

List of medicinal products under additional monitoring

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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

Product name	Active Substance (s)	Reason (s) on list	Marketing Authorisation Holder (s)	Link to Product Information
Adcetris	Brentuximab vedotin	New active substance, conditional authorisation	Takeda Global Research and Development Centre (Europe) Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002455/human_med_001588.jsp&mid=WC0b01ac058001d124
Aldurazyme	Laronidase	Authorised under exceptional circumstances	Genzyme Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000477/human_med_000636.jsp&mid=WC0b01ac058001d124
AMYVID	Florbetapir [18F]	New active substance	Eli Lilly Nederlands B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002422/human_med_001611.jsp&mid=WC0b01ac058001d124
Arzerra	Ofatumumab	Conditional authorisation	Glaxo Group Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001131/human_med_001300.jsp&mid=WC0b01ac058001d124
Atriance	Nelarabine	Authorised under exceptional circumstances	Glaxo Group Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000752/human_med_000656.jsp&mid=WC0b01ac058001d124
ATryn	Anti-thrombin alpha	Authorised under exceptional circumstances	GTC Biotherapeutics UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000587/human_med_000658.jsp&mid=WC0b01ac058001d124
Benlysta	Belimumab	New active substance	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002015/human_med_001466.jsp&mid=WC0b01ac058001d124
Betmiga	Mirabegron	New active substance	Astellas Pharma Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002388/human_med_001605.jsp&mid=WC0b01ac058001d124
Bexsero	Meningococcal group-B vaccine (rDNA, component, adsorbed)	New active substance	Novartis Vaccines and Diagnostics S.r.l.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002333/human_med_001614.jsp&mid=WC0b01ac058001d124
BindRen	Colestilan	New active substance	Mitsubishi Pharma Europe Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002373/human_med_001613.jsp&mid=WC0b01ac058001d124
Bosulf	Bosutinib	New active substance, conditional authorisation	Pfizer Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002706/human_med_001570.jsp&mid=WC0b01ac058001d124
Bretaris Genuiar	Acidinium bromide	New active substance, PASS ¹	Almirall, S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002315/human_med_001529.jsp&mid=WC0b01ac058001d124
Caprelsa	Vandetanib	New active substance, conditional authorisation	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000796/human_med_000691.jsp&mid=WC0b01ac058001d124
Ceplene	Histamine dihydrochloride	Authorised under exceptional circumstances	Meda AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000699/human_med_000696.jsp&mid=WC0b01ac058001d124
Champix	Varenicline	PASS	Pfizer	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001207/human_med_001448.jsp&mid=WC0b01ac058001d124
Cinryze	c1 inhibitor, human	PASS	ViroPharma SPRL	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/content/000155.iso&mid=WC0b01ac0580036d63
Clevidipex emulsion for injection 0.5 mg/ml	Clevidipine	New active substance	The Medicines Company UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002490/human_med_001597.jsp&mid=WC0b01ac058001d124
Constella	Linacotide	New active substance	Almirall, S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002136/human_med_001578.jsp&mid=WC0b01ac058001d124
Cuprymina	Copper (64Cu) chloride	New active substance	Sparkle S.r.l	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002221/human_med_001589.jsp&mid=WC0b01ac058001d124
Dacogen	Decitabine	New active substance	Janssen-Cilag International B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002398/human_med_001415.jsp&mid=WC0b01ac058001d124
Daliresp	Roflumilast	PASS	Takeda GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001179/human_med_001363.jsp&mid=WC0b01ac058001d124
Daxas	Roflumilast	PASS	Takeda GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000664/human_med_000742.jsp&mid=WC0b01ac058001d124
Diacomit	Stripentol	Conditional authorisation	Biocodex	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002087/human_med_001511.jsp&mid=WC0b01ac058001d124
Difficilr	Fidaxomicin	New active substance	Astellas Pharma Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002293/human_med_001512.jsp&mid=WC0b01ac058001d124
Edarbi	Azilsartan medoxomil	New active substance	Takeda Global Research and Development Centre (Europe) Ltd.	

