

List of medicinal products under additional monitoring

Related Information:

[Additional monitoring explained:](#)

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

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

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

To note: All products added to the list in July 2015 are highlighted in red font.

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information	Date of Inclusion
ABASRIA	Insulin glargine	New biological	Eli Lilly Regional Operations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002835/human_med_001790.jsp&mid=WC0b01ac058001d124	October 2014
Accofil	Filgrastim	New biological	Accord Healthcare Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003956/human_med_001798.jsp&mid=WC0b01ac058001d124	October 2014
Adcetris	Brentuximab vedotin	New active substance, conditional authorisation	Takeda Global Research and Development Centre (Europe) Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002455/human_med_001588.jsp&mid=WC0b01ac058001d124	April 2013
Adempas	Riociguat	New active substance	Bayer Pharma AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002737/human_med_001733.jsp&mid=WC0b01ac058001d124	April 2014
Akynzeo	Netupitant/palonosetron	New active substance	Helsinn Birex Pharmaceuticals Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003728/human_med_001862.jsp&mid=WC0b01ac058001d124	June 2015
Albumeon	Human albumin	New biological	CSL Behring GmbH	http://www.pei.de/SharedDocs/arzneimittel/am-aus-blut/albumin/PEI-H-11655-01-1.html	July 2015
Aldurazyme	Laronidase	Authorised under exceptional circumstances	Genzyme Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000477/human_med_000636.jsp&mid=WC0b01ac058001d124	April 2013
AMYVID	Florbetapir [18F]	New active substance	Eli Lilly Nederlands B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002422/human_med_001611.jsp&mid=WC0b01ac058001d124	April 2013
Anoro	Umeclidinium bromide/vilanterol trifenate	New active substance, PASS ¹	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002751/human_med_001754.jsp&mid=WC0b01ac058001d124	June 2014
Apleek	Ethinyl estradiol/gestodene	PASS ¹	Bayer Pharma AG	http://www.cbg-meb.nl/CBG/nl/_search/SplitScreen/default.htm?qry=apleek&language=nl	September 2014
Atriance	Nelarabine	Authorised under exceptional circumstances	Glaxo Group Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000752/human_med_000656.jsp&mid=WC0b01ac058001d124	April 2013
ATryn	Anti-thrombin alpha	Authorised under exceptional circumstances	GTC Biotherapeutics UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000587/human_med_000658.jsp&mid=WC0b01ac058001d124	April 2013
Aubagio	Teriflunomide	New active substance	Sanofi-aventis Groupe	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002514/human_med_001645.jsp&mid=WC0b01ac058001d124	October 2013
Bemfola	Follitropin alfa	New biological	FINOX Biotech AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002615/human_med_001734.jsp&mid=WC0b01ac058001d124	May 2014
Benlysta	Belimumab	New active substance	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002015/human_med_001466.jsp&mid=WC0b01ac058001d124	April 2013
Betmiga	Mirabegron	New active substance	Astellas Pharma Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002388/human_med_001605.jsp&mid=WC0b01ac058001d124	April 2013
Bexsero	Meningococcal group-B vaccine (rDNA, component, adsorbed)	New active substance	Novartis Vaccines and Diagnostics S.r.l.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002333/human_med_001614.jsp&mid=WC0b01ac058001d124	April 2013
Bosulif	Bosutinib	New active substance, conditional authorisation	Pfizer Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002373/human_med_001613.jsp&mid=WC0b01ac058001d124	April 2013
Bretaris Genuair	Acclidinium bromide	New active substance, PASS ¹	Almirall, S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002706/human_med_001570.jsp&mid=WC0b01ac058001d124	April 2013
Brimica Genuair	Acclidinium bromide/formoterol fumarate dihydrate	PASS ¹	Almirall, S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003969/human_med_001806.jsp&mid=WC0b01ac058001d124	December 2014

