

27 April 2020
EMA/245297/2013 Rev. 77*
Human Medicines Division

List of medicinal products under additional monitoring

Related Information:

[Additional monitoring explained:](#)

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

[Good Pharmacovigilance Practice Module on additional monitoring:](#)

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

To note: All products added to the list in April 2020 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.

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Acarizax (also known in some EU countries as MITIZAX)	Standardised allergen extract from house dust mites	New Biological	ALK-Abelló A/S	https://portal.dimdi.de/amispb/doc/pei/Web/2613318-spcde-20180701.pdf	May 2016
Adcetris	Brentuximab vedotin	Conditional marketing authorisation	Takeda Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002455/human_med_001588.jsp&mid=WC0b01ac058001d124	April 2013
Adynovi	Rurioctocog alfa pegol	New active substance and <i>new biological</i> , PASS ¹	Baxalta Innovations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004195/human_med_002204.jsp&mid=WC0b01ac058001d124	January 2018
Afstyla	Ionoctocog alfa	New active substance and <i>new biological</i>	CSL Behring GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004075/human_med_002055.jsp&mid=WC0b01ac058001d124	January 2017
Aimovig	Erenumab	New active substance and <i>new biological</i>	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004447/human_med_002275.jsp&mid=WC0b01ac058001d124	September 2018
Aitaro	Standardised allergen extract from house dust mites	New Biological	ALK-Abelló A/S	https://portal.dimdi.de/amispb/doc/pei/Web/2613636-spcde-20180701.pdf	June 2016
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	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004164/human_med_002068.jsp&mid=WC0b01ac058001d124	March 2017
Alofisel	Darvadstrocel	New active substance and <i>new biological</i>	Takeda Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004258/human_med_002222.jsp&mid=WC0b01ac058001d124	April 2018
Alpivab	Peramivir	New active substance	BioCryst UK Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004299/human_med_002243.jsp&mid=WC0b01ac058001d124	May 2018
Alprolix	Eftrenonacog alfa	New active substance and <i>new biological</i>	Swedish Orphan Biovitrum AB (publ)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004142/human_med_001973.jsp&mid=WC0b01ac058001d124	May 2016
Alunbrig	Brigatinib	New active substance	Takeda Pharma A/S	https://www.ema.europa.eu/documents/product-information/alunbrig-epar-product-information_en.pdf	December 2018
Amgevita	Adalimumab	New biological	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004212/human_med_002081.jsp&mid=WC0b01ac058001d124	April 2017
Amitend (also known in some EU countries as ACARIZAX)	Standardised allergen extract from house dust mites	New Biological	ALK-Abelló A/S	https://portal.dimdi.de/amispb/doc/pei/Web/2613637-spcde-20180701.pdf	July 2016
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
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

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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
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> , conditional marketing authorisation	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
Benepali	Etanercept	New biological	Samsung Bioepis UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004007/human_med_001944.jsp&mid=WC0b01ac058001d124	January 2016
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
BioThrax (also known as BaciThrax in France)	Anthrax antigen filtrate	New biological	Emergent Sales and Marketing Germany GmbH	https://portal.dimdi.de/amispb/doc/pei/Web/2604178-spcde-20180901.pdf	June 2018
Blinicyto	Blinatumomab	New active substance and new biological, 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
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
Brivect	Brivaracetam	New active substance	UCB Pharma S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003898/human_med_001945.jsp&mid=WC0b01ac058001d124	January 2016
Cablivi	Caplacizumab	New active substance <i>and new biological</i>	Ablynx N.V.	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004426/WC500255071.pdf	September 2018
Cabometyx	Cabozantinib	New active substance	Ipsen Pharma	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004163/human_med_002018.jsp&mid=WC0b01ac058001d124	September 2016
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 sigma-tau	Chenodeoxycholic acid	Authorised under exceptional circumstances, PASS ¹	Sigma-tau Arzneimittel 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

