

07 August 2014  
EMA/485269/2014  
Compliance and Inspection

## Initial notices for parallel distribution – July 2014

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

| Parallel distributor                | Date of notification | Product name | Strength | Pharmaceutical dosage form | Pack size                               | EU-number       | Member State(s) of Origin                                                                                                                                                               | Member State(s) of Destination | Date of Notice letter |
|-------------------------------------|----------------------|--------------|----------|----------------------------|-----------------------------------------|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|-----------------------|
| Doncaster Pharmaceuticals Group Ltd | 14/07/2014           | Abilify      | 1 mg/ml  | Oral solution              | 1 bottle + 1 cup + 1 calibrated dropper | EU/1/04/276/034 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Portugal, Spain, Sweden, The Netherlands, United Kingdom                | Ireland, Malta, United Kingdom | 23/07/2014            |
| B2B Medical GmbH                    | 07/07/2014           | Actos        | 30 mg    | Tablet                     | 112 tablets                             | EU/1/00/150/027 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Germany                        | 10/07/2014            |

|                    |            |          |           |                                 |                |                 |                                                                                                                                                                                                                                                                                                             |                         |            |
|--------------------|------------|----------|-----------|---------------------------------|----------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| kohlpharma GmbH    | 03/07/2014 | Advagraf | 3 mg      | Prolonged-release capsule, hard | 50 x 1 capsule | EU/1/07/387/022 | Austria, Belgium, Denmark, Finland, France, Greece, Hungary, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                               | Germany                 | 10/07/2014 |
| Lexon (UK) Ltd     | 22/07/2014 | Aerius   | 0.5 mg/ml | Oral solution                   | 1 bottle       | EU/1/00/160/065 | 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 | 31/07/2014 |
| HAEMATO PHARM GmbH | 25/07/2014 | Aerius   | 5 mg      | Film-coated tablet              | 20 tablets     | EU/1/00/160/009 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom          | Germany                 | 28/07/2014 |

|                      |            |        |        |                        |             |                 |                                                                                                                                                                                                                                                                                                    |         |            |
|----------------------|------------|--------|--------|------------------------|-------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| HAEMATO PHARM GmbH   | 25/07/2014 | Aerius | 5 mg   | Film-coated tablet     | 50 tablets  | EU/1/00/160/012 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 30/07/2014 |
| HAEMATO PHARM GmbH   | 25/07/2014 | Aerius | 5 mg   | Film-coated tablet     | 100 tablets | EU/1/00/160/013 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 30/07/2014 |
| European Pharma B.V. | 05/05/2014 | Aloxi  | 250 µg | Solution for injection | 1 vial      | EU/1/04/306/001 | Austria, Belgium, Czech Republic, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Romania, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                              | Germany | 03/07/2014 |

|            |            |         |        |                        |                  |                 |                                                                                                                                                                                                                                                                                                     |        |            |
|------------|------------|---------|--------|------------------------|------------------|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|------------|
| Orifarm AB | 21/07/2014 | Aranesp | 150 µg | Solution for injection | 1 pre-filled pen | EU/1/01/185/054 | 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 | 25/07/2014 |
| Orifarm AB | 21/07/2014 | Aranesp | 40 µg  | Solution for injection | 1 pre-filled pen | EU/1/01/185/049 | 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 | 25/07/2014 |
| Orifarm AB | 21/07/2014 | Aranesp | 60 µg  | Solution for injection | 1 pre-filled pen | EU/1/01/185/051 | 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 | 25/07/2014 |

|                               |            |         |                     |                    |             |                 |                                                                                                                                                                                                                                                                                          |         |            |
|-------------------------------|------------|---------|---------------------|--------------------|-------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| Orifarm GmbH                  | 27/02/2014 | AUBAGIO | 14 mg               | Film-coated tablet | 84 tablets  | EU/1/13/838/003 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                | Germany | 09/07/2014 |
| Orifarm GmbH                  | 27/02/2014 | AUBAGIO | 14 mg               | Film-coated tablet | 28 tablets  | EU/1/13/838/002 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                | Germany | 09/07/2014 |
| Eurim-Pharm Arzneimittel GmbH | 17/06/2014 | Axura   | 5 mg/pump actuation | Oral solution      | 1 bottle    | EU/1/02/218/006 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                     | Germany | 16/07/2014 |
| HAEMATO PHARM GmbH            | 25/07/2014 | AZILECT | 1 mg                | Tablet             | 100 tablets | EU/1/04/304/005 | Austria, Belgium, 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 | 31/07/2014 |
| HAEMATO PHARM GmbH            | 25/07/2014 | AZILECT | 1 mg                | Tablet             | 100 tablets | EU/1/04/304/005 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                  | Denmark | 31/07/2014 |

|                      |            |           |        |                          |                |                 |                                                                                                                                                                                         |         |            |
|----------------------|------------|-----------|--------|--------------------------|----------------|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| Docpharm GmbH&CoKGaA | 19/05/2014 | Baraclude | 1 mg   | Film-coated tablet       | 90 x 1 tablets | EU/1/06/343/007 | Austria, Belgium, Cyprus, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom          | Germany | 21/07/2014 |
| Emra-Med             | 09/07/2014 | Betmiga   | 50 mg  | Prolonged-release tablet | 30 tablets     | EU/1/12/809/010 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Germany | 10/07/2014 |
| Emra-Med             | 09/07/2014 | Betmiga   | 50 mg  | Prolonged-release tablet | 100 tablets    | EU/1/12/809/017 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Germany | 11/07/2014 |
| Emra-Med             | 09/07/2014 | Betmiga   | 50 mg  | Prolonged-release tablet | 100 tablets    | EU/1/12/809/018 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom | Germany | 10/07/2014 |
| Pharma Gerke GmbH    | 01/10/2013 | Bonviva   | 150 mg | Film-coated tablet       | 1 tablet       | EU/1/03/265/003 | Austria, Belgium, Czech Republic, Estonia, Finland, France, Greece, Ireland, Italy, Latvia, Lithuania, Norway, Poland, Portugal, Spain, Sweden, The Netherlands, United Kingdom         | Germany | 02/07/2014 |

|                   |            |           |        |                                |             |                 |                                                                                                                                                                                                                                                                                                             |                         |            |
|-------------------|------------|-----------|--------|--------------------------------|-------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| Pharma Gerke GmbH | 01/10/2013 | Bonviva   | 150 mg | Film-coated tablet             | 3 tablets   | EU/1/03/265/004 | Austria, Belgium, Czech Republic, Estonia, Finland, France, Greece, Ireland, Italy, Latvia, Lithuania, Norway, Poland, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                             | Germany                 | 02/07/2014 |
| FD Pharma GmbH    | 28/07/2014 | Comtess   | 200 mg | Film-coated tablet             | 100 tablets | EU/1/98/082/003 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                               | Germany                 | 31/07/2014 |
| Ethigen Limited   | 25/07/2014 | Corlontor | 5 mg   | Film-coated tablet             | 56 tablets  | EU/1/05/317/003 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 31/07/2014 |
| ADL Pharma GmbH   | 08/05/2014 | Cymbalta  | 30 mg  | Gastro-resistant capsule, hard | 98 capsules | EU/1/04/296/009 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                     | Germany                 | 01/07/2014 |

|                     |            |                |                |                        |                                 |                 |                                                                                                                                                                                                                                                                                                             |         |            |
|---------------------|------------|----------------|----------------|------------------------|---------------------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| Inopha GmbH         | 27/05/2014 | Dificlir       | 200 mg         | Film-coated tablet     | 2 x 10 tablets                  | EU/1/11/733/004 | 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 | 02/07/2014 |
| Emra-Med            | 27/06/2014 | Efient         | 5 mg           | Film-coated tablet     | 98 tablets                      | EU/1/08/503/007 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Germany | 01/07/2014 |
| NewNeopharm BV      | 26/06/2014 | Eklira Genuair | 322 µg         | Inhalation powder      | 1 inhaler with 60 actuations    | EU/1/12/778/002 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Denmark | 15/07/2014 |
| axicorp Pharma B.V. | 25/07/2014 | Elonva         | 150 micrograms | Solution for injection | 1 pre-filled syringe + 1 needle | EU/1/09/609/002 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                | Germany | 29/07/2014 |

|                             |            |         |                 |                                          |                                       |                 |                                                                                                                                                                                                                                                                                                     |         |            |
|-----------------------------|------------|---------|-----------------|------------------------------------------|---------------------------------------|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| ABACUS MEDICINE A/S         | 30/06/2014 | Enbrel  | 50 mg           | Solution for injection in pre-filled pen | 4 pre-filled pens + 4 alcohol swabs   | EU/1/99/126/020 | 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  | 03/07/2014 |
| Veron Pharma Vertriebs GmbH | 11/07/2014 | Enbrel  | 50 mg           | Solution for injection in pre-filled pen | 4 pre-filled pens + 4 alcohol swabs   | EU/1/99/126/020 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                    | Germany | 15/07/2014 |
| Veron Pharma Vertriebs GmbH | 11/07/2014 | Enbrel  | 50 mg           | Solution for injection in pre-filled pen | 12 pre-filled pens + 12 alcohol swabs | EU/1/99/126/021 | Austria                                                                                                                                                                                                                                                                                             | Germany | 15/07/2014 |
| Emra-Med                    | 24/07/2014 | Esmya   | 5 mg            | Tablet                                   | 28 tablets                            | EU/1/12/750/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                             | Germany | 31/07/2014 |
| European Pharma B.V.        | 03/04/2014 | Eucreas | 50 mg / 1000 mg | Film-coated tablet                       | 120 tablets                           | EU/1/07/425/010 | Austria, Belgium, Bulgaria, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                               | Germany | 03/07/2014 |

