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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 September 2017 are shown in red font. All products removed from the list are shown with a strikethrough for the period of one month after which they are excluded.**

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Abasaqlar (previously Abasria)	Insulin glargine	New biological	Eli Lilly Regional Operations GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002835/human_med_001790.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002835/human_med_001790.jsp&amp;mid=WCoB01ac058001d124</a>	October 2014
Acarizax	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> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003956/human_med_001798.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003956/human_med_001798.jsp&amp;mid=WCoB01ac058001d124</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/002455/human_med_001588.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002455/human_med_001588.jsp&amp;mid=WCoB01ac058001d124</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/002737/human_med_001733.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002737/human_med_001733.jsp&amp;mid=WCoB01ac058001d124</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/004075/human_med_002055.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004075/human_med_002055.jsp&amp;mid=WCoB01ac058001d124</a>	April 2014
Afstyla	Ionococog alfa	New active substance	CSL Behring GmbH	<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> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003728/human_med_001862.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003728/human_med_001862.jsp&amp;mid=WCoB01ac058001d124</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> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003728/human_med_001862.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003728/human_med_001862.jsp&amp;mid=WCoB01ac058001d124</a>	June 2016
Akynzeo	Netupitant/palonosetron	New active substance	Helsinn Birex Pharmaceuticals Ltd	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2612980-spcde-20160401.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2612980-spcde-20160401.pdf</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004164/human_med_002068.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004164/human_med_002068.jsp&amp;mid=WCoB01ac058001d124</a>	June 2015
Albumeon	Human albumin	New biological	CSL Behring GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004142/human_med_001973.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004142/human_med_001973.jsp&amp;mid=WCoB01ac058001d124</a>	July 2015
Alecensa	Alectinib	New active substance, conditional authorisation	Roche Registration Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004212/human_med_002081.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004212/human_med_002081.jsp&amp;mid=WCoB01ac058001d124</a>	March 2017
Alprolix	Eftrenonacoq alfa	New active substance	Biogen Idec Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004212/human_med_002081.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004212/human_med_002081.jsp&amp;mid=WCoB01ac058001d124</a>	May 2016
Amgevita	Adalimumab	New biological	Amgen Europe B.V.	<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>	April 2017
Amitend	Standardised allergen extract from house dust mites	New Biological	ALK-Abelló A/S	<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> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002422/human_med_001611.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002422/human_med_001611.jsp&amp;mid=WCoB01ac058001d124</a>	July 2016
AMITIZA 24 microgram soft capsules	Lubiproston	New active substance	Sucampo Pharma Europe Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002422/human_med_001611.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002422/human_med_001611.jsp&amp;mid=WCoB01ac058001d124</a>	September 2015
AMYVID	Florbetapir [18F]	New active substance	Eli Lilly Nederland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002751/human_med_001754.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002751/human_med_001754.jsp&amp;mid=WCoB01ac058001d124</a>	April 2013
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/002751/human_med_001754.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002751/human_med_001754.jsp&amp;mid=WCoB01ac058001d124</a>	June 2014

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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> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000752/human_med_000656.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000752/human_med_000656.jsp&amp;mid=W</a>	September 2014
Atriance	Nelarabine	Authorised under exceptional circumstances	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000587/human_med_000658.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000587/human_med_000658.jsp&amp;mid=W</a>	April 2013
ATryn	Anti-thrombin alpha	Authorised under exceptional circumstances	GTC Biotherapeutics UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002514/human_med_001645.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002514/human_med_001645.jsp&amp;mid=W</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/004197/human_med_002100.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004197/human_med_002100.jsp&amp;mid=W</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.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004197/human_med_002100.jsp&amp;mid=W</a>	June 2017
<b>Bavencio</b>	<b>Avelumab</b>	<b>New active substance, conditional marketing author Merck Serono Europe Limited</b>		Not yet available <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002615/human_med_001734.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002615/human_med_001734.jsp&amp;mid=W</a>	<b>September 2017</b>
Bemfola	Follitropin alfa	New biological	Gedeon Richter Plc.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004007/human_med_001944.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004007/human_med_001944.jsp&amp;mid=W</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/002015/human_med_001466.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002015/human_med_001466.jsp&amp;mid=W</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/004119/human_med_002109.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004119/human_med_002109.jsp&amp;mid=W</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/002388/human_med_001605.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002388/human_med_001605.jsp&amp;mid=W</a>	July 2017
Betmiga	Mirabegron	New active substance	Astellas Pharma Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002333/human_med_001614.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002333/human_med_001614.jsp&amp;mid=W</a>	April 2013
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/003731/human_med_001921.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003731/human_med_001921.jsp&amp;mid=W</a>	April 2013
Blincyto	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/004723/human_med_002125.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004723/human_med_002125.jsp&amp;mid=W</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/002373/human_med_001613.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002373/human_med_001613.jsp&amp;mid=W</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/002706/human_med_001570.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002706/human_med_001570.jsp&amp;mid=W</a>	April 2013
Bretaris Genuair	Acidinium 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/003969/human_med_001806.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003969/human_med_001806.jsp&amp;mid=W</a>	April 2013
Brimica Genuair	Acidinium 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/004065/human_med_002111.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004065/human_med_002111.jsp&amp;mid=W</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/002717/human_med_001714.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002717/human_med_001714.jsp&amp;mid=W</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/003898/human_med_001945.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003898/human_med_001945.jsp&amp;mid=W</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/004163/human_med_002018.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004163/human_med_002018.jsp&amp;mid=W</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/002315/human_med_001529.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002315/human_med_001529.jsp&amp;mid=W</a>	September 2016
Caprelsa	Vandetanib	Conditional authorisation	Genzyme B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000796/human_med_000691.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000796/human_med_000691.jsp&amp;mid=W</a>	April 2013
Ceplene	Histamine dihydrochloride	Authorised under exceptional circumstances	Meda AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003724/human_med_001840.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003724/human_med_001840.jsp&amp;mid=W</a>	April 2013
Cerdelga	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/004061/human_med_002019.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004061/human_med_002019.jsp&amp;mid=W</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.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004061/human_med_002019.jsp&amp;mid=W</a>	April 2017

