



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

7 May 2015  
EMA/304193/2015  
Compliance and Inspection

## Initial notices for parallel distribution – April 2015

**Please note that the highlighted products are Veterinary medicines**

| Parallel distributor | Date of notification | Product name | Strength  | Pharmaceutical dosage form | Pack size | EU-number       | Member State(s) of Origin                                                                                                                                                                                                                                                                          | Member State(s) of Destination | Date of Notice letter |
|----------------------|----------------------|--------------|-----------|----------------------------|-----------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|-----------------------|
| Paranova Danmark AS  | 30/03/2015           | Abilify      | 7.5 mg/ml | Solution for injection     | 1 vial    | EU/1/04/276/036 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Denmark                        | 13/04/2015            |



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| 2 Care 4      | 27/03/2015 | Aclasta  | 5 mg/<br>100 ml | Solution for<br>infusion           | 1 bottle    | EU/1/05/308/001 | Austria, Belgium, Bulgaria,<br>Croatia, Czech Republic,<br>Denmark, Estonia, Finland,<br>France, Greece, Hungary,<br>Iceland, Ireland, Italy,<br>Latvia, Lithuania,<br>Luxembourg, Malta, Norway,<br>Poland, Portugal, Romania,<br>Slovak Republic, Slovenia,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom                | Germany            | 09/04/2015 |
| BModesto B.V. | 20/04/2015 | Advagraf | 1 mg            | Prolonged-release<br>capsule, hard | 30 capsules | EU/1/07/387/003 | Austria, Belgium, Bulgaria,<br>Croatia, Cyprus, Czech<br>Republic, Denmark, Estonia,<br>Finland, France, Germany,<br>Greece, Hungary, Iceland,<br>Ireland, Italy, Latvia,<br>Liechtenstein, Lithuania,<br>Luxembourg, Malta, Norway,<br>Poland, Portugal, Romania,<br>Slovak Republic, Slovenia,<br>Spain, Sweden, United<br>Kingdom | The<br>Netherlands | 24/04/2015 |
| BModesto B.V. | 20/04/2015 | Advagraf | 3 mg            | Prolonged-release<br>capsule, hard | 30 capsules | EU/1/07/387/011 | Austria, Belgium, Bulgaria,<br>Croatia, Cyprus, Czech<br>Republic, Denmark, Estonia,<br>Finland, France, Germany,<br>Greece, Hungary, Iceland,<br>Ireland, Italy, Latvia,<br>Liechtenstein, Lithuania,<br>Luxembourg, Malta, Norway,<br>Poland, Portugal, Romania,<br>Slovak Republic, Slovenia,<br>Spain, Sweden, United<br>Kingdom | The<br>Netherlands | 24/04/2015 |

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| BModesto B.V.   | 20/04/2015 | Advagraf | 5 mg   | Prolonged-release capsule, hard | 30 capsules     | EU/1/07/387/007 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom | The Netherlands | 24/04/2015 |
| CC Pharma       | 27/02/2015 | Advagraf | 0.5 mg | Prolonged-release capsule, hard | 100 capsules    | EU/1/07/387/009 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                | Germany         | 17/04/2015 |
| FD Pharma GmbH  | 17/04/2015 | Advagraf | 3 mg   | Prolonged-release capsule, hard | 100 x 1 capsule | EU/1/07/387/023 | Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                                   | Germany         | 29/04/2015 |
| kohlpharma GmbH | 10/04/2015 | Advagraf | 1 mg   | Prolonged-release capsule, hard | 50 x 1 capsule  | EU/1/07/387/018 | Austria, Belgium, Denmark, Estonia, Finland, France, Greece, Ireland, Italy, Latvia, Lithuania, Norway, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                           | Germany         | 16/04/2015 |

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| EMRA-Med | 16/04/2015 | Aerius | 5 mg   | Orodispersible tablet | 18 tablets | EU/1/00/160/054 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 17/04/2015 |
| EMRA-Med | 16/04/2015 | Aerius | 5 mg   | Orodispersible tablet | 60 tablets | EU/1/00/160/058 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 17/04/2015 |
| EMRA-Med | 16/04/2015 | Aerius | 5 mg   | Orodispersible tablet | 90 tablets | EU/1/00/160/059 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 17/04/2015 |
| EMRA-Med | 16/04/2015 | Aerius | 2.5 mg | Orodispersible tablet | 18 tablets | EU/1/00/160/042 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                         | Germany | 21/04/2015 |

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| EMRA-Med            | 16/04/2015 | Aerius | 2.5 mg | Orodispersible tablet | 60 tablets | EU/1/00/160/046 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                       | Germany | 21/04/2015 |
| EMRA-Med            | 16/04/2015 | Aerius | 2.5 mg | Orodispersible tablet | 90 tablets | EU/1/00/160/047 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                       | Germany | 21/04/2015 |
| Euromedicines, S.L. | 11/03/2015 | Aerius | 5 mg   | Film-coated tablet    | 20 tablets | EU/1/00/160/009 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Sweden, The Netherlands, United Kingdom | Spain   | 13/04/2015 |
| HAEMATO PHARM GmbH  | 25/03/2015 | Aerius | 5 mg   | Film-coated tablet    | 30 tablets | EU/1/00/160/011 | Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom   | Austria | 07/04/2015 |

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| HAEMATO PHARM GmbH    | 27/03/2015 | Aerius  | 5 mg      | Film-coated tablet                                         | 10 tablets | EU/1/00/160/006 | Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Austria | 10/04/2015 |
| Orifarm GmbH          | 15/04/2015 | Aerius  | 0.5 mg/ml | Oral solution                                              | 1 bottle   | EU/1/00/160/066 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                   | Germany | 16/04/2015 |
| Paranova Läkemedel AB | 21/04/2015 | Altargo | 10 mg/g   | Ointment                                                   | 1 tube     | EU/1/07/390/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                                                                                    | Sweden  | 23/04/2015 |
| Orifarm OY            | 10/03/2015 | Angiox  | 250 mg    | Powder for concentrate for solution for injection/infusion | 10 vials   | EU/1/04/289/001 | Austria, Belgium, Cyprus, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Finland | 13/04/2015 |

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| B&S Healthcare          | 30/03/2015 | Apidra  | 100 Units/ml       | Solution for injection | 5 pre-filled pens     | EU/1/04/285/032 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                  | Ireland, United Kingdom | 29/04/2015 |
| EmrA-Med                | 20/04/2015 | Arixtra | 5 mg/ 0.4 ml       | Solution for injection | 7 pre-filled syringes | EU/1/02/206/010 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                           | Germany                 | 30/04/2015 |
| G-Pharma Ltd            | 15/04/2015 | Azarga  | 10 mg/ml / 5 mg/ml | Eye drops, suspension  | 1 bottle              | EU/1/08/482/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                  | Ireland, United Kingdom | 22/04/2015 |
| Kosei Pharma UK Limited | 08/04/2015 | Azarga  | 10 mg/ml / 5 mg/ml | Eye drops, suspension  | 1 bottle              | EU/1/08/482/001 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 13/04/2015 |

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| ABACUS MEDICINE A/S | 14/04/2015 | Baraclude | 0.5 mg   | Film-coated tablet     | 30 x 1 tablets       | EU/1/06/343/003 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, The Netherlands, United Kingdom | Sweden  | 16/04/2015 |
| Medicopharm AG      | 22/04/2015 | Baraclude | 0.5 mg   | Film-coated tablet     | 90 x 1 tablets       | EU/1/06/343/006 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                              | Germany | 30/04/2015 |
| HAEMATO PHARM GmbH  | 21/04/2015 | Bonviva   | 3 mg/3ml | Solution for injection | 1 pre-filled syringe | EU/1/03/265/005 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom  | Germany | 23/04/2015 |

