Medicinal products — List of marketing authorisations granted by the EEA EFTA States for the second half of 2016

(2018/C 195/11)

Subcommittee I on the free movement of goods

To be noted by the EEA Joint Committee

With reference to EEA Joint Committee Decision No 74/1999 of 28 May 1999, the EEA Joint Committee is invited to note the following lists concerning marketing authorisations for medicinal products for the period 1 July-31 December 2016, at their meeting on 17 March 2017:

Annex I List of new marketing authorisations

Annex II List of renewed marketing authorisations

Annex III List of extended marketing authorisations

Annex IV List of withdrawn marketing authorisations

Annex V List of suspended marketing authorisations

ANNEX I

List of new marketing authorisations

The following marketing authorisations have been granted in the EEA EFTA States during the period 1 July-31 December 2016:

EU Number	Product	Country	Date of authorisation
EU/1/12/793	Xalkori (Switch to non-conditional)	Liechtenstein	31.12.2016
EU/1/13/848	Erivedge (Switch to non-conditional)	Liechtenstein	31.12.2016
EU/1/15/1066	Ongentys	Iceland	13.7.2016
EU/1/15/1066	Ongentys	Norway	4.7.2016
EU/1/16/1091	Atazanavir Mylan	Iceland	29.8.2016
EU/1/16/1091	Atazanavir Mylan	Norway	2.9.2016
EU/1/16/1091	Atazanavir Mylan	Liechtenstein	31.8.2016
EU/1/16/1094	Ninlaro	Liechtenstein	31.12.2016
EU/1/16/1094	Ninlaro	Iceland	7.12.2016
EU/1/16/1094	Ninlaro	Norway	28.11.2016
EU/1/16/1102	Bortezomib SUN	Iceland	11.8.2016
EU/1/16/1102	Bortezomib SUN	Norway	12.8.2016
EU/1/16/1102	Bortezomib SUN	Liechtenstein	31.8.2016
EU/1/16/1103	Neparvis	Iceland	4.7.2016
EU/1/16/1105	EndolucinBeta	Iceland	25.7.2016
EU/1/16/1105	EndolucinBeta	Norway	27.7.2016
EU/1/16/1105	EndolucinBeta	Liechtenstein	31.8.2016
EU/1/16/1107	ZINBRYTA	Iceland	14.7.2016
EU/1/16/1107	Zinbryta	Norway	7.7.2016

EU Number	Product	Country	Date of authorisation
EU/1/16/1107	Zinbryta	Liechtenstein	31.8.2016
EU/1/16/1108	Qtern	Iceland	25.7.2016
EU/1/16/1108	Qtern	Norway	4.8.2016
EU/1/16/1108	Qtern	Liechtenstein	31.8.2016
EU/1/16/1109	ZAVICEFTA	Iceland	12.7.2016
EU/1/16/1109	Zavicefta	Norway	1.7.2016
EU/1/16/1112	Odefsey	Iceland	12.7.2016
EU/1/16/1113	Enzepi	Iceland	14.7.2016
EU/1/16/1113	Enzepi	Norway	26.7.2016
EU/1/16/1113	Enzepi	Liechtenstein	31.8.2016
EU/1/16/1114	Bortezomib Hospira	Iceland	10.8.2016
EU/1/16/1114	Bortezomib Hospira	Norway	12.8.2016
EU/1/16/1114	Bortezomib Hospira	Liechtenstein	31.8.2016
EU/1/16/1115	Pemetrexed Fresenius Kabi	Iceland	16.8.2016
EU/1/16/1115	Pemetrexed Fresenius Kabi	Norway	11.8.2016
EU/1/16/1116	Epclusa	Iceland	12.7.2016
EU/1/16/1116	Epclusa	Norway	11.7.2016
EU/1/16/1116	Epclusa	Liechtenstein	31.8.2016
EU/1/16/1119	Zepatier	Iceland	11.8.2016
EU/1/16/1119	Zepatier	Norway	4.8.2016
EU/1/16/1119	Zepatier	Liechtenstein	31.8.2016
EU/1/16/1121	Zalmoxis	Iceland	7.9.2016

