

25 March 2015
EMA/245297/2013 Rev.21
Inspections & Human Medicines Pharmaco-vigilance

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 March 2015 are highlighted in red font.

| Product name | Active Substance (s) | Reason (s) on list | Marketing Authorisation Holder (s) | Link to Product Information | Date of Inclusion |
|------------------|---|---|---|---|-------------------|
| ABASRIA | Insulin glargine | New biological | Eli Lilly Regional Operations GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002835/human_med_001790.jsp&mid=WC0b01ac058001d124 | October 2014 |
| Accofil | Filgrastim | New biological | Accord Healthcare Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003956/human_med_001798.jsp&mid=WC0b01ac058001d124 | October 2014 |
| Adcetris | Brentuximab vedotin | New active substance, conditional authorisation | Takeda Global Research and Development Centre (Europe) Ltd. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002455/human_med_001588.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Adempas | Riociguat | New active substance | Bayer Pharma AG | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002737/human_med_001733.jsp&mid=WC0b01ac058001d124 | April 2014 |
| Aldurazyme | Laronidase | Authorised under exceptional circumstances | Genzyme Europe B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000477/human_med_000636.jsp&mid=WC0b01ac058001d124 | April 2013 |
| AMYVID | Florbetapir [18F] | New active substance | Eli Lilly Nederlands B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002422/human_med_001611.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Anoro | Umeclidinium bromide/vilanterol trifenate | New active substance, PASS ¹ | Glaxo Group Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002751/human_med_001754.jsp&mid=WC0b01ac058001d124 | June 2014 |
| Apleek | Ethinyl estradiol/gestodene | PASS ¹ | Bayer Pharma AG | http://www.cbg-meb.nl/CBG/nl/search/SplitScreen/default.htm?qry=apleek&language=nl | September 2014 |
| 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 | April 2013 |
| Atriance | Nelarabine | Authorised under exceptional circumstances | Glaxo Group Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000752/human_med_000656.jsp&mid=WC0b01ac058001d124 | April 2013 |
| ATryn | Anti-thrombin alpha | Authorised under exceptional circumstances | GTC Biotherapeutics UK Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000587/human_med_000658.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Aubagio | Teriflunomide | New active substance | Sanofi-aventis Groupe | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002514/human_med_001645.jsp&mid=WC0b01ac058001d124 | October 2013 |
| Bemfola | Follitropin alfa | New biological | FINOX Biotech AG | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002615/human_med_001734.jsp&mid=WC0b01ac058001d124 | May 2014 |
| Benlysta | Belimumab | New active substance | Glaxo Group Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002015/human_med_001466.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Betmiga | Mirabegron | New active substance | Astellas Pharma Europe B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002388/human_med_001605.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Bexsero | Meningococcal group-B vaccine (rDNA, component, adsorbed) | New active substance | Novartis Vaccines and Diagnostics S.r.l. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002333/human_med_001614.jsp&mid=WC0b01ac058001d124 | April 2013 |
| BindRen | Colestilan | New active substance | Mitsubishi Pharma Europe Ltd. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002377/human_med_001595.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Bosulif | Bosutinib | New active substance, conditional authorisation | Pfizer Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002373/human_med_001613.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Bretaris Genuair | Acridinium bromide | New active substance, PASS ¹ | Almirall, S.A. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002706/human_med_001570.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Brimica Genuair | Acridinium bromide/formoterol fumarate dihydrate | PASS ¹ | Almirall, S.A. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003969/human_med_001806.jsp&mid=WC0b01ac058001d124 | December 2014 |