Brintellix	Vortioxetine	New active substance	H. Lundbeck A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002717/human_med_001714.jsp&mid=WC0b01ac058001d124	February 2014
Caprelsa	Vandetanib	New active substance, conditional authorisation	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002315/human_med_001529.jsp&mid=WC0b01ac058001d124	April 2013
Ceplene	Histamine dihydrochloride	Authorised under exceptional circumstances	Meda AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000796/human_med_000691.jsp&mid=WC0b01ac058001d124	April 2013
Cerdelga	Eliglustat	New active substance, PASS ¹	Genzyme Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003724/human_med_001840.jsp&mid=WC0b01ac058001d124	February 2015
Champix	Varenicline	PASS ¹	Pfizer	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000699/human_med_000696.jsp&mid=WC0b01ac058001d124	April 2013
Cilostazol-containing medicinal products (For full list of products see Annex VIII)	Cilostazol	PASS ¹	Various (For full list see Annex VIII)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63	September 2013
Cinryze	c1 inhibitor, human	PASS ¹	ViroPharma SPRL	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001207/human_med_001448.jsp&mid=WC0b01ac058001d124	April 2013
Cleviprex emulsion for injection 0.5 mg/ml	Clevidipine	New active substance	The Medicines Company UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63	April 2013
Cluvot	Human plasma coagulation factor XIII	New biological	CSL Behring GmbH	http://www.pei.de/SiteGlobals/Forms/Suche/Servicesuche_Formular.html?resourcelid=3248420&sortOrder=score+desc&input_ =3245768&submit_x=0&submit_y=0&gts=3246608_list%253DdateOfIssuue_dt%252Bdesc&pageLocale=de&templateQueryString=cluvot	May 2015
Combined hormonal contraceptives containing chlormadinone (For full list of products see Annex IX)	Chlormadinone Ethinylestradiol, Chlormadinone Acetate Ethinylestradiol	PASS ¹	Various (For full list see Annex IX)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63	June 2014
Cometriq	Cabozantinib	New active substance, conditional authorisation	TMC Pharma Services Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002640/human_med_001726.jsp&mid=WC0b01ac058001d124	May 2014
Constella	Linaclotide	New active substance	Almirall, S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002490/human_med_001597.jsp&mid=WC0b01ac058001d124	April 2013
Corlentor	Ivabradine	PASS ¹	Les Laboratoires Servier	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Corlentor_and_Procoralan/human_referral_prac_000044.jsp&mid=WC0b01ac05805c516f&source=homeMedSearch&category=human	February 2015
Cosentyx	Secukinumab	New active substance	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003729/human_med_001832.jsp&mid=WC0b01ac058001d124	February 2015
Cuprymina	Copper (64Cu) chloride	New active substance	Sparkle S.r.l	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002136/human_med_001578.jsp&mid=WC0b01ac058001d124	April 2013
Cyproterone acetate and Ethinylestradiol containing medicinal products (For full list of products see Annex I)	Cyproterone acetate and Ethinylestradiol	PASS ¹	Various (For full list see Annex I)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63	August 2013
Cyramza	Ramucirumab	New active substance	Eli Lilly Nederland B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002829/human_med_001825.jsp&mid=WC0b01ac058001d124	February 2015
Dacogen	Decitabine	New active substance	Janssen-Cilag International B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002221/human_med_001589.jsp&mid=WC0b01ac058001d124	April 2013
Daklinza	Daclatasvir	New active substance	Bristol-Myers Squibb Pharma EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003768/human_med_001792.jsp&mid=WC0b01ac058001d124	September 2014
Daliresp	Roflumilast	PASS ¹	Takeda GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002398/human_med_001415.jsp&mid=WC0b01ac058001d124	June 2013
Daxas	Roflumilast	PASS ¹	Takeda GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001179/human_med_001363.jsp&mid=WC0b01ac058001d124	June 2013
Defitelio	Defibrotide	New biological, authorised under exceptional circumstances	Gentium S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002393/human_med_001646.jsp&mid=WC0b01ac058001d124	November 2013
Delyba	Delamanid	New active substance, conditional authorisation	Otsuka Novel Products GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002552/human_med_001699.jsp&mid=WC0b01ac058001d124	May 2014
Dexametamine sulphate-containing medicinal products in the EU (For full list of products see Annex XII)	Dexametamine sulphate	PASS ¹	Kohne Pharma GmbH (For full list see Annex XII)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Dexametamine_sulphate-containing_medicinal_products_in_the_EU/human_referral_000373.jsp&mid=WC0b01ac05805c516f	September 2014
Dificlir	Fidaxomicin	New active substance	Astellas Pharma Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002087/human_med_001511.jsp&mid=WC0b01ac058001d124	April 2013
Domperidone-containing medicinal products (For full list of products see Annex X)	Domperidone	PASS ¹	Various (For full list see Annex X)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Domperidone-containing_medicines/human_referral_prac_000021.jsp&mid=WC0b01ac05805c516f	July 2014