EU Number	Product	Country	Date of authorisation
EU/1/16/1121	Zalmoxis	Norway	16.9.2016
EU/1/16/1121	Zalmoxis	Liechtenstein	31.10.2016
EU/1/16/1122	Aerivio Spiromax	Iceland	2.9.2016
EU/1/16/1122	Aerivio Spiromax	Norway	8.9.2016
EU/1/16/1122	Aerivio Spiromax	Liechtenstein	31.10.2016
EU/1/16/1123	Airexar Spiromax	Iceland	2.9.2016
EU/1/16/1123	Airexar Spiromax	Norway	13.9.2016
EU/1/16/1123	Airexar Spiromax	Liechtenstein	31.10.2016
EU/1/16/1124	Nordimet	Iceland	7.9.2016
EU/1/16/1124	Nordimet	Norway	30.8.2016
EU/1/16/1124	Nordimet	Liechtenstein	31.8.2016
EU/1/16/1125	Cinqaero	Iceland	7.9.2016
EU/1/16/1125	Cinqaero	Norway	31.8.2016
EU/1/16/1125	Cinqaero	Liechtenstein	31.8.2016
EU/1/16/1126	Truberzi	Iceland	7.10.2016
EU/1/16/1126	Truberzi	Norway	6.10.2016
EU/1/16/1126	Truberzi	Liechtenstein	31.10.2016
EU/1/16/1127	Tenofovir disoproxil Zentiva	Iceland	6.10.2016
EU/1/16/1127	Tenofovir disoproxil Zentiva	Liechtenstein	31.10.2016
EU/1/16/1127	Tenofovir disoproxil Zentiva	Norway	13.10.2016
EU/1/16/1128	Kisplyx	Iceland	7.9.2016
EU/1/16/1128	Kisplyx	Norway	31.8.2016

EU Number	Product	Country	Date of authorisation
EU/1/16/1128	Kisplyx	Liechtenstein	31.8.2016
EU/1/16/1129	Tenofovir disoproxil Mylan	Iceland	16.12.2016
EU/1/16/1129	Tenofovir disoproxil Mylan	Norway	21.12.2016
EU/1/16/1130	Onivyde	Iceland	1.11.2016
EU/1/16/1130	Onivyde	Norway	4.11.2016
EU/1/16/1130	Onivyde	Liechtenstein	31.10.2016
EU/1/16/1131	Thorinane	Iceland	6.10.2016
EU/1/16/1131	Thorinane	Norway	23.9.2016
EU/1/16/1131	Thorinane	Liechtenstein	31.10.2016
EU/1/16/1132	Inhixa	Iceland	7.10.2016
EU/1/16/1132	Inhixa	Norway	5.10.2016
EU/1/16/1132	Inhixa	Liechtenstein	31.10.2016
EU/1/16/1134	Mysildecard	Iceland	6.10.2016
EU/1/16/1134	Mysildecard	Norway	29.9.2016
EU/1/16/1134	Mysildecard	Liechtenstein	31.10.2016
EU/1/16/1135	Sialanar	Iceland	7.10.2016
EU/1/16/1135	Sialanar	Norway	14.10.2016
EU/1/16/1135	Sialanar	Liechtenstein	31.10.2016
EU/1/16/1136	Cabometyx	Iceland	6.10.2016
EU/1/16/1136	CABOMETYX	Norway	20.9.2016
EU/1/16/1136	CABOMETYX	Liechtenstein	31.10.2016
EU/1/16/1137	Granpidam	Liechtenstein	31.12.2016

EU Number	Product	Country	Date of authorisation
EU/1/16/1137	Granpidam	Iceland	6.12.2016
EU/1/16/1137	Granpidam	Norway	28.11.2016
EU/1/16/1138	Venclyxto	Iceland	8.12.2016
EU/1/16/1138	Venclyxto	Norway	13.12.2016
EU/1/16/1139	Ocaliva	Iceland	19.12.2016
EU/1/16/1139	OCALIVA	Norway	12.12.2016
EU/1/16/1141	SomaKit TOC	Iceland	15.12.2016
EU/1/16/1141	SomaKit TOC	Norway	15.12.2016
EU/1/16/1142	Parsabiv	Liechtenstein	31.12.2016
EU/1/16/1142	Parsabiv	Iceland	1.12.2016
EU/1/16/1142	Parsabiv	Norway	22.11.2016
EU/1/16/1143	Lartruvo	Liechtenstein	31.12.2016
EU/1/16/1143	Lartruvo	Iceland	1.12.2016
EU/1/16/1143	Lartruvo	Norway	18.11.2016
EU/1/16/1144	Ivabradine Zentiva	Liechtenstein	31.12.2016
EU/1/16/1144	Ivabradine Zentiva	Iceland	2.12.2016
EU/1/16/1144	Ivabradine Zentiva	Norway	28.11.2016
EU/1/16/1145	Ivabradine JensonR	Liechtenstein	31.12.2016
EU/1/16/1145	Ivabradine JensonR	Iceland	2.12.2016
EU/1/16/1145	Ivabradine JensonR	Norway	5.12.2016
EU/1/16/1146	Glyxambi	Liechtenstein	31.12.2016
EU/1/16/1146	Glyxambi	Iceland	5.12.2016