| | | | | | |
|---|--|--|---|--|----------------|
| Brintellix | Vortioxetine | New active substance | H. Lundbeck A/S | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002717/human_med_001714.jsp&mid=WCOb01ac058001d124 | February 2014 |
| Caprelsa | Vandetanib | New active substance, conditional authorisation | AstraZeneca AB | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002315/human_med_001529.jsp&mid=WCOb01ac058001d124 | April 2013 |
| Ceplene | Histamine dihydrochloride | Authorised under exceptional circumstances | Meda AB | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000796/human_med_000691.jsp&mid=WCOb01ac058001d124 | April 2013 |
| Cerdelga | Eliglustat | New active substance, PASS ¹ | Genzyme Europe B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003724/human_med_001840.jsp&mid=WCOb01ac058001d124 | February 2015 |
| Champix | Varenicline | PASS ¹ | Pfizer | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000699/human_med_000696.jsp&mid=WCOb01ac058001d124 | April 2013 |
| Cilostazol-containing medicinal products (For full list of products see Annex VIII) | Cilostazol | PASS ¹ | Various (For full list see Annex VIII) | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WCOb01ac0580036d63 | September 2013 |
| Cinryze | c1 inhibitor, human | PASS ¹ | ViroPharma SPRL | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001207/human_med_001448.jsp&mid=WCOb01ac058001d124 | April 2013 |
| Cleviprex emulsion for injection 0.5 mg/ml | Clevidipine | New active substance | The Medicines Company UK Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WCOb01ac0580036d63 | April 2013 |
| Combined hormonal contraceptives containing chlormadinone (For full list of products see Annex IX) | Chlormadinone Ethinylestradiol, Chlormadinone Acetate Ethinylestradiol | PASS ¹ | Various (For full list see Annex IX) | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WCOb01ac0580036d63 | June 2014 |
| Cometriq | Cabozantinib | New active substance, conditional authorisation | TMC Pharma Services Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002640/human_med_001726.jsp&mid=WCOb01ac058001d124 | May 2014 |
| Constella | Linaclotide | New active substance | Almirall, S.A. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002490/human_med_001597.jsp&mid=WCOb01ac058001d124 | April 2013 |
| Corlentor | Ivabradine | PASS ¹ | Les Laboratoires Servier | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Corlentor_and_Procoralan/human_referral_prac_000044.jsp&mid=WCOb01ac05805c516f&source=homeMedSearch&category=human | February 2015 |
| Cosentyx | Secukinumab | New active substance | Novartis Europharm Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003729/human_med_001832.jsp&mid=WCOb01ac058001d124 | February 2015 |
| Cuprymina | Copper (64Cu) chloride | New active substance | Sparkle S.r.l | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002136/human_med_001578.jsp&mid=WCOb01ac058001d124 | April 2013 |
| Cyproterone acetate and Ethinylestradiol containing medicinal products (For full list of products see Annex I) | Cyproterone acetate and Ethinylestradiol | PASS ¹ | Various (For full list see Annex I) | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WCOb01ac0580036d63 | August 2013 |
| Cyramza | Ramucirumab | New active substance | Eli Lilly Nederland B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002829/human_med_001825.jsp&mid=WCOb01ac058001d124 | February 2015 |
| Dacogen | Decitabine | New active substance | Janssen-Cilag International B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002221/human_med_001589.jsp&mid=WCOb01ac058001d124 | April 2013 |
| Daklinza | Daclatasvir | New active substance | Bristol-Myers Squibb Pharma EEIG | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003768/human_med_001792.jsp&mid=WCOb01ac058001d124 | September 2014 |
| Daliresp | Roflumilast | PASS ¹ | Takeda GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002398/human_med_001415.jsp&mid=WCOb01ac058001d124 | June 2013 |
| Daxas | Roflumilast | PASS ¹ | Takeda GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001179/human_med_001363.jsp&mid=WCOb01ac058001d124 | June 2013 |
| Defitelio | Defibrotide | New biological, authorised under exceptional circumstances | Gentium S.p.A. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002393/human_med_001646.jsp&mid=WCOb01ac058001d124 | November 2013 |
| Deltyba | Delamanid | New active substance, conditional authorisation | Otsuka Novel Products GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002552/human_med_001699.jsp&mid=WCOb01ac058001d124 | May 2014 |
| Dexamed and associated names (dexamfetamine sulphate-containing medicinal products in the EU) (For full list of products see Annex XII) | Dexamfetamine sulphate | PASS ¹ | Kohne Pharma GmbH (For full list see Annex XII) | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Dexamed_and_associated_names/human_referral_000373.jsp&mid=WCOb01ac05805c516f | September 2014 |
| Dificlir | Fidaxomicin | New active substance | Astellas Pharma Europe B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002087/human_med_001511.jsp&mid=WCOb01ac058001d124 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Domperidone-containing_medicines/human_referral_prac_000021.jsp&mid=WCOb01ac05805c516f | April 2013 |
| Domperidone-containing medicinal products (For full list of products see Annex X) | Domperidone | PASS ¹ | Various (For full list see Annex X) | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003745/human_med_001811.jsp&mid=WCOb01ac058001d124 | July 2014 |
| Duaklir Genuair | Aclidinium bromide/formoterol fumarate dihydrate | PASS ¹ | Almirall, S.A. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002293/human_med_001512.jsp&mid=WCOb01ac058001d124 | December 2014 |
| Edarbi | Azilsartan medoxomil | New active substance | Takeda Global Research and Development Centre (Europe) Ltd. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002293/human_med_001512.jsp&mid=WCOb01ac058001d124 | April 2013 |