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Cinquaero	Reslizumab	New active substance and <i>new biological</i>	Teva B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003912/human_med_002012.jsp&mid=WC0b01ac058001d124	September 2016
Cinryze	c1 inhibitor, human	PASS ¹	Shire Services BVBA	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001207/human_med_001448.jsp&mid=WC0b01ac058001d124	April 2013
Coagadex Combined hormonal contraceptives containing chlormadinone (For full list of products see Annex IX)	Human coagulation factor X Chlormadinone Ethinylestradiol, Chlormadinone Acetate Ethinylestradiol	New biological PASS ¹	Bio Products Laboratory Ltd Various (For full list see Annex IX)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003855/human_med_001967.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	April 2016 June 2014
Cometriq	Cabozantinib	Conditional authorisation	Ipsen Pharma	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002640/human_med_001726.jsp&mid=WC0b01ac058001d124	May 2014
Cotellic	Cobimetinib	New active substance	Roche Registration GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003960/human_med_001925.jsp&mid=WC0b01ac058001d124	December 2015
Cresemba	Isavuconazole	New active substance	Basilea Medical Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002734/human_med_001907.jsp&mid=WC0b01ac058001d124	November 2015
CRYSVITA	Burosumab	New active substance and <i>new biological</i> , PASS ¹	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://portal.dimdi.de/amispb/doc/pei/Web/2613853-spcde-20190601.pdf 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
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	PASS ¹	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
Descovy Dexamed and associated names (dexamfetamine sulphate-containing medicinal products in the EU) (For full list of	Emtricitabine/tenofovir alafenamide Dexamfetamine sulphate	New active substance PASS ¹	Gilead Sciences Ireland UC Various (For full list see Annex XII)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004094/human_med_001978.jsp&mid=WC0b01ac058001d124 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Dexamed_and_associated_names/human_referral_000373.jsp&mid=WC0b01ac05805c516f	May 2016 September 2014
Doptelet	Avatrombopag	New active substance	Dova Pharmaceuticals Ireland Limited	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
Duzallo	Allopurinol / Lesinurad	New active substance	Grünenthal GmbH	https://www.ema.europa.eu/documents/product-information/duzallo-epar-product-information_en.pdf	September 2018
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

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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
Elocta	Efmoroctocog alfa	New active substance and <i>new biological</i>	Swedish Orphan Biovitrum AB (publ)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003964/human_med_001928.jsp&mid=WC0b01ac058001d124	December 2015
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
Empliciti	Elotuzumab	New active substance and <i>new biological</i>	Bristol-Myers Squibb Pharma EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003967/human_med_001968.jsp&mid=WC0b01ac058001d124	May 2016
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
EndolucinBeta Enoxaparin Becat (also known in some EU countries as Losima, Enoxaparin Rovi, Crusia and Arovi)	Lutetium (177 Lu) chloride	New active substance	ITG Isotope Technologies Garching GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003999/human_med_001989.jsp&mid=WC0b01ac058001d124	July 2016
	Enoxaparin sodium	New biological	Laboartorios Farmacéuticos Rovi, S.A.	http://mri.cts-mrp.eu/Human/Product/Details/50005	November 2018
Entresto	Sacubitril/valsartan	New active substance	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004062/human_med_001929.jsp&mid=WC0b01ac058001d124	December 2015
Epclusa	Sofosbuvir/velpatasvir	New active substance	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
Episalvan	Birch bark extract	New active substance	Birken AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003938/human_med_001956.jsp&mid=WC0b01ac058001d124	January 2016
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, conditional marketing authorisation	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
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
Evotaz	Atazanavir / cobicistat	New active substance	Bristol-Myers Squibb Pharma EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003904/human_med_001884.jsp&mid=WC0b01ac058001d124	July 2015
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
Farydak	Panobinostat	New active substance	Secura Bio Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003725/human_med_001895.jsp&mid=WC0b01ac058001d124	September 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
Fexeric	Ferric citrate coordination complex	New active substance, PASS ¹	Akebia Europe Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003776/human_med_001908.jsp&mid=WC0b01ac058001d124	October 2015
Fiasp	Insulin aspart	New biological	Novo Nordisk A/S Laboratoire	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004046/human_med_002063.jsp&mid=WC0b01ac058001d124	March 2017
FibClot	Human Fibrinogen	New Biological	Français du Fractionnement et des Biotechnologies	https://portal.dimdi.de/amispb/doc/pei/Web/2613347-spcde-20180401.pdf	July 2016
Fibryga	Human Fibrinogen	New biological	Octapharma GmbH	https://portal.dimdi.de/amispb/doc/pei/Web/2613723-spcde-20191001.pdf	July 2017
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

