

25 October 2013  
EMA/245297/2013 Rev.5  
Patient Health Protection

## 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 October 2013 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
Adcetris	Brentuximab vedotin	New active substance, conditional authorisation	Takeda Global Research and Development Centre (Europe) Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002455/human_med_001588.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002455/human_med_001588.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Aldurazyme	Laronidase	Authorised under exceptional circumstances	Genzyme Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000477/human_med_000636.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000477/human_med_000636.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
AMYViD	Florbetapir [18F]	New active substance	Eli Lilly Nederlands B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002422/human_med_001611.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002422/human_med_001611.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Arzerra	Ofatumumab	Conditional authorisation	Glaxo Group Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001131/human_med_001300.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001131/human_med_001300.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Atriance	Nelarabine	Authorised under exceptional circumstances	Glaxo Group Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000752/human_med_000656.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000752/human_med_000656.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
ATryn	Anti-thrombin alpha	Authorised under exceptional circumstances	GTC Biotherapeutics UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000587/human_med_000658.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000587/human_med_000658.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
<b>Aubagio</b>	<b>Teriflunomide</b>	<b>New active substance</b>	<b>Sanofi-aventis Groupe</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002514/human_med_001645.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002514/human_med_001645.jsp&amp;mid=WC0b01ac058001d124</a>	<b>October 2013</b>
Benlysta	Belimumab	New active substance	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=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002015/human_med_001466.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Betmiga	Mirabegron	New active substance	Astellas Pharma Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002388/human_med_001605.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002388/human_med_001605.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Bexsero	Meningococcal group-B vaccine (rDNA, component, adsorbed)	New active substance	Novartis Vaccines and Diagnostics 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=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002333/human_med_001614.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
BindRen	Colestilan	New active substance	Mitsubishi Pharma Europe Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002377/human_med_001595.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002377/human_med_001595.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
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=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002373/human_med_001613.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Bretaris Genuair	Aclidinium bromide	New active substance, PASS <sup>1</sup>	Almirall, S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002706/human_med_001570.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002706/human_med_001570.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Caprelsa	Vandetanib	New active substance, conditional authorisation	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002315/human_med_001529.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002315/human_med_001529.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Ceplene	Histamine dihydrochloride	Authorised under exceptional circumstances	Meda AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000796/human_med_000691.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000796/human_med_000691.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Champix	Varenicline	PASS <sup>1</sup>	Pfizer	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000699/human_med_000696.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000699/human_med_000696.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Cinryze	c1 inhibitor, human	PASS <sup>1</sup>	ViroPharma SPRL	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001207/human_med_001448.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001207/human_med_001448.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Cleviprex emulsion for injection 0.5 mg/ml	Clevipidine	New active substance	The Medicines Company UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&amp;mid=WC0b01ac0580036d63">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&amp;mid=WC0b01ac0580036d63</a>	April 2013
Constella	Linacotide	New active substance	Almirall, S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002490/human_med_001597.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002490/human_med_001597.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Cuprymina	Copper (64Cu) chloride	New active substance	Sparkle S.r.l.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002136/human_med_001578.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002136/human_med_001578.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
<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>	<a href="#">Various (For full list see Annex I)</a>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&amp;mid=WC0b01ac0580036d63">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&amp;mid=WC0b01ac0580036d63</a>	August 2013
Dacogen	Decitabine	New active substance	Janssen-Cilag International B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002221/human_med_001589.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002221/human_med_001589.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013

Daliresp	Roflumilast	PASS <sup>1</sup>	Takeda GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002398/human_med_001415.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002398/human_med_001415.jsp&amp;mid=WC0b01ac058001d124</a>	June 2013
Daxas	Roflumilast	PASS <sup>1</sup>	Takeda GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001179/human_med_001363.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001179/human_med_001363.jsp&amp;mid=WC0b01ac058001d124</a>	June 2013