| | | | | | |
|---|---|---|--|---|----------------|
| Edurant | Rilpivirine | New active substance | Janssen-Cilag International B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002264/human_med_001513.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Eklira Genuair | Acridinium bromide | New active substance, PASS ¹ | Almirall, S.A. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002211/human_med_001571.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Elaprase | Idursulfase | Authorised under exceptional circumstances | Shire Human Genetic Therapies AB | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000700/human_med_000757.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Eliquis | Apixaban | New active substance | Bristol Myers Squibb/ Pfizer EEIG | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002148/human_med_001449.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Elvanse ² | Lisdexamphetamine | New active substance | Shire Pharmaceutical Contracts Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63 | April 2013 |
| Entyvio | Vedolizumab | New active substance | Takeda Pharma A/S | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002782/human_med_001751.jsp&mid=WC0b01ac058001d124 | June 2014 |
| Enurev Breezhaler | Glycopyrronium bromide | PASS ¹ | Novartis Europharm Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002691/human_med_001579.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Eperzan | Albiglutide | New active substance | GlaxoSmithKline Trading Services Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002735/human_med_001735.jsp&mid=WC0b01ac058001d124 | April 2014 |
| Erivedge | Vismodegib | New active substance, conditional authorisation | Roche Registration Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002602/human_med_001659.jsp&mid=WC0b01ac058001d124 | August 2013 |
| Esbriet | Pirfenidone | New active substance, PASS ¹ | InterMune UK Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002154/human_med_001417.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Eurartesim | Dihydroartemisinin/piperaquine phosphate | New active substance, PASS ¹ | Sigma-tau Industrie Farmaceutiche Riunite S.p.A. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001199/human_med_001450.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Evarrest | Human fibrinogen/human thrombin | New biological | Omrix Biopharmaceuticals N. V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002515/human_med_001675.jsp&mid=WC0b01ac058001d124 | November 2013 |
| Eviplera | Emtricitabine/rilpivirine/tenofovir disoproxil | New active substance | Gilead Sciences International Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002312/human_med_001514.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Evoltra | Clofarabine | Authorised under exceptional circumstances | Genzyme Europe B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000613/human_med_000773.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Exjade | Deferasirox | PASS ¹ | Novartis Europharm Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000670/human_med_000780.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Exviera | Dasabuvir | New active substance | AbbVie Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003837/human_med_001833.jsp&mid=WC0b01ac058001d124 | February 2015 |
| Eylea | Aflibercept | New active substance | Bayer Pharma AG | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002392/human_med_001598.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Fampyra | Fampridine | New active substance, conditional authorisation | BIOGEN IDEC LTD. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002097/human_med_001432.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Firdapse | Amifampridine | Authorised under exceptional circumstances | BioMarin Europe Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001032/human_med_001298.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Fluenz | Influenza vaccine (intranasal, live attenuated) | New active substance | MedImmune LLC | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001101/human_med_001405.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Fluenz Tetra | Influenza vaccine (live attenuated, nasal) | New biological | MedImmune LLC | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002617/human_med_001713.jsp&mid=WC0b01ac058001d124 | January 2014 |
| Flupirtine-containing medicinal products (For full list of products see Annex VI) | Flupirtine | PASS ¹ | Various (For full list see Annex VI) | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63 | February 2014 |
| Forxiga | Dapagliflozin | New active substance | Bristol-Myers Squibb / AstraZeneca EEIG | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002322/human_med_001546.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Fycompa | Perampanel | New active substance | Eisai Europe Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002434/human_med_001572.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Gazyvaro | Obinutuzumab | New active substance | Roche Registration Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002799/human_med_001780.jsp&mid=WC0b01ac058001d124 | September 2014 |
| Geonistin tablete za rodnicu | Oxytetracyclin, nistatin | PASS ¹ | Pliva Hrvatska d.o.o. | http://www.halmed.hr/?ln=en&w=ljkekovi&d=opsirnije&id=10529 | June 2014 |
| Gilenya | Fingolimod hydrochloride | New active substance, PASS ¹ | Novartis Europharm Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002202/human_med_001433.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Giotrif | Afatinib | New active substance | Boehringer Ingelheim International GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002280/human_med_001698.jsp&mid=WC0b01ac058001d124 | October 2013 |
| Glivec | Imatinib | PASS ¹ | Novartis Europharm Ltd. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000406/human_med_000808.jsp&mid=WC0b01ac058001d124 | September 2014 |