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
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/spcpil/documents/spcpil/con1466141046287.pdf">http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1466141046287.pdf</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cilostazol-containing_medicines/human_referral_000338.jsp&amp;mid=WCOb01ac05800c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cilostazol-containing_medicines/human_referral_000338.jsp&amp;mid=WCOb01ac05800c516f</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/medicines/003912/human_med_002012.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003912/human_med_002012.jsp&amp;mid=WCOb01ac058001d124</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001207/human_med_001448.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001207/human_med_001448.jsp&amp;mid=WCOb01ac058001d124</a>	September 2013
Cinquaero	Reslizumab	New active substance	Teva Pharmaceuticals Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001207/human_med_001448.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001207/human_med_001448.jsp&amp;mid=WCOb01ac058001d124</a>	September 2016
Cinryze	c1 inhibitor, human	PASS <sup>1</sup>	ViroPharma SPRL	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001207/human_med_001448.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001207/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> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003855/human_med_001967.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003855/human_med_001967.jsp&amp;mid=WCOb01ac058001d124</a>	May 2015
Coagadex	Human coagulation factor X	New biological	Bio Products Laboratory Ltd	<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=WCOb01ac05800c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Combined_hormonal_contraceptives/human_referral_prac_000016.jsp&amp;mid=WCOb01ac05800c516f</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002640/human_med_001726.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002640/human_med_001726.jsp&amp;mid=WCOb01ac058001d124</a>	April 2016
<a href="#">Combined hormonal contraceptives containing chlormadinone (For full list of products see Annex IX)</a>	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/medicines/002640/human_med_001726.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002640/human_med_001726.jsp&amp;mid=WCOb01ac058001d124</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/002498/human_med_001597.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002498/human_med_001597.jsp&amp;mid=WCOb01ac058001d124</a> <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=WCOb01ac05800c516f&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=WCOb01ac05800c516f&amp;source=homeMedSearch&amp;category=human</a>	May 2014
<del>Constellia*</del>	<del>Linaclotide</del>	<del>New active substance</del>	<del>Allergan Pharmaceuticals International Ltd.</del>	<del><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=WCOb01ac05800c516f&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=WCOb01ac05800c516f&amp;source=homeMedSearch&amp;category=human</a></del>	<del>April 2013</del>
Corlentor	Ivabradine	PASS <sup>1</sup>	Les Laboratoires Servier	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003729/human_med_001832.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003729/human_med_001832.jsp&amp;mid=WCOb01ac058001d124</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003960/human_med_001925.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003960/human_med_001925.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Cosentyx	Secukinumab	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003960/human_med_001925.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003960/human_med_001925.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Cotellic	Cobimetinib	New active substance	Roche Registration Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002734/human_med_001907.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002734/human_med_001907.jsp&amp;mid=WCOb01ac058001d124</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002136/human_med_001578.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002136/human_med_001578.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/002136/human_med_001578.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002136/human_med_001578.jsp&amp;mid=WCOb01ac058001d124</a>	November 2015
<del>Cuprymina **</del>	<del>Copper (64Cu) chloride</del>	<del>New active substance</del>	<del>Sparkle S.r.l.</del>	<del><a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002136/human_med_001578.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002136/human_med_001578.jsp&amp;mid=WCOb01ac058001d124</a></del>	<del>April 2013</del>
<b>Cuvitru 200 mg/ml solution for injection</b>	<b>Immunglobulin</b>	<b>New biological</b>	<b>Baxalta Innovations GmbH, Austria</b>	<a href="http://mri.cts-mrp.eu/Human/Product/Details/47869">http://mri.cts-mrp.eu/Human/Product/Details/47869</a>	<b>September 2017</b>
<a href="#">Cyproterone acetate and Ethinylestradiol containing medicinal products (For full list of products see Annex I)</a>	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=WCOb01ac05800c516f">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=WCOb01ac05800c516f</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002829/human_med_001825.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002829/human_med_001825.jsp&amp;mid=WCOb01ac058001d124</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003768/human_med_001792.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003768/human_med_001792.jsp&amp;mid=WCOb01ac058001d124</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/003768/human_med_001792.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003768/human_med_001792.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/002398/human_med_001415.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002398/human_med_001415.jsp&amp;mid=WCOb01ac058001d124</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004077/human_med_001979.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004077/human_med_001979.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Daliresp	Roflumilast	PASS <sup>1</sup>	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001179/human_med_001363.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001179/human_med_001363.jsp&amp;mid=WCOb01ac058001d124</a>	June 2013
Darzalex	Daratumumab	New active substance	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001179/human_med_001363.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001179/human_med_001363.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/002393/human_med_001646.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002393/human_med_001646.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/002393/human_med_001646.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002393/human_med_001646.jsp&amp;mid=WCOb01ac058001d124</a>	November 2013

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Delyba	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/002552/human_med_001699.jsp&amp;mid=WCOB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002552/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/004094/human_med_001978.jsp&amp;mid=WCOB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004094/human_med_001978.jsp&amp;mid=WCOB01ac058001d124</a>	May 2016
<a href="#">Dexamed and associated names (dexamfetamine sulphate-containing medicinal products in the EU) (For full list of products see Annex XII)</a>	Dexamfetamine 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/Dexamed_and_associated_names/human_referral_000373.jsp&amp;mid=WCOB01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Dexamed_and_associated_names/human_referral_000373.jsp&amp;mid=WCOB01ac05805c516f</a>	September 2014
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/003918/human_med_002104.jsp&amp;mid=WCOB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003918/human_med_002104.jsp&amp;mid=WCOB01ac058001d124</a>	May 2017
<a href="#">Domperidone-containing medicinal products (For full list of products see Annex X)</a>	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	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/003745/human_med_001811.jsp&amp;mid=WCOB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003745/human_med_001811.jsp&amp;mid=WCOB01ac058001d124</a>	December 2014
Ebymect	Dapagliflozin/metformin	New active substance	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004162/human_med_001926.jsp&amp;mid=WCOB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004162/human_med_001926.jsp&amp;mid=WCOB01ac058001d124</a>	November 2015
Edistride	Dapaqliflozin	New active substance	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004161/human_med_001927.jsp&amp;mid=WCOB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004161/human_med_001927.jsp&amp;mid=WCOB01ac058001d124</a>	November 2015
Eklira 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/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	Efmoroctocog 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 <sup>2</sup>	Lisdexamphetamine	New active substance	Shire Pharmaceutical Contracts Limited	<a href="http://www.mhra.gov.uk/home/groups/spccpil/documents/spccpil/con1470374084134.pdf">http://www.mhra.gov.uk/home/groups/spccpil/documents/spccpil/con1470374084134.pdf</a> <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>	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/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>	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/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>	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/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>	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/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>	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/002070/human_med_001929.jsp&amp;mid=WCOB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002070/human_med_001929.jsp&amp;mid=WCOB01ac058001d124</a>	April 2013
<b>Enzepi ***</b>	<b>Pancreas powder</b>	<b>New biological</b>	<b>Allergan Pharmaceuticals International Limited</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002070/human_med_001929.jsp&amp;mid=WCOB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002070/human_med_001929.jsp&amp;mid=WCOB01ac058001d124</a>	<b>July 2016</b>
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 Limited	<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

