

28 March 2018  
EMA/245297/2013 Rev.54  
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](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](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 March 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 Nederland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02835/human_med_001790.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02835/human_med_001790.jsp&amp;mid=WC0b01ac058001d124</a>	October 2014
Acarizax (also known in some EU countries as MITIZAX)	Standardised allergen extract from house dust mites	New Biological	ALK-Abelló A/S	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613318-spcde-20170401.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613318-spcde-20170401.pdf</a>	May 2016
Accofil	Filgrastim	New biological	Accord Healthcare Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03956/human_med_001798.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03956/human_med_001798.jsp&amp;mid=WC0b01ac058001d124</a>	October 2014
Adcetris	Brentuximab vedotin	New active substance, conditional authorisation	Takeda Pharma A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02455/human_med_001588.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02455/human_med_001588.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Adempas	Riociquat	New active substance	Bayer AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02737/human_med_001733.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02737/human_med_001733.jsp&amp;mid=WC0b01ac058001d124</a>	April 2014
Adynovi	Rurioctocog alfa peqol	New active substance, PASS <sup>1</sup>	Baxalta Innovations GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04195/human_med_002204.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04195/human_med_002204.jsp&amp;mid=WC0b01ac058001d124</a>	January 2018
Afstyla	Ionoctocog alfa	New active substance	CSL Behring GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04075/human_med_002055.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04075/human_med_002055.jsp&amp;mid=WC0b01ac058001d124</a>	January 2017
Aitaro	Standardised allergen extract from house dust mites	New Biological	ALK-Abelló A/S	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613636-spcde-20170401.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613636-spcde-20170401.pdf</a>	June 2016
Akynzeo	Netupitant/palonosetron	New active substance	Helsinn Birex Pharmaceuticals Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03728/human_med_001862.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03728/human_med_001862.jsp&amp;mid=WC0b01ac058001d124</a>	June 2015
Alecensa	Alectinib	New active substance	Roche Registration GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04164/human_med_002068.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04164/human_med_002068.jsp&amp;mid=WC0b01ac058001d124</a>	March 2017
Alprolix	Eftrenonacoq alfa	New active substance	Swedish Orphan Biovitrum AB (publ)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04142/human_med_001973.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04142/human_med_001973.jsp&amp;mid=WC0b01ac058001d124</a>	May 2016
Amqevita	Adalimumab	New biological	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04212/human_med_002081.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04212/human_med_002081.jsp&amp;mid=WC0b01ac058001d124</a>	April 2017
Amitend (also known in some EU countries as ACARIZAX)	Standardised allergen extract from house dust mites	New Biological	ALK-Abelló A/S	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613637-spcde-20170401.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613637-spcde-20170401.pdf</a>	July 2016
AMITIZA 24 microgram soft capsules	Lubiproston	New active substance	Sucampo Pharma Europe Ltd.	<a href="http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1459748713655.pdf">http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1459748713655.pdf</a>	September 2015
Anoro	Umeclidinium bromide/vilanterol trifenate	New active substance, PASS <sup>1</sup>	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02751/human_med_001754.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02751/human_med_001754.jsp&amp;mid=WC0b01ac058001d124</a>	June 2014
Apleek	Ethinyl estradiol/gestodene	PASS <sup>1</sup>	Bayer Pharma AG	<a href="http://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA1410-069-001_04042014155117.pdf">http://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA1410-069-001_04042014155117.pdf</a>	September 2014

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Atriance	Nelarabine	Authorised under exceptional circumstances	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000752/human_med_000656.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000752/human_med_000656.isp&amp;mid=WCOb01ac058001d124</a>	April 2013
ATryn	Anti-thrombin alpha	Authorised under exceptional circumstances	Laboratoire français du Fractionnement et des Biotechnologies	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000587/human_med_000658.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000587/human_med_000658.isp&amp;mid=WCOb01ac058001d124</a>	April 2013
Aubagio	Teriflunomide	New active substance	Sanofi-aventis Groupe	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002514/human_med_001645.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002514/human_med_001645.isp&amp;mid=WCOb01ac058001d124</a>	October 2013
Axumin	Fluciclovine ( <sup>18</sup> F)	New active substance	Blue Earth Diagnostics Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004197/human_med_002100.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004197/human_med_002100.isp&amp;mid=WCOb01ac058001d124</a>	June 2017
Bavencio	Avelumab	New active substance, conditional authorisation	Merck Serono Europe Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004338/human_med_002157.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004338/human_med_002157.isp&amp;mid=WCOb01ac058001d124</a>	September 2017
Bemfoia	Follitropin alfa	New biological	Gedeon Richter Plc.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002615/human_med_001734.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002615/human_med_001734.isp&amp;mid=WCOb01ac058001d124</a>	May 2014
Benepali	Etanercept	New biological	Samsung Bioepis UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004007/human_med_001944.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004007/human_med_001944.isp&amp;mid=WCOb01ac058001d124</a>	January 2016
Benlysta	Belimumab	PASS <sup>1</sup>	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002015/human_med_001466.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002015/human_med_001466.isp&amp;mid=WCOb01ac058001d124</a>	April 2013
Besponsa	Inotuzumab ozoqamicin	New active substance	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004119/human_med_002109.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004119/human_med_002109.isp&amp;mid=WCOb01ac058001d124</a>	July 2017
Bexsero	Meningococcal group-B vaccine (rDNA, component, adsorbed)	New active substance	GSK Vaccines S.r.l.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002333/human_med_001614.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002333/human_med_001614.isp&amp;mid=WCOb01ac058001d124</a>	April 2013
Blinicyto	Blinatumomab	New active substance, conditional authorisation	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003731/human_med_001921.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003731/human_med_001921.isp&amp;mid=WCOb01ac058001d124</a>	December 2015
Blitzima	Rituximab	New biological	Celltrion Healthcare Hungary Kft.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004723/human_med_002125.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004723/human_med_002125.isp&amp;mid=WCOb01ac058001d124</a>	July 2017
Bosulif	Bosutinib	New active substance, conditional authorisation	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002373/human_med_001613.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002373/human_med_001613.isp&amp;mid=WCOb01ac058001d124</a>	April 2013
Bretaris Genuair	Acclidinium bromide	New active substance, PASS <sup>1</sup>	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002706/human_med_001570.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002706/human_med_001570.isp&amp;mid=WCOb01ac058001d124</a>	April 2013
Brimica Genuair	Acclidinium bromide/formoterol fumarate dihydrate	PASS <sup>1</sup>	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003969/human_med_001806.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003969/human_med_001806.isp&amp;mid=WCOb01ac058001d124</a>	December 2014
Brineura	Cerliponase alfa	New active substance, authorised under exceptional circumstances, PASS <sup>1</sup>	BioMarin International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004065/human_med_002111.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004065/human_med_002111.isp&amp;mid=WCOb01ac058001d124</a>	June 2017
Brintellix	Vortioxetine	New active substance	H. Lundbeck A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002717/human_med_001714.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002717/human_med_001714.isp&amp;mid=WCOb01ac058001d124</a>	February 2014
Briviact	Brivaracetam	New active substance	UCB Pharma S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003898/human_med_001945.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003898/human_med_001945.isp&amp;mid=WCOb01ac058001d124</a>	January 2016
Cabometyx	Cabozantinib	New active substance	IpSen Pharma	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004163/human_med_002018.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004163/human_med_002018.isp&amp;mid=WCOb01ac058001d124</a>	September 2016
Caprelsa	Vandetanib	Conditional authorisation	Genzyme Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002315/human_med_001529.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002315/human_med_001529.isp&amp;mid=WCOb01ac058001d124</a>	April 2013
Ceplene	Histamine dihydrochloride	Authorised under exceptional circumstances	Noventia Pharma Srl	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000796/human_med_000691.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000796/human_med_000691.isp&amp;mid=WCOb01ac058001d124</a>	April 2013
Cerdelqa	Eliqlustat	New active substance, PASS <sup>1</sup>	Genzyme Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003724/human_med_001840.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003724/human_med_001840.isp&amp;mid=WCOb01ac058001d124</a>	February 2015
Chenodeoxycholic acid sigma-tau	Chenodeoxycholic acid	Authorised under exceptional circumstances, PASS <sup>1</sup>	Sigma-tau Arzneimittel GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004061/human_med_002019.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004061/human_med_002019.isp&amp;mid=WCOb01ac058001d124</a>	April 2017
Cidofovir 75 mg/ml Concentrate for Solution for Infusion	Cidofovir	PASS <sup>1</sup>	Emcure Pharma UK Limited	<a href="http://www.mhra.gov.uk/home/groups/sppcil/documents/sppcil/con1466141046287.pdf">http://www.mhra.gov.uk/home/groups/sppcil/documents/sppcil/con1466141046287.pdf</a>	May 2016
<a href="#">Cilostazol-containing medicinal products (For full list of products see Annex VIII)</a>	Cilostazol	PASS <sup>1</sup>	Various (For full list see Annex VIII)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cilostazol-containing_medicines/human_referral_000338.isp&amp;mid=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cilostazol-containing_medicines/human_referral_000338.isp&amp;mid=WCOb01ac05805c516f</a>	September 2013

