



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 April 2014  
EMA/227993/2014  
Compliance and Inspection

## Initial notices for parallel distribution – March 2014

| 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 |
|----------------------|----------------------|--------------|----------|----------------------------|----------------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|-----------------------|
| axicorp Pharma GmbH  | 29/01/2014           | Abilify      | 5 mg     | Tablet                     | 56 x 1 tablets (unit dose) | EU/1/04/276/004 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany                        | 06/03/2014            |

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An agency of the European Union



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| axicorp Pharma GmbH | 29/01/2014 | Abilify | 5 mg  | Tablet | 28 x 1 tablets (unit dose) | EU/1/04/276/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Hungary, Iceland, Italy, Latvia, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                             | Germany | 06/03/2014 |
| axicorp Pharma GmbH | 29/01/2014 | Abilify | 5 mg  | Tablet | 14 x 1 tablets (unit dose) | EU/1/04/276/001 | 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 | 06/03/2014 |
| axicorp Pharma GmbH | 30/01/2014 | Abilify | 10 mg | Tablet | 28 x 1 tablets (unit dose) | EU/1/04/276/007 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Hungary, Iceland, Italy, Latvia, Luxembourg, Malta, Norway, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom                                                                                                    | Germany | 06/03/2014 |
| axicorp Pharma GmbH | 30/01/2014 | Abilify | 15 mg | Tablet | 28 x 1 tablets (unit dose) | EU/1/04/276/012 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Hungary, Iceland, Italy, Latvia, Luxembourg, Malta, Norway, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom                                                                                                    | Germany | 06/03/2014 |

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| axicorp Pharma GmbH    | 30/01/2014 | Abilify | 30 mg | Tablet | 28 x 1 tablets (unit dose) | EU/1/04/276/017 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Hungary, Iceland, Italy, Latvia, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                            | Germany                 | 06/03/2014 |
| Necessity Supplies Ltd | 09/10/2013 | Abilify | 10 mg | Tablet | 28 x 1                     | EU/1/04/276/007 | 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 | 05/03/2014 |
| Necessity Supplies Ltd | 09/10/2013 | Abilify | 15 mg | Tablet | 28 x 1                     | EU/1/04/276/012 | 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 | 05/03/2014 |

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| 2 Care 4             | 10/03/2014 | ABILIFY<br>MAINTENA | 400 mg         | Powder and<br>solvent for<br>prolonged-release<br>suspension for<br>injection | 1 powder vial<br>+ 1 solvent<br>vial +<br>1 syringe with<br>pre-attached<br>needle +<br>1 disposable<br>syringe with<br>luer lock tip +<br>1 vial adapter<br>+ 2 needles<br>(38 and 50<br>mm) | EU/1/13/882/002 | Austria, Belgium, Finland,<br>France, Germany, Greece,<br>Iceland, Ireland, Italy,<br>Luxembourg, Malta,<br>Norway, Portugal, Spain,<br>Sweden, The Netherlands,<br>United Kingdom                                                                                                                                                              | Denmark | 20/03/2014 |
| Inopha GmbH          | 28/02/2014 | Aclasta             | 5 mg/100<br>ml | Solution for<br>infusion                                                      | 1 bottle                                                                                                                                                                                      | EU/1/05/308/001 | Austria, Belgium, Bulgaria,<br>Croatia, Cyprus, Czech<br>Republic, Denmark,<br>Estonia, Finland, France,<br>Greece, Hungary, Iceland,<br>Ireland, Italy, Latvia,<br>Liechtenstein, Lithuania,<br>Luxembourg, Malta,<br>Norway, Poland, Portugal,<br>Romania, Slovak Republic,<br>Slovenia, Spain, Sweden,<br>The Netherlands, United<br>Kingdom | Germany | 07/03/2014 |
| Pharma Gerke<br>GmbH | 20/12/2013 | Actos               | 45 mg          | Tablet                                                                        | 98 tablets                                                                                                                                                                                    | EU/1/00/150/015 | Austria, Belgium, Finland,<br>France, Greece, Ireland,<br>Italy, Norway, Portugal,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom                                                                                                                                                                                                      | Germany | 26/03/2014 |
| Pharma Gerke<br>GmbH | 20/12/2013 | Actos               | 45 mg          | Tablet                                                                        | 112 tablets                                                                                                                                                                                   | EU/1/00/150/029 | Austria, Belgium, Finland,<br>France, Greece, Ireland,<br>Italy, Norway, Portugal,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom                                                                                                                                                                                                      | Germany | 26/03/2014 |

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| 2 Care 4                  | 27/02/2014 | Advagraf | 0.5 mg | Prolonged-release capsule, hard | 50 capsules  | EU/1/07/387/002 | Austria, Belgium, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                          | Sweden  | 05/03/2014 |
| 2 Care 4                  | 27/02/2014 | Advagraf | 1 mg   | Prolonged-release capsule, hard | 50 capsules  | EU/1/07/387/004 | Austria, Belgium, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                          | Sweden  | 05/03/2014 |
| 2 Care 4                  | 27/02/2014 | Advagraf | 3 mg   | Prolonged-release capsule, hard | 50 capsules  | EU/1/07/387/012 | Austria, Belgium, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                          | Sweden  | 05/03/2014 |
| 2 Care 4                  | 27/02/2014 | Advagraf | 5 mg   | Prolonged-release capsule, hard | 50 capsules  | EU/1/07/387/008 | Austria, Belgium, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                          | Sweden  | 05/03/2014 |
| ACA Müller ADAG Pharma AG | 25/02/2014 | Advagraf | 3 mg   | Prolonged-release capsule, hard | 100 capsules | EU/1/07/387/013 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom | Germany | 06/03/2014 |

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| ACA Müller ADAG Pharma AG  | 06/03/2014 | Advagraf | 0.5 mg | Prolonged-release capsule, hard                  | 100 capsules | EU/1/07/387/009 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom                                                                         | Germany | 20/03/2014 |
| NORTHERN MEDICAL GROUP APS | 21/02/2014 | Afinitor | 10 mg  | Tablet                                           | 30 tablets   | EU/1/09/538/004 | 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, Spain, The Netherlands, United Kingdom | Sweden  | 11/03/2014 |
| NORTHERN MEDICAL GROUP APS | 21/02/2014 | Afinitor | 5 mg   | Tablet                                           | 30 tablets   | EU/1/09/538/001 | 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, Spain, The Netherlands, United Kingdom | Sweden  | 11/03/2014 |
| European Pharma B.V.       | 22/01/2014 | Alimta   | 500 mg | Powder for concentrate for solution for infusion | 1 vial       | EU/1/04/290/001 | Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                               | Germany | 06/03/2014 |