Diacomit	Stiripentol	Conditional authorisation	Biocodex	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000664/human_med_000742.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000664/human_med_000742.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Dificlir	Fidaxomicin	New active substance	Astellas Pharma Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002087/human_med_001511.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002087/human_med_001511.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Edarbi	Azilsartan medoxomil	New active substance	Takeda Global Research and Development Centre (Europe) Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002293/human_med_001512.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002293/human_med_001512.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Eduvant	Rilpivirine	New active substance	Janssen-Cilag International B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cilostazol-containing_medicines/human_referral_000338.jsp&amp;mid=WC0b01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cilostazol-containing_medicines/human_referral_000338.jsp&amp;mid=WC0b01ac05805c516f</a>	April 2013
Ekistol	Cilostazol	PASS <sup>1</sup>	LACER S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002211/human_med_001571.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002211/human_med_001571.jsp&amp;mid=WC0b01ac058001d124</a>	September 2013
Eklira Genuair	Acridinium bromide	New active substance, PASS <sup>1</sup>	Almirall, S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000700/human_med_000757.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000700/human_med_000757.jsp&amp;mid=WC0b01ac058001d124</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/002148/human_med_001449.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002148/human_med_001449.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Eliquis	Apixaban	New active substance	Bristol Myers Squibb/ Pfizer EEIG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&amp;mid=WC0b01ac0580036d63">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&amp;mid=WC0b01ac0580036d63</a>	April 2013
Elvanse <sup>2</sup>	Lisdexamphetamine	New active substance	Shire Pharmaceutical Contracts Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002691/human_med_001579.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002691/human_med_001579.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Enurev Breezhaler	Glycopyrronium bromide	PASS <sup>1</sup>	Novartis Europharm Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002602/human_med_001659.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002602/human_med_001659.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Erivedge	Vismodegib	New active substance, conditional authorisation	Roche Registration Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002154/human_med_001417.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002154/human_med_001417.jsp&amp;mid=WC0b01ac058001d124</a>	August 2013
Esbriet	Pirfenidone	New active substance, PASS <sup>1</sup>	InterMune UK Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001199/human_med_001450.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001199/human_med_001450.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Eurartesim	Dihydroartemisinin / piperaquine phosphate	New active substance, PASS <sup>1</sup>	Sigma-tau Industrie Farmaceutiche Riunite S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002312/human_med_001514.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002312/human_med_001514.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Eviplera	Emtricitabine / rilpivirine / tenofovir disoproxil	New active substance	Gilead Sciences International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000613/human_med_000773.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000613/human_med_000773.jsp&amp;mid=WC0b01ac058001d124</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/000670/human_med_000780.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000670/human_med_000780.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Exjade	Deferasirox	PASS <sup>1</sup>	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002392/human_med_001598.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002392/human_med_001598.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Eylea	Aflibercept	New active substance	Bayer Pharma AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002097/human_med_001432.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002097/human_med_001432.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Fampyra	Fampridine	New active substance, conditional authorisation	BIOGEN IDEC LTD.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001032/human_med_001298.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001032/human_med_001298.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Firdapse	Amifampridine	Authorised under exceptional circumstances	BioMarin Europe Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001101/human_med_001405.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001101/human_med_001405.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Fluenz	Influenza vaccine (intranasal, live attenuated)	New active substance	MedImmune LLC	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002322/human_med_001546.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002322/human_med_001546.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Forxiga	Dapagliflozin	New active substance	Bristol-Myers Squibb / AstraZeneca EEIG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002434/human_med_001572.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002434/human_med_001572.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Fycompa	Perampanel	New active substance	Eisai Europe Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002202/human_med_001433.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002202/human_med_001433.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Gilenya	Fingolimod hydrochloride	New active substance, PASS <sup>1</sup>	Novartis Europharm Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002280/human_med_001698.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002280/human_med_001698.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
<b>Giotrif</b>	<b>Afatinib</b>	<b>New active substance</b>	<b>Boehringer Ingelheim International GmbH</b>	<b><a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002145/human_med_001480.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002145/human_med_001480.jsp&amp;mid=WC0b01ac058001d124</a></b>	<b>October 2013</b>
