

19 April 2024
EMA/245297/2013 Rev. 121*
Human Medicines Division

List of medicinal products under additional monitoring

Related Information:

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

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

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

<https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/good-pharmacovigilance-practices>

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

To note: All products added to the list in April 2024 are shown in red font. All products removed from the list are shown with a strikethrough for the period of one month after which they are excluded. For products newly added to the list, EMA will update the 'Product details' section of the medicine page on EMA's corporate website when it publishes the revised summary of product characteristics.

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Abevmy	bevacizumab	New biological New biological, new active substance, conditional marketing authorisation, PASS ¹	Biosimilar Collaborations Ireland Limited	https://www.ema.europa.eu/en/documents/pr+E21:E372oduct-information/abevmy-epar-product-information_en.pdf	May/21
Abecma	idecabtagene vicleucel respiratory syncytial virus vaccine (bivalent, recombinant)	PASS ¹	Bristol-Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/abecma-epar-product-information_en.pdf	September 2021
Abrysvo		New biological New biological, new active-substance, conditional marketing-authorisation	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/abrysvo-epar-product-information_en.pdf	September 2023
Adakveo	crizanlizumab	conditional marketing authorisation	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/adakveo-epar-product-information_en.pdf	November 2020
Adynovi	Rurioctocog alfa pegol	PASS ¹	Baxalta Innovations GmbH	https://www.ema.europa.eu/en/documents/product-information/adynovi-epar-product-information_en.pdf	January 2018
Adtralza	tralokinumab	New active substance and <i>new biological</i>	Leo Pharma A/S	https://www.ema.europa.eu/en/documents/product-information/adtralza-epar-product-information_en.pdf	June 2021
Afluria Tetra	Influenza vaccine (split virion, inactivated)	New biological	Seqirus Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/afluria-tetra-epar-product-information_en.pdf	September 2020
AGAMREE	vamorolone	New active substance	Santhera Pharmaceuticals (Deutschland) GmbH	https://www.ema.europa.eu/en/documents/product-information/agamree-epar-product-information_en.pdf	January 2024
Aklief	trifarotene	New active substance	Galderma Nordic AB	http://mri.cts-mrp.eu/Human/Product/Details/58971	December 2021
Alymsys	bevacizumab	New biological	Mabxience Research SL	https://www.ema.europa.eu/en/documents/product-information/alymsys-epar-product-information_en.pdf	April 2021

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Amsparity	Adalimumab	New biological	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/amsparity-epar-product-information_en.pdf	February 2020
Amvuttra	vutrisiran umecicium bromide/vilanterol	New active substance	Alnylam Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/amvuttra-epar-product-information_en.pdf	September 2022
Anoro Ellipta	trifenatate pneumococcal polysaccharide conjugate	PASS ¹	GlaxoSmithKline (Ireland) Limited	https://www.ema.europa.eu/en/documents/product-information/anoro-ellipta-epar-product-information_en.pdf	June 2014
Apexxnar	vaccine (20-valent,	New biological	□ Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/apexxnar-epar-product-information_en.pdf	March 2022
Apretude	cabotegravir	New active substance	VIIV Healthcare BV	https://www.ema.europa.eu/en/documents/product-information/apretude-epar-product-information_en.pdf	September 2023
AQUIPTA	atogepant respiratory syncytial Virus (RSV) vaccine	New active substance	AbbVie Deutschland GmbH & Co. KG	https://www.ema.europa.eu/en/documents/product-information/aquipta-epar-product-information_en.pdf	September 2023
Arexvy	(recombinant, adjuvanted)	New active substance and new biological	GlaxoSmithKline Biologicals S.A.	https://www.ema.europa.eu/en/documents/product-information/arexvy-epar-product-information_en.pdf	June 2023
Artesunate Amivas	artesanate	New active substance	Amivas Ireland Ltd	https://www.ema.europa.eu/en/documents/product-information/artesunate-amivas-epar-product-information_en.pdf	Dec/21
Aspaveli	pegcetacoplan	New active substance	□ Swedish Orphan Biovitrum AB (publ)	https://www.ema.europa.eu/en/documents/product-information/aspaveli-epar-product-information_en.pdf	January 2022
Atgam	anti-human T-lymphocyte immunoglobulin	New biological	Pfizer Pharma GmbH	https://www.ema.europa.eu/en/documents/product-information/atgam-epar-product-information_en.pdf	March 2022
Atriance	Nelarabine	Authorised under exceptional circumstances	Sandoz Pharmaceuticals d.d.	https://www.ema.europa.eu/en/documents/product-information/atriance-epar-product-information_en.pdf	April 2013
Aybintio	bevacizumab	New biological	Samsung Bioepis NL B.V.	https://www.ema.europa.eu/en/documents/product-information/aybintio-epar-product-information_en.pdf	August 2020
AYVAKYT	avapritinib	New active substance, conditional marketing authorisation	Blueprint Medicines (Netherlands) B.V.	https://www.ema.europa.eu/en/documents/product-information/ayvakyt-epar-product-information_en.pdf	September 2020
Bavencio	Avelumab	New active substance and <i>new biological</i> ,	Merck Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/bavencio-epar-product-information_en.pdf	September 2017
BEKEMV	eculizumab	New biological	Amgen Technology (Ireland) UC	https://www.ema.europa.eu/en/documents/product-information/bekemv-epar-product-information_en.pdf	April 2023
Benlysta	Belimumab	PASS ¹	Glaxo Group Ltd	https://www.ema.europa.eu/en/documents/product-information/benlysta-epar-product-information_en.pdf	April 2013
Beovu	Brolucizumab	New active substance and <i>new biological</i>	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/beovu-epar-product-information_en.pdf	February 2020
Beyfortus	irsevimumab	New active substance and <i>new biological</i>	Sanofi Winthrop Industrie	https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf	November 2022
BIMERVAX	COVID-19 Vaccine (recombinant, adjuvanted)	New active substance and new biological	Eipra Human Health, S.L.U.	https://www.ema.europa.eu/en/documents/product-information/bimervax-epar-product-information_en.pdf	April 2023
Bimzelx	bimekizumab	New active substance and new biological	UCB Pharma S.A.	https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf	September 2021