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| Mediwin Ltd             | 23/03/2015 | Bonviva          | 150 mg | Film-coated tablet | 1 tablet                     | EU/1/03/265/003 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Italy                   | 10/04/2015 |
| O.P.D. Laboratories Ltd | 26/03/2015 | Bretaris Genuair | 322 µg | Inhalation powder  | 1 inhaler with 60 actuations | EU/1/12/781/002 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                            | United Kingdom          | 21/04/2015 |
| B&S Healthcare          | 19/03/2015 | Brilique         | 90 mg  | Film-coated tablet | 56 tablets                   | EU/1/10/655/004 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                             | Ireland, United Kingdom | 07/04/2015 |
| Dr Fisher Farma BV      | 25/03/2015 | Brilique         | 90 mg  | Film-coated tablet | 100 x 1 tablet (unit dose)   | EU/1/10/655/006 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom   | The Netherlands         | 21/04/2015 |

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| Orifarm AS          | 22/04/2015 | Brilique | 90 mg   | Film-coated tablet                    | 100 x 1 tablet<br>(unit dose)                           | EU/1/10/655/006 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                      | Denmark | 30/04/2015 |
| ABACUS MEDICINE A/S | 27/04/2015 | Caelyx   | 2 mg/ml | Concentrate for solution for infusion | 1 vial                                                  | EU/1/96/011/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Poland, Portugal, Spain, The Netherlands, United Kingdom                                                                                                             | Sweden  | 28/04/2015 |
| ABACUS MEDICINE A/S | 27/03/2015 | Cimzia   | 200 mg  | Solution for injection                | 6 (3 x 2) pre-filled syringes + 6 (3 x 2) alcohol wipes | EU/1/09/544/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                      | Germany | 01/04/2015 |
| ABACUS MEDICINE A/S | 27/03/2015 | Cimzia   | 200 mg  | Solution for injection                | 2 pre-filled syringes + 2 alcohol wipes                 | EU/1/09/544/001 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, The Netherlands, United Kingdom | Sweden  | 08/04/2015 |

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| ABACUS MEDICINE A/S | 09/04/2015 | Cinryze   | 500 U          | Powder and solvent for solution for injection | 2 vials + 2 vials                                              | EU/1/11/688/001 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, The Netherlands, United Kingdom         | Sweden                  | 10/04/2015 |
| Ethigen Limited     | 21/04/2015 | Competact | 15 mg / 850 mg | Film-coated tablet                            | 56 tablets                                                     | EU/1/06/354/005 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 24/04/2015 |
| Paranova Oy         | 11/03/2015 | Cyanokit  | 5 g            | Powder for solution for infusion              | 1 vial + 1 infusion set + 1 transfer device + 1 short catheter | EU/1/07/420/002 | Austria, Belgium, Cyprus, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                              | Finland                 | 15/04/2015 |
| Mediwin Ltd         | 01/04/2015 | Cymbalta  | 30 mg          | Gastro-resistant capsule, hard                | 28 capsules                                                    | EU/1/04/296/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                                             | United Kingdom          | 14/04/2015 |

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| Medcor Pharmaceuticals BV | 31/03/2015 | Duaklir Genuair  | 340 µg / 12 µg  | Inhalation powder | 1 inhaler with 60 actuations | EU/1/14/964/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, United Kingdom         | The Netherlands | 24/04/2015 |
| Orifarm AS                | 30/03/2015 | DuoResp Spiromax | 160 µg / 4.5 µg | Inhalation powder | 1 inhaler (120 doses)        | EU/1/14/920/001 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Denmark         | 16/04/2015 |
| Orifarm AS                | 30/03/2015 | DuoResp Spiromax | 160 µg / 4.5 µg | Inhalation powder | 3 inhalers (3x120 doses)     | EU/1/14/920/003 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Denmark         | 16/04/2015 |
| Orifarm AS                | 30/03/2015 | DuoResp Spiromax | 320 µg / 9 µg   | Inhalation powder | 1 inhaler (60 doses)         | EU/1/14/920/004 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Denmark         | 16/04/2015 |
| Orifarm AS                | 30/03/2015 | DuoResp Spiromax | 320 µg / 9 µg   | Inhalation powder | 3 inhalers (3x60 doses)      | EU/1/14/920/006 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Denmark         | 16/04/2015 |

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| Chemvet Pharma ApS     | 25/03/2015 | DuoTrav        | 40 µg/ml / 5 mg/ml | Eye drops, solution                              | 3 bottles                    | EU/1/06/338/002 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Poland, Portugal, Romania, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                                                                                       | Denmark                 | 08/04/2015 |
| SHAKESPEARE PHARMA LTD | 21/04/2015 | DuoTrav        | 40 µg/ml / 5 mg/ml | Eye drops, solution                              | 1 bottle                     | EU/1/06/338/001 | Austria, Belgium, Bulgaria, Croatia, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands                                                                             | Ireland, United Kingdom | 23/04/2015 |
| Orifarm GmbH           | 31/03/2015 | ECALTA         | 100 mg             | Powder for concentrate for solution for infusion | 1 vial                       | EU/1/07/416/002 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                   | Germany                 | 29/04/2015 |
| Ethigen Limited        | 24/03/2015 | Eklira Genuair | 322 µg             | Inhalation powder                                | 1 inhaler with 60 actuations | EU/1/12/778/002 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 07/04/2015 |

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| G-Pharma Ltd    | 01/04/2015 | Eklira Genuair | 322 µg | Inhalation powder  | 1 inhaler with 60 actuations | EU/1/12/778/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Ireland, United Kingdom | 15/04/2015 |
| Lexon (UK) Ltd  | 20/04/2015 | Eklira Genuair | 322 µg | Inhalation powder  | 1 inhaler with 60 actuations | EU/1/12/778/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Latvia, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                             | Ireland, United Kingdom | 28/04/2015 |
| B&S Healthcare  | 22/04/2015 | Eliquis        | 5 mg   | Film-coated tablet | 60 tablets                   | EU/1/11/691/009 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Ireland, United Kingdom | 27/04/2015 |
| Ethigen Limited | 16/04/2015 | Eliquis        | 2.5 mg | Film-coated tablet | 60 tablets                   | EU/1/11/691/003 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 22/04/2015 |

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| Ethigen Limited         | 16/04/2015 | Eliquis | 5 mg   | Film-coated tablet | 56 tablets | EU/1/11/691/008 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom        | 22/04/2015 |
| Ethigen Limited         | 16/04/2015 | Eliquis | 5 mg   | Film-coated tablet | 60 tablets | EU/1/11/691/009 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom        | 22/04/2015 |
| O.P.D. Laboratories Ltd | 01/04/2015 | Eliquis | 2.5 mg | Film-coated tablet | 60 tablets | EU/1/11/691/003 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                                    | United Kingdom                 | 13/04/2015 |
| Cross Healthcare Ltd    | 13/04/2015 | ellaOne | 30 mg  | Tablet             | 1 tablet   | EU/1/09/522/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Ireland, Malta, United Kingdom | 16/04/2015 |

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| Orifarm GmbH                  | 16/04/2015 | Elonva  | 100 micro-grams   | Solution for injection                        | 1 pre-filled syringe + 1 needle                                                 | EU/1/09/609/001 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                 | Germany        | 21/04/2015 |
| axicorp Pharma GmbH           | 16/04/2015 | Emtriva | 200 mg            | Capsule, hard                                 | 30 capsules                                                                     | EU/1/03/261/001 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom | Germany        | 20/04/2015 |
| Paranova Danmark AS           | 18/03/2015 | Enbrel  | 10 mg             | Powder and solvent for solution for injection | 4 vials + 4 pre-filled syringes + 4 needles + 4 vial adaptors + 8 alcohol swabs | EU/1/99/126/022 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                   | Denmark        | 20/04/2015 |
| PHARMEDEX s.r.o.              | 10/03/2014 | EVRA    | 600 µg / 6 mg     | Transdermal patch                             | 9 transdermal patches                                                           | EU/1/02/223/002 | Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                         | Czech Republic | 13/04/2015 |
| Eurim-Pharm Arzneimittel GmbH | 26/03/2015 | Exelon  | 4.6 mg / 24 hours | Transdermal patch                             | 42 sachets                                                                      | EU/1/98/066/031 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Poland, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom                                                     | Germany        | 09/04/2015 |

