

31 January 2018
EMA/245297/2013 Rev.52
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 January 2018 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
Abasaqlar (previously Abasria)	Insulin glargine	New biological	Eli Lilly Regional Operations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02835/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
Accofil	Filgrastim	New biological	Accord Healthcare Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03956/human_med_001798.jsp&mid=WC0b01ac058001d124	October 2014
Adcetris	Brentuximab vedotin	New active substance, conditional authorisation	Takeda Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02455/human_med_001588.jsp&mid=WC0b01ac058001d124	April 2013
Adempas	Riociquat	New active substance	Bayer AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02737/human_med_001733.jsp&mid=WC0b01ac058001d124	April 2014
Adynovi	Rurioctocog alfa pegol	New active substance, PASS¹	Baxalta Innovations GmbH	Not yet available	January 2018
Afstyla	Ionoctocog alfa	New active substance	CSL Behring GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04075/human_med_002055.jsp&mid=WC0b01ac058001d124	January 2017
Aitaro	Standardised allergen extract from house dust mites	New Biological	ALK-Abelló A/S	https://portal.dimdi.de/amispb/doc/pei/Web/2613636-spcde-20170401.pdf	June 2016
Akynzeo	Netupitant/palonosetron	New active substance	Helsinn Birex Pharmaceuticals Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03728/human_med_001862.jsp&mid=WC0b01ac058001d124	June 2015
Albumoon*	Human albumin	New biological	CSL Behring GmbH	https://portal.dimdi.de/amispb/doc/pei/Web/2612980-spcde-20160401.pdf	July 2015
Alecensa	Alectinib	New active substance	Roche Registration Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04164/human_med_002068.jsp&mid=WC0b01ac058001d124	March 2017
Alprolix	Eftrenonacoq alfa	New active substance	Swedish Orphan Biovitrum AB (publ)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04142/human_med_001973.jsp&mid=WC0b01ac058001d124	May 2016
Amqevita	Adalimumab	New biological	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04212/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-20170401.pdf	July 2016
AMITIZA 24 microgram soft capsules	Lubiproston	New active substance	Sucampo Pharma Europe Ltd.	http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1459748713655.pdf	September 2015
Anoro	Umeclidinium bromide/vilanterol trifenate	New active substance, PASS ¹	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02751/human_med_001754.jsp&mid=WC0b01ac058001d124	June 2014

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Apleek	Ethinyl estradiol/gestodene	PASS ¹	Bayer Pharma AG	http://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA1410-069-001_04042014155117.pdf	September 2014
Atriance	Nelarabine	Authorised under exceptional circumstances	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00752/human_med_000656.isp&mid=WCOb01ac058001d124	April 2013
ATryn	Anti-thrombin alpha	Authorised under exceptional circumstances	Laboratoire français du Fractionnement et des Biotechnologies	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00587/human_med_000658.isp&mid=WCOb01ac058001d124	April 2013
Aubagio	Teriflunomide	New active substance	Sanofi-aventis Groupe	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02514/human_med_001645.isp&mid=WCOb01ac058001d124	October 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/04197/human_med_002100.isp&mid=WCOb01ac058001d124	June 2017
Bavencio	Avelumab	New active substance, conditional authorisation	Merck Serono Europe Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04338/human_med_002157.isp&mid=WCOb01ac058001d124	September 2017
Bemfola	Follitropin alfa	New biological	Gedeon Richter Plc.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02615/human_med_001734.isp&mid=WCOb01ac058001d124	May 2014
Benepali	Etanercept	New biological	Samsung Bioepis UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04007/human_med_001944.isp&mid=WCOb01ac058001d124	January 2016
Benlysta	Belimumab	PASS ¹	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02015/human_med_001466.isp&mid=WCOb01ac058001d124	April 2013
Besponsa	Inotuzumab ozoqamicin	New active substance	Pfizer Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04119/human_med_002109.isp&mid=WCOb01ac058001d124	July 2017
Bexsero	Meningococcal group-B vaccine (rDNA, component, adsorbed)	New active substance	GSK Vaccines S.r.l.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02333/human_med_001614.isp&mid=WCOb01ac058001d124	April 2013
Blinicyto	Blinatumomab	New active substance, conditional authorisation	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03731/human_med_001921.isp&mid=WCOb01ac058001d124	December 2015
Blitzima	Rituximab	New biological	Celltrion Healthcare Hungary Kft.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04723/human_med_002125.isp&mid=WCOb01ac058001d124	July 2017
Bosulif	Bosutinib	New active substance, conditional authorisation	Pfizer Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02373/human_med_001613.isp&mid=WCOb01ac058001d124	April 2013
Bretaris Genuair	Acridinium bromide	New active substance, PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02706/human_med_001570.isp&mid=WCOb01ac058001d124	April 2013
Brimica Genuair	Acridinium bromide/formoterol fumarate dihydrate	PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03969/human_med_001806.isp&mid=WCOb01ac058001d124	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/04065/human_med_002111.isp&mid=WCOb01ac058001d124	June 2017
Brintellix	Vortioxetine	New active substance	H. Lundbeck A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02717/human_med_001714.isp&mid=WCOb01ac058001d124	February 2014
Briviact	Brivaracetam	New active substance	UCB Pharma S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03898/human_med_001945.isp&mid=WCOb01ac058001d124	January 2016
Cabometyx	Cabozantinib	New active substance	Ipsen Pharma	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04163/human_med_002018.isp&mid=WCOb01ac058001d124	September 2016
Caprelsa	Vandetanib	Conditional authorisation	Genzyme Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02315/human_med_001529.isp&mid=WCOb01ac058001d124	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/00796/human_med_000691.isp&mid=WCOb01ac058001d124	April 2013
Cerdelga	Eliqlustat	New active substance, PASS ¹	Genzyme Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03724/human_med_001840.isp&mid=WCOb01ac058001d124	February 2015
Chenodeoxycholic acid siqma-tau	Chenodeoxycholic acid	Authorised under exceptional circumstances, PASS ¹	Siqma-tau Arzneimittel GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04061/human_med_002019.isp&mid=WCOb01ac058001d124	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/sppcil/documents/sppcil/con1466141046287.pdf	May 2016