Glybera	Alipogene tiparovvec	New active substance, authorised under exceptional circumstances	uniQure biopharma B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002084/human_med_001427.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002084/human_med_001427.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Halaven	Eribulin mesylate	New active substance	Eisai Europe Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002702/human_med_001640.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002702/human_med_001640.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Hexacima	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	New biological	Sanofi Pasteur S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002796/human_med_001641.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002796/human_med_001641.jsp&amp;mid=WC0b01ac058001d124</a>	July 2013
Hexyon	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	New biological	Sanofi Pasteur MSD, SNC	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002127/human_med_001440.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002127/human_med_001440.jsp&amp;mid=WC0b01ac058001d124</a>	July 2013
Hizentra	Human normal immunoglobulin	New biological	CSL Behring GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002491/human_med_001647.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002491/human_med_001647.jsp&amp;mid=WC0b01ac058001d124</a>	September 2013
HyQvia	Human normal immunoglobulin	New biological	Baxter Innovations GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002491/human_med_001647.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002491/human_med_001647.jsp&amp;mid=WC0b01ac058001d124</a>	September 2013

Iclusig	Ponatinib	New active substance	Ariad Pharma Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002695/human_med_001656.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002695/human_med_001656.jsp&amp;mid=WC0b01ac058001d124</a>	August 2013
Ilaris	Canakinumab	Authorised under exceptional circumstances	Novartis Europharm Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001109/human_med_000826.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001109/human_med_000826.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Imvanex	Modified Vaccinia Ankara virus – Bavarian Nordic (MVA-BN) live virus	New active substance, authorised under exceptional circumstances	Bavarian Nordic A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002596/human_med_001666.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002596/human_med_001666.jsp&amp;mid=WC0b01ac058001d124</a>	September 2013
Incivo	Telaprevir	New active substance	Janssen-Cilag International B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002313/human_med_001487.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002313/human_med_001487.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Increlex	Mecasermin	Authorised under exceptional circumstances	Ipsen Pharma	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000704/human_med_000829.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000704/human_med_000829.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
<b>Incrsync</b>	<b>Alogliptin/pioglitazone</b>	<b>New active substance</b>	<b>Takeda Pharma A/S</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002178/human_med_001694.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002178/human_med_001694.jsp&amp;mid=WC0b01ac058001d124</a>	<b>October 2013</b>
<b>Inflectra</b>	<b>Infliximab</b>	<b>New biological</b>	<b>Hospira UK Limited</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002778/human_med_001677.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002778/human_med_001677.jsp&amp;mid=WC0b01ac058001d124</a>	<b>October 2013</b>
Influsplit Tetra <sup>3</sup>	Influenza virus inactivated split virion	New biological	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&amp;mid=WC0b01ac0580036d63">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&amp;mid=WC0b01ac0580036d63</a>	April 2013
Inlyta	Axitinib	New active substance	Pfizer Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002406/human_med_001573.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002406/human_med_001573.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Intelligence	Etavirine	Conditional authorisation	Janssen-Cilag International N.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000900/human_med_000844.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000900/human_med_000844.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Invirase	Saquinavir	PASS <sup>1</sup>	Roche Registration Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000113/human_med_000849.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000113/human_med_000849.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Ipreziv	Azilsartan medoxomil	New active substance	Takeda Global Research and Development Centre (Europe) Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002517/human_med_001515.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002517/human_med_001515.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Jakavi	Ruxolitinib	New active substance, PASS <sup>1</sup>	Novartis Europharm Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002464/human_med_001568.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002464/human_med_001568.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Jentadueto	Linagliptin/metformin	New active substance	Boehringer Ingelheim International GMBH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002279/human_med_001574.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002279/human_med_001574.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Jetrea	Ocriplasmin	New active substance	ThromboGenics NV	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002381/human_med_001629.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002381/human_med_001629.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Jevtana	Cabazitaxel	New active substance	Sanofi-Aventis	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002018/human_med_001428.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002018/human_med_001428.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Kalydeco	Ivacaftor	New active substance, PASS <sup>1</sup>	Vertex Pharmaceuticals (U.K.) Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002494/human_med_001575.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002494/human_med_001575.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Krystexxa	Pegloticase	New active substance, PASS <sup>1</sup>	Savient Pharma Ireland Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002208/human_med_001591.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002208/human_med_001591.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