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Cinquaero	Reslizumab	New active substance	Teva Pharmaceuticals Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03912/human_med_002012.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03912/human_med_002012.jsp&amp;mid=WCOb01ac058001d124</a>	September 2016
Cinryze	c1 inhibitor, human	PASS <sup>1</sup>	Shire Services BVBA	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01207/human_med_001448.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01207/human_med_001448.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Cluvot	Human plasma coagulation factor XIII	New biological	CSL Behring GmbH	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613030-spcde-20160401.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613030-spcde-20160401.pdf</a>	May 2015
Coquadex	Human coagulation factor X	New biological	Bio Products Laboratory Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03855/human_med_001967.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03855/human_med_001967.jsp&amp;mid=WCOb01ac058001d124</a>	April 2016
<a href="#">Combined hormonal contraceptives containing chlormadinone</a> (For full list of products see Annex IX)	Chlormadinone Ethinylestradiol, Chlormadinone Acetate Ethinylestradiol	PASS <sup>1</sup>	Various (For full list see Annex IX)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Combined_hormonal_contraceptives/human_referral_prac_000016.jsp&amp;mid=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Combined_hormonal_contraceptives/human_referral_prac_000016.jsp&amp;mid=WCOb01ac05805c516f</a>	June 2014
Cometriq	Cabozantinib	New active substance, conditional authorisation	Ipsen Pharma	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02640/human_med_001726.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02640/human_med_001726.jsp&amp;mid=WCOb01ac058001d124</a>	May 2014
Corlentor	Ivabradine	PASS <sup>1</sup>	Les Laboratoires Servier	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Corlentor_and_Procoralan/human_referral_prac_000044.jsp&amp;mid=WCOb01ac05805c516f&amp;source=homeMedSearch&amp;category=human">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Corlentor_and_Procoralan/human_referral_prac_000044.jsp&amp;mid=WCOb01ac05805c516f&amp;source=homeMedSearch&amp;category=human</a>	February 2015
Cosentivx	Secukinumab	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03729/human_med_001832.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03729/human_med_001832.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Cotellic	Cobimetinib	New active substance	Roche Registration GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03960/human_med_001925.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03960/human_med_001925.jsp&amp;mid=WCOb01ac058001d124</a>	December 2015
Cresemba	Isavuconazole	New active substance	Basilea Medical Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02734/human_med_001907.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02734/human_med_001907.jsp&amp;mid=WCOb01ac058001d124</a>	November 2015
<b>CRYSVITA</b>	<b>Burosumab</b>	<b>New active substance, PASS<sup>1</sup></b>	<b>Kyowa Kirin Limited</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004275/human_med_002224.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004275/human_med_002224.jsp&amp;mid=WCOb01ac058001d124</a>	<b>March 2018</b>
Cuvitru 200 mg/ml solution for injection (also known in some EU countries as Ventygard)	Immunoglobulin	New biological	Baxalta Innovations GmbH, Austria	<a href="http://mri.cts-mrp.eu/Human/Product/Details/47869">http://mri.cts-mrp.eu/Human/Product/Details/47869</a>	September 2017
Cyltezo	Adalimumab	New biological	Boehringer Ingelheim International GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04319/human_med_002181.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04319/human_med_002181.jsp&amp;mid=WCOb01ac058001d124</a>	November 2017
<a href="#">Cyproterone acetate and Ethinylestradiol containing medicinal products</a> (For full list of products see Annex I)	Cyproterone acetate and Ethinylestradiol	PASS <sup>1</sup>	Various (For full list see Annex I)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cyproterone_and_ethinylestradiol-containing_medicines/human_referral_prac_000017.jsp&amp;mid=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cyproterone_and_ethinylestradiol-containing_medicines/human_referral_prac_000017.jsp&amp;mid=WCOb01ac05805c516f</a>	August 2013
Cyramza	Ramucirumab	New active substance	Eli Lilly Nederland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02829/human_med_001825.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02829/human_med_001825.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Daklinza	Daclatasvir	New active substance, PASS <sup>1</sup>	Bristol-Myers Squibb Pharma EEIG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03768/human_med_001792.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03768/human_med_001792.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Darzalex	Daratumumab	New active substance	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04077/human_med_001979.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04077/human_med_001979.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
Daxas	Roflumilast	PASS <sup>1</sup>	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01179/human_med_001363.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01179/human_med_001363.jsp&amp;mid=WCOb01ac058001d124</a>	June 2013
Defitelio	Defibrotide	New biological, authorised under exceptional circumstances	Gentium S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02393/human_med_001646.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02393/human_med_001646.jsp&amp;mid=WCOb01ac058001d124</a>	November 2013
Deltyba	Delamanid	New active substance, conditional authorisation	Otsuka Novel Products GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02552/human_med_001699.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02552/human_med_001699.jsp&amp;mid=WCOb01ac058001d124</a>	May 2014
Descovy	Emtricitabine/tenofovir alafenamide	New active substance	Gilead Sciences International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04094/human_med_001978.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04094/human_med_001978.jsp&amp;mid=WCOb01ac058001d124</a>	May 2016
<a href="#">Dexametamine sulphate-containing medicinal products in the EU</a> (For full list of products see Annex XII)	Dexametamine sulphate	PASS <sup>1</sup>	Various (For full list see Annex XII)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Dexametamine_sulphate-containing_medicines/human_referral_000373.jsp&amp;mid=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Dexametamine_sulphate-containing_medicines/human_referral_000373.jsp&amp;mid=WCOb01ac05805c516f</a>	September 2014