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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
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	Mylan S.A.S.	https://www.ema.europa.eu/documents/product-information/fulphila-epar-product-information_en.pdf	November 2018
Galafold	Migalastat	New active substance	Amicus Therapeutics UK Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004059/human_med_001981.jsp&mid=WC0b01ac058001d124	June 2016
Gammplex 10%	Human normal immunoglobulin	New biological	Bio Products GmbH, Neu-Isenburg, DE	https://portal.dimdi.de/amispb/doc/pei/Web/2613785-spcde-20190301.pdf	September 2019
Genvoya	Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide	New active substance	Gilead Sciences Ireland UC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004042/human_med_001940.jsp&mid=WC0b01ac058001d124	December 2015
Giapreza	Angiotensin II acetate	New active substance	La Jolla Pharmaceutical II B.V.	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	PASS ¹	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
Hepaxane	Enoxaparin sodium	New biological	Chemi S.P.A.	Not available	November 2018
Hetlioz	Tasimelteon	New active substance	Vanda Pharmaceuticals Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003870/human_med_001873.jsp&mid=WC0b01ac058001d124	July 2015
Holoclar	Ex vivo expanded autologous human corneal epithelial cells containing stem cells	Conditional marketing authorisation	Chiesi Farmaceutici S.P.A.	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 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Hydroxyethyl_starch-containing_medicines/human_referral_prac_000029.jsp&mid=WC0b01ac05805c516f	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)		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
Ibrance	Palbociclib	New active substance	Pfizer Europe MA EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003853/human_med_002034.jsp&mid=WC0b01ac058001d124	November 2016

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
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
Idelvion	Albutrepenonacog alfa	New active substance and <i>new biological</i>	CSL Behring GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003955/human_med_001974.jsp&mid=WC0b01ac058001d124	June 2016
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
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
Imlygic	Talimogene laherparepvec	New active substance and <i>new biological</i>	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002771/human_med_001941.jsp&mid=WC0b01ac058001d124	January 2016
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/ProduktSzczegoly.aspx?id=37540	September 2018
Inhixa	Enoxaparin sodium	New biological	Tachdow Pharma Netherlands B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004264/human_med_002020.jsp&mid=WC0b01ac058001d124	September 2016
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
Intrarosa	Prasterone	PASS ¹	Endoceutics Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004138/human_med_002210.jsp&mid=WC0b01ac058001d124	February 2018
Intravenous iron-containing medicinal products (For full list see Annex III)	Ferric carboxymaltose, iron dextran, sodium ferric gluconate, iron isomaltoside, iron sucrose	PASS ¹	Various (For full list see Annex III)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/intravenous_iron-containing_medical_products/human_referral_000343.jsp&mid=WC0b01ac058001d124	January 2014
Intuniv	Guanfacine	PASS ¹	Shire Pharmaceuticals Ireland Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003759/human_med_001910.jsp&mid=WC0b01ac058001d124	September 2015
Iqymune (also known in some EU countries as OPTIGLOBIN)	Human normal immunoglobulin	New biological	Laboratoire Francais du Fractionnement et des Biotechnologies	https://portal.dimdi.de/amispb/doc/pei/Web/2613314-spcde-20190801.pdf	September 2016
Isturisa	Osilodrostat	New active substance	Nbvaris Europharm Limited	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://portal.dimdi.de/amispb/doc/pei/Web/2613926-spcde-20191001.pdf	September 2019
Jaydess (also known in some EU countries as Flere)	Levonorgestrel	PASS ¹	Bayer AB	https://docetp.mpa.se/LMF/Jaydess%20intrauterine%20delivery%20system%20EN%20SmPC.doc	November 2013
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	Damococog 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
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
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	New active substance and <i>new biological</i> , 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

