	New biological	H. Lundbeck A/S	<a href="https://www.ema.europa.eu/en/documents/product-information/vyepti-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vyepti-epar-product-information_en.pdf</a>	February 2022
Vyjuvek	Bremagene geperpavec	New active substance, new biological, PASS <sup>1</sup>	Krystal Biotech Netherlands B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/vyjuvek-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vyjuvek-epar-product-information_en.pdf</a>	May 2025
Vyloy	zolbetuximab	New biological	Astellas Pharma Europe B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/vyloy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vyloy-epar-product-information_en.pdf</a>	October 2024
Vyndaqel	Tafamidis	Authorised under exceptional circumstances	Pfizer Europa MA EEG	<a href="https://www.ema.europa.eu/en/documents/product-information/vyndaqel-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vyndaqel-epar-product-information_en.pdf</a>	April 2013
Vyvgart	efgartigimod alfa	New active substance and new biological	argenx BV	<a href="https://www.ema.europa.eu/en/documents/product-information/vyvgart-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vyvgart-epar-product-information_en.pdf</a>	September 2022
Wainzua	eplontersen	New active substance	AstraZeneca AB	<a href="https://www.ema.europa.eu/en/documents/product-information/wainzua-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/wainzua-epar-product-information_en.pdf</a>	March 2025
Wakix	Pitolisant hydrochloride	PASS <sup>1</sup>	Bioprojet Pharma	<a href="https://www.ema.europa.eu/en/documents/product-information/wakix-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/wakix-epar-product-information_en.pdf</a>	April 2016
Waskyra	etuvetidigene autotemcel	New active substance, new biological and PASS	Fondazione Telethon ETS	<a href="https://www.ema.europa.eu/en/documents/product-information/waskyra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/waskyra-epar-product-information_en.pdf</a>	January 2026
Waylivra	Volanesorsen	Conditional marketing authorisation	Akcea Therapeutics Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/waylivra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/waylivra-epar-product-information_en.pdf</a>	May 2019

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WAYRILZ	rilzabrutinib	New active substance	Sanofi B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/wayrilz-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/wayrilz-epar-product-information_en.pdf</a>	January 2026
Wegovy	semaglutide	New biological	Novo Nordisk A/S	<a href="https://www.ema.europa.eu/en/documents/product-information/wegovy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/wegovy-epar-product-information_en.pdf</a>	January 2022
WELIREG	belzutifan	New active substance and conditional marketing authorisation	Merck Sharp & Dohme B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/welireg-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/welireg-epar-product-information_en.pdf</a>	February 2025
Wezenla	Ustekinumab	New biological	Amgen Technology (Ireland) UC	<a href="https://www.ema.europa.eu/en/documents/product-information/wezenla-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/wezenla-epar-product-information_en.pdf</a>	July 2024
Winlevi	Clascoterone	New active substance	Cassiopea S.p.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/winlevi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/winlevi-epar-product-information_en.pdf</a>	October 2025
Winrevair	sotatercept	New active substance, new biological	Merck Sharp & Dohme B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/winrevair-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/winrevair-epar-product-information_en.pdf</a>	September 2024
Wyost	denosumab	New biological	Sandoz GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/wyost-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/wyost-epar-product-information_en.pdf</a>	May 2024
Xbryk	denosumab	New biological	Samsung Bioepis NL B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/xbryk-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/xbryk-epar-product-information_en.pdf</a>	February 2025
Xbonzy	denosumab	New biological	Reddy Holding GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/xbonzy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/xbonzy-epar-product-information_en.pdf</a>	November 2025
Xembify	Human normal Immunoglobulin	New biological	Instituto Grifols S.A.	<a href="https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdidentifier=7001176">https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;mpdidentifier=7001176</a> <a href="https://www.ema.europa.eu/en/documents/product-information/xembify-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/xembify-epar-product-information_en.pdf</a>	March 2022
Xenpozyme	olipudase alfa	New active substance, new biological	Genzyme Europe B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/xenpozyme-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/xenpozyme-epar-product-information_en.pdf</a>	July 2022
Ximluci	etanercept	New biological	STADA Arzneimittel AG	<a href="https://www.ema.europa.eu/en/documents/product-information/ximluci-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ximluci-epar-product-information_en.pdf</a>	November 2022
Xofigo	Radium Ra 223 dichloride	PASS <sup>1</sup>	Bayer AG	<a href="https://www.ema.europa.eu/en/documents/product-information/xofigo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/xofigo-epar-product-information_en.pdf</a>	December 2013
Xolremdi	mavorixafor	New active substance, Authorised under exceptional circumstances, PASS	X4 Pharmaceuticals (Austria) GmbH	<a href="https://www.ema.europa.eu/en/documents/product-information/xolremdi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/xolremdi-epar-product-information_en.pdf</a>	May 2026
Yaxwer	denosumab	New biological	Gedeon Richter Plc.	<a href="https://www.ema.europa.eu/en/documents/product-information/yaxwer-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/yaxwer-epar-product-information_en.pdf</a>	July 2025
Yesafili	aflibercept	New biological	Biosimilar Collaborations Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/yesafili-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/yesafili-epar-product-information_en.pdf</a>	September 2023
Yescarta	Axicabtagene ciloleucel	PASS <sup>1</sup>	Kite Pharma EU B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/yescarta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/yescarta-epar-product-information_en.pdf</a>	September 2018
Yesintek	ustekinumab	New biological	Biosimilar Collaborations Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/yesintek-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/yesintek-epar-product-information_en.pdf</a>	February 2025
Yimmugo	Human normal Immunoglobulin	New biological	Biotest Pharma GmbH	<a href="https://portal.dimdi.de/amquifree/am/docoutput/ipadocdisplay.xhtml?globalDocId=E9C019E2F641455FBDB3AF3C8E60006F&amp;directdisplay=true&amp;docid=1">https://portal.dimdi.de/amquifree/am/docoutput/ipadocdisplay.xhtml?globalDocId=E9C019E2F641455FBDB3AF3C8E60006F&amp;directdisplay=true&amp;docid=1</a> <a href="https://www.ema.europa.eu/en/documents/product-information/yimmugo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/yimmugo-epar-product-information_en.pdf</a>	November 2022
Yorvipath	palopegteriparatide	New active substance	Ascendis Pharma Bone Diseases A/S	<a href="https://www.ema.europa.eu/en/documents/product-information/yorvipath-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/yorvipath-epar-product-information_en.pdf</a>	November 2023
Yselty	linzagolix choline	New active substance	Theramex Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/yselty-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/yselty-epar-product-information_en.pdf</a>	June 2022

