

22 October 2021
EMA/245297/2013 Rev. 93*
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 October 2021 are shown in red font. All products removed from the list are shown with a strikethrough for the period of one month after which they are excluded. For products newly added to the list, EMA will update the 'Product details' section of the medicine page on EMA's corporate website when it publishes the revised summary of product characteristics.

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Abevmy	bevacizumab	New biological	Mylan IRE Healthcare Limited	https://www.ema.europa.eu/en/documents/product-information/abevmy-epar-product-information_en.pdf	May/21
Abecma	idecabtagene vicleucel	New biological, new active substance, conditional marketing authorisation, PASS ¹	Celgene Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/abecma-epar-product-information_en.pdf	September 2021
Adakveo	crizanlizumab	New biological, new active substance, conditional marketing authorisation	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/adakveo-epar-product-information_en.pdf	November 2020
Adcetris	Brentuximab vedotin	Conditional marketing authorisation	Takeda Pharma A/S	https://www.ema.europa.eu/en/documents/product-information/adcetris-epar-product-information_en.pdf	April 2013
Adynovi	Rurioctocog alfa pegol	New active substance and <i>new biological</i> , PASS ¹	Baxalta Innovations GmbH	https://www.ema.europa.eu/en/documents/product-information/adynovi-epar-product-information_en.pdf	January 2018
Adtralza	tralokinumab	New active substance and <i>new biological</i>	Leo Pharma A/S	https://www.ema.europa.eu/en/documents/product-information/adtralza-epar-product-information_en.pdf	Jun/21
Afluria Tetra	Influenza vaccine (split virion, inactivated)	New biological	Seqirus Netherlands B.V.	https://www.pei.de/SharedDocs/Arzneimittel/impfstoffe/Mono/Influenza/saisonal/PEI-H-12019-01-1.html	September 2020
Aimovig	Erenumab	New active substance and <i>new biological</i>	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/aimovig-epar-product-information_en.pdf	September 2018
AJOVY	Fremanezumab	New active substance and new biological	Teva GmbH	https://www.ema.europa.eu/en/documents/product-information/ajovy-epar-product-information_en.pdf	April 2019
Alecensa	Alectinib	New active substance	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/alecensa-epar-product-information_en.pdf	March 2017
Alofisel	Darvadstrocel	New active substance and <i>new biological</i>	Takeda Pharma A/S	https://www.ema.europa.eu/en/documents/product-information/alofisel-epar-product-information_en.pdf	April 2018
Alunbrig	Brigatinib	New active substance	Takeda Pharma A/S	https://www.ema.europa.eu/en/documents/product-information/alunbrig-epar-product-information_en.pdf	December 2018
Alymsys	bevacizumab	New biological	Mabxience Research SL	https://www.ema.europa.eu/en/documents/product-information/alymsys-epar-product-information_en.pdf	Apr/21
Amgevita	Adalimumab	New biological	Amgen Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/amgevita-epar-product-information_en.pdf	April 2017
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

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Anoro Ellipta	Umeclidinium bromide/vilanterol trifenate	PASS ¹	GlaxoSmithKline (Ireland) Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002751/human_med_001754.jsp&mid=WC0b01ac058001d124	June 2014
Atriance	Nelarabine	Authorised under exceptional circumstances	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000752/human_med_000656.jsp&mid=WC0b01ac058001d124	April 2013
Axumin	Fluciclovine (¹⁸ F)	New active substance	Blue Earth Diagnostics Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004197/human_med_002100.jsp&mid=WC0b01ac058001d124	June 2017
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
Batrevac Tetra	Influenza virus surface antigens, inactivated (haemagglutinin and neuraminidase)	New biological	Mylan Healthcare B.V.	Not available	September 2019
Bavencio	Avelumab	New active substance and <i>new biological</i> ,	Merck Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004338/human_med_002157.jsp&mid=WC0b01ac058001d124	September 2017
Benlysta	Belimumab	PASS ¹	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002015/human_med_001466.jsp&mid=WC0b01ac058001d124	April 2013
Beovu	Brolucizumab	New active substance and <i>new biological</i>	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/beovu-epar-product-information_en.pdf	February 2020
Besponsa	Inotuzumab ozogamicin	New active substance and <i>new biological</i>	Pfizer Europe MA EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004119/human_med_002109.jsp&mid=WC0b01ac058001d124	July 2017
Besremi	Ropeginterferon alfa-2b	New active substance and new biological	AOP Orphan Pharmaceuticals AG	https://www.ema.europa.eu/en/documents/product-information/besremi-epar-product-information_en.pdf	February 2019
Biktarvy	Bictegravir / emtricitabine / tenofovir alafenamide	New active substance	Gilead Sciences Ireland UC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004449/human_med_002263.jsp&mid=WC0b01ac058001d124	July 2018
Bimzelx	bimekizumab	New active substance and new biological	UCB Pharma S.A.	https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf	Sep/21
BioThrax (also known as BaciThrax in France)	Anthrax antigen filtrate	New biological	Emergent Sales and Marketing Germany GmbH	https://www.pei.de/SharedDocs/Arzneimittel/impfstoffe/Mono/Milzbrand/PEI-H-04350-01-1.html	June 2018
BLNREP	belantamab mafodotin	New active substance, New biological, Conditional marketing authorisation	GlaxoSmithKline (Ireland) Limited	https://www.ema.europa.eu/en/documents/product-information/blenrep-epar-product-information_en.pdf	August 2020
Blinicyto	Blinatumomab	PASS	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003731/human_med_001921.jsp&mid=WC0b01ac058001d124	December 2015
Blitzima	Rituximab	New biological	Celltrion Healthcare Hungary Kft.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004723/human_med_002125.jsp&mid=WC0b01ac058001d124	July 2017
Bylvay	Odevixibat	New active substance, authorised under exceptional circumstances	Albireo AB	https://www.ema.europa.eu/en/documents/product-information/bylvay-epar-product-information_en.pdf	July 2021
Bosulif	Bosutinib	Conditional authorisation	Pfizer Europe MA EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002373/human_med_001613.jsp&mid=WC0b01ac058001d124	April 2013
Braftovi	Encorafenib	New active substance	Pierre Fabre Medicament	https://www.ema.europa.eu/documents/product-information/braftovi-epar-product-information_en.pdf	October 2018
Bretaris Genuair	Acidinium bromide	PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002706/human_med_001570.jsp&mid=WC0b01ac058001d124	April 2013
Brimica Genuair	Acidinium bromide/formoterol fumarate dihydrate	PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003969/human_med_001806.jsp&mid=WC0b01ac058001d124	December 2014
Brineura	Cerliponase alfa	New active substance, authorised under exceptional circumstances, PASS ¹	BioMarin International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004065/human_med_002111.jsp&mid=WC0b01ac058001d124	June 2017
Byfavo	remimazolam	New active substance	PAION Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/byfavo-epar-product-information_en.pdf	April 2021
Cablivi	Caplacizumab	New active substance <i>and new biological</i>	Abylnx N.V.	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004426/WC500255071.pdf	September 2018

