

Produkty lecznicze – Wykaz pozwoleń na dopuszczenie do obrotu udzielonych w drugim półroczu 2015 r. przez państwa EFTA należące do EOG

(2016/C 347/05)

Podkomitet I ds. Swobodnego Przepływu Towarów

Do wiadomości Wspólnego Komitetu EOG

W nawiązaniu do decyzji Wspólnego Komitetu EOG nr 74/1999 z dnia 28 maja 1999 r. Wspólnemu Komitetowi EOG przekazuje się celem przyjęcia do wiadomości na posiedzeniu w dniu 18 marca 2016 r. następujące wykazy dotyczące pozwoleń na dopuszczenie do obrotu produktów leczniczych za okres od dnia 1 lipca do dnia 31 grudnia 2015 r.:

- Załącznik I Wykaz nowych pozwoleń na dopuszczenie do obrotu
 - Załącznik II Wykaz odnowionych pozwoleń na dopuszczenie do obrotu
 - Załącznik III Wykaz przedłużonych pozwoleń na dopuszczenie do obrotu
 - Załącznik IV Wykaz wycofanych pozwoleń na dopuszczenie do obrotu
 - Załącznik V Wykaz zawieszonych pozwoleń na dopuszczenie do obrotu
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ZAŁĄCZNIK I

Wykaz nowych pozwoleń na dopuszczenie do obrotu

W okresie **od dnia 1 lipca do dnia 31 grudnia 2015 r.** udzielone zostały następujące pozwolenia na dopuszczenie do obrotu w państwach EFTA należących do EOG:

| Numer UE | Produkt | Państwo | Data udzielenia zezwolenia |
|--------------|--|---------------|----------------------------|
| EU/1/11/710 | Votubia (przejście do bezwarunkowego pozwolenia) | Liechtenstein | 31.12.2015 |
| EU/1/13/895 | Kolbam | Islandia | 14.12.2015 |
| EU/1/13/895 | Kolbam | Norwegia | 15.12.2015 |
| EU/1/13/895 | Kolbam | Liechtenstein | 31.12.2015 |
| EU/1/15/1005 | Aripiprazole Pharmathen | Islandia | 23.7.2015 |
| EU/1/15/1005 | Aripiprazole Pharmathen | Liechtenstein | 31.8.2015 |
| EU/1/15/1005 | Aripiprazole Pharmathen | Norwegia | 16.7.2015 |
| EU/1/15/1006 | Respreeza | Islandia | 31.8.2015 |
| EU/1/15/1006 | Respreeza | Liechtenstein | 31.8.2015 |
| EU/1/15/1006 | Respreeza | Norwegia | 28.8.2015 |
| EU/1/15/1007 | Gardasil 9 | Islandia | 8.7.2015 |
| EU/1/15/1008 | Hetlioz | Islandia | 4.8.2015 |
| EU/1/15/1008 | Hetlioz | Liechtenstein | 31.8.2015 |
| EU/1/15/1008 | Hetlioz | Norwegia | 16.7.2015 |
| EU/1/15/1009 | Aripiprazole Zentiva | Islandia | 23.7.2015 |
| EU/1/15/1009 | Aripiprazole Zentiva | Norwegia | 16.7.2015 |
| EU/1/15/1010 | Duloxetine Mylan | Islandia | 9.7.2015 |
| EU/1/15/1010 | Duloxetine Mylan | Norwegia | 9.7.2015 |
| EU/1/15/1011 | Pregabalin Sandoz | Islandia | 10.7.2015 |
| EU/1/15/1011 | Pregabalin Sandoz | Norwegia | 17.7.2015 |
| EU/1/15/1012 | Pregabalin Sandoz GmbH | Islandia | 10.7.2015 |
| EU/1/15/1012 | Pregabalin Sandoz GmbH | Norwegia | 17.7.2015 |
| EU/1/15/1013 | Lumark | Norwegia | 13.7.2015 |
| EU/1/15/1013 | Lumark | Islandia | 10.7.2015 |
| EU/1/15/1014 | OPDIVO | Islandia | 10.7.2015 |
| EU/1/15/1014 | Opdivo | Norwegia | 2.7.2015 |
| EU/1/15/1015 | Strensiq | Islandia | 10.9.2015 |