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| Eurim-Pharm<br>Arzneimittel GmbH | 26/03/2015 | Exelon      | 4.6 mg /<br>24 hours          | Transdermal<br>patch | 84 (2 x 42)<br>sachets<br>(multipack) | EU/1/98/066/032 | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Ireland, Italy, Norway,<br>Poland, Portugal, Romania,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom                                      | Germany | 09/04/2015 |
| DOCpharm<br>GmbH&CoKGaA          | 14/04/2015 | Exforge HCT | 5 mg /<br>160 mg /<br>12.5 mg | Film-coated tablet   | 28 tablets                            | EU/1/09/569/002 | Austria, Belgium, Cyprus,<br>Denmark, Finland, France,<br>Greece, Iceland, Ireland,<br>Italy, Liechtenstein,<br>Luxembourg, Malta, Norway,<br>Portugal, Spain, Sweden,<br>The Netherlands, United<br>Kingdom | Germany | 27/04/2015 |
| Docpharm<br>GmbH&CoKGaA          | 27/04/2015 | Exforge HCT | 10 mg /<br>320 mg /<br>25 mg  | Film-coated tablet   | 98 tablets                            | EU/1/09/569/054 | Austria, Belgium, Cyprus,<br>Denmark, Finland, France,<br>Greece, Iceland, Ireland,<br>Italy, Liechtenstein,<br>Luxembourg, Malta, Norway,<br>Portugal, Spain, Sweden,<br>The Netherlands, United<br>Kingdom | Germany | 29/04/2015 |
| Docpharm<br>GmbH&CoKGaA          | 27/04/2015 | Exforge HCT | 5 mg /<br>160 mg /<br>12.5 mg | Film-coated tablet   | 98 tablets                            | EU/1/09/569/006 | Austria, Belgium, Cyprus,<br>Denmark, Finland, France,<br>Greece, Iceland, Ireland,<br>Italy, Liechtenstein,<br>Luxembourg, Malta, Norway,<br>Portugal, Spain, Sweden,<br>The Netherlands, United<br>Kingdom | Germany | 29/04/2015 |
| Orifarm GmbH                     | 16/03/2015 | Exforge HCT | 10 mg /<br>160 mg /<br>25 mg  | Film-coated tablet   | 28 tablets                            | EU/1/09/569/038 | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Iceland, Ireland, Italy,<br>Luxembourg, Norway,<br>Portugal, Spain, Sweden,<br>The Netherlands, United<br>Kingdom                                  | Germany | 13/04/2015 |

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| Orifarm GmbH | 17/03/2015 | Exforge HCT | 10 mg /<br>160 mg /<br>25 mg | Film-coated tablet                                     | 98 tablets                                             | EU/1/09/569/042 | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Iceland, Ireland, Italy,<br>Luxembourg, Norway,<br>Portugal, Spain, Sweden,<br>The Netherlands, United<br>Kingdom                                                                                                                                                         | Germany | 13/04/2015 |
| Orifarm GmbH | 06/11/2014 | Exforge HCT | 5 mg /<br>160 mg /<br>25 mg  | Film-coated tablet                                     | 98 tablets                                             | EU/1/09/569/030 | Austria, Belgium, Croatia,<br>Denmark, Finland, France,<br>Greece, Iceland, Ireland,<br>Italy, Luxembourg, Norway,<br>Portugal, Spain, Sweden,<br>The Netherlands, United<br>Kingdom                                                                                                                                                | Germany | 15/04/2015 |
| Orifarm GmbH | 06/11/2014 | Exforge HCT | 5 mg /<br>160 mg /<br>25 mg  | Film-coated tablet                                     | 28 tablets                                             | EU/1/09/569/026 | Austria, Belgium, Croatia,<br>Denmark, Finland, France,<br>Greece, Iceland, Ireland,<br>Italy, Luxembourg, Norway,<br>Portugal, Spain, Sweden,<br>The Netherlands, United<br>Kingdom                                                                                                                                                | Germany | 15/04/2015 |
| Orifarm GmbH | 23/04/2015 | Extavia     | 250 µg /<br>ml               | Powder and<br>solvent for<br>solution for<br>injection | 15 vials + 15<br>pre-filled<br>syringes (luer<br>lock) | EU/1/08/454/008 | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Iceland, Ireland, Italy,<br>Lithuania, Luxembourg,<br>Norway, Portugal, Spain,<br>Sweden, The Netherlands,<br>United Kingdom                                                                                                                                              | Germany | 30/04/2015 |
| Orifarm AS   | 18/03/2015 | Forxiga     | 5 mg                         | Film-coated tablet                                     | 30 x 1 tablet<br>(unit dose)                           | EU/1/12/795/004 | Austria, Belgium, Bulgaria,<br>Cyprus, Czech Republic,<br>Estonia, Finland, France,<br>Germany, Greece, Hungary,<br>Iceland, Ireland, Italy,<br>Latvia, Liechtenstein,<br>Lithuania, Luxembourg,<br>Malta, Norway, Poland,<br>Portugal, Romania, Slovak<br>Republic, Slovenia, Spain,<br>Sweden, The Netherlands,<br>United Kingdom | Denmark | 21/04/2015 |

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| Orifarm AS                    | 18/03/2015 | Forxiga | 5 mg                | Film-coated tablet  | 90 x 1 tablet<br>(unit dose)     | EU/1/12/795/005 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Denmark        | 21/04/2015 |
| SHAKESPEARE PHARMA LTD        | 21/04/2015 | Forxiga | 10 mg               | Film-coated tablet  | 28 tablets                       | EU/1/12/795/007 | Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                                                                        | United Kingdom | 24/04/2015 |
| Eurim-Pharm Arzneimittel GmbH | 31/03/2015 | Ganfort | 300 µg/ml / 5 mg/ml | Eye drops, solution | 90 single-dose containers (LPDE) | EU/1/06/340/005 | Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Greece, Hungary, Ireland, Italy, Norway, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                   | Germany        | 16/04/2015 |
| Eurim-Pharm Arzneimittel GmbH | 23/04/2015 | Gilenya | 0.5 mg              | Capsule, hard       | 28 capsules                      | EU/1/11/677/005 | Belgium, Germany                                                                                                                                                                                                                                                                                   | Austria        | 27/04/2015 |
| CC Pharma                     | 01/04/2015 | Giotrif | 40 mg               | Film-coated tablet  | 28 x 1 tablet<br>(unit dose)     | EU/1/13/879/009 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                               | Germany        | 10/04/2015 |
| CC Pharma                     | 29/04/2015 | Giotrif | 30 mg               | Film-coated tablet  | 28 x 1 tablet<br>(unit dose)     | EU/1/13/879/006 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                               | Germany        | 30/04/2015 |

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| ACA Müller ADAG Pharma AG | 17/04/2015 | GONAL-f   | 450 IU/0.75 ml (33 micrograms/0.75 ml) | Solution for injection in pre-filled pen         | 1 pre-filled pen + 12 needles | EU/1/95/001/034 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom | Germany                        | 27/04/2015 |
| Paranova Danmark AS       | 14/04/2015 | Hepsera   | 10 mg                                  | Tablet                                           | 30 tablets                    | EU/1/03/251/001 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                   | Denmark                        | 21/04/2015 |
| Canoma Pharma GmbH        | 27/03/2015 | Herceptin | 150 mg                                 | Powder for concentrate for solution for infusion | 1 vial                        | EU/1/00/145/001 | Austria, Belgium, Czech Republic, Denmark, Finland, France, Greece, Hungary, Italy, Norway, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                                     | Germany                        | 07/04/2015 |
| Cross Healthcare Ltd      | 01/04/2015 | Humalog   | 100 U/ml                               | Suspension for injection                         | 5 pens                        | EU/1/96/007/033 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                          | Ireland, Malta, United Kingdom | 16/04/2015 |

