IV

*(Notices)*

# NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

# EUROPEAN COMMISSION

## Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 March 2016 to 31 March 2016

*(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council ([1]))*

(2016/C 154/01)

([1]) OJ L 136, 30.4.2004, p. 1.

— **Issuing of a marketing authorisation** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

| Date of the decision | Name of the medicinal product | INN (International Non-Proprietary Name) | Holder of the marketing authorisation | Number of the entry in the Community Register | Pharmaceutical form | ATC code (Anatomical Therapeutic Chemical Code) | Date of notification |
|---|---|---|---|---|---|---|---|
| 16.3.2016 | Coagadex | human coagulation factor X | Bio Products Laboratory Ltd<br>Dagger Lane, Elstree, Hertfordshire WD6 3BX, United Kingdom | EU/1/16/1087 | Powder and solvent for solution for injection | B02BD13 | 18.3.2016 |
| 16.3.2016 | Neofordex | dexamethasone | Laboratoires CTRS<br>63 rue de l'Est, F-92100 Boulogne-Billancourt, France | EU/1/15/1053 | Tablet | H02AB02 | 18.3.2016 |
| 22.3.2016 | Amlodipine/Valsartan Mylan | amlodipine/valsartan | Mylan S.A.S<br>117 allée des Parcs, F-69800 Saint Priest, France | EU/1/16/1092 | Film-coated tablet | C09DB01 | 29.3.2016 |
| 31.3.2016 | Wakix | Pitolisant hydrochloride | Bioprojet Pharma<br>9 rue Rameau, F-75002 Paris, France | EU/1/15/1068 | Film-coated tablet | N07XX11 | 4.4.2016 |
| 31.3.2016 | Zonisamide Mylan | zonisamide | Mylan S.A.S<br>117 allée des Parcs, F-69800 Saint Priest, France | EU/1/16/1093 | Capsule, hard | N03AX15 | 4.4.2016 |

— **Modification of a marketing authorisation** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

| Date of the decision | Name of the medicinal product | Holder of the marketing authorisation | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 2.3.2016 | Copalia | Novartis Europharm Limited<br>Frimley Business Park, Camberley GU16 7SR, United Kingdom | EU/1/06/372 | 4.3.2016 |
| 2.3.2016 | Dafiro | Novartis Europharm Limited<br>Frimley Business Park, Camberley GU16 7SR, United Kingdom | EU/1/06/371 | 4.3.2016 |
| 2.3.2016 | DuoPlavin | Sanofi Clir SNC<br>54 rue La Boétie, F-75008 Paris, France | EU/1/10/619 | 7.3.2016 |
| 2.3.2016 | Efavirenz Teva | Teva B.V.<br>Swensweg 5, 2031 GA Haarlem, Nederland | EU/1/11/742 | 4.3.2016 |
| 2.3.2016 | Exforge HCT | Novartis Europharm Limited<br>Frimley Business Park, Camberley GU16 7SR, United Kingdom | EU/1/09/569 | 4.3.2016 |
| 2.3.2016 | Faslodex | AstraZeneca UK Limited<br>Alderley Park, Macclesfield, Cheshire, SK10 4TG United Kingdom | EU/1/03/269 | 4.3.2016 |
| 2.3.2016 | Jentadueto | Boehringer Ingelheim International GmbH<br>Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland | EU/1/12/780 | 7.3.2016 |
| 2.3.2016 | Menveo | GSK Vaccines S.r.l.<br>Via Fiorentina, 1, IT-53100 Siena, Italia | EU/1/10/614 | 4.3.2016 |
| 2.3.2016 | Mozobil | Genzyme Europe B.V.<br>Gooimeer 10, NL-1411 DD Naarden, Nederland | EU/1/09/537 | 4.3.2016 |
| 2.3.2016 | Xydalba | Durata Therapeutics International B.V.<br>Spaces Zuidas II, Barbara Strozzilaan 101, 1083 HN Amsterdam, Nederland | EU/1/14/986 | 4.3.2016 |
| 7.3.2016 | Avamys | Glaxo Group Ltd<br>980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom | EU/1/07/434 | 9.3.2016 |
| 7.3.2016 | Dacogen | Janssen-Cilag International NV<br>Turnhoutseweg 30, B-2340 Beerse, België | EU/1/12/792 | 9.3.2016 |
| 7.3.2016 | Signifor | Novartis Europharm Limited<br>Frimley Business Park, Camberley GU16 7SR, United Kingdom | EU/1/12/753 | 9.3.2016 |