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Ketoconazole HRA	Ketoconazole	PASS ¹	ERA 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
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
Keytruda	Pembrolizumab	New active substance and new biological	Merck Sharp & Dohme B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003820/human_med_001886.jsp&mid=WC0b01ac058001d124	July 2015
Kisplyx	Lenvatinib	New active substance	Eisai Europe Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004224/human_med_002021.jsp&mid=WC0b01ac058001d124	September 2016
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
Kolbam (previously Cholic Acid FGK)	Cholic acid	Authorised under exceptional circumstances	Retrophin Europe Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002081/human_med_001718.jsp&mid=WC0b01ac058001d124	May 2014
Kovaltry	Octocog alfa	New biological	Bayer AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003825/human_med_001959.jsp&mid=WC0b01ac058001d124	March 2016
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
Kyprolis	Carfilzomib	New active substance	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003790/human_med_001932.jsp&mid=WC0b01ac058001d124	November 2015
Lamzedo	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
Lenalidomide Accord	Lenalidomide	Restrictions with regards to the safe and effective use of the medicinal product	Accord Healthcare Limited	https://www.ema.europa.eu/documents/product-information/lenalidomide-accord-epar-product-information_en.pdf	October 2018
Lenvima	Lenvatinib	New active substance	Eisai Europe Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003727/human_med_001864.jsp&mid=WC0b01ac058001d124	June 2015
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
Lifmior	Etanercept	New biological	Pfizer Europe MA EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004167/human_med_002080.jsp&mid=WC0b01ac058001d124	February 2017
Liumjev	Insulin lispro	New biological	Eli Lilly Nederland B.V.	Not available	April 2020
Lixiana	Edoxaban	New active substance	Daiichi Sankyo Europe GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002629/human_med_001874.jsp&mid=WC0b01ac058001d124	July 2015
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
Lonsurf	Trifluridine / tipiracil	New active substance	Les Laboratoires Servier	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003897/human_med_001975.jsp&mid=WC0b01ac058001d124	May 2016
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
Lumark	Lutetium, isotope of mass 177	New active substance	IDB Holland B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002749/human_med_001875.jsp&mid=WC0b01ac058001d124	July 2015
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

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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
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
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 http://www.produktresume.dk/docushare/dsweb/Get/Document-34320/Meriofert+Set%2C+pulver+og+solvens+til+injektionsv%C3%A6ske%2C+op+%C3%B8sning+75+IE+og+150+IE.docx	September 2018
Meriofert (also known in some EU countries as Fertinorm and Eigenorm)	Menotrophin	New biological	Laboratoires Génévrier SA	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004368/human_med_002057.jsp&mid=WC0b01ac058001d124	March 2015
Movymia	Teriparatide	New biological	STADA Arzneimittel AG	https://www.ema.europa.eu/en/documents/product-information/mulpleo-previously-lusutrombopag-shionogi-epar-product-information_en.pdf	January 2017
Mulpleo (previously Lusutrombopag Shionogi)	Lusutrombopag	New active substance	Shionogi B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004728/human_med_002217.jsp&mid=WC0b01ac058001d124	February 2019
Mvasi	Bevacizumab	New biological	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004218/human_med_002251.jsp&mid=WC0b01ac058001d124	January 2018
Myalepta	Metreleptin	New active substance, new biological, authorized under exceptional circumstances	Aegerion Pharmaceuticals B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004204/human_med_002252.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/003687/human_med_001845.jsp&mid=WC0b01ac058001d124	May 2018
Mysimba	Naltrexone / bupropion	PASS ¹	Orexigen Therapeutics Ireland Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000640/human_med_000918.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/003861/human_med_002093.jsp&mid=WC0b01ac058001d124	April 2013
Natpar	Parathyroid hormone	Conditional authorisation	Shire Pharmaceuticals Ireland Limited	http://www.leki-informacje.pl/sites/default/files/Charakterystyka-20160219000000-1576_N-20160308000147.pdf	May 2017
Neoparin	Enoxaparinum natricum	New biological	SciencePharma spółka z ograniczoną odpowiedzialnością spółka komandytowa	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004343/human_med_001982.jsp&mid=WC0b01ac058001d124	April 2016
Neparvis	Sacubitril / valsartan	New active substance	Novartis Europharm Limited	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004030/WC500255241.pdf	June 2016
Nerlynx	Neratinib	New active substance	Puma Biotechnology, Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002246/human_med_001582.jsp&mid=WC0b01ac058001d124	September 2018
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/003844/human_med_001998.jsp&mid=WC0b01ac058001d124	April 2013
Nilemdo	bempedoic acid	New active substance	FGK Representative Service GmbH	Not available	April 2020
Ninlaro	Ixazomib	New active substance, conditional authorisation	Takeda Pharma A/S	https://www.ema.europa.eu/en/documents/product-information/nubeqa-epar-product-information_en.pdf	November 2016
NUBEQA	darolutamide	New active substance	Bayer AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003860/human_med_001933.jsp&mid=WC0b01ac058001d124	April 2020
Nucala	Mepolizumab	New active substance and <i>new biological</i>	GlaxoSmithKline Trading Services Limited	https://www.ema.europa.eu/en/documents/product-information/nuceiva-epar-product-information_en.pdf	January 2016
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	FGK Representative Service GmbH	Not available	April 2020