| | | | | | |
|---|---|--|---|---|-------------------|
| Glybera | Alipogene tiparovec | New active substance, authorised under exceptional circumstances | uniQure biopharma B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002145/human_med_001480.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Grastofil | Filgrastim | New biological | Apotex Europe B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002150/human_med_001688.jsp&mid=WC0b01ac058001d124 | November 2013 |
| Halaven | Eribulin mesylate | New active substance | Eisai Europe Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002084/human_med_001427.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Harvoni | Ledipasvir/sofosbuvir | New active substance | Gilead Sciences International Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003850/human_med_001813.jsp&mid=WC0b01ac058001d124 | December 2014 |
| Hexacima | Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed) | New biological | Sanofi Pasteur S.A. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002702/human_med_001640.jsp&mid=WC0b01ac058001d124 | July 2013 |
| Hexyon | Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed) | New biological | Sanofi Pasteur MSD, SNC | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002796/human_med_001641.jsp&mid=WC0b01ac058001d124 | July 2013 |
| Hizentra | Human normal immunoglobulin | New biological | CSL Behring GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002127/human_med_001440.jsp&mid=WC0b01ac058001d124 | September 2013 |
| Holoclar | Ex vivo expanded autologous human corneal epithelial cells containing stem cells | New active substance, conditional authorisation | Chiesi Farmaceutici S.P.A. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002450/human_med_001844.jsp&mid=WC0b01ac058001d124 | March 2015 |
| Hydroxyethyl starch (HES)-containing medicinal products (For full list see Annex V) | Hydroxyethyl starch | PASS ¹ | Various (For full list see Annex V) | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63 | January 2014 |
| HyQvia | Human normal immunoglobulin | New biological | Baxter Innovations GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002491/human_med_001647.jsp&mid=WC0b01ac058001d124 | September 2013 |
| Iclusig | Ponatinib | New active substance | Ariad Pharma Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002695/human_med_001656.jsp&mid=WC0b01ac058001d124 | August 2013 |
| Ilaris | Canakinumab | Authorised under exceptional circumstances | Novartis Europharm Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001109/human_med_000826.jsp&mid=WC0b01ac058001d124 | April 2013 |
| IMBRUVICA | Ibrutinib | New active substance | Janssen-Cilag International NV | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003791/human_med_001801.jsp&mid=WC0b01ac058001d124 | November 2014 |
| Imnovid (formerly Pomalidomide Celgene) | Pomalidomide | New active substance, PASS ¹ | Celgene Europe Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002682/human_med_001669.jsp&mid=WC0b01ac058001d124 | September 2013 |
| Imvanex | Modified Vaccinia Ankara virus – Bavarian Nordic (MVA-BN) live virus | New active substance, authorised under exceptional circumstances | Bavarian Nordic A/S | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002596/human_med_001666.jsp&mid=WC0b01ac058001d124 | September 2013 |
| Incivo | Telaprevir | New active substance | Janssen-Cilag International B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002313/human_med_001487.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Increlex | Mecasermin | Authorised under exceptional circumstances | Ipsen Pharma | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000704/human_med_000829.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Incresync | Alogliptin/pioglitazone | New active substance | Takeda Pharma A/S | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002178/human_med_001694.jsp&mid=WC0b01ac058001d124 | October 2013 |
| Incruse | Umeclidinium bromide | New active substance | Glaxo Group Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002809/human_med_001755.jsp&mid=WC0b01ac058001d124 | May 2014 |
| Inflectra | Infliximab | New biological | Hospira UK Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002778/human_med_001677.jsp&mid=WC0b01ac058001d124 | October 2013 |
| Influsplit Tetra ³ | Influenza virus inactivated split virion | New biological | Glaxo Group Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63 | April 2013 |
| Inlyta | Axitinib | New active substance | Pfizer Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002406/human_med_001573.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Invokana | Canagliflozin | New active substance | Janssen-Cilag International N.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002649/human_med_001707.jsp&mid=WC0b01ac058001d124 | December 2013 |
| Ipreziv | Azilsartan medoxomil | New active substance | Takeda Global Research and Development Centre (Europe) Ltd. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002517/human_med_001515.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Intravenous iron-containing medicinal products (For full list see Annex III) | Ferric carboxymaltose, iron dextran, sodium ferric gluconate, iron isomaltoside, iron sucrose | PASS ¹ | Various (For full list see Annex III) | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63 | January 2014 |
| Izinova / Eziclen | Sulphate anhydrous, magnesium sulphate heptahydrate, potassium sulphate | PASS ¹ | IPSEN PHARMA | http://agence-prd.ansm.sante.fr/php/ecodex/frames.php?specid=65236258&typedoc=R&ref=R0222102.htm | June 2014 |
| Jakavi | Ruxolitinib | New active substance, PASS ¹ | Novartis Europharm Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002464/human_med_001568.jsp&mid=WC0b01ac058001d124 | April 2013 |