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Esbriet	Pirfenidone	PASS <sup>1</sup>	Roche Registration Limited	<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>	April 2013
Eurartesim	Dihydroartemisinin/piperazine phosphate	PASS <sup>1</sup>	Siama-tau Industrie Farmaceutiche Riunite 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
Evarrest	Human fibrinogen/human thrombin	New biological	Omrix Biopharmaceuticals N. V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002515/human_med_001675.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002515/human_med_001675.jsp&amp;mid=WCoB01ac058001d124</a>	November 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
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/003837/human_med_001833.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003837/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/003725/human_med_001895.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003725/human_med_001895.jsp&amp;mid=WCoB01ac058001d124</a>	September 2015
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/003776/human_med_001908.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003776/human_med_001908.jsp&amp;mid=WCoB01ac058001d124</a>	October 2015
Fiasp	Insulin aspart	New biological	Novo Nordisk A/S	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613347-spcde-20160201.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613347-spcde-20160201.pdf</a>	March 2017
FibClot	Human Fibrinogen	New Biological	Laboratoire Francais du Fractionnement et des Biotechnologies	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613723-spcde-20170401.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613723-spcde-20170401.pdf</a>	July 2016
Fibryqa	Human Fibrinogen	New biological	Octapharma GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001032/human_med_001298.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001032/human_med_001298.jsp&amp;mid=WCoB01ac058001d124</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/004020/human_med_001980.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004020/human_med_001980.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/002617/human_med_001713.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002617/human_med_001713.jsp&amp;mid=WCoB01ac058001d124</a>	June 2016
Fluenz Tetra	Influenza vaccine (live attenuated, nasal)	New biological	MedImmune LLC	<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>	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/medicines/002322/human_med_001546.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002322/human_med_001546.jsp&amp;mid=WCoB01ac058001d124</a>	February 2014
<del><b>Forigo ****</b></del>	<del><b>Depogiflozin</b></del>	<del><b>New active substance</b></del>	<del><b>AstraZeneca AB</b></del>		<del><b>April 2013</b></del>
<b>Fotivda</b>	<b>Tivozanib</b>	<b>New active substance</b>	<b>EUSA Pharma (UK) Limited</b>	Not yet available	<b>September 2017</b>
Galafold	Migalastat	New active substance	Amicus Therapeutics UK Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004059/human_med_001981.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004059/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 & Ziegler Radiopharma GmbH	<a href="http://www.produktresumee.dk/docushare/dsweb/Get/Document-t-33097/Galliapharm%2C+radionuclide+generator.docx">http://www.produktresumee.dk/docushare/dsweb/Get/Document-t-33097/Galliapharm%2C+radionuclide+generator.docx</a>	April 2016
Gardasil 9	Human papillomavirus 9-valent vaccine (recombinant, adsorbed)	New active substance	Sanofi Pasteur MSD, SNC	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003852/human_med_001863.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003852/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/002799/human_med_001780.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002799/human_med_001780.jsp&amp;mid=WCoB01ac058001d124</a>	September 2014
Genvoxa	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/004042/human_med_001940.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004042/human_med_001940.jsp&amp;mid=WCoB01ac058001d124</a>	December 2015
Geonistin tablete za rodnicu	Oxytetracyclin, nistatin	PASS <sup>1</sup>	Pliva Hrvatska d.o.o.	<a href="http://www.halmed.hr/upl/lijekovi/SPC/UP-I-530-09-12-02-02.pdf">http://www.halmed.hr/upl/lijekovi/SPC/UP-I-530-09-12-02-02.pdf</a>	June 2014

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Gilenya	Finqolimid hydrochloride	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002202/human_med_001433.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002202/human_med_001433.jsp&amp;mid=W C0b01ac058001d124</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/002280/human_med_001698.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002280/human_med_001698.jsp&amp;mid=W C0b01ac058001d124</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/000406/human_med_000808.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000406/human_med_000808.jsp&amp;mid=W C0b01ac058001d124</a>	September 2014
Glybera	Alipogene tiparovec	New active substance, authorised under exceptional circumstances	uniQure biopharma B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002145/human_med_001480.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002145/human_med_001480.jsp&amp;mid=W C0b01ac058001d124</a>	April 2013
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/003833/human_med_002032.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003833/human_med_002032.jsp&amp;mid=W C0b01ac058001d124</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/002150/human_med_001688.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002150/human_med_001688.jsp&amp;mid=W C0b01ac058001d124</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/003850/human_med_001813.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003850/human_med_001813.jsp&amp;mid=W C0b01ac058001d124</a>	December 2014
Hetlioz	Tasimelteon	New active substance	Vanda Pharmaceuticals Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003870/human_med_001873.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003870/human_med_001873.jsp&amp;mid=W C0b01ac058001d124</a>	July 2015
Hexacima	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	New biological	Sanofi Pasteur S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002702/human_med_001640.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002702/human_med_001640.jsp&amp;mid=W C0b01ac058001d124</a>	July 2013
Hexyon	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	New biological	Sanofi Pasteur MSD, SNC	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002796/human_med_001641.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002796/human_med_001641.jsp&amp;mid=W C0b01ac058001d124</a>	July 2013
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/002450/human_med_001844.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002450/human_med_001844.jsp&amp;mid=W C0b01ac058001d124</a>	March 2015
<a href="#">Hydroxyethyl starch (HES)-containing medicinal products (For full list see Annex V)</a>	Hydroxyethyl starch	PASS <sup>1</sup>	Various (For full list see Annex V)	<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=W C0b01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Hydroxyethyl_starch-containing_medicines/human_referral_prac_000029.jsp&amp;mid=W C0b01ac05805c516f</a>	January 2014
HvOvia	Human normal immunoglobulin	New biological	Baxter Innovations GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002491/human_med_001647.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002491/human_med_001647.jsp&amp;mid=W C0b01ac058001d124</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/004147/human_med_001958.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004147/human_med_001958.jsp&amp;mid=W C0b01ac058001d124</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/003853/human_med_002034.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003853/human_med_002034.jsp&amp;mid=W C0b01ac058001d124</a>	November 2016
Iclusiq	Ponatinib	New active substance	Incyte Biosciences UK Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002695/human_med_001656.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002695/human_med_001656.jsp&amp;mid=W C0b01ac058001d124</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/003955/human_med_001974.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003955/human_med_001974.jsp&amp;mid=W C0b01ac058001d124</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/003791/human_med_001801.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003791/human_med_001801.jsp&amp;mid=W C0b01ac058001d124</a>	November 2014
Imlygic	Talimogene laherparepvec	New active substance	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002771/human_med_001941.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002771/human_med_001941.jsp&amp;mid=W C0b01ac058001d124</a>	January 2016
Imnovid (formerly Pomalidomide Celgene)	Pomalidomide	New active substance, PASS <sup>1</sup>	Celgene Europe Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002682/human_med_001669.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002682/human_med_001669.jsp&amp;mid=W C0b01ac058001d124</a>	September 2013
<b>Imraldi</b>	<b>Adalimumab</b>	<b>New active substance</b>	<b>Samsung Bioepis UK Limited</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004279/human_med_002147.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004279/human_med_002147.jsp&amp;mid=W C0b01ac058001d124</a>	<b>September 2017</b>
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/002596/human_med_001666.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002596/human_med_001666.jsp&amp;mid=W C0b01ac058001d124</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/000704/human_med_000829.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000704/human_med_000829.jsp&amp;mid=W C0b01ac058001d124</a>	April 2013