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| Paranova Danmark AS   | 19/03/2015 | Inovelon   | 200 mg    | Film-coated tablet       | 60 tablets        | EU/1/06/378/009 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom  | Denmark | 09/04/2015 |
| Paranova Läkemedel AB | 23/04/2015 | Inovelon   | 400 mg    | Film-coated tablet       | 100 tablets       | EU/1/06/378/015 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, The Netherlands, United Kingdom | Sweden  | 27/04/2015 |
| Paranova Danmark AS   | 24/03/2015 | Insulatard | 100 iu/ml | Suspension for injection | 5 pre-filled pens | EU/1/02/233/011 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom  | Denmark | 07/04/2015 |

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| Orifarm GmbH              | 17/04/2015 | Insuman   | 100 IU/ml | Suspension for injection | 5 cartridges       | EU/1/97/030/050 | Austria, Belgium, Denmark, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom              | Germany         | 29/04/2015 |
| Pharma Gerke GmbH         | 30/01/2015 | Insuman   | 100 IU/ml | Solution for injection   | 10 cartridges      | EU/1/97/030/056 | Austria, Belgium, Bulgaria, Czech Republic, Finland, France, Greece, Ireland, Italy, Norway, Poland, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom  | Germany         | 24/04/2015 |
| Pharma Gerke GmbH         | 13/04/2015 | Insuman   | 100 IU/ml | Suspension for injection | 10 pre-filled pens | EU/1/97/030/151 | Austria, Belgium, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Norway, Poland, Portugal, Romania, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom  | Germany         | 24/04/2015 |
| Medcor Pharmaceuticals BV | 31/03/2015 | Isentress | 400 mg    | Film-coated tablet       | 60 tablets         | EU/1/07/436/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, United Kingdom | The Netherlands | 14/04/2015 |

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| Medartuum AB | 20/04/2015 | Jakavi | 10 mg | Tablet | 56 tablets | EU/1/12/773/015 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, The Netherlands, United Kingdom | Sweden  | 27/04/2015 |
| Orifarm OY   | 10/03/2015 | Jakavi | 15 mg | Tablet | 56 tablets | EU/1/12/773/008 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom           | Finland | 16/04/2015 |
| Orifarm OY   | 10/03/2015 | Jakavi | 5 mg  | Tablet | 56 tablets | EU/1/12/773/005 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom           | Finland | 17/04/2015 |

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| Interport Ltd           | 31/03/2015 | Januvia | 25 mg  | Film-coated tablet | 28 tablets                 | EU/1/07/383/002 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, The Netherlands, United Kingdom           | United Kingdom          | 08/04/2015 |
| Kosei Pharma UK Limited | 17/03/2015 | Januvia | 100 mg | Film-coated tablet | 98 tablets                 | EU/1/07/383/017 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands | Ireland, United Kingdom | 21/04/2015 |
| YMD PHARMA LIMITED      | 03/11/2014 | Latuda  | 37 mg  | Film-coated tablet | 28 x 1 tablets (unit dose) | EU/1/14/913/009 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                  | Ireland, United Kingdom | 15/04/2015 |

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| Mediwin Ltd                | 16/03/2015 | Levitra  | 20 mg     | Film-coated tablet                    | 4 tablets | EU/1/03/248/010 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                       | Italy          | 09/04/2015 |
| Interport Ltd              | 31/03/2015 | Lumigan  | 0.3 mg/ml | Eye drops, solution                   | 1 bottle  | EU/1/02/205/001 | Austria, Belgium, France, Germany, Greece, Italy, Malta, Norway, Spain, Sweden, The Netherlands                                                                                                                                                                                                             | United Kingdom | 10/04/2015 |
| Lunapharm Deutschland GmbH | 25/02/2015 | Mabthera | 100 mg    | Concentrate for solution for infusion | 2 vials   | EU/1/98/067/001 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany        | 15/04/2015 |
| Lunapharm Deutschland GmbH | 25/02/2015 | Mabthera | 500 mg    | Concentrate for solution for infusion | 1 vial    | EU/1/98/067/002 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany        | 15/04/2015 |

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| B2B Medical GmbH   | 07/04/2015 | Micardis    | 80 mg   | Tablet                 | 98 tablets            | EU/1/98/090/008 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                              | Germany | 16/04/2015 |
| HAEMATO PHARM GmbH | 08/04/2015 | Mimpara     | 30 mg   | Film-coated tablet     | 28 tablets            | EU/1/04/292/002 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, The Netherlands, United Kingdom         | Sweden  | 10/04/2015 |
| 2 Care 4           | 31/03/2015 | MULTAQ      | 400 mg  | Film-coated tablet     | 20 tablets            | EU/1/09/591/001 | Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                                                                                                                    | Sweden  | 08/04/2015 |
| HAEMATO PHARM GmbH | 29/04/2015 | NeoRecormon | 2000 IU | Solution for injection | 6 pre-filled syringes | EU/1/97/031/030 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Sweden  | 30/04/2015 |

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| BB Farma s.r.l. | 01/04/2015 | Neupro | 2 mg/24h | Transdermal patch | 84 patches | EU/1/05/331/018 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 10/04/2015 |
| BB Farma s.r.l. | 07/04/2015 | Neupro | 3 mg/24h | Transdermal patch | 84 patches | EU/1/05/331/053 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 10/04/2015 |
| BB Farma s.r.l. | 07/04/2015 | Neupro | 4 mg/24h | Transdermal patch | 84 patches | EU/1/05/331/024 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 10/04/2015 |

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| BB Farma s.r.l. | 07/04/2015 | Neupro  | 6 mg/24h | Transdermal patch     | 84 patches | EU/1/05/331/030 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 10/04/2015 |
| BB Farma s.r.l. | 07/04/2015 | Neupro  | 8 mg/24h | Transdermal patch     | 84 patches | EU/1/05/331/036 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 10/04/2015 |
| FD Pharma GmbH  | 10/04/2015 | Neupro  | 4 mg/24h | Transdermal patch     | 7 patches  | EU/1/05/331/004 | Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Norway, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                   | Germany | 15/04/2015 |
| CC Pharma       | 01/04/2015 | Nevanac | 1 mg/ml  | Eye drops, suspension | 1 bottle   | EU/1/07/433/001 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                        | Germany | 08/04/2015 |

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| Eurim-Pharm Arzneimittel GmbH | 10/03/2015 | Nivestim | 30 MU (300 µg/ 0.5 ml) | Solution for injection/infusion | 5 pre-filled syringes | EU/1/10/631/005 | Austria, Belgium, Denmark, Finland, France, Greece, Hungary, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                           | Germany        | 13/04/2015 |
| Eurim-Pharm Arzneimittel GmbH | 18/03/2015 | Nivestim | 48 MU (480 µg/ 0.5 ml) | Solution for injection/infusion | 5 pre-filled syringes | EU/1/10/631/008 | Austria, Belgium, Czech Republic, Denmark, Finland, France, Greece, Hungary, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                           | Germany        | 13/04/2015 |
| HAEMATO PHARM GmbH            | 14/04/2015 | Norvir   | 100 mg                 | Film-coated tablet              | 30 tablets            | EU/1/96/016/005 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Germany        | 20/04/2015 |
| Interport Ltd                 | 20/04/2015 | NovoMix  | 100 U/ml               | Suspension for injection        | 5 pre-filled pens     | EU/1/00/142/009 | Austria, Belgium, Czech Republic, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Spain, The Netherlands  | United Kingdom | 24/04/2015 |
| Interport Ltd                 | 17/04/2015 | NovoMix  | 100 U/ml               | Suspension for injection        | 5 cartridges          | EU/1/00/142/004 | Austria, Belgium, Czech Republic, Finland, France, Germany, Greece, Ireland, Italy, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Spain, The Netherlands                   | United Kingdom | 27/04/2015 |

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| Interport Ltd       | 17/04/2015 | NovoRapid | 100 U/ml | Solution for injection | 5 cartridges | EU/1/99/119/003 | Austria, Belgium, Bulgaria, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, The Netherlands                                                                     | United Kingdom | 23/04/2015 |
| NewNeopharm BV      | 27/02/2015 | NovoRapid | 100 U/ml | Solution for injection | 1 vial       | EU/1/99/119/001 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Denmark        | 27/04/2015 |
| Paranova Danmark AS | 31/03/2015 | NovoRapid | 100 U/ml | Solution for injection | 1 vial       | EU/1/99/119/001 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Denmark        | 09/04/2015 |
| Pharma Gerke GmbH   | 30/03/2015 | NovoRapid | 100 U/ml | Solution for injection | 5 cartridges | EU/1/99/119/024 | Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                        | Germany        | 08/04/2015 |