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Cibinqo	abrocitinib	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/cibinqo-epar-product-information_en.pdf	January 2022
Cidofovir 75 mg/ml Concentrate for Solution for Infusion	Cidofovir	PASS ¹	Emcure Pharma UK Limited	http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1466141046287.pdf	May 2016
Cinryze	c1 inhibitor, human	PASS ¹	Takeda Manufacturing Austria AG	https://www.ema.europa.eu/en/documents/product-information/cinryze-epar-product-information_en.pdf	April 2013
Colevance	enoxaparin sodium	New biological	Venipharm	N/A	January 2022
Columvi <u>Combined hormonal contraceptives containing chlormadinone (For full list of products see Annex I)</u>	glofitamab Chlormadinone Ethinylestradiol, Chlormadinone Acetate Ethinylestradiol	New active substance, new biological and conditional marketing authorisation PASS ¹	Roche Registration GmbH <u>Various (For full list see Annex IX)</u>	https://www.ema.europa.eu/en/documents/product-information/columvi-epar-product-information_en.pdf <u>Combined hormonal contraceptives European Medicines Agency (europa.eu)</u>	July 2023 June 2014
Comirnaty	COVID-19 mRNA Vaccine (nucleoside modified)	New active substance and new biological	BioNTech Manufacturing GmbH	https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf	Jan/21
Copiktra	duvelisib	New active substance	Secura Bio Limited	https://www.ema.europa.eu/en/documents/product-information/copiktra-epar-product-information_en.pdf	Jun/21
Cyproterone acetate and Ethinylestradiol containing medicinal products (For full list of products see Annex I)	Cyproterone acetate and Ethinylestradiol	PASS¹	Various (For full list see Annex I)	https://view.officeapps.live.com/ov/view.aspx?src=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fdocuments%2Fadditio%2Fannex-i-list-cyproterone-acetate-ethinylestradiol-containing-medicinal-products-european-union-en.xls&wdOrigin=BROWSELINK	August 2013
Daurismo	Glasdegib	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/daurismo-epar-product-information_en.pdf	July 2020
Dectova	Zanamivir	Authorised under exceptional circumstances	GlaxoSmithKline Trading Services Limited	https://www.ema.europa.eu/en/documents/product-information/dectova-epar-product-information_en.pdf	May 2019
Defitelio	Defibrotide	Authorised under exceptional circumstances	Gentium S.p.A.	https://www.ema.europa.eu/en/documents/product-information/defitelio-epar-product-information_en.pdf	November 2013
Deltyba	Delamanid ACIDINIUM bromide/formoterol fumarate dihydrate	Conditional authorisation PASS ¹	Otsuka Novel Products GmbH Covis Pharma Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/deltyba-epar-product-information_en.pdf https://www.ema.europa.eu/en/documents/product-information/duaklir-genuair-epar-product-information_en.pdf	May 2014 December 2014
Drovelis	drospirenone/estetrol	New active substance	Gedeon Richter Plc.	https://www.ema.europa.eu/en/documents/product-information/drovelis-epar-product-information_en.pdf	June 2021
Ebglyss	Ibrikizumab	New active substance, new biological	Almirall S.A.	https://www.ema.europa.eu/en/documents/product-information/ebglyss-epar-product-information_en.pdf	November 2023
Ebvallo	Tabelecleucel	New active substance and new biological, Authorised under exceptional circumstances	Pierre Fabre Medicament	https://www.ema.europa.eu/en/documents/product-information/ebvallo-epar-product-information_en.pdf	January 2023
Eklira Genuair	Aclidinium bromide	PASS ¹	Covis Pharma Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/eklira-genuair-epar-product-information_en.pdf	April 2013
Eladynos	abaloparatide	New active substance	Theramex Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/eladynos-epar-product-information_en.pdf	January 2023

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Elaprase	Idursulfase	Authorised under exceptional circumstances	Takeda Pharmaceuticals International AG Ireland Branch	https://www.ema.europa.eu/en/documents/product-information/elaprase-epar-product-information_en.pdf	April 2013
Elfabrio	pegunigalsidase alfa	New active substance and new biological	Chiesi Farmaceutici S.p.A.	https://www.ema.europa.eu/en/documents/product-information/elfabrio-epar-product-information_en.pdf	May 2023
□ Elucirem	gadopiclenol	New active substance	Guerbet	<u>Not available</u>	January 2024
ELREXFIO	elranatamab Quadrivalent Influenza Vaccine (Split Virion, Inactivated)	New biological, new active substance, conditional marketing authorisation	Pfizer Europe MA EEIG	<u>Not available</u>	January 2024
Efluelda		New biological	Sanofi Pasteur	https://cima.aemps.es/cima/dochtml/ft/85068/FT_85068.html	February 2021
ELZONRIS	tagraxofusp	New active substance and new biological, Authorised under exceptional circumstances	Stemline Therapeutics B.V.	https://www.ema.europa.eu/en/documents/product-information/elzonris-epar-product-information_en.pdf	January 2021
Enhertu	trastuzumab deruxtecan	New biological, new active substance, conditional marketing authorisation	Daiichi Sankyo Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/enhertu-epar-product-information_en.pdf	January 2021
Enspryng Enoxaparin Becat (also known in some EU countries as Losima,	satralizumab Enoxaparin sodium	New active substance, new biological New biological	Roche Registration GmbH Laboartorios Farmacéuticos Rovi, S.A.	https://www.ema.europa.eu/en/documents/product-information/enspryng-epar-product-information_en.pdf http://mri.cts-mrp.eu/Human/Product/Details/50005	July 2021 November 2018
ENOXAPARINE LEDRAXEN	enoxaparin sodium	New biological	VENIPHARM	<u>Not available</u>	September 2022
Enrylaze	Enisantaspase	New active substance, new biological	Novartis Pharmaceuticals Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/enrylaze-epar-product-information_en.pdf	September 2023
Enjaymo	Enatimlimab	New active substance, new biological	Genzyme Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/enjaymo-epar-product-information_en.pdf	November 2022
Ervebo	Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)	New active substance, new biological	Merck Sharp & Dohme B.V.	https://www.ema.europa.eu/en/documents/product-information/ervebo-epar-product-information_en.pdf	November 2019
Epysqli	Enatuzumab	New biological	Samsung Bioepis NL B.V.	https://www.ema.europa.eu/en/documents/product-information/epysqli-epar-product-information_en.pdf	June 2023
Esperoct	Turoctocog alfa pegol	PASS ¹ New active substance, new biological, PASS ¹ , authorised under exceptional circumstances	Novo Nordisk A/S	https://www.ema.europa.eu/en/documents/product-information/esperoct-epar-product-information_en.pdf	June 2019
Evkeeza	evinacumab		Ultragenyx Germany GmbH	https://www.ema.europa.eu/en/documents/product-information/evkeeza-epar-product-information_en.pdf	July 2021
Evrenzo	roxadustat	New active substance	Astellas Pharma Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/evrenzo-epar-product-information_en.pdf	September 2021
Evrysdi	risdiplam	New active substance	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/evrysdi-epar-product-information_en.pdf	April 2021
Evenity	Romosozumab	New active substance, new biological	UCB Pharma S.A.	https://www.ema.europa.eu/en/documents/product-information/evenity-epar-product-information_en.pdf	January 2020
Evoltra	Clofarabine	Authorised under exceptional circumstances	Genzyme Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/evoltra-epar-product-information_en.pdf	April 2013

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Evusheld	tixagevimab, cilgavimab	New active substance, new biological	☐ AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/evusheld-epar-product-information_en.pdf	March 2022
Exblifep	cefepime / enmetazobactam	New active substance	ADVANZ PHARMA Limited	https://www.ema.europa.eu/en/documents/product-information/exblifep-epar-product-information_en.pdf	April 2024
Exjade	Deferasirox	PASS ¹	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/exjade-epar-product-information_en.pdf	April 2013
Fetcroja	Cefiderocol	New active substance	Shionogi B.V.	https://www.ema.europa.eu/en/documents/product-information/fetcroja-epar-product-information_en.pdf	May 2020
Fintepla	fenfluramine	PASS ¹	UCB Pharma S.A.	https://www.ema.europa.eu/en/documents/product-information/fintepla-epar-product-information_en.pdf	January 2021
Firdapse	Amifampridine	Authorised under exceptional circumstances	BioMarin Europe Ltd	https://www.ema.europa.eu/en/documents/product-information/firdapse-epar-product-information_en.pdf	April 2013
Fluad Tetra	Influenza vaccine (surface antigen, inactivated, adjuvanted)	New biological	Seqirus Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/fluad-tetra-epar-product-information_en.pdf	June 2020
Gavreto	Pralsetinib	New active substance and under conditional marketing authorisation	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/gavreto-epar-product-information_en.pdf	November 2021
Giapreza	Angiotensin II acetate	New active substance	PAION Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/giapreza-epar-product-information_en.pdf	September 2019
Givlaari	Givosiran	New active substance	Alnylam Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/givlaari-epar-product-information_en.pdf	March 2020
Grasustek	Pegfilgrastim	New biological	Juta Pharma GmbH	https://www.ema.europa.eu/en/documents/product-information/grasustek-epar-product-information_en.pdf	July 2019
Hemgenix	etranacogene dezaparvovec	new biological, new active substance and Conditional Marketing Authorisation, PASS	CSL Behring GmbH	https://www.ema.europa.eu/en/documents/product-information/hemgenix-epar-product-information_en.pdf	March 2023
Hepaxane	Enoxaparin sodium	New biological	Chemi S.P.A	Not available	November 2018
Hepcludex	bulevirtide	new active substance	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/hepcludex-epar-product-information_en.pdf	August 2020
Heplisav B	hepatitis B surface antigen	New biological	Dynavax GmbH	https://www.ema.europa.eu/en/documents/assessment-report/heplisav-b-epar-public-assessment-report_en.pdf	March 2021
Herwenda	trastuzumab ex vivo expanded	New biological	Sandoz GmbH	https://www.ema.europa.eu/en/documents/product-information/herwenda-epar-product-information_en.pdf	November 2023
Holoclar	autologous human corneal epithelial cells containing	Conditional marketing authorisation	Holostem S.r.l.	https://www.ema.europa.eu/en/documents/product-information/holoclar-epar-product-information_en.pdf	March 2015
Hukyndra	Adalimumab	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/hukyndra-epar-product-information_en.pdf	November 2021
<u>containing medicinal products (For full list see</u>	Hydroxyethyl starch	PASS ¹	<u>Various (For full list see Annex V)</u>	https://www.ema.europa.eu/en/medicines/human/referrals/hydroxyethyl-starch-solutions-infusion-0	January 2014
Idefirix	imlifidase	New biological	Hansa Biopharma AB	https://www.ema.europa.eu/en/documents/product-information/idefirix-epar-product-information_en.pdf	Sep/20

