

25 July 2018  
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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 July 2018 are shown in red font. All products removed from the list are shown with a strikethrough for the period of one month after which they are excluded.**

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Abasaqlar (previously Abasria)	Insulin glargine	New biological	Eli Lilly Nederland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02835/human_med_001790.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02835/human_med_001790.jsp&amp;mid=WCOb01ac058001d124</a>	October 2014
Acarizax (also known in some EU countries as MITIZAX)	Standardised allergen extract from house dust mites	New Biological	ALK-Abelló A/S	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613318-spcede-20170401.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613318-spcede-20170401.pdf</a>	May 2016
Accofil	Filgrastim	New biological	Accord Healthcare Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03956/human_med_001798.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03956/human_med_001798.jsp&amp;mid=WCOb01ac058001d124</a>	October 2014
Adcetris	Brentuximab vedotin	New active substance and <i>new biological</i> , conditional marketing authorisation	Takeda Pharma A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02455/human_med_001588.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02455/human_med_001588.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/02737/human_med_001733.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02737/human_med_001733.jsp&amp;mid=WCOb01ac058001d124</a>	April 2014
Adynovi	Rurioctocog alfa pegol	New active substance and <i>new biological</i> , PASS <sup>1</sup>	Baxalta Innovations GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04195/human_med_002204.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04195/human_med_002204.jsp&amp;mid=WCOb01ac058001d124</a>	January 2018
Afstyla	lonococog alfa	New active substance and <i>new biological</i>	CSL Behring GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04075/human_med_002055.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04075/human_med_002055.jsp&amp;mid=WCOb01ac058001d124</a>	January 2017
Altaro	Standardised allergen extract from house dust mites	New Biological	ALK-Abelló A/S	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613636-spcede-20170401.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613636-spcede-20170401.pdf</a>	June 2016
Akynzeo	Netupitant/palonosetron	New active substance	Helsinn Birex Pharmaceuticals Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03728/human_med_001862.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03728/human_med_001862.jsp&amp;mid=WCOb01ac058001d124</a>	June 2015
Alecensa	Alectinib	New active substance	Roche Registration GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04164/human_med_002068.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04164/human_med_002068.jsp&amp;mid=WCOb01ac058001d124</a>	March 2017
Alofisel	Darvadstrocel	New active substance and <i>new biological</i>	Takeda Pharma A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04258/human_med_002222.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04258/human_med_002222.jsp&amp;mid=WCOb01ac058001d124</a>	April 2018
Alpivab	Peramivir	New active substance	BioCryst UK Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04299/human_med_002243.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04299/human_med_002243.jsp&amp;mid=WCOb01ac058001d124</a>	May 2018
Alprolix	Eftrenacoq alfa	New active substance and <i>new biological</i>	Swedish Orphan Biovitrum AB (publ)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04142/human_med_001973.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04142/human_med_001973.jsp&amp;mid=WCOb01ac058001d124</a>	May 2016
Amgevita	Adalimumab	New biological	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04212/human_med_002081.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04212/human_med_002081.jsp&amp;mid=WCOb01ac058001d124</a>	April 2017
Amitend (also known in some EU countries as ACARIZAX)	Standardised allergen extract from house dust mites	New Biological	ALK-Abelló A/S	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613637-spcede-20170401.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613637-spcede-20170401.pdf</a>	July 2016
AMITIZA 24 microgram soft capsules	Lubiproston	New active substance	Sucampo Pharma Europe Ltd.	<a href="http://www.mhra.gov.uk/home/groups/sppcil/documents/sppcil/con1459748713655.pdf">http://www.mhra.gov.uk/home/groups/sppcil/documents/sppcil/con1459748713655.pdf</a>	September 2015
Anoro	Umeclidinium bromide/Vilanterol trifenatate	New active substance, PASS <sup>1</sup>	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02751/human_med_001754.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02751/human_med_001754.jsp&amp;mid=WCOb01ac058001d124</a>	June 2014
Apleek	Ethinyl estradiol/gestodene	PASS <sup>1</sup>	Bayer Pharma AG	<a href="http://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA1410-069-001_04042014155117.pdf">http://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA1410-069-001_04042014155117.pdf</a>	September 2014

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Atriance	Nelarabine	Authorised under exceptional circumstances	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000752/human_med_000656.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000752/human_med_000656.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
ATryn	Anti-thrombin alpha	Authorised under exceptional circumstances	Laboratoire français du Fractionnement et des Biotechnologies	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000587/human_med_000658.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000587/human_med_000658.jsp&amp;mid=WCOb01ac058001d124</a>	April 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=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004197/human_med_002100.jsp&amp;mid=WCOb01ac058001d124</a>	June 2017
Bavencio	Avelumab	New active substance and <i>new biological</i> , conditional marketing authorisation	Merck Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004338/human_med_002157.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004338/human_med_002157.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Bemfola	Follitropin alfa	New biological	Gedeon Richter Plc.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002615/human_med_001734.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002615/human_med_001734.jsp&amp;mid=WCOb01ac058001d124</a>	May 2014
Benepali	Etanercept	New biological	Samsung Bioepis UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004007/human_med_001944.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004007/human_med_001944.jsp&amp;mid=WCOb01ac058001d124</a>	January 2016
Benlysta	Belimumab	PASS <sup>1</sup>	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002015/human_med_001466.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002015/human_med_001466.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Besponsa	Inotuzumab ozoqamicin	New active substance and <i>new biological</i>	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004119/human_med_002109.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004119/human_med_002109.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Bexsero	Meningococcal group-B vaccine (rDNA, component, adsorbed)	New active substance and <i>new biological</i>	GSK Vaccines S.r.l.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002333/human_med_001614.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002333/human_med_001614.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
<b>Biktarvy</b>	<b>Bictegravir / emtricitabine / tenofovir alafenamide</b>	<b>New active substance</b>	<b>Gilead Sciences International Limited</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004449/human_med_002263.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004449/human_med_002263.jsp&amp;mid=WCOb01ac058001d124</a>	<b>July 2018</b>
BioThrax (also known as BaciThrax in France)	Anthrax antigen filtrate	New biological	Emergent Sales and Marketing Germany GmbH	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2604178-spccen-20180401.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2604178-spccen-20180401.pdf</a>	June 2018
Blincyto	Blinatumomab	New active substance and <i>new biological</i>	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003731/human_med_001921.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003731/human_med_001921.jsp&amp;mid=WCOb01ac058001d124</a>	December 2015
Blitzima	Rituximab	New biological	Celltrion Healthcare Hungary Kft.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004723/human_med_002125.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004723/human_med_002125.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Bosulfif	Bosutinib	New active substance, conditional authorisation	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002373/human_med_001613.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002373/human_med_001613.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Bretaris Genuair	Acclidinium bromide	New active substance, PASS <sup>1</sup>	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002706/human_med_001570.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002706/human_med_001570.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Brimica Genuair	Acclidinium bromide/formoterol fumarate dihydrate	PASS <sup>1</sup>	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003969/human_med_001806.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003969/human_med_001806.jsp&amp;mid=WCOb01ac058001d124</a>	December 2014
Brineura	Cerliponase alfa	New active substance, authorised under exceptional circumstances, PASS <sup>1</sup>	BioMarin International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004065/human_med_002111.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004065/human_med_002111.jsp&amp;mid=WCOb01ac058001d124</a>	June 2017
Brintellix	Vortioxetine	New active substance	H. Lundbeck A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002717/human_med_001714.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002717/human_med_001714.jsp&amp;mid=WCOb01ac058001d124</a>	February 2014
Brivect	Brivaracetam	New active substance	UCB Pharma S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003898/human_med_001945.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003898/human_med_001945.jsp&amp;mid=WCOb01ac058001d124</a>	January 2016
Cabometyx	Cabozantinib	New active substance	Ipsen Pharma	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004163/human_med_002018.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004163/human_med_002018.jsp&amp;mid=WCOb01ac058001d124</a>	September 2016
Caprelsa	Vandetanib	Conditional authorisation	Genzyme Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002315/human_med_001529.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002315/human_med_001529.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Ceplene	Histamine dihydrochloride	Authorised under exceptional circumstances	Noventia Pharma Srl	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000796/human_med_000691.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000796/human_med_000691.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Cerdelga	Eliquisat	New active substance, PASS <sup>1</sup>	Genzyme Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003724/human_med_001840.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003724/human_med_001840.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Chenodeoxycholic acid siama-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=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004061/human_med_002019.jsp&amp;mid=WCOb01ac058001d124</a>	April 2017
Cidofovir 75 mg/ml Concentrate for Solution for Infusion	Cidofovir	PASS <sup>1</sup>	Emcure Pharma UK Limited	<a href="http://www.mhra.gov.uk/home/groups/sppcpl/documents/sppcpl/con1466141046287.pdf">http://www.mhra.gov.uk/home/groups/sppcpl/documents/sppcpl/con1466141046287.pdf</a>	May 2016
<a href="#">Cilostazol-containing medicinal products (For full list of products see Annex VIII)</a>	Cilostazol	PASS <sup>1</sup>	Various (For full list see Annex VIII)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cilostazol-containing_medicines/human_referral_000338.jsp&amp;mid=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cilostazol-containing_medicines/human_referral_000338.jsp&amp;mid=WCOb01ac05805c516f</a>	September 2013
Cinquaero	Reslizumab	New active substance and <i>new biological</i>	Teva Pharmaceuticals Limited	<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>	September 2016