| Numer UE | Produkt | Państwo | Data udzielenia zezwolenia |
|--------------|------------------------------|---------------|----------------------------|
| EU/1/15/1015 | Strensiq | Liechtenstein | 31.10.2015 |
| EU/1/15/1015 | Strensiq | Norwegia | 14.9.2015 |
| EU/1/15/1016 | Repatha | Islandia | 14.8.2015 |
| EU/1/15/1016 | Repatha | Liechtenstein | 31.8.2015 |
| EU/1/15/1016 | Repatha | Norwegia | 5.8.2015 |
| EU/1/15/1017 | Docetaxel Hospira UK Limited | Islandia | 4.9.2015 |
| EU/1/15/1017 | Docetaxel Hospira UK limited | Liechtenstein | 31.10.2015 |
| EU/1/15/1017 | Docetaxel Hospira UK Limited | Norwegia | 7.9.2015 |
| EU/1/15/1018 | Omidria | Islandia | 19.8.2015 |
| EU/1/15/1018 | Omidria | Liechtenstein | 31.8.2015 |
| EU/1/15/1018 | Omidria | Norwegia | 26.8.2015 |
| EU/1/15/1019 | Bortezomib Accord | Islandia | 19.8.2015 |
| EU/1/15/1019 | Bortezomib Accord | Liechtenstein | 31.8.2015 |
| EU/1/15/1019 | Bortezomib Accord | Norwegia | 11.8.2015 |
| EU/1/15/1020 | Raxone | Islandia | 15.9.2015 |
| EU/1/15/1020 | Raxone | Liechtenstein | 31.10.2015 |
| EU/1/15/1020 | Raxone | Norwegia | 30.9.2015 |
| EU/1/15/1021 | Pregabalin Zentiva | Islandia | 14.8.2015 |
| EU/1/15/1021 | Pregabalin Zentiva | Liechtenstein | 31.8.2015 |
| EU/1/15/1021 | Pregabalin Zentiva | Norwegia | 10.8.2015 |
| EU/1/15/1022 | Unituxin | Islandia | 21.8.2015 |
| EU/1/15/1022 | Unituxin | Liechtenstein | 31.8.2015 |
| EU/1/15/1022 | Unituxin | Norwegia | 25.8.2015 |
| EU/1/15/1023 | Farydak | Islandia | 4.9.2015 |
| EU/1/15/1023 | Farydak | Liechtenstein | 31.10.2015 |
| EU/1/15/1023 | Farydak | Norwegia | 7.9.2015 |
| EU/1/15/1024 | KEYTRUDA | Islandia | 13.8.2015 |
| EU/1/15/1024 | KEYTRUDA | Liechtenstein | 31.8.2015 |
| EU/1/15/1024 | KEYTRUDA | Norwegia | 11.8.2015 |
| EU/1/15/1025 | Evotaz | Islandia | 12.8.2015 |
| EU/1/15/1025 | EVOTAZ | Liechtenstein | 31.8.2015 |
| EU/1/15/1025 | EVOTAZ | Norwegia | 10.8.2015 |

| Numer UE | Produkt | Państwo | Data udzielenia zezwolenia |
|--------------|---------------------|---------------|----------------------------|
| EU/1/15/1026 | Nivolumab BMS | Islandia | 28.12.2015 |
| EU/1/15/1026 | Nivolumab BMS | Liechtenstein | 31.8.2015 |
| EU/1/15/1026 | Nivolumab BMS | Norwegia | 11.8.2015 |
| EU/1/15/1027 | Pregabalin Accord | Islandia | 2.9.2015 |
| EU/1/15/1027 | Pregabalin Accord | Liechtenstein | 31.10.2015 |
| EU/1/15/1027 | Pregabalin Accord | Norwegia | 7.9.2015 |
| EU/1/15/1028 | Duloxetine Zentiva | Islandia | 31.8.2015 |
| EU/1/15/1028 | Duloxetine Zentiva | Liechtenstein | 31.8.2015 |
| EU/1/15/1028 | Duloxetine Zentiva | Norwegia | 23.9.2015 |
| EU/1/15/1029 | Aripiprazole Sandoz | Islandia | 31.8.2015 |
| EU/1/15/1029 | Aripiprazole Sandoz | Liechtenstein | 31.8.2015 |
| EU/1/15/1029 | Aripiprazole Sandoz | Norwegia | 25.8.2015 |
| EU/1/15/1030 | Odomzo | Islandia | 1.9.2015 |
| EU/1/15/1030 | Odomzo | Liechtenstein | 31.8.2015 |
| EU/1/15/1030 | Odomzo | Norwegia | 4.9.2015 |
| EU/1/15/1031 | Praluent | Islandia | 16.10.2015 |
| EU/1/15/1031 | Praluent | Liechtenstein | 31.10.2015 |
| EU/1/15/1031 | Praluent | Norwegia | 1.10.2015 |
| EU/1/15/1032 | Zerbaxa | Islandia | 23.9.2015 |
| EU/1/15/1032 | Zerbaxa | Liechtenstein | 31.10.2015 |
| EU/1/15/1032 | Zerbaxa | Norwegia | 13.10.2015 |
| EU/1/15/1033 | Kanuma | Islandia | 2.9.2015 |
| EU/1/15/1033 | Kanuma | Liechtenstein | 31.8.2015 |
| EU/1/15/1033 | Kanuma | Norwegia | 10.9.2015 |
| EU/1/15/1034 | Pemetrexed Lilly | Islandia | 21.9.2015 |
| EU/1/15/1034 | Pemetrexed Lilly | Liechtenstein | 31.10.2015 |
| EU/1/15/1034 | Pemetrexed Lilly | Norwegia | 21.9.2015 |
| EU/1/15/1035 | Obizur | Islandia | 18.11.2015 |
| EU/1/15/1035 | Obizur | Norwegia | 30.11.2015 |
| EU/1/15/1035 | Obizur | Liechtenstein | 31.12.2015 |
| EU/1/15/1036 | CRESEMBA | Islandia | 23.10.2015 |
| EU/1/15/1036 | Cresemba | Liechtenstein | 31.10.2015 |