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Imcivree	Setmelanotide	New active substance	Rhythm Pharmaceuticals Netherlands B.V	https://www.ema.europa.eu/en/documents/product-information/imcivree-epar-product-information_en.pdf	July 2021
IMJUDO	tremelimumab	New active substance and New biological	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/imjudo-epar-product-information_en.pdf	March 2023
Imnovid (formerly Pomalidomide Celgene)	Pomalidomide	PASS ¹	Celgene Europe Limited	https://www.ema.europa.eu/en/documents/product-information/innovid-epar-product-information_en.pdf	September 2013
Imvanex	smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara)	Authorised under exceptional circumstances	Bavarian Nordic A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002596/human_med_001666.jsp&mid=WCOB01ac058001d124	September 2013
Inaqovi	decitabine / cedazuridine	New active substance	Otsuka Pharmaceutical Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/imvanex-epar-product-information_en.pdf	September 2023
Increlex	Mecasermin	Authorised under exceptional circumstances	Ipsen Pharma	https://www.ema.europa.eu/en/documents/product-information/increlex-epar-product-information_en.pdf	April 2013
Incruse Ellipta	Umeclidinium bromide	PASS ¹	GlaxoSmithKlein (Ireland) Limited	https://www.ema.europa.eu/en/documents/product-information/incruse-ellipta-epar-product-information_en.pdf	May 2014
Inrebic	fedratinib	New active substance	Bristol-Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/inrebic-epar-product-information_en.pdf	February 2021
Insulin aspart Sanofi	Insulin aspart	New biological	Sanofi Winthrop Industrie	https://www.ema.europa.eu/en/documents/product-information/insulin-lispro-sanofi-epar-product-information_en.pdf	July 2020
Intuniv	Guanfacine	PASS ¹	Takeda Pharmaceuticals International AG Ireland Branch	https://www.ema.europa.eu/en/documents/product-information/intuniv-epar-product-information_en.pdf	September 2015
Iqymune	Human normal immunoglobulin	New biological	Laboratoire Francais du Fractionnement et des Biotechnologies	s.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdid=entifier=2613314	September 2016
Isturisa	Osilodrostat	New active substance	Recordati Rare Diseases	https://www.ema.europa.eu/en/documents/product-information/isturisa-epar-product-information_en.pdf	January 2020
Itulazax	Standardised allergen extract from birch	New biological	ALK-Abelló A/S	s.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdid=entifier=2613926	September 2019
Jaydess (also known in some EU countries as Fleree)	Levonorgestrel	PASS ¹	Bayer AB	https://docetp.mpa.se/LMF/Jaydess%20intrauterine%20delivery%20system%20ENG%20SmPC.doc	November 2013
Jaypirca	pirtobrutinib	New active substance, Conditional marketing authorisation	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/jaypirca-epar-product-information_en.pdf	November 2023
JCOVDEN	COVID-19 vaccine (Ad26.COV2-S [recombinant])	New active substance, /new biological	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf	Mar/21
JEMPERLI	dostarlimab	New active substance, new biological	GlaxoSmithKline (Ireland) Limited	https://www.ema.europa.eu/en/documents/product-information/jemperli-epar-product-information_en.pdf	May 2021
Jinarc	Tolvaptan	PASS ¹	Otsuka Pharmaceutical Europe Ltd.	https://www.ema.europa.eu/en/documents/product-information/jinarc-epar-product-information_en.pdf	June 2015
Jyseleca	filgotinib	New active substance	Galapagos NV	https://www.ema.europa.eu/en/documents/product-information/jyseleca-epar-product-information_en.pdf	October 2020
Kaftrio	ivacaftor / tezacaftor / elex:	New active substance	Vertex Pharmaceuticals (Ireland) Limited	https://www.ema.europa.eu/en/documents/product-information/kaftrio-epar-product-information_en.pdf	August 2020

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Kanuma	Sebelipase alfa	PASS ¹	Alexion Europe SAS	https://www.ema.europa.eu/en/documents/product-information/kanuma-epar-product-information_en.pdf	September 2015
Kapruvia	difelikefalin	New active substance	Vifor Fresenius Medical Care Renal Pharma France	https://www.ema.europa.eu/en/documents/product-information/kapruvia-epar-product-information_en.pdf	May/22
Kauliv	teriparatide	New biological	Strides Pharma (Cyprus) Ltd.	https://www.ema.europa.eu/en/documents/product-information/kauliv-epar-product-information_en.pdf	February 2023
Kerendia	finerenone	New active substance	Bayer AG	https://www.ema.europa.eu/en/documents/product-information/kerendia-epar-product-information_en.pdf	March 2022
Kesimpta	ofatumumab	New biological	Novartis Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/kesimpta-epar-product-information_en.pdf	April 2021
Ketoconazole HRA	Ketoconazole	PASS ¹	ERA Pharma Rare Diseases	https://www.ema.europa.eu/en/documents/product-information/ketoconazole-hra-epar-product-information_en.pdf	December 2014
Kinpeygo	budesonide	Conditional marketing authorisation	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/kinpeygo-epar-product-information_en.pdf	July 2022
KIMMTRAK	tebentafusp	New active substance and <i>new biological</i>	Immunocore Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/kimmtrak-epar-product-information_en.pdf	Apr/22
Kixelle Kirsty	Insulin aspart	New biological	Mylan IRE Healthcare Limited	https://www.ema.europa.eu/en/documents/product-information/kirsty-epar-product-information_en.pdf	February 2021
Klisyri	Tirbanibulin	New active substance, PASS ¹	Almirall, S.A.	https://www.ema.europa.eu/en/documents/product-information/klisyri-epar-product-information_en.pdf	July 2021
Koselugo	selumetinib	New active substance, conditional marketing authorisation, PASS ¹	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/koselugo-epar-product-information_en.pdf	June 2021
Kymriah	Tisagenlecleucel	PASS	Novartis Europharm Limited	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004090/WC500255529.pdf	September 2018
Krazati	miragrasib	New active substance, Conditional Marketing Authorisation	Mirati Therapeutics B.V.	Not available	January 2024
Lamzede	Velmanase alfa umecicidium bromide/vilanterol trifenatate	authorised under exceptional circumstances	Chiesi Farmaceutici S.p.A.	https://www.ema.europa.eu/en/documents/product-information/lamzede-epar-product-information_en.pdf	April 2018
Laventair Ellipta		PASS ¹	Glaxo Group Ltd	https://www.ema.europa.eu/en/documents/product-information/laventair-ellipta-epar-product-information_en.pdf	June 2014
Ledraxen	Enoxaparin sodium	New biological	Venipharm	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?mpdidentifier=2196232	February 2019
Lemtrada	Alemtuzumab	PASS ¹	Sanofi Belgium	https://www.ema.europa.eu/en/documents/product-information/lemtrada-epar-product-information_en.pdf	January 2020
Leqvio	inclisiran autologous CD34+ cell enriched population that contains hematopoietic	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/leqvio-epar-product-information_en.pdf	Jan/21
Libmeldy		New active substance and new biological, PASS ¹	Orchard Therapeutics (Netherlands) B.V.	https://www.ema.europa.eu/en/documents/product-information/libmeldy-epar-product-information_en.pdf	Jan/21
LIBTAYO	Cemiplimab	New active substance, new biological	Regeneron Ireland U.C.	https://www.ema.europa.eu/en/documents/product-information/libtayo-epar-product-information_en.pdf	July 2019