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Cinryze	c1 inhibitor, human	PASS <sup>1</sup>	Shire Services BVBA	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01207/human_med_001448.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01207/human_med_001448.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Cluvot	Human plasma coagulation factor XIII	New biological	CSL Behring GmbH	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613030-spcede-20180101.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613030-spcede-20180101.pdf</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/medicines/03855/human_med_001967.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03855/human_med_001967.jsp&amp;mid=WCOb01ac058001d124</a>	April 2016
<a href="#">Combined hormonal contraceptives containing chlormadinone (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/referrals/Combined_hormonal_contraceptives/human_referral_prac_000016.jsp&amp;mid=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Combined_hormonal_contraceptives/human_referral_prac_000016.jsp&amp;mid=WCOb01ac05805c516f</a>	June 2014
Cometriq	Cabozantinib	New active substance, conditional authorisation	Ipsen Pharma	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02640/human_med_001726.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02640/human_med_001726.jsp&amp;mid=WCOb01ac058001d124</a>	May 2014
Corlentor	Ivabradine	PASS <sup>1</sup>	Les Laboratoires Servier	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Corlentor_and_Procoralan/human_referral_prac_000044.jsp&amp;mid=WCOb01ac05805c516f&amp;source=homeMedSearch&amp;category=human">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Corlentor_and_Procoralan/human_referral_prac_000044.jsp&amp;mid=WCOb01ac05805c516f&amp;source=homeMedSearch&amp;category=human</a>	February 2015
Cosentyx	Secukinumab	New active substance and <i>new biological</i>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03729/human_med_001832.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03729/human_med_001832.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Cotellic	Cobimetinib	New active substance	Roche Registration GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03960/human_med_001925.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03960/human_med_001925.jsp&amp;mid=WCOb01ac058001d124</a>	December 2015
Cresemba	Isavuconazole	New active substance	Basilea Medical Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02734/human_med_001907.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02734/human_med_001907.jsp&amp;mid=WCOb01ac058001d124</a>	November 2015
CRYSVITA	Burosumab	New active substance and <i>new biological</i> , PASS <sup>1</sup>	Kyowa Kirin Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04275/human_med_002224.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04275/human_med_002224.jsp&amp;mid=WCOb01ac058001d124</a>	March 2018
Cuvitru 200 mg/ml solution for injection (also known in some EU countries as Ventygard)	Immunglobulin	New biological	Baxalta Innovations GmbH, Austria	<a href="http://mri.cts-mrp.eu/Human/Product/Details/47869">http://mri.cts-mrp.eu/Human/Product/Details/47869</a>	September 2017
Cyttezo	Adalimumab	New biological	Boehringer Ingelheim International GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04319/human_med_002181.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04319/human_med_002181.jsp&amp;mid=WCOb01ac058001d124</a>	November 2017
<a href="#">Cyproterone acetate and Ethinylestradiol containing medicinal products (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=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cyproterone_and_ethinylestradiol_containing_medicines/human_referral_prac_000017.jsp&amp;mid=WCOb01ac05805c516f</a>	August 2013
Cyramza	Ramucirumab	New active substance and <i>new biological</i>	Eli Lilly Nederland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02829/human_med_001825.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02829/human_med_001825.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Daklinza	Daclatasvir	New active substance, PASS <sup>1</sup>	Bristol-Myers Squibb Pharma EEIG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03768/human_med_001792.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03768/human_med_001792.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Darzalex	Daratumumab	New active substance and <i>new biological</i>	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04077/human_med_001979.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04077/human_med_001979.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
Daxas	Roflumilast	PASS <sup>1</sup>	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01179/human_med_001363.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01179/human_med_001363.jsp&amp;mid=WCOb01ac058001d124</a>	June 2013
Defitelio	Defibrotide	Authorised under exceptional circumstances	Gentium S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02393/human_med_001646.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02393/human_med_001646.jsp&amp;mid=WCOb01ac058001d124</a>	November 2013
Deltiba	Delamanid	New active substance, conditional authorisation	Otsuka Novel Products GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02552/human_med_001699.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02552/human_med_001699.jsp&amp;mid=WCOb01ac058001d124</a>	May 2014
Descovy	Emtricitabine/tenofovir alafenamide	New active substance	Gilead Sciences Ireland UC	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04094/human_med_001978.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04094/human_med_001978.jsp&amp;mid=WCOb01ac058001d124</a>	May 2016
<a href="#">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/03918/human_med_002104.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03918/human_med_002104.jsp&amp;mid=WCOb01ac058001d124</a>	May 2017
<a href="#">Domperidone-containing medicinal products (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

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Duaklir Genuair	Acildinium bromide/formoterol fumarate dihydrate	PASS <sup>1</sup>	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03745/human_med_001811.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03745/human_med_001811.jsp&amp;mid=WCOb01ac058001d124</a>	December 2014
Dupixent	Dupilumab	New active substance and <i>new biological</i>	Sanofi-Aventis groupe	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04390/human_med_002158.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04390/human_med_002158.jsp&amp;mid=WCOb01ac058001d124</a>	October 2017
Eklira Genuair	Acildinium 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/02221/human_med_001571.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02221/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/00700/human_med_000757.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00700/human_med_000757.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Elebrato Ellipta	Fluticasone furoate/umeclidinium/vilanterol	New active substance	GlaxoSmithKline Trading Services Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04781/human_med_002182.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04781/human_med_002182.jsp&amp;mid=WCOb01ac058001d124</a>	May 2018
Elocta	Efmorotocoq alfa	New active substance and <i>new biological</i>	Swedish Orphan Biovitrum AB (publ)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03964/human_med_001928.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03964/human_med_001928.jsp&amp;mid=WCOb01ac058001d124</a>	December 2015
Elvanse	Lisdexamphetamine	New active substance	Shire Pharmaceutical Contracts Limited	<a href="http://www.mhra.gov.uk/home/groups/sppcil/documents/sppcil/con1470374084134.pdf">http://www.mhra.gov.uk/home/groups/sppcil/documents/sppcil/con1470374084134.pdf</a>	April 2013
Empliciti	Elotuzumab	New active substance and <i>new biological</i>	Bristol-Myers Squibb Pharma EEIG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03967/human_med_001968.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03967/human_med_001968.jsp&amp;mid=WCOb01ac058001d124</a>	May 2016
ENANPLUS (also known in some EU countries as Skudexa, Skudexum and Lenizak)	Tramadol hydrochloride/ dexketoprofen	PASS <sup>1</sup>	LABORATORIOS MENARINI	<a href="https://cima.aemps.es/cima/dochtml/p/80925/P_80925.html">https://cima.aemps.es/cima/dochtml/p/80925/P_80925.html</a>	April 2018
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/03999/human_med_001989.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03999/human_med_001989.jsp&amp;mid=WCOb01ac058001d124</a>	July 2016
Entresto	Sacubitril/valsartan	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04062/human_med_001929.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04062/human_med_001929.jsp&amp;mid=WCOb01ac058001d124</a>	December 2015
Entyvio	Vedolizumab	New active substance and <i>new biological</i>	Takeda Pharma A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02782/human_med_001751.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02782/human_med_001751.jsp&amp;mid=WCOb01ac058001d124</a>	June 2014
Epclusa	Sofosbuvir/velpatasvir	New active substance	Gilead Sciences Ireland UC	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04210/human_med_001997.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04210/human_med_001997.jsp&amp;mid=WCOb01ac058001d124</a>	July 2016
Eperzan	Albiquotide	New active substance and <i>new biological</i>	GlaxoSmithKline Trading Services Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02735/human_med_001735.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02735/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/03938/human_med_001956.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03938/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/04192/human_med_002112.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04192/human_med_002112.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Erivedge	Vismodegib	New active substance	Roche Registration GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02602/human_med_001659.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02602/human_med_001659.jsp&amp;mid=WCOb01ac058001d124</a>	August 2013
Eurartesim	Dihydroartemisinin/piperaquine phosphate	PASS <sup>1</sup>	Alfasiqma S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01199/human_med_001450.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01199/human_med_001450.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Evoltra	Clofarabine	Authorised under exceptional circumstances	Genzyme Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00613/human_med_000773.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00613/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/03904/human_med_001884.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03904/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/00670/human_med_000780.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00670/human_med_000780.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Exviera	Dasabuvir	New active substance, PASS <sup>1</sup>	AbbVie Deutschland GmbH & Co. KG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03837/human_med_001833.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03837/human_med_001833.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Farydak	Panobinostat	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03725/human_med_001895.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03725/human_med_001895.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
Fasenra	Benralizumab	New active substance and <i>new biological</i>	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04433/human_med_002207.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04433/human_med_002207.jsp&amp;mid=WCOb01ac058001d124</a>	January 2018
Fexeric	Ferric citrate coordination complex	New active substance, PASS <sup>1</sup>	Keryx Biopharma UK Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03776/human_med_001908.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03776/human_med_001908.jsp&amp;mid=WCOb01ac058001d124</a>	October 2015
Fiasp	Insulin aspart	New biological	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04046/human_med_002063.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04046/human_med_002063.jsp&amp;mid=WCOb01ac058001d124</a>	March 2017
FibClot	Human Fibrinogen	New Biological	Laboratoire Francals du Fractionnement et des Biotechnologies	<a href="https://portal.dimdl.de/amispb/doc/pei/Web/2613347-spcde-20180401.pdf">https://portal.dimdl.de/amispb/doc/pei/Web/2613347-spcde-20180401.pdf</a>	July 2016