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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
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
Odefsey	Emtricitabine / rilpivirine / tenofovir alafenamide	New active substance	Gilead Sciences Ireland UC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004156/human_med_001991.jsp&mid=WC0b01ac058001d124	June 2016
Ondexxya	Andexanet alfa	New active substance, new biological and conditional marketing authorisation	Portola Netherlands B.V.	https://www.ema.europa.eu/en/documents/product-information/ondexxya-epar-product-information_en.pdf	May 2019
Odomzo	Sonidegib	New active substance	Sun Pharmaceutical Industries Europe BV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002839/human_med_001897.jsp&mid=WC0b01ac058001d124	September 2015
Ogivri	Trastuzumab	New biological	Mylan S.A.S.	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
Oncaspar	Pegaspargase	New biological	Les Laboratoires Servier	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003789/human_med_001949.jsp&mid=WC0b01ac058001d124	January 2016
Ongentys	Opicapone	New active substance	Bial - Portela & C ^a , SA	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002790/human_med_001950.jsp&mid=WC0b01ac058001d124	July 2016
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
Opdivo	Nivolumab	New active substance	Bristol-Myers Squibb Pharma EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003985/human_med_001876.jsp&mid=WC0b01ac058001d124	July 2015
Orkambi	Lumacaftor/Ivacaftor	New active substance, 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
Ozanex (also known in some EU countries as Ozenoxacin)	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
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
Panzyga	Human normal immunoglobulin	New biological	Octapharma GmbH	https://portal.dimdi.de/amispb/doc/pei/Web/2613595-spcde-20190601.pdf	July 2016
Parsabiv	Etelcalcetide	New active substance	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003995/human_med_002037.jsp&mid=WC0b01ac058001d124	November 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	Cinfa Biotech S.L.	https://www.ema.europa.eu/documents/product-information/pelmeg-epar-product-information_en.pdf	December 2018
Penthrox	Methoxyflurane	PASS ¹	Medical Developments UK Ltd	http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1467955147758.pdf	June 2016

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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
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
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
Praluent	Alirocumab	New active substance and <i>new biological</i>	Sanofi-Aventis Groupe	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003882/human_med_001915.jsp&mid=WC0b01ac058001d124	October 2015
Praxbind	Idarucizumab	New active substance and <i>new biological</i>	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003986/human_med_001938.jsp&mid=WC0b01ac058001d124	December 2015
Prevymis	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
Qarziba (previously Dinutuximab beta EUSA and Dinutuximab beta Apeiron)	Dinutuximab beta	New biological, authorised under exceptional circumstances, PASS ¹	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
Quofenix	Delafloxacin	New active substance	Al 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://portal.dimdi.de/amispb/doc/pei/Web/2613788-spcde-20180101.pdf	April 2018
Rapibloc (also known in some EU countries as RAPLOC and Runrapiq)	Landiolol	New active substance	AOP Orphan Pharmaceuticals	Not available	July 2016
Ravicti	Glycerol phenylbutyrate	New active substance, PASS ¹	Horizon Pharma Ireland Limited	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
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
Rekvelle	Follitropin delta	New biological	Ferring Pharmaceuticals A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003994/human_med_002044.jsp&mid=WC0b01ac058001d124	May 2017
Repatha	Evolocumab	New active substance and new biological	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003766/human_med_001890.jsp&mid=WC0b01ac058001d124	September 2015
Respreeza	Human alpha1-proteinase inhibitor	New biological	CSL Behring GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002739/human_med_001904.jsp&mid=WC0b01ac058001d124	September 2015
<u>Retinoid-containing medicinal products and related substances (acitretin, alitretinoin and isotretinoin)</u>	Acitretin, Alitretinoin, Isotretinoin	PASS ¹	Various for full list see Annex XIV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Retinoids_containing_medicinal_products/human_referral_prac_000061.jsp&mid=WC0b01ac05805c516f	September 2018
Revestive	Teduglutide	PASS ¹	Nycomed Denmark ApS	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	Celgene Europe B.V.	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