|                       |            |          |                         |                    |             |                 |                                                                                                                                                                                                                      |         |            |
|-----------------------|------------|----------|-------------------------|--------------------|-------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| Milinda GmbH & Co. KG | 02/07/2014 | Eucreas  | 50 mg / 1000 mg         | Film-coated tablet | 120 tablets | EU/1/07/425/010 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                      | Germany | 08/07/2014 |
| Milinda GmbH & Co. KG | 02/07/2014 | Eucreas  | 50 mg / 1000 mg         | Film-coated tablet | 180 tablets | EU/1/07/425/011 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                      | Germany | 08/07/2014 |
| Milinda GmbH & Co. KG | 02/07/2014 | Eucreas  | 50 mg / 850 mg          | Film-coated tablet | 120 tablets | EU/1/07/425/004 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                      | Germany | 08/07/2014 |
| Milinda GmbH & Co. KG | 02/07/2014 | Eucreas  | 50 mg / 850 mg          | Film-coated tablet | 180 tablets | EU/1/07/425/005 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                      | Germany | 08/07/2014 |
| axicorp Pharma B.V.   | 12/05/2014 | Eviplera | 200 mg / 25 mg / 245 mg | Film-coated tablet | 30 tablets  | EU/1/11/737/001 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Lithuania, Luxembourg, Malta, Norway, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom | Germany | 08/07/2014 |

|                               |            |          |                         |                    |                     |                 |                                                                                                                                                                                                                                                                                              |         |            |
|-------------------------------|------------|----------|-------------------------|--------------------|---------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| axicorp Pharma B.V.           | 12/05/2014 | Eviplera | 200 mg / 25 mg / 245 mg | Film-coated tablet | 90 (3 x 30) tablets | EU/1/11/737/002 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Lithuania, Luxembourg, Malta, Norway, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                                         | Germany | 08/07/2014 |
| Eurim-Pharm Arzneimittel GmbH | 15/01/2014 | Eviplera | 200 mg / 25 mg / 245 mg | Film-coated tablet | 30 tablets          | EU/1/11/737/001 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                         | Germany | 08/07/2014 |
| Eurim-Pharm Arzneimittel GmbH | 15/01/2014 | Eviplera | 200 mg / 25 mg / 245 mg | Film-coated tablet | 90 (3 x 30) tablets | EU/1/11/737/002 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                         | Germany | 08/07/2014 |
| axicorp Pharma B.V.           | 14/07/2014 | Exelon   | 1.5 mg                  | Capsule, hard      | 112 capsules        | EU/1/98/066/003 | 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 | 17/07/2014 |
| 2 Care 4                      | 11/07/2014 | Exelon   | 13.3 mg / 24 hours      | Transdermal patch  | 30 sachets          | EU/1/98/066/028 | Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                                                                                            | Sweden  | 15/07/2014 |

|                                     |            |        |                       |                      |                                       |                 |                                                                                                                                                                                    |         |            |
|-------------------------------------|------------|--------|-----------------------|----------------------|---------------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| 2 Care 4                            | 15/07/2014 | Exelon | 13.3 mg /<br>24 hours | Transdermal<br>patch | 30 sachets                            | EU/1/98/066/028 | 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 | 17/07/2014 |
| 2 Care 4                            | 25/07/2014 | Exelon | 13.3 mg /<br>24 hours | Transdermal<br>patch | 30 sachets                            | EU/1/98/066/028 | 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 | 28/07/2014 |
| 2 Care 4                            | 25/07/2014 | Exelon | 13.3 mg /<br>24 hours | Transdermal<br>patch | 60 (2 x 30)<br>sachets<br>(multipack) | EU/1/98/066/029 | 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 | 28/07/2014 |
| Eurim-Pharm<br>Arzneimittel<br>GmbH | 25/06/2014 | Exelon | 13.3 mg /<br>24 hours | Transdermal<br>patch | 60 (2 x 30)<br>sachets<br>(multipack) | EU/1/98/066/029 | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Ireland, Italy, Norway,<br>Portugal, Slovenia, Spain,<br>Sweden, The Netherlands,<br>United Kingdom                      | Germany | 16/07/2014 |
| Eurim-Pharm<br>Arzneimittel<br>GmbH | 25/06/2014 | Exelon | 13.3 mg /<br>24 hours | Transdermal<br>patch | 90 (3 x 30)<br>sachets<br>(multipack) | EU/1/98/066/030 | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Ireland, Italy, Norway,<br>Portugal, Slovenia, Spain,<br>Sweden, The Netherlands,<br>United Kingdom                      | Germany | 16/07/2014 |
| Eurim-Pharm<br>Arzneimittel<br>GmbH | 25/06/2014 | Exelon | 13.3 mg /<br>24 hours | Transdermal<br>patch | 30 sachets                            | EU/1/98/066/028 | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Ireland, Italy, Norway,<br>Portugal, Slovenia, Spain,<br>Sweden, The Netherlands,<br>United Kingdom                      | Germany | 16/07/2014 |

|                        |            |        |                       |                      |                                       |                 |                                                                                                                                                                                                                                                                                                                                                  |         |            |
|------------------------|------------|--------|-----------------------|----------------------|---------------------------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| Medartuum AB           | 01/07/2014 | Exelon | 13.3 mg /<br>24 hours | Transdermal<br>patch | 90 (3 x 30)<br>sachets<br>(multipack) | EU/1/98/066/030 | 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  | 03/07/2014 |
| NewNeopharm BV         | 17/07/2014 | Exelon | 13.3 mg /<br>24 hours | Transdermal<br>patch | 30 sachets                            | EU/1/98/066/028 | Austria, Belgium, Bulgaria,<br>Croatia, Cyprus, Czech<br>Republic, 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     | Denmark | 21/07/2014 |
| axicorp Pharma<br>B.V. | 14/07/2014 | Exelon | 3 mg                  | Capsule, hard        | 112 capsules                          | EU/1/98/066/006 | Austria, Belgium, Bulgaria,<br>Croatia, Cyprus, Czech<br>Republic, Denmark,<br>Estonia, Finland, France,<br>Greece, Hungary, Iceland,<br>Ireland, Italy, Latvia,<br>Lithuania, Luxembourg,<br>Malta, Norway, Poland,<br>Portugal, Romania, Slovak<br>Republic, Slovenia, Spain,<br>Sweden, The Netherlands,<br>United Kingdom                    | Germany | 17/07/2014 |

|                     |            |        |                   |                   |                                 |                 |                                                                                                                                                                                                                                                                                              |         |            |
|---------------------|------------|--------|-------------------|-------------------|---------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| axicorp Pharma B.V. | 14/07/2014 | Exelon | 4.5 mg            | Capsule, hard     | 112 capsules                    | EU/1/98/066/009 | 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 | 17/07/2014 |
| axicorp Pharma B.V. | 23/07/2014 | Exelon | 4.6 mg / 24 hours | Transdermal patch | 90 (3 x 30) sachets (multipack) | EU/1/98/066/022 | 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 | 25/07/2014 |
| axicorp Pharma B.V. | 25/07/2014 | Exelon | 9.5 mg / 24 hours | Transdermal patch | 60 (2 x 30) sachets (multipack) | EU/1/98/066/025 | 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 | 29/07/2014 |

|                               |            |        |                   |                   |                                 |                 |                                                                                                                                                                                                                                                                                              |         |            |
|-------------------------------|------------|--------|-------------------|-------------------|---------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| axicorp Pharma B.V.           | 25/07/2014 | Exelon | 9.5 mg / 24 hours | Transdermal patch | 90 (3 x 30) sachets (multipack) | EU/1/98/066/026 | 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 | 29/07/2014 |
| axicorp Pharma B.V.           | 25/07/2014 | Exelon | 9.5 mg / 24 hours | Transdermal patch | 84 (2 x 42) sachets (multipack) | EU/1/98/066/034 | 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 | 29/07/2014 |
| Eurim-Pharm Arzneimittel GmbH | 25/06/2014 | Exelon | 9.5 mg / 24 hours | Transdermal patch | 84 (2 x 42) sachets (multipack) | EU/1/98/066/034 | Austria, Belgium, Czech Republic, Denmark, Finland, France, Greece, Hungary, Ireland, Italy, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                                                                                                     | Germany | 16/07/2014 |
| Eurim-Pharm Arzneimittel GmbH | 25/06/2014 | Exelon | 9.5 mg / 24 hours | Transdermal patch | 42 sachets                      | EU/1/98/066/033 | Austria, Belgium, Czech Republic, Denmark, France, Greece, Hungary, Ireland, Italy, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                                                                                                              | Germany | 16/07/2014 |

|                                            |            |         |                   |                    |            |                 |                                                                                                                                                                                                                                                                                                             |         |            |
|--------------------------------------------|------------|---------|-------------------|--------------------|------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| axicorp Pharma GmbH<br>Axicorp Pharma GmbH | 15/05/2014 | Exforge | 10 mg /<br>160 mg | Film-coated tablet | 98 tablets | EU/1/06/370/023 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 15/07/2014 |
| axicorp Pharma GmbH                        | 15/05/2014 | Exforge | 5 mg /<br>160 mg  | Film-coated tablet | 28 tablets | EU/1/06/370/011 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 15/07/2014 |
| Axicorp Pharma GmbH                        | 15/05/2014 | Exforge | 5 mg /<br>160 mg  | Film-coated tablet | 56 tablets | EU/1/06/370/013 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 15/07/2014 |

|                     |            |         |               |                    |            |                 |                                                                                                                                                                                                                                                                                                             |                 |            |
|---------------------|------------|---------|---------------|--------------------|------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|------------|
| Axicorp Pharma GmbH | 15/05/2014 | Exforge | 5 mg / 160 mg | Film-coated tablet | 98 tablets | EU/1/06/370/015 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany         | 15/07/2014 |
| Dr Fisher Farma BV  | 18/06/2014 | Exforge | 5 mg / 160 mg | Film-coated tablet | 30 tablets | EU/1/06/370/012 | 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, United Kingdom                  | The Netherlands | 01/07/2014 |
| FD Pharma GmbH      | 18/07/2014 | Exforge | 5 mg / 160 mg | Film-coated tablet | 98 tablets | EU/1/06/370/015 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                               | Germany         | 22/07/2014 |