| | | | | | |
|-------------------------------------|---|--|---|---|-------------------|
| Jardiance | Empagliflozin | New active substance | Boehringer Ingelheim International GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002677/human_med_001764.jsp&mid=WC0b01ac058001d124 | June 2014 |
| Jaydess | Levonorgestrel | PASS ¹ | Bayer AB | http://www.lakemedelsverket.se/LMF/Lakemedelsinformation/?nplid=20111208000069&type=product#/?&_suid=138513307171006085398397649693 | November 2013 |
| Jentadueto | Linagliptin/metformin | New active substance | Boehringer Ingelheim International GMBH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002279/human_med_001574.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Jetrea | Ocriplasmin | New active substance | ThromboGenics NV | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002381/human_med_001629.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Jevtana | Cabazitaxel | New active substance | Sanofi-Aventis | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002018/human_med_001428.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Kadcyla | Trastuzumab emtansine | New active substance | Roche Registration Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002389/human_med_001712.jsp&mid=WC0b01ac058001d124 | December 2013 |
| Kalydeco | Ivacaftor | New active substance, PASS ¹ | Vertex Pharmaceuticals (U.K.) Ltd. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002494/human_med_001575.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Ketoconazole HRA | Ketoconazole | PASS ¹ | Laboratoire HRA Pharma | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003906/human_med_001814.jsp&mid=WC0b01ac058001d124 | December 2014 |
| Kolbam (previously Cholic Acid FGK) | Cholic acid | Authorised under exceptional circumstances | FGK Representative Service GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002081/human_med_001718.jsp&mid=WC0b01ac058001d124 | May 2014 |
| Krystexxa | Pegloticase | New active substance, PASS ¹ | Savient Pharma Ireland Ltd. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002208/human_med_001591.jsp&mid=WC0b01ac058001d124 | April 2013 |
| LacTEST | Gaxilose | New active substance | Venter Pharma S.L. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/genera_l_content_000155.jsp&mid=WC0b01ac0580036d63 | April 2013 |
| Latuda | Lurasidone | New active substance | Takeda Pharma A/S | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002713/human_med_001737.jsp&mid=WC0b01ac058001d124 | April 2014 |
| Laventair | Umeclidinium bromide/vilanterol trifenate | New active substance, PASS ¹ | Glaxo Group Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003754/human_med_001756.jsp&mid=WC0b01ac058001d124 | June 2014 |
| Lemtrada | Alemtuzumab | New biological | Genzyme Therapeutics Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003718/human_med_001678.jsp&mid=WC0b01ac058001d124 | October 2013 |
| Libertek | Roflumilast | PASS ¹ | Takeda GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002399/human_med_001416.jsp&mid=WC0b01ac058001d124 | June 2013 |
| Lojuxta | Lomitapide | New active substance, authorised under exceptional circumstances | Aegerion Pharmaceuticals SAS | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002578/human_med_001668.jsp&mid=WC0b01ac058001d124 | September 2013 |
| Lonquex | Lipegfilgrastim | New active substance, PASS ¹ | Teva Pharma B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002556/human_med_001667.jsp&mid=WC0b01ac058001d124 | September 2013 |
| Lymphoseek | Tilmanocept | New active substance | Navidea Biopharmaceuticals Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002085/human_med_001827.jsp&mid=WC0b01ac058001d124 | December 2014 |
| Lynparza | Olaparib | New active substance | AstraZeneca AB | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003726/human_med_001831.jsp&mid=WC0b01ac058001d124 | February 2015 |
| Lyxumia | Lixisenatide | New active substance | Sanofi-Aventis | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002445/human_med_001615.jsp&mid=WC0b01ac058001d124 | April 2013 |
| MACI ⁴ | Matrix applied characterised autologous cultured chondrocytes | New active substance | Aastrom Biosciences DK ApS | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002522/human_med_001660.jsp&mid=WC0b01ac058001d124 | August 2013 |
| Mekinist | Trametinib | New active substance | Glaxo Group Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002643/human_med_001772.jsp&mid=WC0b01ac058001d124 | September 2014 |
| Meriofert | Menotrophin | New biological | Laboratoires Genévrier SA | http://www.produktresume.dk/docushare/dsweb/View/Collection-109 | March 2015 |
| Moventig | Naloxegol | New active substance | AstraZeneca AB | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002810/human_med_001816.jsp&mid=WC0b01ac058001d124 | January 2015 |
| Naglazyme | Galsulfase | Authorised under exceptional circumstances | BioMarin Europe Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000640/human_med_000918.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Neuraceq | Florbetaben (18F) | New active substance | Piramal Imaging GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002553/human_med_001716.jsp&mid=WC0b01ac058001d124 | March 2014 |
| NexoBrid | Concentrate of proteolytic enzymes enriched in bromelain | New active substance, PASS ¹ | MediWound Germany GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002246/human_med_001582.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Nimenrix | Meningococcal group A, C, W 135 and Y conjugate vaccine | New active substance | GlaxoSmithKline Biologicals, S.A. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002226/human_med_001548.jsp&mid=WC0b01ac058001d124 | April 2013 |
| NovoEight | Turoctocog alfa | New active substance | Novo Nordisk A/S | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002719/human_med_001701.jsp&mid=WC0b01ac058001d124 | December 2013 |