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
LiMAXetin 4 mg/ml Injektionslösung	Methacetin	New active substance	Humedics GmbH	https://portal.dimdi.de/amquifree/am/docoutput/additionaldocs.xhtml?directdisplay=true&mpdidentifier=2196936	May 2020
Libmyris	Adalimumab	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/libmyris-epar-product-information_en.pdf	November 2021
Litfulo	ritlecitinib	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/litfulo-epar-product-information_en.pdf	September 2023
Liumjev	Insulin lispro	New biological	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/lyumjev-previously-liumjev-epar-product-information_en.pdf	April 2020
Livmarli	maralixibat chloride	New active substance, Authorised under exceptional circumstances	Mirum Pharmaceuticals International B.V.	https://www.ema.europa.eu/en/documents/product-information/livmarli-epar-product-information_en.pdf	January 2023
Livogiva	teriparatide	New biological	Theramex Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/livogiva-epar-product-information_en.pdf	Aug/20
LIVTENCITY	Maribavir	New active substance	Takeda Pharmaceuticals International AG Ireland Branch	https://www.ema.europa.eu/en/documents/product-information/livtencity-epar-product-information_en.pdf	November 2022
Loargys	pegzilarginase	New active substance, New biological, PASS ¹	Inmedica Pharma AB	https://www.ema.europa.eu/en/documents/product-information/loargys-epar-product-information_en.pdf	January 2024
Locametz	gozetotide	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/locametz-epar-product-information_en.pdf	January 2023
Lojuxta	Lomitapide	Authorised under exceptional circumstances	Amryt Pharmaceuticals DAC	https://www.ema.europa.eu/en/documents/product-information/lojuxta-epar-product-information_en.pdf	September 2013
Lonapegsomatropin Ascenc	Lonapegsomatropin	New active substance and new biological	Ascendis Pharma Endocrinology Division A/S	https://www.ema.europa.eu/en/documents/product-information/lonapegsomatropin-ascendis-pharma-epar-product-information_en.pdf	January 2022
Lorviqua	Lorlatinib	New active substance and conditional marketing authorisation	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/lorviqua-epar-product-information_en.pdf	May 2019
Lunsumio	mosunetuzumab	New active substance, new biological and conditional marketing authorisation	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/lunsumio-epar-product-information_en.pdf	June 2022
LUMYKRAS	sotorasib	New active substance, Conditional marketing authorisation	Amgen Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/lumykras-epar-product-information_en.pdf	January 2022
Lupkynis	voclosporin	New active substance	Otsuka Pharmaceutical Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/lupkynis-epar-product-information_en.pdf	September 2022
Luxturna	Voretigene neparvovec	PASS	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/luxturna-epar-product-information_en.pdf	December 2018
Lydisilka	drospirenone/estetrol	New active substance	Estetra SRL	https://www.ema.europa.eu/en/documents/product-information/lydisilka-epar-product-information_en.pdf	June 2021
Lyfnua	gefapixant	New active substance	Merck Sharp & Dohme B.V.	https://www.ema.europa.eu/en/documents/product-information/lyfnua-epar-product-information_en.pdf	September 2023
Lytgobi	futibatinib	New active substance, Conditional marketing authorisation	Taiho Pharma Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/lytgobi-epar-product-information_en.pdf	July 2023
Mayzent	Siponimod	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/mayzent-epar-product-information_en.pdf	January 2020

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Medikinet retard 10 / 20 / 30 / 40 / 5 / 50 / 60 mg	Methylphenidate hydrochloride	PASS ¹	Medice Arzneimittel Püttner GmbH Co. KG	Not available	May 2018
MenQuadfi	Meningococcal group A, C, W and Y conjugate vaccine	New biological	Sanofi Pasteur	https://www.ema.europa.eu/en/documents/product-information/menquadfi-epar-product-information_en.pdf	December 2020
Mepsevii	Vestronidase alfa	Authorized under exceptional circumstances	Ultragenyx Germany GmbH	https://www.ema.europa.eu/en/documents/product-information/mepsevii-epar-product-information_en.pdf	September 2018
Minjuvi	Tafasitamab	New active substance, new biological and conditional marketing authorisation	Incyte Biosciences Distribution B.V.	https://www.ema.europa.eu/en/documents/product-information/minjuvi-epar-product-information_en.pdf	September 2021
Mounjaro	tirzepatide	New active substance	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/mounjaro-epar-product-information_en.pdf	September 2022
Mvabea	Ebola vaccine (MVA-BN-Filo [recombinant])	New active substance, new biological, authorised under exceptional circumstances	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/mvabea-epar-product-information_en.pdf	July 2020
Myalepta	Metreleptin	Authorized under exceptional circumstances	Amryt Pharmaceuticals DAC	https://www.ema.europa.eu/en/documents/product-information/myalepta-epar-product-information_en.pdf	September 2018
Mysimba	Naltrexone / bupropion	PASS ¹	Orexigen Therapeutics Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/mysimba-epar-product-information_en.pdf	April 2015
NADROPARINE CALCIQUE ASPEN	nadroparin calcium	New biological	ASPEN PHARMA TRADING LIMITED	Not available	September 2022
Natpar	Parathyroid hormone	Conditional authorisation	Shire Pharmaceuticals Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/natpar-epar-product-information_en.pdf	May 2017
Nepexto	Etanercept	New biological	Biosimilar Collaborations Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/nepexto-epar-product-information_en.pdf	June 2020
NEXPOVIO	selinexor	New active substance	Karyopharm Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/nexpovio-epar-product-information_en.pdf	April 2021
Nexviadyme	avalglucosidase alfa	New active substance and new biological	Genzyme Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/nexviadyme-epar-product-information_en.pdf	July 2022
Ngenla	somatogon	New active substance and new biological	☐ Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/ngenla-epar-product-information_en.pdf	February 2022
Nilemdo	bempedoic acid	New active substance	Daiichi Sankyo Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/nilemdo-epar-product-information_en.pdf	April 2020
NUBEQA	darolutamide	New active substance	Bayer AG	https://www.ema.europa.eu/en/documents/product-information/nubeqa-epar-product-information_en.pdf	April 2020
Nuceiva	Botulinum toxin type A	New biological	Evolus Pharma B.V	https://www.ema.europa.eu/en/documents/product-information/nuceiva-epar-product-information_en.pdf	October 2019
NULIBRY	fosdenopterin	New active substance, authorised under exceptional circumstances	MC Pharma (EU) Limited	https://www.ema.europa.eu/en/documents/product-information/nulibry-epar-product-information_en.pdf	September 2022
Nustendi	bempedoic acid / ezetimibe	New active substance	Daiichi Sankyo Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/nustendi-epar-product-information_en.pdf	April 2020
Nuvaxovid	SARS-CoV-2 recombinant spike protein	New active substance and new biological	Novavax CZ, a.s	https://www.ema.europa.eu/en/documents/product-information/nuvaxovid-epar-product-information_en.pdf	January 2022