LacTEST	Gasiloxe	New active substance	Venter Pharma S.L.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&amp;mid=WC0b01ac0580036d63">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&amp;mid=WC0b01ac0580036d63</a>	April 2013
<b>Lemtrada</b>	<b>Alemtuzumab</b>	<b>New biological</b>	<b>Genzyme Therapeutics Ltd</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003718/human_med_001678.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003718/human_med_001678.jsp&amp;mid=WC0b01ac058001d124</a>	<b>October 2013</b>
Libertek	Roflumilast	PASS <sup>1</sup>	Takeda GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002399/human_med_001416.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002399/human_med_001416.jsp&amp;mid=WC0b01ac058001d124</a>	June 2013
Lojuxta	Lomitapide	New active substance, authorised under exceptional circumstances	Aegerion Pharmaceuticals SAS	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002578/human_med_001668.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002578/human_med_001668.jsp&amp;mid=WC0b01ac058001d124</a>	September 2013
Lonquex	Lipegfilgrastim	New active substance, PASS <sup>1</sup>	Teva Pharma B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002556/human_med_001667.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002556/human_med_001667.jsp&amp;mid=WC0b01ac058001d124</a>	September 2013
Lyxumia	Lixisenatide	New active substance	Sanofi-Aventis	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002445/human_med_001615.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002445/human_med_001615.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
MACI	Matrix applied characterised autologous cultured chondrocytes	New active substance	Genzyme Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002522/human_med_001660.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002522/human_med_001660.jsp&amp;mid=WC0b01ac058001d124</a>	August 2013
Naglazyme	Galsulfase	Authorised under exceptional circumstances	BioMarin Europe Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000640/human_med_000918.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000640/human_med_000918.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
NexoBrid	Concentrate of proteolytic enzymes enriched in bromelain	New active substance, PASS <sup>1</sup>	Teva Pharma GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002246/human_med_001582.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002246/human_med_001582.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Nimenrix	Meningococcal group A, C, W 135 and Y conjugate vaccine	New active substance	GlaxoSmithKline Biologicals, S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002226/human_med_001548.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002226/human_med_001548.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
NovoThirteen	Catridecacog	New active substance	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002284/human_med_001576.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002284/human_med_001576.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Nulojix	Belatacept	New active substance	Bristol Myers Squibb Pharma EEIG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002098/human_med_001459.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002098/human_med_001459.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Opgenra	Eptotermin alfa	PASS <sup>1</sup>	Olympus Biotech International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000819/human_med_000950.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000819/human_med_000950.jsp&amp;mid=WC0b01ac058001d124</a>	July 2013
Optimark	Gadoversetamide	PASS <sup>1</sup>	Covidien Deutschland GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000745/human_med_000953.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000745/human_med_000953.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
<b>Orphacol</b>	<b>Cholic acid</b>	<b>Authorised under exceptional circumstances</b>	<b>Laboratoires CTRS</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001250/human_med_001419.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001250/human_med_001419.jsp&amp;mid=WC0b01ac058001d124</a>	<b>October 2013</b>

Osseor	Strontium ranelate	PASS <sup>1</sup>	Les Laboratoires Servier	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000561/human_med_000963.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000561/human_med_000963.jsp&amp;mid=WC0b01ac058001d124</a>	August 2013
Pandemrix	Influenza vaccine (H1N1)v (split virion, inactivated, adjuvanted) A/California/7/2009 (H1N1)v like strain (x-179a)	PASS <sup>1</sup>	GlaxoSmithKline Biologicals	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000832/human_med_000965.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000832/human_med_000965.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Perjeta	Pertuzumab	New active substance	Roche Registration Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002547/human_med_001628.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002547/human_med_001628.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Picato	Ingenol mebutate	New active substance	Leo Pharma A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002275/human_med_001600.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002275/human_med_001600.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Pixuvri	Pixantrone	New active substance, conditional authorisation	CTI Life Sciences Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002055/human_med_001549.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002055/human_med_001549.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Pletal	Cilostazol	PASS <sup>1</sup>	Otsuka Pharmaceutical Europe Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cilostazol-containing_medicines/human_referral_000338.jsp&amp;mid=WC0b01ac05805c516f">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Cilostazol-containing_medicines/human_referral_000338.jsp&amp;mid=WC0b01ac05805c516f</a>	September 2013
Pomalidomide Celgene	Pomalidomide	New active substance, PASS <sup>1</sup>	Celgene Europe Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002682/human_med_001669.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002682/human_med_001669.jsp&amp;mid=WC0b01ac058001d124</a>	September 2013
Prialt	Ziconotide	Authorised under exceptional circumstances	Eisai Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000551/human_med_000989.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000551/human_med_000989.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
