

23 September 2019
EMA/245297/2013 Rev.70corr1
Inspections & Human Medicines
Pharmacovigilance

List of medicinal products under additional monitoring

Related Information:

[Additional monitoring explained:](#)

http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000365.jsp

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

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp

To note: All products added to the list in September 2019 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
Abasaglar (previously Abasria)	Insulin glargine	New biological	Eli Lilly Nederland B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002035/human_med_001790.jsp&mid=WC0b01ac058001d124	October 2014
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-20170401.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 peqol	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	Ionococog 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
Akynzeo	Netupitant/palonosetron	New active substance	Helsinn Birex Pharmaceuticals Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003728/human_med_001862.jsp&mid=WC0b01ac058001d124	June 2015
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	Eftrenocog 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
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

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Batrevac Tetra	Influenza virus surface antigens, inactivated (haemagglutinin and neuraminidase)	New biological	Mylan Healthcare B.V.	Not yet 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
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
Blincyto	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	Acclidinium 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	Acclidinium 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
Briviact	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
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	Eliquisat	New active substance, 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 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cidofovir-containing-medicines/human-referral_000338.jsp&mid=WC0b01ac058001d124	May 2016
Gilestazol-containing medicinal products (For full list of products see Annex VIII)	Gilestazol	PASS⁺	Various (For full list see Annex VIII)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Gilestazol-containing-medicines/human-referral_000338.jsp&mid=WC0b01ac058001d124	September 2013
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
Coaquadex 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=WC0b01ac058001d124	April 2016 June 2014

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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=WCOb01ac058001d124	May 2014
Cesentix	Secukinumab	New active substance and new biological	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003729/human_med_001832.jsp&mid=WCOb01ac058001d124	February 2015
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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	March 2018
Cutaquig	Human normal immunoglobulin	New Biological	Octapharma GmbH	https://portal.dimdi.de/amispb/doc/pei/Web/2613853-spcde-20190601.pdf	March 2019
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)	Immunglobulin	New biological	Baxalta Innovations GmbH, Austria	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=WCOb01ac05805c516f	September 2017
	Cyproterone acetate and Ethinylestradiol	PASS ¹	Various (For full list see Annex I)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002829/human_med_001825.jsp&mid=WCOb01ac058001d124	August 2013
Cyramza	Ramucirumab	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/003768/human_med_001792.jsp&mid=WCOb01ac058001d124	February 2015
Daklinza	Daclatasvir	New active substance, PASS ¹	Bristol-Myers Squibb Pharma EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004077/human_med_001979.jsp&mid=WCOb01ac058001d124	September 2014
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/001179/human_med_001363.jsp&mid=WCOb01ac058001d124	June 2016
Daxas	Roflumilast	PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002552/human_med_001699.jsp&mid=WCOb01ac058001d124	June 2013
Dectova	Zanamivir	Authorised under exceptional circumstances	GlaxoSmithKline Trading Services Limited	Not yet available	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=WCOb01ac058001d124	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
Deltysba	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=WCOb01ac058001d124	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	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=WCOb01ac058001d124 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Dexamed-and-associated-names/human_referral_000373.jsp&mid=WCOb01ac05805c516f	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/medicines/003918/human_med_002104.jsp&mid=WCOb01ac058001d124 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Domperidone-containing-medicines/human_referral_prac_000021.jsp&mid=WCOb01ac05805c516f	September 2014
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=WCOb01ac058001d124 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Domperidone-containing-medicines/human_referral_prac_000021.jsp&mid=WCOb01ac05805c516f	May 2017
	Domperidone	PASS ¹	Various (For full list see Annex X)	https://www.ema.europa.eu/en/documents/product-information/doptelet-epar-product-information_en.pdf	July 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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	May 2018

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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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	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
Esperoct	Turoctocog alfa peqol	New active substance, new biological, PASS ¹	Novo Nordisk A/S	Not yet available	June 2019
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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	April 2013
Exviera	Dasabuvir	New active substance, 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=WCOb01ac058001d124	February 2015
Farydak	Panobinostat	New active substance	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003725/human_med_001895.jsp&mid=WCOb01ac058001d124	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=WCOb01ac058001d124	January 2018
Fexeric	Ferric citrate coordination complex	New active substance, PASS ¹	Keryx Biopharma UK Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003776/human_med_001908.jsp&mid=WCOb01ac058001d124	October 2015
Fiasp	Insulin aspart	New biological	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004046/human_med_002063.jsp&mid=WCOb01ac058001d124	March 2017
FibClot	Human Fibrinogen	New Biological	Laboratoire 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-20190301.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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	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	Miqalastat	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=WCOb01ac058001d124	June 2016