Duaklir Genuair	Acridinium bromide/formoterol fumarate dihydrate	PASS ¹	Almirall, S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003745/human_med_001811.jsp&mid=WC0b01ac058001d124	December 2014
Edarbi	Azilsartan medoxomil	New active substance	Takeda Global Research and Development Centre (Europe) Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002293/human_med_001512.jsp&mid=WC0b01ac058001d124	April 2013
Edurant	Rilpivirine	New active substance	Janssen-Cilag International B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002264/human_med_001513.jsp&mid=WC0b01ac058001d124	April 2013
Ekliira Genuair	Acridinium bromide	New active substance, PASS ¹	Almirall, S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002211/human_med_001571.jsp&mid=WC0b01ac058001d124	April 2013
Elaprase	Idursulfase	Authorised under exceptional circumstances	Shire Human Genetic Therapies AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000700/human_med_000757.jsp&mid=WC0b01ac058001d124	April 2013
Eliquis	Apixaban	New active substance	Bristol Myers Squibb/ Pfizer EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002148/human_med_001449.jsp&mid=WC0b01ac058001d124	April 2013
Elvanse ²	Lisdexamphetamine	New active substance	Shire Pharmaceutical Contracts Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63	April 2013
Entyvio	Vedolizumab	New active substance	Takeda Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002782/human_med_001751.jsp&mid=WC0b01ac058001d124	June 2014
Enurev Breezhaler	Glycopyrronium bromide	PASS ¹	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002691/human_med_001579.jsp&mid=WC0b01ac058001d124	April 2013
Eperzan	Albiglutide	New active substance	GlaxoSmithKline Trading Services Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002735/human_med_001735.jsp&mid=WC0b01ac058001d124	April 2014
Erivedge	Vismodegib	New active substance, conditional authorisation	Roche Registration Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002602/human_med_001659.jsp&mid=WC0b01ac058001d124	August 2013
Esbriet	Pirfenidone	New active substance, PASS ¹	InterMune UK Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002154/human_med_001417.jsp&mid=WC0b01ac058001d124	April 2013
Eurartesim	Dihydroartemisinin/piperaquine phosphate	New active substance, PASS ¹	Sigma-tau Industrie Farmaceutiche Riunite S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001199/human_med_001450.jsp&mid=WC0b01ac058001d124	April 2013
Evarrest	Human fibrinogen/human thrombin	New biological	Omrix Biopharmaceuticals N. V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002515/human_med_001675.jsp&mid=WC0b01ac058001d124	November 2013
Eviplera	Emtricitabine/rilpivirine/tenofovir disoproxil	New active substance	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002312/human_med_001514.jsp&mid=WC0b01ac058001d124	April 2013
Evoltra	Clofarabine	Authorised under exceptional circumstances	Genzyme Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000613/human_med_000773.jsp&mid=WC0b01ac058001d124	April 2013
Evotaz	Atazanavir / cobicistat	New active substance	Bristol-Myers Squibb Pharma EEIG	Not yet available	July 2015
Exjade	Deferasirox	PASS ¹	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000670/human_med_000780.jsp&mid=WC0b01ac058001d124	April 2013
Exviera	Dasabuvir	New active substance	AbbVie Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003837/human_med_001833.jsp&mid=WC0b01ac058001d124	February 2015
Eylea	Aflibercept	New active substance	Bayer Pharma AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002392/human_med_001598.jsp&mid=WC0b01ac058001d124	April 2013
Fampyra	Fampridine	New active substance, conditional authorisation	BIOGEN IDEC LTD.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002097/human_med_001432.jsp&mid=WC0b01ac058001d124	April 2013
Firdapse	Amifampridine	Authorised under exceptional circumstances	BioMarin Europe Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001032/human_med_001298.jsp&mid=WC0b01ac058001d124	April 2013
Fluenz	Influenza vaccine (intranasal, live attenuated)	New active substance	MedImmune LLC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001101/human_med_001405.jsp&mid=WC0b01ac058001d124	April 2013
Fluenz Tetra	Influenza vaccine (live attenuated, nasal)	New biological	MedImmune LLC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002617/human_med_001713.jsp&mid=WC0b01ac058001d124	January 2014
Flupirtine-containing medicinal products (For full list of products see Annex VI)	Flupirtine	PASS ¹	Various (For full list see Annex VI)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63	February 2014
Forxiga	Dapagliflozin	New active substance	Bristol-Myers Squibb / AstraZeneca EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002322/human_med_001546.jsp&mid=WC0b01ac058001d124	April 2013
Fycompa	Perampanel	New active substance	Eisai Europe Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002434/human_med_001572.jsp&mid=WC0b01ac058001d124	April 2013
Gardasil 9	Human papillomavirus 9-valent vaccine (recombinant, adsorbed)	New active substance	Sanofi Pasteur MSD SNC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003852/human_med_001863.jsp&mid=WC0b01ac058001d124	June 2015
Gazyvaro	Obinutuzumab	New active substance	Roche Registration Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002799/human_med_001780.jsp&mid=WC0b01ac058001d124	September 2014

Geonistin tablete za rodnicu	Oxytetracyclin, nistatin	PASS ¹	Pliva Hrvatska d.o.o.	http://www.halmed.hr/?ln=en&w=lijekovi&d=opsirnije&id=10529	June 2014
Gilenya	Fingolimod hydrochloride	New active substance, PASS ¹	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002202/human_med_001433.jsp&mid=WC0b01ac058001d124	April 2013
Giotrif	Afatinib	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002280/human_med_001698.jsp&mid=WC0b01ac058001d124	October 2013
Glivec	Imatinib	PASS ¹	Novartis Europharm Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000406/human_med_000808.jsp&mid=WC0b01ac058001d124	September 2014
Glybera	Alipogene tiparovec	New active substance, authorised under exceptional circumstances	uniQure biopharma B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002145/human_med_001480.jsp&mid=WC0b01ac058001d124	April 2013
Grastofil	Filgrastim	New biological	Apotex Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002150/human_med_001688.jsp&mid=WC0b01ac058001d124	November 2013
Halaven	Eribulin mesylate	New active substance	Eisai Europe Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002084/human_med_001427.jsp&mid=WC0b01ac058001d124	April 2013
Harvoni	Ledipasvir/sofosbuvir	New active substance	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003850/human_med_001813.jsp&mid=WC0b01ac058001d124	December 2014
Hetlioz	Tasimelepton	New active substance	Vanda Pharmaceuticals Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003870/human_med_001873.jsp&mid=WC0b01ac058001d124	July 2015
Hexacima	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	New biological	Sanofi Pasteur S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002702/human_med_001640.jsp&mid=WC0b01ac058001d124	July 2013
Hexyon	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	New biological	Sanofi Pasteur MSD, SNC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002796/human_med_001641.jsp&mid=WC0b01ac058001d124	July 2013
Hizentra	Human normal immunoglobulin	New biological	CSL Behring GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002127/human_med_001440.jsp&mid=WC0b01ac058001d124	September 2013
Holoclar	Ex vivo expanded autologous human corneal epithelial cells containing stem cells	New active substance, conditional authorisation	Chiesi Farmaceutici S.P.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002450/human_med_001844.jsp&mid=WC0b01ac058001d124	March 2015
Hydroxyethyl starch (HES)-containing medicinal products (For full list see Annex V)	Hydroxyethyl starch	PASS ¹	Various (For full list see Annex V)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63	January 2014
HyQvia	Human normal immunoglobulin	New biological	Baxter Innovations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002491/human_med_001647.jsp&mid=WC0b01ac058001d124	September 2013
Iclusig	Ponatinib	New active substance	Ariad Pharma Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002695/human_med_001656.jsp&mid=WC0b01ac058001d124	August 2013
Ilaris	Canakinumab	Authorised under exceptional circumstances	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001109/human_med_000826.jsp&mid=WC0b01ac058001d124	April 2013
IMBRUVICA	Ibrutinib	New active substance	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003791/human_med_001801.jsp&mid=WC0b01ac058001d124	November 2014
Imnovid (formerly Pomalidomide Celgene)	Pomalidomide	New active substance, PASS ¹	Celgene Europe Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002682/human_med_001669.jsp&mid=WC0b01ac058001d124	September 2013
Imvanex	Modified Vaccinia Ankara virus – Bavarian Nordic (MVA-BN) live virus	New active substance, authorised under exceptional circumstances	Bavarian Nordic A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002596/human_med_001666.jsp&mid=WC0b01ac058001d124	September 2013
Incivo	Telaprevir	New active substance	Janssen-Cilag International B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002313/human_med_001487.jsp&mid=WC0b01ac058001d124	April 2013
Increlex	Mecasermin	Authorised under exceptional circumstances	Ipsen Pharma	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000704/human_med_000829.jsp&mid=WC0b01ac058001d124	April 2013
Incrasyn	Alogliptin/pioglitazone	New active substance	Takeda Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002178/human_med_001694.jsp&mid=WC0b01ac058001d124	October 2013
Incruse	Umeclidinium bromide	New active substance	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002809/human_med_001755.jsp&mid=WC0b01ac058001d124	May 2014
Inflixtra	Infliximab	New biological	Hospira UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002778/human_med_001677.jsp&mid=WC0b01ac058001d124	October 2013
Influsplit Tetra ³	Influenza virus inactivated split virion	New biological	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63	April 2013
Inlyta	Axitinib	New active substance	Pfizer Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002406/human_med_001573.jsp&mid=WC0b01ac058001d124	April 2013