EU Number	Product	Country	Date of authorisation
EU/1/16/1146	Glyxambi	Norway	9.12.2016
EU/1/16/1147	IBRANCE	Liechtenstein	31.12.2016
EU/1/16/1147	Ibrance	Iceland	1.12.2016
EU/1/16/1147	IBRANCE	Norway	15.11.2016
EU/1/16/1148	Emtricitabin/Tenofovir disoproxil Zentiva	Liechtenstein	31.12.2016
EU/1/16/1148	Emtricitabine/Tenofovir disoproxil Zentiva	Iceland	1.12.2016
EU/1/16/1148	Emtricitabine/Tenofovir disoproxil Zentvia	Norway	15.11.2016
EU/1/16/1151	Emtricitabine/Tenofovir disproxil Krka	Norway	21.12.2016
EU/1/16/1151	Emtricitabine/Tenofovir disoproxil Krka	Iceland	14.12.2016
EU/2/16/196	Sevocalm	Norway	11.7.2016
EU/2/16/196	Sevocalm	Liechtenstein	31.8.2016
EU/2/16/196	Sevocalm	Iceland	12.7.2016
EU/2/16/198	Sedadex	Iceland	22.8.2016
EU/2/16/198	Sedadex	Norway	30.8.2016
EU/2/16/198	Sedadex	Liechtenstein	31.8.2016
EU/2/16/199	Eravac	Iceland	10.10.2016
EU/2/16/199	ERAVAC	Norway	5.10.2016
EU/2/16/199	ERAVAC	Liechtenstein	31.10.2016
EU/2/16/200	Cepedex	Iceland	19.12.2016

ANNEX II

List of renewed marketing authorisations

The following marketing authorisations have been renewed in the EEA EFTA States during the period 1 July-31 December 2016:

EU Number	Product	Country	Date of authorisation
EU/1/06/347	Sutent	Liechtenstein	31.12.2016
EU/1/06/347	Sutent	Iceland	1.12.2016
EU/1/06/347	Sutent	Norway	15.11.2016
EU/1/06/355	ATryn	Iceland	26.7.2016
EU/1/06/355	ATryn	Norway	10.8.2016
EU/1/06/355	ATryn	Liechtenstein	31.8.2016
EU/1/06/360	Champix	Iceland	13.7.2016
EU/1/06/360	Champix	Norway	7.7.2016
EU/1/06/360	Champix	Liechtenstein	31.8.2016
EU/1/06/361	Luminity	Iceland	26.7.2016
EU/1/06/361	Luminity	Norway	6.8.2016
EU/1/06/361	Luminity	Liechtenstein	31.8.2016
EU/1/06/362	Byetta	Iceland	18.8.2016
EU/1/06/363	Sprycel	Iceland	18.8.2016
EU/1/06/363	Sprycel	Norway	12.8.2016
EU/1/06/363	Sprycel	Liechtenstein	31.8.2016
EU/1/06/364	Adrovance	Iceland	16.10.2016
EU/1/06/365	Elaprase	Iceland	16.10.2016
EU/1/06/366	Tandemact	Iceland	16.10.2016

EU Number	Product	Country	Date of authorisation
EU/1/06/374	Lucentis	Liechtenstein	31.12.2016
EU/1/06/374	Lucentis	Iceland	2.12.2016
EU/1/06/374	Lucentis	Norway	22.11.2016
EU/1/06/379	Cystadane	Iceland	7.12.2016
EU/1/06/379	Cystadane	Norway	29.11.2016
EU/1/11/699	Fampyra	Norway	8.7.2016
EU/1/11/701	Levatiracetam Teva	Norway	4.8.2016
EU/1/11/701	Levetiracetam Teva	Iceland	26.7.2016
EU/1/11/701	Levetiracetam Teva	Liechtenstein	31.8.2016
EU/1/11/706	Levodopa/Carbidopa/Entacapone Orion	Norway	15.9.2016
EU/1/11/711	Matever	Iceland	14.7.2016
EU/1/11/711	Matever	Norway	7.7.2016
EU/1/11/711	Matever	Liechtenstein	31.8.2016
EU/1/11/712	Levetiracetam Accord	Iceland	10.8.2016
EU/1/11/712	Levetiracetam Accord	Norway	11.8.2016
EU/1/11/712	Levetiracetam Accord	Liechtenstein	31.8.2016
EU/1/11/713	Levetiracetam Actavis	Iceland	5.10.2016
EU/1/11/713	Levetiracetam Actavis	Norway	30.9.2016
EU/1/11/713	Levetiracetam Actavis	Liechtenstein	31.10.2016
EU/1/11/715	Plenadren	Iceland	15.8.2016
EU/1/11/715	Plenadren	Norway	15.8.2016
EU/1/11/715	Plenadren	Liechtenstein	31.8.2016