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Calquence	acalabrutinib	New active substance	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/calquence-epar-product-information_en.pdf	November 2020
Caprelsa	Vandetanib	Conditional authorisation	Genzyme Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002315/human_med_001529.jsp&mid=WC0b01ac058001d124	April 2013
Cegfila (previously Pegfilgrastim Mundipharma)	Pegfilgrastim	New biological	Mundipharma Corporation (Ireland) Limited	https://www.ema.europa.eu/documents/product-information/cegfila-epar-product-information_en.pdf	January 2020
Ceplene	Histamine dihydrochloride	Authorised under exceptional circumstances	Noventia Pharma Srl	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000796/human_med_000691.jsp&mid=WC0b01ac058001d124	April 2013
Cerdelga	Eliglustat	PASS ¹	Genzyme Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003724/human_med_001840.jsp&mid=WC0b01ac058001d124	February 2015
Chenodeoxycholic acid Leadiant (previously known as Chenodeoxycholic acid sigma-tau)	Chenodeoxycholic acid	Authorised under exceptional circumstances	Leadiant GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004061/human_med_002019.jsp&mid=WC0b01ac058001d124	April 2017
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 Combined hormonal contraceptives containing chlormadinone (For full list of products see Annex IX)	c1 inhibitor, human Chlormadinone Ethinylestradiol, Chlormadinone Acetate Ethinylestradiol	PASS ¹ PASS ¹	Shire Services BVBA Various (For full list see Annex IX)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001207/human_med_001448.jsp&mid=WC0b01ac058001d124 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Combined_hormonal_contraceptives/human_referral_prac_000016.jsp&mid=WC0b01ac05805c516f http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002640/human_med_001726.jsp&mid=WC0b01ac058001d124	April 2013 June 2014
Cometriq	Cabozantinib	Conditional authorisation	Ipsen-Pharma		May 2014
Comirnaty	COVID-19 mRNA Vaccine (nucleoside modified)	Conditional marketing authorisation / New active substance and new biological	BioNTech Manufacturing GmbH	https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf	Jan/21
Copiktra	duvelisib	New active substance	Verastem-Europe GmbH Secura Bio Limited	https://www.ema.europa.eu/en/documents/product-information/copiktra-epar-product-information_en.pdf	Jun/21
COVID-19 Vaccine Janssen	COVID-19 vaccine (Ad26.COV2-S [recombinant])	Conditional marketing authorisation / 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
CRYSVITA	Burosumab	New active substance, new biological and conditional authorisation	Kyowa Kirin Holdings B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004275/human_med_002224.jsp&mid=WC0b01ac058001d124	March 2018
Cutaquig Cuvitru 200 mg/ml solution for injection (also known in some EU countries as Ventygard) Cyproterone acetate and Ethinylestradiol containing medicinal products (For full list of products see Annex I)	Human normal immunoglobulin Immunglobulin Cyproterone acetate and Ethinylestradiol	New Biological New biological PASS ¹	Octapharma GmbH Baxalta Innovations GmbH, Austria Various (For full list see Annex I)	https://www.pei.de/SharedDocs/Arzneimittel/sera/PEI-H-11936-01-1.html http://mri.cts-mrp.eu/Human/Product/Details/47869 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cyproterone_and_ethinylestradiol-containing_medicines/human_referral_prac_000017.jsp&mid=WC0b01ac05805c516f	March 2019 September 2017 August 2013
Darzalex	Daratumumab	New active substance and <i>new biological</i>	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004077/human_med_001979.jsp&mid=WC0b01ac058001d124	June 2016
Daurismo	Glasdegib	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/daurismo-epar-product-information_en.pdf	July 2020
Daxas	Roflumilast	PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001179/human_med_001363.jsp&mid=WC0b01ac058001d124	June 2013
Dectova	Zanamivir	Authorised under exceptional circumstances	GlaxoSmithKline Trading Services Limited	https://www.ema.europa.eu/en/documents/product-information/dectova-epar-product-information_en.pdf	May 2019
Defitelio	Defibrotide	Authorised under exceptional circumstances	Gentium S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002393/human_med_001646.jsp&mid=WC0b01ac058001d124	November 2013
Delstrigo	Doravirine / Lamivudine / Tenofovir disoproxil	New active substance	Merck Sharp & Dohme B.V.	https://www.ema.europa.eu/documents/product-information/delstrigo-epar-product-information_en.pdf	December 2018
Deltyba	Delamanid	Conditional authorisation	Otsuka Novel Products GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002552/human_med_001699.jsp&mid=WC0b01ac058001d124	May 2014
Dengvaxia	Dengue tetravalent vaccine (live, attenuated)	New active substance and <i>new biological</i>	Sanofi Pasteur	https://www.ema.europa.eu/documents/product-information/dengvaxia-epar-product-information_en.pdf	January 2019

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Descovy Dexamed and associated names (dexamfetamine sulphate-containing medicinal products in the EU) (For full list of	Emtricitabine/tenofovir alafenamide	New active substance	Gilead Sciences Ireland UC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004094/human_med_001978.jsp&mid=WC0b01ac058001d124	May 2016
	Dexamfetamine sulphate	PASS ¹	Various (For full list see Annex XII)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Dexamed_and_associated_names/human_referral_000373.jsp&mid=WC0b01ac058001c516f	September 2014
Doptelet	Avatrombopag	New active substance	Swedish Orphan Biovitrum AB (publ)	https://www.ema.europa.eu/en/documents/product-information/doptelet-epar-product-information_en.pdf	June 2019
Duaklir Genuair	Aclidinium bromide/formoterol fumarate dihydrate	PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003745/human_med_001811.jsp&mid=WC0b01ac058001d124	December 2014
Dupixent	Dupilumab	New active substance and <i>new biological</i>	Sanofi-Aventis groupe	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004390/human_med_002158.jsp&mid=WC0b01ac058001d124	October 2017
Drovelis	drosiprenone/estetrol	New active substance	Gedeon Richter Plc.	https://www.ema.europa.eu/en/documents/product-information/drovelis-epar-product-information_en.pdf	June 2021
Eklira Genuair	Aclidinium bromide	PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002211/human_med_001571.jsp&mid=WC0b01ac058001d124	April 2013
Elaprase	Idursulfase	Authorised under exceptional circumstances	Shire Human Genetic Therapies AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000700/human_med_000757.jsp&mid=WC0b01ac058001d124	April 2013
Elebrato Ellipta	Fluticasone furoate/umeclidinium/vilanterol	New active substance	GlaxoSmithKline Trading Services Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004781/human_med_002182.jsp&mid=WC0b01ac058001d124	May 2018
Efluelda	Quadrivalent Influenza Vaccine (Split Virion, Inactivated)	New biological	Sanofi Pasteur	https://cima.aemps.es/cima/dochtml/ft/85068/FT_85068.html	February 2021
ELZONRIS	tagraxofusp	New active substance and new biological, Authorised under exceptional circumstances	Stemline Therapeutics B.V.	https://www.ema.europa.eu/en/documents/product-information/elzonris-epar-product-information_en.pdf	January 2021
Emgality	Galcanezumab	New active substance and <i>new biological</i>	Eli Lilly Netherland B.V.	https://www.ema.europa.eu/documents/product-information/emgality-epar-product-information_en.pdf	November 2018
ENANPLUS (also known in some EU countries as Skudexa, Skudexum and Lenizak)	Tramadol hydrochloride/ dexketoprofen	PASS ¹	LABORATORIOS MENARINI	https://cima.aemps.es/cima/dochtml/p/80925/P_80925.html	April 2018
Enhertu	trastuzumab deruxtecan	New biological, new active substance, conditional marketing authorisation	Daiichi Sankyo Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/enhertu-epar-product-information_en.pdf	January 2021
Enspryng	satralizumab	New active substance, new biological	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/enspryng-epar-product-information_en.pdf	July 2021
Enoxaparin Becat (also known in some EU countries as Losima, Enoxaparin Rovi, Crusia and Arovi)	Enoxaparin sodium	New biological	Laboartorios Farmacéuticos Rovi, S.A.	http://mri.cts-mrp.eu/Human/Product/Details/50005	November 2018
Epclusa	Sofosbuvir/velpatasvir	PASS ¹	Gilead Sciences Ireland UC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004210/human_med_001997.jsp&mid=WC0b01ac058001d124	July 2016
Equidacent	bevacizumab	New biological	Centus Biotherapeutics Europe Limited	https://www.ema.europa.eu/en/documents/product-information/equidacent-epar-product-information_en.pdf	September 2020
Erelzi	Etanercept	New biological	Sandoz GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004192/human_med_002112.jsp&mid=WC0b01ac058001d124	July 2017
Erleada	Apalutamide	New active substance	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/erleada-epar-product-information_en.pdf	January 2019
Ervebo	Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)	New active substance, new biological	Merck Sharp & Dohme B.V.	https://www.ema.europa.eu/en/documents/product-information/ervebo-epar-product-information_en.pdf	November 2019
Esperoct	Turoctocog alfa pegol	New active substance, new biological, PASS ¹	Novo Nordisk A/S	https://www.ema.europa.eu/documents/product-information/esperoct-epar-product-information_en.pdf	June 2019
Evkeeza	evinacumab	New active substance, new biological, PASS ¹ , authorised under exceptional circumstances	Regeneron Ireland Designated Activity Company (DAC)	https://www.ema.europa.eu/en/documents/product-information/evkeeza-epar-product-information_en.pdf	July 2021
Evrenzo	roxadustat	New active substance	Astellas Pharma Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/evrenzo-epar-product-information_en.pdf	September 2021
Evrysdi	risdiplam	New active substance, conditional marketing authorisation	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/evrysdi-epar-product-information_en.pdf	April 2021