Invokana	Canagliflozin	New active substance	Janssen-Cilag International N.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002649/human_med_001707.jsp&mid=WC0b01ac058001d124	December 2013
Ipreziv	Azilsartan medoxomil	New active substance	Takeda Global Research and Development Centre (Europe) Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002517/human_med_001515.jsp&mid=WC0b01ac058001d124	April 2013
Intravenous iron-containing medicinal products (For full list see Annex III)	Ferric carboxymaltose, iron dextran, sodium ferric gluconate, iron isomaltoside, iron sucrose	PASS ¹	Various (For full list see Annex III)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63	January 2014
Izinova / Eziclen	Sulphate anhydrous, magnesium sulphate heptahydrate, potassium sulphate	PASS ¹	IPSEN PHARMA	http://agence-prd.ansm.sante.fr/php/ecodex/frames.php?specid=65236258&typedoc=R&ref=R0222102.htm	June 2014
Jakavi	Ruxolitinib	New active substance, PASS ¹	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002464/human_med_001568.jsp&mid=WC0b01ac058001d124	April 2013
Jardiance	Empagliflozin	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002677/human_med_001764.jsp&mid=WC0b01ac058001d124	June 2014
Jaydess	Levonorgestrel	PASS ¹	Bayer AB	http://www.lakemedelsverket.se/LMF/Lakemedelsinformation/?nplid=2011120800069&type=product#/?&_suid=138513307171006085398397649693	November 2013
Jentadueto	Linagliptin/metformin	New active substance	Boehringer Ingelheim International GMBH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002279/human_med_001574.jsp&mid=WC0b01ac058001d124	April 2013
Jetrea	Ocriplasmin	New active substance	ThromboGenics NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002381/human_med_001629.jsp&mid=WC0b01ac058001d124	April 2013
Jevtana	Cabazitaxel	New active substance	Sanofi-Aventis	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002018/human_med_001428.jsp&mid=WC0b01ac058001d124	April 2013
Jinarc	Tolvaptan	PASS ¹	Otsuka Pharmaceutical Europe Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002788/human_med_001857.jsp&mid=WC0b01ac058001d124	June 2015
Kadcyla	Trastuzumab emtansine	New active substance	Roche Registration Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002389/human_med_001712.jsp&mid=WC0b01ac058001d124	December 2013
Kalydeco	Ivacaftor	New active substance, PASS ¹	Vertex Pharmaceuticals (U.K.) Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002494/human_med_001575.jsp&mid=WC0b01ac058001d124	April 2013
Kengrexal	Cangrelor	New active substance	The Medicines Company UK Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003773/human_med_001852.jsp&mid=WC0b01ac058001d124	April 2015
Ketoconazole HRA	Ketoconazole	PASS ¹	Laboratoire HRA Pharma	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003906/human_med_001814.jsp&mid=WC0b01ac058001d124	December 2014
Keytruda	Pembrolizumab	New active substance	Merck Sharp & Dohme Limited	Not yet available	July 2015
Kolbam (previously Cholic Acid FGK)	Cholic acid	Authorised under exceptional circumstances	FGK Representative Service GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002081/human_med_001718.jsp&mid=WC0b01ac058001d124	May 2014
Krystexxa	Pegloticase	New active substance, PASS ¹	Savient Pharma Ireland Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002208/human_med_001591.jsp&mid=WC0b01ac058001d124	April 2013
LacTEST	Gaxilose	New active substance	Venter Pharma S.L.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63	April 2013
Latuda	Lurasidone	New active substance	Takeda Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002713/human_med_001737.jsp&mid=WC0b01ac058001d124	April 2014
Laventair	Umeclidinium bromide/vilanterol trifenate	New active substance, PASS ¹	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003754/human_med_001756.jsp&mid=WC0b01ac058001d124	June 2014
Lemtrada	Alemtuzumab	New biological	Genzyme Therapeutics Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003718/human_med_001678.jsp&mid=WC0b01ac058001d124	October 2013
Lenvima	Lenvatinib	New active substance	Eisai Europe Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003727/human_med_001864.jsp&mid=WC0b01ac058001d124	June 2015
Libertek	Roflumilast	PASS ¹	Takeda GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002399/human_med_001416.jsp&mid=WC0b01ac058001d124	June 2013
Lixiana	Edoxaban	New active substance	Daiichi Sankyo Europe GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002629/human_med_001874.jsp&mid=WC0b01ac058001d124	July 2015
Lojuxta	Lomitapide	New active substance, authorised under exceptional circumstances	Aegerion Pharmaceuticals SAS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002578/human_med_001668.jsp&mid=WC0b01ac058001d124	September 2013
Lonquex	Lipegfilgrastim	New active substance, PASS ¹	Teva Pharma B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002556/human_med_001667.jsp&mid=WC0b01ac058001d124	September 2013
Lumark	Lutetium, isotope of mass 177	New active substance	IDB Radiopharmacy B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002749/human_med_001875.jsp&mid=WC0b01ac058001d124	July 2015