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Fibryga	Human Fibrinogen	New biological	Octapharma GmbH	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613723-spcede-20170401.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613723-spcede-20170401.pdf</a>	July 2017
Firdapse	Amifampridine	Authorised under exceptional circumstances	BioMarin Europe Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01032/human_med_001298.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01032/human_med_001298.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Flixabi	Infliximab	New biological	Samsung Bioepis UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04020/human_med_001980.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04020/human_med_001980.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
Fluenz Tetra	Influenza vaccine (live attenuated, nasal)	New biological	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02617/human_med_001713.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02617/human_med_001713.jsp&amp;mid=WCOb01ac058001d124</a>	January 2014
<a href="#">Flupirtine-containing medicinal products (For full list of products see Annex VI) *****</a>	<b>Flupirtine</b>	<b>PASS<sup>+</sup></b>	<b>Various (For full list see Annex VI)</b>	<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=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Flupirtine-containing_medicines/human_referral_prac_000019.jsp&amp;mid=WCOb01ac058001d124</a>	<b>February 2014</b>
Fotivda	Tivozanib	New active substance	EUSA Pharma (UK) Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04131/human_med_002146.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04131/human_med_002146.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Galafold	Miqalastat	New active substance	Amicus Therapeutics UK Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04059/human_med_001981.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04059/human_med_001981.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
GalliaPharm	Germanium ( <sup>68</sup> Ge) chloride/gallium ( <sup>68</sup> Ga) chloride	New active substance	Eckert & Ziegler Radiopharma GmbH	<a href="http://www.produkttresume.dk/docshare/dsweb/Get/Document-33097/GalliaPharm%2C+radionuclide+generator.docx">http://www.produkttresume.dk/docshare/dsweb/Get/Document-33097/GalliaPharm%2C+radionuclide+generator.docx</a>	April 2016
Gardasil 9	Human papillomavirus 9-valent vaccine (recombinant, adsorbed)	New active substance and <i>new biological</i>	MSD VACCINS	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03852/human_med_001863.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03852/human_med_001863.jsp&amp;mid=WCOb01ac058001d124</a>	June 2015
Gazyvaro	Obinutuzumab	New active substance and <i>new biological</i>	Roche Registration Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02799/human_med_001780.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02799/human_med_001780.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Genvoya	Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide	New active substance	Gilead Sciences Ireland UC	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04042/human_med_001940.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04042/human_med_001940.jsp&amp;mid=WCOb01ac058001d124</a>	December 2015
Gilenya	Fingolimod hydrochloride	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02202/human_med_001433.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02202/human_med_001433.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Glivec	Imatinib	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00406/human_med_000808.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00406/human_med_000808.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Glyxambi	Empagliflozin/linagliptin	New active substance	Boehringer Ingelheim International GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03833/human_med_002032.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03833/human_med_002032.jsp&amp;mid=WCOb01ac058001d124</a>	May 2017
Grastofil	Filgrastim	New biological	Apotex Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02150/human_med_001688.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02150/human_med_001688.jsp&amp;mid=WCOb01ac058001d124</a>	November 2013
Harvoni	Ledipasvir/sofosbuvir	New active substance, PASS <sup>1</sup>	Gilead Sciences Ireland UC	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03850/human_med_001813.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03850/human_med_001813.jsp&amp;mid=WCOb01ac058001d124</a>	December 2014
Hemlibra	Emicizumab	New active substance and <i>new biological</i>	Roche Registration GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04406/human_med_002236.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04406/human_med_002236.jsp&amp;mid=WCOb01ac058001d124</a>	March 2018
Herzuma	Trastuzumab	New biological	Celltrion Healthcare Hungary Kft.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02575/human_med_002230.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02575/human_med_002230.jsp&amp;mid=WCOb01ac058001d124</a>	February 2018
Hettlioz	Tasimeleone	New active substance	Vanda Pharmaceuticals Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03870/human_med_001873.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03870/human_med_001873.jsp&amp;mid=WCOb01ac058001d124</a>	July 2015
Holoclar	Ex vivo expanded autologous human corneal epithelial cells containing stem cells	New active substance and <i>new biological</i> , conditional marketing authorisation	Chiesi Farmaceutici S.P.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02450/human_med_001844.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02450/human_med_001844.jsp&amp;mid=WCOb01ac058001d124</a>	March 2015
<a href="#">Hydroxyethyl starch (HES)-containing medicinal products (For full list see Annex V)</a>	Hydroxyethyl starch	PASS <sup>1</sup>	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=WCOb01ac058005c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Hydroxyethyl_starch-containing_medicines/human_referral_prac_000029.jsp&amp;mid=WCOb01ac058005c516f</a>	January 2014
HyQvia	Human normal immunoglobulin	PASS <sup>1</sup>	Baxalta Innovations GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02491/human_med_001647.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02491/human_med_001647.jsp&amp;mid=WCOb01ac058001d124</a>	September 2013
Iblias	Octocog alfa	New biological	Bayer AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04147/human_med_001958.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04147/human_med_001958.jsp&amp;mid=WCOb01ac058001d124</a>	March 2016
Ibrance	Palbociclib	New active substance	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03853/human_med_002034.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03853/human_med_002034.jsp&amp;mid=WCOb01ac058001d124</a>	November 2016
Iclusiq	Ponatinib	PASS <sup>1</sup>	Incyte Biosciences Distribution B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02695/human_med_001656.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02695/human_med_001656.jsp&amp;mid=WCOb01ac058001d124</a>	August 2013