| Numer UE | Produkt | Państwo | Data udzielenia zezwolenia |
|--------------|---------------------|---------------|----------------------------|
| EU/1/15/1036 | Cresemba | Norwegia | 11.11.2015 |
| EU/1/15/1037 | Pemetrexed Sandoz | Islandia | 15.10.2015 |
| EU/1/15/1037 | Pemetrexed Sandoz | Liechtenstein | 31.10.2015 |
| EU/1/15/1037 | Pemetrexed Sandoz | Norwegia | 24.9.2015 |
| EU/1/15/1038 | Pemetrexed medac | Islandia | 11.12.2015 |
| EU/1/15/1038 | Pemetrexed medac | Norwegia | 14.12.2015 |
| EU/1/15/1038 | Pemetrexed medac | Liechtenstein | 31.12.2015 |
| EU/1/15/1039 | Fexeric | Islandia | 16.10.2015 |
| EU/1/15/1039 | Fexeric | Liechtenstein | 31.10.2015 |
| EU/1/15/1039 | Fexeric | Norwegia | 13.10.2015 |
| EU/1/15/1040 | Intuniv | Islandia | 21.9.2015 |
| EU/1/15/1040 | Intuniv | Liechtenstein | 31.10.2015 |
| EU/1/15/1040 | Intuniv | Norwegia | 23.9.2015 |
| EU/1/15/1041 | Ivabradine Anpharm | Islandia | 15.10.2015 |
| EU/1/15/1041 | Ivabradine Anpharm | Liechtenstein | 31.10.2015 |
| EU/1/15/1041 | Ivabradine Anpharm | Norwegia | 1.10.2015 |
| EU/1/15/1042 | Zalviso | Liechtenstein | 31.10.2015 |
| EU/1/15/1042 | Zalviso | Islandia | 16.10.2015 |
| EU/1/15/1042 | Zalviso | Norwegia | 13.10.2015 |
| EU/1/15/1043 | Nucala | Islandia | 29.12.2015 |
| EU/1/15/1043 | Nucala | Norwegia | 10.12.2015 |
| EU/1/15/1043 | Nucala | Liechtenstein | 31.12.2015 |
| EU/1/15/1044 | Numient | Islandia | 14.12.2015 |
| EU/1/15/1044 | Numient | Norwegia | 22.12.2015 |
| EU/1/15/1044 | Numient | Liechtenstein | 31.12.2015 |
| EU/1/15/1045 | Aripiprazole Accord | Islandia | 20.11.2015 |
| EU/1/15/1045 | Aripiprazole Accord | Norwegia | 3.12.2015 |
| EU/1/15/1045 | Aripiprazole Accord | Liechtenstein | 31.12.2015 |
| EU/1/15/1046 | Elocta | Islandia | 11.12.2015 |
| EU/1/15/1046 | Elocta | Norwegia | 17.12.2015 |
| EU/1/15/1046 | Elocta | Liechtenstein | 31.12.2015 |
| EU/1/15/1047 | Blinicyto | Islandia | 23.12.2015 |