| | | | | | |
|-----------------|---|---|---|---|----------------|
| NovoThirteen | Catridecacog | New active substance | Novo Nordisk A/S | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002284/human_med_001576.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Nulojix | Belatacept | New active substance | Bristol Myers Squibb Pharma EEIG | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002098/human_med_001459.jsp&mid=WC0b01ac058001d124 | April 2013 |
| | Alanine, arginine, aspartic acid, calcium chloride, cysteine, glucose monohydrate, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, magnesium acetate, methionine, olive oil, ornithine hydrochloride, henylalanine, potassium acetate, proline, serine, sodium chloride, sodium glycerophosphate, soybean oil, taurine, threonine, tryptophan, tyrosine, valine | PASS ¹ | Baxter (For full list see Annex XI) | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Numeta_G13E_and_Numeta_G16E_emulsion_for_infusion/human_referral_prac_000027.jsp&mid=WC0b01ac05805c516f | September 2014 |
| Nuwiq | Simoctocog alfa | New active substance | Octapharma AB | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002813/human_med_001781.jsp&mid=WC0b01ac058001d124 | September 2014 |
| Ofev | Nintedanib | New active substance | Boehringer Ingelheim International GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003821/human_med_001834.jsp&mid=WC0b01ac058001d124 | February 2015 |
| OLYSIO | Simeprevir | New active substance | Janssen-Cilag International NV | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002777/human_med_001766.jsp&mid=WC0b01ac058001d124 | June 2014 |
| Opgenra | Eptotermin alfa | PASS ¹ | Olympus Biotech International Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000819/human_med_000950.jsp&mid=WC0b01ac058001d124 | July 2013 |
| Opsumit | Macitentan | New active substance | Actelion Registration Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002697/human_med_001717.jsp&mid=WC0b01ac058001d124 | February 2014 |
| Optimark | Gadoversetamide | PASS ¹ | Covidien Deutschland GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000745/human_med_000953.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Orphacol | Cholic acid | Authorised under exceptional circumstances | Laboratoires CTRS | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001250/human_med_001419.jsp&mid=WC0b01ac058001d124 | October 2013 |
| Osseor | Strontium ranelate | PASS ¹ | Les Laboratoires Servier | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000561/human_med_000963.jsp&mid=WC0b01ac058001d124 | August 2013 |
| Otezla | Apremilast | New active substance | Celgene Europe Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003746/human_med_001835.jsp&mid=WC0b01ac058001d124 | February 2015 |
| Ovaleap | Follitropin alfa | New biological | Teva Pharma B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002608/human_med_001689.jsp&mid=WC0b01ac058001d124 | November 2013 |
| Pandemrix | Influenza vaccine (H1N1)v (split virion, inactivated, adjuvanted) A/California/7/2009 (H1N1)v like strain (x-179a) | PASS ¹ | GlaxoSmithKline Biologicals | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000832/human_med_000965.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Perjeta | Pertuzumab | New active substance | Roche Registration Ltd. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002547/human_med_001628.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Picato | Ingenol mebutate | New active substance | Leo Pharma A/S | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002275/human_med_001600.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Pixuvri | Pixantrone | New active substance, conditional authorisation | CTI Life Sciences Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002055/human_med_001549.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Plegridy | Peginterferon beta-1a | New active substance | Biogen Idec Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002827/human_med_001782.jsp&mid=WC0b01ac058001d124 | September 2014 |
| Procoralan | Ivabradine | PASS ¹ | Les Laboratoires Servier | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Corlentor_and_Procoralan/human_referral_prac_000044.jsp&mid=WC0b01ac05805c516f&source=homeMedSearch&category=human | February 2015 |
| Protelos | Strontium ranelate | PASS ¹ | Les Laboratoires Servier | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000560/human_med_000999.jsp&mid=WC0b01ac058001d124 | August 2013 |
| Provenge | Autologous peripheral blood mononuclear cells activated with PAP-GM-CSF (Sipuleucel-T) | New active substance, PASS ¹ | Dendreon UK Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002513/human_med_001680.jsp&mid=WC0b01ac058001d124 | October 2013 |
| Relvar Ellipta | Fluticasone furoate/vilanterol trifenate | New active substance, PASS ¹ | Glaxo Group Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002673/human_med_001708.jsp&mid=WC0b01ac058001d124 | December 2013 |
| Remsima | Infliximab | New biological | Celltrion Healthcare Hungary Kft. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002576/human_med_001682.jsp&mid=WC0b01ac058001d124 | October 2013 |
| Replagal | Agalsidase alfa | Authorised under exceptional circumstances | Shire Human Genetic Therapies AB | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000369/human_med_001029.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Revestive | Teduglutide | New active substance, PASS ¹ | Nycomed Danmark ApS | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002345/human_med_001583.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Revinty Ellipta | Fluticasone furoate/vilanterol trifenate | PASS ¹ | Glaxo Group Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002745/human_med_001768.jsp&mid=WC0b01ac058001d124 | May 2014 |

| | | | | | |
|---|--|--|--|---|----------------|
| Revlimid | Lenalidomide | PASS ¹ | Celgene Europe Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000717/human_med_001034.jsp&mid=WC0b01ac058001d124 | June 2014 |
| Rezolsta | Darunavir/cobicistat | New active substance | Janssen-Cilag International NV | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002819/human_med_001817.jsp&mid=WC0b01ac058001d124 | February 2015 |
| Rienso | Ferumoxytol | New active substance, PASS ¹ | Takeda Global Research and Development Centre (Europe) Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002215/human_med_001569.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Rixubis | Nonacog gamma | New biological | Baxter Innovations GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003771/human_med_001830.jsp&mid=WC0b01ac058001d124 | February 2015 |
| Ryzodeg | Insulin degludec/insulin aspart | New active substance | Novo Nordisk A/S | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002499/human_med_001608.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Scenesse | Afamelanotide | New active substance, authorised under exceptional circumstances | Clinuvel UK Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002548/human_med_001826.jsp&mid=WC0b01ac058001d124 | January 2015 |
| Seebri Breezhaler | Glycopyrronium bromide | PASS ¹ | Novartis Europharm | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002430/human_med_001580.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Selincro | Nalmefene | New active substance | H. Lundbeck A/S | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002583/human_med_001620.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Senshio | Ospemifene | New active substance, PASS ¹ | Shionogi Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002780/human_med_001837.jsp&mid=WC0b01ac058001d124 | February 2015 |
| Signifor | Pasireotide | New active substance | Novartis Europharm Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002052/human_med_001547.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Sirturo | Bedaquiline | New active substance, conditional authorisation | Janssen-Cilag International N.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002614/human_med_001730.jsp&mid=WC0b01ac058001d124 | March 2014 |
| Somatropin Biopartners | Somatropin | New biological | BioPartners GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002196/human_med_001672.jsp&mid=WC0b01ac058001d124 | September 2013 |
| Sovaldi | Sofosbuvir | New active substance | Gilead Sciences International Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002798/human_med_001723.jsp&mid=WC0b01ac058001d124 | February 2014 |
| Spedra | Avanafil | New active substance | Vivus B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002581/human_med_001661.jsp&mid=WC0b01ac058001d124 | August 2013 |
| Stivarga | Regorafenib | New active substance | Bayer Pharma AG | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002573/human_med_001684.jsp&mid=WC0b01ac058001d124 | September 2013 |
| Stribild | Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil | New active substance | Gilead Sciences International Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002574/human_med_001654.jsp&mid=WC0b01ac058001d124 | July 2013 |
| Striverdi Respimat | Olodaterol | New active substance, PASS ¹ | Boehringer Ingelheim International GmbH | http://www.cbg-meb.nl/CBG/en/human-medicines/geneesmiddeleninformatiebank/default.htm | February 2015 |
| Sylvant | Siltuximab | New active substance, PASS ¹ | Janssen-Cilag International NV | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003708/human_med_001769.jsp&mid=WC0b01ac058001d124 | June 2014 |
| Tafinlar | Dabrafenib | New active substance | GlaxoSmithKline Trading Services Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002604/human_med_001683.jsp&mid=WC0b01ac058001d124 | September 2013 |
| Targocid and associated names (teicoplanin-containing medicinal products) (For full list see Annex VII) | Teicoplanin | PASS ¹ | Various (For full list see Annex VII) | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63 | February 2014 |
| Teysono | Tegafur/gimeracil/oteracil | New active substance | Nordic Group B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001242/human_med_001422.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Thiocolchicoside-containing medicinal products (For full list see Annex IV) | Thiocolchicoside | PASS ¹ | Various (For full list see Annex IV) | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63 | January 2014 |
| Tivicay | Dolutegravir | New active substance | ViiV Healthcare UK Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002753/human_med_001720.jsp&mid=WC0b01ac058001d124 | February 2014 |
| Tovanor Breezhaler | Glycopyrronium bromide | PASS ¹ | Novartis Europharm Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002690/human_med_001581.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Trajenta | Linagliptin | New active substance | Boehringer Ingelheim International GMBH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002110/human_med_001482.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Translarna | Ataluren | New active substance, conditional authorisation | PTC Therapeutics Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002720/human_med_001742.jsp&mid=WC0b01ac058001d124 | September 2014 |
| Tresiba | Insulin degludec | New active substance | Novo Nordisk A/S | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002498/human_med_001609.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Trimetazidine-containing medicinal products (For full list of products see Annex II) | Trimetazidine | PASS ¹ | Various (For full list see Annex II) | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63 | November 2013 |
| Triumeq | Dolutegravir/abacavir/lamivudine | New active substance | ViiV Healthcare UK Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002754/human_med_001796.jsp&mid=WC0b01ac058001d124 | October 2014 |