| Date of the decision | Name of the medicinal product | Holder of the marketing authorisation | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 7.3.2016 | Triumeq | ViiV Healthcare UK Limited<br>980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom | EU/1/14/940 | 9.3.2016 |
| 10.3.2016 | Celsentri | ViiV Healthcare UK Limited<br>980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom | EU/1/07/418 | 14.3.2016 |
| 10.3.2016 | Onglyza | AstraZeneca AB<br>SE-151 85 Södertälje, Sverige | EU/1/09/545 | 14.3.2016 |
| 11.3.2016 | Deltyba | Otsuka Novel Products GmbH<br>Erika-Mann-Straße 21, D-80636 München, Deutschland | EU/1/13/875 | 16.3.2016 |
| 11.3.2016 | Savene | Clinigen Healthcare Limited<br>Pitcairn House, Crown Square, First Avenue, Burton-on-Trent, Staffordshire DE14 2WW, United Kingdom | EU/1/06/350 | 16.3.2016 |
| 11.3.2016 | Topotecan Teva | Teva B.V.<br>Swensweg 5, 2031 GA Haarlem, Nederland | EU/1/09/552 | 16.3.2016 |
| 16.3.2016 | Cuprymina | SPARKLE S.r.l.<br>Località Cavallino, 62010 Montecosaro (MC), Italia | EU/1/12/784 | 21.3.2016 |
| 22.3.2016 | Copalia HCT | Novartis Europharm Limited<br>Frimley Business Park, Camberley GU16 7SR, United Kingdom | EU/1/09/575 | 29.3.2016 |
| 22.3.2016 | Exforge | Novartis Europharm Limited<br>Frimley Business Park, Camberley GU16 7SR, United Kingdom | EU/1/06/370 | 29.3.2016 |
| 22.3.2016 | Exjade | Novartis Europharm Limited<br>Frimley Business Park, Camberley GU16 7SR, United Kingdom | EU/1/06/356 | 29.3.2016 |
| 22.3.2016 | Iclusig | ARIAD Pharma Ltd<br>Riverbridge House, Guildford Road, Leatherhead, Surrey KT22 9AD, United Kingdom | EU/1/13/839 | 29.3.2016 |
| 22.3.2016 | Kepivance | Swedish Orphan Biovitrum AB (publ)<br>SE-112 76 Stockholm, Sverige | EU/1/05/314 | 29.3.2016 |
| 22.3.2016 | Laventair | Glaxo Group Ltd<br>980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom | EU/1/14/899 | 29.3.2016 |

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|---|---|---|---|---|
| 22.3.2016 | Mekinist | Novartis Europharm Limited<br>Frimley Business Park, Camberley GU16 7SR, United Kingdom | EU/1/14/931 | 29.3.2016 |
| 22.3.2016 | Pixuvri | CTI Life Sciences Ltd<br>Highlands House, Basingstoke Road, Spencers Wood, Reading, Berkshire RG7 1NT, United Kingdom | EU/1/12/764 | 29.3.2016 |
| 22.3.2016 | Trajenta | Boehringer Ingelheim International GmbH<br>Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland | EU/1/11/707 | 29.3.2016 |
| 22.3.2016 | Zykadia | Novartis Europharm Limited<br>Frimley Business Park, Camberley GU16 7SR, United Kingdom | EU/1/15/999 | 29.3.2016 |
| 23.3.2016 | Elocta | Swedish Orphan Biovitrum AB (publ)<br>SE-112 76 Stockholm, Sverige | EU/1/15/1046 | 30.3.2016 |
| 30.3.2016 | Abseamed | Medice Arzneimittel Pütter GmbH & Co KG<br>Kuhloweg 37, D-58638 Iserlohn, Deutschland | EU/1/07/412 | 1.4.2016 |
| 30.3.2016 | Anoro | Glaxo Group Ltd<br>980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom | EU/1/14/898 | 1.4.2016 |
| 30.3.2016 | Evra | Janssen-Cilag International NV<br>Turnhoutseweg 30, B-2340 Beerse, België | EU/1/02/223 | 1.4.2016 |
| 30.3.2016 | TachoSil | Takeda Austria GmbH<br>St.-Peter-Strasse 25, A-4020 Linz, Österreich | EU/1/04/277 | 1.4.2016 |
| 30.3.2016 | Vidaza | Celgene Europe Limited<br>1 Longwalk Road, Stockley Park, Uxbridge UB11 1DB, United Kingdom | EU/1/08/488 | 1.4.2016 |
| 31.3.2016 | Betmiga | Astellas Pharma Europe B.V.<br>Sylviusweg 62, NL-2333 BE Leiden, Nederland | EU/1/12/809 | 4.4.2016 |
| 31.3.2016 | Binocrit | Sandoz GmbH<br>Biochemiestrasse 10, A-6250 Kundl, Österreich | EU/1/07/410 | 4.4.2016 |
| 31.3.2016 | Caelyx | Janssen-Cilag International NV<br>Turnhoutseweg 30, B-2340 Beerse, België | EU/1/96/011 | 4.4.2016 |
| 31.3.2016 | Capecitabine Teva | Teva B.V.<br>Swensweg 5, 2031 GA Haarlem, Nederland | EU/1/12/761 | 4.4.2016 |