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| CC Pharma           | 16/04/2015 | Noxafil   | 100 mg      | Gastro-resistant tablet             | 24 tablets    | EU/1/05/320/002 | Austria, Belgium, Czech Republic, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                               | Germany | 23/04/2015 |
| CC Pharma           | 16/04/2015 | Noxafil   | 100 mg      | Gastro-resistant tablet             | 96 tablets    | EU/1/05/320/003 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                         | Germany | 23/04/2015 |
| axicorp Pharma B.V. | 16/04/2015 | Omnitrope | 5 mg/ 1.5ml | Solution for injection in cartridge | 5 cartridges  | EU/1/06/332/014 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 30/04/2015 |
| kohlpharma GmbH     | 14/04/2015 | Omnitrope | 5 mg/ 1.5ml | Solution for injection in cartridge | 10 cartridges | EU/1/06/332/015 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                         | Germany | 24/04/2015 |
| kohlpharma GmbH     | 14/04/2015 | Omnitrope | 5 mg/ 1.5ml | Solution for injection in cartridge | 5 cartridges  | EU/1/06/332/014 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                         | Germany | 24/04/2015 |

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| Doncaster Pharmaceuticals Group Ltd | 14/04/2015 | Onglyza  | 2.5 mg  | Film-coated tablet  | 28 tablets | EU/1/09/545/012 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                    | Ireland, Malta, United Kingdom | 16/04/2015 |
| Necessity Supplies Ltd              | 01/04/2015 | Onglyza  | 5 mg    | Film-coated tablet  | 28 tablets | EU/1/09/545/006 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom        | 16/04/2015 |
| axicorp Pharma GmbH                 | 16/04/2015 | Opatanol | 1 mg/ml | Eye drops, solution | 1 bottle   | EU/1/02/217/001 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                | Germany                        | 20/04/2015 |

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| Euromedicines, S.L.     | 21/04/2015 | Opatanol | 1 mg/ml | Eye drops, solution      | 1 bottle    | EU/1/02/217/001 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Sweden, The Netherlands, United Kingdom | Spain          | 24/04/2015 |
| O.P.D. Laboratories Ltd | 08/04/2015 | Opatanol | 1 mg/ml | Eye drops, solution      | 1 bottle    | EU/1/02/217/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                             | United Kingdom | 21/04/2015 |
| 2 Care 4                | 16/04/2015 | Oprymea  | 0.52 mg | Prolonged-release tablet | 10 tablets  | EU/1/08/469/030 | Austria, Belgium, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                              | Denmark        | 21/04/2015 |
| 2 Care 4                | 16/04/2015 | Oprymea  | 0.52 mg | Prolonged-release tablet | 100 tablets | EU/1/08/469/033 | Austria, Belgium, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                              | Denmark        | 21/04/2015 |
| 2 Care 4                | 16/04/2015 | Oprymea  | 2.1 mg  | Prolonged-release tablet | 100 tablets | EU/1/08/469/045 | Austria, Belgium, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                              | Denmark        | 21/04/2015 |

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| European Pharma B.V. | 24/04/2015 | Orfadin    | 10 mg          | Capsule, hard                                 | 60 capsules          | EU/1/04/303/003 | Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                        | Germany | 30/04/2015 |
| European Pharma B.V. | 22/04/2015 | Orfadin    | 5 mg           | Capsule, hard                                 | 60 capsules          | EU/1/04/303/002 | Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                        | Germany | 30/04/2015 |
| axicorp Pharma GmbH  | 16/04/2015 | Orgalutran | 0.25 mg/0.5 ml | Solution for injection                        | 1 pre-filled syringe | EU/1/00/130/001 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom       | Germany | 20/04/2015 |
| Orifarm AS           | 17/03/2015 | Pergoveris | 150 IU / 75 IU | Powder and solvent for solution for injection | 1 vial + 1 vial      | EU/1/07/396/001 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Denmark | 27/04/2015 |

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| Orifarm AS              | 17/03/2015 | Pergoveris | 150 IU / 75 IU    | Powder and solvent for solution for injection | 10 vials + 10 vials                                   | EU/1/07/396/003 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Denmark        | 27/04/2015 |
| O.P.D. Laboratories Ltd | 01/04/2015 | Picato     | 150 micro-grams/g | Gel                                           | 3 tubes                                               | EU/1/12/796/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                  | United Kingdom | 21/04/2015 |
| CC Pharma               | 14/04/2015 | Plegridy   | 125 mcg           | Solution for injection                        | 2 pre-filled pens                                     | EU/1/14/934/005 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                               | Germany        | 15/04/2015 |
| CC Pharma               | 14/04/2015 | Plegridy   | 63 mcg; 94 mcg    | Solution for injection                        | 1 pre-filled pen (63 mcg) + 1 pre-filled pen (94 mcg) | EU/1/14/934/002 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                               | Germany        | 15/04/2015 |
| kohlpharma GmbH         | 09/04/2015 | Plegridy   | 125 mcg           | Solution for injection                        | 2 pre-filled pens                                     | EU/1/14/934/005 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                               | Germany        | 24/04/2015 |

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| kohlpharma GmbH       | 07/04/2015 | Plegridy   | 63 mcg;<br>94 mcg | Solution for<br>injection | 1 pre-filled pen<br>(63 mcg) + 1<br>pre-filled pen<br>(94 mcg) | EU/1/14/934/002 | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Ireland, Italy, Norway,<br>Portugal, Spain, Sweden,<br>The Netherlands, United<br>Kingdom                                                                                                                                                    | Germany                       | 24/04/2015 |
| Canoma Pharma<br>GmbH | 21/04/2015 | Prezista   | 600 mg            | Film-coated tablet        | 60 tablets                                                     | EU/1/06/380/002 | Austria, Belgium, Czech<br>Republic, Denmark, Finland,<br>France, Greece, Hungary,<br>Italy, Norway, Portugal,<br>Slovak Republic, Spain,<br>Sweden, The Netherlands,<br>United Kingdom                                                                                                                | Germany                       | 24/04/2015 |
| Ethigen Limited       | 21/04/2015 | Procoralan | 5 mg              | Film-coated tablet        | 56 tablets                                                     | EU/1/05/316/003 | Austria, Belgium, Croatia,<br>Cyprus, Czech Republic,<br>Denmark, Finland, France,<br>Germany, Greece, Iceland,<br>Ireland, Italy, Liechtenstein,<br>Lithuania, Luxembourg,<br>Malta, Norway, Portugal,<br>Romania, Slovak Republic,<br>Slovenia, Spain, Sweden,<br>The Netherlands, United<br>Kingdom | Ireland,<br>United<br>Kingdom | 27/04/2015 |
| Ethigen Limited       | 21/04/2015 | Procoralan | 7.5 mg            | Film-coated tablet        | 56 tablets                                                     | EU/1/05/316/010 | Austria, Belgium, Croatia,<br>Cyprus, Czech Republic,<br>Denmark, Finland, France,<br>Germany, Greece, Iceland,<br>Ireland, Italy, Liechtenstein,<br>Lithuania, Luxembourg,<br>Malta, Norway, Portugal,<br>Romania, Slovak Republic,<br>Slovenia, Spain, Sweden,<br>The Netherlands, United<br>Kingdom | Ireland,<br>United<br>Kingdom | 27/04/2015 |

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| MPT Pharma              | 21/04/2015 | Procoralan | 5 mg   | Film-coated tablet           | 56 tablets | EU/1/05/316/003 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                    | Ireland, Malta, United Kingdom | 28/04/2015 |
| O.P.D. Laboratories Ltd | 01/04/2015 | Procoralan | 5 mg   | Film-coated tablet           | 56 tablets | EU/1/05/316/003 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                                    | United Kingdom                 | 13/04/2015 |
| kohlpharma GmbH         | 13/04/2015 | Protelos   | 2 g    | Granules for oral suspension | 28 sachets | EU/1/04/288/003 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                                 | Germany                        | 24/04/2015 |
| Kosei Pharma UK Limited | 22/04/2015 | Ranexa     | 375 mg | Prolonged-release tablet     | 60 tablets | EU/1/08/462/001 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom        | 27/04/2015 |