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| Paranova<br>Läkemedel AB | 11/03/2014 | Aloxi   | 250 µg | Solution for<br>injection | 1 vial                                        | EU/1/04/306/001 | Austria, Belgium, Cyprus,<br>Denmark, Finland, France,<br>Germany, Greece, Iceland,<br>Ireland, Italy,<br>Liechtenstein, Luxembourg,<br>Malta, Norway, Portugal,<br>Spain, The Netherlands,<br>United Kingdom                                                                                                                        | Sweden | 26/03/2014 |
| Cross Pharma AB          | 25/02/2014 | Aranesp | 100 µg | Solution for<br>injection | 4 pre-filled<br>syringes with<br>needle guard | EU/1/01/185/091 | 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 | 11/03/2014 |
| Cross Pharma AB          | 25/02/2014 | Aranesp | 150 µg | Solution for<br>injection | 4 pre-filled<br>syringes with<br>needle guard | EU/1/01/185/095 | 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 | 11/03/2014 |

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| Cross Pharma AB       | 25/02/2014 | Aranesp | 300 µg                             | Solution for injection | 1 pre-filled syringe with needle guard | EU/1/01/185/096 | 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  | 11/03/2014 |
| Milinda GmbH & Co. KG | 13/03/2014 | Avonex  | 30 µg/<br>0.5 ml<br>(6 million IU) | Solution for injection | 4 pre-filled pens                      | EU/1/97/033/005 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                     | Germany | 28/03/2014 |
| Milinda GmbH & Co. KG | 13/03/2014 | Avonex  | 30 µg/<br>0.5 ml<br>(6 million IU) | Solution for injection | 12 pre-filled pens                     | EU/1/97/033/006 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                     | Germany | 28/03/2014 |
| B2B Medical GmbH      | 19/02/2014 | Axura   | 10 mg                              | Film-coated tablet     | 98 tablets                             | EU/1/02/218/014 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Poland, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                     | Germany | 11/03/2014 |

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| 2 Care 4               | 19/03/2014 | Azopt    | 10 mg/ml | Eye drops, suspension                            | 3 bottles  | EU/1/00/129/003 | Austria, Belgium, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Spain, The Netherlands, United Kingdom                                                                                                  | Sweden                  | 28/03/2014 |
| Orifarm AB             | 12/03/2014 | Betmiga  | 25 mg    | Prolonged-release tablet                         | 90 tablets | EU/1/12/809/005 | 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                  | 26/03/2014 |
| Necessity Supplies Ltd | 09/10/2013 | CellCept | 500 mg   | Film-coated tablet                               | 50 tablets | EU/1/96/005/002 | United Kingdom                                                                                                                                                                                                                                                                                               | Ireland, United Kingdom | 18/03/2014 |
| ABACUS MEDICINE A/S    | 04/03/2014 | Cerezyme | 400 U    | Powder for concentrate for solution for infusion | 1 vial     | EU/1/97/053/003 | 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                  | 13/03/2014 |

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| Dr Fisher Farma BV             | 25/02/2014 | Champix | 1.0 mg            | Film-coated tablet | 28 tablets                      | EU/1/06/360/015 | 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, Sweden, United Kingdom | The Netherlands | 05/03/2014 |
| Dr Fisher Farma BV             | 26/02/2014 | Champix | 0.5 mg and 1.0 mg | Film-coated tablet | 11 x 0.5 mg + 14 x 1 mg tablets | EU/1/06/360/014 | 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 | 05/03/2014 |
| Euro Registratie Collectief BV | 19/03/2014 | Champix | 0.5 mg and 1.0 mg | Film-coated tablet | 11 x 0.5 mg + 14 x 1 mg tablets | EU/1/06/360/014 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, United Kingdom                                                                                                                                    | The Netherlands | 21/03/2014 |
| Euro Registratie Collectief BV | 19/03/2014 | Champix | 1.0 mg            | Film-coated tablet | 28 tablets                      | EU/1/06/360/015 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, United Kingdom                                                                                                                                    | The Netherlands | 21/03/2014 |

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| Medcor Pharmaceuticals BV | 18/02/2014 | Champix | 0.5 mg and 1.0 mg | Film-coated tablet | 11 x 0.5 mg + 14 x 1 mg tablets                    | EU/1/06/360/014 | Austria, Belgium, Cyprus, Denmark, Finland, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, United Kingdom                          | The Netherlands         | 28/03/2014 |
| Medcor Pharmaceuticals BV | 18/02/2014 | Champix | 1.0 mg            | Film-coated tablet | 28 tablets                                         | EU/1/06/360/015 | Austria, Belgium, Cyprus, Denmark, Finland, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, United Kingdom                          | The Netherlands         | 28/03/2014 |
| Orifarm AS                | 24/02/2014 | Champix | 0.5 mg and 1.0 mg | Film-coated tablet | 11 x 0.5 mg + 14 x 1 mg tablets + 28 x 1mg tablets | EU/1/06/360/023 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom          | Denmark                 | 04/03/2014 |
| Lexon (UK) Ltd            | 26/02/2014 | Comtess | 200 mg            | Film-coated tablet | 30 tablets                                         | EU/1/98/082/001 | 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 | 19/03/2014 |

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| Lexon (UK) Ltd | 26/02/2014 | Comtess   | 200 mg         | Film-coated tablet | 100 tablets | EU/1/98/082/003 | 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 | 19/03/2014 |
| 2 Care 4       | 03/02/2014 | Constella | 290 micrograms | Capsule, hard      | 28 capsules | EU/1/12/801/002 | Austria, Belgium, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                          | Germany                 | 05/03/2014 |
| 2 Care 4       | 24/02/2014 | Constella | 290 micrograms | Capsule, hard      | 28 capsules | EU/1/12/801/002 | Austria, Belgium, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                         | Denmark                 | 04/03/2014 |
| 2 Care 4       | 24/02/2014 | Constella | 290 micrograms | Capsule, hard      | 28 capsules | EU/1/12/801/002 | Austria, Belgium, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                         | Sweden                  | 04/03/2014 |

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| Paranova Danmark AS | 14/03/2014 | Constella | 290 micrograms | Capsule, hard                  | 28 capsules | EU/1/12/801/002 | 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 | 21/03/2014 |
| ABACUS MEDICINE A/S | 28/02/2014 | Cymbalta  | 60 mg          | Gastro-resistant capsule, hard | 98 capsules | EU/1/04/296/004 | 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  | 04/03/2014 |
| FD Pharma GmbH      | 17/03/2014 | Cymbalta  | 30 mg          | Gastro-resistant capsule, hard | 98 capsules | EU/1/04/296/009 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Latvia, Lithuania, Norway, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                           | Germany | 26/03/2014 |