| Numer UE | Produkt | Państwo | Data udzielenia zezwolenia |
|--------------|--------------------|---------------|----------------------------|
| EU/1/15/1047 | Blinicyto | Norwegia | 1.12.2015 |
| EU/1/15/1047 | Blinicyto | Liechtenstein | 31.12.2015 |
| EU/1/15/1048 | Cotellic | Islandia | 11.12.2015 |
| EU/1/15/1048 | Cotellic | Norwegia | 30.11.2015 |
| EU/1/15/1048 | Cotellic | Liechtenstein | 31.12.2015 |
| EU/1/15/1050 | Ionsys | Islandia | 24.11.2015 |
| EU/1/15/1050 | IONSYS | Norwegia | 10.12.2015 |
| EU/1/15/1050 | IONSYS | Liechtenstein | 31.12.2015 |
| EU/1/15/1051 | Ebymect | Islandia | 23.11.2015 |
| EU/1/15/1051 | Ebymect | Norwegia | 10.12.2015 |
| EU/1/15/1051 | Ebymect | Liechtenstein | 31.12.2015 |
| EU/1/15/1052 | Edistride | Islandia | 17.11.2015 |
| EU/1/15/1052 | Edistride | Norwegia | 3.12.2015 |
| EU/1/15/1052 | Edistride | Liechtenstein | 31.12.2015 |
| EU/1/15/1054 | Cinacalcet Mylan | Islandia | 24.11.2015 |
| EU/1/15/1054 | Cinacalcet Mylan | Norwegia | 30.11.2015 |
| EU/1/15/1054 | Cinacalcet Mylan | Liechtenstein | 31.12.2015 |
| EU/1/15/1055 | CIAMBRA | Islandia | 29.12.2015 |
| EU/1/15/1055 | Ciambra | Norwegia | 10.12.2015 |
| EU/1/15/1055 | Ciambra | Liechtenstein | 31.12.2015 |
| EU/1/15/1056 | Praxbind | Islandia | 11.12.2015 |
| EU/1/15/1056 | Praxbind | Norwegia | 10.12.2015 |
| EU/1/15/1056 | Praxbind | Liechtenstein | 31.12.2015 |
| EU/1/15/1057 | Pemetrexed Hospira | Islandia | 11.12.2015 |
| EU/1/15/1057 | Pemetrexed Hospira | Norwegia | 1.12.2015 |
| EU/1/15/1057 | Pemetrexed Hospira | Liechtenstein | 31.12.2015 |
| EU/1/15/1058 | Entresto | Islandia | 11.12.2015 |
| EU/1/15/1058 | Entresto | Norwegia | 26.11.2015 |
| EU/1/15/1058 | Entresto | Liechtenstein | 31.12.2015 |
| EU/1/15/1059 | Orkambi | Islandia | 8.12.2015 |
| EU/1/15/1059 | Orkambi | Norwegia | 10.12.2015 |
| EU/1/15/1059 | Orkambi | Liechtenstein | 31.12.2015 |

| Numer UE | Produkt | Państwo | Data udzielenia zezwolenia |
|--------------|-------------------------|---------------|----------------------------|
| EU/1/15/1060 | Kyprolis | Islandia | 24.11.2015 |
| EU/1/15/1060 | Kyprolis | Norwegia | 1.12.2015 |
| EU/1/15/1060 | Kyprolis | Liechtenstein | 31.12.2015 |
| EU/1/15/1061 | Genvoya | Islandia | 9.12.2015 |
| EU/1/15/1061 | Genvoya | Norwegia | 10.12.2015 |
| EU/1/15/1061 | Genvoya | Liechtenstein | 31.12.2015 |
| EU/1/15/1062 | Ravicti | Islandia | 15.12.2015 |
| EU/1/15/1062 | Ravicti | Norwegia | 10.12.2015 |
| EU/1/15/1062 | Ravicti | Liechtenstein | 31.12.2015 |
| EU/1/15/993 | Lixiana | Islandia | 10.7.2015 |
| EU/1/15/993 | Lixiana | Norwegia | 6.7.2015 |
| EU/1/15/997 | Pregabalin Mylan | Islandia | 13.7.2015 |
| EU/1/15/997 | Pregabalin Mylan | Liechtenstein | 31.8.2015 |
| EU/1/15/997 | Pregabalin Mylan | Norwegia | 16.7.2015 |
| EU/1/15/998 | Pregabalin Mylan Pharma | Islandia | 13.7.2015 |
| EU/1/15/998 | Pregabalin Mylan Pharma | Liechtenstein | 31.8.2015 |
| EU/1/15/998 | Pregabalin Mylan Pharma | Norwegia | 16.7.2015 |
| EU/2/15/181 | Sileo | Islandia | 8.7.2015 |
| EU/2/15/182 | Innovax ILT | Liechtenstein | 31.8.2015 |
| EU/2/15/182 | Innovax-ILT | Islandia | 24.7.2015 |
| EU/2/15/182 | Innovax-ILT | Norwegia | 30.7.2015 |
| EU/2/15/183 | Canigen L4 | Islandia | 6.8.2015 |
| EU/2/15/183 | Canigen L4 | Liechtenstein | 31.8.2015 |
| EU/2/15/183 | Canigen L4 | Norwegia | 30.7.2015 |
| EU/2/15/184 | UpCard | Islandia | 20.8.2015 |
| EU/2/15/184 | UpCard | Liechtenstein | 31.10.2015 |
| EU/2/15/184 | UpCard | Norwegia | 10.8.2015 |
| EU/2/15/185 | Fortekor Plus | Islandia | 21.9.2015 |
| EU/2/15/185 | FORTEKOR PLUS | Liechtenstein | 31.10.2015 |
| EU/2/15/185 | Fortekor Plus | Norwegia | 6.10.2015 |
| EU/2/15/186 | Novaquin | Islandia | 15.9.2015 |
| EU/2/15/186 | Novaquin | Liechtenstein | 31.10.2015 |