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Dinutuximab beta Apeiron	Dinutuximab beta	New biological, authorised under exceptional circumstances, PASS <sup>1</sup>	EUSA Pharma (UK) Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03918/human_med_002104.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03918/human_med_002104.jsp&amp;mid=WCOb01ac058001d124</a>	May 2017
<a href="#">Domperidone-containing medicinal products</a> (For full list of products see Annex X)	Domperidone	PASS <sup>1</sup>	Various (For full list see Annex X)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Domperidone-containing_medicines/human_referral_prac_000021.jsp&amp;mid=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Domperidone-containing_medicines/human_referral_prac_000021.jsp&amp;mid=WCOb01ac05805c516f</a>	July 2014
Duaklir Genuair	Acridinium bromide/formoterol fumarate dihydrate	PASS <sup>1</sup>	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03745/human_med_001811.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03745/human_med_001811.jsp&amp;mid=WCOb01ac058001d124</a>	December 2014
Dupixent	Dupilumab	New active substance	Sanofi-Aventis groupe	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04390/human_med_002158.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04390/human_med_002158.jsp&amp;mid=WCOb01ac058001d124</a>	October 2017
Ebymect	Dapaqiflozin/meffomin	New active substance	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04162/human_med_001926.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04162/human_med_001926.jsp&amp;mid=WCOb01ac058001d124</a>	November 2015
Eklira Genuair	Acridinium bromide	New active substance, PASS <sup>1</sup>	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002211/human_med_001571.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002211/human_med_001571.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Elaprase	Idursulfase	Authorised under exceptional circumstances	Shire Human Genetic Therapies AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000700/human_med_000757.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000700/human_med_000757.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Elocta	Efmoroctocoq alfa	New active substance	Swedish Orphan Biovitrum AB (publ)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003964/human_med_001928.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003964/human_med_001928.jsp&amp;mid=WCOb01ac058001d124</a>	December 2015
Elvanse	Lisdexamphetamine	New active substance	Shire Pharmaceutical Contracts Limited	<a href="http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1470374084134.pdf">http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1470374084134.pdf</a>	April 2013
Empliciti	Elotuzumab	New active substance	Bristol-Myers Squibb Pharma EEIG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003967/human_med_001968.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003967/human_med_001968.jsp&amp;mid=WCOb01ac058001d124</a>	May 2016
EndolucinBeta	Lutetium (177 Lu) chloride	New active substance	ITG Isotope Technologies Garching GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003999/human_med_001989.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003999/human_med_001989.jsp&amp;mid=WCOb01ac058001d124</a>	July 2016
Entresto	Sacubitril/valsartan	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004062/human_med_001929.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004062/human_med_001929.jsp&amp;mid=WCOb01ac058001d124</a>	December 2015
Entyvio	Vedolizumab	New active substance	Takeda Pharma A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002782/human_med_001751.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002782/human_med_001751.jsp&amp;mid=WCOb01ac058001d124</a>	June 2014
Enurev Breezhaler	Glycopyrronium bromide	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002691/human_med_001579.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002691/human_med_001579.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Epclusa	Sofosbuvir/velpatasvir	New active substance	Gilead Sciences International Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004210/human_med_001997.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004210/human_med_001997.jsp&amp;mid=WCOb01ac058001d124</a>	July 2016
Eperzan	Albiglutide	New active substance	GlaxoSmithKline Trading Services Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002735/human_med_001735.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002735/human_med_001735.jsp&amp;mid=WCOb01ac058001d124</a>	April 2014
Episalvan	Birch bark extract	New active substance	Birken AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003938/human_med_001956.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003938/human_med_001956.jsp&amp;mid=WCOb01ac058001d124</a>	January 2016
Erelzi	Etanercept	New biological	Sandoz GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004192/human_med_002112.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004192/human_med_002112.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Erivedge	Vismodegib	New active substance	Roche Registration GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002602/human_med_001659.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002602/human_med_001659.jsp&amp;mid=WCOb01ac058001d124</a>	August 2013
<del>Esbriet *</del>	<del>Pirfenidone</del>	<del>PASS<sup>1</sup></del>	<del>Roche Registration Limited</del>	<del><a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002154/human_med_001417.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002154/human_med_001417.jsp&amp;mid=WCOb01ac058001d124</a></del>	<del>April 2013</del>
Eurartesim	Dihydroartemisinin/piperaquine phosphate	PASS <sup>1</sup>	Alfaisigma S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001199/human_med_001450.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001199/human_med_001450.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Evoltra	Clofarabine	Authorised under exceptional circumstances	Genzyme Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000613/human_med_000773.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000613/human_med_000773.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Evotaz	Atazanavir / cobicistat	New active substance	Bristol-Myers Squibb Pharma EEIG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003904/human_med_001884.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003904/human_med_001884.jsp&amp;mid=WCOb01ac058001d124</a>	July 2015
Exjade	Deferasirox	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000670/human_med_000780.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000670/human_med_000780.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Exviera	Dasabuvir	New active substance, PASS <sup>1</sup>	AbbVie Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03837/human_med_001833.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03837/human_med_001833.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Farydak	Panobinostat	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03725/human_med_001895.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03725/human_med_001895.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
Fasenra	Benralizumab	New biological	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04433/human_med_002207.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04433/human_med_002207.jsp&amp;mid=WCOb01ac058001d124</a>	January 2018
Fexeric	Ferric citrate coordination complex	New active substance, PASS <sup>1</sup>	Keryx Biopharma UK Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03776/human_med_001908.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03776/human_med_001908.jsp&amp;mid=WCOb01ac058001d124</a>	October 2015
Flasp	Insulin aspart	New biological	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04046/human_med_002063.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04046/human_med_002063.jsp&amp;mid=WCOb01ac058001d124</a>	March 2017
FibClot	Human Fibrinogen	New Biological	Laboratoire Français du Fractionnement et des Biotechnologies	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613347-spcdc-20160201.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613347-spcdc-20160201.pdf</a>	July 2016
Fibryqa	Human Fibrinogen	New biological	Octapharma GmbH	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613723-spcdc-20170401.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613723-spcdc-20170401.pdf</a>	July 2017
Firdapse	Amifampridine	Authorised under exceptional circumstances	BioMarin Europe Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01032/human_med_001298.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01032/human_med_001298.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Flixabi	Infliximab	New biological	Samsung Bioepis UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04020/human_med_001980.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04020/human_med_001980.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
Fluenz Tetra	Influenza vaccine (live attenuated, nasal)	New biological	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02617/human_med_001713.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02617/human_med_001713.jsp&amp;mid=WCOb01ac058001d124</a>	January 2014
<a href="#">Flupirtine-containing medicinal products (For full list of products see Annex VI)</a>	Flupirtine	PASS <sup>1</sup>	Various (For full list see Annex VI)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Flupirtine-containing_medicines/human_referral_prac_000019.jsp&amp;mid=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Flupirtine-containing_medicines/human_referral_prac_000019.jsp&amp;mid=WCOb01ac05805c516f</a>	February 2014
Fotivda	Tivozanib	New active substance	EUSA Pharma (UK) Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04131/human_med_002146.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04131/human_med_002146.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Galafold	Migalastat	New active substance	Amicus Therapeutics UK Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04059/human_med_001981.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04059/human_med_001981.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
GalliaPharm	Germanium ( <sup>68</sup> Ge) chloride/gallium ( <sup>68</sup> Ga) chloride	New active substance	Eckert & Zieqler Radiopharma GmbH	<a href="http://www.produktresumee.dk/docushare/dsweb/Get/Document-33097/GalliaPharm%2C+radionuclide+generator.docx">http://www.produktresumee.dk/docushare/dsweb/Get/Document-33097/GalliaPharm%2C+radionuclide+generator.docx</a>	April 2016
Gardasil 9	Human papillomavirus 9-valent vaccine (recombinant, adsorbed)	New active substance	MSD VACCINS	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03852/human_med_001863.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03852/human_med_001863.jsp&amp;mid=WCOb01ac058001d124</a>	June 2015
Gazyvaro	Obinutuzumab	New active substance	Roche Registration Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02799/human_med_001780.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02799/human_med_001780.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Genvoya	Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide	New active substance	Gilead Sciences International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04042/human_med_001940.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04042/human_med_001940.jsp&amp;mid=WCOb01ac058001d124</a>	December 2015
Gilenya	Fingolimod hydrochloride	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02202/human_med_001433.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02202/human_med_001433.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Giotrif	Afatinib	New active substance	Boehringer Ingelheim International GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02280/human_med_001698.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02280/human_med_001698.jsp&amp;mid=WCOb01ac058001d124</a>	October 2013
Glivec	Imatinib	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00406/human_med_000808.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00406/human_med_000808.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
<b>Glybera **</b>	<b>Atipogene tiparvovec</b>	<b>New active substance, authorised under exceptional circumstances</b>	<b>uniQure Biopharma B.V.</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002145/human_med_001480.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002145/human_med_001480.jsp&amp;mid=WCOb01ac058001d124</a>	<b>April 2013</b>
Glyxambi	Empagliflozin/linagliptin	New active substance	Boehringer Ingelheim International GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03833/human_med_002032.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03833/human_med_002032.jsp&amp;mid=WCOb01ac058001d124</a>	May 2017
Grastofil	Filgrastim	New biological	Apotex Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02150/human_med_001688.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02150/human_med_001688.jsp&amp;mid=WCOb01ac058001d124</a>	November 2013
Harvoni	Ledipasvir/sofosbuvir	New active substance, PASS <sup>1</sup>	Gilead Sciences International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03850/human_med_001813.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03850/human_med_001813.jsp&amp;mid=WCOb01ac058001d124</a>	December 2014

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
<b>Hemlibra</b>	<b>Emicizumab</b>	<b>New active substance</b>	<b>Roche Registration Limited</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004406/human_med_002236.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004406/human_med_002236.jsp&amp;mid=WCOb01ac058001d124</a>	<b>March 2018</b>
Herzuma	Trastuzumab	New biological	Celltrion Healthcare Hungary Kft.	<a href="#">Not yet available</a>	February 2018
Hettloz	Tasimelteon	New active substance	Vanda Pharmaceuticals Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03870/human_med_001873.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03870/human_med_001873.jsp&amp;mid=WCOb01ac058001d124</a>	July 2015
Holoclar	Ex vivo expanded autologous human corneal epithelial cells containing stem cells	New active substance, conditional authorisation	Chiesi Farmaceutici S.P.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02450/human_med_001844.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02450/human_med_001844.jsp&amp;mid=WCOb01ac058001d124</a>	March 2015
<a href="#">Hydroxyethyl starch (HES)-containing medicinal products (For full list see Annex V)</a>	Hydroxyethyl starch	PASS <sup>1</sup>	<a href="#">Various (For full list see Annex V)</a>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Hydroxyethyl_starch-containing_medicines/human_referral_prac_000029.jsp&amp;mid=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Hydroxyethyl_starch-containing_medicines/human_referral_prac_000029.jsp&amp;mid=WCOb01ac05805c516f</a>	January 2014
HvQvia	Human normal immunoglobulin	PASS <sup>1</sup>	Baxalta Innovations GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02491/human_med_001647.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02491/human_med_001647.jsp&amp;mid=WCOb01ac058001d124</a>	September 2013
Iblias	Octocoq alfa	New biological	Bayer AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04147/human_med_001958.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04147/human_med_001958.jsp&amp;mid=WCOb01ac058001d124</a>	March 2016
Ibrance	Palbociclib	New active substance	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03853/human_med_002034.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03853/human_med_002034.jsp&amp;mid=WCOb01ac058001d124</a>	November 2016
Iclusiq	Ponatinib	PASS <sup>1</sup>	Incyte Biosciences UK Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02695/human_med_001656.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02695/human_med_001656.jsp&amp;mid=WCOb01ac058001d124</a>	August 2013
Idelvion	Albutrepenonacoq alfa	New active substance	CSL Behring GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03955/human_med_001974.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03955/human_med_001974.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
IMBRUVICA	Ibrutinib	New active substance	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03791/human_med_001801.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03791/human_med_001801.jsp&amp;mid=WCOb01ac058001d124</a>	November 2014
Imlyqic	Talimoqene laherparepvec	New active substance	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02771/human_med_001941.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02771/human_med_001941.jsp&amp;mid=WCOb01ac058001d124</a>	January 2016
Imnovid (formerly Pomalidomide Celqene)	Pomalidomide	New active substance, PASS <sup>1</sup>	Celqene Europe Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02682/human_med_001669.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02682/human_med_001669.jsp&amp;mid=WCOb01ac058001d124</a>	September 2013
Imraldi	Adalimumab	New biological	Samsung Bioepis UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04279/human_med_002147.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04279/human_med_002147.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Imvanex	Modified Vaccinia Ankara virus – Bavarian Nordic (MVA-BN) live virus	New active substance, authorised under exceptional circumstances	Bavarian Nordic A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02596/human_med_001666.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02596/human_med_001666.jsp&amp;mid=WCOb01ac058001d124</a>	September 2013
Increlex	Mecasermin	Authorised under exceptional circumstances	Ipsen Pharma	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00704/human_med_000829.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00704/human_med_000829.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Incresync	Alogliptin/pioglitazone	New active substance	Takeda Pharma A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02178/human_med_001694.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02178/human_med_001694.jsp&amp;mid=WCOb01ac058001d124</a>	October 2013
Incruse	Umeclidinium bromide	New active substance, PASS <sup>1</sup>	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02809/human_med_001755.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02809/human_med_001755.jsp&amp;mid=WCOb01ac058001d124</a>	May 2014
Infectra	Infliximab	New biological	Hospira UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02778/human_med_001677.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02778/human_med_001677.jsp&amp;mid=WCOb01ac058001d124</a>	October 2013
Influsplit Tetra	Influenza virus inactivated split virion	New biological	Glaxo Group Ltd	<a href="https://portal.dlmdi.de/amispb/doc/pei/Web/2612711-spcde-20170401.pdf">https://portal.dlmdi.de/amispb/doc/pei/Web/2612711-spcde-20170401.pdf</a>	April 2013
Inhixa	Enoxaparin sodium	New biological	Techdow Europe AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04264/human_med_002020.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04264/human_med_002020.jsp&amp;mid=WCOb01ac058001d124</a>	September 2016
Insulin lispro Sanofi	Insulin lispro	New biological	Sanofi-Aventis groupe	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04303/human_med_002129.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04303/human_med_002129.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Intrarosa	Prasterone	PASS <sup>1</sup>	Endoceutics Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04138/human_med_002210.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04138/human_med_002210.jsp&amp;mid=WCOb01ac058001d124</a>	February 2018
<a href="#">Intravenous iron-containing medicinal products (For full list see Annex III)</a>	Ferric carboxymaltose, iron dextran, sodium ferric gluconate, iron isomaltoside, iron sucrose	PASS <sup>1</sup>	<a href="#">Various (For full list see Annex III)</a>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Int_ravenous_iron-containing_medicinal_products/human_referral_000343.jsp&amp;mid=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Int_ravenous_iron-containing_medicinal_products/human_referral_000343.jsp&amp;mid=WCOb01ac05805c516f</a>	January 2014