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| Necessity Supplies Ltd | 14/03/2014 | Cymbalta | 30 mg | Gastro-resistant capsule, hard | 28 capsules | EU/1/04/296/001 | 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 | 25/03/2014 |
| Necessity Supplies Ltd | 14/03/2014 | Cymbalta | 60 mg | Gastro-resistant capsule, hard | 28 capsules | EU/1/04/296/002 | 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 | 25/03/2014 |
| Emra-Med               | 27/02/2014 | Ebixa    | 10 mg | Film-coated tablet             | 28 tablets  | EU/1/02/219/007 | 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          | Austria                 | 06/03/2014 |

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| STRATHCLYDE<br>PHARMACEUTICAL<br>S LTD | 28/02/2014 | Ebixa          | 10 mg  | Film-coated tablet | 30 tablets                      | EU/1/02/219/001 | 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>Sweden, The Netherlands,<br>United Kingdom | Ireland,<br>Malta,<br>United<br>Kingdom | 26/03/2014 |
| Orifarm GmbH                           | 17/02/2014 | Efient         | 5 mg   | Film-coated tablet | 98 tablets                      | EU/1/08/503/007 | 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                                 | 05/03/2014 |
| Paranova Danmark<br>AS                 | 20/02/2014 | Eklira Genuair | 322 µg | Inhalation powder  | 1 inhaler with<br>60 actuations | EU/1/12/778/002 | Austria, Belgium, Cyprus,<br>Finland, France, Germany,<br>Greece, Iceland, Ireland,<br>Italy, Liechtenstein,<br>Luxembourg, Malta,<br>Norway, Portugal, Spain,<br>Sweden, The Netherlands,<br>United Kingdom                                                                                                                                 | Denmark                                 | 05/03/2014 |
| STRATHCLYDE<br>PHARMACEUTICAL<br>S LTD | 05/03/2014 | Eliquis        | 2.5 mg | Film-coated tablet | 10 tablets                      | EU/1/11/691/001 | 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>Sweden, The Netherlands,<br>United Kingdom | Ireland,<br>Malta,<br>United<br>Kingdom | 26/03/2014 |

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| STRATHCLYDE<br>PHARMACEUTICAL<br>S LTD | 05/03/2014 | Eliquis | 2.5 mg | Film-coated tablet | 20 tablets                   | EU/1/11/691/002 | 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>Sweden, The Netherlands,<br>United Kingdom | Ireland,<br>Malta,<br>United<br>Kingdom | 26/03/2014 |
| STRATHCLYDE<br>PHARMACEUTICAL<br>S LTD | 05/03/2014 | Eliquis | 2.5 mg | Film-coated tablet | 60 x 1 tablet<br>(unit dose) | EU/1/11/691/004 | 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>Sweden, The Netherlands,<br>United Kingdom | Ireland,<br>Malta,<br>United<br>Kingdom | 26/03/2014 |
| STRATHCLYDE<br>PHARMACEUTICAL<br>S LTD | 11/03/2014 | Eliquis | 5 mg   | Film-coated tablet | 56 tablets                   | EU/1/11/691/008 | 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>Sweden, The Netherlands,<br>United Kingdom | Ireland,<br>Malta,<br>United<br>Kingdom | 19/03/2014 |

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| axicorp Pharma GmbH | 14/01/2014 | ellaOne         | 30 mg  | Tablet                                   | 1 tablet                              | EU/1/09/522/001 | 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 | 03/03/2014 |
| Inopha GmbH         | 14/03/2014 | Enbrel          | 50 mg  | Solution for injection in pre-filled pen | 12 pre-filled pens + 12 alcohol swabs | EU/1/99/126/021 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                      | Germany | 21/03/2014 |
| 2 Care 4            | 12/03/2014 | Entacapone Teva | 200 mg | Film-coated tablet                       | 100 tablets                           | EU/1/10/665/003 | Austria, Belgium, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                             | Denmark | 14/03/2014 |
| Orifarm AS          | 07/02/2014 | Esbriet         | 267 mg | Capsule, hard                            | 63 (1 x 21 and 1 x 42) capsules       | EU/1/11/667/001 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                      | Denmark | 12/03/2014 |

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| Emra-Med            | 18/03/2014 | Exforge HCT | 5 mg /<br>160 mg /<br>12.5 mg | Film-coated tablet                            | 98 tablets                                       | EU/1/09/569/006 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                            | Germany                 | 21/03/2014 |
| PHARMACHIM AB       | 10/03/2014 | Extavia     | 250 µg / ml                   | Powder and solvent for solution for injection | 15 vials +<br>15 pre-filled syringes (luer cone) | EU/1/08/454/002 | Austria, Belgium, Croatia, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, The Netherlands, United Kingdom                                                      | Sweden                  | 18/03/2014 |
| Paranova Danmark AS | 03/03/2014 | Forxiga     | 5 mg                          | Film-coated tablet                            | 28 tablets                                       | EU/1/12/795/002 | 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                 | 13/03/2014 |
| Lexon (UK) Ltd      | 21/03/2014 | FOSAVANCE   | 70 mg /<br>5600 IU            | Tablet                                        | 4 tablets                                        | EU/1/05/310/007 | 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 | 26/03/2014 |

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| axicorp Pharma GmbH    | 25/03/2014 | Gardasil   | --       | Suspension for injection | 1 pre-filled syringe + 2 needles | EU/1/06/357/007 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Iceland, Ireland, Italy, Latvia, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                       | Germany                        | 31/03/2014 |
| Inopha GmbH            | 11/03/2014 | Glivec     | 400 mg   | Film-coated tablet       | 90 film-coated tablets           | EU/1/01/198/013 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                                        | Germany                        | 19/03/2014 |
| 2 Care 4               | 28/01/2014 | Gripovac 3 | --       | Suspension for injection | 1 bottle                         | EU/2/09/102/005 | Austria, Belgium, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Poland, Portugal, Spain, The Netherlands, United Kingdom                                                                                                                                            | Denmark                        | 05/03/2014 |
| Necessity Supplies Ltd | 09/10/2013 | Humalog    | 100 U/ml | Suspension for injection | 5 cartridges                     | EU/1/96/007/008 | 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, Malta, United Kingdom | 24/03/2014 |