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Cilostazol-containing medicinal products (For full list of products see Annex VIII)	Cilostazol	PASS ¹	Various (For full list see Annex VIII)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cilostazol-containing_medicines/human_referral_000338.jsp&mid=WCOb01ac05805c516f	September 2013
Cinquaero	Reslizumab	New active substance	Teva Pharmaceuticals Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03912/human_med_002012.jsp&mid=WCOb01ac058001d124	September 2016
Cinryze	c1 inhibitor, human	PASS ¹	Shire Services BVBA	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01207/human_med_001448.jsp&mid=WCOb01ac058001d124	April 2013
Cluvot	Human plasma coagulation factor XIII	New biological	CSL Behring GmbH	https://portal.dimdi.de/amispb/doc/pei/Web/2613030-spcde-20160401.pdf	May 2015
Coagadex	Human coagulation factor X	New biological	Bio Products Laboratory Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03855/human_med_001967.jsp&mid=WCOb01ac058001d124	April 2016
Combined hormonal contraceptives containing chlormadinone (For full list of products see Annex IX)	Chlormadinone Ethinylestradiol, Chlormadinone Acetate Ethinylestradiol	PASS ¹	Various (For full list see Annex IX)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Combined_hormonal_contraceptives/human_referral_prac_000016.jsp&mid=WCOb01ac05805c516f	June 2014
Cometriq	Cabozantinib	New active substance, conditional authorisation	Ipsen Pharma	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02640/human_med_001726.jsp&mid=WCOb01ac058001d124	May 2014
Corlentor	Ivabradine	PASS ¹	Les Laboratoires Servier	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Corlentor_and_Procoralan/human_referral_prac_000044.jsp&mid=WCOb01ac05805c516f&source=homeMedSearch&category=human	February 2015
Cosentyx	Secukinumab	New active substance	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03729/human_med_001832.jsp&mid=WCOb01ac058001d124	February 2015
Cotellic	Cobimetinib	New active substance	Roche Registration Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03960/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/02734/human_med_001907.jsp&mid=WCOb01ac058001d124	November 2015
Cuvitru 200 mg/ml solution for injection (also known in some EU countries as Ventygard)	Immunglobulin	New biological	Baxalta Innovations GmbH, Austria	http://mri.cts-mrp.eu/Human/Product/Details/47869	September 2017
Cyltezo	Adalimumab	New biological	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04319/human_med_002181.jsp&mid=WCOb01ac058001d124	November 2017
Cyproterone acetate and Ethinylestradiol containing medicinal products (For full list of products see Annex I)	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/referrals/Cyproterone_and_ethinylestradiol-containing_medicines/human_referral_prac_000017.jsp&mid=WCOb01ac05805c516f	August 2013
Cyramza	Ramucirumab	New active substance	Eli Lilly Nederland B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02829/human_med_001825.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/03768/human_med_001792.jsp&mid=WCOb01ac058001d124	September 2014
Deliresp**	Roflumilast	PASS¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/062399/human_med_001415.jsp&mid=WCOb01ac058001d124	June 2013
Darzalex	Daratumumab	New active substance	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04077/human_med_001979.jsp&mid=WCOb01ac058001d124	June 2016
Daxas	Roflumilast	PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01179/human_med_001363.jsp&mid=WCOb01ac058001d124	June 2013
Defitelio	Defibrotide	New biological, authorised under exceptional circumstances	Gentium S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02393/human_med_001646.jsp&mid=WCOb01ac058001d124	November 2013
Deltvba	Delamanid	New active substance, conditional authorisation	Otsuka Novel Products GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02552/human_med_001699.jsp&mid=WCOb01ac058001d124	May 2014
Descovy	Emtricitabine/tenofovir alafenamide	New active substance	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04094/human_med_001978.jsp&mid=WCOb01ac058001d124	May 2016

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Dexamed and associated names (dexamfetamine sulphate-containing medicinal products in the EU) (For full list of products see Annex XII)	Dexamfetamine sulphate	PASS ¹	Various (For full list see Annex XII)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Dexamed_and_associated_names/human_referral_000373.jsp&mid=WCOb01ac05805c516f	September 2014
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/03918/human_med_002104.jsp&mid=WCOb01ac058001d124	May 2017
Domperidone-containing medicinal products (For full list of products see Annex X)	Domperidone	PASS ¹	Various (For full list see Annex X)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Domperidone-containing_medicines/human_referral_prac_000021.jsp&mid=WCOb01ac05805c516f	July 2014
Duaklir Genuair	Acclidinium bromide/formoterol fumarate dihydrate	PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03745/human_med_001811.jsp&mid=WCOb01ac058001d124	December 2014
Dupixent	Dupilumab	New active substance	Sanofi-Aventis groupe	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04390/human_med_002158.jsp&mid=WCOb01ac058001d124	October 2017
Ebymect	Dapaqliflozin/mefomfin	New active substance	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04162/human_med_001926.jsp&mid=WCOb01ac058001d124	November 2015
Eklira Genuair	Acclidinium bromide	New active substance, PASS ¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02211/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/00700/human_med_000757.jsp&mid=WCOb01ac058001d124	April 2013
Elocta	Efmoroctocoq alfa	New active substance	Swedish Orphan Biovitrum AB (publ)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03964/human_med_001928.jsp&mid=WCOb01ac058001d124	December 2015
Elvanse	Lisdexamphetamine	New active substance	Shire Pharmaceutical Contracts Limited	http://www.mhra.gov.uk/home/groups/sppcil/documents/sppcil/con1470374084134.pdf	April 2013
Empliciti	Elotuzumab	New active substance	Bristol-Myers Squibb Pharma EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03967/human_med_001968.jsp&mid=WCOb01ac058001d124	May 2016
EndolucinBeta	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/03999/human_med_001989.jsp&mid=WCOb01ac058001d124	July 2016
Entresto	Sacubitril/valsartan	New active substance	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04062/human_med_001929.jsp&mid=WCOb01ac058001d124	December 2015
Entyvio	Vedolizumab	New active substance	Takeda Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02782/human_med_001751.jsp&mid=WCOb01ac058001d124	June 2014
Enurev Breezhaler	Glycopyrronium bromide	PASS ¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02691/human_med_001579.jsp&mid=WCOb01ac058001d124	April 2013
Epclusa	Sofosbuvir/velpatasvir	New active substance	Gilead Sciences International Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04210/human_med_001997.jsp&mid=WCOb01ac058001d124	July 2016
Eperzan	Albiquatide	New active substance	GlaxoSmithKline Trading Services Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02735/human_med_001735.jsp&mid=WCOb01ac058001d124	April 2014
Episalvan	Birch bark extract	New active substance	Birken AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03938/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/04192/human_med_002112.jsp&mid=WCOb01ac058001d124	July 2017
Eriveda	Vismodegib	New active substance	Roche Registration Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02602/human_med_001659.jsp&mid=WCOb01ac058001d124	August 2013
Esbriet	Pirfenidone	PASS ¹	Roche Registration Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02154/human_med_001417.jsp&mid=WCOb01ac058001d124	April 2013
Eurartesim	Dihydroartemisinin/piperaquine phosphate	PASS ¹	Alfasiqma S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01199/human_med_001450.jsp&mid=WCOb01ac058001d124	April 2013
Evoltra	Clofarabine	Authorised under exceptional circumstances	Genzyme Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00613/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/03904/human_med_001884.jsp&mid=WCOb01ac058001d124	July 2015