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Intuniv	Guanfacine	PASS <sup>1</sup>	Shire Pharmaceuticals Ireland Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003759/human_med_001910.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003759/human_med_001910.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
Invokana	Canagliflozin	New active substance	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002649/human_med_001707.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002649/human_med_001707.jsp&amp;mid=WCOb01ac058001d124</a>	December 2013
Iqymune (also known in some EU countries as OPTIGLOBIN)	Human normal immunoglobulin	New biological	Laboratoire Francais du Fractionnement et des Biotechnologies	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613314-spocde-20170301.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613314-spocde-20170301.pdf</a>	September 2016
Ivabradine Anpharm	Ivabradine	PASS <sup>1</sup>	ANPHARM Przedsiębiorstwo Farmaceutyczne S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004187/human_med_001911.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004187/human_med_001911.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
Izinova (also known in some EU countries as Eziclen)	Sodium sulphate anhydrous, magnesium sulphate heptahydrate, potassium sulphate	PASS <sup>1</sup>	IPSEN PHARMA	<a href="http://agence-prd.ansm.sante.fr/php/ecodex/frames.php?specid=65236258&amp;typedoc=R&amp;ref=R0222102.htm">http://agence-prd.ansm.sante.fr/php/ecodex/frames.php?specid=65236258&amp;typedoc=R&amp;ref=R0222102.htm</a>	June 2014
Jardiance	Empagliflozin	New active substance	Boehringer Ingelheim International GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002677/human_med_001764.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002677/human_med_001764.jsp&amp;mid=WCOb01ac058001d124</a>	June 2014
Jaydess (also known in some EU countries as Fleree)	Levonorgestrel	PASS <sup>1</sup>	Bayer AB	<a href="https://doceip.mpa.se/LMF/Jaydess%20intrauterine%20delivery%20system%20FENG%20SmPC.doc">https://doceip.mpa.se/LMF/Jaydess%20intrauterine%20delivery%20system%20FENG%20SmPC.doc</a>	November 2013
Jinarc	Tolvaptan	PASS <sup>1</sup>	Otsuka Pharmaceutical Europe Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002788/human_med_001857.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002788/human_med_001857.jsp&amp;mid=WCOb01ac058001d124</a>	June 2015
Kadcyla	Trastuzumab emtansine	New active substance	Roche Registration Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002389/human_med_001712.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002389/human_med_001712.jsp&amp;mid=WCOb01ac058001d124</a>	December 2013
Kalydeco	Ivacaftor	PASS <sup>1</sup>	Vertex Pharmaceuticals (U.K.) Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002494/human_med_001575.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002494/human_med_001575.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Kanuma	Sebelipase alfa	New active substance, PASS <sup>1</sup>	Alexion Europe SAS	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004004/human_med_001896.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004004/human_med_001896.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
Kengrexal	Cangrelor	New active substance	Chiesi Farmaceutici S.P.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003773/human_med_001852.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003773/human_med_001852.jsp&amp;mid=WCOb01ac058001d124</a>	April 2015
Ketoconazole HRA	Ketoconazole	PASS <sup>1</sup>	Laboratoire HRA Pharma	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003906/human_med_001814.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003906/human_med_001814.jsp&amp;mid=WCOb01ac058001d124</a>	December 2014
Kevzara	Sarilumab	New active substance	Sanofi-Aventis groupe	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004254/human_med_002114.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004254/human_med_002114.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Keytruda	Pembrolizumab	New active substance	Merck Sharp & Dohme Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003820/human_med_001886.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003820/human_med_001886.jsp&amp;mid=WCOb01ac058001d124</a>	July 2015
Kisplyx	Lenvatinib	New active substance	Eisai Europe Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004224/human_med_002021.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004224/human_med_002021.jsp&amp;mid=WCOb01ac058001d124</a>	September 2016
Kisqali	Ribociclib	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004213/human_med_002149.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004213/human_med_002149.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Kolbam (previously Cholic Acid FGK)	Cholic acid	Authorised under exceptional circumstances	Retrophin Europe Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002081/human_med_001718.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002081/human_med_001718.jsp&amp;mid=WCOb01ac058001d124</a>	May 2014
Kovaltry	Octocoq alfa	New biological	Bayer AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003825/human_med_001959.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003825/human_med_001959.jsp&amp;mid=WCOb01ac058001d124</a>	March 2016
Kyntheum	Brodalumab	New active substance	Leo Pharma A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003959/human_med_002054.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003959/human_med_002054.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Kyprolis	Carfilzomib	New active substance	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003790/human_med_001932.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003790/human_med_001932.jsp&amp;mid=WCOb01ac058001d124</a>	November 2015
Lartruvo	Olaratumab	New active substance, conditional authorisation	Eli Lilly Nederland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004216/human_med_002036.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004216/human_med_002036.jsp&amp;mid=WCOb01ac058001d124</a>	November 2016
Latuda	Lurasidone	New active substance	Aziende Chimiche Riunite Angelini Francesco – A.C.R.A.F. S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002713/human_med_001737.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002713/human_med_001737.jsp&amp;mid=WCOb01ac058001d124</a>	April 2014
Laventair	Umeclidinium bromide/vilanterol trifenate	New active substance, PASS <sup>1</sup>	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003754/human_med_001756.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003754/human_med_001756.jsp&amp;mid=WCOb01ac058001d124</a>	June 2014
Lemtrada	Alemtuzumab	New biological	Genzyme Therapeutics Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003718/human_med_001678.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003718/human_med_001678.jsp&amp;mid=WCOb01ac058001d124</a>	October 2013