|                               |            |         |              |                                               |                                               |                 |                                                                                                                                                                                                                                                                                                             |         |            |
|-------------------------------|------------|---------|--------------|-----------------------------------------------|-----------------------------------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| axicorp Pharma GmbH           | 15/05/2014 | Exforge | 5 mg / 80 mg | Film-coated tablet                            | 98 tablets                                    | EU/1/06/370/007 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 15/07/2014 |
| axicorp Pharma B.V.           | 14/07/2014 | Exjade  | 250 mg       | Dispersible tablet                            | 84 tablets                                    | EU/1/06/356/004 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                | Germany | 17/07/2014 |
| Eurim-Pharm Arzneimittel GmbH | 04/06/2014 | Extavia | 250 µg / ml  | Powder and solvent for solution for injection | 15 vials + 15 pre-filled syringes (luer lock) | EU/1/08/454/008 | Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Norway, Portugal, Romania, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                                               | Germany | 09/07/2014 |

|                               |            |         |             |                                               |                                                                         |                 |                                                                                                                                                                                                                                              |         |            |
|-------------------------------|------------|---------|-------------|-----------------------------------------------|-------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| Eurim-Pharm Arzneimittel GmbH | 04/06/2014 | Extavia | 250 µg / ml | Powder and solvent for solution for injection | 45 (3x15) vials + 45 (3x15) pre-filled syringes (luer lock) (multipack) | EU/1/08/454/009 | Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Norway, Portugal, Romania, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                | Germany | 09/07/2014 |
| Orifarm GmbH                  | 04/07/2014 | Eylea   | 40 mg/ml    | Solution for injection                        | 1 vial                                                                  | EU/1/12/797/002 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                    | Germany | 09/07/2014 |
| HAEMATO PHARM GmbH            | 25/07/2014 | Fampyra | 10 mg       | Prolonged-release tablet                      | 28 tablets                                                              | EU/1/11/699/003 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Slovak Republic, Spain, The Netherlands, United Kingdom | Sweden  | 31/07/2014 |
| HAEMATO PHARM GmbH            | 25/07/2014 | Fampyra | 10 mg       | Prolonged-release tablet                      | 56 tablets                                                              | EU/1/11/699/004 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Slovak Republic, Spain, The Netherlands, United Kingdom | Sweden  | 31/07/2014 |

|                      |            |         |             |                        |                   |                 |                                                                                                                                                                                                                                                                                                    |                         |            |
|----------------------|------------|---------|-------------|------------------------|-------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| HAEMATO PHARM GmbH   | 28/07/2014 | Forsteo | 20 µg/80 µl | Solution for injection | 3 pre-filled pens | EU/1/03/247/002 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Austria, Germany        | 31/07/2014 |
| 2 Care 4             | 27/06/2014 | Forxiga | 10 mg       | Film-coated tablet     | 28 tablets        | EU/1/12/795/007 | Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                                                                                                  | Sweden                  | 03/07/2014 |
| 2 Care 4             | 27/06/2014 | Forxiga | 10 mg       | Film-coated tablet     | 98 tablets        | EU/1/12/795/008 | Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                                                                                                  | Sweden                  | 03/07/2014 |
| Amimed Direct Ltd    | 30/06/2014 | Forxiga | 10 mg       | Film-coated tablet     | 28 tablets        | EU/1/12/795/007 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                          | Ireland, United Kingdom | 24/07/2014 |
| European Pharma B.V. | 21/01/2014 | Forxiga | 10 mg       | Film-coated tablet     | 28 tablets        | EU/1/12/795/007 | Austria                                                                                                                                                                                                                                                                                            | Germany                 | 15/07/2014 |
| European Pharma B.V. | 21/01/2014 | Forxiga | 10 mg       | Film-coated tablet     | 98 tablets        | EU/1/12/795/008 | Austria                                                                                                                                                                                                                                                                                            | Germany                 | 15/07/2014 |

|                     |            |          |                     |                          |                                     |                 |                                                                                                                                                                                                                                                       |                         |            |
|---------------------|------------|----------|---------------------|--------------------------|-------------------------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| Amimed Direct Ltd   | 30/06/2014 | Forxiga  | 5 mg                | Film-coated tablet       | 28 tablets                          | EU/1/12/795/002 | 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 | 08/07/2014 |
| kohlpharma GmbH     | 24/07/2014 | Ganfort  | 300 µg/ml / 5 mg/ml | Eye drops, solution      | 30 single-dose containers (LPDE)    | EU/1/06/340/004 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                  | Germany                 | 29/07/2014 |
| kohlpharma GmbH     | 24/07/2014 | Ganfort  | 300 µg/ml / 5 mg/ml | Eye drops, solution      | 90 single-dose containers (LPDE)    | EU/1/06/340/005 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                  | Germany                 | 29/07/2014 |
| axicorp Pharma GmbH | 14/07/2014 | Gardasil | --                  | Suspension for injection | 10 pre-filled syringes + 20 needles | EU/1/06/357/008 | 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                 | 18/07/2014 |
| 2 Care 4            | 24/07/2014 | Gilenya  | 0.5 mg              | Capsule, hard            | 28 capsules                         | EU/1/11/677/005 | Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                                                     | Sweden                  | 30/07/2014 |

|                    |            |           |             |                          |                                              |                 |                                                                                                                                                                                                                                                                                            |                 |            |
|--------------------|------------|-----------|-------------|--------------------------|----------------------------------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|------------|
| HAEMATO PHARM GmbH | 28/07/2014 | Gilenya   | 0.5 mg      | Capsule, hard            | 28 capsules                                  | EU/1/11/677/005 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Latvia, Liechtenstein, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Spain, The Netherlands, United Kingdom                               | Sweden          | 29/07/2014 |
| Dr Fisher Farma BV | 24/06/2014 | Glivec    | 100 mg      | Film-coated tablet       | 120 film-coated tablets                      | EU/1/01/198/011 | 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, United Kingdom | The Netherlands | 07/07/2014 |
| Chemvet Pharma ApS | 03/07/2014 | HBVAXPRO  | 5 µg/0.5 ml | Suspension for injection | 1 pre-filled syringe with 2 separate needles | EU/1/01/183/024 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                                            | Denmark         | 14/07/2014 |
| Orifarm OY         | 13/05/2014 | Herceptin | 600 mg      | Solution for injection   | 1 vial                                       | EU/1/00/145/002 | Austria, Belgium, Cyprus, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                    | Finland         | 25/07/2014 |

|                   |            |          |           |                        |          |                 |                                                                                                                                                                                                                                                                   |                         |            |
|-------------------|------------|----------|-----------|------------------------|----------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| kohlpharma GmbH   | 04/06/2014 | Hizentra | 200 mg/ml | Solution for injection | 10 vials | EU/1/11/687/005 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                              | Germany                 | 09/07/2014 |
| kohlpharma GmbH   | 04/06/2014 | Hizentra | 200 mg/ml | Solution for injection | 20 vials | EU/1/11/687/006 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                              | Germany                 | 09/07/2014 |
| kohlpharma GmbH   | 04/06/2014 | Hizentra | 200 mg/ml | Solution for injection | 20 vials | EU/1/11/687/012 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                              | Germany                 | 09/07/2014 |
| Amimed Direct Ltd | 30/06/2014 | Humalog  | 100 U/ml  | Solution for injection | 5 pens   | EU/1/96/007/031 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Liechtenstein, Lithuania, Luxembourg, Norway, Poland, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 10/07/2014 |

|                      |            |               |          |                                     |                                                |                 |                                                                                                                                                                                                                                                                   |                         |            |
|----------------------|------------|---------------|----------|-------------------------------------|------------------------------------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| Amimed Direct Ltd    | 30/06/2014 | Humalog       | 100 U/ml | Suspension for injection            | 5 pens                                         | EU/1/96/007/033 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Liechtenstein, Lithuania, Luxembourg, Norway, Poland, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 10/07/2014 |
| Amimed Direct Ltd    | 30/06/2014 | Humalog       | 100 U/ml | Suspension for injection            | 5 pens                                         | EU/1/96/007/035 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Liechtenstein, Lithuania, Luxembourg, Norway, Poland, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 10/07/2014 |
| Canoma Pharma GmbH   | 26/06/2014 | Humira        | 40 mg    | Solution for injection              | 6 pre-filled syringes + 6 alcohol pads         | EU/1/03/256/005 | Austria, Belgium, France, Greece, Italy, Norway, Sweden, United Kingdom                                                                                                                                                                                           | Germany                 | 03/07/2014 |
| European Pharma B.V. | 10/03/2014 | Infanrix hexa | --       | Powder and suspension for injection | 10 vials + 10 pre-filled syringes + 20 needles | EU/1/00/152/006 | Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                      | Germany                 | 08/07/2014 |
| European Pharma B.V. | 10/03/2014 | Infanrix hexa | --       | Powder and suspension for injection | 20 vials + 20 pre-filled syringes + 40 needles | EU/1/00/152/007 | Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                      | Germany                 | 08/07/2014 |

|                      |            |           |           |                          |                    |                 |                                                                                                                                                                                                                                                                                              |         |            |
|----------------------|------------|-----------|-----------|--------------------------|--------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| CC Pharma            | 09/07/2014 | Inovelon  | 400 mg    | Film-coated tablet       | 200 tablets        | EU/1/06/378/016 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                         | Germany | 11/07/2014 |
| axicorp Pharma GmbH  | 02/06/2014 | Insuman   | 100 IU/ml | Suspension for injection | 10 pre-filled pens | EU/1/97/030/163 | 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 | 10/07/2014 |
| European Pharma B.V. | 25/06/2014 | Insuman   | 100 IU/ml | Solution for injection   | 5 cartridges       | EU/1/97/030/054 | Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                  | Germany | 02/07/2014 |
| Emra-Med             | 24/07/2014 | Isentress | 400 mg    | Film-coated tablet       | 60 tablets         | EU/1/07/436/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                      | Germany | 31/07/2014 |
| Orifarm GmbH         | 05/06/2014 | Isentress | 400 mg    | Film-coated tablet       | 60 tablets         | EU/1/07/436/001 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                    | Germany | 01/07/2014 |