Edurant	Rilpivirine	New active substance	Janssen-Cilag International B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002264/human_med_001513.jsp&mid=WC0b01ac058001d124
Eklira Genuair	Acclidinium bromide	New active substance, PASS	Almirall, S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002211/human_med_001571.jsp&mid=WC0b01ac058001d124
Elaprase	Idursulfase	Authorised under exceptional circumstances	Shire Human Genetic Therapies AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000700/human_med_000757.jsp&mid=WC0b01ac058001d124
Elleqis	Apixaban	New active substance	Bristol Myers Squibb/ Pfizer EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/000155.jsp&mid=WC0b01ac0580036d63
Elvanse ²	Lisdexamphetamine	New active substance	Shire Pharmaceutical Contracts Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002691/human_med_001579.jsp&mid=WC0b01ac058001d124
Enurev Breezhaler	Glycopyrronium bromide	PASS	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002154/human_med_001417.jsp&mid=WC0b01ac058001d124
Esbriet	Pirfenidone	New active substance, PASS	InterMune UK Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001199/human_med_001450.jsp&mid=WC0b01ac058001d124
Eurartesim	Dihydroartemisinin / piperazine phosphate	New active substance, PASS	Sigma-tau Industrie Farmaceutiche Riunite S.p.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002312/human_med_001514.jsp&mid=WC0b01ac058001d124
Eviplera	Emtricitabine / rilpivirine / tenofovir disoproxil	New active substance	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000613/human_med_000773.jsp&mid=WC0b01ac058001d124
Evoltra	Clofarabine	Authorised under exceptional circumstances	Genzyme Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000670/human_med_000780.jsp&mid=WC0b01ac058001d124
Exjade	Deferasirox	PASS	Novartis Europharm Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002392/human_med_001598.jsp&mid=WC0b01ac058001d124
Eylea	Aflibercept	New active substance	Bayer Pharma AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002097/human_med_001432.jsp&mid=WC0b01ac058001d124
Fampyra	Fampridine	New active substance, conditional authorisation	BIOGEN IDEC LTD.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001032/human_med_001298.jsp&mid=WC0b01ac058001d124
Firdapse	Amifampridine	Authorised under exceptional circumstances	BioMarin Europe Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001101/human_med_001405.jsp&mid=WC0b01ac058001d124
Fluenz	Influenza vaccine (intranasal, live attenuated)	New active substance	MedImmune LLC	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002322/human_med_001546.jsp&mid=WC0b01ac058001d124
Forxiga	Dapagliflozin	New active substance	Bristol-Myers Squibb / AstraZeneca EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002434/human_med_001572.jsp&mid=WC0b01ac058001d124
Fycompa	Perampanel	New active substance	Eisai Europe Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002202/human_med_001433.jsp&mid=WC0b01ac058001d124
Gilenya	Fingolimod hydrochloride	New active substance, PASS	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002145/human_med_001480.jsp&mid=WC0b01ac058001d124
Glybera	Alipogene tiparvovec	New active substance, Authorised under exceptional circumstances	uniQure biopharma B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002084/human_med_001427.jsp&mid=WC0b01ac058001d124
Halaven	Eribulin mesylate	New active substance	Eisai Europe Ltd	EPAR in preparation
Hexacima	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	New active substance	Sanofi Pasteur S.A.	EPAR in preparation
Hexyon	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	New active substance	Sanofi Pasteur MSD, SNC	EPAR in preparation
Ilaris	Canakinumab	Authorised under exceptional circumstances	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001109/human_med_000826.jsp&mid=WC0b01ac058001d124
Incivo	Telaprevir	New active substance	Janssen-Cilag International B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002313/human_med_001487.jsp&mid=WC0b01ac058001d124
Increlex	Mecasermin	Authorised under exceptional circumstances	Ipsen Pharma	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000704/human_med_000829.jsp&mid=WC0b01ac058001d124
Influsplit Tetra ³	Influenza virus inactivated split virion	New Biological	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/000155.jsp&mid=WC0b01ac0580036d63
Inlyta	Axitinib	New active substance	Pfizer Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002406/human_med_001573.jsp&mid=WC0b01ac058001d124
Intelence	Etavirine	Conditional authorisation	Janssen-Cilag International N.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000900/human_med_000844.jsp&mid=WC0b01ac058001d124
Invirase	Saquinavir	PASS	Roche Registration Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000113/human_med_000849.jsp&mid=WC0b01ac058001d124
Ipreziv	Azilsartan medoxomil	New active substance	Takeda Global Research and Development Centre (Europe) Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002517/human_med_001515.jsp&mid=WC0b01ac058001d124
Jakavi	Ruxolitinib	New active substance, PASS	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002464/human_med_001568.jsp&mid=WC0b01ac058001d124
Jentadueto	Linagliptin/metformin	New active substance	Boehringer Ingelheim International GMBH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002279/human_med_001574.jsp&mid=WC0b01ac058001d124