Lymphoseek	Tilmanocept	New active substance	Navidea Biopharmaceuticals Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002085/human_med_001827.jsp&mid=WC0b01ac058001d124	December 2014
Lynparza	Olaparib	New active substance	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003726/human_med_001831.jsp&mid=WC0b01ac058001d124	February 2015
Lyxumia	Lixisenatide	New active substance	Sanofi-Aventis	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002445/human_med_001615.jsp&mid=WC0b01ac058001d124	April 2013
MACI ⁴	Matrix applied characterised autologous cultured chondrocytes	New active substance	Aastrom Biosciences DK ApS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002522/human_med_001660.jsp&mid=WC0b01ac058001d124	August 2013
Mekinist	Trametinib	New active substance	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002643/human_med_001772.jsp&mid=WC0b01ac058001d124	September 2014
Meriofert	Menotrophin	New biological	Laboratoires Genévrier SA	http://www.produktresume.dk/docushare/dsweb/View/Collection-109	March 2015
Moventig	Naloxegol	New active substance	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002810/human_med_001816.jsp&mid=WC0b01ac058001d124	January 2015
Mysimba	Naltrexone / bupropion	PASS ¹	Orexigen Therapeutics Ireland Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003687/human_med_001845.jsp&mid=WC0b01ac058001d124	April 2015
Naglazyme	Galsulfase	Authorised under exceptional circumstances	BioMarin Europe Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000640/human_med_000918.jsp&mid=WC0b01ac058001d124	April 2013
Neuraceq	Florbetaben (18F)	New active substance	Piramal Imaging GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002553/human_med_001716.jsp&mid=WC0b01ac058001d124	March 2014
NexoBrid	Concentrate of proteolytic enzymes enriched in bromelain	New active substance, PASS ¹	MediWound Germany GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002246/human_med_001582.jsp&mid=WC0b01ac058001d124	April 2013
Nimenrix	Meningococcal group A, C, W 135 and Y conjugate vaccine	New active substance	GlaxoSmithKline Biologicals, S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002226/human_med_001548.jsp&mid=WC0b01ac058001d124	April 2013
NovoEight	Turoctocog alfa	New active substance	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002719/human_med_001701.jsp&mid=WC0b01ac058001d124	December 2013
NovoThirteen	Catridecacog	New active substance	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002284/human_med_001576.jsp&mid=WC0b01ac058001d124	April 2013
Nulojix	Belatacept	New active substance	Bristol Myers Squibb Pharma EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002098/human_med_001459.jsp&mid=WC0b01ac058001d124	April 2013
Numeta G16%E medicinal products in the European Union (For full list of products see Annex XI)	Alanine, arginine, aspartic acid, calcium chloride, cysteine, glucose monohydrate, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, magnesium acetate, methionine, olive oil, ornithine hydrochloride, henylalanine, potassium acetate, proline, serine, sodium chloride, sodium glycerophosphate, soybean oil, taurine, threonine, tryptophan, tyrosine, valine	PASS ¹	Baxter (For full list see Annex XI)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Numeta_G13E_and_Numeta_G16E_emulsion_for_infusion/human_referral_prac_000027.jsp&mid=WC0b01ac05805c516f	September 2014
Nuwiq	Simoctocog alfa	New active substance	Octapharma AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002813/human_med_001781.jsp&mid=WC0b01ac058001d124	September 2014
Ofev	Nintedanib	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003821/human_med_001834.jsp&mid=WC0b01ac058001d124	February 2015
OLYSIO	Simeprevir	New active substance	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002777/human_med_001766.jsp&mid=WC0b01ac058001d124	June 2014
Opdivo	Nivolumab	New active substance	Bristol-Myers Squibb Pharma EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003985/human_med_001876.jsp&mid=WC0b01ac058001d124	July 2015
Opgenra	Eptotermin alfa	PASS ¹	Olympus Biotech International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000819/human_med_000950.jsp&mid=WC0b01ac058001d124	July 2013
Opsumit	Macitentan	New active substance	Actelion Registration Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002697/human_med_001717.jsp&mid=WC0b01ac058001d124	February 2014
Optimark	Gadoversetamide	PASS ¹	Covidien Deutschland GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000745/human_med_000953.jsp&mid=WC0b01ac058001d124	April 2013
Orbactiv	Oritavancin	New active substance	The Medicines Company UK Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003785/human_med_001853.jsp&mid=WC0b01ac058001d124	April 2015
Orphacol	Cholic acid	Authorised under exceptional circumstances	Laboratoires CTRS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001250/human_med_001419.jsp&mid=WC0b01ac058001d124	October 2013
Osseor	Strontium ranelate	PASS ¹	Les Laboratoires Servier	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000561/human_med_000963.jsp&mid=WC0b01ac058001d124	August 2013