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Exjade	Deferasirox	PASS ¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00670/human_med_000780.isp&mid=WCOb01ac058001d124	April 2013
Exviera	Dasabuvir	New active substance, PASS ¹	AbbVie Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03837/human_med_001833.isp&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/03725/human_med_001895.isp&mid=WCOb01ac058001d124	September 2015
Fasenra	Benralizumab	New biological	AstraZeneca AB	Not yet available	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/03776/human_med_001908.isp&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/04046/human_med_002063.isp&mid=WCOb01ac058001d124	March 2017
FibClot	Human Fibrinogen	New Biological	Laboratoire Francais du Fractionnement et des Biotechnologies	https://portal.dimdi.de/amispb/doc/pei/Web/2613347-spcde-20160201.pdf	July 2016
Fibryga	Human Fibrinogen	New biological	Octapharma GmbH	https://portal.dimdi.de/amispb/doc/pei/Web/2613723-spcde-20170401.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/01032/human_med_001298.isp&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/04020/human_med_001980.isp&mid=WCOb01ac058001d124	June 2016
Fluenz Tetra	Influenza vaccine (live attenuated, nasal)	New biological	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02617/human_med_001713.isp&mid=WCOb01ac058001d124	January 2014
Flupirtine-containing medicinal products (For full list of products see Annex VI)	Flupirtine	PASS ¹	Various (For full list see Annex VI)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Fluopirtine-containing_medicines/human_referral_prac_000019.isp&mid=WCOb01ac05805c516f	February 2014
Fotivda	Tivozanib	New active substance	EUSA Pharma (UK) Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04131/human_med_002146.isp&mid=WCOb01ac058001d124	September 2017
Galafold	Miqalastat	New active substance	Amicus Therapeutics UK Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04059/human_med_001981.isp&mid=WCOb01ac058001d124	June 2016
GalliaPharm	Germanium (⁶⁸ Ge) chloride/gallium (⁶⁸ Ga) chloride	New active substance	Eckert & Zieqler Radiopharma GmbH	http://www.produktresume.dk/docushare/dsweb/Get/Document-33097/Galliapharm%2C+radionuclide+generator.docx	April 2016
Gardasil 9	Human papillomavirus 9-valent vaccine (recombinant, adsorbed)	New active substance	MSD VACCINS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03852/human_med_001863.isp&mid=WCOb01ac058001d124	June 2015
Gazyvaro	Obinutuzumab	New active substance	Roche Registration Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02799/human_med_001780.isp&mid=WCOb01ac058001d124	September 2014
Genvoya	Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide	New active substance	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04042/human_med_001940.isp&mid=WCOb01ac058001d124	December 2015
Gilenya	Fingolimod hydrochloride	PASS ¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02202/human_med_001433.isp&mid=WCOb01ac058001d124	April 2013
Giotrif	Afatinib	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02280/human_med_001698.isp&mid=WCOb01ac058001d124	October 2013
Glivec	Imatinib	PASS ¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00406/human_med_000808.isp&mid=WCOb01ac058001d124	September 2014
Glybera	Alipogene tiparovec	New active substance, authorised under exceptional circumstances	uniQure biopharma B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02145/human_med_001480.isp&mid=WCOb01ac058001d124	April 2013
Glyxambi	Empagliflozin/linagliptin	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03833/human_med_002032.isp&mid=WCOb01ac058001d124	May 2017
Grastofil	Filgrastim	New biological	Apotex Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02150/human_med_001688.isp&mid=WCOb01ac058001d124	November 2013

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Harvoni	Ledipasvir/sofosbuvir	New active substance, PASS ¹	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03850/human_med_001813.jsp&mid=WCOb01ac058001d124	December 2014
Hetlioz	Tasimelepton	New active substance	Vanda Pharmaceuticals Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03870/human_med_001873.jsp&mid=WCOb01ac058001d124	July 2015
Hexacima	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	New biological	Sanofi Pasteur S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02702/human_med_001640.jsp&mid=WCOb01ac058001d124	July 2013
Hexyon	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	New biological	Sanofi Pasteur MSD, SNC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02796/human_med_001641.jsp&mid=WCOb01ac058001d124	July 2013
Holoclar	Ex vivo expanded autologous human corneal epithelial cells containing stem cells	New active substance, conditional authorisation	Chiesi Farmaceutici S.P.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02450/human_med_001844.jsp&mid=WCOb01ac058001d124	March 2015
Hydroxyethyl starch (HES)-containing medicinal products (For full list see Annex V)	Hydroxyethyl starch	PASS ¹	Various (For full list see Annex V)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Hydroxyethyl_starch-containing_medicines/human_referral_prac_000029.jsp&mid=WCOb01ac05805c516f	January 2014
HvQvia	Human normal immunoglobulin	New biological	Baxalta Innovations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02491/human_med_001647.jsp&mid=WCOb01ac058001d124	September 2013
Iblias	Octocog alfa	New biological	Bayer AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04147/human_med_001958.jsp&mid=WCOb01ac058001d124	March 2016
Ibrance	Palbociclib	New active substance	Pfizer Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03853/human_med_002034.jsp&mid=WCOb01ac058001d124	November 2016
Iclusiq	Ponatinib	New active substance	Incyte Biosciences UK Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02695/human_med_001656.jsp&mid=WCOb01ac058001d124	August 2013
Idelvion	Albutrepenonacoq alfa	New active substance	CSL Behring GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03955/human_med_001974.jsp&mid=WCOb01ac058001d124	June 2016
IMBRUVICA	Ibrutinib	New active substance	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03791/human_med_001801.jsp&mid=WCOb01ac058001d124	November 2014
Imlyqic	Talimoqene laherparepvec	New active substance	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02771/human_med_001941.jsp&mid=WCOb01ac058001d124	January 2016
Imnovid (formerly Pomalidomide Celgene)	Pomalidomide	New active substance, PASS ¹	Celgene Europe Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02682/human_med_001669.jsp&mid=WCOb01ac058001d124	September 2013
Imraldi	Adalimumab	New active substance	Samsung Bioepis UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04279/human_med_002147.jsp&mid=WCOb01ac058001d124	September 2017
Imvanex	Modified Vaccinia Ankara virus – Bavarian Nordic (MVA-BN) live virus	New active substance, authorised under exceptional circumstances	Bavarian Nordic A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02596/human_med_001666.jsp&mid=WCOb01ac058001d124	September 2013
Increlex	Mecasermin	Authorised under exceptional circumstances	Ipsen Pharma	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00704/human_med_000829.jsp&mid=WCOb01ac058001d124	April 2013
Incresync	Alogliptin/pioglitazone	New active substance	Takeda Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02178/human_med_001694.jsp&mid=WCOb01ac058001d124	October 2013
Incruse	Umeclidinium bromide	New active substance, PASS ¹	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02809/human_med_001755.jsp&mid=WCOb01ac058001d124	May 2014
Inflectra	Infliximab	New biological	Hospira UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02778/human_med_001677.jsp&mid=WCOb01ac058001d124	October 2013
Influsplit Tetra	Influenza virus inactivated split virion	New biological	Glaxo Group Ltd	https://portal.dimdi.de/amispb/doc/pei/Web/2612711-spcde-20170401.pdf	April 2013
Inhixa	Enoxaparin sodium	New biological	Techdow Europe AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04264/human_med_002020.jsp&mid=WCOb01ac058001d124	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/04303/human_med_002129.jsp&mid=WCOb01ac058001d124	September 2017