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Evenity	Romosozumab	New active substance, new biological	UCB Pharma S.A.	https://www.ema.europa.eu/en/documents/product-information/evenity-epar-product-information_en.pdf	January 2020
Evoltra	Clofarabine	Authorised under exceptional circumstances	Genzyme Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000613/human_med_000773.jsp&mid=WC0b01ac058001d124	April 2013
Exjade	Deferasirox	PASS ¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000670/human_med_000780.jsp&mid=WC0b01ac058001d124	April 2013
Exviera	Dasabuvir	PASS ¹	AbbVie Deutschland GmbH & Co. KG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003837/human_med_001833.jsp&mid=WC0b01ac058001d124	February 2015
Fasenra	Benralizumab	New active substance and <i>new biological</i>	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004433/human_med_002207.jsp&mid=WC0b01ac058001d124	January 2018
Fetroja	Cefiderocol	New active substance	Shionogi B.V.	https://www.ema.europa.eu/en/documents/product-information/fetroja-epar-product-information_en.pdf	May 2020
Fibryga	Human Fibrinogen	New biological	Octapharma GmbH	https://www.pei.de/SharedDocs/Arzneimittel/am-aus-blut/fibrinkleber/PEI-H-11879-01-1.html	July 2017
Fintepla	fenfluramine	PASS ¹	Zogenix ROI Limited	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	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001032/human_med_001298.jsp&mid=WC0b01ac058001d124	April 2013
Flixabi	Infliximab	New biological	Samsung Bioepis UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004020/human_med_001980.jsp&mid=WC0b01ac058001d124	June 2016
Fluad Tetra	Influenza vaccine (surface antigen, inactivated, adjuvanted)	New biological	Seqirus Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/fluad-tetra-epar-product-information_en.pdf	June 2020
Flucelvax Tetra	Influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	New biological	Seqirus Netherlands B.V.	https://www.ema.europa.eu/documents/product-information/flucelvax-tetra-epar-product-information_en.pdf	January 2019
Fotivda	Tivozanib	New active substance	EUSA Pharma (Netherlands) B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004131/human_med_002146.jsp&mid=WC0b01ac058001d124	September 2017
Fulphila	Pegfilgrastim	New biological	Viartis Limited	https://www.ema.europa.eu/documents/product-information/fulphila-epar-product-information_en.pdf	November 2018
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
Gilenya	Fingolimod hydrochloride	PASS¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002202/human_med_001433.jsp&mid=WC0b01ac058001d124	April 2013
Glivec	Imatinib	PASS ¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000406/human_med_000808.jsp&mid=WC0b01ac058001d124	September 2014
Glyxambi	Empagliflozin/linagliptin	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003833/human_med_002032.jsp&mid=WC0b01ac058001d124	May 2017
Grasustek	Pegfilgrastim	New biological	Juta Pharma GmbH	https://www.ema.europa.eu/en/documents/product-information/grasustek-epar-product-information_en.pdf	July 2019
Halimatoz	Adalimumab	New biological	Sandoz GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004866/human_med_002266.jsp&mid=WC0b01ac058001d124	September 2018
Harvoni	Ledipasvir/sofosbuvir	New active substance, PASS ¹	Gilead Sciences Ireland UC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003850/human_med_001813.jsp&mid=WC0b01ac058001d124	December 2014
Hefiya	Adalimumab	New biological	Sandoz GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004865/human_med_002267.jsp&mid=WC0b01ac058001d124	September 2018
Hemlibra	Emicizumab	New active substance and <i>new biological</i>	Roche Registration GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004406/human_med_002236.jsp&mid=WC0b01ac058001d124	March 2018
Herzuma	Trastuzumab	New biological	Celltrion Healthcare Hungary Kft.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002575/human_med_002230.jsp&mid=WC0b01ac058001d124	February 2018

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Hepaxane	Enoxaparin sodium	New biological	Chemi S.P.A	Not available	November 2018
Hepcludex	bulevirtide	new active substance, conditional MA	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/hepcludex-epar-product-information_en.pdf	August 2020
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
Holoclar	Ex vivo expanded autologous human corneal epithelial cells containing stem cells	Conditional marketing authorisation	Chiesi Farmaceutici S.P.A., Italy	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002450/human_med_001844.jsp&mid=WC0b01ac058001d124	March 2015
Hulio	Adalimumab	New biological	Mylan S.A.S.	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004429/WC500255749.pdf	September 2018
Hydroxyethyl starch (HES)-containing medicinal products (For full list see Annex V)	Hydroxyethyl starch	PASS ¹	Various (For full list see Annex V)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Hydroxyethyl_starch-containing_medicines/human_referral_prac_000029.jsp&mid=WC0b01ac058001d124	January 2014
HyQvia	Human normal immunoglobulin	PASS ¹	Baxalta Innovations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002491/human_med_001647.jsp&mid=WC0b01ac058001d124	September 2013
Hyrimoz	Adalimumab	New biological	Sandoz GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004320/human_med_002268.jsp&mid=WC0b01ac058001d124	September 2018
Iclusig	Ponatinib	PASS ¹	Incyte Biosciences Distribution B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002695/human_med_001656.jsp&mid=WC0b01ac058001d124	March 2018
Idacio	Adalimumab	New biological	Fresenius Kabi Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/idacio-epar-product-information_en.pdf	April 2019
Idefirix	imlifidase	New biological	Hansa Biopharma AB	https://www.ema.europa.eu/en/documents/product-information/idefirix-epar-product-information_en.pdf	Sep/20
Ilumetri	Tildrakizumab	New active substance and <i>new biological</i>	Almirall S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004514/smops/Positive/human_smop_001325.jsp&mid=WC0b01ac058001d127&source=homeMedSearch&category=human	September 2018
Imcivree	Setmelanotide	New active substance	Rhythm Pharmaceuticals Limited	https://www.ema.europa.eu/en/documents/product-information/imcivree-epar-product-information_en.pdf	July 2021
Imfinzi	Durvalumab	New active substance and <i>new biological</i>	AstraZeneca AB	https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/medicines-under-additional-monitoring/list-medicines-under-additional-monitoring	October 2018
Imnovid (formerly Pomalidomide Celgene)	Pomalidomide	PASS ¹	Celgene Europe Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002682/human_med_001669.jsp&mid=WC0b01ac058001d124	September 2013
Imraldi	Adalimumab	New biological	Samsung Bioepis UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004279/human_med_002147.jsp&mid=WC0b01ac058001d124	September 2017
Imvanex	Modified Vaccinia Ankara virus – Bavarian Nordic (MVA-BN) live virus	Authorised under exceptional circumstances	Bavarian Nordic A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002596/human_med_001666.jsp&mid=WC0b01ac058001d124	September 2013
Increlex	Mecasermin	Authorised under exceptional circumstances	Ipsen Pharma	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000704/human_med_000829.jsp&mid=WC0b01ac058001d124	April 2013
Incruse Ellipta	Umeclidinium bromide	PASS ¹	GlaxoSmithKlein (Ireland) Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002809/human_med_001755.jsp&mid=WC0b01ac058001d124	May 2014
Influvac Tetra	Influenza vaccine (surface antigen, inactivated)	New biological	Mylan IRE Healthcare Ltd	http://pub.rejestrymedyczne.csioz.gov.pl/ProduktSzczeqoly.aspx?id=37540	September 2018
Inrebic	fedratinib	New active substance	Celgene Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/inrebic-epar-product-information_en.pdf	February 2021
Insulin lispro Sanofi	Insulin lispro	New biological	Sanofi-Aventis groupe	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004303/human_med_002129.jsp&mid=WC0b01ac058001d124	September 2017
Insulin aspart Sanofi	Insulin aspart	New biological	Sanofi-Aventis groupe	https://www.ema.europa.eu/en/documents/product-information/insulin-lispro-sanofi-epar-product-information_en.pdf	July 2020
Intrarosa	Prasterone	PASS ¹	Endoceutics Ltd. Shire Pharmaceuticals Ireland Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004138/human_med_002210.jsp&mid=WC0b01ac058001d124	February 2018
Intuniv	Guanfacine	PASS ¹	Takeda Pharmaceuticals International AG Ireland Branch	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003759/human_med_001910.jsp&mid=WC0b01ac058001d124	September 2015