Otezla	Apremilast	New active substance	Celgene Europe Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003746/human_med_001835.jsp&mid=WC0b01ac058001d124	February 2015
Ovaleap	Follitropin alfa	New biological	Teva Pharma B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002608/human_med_001689.jsp&mid=WC0b01ac058001d124	November 2013
Pandemrix	Influenza vaccine (H1N1)v (split virion, inactivated, adjuvanted) A/California/7/2009 (H1N1)v like strain (x-179a)	PASS ¹	GlaxoSmithKline Biologicals	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000832/human_med_000965.jsp&mid=WC0b01ac058001d124	April 2013
Perjeta	Pertuzumab	New active substance	Roche Registration Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002547/human_med_001628.jsp&mid=WC0b01ac058001d124	April 2013
Picato	Ingenol mebutate	New active substance	Leo Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002275/human_med_001600.jsp&mid=WC0b01ac058001d124	April 2013
Pixuvri	Pixantrone	New active substance, conditional authorisation	CTI Life Sciences Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002055/human_med_001549.jsp&mid=WC0b01ac058001d124	April 2013
Plegridy	Peginterferon beta-1a	New active substance	Biogen Idec Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002827/human_med_001782.jsp&mid=WC0b01ac058001d124	September 2014
Procoralan	Ivabradine	PASS ¹	Les Laboratoires Servier	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Corlantor_and_Procoralan/human_referral_prac_000044.jsp&mid=WC0b01ac05805c516f&source=homeMedSearch&category=human	February 2015
Protelos	Strontium ranelate	PASS ¹	Les Laboratoires Servier	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000560/human_med_000999.jsp&mid=WC0b01ac058001d124	August 2013
Quinsair	Levofloxacin	PASS ¹	Aptalis Pharma SAS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002789/human_med_001846.jsp&mid=WC0b01ac058001d124	April 2015
Raplixa	Human fibrinogen / human thrombin	New biological	ProFibrix BV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002807/human_med_001854.jsp&mid=WC0b01ac058001d124	April 2015
Relvar Ellipta	Fluticasone furoate/vilanterol trifenate	New active substance, PASS ¹	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002673/human_med_001708.jsp&mid=WC0b01ac058001d124	December 2013
Remsima	Infliximab	New biological	Celltrion Healthcare Hungary Kft.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002576/human_med_001682.jsp&mid=WC0b01ac058001d124	October 2013
Replagal*	Agalsidase alfa	Authorised under exceptional circumstances	Shire Human Genetic Therapies AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000369/human_med_001029.jsp&mid=WC0b01ac058001d124	April 2013
Revestive	Teduglutide	New active substance, PASS ¹	Nycomed Danmark ApS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002345/human_med_001583.jsp&mid=WC0b01ac058001d124	April 2013
Revinty Ellipta	Fluticasone furoate/vilanterol trifenate	PASS ¹	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002745/human_med_001768.jsp&mid=WC0b01ac058001d124	May 2014
Revlimid	Lenalidomide	PASS ¹	Celgene Europe Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000717/human_med_001034.jsp&mid=WC0b01ac058001d124	June 2014
Rezolsta	Darunavir/cobicistat	New active substance	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002819/human_med_001817.jsp&mid=WC0b01ac058001d124	February 2015
Ristempa	Pegfilgrastim	New biological	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003910/human_med_001859.jsp&mid=WC0b01ac058001d124	April 2015
Rixubis	Nonacog gamma	New biological	Baxter Innovations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003771/human_med_001830.jsp&mid=WC0b01ac058001d124	February 2015
Ryzodeg	Insulin degludec/insulin aspart	New active substance	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002499/human_med_001608.jsp&mid=WC0b01ac058001d124	April 2013
Saxenda	Liraglutide	New biological	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003780/human_med_001855.jsp&mid=WC0b01ac058001d124	April 2015
Scenesse	Afamelanotide	New active substance, authorised under exceptional circumstances	Clinuvel UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002548/human_med_001826.jsp&mid=WC0b01ac058001d124	January 2015
Seasonique	Levonorgestrel/ethinylestradiol	PASS ¹	Teva Pharma B.V.	Not yet available	June 2015
Seebri Breezhaler	Glycopyrronium bromide	PASS ¹	Novartis Europharm	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002430/human_med_001580.jsp&mid=WC0b01ac058001d124	April 2013
Selincro	Nalmefene	New active substance	H. Lundbeck A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002583/human_med_001620.jsp&mid=WC0b01ac058001d124	April 2013
Senshio	Ospemifene	New active substance, PASS ¹	Shionogi Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002780/human_med_001837.jsp&mid=WC0b01ac058001d124	February 2015
Signifor	Pasireotide	New active substance	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002052/human_med_001547.jsp&mid=WC0b01ac058001d124	April 2013