| Numer UE | Produkt | Państwo | Data udzielenia zezwolenia |
|-------------|------------------------|---------------|----------------------------|
| EU/2/15/186 | Novaquin | Norwegia | 6.10.2015 |
| EU/2/15/187 | Porcilis PCV ID | Islandia | 2.9.2015 |
| EU/2/15/187 | Porcilis PCV ID | Liechtenstein | 31.10.2015 |
| EU/2/15/187 | Porcilis PCV ID | Norwegia | 9.9.2015 |
| EU/2/15/188 | Vectormune ND | Islandia | 21.9.2015 |
| EU/2/15/188 | Vectormune ND | Liechtenstein | 31.10.2015 |
| EU/2/15/188 | Vectormune ND | Norwegia | 6.10.2015 |
| EU/2/15/189 | Zycortal | Islandia | 20.11.2015 |
| EU/2/15/189 | Zycortal | Norwegia | 3.12.2015 |
| EU/2/15/189 | Zycortal | Liechtenstein | 31.12.2015 |
| EU/2/15/190 | Suvaxyn Circo + MH RTU | Norwegia | 4.12.2015 |
| EU/2/15/190 | Suvaxyn Circo + MH RTU | Liechtenstein | 31.12.2015 |
| EU/2/15/190 | Suvaxyn Circo+MH RTU | Islandia | 16.11.2015 |
| EU/2/15/191 | Simparica | Islandia | 20.11.2015 |
| EU/2/15/191 | Simparica | Norwegia | 4.12.2015 |
| EU/2/15/191 | Simparica | Liechtenstein | 31.12.2015 |
| EU/2/15/192 | Velactis | Islandia | 30.12.2015 |
| EU/2/15/192 | Velactis | Liechtenstein | 31.12.2015 |
| EU/2/15/193 | Imrestor | Liechtenstein | 31.12.2015 |

ZAŁĄCZNIK II

Wykaz odnowionych pozwoleń na dopuszczenie do obrotu

W okresie **od dnia 1 lipca do dnia 31 grudnia 2015 r.** odnowiono następujące pozwolenia na dopuszczenie do obrotu w państwach EFTA należących do EOG:

| Numer UE | Produkt | Państwo | Data udzielenia zezwolenia |
|-------------|----------------------|---------------|----------------------------|
| EU/1/00/146 | Keppra | Islandia | 31.8.2015 |
| EU/1/00/146 | Keppra | Liechtenstein | 31.10.2015 |
| EU/1/00/146 | Keppra | Norwegia | 8.9.2015 |
| EU/1/05/310 | Fosavance | Islandia | 24.8.2015 |
| EU/1/05/312 | Xyrem | Islandia | 15.10.2015 |
| EU/1/05/312 | Xyrem | Liechtenstein | 31.10.2015 |
| EU/1/05/312 | Xyrem | Norwegia | 14.10.2015 |
| EU/1/05/315 | Aptivus | Islandia | 10.7.2015 |
| EU/1/05/315 | Aptivus | Norwegia | 2.7.2015 |
| EU/1/05/319 | Xolair | Islandia | 9.7.2015 |
| EU/1/05/319 | Xolair | Norwegia | 7.7.2015 |
| EU/1/05/323 | ProQuad | Liechtenstein | 31.12.2015 |
| EU/1/05/325 | Macugen | Islandia | 9.12.2015 |
| EU/1/05/325 | Macugen | Norwegia | 30.11.2015 |
| EU/1/05/325 | Macugen | Liechtenstein | 31.12.2015 |
| EU/1/10/639 | Telmisartan Actavis | Islandia | 9.7.2015 |
| EU/1/10/639 | Telmisartan Actavis | Norwegia | 8.7.2015 |
| EU/1/10/641 | Ruconest | Islandia | 16.10.2015 |
| EU/1/10/641 | Ruconest | Norwegia | 14.10.2015 |
| EU/1/10/641 | Ruconest | Liechtenstein | 31.12.2015 |
| EU/1/10/642 | Ibandronic Acid Teva | Islandia | 9.7.2015 |
| EU/1/10/642 | Ibandronic Acid Teva | Norwegia | 16.7.2015 |
| EU/1/10/644 | PecFent | Islandia | 27.8.2015 |
| EU/1/10/644 | PecFent | Norwegia | 10.8.2015 |
| EU/1/10/645 | Brinavess | Islandia | 19.8.2015 |
| EU/1/10/645 | Brinavess | Liechtenstein | 31.8.2015 |
| EU/1/10/645 | Brinavess | Norwegia | 26.8.2015 |