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Idelvion	Albutrepenonacoq alfa	New active substance and <i>new biological</i>	CSL Behring GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03955/human_med_001974.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03955/human_med_001974.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
IMBRUVICA	Ibrutinib	New active substance	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03791/human_med_001801.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03791/human_med_001801.jsp&amp;mid=WCOb01ac058001d124</a>	November 2014
Imlygic	Talimogene laherparepvec	New active substance and <i>new biological</i>	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02771/human_med_001941.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02771/human_med_001941.jsp&amp;mid=WCOb01ac058001d124</a>	January 2016
Imnovid (formerly Pomalidomide Celgene)	Pomalidomide	PASS <sup>1</sup>	Celgene Europe Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02682/human_med_001669.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02682/human_med_001669.jsp&amp;mid=WCOb01ac058001d124</a>	September 2013
Imraldi	Adalimumab	New biological	Samsunq Bioepis UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04279/human_med_002147.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04279/human_med_002147.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Imvanex	Modified Vaccinia Ankara virus – Bavarian Nordic (MVA-BN) live virus	Authorised under exceptional circumstances	Bavarian Nordic A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02596/human_med_001666.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02596/human_med_001666.jsp&amp;mid=WCOb01ac058001d124</a>	September 2013
Increlex	Mecasermin	Authorised under exceptional circumstances	Ipsen Pharma	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00704/human_med_000829.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00704/human_med_000829.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Incruse	Umeclidinium bromide	New active substance, PASS <sup>1</sup>	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02809/human_med_001755.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02809/human_med_001755.jsp&amp;mid=WCOb01ac058001d124</a>	May 2014
<del>Inflectra*</del>	<del>Infliximab</del>	<del>New biological</del>	<del>Hespira UK Limited</del>	<del><a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002778/human_med_001677.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002778/human_med_001677.jsp&amp;mid=WCOb01ac058001d124</a></del>	<del>October 2013</del>
Inhixa	Enoxaparin sodium	New biological	Techdow Europe AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04264/human_med_002020.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04264/human_med_002020.jsp&amp;mid=WCOb01ac058001d124</a>	September 2016
Insulin lispro Sanofi	Insulin lispro	New biological	Sanofi-Aventis groupe	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04303/human_med_002129.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04303/human_med_002129.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Intrarosa	Prasterone	PASS <sup>1</sup>	Endoceutics Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04138/human_med_002210.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04138/human_med_002210.jsp&amp;mid=WCOb01ac058001d124</a>	February 2018
<a href="#">Intravenous iron-containing medicinal products (For full list see Annex III)</a>	Ferric carboxymaltose, iron dextran, sodium ferric gluconate, iron isomaltoside, iron sucrose	PASS <sup>1</sup>	<a href="#">Various (For full list see Annex III)</a>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Int_ravenous_iron-containing_medicinal_products/human_referral_000343.jsp&amp;mid=WCOb01ac058005c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Int_ravenous_iron-containing_medicinal_products/human_referral_000343.jsp&amp;mid=WCOb01ac058005c516f</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/03759/human_med_001910.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03759/human_med_001910.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
Invokana	Canaqliflozin	New active substance	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02649/human_med_001707.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02649/human_med_001707.jsp&amp;mid=WCOb01ac058001d124</a>	December 2013
Iqymune (also known in some EU countries as OPTIGLOBIN)	Human normal immunoglobulin	New biological	Laboratoire Francais du Fractionnement et des Biotechnologies	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/26173314-spcde-20170301.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/26173314-spcde-20170301.pdf</a>	September 2016
Ivabradine Anpharm	Ivabradine	PASS <sup>1</sup>	ANPHARM Przedsiębiorstwo Farmaceutyczne S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04187/human_med_001911.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04187/human_med_001911.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
Izinova (also known in some EU countries as Eziclen)	Sodium sulphate anhydrous, magnesium sulphate heptahydrate, potassium sulphate	PASS <sup>1</sup>	IPSEN PHARMA	<a href="http://agence-prd.ansm.sante.fr/php/ecodex/frames.php?specid=65236258&amp;typedoc=R&amp;ref=R0222102.htm">http://agence-prd.ansm.sante.fr/php/ecodex/frames.php?specid=65236258&amp;typedoc=R&amp;ref=R0222102.htm</a>	June 2014
Jardiance	Empagliflozin	New active substance	Boehringer Ingelheim International GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02677/human_med_001764.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02677/human_med_001764.jsp&amp;mid=WCOb01ac058001d124</a>	June 2014
Jaydess (also known in some EU countries as Fieree)	Levonorgestrel	PASS <sup>1</sup>	Bayer AB	<a href="https://docetp.mpa.se/LMF/Jaydess%20Intrauterine%20delivery%20system%20ENG%20SmpC.doc">https://docetp.mpa.se/LMF/Jaydess%20Intrauterine%20delivery%20system%20ENG%20SmpC.doc</a>	November 2013
Jinarc	Tolvaptan	PASS <sup>1</sup>	Otsuka Pharmaceutical Europe Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02788/human_med_001857.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02788/human_med_001857.jsp&amp;mid=WCOb01ac058001d124</a>	June 2015
Juluca	Dolutegravir / rilpivirine	New active substance	Viiv Healthcare UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/042427/human_med_002254.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/042427/human_med_002254.jsp&amp;mid=WCOb01ac058001d124</a>	May 2018
Kadcyla	Trastuzumab emtansine	New active substance and <i>new biological</i>	Roche Registration GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02389/human_med_001712.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02389/human_med_001712.jsp&amp;mid=WCOb01ac058001d124</a>	December 2013
Kalvdeco	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/02494/human_med_001575.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02494/human_med_001575.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Kanjinti	Trastuzumab	New biological	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04361/human_med_002255.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04361/human_med_002255.jsp&amp;mid=WCOb01ac058001d124</a>	May 2018
Kanuma	Sebelipase alfa	New active substance and <i>new biological</i> , PASS <sup>1</sup>	Alexion Europe SAS	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04004/human_med_001896.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04004/human_med_001896.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
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/03773/human_med_001852.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03773/human_med_001852.jsp&amp;mid=WCOb01ac058001d124</a>	April 2015
Ketoconazole HRA	Ketoconazole	PASS <sup>1</sup>	Laboratoire HRA Pharma	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03906/human_med_001814.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03906/human_med_001814.jsp&amp;mid=WCOb01ac058001d124</a>	December 2014
Kevzara	Sarilumab	New active substance and <i>new biological</i>	Sanofi-Aventis groupe	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04254/human_med_002114.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04254/human_med_002114.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Keytruda	Pembrolizumab	New active substance and <i>new biological</i>	Merck Sharp & Dohme B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03820/human_med_001886.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03820/human_med_001886.jsp&amp;mid=WCOb01ac058001d124</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/04224/human_med_002021.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04224/human_med_002021.jsp&amp;mid=WCOb01ac058001d124</a>	September 2016
Kisqali	Ribociclib	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04213/human_med_002149.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04213/human_med_002149.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Kolbam (previously Cholic Acid FGK)	Cholic acid	Authorised under exceptional circumstances	Retrophin Europe Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02081/human_med_001718.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02081/human_med_001718.jsp&amp;mid=WCOb01ac058001d124</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/03825/human_med_001959.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03825/human_med_001959.jsp&amp;mid=WCOb01ac058001d124</a>	March 2016
Kyntheum	Brodalumab	New active substance and <i>new biological</i>	Leo Pharma A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03959/human_med_002054.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03959/human_med_002054.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Kyprolis	Carfilzomib	New active substance	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03790/human_med_001932.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03790/human_med_001932.jsp&amp;mid=WCOb01ac058001d124</a>	November 2015
Lamzede	Velmanase alfa	New active substance, authorised under exceptional circumstances	Chiesi Farmaceutici S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03922/human_med_002231.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03922/human_med_002231.jsp&amp;mid=WCOb01ac058001d124</a>	April 2018
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/04216/human_med_002036.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04216/human_med_002036.jsp&amp;mid=WCOb01ac058001d124</a>	November 2016
Latuda	Lurasidone	New active substance	Aziende Chimiche Riunite Anghelini Francesco – A.C.R.A.F. S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02713/human_med_001737.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02713/human_med_001737.jsp&amp;mid=WCOb01ac058001d124</a>	April 2014
Laventair	Umeclidinium bromide/vilanterol trifenate	New active substance, PASS <sup>1</sup>	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03754/human_med_001756.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03754/human_med_001756.jsp&amp;mid=WCOb01ac058001d124</a>	June 2014
<del>Lemtrade**</del>	<del>Atemtuzumab</del>	<del>New biological</del>	<del>Genzyme Therapeutics Ltd</del>	<del><a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0093718/human_med_001670.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0093718/human_med_001670.jsp&amp;mid=WCOb01ac058001d124</a></del>	<del>October 2013</del>
Lenvima	Lenvatinib	New active substance	Eisai Europe Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03727/human_med_001864.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03727/human_med_001864.jsp&amp;mid=WCOb01ac058001d124</a>	June 2015
Lifmior	Etanercept	New biological	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04167/human_med_002080.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04167/human_med_002080.jsp&amp;mid=WCOb01ac058001d124</a>	February 2017
Lixiana	Edoxaban	New active substance	Daiichi Sankyo Europe GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02629/human_med_001874.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02629/human_med_001874.jsp&amp;mid=WCOb01ac058001d124</a>	July 2015
Lojuxta	Lomitapide	Authorised under exceptional circumstances	Aegerion Pharmaceuticals Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02578/human_med_001668.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02578/human_med_001668.jsp&amp;mid=WCOb01ac058001d124</a>	September 2013
Lokelma	Sodium zirconium cyclosilicate	New active substance	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04029/human_med_002084.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04029/human_med_002084.jsp&amp;mid=WCOb01ac058001d124</a>	April 2018
Lonquex	Lipeflirastim	PASS <sup>1</sup>	UAB "Sicor Biotech"	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02556/human_med_001667.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02556/human_med_001667.jsp&amp;mid=WCOb01ac058001d124</a>	September 2013
Lonsurf	Trifluridine / tipiracil	New active substance	Les Laboratoires Servier	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03897/human_med_001975.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03897/human_med_001975.jsp&amp;mid=WCOb01ac058001d124</a>	May 2016
Lumark	Lutetium, isotope of mass 177	New active substance	IDB Holland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02749/human_med_001875.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02749/human_med_001875.jsp&amp;mid=WCOb01ac058001d124</a>	July 2015
Lusduna	Insulin glargine	New biological	Merck Sharp & Dohme B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04101/human_med_002058.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04101/human_med_002058.jsp&amp;mid=WCOb01ac058001d124</a>	January 2017
Lutathera	Lutetium ( <sup>177</sup> Lu) oxodotreotide	New active substance	Advanced Accelerator Applications	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04123/human_med_002163.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04123/human_med_002163.jsp&amp;mid=WCOb01ac058001d124</a>	October 2017
Lymphoseek	Tilmanocept	New active substance	Norgine B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02085/human_med_001827.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02085/human_med_001827.jsp&amp;mid=WCOb01ac058001d124</a>	December 2014
Lynparza	Olaparib	New active substance	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03726/human_med_001831.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03726/human_med_001831.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
MAC1 <sup>2</sup>	Matrix applied characterised autologous cultured chondrocytes	New active substance <i>and new biological</i>	Vericel Denmark ApS	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02522/human_med_001660.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02522/human_med_001660.jsp&amp;mid=WCOb01ac058001d124</a>	August 2013
Maviret	Glecaprevir / pibrentasvir	New active substance, PASS <sup>1</sup>	AbbVie Deutschland GmbH & Co. KG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04430/human_med_002151.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04430/human_med_002151.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Medikinet retard 10 / 20 / 30 / 40 / 5 / 50 / 60 mg	Methylphenidate hydrochloride	PASS <sup>1</sup>	Medice Arzneimittel Puttnr GmbH Co. KG	Not available	May 2018
Mekinist	Trametinib	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02643/human_med_001772.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02643/human_med_001772.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Meriofert (also known in some EU countries as Fertinorm and Eigenorm)	Menotrophin	New biological	Laboratoires Genévrier SA	<a href="http://www.produktresume.dk/docushare/dsweb/Get/Document-34320/Meriofert+Set%2C+pulver+og+solvens+til+injektionsv%C3%A6ske%2C+opl%C3%B8sning+75+IE+og+150+IE.docx">http://www.produktresume.dk/docushare/dsweb/Get/Document-34320/Meriofert+Set%2C+pulver+og+solvens+til+injektionsv%C3%A6ske%2C+opl%C3%B8sning+75+IE+og+150+IE.docx</a>	March 2015
Moventiq	Naloxegol	New active substance	Kyowa Kirin Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02810/human_med_001816.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02810/human_med_001816.jsp&amp;mid=WCOb01ac058001d124</a>	January 2015
Movymia	Teriparatide	New biological	STADA Arzneimittel AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04368/human_med_002057.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04368/human_med_002057.jsp&amp;mid=WCOb01ac058001d124</a>	January 2017
Mvasi	bevacizumab	New biological	Amaen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04728/human_med_002217.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04728/human_med_002217.jsp&amp;mid=WCOb01ac058001d124</a>	January 2018
Mylotarg	Gemtuzumab ozogamicin	New active substance <i>and new biological</i>	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04204/human_med_002252.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04204/human_med_002252.jsp&amp;mid=WCOb01ac058001d124</a>	May 2018
Mysimba	Naltrexone / bupropion	PASS <sup>1</sup>	Orexigen Therapeutics Ireland Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03687/human_med_001845.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03687/human_med_001845.jsp&amp;mid=WCOb01ac058001d124</a>	April 2015
Naqlazyme	Galsulfase	Authorised under exceptional circumstances	BioMarin Europe Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00640/human_med_000918.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00640/human_med_000918.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Natpar	Parathyroid hormone	Conditional authorisation	Shire Pharmaceuticals Ireland Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03861/human_med_002093.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03861/human_med_002093.jsp&amp;mid=WCOb01ac058001d124</a>	May 2017
Neoparin	Enoxaparinum natricum	New biological	SciencePharma spółka z ograniczoną odpowiedzialnością spółka komandytowa	<a href="http://www.leki-informacje.pl/sites/default/files/Charakterystyka-2016021900000-1576_N-20160308000147.pdf">http://www.leki-informacje.pl/sites/default/files/Charakterystyka-2016021900000-1576_N-20160308000147.pdf</a>	April 2016
Neparvis	Sacubitril / valsartan	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04343/human_med_001982.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04343/human_med_001982.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
Neuraceq	Florbetaben (18F)	New active substance	Piramal Imaging Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02553/human_med_001716.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02553/human_med_001716.jsp&amp;mid=WCOb01ac058001d124</a>	March 2014
NexoBrid	Concentrate of proteolytic enzymes enriched in bromelain	PASS <sup>1</sup>	MediWound Germany GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02246/human_med_001582.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02246/human_med_001582.jsp&amp;mid=WCOb01ac058001d124</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/03844/human_med_001998.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03844/human_med_001998.jsp&amp;mid=WCOb01ac058001d124</a>	November 2016
NovoEight	Turoctocog alfa	New active substance <i>and new biological</i>	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02719/human_med_001701.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02719/human_med_001701.jsp&amp;mid=WCOb01ac058001d124</a>	December 2013
Nucala	Mepolizumab	New active substance <i>and new biological</i>	GlaxoSmithKline Trading Services Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03860/human_med_001933.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03860/human_med_001933.jsp&amp;mid=WCOb01ac058001d124</a>	January 2016
<a href="#">Numeta G16%E medicinal products in the European Union (For full list of products see Annex XI)</a>	Alanine, arginine, aspartic acid, calcium chloride, cysteine, glucose monohydrate, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, magnesium acetate, methionine, olive oil, ornithine hydrochloride, henylalanine, potassium acetate, proline, serine, sodium chloride, sodium glycerophosphate, soybean oil, taurine, threonine, tryptophan, tyrosine, valine	PASS <sup>1</sup>	<a href="#">Baxter (For full list see Annex XI)</a>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Nu%20meta_G13F_and_Nu%20meta_G16F_emulsion_for_infusion/human_referral_prac_000027.jsp&amp;mid=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Nu%20meta_G13F_and_Nu%20meta_G16F_emulsion_for_infusion/human_referral_prac_000027.jsp&amp;mid=WCOb01ac05805c516f</a>	September 2014
Nuwiq	Simoctocog alfa	New active substance <i>and new biological</i>	Octapharma AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02813/human_med_001781.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02813/human_med_001781.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Obizur	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/02792/human_med_001918.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02792/human_med_001918.jsp&amp;mid=WCOb01ac058001d124</a>	November 2015
Ocaliva	Obeticholic acid	New active substance, conditional authorisation	Intercept Pharma Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04093/human_med_002043.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04093/human_med_002043.jsp&amp;mid=WCOb01ac058001d124</a>	January 2017
Ocrevus	Ocrelizumab	New active substance <i>and new biological</i>	Roche Registration GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04043/human_med_002187.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04043/human_med_002187.jsp&amp;mid=WCOb01ac058001d124</a>	January 2018



Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Odefsey	Emtricitabine / rilpivirine / tenofovir alafenamide	New active substance	Gilead Sciences Ireland UC	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/04156/human_med_001991.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/04156/human_med_001991.jsp&amp;mid=WCOb01ac058001d124</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/0/02839/human_med_001897.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/02839/human_med_001897.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
Ofev	Nintedanib	New active substance	Boehringer Ingelheim International GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03821/human_med_001834.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03821/human_med_001834.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Olumiant	Baricitinib	New active substance	Eli Lilly Nederland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/04085/human_med_002074.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/04085/human_med_002074.jsp&amp;mid=WCOb01ac058001d124</a>	February 2017
Oncaspar	Peqasparqase	New biological	Baxalta Innovations GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03789/human_med_001949.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03789/human_med_001949.jsp&amp;mid=WCOb01ac058001d124</a>	January 2016
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/0/02790/human_med_001950.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/02790/human_med_001950.jsp&amp;mid=WCOb01ac058001d124</a>	July 2016
Ontruzant	Trastuzumab	New biological	Samsung Bioepis UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/04323/human_med_002188.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/04323/human_med_002188.jsp&amp;mid=WCOb01ac058001d124</a>	November 2017
Opdivo	Nivolumab	New active substance	Bristol-Myers Squibb Pharma EEIG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03985/human_med_001876.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03985/human_med_001876.jsp&amp;mid=WCOb01ac058001d124</a>	July 2015
Opsumit	Macitentan	New active substance	Actelion Registration Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/02697/human_med_001717.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/02697/human_med_001717.jsp&amp;mid=WCOb01ac058001d124</a>	February 2014
<b>Optimark* **</b>	<b>Godoversetamide</b>	<b>PASS<sup>+</sup></b>	<b>Mallinckrodt-Deutschland-GmbH</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/060745/human_med_000953.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/060745/human_med_000953.jsp&amp;mid=WCOb01ac058001d124</a>	<b>April 2013</b>
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/0/03785/human_med_001853.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03785/human_med_001853.jsp&amp;mid=WCOb01ac058001d124</a>	April 2015
Orkambi	Lumacaftor/Ivacaftor	New active substance, PASS <sup>1</sup>	Vertex Pharmaceuticals (Europe) Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03954/human_med_001935.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03954/human_med_001935.jsp&amp;mid=WCOb01ac058001d124</a>	December 2015
Orphacol	Cholic acid	Authorised under exceptional circumstances	Laboratoires CTRS	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/01250/human_med_001419.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/01250/human_med_001419.jsp&amp;mid=WCOb01ac058001d124</a>	October 2013
Osseor	Strontium ranelate	PASS <sup>1</sup>	Les Laboratoires Servier	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/00561/human_med_000963.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/00561/human_med_000963.jsp&amp;mid=WCOb01ac058001d124</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/0/03746/human_med_001835.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03746/human_med_001835.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Oxervate	Cenegermin	New active substance and <i>new biological</i>	Dompé farmaceutici S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/04209/human_med_002135.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/04209/human_med_002135.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Ozanex (also known in some EU countries as C Ozenoxacin)		New active substance	Ferrer Internacional S.A.	<a href="https://cima.aemps.es/cima/dochtml/ft/82357/FichaTecnica_82357.html">https://cima.aemps.es/cima/dochtml/ft/82357/FichaTecnica_82357.html</a>	November 2017
Ozempic	Semaglutide	New active substance and <i>new biological</i>	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/04174/human_med_002211.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/04174/human_med_002211.jsp&amp;mid=WCOb01ac058001d124</a>	February 2018
Pandemic influenza vaccine H5N1 AstraZeneca	Pandemic influenza vaccine (H5N1) (live attenuated, nasal)	New active substance and <i>new biological</i> , conditional marketing authorisation	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03963/human_med_001984.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03963/human_med_001984.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
Panzyga	Human normal immunoglobulin	New Biological	Octapharma GmbH	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613595-spcde-20170501.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613595-spcde-20170501.pdf</a>	July 2016
Parsabiv	Etelcalcetide	New active substance	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03995/human_med_002037.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03995/human_med_002037.jsp&amp;mid=WCOb01ac058001d124</a>	November 2016
Pentrox	Methoxyflurane	PASS <sup>1</sup>	Medical Developments UK Ltd	<a href="http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1467955147758.pdf">http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1467955147758.pdf</a>	June 2016
Pixuvri	Pixantrone	New active substance, conditional authorisation	CTI Life Sciences Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/02055/human_med_001549.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/02055/human_med_001549.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Plegridy	Peginterferon beta-1a	New active substance and <i>new biological</i>	Biogen Idec Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/02827/human_med_001782.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/02827/human_med_001782.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Portrazza	Necitumumab	New active substance and <i>new biological</i>	Eli Lilly Nederland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03886/human_med_001953.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03886/human_med_001953.jsp&amp;mid=WCOb01ac058001d124</a>	March 2016
Praluent	Alirocumab	New active substance and <i>new biological</i>	Sanofi-Aventis Groupe	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03882/human_med_001915.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03882/human_med_001915.jsp&amp;mid=WCOb01ac058001d124</a>	October 2015
Praxbind	Idarucizumab	New active substance and <i>new biological</i>	Boehringer Ingelheim International GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03986/human_med_001938.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/0/03986/human_med_001938.jsp&amp;mid=WCOb01ac058001d124</a>	December 2015