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Incesync	Aloqliptin/pioglitazone	New active substance	Takeda Pharma A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002178/human_med_001694.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002178/human_med_001694.jsp&amp;mid=W-C0b01ac058001d124</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/002809/human_med_001755.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002809/human_med_001755.jsp&amp;mid=W-C0b01ac058001d124</a>	May 2014
Inflixtra	Infliximab	New biological	Hospira UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002778/human_med_001677.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002778/human_med_001677.jsp&amp;mid=W-C0b01ac058001d124</a>	October 2013
Influsplit Tetra <sup>3</sup>	Influenza virus inactivated split virion	New biological	Glaxo Group Ltd	<a href="http://portal.dimdi.de/amispb/doc/pei/Web/2612711-spcde-20160401.pdf">http://portal.dimdi.de/amispb/doc/pei/Web/2612711-spcde-20160401.pdf</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004264/human_med_002020.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004264/human_med_002020.jsp&amp;mid=W-C0b01ac058001d124</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/004264/human_med_002020.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004264/human_med_002020.jsp&amp;mid=W-C0b01ac058001d124</a>	September 2016
<b>Insulin Iispro Sanofi</b>	<b>Insulin Iispro</b>	<b>New biological</b>	<b>Sanofi-Aventis groupe</b>	<b>Not yet available</b>	<b>September 2017</b>
<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>	Various (For full list see Annex III)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Intravenous_iron-containing_medicinal_products/human_referral_000343.jsp&amp;mid=W-C0b01ac058005c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Intravenous_iron-containing_medicinal_products/human_referral_000343.jsp&amp;mid=W-C0b01ac058005c516f</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003759/human_med_001910.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003759/human_med_001910.jsp&amp;mid=W-C0b01ac058001d124</a>	January 2014
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=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003759/human_med_001910.jsp&amp;mid=W-C0b01ac058001d124</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=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002649/human_med_001707.jsp&amp;mid=W-C0b01ac058001d124</a>	December 2013
Iqymune	Human normal immunoglobulin	Newly licensed biological	Laboratoire Francais du Fractionnement et des Biotechnologies	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613314-spcde-20170301.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613314-spcde-20170301.pdf</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004187/human_med_001911.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004187/human_med_001911.jsp&amp;mid=W-C0b01ac058001d124</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=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004187/human_med_001911.jsp&amp;mid=W-C0b01ac058001d124</a>	September 2015
Izinova / Eziclen	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=R022102.htm">http://agence-prd.ansm.sante.fr/php/ecodex/frames.php?specid=65236258&amp;typedoc=R&amp;ref=R022102.htm</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002677/human_med_001764.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002677/human_med_001764.jsp&amp;mid=W-C0b01ac058001d124</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=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002677/human_med_001764.jsp&amp;mid=W-C0b01ac058001d124</a>	June 2014
Jaydess	Levonorgestrel	PASS <sup>1</sup>	Bayer AB	<a href="https://docetp.mpa.se/LMF/Jaydess%20intrauterine%20deliver%20system%20ENG%20SMP.doc">https://docetp.mpa.se/LMF/Jaydess%20intrauterine%20deliver%20system%20ENG%20SMP.doc</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002381/human_med_001629.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002381/human_med_001629.jsp&amp;mid=W-C0b01ac058001d124</a>	November 2013
Jetrea	Ocriplasmin	New active substance	ThromboGenics NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002788/human_med_001857.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002788/human_med_001857.jsp&amp;mid=W-C0b01ac058001d124</a>	April 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/002389/human_med_001712.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002389/human_med_001712.jsp&amp;mid=W-C0b01ac058001d124</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/002494/human_med_001575.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002494/human_med_001575.jsp&amp;mid=W-C0b01ac058001d124</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/004004/human_med_001896.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004004/human_med_001896.jsp&amp;mid=W-C0b01ac058001d124</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/003773/human_med_001852.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003773/human_med_001852.jsp&amp;mid=W-C0b01ac058001d124</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/003906/human_med_001814.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003906/human_med_001814.jsp&amp;mid=W-C0b01ac058001d124</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/004254/human_med_002114.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004254/human_med_002114.jsp&amp;mid=W-C0b01ac058001d124</a>	December 2014
Kezvara	Sarilumab	New active substance	Sanofi-Aventis groupe	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003820/human_med_001886.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003820/human_med_001886.jsp&amp;mid=W-C0b01ac058001d124</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/004224/human_med_002021.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004224/human_med_002021.jsp&amp;mid=W-C0b01ac058001d124</a>	July 2015
Kisplix	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=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004224/human_med_002021.jsp&amp;mid=W-C0b01ac058001d124</a>	September 2016

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
<b>Kisqali</b>	<b>Ribociclib</b>	<b>New active substance</b>	<b>Novartis Europharm Limited</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004213/human_med_002149.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004213/human_med_002149.jsp&amp;mid=W-C0b01ac058001d124</a>	<b>September 2017</b>
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=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002081/human_med_001718.jsp&amp;mid=W-C0b01ac058001d124</a>	May 2014
Kovaltry	Octocog 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=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003825/human_med_001959.jsp&amp;mid=W-C0b01ac058001d124</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=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003959/human_med_002054.jsp&amp;mid=W-C0b01ac058001d124</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=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003790/human_med_001932.jsp&amp;mid=W-C0b01ac058001d124</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=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004216/human_med_002036.jsp&amp;mid=W-C0b01ac058001d124</a>	November 2016
Latuda	Lurasidone	New active substance	Sunovion Pharmaceuticals Europe Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003754/human_med_001756.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003754/human_med_001756.jsp&amp;mid=W-C0b01ac058001d124</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/003718/human_med_001678.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003718/human_med_001678.jsp&amp;mid=W-C0b01ac058001d124</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/003727/human_med_001864.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003727/human_med_001864.jsp&amp;mid=W-C0b01ac058001d124</a>	October 2013
Lenvima	Lenvatinib	New active substance	Eisai Europe Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003939/human_med_001416.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003939/human_med_001416.jsp&amp;mid=W-C0b01ac058001d124</a>	June 2015
Libertek	Roflumilast	PASS <sup>1</sup>	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004167/human_med_002080.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004167/human_med_002080.jsp&amp;mid=W-C0b01ac058001d124</a>	June 2013
Lifmior	Etanercept	New biological	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002629/human_med_001874.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002629/human_med_001874.jsp&amp;mid=W-C0b01ac058001d124</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/002578/human_med_001668.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002578/human_med_001668.jsp&amp;mid=W-C0b01ac058001d124</a>	July 2015
Lojuxta	Lomitapide	New active substance, authorised under exceptional circumstances	Aegerion Pharmaceuticals SAS	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002556/human_med_001667.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002556/human_med_001667.jsp&amp;mid=W-C0b01ac058001d124</a>	September 2013
Lonquex	Lipeqfilqrastim	New active substance, PASS <sup>1</sup>	Teva Pharma B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003897/human_med_001975.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003897/human_med_001975.jsp&amp;mid=W-C0b01ac058001d124</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/002749/human_med_001875.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002749/human_med_001875.jsp&amp;mid=W-C0b01ac058001d124</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/004101/human_med_002058.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004101/human_med_002058.jsp&amp;mid=W-C0b01ac058001d124</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/002085/human_med_001827.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002085/human_med_001827.jsp&amp;mid=W-C0b01ac058001d124</a>	January 2017
Lymphoseek	Tilmanocept	New active substance	Norgine B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003726/human_med_001831.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003726/human_med_001831.jsp&amp;mid=W-C0b01ac058001d124</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/002445/human_med_001615.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002445/human_med_001615.jsp&amp;mid=W-C0b01ac058001d124</a>	February 2015
Lyxumia	Lixisenatide	New active substance	Sanofi-Aventis	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002522/human_med_001660.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002522/human_med_001660.jsp&amp;mid=W-C0b01ac058001d124</a>	April 2013
MACI <sup>4</sup>	Matrix applied characterised autologous cultured chondrocytes	New active substance	Aastrom Biosciences DK ApS	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004430/human_med_002151.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004430/human_med_002151.jsp&amp;mid=W-C0b01ac058001d124</a>	August 2013
<b>Maviret</b>	<b>Glecaprevir / pibrentasvir</b>	<b>New active substance, PASS<sup>1</sup></b>	<b>AbbVie Ltd</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002643/human_med_001772.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002643/human_med_001772.jsp&amp;mid=W-C0b01ac058001d124</a>	<b>September 2017</b>
Mekinist	Trametinib	New active substance	Novartis Europharm Limited	<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>	September 2014
Meriofert	Menotrophin	New biological	Laboratoires Génévrier SA		March 2015



Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Moventiq	Naloxegol	New active substance	Kyowa Kirin Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002810/human_med_001816.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002810/human_med_001816.jsp&amp;mid=W C0b01ac058001d124</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/004368/human_med_002057.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004368/human_med_002057.jsp&amp;mid=W C0b01ac058001d124</a>	January 2017
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/003687/human_med_001845.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003687/human_med_001845.jsp&amp;mid=W C0b01ac058001d124</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/000640/human_med_000918.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000640/human_med_000918.jsp&amp;mid=W C0b01ac058001d124</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/003861/human_med_002093.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003861/human_med_002093.jsp&amp;mid=W C0b01ac058001d124</a>	May 2017
Neoparin	Enoxaparinum natricum	New biological	SciencePharma spółka z ograniczoną odpowiedzialnością spółka komandytowa	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004343/human_med_001982.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004343/human_med_001982.jsp&amp;mid=W C0b01ac058001d124</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/002553/human_med_001716.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002553/human_med_001716.jsp&amp;mid=W C0b01ac058001d124</a>	June 2016
Neuraceq	Florbetaben (18F)	New active substance	Piramal Imaging GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002246/human_med_001582.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002246/human_med_001582.jsp&amp;mid=W C0b01ac058001d124</a>	March 2014
NexoBrid	Concentrate of proteolytic enzymes enriched in bromelain	New active substance, PASS <sup>1</sup>	MediWound Germany GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003844/human_med_001998.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003844/human_med_001998.jsp&amp;mid=W C0b01ac058001d124</a>	April 2013
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/002719/human_med_001701.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002719/human_med_001701.jsp&amp;mid=W C0b01ac058001d124</a>	November 2016
NovoEight	Turoctocog alfa	New active substance	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003860/human_med_001933.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003860/human_med_001933.jsp&amp;mid=W C0b01ac058001d124</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/referrals/Numeta_G13E_and_Numeta_G16E_emulsi on_for_infusion/human_referral_prac_00027.jsp&amp;mid=WC0b01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Numeta_G13E_and_Numeta_G16E_emulsi on_for_infusion/human_referral_prac_00027.jsp&amp;mid=WC0b01ac05805c516f</a>	January 2016
	Alanine, arginine, aspartic acid, calcium chloride, cysteine, glucose monohydrate, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, magnesium acetate, methionine, olive oil, ornithine hydrochloride, henylationine, 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_emulsi on_for_infusion/human_referral_prac_00027.jsp&amp;mid=WC0b01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Numeta_G13E_and_Numeta_G16E_emulsi on_for_infusion/human_referral_prac_00027.jsp&amp;mid=WC0b01ac05805c516f</a>	September 2014
Numeta G16%E medicinal products in the European Union (For full list of products see Annex XI)					
Nuwiq	Simoctocog alfa	New active substance	Octapharma AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002813/human_med_001781.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002813/human_med_001781.jsp&amp;mid=W C0b01ac058001d124</a>	September 2014
Obizur	Susoctocog 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/002792/human_med_001918.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002792/human_med_001918.jsp&amp;mid=W C0b01ac058001d124</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/004093/human_med_002043.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004093/human_med_002043.jsp&amp;mid=W C0b01ac058001d124</a>	January 2017
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/004156/human_med_001991.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004156/human_med_001991.jsp&amp;mid=W C0b01ac058001d124</a>	June 2016
Odomzo	Sonidegib	New active substance	Sun Pharmaceutical Industries Europe BV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002839/human_med_001897.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002839/human_med_001897.jsp&amp;mid=W C0b01ac058001d124</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/003821/human_med_001834.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003821/human_med_001834.jsp&amp;mid=W C0b01ac058001d124</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/004085/human_med_002074.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004085/human_med_002074.jsp&amp;mid=W C0b01ac058001d124</a>	February 2017
OLYSIO	Simeprevir	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/002777/human_med_001766.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002777/human_med_001766.jsp&amp;mid=W C0b01ac058001d124</a>	June 2014
Oncaspar	Pegaspargase	New biological	Baxalta Innovations GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003789/human_med_001949.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003789/human_med_001949.jsp&amp;mid=W C0b01ac058001d124</a>	January 2016