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Iqymune	Human normal immunoglobulin	New biological	Laboratoire Francais du Fractionnement et des Biotechnologies	https://www.pei.de/SharedDocs/arzneimittel/sera/PEI-H-11751-01-1.html	September 2016
Isturisa	Osilodrostat	New active substance	Recordati Rare Diseases	https://www.ema.europa.eu/en/documents/product-information/isturisa-epar-product-information_en.pdf	January 2020
Itulazax	Standardised allergen extract from birch	New biological	ALK-Abelló A/S	https://www.pei.de/SharedDocs/arzneimittel/allergene/therapie/axicorp/PEI-H-12070-01-1.html	September 2019
Jaydess (also known in some EU countries as Fleree)	Levonorgestrel	PASS ¹	Bayer AB	https://docetp.mpa.se/LMF/Jaydess%20intrauterine%20delivery%20system%20ENG%20SmPC.doc	November 2013
JEMPERLI	dostarlimab	New active substance, new biological, conditional marketing authorisation	GlaxoSmithKline (Ireland) Limited	https://www.ema.europa.eu/en/documents/product-information/jemperli-epar-product-information_en.pdf	May 2021
Jinarc	Tolvaptan	PASS ¹	Otsuka Pharmaceutical Europe Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002788/human_med_001857.jsp&mid=WC0b01ac058001d124	June 2015
Jivi	Damoctocog alfa pegol	New active substance, new biological, PASS	Bayer AG	https://www.ema.europa.eu/documents/product-information/jivi-epar-product-information_en.pdf	December 2018
Jyseleca	filgotinib	New active substance	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/jyseleca-epar-product-information_en.pdf	October 2020
Juluca	Dolutegravir / rilpivirine	New active substance	ViiV Healthcare UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004427/human_med_002254.jsp&mid=WC0b01ac058001d124	May 2018
Kaftrio	ivacaftor / tezacaftor / elexacaftor	New active substance	Vertex Pharmaceuticals (Ireland) Limited	https://www.ema.europa.eu/en/documents/product-information/kaftrio-epar-product-information_en.pdf	August 2020
Kanjinti	Trastuzumab	New biological	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004361/human_med_002255.jsp&mid=WC0b01ac058001d124	May 2018
Kanuma	Sebelipase alfa	PASS ¹	Alexion Europe SAS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004004/human_med_001896.jsp&mid=WC0b01ac058001d124	September 2015
Ketoconazole HRA	Ketoconazole	PASS ¹	HRA Pharma Rare Diseases	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003906/human_med_001814.jsp&mid=WC0b01ac058001d124	December 2014
Kesimpta	ofatumumab	New biological	Novartis Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/kesimpta-epar-product-information_en.pdf	April 2021
Kevzara	Sarilumab	New active substance and <i>new biological</i>	Sanofi-Aventis groupe	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004254/human_med_002114.jsp&mid=WC0b01ac058001d124	July 2017
Kisqali	Ribociclib	New active substance	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004213/human_med_002149.jsp&mid=WC0b01ac058001d124	September 2017
Kixelle	Insulin aspart	New biological	Mylan IRE Healthcare Limited	https://www.ema.europa.eu/en/documents/product-information/kirsty-epar-product-information_en.pdf	February 2021
Klisyri	Tirbanibulin	New active substance, PASS ¹	Almirall, S.A.	https://www.ema.europa.eu/en/documents/product-information/klisyri-epar-product-information_en.pdf	July 2021
Koselugo	selumetinib	New active substance, conditional marketing authorisation	AstraZeneca AB	Not available	June 2021
Kymriah	Tisagenlecleucel	New active substance, new biological, PASS	Novartis Europharm Limited	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004090/WC500255529.pdf	September 2018
Kyntheum	Brodalumab	New active substance and <i>new biological</i>	Leo Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003959/human_med_002054.jsp&mid=WC0b01ac058001d124	July 2017
Lamzede	Velmanase alfa	New active substance, new biological, authorised under exceptional circumstances	Chiesi Farmaceutici S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003922/human_med_002231.jsp&mid=WC0b01ac058001d124	April 2018
Laventair Ellipta	Umeclidinium bromide/vilanterol trifenate	PASS ¹	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003754/human_med_001756.jsp&mid=WC0b01ac058001d124	June 2014
Ledraxen	Enoxaparin sodium	New biological	Venipharm	Not available	February 2019
Lemtrada	Alemtuzumab	PASS ¹	Sanofi Belgium	https://www.ema.europa.eu/en/documents/product-information/lemtrada-epar-product-information_en.pdf	January 2020

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Leqvio	inclisiran autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex vivo using a lentiviral vector encoding	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/leqvio-epar-product-information_en.pdf	Jan/21
Libmeldy		New active substance and new biological, PASS ¹	Orchard Therapeutics (Netherlands) B.V.	https://www.ema.europa.eu/en/documents/product-information/libmeldy-epar-product-information_en.pdf	Jan/21
LIBTAYO	Cemiplimab	New active substance, new biological and conditional marketing authorisation	Regeneron Ireland U.C.	https://www.ema.europa.eu/en/documents/product-information/libtayo-epar-product-information_en.pdf	July 2019
LiMAXetin 4 mg/ml Injektionslösung	Methacetin	New active substance	Humedics GmbH	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?directdisplay=true&mpdidentifier=2196936	May 2020
Liumjev	Insulin lispro	New biological	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/liumjev-previously-liumjev-epar-product-information_en.pdf	April 2020
Livogiva	teriparatide	New biological	Theramex Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/livogiva-epar-product-information_en.pdf	Aug/20
Lojuxta	Lomitapide	Authorised under exceptional circumstances	Amryt Pharmaceuticals DAC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002578/human_med_001668.jsp&mid=WC0b01ac058001d124	September 2013
Lokelma	Sodium zirconium cyclosilicate	New active substance	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004029/human_med_002084.jsp&mid=WC0b01ac058001d124	April 2018
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
Lutathera	Lutetium (¹⁷⁷ Lu) oxodotreotide	New active substance	Advanced Accelerator Applications	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004123/human_med_002163.jsp&mid=WC0b01ac058001d124	October 2017
Luxturna	Voretigene neparovec	New active substance, new biological, PASS	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/luxturna-epar-product-information_en.pdf	December 2018
Lydisilka	drospirenone/estetrol	New active substance	Estetra SRL	https://www.ema.europa.eu/en/documents/product-information/lydisilka-epar-product-information_en.pdf	June 2021
Macimorelin Aeterna Zentaris	Macimorelin	New active substance	Æterna Zentaris GmbH	https://www.ema.europa.eu/en/documents/product-information/macimorelin-aeterna-zentaris-epar-product-information_en.pdf	January 2019
Maviret	Glecaprevir / pibrentasvir	New active substance, PASS ¹	AbbVie Deutschland GmbH & Co. KG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004430/human_med_002151.jsp&mid=WC0b01ac058001d124	September 2017
Mayzent	Siponimod	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/mayzent-epar-product-information_en.pdf	January 2020
Medikinet retard 10 / 20 / 30 / 40 / 5 / 50 / 60 mg	Methylphenidate hydrochloride	PASS ¹	Medice Arzneimittel Püttner GmbH Co. KG	Not available	May 2018
Mektovi	Binimetinib	New active substance	Pierre Fabre Medicament	https://www.ema.europa.eu/documents/product-information/mektovi-epar-product-information_en.pdf	October 2018
MenQuadfi	Meningococcal group A, C, W and Y conjugate vaccine	New biological	Sanofi Pasteur	https://www.ema.europa.eu/en/documents/product-information/menquadfi-epar-product-information_en.pdf	December 2020
Mepsevii	Vestronidase alfa	New active substance, <i>new biological</i> , authorized under exceptional circumstances	Ultragenyx Germany GmbH	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004438/WC500254544.pdf	September 2018
Minjuvi	Tafasitamab	New active substance, new biological and conditional marketing authorisation	Incyte Biosciences Distribution B.V.	https://www.ema.europa.eu/en/documents/product-information/minjuvi-epar-product-information_en.pdf	September 2021
Mulpleo (previously Lusutrombopag Shionogi)	Lusutrombopag	New active substance	Shionogi B.V.	https://www.ema.europa.eu/en/documents/product-information/mulpleo-previously-lusutrombopag-shionogi-epar-product-information_en.pdf	February 2019
Mvabea	Ebola vaccine (MVA-BN-Filo [recombinant])	New active substance, new biological Authorised under exceptional circumstances	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/mvabea-epar-product-information_en.pdf	July 2020
Mvasi	Bevacizumab	New biological	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004728/human_med_002217.jsp&mid=WC0b01ac058001d124	January 2018
Myalepta	Metreleptin	New active substance, new biological, authorized under exceptional circumstances	Amryt Pharmaceuticals DAC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004218/human_med_002251.jsp&mid=WC0b01ac058001d124	September 2018
Mylotarg	Gemtuzumab ozogamicin	New active substance and <i>new biological</i>	Pfizer Europe MA EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004204/human_med_002252.jsp&mid=WC0b01ac058001d124	May 2018