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Lenvima	Lenvatinib	New active substance	Eisai Europe Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03727/human_med_001864.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03727/human_med_001864.isp&amp;mid=WCOb01ac058001d124</a>	June 2015
Lifmior	Etanercept	New biological	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04167/human_med_002080.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04167/human_med_002080.isp&amp;mid=WCOb01ac058001d124</a>	February 2017
Lixiana	Edoxaban	New active substance	Daiichi Sankyo Europe GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02629/human_med_001874.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02629/human_med_001874.isp&amp;mid=WCOb01ac058001d124</a>	July 2015
Lojuxta	Lomitapide	New active substance, authorised under exceptional circumstances	Aegerion Pharmaceuticals Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02578/human_med_001668.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02578/human_med_001668.isp&amp;mid=WCOb01ac058001d124</a>	September 2013
Lonquex	Lipeglifragstim	New active substance, PASS <sup>1</sup>	UAB "Sicor Biotech"	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02556/human_med_001667.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02556/human_med_001667.isp&amp;mid=WCOb01ac058001d124</a>	September 2013
Lonsurf	Trifluridine / tipiracil	New active substance	Les Laboratoires Servier	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03897/human_med_001975.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03897/human_med_001975.isp&amp;mid=WCOb01ac058001d124</a>	May 2016
Lumark	Lutetium, isotope of mass 177	New active substance	IDB Holland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02749/human_med_001875.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02749/human_med_001875.isp&amp;mid=WCOb01ac058001d124</a>	July 2015
Lusduna	Insulin glargine	New biological	Merck Sharp & Dohme Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04101/human_med_002058.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04101/human_med_002058.isp&amp;mid=WCOb01ac058001d124</a>	January 2017
Lutathera	Lutetium ( <sup>177</sup> Lu) oxodotreotide	New active substance	Advanced Accelerator Applications	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04123/human_med_002163.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04123/human_med_002163.isp&amp;mid=WCOb01ac058001d124</a>	October 2017
Lymphoseek	Tilmanocept	New active substance	Norain B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02085/human_med_001827.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02085/human_med_001827.isp&amp;mid=WCOb01ac058001d124</a>	December 2014
Lynparza	Olaparib	New active substance	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03726/human_med_001831.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03726/human_med_001831.isp&amp;mid=WCOb01ac058001d124</a>	February 2015
MACI <sup>2</sup>	Matrix applied characterised autologous cultured chondrocytes	New active substance	Vericel Denmark ApS	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02522/human_med_001660.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02522/human_med_001660.isp&amp;mid=WCOb01ac058001d124</a>	August 2013
Maviret	Glecaprevir / pibrentasvir	New active substance, PASS <sup>1</sup>	AbbVie Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04430/human_med_002151.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04430/human_med_002151.isp&amp;mid=WCOb01ac058001d124</a>	September 2017
Mekinist	Trametinib	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02643/human_med_001772.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02643/human_med_001772.isp&amp;mid=WCOb01ac058001d124</a>	September 2014
Meriofert (also known in some EU countries as Fertinorm and Eigenorm)	Menotrophin	New biological	Laboratoires Genévrier SA	<a href="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">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</a>	March 2015
Moventiq	Naloxeqol	New active substance	Kyowa Kirin Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02810/human_med_001816.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02810/human_med_001816.isp&amp;mid=WCOb01ac058001d124</a>	January 2015
Movymia	Teriparatide	New biological	STADA Arzneimittel AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04368/human_med_002057.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04368/human_med_002057.isp&amp;mid=WCOb01ac058001d124</a>	January 2017
Mvasi	bevacizumab	New biological	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04728/human_med_002217.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04728/human_med_002217.isp&amp;mid=WCOb01ac058001d124</a>	January 2018
Mysimba	Naltrexone / bupropion	PASS <sup>1</sup>	Orexigen Therapeutics Ireland Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03687/human_med_001845.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03687/human_med_001845.isp&amp;mid=WCOb01ac058001d124</a>	April 2015
Naglazyme	Galsulfase	Authorised under exceptional circumstances	BioMarin Europe Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00640/human_med_000918.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00640/human_med_000918.isp&amp;mid=WCOb01ac058001d124</a>	April 2013
Natpar	Parathyroid hormone	Conditional authorisation	Shire Pharmaceuticals Ireland Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03861/human_med_002093.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03861/human_med_002093.isp&amp;mid=WCOb01ac058001d124</a>	May 2017
Neoparin	Enoxaparinum natriicum	New biological	SciencePharma spółka z ograniczoną odpowiedzialnością spółka komandytowa	<a href="http://www.leki-informacje.pl/sites/default/files/Charakterystyka-20160219000000-1576_N-20160308000147.pdf">http://www.leki-informacje.pl/sites/default/files/Charakterystyka-20160219000000-1576_N-20160308000147.pdf</a>	April 2016
Neparvis	Sacubitril / valsartan	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04343/human_med_001982.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04343/human_med_001982.isp&amp;mid=WCOb01ac058001d124</a>	June 2016
Neuraceq	Florbetaben (18F)	New active substance	Piramal Imaging Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02553/human_med_001716.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02553/human_med_001716.isp&amp;mid=WCOb01ac058001d124</a>	March 2014
NexoBrid	Concentrate of proteolytic enzymes enriched in bromelain	PASS <sup>1</sup>	MediWound Germany GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02246/human_med_001582.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02246/human_med_001582.isp&amp;mid=WCOb01ac058001d124</a>	April 2013



Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Ninlaro	Ixazomib	New active substance, conditional authorisation	Takeda Pharma A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03844/human_med_001998.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03844/human_med_001998.jsp&amp;mid=WCOb01ac058001d124</a>	November 2016
NovoEight	Turoctocoq alfa	New active substance	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02719/human_med_001701.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02719/human_med_001701.jsp&amp;mid=WCOb01ac058001d124</a>	December 2013
Nucala	Mepolizumab	New active substance	GlaxoSmithKline Trading Services Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03860/human_med_001933.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03860/human_med_001933.jsp&amp;mid=WCOb01ac058001d124</a>	January 2016
<a href="#">Numeta G16%E medicinal products in the European Union (For full list of products see Annex XI)</a>	Alanine, arginine, aspartic acid, calcium chloride, cysteine, glucose monohydrate, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, magnesium acetate, methionine, olive oil, ornithine hydrochloride, phenylalanine, potassium acetate, proline, serine, sodium chloride, sodium glycerophosphate, soybean oil, taurine, threonine, tryptophan, tyrosine, valine	PASS <sup>1</sup>	Baxter (For full list see Annex XI)	<a href="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&amp;mid=WCOb01ac05805c516f">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&amp;mid=WCOb01ac05805c516f</a>	September 2014
Nuwiq	Simoctocoq alfa	New active substance	Octapharma AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02813/human_med_001781.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02813/human_med_001781.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Obizur	Susoctocoq alfa	New active substance, authorised under exceptional circumstances	Baxalta Innovations GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02792/human_med_001918.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02792/human_med_001918.jsp&amp;mid=WCOb01ac058001d124</a>	November 2015
Ocaliva	Obeticholic acid	New active substance, conditional authorisation	Intercept Pharma Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04093/human_med_002043.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04093/human_med_002043.jsp&amp;mid=WCOb01ac058001d124</a>	January 2017
Ocrevus	Ocrelizumab	New active substance	Roche Registration Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04043/human_med_002187.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04043/human_med_002187.jsp&amp;mid=WCOb01ac058001d124</a>	January 2018
Odefsey	Emtricitabine / rilpivirine / tenofovir alafenamide	New active substance	Gilead Sciences International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04156/human_med_001991.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04156/human_med_001991.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
Odomzo	Sonideqib	New active substance	Sun Pharmaceutical Industries Europe BV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02839/human_med_001897.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02839/human_med_001897.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
Ofev	Nintedanib	New active substance	Boehringer Ingelheim International GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03821/human_med_001834.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03821/human_med_001834.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Olumiant	Baricitinib	New active substance	Eli Lilly Nederland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04085/human_med_002074.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04085/human_med_002074.jsp&amp;mid=WCOb01ac058001d124</a>	February 2017
<b>OLYSIO ***</b>	<b>Simeprevir</b>	<b>New active substance, PASS<sup>+</sup></b>	<b>Janssen-Cilag International NV</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/082777/human_med_001766.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/082777/human_med_001766.jsp&amp;mid=WCOb01ac058001d124</a>	<b>June 2014</b>
Oncaspar	Pegaspargase	New biological	Baxalta Innovations GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03789/human_med_001949.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03789/human_med_001949.jsp&amp;mid=WCOb01ac058001d124</a>	January 2016
Ongentys	Opicapone	New active substance	Bial - Portela & Cº, SA	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02790/human_med_001950.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02790/human_med_001950.jsp&amp;mid=WCOb01ac058001d124</a>	July 2016
Ontruzant	Trastuzumab	New biological	Samsung Bioepis UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04323/human_med_002188.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04323/human_med_002188.jsp&amp;mid=WCOb01ac058001d124</a>	November 2017
Opdivo	Nivolumab	New active substance	Bristol-Myers Squibb Pharma EEIG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03985/human_med_001876.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03985/human_med_001876.jsp&amp;mid=WCOb01ac058001d124</a>	July 2015
Opsumit	Macitentan	New active substance	Actelion Registration Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02697/human_med_001717.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02697/human_med_001717.jsp&amp;mid=WCOb01ac058001d124</a>	February 2014
Optimark	Gadoversetamide	PASS <sup>1</sup>	Mallinckrodt Deutschland GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00745/human_med_000953.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00745/human_med_000953.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Orbactiv	Oritavancin	New active substance	The Medicines Company UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03785/human_med_001853.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03785/human_med_001853.jsp&amp;mid=WCOb01ac058001d124</a>	April 2015
Orkambi	Lumacaftor/Ivacaftor	New active substance, PASS <sup>1</sup>	Vertex Pharmaceuticals (Europe) Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03954/human_med_001935.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03954/human_med_001935.jsp&amp;mid=WCOb01ac058001d124</a>	December 2015
Orphacol	Cholic acid	Authorised under exceptional circumstances	Laboratoires CTRS	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01250/human_med_001419.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01250/human_med_001419.jsp&amp;mid=WCOb01ac058001d124</a>	October 2013
Osseor	Strontium ranelate	PASS <sup>1</sup>	Les Laboratoires Servier	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00561/human_med_000963.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00561/human_med_000963.jsp&amp;mid=WCOb01ac058001d124</a>	August 2013