| Date of the decision | Name of the medicinal product | Holder of the marketing authorisation | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 31.3.2016 | Ecansya | Krka, d. d., Novo Mesto<br>Šmarješka cesta 6, 8501 Novo mesto, Slovenija | EU/1/12/763 | 4.4.2016 |
| 31.3.2016 | Epoetin alfa Hexal | Hexal AG<br>Industriestrasse 25, D-83607 Holzkirchen, Deutschland | EU/1/07/411 | 4.4.2016 |
| 31.3.2016 | Eviplera | Gilead Sciences International Limited<br>Cambridge CB21 6GT, United Kingdom | EU/1/11/737 | 4.4.2016 |
| 31.3.2016 | Giotrif | Boehringer Ingelheim International GmbH<br>Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland | EU/1/13/879 | 4.4.2016 |
| 31.3.2016 | Lynparza | AstraZeneca AB<br>SE-151 85 Södertälje, Sverige | EU/1/14/959 | 4.4.2016 |
| 31.3.2016 | Revatio | Pfizer Limited<br>Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom | EU/1/05/318 | 4.4.2016 |
| 31.3.2016 | Ruconest | Pharming Group N.V.<br>Darwinweg 24, NL-2333 CR Leiden, Nederland | EU/1/10/641 | 4.4.2016 |
| 31.3.2016 | Vargatef | Boehringer Ingelheim International GmbH<br>Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland | EU/1/14/954 | 4.4.2016 |

— **Withdrawal of a marketing authorisation** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)

| Date of the decision | Name of the medicinal product | Holder of the marketing authorisation | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 2.3.2016 | Nuedexta | Jenson Pharmaceutical Services Ltd<br>Carradine House 237 Regents Park Road, London N3 3LF, United Kingdom | EU/1/13/833 | 4.3.2016 |

— **Suspension of a marketing authorisation** (Article 20 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)

| Date of the decision | Name of the medicinal product | Holder of the marketing authorisation | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 23.3.2016 | Zydelig | Gilead Sciences International Limited<br>Cambridge CB21 6GT, United Kingdom | EU/1/14/938 | 30.3.2016 |

— **Modification of a marketing authorisation** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

| Date of the decision | Name of the medicinal product | Holder of the marketing authorisation | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 8.3.2016 | Palladia | Zoetis Belgium S.A.<br>Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/09/100 | 10.3.2016 |
| 15.3.2016 | BLUEVAC BTV8 | CZ Veterinaria, S.A.<br>La Relva s/n, 36400 Porriño, España | EU/2/11/122 | 17.3.2016 |
| 15.3.2016 | Versican Plus DHPPi | Zoetis Belgium S.A.<br>Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/14/169 | 17.3.2016 |
| 15.3.2016 | Versican Plus DHPPi/L4 | Zoetis Belgium S.A.<br>Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/14/164 | 17.3.2016 |
| 15.3.2016 | Versican Plus DHPPi/L4R | Zoetis Belgium S.A.<br>Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/14/163 | 17.3.2016 |

Anyone wishing to consult the public assessment report on the medicinal products in question and the decisions relating thereto is invited to contact:

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