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
ZADENVI	denosumab	New biological	Zentiva k.s.	<a href="https://www.ema.europa.eu/en/documents/product-information/zadenvi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zadenvi-epar-product-information_en.pdf</a>	July 2025
Zandoriah	fariparatide	New biological	CINNAGEN CO, UNIPESSOAL LDA.	<a href="https://www.ema.europa.eu/en/documents/product-information/zandoriah-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zandoriah-epar-product-information_en.pdf</a>	May 2026
Zefylti	Filgrastim	New biological	<del>CuraTeQ Biologics s.r.o.</del> CuraTeQ Biologics (Malta) Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/zefylti-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zefylti-epar-product-information_en.pdf</a>	February 2025
Zemcelpro	dorocubice / allogeneic umbilical cord-derived CD34- cells, non-expanded	New active substance, New biological and Conditional marketing authorisation	Cbrdex Biologics International Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/zemcelpro-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zemcelpro-epar-product-information_en.pdf</a>	September 2025
Zercepac	trastuzumab	New Biological, New active substance	Accord Healthcare S.L.U.	<a href="https://www.ema.europa.eu/en/documents/product-information/zercepac-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zercepac-epar-product-information_en.pdf</a>	August 2020
 ZEPZELCA	lurbinectedin	New active substance	Pharma Mar S.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/zepzelca-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zepzelca-epar-product-information_en.pdf</a>	June 2026
Zilbrysq	zilucoplan	New active substance	UCB Pharma S.A.	<a href="https://www.ema.europa.eu/en/documents/product-information/zilbrysq-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zilbrysq-epar-product-information_en.pdf</a>	December 2023
Ziihera	zanidatamab	New active substance, New biological and Conditional marketing authorisation	AbbVie Pharmaceuticals Ireland Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/ziihera-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ziihera-epar-product-information_en.pdf</a>	July 2025
Zokinvy	Lonafarnib	New active substance, authorised under exceptional circumstances	TMC Pharma (EU) Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/zokinvy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zokinvy-epar-product-information_en.pdf</a>	July 2022
Zolgensma	Onasemnogene abeparvovec	New active substance, new biological	Novartis Europharm Limited	<a href="https://www.ema.europa.eu/en/documents/product-information/zolgensma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zolgensma-epar-product-information_en.pdf</a>	May 2020
ZTALMY	zanaxolone	New active substance	Immedica Pharma AB	<a href="https://www.ema.europa.eu/en/documents/product-information/ztalmy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ztalmy-epar-product-information_en.pdf</a>	September 2023
Zurzuvae	Zuranolone	New active substance	Biogen Netherlands B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/zurzuvae-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zurzuvae-epar-product-information_en.pdf</a>	October 2025
Zvogra	denosumab	New biological	STADA Arzneimittel AG	<a href="https://www.ema.europa.eu/en/documents/product-information/zvogra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zvogra-epar-product-information_en.pdf</a>	November 2025
Zynlonta	loncastuximab tesirine	New active substance, new biological and Conditional marketing authorisation	ADC Therapeutics (NL) B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/zynlonta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zynlonta-epar-product-information_en.pdf</a>	January 2023
ZYNYZ	retifanlimab	New active substance, New biological	Imcyte Biosciences Distribution B.V.	<a href="https://www.ema.europa.eu/en/documents/product-information/zynyz-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zynyz-epar-product-information_en.pdf</a>	May 2024

<sup>1</sup> 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.

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