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| Necessity Supplies Ltd | 09/10/2013 | Humalog | 100 U/ml | Suspension for injection | 5 cartridges                                    | EU/1/96/007/006 | 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, Malta, United Kingdom | 24/03/2014 |
| Necessity Supplies Ltd | 13/12/2013 | Humalog | 100 U/ml | Solution for injection   | 5 cartridges                                    | EU/1/96/007/004 | 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        | 24/03/2014 |
| Medicopharm AG         | 27/02/2014 | Humira  | 40 mg    | Solution for injection   | 2 pre-filled pens + 2 alcohol pads in a blister | EU/1/03/256/008 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                             | Germany                        | 13/03/2014 |
| Medicopharm AG         | 20/03/2014 | Humira  | 40 mg    | Solution for injection   | 6 pre-filled pens + 6 alcohol pads in a blister | EU/1/03/256/010 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                             | Germany                        | 24/03/2014 |

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| ACA Müller ADAG Pharma AG | 19/02/2014 | Infanrix hexa | --     | Powder and suspension for suspension for injection | 20 vials + 20 pre-filled syringes + 40 needles | EU/1/00/152/007 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Poland, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Germany                        | 05/03/2014 |
| Eureco-Pharma B.V.        | 14/03/2014 | Inlyta        | 1 mg   | Film-coated tablet                                 | 56 tablets                                     | EU/1/12/777/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, United Kingdom                                 | The Netherlands                | 18/03/2014 |
| Eureco-Pharma B.V.        | 14/03/2014 | Inlyta        | 5 mg   | Film-coated tablet                                 | 56 tablets                                     | EU/1/12/777/005 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, United Kingdom                                 | The Netherlands                | 18/03/2014 |
| necessity Supplies Ltd    | 14/10/2013 | Inovelon      | 100 mg | Film-coated tablet                                 | 10 tablets                                     | EU/1/06/378/001 | 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 | 18/03/2014 |

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| Necessity Supplies Ltd | 14/10/2013 | Inovelon  | 200 mg    | Film-coated tablet       | 60 tablets    | EU/1/06/378/009 | 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 | 18/03/2014 |
| Necessity Supplies Ltd | 20/03/2014 | Inovelon  | 400 mg    | Film-coated tablet       | 60 tablets    | EU/1/06/378/014 | 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        | 26/03/2014 |
| European Pharma B.V.   | 21/03/2014 | Insuman   | 100 IU/ml | Suspension for injection | 10 cartridges | EU/1/97/030/064 | Austria, Belgium, Czech Republic, Finland, France, Greece, Ireland, Italy, Norway, Poland, Portugal, Romania, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                                                                    | Germany                        | 28/03/2014 |
| axicorp Pharma B.V.    | 25/02/2014 | INTELENCE | 200 mg    | Tablet                   | 60 tablets    | EU/1/08/468/002 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany                        | 04/03/2014 |

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| ABACUS MEDICINE<br>A/S  | 27/02/2014 | Invirase | 500 mg | Film-coated tablet | 1 bottle   | EU/1/96/026/002 | Austria, Belgium, Bulgaria,<br>Croatia, Cyprus, Czech<br>Republic, Denmark,<br>Estonia, Finland, France,<br>Greece, Hungary, Iceland,<br>Ireland, Italy, Latvia,<br>Liechtenstein, Lithuania,<br>Luxembourg, Malta,<br>Norway, Poland, Portugal,<br>Romania, Slovak Republic,<br>Slovenia, Spain, Sweden,<br>The Netherlands, United<br>Kingdom | Germany | 04/03/2014 |
| European Pharma<br>B.V. | 05/03/2014 | Iressa   | 250 mg | Film-coated tablet | 30 tablets | EU/1/09/526/002 | Austria, Belgium, Bulgaria,<br>Finland, France, Greece,<br>Ireland, Italy, Norway,<br>Portugal, Slovak Republic,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom                                                                                                                                                                        | Germany | 27/03/2014 |
| European Pharma<br>B.V. | 10/03/2014 | Iressa   | 250 mg | Film-coated tablet | 30 tablets | EU/1/09/526/001 | Austria, Belgium, Bulgaria,<br>Finland, France, Greece,<br>Ireland, Italy, Norway,<br>Portugal, Slovak Republic,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom                                                                                                                                                                        | Germany | 18/03/2014 |
| 2 Care 4                | 06/03/2014 | Januvia  | 25 mg  | Film-coated tablet | 98 tablets | EU/1/07/383/005 | Austria, Belgium, Denmark,<br>Finland, France, Germany,<br>Greece, Iceland, Ireland,<br>Italy, Luxembourg, Malta,<br>Norway, Portugal, Spain,<br>The Netherlands, United<br>Kingdom                                                                                                                                                             | Sweden  | 12/03/2014 |
| 2 Care 4                | 06/03/2014 | Januvia  | 50 mg  | Film-coated tablet | 98 tablets | EU/1/07/383/011 | Austria, Belgium, Denmark,<br>Finland, France, Germany,<br>Greece, Iceland, Ireland,<br>Italy, Luxembourg, Malta,<br>Norway, Portugal, Spain,<br>The Netherlands, United<br>Kingdom                                                                                                                                                             | Sweden  | 12/03/2014 |

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| 2 Care 4     | 06/03/2014 | Januvia | 50 mg | Film-coated tablet | 28 tablets | EU/1/07/383/008 | Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                                                                                                           | Sweden                         | 13/03/2014 |
| G-Pharma Ltd | 14/03/2014 | Januvia | 50 mg | Film-coated tablet | 28 tablets | EU/1/07/383/008 | 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        | 19/03/2014 |
| G-Pharma Ltd | 19/03/2014 | Januvia | 25 mg | Film-coated tablet | 28 tablets | EU/1/07/383/002 | 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        | 24/03/2014 |
| MPT Pharma   | 27/02/2014 | Januvia | 25 mg | Film-coated tablet | 98 tablets | EU/1/07/383/005 | 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, Malta, United Kingdom | 17/03/2014 |

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| MPT Pharma          | 27/02/2014 | Januvia | 50 mg   | Film-coated tablet | 98 tablets  | EU/1/07/383/011 | 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, Malta, United Kingdom | 17/03/2014 |
| Willbay Limited     | 10/02/2014 | Januvia | 100 mg  | Film-coated tablet | 28 tablets  | EU/1/07/383/014 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                            | United Kingdom                 | 12/03/2014 |
| ABACUS MEDICINE A/S | 27/02/2014 | Keppra  | 1000 mg | Film-coated tablet | 200 tablets | EU/1/00/146/026 | 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                        | 03/03/2014 |