|                                        |            |         |                    |                    |            |                 |                                                                                                                                                                                                                                                                                                             |                                         |            |
|----------------------------------------|------------|---------|--------------------|--------------------|------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|------------|
| Orifarm AS                             | 21/07/2014 | Jakavi  | 15 mg              | Tablet             | 56 tablets | EU/1/12/773/008 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Denmark                                 | 29/07/2014 |
| Orifarm AS                             | 21/07/2014 | Jakavi  | 20 mg              | Tablet             | 56 tablets | EU/1/12/773/011 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Denmark                                 | 29/07/2014 |
| Orifarm AS                             | 21/07/2014 | Jakavi  | 5 mg               | Tablet             | 56 tablets | EU/1/12/773/005 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Denmark                                 | 29/07/2014 |
| STRATHCLYDE<br>PHARMACEUTICAL<br>S LTD | 21/07/2014 | Janumet | 50 mg /<br>1000 mg | Film-coated tablet | 56 tablets | EU/1/08/455/010 | 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,<br>Malta,<br>United<br>Kingdom | 30/07/2014 |

|                                        |            |         |                    |                    |            |                 |                                                                                                                                                                                                                                                                                                                                              |                                         |            |
|----------------------------------------|------------|---------|--------------------|--------------------|------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|------------|
| STRATHCLYDE<br>PHARMACEUTICAL<br>S LTD | 21/07/2014 | Janumet | 50 mg /<br>1000 mg | Film-coated tablet | 28 tablets | EU/1/08/455/009 | 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 | 30/07/2014 |
| 2 Care 4                               | 27/06/2014 | Januvia | 25 mg              | Film-coated tablet | 98 tablets | EU/1/07/383/005 | 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                                 | 01/07/2014 |
| 2 Care 4                               | 27/06/2014 | Januvia | 50 mg              | Film-coated tablet | 98 tablets | EU/1/07/383/011 | 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                                 | 01/07/2014 |
| Chemilines Ltd                         | 21/07/2014 | Januvia | 50 mg              | Film-coated tablet | 28 tablets | EU/1/07/383/008 | Austria, Belgium, Bulgaria,<br>Cyprus, Czech Republic,<br>Denmark, Finland, France,<br>Germany, Greece, Hungary,<br>Italy, Latvia, Lithuania,<br>Luxembourg, Malta,<br>Norway, Poland, Portugal,<br>Romania, Slovak Republic,<br>Spain, Sweden, The<br>Netherlands                                                                           | Ireland,<br>United<br>Kingdom           | 25/07/2014 |

|                |            |         |         |                    |             |                 |                                                                                                                                                                                                                                                                                                             |                         |            |
|----------------|------------|---------|---------|--------------------|-------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| Ginova Ltd     | 01/07/2014 | Januvia | 50 mg   | Film-coated tablet | 28 tablets  | EU/1/07/383/008 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands                                                  | United Kingdom          | 09/07/2014 |
| PI-Pharma N.V. | 18/06/2014 | Keppra  | 1000 mg | Film-coated tablet | 100 tablets | EU/1/00/146/025 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                | Belgium, Luxembourg     | 03/07/2014 |
| Lexon (UK) Ltd | 26/06/2014 | 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 | 02/07/2014 |

|                      |            |                |              |                                               |                                                  |                 |                                                                                                                                                                                                                                                                                              |         |            |
|----------------------|------------|----------------|--------------|-----------------------------------------------|--------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| axicorp Pharma B.V.  | 12/05/2014 | KOGENATE Bayer | 1000 IU      | Powder and solvent for solution for injection | 1 vial + 1 pre-filled syringe + 1 Bio-Set device | EU/1/00/143/006 | 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 | 08/07/2014 |
| European Pharma B.V. | 09/04/2014 | Lantus         | 100 Units/ml | Solution for injection                        | 5 vials                                          | EU/1/00/134/033 | Austria, Belgium, Croatia, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                | Germany | 21/07/2014 |
| axicorp Pharma B.V.  | 11/07/2014 | Lonquex        | 6 mg         | Solution for injection                        | 1 pre-filled syringe with safety device          | EU/1/13/856/001 | 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 | 15/07/2014 |

|                     |            |          |          |                        |                                                           |                 |                                                                                                                                                                                                                                                                                                             |         |            |
|---------------------|------------|----------|----------|------------------------|-----------------------------------------------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| Inopha GmbH         | 23/07/2014 | Lonquex  | 6 mg     | Solution for injection | 1 pre-filled syringe with safety device                   | EU/1/13/856/001 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 25/07/2014 |
| Orifarm GmbH        | 17/06/2014 | Lonquex  | 6 mg     | Solution for injection | 1 pre-filled syringe with safety device                   | EU/1/13/856/001 | Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                               | Germany | 21/07/2014 |
| axicorp Pharma B.V. | 11/07/2014 | Lucentis | 10 mg/ml | Solution for injection | 1 vial + 1 filter needle + 1 injection needle + 1 syringe | EU/1/06/374/001 | 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 | 15/07/2014 |

|                     |            |          |           |                        |                      |                 |                                                                                                                                                                                                                                        |         |            |
|---------------------|------------|----------|-----------|------------------------|----------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| Emra-Med            | 24/07/2014 | Lucentis | 10 mg/ml  | Solution for injection | 1 pre-filled syringe | EU/1/06/374/003 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                | Germany | 29/07/2014 |
| Orifarm GmbH        | 29/07/2014 | Lucentis | 10 mg/ml  | Solution for injection | 1 pre-filled syringe | EU/1/06/374/003 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                             | Germany | 31/07/2014 |
| axicorp Pharma GmbH | 08/07/2014 | Lumigan  | 0.1 mg/ml | Eye drops, solution    | 1 bottle             | EU/1/02/205/003 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Portugal, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 15/07/2014 |
| axicorp Pharma GmbH | 08/07/2014 | Lumigan  | 0.1 mg/ml | Eye drops, solution    | 3 bottles            | EU/1/02/205/004 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Portugal, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 15/07/2014 |

|                           |            |         |           |                     |            |                 |                                                                                                                                                                                                                                                                                              |         |            |
|---------------------------|------------|---------|-----------|---------------------|------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| ACA Müller ADAG Pharma AG | 14/07/2014 | Lumigan | 0.3 mg/ml | Eye drops, solution | 3 bottles  | EU/1/02/205/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                      | Germany | 18/07/2014 |
| axicorp Pharma GmbH       | 08/07/2014 | Lumigan | 0.3 mg/ml | Eye drops, solution | 3 bottles  | EU/1/02/205/002 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Portugal, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                                                       | Germany | 15/07/2014 |
| EuroPharma DK ApS         | 17/07/2014 | Lumigan | 0.3 mg/ml | Eye drops, solution | 3 bottles  | EU/1/02/205/002 | Austria, Belgium, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Portugal, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                               | Denmark | 18/07/2014 |
| ACA Müller ADAG Pharma AG | 14/07/2014 | Lumigan | 25 mg     | Film-coated tablet  | 30 tablets | EU/1/11/736/001 | 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 | 17/07/2014 |

|                            |            |              |               |               |             |                 |                                                                                                                                                                                                                     |                                |            |
|----------------------------|------------|--------------|---------------|---------------|-------------|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|------------|
| Orifarm GmbH               | 03/07/2014 | Lyrica       | 20 mg/ml      | Oral solution | 1 bottle    | EU/1/04/279/044 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                           | Germany                        | 14/07/2014 |
| ACA Müller ADAG Pharma AG  | 24/07/2014 | Lyrica       | 200 mg        | Capsule, hard | 84 capsules | EU/1/04/279/021 | Austria, Belgium, Croatia, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Romania, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany                        | 30/07/2014 |
| ORDINANT MEDICAL SOLUTIONS | 20/06/2014 | Lyrica       | 50 mg         | Capsule, hard | 84 capsules | EU/1/04/279/009 | Ireland, Malta, United Kingdom                                                                                                                                                                                      | Ireland, Malta, United Kingdom | 09/07/2014 |
| ORDINANT MEDICAL SOLUTIONS | 20/06/2014 | Lyrica       | 100 mg        | Capsule, hard | 84 capsules | EU/1/04/279/015 | Ireland, Malta, United Kingdom                                                                                                                                                                                      | Ireland, Malta, United Kingdom | 09/07/2014 |
| axicorp Pharma GmbH        | 07/04/2014 | MicardisPlus | 80 mg / 25 mg | Tablet        | 98 tablets  | EU/1/02/213/023 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                            | Germany                        | 09/07/2014 |

|                      |            |          |          |                                  |            |                 |                                                                                                                                                                                                                                                                                                             |                         |            |
|----------------------|------------|----------|----------|----------------------------------|------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| EuroPharma DK ApS    | 23/07/2014 | Mycamine | 100 mg   | Powder for solution for infusion | 1 vial     | EU/1/08/448/002 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany                 | 29/07/2014 |
| Chemilines Ltd       | 20/06/2014 | Neupro   | 2 mg/24h | Transdermal patch                | 7 patches  | EU/1/05/331/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                                             | Ireland, United Kingdom | 02/07/2014 |
| Chemilines Ltd       | 20/06/2014 | Neupro   | 2 mg/24h | Transdermal patch                | 28 patches | EU/1/05/331/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                                             | Ireland, United Kingdom | 02/07/2014 |
| Docpharm GmbH&CoKGaA | 15/07/2014 | Neupro   | 2 mg/24h | Transdermal patch                | 84 patches | EU/1/05/331/018 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Germany                 | 30/07/2014 |

