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*(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 August 2013 to 31 August 2013

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

(2013/C 282/01)

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

— **Issuing of a marketing authorization (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 authorization | Number of the entry in the Community Register | Pharmaceutical form | ATC code (Anatomical Therapeutic Chemical Code) | Date of notification |
|---|---|---|---|---|---|---|---|
| 5.8.2013 | Pomalidomide Celgene | Pomalidomide | Celgene Europe Limited<br>1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom | EU/1/13/850 | Capsule, hard | L04AX06 | 8.8.2013 |
| 5.8.2013 | Somatropin Biopartners | somatropin | BioPartners GmbH<br>Kaiserpassage 11, D-72764 Reutlingen, Deutschland | EU/1/13/849 | Powder and solvent for prolonged-release suspension for injection | H01AC01 | 8.8.2013 |
| 12.8.2013 | Voncento | human coagulation factor VIII/human von Willebrand factor | CSL Behring GmbH<br>Emil-von-Behring-Straße 76, D-35041 Marburg, Deutschland | EU/1/13/857 | Powder and solvent for solution for injection/infusion | B02BD06 | 14.8.2013 |
| 26.8.2013 | AUBAGIO | Teriflunomide | Sanofi-Aventis groupe<br>54 rue La Boétie, F-75008 Paris, France | EU/1/13/838 | Film-coated tablet | L04AA31 | 29.8.2013 |
| 26.8.2013 | Cholib | fenofibrate/simvastatin | Abbott Healthcare Products Ltd<br>Mansbridge Road, West End Southampton, SO18 3JD, United Kingdom | EU/1/13/866 | Film-coated tablet | C10BA04 | 28.8.2013 |
| 26.8.2013 | Nexium Control | esomeprazole | AstraZeneca AB<br>SE-151 85 Södertälje, Sverige | EU/1/13/860 | Gastro-resistant tablet | A02BC05 | 29.8.2013 |
| 26.8.2013 | Stivarga | regorafenib | Bayer Pharma AG<br>D-13342 Berlin, Deutschland | EU/1/13/858 | Film-coated tablet | L01XE21 | 29.8.2013 |
| 26.8.2013 | Tafinlar | DABRAFENIB | GlaxoSmithKline Trading Services Limited<br>6900 Cork Airport Business Park, Kinsale Road, Cork, Ireland | EU/1/13/865 | Capsule, hard | L01XE23 | 29.8.2013 |

— **Modification of a marketing authorization (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 authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 5.8.2013 | Icandra | Novartis Europharm Limited<br>Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/484 | 8.8.2013 |
| 5.8.2013 | Marixino | Consilient Health Ltd.<br>Beaux Lane House, Mercer Street Lower, Dublin 2, Ireland | EU/1/13/820 | 8.8.2013 |
| 5.8.2013 | Rasilamlo | Novartis Europharm Limited<br>Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/11/686 | 8.8.2013 |
| 5.8.2013 | Xarelto | Bayer Pharma AG<br>D-13342 Berlin, Deutschland | EU/1/08/472 | 8.8.2013 |
| 5.8.2013 | Zomarist | Novartis Europharm Limited<br>Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/483 | 8.8.2013 |
| 12.8.2013 | Circadin | RAD Neurim Pharmaceuticals EEC Limited<br>One Forbury Square, The Forbury, Reading, Berkshire RG1 3EB, United Kingdom | EU/1/07/392 | 14.8.2013 |
| 12.8.2013 | Pixuvri | CTI Life Sciences Ltd<br>Biopark, Broadwater Road, Welwyn Garden City, Hertfordshire AL73AX, United Kingdom | EU/1/12/764 | 14.8.2013 |
| 12.8.2013 | Signifor | Novartis Europharm Limited<br>Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/12/753 | 14.8.2013 |
| 12.8.2013 | Twynsta | Boehringer Ingelheim International GmbH<br>Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland | EU/1/10/648 | 14.8.2013 |
| 12.8.2013 | Zavesca | Actelion Registration Ltd<br>Cheswick Tower, 13th floor, 389 Cheswick High Road, London W4 4AL, United Kingdom | EU/1/02/238 | 14.8.2013 |
| 14.8.2013 | Conbriza | Pfizer Limited<br>Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom | EU/1/09/511 | 19.8.2013 |
| 14.8.2013 | FLUENZ | MedImmune, LLC<br>Lagelandseweg 78, NL-6545 CG Nijmegen, Nederland | EU/1/10/661 | 19.8.2013 |
| 14.8.2013 | IOA | Organon N.V.<br>Kloosterstraat 6, NL-5349 AB Oss, Nederland | EU/1/11/689 | 19.8.2013 |

