

## 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 Modules: [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)

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information
Adasuve	Loxapine	New active substance	Alexza UK Ltd	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002400/human_med_001618.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002400/human_med_001618.jsp&amp;mid=WC0b01ac058001d124</a>
Adcetris	Brentuximab vedotin	New active substance, conditional authorisation, PASS <sup>1</sup>	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>
Aldurazyme	Laronidase	Authorised under exceptional circumstances, PASS	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>
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>
Arzerra	Ofatumumab	Conditional authorisation, PASS	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>
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>
ATryn	Anti-thrombin alpha	Authorised under exceptional circumstances, PASS	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>
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>
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>
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>
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>
Bosulif	Bosutinib	New active substance, conditional authorisation, PASS	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>
Bretaris Genuair	Aclidinium bromide	New active substance, PASS	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>
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>
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>
Champix	Varenicline	PASS	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>
Cinryze	c1 inhibitor, human	PASS	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>
Cleviprex emulsion for injection 0.5 mg/ml	Clevidipine	New active substance	The Medicines Company UK Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general_content_000155.jsp&amp;mid=WC0b01ac0580036d63">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general_content_000155.jsp&amp;mid=WC0b01ac0580036d63</a>
Constella	Linaclotide	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>
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>
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>
Dexdor	Dexmedetomidine	New active substance	Orion Corporation	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002268/human_med_001485.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002268/human_med_001485.jsp&amp;mid=WC0b01ac058001d124</a>
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>
Difliclr	Fidaxomicin	New active substance	FGK Representative Service GmbH	<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>
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>

Edurant	Rilpivirine	New active substance	Janssen-Cilag International B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002264/human_med_001513.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002264/human_med_001513.jsp&amp;mid=WC0b01ac058001d124</a>
Eklira Genuair	Acridinium bromide	New active substance, PASS	Almirall, 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>
Elaprase	Idursulfase	Authorised under exceptional circumstances	Shire Human Genetic Therapies AB	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000700/human_med_000757.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000700/human_med_000757.jsp&amp;mid=WC0b01ac058001d124</a>
Eliquis	Apixaban	New active substance	Bristol Myers Squibb/ Pfizer EEIG	<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>
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/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>
Enurev Breezhaler	Glycopyrronium bromide	New active substance, PASS	Novartis Europharm Ltd	<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>
Esbriet	Pirfenidone	New active substance, PASS	InterMune UK Ltd	<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>
Eurartesim	Dihydroartemisinin / piperazine phosphate	New active substance, PASS	Sigma-tau Industrie Farmaceutiche Riunite S.p.A.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001199/human_med_001450.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001199/human_med_001450.jsp&amp;mid=WC0b01ac058001d124</a>
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/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>
Evoltra	Clofarabine	Authorised under exceptional circumstances	Genzyme Europe B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000613/human_med_000773.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000613/human_med_000773.jsp&amp;mid=WC0b01ac058001d124</a>
Exjade	Deferasirox	PASS	Novartis Europharm Limited	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000670/human_med_000780.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000670/human_med_000780.jsp&amp;mid=WC0b01ac058001d124</a>
Eylea	Aflibercept	New active substance	Bayer Pharma AG	<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>
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/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>
Firdapse	Amifampridine	Authorised under exceptional circumstances, PASS	BioMarin Europe 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>
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/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>
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/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>
Fycompa	Perampanel	New active substance	Eisai Europe Ltd	<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>
Gilenya	Fingolimod hydrochloride	New active substance, PASS	Novartis Europharm 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>
Glybera	Alipogene tiparvec	New active substance, Authorised under exceptional circumstances, PASS	uniQure biopharma B.V.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002145/human_med_001480.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002145/human_med_001480.jsp&amp;mid=WC0b01ac058001d124</a>
Halaven	Eribulin mesylate	New active substance	Eisai Europe Ltd	<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>
Ilaris	Canakinumab	Authorised under exceptional circumstances, PASS	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>
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>
Increlex	Mecasermin	Authorised under exceptional circumstances, PASS	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>
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>
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>
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>
Invirase	Saquinavir	PASS	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>
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>
Jakavi	Ruxolitinib	New active substance, PASS	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>
Jentaduetto	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>
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>

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>
Kalydeco	Ivacaftor	New active substance, PASS	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>
Krystexxa	Pegloticase	New active substance, PASS	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>
LacTEST	Gaxilose	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>
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>
Naglazyme	Galsulfase	Authorised under exceptional circumstances, PASS	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>
NexoBrid	Concentrate of proteolytic enzymes enriched in bromelain	New active substance, PASS	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>
Nimenrix	Meningococcal group A, C, W 135 and Y conjugate vaccine	New active substance, PASS	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>
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>
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>
Optimark	Gadolinium	PASS	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>
Pandemrix	Influenza vaccine (H1N1)v (split virion, inactivated, adjuvanted) A/California/7/2009 (H1N1)v like strain (x-179a)	PASS	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>
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>
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>
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>
Prialt	Ziconotide	Authorised under exceptional circumstances, PASS	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>
Replagal	Agalsidase alfa	Authorised under exceptional circumstances, PASS	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>
Revestive	Teduglutide	New active substance, PASS	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>
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>
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>
Seebri Breezhaler	Glycopyrronium bromide	New active substance, PASS	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>
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>
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>
Teysuno	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>
Tovanor Breezhaler	Glycopyrronium bromide	New active substance, PASS	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>
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>
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>
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>
Tygacil	Tigecycline	PASS	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>
Tysabri	Natalizumab	PASS	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>
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>

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>
Vedrop	Tocofersolan d-alpha tocopheryl polyethylene glycol succinate	Authorised under exceptional circumstances, PASS	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>
Ventavis	Iloprost	Authorised under exceptional circumstances	Bayer Pharma AG	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000474/human_med_001133.jsp&amp;mid=WC0b01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000474/human_med_001133.jsp&amp;mid=WC0b01ac058001d124</a>
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>
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>
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>
Vyndaqel	Tafamidis	Authorised under exceptional circumstances, New active substance, PASS	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>
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>
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>
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>
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>
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>
Yervoy	Ipilimumab	New active substance, PASS	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>
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>
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>
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>
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>
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>

<sup>1</sup>PASS: Post-authorisation safety study. A 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