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Nyvepria	pegfilgrastim	New biological	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/nyvepria-epar-product-information_en.pdf	December 2020
Obizur	Susoctocog alfa	Authorised under exceptional circumstances	Baxalta Innovations GmbH	https://www.ema.europa.eu/en/documents/product-information/obizur-epar-product-information_en.pdf	November 2015
Obiltoxaximab SFL NYXTHRACIS	obiltoxaximab	New active substance, new biological, authorised under exceptional circumstances	SFL Pharmaceuticals Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/obiltoxaximab-sfl-epar-product-information_en.pdf	December 2020
Ocaliva	Obeticholic acid	Conditional authorisation	ADVANZ PHARMA Limited	https://www.ema.europa.eu/en/documents/product-information/ocaliva-epar-product-information_en.pdf	January 2017
Ondexxya	Andexanet alfa	New active substance, new biological and conditional marketing authorisation	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/ondexxya-epar-product-information_en.pdf	May 2019
Ontozry	cenobamate	New active substance	Angelini Pharma S.p.A	https://www.ema.europa.eu/en/documents/product-information/ontozry-epar-product-information_en.pdf	April 2021
Omjjara	momelotinib	New active substance	GlaxoSmithKline Trading Services Limited	Not available	February 2024
OmvoH	mirikizumab	New active substance, new biological	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/omvoh-epar-product-information_en.pdf	June 2023
Opdualag	nivolumab/relatlimab	New active substance, new biological	Bristol Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/opdualag-epar-product-information_en.pdf	September 2022
Orladeyo	berotralstat Allergen extract from house dust mites	New active substance	Biocryst Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/orladeyo-epar-product-information_en.pdf	May 2021
Orylmyte	(Dermatophagoides)	New biological	Stallergenes	https://portal.dimdi.de/amguifree/am/docoutput/additionaldoc	July 2021
Orgovyx	relugolix	New active substance	Myovant Sciences Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/orgovyx-epar-product-information_en.pdf	May/22
Orphacol	Cholic acid	Authorised under exceptional circumstances	Laboratoires CTRS	https://www.ema.europa.eu/en/documents/product-information/orphacol-epar-product-information_en.pdf	October 2013
ORSERDU	elacestrant	New active substance	Stemline Therapeutics B.V.	https://www.ema.europa.eu/en/documents/product-information/orserdu-epar-product-information_en.pdf	September 2023
Oxbryta	Voxelotor	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/oxbryta-epar-product-information_en.pdf	February 2022
Oyavas	bevacizumab	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/oyavas-epar-product-information_en.pdf	April 2021
Ozanex (also known in some countries as Ozenoxacin)	Ozenoxacin	New active substance	Ferrer Internacional S.A.	https://cima.aemps.es/cima/dochtml/ft/82357/FichaTecnica_82357.html	November 2017
Oxlumo	lumasiran	New active substance	Alnylam Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/oxlumo-epar-product-information_en.pdf	December 2020
Padcev	enfortumab vedotin	New active substance and <i>new biological</i>	Astellas Pharma Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/padcev-epar-product-information_en.pdf	April 2022
Palforzia	Defatted powder of Arachis	New biological	Immune Therapeutics Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/palforzia-epar-product-information_en.pdf	November 2022

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Palynziq Pandemic influenza vaccine H5N1 AstraZeneca	Pegvaliase Pandemic influenza vaccine (H5N1) (live attenuated, nasal)	New active substance and <i>new biological</i>	BioMarin International Limited	https://www.ema.europa.eu/en/documents/product-information/palynziq-epar-product-information_en.pdf	May 2019
	□ ritonavir/ (1R,2S,5S)-N-((1S)-1-Cyano-2-((3S)-2-	Conditional marketing authorisation	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/pandemic-influenza-vaccine-h5n1-astrazeneca-epar-product-information_en.pdf	June 2016
Paxlovid		New active substance	□ Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/paxlovid-epar-product-information_en.pdf	February 2022
Pegfilgrastim Mundipharma	Pegfilgrastim	New biological	□ Mundipharma Biologics S.L.	https://www.ema.europa.eu/en/documents/product-information/pegfilgrastim-mundipharma-epar-product-information_en.pdf	January 2020
Pemazyre	pemigatinib	New active substance, conditional marketing authorisation	□ Incyte Biosciences Distribution B.V.	https://www.ema.europa.eu/en/documents/product-information/pemazyre-epar-product-information_en.pdf	Apr/21
Percolozin	enoxaparin sodium	New biological	□ Venipharm	N/A	January 2022
Phesgo	pertuzumab / trastuzumab	New biological	□ Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/phesgo-epar-product-information_en.pdf	Jan/21
Piqray	Alpelisib	New active substance	□ Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information_en.pdf	August 2020
Pluvicto	Lu-177 titanium (177Lu) vipivotide tetraxetan	New active substance	□ Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/pluvicto-epar-product-information_en.pdf	January 2023
Polivy	Polatuzumab vedotin	New active substance, new biological	□ Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/polivy-epar-product-information_en.pdf	January 2020
Ponvory	ponesimod	New active substance	□ Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/ponvory-epar-product-information_en.pdf	June 2021
Pombiliti	cipaglicosidase alfa	New active substance, new biological	□ Amicus Therapeutics Europe Limited	https://www.ema.europa.eu/en/documents/product-information/pombiliti-epar-product-information_en.pdf	April 2023
PreHevbri	Hepatitis B vaccine (recombinant, adsorbed)	New biological	□ VBI Vaccines B.V.	https://www.ema.europa.eu/en/documents/product-information/prehevbri-epar-product-information_en.pdf	May/22
Pylclari	piflufolastat (18F)	New active substance	□ CURIUM PET France	https://www.ema.europa.eu/en/documents/product-information/pylclari-epar-product-information_en.pdf	September 2023
Pyrukynd Dovprela (previously known as Pretomanid FGK) Qarziba (previously Dinutuximab beta EUSA and Dinutuximab beta	mitapivat	New active substance	□ Aegios Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/pyrukynd-epar-product-information_en.pdf	November 2022
	pretomanid	New active substance	□ Mylan IRE Healthcare Limited	https://www.ema.europa.eu/en/documents/product-information/pretomanid-fgk-epar-product-information_en.pdf	August 2020
	Dinutuximab beta	Authorised under exceptional circumstances	□ EUSA Pharma (UK) Limited	https://www.ema.europa.eu/en/documents/product-information/qarziba-epar-product-information_en.pdf	May 2017
Qdenga	dengue tetravalent vaccine (live, attenuated)	New biological	□ Takeda GmbH	https://www.ema.europa.eu/en/documents/product-information/qdenga-epar-product-information_en.pdf	December 2022
QINLOCK	ripretinib	New active substance	□ Deciphera Pharmaceuticals (Netherlands) B.V.	https://www.ema.europa.eu/en/documents/product-information/qinlock-epar-product-information_en.pdf	Dec/21
Quinsair	Levofloxacin	PASS ¹	□ Chiesi Farmaceutici S.p.A.	https://www.ema.europa.eu/en/documents/product-information/quinsair-epar-product-information_en.pdf	April 2015