| | | | | | |
|---|--|--|--|---|-------------------|
| Trobalt | Retigabine | New active substance | Glaxo Group Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001245/human_med_001431.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Trulicity | Dulaglutide | New active substance | Eli Lilly Nederland B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002825/human_med_001821.jsp&mid=WC0b01ac058001d124 | December 2014 |
| Tybst | Cobicistat | New active substance | Gilead Sciences International Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002572/human_med_001690.jsp&mid=WC0b01ac058001d124 | October 2013 |
| Tygacil | Tigecycline | PASS ¹ | Pfizer Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000644/human_med_001118.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Tysabri | Natalizumab | PASS ¹ | Elan Pharma International Ltd. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000603/human_med_001119.jsp&mid=WC0b01ac058001d124 | April 2013 |
| 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 | April 2013 |
| Ultibro Breezhaler | Indacaterol/glycopyrronium bromide | PASS ¹ | Novartis Europharm Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002679/human_med_001691.jsp&mid=WC0b01ac058001d124 | October 2013 |
| Ulnar Breezhaler | indacaterol/glycopyrronium bromide | PASS ¹ | Novartis Europharm Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003875/human_med_001758.jsp&mid=WC0b01ac058001d124 | July 2014 |
| Valproate and related substances (sodium valproate, valproic acid, valproate semisodium, valpromide-containing medicinal products) (For full list of products see Annex XIII) | Sodium valproate, valproic acid, valproate semisodium, valpromide | PASS ¹ | Various (For full list see Annex XIII) | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63 | January 2015 |
| Vargatef | Nintedanib | New active substance | Boehringer Ingelheim International GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002569/human_med_001822.jsp&mid=WC0b01ac058001d124 | December 2014 |
| Vedrop | Tocofersolan d-alpha tocopheryl polyethylene glycol succinate | Authorised under exceptional circumstances | Orphan Europe S.A.R.L. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000920/human_med_001129.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Velphoro | Mixture of polynuclear iron(iii)-oxyhydroxide, sucrose and starches | New active substance | Vifor Fresenius Medical Care Renal Pharma France | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002705/human_med_001795.jsp&mid=WC0b01ac058001d124 | September 2014 |
| Vepacel | A/H5N1 pre-pandemic influenza vaccine (whole virion, vero cell derived, inactivated) | New active substance | Baxter Innovations GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002089/human_med_001543.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Vibativ | Telavancin | PASS ¹ | Clinigen Healthcare Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001240/human_med_001467.jsp&mid=WC0b01ac058001d124 | May 2014 |
| Victrelis | Boceprevir | New active substance | Merck Sharp & Dohme Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002332/human_med_001464.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Viekirax | Ombitasvir/paritaprevir/ritonavir | New active substance | AbbVie Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003839/human_med_001838.jsp&mid=WC0b01ac058001d124 | February 2015 |
| Vimizim | Elosulfase alfa | New active substance, PASS ¹ | BioMarin Europe Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002779/human_med_001759.jsp&mid=WC0b01ac058001d124 | June 2014 |
| Vipdomet | Alogliptin/metformin | New active substance | Takeda Pharma A/S | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002654/human_med_001695.jsp&mid=WC0b01ac058001d124 | October 2013 |
| Vipidia | Alogliptin | New active substance | Takeda Pharma A/S | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002182/human_med_001696.jsp&mid=WC0b01ac058001d124 | October 2013 |
| Vitekta | Elvitegravir | New active substance | Gilead Sciences International Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002577/human_med_001710.jsp&mid=WC0b01ac058001d124 | December 2013 |
| Vizamyl | Flutemetamol (18F) | New active substance | GE Healthcare Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002557/human_med_001794.jsp&mid=WC0b01ac058001d124 | September 2014 |
| Vokanamet | Canagliflozin/metformin hydrochloride | New active substance | Janssen-Cilag International NV | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002656/human_med_001760.jsp&mid=WC0b01ac058001d124 | May 2014 |
| Voncento | Human coagulation factor VIII/human von Willebrand factor | New biological | CLS Behring GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002493/human_med_001670.jsp&mid=WC0b01ac058001d124 | October 2013 |
| Votubia | Everolimus | Conditional authorisation | Novartis Europharm Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002311/human_med_001484.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Vyndaqel | Tafamidis | New active substance, authorised under exceptional circumstances | Pfizer Speciality UK Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002294/human_med_001498.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Xadago | Safinamide | New active substance | Zambon S.p.A. | Not yet available | March 2015 |
| Xagrid | Anagrelide | Authorised under exceptional circumstances | Shire Pharmaceutical Contracts Ltd. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000480/human_med_001153.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Xalkori | Crizotinib | New active substance, conditional authorisation | Pfizer Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002489/human_med_001592.jsp&mid=WC0b01ac058001d124 | April 2013 |