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Mysimba	Naltrexone / bupropion	PASS ¹	Orexigen Therapeutics Ireland Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003687/human_med_001845.jsp&mid=WC0b01ac058001d124	April 2015
Naglazyme	Galsulfase	Authorised under exceptional circumstances	BioMarin International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000640/human_med_000918.jsp&mid=WC0b01ac058001d124	April 2013
Natpar	Parathyroid hormone	Conditional authorisation	Shire Pharmaceuticals Ireland Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003861/human_med_002093.jsp&mid=WC0b01ac058001d124	May 2017
Nerlynx	Neratinib	New active substance	Pierre Fabre Médicament	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004030/WC500255241.pdf	September 2018
Nepexto	Etanercept	New biological	Mylan IRE Healthcare Limited	https://www.ema.europa.eu/en/documents/product-information/nepexto-epar-product-information_en.pdf	June 2020
NEXPOVIO	selinexor	New active substance, conditional authorisation	Karyopharm Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/nexpovio-epar-product-information_en.pdf	April 2021
NexoBrid	Concentrate of proteolytic enzymes enriched in bromelain	PASS ¹	MediWound Germany GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002246/human_med_001582.jsp&mid=WC0b01ac058001d124	April 2013
Nilemdo	bempedoic acid	New active substance	Daiichi Sankyo Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/nilemdo-epar-product-information_en.pdf	April 2020
Ninlaro	Ixazomib	New active substance, conditional authorisation	Takeda Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003844/human_med_001998.jsp&mid=WC0b01ac058001d124	November 2016
NUBEQA	darolutamide	New active substance	Bayer AG	https://www.ema.europa.eu/en/documents/product-information/nubeqa-epar-product-information_en.pdf	April 2020
Nuceiva	Botulinum toxin type A	New biological	Evolus Pharma Limited	https://www.ema.europa.eu/en/documents/product-information/nuceiva-epar-product-information_en.pdf	October 2019
Nustendi	bempedoic acid / ezetimibe	New active substance	Daiichi Sankyo Europe GmbH	https://www.ema.europa.eu/en/documents/product-information/nustendi-epar-product-information_en.pdf	April 2020
Nyvepria	pegfilgrastim	New biological	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/nyvepria-epar-product-information_en.pdf	December 2020
Obizur	Susoctocog alfa	New active substance, authorised under exceptional circumstances	Baxalta Innovations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002792/human_med_001918.jsp&mid=WC0b01ac058001d124	November 2015
Obiltoxaximab SFL	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	New active substance, conditional authorisation	Intercept Pharma Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004093/human_med_002043.jsp&mid=WC0b01ac058001d124	January 2017
Ocrevus	Ocrelizumab	New active substance and <i>new biological</i>	Roche Registration GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004043/human_med_002187.jsp&mid=WC0b01ac058001d124	January 2018
Ondexxya	Andexanet alfa	New active substance, new biological and conditional marketing authorisation	Alexion Europe S.A.S.	https://www.ema.europa.eu/en/documents/product-information/ondexxya-epar-product-information_en.pdf	May 2019
Onbevzi	bevacizumab	New biological	Samsung Bioepis NL B.V.	https://www.ema.europa.eu/en/documents/product-information/onbevzi-epar-product-information_en.pdf	January 2021
Ogivri	Trastuzumab	New biological	Mylan S.A.S. Viatrix Limited	https://www.ema.europa.eu/documents/product-information/ogivri-epar-product-information_en.pdf	January 2019
Olumiant	Baricitinib	New active substance	Eli Lilly Nederland B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004085/human_med_002074.jsp&mid=WC0b01ac058001d124	February 2017
Ontruzant	Trastuzumab	New biological	Samsung Bioepis UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004323/human_med_002188.jsp&mid=WC0b01ac058001d124	November 2017
Onpattro	Patisiran	New active substance	Alnylam Netherlands B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004699/smops/Positive/human_smop_001335.jsp&mid=WC0b01ac058001d127	September 2018
Ontozry	cenobamate	New active substance	Arvelle Therapeutics Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/ontozry-epar-product-information_en.pdf	April 2021
Orladeyo	berotralstat	New active substance	Biocryst Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/orladeyo-epar-product-information_en.pdf	May 2021

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Orylmyte	Allergen extract from house dust mites (Dermatophagoides pteronyssinus and Dermatophagoides farinae)	New biological	Stallergenes	https://portal.dimdi.de/amguifree/am/docoutput/additionaldocs.xhtml?mpdidentifier=7000390	July 2021
Orkambi	Lumacaftor/Ivacaftor	PASS ¹	Vertex Pharmaceuticals (Ireland) Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003954/human_med_001935.jsp&mid=WC0b01ac058001d124	December 2015
Orphacol	Cholic acid	Authorised under exceptional circumstances	Laboratoires CTRS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001250/human_med_001419.jsp&mid=WC0b01ac058001d124	October 2013
Oxervate	Cenegermín	New active substance and <i>new biological</i>	Dompé farmaceutici S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004209/human_med_002135.jsp&mid=WC0b01ac058001d124	July 2017
Oyavas	bevacizumab	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/oyavas-epar-product-information_en.pdf	April 2021
Ozanex (also known in some EU countries as	Ozenoxacin	New active substance	Ferrer Internacional S.A.	https://cima.aemps.es/cima/dochtml/ft/82357/FichaTecnica_82357.html	November 2017
Ozempic	Semaglutide	New active substance and <i>new biological</i>	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004174/human_med_002211.jsp&mid=WC0b01ac058001d124	February 2018
Oxlumo	lumasiran	New active substance	Alnylam Netherlands B.V.	Not available	December 2020
Palynziq	Pegvaliase	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
Pandemic influenza vaccine H5N1 AstraZeneca	Pandemic influenza vaccine (H5N1) (live attenuated, nasal)	New active substance and <i>new biological</i> , conditional marketing authorisation	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003963/human_med_001984.jsp&mid=WC0b01ac058001d124	June 2016
Pegfilgrastim Mundipharma	Pegfilgrastim	New biological	Mundipharma Biologics S.L.	https://www.ema.europa.eu/en/documents/product-information/pegfilgrastim-mundi	January 2020
Pelgraz	Pegfilgratim	New biological	Accord Healthcare Limited	https://www.ema.europa.eu/documents/product-information/pelgraz-epar-product-information_en.pdf	October 2018
Pelmeg	Pegfilgrastim	New biological	Mundipharma Biologics S.L.	https://www.ema.europa.eu/documents/product-information/pelmeg-epar-product-information_en.pdf	December 2018
Pemazyre	pemigatinib	New active substance, conditional marketing authorisation	Incyte Biosciences Distribution B.V.	https://www.ema.europa.eu/en/documents/product-information/pemazyre-epar-product-information_en.pdf	Apr/21
Phesgo	pertuzumab / trastuzumab	New biological	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/phesgo-epar-product-information_en.pdf	Jan/21
Pifeltro	Doravirine	New active substance	Merck Sharp & Dohme B.V.	https://www.ema.europa.eu/documents/product-information/pifeltro-epar-product-information_en.pdf	December 2018
Piqray	Alpelisib	New active substance	Novartis Europharm Limited	https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information_en.pdf	August 2020
Polivy	Polatuzumab vedotin	New active substance, new biological, conditional marketing authorisation	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/polivy-epar-product-information_en.pdf	January 2020
Ponvory	ponesimod	New active substance	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/ponvory-epar-product-information_en.pdf	June 2021
Portrazza	Necitumumab	New active substance and <i>new biological</i>	Eli Lilly Nederland B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003886/human_med_001953.jsp&mid=WC0b01ac058001d124	March 2016
Poteligeo	Mogamulizumab	New active substance and <i>new biological</i>	Kyowa Kirin Holdings B.V.	https://www.ema.europa.eu/documents/product-information/poteligeo-epar-product-information_en.pdf	December 2018
Prevmis	Letermovir	New active substance	Merck Sharp & Dohme B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004536/human_med_002200.jsp&mid=WC0b01ac058001d124	January 2018
Dovprela (previously known as Pretomanid FGK)	pretomanid	new active substance, conditional MA	Mylan IRE Healthcare Limited	https://www.ema.europa.eu/en/documents/product-information/pretomanid-fgk-epar-product-information_en.pdf	August 2020
Qarziba (previously Dinutuximab beta EUSA and Dinutuximab beta Apeiron)	Dinutuximab beta	New biological, authorised under exceptional circumstances	EUSA Pharma (UK) Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003918/human_med_002104.jsp&mid=WC0b01ac058001d124	May 2017
Quinsair	Levofloxacin	PASS ¹	Chiesi Farmaceutici S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002789/human_med_001846.jsp&mid=WC0b01ac058001d124	April 2015