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Onqentys	Opicapone	New active substance	Bial - Portela & C <sup>a</sup> , SA	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002790/human_med_001950.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002790/human_med_001950.jsp&amp;mid=W-C0b01ac058001d124</a>	July 2016
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/003985/human_med_001876.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003985/human_med_001876.jsp&amp;mid=W-C0b01ac058001d124</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/002697/human_med_001717.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002697/human_med_001717.jsp&amp;mid=W-C0b01ac058001d124</a>	February 2014
Optimark	Gadoversetamide	PASS <sup>1</sup>	Gueberr	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000745/human_med_000953.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000745/human_med_000953.jsp&amp;mid=W-C0b01ac058001d124</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/003785/human_med_001853.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003785/human_med_001853.jsp&amp;mid=W-C0b01ac058001d124</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/003954/human_med_001935.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003954/human_med_001935.jsp&amp;mid=W-C0b01ac058001d124</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/001250/human_med_001419.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001250/human_med_001419.jsp&amp;mid=W-C0b01ac058001d124</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/000561/human_med_000963.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000561/human_med_000963.jsp&amp;mid=W-C0b01ac058001d124</a>	August 2013
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=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003746/human_med_001835.jsp&amp;mid=W-C0b01ac058001d124</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=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002608/human_med_001689.jsp&amp;mid=W-C0b01ac058001d124</a>	November 2013
Oxervate	Cenegermine	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=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004209/human_med_002135.jsp&amp;mid=W-C0b01ac058001d124</a>	July 2017
Pandemic influenza vaccine H5N1 AstraZeneca	Pandemic influenza vaccine (H5N1) (live attenuated, nasal)	New active substance, conditional authorisation	AstraZeneca AB	<a href="https://portal.dimdi.de/ams/pe/doc/pei/Web/2613595-spcde-20170501.pdf">https://portal.dimdi.de/ams/pe/doc/pei/Web/2613595-spcde-20170501.pdf</a>	June 2016
Panzyga	Human normal immunoglobulin	New Biological	Octapharma GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003995/human_med_002037.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003995/human_med_002037.jsp&amp;mid=W-C0b01ac058001d124</a>	July 2016
Parsabiv	Etelcalcetide	New active substance	Amgen Europe B.V.	<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>	November 2016
Pentrox	Methoxyflurane	PASS <sup>1</sup>	Medical Developments UK Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002547/human_med_001628.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002547/human_med_001628.jsp&amp;mid=W-C0b01ac058001d124</a>	June 2016
Perjeta	Pertuzumab	New active substance, PASS <sup>1</sup>	Roche Registration Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002055/human_med_001549.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002055/human_med_001549.jsp&amp;mid=W-C0b01ac058001d124</a>	April 2013
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/002827/human_med_001782.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002827/human_med_001782.jsp&amp;mid=W-C0b01ac058001d124</a>	April 2013
Plegridy	Peginterferon beta-1a	New active substance	Bioden Idec Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003886/human_med_001953.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003886/human_med_001953.jsp&amp;mid=W-C0b01ac058001d124</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/003882/human_med_001915.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003882/human_med_001915.jsp&amp;mid=W-C0b01ac058001d124</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/003986/human_med_001938.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003986/human_med_001938.jsp&amp;mid=W-C0b01ac058001d124</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/referrals/Corlentor_and_Procoralan/human_referral_prac_000044.jsp&amp;mid=W-C0b01ac05805c516f&amp;source=homeMe">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Corlentor_and_Procoralan/human_referral_prac_000044.jsp&amp;mid=W-C0b01ac05805c516f&amp;source=homeMe</a>	December 2015
Procoralan	Ivabradine	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=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000560/human_med_000999.jsp&amp;mid=W-C0b01ac058001d124</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/004057/human_med_002000.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004057/human_med_002000.jsp&amp;mid=W-C0b01ac058001d124</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/002789/human_med_001846.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002789/human_med_001846.jsp&amp;mid=W-C0b01ac058001d124</a>	July 2016
Quinsair	Levofloxacin	PASS <sup>1</sup>	Raptor Pharmaceuticals Europe BV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002789/human_med_001846.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002789/human_med_001846.jsp&amp;mid=W-C0b01ac058001d124</a>	April 2015

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Rapibloc	Landiolol	New active substance	AOP Orphan Pharmaceuticals	Not available <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002807/human_med_001854.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002807/human_med_001854.jsp&amp;mid=W</a>	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/003822/human_med_001939.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003822/human_med_001939.jsp&amp;mid=W</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/003834/human_med_001900.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003834/human_med_001900.jsp&amp;mid=W</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/002770/human_med_002136.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002770/human_med_002136.jsp&amp;mid=W</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/004178/human_med_002107.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004178/human_med_002107.jsp&amp;mid=W</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/003994/human_med_002044.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003994/human_med_002044.jsp&amp;mid=W</a>	June 2017
Rekovellev	Follitropin delta	New biological	Ferring Pharmaceuticals A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002673/human_med_001708.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002673/human_med_001708.jsp&amp;mid=W</a>	May 2017
Relvar Ellipta	Fluticasone furoate/vilanterol trifrenatate	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/002576/human_med_001682.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002576/human_med_001682.jsp&amp;mid=W</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/003766/human_med_001890.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003766/human_med_001890.jsp&amp;mid=W</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/002739/human_med_001904.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002739/human_med_001904.jsp&amp;mid=W</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/002345/human_med_001583.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002345/human_med_001583.jsp&amp;mid=W</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/002745/human_med_001768.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002745/human_med_001768.jsp&amp;mid=W</a>	April 2013
Revinty Ellipta	Fluticasone furoate/vilanterol trifrenatate	PASS <sup>1</sup>	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000717/human_med_001034.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000717/human_med_001034.jsp&amp;mid=W</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/002819/human_med_001817.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002819/human_med_001817.jsp&amp;mid=W</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/003910/human_med_001859.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003910/human_med_001859.jsp&amp;mid=W</a>	February 2015
Ristempa	Pegfilgrastim	New biological	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004725/human_med_002137.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004725/human_med_002137.jsp&amp;mid=W</a>	April 2015
Ritemvia	Rituximab	New biological	Celltrion Healthcare Hungary Kft.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003903/human_med_002095.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003903/human_med_002095.jsp&amp;mid=W</a>	July 2017
Rixathon	Rituximab	New biological	Sandoz GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004729/human_med_002116.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004729/human_med_002116.jsp&amp;mid=W</a>	June 2017
Riximyo	Rituximab	New biological	Sandoz GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003771/human_med_001830.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003771/human_med_001830.jsp&amp;mid=W</a>	June 2017
Rixubis	Nonacog gamma	New biological	Baxter Innovations GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004654/human_med_002085.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004654/human_med_002085.jsp&amp;mid=W</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/004339/human_med_002096.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004339/human_med_002096.jsp&amp;mid=W</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/002499/human_med_001608.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002499/human_med_001608.jsp&amp;mid=W</a>	May 2017
Rvzodeq	Insulin deludec/insulin aspart	New active substance	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003780/human_med_001855.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003780/human_med_001855.jsp&amp;mid=W</a>	April 2013
Saxenda	Liraglutide	New biological	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002548/human_med_001826.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002548/human_med_001826.jsp&amp;mid=W</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/002548/human_med_001826.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002548/human_med_001826.jsp&amp;mid=W</a>	January 2015