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Previmis	Letermovir	New active substance	Merck Sharp & Dohme Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04536/human_med_002200.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04536/human_med_002200.jsp&amp;mid=WCOb01ac058001d124</a>	January 2018
Procoralan	Ivabradine	PASS <sup>1</sup>	Les Laboratoires Servier	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/CoRlenor_and_Procoralan/human_referral_prac_000044.jsp&amp;mid=WCOb01ac05805c516f&amp;source=homeMedSearch&amp;category=human">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/CoRlenor_and_Procoralan/human_referral_prac_000044.jsp&amp;mid=WCOb01ac05805c516f&amp;source=homeMedSearch&amp;category=human</a>	February 2015
Protelos	Strontium ranelate	PASS <sup>1</sup>	Les Laboratoires Servier	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000560/human_med_000999.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000560/human_med_000999.jsp&amp;mid=WCOb01ac058001d124</a>	August 2013
Quinsair	Levofloxacin	PASS <sup>1</sup>	Chiesi Farmaceutici S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002789/human_med_001846.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002789/human_med_001846.jsp&amp;mid=WCOb01ac058001d124</a>	April 2015
Raqwizax	Standardised allergen extract of pollen from Short Raqweed ( <i>Ambrosia artemisiifolia</i> )	New Biological	ALK-Abelló A/S	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613788-spcde-20180101.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613788-spcde-20180101.pdf</a>	April 2018
Rapibloc (also known in some EU countries as RAPLOC and Runraqlq)	Landiolol	New active substance	AOP Orphan Pharmaceuticals	Not available	July 2016
Ravictl	Glycerol phenylbutyrate	New active substance, PASS <sup>1</sup>	Horizon Pharma Ireland Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003822/human_med_001939.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003822/human_med_001939.jsp&amp;mid=WCOb01ac058001d124</a>	January 2016
Raxone	Idebenone	Authorised under exceptional circumstances	Santhera Pharmaceuticals (Deutschland) GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003834/human_med_001900.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003834/human_med_001900.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
Reagila	Cariprazine	New active substance	Gedeon Richter Plc.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002770/human_med_002136.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002770/human_med_002136.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Refixia	Nonacog beta pegol	New active substance and <i>new biological</i> , PASS <sup>1</sup>	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004178/human_med_002107.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004178/human_med_002107.jsp&amp;mid=WCOb01ac058001d124</a>	June 2017
Rekovellev	Follitropin delta	New biological	Ferring Pharmaceuticals A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003994/human_med_002044.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003994/human_med_002044.jsp&amp;mid=WCOb01ac058001d124</a>	May 2017
Relvar Ellipta	Fluticasone furoate/vilanterol trifenate	New active substance, PASS <sup>1</sup>	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002673/human_med_001708.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002673/human_med_001708.jsp&amp;mid=WCOb01ac058001d124</a>	December 2013
<del>Remsima*</del>	<del>Infliximab</del>	<del>New biological</del>	<del>Celltrion Healthcare Hungary Kft.</del>	<del><a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002576/human_med_001682.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002576/human_med_001682.jsp&amp;mid=WCOb01ac058001d124</a></del>	<del>October 2013</del>
Repatha	Evolocumab	New active substance and <i>new biological</i>	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003766/human_med_001890.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003766/human_med_001890.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
Respreeza	Human alpha1-proteinase inhibitor	New biological	CSL Behring GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002739/human_med_001904.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002739/human_med_001904.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
Revestive	Teduqlutide	PASS <sup>1</sup>	Shire Pharmaceuticals Ireland Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002345/human_med_001583.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002345/human_med_001583.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Revinty Ellipta	Fluticasone furoate/vilanterol trifenate	PASS <sup>1</sup>	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002745/human_med_001768.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002745/human_med_001768.jsp&amp;mid=WCOb01ac058001d124</a>	May 2014
Revlimid	Lenalidomide	PASS <sup>1</sup>	Celgene Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000717/human_med_001034.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000717/human_med_001034.jsp&amp;mid=WCOb01ac058001d124</a>	June 2014
Rezolsta	Darunavir/cobicistat	New active substance	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002819/human_med_001817.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002819/human_med_001817.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Ritemvia	Rituximab	New biological	Celltrion Healthcare Hungary Kft.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004725/human_med_002137.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004725/human_med_002137.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Rituzena (previously 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
Rixathon	Rituximab	New biological	Sandoz GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003903/human_med_002095.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003903/human_med_002095.jsp&amp;mid=WCOb01ac058001d124</a>	June 2017
Riximyo	Rituximab	New biological	Sandoz GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004729/human_med_002116.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004729/human_med_002116.jsp&amp;mid=WCOb01ac058001d124</a>	June 2017
Rixubis	Nonacoq gamma	New biological	Baxalta Innovations GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003771/human_med_001830.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003771/human_med_001830.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Rolufita	Urmeclidinium	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/004654/human_med_002085.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004654/human_med_002085.jsp&amp;mid=WCOb01ac058001d124</a>	March 2017
Roteas	Edoxaban	New active substance	Daiichi Sankyo Europe GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004339/human_med_002096.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004339/human_med_002096.jsp&amp;mid=WCOb01ac058001d124</a>	May 2017
Rubraca	Rucaparib	New active substance, conditional marketing authorisation	Clovis Oncology UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004272/human_med_002215.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004272/human_med_002215.jsp&amp;mid=WCOb01ac058001d124</a>	June 2018

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Rydapt	Midostaurin	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04095/human_med_002155.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04095/human_med_002155.jsp&amp;mid=WCOb01ac058001d124</a>	October 2017
Saxenda	Liraoglutide	New biological	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03780/human_med_001855.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03780/human_med_001855.jsp&amp;mid=WCOb01ac058001d124</a>	April 2015
Scenesse	Afamelanotide	New active substance, authorised under exceptional circumstances	Clinuvel UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02548/human_med_001826.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02548/human_med_001826.jsp&amp;mid=WCOb01ac058001d124</a>	January 2015
Seasonique	Levonorgestrel/ethinylestradiol	PASS <sup>1</sup>	Teva Pharma B.V.	Not available	June 2015
Segluromet	Ertugliflozin / metformin hydrochloride	New active substance	Merck Sharp & Dohme Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04314/human_med_002238.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04314/human_med_002238.jsp&amp;mid=WCOb01ac058001d124</a>	April 2018
Semglee	Insulin glargine	New biological	Mylan S.A.S.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04280/human_med_002239.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04280/human_med_002239.jsp&amp;mid=WCOb01ac058001d124</a>	April 2018
Senshio	Ospemifene	New active substance, PASS <sup>1</sup>	Shionqi Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02780/human_med_001837.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02780/human_med_001837.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Shingrix	Herpes zoster vaccine (recombinant, adjuvanted)	New active substance and <i>new biological</i>	GlaxoSmithKline Biologics S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04336/human_med_002240.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04336/human_med_002240.jsp&amp;mid=WCOb01ac058001d124</a>	April 2018
Sirturo	Bedaquiline	New active substance, conditional authorisation	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02614/human_med_001730.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02614/human_med_001730.jsp&amp;mid=WCOb01ac058001d124</a>	March 2014
Sivextro	Tedizolid phosphate	New active substance	Merck Sharp & Dohme Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02846/human_med_001856.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02846/human_med_001856.jsp&amp;mid=WCOb01ac058001d124</a>	April 2015
SomaKIT TOC	Edotreotide	New active substance	Advanced Accelerator Applications	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04140/human_med_002038.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04140/human_med_002038.jsp&amp;mid=WCOb01ac058001d124</a>	December 2016
<b>Somatropin Biopartners *****</b>	<b>Somatropin</b>	<b>New biological</b>	<b>BioPartners GmbH</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/092196/human_med_001672.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/092196/human_med_001672.jsp&amp;mid=WCOb01ac058001d124</a>	<b>September 2013</b>
Sonazoid powder and solvent for solution of for injection 8 microliter/ml	Perflubutan	New active substance	GE HEALTHCARE AS	Not available	November 2016
Sovaldi	Sofosbuvir	New active substance, PASS <sup>1</sup>	Gilead Sciences Ireland UC	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02798/human_med_001723.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02798/human_med_001723.jsp&amp;mid=WCOb01ac058001d124</a>	February 2014
Spectrila	Asparaginase	New biological	Medac Gesellschaft für klinische Spezialpräparate mbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02661/human_med_001954.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02661/human_med_001954.jsp&amp;mid=WCOb01ac058001d124</a>	January 2016
Spherox	Spheroids of human autologous matrix-associated chondrocytes	New active substance and <i>new biological</i>	CO.DON AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02736/human_med_002138.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02736/human_med_002138.jsp&amp;mid=WCOb01ac058001d124</a>	July 2017
Spinraza	Nusinersen	New active substance	Biogen Idec Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04312/human_med_002119.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04312/human_med_002119.jsp&amp;mid=WCOb01ac058001d124</a>	June 2017
Spiolto Respimat	Tiotropium Bromide Monohydrate / Olodaterol Hydrochloride	New active substance	Boehringer Ingelheim International GmbH	<a href="http://db.cbq-meb.nl/IB-teksten/h115528.pdf">http://db.cbq-meb.nl/IB-teksten/h115528.pdf</a>	September 2016
Steglatro	Ertugliflozin	New active substance	Merck Sharp & Dohme Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04315/human_med_002241.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04315/human_med_002241.jsp&amp;mid=WCOb01ac058001d124</a>	April 2018
Steglujan	Ertugliflozin / sitagliptin	New active substance	Merck Sharp & Dohme Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04313/human_med_002242.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04313/human_med_002242.jsp&amp;mid=WCOb01ac058001d124</a>	April 2018
Strensiq	Asfotase alfa	New active substance and <i>new biological</i> , authorised under exceptional circumstances	Alexion Europe SAS	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03794/human_med_001901.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03794/human_med_001901.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
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 and <i>new biological</i> , PASS <sup>1</sup>	GlaxoSmithKline Trading Services Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03854/human_med_001985.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03854/human_med_001985.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
Striverdi Respimat (also known in some EU countries as Infortispir Respimat)	Olodaterol	New active substance, PASS <sup>1</sup>	Boehringer Ingelheim International GmbH	<a href="http://db.cbq-meb.nl/IB-teksten/h112058.pdf">http://db.cbq-meb.nl/IB-teksten/h112058.pdf</a>	February 2015
Sulliqua	Insulin glargine / lixisenatide	New active substance and <i>new biological</i>	Sanofi-Aventis groupe	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04243/human_med_002064.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04243/human_med_002064.jsp&amp;mid=WCOb01ac058001d124</a>	March 2017
Sylvant	Siltuximab	New active substance and <i>new biological</i> , PASS <sup>1</sup>	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03708/human_med_001769.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03708/human_med_001769.jsp&amp;mid=WCOb01ac058001d124</a>	June 2014
Symtuza	Darunavir / cobicistat / emtricitabine / tenofovir alafenamide	New active substance	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04391/human_med_002165.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04391/human_med_002165.jsp&amp;mid=WCOb01ac058001d124</a>	October 2017