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Otezla	Apremilast	New active substance	Celgene Europe Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003746/human_med_001835.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003746/human_med_001835.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Ovaleap	Follitropin alfa	New biological	Teva B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002608/human_med_001689.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002608/human_med_001689.jsp&amp;mid=WCOb01ac058001d124</a>	November 2013
Oxervate	Cenegermín	New active substance	Dompé farmaceutici S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004209/human_med_002135.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004209/human_med_002135.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Ozanex (also known in some EU countries as C Ozonoxacin)		New active substance	Ferrer Internacional S.A.	<a href="https://cima.aemps.es/cima/dochtml/ft/82357/FichaTecnica_82357.html">https://cima.aemps.es/cima/dochtml/ft/82357/FichaTecnica_82357.html</a>	November 2017
Ozempic	Semaglutide	New active substance	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004174/human_med_002211.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004174/human_med_002211.jsp&amp;mid=WCOb01ac058001d124</a>	February 2018
Pandemic influenza vaccine H5N1 AstraZeneca	Pandemic influenza vaccine (H5N1) (live attenuated, nasal)	New active substance, conditional authorisation	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003963/human_med_001984.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003963/human_med_001984.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
Panzvqa	Human normal immunoglobulin	New Biological	Octapharma GmbH	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613595-spcde-20170501.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613595-spcde-20170501.pdf</a>	July 2016
Parsabiv	Etelcalcetide	New active substance	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003995/human_med_002037.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003995/human_med_002037.jsp&amp;mid=WCOb01ac058001d124</a>	November 2016
Penthrox	Methoxyflurane	PASS <sup>1</sup>	Medical Developments UK Ltd	<a href="http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1467955147758.pdf">http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1467955147758.pdf</a>	June 2016
Pixuvri	Pixantrone	New active substance, conditional authorisation	CTI Life Sciences Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002055/human_med_001549.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002055/human_med_001549.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Plegridy	Peginterferon beta-1a	New active substance	Biogen Idec Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002827/human_med_001782.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002827/human_med_001782.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Portrazza	Necitumumab	New active substance	Eli Lilly Nederland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003886/human_med_001953.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003886/human_med_001953.jsp&amp;mid=WCOb01ac058001d124</a>	March 2016
Praluent	Alirocumab	New active substance	Sanofi-Aventis Groupe	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003882/human_med_001915.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003882/human_med_001915.jsp&amp;mid=WCOb01ac058001d124</a>	October 2015
Praxbind	Idarucizumab	New active substance	Boehringer Ingelheim International GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003986/human_med_001938.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003986/human_med_001938.jsp&amp;mid=WCOb01ac058001d124</a>	December 2015
Prevmis	Letermovir	New active substance	Merck Sharp & Dohme Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004536/human_med_002200.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004536/human_med_002200.jsp&amp;mid=WCOb01ac058001d124</a>	January 2018
Procoralan	Ivabradine	PASS <sup>1</sup>	Les Laboratoires Servier	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Co_rlentor_and_Procoralan/human_referral_prac_000044.jsp&amp;mid=WCOb01ac05805c516f&amp;source=homeMedSearch&amp;category=human">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Co_rlentor_and_Procoralan/human_referral_prac_000044.jsp&amp;mid=WCOb01ac05805c516f&amp;source=homeMedSearch&amp;category=human</a>	February 2015
Protelos	Strontium ranelate	PASS <sup>1</sup>	Les Laboratoires Servier	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000560/human_med_000999.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000560/human_med_000999.jsp&amp;mid=WCOb01ac058001d124</a>	August 2013
Qtern	Saxagliptin / dapagliflozin	New active substance	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004057/human_med_002000.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004057/human_med_002000.jsp&amp;mid=WCOb01ac058001d124</a>	July 2016
Quinsair	Levofloxacin	PASS <sup>1</sup>	Chiesi Orphan B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002789/human_med_001846.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002789/human_med_001846.jsp&amp;mid=WCOb01ac058001d124</a>	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	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002807/human_med_001854.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002807/human_med_001854.jsp&amp;mid=WCOb01ac058001d124</a>	April 2015
Ravicti	Glycerol phenylbutyrate	New active substance, PASS <sup>1</sup>	Horizon Pharma Ireland Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003822/human_med_001939.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003822/human_med_001939.jsp&amp;mid=WCOb01ac058001d124</a>	January 2016
Raxone	Idebenone	Authorised under exceptional circumstances	Santhera Pharmaceuticals (Deutschland) GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003834/human_med_001900.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003834/human_med_001900.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
Reagila	Cariprazine	New active substance	Gedeon Richter Plc.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002770/human_med_002136.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002770/human_med_002136.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Refixia	Nonacog beta pegol	New active substance, PASS <sup>1</sup>	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004178/human_med_002107.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004178/human_med_002107.jsp&amp;mid=WCOb01ac058001d124</a>	June 2017

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Rekovelte	Follitropin delta	New biological	Ferring Pharmaceuticals A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03994/human_med_002044.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03994/human_med_002044.isp&amp;mid=WCOb01ac058001d124</a>	May 2017
Relvar Ellipta	Fluticasone furoate/vilanterol trifenate	New active substance, PASS <sup>1</sup>	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02673/human_med_001708.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02673/human_med_001708.isp&amp;mid=WCOb01ac058001d124</a>	December 2013
Remsima	Infliximab	New biological	Celltrion Healthcare Hungary Kft.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02576/human_med_001682.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02576/human_med_001682.isp&amp;mid=WCOb01ac058001d124</a>	October 2013
Repatha	Evolocumab	New active substance	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03766/human_med_001890.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03766/human_med_001890.isp&amp;mid=WCOb01ac058001d124</a>	September 2015
Respreeza	Human alpha1-proteinase inhibitor	New biological	CSL Behring GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02739/human_med_001904.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02739/human_med_001904.isp&amp;mid=WCOb01ac058001d124</a>	September 2015
Revestive	Teduglutide	PASS <sup>1</sup>	Shire Pharmaceuticals Ireland Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02345/human_med_001583.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02345/human_med_001583.isp&amp;mid=WCOb01ac058001d124</a>	April 2013
Revinty Ellipta	Fluticasone furoate/vilanterol trifenate	PASS <sup>1</sup>	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02745/human_med_001768.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02745/human_med_001768.isp&amp;mid=WCOb01ac058001d124</a>	May 2014
Revlimid	Lenalidomide	PASS <sup>1</sup>	Celgene Europe Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00717/human_med_001034.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00717/human_med_001034.isp&amp;mid=WCOb01ac058001d124</a>	June 2014
Rezolsta	Darunavir/cobicistat	New active substance	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02819/human_med_001817.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02819/human_med_001817.isp&amp;mid=WCOb01ac058001d124</a>	February 2015
Ritemvia	Rituximab	New biological	Celltrion Healthcare Hungary Kft.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04725/human_med_002137.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04725/human_med_002137.isp&amp;mid=WCOb01ac058001d124</a>	July 2017
Rixathon	Rituximab	New biological	Sandoz GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03903/human_med_002095.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03903/human_med_002095.isp&amp;mid=WCOb01ac058001d124</a>	June 2017
Riximyo	Rituximab	New biological	Sandoz GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04729/human_med_002116.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04729/human_med_002116.isp&amp;mid=WCOb01ac058001d124</a>	June 2017
Rixubis	Nonacoq gamma	New biological	Baxalta Innovations GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03771/human_med_001830.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03771/human_med_001830.isp&amp;mid=WCOb01ac058001d124</a>	February 2015
Rolufta	Umeclidinium	New active substance, PASS <sup>1</sup>	GlaxoSmithKline Trading Services Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04654/human_med_002085.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04654/human_med_002085.isp&amp;mid=WCOb01ac058001d124</a>	March 2017
Roteas	Edoxaban	New active substance	Daiichi Sankyo Europe GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04339/human_med_002096.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04339/human_med_002096.isp&amp;mid=WCOb01ac058001d124</a>	May 2017
Rydapt	Midostaurin	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04095/human_med_002155.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04095/human_med_002155.isp&amp;mid=WCOb01ac058001d124</a>	October 2017
Saxenda	Liraglutide	New biological	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03780/human_med_001855.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03780/human_med_001855.isp&amp;mid=WCOb01ac058001d124</a>	April 2015
Scenesse	Afamelanotide	New active substance, authorised under exceptional circumstances	Clinuvel UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02548/human_med_001826.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02548/human_med_001826.isp&amp;mid=WCOb01ac058001d124</a>	January 2015
Seasonique	Levonorgestrel/ethinylestradiol	PASS <sup>1</sup>	Teva Pharma B.V.	Not available	June 2015
Seebri Breezhaler	Glycopyrronium bromide	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02430/human_med_001580.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02430/human_med_001580.isp&amp;mid=WCOb01ac058001d124</a>	April 2013
Senshio	Ospemifene	New active substance, PASS <sup>1</sup>	Shionogi Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02780/human_med_001837.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02780/human_med_001837.isp&amp;mid=WCOb01ac058001d124</a>	February 2015
Sirturo	Bedaquiline	New active substance, conditional authorisation	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02614/human_med_001730.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02614/human_med_001730.isp&amp;mid=WCOb01ac058001d124</a>	March 2014
Sivextro	Tedizolid phosphate	New active substance	Merck Sharp & Dohme Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02846/human_med_001856.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02846/human_med_001856.isp&amp;mid=WCOb01ac058001d124</a>	April 2015
Solymbic	Adalimumab	New biological	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04373/human_med_002076.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04373/human_med_002076.isp&amp;mid=WCOb01ac058001d124</a>	April 2017
SomaKit TOC	Edotreotide	New active substance	Advanced Accelerator Applications	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04140/human_med_002038.isp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04140/human_med_002038.isp&amp;mid=WCOb01ac058001d124</a>	December 2016