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| Kosei Pharma UK Limited | 22/04/2015 | Ranexa         | 500 mg                           | Prolonged-release tablet         | 60 tablets          | EU/1/08/462/003 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 27/04/2015 |
| G-Pharma Ltd            | 06/03/2015 | Relvar Ellipta | 184 micro-grams / 22 micro-grams | Inhalation powder, pre-dispensed | 1 x 30 dose inhaler | EU/1/13/886/005 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Ireland, United Kingdom | 27/04/2015 |
| G-Pharma Ltd            | 06/03/2015 | Relvar Ellipta | 92 micro-grams / 22 micro-grams  | Inhalation powder, pre-dispensed | 1 x 30 dose inhaler | EU/1/13/886/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Ireland, United Kingdom | 27/04/2015 |
| O.P.D. Laboratories Ltd | 10/04/2015 | Relvar Ellipta | 184 micro-grams / 22 micro-grams | Inhalation powder, pre-dispensed | 1 x 30 dose inhaler | EU/1/13/886/005 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                                    | United Kingdom          | 23/04/2015 |

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| Pharmaram Ltd        | 23/03/2015 | Relvar Ellipta | 184 micro-grams / 22 micro-grams | Inhalation powder, pre-dispensed                 | 1 x 30 dose inhaler | EU/1/13/886/005 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                 | Ireland, Malta, United Kingdom | 01/04/2015 |
| axicorp Pharma B.V.  | 16/04/2015 | Remicade       | 100 mg                           | Powder for concentrate for solution for infusion | 1 vial              | EU/1/99/116/001 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Romania, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                                           | Germany                        | 24/04/2015 |
| European Pharma B.V. | 15/04/2015 | Remicade       | 100 mg                           | Powder for concentrate for solution for infusion | 3 vials             | EU/1/99/116/003 | Austria, Belgium, Czech Republic, Estonia, Finland, France, Greece, Ireland, Italy, Latvia, Lithuania, Norway, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                                                                     | Germany                        | 16/04/2015 |
| axicorp Pharma GmbH  | 10/04/2015 | Remsima        | 100 mg                           | Powder for concentrate for solution for infusion | 1 vial              | EU/1/13/853/001 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany                        | 16/04/2015 |

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| axicorp Pharma GmbH | 10/04/2015 | Remsima | 100 mg | Powder for concentrate for solution for infusion | 2 Vials | EU/1/13/853/002 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 16/04/2015 |
| axicorp Pharma GmbH | 10/04/2015 | Remsima | 100 mg | Powder for concentrate for solution for infusion | 3 Vials | EU/1/13/853/003 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 16/04/2015 |
| axicorp Pharma GmbH | 10/04/2015 | Remsima | 100 mg | Powder for concentrate for solution for infusion | 4 Vials | EU/1/13/853/004 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 16/04/2015 |

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| axicorp Pharma GmbH | 10/04/2015 | Remsima  | 100 mg          | Powder for concentrate for solution for infusion | 5 Vials               | EU/1/13/853/005 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom       | Germany                 | 16/04/2015 |
| Inopha GmbH         | 30/03/2015 | Remsima  | 100 mg          | Powder for concentrate for solution for infusion | 3 Vials               | EU/1/13/853/003 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany                 | 08/04/2015 |
| G-Pharma Ltd        | 09/04/2015 | Resolor  | 2 mg            | Film-coated tablet                               | 28 x 1 tablet         | EU/1/09/581/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                   | Ireland, United Kingdom | 15/04/2015 |
| kohlpharma GmbH     | 13/04/2015 | Retacrit | 10000 IU/1.0 ml | Solution for injection                           | 6 pre-filled syringes | EU/1/07/431/016 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                               | Germany                 | 16/04/2015 |

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| kohlpharma GmbH              | 27/04/2015 | Retacrit           | 6000 IU/<br>0.6 ml | Solution for<br>injection               | 6 pre-filled<br>syringes | EU/1/07/431/012 | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Ireland, Italy, Norway,<br>Portugal, Spain, Sweden,<br>The Netherlands, United<br>Kingdom                                                                                           | Germany            | 28/04/2015 |
| O.P.D. Laboratories<br>Ltd   | 23/03/2015 | REVINTY<br>ELLIPTA | 184 µg /<br>22 µg  | Inhalation<br>powder, pre-<br>dispensed | 1 inhaler (30<br>doses)  | EU/1/14/929/005 | Austria, Belgium, Cyprus,<br>Denmark, Finland, France,<br>Germany, Greece, Iceland,<br>Ireland, Italy, Luxembourg,<br>Malta, Norway, Portugal,<br>Spain, Sweden, The<br>Netherlands                                                           | United<br>Kingdom  | 08/04/2015 |
| O.P.D. Laboratories<br>Ltd   | 23/03/2015 | REVINTY<br>ELLIPTA | 92 µg /<br>22 µg   | Inhalation<br>powder, pre-<br>dispensed | 1 inhaler (30<br>doses)  | EU/1/14/929/002 | Austria, Belgium, Cyprus,<br>Denmark, Finland, France,<br>Germany, Greece, Iceland,<br>Ireland, Italy, Luxembourg,<br>Malta, Norway, Portugal,<br>Spain, Sweden, The<br>Netherlands                                                           | United<br>Kingdom  | 08/04/2015 |
| ACA Müller ADAG<br>Pharma AG | 31/03/2015 | Reyataz            | 200 mg             | Capsule, hard                           | 60 capsules              | EU/1/03/267/006 | Austria, Belgium, Bulgaria,<br>Cyprus, Denmark, Finland,<br>France, Greece, Iceland,<br>Ireland, Italy, Liechtenstein,<br>Lithuania, Luxembourg,<br>Malta, Norway, Portugal,<br>Romania, Spain, Sweden,<br>The Netherlands, United<br>Kingdom | Germany            | 13/04/2015 |
| Medcor<br>Pharmaceuticals BV | 17/04/2015 | Reyataz            | 150 mg             | Capsule, hard                           | 60 capsules              | EU/1/03/267/003 | Austria, Belgium, Cyprus,<br>Denmark, Finland, France,<br>Germany, Greece, Iceland,<br>Ireland, Italy, Liechtenstein,<br>Luxembourg, Malta, Norway,<br>Portugal, Spain, Sweden,<br>United Kingdom                                             | The<br>Netherlands | 28/04/2015 |

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| Canoma Pharma GmbH | 28/04/2015 | RoActemra         | 162 mg        | Solution for injection in pre-filled syringe | 12 (3 x 4) pre-filled syringes (multipack)                    | EU/1/08/492/008 | Austria, Belgium, Denmark, Finland, France, Greece, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                                          | Germany                 | 29/04/2015 |
| Orifarm OY         | 10/03/2015 | Ruconest          | 2100 IU       | Powder for solution for injection            | 1 vial                                                        | EU/1/10/641/001 | Austria, Belgium, Cyprus, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                              | Finland                 | 20/04/2015 |
| Paranova Oy        | 11/03/2015 | Ruconest          | 2100 IU       | Powder for solution for injection            | 1 vial                                                        | EU/1/10/641/001 | Austria, Belgium, Cyprus, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                              | Finland                 | 15/04/2015 |
| CC Pharma          | 22/04/2015 | Seebri Breezhaler | 44 micro-gram | Inhalation powder, hard capsule              | 90 (3 x 30 x 1) capsules (unit dose) (multipack) + 3 inhalers | EU/1/12/788/004 | Austria                                                                                                                                                                                                                                                                                                              | Germany                 | 30/04/2015 |
| Lexon (UK) Ltd     | 17/04/2015 | Seebri Breezhaler | 44 micro-gram | Inhalation powder, hard capsule              | 30 x 1 capsules (unit dose) + 1 inhaler                       | EU/1/12/788/003 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 24/04/2015 |