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Seasonique	Levonorgestrel/ethinylestradiol	PASS <sup>1</sup>	Teva Pharma B.V.	Not available <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002430/human_med_001580.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002430/human_med_001580.jsp&amp;mid=W</a>	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/002583/human_med_001620.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002583/human_med_001620.jsp&amp;mid=W</a>	April 2013
Selincro	Nalmefene	New active substance	H. Lundbeck A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002780/human_med_001837.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002780/human_med_001837.jsp&amp;mid=W</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/002614/human_med_001730.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002614/human_med_001730.jsp&amp;mid=W</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/002846/human_med_001856.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002846/human_med_001856.jsp&amp;mid=W</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/004373/human_med_002076.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004373/human_med_002076.jsp&amp;mid=W</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/004140/human_med_002038.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004140/human_med_002038.jsp&amp;mid=W</a>	April 2017
SomaKit TOC	Edotretotide	New active substance	Advanced Accelerator Applications	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002196/human_med_001672.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002196/human_med_001672.jsp&amp;mid=W</a>	December 2016
Somatropin Biopartners	Somatropin	New biological	BioPartners GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002196/human_med_001672.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002196/human_med_001672.jsp&amp;mid=W</a>	September 2013
Sonazoid powder and solvent for solution of for injection 8 microliter/ml	Perflurobutan	New active substance	GE HEALTHCARE AS	Not available <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002798/human_med_001723.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002798/human_med_001723.jsp&amp;mid=W</a>	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/002661/human_med_001954.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002661/human_med_001954.jsp&amp;mid=W</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/002581/human_med_001661.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002581/human_med_001661.jsp&amp;mid=W</a>	January 2016
Spedra	Avanafil	New active substance	Vivus B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002736/human_med_002138.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002736/human_med_002138.jsp&amp;mid=W</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/004312/human_med_002119.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004312/human_med_002119.jsp&amp;mid=W</a>	July 2017
Spinraza	Nusinersen	New active substance	BioGen Idec Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004312/human_med_002119.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004312/human_med_002119.jsp&amp;mid=W</a>	June 2017
Spiolto Resimat	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> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002573/human_med_001684.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002573/human_med_001684.jsp&amp;mid=W</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/003794/human_med_001901.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003794/human_med_001901.jsp&amp;mid=W</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/002574/human_med_001654.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002574/human_med_001654.jsp&amp;mid=W</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/003854/human_med_001985.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003854/human_med_001985.jsp&amp;mid=W</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/003854/human_med_001985.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003854/human_med_001985.jsp&amp;mid=W</a>	June 2016
Striverdi Resimat	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> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004243/human_med_002064.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004243/human_med_002064.jsp&amp;mid=W</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/003708/human_med_001769.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003708/human_med_001769.jsp&amp;mid=W</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/003770/human_med_001865.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003770/human_med_001865.jsp&amp;mid=W</a>	June 2014
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/003770/human_med_001865.jsp&amp;mid=W">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003770/human_med_001865.jsp&amp;mid=W</a>	June 2015

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Tafinlar	Dabrafenib	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002604/human_med_001683.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002604/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/004124/human_med_001961.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004124/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/003943/human_med_001977.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003943/human_med_001977.jsp&amp;mid=WCoB01ac058001d124</a>	May 2016
<a href="#">Targocid and associated names (teicoplanin-containing medicinal products)</a> (For full list see Annex VII)	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
Terrosa	Teriparatide	New biological	Gedeon Richter Plc.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003916/human_med_002060.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003916/human_med_002060.jsp&amp;mid=WCoB01ac058001d124</a>	January 2017
<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=WCoB01ac05805c516f&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=WCoB01ac05805c516f&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/003795/human_med_002024.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003795/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/002753/human_med_001720.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002753/human_med_001720.jsp&amp;mid=WCoB01ac058001d124</a>	February 2014
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/002690/human_med_001581.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002690/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/002720/human_med_001742.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002720/human_med_001742.jsp&amp;mid=WCoB01ac058001d124</a>	September 2014
Tresiba	Insulin degludec	New active substance	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002498/human_med_001609.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002498/human_med_001609.jsp&amp;mid=WCoB01ac058001d124</a>	April 2013
<a href="#">Trimetazidine-containing medicinal products</a> (For full list of products see Annex II)	Trimetazidine	PASS <sup>1</sup>	Various (For full list see Annex II)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Trimetazidine/human_referral_000315.jsp&amp;mid=WCoB01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Trimetazidine/human_referral_000315.jsp&amp;mid=WCoB01ac05805c516f</a>	November 2013
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/002754/human_med_001796.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002754/human_med_001796.jsp&amp;mid=WCoB01ac058001d124</a>	October 2014
Truberzi	Eluxadolone	New active substance	Allergan Pharmaceuticals International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004098/human_med_002025.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004098/human_med_002025.jsp&amp;mid=WCoB01ac058001d124</a>	October 2016
Trulicity	Dulaglutide	New active substance	Eli Lilly Nederland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002825/human_med_001821.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002825/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/004051/human_med_002101.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004051/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/004112/human_med_002077.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004112/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/004724/human_med_002140.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004724/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/002572/human_med_001690.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002572/human_med_001690.jsp&amp;mid=WCoB01ac058001d124</a>	October 2013
Tysabri	Natalizumab	PASS <sup>1</sup>	Elian Pharma International Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000603/human_med_001119.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000603/human_med_001119.jsp&amp;mid=WCoB01ac058001d124</a>	April 2013
Ultibro 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/002679/human_med_001691.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002679/human_med_001691.jsp&amp;mid=WCoB01ac058001d124</a>	October 2013
Ulnar 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/003875/human_med_001758.jsp&amp;mid=WCoB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003875/human_med_001758.jsp&amp;mid=WCoB01ac058001d124</a>	July 2014

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Upravi	Selexipaq	New active substance	Actellon Registration Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003774/human_med_001970.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003774/human_med_001970.jsp&amp;mid=W C0b01ac058001d124</a>	June 2016
<a href="#">Valproate and related substances (sodium valproate, valproic acid, valproate semisodium, valpromide-containing medicinal products). (For full list of products see Annex XIII)</a>	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=WC0b01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Valproate_and_related_substances/human_referral_prac_000032.jsp&amp;mid=WC0b01ac05805c516f</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002569/human_med_001822.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002569/human_med_001822.jsp&amp;mid=W C0b01ac058001d124</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/004196/human_med_002097.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004196/human_med_002097.jsp&amp;mid=W C0b01ac058001d124</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/003982/human_med_001962.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003982/human_med_001962.jsp&amp;mid=W C0b01ac058001d124</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="https://portal.dimdi.de/amispb/doc/pei/Web/2613624-spcde-20161201.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613624-spcde-20161201.pdf</a> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000920/human_med_001129.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000920/human_med_001129.jsp&amp;mid=W C0b01ac058001d124</a>	February 2016
Vaxiqrip Tetra	Influenza vaccine (split virion, inactivated)	New biological	Sanofi Pasteur MSD GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002705/human_med_001795.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002705/human_med_001795.jsp&amp;mid=W C0b01ac058001d124</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/004180/human_med_002141.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004180/human_med_002141.jsp&amp;mid=W C0b01ac058001d124</a>	April 2013
Velphoro	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/004169/human_med_002061.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004169/human_med_002061.jsp&amp;mid=W C0b01ac058001d124</a>	September 2014
<b>Veltassa</b>	<b>Patiromer</b>	<b>New active substance</b>	<b>Vifor Fresenius Medical Care Renal Pharma France</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004106/human_med_002045.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004106/human_med_002045.jsp&amp;mid=W C0b01ac058001d124</a>	<b>September 2017</b>
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/004106/human_med_002045.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004106/human_med_002045.jsp&amp;mid=W C0b01ac058001d124</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/002089/human_med_001543.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002089/human_med_001543.jsp&amp;mid=W C0b01ac058001d124</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/001240/human_med_001467.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001240/human_med_001467.jsp&amp;mid=W C0b01ac058001d124</a>	April 2013
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/003839/human_med_001838.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003839/human_med_001838.jsp&amp;mid=W C0b01ac058001d124</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/004459/human_med_002078.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004459/human_med_002078.jsp&amp;mid=W C0b01ac058001d124</a>	February 2015
Vihuma	Simococog alfa	New active substance	Octapharma AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002779/human_med_001759.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002779/human_med_001759.jsp&amp;mid=W C0b01ac058001d124</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/002654/human_med_001695.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002654/human_med_001695.jsp&amp;mid=W C0b01ac058001d124</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/002182/human_med_001696.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002182/human_med_001696.jsp&amp;mid=W C0b01ac058001d124</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/002557/human_med_001794.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002557/human_med_001794.jsp&amp;mid=W C0b01ac058001d124</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/002656/human_med_001760.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002656/human_med_001760.jsp&amp;mid=W C0b01ac058001d124</a>	September 2014
Vokanamet	Canagliflozin/metformin hydrochloride	New active substance	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002493/human_med_001670.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002493/human_med_001670.jsp&amp;mid=W C0b01ac058001d124</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/002294/human_med_001498.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002294/human_med_001498.jsp&amp;mid=W C0b01ac058001d124</a>	October 2013
<b>Vosevi</b>	<b>Sofosbuvir / velpatasvir / voxilaprevir</b>	<b>New active substance, PASS<sup>1</sup></b>	<b>Gilead Sciences International Limited</b>	Not yet available <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002294/human_med_001498.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002294/human_med_001498.jsp&amp;mid=W C0b01ac058001d124</a>	<b>September 2017</b>
Vynndaqel	Tafamidis	Authorised under exceptional circumstances	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002294/human_med_001498.jsp&amp;mid=W C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002294/human_med_001498.jsp&amp;mid=W C0b01ac058001d124</a>	April 2013