|                        |            |        |          |                   |            |                 |                                                                                                                                                                                                                                                                                                                      |                         |            |
|------------------------|------------|--------|----------|-------------------|------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| HAEMATO PHARM GmbH     | 25/07/2014 | Neupro | 2 mg/24h | Transdermal patch | 84 patches | EU/1/05/331/018 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                                      | Germany                 | 30/07/2014 |
| Necessity Supplies Ltd | 28/05/2014 | Neupro | 2 mg/24h | Transdermal patch | 28 patches | EU/1/05/331/002 | 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 | 10/07/2014 |
| Chemilines Ltd         | 20/06/2014 | Neupro | 4 mg/24h | Transdermal patch | 7 patches  | EU/1/05/331/004 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                                                      | Ireland, United Kingdom | 02/07/2014 |
| Chemilines Ltd         | 20/06/2014 | Neupro | 4 mg/24h | Transdermal patch | 28 patches | EU/1/05/331/005 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                                                      | Ireland, United Kingdom | 02/07/2014 |

|                        |            |        |          |                   |            |                 |                                                                                                                                                                                                                                                                                                                      |                         |            |
|------------------------|------------|--------|----------|-------------------|------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| Docpharm GmbH&CoKGaA   | 15/07/2014 | Neupro | 4 mg/24h | Transdermal patch | 84 patches | EU/1/05/331/024 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                              | Germany                 | 30/07/2014 |
| HAEMATO PHARM GmbH     | 25/07/2014 | Neupro | 4 mg/24h | Transdermal patch | 84 patches | EU/1/05/331/024 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                                      | Germany                 | 30/07/2014 |
| Necessity Supplies Ltd | 28/05/2014 | Neupro | 4 mg/24h | Transdermal patch | 28 patches | EU/1/05/331/005 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom | 10/07/2014 |
| Docpharm GmbH&CoKGaA   | 15/07/2014 | Neupro | 6 mg/24h | Transdermal patch | 84 patches | EU/1/05/331/030 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                              | Germany                 | 30/07/2014 |

|                        |            |        |          |                   |            |                 |                                                                                                                                                                                                                                                                                                                      |                         |            |
|------------------------|------------|--------|----------|-------------------|------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| HAEMATO PHARM GmbH     | 25/07/2014 | Neupro | 6 mg/24h | Transdermal patch | 84 patches | EU/1/05/331/030 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                                      | Germany                 | 30/07/2014 |
| Necessity Supplies Ltd | 28/05/2014 | Neupro | 6 mg/24h | Transdermal patch | 28 patches | EU/1/05/331/008 | 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 | 10/07/2014 |
| Docpharm GmbH&CoKGaA   | 15/07/2014 | Neupro | 8 mg/24h | Transdermal patch | 84 patches | EU/1/05/331/036 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                              | Germany                 | 30/07/2014 |

|                        |            |         |          |                       |            |                 |                                                                                                                                                                                                                                                                                                                      |                         |            |
|------------------------|------------|---------|----------|-----------------------|------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| HAEMATO PHARM GmbH     | 25/07/2014 | Neupro  | 8 mg/24h | Transdermal patch     | 84 patches | EU/1/05/331/036 | Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom                                      | Germany                 | 30/07/2014 |
| Necessity Supplies Ltd | 28/05/2014 | Neupro  | 8 mg/24h | Transdermal patch     | 28 patches | EU/1/05/331/011 | 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 | 10/07/2014 |
| Pharma Gerke GmbH      | 24/03/2014 | Nevanac | 1 mg/ml  | Eye drops, suspension | 1 bottle   | EU/1/07/433/001 | Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                                          | Germany                 | 22/07/2014 |

|                |            |           |                        |                                 |                       |                 |                                                                                                                                                                                                                                                                                                     |                         |            |
|----------------|------------|-----------|------------------------|---------------------------------|-----------------------|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| Orifarm AB     | 11/07/2014 | Nevanac   | 3 mg/ml                | Eye drops, suspension           | 1 bottle              | EU/1/07/433/002 | 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                  | 14/07/2014 |
| Medicopharm AG | 04/06/2014 | Nivestim  | 30 MU (300 µg/ 0.5 ml) | Solution for injection/infusion | 5 pre-filled syringes | EU/1/10/631/005 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                     | Germany                 | 23/07/2014 |
| Medicopharm AG | 04/06/2014 | Nivestim  | 48 MU (480 µg/ 0.5 ml) | Solution for injection/infusion | 5 pre-filled syringes | EU/1/10/631/008 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                     | Germany                 | 23/07/2014 |
| G-Pharma Ltd   | 24/07/2014 | NovoRapid | 100 U/ml               | Solution for injection          | 5 cartridges          | EU/1/99/119/003 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Poland, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                            | Ireland, United Kingdom | 31/07/2014 |

|                        |            |                   |        |                                 |                                           |                 |                                                                                                                                                                                                                                                                                                                      |                         |            |
|------------------------|------------|-------------------|--------|---------------------------------|-------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| HAEMATO PHARM GmbH     | 28/07/2014 | Onbrez Breezhaler | 150 µg | Inhalation powder, hard capsule | 30 (3 x 10) capsules + 1 inhaler          | EU/1/09/593/002 | 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          | Austria, Germany        | 30/07/2014 |
| HAEMATO PHARM GmbH     | 28/07/2014 | Onbrez Breezhaler | 150 µg | Inhalation powder, hard capsule | 3 x (30 capsules + 1 inhaler) (multipack) | EU/1/09/593/004 | 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          | Germany                 | 30/07/2014 |
| Necessity Supplies Ltd | 28/05/2014 | Onbrez Breezhaler | 300 µg | Inhalation powder, hard capsule | 30 (3 x 10) capsules + 1 inhaler          | EU/1/09/593/007 | 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 | 02/07/2014 |

|                    |            |          |         |                     |            |                 |                                                                                                                                                                                                                                                 |                         |            |
|--------------------|------------|----------|---------|---------------------|------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| G-Pharma Ltd       | 20/06/2014 | Onglyza  | 2.5 mg  | Film-coated tablet  | 28 tablets | EU/1/09/545/012 | 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 | 03/07/2014 |
| Chemvet Pharma ApS | 03/07/2014 | Onglyza  | 5 mg    | Film-coated tablet  | 28 tablets | EU/1/09/545/002 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Denmark                 | 02/07/2014 |
| G-Pharma Ltd       | 20/06/2014 | Onglyza  | 5 mg    | Film-coated tablet  | 28 tablets | EU/1/09/545/006 | 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 | 03/07/2014 |
| Pharma Gerke GmbH  | 03/04/2014 | Opatanol | 1 mg/ml | Eye drops, solution | 1 bottle   | EU/1/02/217/001 | Austria, Belgium, Bulgaria, Czech Republic, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                                          | Germany                 | 03/07/2014 |

|                     |            |           |                        |                                          |                             |                 |                                                                                                                                                                                                                                                                                                              |         |            |
|---------------------|------------|-----------|------------------------|------------------------------------------|-----------------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| Cross Pharma AB     | 15/07/2014 | Ovitrelle | 250 micrograms         | Solution for injection in pre-filled pen | 1 pre-filled pen + 1 needle | EU/1/00/165/008 | 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, The Netherlands, United Kingdom | Sweden  | 18/07/2014 |
| axicorp Pharma GmbH | 14/07/2014 | Ovitrelle | 250 micrograms /0.5 ml | Solution for injection                   | 1 pre-filled syringe        | EU/1/00/165/007 | 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 | 18/07/2014 |
| Axicorp Pharma B.V. | 25/07/2014 | Pegasys   | 180 µg                 | Solution for injection                   | 1 pre-filled pen            | EU/1/02/221/014 | 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 | 29/07/2014 |

|                          |            |            |                   |                                                                              |                                                              |                 |                                                                                                                                                                                                                                                                                                                                      |         |            |
|--------------------------|------------|------------|-------------------|------------------------------------------------------------------------------|--------------------------------------------------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| Paranova<br>Läkemedel AB | 25/07/2014 | Pegasys    | 180 µg            | Solution for<br>injection                                                    | 4 pre-filled<br>pens                                         | EU/1/02/221/015 | 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  | 30/07/2014 |
| Cross Pharma AB          | 22/07/2014 | PegIntron  | 50<br>micrograms  | Powder and<br>solvent for<br>solution for<br>injection in pre-<br>filled pen | 4 pens +<br>4 injection<br>needles +<br>8 cleansing<br>swabs | EU/1/00/131/032 | 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  | 23/07/2014 |
| kohlpharma GmbH          | 25/07/2014 | Pergoveris | 150 IU /<br>75 IU | Powder and<br>solvent for<br>solution for<br>injection                       | 1 vial +<br>1 vial                                           | EU/1/07/396/001 | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Ireland, Italy, Norway,<br>Poland, Portugal, Spain,<br>Sweden, The Netherlands,<br>United Kingdom                                                                                                                                                                          | Germany | 29/07/2014 |
| kohlpharma GmbH          | 25/07/2014 | Pergoveris | 150 IU /<br>75 IU | Powder and<br>solvent for<br>solution for<br>injection                       | 3 vials +<br>3 vials                                         | EU/1/07/396/002 | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Ireland, Italy, Norway,<br>Poland, Portugal, Spain,<br>Sweden, The Netherlands,<br>United Kingdom                                                                                                                                                                          | Germany | 29/07/2014 |