| | | | | | |
|--------------------|--------------------------------------|--|---|---|-------------------|
| Xarelto | Rivaroxaban | PASS ¹ | Bayer Pharma AG | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000944/human_med_001155.jsp&mid=WC0b01ac058001d124 | July 2013 |
| Xgeva | Denosumab | New biological | Amgen Europe B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002173/human_med_001463.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Xiapex | Collagenase Clostridium histolyticum | New active substance | Auxilium UK Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002048/human_med_001423.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Xigduo | Dapagliflozin/metformin | New active substance | Bristol-Myers Squibb/AstraZeneca EEIG | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002672/human_med_001721.jsp&mid=WC0b01ac058001d124 | February 2014 |
| Xofigo | Radium Ra 223 dichloride | New active substance | Bayer Pharma AG | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002653/human_med_001692.jsp&mid=WC0b01ac058001d124 | December 2013 |
| Xoterna Breezhaler | Indacaterol/glycopyrronium bromide | PASS ¹ | Novartis Europharm Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003755/human_med_001693.jsp&mid=WC0b01ac058001d124 | October 2013 |
| Xtandi | Enzalutamide | New active substance | Astellas Pharma Europe B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002639/human_med_001663.jsp&mid=WC0b01ac058001d124 | August 2013 |
| Xultophy | Insulin degludec/liraglutide | New biological | Novo Nordisk A/S | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002647/human_med_001802.jsp&mid=WC0b01ac058001d124 | October 2014 |
| Xydalba | Dalbavancin | New active substance | Durata Therapeutics International B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002840/human_med_001848.jsp&mid=WC0b01ac058001d124 | March 2015 |
| Yellox | Bromfenac | New active substance | Croma-Pharma GmbH | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001198/human_med_001455.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Yervoy | Ipilimumab | New active substance, PASS ¹ | Bristol Myers Squibb Pharma EEIG | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002213/human_med_001465.jsp&mid=WC0b01ac058001d124 | April 2013 |
| 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 | April 2013 |
| Zaltrap | Aflibercept | New active substance | Sanofi-Aventis | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002532/human_med_001617.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Zelboraf | Vemurafenib | New active substance | Roche Registration Ltd | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002409/human_med_001544.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Zinforo | Ceftaroline fosamil | New active substance | AstraZeneca AB | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002252/human_med_001584.jsp&mid=WC0b01ac058001d124 | April 2013 |
| Zoely | Nomegestrol/Estradiol | PASS ¹ | Theramex S.r.l. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001213/human_med_001452.jsp&mid=WC0b01ac058001d124 | January 2014 |
| Zontivity | Vorapaxar | New active substance | Merck Sharp & Dohme Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002814/human_med_001839.jsp&mid=WC0b01ac058001d124 | February 2015 |
| Zydelig | Idelalisib | New active substance | Gilead Sciences International Limited | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003843/human_med_001803.jsp&mid=WC0b01ac058001d124 | October 2014 |
| Zytiga | Abiraterone | New active substance | Janssen-Cilag International B.V. | http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002321/human_med_001499.jsp&mid=WC0b01ac058001d124 | April 2013 |

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

² Also known in some EU countries as Tyvense.

³ Also known in some EU countries as Fluarix Tetra.

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

*Following the fulfilment of the specific obligation of the conditional marketing authorisation, a marketing authorisation not subject to further specific obligations has been granted. Therefore, this product is no longer under additional monitoring.