| Numer UE | Produkt | Państwo | Data udzielenia zezwolenia |
|-------------|----------------------------|---------------|----------------------------|
| EU/1/10/646 | VPRIV | Islandia | 9.7.2015 |
| EU/1/10/646 | VPRIV | Norwegia | 7.7.2015 |
| EU/1/10/648 | Twynsta | Islandia | 1.9.2015 |
| EU/1/10/648 | Twynsta | Liechtenstein | 31.10.2015 |
| EU/1/10/648 | Twynsta | Norwegia | 8.9.2015 |
| EU/1/10/651 | Clopidogrel HCS | Islandia | 9.7.2015 |
| EU/1/10/651 | Clopidogrel HCS | Norwegia | 1.7.2015 |
| EU/1/10/654 | Leflunomide ratiopharm | Islandia | 10.7.2015 |
| EU/1/10/654 | Leflunomide ratiopharm | Norwegia | 2.7.2015 |
| EU/1/10/655 | Brilique | Islandia | 13.8.2015 |
| EU/1/10/655 | Brilique | Liechtenstein | 31.8.2015 |
| EU/1/10/655 | Brilique | Norwegia | 26.8.2015 |
| EU/1/10/658 | Aflunov | Islandia | 13.8.2015 |
| EU/1/10/658 | Aflunov | Liechtenstein | 31.8.2015 |
| EU/1/10/658 | Aflunov | Norwegia | 14.8.2015 |
| EU/1/10/659 | Iasibon | Norwegia | 20.10.2015 |
| EU/1/10/659 | Iasibon | Islandia | 14.10.2015 |
| EU/1/10/659 | Iasibon | Liechtenstein | 31.10.2015 |
| EU/1/10/660 | Potactasol | Islandia | 22.10.2015 |
| EU/1/10/660 | Potactasol | Liechtenstein | 31.10.2015 |
| EU/1/10/660 | Potactasol | Norwegia | 16.10.2015 |
| EU/1/10/663 | Lamivudine/Zidovudine Teva | Norwegia | 10.12.2015 |
| EU/1/10/663 | Lamivudine/Zidovudine Teva | Islandia | 9.12.2015 |
| EU/1/10/663 | Lamivudine/Zidovudine Teva | Liechtenstein | 31.12.2015 |
| EU/1/10/665 | Entacapone Teva | Islandia | 10.12.2015 |
| EU/1/10/665 | Entacapone Teva | Norwegia | 10.12.2015 |
| EU/1/10/665 | Entacapone Teva | Liechtenstein | 31.12.2015 |
| EU/1/11/667 | Esbriet | Islandia | 15.9.2015 |
| EU/1/11/667 | Esbriet | Liechtenstein | 31.10.2015 |
| EU/1/11/667 | Esbriet | Norwegia | 16.9.2015 |
| EU/1/11/669 | Teysuno | Islandia | 8.12.2015 |
| EU/1/11/669 | Teysuno | Norwegia | 1.12.2015 |