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
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/Int_ravenous_iron-containing_medicinal_products/human_referral_000343.jsp&mid=WC0b01ac058005c516f	January 2014
Intuniv	Guanfacine	PASS ¹	Shire Pharmaceuticals Ireland Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03759/human_med_001910.jsp&mid=WC0b01ac058001d124	September 2015
Invokana	Canaqliflozin	New active substance	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02649/human_med_001707.jsp&mid=WC0b01ac058001d124	December 2013
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-20170301.pdf	September 2016
Ivabradine Anpharm	Ivabradine	PASS ¹	ANPHARM Przedsiębiorstwo Farmaceutyczne S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04187/human_med_001911.jsp&mid=WC0b01ac058001d124	September 2015
Izinova (also known in some EU countries as Eziclen)	Sulphate anhydrous, magnesium sulphate heptahydrate, potassium sulphate	PASS ¹	IPSEN PHARMA	http://agence-prd.ansm.sante.fr/php/ecodex/frames.php?specid=65236258&typedoc=R&ref=R0222102.htm	June 2014
Jardiance	Empagliflozin	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02677/human_med_001764.jsp&mid=WC0b01ac058001d124	June 2014
Jaydess (also known in some EU countries as Fleree)	Levonorgestrel	PASS ¹	Bayer AB	https://docep.mpa.se/LMF/Jaydess%20intrauterine%20delivery%20system%20FENG%20SmPC.doc	November 2013
Jetrea***	Ocriplasmin	New active substance	ThromboGenics NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002381/human_med_001629.jsp&mid=WC0b01ac058001d124	April 2013
Jinarc	Tolvaptan	PASS ¹	Otsuka Pharmaceutical Europe Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02788/human_med_001857.jsp&mid=WC0b01ac058001d124	June 2015
Kadcyla	Trastuzumab emtansine	New active substance	Roche Registration Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02389/human_med_001712.jsp&mid=WC0b01ac058001d124	December 2013
Kalvedco	Ivacaftor	PASS ¹	Vertex Pharmaceuticals (U.K.) Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02494/human_med_001575.jsp&mid=WC0b01ac058001d124	April 2013
Kanuma	Sebelipase alfa	New active substance, PASS ¹	Alexion Europe SAS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04004/human_med_001896.jsp&mid=WC0b01ac058001d124	September 2015
Kenprexal	Canagrelor	New active substance	Chiesi Farmaceutici S.P.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03773/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/03906/human_med_001814.jsp&mid=WC0b01ac058001d124	December 2014
Kevzara	Sarilumab	New active substance	Sanofi-Aventis groupe	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04254/human_med_002114.jsp&mid=WC0b01ac058001d124	July 2017
Keytruda	Pembrolizumab	New active substance	Merck Sharp & Dohme Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03820/human_med_001886.jsp&mid=WC0b01ac058001d124	July 2015
Kispilyx	Lenvatinib	New active substance	Eisai Europe Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04224/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/04213/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/02081/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/03825/human_med_001959.jsp&mid=WC0b01ac058001d124	March 2016
Kyntheum	Brodalumab	New active substance	Leo Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03959/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/03790/human_med_001932.jsp&mid=WC0b01ac058001d124	November 2015
Lartruvo	Olaratumab	New active substance, conditional authorisation	Eli Lilly Nederland B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04216/human_med_002036.jsp&mid=WC0b01ac058001d124	November 2016

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Latuda	Lurasidone	New active substance	Sunovion Pharmaceuticals Europe Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02713/human_med_001737.jsp&mid=WCOb01ac058001d124	April 2014
Laventair	Umeclidinium bromide/vilanterol trifenate	New active substance, PASS ¹	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03754/human_med_001756.jsp&mid=WCOb01ac058001d124	June 2014
Lemtrada	Alemtuzumab	New biological	Genzyme Therapeutics Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03718/human_med_001678.jsp&mid=WCOb01ac058001d124	October 2013
Lenvima	Lenvatinib	New active substance	Eisai Europe Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03727/human_med_001864.jsp&mid=WCOb01ac058001d124	June 2015
Libertek****	Refumilast	PASS¹	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002329/human_med_001416.jsp&mid=WCOb01ac058001d124	June 2013
Lifmior	Etanercept	New biological	Pfizer Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04167/human_med_002080.jsp&mid=WCOb01ac058001d124	February 2017
Lixiana	Edoxaban	New active substance	Daiichi Sankyo Europe GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02629/human_med_001874.jsp&mid=WCOb01ac058001d124	July 2015
Lojuxta	Lomitapide	New active substance, authorised under exceptional circumstances	Aegerion Pharmaceuticals Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02578/human_med_001668.jsp&mid=WCOb01ac058001d124	September 2013
Lonquex	Lipeqflirastim	New active substance, PASS ¹	UAB "Sicor Biotech"	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02556/human_med_001667.jsp&mid=WCOb01ac058001d124	September 2013
Lonsurf	Trifluridine / tipiracil	New active substance	Les Laboratoires Servier	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03897/human_med_001975.jsp&mid=WCOb01ac058001d124	May 2016
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/02749/human_med_001875.jsp&mid=WCOb01ac058001d124	July 2015
Lusduna	Insulin glargine	New biological	Merck Sharp & Dohme Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04101/human_med_002058.jsp&mid=WCOb01ac058001d124	January 2017
Lutathera	Lutetium (¹⁷⁷ Lu) oxodotreotide	New active substance	Advanced Accelerator Applications	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04123/human_med_002163.jsp&mid=WCOb01ac058001d124	October 2017
Lymphoseek	Tilmanocept	New active substance	Norgine B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02085/human_med_001827.jsp&mid=WCOb01ac058001d124	December 2014
Lynparza	Olaparib	New active substance	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03726/human_med_001831.jsp&mid=WCOb01ac058001d124	February 2015
MACI ²	Matrix applied characterised autologous cultured chondrocytes	New active substance	Vericel Denmark ApS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02522/human_med_001660.jsp&mid=WCOb01ac058001d124	August 2013
Maviret	Glecaprevir / pibrentasvir	New active substance, PASS ¹	AbbVie Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04430/human_med_002151.jsp&mid=WCOb01ac058001d124	September 2017
Mekinist	Trametinib	New active substance	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02643/human_med_001772.jsp&mid=WCOb01ac058001d124	September 2014
Meriofert (also known in some EU countries as Fertinorm and Eiqenorm)	Menotrophin	New biological	Laboratoires Genévrier 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	Naloxeqol	New active substance	Kyowa Kirin Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02810/human_med_001816.jsp&mid=WCOb01ac058001d124	January 2015
Movymia	Teriparatide	New biological	STADA Arzneimittel AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04368/human_med_002057.jsp&mid=WCOb01ac058001d124	January 2017
Mvasi	bevacizumab	New biological	Amaen Europe B.V.	Not yet available	January 2018
Mysimba	Naltrexone / bupropion	PASS ¹	Orexigen Therapeutics Ireland Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03687/human_med_001845.jsp&mid=WCOb01ac058001d124	April 2015
Naglazyme	Galsulfase	Authorised under exceptional circumstances	BioMarin Europe Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00640/human_med_000918.jsp&mid=WCOb01ac058001d124	April 2013
Natpar	Parathyroid hormone	Conditional authorisation	Shire Pharmaceuticals Ireland Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03861/human_med_002093.jsp&mid=WCOb01ac058001d124	May 2017