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| Eurim-Pharm<br>Arzneimittel GmbH | 18/03/2015 | Selincro | 18 mg | Film-coated tablet          | 14 tablets                                | EU/1/12/815/002 | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Ireland, Italy, Norway,<br>Portugal, Spain, Sweden,<br>The Netherlands, United<br>Kingdom                                                                                                                                                | Germany | 10/04/2015 |
| Eurim-Pharm<br>Arzneimittel GmbH | 18/03/2015 | Selincro | 18 mg | Film-coated tablet          | 49 tablets                                | EU/1/12/815/006 | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Ireland, Italy, Norway,<br>Portugal, Spain, Sweden,<br>The Netherlands, United<br>Kingdom                                                                                                                                                | Germany | 14/04/2015 |
| Pharma Gerke GmbH                | 27/04/2015 | Selincro | 18 mg | Film-coated tablet          | 49 tablets                                | EU/1/12/815/006 | Austria, Belgium, Finland,<br>France, Greece, Ireland,<br>Italy, Norway, Portugal,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom                                                                                                                                                         | Germany | 30/04/2015 |
| Pharma Gerke GmbH                | 27/04/2015 | Selincro | 18 mg | Film-coated tablet          | 14 tablets                                | EU/1/12/815/002 | Austria, Belgium, Finland,<br>France, Greece, Ireland,<br>Italy, Norway, Portugal,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom                                                                                                                                                         | Germany | 30/04/2015 |
| Orifarm GmbH                     | 16/04/2015 | Silgard  | --    | Suspension for<br>injection | 10 pre-filled<br>syringes + 20<br>needles | EU/1/06/358/008 | Austria, Belgium, Bulgaria,<br>Czech Republic, Denmark,<br>Estonia, Finland, France,<br>Greece, Hungary, Iceland,<br>Ireland, Italy, Latvia,<br>Lithuania, Luxembourg,<br>Norway, Poland, Portugal,<br>Romania, Slovak Republic,<br>Slovenia, Spain, Sweden,<br>The Netherlands, United<br>Kingdom | Germany | 30/04/2015 |

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| EMRA-Med               | 23/03/2015 | SIMBRINZA | 10 mg/ml<br>/ 2 mg/ml | Eye drops,<br>suspension | 3 Bottles  | EU/1/14/933/002 | Austria, Belgium, Cyprus,<br>Denmark, Finland, France,<br>Greece, Iceland, Ireland,<br>Italy, Liechtenstein,<br>Luxembourg, Malta, Norway,<br>Portugal, Spain, Sweden,<br>The Netherlands, United<br>Kingdom                                                                                                                         | Germany | 09/04/2015 |
| EMRA-Med               | 23/03/2015 | SIMBRINZA | 10 mg/ml<br>/ 2 mg/ml | Eye drops,<br>suspension | 1 Bottle   | EU/1/14/933/001 | Austria, Belgium, Cyprus,<br>Denmark, Finland, France,<br>Greece, Iceland, Ireland,<br>Italy, Liechtenstein,<br>Luxembourg, Malta, Norway,<br>Portugal, Spain, Sweden,<br>The Netherlands, United<br>Kingdom                                                                                                                         | Germany | 09/04/2015 |
| ABACUS MEDICINE<br>A/S | 22/04/2015 | Sprycel   | 70 mg                 | Film-coated tablet       | 60 tablets | EU/1/06/363/003 | Austria, Belgium, Bulgaria,<br>Cyprus, Czech Republic,<br>Denmark, Estonia, Finland,<br>France, Germany, Greece,<br>Hungary, Iceland, Ireland,<br>Italy, Latvia, Liechtenstein,<br>Lithuania, Luxembourg,<br>Malta, Norway, Poland,<br>Portugal, Romania, Slovak<br>Republic, Slovenia, Spain,<br>The Netherlands, United<br>Kingdom | Sweden  | 24/04/2015 |
| Orifarm AS             | 21/04/2015 | Sprycel   | 100 mg                | Film-coated tablet       | 30 tablets | EU/1/06/363/010 | Austria, Belgium, Bulgaria,<br>Cyprus, Czech Republic,<br>Estonia, Finland, France,<br>Germany, Greece, Hungary,<br>Iceland, Ireland, Italy,<br>Latvia, Liechtenstein,<br>Lithuania, Luxembourg,<br>Malta, Norway, Poland,<br>Portugal, Romania, Slovak<br>Republic, Slovenia, Spain,<br>Sweden, The Netherlands,<br>United Kingdom  | Denmark | 22/04/2015 |

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| ABACUS MEDICINE A/S  | 30/03/2015 | Stelara | 45 mg | Solution for injection in pre-filled syringe | 1 pre-filled syringe | EU/1/08/494/003 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom           | Germany | 08/04/2015 |
| ABACUS MEDICINE A/S  | 14/04/2015 | Stelara | 90 mg | Solution for injection in pre-filled syringe | 1 pre-filled syringe | EU/1/08/494/004 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, The Netherlands, United Kingdom | Sweden  | 17/04/2015 |
| Docpharm GmbH&CoKGaA | 07/04/2015 | Sutent  | 25 mg | Capsule, hard                                | 30 capsules          | EU/1/06/347/002 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                             | Germany | 15/04/2015 |
| Docpharm GmbH&CoKGaA | 07/04/2015 | Sutent  | 50 mg | Capsule, hard                                | 30 capsules          | EU/1/06/347/003 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                             | Germany | 15/04/2015 |

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| Eureco-Pharma B.V. | 23/03/2015 | Sutent  | 50 mg | Capsule, hard     | 30 capsules | EU/1/06/347/003 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom                  | The Netherlands | 20/04/2015 |
| EuroPharma DK ApS  | 09/04/2015 | Sycrest | 10 mg | Sublingual tablet | 60 tablets  | EU/1/10/640/005 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany         | 15/04/2015 |
| EuroPharma DK ApS  | 09/04/2015 | Sycrest | 5 mg  | Sublingual tablet | 60 tablets  | EU/1/10/640/002 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany         | 15/04/2015 |

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| ABACUS MEDICINE A/S  | 08/04/2015 | Tarceva  | 150 mg | Film-coated tablet | 30 tablets | EU/1/05/311/003 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany                        | 20/04/2015 |
| European Pharma B.V. | 08/04/2015 | Tivicay  | 50 mg  | Film-coated tablet | 30 tablets | EU/1/13/892/001 | Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                                 | Germany                        | 10/04/2015 |
| HAEMATO PHARM GmbH   | 23/04/2015 | Tivicay  | 50 mg  | Film-coated tablet | 30 tablets | EU/1/13/892/001 | Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Austria                        | 27/04/2015 |
| G-Pharma Ltd         | 08/04/2015 | Trajenta | 5 mg   | Film-coated tablet | 28 tablets | EU/1/11/707/003 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                            | Ireland, United Kingdom        | 13/04/2015 |
| PCO Manufacturing    | 01/04/2015 | Trajenta | 5 mg   | Film-coated tablet | 28 tablets | EU/1/11/707/003 | Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                   | Ireland, Malta, United Kingdom | 09/04/2015 |

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| MPT Pharma             | 17/03/2015 | Travatan | 40 µg/ml                | Eye drops, solution | 1 bottle                        | EU/1/01/199/001 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Ireland, Malta, United Kingdom | 07/04/2015 |
| SHAKESPEARE PHARMA LTD | 21/04/2015 | Travatan | 40 µg/ml                | Eye drops, solution | 1 bottle                        | EU/1/01/199/001 | Austria, Belgium, Bulgaria, Croatia, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands                                                                             | Ireland, United Kingdom        | 24/04/2015 |
| CC Pharma              | 10/04/2015 | Triumeq  | 50 mg / 600 mg / 300 mg | Film-coated tablet  | 90 (3 x 30) tablets (multipack) | EU/1/14/940/002 | Ireland, The Netherlands, United Kingdom                                                                                                                                                                                                                                                                             | Germany                        | 20/04/2015 |
| FD Pharma GmbH         | 10/04/2015 | Triumeq  | 50 mg / 600 mg / 300 mg | Film-coated tablet  | 30 tablets                      | EU/1/14/940/001 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                        | Germany                        | 23/04/2015 |
| Paranova Oy            | 11/03/2015 | Triumeq  | 50 mg / 600 mg / 300 mg | Film-coated tablet  | 30 tablets                      | EU/1/14/940/001 | Austria, Belgium, Cyprus, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                              | Finland                        | 20/04/2015 |