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| ABACUS MEDICINE<br>A/S       | 12/03/2014 | Keppra | 500 mg  | Film-coated tablet | 200 tablets | EU/1/00/146/013 | Austria, Belgium, Bulgaria,<br>Croatia, Cyprus, Czech<br>Republic, Denmark,<br>Estonia, Finland, France,<br>Greece, Hungary, Iceland,<br>Ireland, Italy, Latvia,<br>Liechtenstein, Lithuania,<br>Luxembourg, Malta,<br>Norway, Poland, Portugal,<br>Romania, Slovak Republic,<br>Slovenia, Spain, Sweden,<br>The Netherlands, United<br>Kingdom | Germany                       | 18/03/2014 |
| ACA Müller ADAG<br>Pharma AG | 07/03/2014 | Keppra | 1000 mg | Film-coated tablet | 200 tablets | EU/1/00/146/026 | Austria, Belgium, Bulgaria,<br>Cyprus, Denmark, Finland,<br>France, Greece, Iceland,<br>Ireland, Italy,<br>Liechtenstein, Luxembourg,<br>Malta, Norway, Poland,<br>Portugal, Spain, Sweden,<br>The Netherlands, United<br>Kingdom                                                                                                               | Germany                       | 19/03/2014 |
| Amimed Direct Ltd            | 04/03/2014 | Keppra | 250 mg  | Film-coated tablet | 30 tablets  | EU/1/00/146/002 | 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>Sweden, The Netherlands,<br>United Kingdom    | Ireland,<br>United<br>Kingdom | 11/03/2014 |

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| Amimed Direct Ltd             | 04/03/2014 | Keppra  | 500 mg    | Film-coated tablet    | 30 tablets | EU/1/00/146/008 | 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 | 11/03/2014 |
| Eurim-Pharm Arzneimittel GmbH | 27/02/2014 | Kiovig  | 100 mg/ml | Solution for infusion | 1 vial     | EU/1/05/329/006 | Austria, Belgium, Czech Republic, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                       | Germany                 | 11/03/2014 |
| Emra-Med                      | 04/03/2014 | Lumigan | 0.1 mg/ml | Eye drops, solution   | 1 bottle   | EU/1/02/205/003 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Germany                 | 06/03/2014 |
| Emra-Med                      | 04/03/2014 | Lumigan | 0.1 mg/ml | Eye drops, solution   | 3 bottles  | EU/1/02/205/004 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Germany                 | 06/03/2014 |

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| ACA Müller ADAG Pharma AG | 21/03/2014 | Lyrica | 100 mg | Capsule, hard | 21 capsules | EU/1/04/279/014 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Romania, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                                                                                        | Germany                 | 28/03/2014 |
| Emra-Med                  | 10/03/2014 | Lyrica | 225 mg | Capsule, hard | 56 capsules | EU/1/04/279/034 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                              | Germany                 | 26/03/2014 |
| kohlpharma GmbH           | 04/03/2014 | Lyrica | 200 mg | Capsule, hard | 84 capsules | EU/1/04/279/021 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                                 | Germany                 | 20/03/2014 |
| necessity Supplies Ltd    | 12/09/2013 | Lyrica | 100 mg | Capsule, hard | 84 capsules | EU/1/04/279/015 | 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, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 04/03/2014 |

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| Necessity Supplies Ltd | 12/09/2013 | Lyrica | 25 mg | Capsule, hard | 14 capsules | EU/1/04/279/001 | 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 | 04/03/2014 |
| Necessity Supplies Ltd | 12/09/2013 | Lyrica | 25 mg | Capsule, hard | 56 capsules | EU/1/04/279/003 | 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 | 04/03/2014 |
| Necessity Supplies Ltd | 12/09/2013 | Lyrica | 50 mg | Capsule, hard | 56 capsules | EU/1/04/279/008 | 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 | 04/03/2014 |

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| Necessity Supplies Ltd | 14/03/2014 | Lyrica | 100 mg | Capsule, hard | 21 capsules | EU/1/04/279/014 | 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 | 27/03/2014 |
| Necessity Supplies Ltd | 14/03/2014 | Lyrica | 150 mg | Capsule, hard | 14 capsules | EU/1/04/279/017 | 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 | 20/03/2014 |
| Necessity Supplies Ltd | 14/03/2014 | Lyrica | 50 mg  | Capsule, hard | 21 capsules | EU/1/04/279/007 | 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, The Netherlands, United Kingdom | Ireland, United Kingdom | 20/03/2014 |

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| Willbay Limited     | 23/01/2014 | Lyrica  | 25 mg            | Capsule, hard          | 56 capsules          | EU/1/04/279/003 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands        | United Kingdom | 25/03/2014 |
| Willbay Limited     | 23/01/2014 | Lyrica  | 75 mg            | Capsule, hard          | 56 capsules          | EU/1/04/279/012 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands        | United Kingdom | 25/03/2014 |
| axicorp Pharma B.V. | 05/12/2013 | Mircera | 75 µg/<br>0.3 ml | Solution for injection | 1 pre-filled syringe | EU/1/07/400/009 | Austria, Belgium, Bulgaria, Denmark, Finland, France, Greece, Hungary, Italy, Latvia, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                  | Germany        | 19/03/2014 |
| Emra-Med            | 18/03/2014 | MULTAQ  | 400 mg           | Film-coated tablet     | 50 tablets           | EU/1/09/591/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Germany        | 21/03/2014 |
| hvd medical GmbH    | 14/03/2014 | Neupro  | 6 mg/<br>24h     | Transdermal patch      | 28 patches           | EU/1/05/331/008 | Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                             | Germany        | 28/03/2014 |

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| hvd medical GmbH           | 14/03/2014 | Neupro | 8 mg/<br>24h | Transdermal<br>patch | 28 patches | EU/1/05/331/011 | Austria, Belgium, Finland,<br>France, Greece, Ireland,<br>Italy, Norway, Portugal,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom                                                                                                                                                   | Germany                       | 28/03/2014 |
| Kosei Pharma UK<br>Limited | 25/02/2014 | Neupro | 2 mg/<br>24h | Transdermal<br>patch | 7 patches  | EU/1/05/331/001 | Austria, Belgium, Croatia,<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, Portugal,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom | Ireland,<br>United<br>Kingdom | 06/03/2014 |
| Kosei Pharma UK<br>Limited | 25/02/2014 | Neupro | 2 mg/<br>24h | Transdermal<br>patch | 28 patches | EU/1/05/331/002 | Austria, Belgium, Croatia,<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, Portugal,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom | Ireland,<br>United<br>Kingdom | 06/03/2014 |
| Kosei Pharma UK<br>Limited | 25/02/2014 | Neupro | 4 mg/<br>24h | Transdermal<br>patch | 7 patches  | EU/1/05/331/004 | Austria, Belgium, Croatia,<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, Portugal,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom | Ireland,<br>United<br>Kingdom | 06/03/2014 |