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=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000560/human_med_000999.jsp&amp;mid=WC0b01ac058001d124</a>	August 2013
<b>Provenge</b>	<b>Autologous peripheral blood mononuclear cells activated with PAP-GM-CSF (Sipuleucel-T)</b>	<b>New active substance, PASS<sup>1</sup></b>	<b>Dendreon UK Ltd</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002513/human_med_001680.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002513/human_med_001680.jsp&amp;mid=WC0b01ac058001d124</a>	<b>October 2013</b>
<b>Remsima</b>	<b>Infliximab</b>	<b>New biological</b>	<b>Celltrion Healthcare Hungary Kft.</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002576/human_med_001682.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002576/human_med_001682.jsp&amp;mid=WC0b01ac058001d124</a>	<b>October 2013</b>
Replagal	Agalsidase alfa	Authorised under exceptional circumstances	Shire Human Genetic Therapies AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000369/human_med_001029.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000369/human_med_001029.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Revestive	Teduglutide	New active substance, PASS <sup>1</sup>	Nycomed Danmark ApS	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002345/human_med_001583.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002345/human_med_001583.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Rienso	Ferumoxytol	New active substance	Takeda Global Research and Development Centre (Europe) Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002215/human_med_001569.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002215/human_med_001569.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Ryzodeg	Insulin degludec/insulin aspart	New active substance	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002499/human_med_001608.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002499/human_med_001608.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Seebri Breezhaler	Glycopyrronium bromide	PASS <sup>1</sup>	Novartis Europharm	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002430/human_med_001580.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002430/human_med_001580.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Selincro	Nalmefene	New active substance	H. Lundbeck A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002583/human_med_001620.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002583/human_med_001620.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Signifor	Pasireotide	New active substance	Novartis Europharm Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002052/human_med_001547.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002052/human_med_001547.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Somatropin Biopartners	Somatropin	New biological	BioPartners GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002196/human_med_001672.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002196/human_med_001672.jsp&amp;mid=WC0b01ac058001d124</a>	September 2013
Spedra	Avanafil	New active substance	Vivus B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002581/human_med_001661.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002581/human_med_001661.jsp&amp;mid=WC0b01ac058001d124</a>	August 2013
Stivarga	Regorafenib	New active substance	Bayer Pharma AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002573/human_med_001684.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002573/human_med_001684.jsp&amp;mid=WC0b01ac058001d124</a>	September 2013
Stribild	Elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil	New active substance	Gilead Sciences International Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002574/human_med_001654.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002574/human_med_001654.jsp&amp;mid=WC0b01ac058001d124</a>	July 2013
Tafinlar	Dabrafenib	New active substance	GlaxoSmithKline Trading Services Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002604/human_med_001683.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002604/human_med_001683.jsp&amp;mid=WC0b01ac058001d124</a>	September 2013
Teysono	Tegafur / gimeracil / oteracil	New active substance	Nordic Group B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001242/human_med_001422.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001242/human_med_001422.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Tovanor Breezhaler	Glycopyrronium bromide	PASS <sup>1</sup>	Novartis Europharm Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002690/human_med_001581.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002690/human_med_001581.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Trajenta	Linagliptin	New active substance	Boehringer Ingelheim International GMBH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002110/human_med_001482.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002110/human_med_001482.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Tresiba	Insulin degludec	New active substance	Novo Nordisk A/S	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002498/human_med_001609.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002498/human_med_001609.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Trobalt	Retigabine	New active substance	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001245/human_med_001431.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001245/human_med_001431.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
<b>Tybost</b>	<b>Cobicistat</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/002572/human_med_001690.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002572/human_med_001690.jsp&amp;mid=WC0b01ac058001d124</a>	<b>October 2013</b>
Tygacil	Tigecycline	PASS <sup>1</sup>	Pfizer Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000644/human_med_001118.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000644/human_med_001118.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Tysabri	Natalizumab	PASS <sup>1</sup>	Elan Pharma International Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000603/human_med_001119.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000603/human_med_001119.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Tyverb	Lapatinib	Conditional authorisation	Glaxo Group Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000795/human_med_001120.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000795/human_med_001120.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013

<b>Ultibro Breezhaler</b>	<b>Indacaterol/glycopyrronium bromide</b>	<b>PASS<sup>1</sup></b>	<b>Novartis Europharm Ltd</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002679/human_med_001691.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002679/human_med_001691.jsp&amp;mid=WC0b01ac058001d124</a>	<b>October 2013</b>