Jetrea	Ocriplasmin	New active substance	ThromboGenics NV	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002381/human_med_001629.jsp&mid=WC0b01ac058001d124
Jevtana	Cabazitaxel	New active substance	Sanofi-Aventis	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002018/human_med_001428.jsp&mid=WC0b01ac058001d124
Kalydeco	Ivacaftor	New active substance, PASS	Vertex Pharmaceuticals (U.K.) Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002494/human_med_001575.jsp&mid=WC0b01ac058001d124
Krystexxa	Pegloticase	New active substance, PASS	Savient Pharma Ireland Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002208/human_med_001591.jsp&mid=WC0b01ac058001d124
LacTEST	Gasiloxe	New active substance	Venter Pharma S.L.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002399/human_med_001416.jsp&mid=WC0b01ac058001d124
Libertek	Roflumilast	PASS	Takeda GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002445/human_med_001615.jsp&mid=WC0b01ac058001d124
Lyxumia	Lixisenatide	New active substance	Sanofi-Aventis	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000640/human_med_000918.jsp&mid=WC0b01ac058001d124
Naglazyme	Galsulfase	Authorised under exceptional circumstances	BioMarin Europe Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002246/human_med_001582.jsp&mid=WC0b01ac058001d124
NexoBrid	Concentrate of proteolytic enzymes enriched in bromelain	New active substance, PASS	Teva Pharma GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002226/human_med_001548.jsp&mid=WC0b01ac058001d124
Nimenrix	Meningococcal group A, C, W 135 and Y conjugate vaccine	New active substance	GlaxoSmithKline Biologicals, S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002284/human_med_001576.jsp&mid=WC0b01ac058001d124
NovoThirteen	Catridecacog	New active substance	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002098/human_med_001459.jsp&mid=WC0b01ac058001d124
Nulojix	Belatacept	New active substance	Bristol Myers Squibb Pharma EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000819/human_med_000950.jsp&mid=WC0b01ac058001d124
Opgenra	Eptotermin alfa	PASS	Olympus Biotech International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000745/human_med_000953.jsp&mid=WC0b01ac058001d124
Optimark	Gadoversetamide	PASS	Coviden Deutschland GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000832/human_med_000965.jsp&mid=WC0b01ac058001d124
Pandemrix	Influenza vaccine (H1N1)v (split virion, inactivated, adjuvanted) A/California/7/2009 (H1N1)v like strain (x-179a)	PASS	GlaxoSmithKline Biologicals	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002547/human_med_001628.jsp&mid=WC0b01ac058001d124
Perjeta	Pertuzumab	New active substance	Roche Registration Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002275/human_med_001600.jsp&mid=WC0b01ac058001d124
Picato	Ingenol mebutate	New active substance	Leo Pharma A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002055/human_med_001549.jsp&mid=WC0b01ac058001d124
Pixuvri	Pixantrone	New active substance, conditional authorisation	CTI Life Sciences Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000551/human_med_000989.jsp&mid=WC0b01ac058001d124
Prialt	Ziconotide	Authorised under exceptional circumstances	Eisai Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000369/human_med_001029.jsp&mid=WC0b01ac058001d124
Replagal	Agalsidase alfa	Authorised under exceptional circumstances	Shire Human Genetic Therapies AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002345/human_med_001583.jsp&mid=WC0b01ac058001d124
Revestive	Teduglutide	New active substance, PASS	Nycomed Danmark ApS	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002215/human_med_001569.jsp&mid=WC0b01ac058001d124
Rienso	Ferumoxytol	New active substance	Takeda Global Research and Development Centre (Europe) Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002499/human_med_001608.jsp&mid=WC0b01ac058001d124
Ryzodeg	Insulin degludec/insulin aspart	New active substance	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002430/human_med_001580.jsp&mid=WC0b01ac058001d124
Seebri Breezhaler	Glycopyrronium bromide	PASS	Novartis Europharm	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002583/human_med_001620.jsp&mid=WC0b01ac058001d124
Selincro	Nalmefene	New active substance	H. Lundbeck A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002052/human_med_001547.jsp&mid=WC0b01ac058001d124
Signifor	Pasireotide	New active substance	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002574/human_med_001654.jsp&mid=WC0b01ac058001d124
Stribild	Elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil	New active substance	Gilead Sciences International Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001242/human_med_001422.jsp&mid=WC0b01ac058001d124
Teysuno	Tegafur / gimeracil / oteracil	New active substance	Nordic Group B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002690/human_med_001581.jsp&mid=WC0b01ac058001d124
Tovonor Breezhaler	Glycopyrronium bromide	PASS	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002110/human_med_001482.jsp&mid=WC0b01ac058001d124
Trajenta	Linagliptin	New active substance	Boehringer Ingelheim International GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002498/human_med_001609.jsp&mid=WC0b01ac058001d124
Tresiba	Insulin degludec	New active substance	Novo Nordisk A/S	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001245/human_med_001431.jsp&mid=WC0b01ac058001d124
Trobalt	Retigabine	New active substance	Glaxo Group Ltd	