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| Kosei Pharma UK Limited | 25/02/2014 | Neupro | 4 mg/24h | Transdermal patch | 28 patches | EU/1/05/331/005 | Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 06/03/2014 |
| Kosei Pharma UK Limited | 25/02/2014 | Neupro | 6 mg/24h | Transdermal patch | 7 patches  | EU/1/05/331/007 | Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 06/03/2014 |
| Kosei Pharma UK Limited | 25/02/2014 | Neupro | 8 mg/24h | Transdermal patch | 7 patches  | EU/1/05/331/010 | Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 06/03/2014 |

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| Kosei Pharma UK Limited | 25/02/2014 | Neupro  | 8 mg/24h | Transdermal patch     | 28 patches | EU/1/05/331/011 | Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 06/03/2014 |
| Kosei Pharma UK Limited | 07/03/2014 | Neupro  | 6 mg/24h | Transdermal patch     | 28 patches | EU/1/05/331/008 | Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 17/03/2014 |
| 2 Care 4                | 04/03/2014 | Nevanac | 3 mg/ml  | Eye drops, suspension | 1 bottle   | EU/1/07/433/002 | Austria, Belgium, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                               | Denmark                 | 12/03/2014 |
| 2 Care 4                | 04/03/2014 | Nevanac | 3 mg/ml  | Eye drops, suspension | 1 bottle   | EU/1/07/433/002 | Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                                                              | Sweden                  | 20/03/2014 |

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| kohlpharma GmbH        | 04/03/2014 | Nexavar           | 200 mg   | Film-coated tablet              | 112 tablets                      | EU/1/06/342/001 | Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Greece, Ireland, Italy, Latvia, Lithuania, Norway, Poland, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom                                                                                | Germany                        | 20/03/2014 |
| Dr Fisher Farma BV     | 28/02/2014 | NovoMix           | 100 U/ml | Suspension for injection        | 10 cartridges                    | EU/1/00/142/005 | 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                | 25/03/2014 |
| Dr Fisher Farma BV     | 26/02/2014 | NovoRapid         | 100 U/ml | Solution for injection          | 10 cartridges                    | EU/1/99/119/006 | 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                | 05/03/2014 |
| Necessity Supplies Ltd | 14/10/2013 | Onbrez Breezhaler | 150 µg   | Inhalation powder, hard capsule | 30 (3 x 10) capsules + 1 inhaler | EU/1/09/593/002 | Austria, Belgium, Bulgaria, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Poland, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                        | Ireland, Malta, United Kingdom | 13/03/2014 |

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| Axicorp Pharma B.V. | 03/03/2014 | Pegasys | 180 µg | Solution for injection | 12 pre-filled pens | EU/1/02/221/016  | Austria, Belgium, Bulgaria, 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 | 12/03/2014 |
| Axicorp Pharma B.V. | 03/03/2014 | Pegasys | 180 µg | Solution for injection | 4 pre-filled pens  | EU/1/02/221/015  | Austria, Belgium, Bulgaria, 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 | 12/03/2014 |
| ABACUS MEDICINE A/S | 19/02/2014 | Plavix  | 75 mg  | Film-coated tablet     | 100 tablets        | EU/1/98/069/004a | 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 | 05/03/2014 |

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| kohlpharma GmbH                 | 17/12/2013 | Pradaxa    | 110 mg          | Capsule, hard      | 60 x 1 capsules (unit dose) | EU/1/08/442/007 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                        | Germany                        | 03/03/2014 |
| STRATHCLYDE PHARMACEUTICALS LTD | 26/02/2014 | Pradaxa    | 150 mg          | Capsule, hard      | 60 x 1 capsules (unit dose) | EU/1/08/442/011 | 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, Malta, United Kingdom | 04/03/2014 |
| axicorp Pharma GmbH             | 05/12/2013 | PritorPlus | 80 mg / 12.5 mg | Tablet             | 98 tablets                  | EU/1/02/215/010 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                     | Germany                        | 20/03/2014 |
| Cross Pharma AB                 | 10/03/2014 | Procoralan | 5 mg            | Film-coated tablet | 112 tablets                 | EU/1/05/316/007 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Romania, Slovak Republic, Slovenia, Spain, The Netherlands, United Kingdom                                                                | Sweden                         | 17/03/2014 |

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| Emra-Med                         | 03/03/2014 | Prolia   | 60 mg/ml | Solution for injection | 1 pre-filled syringe with automatic needle guard (blistered) | EU/1/10/618/003 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                    | Germany                 | 28/03/2014 |
| axicorp Pharma B.V.              | 11/03/2014 | Rebif    | 22 µg    | Solution for injection | 12 pre-filled pens                                           | EU/1/98/063/013 | Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Lithuania, Luxembourg, Malta, Norway, Portugal, Romania, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany                 | 27/03/2014 |
| Shipping Dynamics Scandinavia AB | 20/03/2014 | Revlimid | 25 mg    | Capsule, hard          | 21 capsules                                                  | EU/1/07/391/004 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                   | Sweden                  | 31/03/2014 |
| Lexon (UK) Ltd                   | 27/02/2014 | Ristaben | 25 mg    | Film-coated tablet     | 28 tablets                                                   | EU/1/10/621/002 | 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 | 12/03/2014 |

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| Lexon (UK) Ltd  | 28/02/2014 | Ristaben | 50 mg  | Film-coated tablet | 28 tablets | EU/1/10/621/008 | 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 | 21/03/2014 |
| Willbay Limited | 10/02/2014 | Ristaben | 25 mg  | Film-coated tablet | 28 tablets | EU/1/10/621/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                 | United Kingdom          | 06/03/2014 |
| Willbay Limited | 10/02/2014 | Ristaben | 50 mg  | Film-coated tablet | 28 tablets | EU/1/10/621/008 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                 | United Kingdom          | 06/03/2014 |
| Willbay Limited | 24/02/2014 | Ristaben | 100 mg | Film-coated tablet | 28 tablets | EU/1/10/621/014 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                 | United Kingdom          | 06/03/2014 |

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| Paranova Danmark AS   | 10/02/2014 | Seebri Breezhaler | 44 microgram | Inhalation powder, hard capsule | 30 capsules + 1 inhaler | EU/1/12/788/003 | 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 | 05/03/2014 |
| Paranova Läkemedel AB | 10/02/2014 | Seebri Breezhaler | 44 microgram | Inhalation powder, hard capsule | 30 capsules + 1 inhaler | EU/1/12/788/003 | 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, The Netherlands, United Kingdom | Sweden  | 26/03/2014 |
| axicorp Pharma B.V.   | 18/03/2014 | Sifrol            | 1.57 mg      | Prolonged-release tablet        | 30 tablets              | EU/1/97/050/029 | 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 | 28/03/2014 |