Vectibix	Panitumumab	Conditional authorisation	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000741/human_med_001128.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000741/human_med_001128.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
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/000920/human_med_001129.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000920/human_med_001129.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Vepacel	A/H5N1 pre-pandemic influenza vaccine (whole virion, vero cell derived, inactivated)	New active substance	Baxter Innovations GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002089/human_med_001543.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002089/human_med_001543.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Victrelis	Boceprevir	New active substance	Merck Sharp & Dohme Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002332/human_med_001464.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002332/human_med_001464.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
<b>Vipdomet</b>	<b>Alogliptin/metformin</b>	<b>New active substance</b>	<b>Takeda Pharma A/S</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002654/human_med_001695.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002654/human_med_001695.jsp&amp;mid=WC0b01ac058001d124</a>	<b>October 2013</b>
<b>Vipidia</b>	<b>Alogliptin</b>	<b>New active substance</b>	<b>Takeda Pharma A/S</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002182/human_med_001696.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002182/human_med_001696.jsp&amp;mid=WC0b01ac058001d124</a>	<b>October 2013</b>
<b>Voncento</b>	<b>Human coagulation factor VIII / human von Willebrand factor</b>	<b>New biological</b>	<b>CLS Behring GmbH</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002493/human_med_001670.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002493/human_med_001670.jsp&amp;mid=WC0b01ac058001d124</a>	<b>October 2013</b>
Votubia	Everolimus	Conditional authorisation	Novartis Europharm Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002311/human_med_001484.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002311/human_med_001484.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Vyndaqel	Tafamidis	New active substance, authorised under exceptional circumstances	Pfizer Speciality UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002294/human_med_001498.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002294/human_med_001498.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Xagrid	Anagrelide	Authorised under exceptional circumstances	Shire Pharmaceutical Contracts Ltd.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000480/human_med_001153.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000480/human_med_001153.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Xalkori	Crizotinib	New active substance, conditional authorisation	Pfizer Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002489/human_med_001592.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002489/human_med_001592.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Xarelto	Rivaroxaban	PASS <sup>1</sup>	Bayer Pharma AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000944/human_med_001155.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000944/human_med_001155.jsp&amp;mid=WC0b01ac058001d124</a>	July 2013
Xgeva	Denosumab	New biological	Amgen Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002173/human_med_001463.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002173/human_med_001463.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Xiapex	Collagenase Clostridium histolyticum	New active substance	Pfizer Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002048/human_med_001423.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002048/human_med_001423.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
<b>Xoterna Breezhaler</b>	<b>Indacaterol/glycopyrronium bromide</b>	<b>PASS<sup>1</sup></b>	<b>Novartis Europharm Ltd</b>	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003755/human_med_001693.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003755/human_med_001693.jsp&amp;mid=WC0b01ac058001d124</a>	<b>October 2013</b>
Xtandi	Enzalutamide	New active substance	Astellas Pharma Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002639/human_med_001663.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002639/human_med_001663.jsp&amp;mid=WC0b01ac058001d124</a>	August 2013
Yellox	Bromfenac	New active substance	Croma-Pharma GmbH	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001198/human_med_001455.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001198/human_med_001455.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Yervoy	Ipilimumab	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/002213/human_med_001465.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002213/human_med_001465.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Yondelis	Trabectedin	Authorised under exceptional circumstances	Pharma Mar, S.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000773/human_med_001165.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000773/human_med_001165.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Zaltrap	Aflibercept	New active substance	Sanofi-Aventis	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002532/human_med_001617.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002532/human_med_001617.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Zelboraf	Vemurafenib	New active substance	Roche Registration Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002409/human_med_001544.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002409/human_med_001544.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Zinforo	Ceftaroline fosamil	New active substance	AstraZeneca AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002252/human_med_001584.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002252/human_med_001584.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013
Zytiga	Abiraterone	New active substance	Janssen-Cilag International B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002321/human_med_001499.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002321/human_med_001499.jsp&amp;mid=WC0b01ac058001d124</a>	April 2013

<sup>1</sup> PASS: Post-authorisation safety study. Study designed to confirm, further characterise or refute a safety signal which has been associated with a specific drug.

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

<sup>3</sup> Also known in some EU countries as Fluarix Tetra.