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Quofenix	Delafloxacin	New active substance	A. Menarini - Industrie Farmaceutiche Riunite - s.r.l.	https://www.ema.europa.eu/en/documents/product-information/quofenix-epar-product-information_en.pdf	January 2020
Ragwizax	Standardised allergen extract of pollen from Short Ragweed (<i>Ambrosia artemisiifolia</i>)	New biological	ALK-Abelló A/S	https://www.pei.de/SharedDocs/Arzneimittel/allergene/therapie/alk/PEI-H-11913-01-1.html	April 2018
Ravicti	Glycerol phenylbutyrate	PASS ¹	Immedica Pharma AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003822/human_med_001939.jsp&mid=WC0b01ac058001d124	January 2016
Raxone	Idebenone	Authorised under exceptional circumstances	Santhera Pharmaceuticals (Deutschland) GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003834/human_med_001900.jsp&mid=WC0b01ac058001d124	September 2015
Reagila	Cariprazine	New active substance	Gedeon Richter Plc.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002770/human_med_002136.jsp&mid=WC0b01ac058001d124	July 2017
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	New active substance and <i>new biological</i> , PASS ¹	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004178/human_med_002107.jsp&mid=WC0b01ac058001d124	June 2017
REKAMBYS Retinoid-containing medicinal products and related substances (acitretin, alitretinoin and isotretinoin)	rilpivirine	PASS ¹	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Retinoids_containing_medicinal_products/human_referral_prac_000061.jsp&mid=WC0b01ac05805c516f	Jan/21
	Acitretin, Alitretinoin, Isotretinoin	PASS ¹	Various for full list see Annex XIV	http://www.ema.europa.eu/en/documents/product-information/rekambys-epar-product-information_en.pdf	September 2018
Retsevmo	selpercatinib	New active substance, Conditional marketing authorisation	Eli Lilly Nederland B.V.	https://www.ema.europa.eu/en/documents/product-information/retsevmo-epar-product-information_en.pdf	February 2021
Revestive	Teduglutide	PASS ¹	Shire Pharmaceuticals Ireland Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002345/human_med_001583.jsp&mid=WC0b01ac058001d124	April 2013
Revlimid	Lenalidomide	PASS ¹	Bristol-Myers Squibb Pharma EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000717/human_med_001034.jsp&mid=WC0b01ac058001d124	June 2014
Rhokiinsa	Netarsudil	New active substance	Aerie Pharmaceuticals Ireland Ltd	https://www.ema.europa.eu/en/documents/product-information/rhokiinsa-epar-product-information_en.pdf	December 2019
Rinvoq	Upadacitinib	New active substance	AbbVie Deutschland GmbH & Co. KG	https://www.ema.europa.eu/en/documents/product-information/rinvoq-epar-product-information_en.pdf	January 2020
Ritemvia	Rituximab	New biological	Celltrion Healthcare Hungary Kft.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004725/human_med_002137.jsp&mid=WC0b01ac058001d124	July 2017
Rixathon	Rituximab	New biological	Sandoz GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003903/human_med_002095.jsp&mid=WC0b01ac058001d124	June 2017
Riximyo	Rituximab	New biological	Sandoz GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004729/human_med_002116.jsp&mid=WC0b01ac058001d124	June 2017
Rizmoic	Naldemedine	New active substance	Shionogi B.V.	https://www.ema.europa.eu/en/documents/product-information/rizmoic-epar-product-information_en.pdf	February 2019
Roclanda	Latanoprost / netarsudil	New active substance	Aerie Pharmaceuticals Ireland Ltd	https://www.ema.europa.eu/en/documents/product-information/roclanda-epar-product-information_en.pdf	January 2021
Rolufta Ellipta (previously Rolufta)	Umeclidinium	PASS ¹	GlaxoSmithKline Trading Services Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004654/human_med_002085.jsp&mid=WC0b01ac058001d124	March 2017
Roteas	Edoxaban	New active substance	Berlin-Chemie AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004339/human_med_002096.jsp&mid=WC0b01ac058001d124	May 2017
Rozlytrek	entrectinib	new active substance, conditional MA	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/rozlytrek-epar-product-information_en.pdf	August 2020
Rubraca	Rucaparib	New active substance, conditional marketing authorisation	Clovis Oncology UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004272/human_med_002215.jsp&mid=WC0b01ac058001d124	June 2018
Rukobia	fostemsavir	New active substance	ViiV Healthcare BV	https://www.ema.europa.eu/en/documents/product-information/rukobia-epar-product-information_en.pdf	Feb/21

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Ruxience	Rituximab	New biological	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/ruxience-epar-product-information_en.pdf	April 2020
Rxulti	Brexpiprazole	New active substance	Otsuka Pharmaceutical Europe Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003841/smops/Positive/human_smop_001298.jsp&mid=WC0b01ac058001d127	September 2018
Rybelsus	Semaglutide	New biological	Novo Nordisk A/S	https://www.ema.europa.eu/en/medicines/human/EPAR/rybelsus	April 2020
Rydapt	Midostaurin	New active substance	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004095/human_med_002155.jsp&mid=WC0b01ac058001d124	October 2017
Sarclisa	Isatuximab	New active substance and <i>new biological</i>	Sanofi-Aventis groupe	https://www.ema.europa.eu/en/documents/product-information/sarclisa-epar-product-information_en.pdf	June 2020
Scenesse	Afamelanotide	Authorised under exceptional circumstances	Clinuvel UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002548/human_med_001826.jsp&mid=WC0b01ac058001d124	January 2015
Seasonique	Levonorgestrel/ethinylestradiol	PASS ¹	Theramex	Not available	June 2015
Segluromet	Ertugliflozin / metformin hydrochloride	New active substance	Merck Sharp & Dohme Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004314/human_med_002238.jsp&mid=WC0b01ac058001d124	April 2018
Semglee	Insulin glargine	New biological	Mylan S.A.S.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004280/human_med_002239.jsp&mid=WC0b01ac058001d124	April 2018
Senshio	Ospemifene	PASS ¹	Shionogi Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002780/human_med_001837.jsp&mid=WC0b01ac058001d124	February 2015
Shingrix	Herpes zoster vaccine (recombinant, adjuvanted)	New active substance and <i>new biological</i>	GlaxoSmithKline Biologicals S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004336/human_med_002240.jsp&mid=WC0b01ac058001d124	April 2018
Sirturo	Bedaquiline	Conditional authorisation	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002614/human_med_001730.jsp&mid=WC0b01ac058001d124	March 2014
Sixmo	Buprenorphine	New biological, PASS ¹	L. Molteni & C. dei F.lli Alitti Soc.Es.S.p.A	https://www.ema.europa.eu/en/documents/product-information/sixmo-epar-product-information_en.pdf	July 2019
Skyrizi	Risankizumab	New active substance <i>and new biological</i>	AbbVie Deutschland GmbH & Co. KG	https://www.ema.europa.eu/en/documents/product-information/skyrizi-epar-product-information_en.pdf	May 2019
Skysona	Elivaldogene autotemcel	New active substance and new biological, PASS ¹	bluebird bio (Netherlands) B.V.	https://www.ema.europa.eu/en/documents/product-information/skysona-epar-product-information_en.pdf	July 2021
SomaKit TOC	Edotreotide	New active substance	Advanced Accelerator Applications	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004140/human_med_002038.jsp&mid=WC0b01ac058001d124	December 2016
Sogroya	somapacitan	New active substance and new biological	Novo Nordisk A/S	https://www.ema.europa.eu/en/documents/product-information/sogroya-epar-product-information_en.pdf	Apr/21
Sovaldi	Sofosbuvir	PASS ¹	Gilead Sciences Ireland UC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002798/human_med_001723.jsp&mid=WC0b01ac058001d124	February 2014
Spherox	Spheroids of human autologous matrix-associated chondrocytes	New active substance and <i>new biological</i>	CO.DON AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002736/human_med_002138.jsp&mid=WC0b01ac058001d124	July 2017
Spikevax (previously COVID-19 Vaccine Moderna)	COVID-19 mRNA Vaccine (nucleoside modified)	Conditional marketing authorisation / New active substance and new biological	MODERNA BIOTECH SPAIN, S.L.	https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf	Jan/21
Spinraza	Nusinersen	New active substance	Biogen Netherlands B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004312/human_med_002119.jsp&mid=WC0b01ac058001d124	June 2017
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
Staqvis	Crisaborole	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/staqvis-epar-product-information_en.pdf	April 2020
Steglatro	Ertugliflozin	New active substance	Merck Sharp & Dohme Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004315/human_med_002241.jsp&mid=WC0b01ac058001d124	April 2018
Steglujan	Ertugliflozin / sitagliptin	New active substance	Merck Sharp & Dohme B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004313/human_med_002242.jsp&mid=WC0b01ac058001d124	April 2018