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| axicorp Pharma B.V. | 18/03/2014 | Sifrol  | 1.57 mg | Prolonged-release tablet | 100 tablets                         | EU/1/97/050/030 | 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 | 28/03/2014 |
| kohlpharma GmbH     | 11/03/2014 | Siklos  | 1000 mg | Film-coated tablet       | 30 tablets                          | EU/1/07/397/001 | France                                                                                                                                                                                                                                                                                       | Germany | 28/03/2014 |
| kohlpharma GmbH     | 11/03/2014 | Silgard | --      | Suspension for injection | 10 pre-filled syringes + 20 needles | EU/1/06/358/008 | Austria, Belgium, Czech Republic, Denmark, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Norway, Poland, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                | Germany | 28/03/2014 |
| NewNeopharm BV      | 14/03/2014 | Silgard | --      | Suspension for injection | 1 pre-filled syringe + 2 needles    | EU/1/06/358/007 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                       | Denmark | 18/03/2014 |

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| NORTHERN<br>MEDICAL GROUP<br>APS | 12/02/2014 | Stelara  | 45 mg          | Solution for<br>injection in pre-<br>filled syringe | 1 pre-filled<br>syringe | EU/1/08/494/003 | 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, Spain, The<br>Netherlands, United<br>Kingdom | Sweden                                  | 11/03/2014 |
| MPT Pharma                       | 29/01/2014 | Suboxone | 8 mg /<br>2 mg | Sublingual tablet                                   | 7 tablets               | EU/1/06/359/003 | Austria, Belgium, Cyprus,<br>Denmark, Finland, France,<br>Germany, Greece, Iceland,<br>Ireland, Italy,<br>Liechtenstein, Luxembourg,<br>Malta, Norway, Portugal,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom                                                                                                   | Ireland,<br>Malta,<br>United<br>Kingdom | 24/03/2014 |
| MPT Pharma                       | 29/01/2014 | Suboxone | 8 mg /<br>2 mg | Sublingual tablet                                   | 28 tablets              | EU/1/06/359/004 | Austria, Belgium, Cyprus,<br>Denmark, Finland, France,<br>Germany, Greece, Iceland,<br>Ireland, Italy,<br>Liechtenstein, Luxembourg,<br>Malta, Norway, Portugal,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom                                                                                                   | Ireland,<br>Malta,<br>United<br>Kingdom | 24/03/2014 |

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| STRATHCLYDE<br>PHARMACEUTICAL<br>S LTD | 24/02/2014 | Suboxone | 8 mg /<br>2 mg | Sublingual tablet | 28 tablets                            | EU/1/06/359/004 | 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>Sweden, The Netherlands,<br>United Kingdom | Ireland,<br>Malta,<br>United<br>Kingdom | 03/03/2014 |
| Emra-Med                               | 25/03/2014 | Sycrest  | 10 mg          | Sublingual tablet | 20 tablets                            | EU/1/10/640/004 | Austria, Belgium, Cyprus,<br>Denmark, Finland, France,<br>Greece, Iceland, Ireland,<br>Italy, Liechtenstein,<br>Luxembourg, Malta,<br>Norway, Portugal, Spain,<br>Sweden, The Netherlands,<br>United Kingdom                                                                                                                                 | Germany                                 | 31/03/2014 |
| Emra-Med                               | 25/03/2014 | Sycrest  | 5 mg           | Sublingual tablet | 20 tablets                            | EU/1/10/640/001 | Austria, Belgium, Cyprus,<br>Denmark, Finland, France,<br>Greece, Iceland, Ireland,<br>Italy, Liechtenstein,<br>Luxembourg, Malta,<br>Norway, Portugal, Spain,<br>Sweden, The Netherlands,<br>United Kingdom                                                                                                                                 | Germany                                 | 31/03/2014 |
| Medartuum AB                           | 06/03/2014 | Tasigna  | 200 mg         | Capsule, hard     | 112 capsules<br>(4x28)<br>(multipack) | EU/1/07/422/008 | 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                                  | 13/03/2014 |

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| Necessity Supplies Ltd | 06/02/2014 | TESAVEL | 25 mg | Film-coated tablet | 28 tablets | EU/1/07/435/002 | 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 | 05/03/2014 |
| Necessity Supplies Ltd | 06/02/2014 | TESAVEL | 50 mg | Film-coated tablet | 28 tablets | EU/1/07/435/008 | 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 | 05/03/2014 |
| Willbay Limited        | 20/03/2014 | TESAVEL | 25 mg | Film-coated tablet | 28 tablets | EU/1/07/435/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                     | United Kingdom          | 27/03/2014 |

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| Willbay Limited                | 20/03/2014 | TESAVEL     | 50 mg                  | Film-coated tablet              | 28 tablets            | EU/1/07/435/008 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                     | United Kingdom   | 27/03/2014 |
| Medicopharm AG                 | 03/03/2014 | Tevagrastim | 30 MIU (300 µg/0.5 ml) | Solution for injection/infusion | 5 pre-filled syringes | EU/1/08/445/010 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                      | Germany          | 13/03/2014 |
| kohlpharma GmbH                | 31/01/2014 | Tracleer    | 125 mg                 | Film-coated tablet              | 56 tablets            | EU/1/02/220/004 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                                 | Germany          | 25/03/2014 |
| Euro Registratie Collectief BV | 05/03/2014 | Trajenta    | 5 mg                   | Film-coated tablet              | 30 tablets            | EU/1/11/707/004 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, United Kingdom                                                                                                                                                              | The Netherlands  | 10/03/2014 |
| IPSANA PHARMA GmbH             | 24/01/2014 | Truvada     | 200 mg / 245 mg        | Film-coated tablet              | 30 tablets            | EU/1/04/305/001 | 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 | Austria, Germany | 31/03/2014 |

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| Paranova Danmark AS   | 06/03/2014 | Twinrix Adult | --    | Suspension for injection         | 10 syringes with separate needle | EU/1/96/020/008 | 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 | 11/03/2014 |
| Paranova Läkemedel AB | 11/03/2014 | Tygacil       | 50 mg | Powder for solution for infusion | 10 vials                         | EU/1/06/336/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                                                                           | Sweden  | 26/03/2014 |
| Orifarm AB            | 06/03/2014 | Vfend         | 50 mg | Tablet                           | 56 tablets                       | EU/1/02/212/008 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Portugal, Romania, Slovak Republic, Slovenia, Spain, The Netherlands, United Kingdom                           | Sweden  | 14/03/2014 |