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Gammaflex 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
GalliaPharm	Germanium (⁶⁶Ge) chloride/gallium (⁶⁶Ga) chloride	New active substance	Eckert & Ziegler Radiopharma GmbH	http://www.produktresumee.dk/docushare/dsweb/Get/Document-33097/Galliapharm%2C+radiouclide-generator.docx	April 2016
Gardasil 9	Human papillomavirus 9-valent vaccine (recombinant, adsorbed)	New active substance and <i>new biological</i>	MSD VACCINS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003852/human_med_001863.jsp&mid=WC0b01ac058001d124	June 2015
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
Glapreza	Angiotensin II acetate	New active substance	La Jolla Pharmaceutical II B.V.	Not yet available	September 2019
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 yet available	November 2018
Hettlioz	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	New active substance and <i>new biological</i> , 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=WC0b01ac058005c516f	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
Hlias	Octecog-alfa	New biological	Bayer AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004147/human_med_001950.jsp&mid=WC0b01ac058001d124	March 2016
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
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	Albutrepenonacoq 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 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	June 2016
Ilumetri	Tildrakizumab	New active substance and <i>new biological</i>	Almirall S.A.	https://www.ema.europa.eu/en/human-regulatory/post-authorization/pharmacovigilance/medicines-under-additional-monitoring/list-medicines-under-additional-monitoring	September 2018
Imfinzi	Durvalumab	New active substance and <i>new biological</i>	AstraZeneca AB		October 2018

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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.rejestrmedyczne.csioz.gov.pl/ProduktSzczegoly.aspx?id=37540	September 2018
Inhixa	Enoxaparin sodium	New biological	Techdow Europe AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004264/human_med_002020.jsp&mid=WC0b01ac058001d124	September 2016
Insulin Iispro Sanofi	Insulin Iispro	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_medicinal_products/human_referral_000343.jsp&mid=WC0b01ac05805c5	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
Itulazax	Standardised allergen extract from birch	New biological	ALK-Abelló A/S	https://portal.dimdi.de/amispb/doc/pei/Web/2613926-spcde-20190701.pdf	September 2019
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-20181001.pdf	September 2016
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
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
Kengrexal	Cangrelor	New active substance	Chiesi farmaceutici S.p.A	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003773/human_med_001852.jsp&mid=WC0b01ac058001d124	April 2015
Ketoconazole HRA	Ketoconazole	PASS ¹	Laboratoire HRA Pharma	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 <i>new biological</i>	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	Octocoq 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

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Kromeja	Adalimumab	New biological	Fresenius Kabi Deutschland GmbH	https://www.ema.europa.eu/en/documents/product-information/kromeja-epar-product-information_en.pdf	April 2019
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
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
Lartruvo	Olaratumab	New active substance, conditional authorisation	EH Lilly Nederland B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004216/human_med_002036.jsp&mid=WC0b01ac058001d124	November 2016
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 yet available	February 2019
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.	Not yet available	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
Lixiana	Edoxaban	New active substance	Dalich 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
Lonquex	Lipegfilgrastim	PASS⁺	Teva B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002556/human_med_001667.jsp&mid=WC0b01ac058001d124	September 2013
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	Not yet available	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
Lusutrombopag Shionogi	Lusutrombopag	New active substance	Shionogi B.V.	https://www.ema.europa.eu/en/documents/product-information/lusutrombopag-shionogi-epar-product-information_en.pdf	February 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 neparvovec	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
Lymphoseek	Tilmanocept	New active substance	Norgine B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002085/human_med_001827.jsp&mid=WC0b01ac058001d124	December 2014
Lynparza	Olaparib	New active substance	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003726/human_med_001831.jsp&mid=WC0b01ac058001d124	February 2015
Macimorelin Aeterna Zentaris	Macimorelin	New active substance	Æterna Zentaris GmbH	Not yet available	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
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

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
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
Meriofert (also known in some EU countries as Fertinorm and Eigenorm)	Menotrophin	New biological	Laboratoires Génévrier SA	http://www.produktresume.dk/docushare/dsweb/Get/Document-34320/Meriofert+Set%2C+pulver+og+solvens+til+injektionsv%C3%A6ske%2C+opl%C3%B8sning+75+IE+og+150+IE.docx	March 2015
Moventiq	Naloxegol	New active substance	Kyowa Kirin Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002810/human_med_001816.jsp&mid=WC0b01ac058001d124	January 2015
Movymia	Teriparatide	New biological	STADA Arzneimittel AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004368/human_med_002057.jsp&mid=WC0b01ac058001d124	January 2017
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	Aegerion Pharmaceuticals B.V.	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
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
Neoparin	Enoxaparinum natricum	New biological	SciencePharma spółka z ograniczoną odpowiedzialnością spółka komandytowa	http://www.leki-informacje.pl/sites/default/files/Charakterystyka-20160219000000-1576_N-20160308000147.pdf	April 2016
Neparvis	Sacubitril / valsartan	New active substance	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004343/human_med_001982.jsp&mid=WC0b01ac058001d124	June 2016
Nerlynx	Neratinib	New active substance	Puma Biotechnology, Ltd.	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004030/WC500255241.pdf	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/002246/human_med_001582.jsp&mid=WC0b01ac058001d124	April 2013
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
Nucala	Mepolizumab	New active substance and <i>new biological</i>	GlaxoSmithKline Trading Services Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003860/human_med_001933.jsp&mid=WC0b01ac058001d124	January 2016
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.	Not yet available	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
Ofev	Nintedanib	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003821/human_med_001834.jsp&mid=WC0b01ac058001d124	February 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
Onqentys	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