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Neoparin	Enoxaparinum natricum	New biological	SciencePharma spółka z ograniczoną odpowiedzialnością spółka komandytowa	http://www.leki-informacje.pl/sites/default/files/Charakterystyka-2016021900000-1576_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/04343/human_med_001982.jsp&mid=WCOb01ac058001d124	June 2016
Neuraceq	Florbetaben (18F)	New active substance	Piramal Imaging Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02553/human_med_001716.jsp&mid=WCOb01ac058001d124	March 2014
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/02246/human_med_001582.jsp&mid=WCOb01ac058001d124	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/03844/human_med_001998.jsp&mid=WCOb01ac058001d124	November 2016
NovoEight	Turoctocoq alfa	New active substance	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02719/human_med_001701.jsp&mid=WCOb01ac058001d124	December 2013
Nucala	Mepolizumab	New active substance	GlaxoSmithKline Trading Services Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03860/human_med_001933.jsp&mid=WCOb01ac058001d124	January 2016
Numeta G16%E medicinal products in the European Union (For full list of products see Annex XI)	Alanine, arginine, aspartic acid, calcium chloride, cysteine, glucose monohydrate, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, magnesium acetate, methionine, olive oil, ornithine hydrochloride, henylalanine, potassium acetate, proline, serine, sodium chloride, sodium glycerophosphate, soybean oil, taurine, threonine, tryptophan, tyrosine, valine	PASS ¹	Baxter (For full list see Annex XI)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Numeta_G13E_and_Numeta_G16E_emulsion_for_infusion/human_referral_prac_000027.jsp&mid=WCOb01ac05805c516f	September 2014
Nuwiq	Simoctocoq alfa	New active substance	Octapharma AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02813/human_med_001781.jsp&mid=WCOb01ac058001d124	September 2014
Obizur	Susoctocoq alfa	New active substance, authorised under exceptional circumstances	Baxalta Innovations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02792/human_med_001918.jsp&mid=WCOb01ac058001d124	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/04093/human_med_002043.jsp&mid=WCOb01ac058001d124	January 2017
Ocrevus	Ocrelizumab	New active substance	Roche Registration Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004043/human_med_002187.jsp&mid=WCOb01ac058001d124	January 2018
Odefsey	Emtricitabine / rilpivirine / tenofovir alafenamide	New active substance	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04156/human_med_001991.jsp&mid=WCOb01ac058001d124	June 2016
Odomzo	Sonidegib	New active substance	Sun Pharmaceutical Industries Europe BV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02839/human_med_001897.jsp&mid=WCOb01ac058001d124	September 2015
Ofev	Nintedanib	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03821/human_med_001834.jsp&mid=WCOb01ac058001d124	February 2015
Olumiant	Baricitinib	New active substance	Eli Lilly Nederland B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04085/human_med_002074.jsp&mid=WCOb01ac058001d124	February 2017
OLYSIO	Simeprevir	New active substance, PASS ¹	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02777/human_med_001766.jsp&mid=WCOb01ac058001d124	June 2014
Oncaspar	Pegasparqase	New biological	Baxalta Innovations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03789/human_med_001949.jsp&mid=WCOb01ac058001d124	January 2016
Onqentys	Opicapone	New active substance	Bial - Portela & C ^o , SA	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02790/human_med_001950.jsp&mid=WCOb01ac058001d124	July 2016
Ontruzant	Trastuzumab	New biological	Samsung Bioepis UK Limited	Not yet available	November 2017
Opdivo	Nivolumab	New active substance	Bristol-Myers Squibb Pharma EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03985/human_med_001876.jsp&mid=WCOb01ac058001d124	July 2015
Opsumit	Macitentan	New active substance	Actelion Registration Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02697/human_med_001717.jsp&mid=WCOb01ac058001d124	February 2014
Optimark	Gadoversetamide	PASS ¹	Mallinckrodt Deutschland GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00745/human_med_000953.jsp&mid=WCOb01ac058001d124	April 2013