EU Number	Product	Country	Date of authorisation
EU/1/11/716	Eurartesim	Iceland	15.9.2016
EU/1/11/716	Eurartesim	Norway	15.9.2016
EU/1/11/716	Eurartesim	Liechtenstein	31.10.2016
EU/1/11/717	Vyndaqel	Iceland	10.8.2016
EU/1/11/717	Vyndaqel	Norway	11.8.2016
EU/1/11/717	Vyndaqel	Liechtenstein	31.8.2016
EU/1/11/719	Telmisartan Teva Pharma	Iceland	12.7.2016
EU/1/11/722	Pioglitazone Accord	Iceland	13.12.2016
EU/1/11/722	Pioglitazone Accord	Norway	21.12.2016
EU/1/11/727	Xaluprine	Liechtenstein	31.12.2016
EU/1/11/727	Xaluprine	Iceland	6.12.2016
EU/1/11/727	Xaluprine	Norway	5.12.2016
EU/1/11/728	Pramipexole Accord	Iceland	26.7.2016
EU/1/11/728	Pramipexole Accord	Norway	4.8.2016
EU/1/11/728	Pramipexole Accord	Liechtenstein	31.8.2016
EU/1/11/731	Komboglyze	Iceland	26.7.2016
EU/1/11/731	Komboglyze	Norway	11.8.2016
EU/1/11/731	Komboglyze	Liechtenstein	31.8.2016
EU/1/11/732	Desloratadine Teva	Iceland	15.8.2016
EU/1/11/732	Desloratadine Teva	Norway	22.8.2016
EU/1/11/733	Dificlir	Iceland	29.8.2016
EU/1/11/733	Dificlir	Norway	30.8.2016

EU Number	Product	Country	Date of authorisation
EU/1/11/733	Dificlir	Liechtenstein	31.8.2016
EU/1/11/734	Edarbi	Liechtenstein	31.12.2016
EU/1/11/734	Edarbi	Iceland	2.12.2016
EU/1/11/734	Edarbi	Norway	22.11.2016
EU/1/11/736	EDURANT	Iceland	10.8.2016
EU/1/11/736	EDURANT	Norway	11.8.2016
EU/1/11/736	EDURANT	Liechtenstein	31.8.2016
EU/1/11/737	Eviplera	Iceland	10.8.2016
EU/1/11/737	Eviplera	Norway	11.8.2016
EU/1/11/737	Eviplera	Liechtenstein	31.8.2016
EU/1/11/738	Levetiracetam Actavis Group	Iceland	15.8.2016
EU/1/11/738	Levetiracetam Actavis Group	Norway	2.9.2016
EU/1/11/738	Levetiracetam Actavis Group	Liechtenstein	31.8.2016
EU/1/11/739	Dasselta	Iceland	22.8.2016
EU/1/11/739	Dasselta	Norway	5.9.2016
EU/1/11/739	Dasselta	Liechtenstein	31.8.2016
EU/1/11/740	Ameluz	Liechtenstein	31.12.2016
EU/1/11/740	Ameluz	Iceland	7.12.2016
EU/1/11/740	Ameluz	Norway	5.12.2016
EU/1/11/741	Levetiracetam SUN	Liechtenstein	31.12.2016
EU/1/11/741	Levetiracetam Sun	Iceland	5.12.2016
EU/1/11/741	Levetiracetam SUN	Norway	23.11.2016