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Synjardy	Empagliflozin/metformin	New active substance	Boehringer Ingelheim International GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03770/human_med_001865.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03770/human_med_001865.jsp&amp;mid=WCOb01ac058001d124</a>	June 2015
Taqrisso	Osimertinib	New active substance and <i>new biological</i>	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04124/human_med_001961.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04124/human_med_001961.jsp&amp;mid=WCOb01ac058001d124</a>	February 2016
TAKUDEX (also known in some EU countries as Dextra)	Tramadol hydrochloride/ dexketoprofen	PASS <sup>1</sup>	GUIDOTTI FARMA	<a href="https://cima.aemps.es/cima/dochtml/ft/80802/FT_80802.html">https://cima.aemps.es/cima/dochtml/ft/80802/FT_80802.html</a>	April 2018
Taltz	Ixekizumab	New active substance and <i>new biological</i>	Eli Lilly Nederland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03943/human_med_001977.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03943/human_med_001977.jsp&amp;mid=WCOb01ac058001d124</a>	May 2016
<a href="#">Targocid and associated names (teicoplanin-containing medicinal products) (For full list see Annex VII)</a>	Teicoplanin	PASS <sup>1</sup>	Various (For full list see Annex VII)	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Targocid_and_associated_names/human_referral_000341.jsp&amp;mid=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Targocid_and_associated_names/human_referral_000341.jsp&amp;mid=WCOb01ac05805c516f</a>	February 2014
Tecentriq	Atezolizumab	New active substance and <i>new biological</i>	Roche Registration GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04143/human_med_002166.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04143/human_med_002166.jsp&amp;mid=WCOb01ac058001d124</a>	October 2017
<b>Tegsedi</b>	<b>Inotersen</b>	<b>New active substance</b>	<b>IONIS USA Limited</b>	<b>Not yet available</b>	<b>July 2018</b>
Terrosa	Teriparatide	New biological	Gedeon Richter Plc.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03916/human_med_002060.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03916/human_med_002060.jsp&amp;mid=WCOb01ac058001d124</a>	January 2017
<a href="#">Thiocolchicoside-containing medicinal products (For full list see Annex IV)</a>	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/03795/human_med_002024.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03795/human_med_002024.jsp&amp;mid=WCOb01ac058001d124</a>	September 2016
Tivicav	Dolutegravir	New active substance	Viiv Healthcare BV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02753/human_med_001720.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02753/human_med_001720.jsp&amp;mid=WCOb01ac058001d124</a>	February 2014
Tookad	Padeliporfin	New active substance	Steba Biotech S.A	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04182/human_med_002190.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04182/human_med_002190.jsp&amp;mid=WCOb01ac058001d124</a>	November 2017
Translarna	Ataluren	New active substance, conditional authorisation	PTC Therapeutics Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02720/human_med_001742.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02720/human_med_001742.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Treleqv Ellipta	Fluticasone furoate/umeclidinium/vilanterol	New active substance	GlaxoSmithKline Trading Services Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04363/human_med_002191.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04363/human_med_002191.jsp&amp;mid=WCOb01ac058001d124</a>	May 2018
Tremfya	Guselkumab	New active substance and <i>new biological</i>	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04271/human_med_002183.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04271/human_med_002183.jsp&amp;mid=WCOb01ac058001d124</a>	November 2017
Triumeq	Dolutegravir/abacavir/lamivudine	New active substance	Viiv Healthcare UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02754/human_med_001796.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02754/human_med_001796.jsp&amp;mid=WCOb01ac058001d124</a>	October 2014
Truberzi	Eluxadoline	New active substance	Allergan Pharmaceuticals International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04098/human_med_002025.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04098/human_med_002025.jsp&amp;mid=WCOb01ac058001d124</a>	October 2016
Trulicity	Dulaglutide	New active substance and <i>new biological</i>	Eli Lilly Nederland B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02825/human_med_001821.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02825/human_med_001821.jsp&amp;mid=WCOb01ac058001d124</a>	December 2014
Trumenba	Meningococcal group B vaccine (recombinant, componen	New active substance and <i>new biological</i>	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04051/human_med_002101.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04051/human_med_002101.jsp&amp;mid=WCOb01ac058001d124</a>	June 2017
Truxima	Rituximab	New biological	Celltrion Healthcare Hungary Kft.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04112/human_med_002077.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04112/human_med_002077.jsp&amp;mid=WCOb01ac058001d124</a>	March 2017
Tybst	Cobicistat	New active substance	Gilead Sciences Ireland UC	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02572/human_med_001690.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02572/human_med_001690.jsp&amp;mid=WCOb01ac058001d124</a>	October 2013
Tysabri	Natalizumab	PASS <sup>1</sup>	Biogen Idec Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00603/human_med_001119.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00603/human_med_001119.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Ultibro Breezhaler	Indacaterol/glycopyrronium bromide	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02679/human_med_001691.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02679/human_med_001691.jsp&amp;mid=WCOb01ac058001d124</a>	October 2013
Utunar 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/03875/human_med_001758.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03875/human_med_001758.jsp&amp;mid=WCOb01ac058001d124</a>	July 2014