Tygacil	Tigecycline	PASS	Pfizer Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000644/human_med_001118.jsp&mid=WC0b01ac058001d124
Tysabri	Natalizumab	PASS	Elan Pharma International Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000603/human_med_001119.jsp&mid=WC0b01ac058001d124
Tyverb	Lapatinib	Conditional authorisation	Glaxo Group Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000795/human_med_001120.jsp&mid=WC0b01ac058001d124
Vectibx	Panitumumab	Conditional authorisation	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000741/human_med_001128.jsp&mid=WC0b01ac058001d124
Vedrop	Tocofersolan d-alpha tocopheryl polyethylene glycol succinate	Authorised under exceptional circumstances	Orphan Europe S.A.R.L.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000920/human_med_001129.jsp&mid=WC0b01ac058001d124
Ventavis	Iloprost	Authorised under exceptional circumstances	Bayer Pharma AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000474/human_med_001133.jsp&mid=WC0b01ac058001d124
Vepacel	A/H5N1 pre-pandemic influenza vaccine (whole virion, vero cell derived, inactivated)	New active substance	Baxter Innovations GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002089/human_med_001543.jsp&mid=WC0b01ac058001d124
Victrilis	Boceprevir	New active substance	Merck Sharp & Dohme Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002332/human_med_001464.jsp&mid=WC0b01ac058001d124
Votubia	Everolimus	Conditional authorisation	Novartis Europharm Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002311/human_med_001484.jsp&mid=WC0b01ac058001d124
Vyndaqel	Tafamidis	New active substance, authorised under exceptional circumstances	Pfizer Speciality UK Limited	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002294/human_med_001498.jsp&mid=WC0b01ac058001d124
Xagrid	Anagrelide	Authorised under exceptional circumstances	Shire Pharmaceutical Contracts Ltd.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000480/human_med_001153.jsp&mid=WC0b01ac058001d124
Xalkori	Crizotinib	New active substance, conditional authorisation	Pfizer Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002489/human_med_001592.jsp&mid=WC0b01ac058001d124
Xarelto	Rivaroxaban	PASS	Bayer Pharma AG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000944/human_med_001155.jsp&mid=WC0b01ac058001d124
Xgeva	Denosumab	New biological	Amgen Europe B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002173/human_med_001463.jsp&mid=WC0b01ac058001d124
Xiapex	Collagenase Clostridium histolyticum	New active substance	Pfizer Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002048/human_med_001423.jsp&mid=WC0b01ac058001d124
Yellox	Bromfenac	New active substance	Croma-Pharma GmbH	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001198/human_med_001455.jsp&mid=WC0b01ac058001d124
Yervoy	Ipilimumab	New active substance, PASS	Bristol Myers Squibb Pharma EEIG	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002213/human_med_001465.jsp&mid=WC0b01ac058001d124
Yondelis	Trabectedin	Authorised under exceptional circumstances	Pharma Mar, S.A.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000773/human_med_001165.jsp&mid=WC0b01ac058001d124
Zaltrap	Aflibercept	New active substance	Sanofi-Aventis	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002532/human_med_001617.jsp&mid=WC0b01ac058001d124
Zelboraf	Vemurafenib	New active substance	Roche Registration Ltd	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002409/human_med_001544.jsp&mid=WC0b01ac058001d124
Zinforo	Ceftaroline fosamil	New active substance	AstraZeneca AB	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002252/human_med_001584.jsp&mid=WC0b01ac058001d124
Zytiga	Abiraterone	New active substance	Janssen-Cilag International B.V.	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002321/human_med_001499.jsp&mid=WC0b01ac058001d124

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

² Also known in some EU countries as Tyvensse

³ Also known in some EU countries as Fluarix Tetra