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Quofenix	Delafloxacin	New active substance	Menarini - Industrie Farmaceutiche Riunite - s.r.l.	https://www.ema.europa.eu/en/documents/product-information/quofenix-epar-product-information_en.pdf	January 2020
QUVIVIQ	daridorexant	New active substance	Idorsia Pharmaceuticals Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/quviviq-epar-product-information_en.pdf	May 2022
Ranivisio	ranibizumab	New biological	Midas Pharma GmbH	https://www.ema.europa.eu/en/documents/product-information/ranivisio-epar-product-information_en.pdf	September 2022
Raxone	Idebenone	Authorised under exceptional circumstances	Chiesi Farmaceutici S.p.A.	https://www.ema.europa.eu/en/documents/product-information/raxone-epar-product-information_en.pdf	September 2015
RAYVOW	lasmiditan	New active substance	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/rayvow-epar-product-information_en.pdf	September 2022
Reblozyl	Luspatercept	New active substance	Celgene Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/reblozyl-epar-product-information_en.pdf	July 2020
Recarbrio	Imipenem / cilastatin / relebactam	New active substance	Merck Sharp & Dohme B.V.	https://www.ema.europa.eu/en/documents/product-information/recarbrio-epar-product-information_en.pdf	February 2020
Refixia	Nonacog beta pegol	PASS ¹	Novo Nordisk A/S	https://www.ema.europa.eu/en/documents/product-information/refixia-epar-product-information_en.pdf	June 2017
Regkirona	Regdanvimab	New active substance and <i>new biological</i>	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/regkirona-epar-product-information_en.pdf https://www.ema.europa.eu/en/documents/product-information/kekambys-epar-product-information_en.pdf	November 2021
REKAMBYS	rilpivirine	PASS ¹	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/retsevmo-epar-product-information_en.pdf	Jan/21
Retsevmo	selpercatinib	New active substance, Conditional marketing authorisation	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/retsevmo-epar-product-information_en.pdf	February 2021
Revestive	Teduglutide	PASS ¹	Takeda Pharmaceuticals International AG Ireland Branch	https://www.ema.europa.eu/en/documents/product-information/revestive-epar-product-information_en.pdf	April 2013
Revlimid	Lenalidomide	PASS ¹	Bristol-Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/revlimid-epar-product-information_en.pdf	June 2014
Rezzayo	Rezafungin	New active substance	Mundipharma GmbH	Not available	January 2024
Rhokiinsa	Netarsudil	New active substance	Santen Oy	https://www.ema.europa.eu/en/documents/product-information/rhokiinsa-epar-product-information_en.pdf	December 2019
Rinvoq	Upadacitinib	New active substance	AbbVie Deutschland GmbH & Co. KG	https://www.ema.europa.eu/en/documents/product-information/rinvoq-epar-product-information_en.pdf	January 2020
Rimmyrah	Eranibizumab	New biological	QILU PHARMA SPAIN S.L.	Not available	January 20247
Roclanda	Latanoprost / netarsudil	New active substance	Santen Oy	https://www.ema.europa.eu/en/documents/product-information/roclanda-epar-product-information_en.pdf	January 2021
Roctavian	valoctocogene roxaparvovec	New active substance, new biological, Conditional marketing authorisation and PASS	BioMarin International Limited	https://www.ema.europa.eu/en/documents/product-information/roctavian-epar-product-information_en.pdf	September 2022
Rolufta Ellipta (previously I Umeclidinium		PASS ¹	GlaxoSmithKline Trading Services Limited	https://www.ema.europa.eu/en/documents/product-information/rolufta-ellipta-previously-rolufta-epar-product-information_en.pdf	March 2017

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Ronapreve	Casirivimab/imdevimab	New active substance and <i>new biological</i>	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/ronapreve-epar-product-information_en.pdf	November 2021
Rozlytrek	entrectinib	New active substance, conditional MA	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/rozlytrek-epar-product-information_en.pdf	August 2020
Rukobia	fostemsavir	New active substance	ViiV Healthcare BV	https://www.ema.europa.eu/en/documents/product-information/rukobia-epar-product-information_en.pdf	Feb/21
Ruxience	Rituximab	New biological	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/ruxience-epar-product-information_en.pdf	April 2020
Rybelsus	Semaglutide	New biological	Novo Nordisk A/S	https://www.ema.europa.eu/en/medicines/human/EPAR/rybelsus	April 2020
Rybrevant	Amivantamab	Conditional marketing authorisation, new active substance, new biological	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/rybrevant-epar-product-information_en.pdf	January 2022
Ryeqo	relugolix / estradiol / norethisterone acetate	New active substance	Gedeon Richter Plc.	https://www.ema.europa.eu/en/documents/product-information/ryeqo-epar-product-information_en.pdf	September 2021
Rystiggo	Ebzanolizumab	New active substance, New biological	UCB Pharma S.A.	<u>Not available</u>	January 2024
Ryzneuta	efbemalenograstim alfa	New active substance and new biological	Evive Biotechnology Ireland LTD	<u>Not available</u>	April 2024
Saphnelo	anifrolumab	New active substance and new biological	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/saphnelo-epar-product-information_en.pdf	February 2022
Sarclisa	Isatuximab	New active substance and <i>new biological</i>	Sanofi Winthrop Industrie	https://www.ema.europa.eu/en/documents/product-information/sarclisa-epar-product-information_en.pdf	June 2020
Scemblix	asciminib	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/scemblix-epar-product-information_en.pdf	September 2022
Scenesse	Afamelanotide	Authorised under exceptional circumstances	Clinuvel UK Limited	https://www.ema.europa.eu/en/documents/product-information/scenesse-epar-product-information_en.pdf	January 2015
Sirturo	Bedaquiline	Conditional authorisation	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/sirturo-epar-product-information_en.pdf	March 2014
Sixmo	Buprenorphine	New biological , PASS ¹	L. Molteni & C. dei F.lli Alitti Soc.Es.S.p.A	https://www.ema.europa.eu/en/documents/product-information/sixmo-epar-product-information_en.pdf	July 2019
Skyclarys	omaveloxolone	New active substance	Reata Ireland Limited	<u>Not available</u>	February 2024
Sogroya	somapacitan	New active substance and new biological	Novo Nordisk A/S	https://www.ema.europa.eu/en/documents/product-information/sogroya-epar-product-information_en.pdf	April 2021
Sondelbay	teriparatide	New biological	Accord Healthcare S.L.U.	https://www.ema.europa.eu/en/documents/product-information/sondelbay-epar-product-information_en.pdf	April 2022
SOTYKTU	deucravacitinib	New active substance	Bristol Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/sotyktu-epar-product-information_en.pdf	April 2023
Spikevax (previously COVID-19 Vaccine Moderna)	elasomeran (formally COVID-19 mRNA Vaccine (nucleoside-modified))	New active substance and new biological	MODERNA BIOTECH SPAIN, S.L.	https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf	Jan/21