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Somatropin Biopartners	Somatropin	New biological	BioPartners GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02196/human_med_001672.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02196/human_med_001672.jsp&amp;mid=WCOb01ac058001d124</a>	September 2013
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	New active substance, PASS <sup>1</sup>	Gilead Sciences International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02798/human_med_001723.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02798/human_med_001723.jsp&amp;mid=WCOb01ac058001d124</a>	February 2014
Spectrila	Asparaginase	New biological	Medac Gesellschaft für klinische Spezialpräparate mbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02661/human_med_001954.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02661/human_med_001954.jsp&amp;mid=WCOb01ac058001d124</a>	January 2016
Spedra	Avanafil	New active substance	Menarini International Operations Luxembourg S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02581/human_med_001661.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02581/human_med_001661.jsp&amp;mid=WCOb01ac058001d124</a>	August 2013
Spherox	Spheroids of human autologous matrix-associated chondrocytes	New active substance	CO.DON AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02736/human_med_002138.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02736/human_med_002138.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Spinraza	Nusinersen	New active substance	Bioeqn Idec Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04312/human_med_002119.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04312/human_med_002119.jsp&amp;mid=WCOb01ac058001d124</a>	June 2017
Spilto Respimat	Tiotropium Bromide Monohydrate / Olodaterol Hydrochloride	New active substance	Boehringer Ingelheim International GmbH	<a href="http://db.cbq-meb.nl/IB-teksten/h115528.pdf">http://db.cbq-meb.nl/IB-teksten/h115528.pdf</a>	September 2016
Stivarqa	Regorafenib	New active substance	Bayer AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02573/human_med_001684.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02573/human_med_001684.jsp&amp;mid=WCOb01ac058001d124</a>	September 2013
Strensiq	Asfotase alfa	New active substance, authorised under exceptional circumstances	Alexion Europe SAS	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03794/human_med_001901.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03794/human_med_001901.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
Stribild	Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil	New active substance	Gilead Sciences International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02574/human_med_001654.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02574/human_med_001654.jsp&amp;mid=WCOb01ac058001d124</a>	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 <sup>1</sup>	GlaxoSmithKline Trading Services Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03854/human_med_001985.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03854/human_med_001985.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
Striverdi Respimat (also known in some EU countries as Infortispir Respimat)	Olodaterol	New active substance, PASS <sup>1</sup>	Boehringer Ingelheim International GmbH	<a href="http://db.cbq-meb.nl/IB-teksten/h112058.pdf">http://db.cbq-meb.nl/IB-teksten/h112058.pdf</a>	February 2015
Suliqua	Insulin glargine / lixisenatide	New active substance	Sanofi-Aventis groupe	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04243/human_med_002064.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04243/human_med_002064.jsp&amp;mid=WCOb01ac058001d124</a>	March 2017
Sylvant	Siltuximab	New active substance, PASS <sup>1</sup>	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03708/human_med_001769.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03708/human_med_001769.jsp&amp;mid=WCOb01ac058001d124</a>	June 2014
Symtuza	Darunavir / cobicistat / emtricitabine / tenofovir alafenamide	New active substance	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04391/human_med_002165.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04391/human_med_002165.jsp&amp;mid=WCOb01ac058001d124</a>	October 2017
Synjardy	Empagliflozin/metformin	New active substance	Boehringer Ingelheim International GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03770/human_med_001865.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03770/human_med_001865.jsp&amp;mid=WCOb01ac058001d124</a>	June 2015
Tafinlar	Dabrafenib	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02604/human_med_001683.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02604/human_med_001683.jsp&amp;mid=WCOb01ac058001d124</a>	September 2013
Taqrisso	Osimertinib	New active substance	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04124/human_med_001961.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04124/human_med_001961.jsp&amp;mid=WCOb01ac058001d124</a>	February 2016
Taltz	Ixekizumab	New active substance	Eli Lilly Nederland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03943/human_med_001977.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03943/human_med_001977.jsp&amp;mid=WCOb01ac058001d124</a>	May 2016
<a href="#">Targocid and associated names (teicoplanin-containing medicinal products) (For full list see Annex VII)</a>	Teicoplanin	PASS <sup>1</sup>	Various (For full list see Annex VII)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Targocid_and_associated_names/human_referral_000341.jsp&amp;mid=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Targocid_and_associated_names/human_referral_000341.jsp&amp;mid=WCOb01ac05805c516f</a>	February 2014
Tecentriq	Atezolizumab	New active substance	Roche Registration GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04143/human_med_002166.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04143/human_med_002166.jsp&amp;mid=WCOb01ac058001d124</a>	October 2017
Terrosa	Teriparatide	New biological	Gedeon Richter Plc.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03916/human_med_002060.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03916/human_med_002060.jsp&amp;mid=WCOb01ac058001d124</a>	January 2017

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
<a href="#">Thiocolchicoside-containing medicinal products</a> (For full list see Annex IV)	Thiocolchicoside	PASS <sup>1</sup>	Various (For full list see Annex IV)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Thiocolchicoside-containing_medicines/human_referral_000356.jsp&amp;mid=WCOb01ac058005c516f&amp;source=homeMedSearch&amp;category=human">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Thiocolchicoside-containing_medicines/human_referral_000356.jsp&amp;mid=WCOb01ac058005c516f&amp;source=homeMedSearch&amp;category=human</a>	January 2014
Thiosix	Tioquanin	Authorised under exceptional circumstances	Teva Nederland B.V.	<a href="http://db.cbq-meb.nl/IB-teksten/h114681.pdf">http://db.cbq-meb.nl/IB-teksten/h114681.pdf</a>	May 2015
Thorinane	Enoxaparin sodium	New biological	Techdow Pharma Netherlands B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03795/human_med_002024.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03795/human_med_002024.jsp&amp;mid=WCOb01ac058001d124</a>	September 2016
Tivicay	Dolutegravir	New active substance	ViiV Healthcare UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02753/human_med_001720.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02753/human_med_001720.jsp&amp;mid=WCOb01ac058001d124</a>	February 2014
Tookad	Padeliporfin	New active substance	Steba Biotech S.A	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04182/human_med_002190.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04182/human_med_002190.jsp&amp;mid=WCOb01ac058001d124</a>	November 2017
Tovanor Breezhaler	Glycopyrronium bromide	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02690/human_med_001581.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02690/human_med_001581.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Translarna	Ataluren	New active substance, conditional authorisation	PTC Therapeutics Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02720/human_med_001742.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02720/human_med_001742.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Tremfya	Guselkumab	New active substance	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04271/human_med_002183.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04271/human_med_002183.jsp&amp;mid=WCOb01ac058001d124</a>	November 2017
Triumeq	Dolutegravir/abacavir/lamivudine	New active substance	ViiV Healthcare UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02754/human_med_001796.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02754/human_med_001796.jsp&amp;mid=WCOb01ac058001d124</a>	October 2014
Truberzi	Eluxadoline	New active substance	Allergan Pharmaceuticals International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04098/human_med_002025.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04098/human_med_002025.jsp&amp;mid=WCOb01ac058001d124</a>	October 2016
Trulicity	Dulaqlutide	New active substance	Eli Lilly Nederland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02825/human_med_001821.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02825/human_med_001821.jsp&amp;mid=WCOb01ac058001d124</a>	December 2014
Trumenba	Meningococcal group B vaccine (recombinant, componen	New active substance	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04051/human_med_002101.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04051/human_med_002101.jsp&amp;mid=WCOb01ac058001d124</a>	June 2017
Truxima	Rituximab	New biological	Celltrion Healthcare Hungary Kft.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04112/human_med_002077.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04112/human_med_002077.jsp&amp;mid=WCOb01ac058001d124</a>	March 2017
Tuxella	Rituximab	New biological	Celltrion Healthcare Hungary Kft.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04724/human_med_002140.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04724/human_med_002140.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Tybost	Cobicistat	New active substance	Gilead Sciences International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02572/human_med_001690.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02572/human_med_001690.jsp&amp;mid=WCOb01ac058001d124</a>	October 2013
Tysabri	Natalizumab	PASS <sup>1</sup>	Biogen Idec Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00603/human_med_001119.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00603/human_med_001119.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Ultibro Breezhaler	Indacaterol/dlvcopyrronium bromide	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02679/human_med_001691.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02679/human_med_001691.jsp&amp;mid=WCOb01ac058001d124</a>	October 2013
Ulunar Breezhaler	Indacaterol/dlvcopyrronium bromide	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03875/human_med_001758.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03875/human_med_001758.jsp&amp;mid=WCOb01ac058001d124</a>	July 2014
Uptravi	Selexipag	New active substance	Actellon Registration Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03774/human_med_001970.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03774/human_med_001970.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
<a href="#">Valproate and related substances (sodium valproate, valproic acid, valproate semisodium, valpromide-containing medicinal products)</a> (For full list of products see Annex XIII)	Sodium valproate, valproic acid, valproate semisodium, valpromide	PASS <sup>1</sup>	Various (For full list see Annex XIII)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Valproate_and_related_substances/human_referral_prac_000032.jsp&amp;mid=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Valproate_and_related_substances/human_referral_prac_000032.jsp&amp;mid=WCOb01ac05805c516f</a>	January 2015
Vargatef	Nintedanib	New active substance	Boehringer Ingelheim International GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02569/human_med_001822.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02569/human_med_001822.jsp&amp;mid=WCOb01ac058001d124</a>	December 2014
Varuby	Rolapitant	New active substance	Tesaro UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04196/human_med_002097.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04196/human_med_002097.jsp&amp;mid=WCOb01ac058001d124</a>	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.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03982/human_med_001962.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03982/human_med_001962.jsp&amp;mid=WCOb01ac058001d124</a>	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	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613624-spode-20170701.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613624-spode-20170701.pdf</a>	September 2016
Vedrop	Tocofersolan d-alpha tocopheryl polyethylene glycol succinate	Authorised under exceptional circumstances	Orphan Europe S.A.R.L.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00920/human_med_001129.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00920/human_med_001129.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Velporo	Mixture of polynuclear iron(III)-oxyhydroxide, sucrose and starches	New active substance	Vifor Fresenius Medical Care Renal Pharma France	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02705/human_med_001795.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02705/human_med_001795.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Veltassa	Patiromer	New active substance	Vifor Fresenius Medical Care Renal Pharma France	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04180/human_med_002141.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04180/human_med_002141.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Vemlidy	Tenofovir alafenamide	New active substance	Gilead Sciences International Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04169/human_med_002061.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04169/human_med_002061.jsp&amp;mid=WCOb01ac058001d124</a>	January 2017
Venclyxto	Venetoclax	New active substance, conditional authorisation	AbbVie Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04106/human_med_002045.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04106/human_med_002045.jsp&amp;mid=WCOb01ac058001d124</a>	December 2016
Vepacel	A/H5N1 pre-pandemic influenza vaccine (whole virion, vero cell derived, inactivated)	New active substance	Nanotherapeutics UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02089/human_med_001543.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02089/human_med_001543.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
VeraSeal	Human fibrinogen / human thrombin	New biological	Instituto Grifols, S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04446/human_med_002197.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04446/human_med_002197.jsp&amp;mid=WCOb01ac058001d124</a>	November 2017
Vibativ	Telavancin	PASS <sup>1</sup>	Theravance Biopharma Ireland Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01240/human_med_001467.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01240/human_med_001467.jsp&amp;mid=WCOb01ac058001d124</a>	May 2014
Viekirax	Ombitasvir/paritaprevir/ritonavir	New active substance, PASS <sup>1</sup>	AbbVie Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03839/human_med_001838.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03839/human_med_001838.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Vihuma	Simocotocog alfa	New active substance	Octapharma AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04459/human_med_002078.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04459/human_med_002078.jsp&amp;mid=WCOb01ac058001d124</a>	April 2017
Vimizim	Elosulfase alfa	New active substance, PASS <sup>1</sup>	BioMarin Europe Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02779/human_med_001759.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02779/human_med_001759.jsp&amp;mid=WCOb01ac058001d124</a>	June 2014
Vipdomet	Aloqliptin/metformin	New active substance	Takeda Pharma A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02654/human_med_001695.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02654/human_med_001695.jsp&amp;mid=WCOb01ac058001d124</a>	October 2013
Vipidia	Aloqliptin	New active substance	Takeda Pharma A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02182/human_med_001696.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02182/human_med_001696.jsp&amp;mid=WCOb01ac058001d124</a>	October 2013
Vizamyl	Flutemetamol (18F)	New active substance	GE Healthcare Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02557/human_med_001794.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02557/human_med_001794.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Vokanamet	Canaqliflozin/metformin hydrochloride	New active substance	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02656/human_med_001760.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02656/human_med_001760.jsp&amp;mid=WCOb01ac058001d124</a>	May 2014
Voncento	Human coagulation factor VIII/human von Willebrand factor	New biological	CLS Behring GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02493/human_med_001670.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02493/human_med_001670.jsp&amp;mid=WCOb01ac058001d124</a>	October 2013
Vosevi	Sofosbuvir / velpatasvir / voxilaprevir	New active substance, PASS <sup>1</sup>	Gilead Sciences International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04350/human_med_002153.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04350/human_med_002153.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Vyndaqel	Tafamidis	Authorised under exceptional circumstances	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02294/human_med_001498.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02294/human_med_001498.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Wakix	Pitolisant hydrochloride	New active substance, PASS <sup>1</sup>	Bioprojet Pharma	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02616/human_med_001955.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02616/human_med_001955.jsp&amp;mid=WCOb01ac058001d124</a>	April 2016
Xadaqo	Safinamide	New active substance	Zambon S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02396/human_med_001847.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02396/human_med_001847.jsp&amp;mid=WCOb01ac058001d124</a>	March 2015
Xaqid	Anaerelide	Authorised under exceptional circumstances	Shire Pharmaceutical Contracts Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00480/human_med_001153.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00480/human_med_001153.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Xalkori	Crizotinib	New active substance	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02489/human_med_001592.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02489/human_med_001592.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Xarelto	Rivaroxaban	PASS <sup>1</sup>	Bayer Pharma AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00944/human_med_001155.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00944/human_med_001155.jsp&amp;mid=WCOb01ac058001d124</a>	July 2013
Xeljanz	Tofacitinib	New active substance	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04214/human_med_001662.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04214/human_med_001662.jsp&amp;mid=WCOb01ac058001d124</a>	April 2017