|                        |            |            |                   |                                                        |                                                                                                             |                  |                                                                                                                                                                                                                                                                                                                           |         |            |
|------------------------|------------|------------|-------------------|--------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| kohlpharma GmbH        | 25/07/2014 | Pergoveris | 150 IU /<br>75 IU | Powder and<br>solvent for<br>solution for<br>injection | 10 vials +<br>10 vials                                                                                      | EU/1/07/396/003  | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Ireland, Italy, Norway,<br>Poland, Portugal, Spain,<br>Sweden, The Netherlands,<br>United Kingdom                                                                                                                                                               | Germany | 29/07/2014 |
| ADL Pharma GmbH        | 13/05/2014 | Plavix     | 75 mg             | Film-coated tablet                                     | 100 tablets                                                                                                 | EU/1/98/069/004a | Austria, Belgium, Denmark,<br>Finland, France, Greece,<br>Ireland, Italy, Luxembourg,<br>Malta, Norway, Portugal,<br>Spain, Sweden, The<br>Netherlands, United<br>Kingdom                                                                                                                                                 | Germany | 08/07/2014 |
| axicorp Pharma<br>GmbH | 17/06/2014 | Pradaxa    | 110 mg            | Capsule, hard                                          | 60 x 1<br>capsules<br>(unit dose)                                                                           | EU/1/08/442/007  | Austria, Belgium, Bulgaria,<br>Cyprus, Czech Republic,<br>Denmark, Estonia, Finland,<br>France, Greece, Hungary,<br>Iceland, Ireland, Italy,<br>Latvia, Liechtenstein,<br>Lithuania, Luxembourg,<br>Malta, Norway, Poland,<br>Portugal, Romania, Slovak<br>Republic, Spain, Sweden,<br>The Netherlands, United<br>Kingdom | Germany | 21/07/2014 |
| axicorp Pharma<br>GmbH | 17/06/2014 | Pradaxa    | 110 mg            | Capsule, hard                                          | 100 ct<br>multipack<br>(2 x 50 ct<br>packs<br>(5 blister cards<br>x 10 capsules<br>per bc =<br>50 capsules) | EU/1/08/442/015  | Austria, Belgium, Bulgaria,<br>Cyprus, Czech Republic,<br>Denmark, Estonia, Finland,<br>France, Greece, Hungary,<br>Iceland, Ireland, Italy,<br>Latvia, Liechtenstein,<br>Lithuania, Luxembourg,<br>Malta, Norway, Poland,<br>Portugal, Romania, Slovak<br>Republic, Spain, Sweden,<br>The Netherlands, United<br>Kingdom | Germany | 21/07/2014 |

|                     |            |         |        |               |                                                               |                 |                                                                                                                                                                                                                                                                                                             |                         |            |
|---------------------|------------|---------|--------|---------------|---------------------------------------------------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| axicorp Pharma GmbH | 17/06/2014 | Pradaxa | 110 mg | Capsule, hard | 180<br>(3 x 60 x 1)<br>capsules<br>(unit dose)<br>(multipack) | EU/1/08/442/014 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                    | Germany                 | 21/07/2014 |
| Ginova Ltd          | 11/07/2014 | Pradaxa | 110 mg | Capsule, hard | 60 x 1<br>capsules<br>(unit dose)                             | EU/1/08/442/007 | Austria, Belgium, Cyprus, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                                             | United Kingdom          | 15/07/2014 |
| Lexon (UK) Ltd      | 25/07/2014 | Pradaxa | 110 mg | Capsule, hard | 10 x 1<br>capsules<br>(unit dose)                             | EU/1/08/442/005 | 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, United Kingdom | 30/07/2014 |

|                                 |            |         |        |               |                                                   |                 |                                                                                                                                                                                                                                                                                                             |                                |            |
|---------------------------------|------------|---------|--------|---------------|---------------------------------------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|------------|
| Lexon (UK) Ltd                  | 25/07/2014 | Pradaxa | 110 mg | Capsule, hard | 30 x 1 capsules (unit dose)                       | EU/1/08/442/006 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Ireland, United Kingdom        | 30/07/2014 |
| Lexon (UK) Ltd                  | 25/07/2014 | Pradaxa | 110 mg | Capsule, hard | 60 x 1 capsules (unit dose)                       | EU/1/08/442/007 | 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        | 30/07/2014 |
| STRATHCLYDE PHARMACEUTICALS LTD | 10/07/2014 | Pradaxa | 110 mg | Capsule, hard | 180 (3 x 60 x 1) capsules (unit dose) (multipack) | EU/1/08/442/014 | 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, The Netherlands, United Kingdom | Ireland, Malta, United Kingdom | 21/07/2014 |

|                        |            |         |        |               |                             |                 |                                                                                                                                                                                                                                                                                                                      |                         |            |
|------------------------|------------|---------|--------|---------------|-----------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| Ginova Ltd             | 10/06/2014 | Pradaxa | 150 mg | Capsule, hard | 60 x 1 capsules (unit dose) | EU/1/08/442/011 | Austria, Belgium, Cyprus, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                                                      | United Kingdom          | 07/07/2014 |
| Necessity Supplies Ltd | 06/02/2014 | Pradaxa | 150 mg | Capsule, hard | 30 x 1 capsules (unit dose) | EU/1/08/442/010 | 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 | 11/07/2014 |
| Necessity Supplies Ltd | 06/02/2014 | Pradaxa | 150 mg | Capsule, hard | 60 x 1 capsules (unit dose) | EU/1/08/442/011 | 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 | 11/07/2014 |

|                        |            |          |        |                    |                             |                 |                                                                                                                                                                                                                                                                                                             |                         |            |
|------------------------|------------|----------|--------|--------------------|-----------------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| Necessity Supplies Ltd | 06/02/2014 | Pradaxa  | 75 mg  | Capsule, hard      | 30 x 1 capsules (unit dose) | EU/1/08/442/002 | 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 | 11/07/2014 |
| Paranova Danmark AS    | 04/07/2014 | Previcox | 227 mg | Chewable tablet    | 180 tablets                 | EU/2/04/045/006 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Denmark                 | 10/07/2014 |
| Paranova Danmark AS    | 04/07/2014 | Previcox | 227 mg | Chewable tablet    | 30 tablets                  | EU/2/04/045/004 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Denmark                 | 10/07/2014 |
| FD Pharma GmbH         | 28/05/2014 | Prezista | 400 mg | Film-coated tablet | 60 tablets                  | EU/1/06/380/003 | Austria, Belgium, Czech Republic, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Latvia, Norway, Portugal, Romania, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                                                                             | Germany                 | 25/07/2014 |

|                       |            |          |                 |                        |                                          |                 |                                                                                                                                                                                                                                                                                                     |         |            |
|-----------------------|------------|----------|-----------------|------------------------|------------------------------------------|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| axicorp Pharma B.V.   | 14/07/2014 | Privigen | 100 mg/ml       | Solution for infusion  | 1 vial                                   | EU/1/08/446/001 | 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 | 17/07/2014 |
| Pharma Gerke GmbH     | 02/06/2014 | Protopic | 0.1%            | Ointment               | 1 tube                                   | EU/1/02/201/004 | Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                         | Germany | 09/07/2014 |
| ABACUS MEDICINE A/S   | 03/07/2014 | Puregon  | 900 IU/ 1.08 ml | Solution for injection | 1 cartridge + 3 packs with 3 pen needles | EU/1/96/008/041 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                             | Germany | 16/07/2014 |
| Paranova Läkemedel AB | 03/07/2014 | Qutenza  | 179 mg          | Cutaneous patch        | 1 patch + 1 cleansing gel                | EU/1/09/524/001 | 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  | 09/07/2014 |

|                               |            |          |                   |                                       |                       |                 |                                                                                                                                                                                                                                                                                                             |         |            |
|-------------------------------|------------|----------|-------------------|---------------------------------------|-----------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| Eurim-Pharm Arzneimittel GmbH | 23/07/2014 | Rebif    | 44 µg             | Solution for injection                | 12 pre-filled pens    | EU/1/98/063/016 | Austria, Belgium, Croatia, Denmark, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Norway, Poland, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                                                                          | Germany | 25/07/2014 |
| Orifarm AS                    | 11/06/2014 | Replagal | 1 mg/ml           | Concentrate for solution for infusion | 1 vial                | EU/1/01/189/001 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                     | Denmark | 09/07/2014 |
| Orifarm AB                    | 02/05/2014 | Retacrit | 10000 IU/ 1.0 ml  | Solution for injection                | 6 pre-filled syringes | EU/1/07/431/016 | 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 | Sweden  | 14/07/2014 |
| Orifarm AB                    | 11/07/2014 | Retacrit | 30000 IU/ 0.75 ml | Solution for injection                | 1 pre-filled syringe  | EU/1/07/431/018 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                                                                                    | Sweden  | 14/07/2014 |

|                     |            |           |          |                                       |             |                 |                                                                                                                                                                                                  |                         |            |
|---------------------|------------|-----------|----------|---------------------------------------|-------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| Canoma Pharma GmbH  | 29/07/2014 | Revatio   | 20 mg    | Film-coated tablet                    | 90 tablets  | EU/1/05/318/001 | Austria, Belgium, Denmark, France, Greece, Italy, Norway, Poland, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                       | Germany                 | 31/07/2014 |
| 2 Care 4            | 23/07/2014 | Reyataz   | 200 mg   | Capsule, hard                         | 60 capsules | EU/1/03/267/005 | Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                | Sweden                  | 29/07/2014 |
| Canoma Pharma GmbH  | 03/07/2014 | Reyataz   | 300 mg   | Capsule, hard                         | 30 capsules | EU/1/03/267/008 | Austria, Belgium, Denmark, Finland, France, Greece, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                      | Germany                 | 10/07/2014 |
| B&S Healthcare Ltd  | 14/07/2014 | 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 | Ireland, United Kingdom | 21/07/2014 |
| axicorp Pharma B.V. | 25/06/2014 | RoActemra | 20 mg/ml | Concentrate for solution for infusion | 1 vial      | EU/1/08/492/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Lithuania, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom              | Germany                 | 10/07/2014 |
| Canoma Pharma GmbH  | 12/06/2014 | RoActemra | 20 mg/ml | Concentrate for solution for infusion | 1 vial      | EU/1/08/492/003 | Austria, Belgium, France, Greece, Italy, Norway, Sweden, United Kingdom                                                                                                                          | Germany                 | 09/07/2014 |