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Spravato	Esketamine	Restrictions with regards to the safe and effective use of the medicinal product	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/spravato-epar-product-information_en.pdf	January 2020
Stimufend	Pegfilgrastim	New biological	Fresenius Kabi Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/stimufend-epar-product-information_en.pdf	April 2022
Strensiq	Asfotase alfa Autologous CD34+ enriched cell fraction that contains CD34+ cells	Authorised under exceptional circumstances	Alexion Europe SAS	https://www.ema.europa.eu/en/documents/product-information/strensiq-epar-product-information_en.pdf	September 2015
Strimvelis		PASS ¹	Fondazione Telethon ETS	https://www.ema.europa.eu/en/documents/product-information/strimvelis-epar-product-information_en.pdf	June 2016
Spevigo	Epeosolimab	New active substance, new biological and Conditional marketing authorisation	Boehringer Ingelheim International GmbH	https://www.ema.europa.eu/en/documents/product-information/spevigo-epar-product-information_en.pdf https://portal.dimdi.de/amguitree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdid=antifier=2613841	January 2023
Sublivac Birke	Allergen extract of pollen from Birch	New biological	HAL Allergie GmbH	https://portal.dimdi.de/amguitree/am/docoutput/additionaldocs.xhtml?accessid=amis_off_am_ppv&directdisplay=true&mpdid=antifier=2613842	September 2018
Sublivac Bäume	Allergen extract of pollen from Birch, Alder and Hazel	New biological	HAL Allergie GmbH	https://www.ema.europa.eu/en/documents/product-information/sunlenca-epar-product-information_en.pdf	September 2018
Sunlenca	lenacapavir	New active substance	Gilead Sciences Ireland UC		September 2022
Sulovas	Sulodexide	New biological	Aflofarm Farmacja Polska Sp. z o.o.	http://pub.rejestrymedyczne.csioz.gov.pl/ProduktSzczegoly.aspx?id=38063	December 2018
Sunosi	Solriamfetol quadrivalent influenza vaccine (recombinant, prepared in cell culture)	New active substance	Atrahs Pharma Netherlands B. V.	https://www.ema.europa.eu/en/documents/product-information/sunosi-epar-product-information_en.pdf	January 2020
Supemtek		New biological	Sanofi Pasteur	https://www.ema.europa.eu/en/documents/product-information/supemtek-epar-product-information_en.pdf	November 2020
Sylvant	Siltuximab	PASS ¹	EUSA Pharma (Netherlands) B.V.	https://www.ema.europa.eu/en/documents/product-information/sylvant-epar-product-information_en.pdf	June 2014
Tabrecta	capmatinib	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/tabrecta-epar-product-information_en.pdf	June 2022
Talzenna	Talazoparib	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/talzenna-epar-product-information_en.pdf	June 2019
TALVEY	talquetamab	New active substance, new biological and Conditional marketing authorisation	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/talvey-epar-product-information_en.pdf	September 2023
TAVLESSE	Fostamatinib	New active substance	Instituto Grifols S.A.	https://www.ema.europa.eu/en/documents/product-information/tavlesse-epar-product-information_en.pdf	January 2020
Tavneos	avacopan	New active substance	Vifor Fresenius Medical Care Renal Pharma France	https://www.ema.europa.eu/en/documents/product-information/tavneos-epar-product-information_en.pdf	January 2022
Tecartus	autologous anti-CD19-transduced CD3+ cells	New active substance and new biological/ PASS ¹	Kite Pharma EU B.V.	https://www.ema.europa.eu/en/documents/product-information/tecartus-epar-product-information_en.pdf	Jan/21
Tecovirimat SIGA	tecovirimat monohydrate	Authorised under exceptional circumstances	SIGA Technologies Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/tecovirimat-siga-epar-product-information_en.pdf	January 2022
TECVAYLI	teclistamab	New active substance, new biological and	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/tecvayli-epar-product-information_en.pdf	September 2022

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Temybric Ellipta	Fluticasone furoate / umeclidinib	New active substance	GlaxoSmithKline Trading Services	https://www.ema.europa.eu/en/documents/product-information/temybric-ellipta-epar-product-information_en.pdf	July 2019
Tepkinly	epcoritamab	New active substance, new biological and conditional marketing authorisation	AbbVie Deutschland GmbH & Co. KG	https://www.ema.europa.eu/en/documents/product-information/tepkiny-epar-product-information_en.pdf	October 2023
<input type="checkbox"/> Tepmetko	Tepotinib hydrochloride monohydrate	New active substance	<input type="checkbox"/> Merck Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/tepmetko-epar-product-information_en.pdf	March 2022
Tevimbra	teleslizumab	New biological	BeiGene Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/tevimbra-epar-product-information_en.pdf	September 2023
Tezspire	tezepelumab	New active substance and new biological	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/tezspire-epar-product-information_en.pdf	September 2022
Thiosix	Tioguanin	Authorised under exceptional circumstances	Teva Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/tibsovo-epar-product-information_en.pdf	May 2015
Tibsovo	ivosidenib	New active substance	Roche Laboratoires Servier	http://db.cbg-meb.nl/IB-teksten/h114681.pdf	May 2023
Translarna	Ataluren	Conditional authorisation	PTC Therapeutics Limited	https://www.ema.europa.eu/en/documents/product-information/translarna-epar-product-information_en.pdf	September 2014
Trivalent Influenza Vaccine	Influenza vaccine (split virion)	New biological	Sanofi Pasteur	Not available	May 2019
Trodelyv	sacituzumab govitecan	New active substance and new biological	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/trodelyv-epar-product-information_en.pdf	December 2021
TUKYSA	tucatinib	New active substance	Seagen B.V.	https://www.ema.europa.eu/en/documents/product-information/tukyasa-epar-product-information_en.pdf	Feb/21
Tyenne	teleslizumab	New biological	BeiGene Kabi Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/tyenne-epar-product-information_en.pdf	September 2023
Tyruko	natalizumab	New biological	Sandoz GmbH	https://www.ema.europa.eu/en/documents/product-information/tyruko-epar-product-information_en.pdf	October 2023
Ultomiris	Ravulizumab	New active substance, new biological	Alexion Europe SAS	https://www.ema.europa.eu/en/documents/product-information/ultomiris-epar-product-information_en.pdf	July 2019
Uplizna	inebilizumab	New active substance, new biological	Viela Bio B.V.	https://www.ema.europa.eu/en/documents/product-information/uplizna-epar-product-information_en.pdf	May 2022
Upstaza	Eladocagene exuparvovec	New active substance, new biological, authorised under exceptional circumstances	PTC Therapeutics International Limited	https://www.ema.europa.eu/en/documents/product-information/upstaza-epar-product-information_en-0.pdf	July 2022
Uzpruvo	ustekinumab	New biological	STADA Arzneimittel AG	Not available	January 2024
Vabysmo	Faricimab	New active substance, new biological	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/vabysmo-epar-product-information_en.pdf	September 2022
<u>valproate and related substances (sodium valproate, valproic acid, valproate semisodium, valpromide)</u>		PASS ¹	Various (For full list see Annex XIII)	https://www.ema.europa.eu/en/medicines/human/referrals/valproate-related-substances	January 2015
Vafseo	vandadustat	New active substance	AVEBIA EUROPE Limited	https://www.ema.europa.eu/en/documents/product-information/vafseo-epar-product-information_en.pdf	May 2023