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Xermelo	Telostristat	New active substance	Ipsen Pharma	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03937/human_med_002168.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03937/human_med_002168.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Xgeva	Denosumab	New biological	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02173/human_med_001463.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02173/human_med_001463.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Xigduo	Dapagliflozin/metformin	New active substance	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02672/human_med_001721.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02672/human_med_001721.jsp&amp;mid=WCOb01ac058001d124</a>	February 2014
Xofiqo	Radium Ra 223 dichloride	New active substance	Bayer AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02653/human_med_001692.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02653/human_med_001692.jsp&amp;mid=WCOb01ac058001d124</a>	December 2013
Xoterna Breezhaler	Indacaterol/glycopyrronium bromide	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03755/human_med_001693.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03755/human_med_001693.jsp&amp;mid=WCOb01ac058001d124</a>	October 2013
Xultophy	Insulin degludec/liraglutide	New biological	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02647/human_med_001802.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02647/human_med_001802.jsp&amp;mid=WCOb01ac058001d124</a>	October 2014
Xydalba	Dalbavancin	New active substance	Allergan Pharmaceuticals International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02840/human_med_001848.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02840/human_med_001848.jsp&amp;mid=WCOb01ac058001d124</a>	March 2015
Yanimo RespiMAT	Tiotropium Bromide Monohydrate / Olodaterol Hydrochloride	New active substance	Boehringer Ingelheim International GmbH	<a href="http://db.cbq-meb.nl/IB-teksten/h115529.pdf">http://db.cbq-meb.nl/IB-teksten/h115529.pdf</a>	September 2016
<del>Yervoy ****</del>	<del>Ipilimumab</del>	<del>PASS<sup>1</sup></del>	<del>Bristol-Myers Squibb Pharma-EEIG</del>	<del><a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002213/human_med_001465.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002213/human_med_001465.jsp&amp;mid=WCOb01ac058001d124</a></del>	<del>April 2013</del>
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.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02801/human_med_002016.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02801/human_med_002016.jsp&amp;mid=WCOb01ac058001d124</a>	September 2016
Zavicefta	Ceftazidime / avibactam	New active substance	Pfizer Ireland Pharmaceuticals	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04027/human_med_001993.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04027/human_med_001993.jsp&amp;mid=WCOb01ac058001d124</a>	July 2016
Zejula	Niraparib	New active substance	TESARO UK LIMITED	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04249/human_med_002192.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04249/human_med_002192.jsp&amp;mid=WCOb01ac058001d124</a>	November 2017
Zepatier	Elbasvir / grazoprevir	New active substance	Merck Sharp & Dohme Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04126/human_med_002001.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04126/human_med_002001.jsp&amp;mid=WCOb01ac058001d124</a>	September 2016
Zerbaxa	Ceftolozane / tazobactam	New active substance	Merck Sharp & Dohme Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03772/human_med_001917.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03772/human_med_001917.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
Zevtera 500 mg powder for concentrate for solution for infusion (also known in some EU countries as Mabello)	Ceftobiprole medocartil sodium	New active substance	Basilea Medical Ltd	<a href="http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1448606619300.pdf">http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1448606619300.pdf</a>	June 2016
Zinbryta	Daclizumab	New biological	Biogen Idec Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03862/human_med_001987.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03862/human_med_001987.jsp&amp;mid=WCOb01ac058001d124</a>	July 2016
Zinplava	Bezlotoxumab	New active substance	Merck Sharp & Dohme Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04136/human_med_002062.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04136/human_med_002062.jsp&amp;mid=WCOb01ac058001d124</a>	February 2017
Zoely	Nomegestrol/Estradiol	PASS <sup>1</sup>	Teva B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01213/human_med_001452.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01213/human_med_001452.jsp&amp;mid=WCOb01ac058001d124</a>	January 2014
Zurampic	Lesinurad	New active substance, PASS <sup>1</sup>	Grünenthal GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03932/human_med_001963.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03932/human_med_001963.jsp&amp;mid=WCOb01ac058001d124</a>	March 2016
Zydeliq	Idelalisib	New active substance	Gilead Sciences International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03843/human_med_001803.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03843/human_med_001803.jsp&amp;mid=WCOb01ac058001d124</a>	October 2014
Zykadia	Ceritinib	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03819/human_med_001860.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03819/human_med_001860.jsp&amp;mid=WCOb01ac058001d124</a>	May 2015

<sup>1</sup> 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.

\* The Post Authorisation Safety Study (PASS) previously imposed on Esbriet has been completed, therefore this medicinal product is no longer under additional monitoring.

\*\* The marketing authorisation of Glybera has expired therefore this medicinal product is removed from the list.

\*\*\* At the marketing authorisation holder's request, the marketing authorisation granted by Decision C(2014)3368(final) for "OLYSIO - simeprevir" was withdrawn on 5 March 2018.

\*\*\*\* The Post Authorisation Safety Study (PASS) previously imposed on Yervoy has been completed, therefore this medicinal product is no longer under additional monitoring.

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
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