| Date of the decision | Name of the medicinal product | Holder of the marketing authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 26.8.2013 | ADCETRIS | Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom | EU/1/12/794 | 28.8.2013 |
| 26.8.2013 | Azarga | Alcon Laboratories (UK) Ltd. Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, United Kingdom | EU/1/08/482 | 29.8.2013 |
| 26.8.2013 | Ceplene | Meda AB Box 906, SE-170 09 Solna, Sverige | EU/1/08/477 | 28.8.2013 |
| 26.8.2013 | Eliquis | Bristol-Myers Squibb/Pfizer EEIG Bristol-Myers Squibb House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, United Kingdom | EU/1/11/691 | 29.8.2013 |
| 26.8.2013 | Eylea | Bayer Pharma AG D-13342 Berlin, Deutschland | EU/1/12/797 | 28.8.2013 |
| 26.8.2013 | Herceptin | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/00/145 | 28.8.2013 |
| 26.8.2013 | Hirobriz Breezhaler | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/09/594 | 29.8.2013 |
| 26.8.2013 | Ifirmasta | Krka, d. d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija | EU/1/08/480 | 29.8.2013 |
| 26.8.2013 | Ilaris | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/09/564 | 28.8.2013 |
| 26.8.2013 | Inlyta | Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom | EU/1/12/777 | 29.8.2013 |
| 26.8.2013 | Invega | Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België | EU/1/07/395 | 28.8.2013 |
| 26.8.2013 | Keppra | UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België | EU/1/00/146 | 29.8.2013 |
| 26.8.2013 | Onbrez Breezhaler | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/09/593 | 29.8.2013 |
| 26.8.2013 | Oslif Breezhaler | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/09/586 | 28.8.2013 |
| 26.8.2013 | Pramipexole Teva | Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland | EU/1/08/490 | 29.8.2013 |

| Date of the decision | Name of the medicinal product | Holder of the marketing authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 26.8.2013 | Tarceva | Roche Registration Limited<br>6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/05/311 | 29.8.2013 |
| 26.8.2013 | Tysabri | Biogen Idec Limited<br>Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom | EU/1/06/346 | 29.8.2013 |
| 26.8.2013 | Ventavis | Bayer Pharma AG<br>D-13342 Berlin, Deutschland | EU/1/03/255 | 29.8.2013 |
| 26.8.2013 | XALKORI | Pfizer Limited<br>Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom | EU/1/12/793 | 29.8.2013 |
| 26.8.2013 | Zypadhera | Eli Lilly Nederland B.V.<br>Grootslag 1-5, NL-3991 RA Houten, Nederland | EU/1/08/479 | 29.8.2013 |

— **Modification of a marketing authorization (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 authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 5.8.2013 | Econor | Novartis Animal Health Austria GmbH<br>Biochemiestrasse 10, A-6250 Kundl, Österreich | EU/2/98/010 | 9.8.2013 |
| 12.8.2013 | Trocoxil | Zoetis Belgium S.A.<br>Rue Laid Burniat 1, 1348 Louvain-La-Neuve, Belgique | EU/2/08/084 | 14.8.2013 |
| 14.8.2013 | Cerenia | Zoetis Belgium S.A.<br>Rue Laid Burniat 1, 1348 Louvain-La-Neuve, Belgique | EU/2/06/062 | 19.8.2013 |

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

The European Medicines Agency
7, Westferry Circus,
Canary Wharf
UK-LONDON E14 4H

# Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 August 2013 to 31 August 2013

*(Decisions taken pursuant to Article 34 of Directive 2001/83/EC [1] or Article 38 of Directive 2001/82/EC [2])*

(2013/C 282/02)

## — Issuing, maintenance or modification of a national marketing authorization

| Date of the decision | Name(s) of the medicinal product | Holder(s) of the marketing authorization | Member State concerned | Date of notification |
|---|---|---|---|---|
| 12.8.2013 | Soludox | See Annex I | See Annex I | 13.8.2013 |
| 12.8.2013 | STRENZEN | See Annex II | See Annex II | 14.8.2013 |

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 311, 28.11.2001, p. 1.