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VANFLYTA	quizartinib	New active substance	Daiichi Sankyo Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/vanflyta-epar-product-information_en.pdf	November 2023
Vaxchora	Cholera vaccine (recombinant, live, oral)	New active substance, new biological	Bavarian Nordic A/S	https://www.ema.europa.eu/en/documents/product-information/vaxchora-epar-product-information_en.pdf	May 2020
Vaxneuvance vaxigrip tetra (also known in some EU countries as quadrivalent)	pneumococcal polysaccharide Influenza vaccine (split virion, inactivated)	New active substance, new biological New biological	Merck Sharp & Dohme B.V. Sanofi Pasteur Europe	https://www.ema.europa.eu/en/documents/product-information/vaxneuvance-epar-product-information_en.pdf https://www.ema.europa.eu/en/documents/product-information/vaxigrip-tetra-epar-product-information_en.pdf	January 2022 January 2020
Vaxzevria (previously COVID-19 Vaccine AstraZeneca)	COVID-19 Vaccine (ChAdOx1-S [recombinant])	New active substance and new biological	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-product-information_en.pdf	Feb/21
Vazkepa	Icosapent ethyl Icosahexanoic acid	New active substance	Amarin Pharmaceuticals Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/vazkepa-epar-product-information_en.pdf	Mar/21
Vedrop	tocopheryl polyethylene glycol succinate	Authorised under exceptional circumstances	Recordati Rare Diseases	https://www.ema.europa.eu/en/documents/product-information/vedrop-epar-product-information_en.pdf	April 2013
VEGZELMA	bevacizumab	New biological	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/vegzelma-epar-product-information_en.pdf	September 2022
Veklury	Remdesivir	New active substance	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/veklury-epar-product-information_en.pdf	July 2020
Velsipity	etrasimod	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/velsipity-epar-product-information_en.pdf	February 2024
Verquvo	Vericiguat	New active substance	Bayer AG	https://www.ema.europa.eu/en/documents/product-information/verquvo-epar-product-information_en.pdf	July 2021
Veoza	faxolinetant	New active substance	Astellas Pharma Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/veoza-epar-product-information_en.pdf	January 2024
Vimizim	Elosulfase alfa	PASS ¹	BioMarin International Limited	https://www.ema.europa.eu/en/documents/product-information/vimizim-epar-product-information_en.pdf	June 2014
VITRAKVI	Larotrectinib	Conditional authorisation, new active substance	Bayer AG	https://www.ema.europa.eu/documents/product-information/vitrakvi-epar-product-information_en.pdf	October 2019
Vocabria	cabotegravir	New active substance, PASS ¹ Authorised under exceptional circumstances, new active substance and new biological	ViiV Healthcare BV	https://www.ema.europa.eu/en/documents/product-information/vocabria-epar-product-information_en.pdf	Jan/21
Voraxaze	glucarpidase	Authorised under exceptional circumstances, new active substance and new biological	SERB SAS	https://www.ema.europa.eu/en/documents/product-information/voraxaze-epar-product-information_en.pdf	January 2022
Voxzogo	vosoritide	New active substance and new biological	BioMarin International Limited	https://www.ema.europa.eu/en/documents/product-information/voxzogo-epar-product-information_en.pdf	Sep/21
Vueway	gadopiclenol	New active substance	Bracco Imaging SPA	Not available https://www.ema.europa.eu/en/documents/product-information/vueway-epar-product-information_en.pdf	January 2024
Vydura	rimegepant	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/vydura-epar-product-information_en.pdf	May/22
Vyepti	eptinezumab	New biological	H. Lundbeck A/S	https://www.ema.europa.eu/en/documents/product-information/vyepti-epar-product-information_en.pdf	February 2022

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Vyndaqel	Tafamidis	Authorised under exceptional circumstances	Pfizer Europa MA EEG	https://www.ema.europa.eu/en/documents/product-information/vyndaqel-epar-product-information_en.pdf	April 2013
Vyvgart	efgartigimod alfa	New active substance and new biological	argenx BV	https://www.ema.europa.eu/en/documents/product-information/vyvgart-epar-product-information_en.pdf	September 2022
Wakix	Pitolisant hydrochloride	PASS ¹	Bioprojet Pharma	https://www.ema.europa.eu/en/documents/product-information/wakix-epar-product-information_en.pdf	April 2016
Waylivra	Volanesorsen	New active substance and conditional marketing authorisation	Akcea Therapeutics Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/waylivra-epar-product-information_en.pdf	May 2019
Wegovy	semaglutide	New biological	Novo Nordisk A/S	https://www.ema.europa.eu/en/documents/product-information/wegovy-epar-product-information_en.pdf	January 2022
Xembify	human normal Immunoglobulin	New biological	Instituto Grifols S.A.	https://www.ema.europa.eu/en/documents/product-information/xembify-epar-product-information_en.pdf	March 2022
Xenleta	lefamulin	New active substance	Nabriva Therapeutics Ireland DAC	https://www.ema.europa.eu/en/documents/product-information/xenleta-epar-product-information_en.pdf	August 2020
Xenpozyme	olipudase alfa	New active substance, new biological	Genzyme Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/xenpozyme-epar-product-information_en.pdf	July 2022
Xevudy	Sotrovimab	New active substance, new biological	GlaxoSmithKline Trading Services Limited	https://www.ema.europa.eu/en/documents/product-information/xevudy-epar-product-information_en.pdf	January 2022
Ximluci	Etanercept	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/ximluci-epar-product-information_en.pdf	November 2022
Xofigo	Radium Ra 223 dichloride	PASS ¹	Bayer AG	https://www.ema.europa.eu/en/documents/product-information/xofigo-epar-product-information_en.pdf	December 2013
Xofluza	baloxavir marboxil	New active substance	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/xofluza-epar-product-information_en.pdf	January 2021
Xospata	Gilteritinib	New active substance	Astellas Pharma Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/xospata-epar-product-information_en.pdf	November 2019
Yesafili	aflibercept	New biological	Biosimilar Collaborations Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/yesafili-epar-product-information_en.pdf	September 2023
Yescarta	Axicabtagene ciloleucel	PASS ¹	Kite Pharma EU B.V.	https://www.ema.europa.eu/en/documents/product-information/yescarta-epar-product-information_en.pdf	September 2018
Yimmugo	human normal Immunoglobulin	New biological	Biotest Pharma GmbH	https://www.ema.europa.eu/en/documents/product-information/yimmugo-epar-product-information_en.pdf	November 2022
Yorvipath	palopegteriparatide	New active substance	Ascendis Pharma Bone Diseases A/S	https://www.ema.europa.eu/en/documents/product-information/yorvipath-epar-product-information_en.pdf	November 2023
Yselty	linzagolix choline	New active substance	Theramex Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/yselty-epar-product-information_en.pdf	June 2022
Yuflyma	adalimumab EBOIA vaccine (Ad26.ZEBOV-GP [recombinant])	New biological new active substance, new biological Authorised under exceptional circumstances	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/yuflyma-epar-product-information_en.pdf	March 2021
Zabdeno			Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/zabdeno-epar-product-information_en.pdf	July 2020
Zercepac	trastuzumab	New Biological, New active substance	Accord Healthcare S.L.U.	https://www.ema.europa.eu/en/documents/product-information/zercepac-epar-product-information_en.pdf	August 2020
Zeposia	Ozanimod	New active substance	Bristol-Myers Squibb Pharma EEIG	https://www.ema.europa.eu/en/documents/product-information/zeposia-epar-product-information_en.pdf	June 2020

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Zilbrysq	zilucoplan	New active substance	UCB Pharma S.A.	https://www.ema.europa.eu/en/documents/product-information/zilbrysq-epar-product-information_en.pdf	December 2023
Zokinvy	Lonafarnib	New active substance, authorised under exceptional circumstances	EigerBio Europe Limited	https://www.ema.europa.eu/en/documents/product-information/zokinvy-epar-product-information_en.pdf	July 2022
Zolgensma	Onasemnogene abeparvovec	New active substance, new biological	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/zolgensma-epar-product-information_en.pdf	May 2020
ZTALMY	gan anaxolone	New active substance	Marinus Pharmaceuticals Emerald Limited	https://www.ema.europa.eu/en/documents/product-information/ztalmy-epar-product-information_en.pdf	September 2023
Zynlonta	loncastuximab tesirine	New active substance, new biological and Conditional marketing authorisation	ADC Therapeutics (NL) B.V.	https://www.ema.europa.eu/en/documents/product-information/zynlonta-epar-product-information_en.pdf	January 2023

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

* This list was previously amended on 24 June 2022.

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