|                      |            |           |          |                                       |            |                 |                                                                                                                                                                                                                                                                                              |         |            |
|----------------------|------------|-----------|----------|---------------------------------------|------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| Canoma Pharma GmbH   | 12/06/2014 | RoActemra | 20 mg/ml | Concentrate for solution for infusion | 1 vial     | EU/1/08/492/005 | Austria, Belgium, France, Greece, Italy, Norway, Sweden, United Kingdom                                                                                                                                                                                                                      | Germany | 09/07/2014 |
| Canoma Pharma GmbH   | 14/07/2014 | RoActemra | 20 mg/ml | Concentrate for solution for infusion | 4 vials    | EU/1/08/492/004 | Austria, Belgium, France, Greece, Italy, Lithuania, Norway, Spain, Sweden, United Kingdom                                                                                                                                                                                                    | Germany | 22/07/2014 |
| Canoma Pharma GmbH   | 14/07/2014 | RoActemra | 20 mg/ml | Concentrate for solution for infusion | 4 vials    | EU/1/08/492/006 | Austria, Belgium, France, Greece, Italy, Norway, Spain, Sweden, United Kingdom                                                                                                                                                                                                               | Germany | 22/07/2014 |
| European Pharma B.V. | 25/06/2014 | RoActemra | 20 mg/ml | Concentrate for solution for infusion | 1 vial     | EU/1/08/492/003 | Austria, Belgium, Finland, France, Greece, Hungary, Ireland, Italy, Norway, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                        | Germany | 02/07/2014 |
| European Pharma B.V. | 25/06/2014 | RoActemra | 20 mg/ml | Concentrate for solution for infusion | 4 vials    | EU/1/08/492/004 | Austria, Belgium, Finland, France, Greece, Ireland, Italy, Latvia, Lithuania, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                               | Germany | 02/07/2014 |
| axicorp Pharma B.V.  | 16/06/2014 | Sifrol    | 0.52 mg  | Prolonged-release tablet              | 30 tablets | EU/1/97/050/017 | 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 | 01/07/2014 |

|                               |            |         |         |                                              |                                           |                 |                                                                                                                                                                                                                                                                                              |         |            |
|-------------------------------|------------|---------|---------|----------------------------------------------|-------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| axicorp Pharma B.V.           | 14/07/2014 | Sifrol  | 0.52 mg | Prolonged-release tablet                     | 100 tablets                               | EU/1/97/050/018 | 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 | 18/07/2014 |
| Eurim-Pharm Arzneimittel GmbH | 10/07/2014 | Sifrol  | 1.57 mg | Prolonged-release tablet                     | 30 tablets                                | EU/1/97/050/029 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                         | Germany | 11/07/2014 |
| CC Pharma                     | 22/07/2014 | Siklos  | 1000 mg | Film-coated tablet                           | 30 tablets                                | EU/1/07/397/001 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                         | Germany | 24/07/2014 |
| kohlpharma GmbH               | 27/05/2014 | Simponi | 50 mg   | Solution for injection                       | 3 (3 x 1) pre-filled syringes (multipack) | EU/1/09/546/004 | Austria, Belgium, Czech Republic, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                         | Germany | 02/07/2014 |
| Orifarm GmbH                  | 19/03/2014 | Stelara | 45 mg   | Solution for injection in pre-filled syringe | 1 pre-filled syringe                      | EU/1/08/494/003 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                    | Germany | 24/07/2014 |

|                           |            |         |        |                                               |                      |                 |                                                                                                                                                                                                          |         |            |
|---------------------------|------------|---------|--------|-----------------------------------------------|----------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| kohlpharma GmbH           | 04/06/2014 | Stelara | 90 mg  | Solution for injection in pre-filled syringe  | 1 pre-filled syringe | EU/1/08/494/004 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                     | Germany | 08/07/2014 |
| ACA Müller ADAG Pharma AG | 08/07/2014 | Synagis | 100 mg | Powder and solvent for solution for injection | 1 vial + 1 ampoule   | EU/1/99/117/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom | Germany | 14/07/2014 |
| European Pharma B.V.      | 14/03/2014 | Synagis | 100 mg | Powder and solvent for solution for injection | 1 vial + 1 ampoule   | EU/1/99/117/002 | Austria, Belgium, Czech Republic, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                                             | Germany | 23/07/2014 |
| Orifarm OY                | 21/05/2014 | Synagis | 50 mg  | Powder and solvent for solution for injection | 1 vial + 1 ampoule   | EU/1/99/117/001 | Austria, Belgium, Cyprus, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                  | Finland | 23/07/2014 |
| Canoma Pharma GmbH        | 29/07/2014 | Tarceva | 100 mg | Film-coated tablet                            | 30 tablets           | EU/1/05/311/002 | Austria, Belgium, Czech Republic, Denmark, Finland, France, Greece, Hungary, Italy, Norway, Portugal, Romania, Slovak Republic, Spain, Sweden, The Netherlands, United Kingdom                           | Germany | 31/07/2014 |

|                     |            |                    |               |                                 |                                 |                 |                                                                                                                                                                                                                                                                                              |                 |            |
|---------------------|------------|--------------------|---------------|---------------------------------|---------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|------------|
| Canoma Pharma GmbH  | 03/07/2014 | Tarceva            | 150 mg        | Film-coated tablet              | 30 tablets                      | EU/1/05/311/003 | Czech Republic, Hungary, Romania, Slovak Republic                                                                                                                                                                                                                                            | Germany         | 24/07/2014 |
| Orifarm GmbH        | 23/05/2014 | Tasigna            | 200 mg        | Capsule, hard                   | 112 capsules (4x28) (multipack) | EU/1/07/422/008 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Romania, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                           | Germany         | 08/07/2014 |
| Dr Fisher Farma BV  | 18/07/2014 | Tovanor Breezhaler | 50 micrograms | Inhalation powder, hard capsule | 30 capsules + 1 inhaler         | EU/1/12/790/003 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, United Kingdom                                                                                                              | The Netherlands | 23/07/2014 |
| axicorp Pharma GmbH | 25/07/2014 | Toviaz             | 4 mg          | Prolonged-release tablet        | 56 tablets                      | EU/1/07/386/004 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany         | 28/07/2014 |

|                     |            |         |                 |                          |                   |                 |                                                                                                                                                                                                                                                                                              |         |            |
|---------------------|------------|---------|-----------------|--------------------------|-------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| axicorp Pharma GmbH | 08/04/2014 | Toviaz  | 8 mg            | Prolonged-release tablet | 28 tablets        | EU/1/07/386/008 | 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 | 29/07/2014 |
| axicorp Pharma GmbH | 08/04/2014 | Toviaz  | 8 mg            | Prolonged-release tablet | 56 tablets        | EU/1/07/386/009 | 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 | 29/07/2014 |
| NewNeopharm BV      | 18/07/2014 | Tresiba | 100 U/ml        | Solution for injection   | 5 pre-filled pens | EU/1/12/807/004 | Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                      | Denmark | 23/07/2014 |
| Canoma Pharma GmbH  | 24/07/2014 | Truvada | 200 mg / 245 mg | Film-coated tablet       | 30 tablets        | EU/1/04/305/001 | Czech Republic, Slovak Republic                                                                                                                                                                                                                                                              | Germany | 25/07/2014 |

|                                  |            |                    |                 |                          |                                                     |                 |                                                                                                                                                                                                                                                                                              |         |            |
|----------------------------------|------------|--------------------|-----------------|--------------------------|-----------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| Northern Medical Group ApS.      | 01/07/2014 | Truvada            | 200 mg / 245 mg | Film-coated tablet       | 30 tablets                                          | EU/1/04/305/001 | 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  | 03/07/2014 |
| Shipping Dynamics Scandinavia AB | 11/07/2014 | Truvada            | 200 mg / 245 mg | Film-coated tablet       | 30 tablets                                          | EU/1/04/305/001 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, The Netherlands, United Kingdom                                                                                                     | Sweden  | 23/07/2014 |
| CC Pharma                        | 03/07/2014 | Twinrix Paediatric | --              | Suspension for injection | 1 pre-filled syringe + 2 separate needles x 10 pack | EU/1/97/029/010 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                         | Germany | 07/07/2014 |
| axicorp Pharma B.V.              | 27/06/2014 | Tyverb             | 250 mg          | Film-coated tablet       | 70 tablets                                          | EU/1/07/440/004 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany | 14/07/2014 |

|                    |            |                    |                 |                                          |                                              |                 |                                                                                                                                                                                                                                                                                                              |                 |            |
|--------------------|------------|--------------------|-----------------|------------------------------------------|----------------------------------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|------------|
| Medartuum AB       | 27/06/2014 | Ultibro Breezhaler | 85 mcg / 43 mcg | Inhalation powder, hard capsule          | 90 (3 packs of 30 x 1) capsules + 3 inhalers | EU/1/13/862/004 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, The Netherlands, United Kingdom | Sweden          | 03/07/2014 |
| Dr Fisher Farma BV | 23/06/2014 | Vectibix           | 20 mg/ml        | Concentrate for solution for infusion    | 1 vial                                       | EU/1/07/423/003 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, United Kingdom                                                                                                                              | The Netherlands | 03/07/2014 |
| HAEMATO PHARM GmbH | 28/07/2014 | Vectibix           | 20 mg/ml        | Concentrate for solution for infusion    | 1 vial                                       | EU/1/07/423/003 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom           | Germany         | 30/07/2014 |
| CC Pharma          | 13/06/2014 | Victoza            | 6 mg/ml         | Solution for injection in pre-filled pen | 2 pre-filled pens                            | EU/1/09/529/002 | Norway                                                                                                                                                                                                                                                                                                       | Germany         | 02/07/2014 |
| CC Pharma          | 13/06/2014 | Victoza            | 6 mg/ml         | Solution for injection in pre-filled pen | 10 pre-filled pens                           | EU/1/09/529/005 | Norway                                                                                                                                                                                                                                                                                                       | Germany         | 02/07/2014 |