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Orbactiv	Oritavancin	New active substance	The Medicines Company UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003785/human_med_001853.isp&mid=WCOb01ac058001d124	April 2015
Orkambi	Lumacaftor/Ivacaftor	New active substance, PASS ¹	Vertex Pharmaceuticals (Europe) Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003954/human_med_001935.isp&mid=WCOb01ac058001d124	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.isp&mid=WCOb01ac058001d124	October 2013
Osseor	Strontium ranelate	PASS ¹	Les Laboratoires Servier	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000561/human_med_000963.isp&mid=WCOb01ac058001d124	August 2013
Otezla	Apremilast	New active substance	Celgene Europe Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003746/human_med_001835.isp&mid=WCOb01ac058001d124	February 2015
Ovaleap	Follitropin alfa	New biological	Teva B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002608/human_med_001689.isp&mid=WCOb01ac058001d124	November 2013
Oxervate	Cenegermine	New active substance	Dompé farmaceutici S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004209/human_med_002135.isp&mid=WCOb01ac058001d124	July 2017
Ozanex (also known in some EU countries as C Ozonexacin)	Ozonoxacin	New active substance	Ferrer Internacional S.A.	https://cima.aemps.es/cima/dochtml/ft/82357/FichaTecnica_82357.html	November 2017
Pandemic influenza vaccine H5N1 AstraZeneca	Pandemic influenza vaccine (H5N1) (live attenuated, nasal)	New active substance, conditional authorisation	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003963/human_med_001984.isp&mid=WCOb01ac058001d124	June 2016
Panzyla	Human normal immunoglobulin	New Biological	Octapharma GmbH	https://portal.dimdi.de/amispb/doc/pei/Web/2613595-spcde-20170501.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.isp&mid=WCOb01ac058001d124	November 2016
Pentrox	Methoxyflurane	PASS ¹	Medical Developments UK Ltd	http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1467955147758.pdf	June 2016
Perjeta*****	Pertuzumab	New active substance, PASS⁺	Roche Registration Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0062547/human_med_001620.isp&mid=WCOb01ac058001d124	April 2013
Pixuvri	Pixantrone	New active substance, conditional authorisation	CTI Life Sciences Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002055/human_med_001549.isp&mid=WCOb01ac058001d124	April 2013
Plegridy	Peginterferon beta-1a	New active substance	BioGen Idec Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002827/human_med_001782.isp&mid=WCOb01ac058001d124	September 2014
Portrazza	Necitumumab	New active substance	Eli Lilly Nederland B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003886/human_med_001953.isp&mid=WCOb01ac058001d124	March 2016
Praluent	Alirocumab	New active substance	Sanofi-Aventis Groupe	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003882/human_med_001915.isp&mid=WCOb01ac058001d124	October 2015
Praxbind	Idarucizumab	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003986/human_med_001938.isp&mid=WCOb01ac058001d124	December 2015
Prevmis	Letermovir	New active substance	Merck Sharp & Dohme Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004536/human_med_002200.isp&mid=WCOb01ac058001d124	January 2018
Procoralan	Ivabradine	PASS ¹	Les Laboratoires Servier	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Co_rlentor_and_Procoralan/human_referral_prac_000044.isp&mid=WCOb01ac05805c516f&source=homeMedSearch&category=human	February 2015
Protelos	Strontium ranelate	PASS ¹	Les Laboratoires Servier	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000560/human_med_000999.isp&mid=WCOb01ac058001d124	August 2013
Qtern	Saxagliptin / dapagliflozin	New active substance	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004057/human_med_002000.isp&mid=WCOb01ac058001d124	July 2016
Quinsair	Levofloxacin	PASS ¹	Chiesi Orphan B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002789/human_med_001846.isp&mid=WCOb01ac058001d124	April 2015
Rapibloc (also known in some EU countries as RAPLOC and Runrapiq)	Landiolol	New active substance	AOP Orphan Pharmaceuticals	Not available	July 2016
Raplixa	Human fibrinogen / human thrombin	New biological	Mallinckrodt Pharmaceuticals Ireland Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002807/human_med_001854.isp&mid=WCOb01ac058001d124	April 2015

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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/03822/human_med_001939.isp&mid=WCOb01ac058001d124	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/03834/human_med_001900.isp&mid=WCOb01ac058001d124	September 2015
Reagila	Cariprazine	New active substance	Gedeon Richter Plc.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02770/human_med_002136.isp&mid=WCOb01ac058001d124	July 2017
Refixia	Nonacog beta pegol	New active substance, PASS ¹	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04178/human_med_002107.isp&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/03994/human_med_002044.isp&mid=WCOb01ac058001d124	May 2017
Relvar Ellipta	Fluticasone furoate/vilanterol trifenate	New active substance, PASS ¹	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02673/human_med_001708.isp&mid=WCOb01ac058001d124	December 2013
Remsima	Infliximab	New biological	Celltrion Healthcare Hunqary Kft.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02576/human_med_001682.isp&mid=WCOb01ac058001d124	October 2013
Repatha	Evolocumab	New active substance	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03766/human_med_001890.isp&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/02739/human_med_001904.isp&mid=WCOb01ac058001d124	September 2015
Revestive	Teduqlutide	PASS ¹	Shire Pharmaceuticals Ireland Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02345/human_med_001583.isp&mid=WCOb01ac058001d124	April 2013
Revinty Ellipta	Fluticasone furoate/vilanterol trifenate	PASS ¹	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02745/human_med_001768.isp&mid=WCOb01ac058001d124	May 2014
Revimid	Lenalidomide	PASS ¹	Celgene Europe Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00717/human_med_001034.isp&mid=WCOb01ac058001d124	June 2014
Rezolsta	Darunavir/cobicistat	New active substance	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02819/human_med_001817.isp&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/04725/human_med_002137.isp&mid=WCOb01ac058001d124	July 2017
Rixathon	Rituximab	New biological	Sandoz GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03903/human_med_002095.isp&mid=WCOb01ac058001d124	June 2017
Riximvo	Rituximab	New biological	Sandoz GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04729/human_med_002116.isp&mid=WCOb01ac058001d124	June 2017
Rixubis	Nonacog gamma	New biological	Baxalta Innovations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03771/human_med_001830.isp&mid=WCOb01ac058001d124	February 2015
Rolufta	Umeclidinium	New active substance, PASS ¹	GlaxoSmithKline Trading Services Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04654/human_med_002085.isp&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/04339/human_med_002096.isp&mid=WCOb01ac058001d124	May 2017
Rydapt	Midostaurin	New active substance	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04095/human_med_002155.isp&mid=WCOb01ac058001d124	October 2017
Saxenda	Liraqlutide	New biological	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03780/human_med_001855.isp&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/02548/human_med_001826.isp&mid=WCOb01ac058001d124	January 2015
Seasonique	Levonorgestrel/ethinylestradiol	PASS ¹	Teva Pharma B.V.	Not available	June 2015
Seebri Breezhaler	Glycopyrronium bromide	PASS ¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02430/human_med_001580.isp&mid=WCOb01ac058001d124	April 2013
Senshio	Ospemifene	New active substance, PASS ¹	Shionogi Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02780/human_med_001837.isp&mid=WCOb01ac058001d124	February 2015