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Onpattro	Patisiran	New active substance	Alnylam Netherlands B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004699/smop/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
Orbactiv	Oritavancin	New active substance	Menarini International Operations Luxembourg S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003785/human_med_001853.jsp&mid=WC0b01ac058001d124	April 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
Otezla	Apremilast	New active substance	Geigene Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003746/human_med_001835.jsp&mid=WC0b01ac058001d124	February 2015
Oxervate	Cenegermin	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)		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	Not yet available	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
Panzyqa	Human normal immunoglobulin	New Biological	Octapharma GmbH	https://portal.dimdi.de/amispb/doc/pei/Web/2613595-spcde-20190501.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
Pelqraz	Pegfilgratim	New Biological	Accord Healthcare Limited	https://www.ema.europa.eu/documents/product-information/pelqraz-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
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
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
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
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

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
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=WCOb01ac058001d124	June 2017
Rekovelle	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=WCOb01ac058001d124	May 2017
Repatha	Evolocumab	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/003766/human_med_001890.jsp&mid=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac05805c516f	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=WCOb01ac058001d124	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=WCOb01ac058001d124	June 2014
Rezoista	Barunavir/cobicistat	New active substance	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002819/human_med_001817.jsp&mid=WCOb01ac058001d124	February 2015
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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	June 2017
Rixubis	Nonacoq qamma	New biological	Baxalta Innovations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003771/human_med_001830.jsp&mid=WCOb01ac058001d124	February 2015
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
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=WCOb01ac058001d127	September 2018
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=WCOb01ac058001d124	March 2017
Roteas	Edoxaban	New active substance	Daiichi Sankyo Europe GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004339/human_med_002096.jsp&mid=WCOb01ac058001d124	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=WCOb01ac058001d124	June 2018
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=WCOb01ac058001d124	October 2017
Saxenda	Liraglutide	New biological	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003780/human_med_001855.jsp&mid=WCOb01ac058001d124	April 2015
Scenesse	Afamelanotide	New active substance, 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=WCOb01ac058001d124	January 2015
Seasonique	Levonorgestrel/ethinylestradiol	PASS ¹	Teva Pharma B.V.	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=WCOb01ac058001d124	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=WCOb01ac058001d124	April 2018
Senshio	Ospemifene	New active substance, PASS ¹	Shionogi Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002780/human_med_001837.jsp&mid=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	March 2014
Sivextro	Tedizolid phosphate	New active substance	Merck Sharp & Dohme Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002846/human_med_001856.jsp&mid=WCOb01ac058001d124	April 2015
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

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Skyrizi	Risankizumab	New active substance <i>and new biological</i>	AbbVie Deutschland GmbH & Co. KG	Not yet available	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=WCOb01ac058001d124	December 2016
Sonazoid powder and solvent for solution of for injection 8 microliter/ml	Perflurobutan	New active substance	GE HEALTHCARE AS	Not available	November 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=WCOb01ac058001d124	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=WCOb01ac058001d124	January 2016
Spherox	Spheroids of human autologous matrix-associated chondrocytes	New active substance <i>and 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=WCOb01ac058001d124	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=WCOb01ac058001d124	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
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=WCOb01ac058001d124	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=WCOb01ac058001d124	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 <i>and 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=WCOb01ac058001d124	September 2015
Strimvelis	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 <i>and 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=WCOb01ac058001d124	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
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%20%20G%20GRANULES%20FOR%20ORAL%20SUSPENSION&subsName=&pageID=ThirdLevel&searchTerm=stro	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 <i>and 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=WCOb01ac058001d124	March 2017
Sulovas	Sulodexide	New biological	Aflofarm Farmacja Polska Sp. z o.o.	http://pub.rejstrymedyczne.csioz.gov.pl/ProduktSzczegoly.aspx?id=38063	December 2018
Sylvant	Siltuximab	New active substance <i>and new biological</i> , PASS ¹	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003708/human_med_001769.jsp&mid=WCOb01ac058001d124	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=WCOb01ac058001d124	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/003770/human_med_001865.jsp&mid=WCOb01ac058001d124	June 2015
Tagrisso	Osimertinib	New active substance <i>and new biological</i>	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004124/human_med_001961.jsp&mid=WCOb01ac058001d124	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
Talzenna	Talazoparib	New active substance	Pfizer Europe MA EEIG	Not yet available	June 2019
Taltz	Ixekizumab	New active substance <i>and 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=WCOb01ac058001d124	May 2016
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=WCOb01ac058001d124	February 2014