| Numer UE | Produkt | Państwo | Data udzielenia zezwolenia |
|-------------|------------------|---------------|----------------------------|
| EU/1/11/669 | Teysuno | Liechtenstein | 31.12.2015 |
| EU/1/11/672 | Xeplion | Liechtenstein | 31.12.2015 |
| EU/1/11/673 | Ifirmacombi | Islandia | 10.12.2015 |
| EU/1/11/673 | Ifirmacombi | Norwegia | 30.11.2015 |
| EU/1/11/673 | Ifirmacombi | Liechtenstein | 31.12.2015 |
| EU/1/11/676 | Jevtana | Islandia | 10.12.2015 |
| EU/1/11/676 | JEVTANA | Norwegia | 27.11.2015 |
| EU/1/11/676 | JEVTANA | Liechtenstein | 31.12.2015 |
| EU/1/11/677 | Gilenya | Islandia | 8.12.2015 |
| EU/1/11/677 | Gilenya | Norwegia | 27.11.2015 |
| EU/1/11/678 | Halaven | Islandia | 9.12.2015 |
| EU/1/11/678 | HALAVEN | Norwegia | 27.11.2015 |
| EU/1/11/678 | HALAVEN | Liechtenstein | 31.12.2015 |
| EU/1/11/699 | Fampyra | Islandia | 25.8.2015 |
| EU/1/11/699 | Fampyra | Liechtenstein | 31.8.2015 |
| EU/1/11/699 | Fampyra | Norwegia | 3.8.2015 |
| EU/1/11/710 | Votubia | Islandia | 19.8.2015 |
| EU/1/11/710 | Votubia | Liechtenstein | 31.8.2015 |
| EU/1/11/710 | Votubia | Norwegia | 14.8.2015 |
| EU/1/12/793 | XALKORI | Islandia | 13.8.2015 |
| EU/1/12/793 | Xalkori | Liechtenstein | 31.8.2015 |
| EU/1/12/793 | XALKORI | Norwegia | 17.8.2015 |
| EU/1/12/794 | ADCETRIS | Islandia | 15.10.2015 |
| EU/1/12/794 | ADCETRIS | Norwegia | 30.9.2015 |
| EU/1/12/794 | ADCETRIS | Liechtenstein | 31.12.2015 |
| EU/1/13/902 | Translarna | Islandia | 19.8.2015 |
| EU/1/13/902 | Translarna | Liechtenstein | 31.8.2015 |
| EU/1/13/902 | Translarna | Norwegia | 26.8.2016 |
| EU/1/14/987 | Holoclar | Norwegia | 17.12.2015 |
| EU/1/14/987 | Holoclar | Liechtenstein | 31.12.2015 |
| EU/2/05/055 | Equilis Te | Islandia | 9.7.2015 |
| EU/2/10/108 | BTVPUR ALSap 2-4 | Islandia | 20.8.2015 |

| Numer UE | Produkt | Państwo | Data udzielenia zezwolenia |
|-------------|----------------------------|---------------|----------------------------|
| EU/2/10/108 | BTVPUR ALSap 2-4 | Liechtenstein | 31.8.2015 |
| EU/2/10/108 | BTVPUR ALSap 2-4 | Norwegia | 10.8.2015 |
| EU/2/10/109 | Rhiniseng | Islandia | 23.7.2015 |
| EU/2/10/109 | Rhiniseng | Norwegia | 29.7.2015 |
| EU/2/10/110 | Coxevac | Islandia | 20.8.2015 |
| EU/2/10/110 | Coxevac | Liechtenstein | 31.8.2015 |
| EU/2/10/110 | Coxevac | Norwegia | 13.8.2015 |
| EU/2/10/111 | Meloxoral | Islandia | 15.9.2015 |
| EU/2/10/111 | Meloxoral | Liechtenstein | 31.10.2015 |
| EU/2/10/111 | Meloxoral | Norwegia | 6.10.2015 |
| EU/2/10/112 | BTVPUR ALSap 1 | Islandia | 15.9.2015 |
| EU/2/10/112 | BTVPUR ALSap 1 | Liechtenstein | 31.10.2015 |
| EU/2/10/112 | BTVPUR ALSap 1 | Norwegia | 6.10.2015 |
| EU/2/10/113 | BTVPUR ALSap 1-8 | Islandia | 15.9.2015 |
| EU/2/10/113 | BTVPUR ALSap 1-8 | Norwegia | 6.10.2015 |
| EU/2/10/114 | Hiprabovis IBR Marker Live | Islandia | 20.11.2015 |
| EU/2/10/114 | Hiprabovis IBR Marker Live | Norwegia | 3.12.2015 |
| EU/2/10/114 | Hiprabovis IBR Marker Live | Liechtenstein | 31.12.2015 |
| EU/2/10/117 | Purevax Rabies | Islandia | 30.12.2015 |
| EU/2/10/117 | Purevax Rabies | Norwegia | 18.12.2015 |
| EU/2/10/117 | Purevax Rabies | Liechtenstein | 31.12.2015 |