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|------------------------|------------|--------|--------|--------------------|------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|------------|
| MPT Pharma             | 25/02/2014 | Viagra | 50 mg  | Film-coated tablet | 2 tablets  | EU/1/98/077/014 | 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 | 03/03/2014 |
| Necessity Supplies Ltd | 14/03/2014 | Vimpat | 200 mg | Film-coated tablet | 56 tablets | EU/1/08/470/011 | 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        | 20/03/2014 |
| Orifarm AS             | 25/03/2014 | Vimpat | 100 mg | Film-coated tablet | 56 tablets | EU/1/08/470/005 | 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                        | 31/03/2014 |

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| Eureco-Pharma B.V.   | 17/02/2014 | Votrient | 400 mg | Film-coated tablet | 60 tablets | EU/1/10/628/004 | 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, Sweden, United Kingdom | The Netherlands | 05/03/2014 |
| Docpharm GmbH&CoKGaA | 05/03/2014 | Xarelto  | 15 mg  | Film-coated tablet | 28 tablets | EU/1/08/472/012 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                             | Germany         | 24/03/2014 |
| Docpharm GmbH&CoKGaA | 05/03/2014 | Xarelto  | 15 mg  | Film-coated tablet | 42 tablets | EU/1/08/472/013 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                             | Germany         | 24/03/2014 |
| Docpharm GmbH&CoKGaA | 05/03/2014 | Xarelto  | 15 mg  | Film-coated tablet | 98 tablets | EU/1/08/472/014 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                             | Germany         | 24/03/2014 |

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| Docpharm GmbH&CoKGaA   | 05/03/2014 | Xarelto | 20 mg | Film-coated tablet | 28 tablets | EU/1/08/472/018 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                              | Germany                 | 24/03/2014 |
| Docpharm GmbH&CoKGaA   | 05/03/2014 | Xarelto | 20 mg | Film-coated tablet | 98 tablets | EU/1/08/472/019 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                              | Germany                 | 24/03/2014 |
| Necessity Supplies Ltd | 17/01/2014 | 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 | 05/03/2014 |

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| Necessity Supplies Ltd | 17/01/2014 | Xarelto | 20 mg  | Film-coated tablet                         | 28 tablets                       | EU/1/08/472/018 | 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 | 05/03/2014 |
| Pharma Gerke GmbH      | 13/03/2014 | Xelevia | 50 mg  | Film-coated tablet                         | 98 tablets                       | EU/1/07/382/011 | Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                                          | Germany                 | 21/03/2014 |
| Willbay Limited        | 10/02/2014 | Xelevia | 50 mg  | Film-coated tablet                         | 28 tablets                       | EU/1/07/382/008 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                     | United Kingdom          | 06/03/2014 |
| European Pharma B.V.   | 13/03/2014 | Xeplion | 50 mg  | Prolonged-release suspension for injection | 1 pre-filled syringe + 2 needles | EU/1/11/672/002 | Austria, Belgium, Croatia, Finland, France, Greece, Ireland, Italy, Lithuania, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                      | Germany                 | 21/03/2014 |
| FD Pharma GmbH         | 28/02/2014 | 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, Iceland, Ireland, Italy, Lithuania, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                             | Germany                 | 07/03/2014 |

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| Inopha GmbH                | 28/02/2014 | Xeplion | 150 mg | Prolonged-release suspension for injection | 1 pre-filled syringe + 2 needles | EU/1/11/672/005 | 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 | 18/03/2014 |
| NORTHERN MEDICAL GROUP APS | 12/02/2014 | Xeplion | 100 mg | Prolonged-release suspension for injection | 1 pre-filled syringe + 2 needles | EU/1/11/672/004 | 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, Spain, The Netherlands, United Kingdom                   | Sweden  | 03/03/2014 |
| NORTHERN MEDICAL GROUP APS | 12/02/2014 | Xeplion | 150 mg | Prolonged-release suspension for injection | 1 pre-filled syringe + 2 needles | EU/1/11/672/005 | 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, Spain, The Netherlands, United Kingdom                   | Sweden  | 03/03/2014 |

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| NORTHERN<br>MEDICAL GROUP<br>APS | 12/02/2014 | Xeplion  | 75 mg  | Prolonged-release<br>suspension for<br>injection | 1 pre-filled<br>syringe +<br>2 needles | EU/1/11/672/003 | 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, Spain, The<br>Netherlands, United<br>Kingdom                       | Sweden  | 03/03/2014 |
| Medartuum AB                     | 17/03/2014 | XGEVA    | 120 mg | Solution for<br>injection                        | 1 vial                                 | EU/1/11/703/001 | Austria, Belgium, Bulgaria,<br>Croatia, Cyprus, Czech<br>Republic, Denmark,<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>The Netherlands, United<br>Kingdom | Sweden  | 19/03/2014 |
| Emra-Med                         | 11/12/2013 | Yentreve | 20 mg  | Gastro-resistant<br>capsule, hard                | 28 capsules                            | EU/1/04/280/007 | Austria, Belgium, Cyprus,<br>Denmark, Finland, France,<br>Greece, Iceland, Ireland,<br>Italy, Liechtenstein,<br>Luxembourg, Malta,<br>Norway, Portugal, Spain,<br>Sweden, The Netherlands,<br>United Kingdom                                                                                                                                     | Germany | 13/03/2014 |

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| Orifarm AB          | 04/03/2014 | Yondelis | 0.25 mg          | Powder for concentrate for solution for infusion | 1 vial                                  | EU/1/07/417/001 | 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  | 11/03/2014 |
| Orifarm GmbH        | 26/02/2014 | Yondelis | 0.25 mg          | Powder for concentrate for solution for infusion | 1 vial                                  | EU/1/07/417/001 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                           | Germany | 07/03/2014 |
| axicorp Pharma B.V. | 18/03/2014 | 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, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom        | Germany | 31/03/2014 |

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| axicorp Pharma B.V. | 18/03/2014 | 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, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom        | Germany | 31/03/2014 |
| Orifarm AB          | 14/03/2014 | Zelboraf | 240 mg           | Film-coated tablet              | 56 tablets                              | EU/1/12/751/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                                                                            | Sweden  | 28/03/2014 |
| Medartuum AB        | 04/03/2014 | Zoely    | 2.5 mg / 1.5 mg  | Film-coated tablet              | 84 tablets (72 active + 12 placebo)     | EU/1/11/690/002 | 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  | 11/03/2014 |
| PHARMACHIM AB       | 11/03/2014 | Zoely    | 2.5 mg / 1.5 mg  | Film-coated tablet              | 84 tablets (72 active + 12 placebo)     | EU/1/11/690/002 | Austria, Belgium, Czech Republic, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, The Netherlands, United Kingdom                                                                         | Sweden  | 18/03/2014 |