*ANNEX I*

**LIST OF THE NAME, PHARMACEUTICAL FORM, STRENGTH OF THE VETERINARY MEDICINAL PRODUCT, ANIMAL SPECIES, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDER IN THE MEMBER STATES**

| Member State EU/EEA | Marketing authorisation holder | Name | INN | Pharmaceutical form | Strength | Animal species | Route of administration |
|---|---|---|---|---|---|---|---|
| Austria | Eurovet Animal Health BV<br>Handelsweg 25<br>5531 AE Bladel<br>The Netherlands | Soludox 500 mg/g Pulver zum Eingeben über das Trinkwasser für Schweine und Hühner | doxycycline hyclate | Powder for use in drinking water | 500 mg/g | Pigs and chickens | Oral: In drinking water |
| Czech Republic | Eurovet Animal Health BV<br>Handelsweg 25<br>5531 AE Bladel<br>The Netherlands | Soludox 500 mg/g prášek pro podání v pitné vodě pro prasata | doxycycline hyclate | Powder for use in drinking water | 500 mg/g | Pigs and chickens | Oral: In drinking water |
| Estonia | Eurovet Animal Health BV<br>Handelsweg 25<br>5531 AE Bladel<br>The Netherlands | Soludox 500 mg/g suukaudse lahuse pulber sigadele ja kanadele | doxycycline hyclate | Powder for use in drinking water | 500 mg/g | Pigs and chickens | Oral: In drinking water |
| Finland | Eurovet Animal Health BV<br>Handelsweg 25<br>5531 AE Bladel<br>The Netherlands | Soludox 500 mg/g jauhe juomaveteen sekoitettavaksi sioille ja kanoille | doxycycline hyclate | Powder for use in drinking water | 500 mg/g | Pigs and chickens | Oral: In drinking water |
| France | Eurovet Animal Health BV<br>Handelsweg 25<br>5531 AE Bladel<br>The Netherlands | Soludox 433 mg/g poudre pour administration dans l'eau de boisson des porcs et des poulets | doxycycline hyclate | Powder for use in drinking water | 500 mg/g | Pigs and chickens | Oral: In drinking water |
| Germany | Eurovet Animal Health BV<br>Handelsweg 25<br>5531 AE Bladel<br>The Netherlands | Soludox 500 mg/g Pulver zum Eingeben über das Trinkwasser für Schweine und Hühner | doxycycline hyclate | Powder for use in drinking water | 500 mg/g | Pigs and chickens | Oral: In drinking water |
| Greece | Eurovet Animal Health BV<br>Handelsweg 25<br>5531 AE Bladel<br>The Netherlands | Soludox 500 mg/g υπό μορφή σκόνης για χρήση σε πόσιμο νερό για χοίρους και κοτόπουλα | doxycycline hyclate | Powder for use in drinking water | 500 mg/g | Pigs and chickens | Oral: In drinking water |

| Member State EU/EEA | Marketing authorisation holder | Name | INN | Pharmaceutical form | Strength | Animal species | Route of administration |
|---|---|---|---|---|---|---|---|
| Italy | Eurovet Animal Health BV<br>Handelsweg 25<br>5531 AE Bladel<br>The Netherlands | Soludox 500 mg/g polvere da somministrare nell'acqua da bere per suini e polli | doxycycline hyclate | Powder for use in drinking water | 500 mg/g | Pigs and chickens | Oral: In drinking water |
| Italy | Eurovet Animal Health BV<br>Handelsweg 25<br>5531 AE Bladel<br>The Netherlands | Acquadox 500 mg/g polvere da somministrare nell'acqua da bere per suini e polli | doxycycline hyclate | Powder for use in drinking water | 500 mg/g | Pigs and chickens | Oral: In drinking water |
| Latvia | Eurovet Animal Health BV<br>Handelsweg 25<br>5531 AE Bladel<br>The Netherlands | Soludox 500 mg/g pulveris lietošanai ar dzeramo ūdeni cūkām un vistām | doxycycline hyclate | Powder for use in drinking water | 500 mg/g | Pigs and chickens | Oral: In drinking water |
| The Netherlands | Eurovet Animal Health BV<br>Handelsweg 25<br>5531 AE Bladel<br>The Netherlands | Soludox 500 mg/g poeder voor toediening via het drinkwater voor varkens en kippen | doxycycline hyclate | Powder for use in drinking water | 500 mg/g | Pigs and chickens | Oral: In drinking water |
| Slovakia | Eurovet Animal Health BV<br>Handelsweg 25<br>5531 AE Bladel<br>The Netherlands | Soludox 500 mg/g prášok na použitie v pitnej vode pre ošípané | doxycycline hyclate | Powder for use in drinking water | 500 mg/g | Pigs and chickens | Oral: In drinking water |
| Spain | Eurovet Animal Health BV<br>Handelsweg 25<br>5531 AE Bladel<br>The Netherlands | Soludox 500 mg/g polvo para administración en agua de bebida para porcino y pollos | doxycycline hyclate | Powder for use in drinking water | 500 mg/g | Pigs and chickens | Oral: In drinking water |
| United Kingdom | Eurovet Animal Health BV<br>Handelsweg 25<br>5531 AE Bladel<br>The Netherlands | Soludox 500 mg/g powder for use in drinking water for pigs and chickens | doxycycline hyclate | Powder for use in drinking water | 500 mg/g | Pigs and chickens | Oral: In drinking water |