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Sirturo	Bedaquiline	New active substance, conditional authorisation	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02614/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/02846/human_med_001856.jsp&mid=WCOb01ac058001d124	April 2015
Solymbic	Adalimumab	New biological	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04373/human_med_002076.jsp&mid=WCOb01ac058001d124	April 2017
SomaKit TOC	Edotreotide	New active substance	Advanced Accelerator Applications	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04140/human_med_002038.jsp&mid=WCOb01ac058001d124	December 2016
Somatropin Biopartners	Somatropin	New biological	BioPartners GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02196/human_med_001672.jsp&mid=WCOb01ac058001d124	September 2013
Sonazoid powder and solvent for solution of for injection 8 microliter/ml	Perflubrotan	New active substance	GE HEALTHCARE AS	Not available	November 2016
Sovaldi	Sofosbuvir	New active substance, PASS ¹	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02798/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/02661/human_med_001954.jsp&mid=WCOb01ac058001d124	January 2016
Spedra	Avanafil	New active substance	Menarini International Operations Luxembourg S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02581/human_med_001661.jsp&mid=WCOb01ac058001d124	August 2013
Spherox	Spheroids of human autologous matrix-associated chondrocytes	New active substance	CO.DON AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02736/human_med_002138.jsp&mid=WCOb01ac058001d124	July 2017
Spinraza	Nusinersen	New active substance	Biogen Idec Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04312/human_med_002119.jsp&mid=WCOb01ac058001d124	June 2017
Spioito Respimat	Tiotropium Bromide Monohydrate / Olodaterol Hydrochloride	New active substance	Boehringer Ingelheim International GmbH	http://db.cbq-meb.nl/IB-teksten/h115528.pdf	September 2016
Stivarqa	Regorafenib	New active substance	Bayer AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02573/human_med_001684.jsp&mid=WCOb01ac058001d124	September 2013
Strensiq	Asfotase alfa	New active substance, authorised under exceptional circumstances	Alexion Europe SAS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03794/human_med_001901.jsp&mid=WCOb01ac058001d124	September 2015
Stribild	Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil	New active substance	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02574/human_med_001654.jsp&mid=WCOb01ac058001d124	July 2013
Strimvelis	Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence	New active substance, PASS ¹	GlaxoSmithKline Trading Services Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03854/human_med_001985.jsp&mid=WCOb01ac058001d124	June 2016
Striverdi Respimat (also known in some EU countries as Infortispir Respimat)	Olodaterol	New active substance, PASS ¹	Boehringer Ingelheim International GmbH	http://db.cbq-meb.nl/IB-teksten/h112058.pdf	February 2015
Suliqua	Insulin glargine / Ixisenatide	New active substance	Sanofi-Aventis groupe	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04243/human_med_002064.jsp&mid=WCOb01ac058001d124	March 2017
Sylvant	Siltuximab	New active substance, PASS ¹	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03708/human_med_001769.jsp&mid=WCOb01ac058001d124	June 2014
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/04391/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/03770/human_med_001865.jsp&mid=WCOb01ac058001d124	June 2015
Tafinlar	Dabrafenib	New active substance	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02604/human_med_001683.jsp&mid=WCOb01ac058001d124	September 2013
Taqrisso	Osimertinib	New active substance	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04124/human_med_001961.jsp&mid=WCOb01ac058001d124	February 2016
Taltz	Ixekizumab	New active substance	Eli Lilly Nederland B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03943/human_med_001977.jsp&mid=WCOb01ac058001d124	May 2016

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
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=WCOb01ac05805c516f	February 2014
Tecentriq	Atezolizumab	New active substance	Roche Registration Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04143/human_med_002166.jsp&mid=WCOb01ac058001d124	October 2017
Terrosa	Teriparatide	New biological	Gedeon Richter Plc.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03916/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=homeMedSearch&category=human	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/03795/human_med_002024.jsp&mid=WCOb01ac058001d124	September 2016
Tivicay	Dolutegravir	New active substance	ViiV Healthcare UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02753/human_med_001720.jsp&mid=WCOb01ac058001d124	February 2014
Tookad	Padeliporfin	New active substance	Steba Biotech S.A	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04182/human_med_002190.jsp&mid=WCOb01ac058001d124	November 2017
Tovanor Breezhaler	Glycopyrronium bromide	PASS ¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02690/human_med_001581.jsp&mid=WCOb01ac058001d124	April 2013
Translarna	Ataluren	New active substance, conditional authorisation	PTC Therapeutics Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02720/human_med_001742.jsp&mid=WCOb01ac058001d124	September 2014
Tremfya	Guselkumab	New active substance	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04271/human_med_002183.jsp&mid=WCOb01ac058001d124	November 2017
Triumeq	Dolutegravir/abacavir/lamivudine	New active substance	ViiV Healthcare UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02754/human_med_001796.jsp&mid=WCOb01ac058001d124	October 2014
Truberzi	Eluxadoline	New active substance	Allergan Pharmaceuticals International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04098/human_med_002025.jsp&mid=WCOb01ac058001d124	October 2016
Trulicity	Dulaglutide	New active substance	Eli Lilly Nederland B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02825/human_med_001821.jsp&mid=WCOb01ac058001d124	December 2014
Trumenba	Meningococcal group B vaccine (recombinant, component)	New active substance	Pfizer Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04051/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/04112/human_med_002077.jsp&mid=WCOb01ac058001d124	March 2017
Tuxella	Rituximab	New biological	Celltrion Healthcare Hungary Kft.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04724/human_med_002140.jsp&mid=WCOb01ac058001d124	July 2017
Tybost	Cobicistat	New active substance	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02572/human_med_001690.jsp&mid=WCOb01ac058001d124	October 2013
Tysabri	Natalizumab	PASS ¹	Biogen Idec Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00603/human_med_001119.jsp&mid=WCOb01ac058001d124	April 2013
Ultibro Breezhaler	Indacaterol/glycopyrronium bromide	PASS ¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02679/human_med_001691.jsp&mid=WCOb01ac058001d124	October 2013
Ulnar Breezhaler	Indacaterol/glycopyrronium bromide	PASS ¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03875/human_med_001758.jsp&mid=WCOb01ac058001d124	July 2014
Upravi	Selexipag	New active substance	Actelion Registration Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03774/human_med_001970.jsp&mid=WCOb01ac058001d124	June 2016
Valproate and related substances (sodium valproate, valproic acid, valproate semisodium, valpromide-containing medicinal products) (For full list of products see Annex XIII)	Sodium valproate, valproic acid, valproate semisodium, valpromide	PASS 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