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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
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
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
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	Not available	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
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 and <i>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
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
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
Spectrila	Asparaginase	New biological	Medac Gesellschaft für klinische Spezialpräparate mbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002661/human_med_001954.jsp&mid=WC0b01ac058001d124	January 2016
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
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
Spiolto Respimat	Tiotropium Bromide Monohydrate / Olodaterol Hydrochloride	New active substance	Boehringer Ingelheim International GmbH	http://db.cbq-meb.nl/IB-teksten/h115528.pdf	September 2016
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

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Staquis	Crisaborole	New active substance	Pfizer Europe MA EEIG	Not available	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
Strensiq	Asfotase alfa Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence	New active substance and <i>new biological</i> , 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	encodes for the human ADA cDNA sequence	New active substance and <i>new biological</i> , 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.cbg-meb.nl/IB-teksten/h112058.pdf http://www.mhra.gov.uk/spc-pil/index.htm?prodName=STRONTIUM%20RANELATE%202%20G%20GRANULES%20FOR%20ORAL%20SUSPENSION&subsName=&pageID=ThirdLevel&searchTerm=str	February 2015
Strontium ranelate Aristo 2g granules for oral suspension	Strontium ranelate	PASS ¹	Aristo Pharma Limited	http://www.mhra.gov.uk/spc-pil/index.htm?prodName=STRONTIUM%20RANELATE%202%20G%20GRANULES%20FOR%20ORAL%20SUSPENSION&subsName=&pageID=ThirdLevel&searchTerm=str	April 2019
Sublivac Birke	Allergen extract of pollen from Birch	New biological	HAL Allergie GmbH	https://portal.dimdi.de/amispb/doc/pei/Web/2613841-spcde-20180601.pdf	September 2018
Sublivac Bäume	Allergen extract of pollen from Birch, Alder and Hazel	New biological	HAL Allergie GmbH	https://portal.dimdi.de/amispb/doc/pei/Web/2613842-spcde-20180601.pdf	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	Afiofarm Farmacja Polska Sp. z o.o.	http://pub.rejestrzymedyczne.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
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	Npovember 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 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003770/human_med_001865.jsp&mid=WC0b01ac058001d124	October 2017
Synjardy	Empagliflozin/metformin	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004124/human_med_001961.jsp&mid=WC0b01ac058001d124	June 2015
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	https://cima.aemps.es/cima/dochtml/ft/80802/FT_80802.html	April 2018
Takhzyro	Lanadelumab	New active substance, new biological	Shire Pharmaceuticals Ireland Limited	https://www.ema.europa.eu/documents/product-information/takhzyro-epar-product-information_en.pdf	December 2018
Taltz	Ixekizumab	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/003943/human_med_001977.jsp&mid=WC0b01ac058001d124	May 2016
TAVLESSE	Fostamatinib	New active substance	Bigel Pharmaceuticals B.V.	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
Targocid and associated names (teicoplanin-containing medicinal products) (For full list see Annex VII)	Teicoplanin	PASS ¹	Various (For full list see Annex VII)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Targocid_and_associated_names/human_referral_000341.jsp&mid=WC0b01ac058001d124	February 2014
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