*ANNEX II*

**LIST OF THE NAME, PHARMACEUTICAL FORM, STRENGTH OF THE VETERINARY MEDICINAL PRODUCT, ANIMAL SPECIES, ROUTE OF ADMINISTRATION, APPLICANT IN THE MEMBER STATES**

| Member State EU/EEA | Applicant | Name | INN | Pharmaceutical form | Strength | Animal species | Route of administration |
|---|---|---|---|---|---|---|---|
| Austria | Novartis Animal Health Inc.<br>Schwarzwaldallee 215<br>CH-4058 Basel<br>Switzerland | STRENZEN 500/125 mg/g Pulver zum Eingeben über das Trinkwasser für Schweine | Amoxicillin, clavulanic acid | Powder for use in drinking water | 500/125 mg/g | Pigs | Oral: In drinking water |
| Czech Republic | Novartis Animal Health Inc.<br>Schwarzwaldallee 215<br>CH-4058 Basel<br>Switzerland | STRENZEN 500/125 mg/g prášek pro podání v pitné vodě pro prasata | Amoxicillin, clavulanic acid | Powder for use in drinking water | 500/125 mg/g | Pigs | Oral: In drinking water |
| Denmark | Novartis Animal Health Inc.<br>Schwarzwaldallee 215<br>CH-4058 Basel<br>Switzerland | STRENZEN 500/125 mg pulver til anvendelse i drikkevand til svin | Amoxicillin, clavulanic acid | Powder for use in drinking water | 500/125 mg/g | Pigs | Oral: In drinking water |
| France | Novartis Animal Health Inc.<br>Schwarzwaldallee 215<br>CH-4058 Basel<br>Switzerland | STRENZEN 500/125 mg/g poudre pour eau de boisson porcs | Amoxicillin, clavulanic acid | Powder for use in drinking water | 500/125 mg/g | Pigs | Oral: In drinking water |
| Germany | Novartis Animal Health Inc.<br>Schwarzwaldallee 215<br>CH-4058 Basel<br>Switzerland | STRENZEN 500/125 mg/g Pulver zum Eingeben über das Trinkwasser für Schweine | Amoxicillin, clavulanic acid | Powder for use in drinking water | 500/125 mg/g | Pigs | Oral: In drinking water |
| Ireland | Novartis Animal Health Inc.<br>Schwarzwaldallee 215<br>CH-4058 Basel<br>Switzerland | STRENZEN 500/125 mg/g powder for use in drinking water for pigs | Amoxicillin, clavulanic acid | Powder for use in drinking water | 500/125 mg/g | Pigs | Oral: In drinking water |

| Member State EU/EEA | Applicant | Name | INN | Pharmaceutical form | Strength | Animal species | Route of administration |
|---|---|---|---|---|---|---|---|
| Italy | Novartis Animal Health Inc.<br>Schwarzwaldallee 215<br>CH-4058 Basel<br>Switzerland | STRENZEN 500/125 mg/g polvere per somministrazione in acqua da bere per suini | Amoxicillin, clavulanic acid | Powder for use in drinking water | 500/125 mg/g | Pigs | Oral: In drinking water |
| The Netherlands | Novartis Animal Health Inc.<br>Schwarzwaldallee 215<br>CH-4058 Basel<br>Switzerland | STRENZEN 500/125 mg/g poeder voor gebruik in drinkwater voor varkens. | Amoxicillin, clavulanic acid | Powder for use in drinking water | 500/125 mg/g | Pigs | Oral: In drinking water |
| Portugal | Novartis Animal Health Inc.<br>Schwarzwaldallee 215<br>CH-4058 Basel<br>Switzerland | STRENZEN 500/125 mg/g pó para utilização na água de bebida em suínos | Amoxicillin, clavulanic acid | Powder for use in drinking water | 500/125 mg/g | Pigs | Oral: In drinking water |
| Spain | Novartis Animal Health Inc.<br>Schwarzwaldallee 215<br>CH-4058 Basel<br>Switzerland | STRENZEN 500/125 mg/g polvo para uso en agua de bebida para porcino | Amoxicillin, clavulanic acid | Powder for use in drinking water | 500/125 mg/g | Pigs | Oral: In drinking water |
| United Kingdom | Novartis Animal Health Inc.<br>Schwarzwaldallee 215<br>CH-4058 Basel<br>Switzerland | STRENZEN 500/125 mg/g powder for use in drinking water for pigs | Amoxicillin, clavulanic acid | Powder for use in drinking water | 500/125 mg/g | Pigs | Oral: In drinking water |

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