|                               |            |         |          |                    |             |                 |                                                                                                                                                                                                  |                         |            |
|-------------------------------|------------|---------|----------|--------------------|-------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| Eurim-Pharm Arzneimittel GmbH | 23/07/2014 | Vimpat  | 10 mg/ml | Syrup              | 1 bottle    | EU/1/08/470/018 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                             | Germany                 | 25/07/2014 |
| Orifarm GmbH                  | 16/07/2014 | Vimpat  | 10 mg/ml | Syrup              | 1 bottle    | EU/1/08/470/018 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                        | Germany                 | 17/07/2014 |
| B&S Healthcare Ltd            | 14/07/2014 | Vimpat  | 50 mg    | Film-coated tablet | 14 tablets  | EU/1/08/470/001 | 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 | 23/07/2014 |
| Canoma Pharma GmbH            | 24/07/2014 | Viread  | 245 mg   | Film-coated tablet | 30 tablets  | EU/1/01/200/001 | Czech Republic, Slovak Republic                                                                                                                                                                  | Germany                 | 25/07/2014 |
| Eureco-Pharma B.V.            | 14/07/2014 | XALKORI | 250 mg   | Capsule, hard      | 60 capsules | EU/1/12/793/003 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, United Kingdom                  | The Netherlands         | 17/07/2014 |

|                |            |         |       |                    |            |                 |                                                                                                                                                                                                                                                                                                             |                         |            |
|----------------|------------|---------|-------|--------------------|------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| B&S Healthcare | 18/06/2014 | Xarelto | 10 mg | Film-coated tablet | 30 tablets | EU/1/08/472/007 | 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 | 25/07/2014 |
| G-Pharma Ltd   | 18/07/2014 | Xarelto | 10 mg | Film-coated tablet | 30 tablets | EU/1/08/472/007 | 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 | 23/07/2014 |
| B&S Healthcare | 18/06/2014 | Xarelto | 15 mg | Film-coated tablet | 28 tablets | EU/1/08/472/012 | 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 | 25/07/2014 |
| CC Pharma      | 14/03/2014 | Xarelto | 15 mg | Film-coated tablet | 14 tablets | EU/1/08/472/011 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Poland, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                | Germany                 | 21/07/2014 |

|                                     |            |         |       |                    |            |                 |                                                                                                                                                                                                                                                                                                             |                                |            |
|-------------------------------------|------------|---------|-------|--------------------|------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|------------|
| Chemilines Ltd,                     | 02/07/2014 | Xarelto | 15 mg | Film-coated tablet | 28 tablets | EU/1/08/472/012 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Spain, Sweden, The Netherlands                                                                     | Ireland, United Kingdom        | 17/07/2014 |
| Doncaster Pharmaceuticals Group Ltd | 27/06/2014 | Xarelto | 15 mg | Film-coated tablet | 28 tablets | EU/1/08/472/012 | 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, Malta, United Kingdom | 22/07/2014 |
| FD Pharma GmbH                      | 18/06/2014 | Xarelto | 15 mg | Film-coated tablet | 98 tablets | EU/1/08/472/014 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Norway, Poland, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                       | Germany                        | 24/07/2014 |
| Ginova Ltd                          | 01/07/2014 | Xarelto | 15 mg | Film-coated tablet | 28 tablets | EU/1/08/472/012 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands                                                  | United Kingdom                 | 09/07/2014 |

|                             |            |         |       |                    |            |                 |                                                                                                                                                                                                                                                                                                             |                         |            |
|-----------------------------|------------|---------|-------|--------------------|------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| O.P.D. Laboratories Ltd     | 07/07/2014 | Xarelto | 15 mg | Film-coated tablet | 28 tablets | EU/1/08/472/012 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                           | United Kingdom          | 11/07/2014 |
| Swingward Ltd TA Medihealth | 18/07/2014 | Xarelto | 15 mg | Film-coated tablet | 28 tablets | EU/1/08/472/012 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands                                             | United Kingdom          | 23/07/2014 |
| B&S Healthcare              | 18/06/2014 | Xarelto | 20 mg | Film-coated tablet | 28 tablets | EU/1/08/472/018 | 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 | 25/07/2014 |
| CC Pharma                   | 14/03/2014 | Xarelto | 20 mg | Film-coated tablet | 14 tablets | EU/1/08/472/017 | Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                        | Germany                 | 21/07/2014 |

|                                     |            |         |       |                    |            |                 |                                                                                                                                                                                                                                                                                                             |                                |            |
|-------------------------------------|------------|---------|-------|--------------------|------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|------------|
| Doncaster Pharmaceuticals Group Ltd | 27/06/2014 | Xarelto | 20 mg | Film-coated tablet | 28 tablets | EU/1/08/472/018 | 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 | 22/07/2014 |
| FD Pharma GmbH                      | 20/06/2014 | Xarelto | 20 mg | Film-coated tablet | 98 tablets | EU/1/08/472/019 | Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Norway, Poland, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                       | Germany                        | 25/07/2014 |
| O.P.D. Laboratories Ltd             | 07/07/2014 | Xarelto | 20 mg | Film-coated tablet | 28 tablets | EU/1/08/472/018 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                                           | United Kingdom                 | 11/07/2014 |
| Swingward Ltd TA Medihealth         | 18/07/2014 | Xarelto | 20 mg | Film-coated tablet | 28 tablets | EU/1/08/472/018 | Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands                                             | United Kingdom                 | 23/07/2014 |

|                     |            |         |        |                    |            |                 |                                                                                                                                                                                                                                                                                                             |                         |            |
|---------------------|------------|---------|--------|--------------------|------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| B&S Healthcare      | 10/07/2014 | Xelevia | 100 mg | Film-coated tablet | 28 tablets | EU/1/07/382/014 | 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, The Netherlands, United Kingdom | Ireland, United Kingdom | 17/07/2014 |
| BeachCourse Limited | 24/07/2014 | Xelevia | 100 mg | Film-coated tablet | 28 tablets | EU/1/07/382/014 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands                                                                                                                            | United Kingdom          | 28/07/2014 |
| Chemilines Ltd      | 21/07/2014 | Xelevia | 100 mg | Film-coated tablet | 28 tablets | EU/1/07/382/014 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands                                         | Ireland, United Kingdom | 25/07/2014 |

|                   |            |         |       |                    |            |                 |                                                                                                                                                                                                                                                                                                             |                         |            |
|-------------------|------------|---------|-------|--------------------|------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| B&S Healthcare    | 10/07/2014 | Xelevia | 25 mg | Film-coated tablet | 28 tablets | EU/1/07/382/002 | 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 | 17/07/2014 |
| Lexon (UK) Ltd    | 26/06/2014 | Xelevia | 25 mg | Film-coated tablet | 28 tablets | EU/1/07/382/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, United Kingdom                                                                                                                             | Ireland, United Kingdom | 01/07/2014 |
| Pharma Gerke GmbH | 18/03/2014 | Xelevia | 25 mg | Film-coated tablet | 98 tablets | EU/1/07/382/005 | Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                                                                                                 | Germany                 | 04/07/2014 |
| B&S Healthcare    | 10/07/2014 | Xelevia | 50 mg | Film-coated tablet | 28 tablets | EU/1/07/382/008 | 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 | 17/07/2014 |

|                           |            |         |        |                                            |                                  |                 |                                                                                                                                                                                                                                                                                                             |                         |            |
|---------------------------|------------|---------|--------|--------------------------------------------|----------------------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|
| Dr Fisher Farma BV        | 18/06/2014 | 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, United Kingdom                                                                                                                             | The Netherlands         | 25/07/2014 |
| Lexon (UK) Ltd            | 26/06/2014 | 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, United Kingdom                                                                                                                             | Ireland, United Kingdom | 01/07/2014 |
| ACA Müller ADAG Pharma AG | 23/07/2014 | Xeplion | 100 mg | Prolonged-release suspension for injection | 1 pre-filled syringe + 2 needles | EU/1/11/672/004 | Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                                                                                          | Germany                 | 29/07/2014 |
| ABACUS MEDICINE A/S       | 09/07/2014 | Xeplion | 75 mg  | Prolonged-release suspension for injection | 1 pre-filled syringe + 2 needles | EU/1/11/672/003 | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, United Kingdom | Germany                 | 31/07/2014 |

|                 |            |          |                 |                                                  |                                     |                 |                                                                                                                                                                                         |                 |            |
|-----------------|------------|----------|-----------------|--------------------------------------------------|-------------------------------------|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|------------|
| Emra-Med        | 24/07/2014 | Xtandi   | 40 mg           | Capsule, soft                                    | 112 capsules                        | EU/1/13/846/001 | Austria                                                                                                                                                                                 | Germany         | 28/07/2014 |
| kohlpharma GmbH | 04/07/2014 | Yondelis | 0.25 mg         | Powder for concentrate for solution for infusion | 1 vial                              | EU/1/07/417/001 | Austria, Belgium, Bulgaria, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                          | Germany         | 07/07/2014 |
| kohlpharma GmbH | 04/07/2014 | Yondelis | 1 mg            | Powder for concentrate for solution for infusion | 1 vial                              | EU/1/07/417/002 | Austria, Belgium, Bulgaria, Denmark, Finland, France, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom                                          | Germany         | 07/07/2014 |
| NL Pharma BV    | 14/05/2014 | Zoely    | 2.5 mg / 1.5 mg | Film-coated tablet                               | 84 tablets (72 active + 12 placebo) | EU/1/11/690/002 | Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Poland, Portugal, Spain, Sweden, United Kingdom | The Netherlands | 18/07/2014 |