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
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=WCOb01ac058001d124	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	Not yet available	July 2019
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=WCOb01ac058001d124	January 2017
Thiocolchicoside-containing medicinal products (For full list see Annex IV)	Thiocolchicoside	PASS ¹	Various (For full list see Annex IV)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Thiocolchicoside-containing_medicines/human_referral_000356.jsp&mid=WCOb01ac05805c516f&source=referrals	January 2014
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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	November 2017
Trivalent Influenza Vaccine	Influenza vaccine (split virion, inactivated)	New biological	Sanofi Pasteur	Not yet available	May 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=WCOb01ac058001d124	October 2016
Trulicity	Dulaglutide	New active substance and new biological	Eli Lilly Nederland B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002825/human_med_001821.jsp&mid=WCOb01ac058001d124	December 2014
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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	April 2013
Udenyca	Pegfilgrastim	New biological	ERA Consulting GmbH	https://www.ema.europa.eu/documents/product-information/udenyca-epar-product-information_en.pdf	October 2018
Ultibro Breezhaler	Indacaterol/glycopyrronium bromide	PASS⁺	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002679/human_med_001691.jsp&mid=WCOb01ac058001d124	October 2013
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
Ultunar Breezhaler	Indacaterol/glycopyrronium bromide	PASS⁺	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003075/human_med_001750.jsp&mid=WCOb01ac058001d124	July 2014
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=WCOb01ac058001d124	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 medicinal products)	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=WCOb01ac05805c516f	January 2015
Vargatef	Nintedanib	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002569/human_med_001822.jsp&mid=WCOb01ac058001d124	December 2014
Varuby	Rolapitant	New active substance	Tesaro UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004196/human_med_002097.jsp&mid=WCOb01ac058001d124	May 2017
Vaxelis	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)	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=WCOb01ac058001d124	February 2016

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Vaxigrip Tetra (also known in some EU countries as quadrivalent influenza vaccine (split virion, inactivated))	Influenza vaccine (split virion, inactivated)	New biological	Sanofi Pasteur MSD GmbH	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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	April 2013
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=WCOb01ac058001d124	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	New active substance, 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=WCOb01ac058001d124	February 2015
Vihuma	Simocotocog 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=WCOb01ac058001d124	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=WCOb01ac058001d124	June 2014
Vizamyl	Flutemetamol (18F)	New active substance	GE Healthcare Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002557/human_med_001794.jsp&mid=WCOb01ac058001d124	September 2014
Vizimpro	Dacomitinib	New active substance	Pfizer Europe MA EEIG	Not yet available	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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	April 2016
Waylivra	Volanesorsen	New active substance and conditional marketing authorisation	Akcea Therapeutics Ireland Limited	Not yet available	May 2019
Xadago	Safinamide	New active substance	Zambon S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002396/human_med_001847.jsp&mid=WCOb01ac058001d124	March 2015
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=WCOb01ac058001d124	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=WCOb01ac058001d124	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=WCOb01ac058001d124	September 2017
Xofiqo	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=WCOb01ac058001d124	December 2013
Xoterna Breezhaler	Indacaterol/glycopyrronium bromide	PASS¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003755/human_med_001693.jsp&mid=WCOb01ac058001d124	October 2013
Xultophy	Insulin degludec/liraglutide	New biological	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002647/human_med_001802.jsp&mid=WCOb01ac058001d124	October 2014
Xydalba	Dalbavancin	New active substance	Allergan Pharmaceuticals International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002840/human_med_001848.jsp&mid=WCOb01ac058001d124	March 2015
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

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Yescarta	Axicabtagene ciloleucel Allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (ΔLNGFR) and the	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
Zalmoxis		New active substance and <i>new biological</i> , conditional marketing authorisation	MolMed S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002801/human_med_002016.jsp&mid=WC0b01ac058001d124	September 2016
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	TESARO Bio Netherlands B.V.	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	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
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	Teva B.V.	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
Zydelig	Idelalisib	PASS ¹	Gilead Sciences Ireland UC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003843/human_med_001803.jsp&mid=WC0b01ac058001d124	October 2014
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 βA-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	Sanofi-Aventis groupe	Not yet available	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 26 July 2019.