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
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/002616/human_med_001955.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002616/human_med_001955.jsp&amp;mid=W-C0b01ac058001d124</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/002396/human_med_001847.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002396/human_med_001847.jsp&amp;mid=W-C0b01ac058001d124</a>	March 2015
Xagrid	Anagrelide	Authorised under exceptional circumstances	Shire Pharmaceutical Contracts Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000480/human_med_001153.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000480/human_med_001153.jsp&amp;mid=W-C0b01ac058001d124</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/002489/human_med_001592.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002489/human_med_001592.jsp&amp;mid=W-C0b01ac058001d124</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/000944/human_med_001155.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000944/human_med_001155.jsp&amp;mid=W-C0b01ac058001d124</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/004214/human_med_001662.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004214/human_med_001662.jsp&amp;mid=W-C0b01ac058001d124</a>	April 2017
<b>Xermelo</b>	<b>Telotristat</b>	<b>New active substance</b>	<b>Ipsen Pharma</b>	Not yet available	<b>September 2017</b>
Xgeva	Denosumab	New biological	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002173/human_med_001463.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002173/human_med_001463.jsp&amp;mid=W-C0b01ac058001d124</a>	April 2013
Xiqduo	Dapaqliflozin/metformin	New active substance	Bristol-Myers Squibb / AstraZeneca EEIG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002672/human_med_001721.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002672/human_med_001721.jsp&amp;mid=W-C0b01ac058001d124</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/002653/human_med_001692.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002653/human_med_001692.jsp&amp;mid=W-C0b01ac058001d124</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/003755/human_med_001693.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003755/human_med_001693.jsp&amp;mid=W-C0b01ac058001d124</a>	October 2013
Xtandi	Enzalutamide	New active substance	Astellas Pharma Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002639/human_med_001663.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002639/human_med_001663.jsp&amp;mid=W-C0b01ac058001d124</a>	August 2013
Xultophy	Insulin deqludec/liraqlutide	New biological	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002647/human_med_001802.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002647/human_med_001802.jsp&amp;mid=W-C0b01ac058001d124</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/002840/human_med_001848.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002840/human_med_001848.jsp&amp;mid=W-C0b01ac058001d124</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> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002213/human_med_001465.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002213/human_med_001465.jsp&amp;mid=W-C0b01ac058001d124</a>	September 2016
Yervoy	Ipilimumab	PASS <sup>1</sup>	Bristol-Myers Squibb Pharma EEIG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002801/human_med_002016.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002801/human_med_002016.jsp&amp;mid=W-C0b01ac058001d124</a>	April 2013
Zalmoxis	Allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (ΔLNGFR) and the herpes simplex 1 virus thymidine kinase (HSV-TK Mut2)	New active substance, conditional authorisation	MolMed S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002532/human_med_001617.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002532/human_med_001617.jsp&amp;mid=W-C0b01ac058001d124</a>	September 2016
Zaltrap	Aflibercept	New active substance	Sanofi-Aventis	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004027/human_med_001993.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004027/human_med_001993.jsp&amp;mid=W-C0b01ac058001d124</a>	April 2013
Zavicefta	Ceftazidime / avibactam	New active substance	Pfizer Ireland Pharmaceuticals	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004126/human_med_002001.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004126/human_med_002001.jsp&amp;mid=W-C0b01ac058001d124</a>	July 2016
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/003772/human_med_001917.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003772/human_med_001917.jsp&amp;mid=W-C0b01ac058001d124</a>	September 2016
Zerbaxa	Ceftolozane / tazobactam	New active substance	Merck Sharp & Dohme Limited	<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> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003862/human_med_001987.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003862/human_med_001987.jsp&amp;mid=W-C0b01ac058001d124</a>	September 2015
Zevtera 500 mg powder for concentrate for solution for infusion	Ceftobiprole medocartil sodium	New active substance	Basilea Medical Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004136/human_med_002062.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004136/human_med_002062.jsp&amp;mid=W-C0b01ac058001d124</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/004136/human_med_002062.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004136/human_med_002062.jsp&amp;mid=W-C0b01ac058001d124</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/004136/human_med_002062.jsp&amp;mid=W-C0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004136/human_med_002062.jsp&amp;mid=W-C0b01ac058001d124</a>	February 2017

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Zoely	Nomegestrol/Estradiol	PASS <sup>1</sup>	Theramex S.r.l.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001213/human_med_001452.jsp&amp;mid=W0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001213/human_med_001452.jsp&amp;mid=W0b01ac058001d124</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/003932/human_med_001963.jsp&amp;mid=W0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003932/human_med_001963.jsp&amp;mid=W0b01ac058001d124</a>	March 2016
Zydelig	Idelalisib	New active substance	Gilead Sciences International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003843/human_med_001803.jsp&amp;mid=W0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003843/human_med_001803.jsp&amp;mid=W0b01ac058001d124</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/003819/human_med_001860.jsp&amp;mid=W0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003819/human_med_001860.jsp&amp;mid=W0b01ac058001d124</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.

<sup>2</sup> Also known in some EU countries as Tyvense.

<sup>3</sup> Also known in some EU countries as Fluarix Tetra or Alpha-Rix Tetra.

<sup>4</sup> Product currently suspended following a referral procedure under Article 20 of Regulation (EC) 726/2004.

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

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

\*\*\* At the marketing authorisation holder's request, the marketing authorisation granted by Decision C(2016)4182(final) for the medicinal product "Enzeppi - pancreas powder" was withdrawn on 19 July 2017.

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