ZAŁĄCZNIK III

Wykaz przedłużonych pozwoleń na dopuszczenie do obrotu

W okresie **od dnia 1 lipca do dnia 31 grudnia 2015 r.** przedłużono następujące pozwolenia na dopuszczenie do obrotu w państwach EFTA należących do EOG:

| Numer UE | Produkt | Państwo | Data udzielenia zezwolenia |
|---------------------|----------|----------|----------------------------|
| EU/1/02/240/009-012 | Somavert | Islandia | 13.8.2015 |
| EU/1/02/240/009-012 | Somavert | Norwegia | 6.8.2015 |
| EU/1/04/303/005 | Orfadin | Islandia | 10.7.2015 |
| EU/1/04/303/005 | Orfadin | Norwegia | 13.7.2015 |
| EU/1/06/359/005-006 | Suboxone | Islandia | 20.11.2015 |
| EU/1/06/359/005-006 | Suboxone | Norwegia | 3.12.2015 |
| EU/1/12/782/003-004 | Kalydeco | Islandia | 8.12.2015 |
| EU/1/12/782/003-004 | Kalydeco | Norwegia | 10.12.2015 |
| EU/1/12/782/006 | Iclusig | Norwegia | 14.12.2015 |
| EU/1/13/839/006 | Iclusig | Islandia | 23.12.2015 |
| EU/1/96/016/009 | Norvir | Islandia | 2.9.2015 |
| EU/1/96/016/009 | Norvir | Norwegia | 8.9.2015 |
| EU/2/11/134/021 | Inflacam | Islandia | 30.12.2015 |
| EU/2/11/134/021 | Inflacam | Norwegia | 30.12.2015 |

ZAŁĄCZNIK IV

Wykaz wycofanych pozwoleń na dopuszczenie do obrotu

W okresie **od dnia 1 lipca do dnia 31 grudnia 2015 r.** wycofano następujące pozwolenia na dopuszczenie do obrotu w państwach EFTA należących do EOG:

| Numer UE | Produkt | Państwo | Data wycofania |
|--------------|-------------------------------|---------------|----------------|
| EU/1/01/179 | Osigraft | Liechtenstein | 31.12.2015 |
| EU/1/08/450 | Biograstim | Islandia | 22.10.2015 |
| EU/1/08/450 | Biograstim | Liechtenstein | 31.10.2015 |
| EU/1/08/450 | Biograstim | Norwegia | 7.10.2015 |
| EU/1/08/452 | Pandemrix | Islandia | 17.11.2015 |
| EU/1/11/686 | Rasilamlo | Islandia | 23.7.2015 |
| EU/1/11/686 | Rasilamlo | Norwegia | 18.8.2015 |
| EU/1/14/912 | Zoledronic acid Teva Generics | Islandia | 12.8.2015 |
| EU/1/14/912 | Zoledronic acid Teva Generics | Norwegia | 25.9.2015 |
| EU/1/15/1026 | Nivolumab BMS | Islandia | 28.12.2015 |
| EU/1/15/1026 | Nivolumab BMS | Norwegia | 9.12.2015 |
| EU/1/15/1026 | Nivolumab BMS | Liechtenstein | 31.12.2015 |
| EU/1/99/102 | Sonata | Islandia | 6.8.2015 |
| EU/1/99/102 | Sonata | Liechtenstein | 31.8.2015 |
| EU/1/99/102 | Sonata | Norwegia | 18.8.2015 |
| EU/2/06/064 | ProMeris | Islandia | 7.8.2015 |
| EU/2/06/064 | ProMeris | Liechtenstein | 31.8.2015 |
| EU/2/06/064 | ProMeris | Norwegia | 18.8.2015 |
| EU/2/06/065 | ProMeris Duo | Islandia | 7.8.2015 |
| EU/2/06/065 | ProMeris Duo | Liechtenstein | 31.8.2015 |
| EU/2/06/065 | ProMeris Duo | Norwegia | 26.8.2015 |
| EU/2/97/003 | Dicural | Islandia | 6.11.2015 |
| EU/2/97/003 | Dicural | Liechtenstein | 31.10.2015 |
| EU/2/97/003 | Dicural | Norwegia | 1.12.2015 |

ZAŁĄCZNIK V

Wykaz zawieszonych pozwoleń na dopuszczenie do obrotu

W okresie **od dnia 1 lipca do dnia 31 grudnia 2015 r.** zawieszono następujące pozwolenia na dopuszczenie do obrotu w państwach EFTA należących do EOG:

| Numer UE | Produkt | Państwo | Data zawieszenia |
|-------------|----------|---------------|------------------|
| EU/1/02/226 | InductOs | Islandia | 17.12.2015 |
| EU/1/02/226 | InductOs | Norwegia | 1.12.2015 |
| EU/1/02/226 | InductOs | Liechtenstein | 31.12.2015 |