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| 2 Care 4                         | 27/03/2015 | Twynsta               | 80 mg /<br>10 mg   | Tablet                                          | 98 tablets                                            | EU/1/10/648/027 | Austria, Belgium, Bulgaria,<br>Czech Republic, Denmark,<br>Finland, France, Greece,<br>Iceland, Ireland, Italy,<br>Luxembourg, Malta, Norway,<br>Portugal, Slovak Republic,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom                                                                                                 | Germany           | 20/04/2015 |
| 2 Care 4                         | 27/03/2015 | Twynsta               | 80 mg / 5<br>mg    | Tablet                                          | 98 tablets                                            | EU/1/10/648/020 | Austria, Belgium, Bulgaria,<br>Czech Republic, Denmark,<br>Finland, France, Greece,<br>Iceland, Ireland, Italy,<br>Luxembourg, Malta, Norway,<br>Portugal, Slovak Republic,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom                                                                                                 | Germany           | 20/04/2015 |
| Orifarm AS                       | 13/03/2015 | Ultibro<br>Breezhaler | 85 mcg /<br>43 mcg | Inhalation<br>powder, hard<br>capsule           | 90 (3 packs of<br>30 x 1)<br>capsules + 3<br>inhalers | EU/1/13/862/004 | Austria, Belgium, Bulgaria,<br>Cyprus, Czech Republic,<br>Estonia, Finland, France,<br>Germany, Greece, Hungary,<br>Iceland, Ireland, Italy,<br>Latvia, Liechtenstein,<br>Lithuania, Luxembourg,<br>Malta, Norway, Poland,<br>Portugal, Romania, Slovak<br>Republic, Slovenia, Spain,<br>Sweden, The Netherlands,<br>United Kingdom | Denmark           | 28/04/2015 |
| Eurim-Pharm<br>Arzneimittel GmbH | 31/03/2015 | Velmetia              | 50 mg /<br>850 mg  | Film-coated tablet                              | 56 tablets                                            | EU/1/08/456/003 | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Ireland, Italy, Norway,<br>Portugal, Romania, Spain,<br>Sweden, The Netherlands,<br>United Kingdom                                                                                                                                                                        | Germany           | 08/04/2015 |
| Interport Ltd                    | 27/04/2015 | Victoza               | 6 mg/ml            | Solution for<br>injection in pre-<br>filled pen | 2 pre-filled<br>pens                                  | EU/1/09/529/002 | Austria, Belgium, Finland,<br>France, Germany, Greece,<br>Ireland, Italy, Malta,<br>Norway, Portugal, Spain, The<br>Netherlands                                                                                                                                                                                                     | United<br>Kingdom | 28/04/2015 |

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| Interport Ltd       | 27/04/2015 | Victoza  | 6 mg/ml  | Solution for injection in pre-filled pen | 3 pre-filled pens | EU/1/09/529/003 | Austria, Belgium, Finland, France, Germany, Greece, Ireland, Italy, Malta, Norway, Portugal, Spain, The Netherlands                                                                                                                                                                                         | United Kingdom | 28/04/2015 |
| BB Farma s.r.l.     | 10/04/2015 | Vimpat   | 200 mg   | Film-coated tablet                       | 168 tablets       | EU/1/08/470/012 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                | Germany        | 21/04/2015 |
| Orifarm OY          | 12/03/2015 | Vimpat   | 10 mg/ml | Solution for infusion                    | 1 vial            | EU/1/08/470/016 | Austria, Belgium, Cyprus, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Finland        | 20/04/2015 |
| ABACUS MEDICINE A/S | 22/04/2015 | Votrient | 400 mg   | Film-coated tablet                       | 30 tablets        | EU/1/10/628/003 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany        | 30/04/2015 |

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| Orifarm OY        | 04/03/2015 | Votrient | 400 mg | Film-coated tablet | 60 tablets | EU/1/10/628/004 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                   | Finland                 | 15/04/2015 |
| Amimed Direct Ltd | 15/04/2015 | Xarelto  | 10 mg  | Film-coated tablet | 10 tablets | EU/1/08/472/006 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 17/04/2015 |
| Amimed Direct Ltd | 22/04/2015 | Xarelto  | 15 mg  | Film-coated tablet | 28 tablets | EU/1/08/472/012 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 27/04/2015 |

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| 2 Care 4        | 12/03/2015 | Xeloda  | 500 mg | Film-coated tablet                         | 120 tablets                      | EU/1/00/163/002 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                    | Germany | 07/04/2015 |
| ADL Pharma GmbH | 15/04/2015 | Xeplion | 100 mg | Prolonged-release suspension for injection | 1 pre-filled syringe + 2 needles | EU/1/11/672/004 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                      | Germany | 30/04/2015 |
| BB Farma s.r.l. | 10/04/2015 | Xeplion | 75 mg  | Prolonged-release suspension for injection | 1 pre-filled syringe + 2 needles | EU/1/11/672/003 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 24/04/2015 |
| Orifarm OY      | 12/03/2015 | Xolair  | 150 mg | Solution for injection                     | 1 pre-filled syringe             | EU/1/05/319/008 | Austria, Belgium, Cyprus, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                      | Finland | 20/04/2015 |

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| HAEMATO PHARM GmbH | 01/04/2015 | Xtandi   | 40 mg            | Capsule, soft                                    | 112 capsules                            | EU/1/13/846/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                            | Ireland, United Kingdom | 15/04/2015 |
| Orifarm OY         | 23/03/2015 | Yondelis | 1 mg             | Powder for concentrate for solution for infusion | 1 vial                                  | EU/1/07/417/002 | Austria, Belgium, Cyprus, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Finland                 | 07/04/2015 |
| HAEMATO PHARM GmbH | 25/03/2015 | Zarzio   | 30 MU (60 MU/ml) | Solution for injection/infusion                  | 5 pre-filled syringes with needle guard | EU/1/08/495/003 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany                 | 07/04/2015 |
| HAEMATO PHARM GmbH | 25/03/2015 | Zarzio   | 48 MU (96 MU/ml) | Solution for injection/infusion                  | 5 pre-filled syringes with needle guard | EU/1/08/495/007 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany                 | 07/04/2015 |

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| HAEMATO PHARM GmbH    | 25/03/2015 | Zebinix | 800 mg        | Tablet        | 90 tablets | EU/1/09/514/019 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom            | Germany | 08/04/2015 |
| Paranova Danmark AS   | 13/04/2015 | Zyclara | 3.75 % (w/w/) | Cream         | 28 sachets | EU/1/12/783/002 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                       | Denmark | 21/04/2015 |
| Paranova Läkemedel AB | 13/04/2015 | Zyclara | 3.75 % (w/w/) | Cream         | 28 sachets | EU/1/12/783/002 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                                                                                               | Sweden  | 16/04/2015 |
| Euromedicines, S.L.   | 26/03/2015 | Zyprexa | 5 mg          | Coated tablet | 28         | EU/1/96/022/004 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Sweden, The Netherlands, United Kingdom | Spain   | 10/04/2015 |

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| Euromedicines, S.L. | 31/03/2015 | Zyprexa Velotab | 5 mg      | Orodispersible tablet    | 28     | EU/1/99/125/001 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Sweden, The Netherlands, United Kingdom | Spain | 14/04/2015 |
| BCN Farma SL        | 17/03/2015 | Naxcel          | 100 mg/ml | Suspension for injection | 1 vial | EU/2/05/053/001 | Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Sweden, The Netherlands, United Kingdom                                                                                                                                            | Spain | 14/04/2015 |