Sirturo	Bedaquiline	New active substance, conditional authorisation	Janssen-Cilag International N.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002614/human_med_001730.jsp&mid=WC0b01ac058001d124	March 2014
Sivextro	Tedizolid phosphate	New active substance	Cubist (UK) Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002846/human_med_001856.jsp&mid=WC0b01ac058001d124	April 2015
Somatropin Biopartners	Somatropin	New biological	BioPartners GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002196/human_med_001672.jsp&mid=WC0b01ac058001d124	September 2013
Sovaldi	Sofosbuvir	New active substance	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002798/human_med_001723.jsp&mid=WC0b01ac058001d124	February 2014
Spedra	Avanafil	New active substance	Vivus B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002581/human_med_001661.jsp&mid=WC0b01ac058001d124	August 2013
Stivarga	Regorafenib	New active substance	Bayer Pharma AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002573/human_med_001684.jsp&mid=WC0b01ac058001d124	September 2013
Stribild	Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil	New active substance	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002574/human_med_001654.jsp&mid=WC0b01ac058001d124	July 2013
Striverdi Respimat	Olodaterol	New active substance, PASS ¹	Boehringer Ingelheim International GmbH	http://www.cbq-meb.nl/CBG/en/human-medicines/geneesmiddeleninformatiebank/default.htm	February 2015
Sylvant	Siltuximab	New active substance, PASS ¹	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003708/human_med_001769.jsp&mid=WC0b01ac058001d124	June 2014
Synjardy	Empagliflozin/metformin	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003770/human_med_001865.jsp&mid=WC0b01ac058001d124	June 2015
Tafinlar	Dabrafenib	New active substance	GlaxoSmithKline Trading Services Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002604/human_med_001683.jsp&mid=WC0b01ac058001d124	September 2013
Targocid and associated names (teicoplanin-containing medicinal products). (For full list see Annex VII)	Teicoplanin	PASS ¹	Various (For full list see Annex VII)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63	February 2014
Teysuno	Tegafur/gimeracil/oteracil	New active substance	Nordic Group B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001242/human_med_001422.jsp&mid=WC0b01ac058001d124	April 2013
Thiocolchicoside-containing medicinal products. (For full list see Annex IV)	Thiocolchicoside	PASS ¹	Various (For full list see Annex IV)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63	January 2014
Thiosix	Tioguanin	Authorised under exceptional circumstances	Teva Nederland B.V.	http://db.cbq-meb.nl/Pars/h114680.pdf	May 2015
Tivicay	Dolutegravir	New active substance	ViiV Healthcare UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002753/human_med_001720.jsp&mid=WC0b01ac058001d124	February 2014
Tovanor Breezhaler	Glycopyrronium bromide	PASS ¹	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002690/human_med_001581.jsp&mid=WC0b01ac058001d124	April 2013
Trajenta	Linagliptin	New active substance	Boehringer Ingelheim International GMBH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002110/human_med_001482.jsp&mid=WC0b01ac058001d124	April 2013
Translarna	Ataluren	New active substance, conditional authorisation	PTC Therapeutics Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002720/human_med_001742.jsp&mid=WC0b01ac058001d124	September 2014
Tresiba	Insulin degludec	New active substance	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002498/human_med_001609.jsp&mid=WC0b01ac058001d124	April 2013
Trimetazidine-containing medicinal products. (For full list of products see Annex II)	Trimetazidine	PASS ¹	Various (For full list see Annex II)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63	November 2013
Triumeq	Dolutegravir/abacavir/lamivudine	New active substance	ViiV Healthcare UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002754/human_med_001796.jsp&mid=WC0b01ac058001d124	October 2014
Trobalt	Retigabine	New active substance	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001245/human_med_001431.jsp&mid=WC0b01ac058001d124	April 2013
Trulicity	Dulaglutide	New active substance	Eli Lilly Nederland B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002825/human_med_001821.jsp&mid=WC0b01ac058001d124	December 2014
Tybost	Cobicistat	New active substance	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002572/human_med_001690.jsp&mid=WC0b01ac058001d124	October 2013
Tysabri	Natalizumab	PASS ¹	Elan Pharma International Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000603/human_med_001119.jsp&mid=WC0b01ac058001d124	April 2013
Ultibro Breezhaler	Indacaterol/glycopyrronium bromide	PASS ¹	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002679/human_med_001691.jsp&mid=WC0b01ac058001d124	October 2013
Ulnar Breezhaler	indacaterol/glycopyrronium bromide	PASS ¹	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003875/human_med_001758.jsp&mid=WC0b01ac058001d124	July 2014

[Valproate and related substances \(sodium valproate, valproic acid, valproate semisodium, valpromide-containing medicinal products\) \(For full list of products see Annex XIII\)](#)