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Varqatef	Nintedanib	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02569/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/04196/human_med_002097.jsp&mid=WCOb01ac058001d124	May 2017
Vaxelis Vaxigrip Tetra (also known in some EU countries as quadrivalent influenza vaccine (split virion, inactivated))	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/03982/human_med_001962.jsp&mid=WCOb01ac058001d124	February 2016
	Influenza vaccine (split virion, inactivated)	New biological	Sanofi Pasteur MSD GmbH	https://portal.dimdi.de/amispb/doc/pei/Web/2613624-spcde-20170701.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/00920/human_med_001129.jsp&mid=WCOb01ac058001d124	April 2013
Velporo	Mixture of polynuclear iron(III)-oxyhydroxide, sucrose and starches	New active substance	Vifor Fresenius Medical Care Renal Pharma France	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02705/human_med_001795.jsp&mid=WCOb01ac058001d124	September 2014
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/04180/human_med_002141.jsp&mid=WCOb01ac058001d124	September 2017
Vemlidy	Tenofovir alafenamide	New active substance	Gilead Sciences International Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04169/human_med_002061.jsp&mid=WCOb01ac058001d124	January 2017
Venclyxto	Venetoclax	New active substance, conditional authorisation	AbbVie Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04106/human_med_002045.jsp&mid=WCOb01ac058001d124	December 2016
Vepacel	A/H5N1 pre-pandemic influenza vaccine (whole virion, vero cell derived, inactivated)	New active substance	Nanotherapeutics UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02089/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/04446/human_med_002197.jsp&mid=WCOb01ac058001d124	November 2017
Vibativ	Telavancin	PASS ¹	Theravance Biopharma Ireland Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01240/human_med_001467.jsp&mid=WCOb01ac058001d124	May 2014
Viekirax	Ombitasvir/paritaprevir/ritonavir	New active substance, PASS ¹	AbbVie Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03839/human_med_001838.jsp&mid=WCOb01ac058001d124	February 2015
Vihuma	Simoctocog alfa	New active substance	Octapharma AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04459/human_med_002078.jsp&mid=WCOb01ac058001d124	April 2017
Vimizim	Elosulfase alfa	New active substance, PASS ¹	BioMarin Europe Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02779/human_med_001759.jsp&mid=WCOb01ac058001d124	June 2014
Vipdomet	Aloqliptin/metformin	New active substance	Takeda Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02654/human_med_001695.jsp&mid=WCOb01ac058001d124	October 2013
Vipidia	Aloqliptin	New active substance	Takeda Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02182/human_med_001696.jsp&mid=WCOb01ac058001d124	October 2013
Vizamyl	Flutemetamol (18F)	New active substance	GE Healthcare Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02557/human_med_001794.jsp&mid=WCOb01ac058001d124	September 2014
Vokanamet	Canaqliflozin/metformin hydrochloride	New active substance	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02656/human_med_001760.jsp&mid=WCOb01ac058001d124	May 2014
Voncento	Human coagulation factor VIII/human von Willebrand factor	New biological	CLS Behring GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02493/human_med_001670.jsp&mid=WCOb01ac058001d124	October 2013
Vosevi	Sofosbuvir / velpatasvir / voxilaprevir	New active substance, PASS ¹	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04350/human_med_002153.jsp&mid=WCOb01ac058001d124	September 2017
Vvndaqel	Tafamidis	Authorised under exceptional circumstances	Pfizer Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02294/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/02616/human_med_002153.jsp&mid=WCOb01ac058001d124	April 2016
Xadaaq	Safinamide	New active substance	Zambon S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02396/human_med_001847.jsp&mid=WCOb01ac058001d124	March 2015
Xaavid	Anaarelide	Authorised under exceptional circumstances	Shire Pharmaceutical Contracts Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00480/human_med_001153.jsp&mid=WCOb01ac058001d124	April 2013

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Xalkori	Crizotinib	New active substance	Pfizer Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02489/human_med_001592.jsp&mid=WCOb01ac058001d124	April 2013
Xarelto	Rivaroxaban	PASS ¹	Bayer Pharma AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00944/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/04214/human_med_001662.jsp&mid=WCOb01ac058001d124	April 2017
Xermelo	Telotristat	New active substance	Ipsen Pharma	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03937/human_med_002168.jsp&mid=WCOb01ac058001d124	September 2017
Xqeva	Denosumab	New biological	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02173/human_med_001463.jsp&mid=WCOb01ac058001d124	April 2013
Xiqduo	Dapaqliflozin/metformin	New active substance	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02672/human_med_001721.jsp&mid=WCOb01ac058001d124	February 2014
Xofiqo	Radium Ra 223 dichloride	New active substance	Bayer AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02653/human_med_001692.jsp&mid=WCOb01ac058001d124	December 2013
Xoterna Breezhaler	Indacaterol/glycopyrronium bromide	PASS ¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03755/human_med_001693.jsp&mid=WCOb01ac058001d124	October 2013
Xtandi	Enzalutamide	New active substance	Astellas Pharma Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02639/human_med_001663.jsp&mid=WCOb01ac058001d124	August 2013
Xultophy	Insulin deqludec/liraglutide	New biological	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02647/human_med_001802.jsp&mid=WCOb01ac058001d124	October 2014
Xydalba	Dalbavancin	New active substance	Allerqan Pharmaceuticals International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02840/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
Yervoy	Ipilimumab	PASS ¹	Bristol-Myers Squibb Pharma EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02213/human_med_001465.jsp&mid=WCOb01ac058001d124	April 2013
Zalmoxis	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 herpes simplex 1 virus thymidine kinase (HSV-TK Mut2)	New active substance, conditional authorisation	MolMed S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02801/human_med_002016.jsp&mid=WCOb01ac058001d124	September 2016
Zavicefta	Ceftazidime / avibactam	New active substance	Pfizer Ireland Pharmaceuticals	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04027/human_med_001993.jsp&mid=WCOb01ac058001d124	July 2016
ZeJula	Niraparib	New active substance	TESARO UK LIMITED	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04249/human_med_002192.jsp&mid=WCOb01ac058001d124	November 2017
Zepatier	Elbasvir / grazoprevir	New active substance	Merck Sharp & Dohme Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04126/human_med_002001.jsp&mid=WCOb01ac058001d124	September 2016
Zerbaxa Zevtera 500 mg powder for concentrate for solution for infusion (also known in some EU countries as Mabelio)	Ceftolozane / tazobactam	New active substance	Merck Sharp & Dohme Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03772/human_med_001917.jsp&mid=WCOb01ac058001d124	September 2015
	Ceftobiprole medocartil sodium	New active substance	Basilea Medical Ltd	http://www.mhra.gov.uk/home/groups/spccpil/documents/spccpil/con1448606619300.pdf	June 2016
Zinbryta	Daclizumab	New biological	Biogen Idec Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03862/human_med_001987.jsp&mid=WCOb01ac058001d124	July 2016
Zinplava	Bezlotoxumab	New active substance	Merck Sharp & Dohme Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04136/human_med_002062.jsp&mid=WCOb01ac058001d124	February 2017
Zoely	Nomegestrol/Estradiol	PASS ¹	Teva B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01213/human_med_001452.jsp&mid=WCOb01ac058001d124	January 2014
Zurampic	Lesinurad	New active substance, PASS ¹	Grünenthal GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03932/human_med_001963.jsp&mid=WCOb01ac058001d124	March 2016
Zydeliq	Idelalisib	New active substance	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03843/human_med_001803.jsp&mid=WCOb01ac058001d124	October 2014

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Zykadia	Ceritinib	New active substance	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03819/human_med_001860.jsp&mid=WC0b01ac058001d124	May 2015

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.

* Five years following its authorisation, Albumeon is no longer considered a new active substance. It is therefore removed from this list.

** At the marketing authorisation holder's request, the marketing authorisation granted by Decision C(2011)1467(final) for "Daliresp - roflumilast", has been withdrawn on 11 January 2018.

*** Five years following its authorisation, Jetrea is no longer considered a new active substance. It is therefore removed from this list.

**** At the marketing authorisation holder's request, the marketing authorisation granted by Decision C(2011)1471(final) for "Libertek - roflumilast", has been withdrawn on 11 January 2018.

***** Five years following its authorisation and after completion of the imposed BERENICE PASS, Perjeta is no longer under additional monitoring, therefore it is removed from this list.