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
Terrosa	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
Thorinane	Enoxaparin sodium	New biological	Techdow Pharma Netherlands B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003795/human_med_002024.jsp&mid=WC0b01ac058001d124	September 2016
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	New active substance, conditional authorisation	PTC Therapeutics Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002720/human_med_001742.jsp&mid=WC0b01ac058001d124	September 2014
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	May 2018
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 International Limited	https://www.ema.europa.eu/en/documents/product-information/trogarzo-epar-product-information_en.pdf	October 2019
Truberzi	Eluxadoline	New active substance	Allergan Pharmaceuticals International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004098/human_med_002025.jsp&mid=WC0b01ac058001d124	October 2016
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
Tysabri	Natalizumab	PASS ¹	Biogen Netherlands B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000603/human_med_001119.jsp&mid=WC0b01ac058001d124	April 2013
Udenyca	Pegfilgrastim	New biological	ERA Consulting GmbH	https://www.ema.europa.eu/documents/product-information/udenycan-epar-product-information_en.pdf	October 2018
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
Uptravi	Selexipag	New active substance	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003774/human_med_001970.jsp&mid=WC0b01ac058001d124	June 2016
Vabomere	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
Valproate and related substances (sodium valproate, valproic acid, valproate semisodium, valpromide-containing)	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/Valproate_and_related_substances/human_referral_prac_000032.jsp&mid=WC0b01ac058001d124	January 2015
Vaxelis	Influenza vaccine (split virion, inactivated)	New biological	MCM Vaccine B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003982/human_med_001962.jsp&mid=WC0b01ac058001d124	February 2016
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://portal.dimdi.de/amispb/doc/pei/Web/2613624-spcde-20190801.pdf	September 2016
Vedrop	Tocofersolan d-alpha tocopheryl polyethylene glycol succinate	Authorised under exceptional circumstances	Orphan Europe S.A.R.L.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000920/human_med_001129.jsp&mid=WC0b01ac058001d124	April 2013
Veltassa	Patiromer	New active substance	Vifor Fresenius Medical Care Renal Pharma France	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
Vepacel	A/H5N1 pre-pandemic influenza vaccine (whole virion, vero cell derived, inactivated)	New active substance and <i>new biological</i>	Ology Bioservices Ireland LTD	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002089/human_med_001543.jsp&mid=WC0b01ac058001d124	April 2013

Product name	Active substance (s)	Reason (s) on list	Marketing authorisation holder (s)	Link to product information	Date of inclusion
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
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
Vihuma	Simoctocog alfa	New active substance and <i>new biological</i>	Octapharma AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004459/human_med_002078.jsp&mid=WC0b01ac058001d124	April 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
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
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	New active substance, 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
Xerava	Eravacycline	New active substance	Tetraphase Pharmaceuticals Ireland Limited	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
Xospata	Gilteritinib	New active substance	Holder: Astellas Pharma Europe B.V.	https://www.ema.europa.eu/en/documents/product-information/xospata-epar-product-information_en.pdf	November 2019
Yanimo Respimat	Tiotropium Bromide Monohydrate / Olodaterol Hydrochloride	New active substance	Boehringer Ingelheim International GmbH	http://db.cbq-meb.nl/IB-teksten/h115529.pdf	September 2016
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
Zavicefta	Ceftazidime / avibactam	New active substance	Pfizer Ireland Pharmaceuticals	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004027/human_med_001993.jsp&mid=WC0b01ac058001d124	July 2016
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
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 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003772/human_med_001917.jsp&mid=WC0b01ac058001d124	September 2016
Zerbaxa	Ceftolozane / tazobactam	New active substance	Merck Sharp & Dohme B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003772/human_med_001917.jsp&mid=WC0b01ac058001d124	September 2015
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

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Zinplava	Bezlotoxumab	New active substance and <i>new biological</i>	Merck Sharp & Dohme B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004136/human_med_002062.jsp&mid=WC0b01ac058001d124	February 2017
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
Zurampic	Lesinurad	New active substance, PASS ¹	Grünenthal GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003932/human_med_001963.jsp&mid=WC0b01ac058001d124	March 2016
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	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	Novartis 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 23 March 2020.