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Strensiq	Asfotase alfa Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence	Authorised under exceptional circumstances	Alexion Europe SAS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003794/human_med_001901.jsp&mid=WC0b01ac058001d124	September 2015
Strimvelis	Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence	PASS ¹	Orchard Therapeutics (Netherlands) B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003854/human_med_001985.jsp&mid=WC0b01ac058001d124	June 2016
Striverdi Respimat (also known in some EU countries as Infortispir Respimat)	Olodaterol	PASS ¹	Boehringer Ingelheim International GmbH	http://db.cbq-meb.nl/IB-teksten/h112058.pdf	February 2015
Sublivac Birke	Allergen extract of pollen from Birch	New biological	HAL Allergie GmbH	https://www.pei.de/SharedDocs/Arzneimittel/allergene/therapie/hal/PEI-H-07972-02-1.html	September 2018
Sublivac Bäume	Allergen extract of pollen from Birch, Alder and Hazel	New biological	HAL Allergie GmbH	https://www.pei.de/SharedDocs/Arzneimittel/allergene/therapie/hal/PEI-H-07974-02-1.html	September 2018
Suliqua	Insulin glargine / lixisenatide	New active substance and <i>new biological</i>	Sanofi-Aventis groupe	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004243/human_med_002064.jsp&mid=WC0b01ac058001d124	March 2017
Sulovas	Sulodexide	New biological	Afloom Farmacja Polska Sp. z o.o.	http://pub.rejstrymedyczne.csioz.gov.pl/ProduktSzczegoly.aspx?id=38063	December 2018
Sunosi	Solriamfetol	New active substance	Jazz Pharmaceuticals Ireland Ltd	https://www.ema.europa.eu/en/documents/product-information/sunosi-epar-product-information_en.pdf	January 2020
Supemtek	quadrivalent influenza vaccine (recombinant, prepared in cell culture)	New biological	Sanofi Pasteur	https://www.ema.europa.eu/en/documents/product-information/supemtek-epar-product-information_en.pdf	November 2020
Sylvant	Siltuximab	PASS ¹	EUSA Pharma (Netherlands) B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003708/human_med_001769.jsp&mid=WC0b01ac058001d124	June 2014
Symkevi	Tezacaftor/ivacaftor	New active substance	Vertex Pharmaceuticals (Ireland) Limited	https://www.ema.europa.eu/documents/product-information/symkevi-epar-product-information_en.pdf	November 2018
Symtuza	Darunavir / cobicistat / emtricitabine / tenofovir alafenamide	New active substance	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004391/human_med_002165.jsp&mid=WC0b01ac058001d124	October 2017
Tagrisso	Osimertinib	New active substance and <i>new biological</i>	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004124/human_med_001961.jsp&mid=WC0b01ac058001d124	February 2016
TAKUDEX (also known in some EU countries as Dextra)	Tramadol hydrochloride/ dexketoprofen	PASS ¹	GUIDOTTI FARMA Shire Pharmaceuticals Ireland Limited Takeda Pharmaceuticals International AG Ireland Branch	https://cima.aemps.es/cima/dochtml/ft/80802/FT_80802.html	April 2018
Takhzyro	Lanadelumab	New active substance, new biological	Takeda Pharmaceuticals International AG Ireland Branch	https://www.ema.europa.eu/documents/product-information/takhzyro-epar-product-information_en.pdf	December 2018
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
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
Tecartus	autologous anti-CD19-transduced CD3+ cells	Conditional marketing authorisation / 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
Tecentriq	Atezolizumab	New active substance and <i>new biological</i>	Roche Registration GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004143/human_med_002166.jsp&mid=WC0b01ac058001d124	October 2017
Tegsedi	Inotersen	New active substance	Akcea Therapeutics UK Ltd.	https://www.ema.europa.eu/documents/product-information/tegsedi-epar-product-information_en.pdf	July 2018
Temybric Ellipta	Fluticasone furoate / umeclidinium / vilanterol	New active substance	GlaxoSmithKline Trading Services	https://www.ema.europa.eu/en/documents/product-information/temybric-ellipta-epar-product-information_en.pdf	July 2019
Ferrosa	Teriparatide	New biological	Gedeon Richter Plc.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003916/human_med_002060.jsp&mid=WC0b01ac058001d124	January 2017
Thiosix	Tioguanin	Authorised under exceptional circumstances	Teva Nederland B.V.	http://db.cbq-meb.nl/IB-teksten/h114681.pdf	May 2015
Tookad	Padeliporfin	New active substance	Steba Biotech S.A	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004182/human_med_002190.jsp&mid=WC0b01ac058001d124	November 2017
Translarna	Ataluren	Conditional authorisation	PTC Therapeutics Limited	https://www.ema.europa.eu/en/documents/product-information/translarna-epar-product-information_en.pdf	September 2014

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Trazimera	Trastuzumab	New biological	Pfizer Europa MA EEG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004463/human_med_002282.jsp&mid=WC0b01ac058001d124	September 2018
Trelegy Ellipta	Fluticasone furoate/umeclidinium/vilanterol	New active substance	GlaxoSmithKline Trading Services Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004363/human_med_002191.jsp&mid=WC0b01ac058001d124	November 2017
Tremfya	Guselkumab	New active substance and <i>new biological</i>	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004271/human_med_002183.jsp&mid=WC0b01ac058001d124	November 2017
Trivalent Influenza Vaccine	Influenza vaccine (split virion, inactivated)	New biological	Sanofi Pasteur	Not available	May 2019
Trogarzo	Ibalizumab	New active substance, new biological	Theratechnologies Europe Limited	https://www.ema.europa.eu/en/documents/product-information/trogarzo-epar-product-information_en.pdf	October 2019
Trumenba	Meningococcal group B vaccine (recombinant, component)	New active substance and <i>new biological</i>	Pfizer Europe MA EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004051/human_med_002101.jsp&mid=WC0b01ac058001d124	June 2017
Truxima	Rituximab	New biological	Celltrion Healthcare Hungary Kft.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004112/human_med_002077.jsp&mid=WC0b01ac058001d124	March 2017
TUKYSA	tucatinib	New active substance	Seagen B.V.	https://www.ema.europa.eu/en/documents/product-information/tukysa-epar-product-information_en.pdf	Feb/21
Ultomiris	Ravulizumab	New active substance, new biological	Alexion Europe SAS	https://www.ema.europa.eu/en/documents/product-information/ultomiris-epar-product-information_en.pdf	July 2019
Vaborem (previously Vabomere) Valproate and related substances (sodium valproate, valproic acid, valproate semisodium, valpromide-containing)	Meropenem/vaborbactam	New active substance	Menarini International Operations Luxembourg S.A.	https://www.ema.europa.eu/documents/product-information/vabomere-epar-product-information_en.pdf	December 2018
	Sodium valproate, valproic acid, valproate semisodium, valpromide	PASS ¹	Various (For full list see Annex XIII)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Vaproate_and_related_substances/human_referral_prac_000032.jsp&mid=WC0b01ac05805c516f	January 2015
Vaxchora	Cholera vaccine (recombinant, live, oral)	New active substance, new biological	Emergent Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/vaxchora-epar-product-information_en.pdf	May 2020
Vaxigrip Tetra (also known in some EU countries as quadrivalent influenza vaccine (split virion, inactivated))	Influenza vaccine (split virion, inactivated)	New biological	Sanofi Pasteur Europe	https://www.pei.de/SharedDocs/Arzneimittel/impfstoffe/Mono/Influenza/saisonal/ohne-stammanpassung-2021-2022/PEI-H-11808-02-1.html	September 2016
Vaxzevria (previously COVID-19 Vaccine AstraZeneca)	COVID-19 Vaccine (ChAdOx1-S [recombinant])	Conditional marketing authorisation / New active substance and new biological	AstraZeneca AB	https://www.ema.europa.eu/en/documents/product-information/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-product-information_en.pdf	Feb/21
Vazkepa	Icosapent ethyl	New active substance	Amarin Pharmaceuticals Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/vazkepa-epar-product-information_en.pdf	Mar/21
Vedrop	Tocofersolan d-alpha tocopheryl polyethylene glycol succinate	Authorised under exceptional circumstances	Recordati Rare Diseases	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000920/human_med_001129.jsp&mid=WC0b01ac058001d124	April 2013
Veklury	Remdesivir	New active substance and conditional marketing authorisation	Gilead Sciences Ireland UC	https://www.ema.europa.eu/en/documents/product-information/veklury-epar-product-information_en.pdf	July 2020
Veltassa	Patiromer	New active substance	Vifor Fresenius Medical Care Renal Pharma Fr	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004180/human_med_002141.jsp&mid=WC0b01ac058001d124	September 2017
Vemlidy	Tenofovir alafenamide	New active substance	Gilead Sciences Ireland UC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004169/human_med_002061.jsp&mid=WC0b01ac058001d124	January 2017
Venclyxto	Venetoclax	New active substance	AbbVie Deutschland GmbH & Co. KG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004106/human_med_002045.jsp&mid=WC0b01ac058001d124	December 2016
VeraSeal	Human fibrinogen / human thrombin	New biological	Instituto Grifols, S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004446/human_med_002197.jsp&mid=WC0b01ac058001d124	November 2017
Verquvo	Vericiguat	New active substance	Bayer AG	https://www.ema.europa.eu/en/documents/product-information/verquvo-epar-product-information_en.pdf	July 2021
Verzenios	Abemaciclib	New active substance	Eli Lilly Netherland B.V.	https://www.ema.europa.eu/documents/product-information/verzenios-epar-product-information_en.pdf	October 2018
Veyvondi	Vonicog alfa	New active substance and <i>new biological</i>	Baxalta Innovations GmbH	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004454/WC500255622.pdf	September 2018
Viekirax	Ombitasvir/paritaprevir/ritonavir	PASS ¹	AbbVie Deutschland GmbH & Co. KG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003839/human_med_001838.jsp&mid=WC0b01ac058001d124	February 2015