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Uptravi	Selexipag	New active substance	Actelion Registration Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03774/human_med_001970.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03774/human_med_001970.jsp&amp;mid=WCOb01ac058001d124</a>	June 2016
<a href="#">Valproate and related substances (sodium, valproate, valproic acid, valproate semisodium, valpromide-containing medicinal products) (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/VaIproate_and_related_substances/human_referral_prac_000032.jsp&amp;mid=WCOb01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/VaIproate_and_related_substances/human_referral_prac_000032.jsp&amp;mid=WCOb01ac05805c516f</a>	January 2015
Vargatef	Nintedanib	New active substance	Boehringer Ingelheim International GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02569/human_med_001822.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02569/human_med_001822.jsp&amp;mid=WCOb01ac058001d124</a>	December 2014
Varuby	Rolapitant	New active substance	Tesaro UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04196/human_med_002097.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04196/human_med_002097.jsp&amp;mid=WCOb01ac058001d124</a>	May 2017
Vaxelis Vaxigrip Tetra (also known in some EU countries as quadrivalent influenza vaccine (split virion, inactivated))	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)	New biological	MCM Vaccine B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03982/human_med_001962.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03982/human_med_001962.jsp&amp;mid=WCOb01ac058001d124</a>	February 2016
	Influenza vaccine (split virion, inactivated)	New biological	Sanofi Pasteur MSD GmbH	<a href="https://portal.dimdi.de/amispb/doc/pei/Web/2613624-spdcde-20171201.pdf">https://portal.dimdi.de/amispb/doc/pei/Web/2613624-spdcde-20171201.pdf</a>	September 2016
Vedrop	Tocofersolan d-alpha tocopheryl polyethylene glycol succinate	Authorised under exceptional circumstances	Orphan Europe S.A.R.L.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00920/human_med_001129.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00920/human_med_001129.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
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/02705/human_med_001795.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02705/human_med_001795.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Veltassa	Patromer	New active substance	Vifor Fresenius Medical Care Renal Pharma France	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04180/human_med_002141.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04180/human_med_002141.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Vemlidy	Tenofovir alafenamide	New active substance	Gilead Sciences Ireland UC	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04169/human_med_002061.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04169/human_med_002061.jsp&amp;mid=WCOb01ac058001d124</a>	January 2017
Venclyxto	Venetoclax	New active substance, conditional authorisation	AbbVie Deutschland GmbH & Co. KG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04106/human_med_002045.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04106/human_med_002045.jsp&amp;mid=WCOb01ac058001d124</a>	December 2016
Vepacel	A/H5N1 pre-pandemic influenza vaccine (whole virion, vero cell derived, inactivated)	New active substance and <i>new biological</i>	Nanotherapeutics UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02089/human_med_001543.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02089/human_med_001543.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
VeraSeal	Human fibrinogen / human thrombin	New biological	Instituto Grifols, S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04446/human_med_002197.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04446/human_med_002197.jsp&amp;mid=WCOb01ac058001d124</a>	November 2017
Viekirax	Ombitasvir/paritaprevir/ritonavir	New active substance, PASS <sup>1</sup>	AbbVie Deutschland GmbH & Co. KG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03839/human_med_001838.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03839/human_med_001838.jsp&amp;mid=WCOb01ac058001d124</a>	February 2015
Vihuma	Simoctocog alfa	New active substance and <i>new biological</i>	Octapharma AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04459/human_med_002078.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04459/human_med_002078.jsp&amp;mid=WCOb01ac058001d124</a>	April 2017
Vimizim	Elosulfase alfa	New active substance and <i>new biological</i> , PASS <sup>1</sup>	BioMarin Europe Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02779/human_med_001759.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02779/human_med_001759.jsp&amp;mid=WCOb01ac058001d124</a>	June 2014
Vizamyl	Flutemetamol (18F)	New active substance	GE Healthcare Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02557/human_med_001794.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02557/human_med_001794.jsp&amp;mid=WCOb01ac058001d124</a>	September 2014
Vokanamet	Canaqilfozin/metformin hydrochloride	New active substance	Janssen-Cilag International NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02656/human_med_001760.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02656/human_med_001760.jsp&amp;mid=WCOb01ac058001d124</a>	May 2014
Vosevi	Sofosbuvir / velpatasvir / voxilaprevir	New active substance, PASS <sup>1</sup>	Gilead Sciences Ireland UC	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04350/human_med_002153.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04350/human_med_002153.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Vyndaqel	Tafamidis	Authorised under exceptional circumstances	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02294/human_med_001498.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02294/human_med_001498.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Wakix	Pitolisant hydrochloride	New active substance, PASS <sup>1</sup>	Bioproljet Pharma	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02616/human_med_001955.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02616/human_med_001955.jsp&amp;mid=WCOb01ac058001d124</a>	April 2016
Xadaqo	Safinamide	New active substance	Zambon S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02396/human_med_001847.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02396/human_med_001847.jsp&amp;mid=WCOb01ac058001d124</a>	March 2015
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/00480/human_med_001153.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00480/human_med_001153.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Xalkori	Crizotinib	New active substance	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02489/human_med_001592.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02489/human_med_001592.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Xarelto	Rivaroxaban	PASS <sup>1</sup>	Bayer Pharma AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00944/human_med_001155.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/00944/human_med_001155.jsp&amp;mid=WCOb01ac058001d124</a>	July 2013

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
Xeljanz	Tofacitinib	New active substance	Pfizer Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04214/human_med_001662.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04214/human_med_001662.jsp&amp;mid=WCOb01ac058001d124</a>	April 2017
Xermelo	Telotristat	New active substance	Ipsen Pharma	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03937/human_med_002168.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03937/human_med_002168.jsp&amp;mid=WCOb01ac058001d124</a>	September 2017
Xgeva	Denosumab	New biological	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02173/human_med_001463.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02173/human_med_001463.jsp&amp;mid=WCOb01ac058001d124</a>	April 2013
Xofigo	Radium Ra 223 dichloride	New active substance	Bayer AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02653/human_med_001692.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02653/human_med_001692.jsp&amp;mid=WCOb01ac058001d124</a>	December 2013
Xoterna Breezhaler	Indacaterol/qlucopyrronium bromide	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03755/human_med_001693.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03755/human_med_001693.jsp&amp;mid=WCOb01ac058001d124</a>	October 2013
Xultophy	Insulin deqludec/liraglutide	New biological	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02647/human_med_001802.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02647/human_med_001802.jsp&amp;mid=WCOb01ac058001d124</a>	October 2014
Xydalba	Dalbavancin	New active substance	Allergan Pharmaceuticals International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02840/human_med_001848.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02840/human_med_001848.jsp&amp;mid=WCOb01ac058001d124</a>	March 2015
Yanimo Resplimat	Tiotropium Bromide Monohydrate / Olodaterol Hydrochloride	New active substance	Boehringer Ingelheim International GmbH	<a href="http://db.cba-meb.nl/IB-teksten/h115529.pdf">http://db.cba-meb.nl/IB-teksten/h115529.pdf</a>	September 2016
Zalmoxis	Allogenic 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 and <i>new biological</i> , conditional marketing authorisation	MolMed S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02801/human_med_002016.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/02801/human_med_002016.jsp&amp;mid=WCOb01ac058001d124</a>	September 2016
Zavicefta	Ceftazidime / avibactam	New active substance	Pfizer Ireland Pharmaceuticals	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04027/human_med_001993.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04027/human_med_001993.jsp&amp;mid=WCOb01ac058001d124</a>	July 2016
Zejula	Niraparib	New active substance	TESARO UK LIMITED	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04249/human_med_002192.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04249/human_med_002192.jsp&amp;mid=WCOb01ac058001d124</a>	November 2017
Zepatier	Elbasvir / grazoprevir	New active substance	Merck Sharp & Dohme B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04126/human_med_002001.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04126/human_med_002001.jsp&amp;mid=WCOb01ac058001d124</a>	September 2016
Zerbaxa	Ceftolozane / tazobactam	New active substance	Merck Sharp & Dohme B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03772/human_med_001917.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03772/human_med_001917.jsp&amp;mid=WCOb01ac058001d124</a>	September 2015
	Ceftobiprole medocartil sodium	New active substance	Basilea Medical Ltd	<a href="http://www.mhra.gov.uk/home/groups/sppcil/documents/sppcil/con1448606619300.pdf">http://www.mhra.gov.uk/home/groups/sppcil/documents/sppcil/con1448606619300.pdf</a>	June 2016
Zinplava	Bezlotoxumab	New active substance and <i>new biological</i>	Merck Sharp & Dohme B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04136/human_med_002062.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/04136/human_med_002062.jsp&amp;mid=WCOb01ac058001d124</a>	February 2017
Zoely	Nomegestrol/Estradiol	PASS <sup>1</sup>	Teva B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01213/human_med_001452.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/01213/human_med_001452.jsp&amp;mid=WCOb01ac058001d124</a>	January 2014
Zurampic	Lesinurad	New active substance, PASS <sup>1</sup>	Grünenthal GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03932/human_med_001963.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03932/human_med_001963.jsp&amp;mid=WCOb01ac058001d124</a>	March 2016
Zydella	Idelalisib	New active substance	Gilead Sciences Ireland UC	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03843/human_med_001803.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03843/human_med_001803.jsp&amp;mid=WCOb01ac058001d124</a>	October 2014
Zykadia	Ceritinib	New active substance	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03819/human_med_001860.jsp&amp;mid=WCOb01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/03819/human_med_001860.jsp&amp;mid=WCOb01ac058001d124</a>	May 2015

<sup>1</sup> PASS: Post-authorisation safety study. A PASS is defined in Article 1(15) of Directive 2001/83/EC as any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.

\* Five years after the European Union Reference Date (EURD) for infliximab, Inflectra and Remsina are no longer under additional monitoring. They are therefore removed from this list.

\*\* Five years after the European Union Reference Date (EURD) for alemtuzumab, Lemtrada is no longer under additional monitoring. It is therefore removed from this list.

\*\*\* The marketing authorisation for Optimark has expired following the marketing-authorisation holder's decision not to apply for a renewal. Thus, this product is removed from the list.

\*\*\*\* The marketing authorisation of Somatropin Biopartners has ceased to be valid in the context of the sunset clause (Reg 726/2004, art. 14(4-6)), therefore this product is removed from the list.

\*\*\*\*\* Following the CMDh endorsement of the PRAC recommendation to withdraw the marketing authorisation for all flupirtine containing medicinal products in the European Union, Annex VI (List of flupirtine-containing medicinal products in the European Union) is removed from the the additional monitoring list