	Sodium valproate, valproic acid, valproate semisodium, valpromide	PASS ¹	Various (For full list see Annex XIII)	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63	January 2015
Vargatef	Nintedanib	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002569/human_med_001822.jsp&mid=WC0b01ac058001d124	December 2014
Vedrop	Tocofersolan d-alpha tocopheryl polyethylene glycol succinate	Authorised under exceptional circumstances	Orphan Europe S.A.R.L.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000920/human_med_001129.jsp&mid=WC0b01ac058001d124	April 2013
Velphoro	Mixture of polynuclear iron(iii)-oxyhydroxide, sucrose and starches	New active substance	Vifor Fresenius Medical Care Renal Pharma France	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002705/human_med_001795.jsp&mid=WC0b01ac058001d124	September 2014
Vepacel	A/H5N1 pre-pandemic influenza vaccine (whole virion, vero cell derived, inactivated)	New active substance	Baxter Innovations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002089/human_med_001543.jsp&mid=WC0b01ac058001d124	April 2013
Vibativ	Telavancin	PASS ¹	Clinigen Healthcare Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001240/human_med_001467.jsp&mid=WC0b01ac058001d124	May 2014
Victrelis	Boceprevir	New active substance	Merck Sharp & Dohme Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002332/human_med_001464.jsp&mid=WC0b01ac058001d124	April 2013
Viekirax	Ombitasvir/paritaprevir/ritonavir	New active substance	AbbVie Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003839/human_med_001838.jsp&mid=WC0b01ac058001d124	February 2015
Vimizim	Elosulfase alfa	New active substance, PASS ¹	BioMarin Europe Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002779/human_med_001759.jsp&mid=WC0b01ac058001d124	June 2014
Vipdomet	Alogliptin/metformin	New active substance	Takeda Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002654/human_med_001695.jsp&mid=WC0b01ac058001d124	October 2013
Vipidia	Alogliptin	New active substance	Takeda Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002182/human_med_001696.jsp&mid=WC0b01ac058001d124	October 2013
Vitekta	Elvitegravir	New active substance	Gilead Sciences International Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002577/human_med_001710.jsp&mid=WC0b01ac058001d124	December 2013
Vizamyl	Flutemetamol (18F)	New active substance	GE Healthcare Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002557/human_med_001794.jsp&mid=WC0b01ac058001d124	September 2014
Vokanamet	Canagliflozin/metformin hydrochloride	New active substance	Janssen-Cilag International NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002656/human_med_001760.jsp&mid=WC0b01ac058001d124	May 2014
Voncento	Human coagulation factor VIII/human von Willebrand factor	New biological	CLS Behring GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002493/human_med_001670.jsp&mid=WC0b01ac058001d124	October 2013
Votubia	Everolimus	Conditional authorisation	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002311/human_med_001484.jsp&mid=WC0b01ac058001d124	April 2013
Vyndaqel	Tafamidis	New active substance, authorised under exceptional circumstances	Pfizer Speciality UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002294/human_med_001498.jsp&mid=WC0b01ac058001d124	April 2013
Xadago	Safinamide	New active substance	Zambon S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002396/human_med_001847.jsp&mid=WC0b01ac058001d124	March 2015
Xagrid	Anagrelide	Authorised under exceptional circumstances	Shire Pharmaceutical Contracts Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000480/human_med_001153.jsp&mid=WC0b01ac058001d124	April 2013
Xalkori	Crizotinib	New active substance, conditional authorisation	Pfizer Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002489/human_med_001592.jsp&mid=WC0b01ac058001d124	April 2013
Xarelto	Rivaroxaban	PASS ¹	Bayer Pharma AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000944/human_med_001155.jsp&mid=WC0b01ac058001d124	July 2013
Xgeva	Denosumab	New biological	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002173/human_med_001463.jsp&mid=WC0b01ac058001d124	April 2013
Xiapex	Collagenase Clostridium histolyticum	New active substance	Auxilium UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002048/human_med_001423.jsp&mid=WC0b01ac058001d124	April 2013
Xigduo	Dapagliflozin/metformin	New active substance	Bristol-Myers Squibb/AstraZeneca EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002672/human_med_001721.jsp&mid=WC0b01ac058001d124	February 2014
Xofigo	Radium Ra 223 dichloride	New active substance	Bayer Pharma AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002653/human_med_001692.jsp&mid=WC0b01ac058001d124	December 2013
Xoterna Breezhaler	Indacaterol/glycopyrronium bromide	PASS ¹	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003755/human_med_001693.jsp&mid=WC0b01ac058001d124	October 2013
Xtandi	Enzalutamide	New active substance	Astellas Pharma Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002639/human_med_001663.jsp&mid=WC0b01ac058001d124	August 2013
Xultophy	Insulin degludec/liraglutide	New biological	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002647/human_med_001802.jsp&mid=WC0b01ac058001d124	October 2014

Xydalba	Dalbavancin	New active substance	Durata Therapeutics International B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002840/human_med_001848.jsp&mid=WC0b01ac058001d124	March 2015
Yellox	Bromfenac	New active substance	Croma-Pharma GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001198/human_med_001455.jsp&mid=WC0b01ac058001d124	April 2013
Yervoy	Ipilimumab	New active substance, PASS ¹	Bristol Myers Squibb Pharma EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002213/human_med_001465.jsp&mid=WC0b01ac058001d124	April 2013
Zaltrap	Aflibercept	New active substance	Sanofi-Aventis	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002532/human_med_001617.jsp&mid=WC0b01ac058001d124	April 2013
Zelboraf	Vemurafenib	New active substance	Roche Registration Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002409/human_med_001544.jsp&mid=WC0b01ac058001d124	April 2013
Zinforo	Ceftaroline fosamil	New active substance	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002252/human_med_001584.jsp&mid=WC0b01ac058001d124	April 2013
Zoely	Nomegestrol/Estradiol	PASS ¹	Theramex S.r.l.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001213/human_med_001452.jsp&mid=WC0b01ac058001d124	January 2014
Zontivity	Vorapaxar	New active substance	Merck Sharp & Dohme Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002814/human_med_001839.jsp&mid=WC0b01ac058001d124	February 2015
Zydelig	Idelalisib	New active substance	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003843/human_med_001803.jsp&mid=WC0b01ac058001d124	October 2014
Zykadia	Ceritinib	New active substance, conditional authorisation	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003819/human_med_001860.jsp&mid=WC0b01ac058001d124	May 2015
Zytiga	Abiraterone	New active substance	Janssen-Cilag International B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002321/human_med_001499.jsp&mid=WC0b01ac058001d124	April 2013

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

² Also known in some EU countries as Tyvense.

³ Also known in some EU countries as Fluarix Tetra.

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

*The marketing authorisation initially granted under exceptional circumstances has been amended to bring it outside the scope of Article 14(8) of Regulation (EC) 726/2004 following the fulfillment of all imposed obligations. Thus, this product is no longer under additional monitoring.