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Vihuma	Simoctocog alfa	New active substance and new biological	Octapharma-AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004459/human_med_002078.jsp&mid=WC0b01ac058001d124	February 2017
Vimizim	Elosulfase alfa	PASS ¹	BioMarin International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002779/human_med_001759.jsp&mid=WC0b01ac058001d124	June 2014
VITRAKVI	Larotrectinib	Conditional authorisation, new active substance	Bayer AG	https://www.ema.europa.eu/documents/product-information/vitrakvi-epar-product-information_en.pdf	October 2019
Vizimpro	Dacomitinib	New active substance	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/vizimpro-epar-product-information_en.pdf	April 2019
Vocabria	cabotegravir	New active substance, PASS ¹	ViiV Healthcare BV	https://www.ema.europa.eu/en/documents/product-information/vocabria-epar-product-information_en.pdf	Jan/21
Vosevi	Sofosbuvir / velpatasvir / voxilaprevir	New active substance, PASS ¹	Gilead Sciences Ireland UC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004350/human_med_002153.jsp&mid=WC0b01ac058001d124	September 2017
Voxzogo	vosoritide	New active substance and new biological	BioMarin International Limited	https://www.ema.europa.eu/en/documents/product-information/vozzoqo-epar-product-information_en.pdf	Sep/21
Vyndaqel	Tafamidis	Authorised under exceptional circumstances	Pfizer Europa MA EEG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002294/human_med_001498.jsp&mid=WC0b01ac058001d124	April 2013
Wakix	Pitolisant hydrochloride	PASS ¹	Bioprojet Pharma	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002616/human_med_001955.jsp&mid=WC0b01ac058001d124	April 2016
Waylivra	Volanesorsen	New active substance and conditional marketing authorisation	Akcea Therapeutics Ireland Limited	https://www.ema.europa.eu/en/documents/product-information/waylivra-epar-product-information_en.pdf	May 2019
Xarelto	Rivaroxaban	PASS ¹	Bayer Pharma AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000944/human_med_001155.jsp&mid=WC0b01ac058001d124	July 2013
Xeljanz	Tofacitinib	New active substance	Pfizer Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004214/human_med_001662.jsp&mid=WC0b01ac058001d124	April 2017
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
Xerava	Eravacycline	New active substance	PAION Deutschland GmbH	https://www.ema.europa.eu/documents/product-information/xerava-epar-product-information_en.pdf	October 2018
Xermelo	Telotristat	New active substance	Ipsen Pharma	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003937/human_med_002168.jsp&mid=WC0b01ac058001d124	September 2017
Xofigo	Radium Ra 223 dichloride	PASS ¹	Bayer AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002653/human_med_001692.jsp&mid=WC0b01ac058001d124	December 2013
Xofluza	baloxavir marboxil	New active substance	Roche Registration GmbH	https://www.ema.europa.eu/en/documents/product-information/xofluza-epar-product-information_en.pdf	January 2021
Xospata	Gilteritinib	New active substance	Astellas Pharma Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/xospata-epar-product-information_en.pdf	November 2019
Yescarta	Axicabtagene ciloleucel	New active substance, <i>new biological</i> , PASS	Kite Pharma EU B.V.	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004480/WC500254958.pdf	September 2018
Yuflyma	adalimumab	New biological	Celltrion Healthcare Hungary Kft.	https://www.ema.europa.eu/en/documents/product-information/yuflyma-epar-product-information_en.pdf	March 2021
Zabdeno	Ebola vaccine (Ad26.ZEBOV-GP [recombinant])	New active substance, new biological Authorised under exceptional circumstances	Janssen-Cilag International NV	https://www.ema.europa.eu/en/documents/product-information/zabdeno-epar-product-information_en.pdf	July 2020
Zejula	Niraparib	New active substance	GlaxoSmithKline (Ireland) Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004249/human_med_002192.jsp&mid=WC0b01ac058001d124	November 2017
Zercepac	trastuzumab	New Biological, New active substance	Accord Healthcare S.L.U.	https://www.ema.europa.eu/en/documents/product-information/zercepac-epar-product-information_en.pdf	August 2020
Zepatier	Elbasvir / grazoprevir	New active substance	Merck Sharp & Dohme B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004126/human_med_002001.jsp&mid=WC0b01ac058001d124	September 2016
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
Zessly	Infliximab	New biological	Sandoz GmbH	https://www.ema.europa.eu/en/documents/product-information/zessly-epar-product-information_en.pdf	June 2018
Ziextenzo	Pegfilgrastim	New biological	Sandoz GmbH	https://www.ema.europa.eu/documents/product-information/ziextenzo-epar-product-information_en.pdf	December 2018
Zirabev	Bevacizumab	New biological	Pfizer Europe MA EEIG	https://www.ema.europa.eu/en/documents/product-information/zirabev-epar-product-information_en.pdf	February 2019
Zoely	Nomegestrol/Estradiol	PASS ¹	Theramex Ireland Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001213/human_med_001452.jsp&mid=WC0b01ac058001d124	January 2014
Zolgensma	Onasemnogene abeparvovec	New active substance, new biological and conditional marketing authorisation	AveXis EU Limited	https://www.ema.europa.eu/en/documents/product-information/zolgensma-epar-product-information_en.pdf	May 2020
Zykadia	Ceritinib	New active substance	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003819/human_med_001860.jsp&mid=WC0b01ac058001d124	May 2015
Zynteglo	Autologous CD34+ cells encoding β A-T87Q-globin gene	New active substance and conditional marketing authorisation	Bluebird bio (Netherlands) B.V.	https://www.ema.europa.eu/en/documents/product-information/zynteglo-epar-product-information_en.pdf	June 2019
Zynquista	Sotagliflozin	New active substance, PASS ¹	Navigant Germany GmbH	https://www.ema.europa.eu/en/documents/product-information/zynquista-epar-product-information_en.pdf	May 2019

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 24th September 2021.