EU Number	Product	Country	Date of authorisation
EU/1/11/742	Efavirenz Teva	Iceland	16.10.2016
EU/1/11/742	Efavirenz Teva	Norway	21.10.2016
EU/1/11/743	Repaglinide Accord	Iceland	14.10.2016
EU/1/11/743	Repaglinide Accord	Norway	21.10.2016
EU/1/11/745	Desloratadin Actavis	Liechtenstein	31.12.2016
EU/1/11/745	Desloratadine Actavis	Iceland	2.12.2016
EU/1/11/745	Desloratadine Actavis	Norway	25.11.2016
EU/1/11/746	Desloratadine ratiopharm	Iceland	15.8.2016
EU/1/11/746	Desloratadine ratiopharm	Norway	22.8.2016
EU/1/11/746	Desloratadine ratiopharm	Liechtenstein	31.8.2016
EU/1/11/747	Colobreathe	Iceland	10.10.2016
EU/1/11/747	Colobreathe	Norway	13.10.2016
EU/1/11/747	Colobreathe	Liechtenstein	31.10.2016
EU/1/12/750	Esmya	Liechtenstein	31.12.2016
EU/1/12/750	Esmya	Iceland	5.12.2016
EU/1/12/750	Esmya	Norway	29.11.2016
EU/1/12/751	Zelboraf	Norway	6.10.2016
EU/1/12/751	Zelboraf	Iceland	10.10.2016
EU/1/12/751	Zelboraf	Liechtenstein	31.10.2016
EU/1/12/753	Signifor	Liechtenstein	31.12.2016
EU/1/12/753	Signifor	Iceland	6.12.2016
EU/1/12/753	Signifor	Norway	24.11.2016

EU Number	Product	Country	Date of authorisation
EU/1/12/755	Pioglitazone Actavis	Liechtenstein	31.12.2016
EU/1/12/755	Pioglitazone Actavis	Norway	9.12.2016
EU/1/12/755	Pioglitazone Actavis	Iceland	2.12.2016
EU/1/12/756	Glidipion	Norway	9.12.2016
EU/1/12/756	Glidipion	Liechtenstein	31.12.2016
EU/1/12/756	Glidipion	Iceland	2.12.2016
EU/1/12/763	Ecansya	Norway	23.12.2016
EU/1/12/793	XALKORI	Iceland	10.8.2016
EU/1/12/793	XALKORI	Norway	12.8.2016
EU/1/12/793	XALKORI	Liechtenstein	31.8.2016
EU/1/12/794	ADCETRIS	Liechtenstein	31.10.2016
EU/1/12/794	ADCETRIS	Iceland	2.11.2016
EU/1/12/794	ADCETRIS	Norway	8.11.2016
EU/1/15/1047	Blincyto	Iceland	10.10.2016
EU/1/15/1047	Blincyto	Norway	29.9.2016
EU/1/15/1047	Blincyto	Liechtenstein	31.10.2016
EU/1/16/1086	Tagrisso	Iceland	19.12.2016
EU/2/06/061	Nobilis Influenza H5N2	Iceland	13.7.2016
EU/2/11/128	Emdocam	Iceland	13.7.2016
EU/2/11/132	Nobivac Myxo-RHD	Iceland	25.8.2016
EU/2/11/132	Nobivac Myxo-RHD	Norway	30.8.2016
EU/2/11/132	Nobivac Myxo-RHD	Liechtenstein	31.10.2016

EU Number	Product	Country	Date of authorisation
EU/2/11/133	Recocam	Iceland	17.8.2016
EU/2/11/133	Recocam	Norway	25.8.2016
EU/2/11/133	Recocam	Liechtenstein	31.8.2016
EU/2/11/134	Inflacam	Liechtenstein	31.12.2016
EU/2/11/134	Inflacam	Iceland	2.12.2016
EU/2/11/134	Inflacam	Norway	25.11.2016
EU/2/11/135	Panacur AquaSol	Liechtenstein	31.8.2016
EU/2/11/135	Panacur AquaSol	Iceland	2.9.2016
EU/2/11/135	Panacur AquaSol	Norway	5.9.2016
EU/2/11/137	Activyl Tick Plus	Norway	23.12.2016
EU/2/12/139	Zulvac 1+8 Bovis	Iceland	19.12.2016

ANNEX III

List of extended marketing authorisations

The following marketing authorisations have been extended in the EEA EFTA States during the period 1 July-31 December 2016:

EU Number	Product	Country	Date of authorisation
EU/1/03/267/012	Reyataz	Iceland	13.7.2016
EU/1/08/494/005	Stelara	Norway	24.11.2016
EU/1/08/494/005	Stelara	Iceland	5.12.2016
EU/1/11/714/002-003	Zytiga	Iceland	1.12.2016
EU/1/11/714/003	Zytiga	Norway	25.11.2016
EU/1/12/776/024	Fycompa	Iceland	11.10.2016
EU/1/12/776/024	Fycompa	Norway	10.10.2016
EU/1/14/939/005-006	Daklinza	Iceland	13.7.2016
EU/1/14/939/005-006	Daklinza	Norway	4.7.2016
EU/1/15/1024/002	KEYTRUDA	Iceland	24.8.2016
EU/1/15/1024/002	KEYTRUDA	Norway	26.8.2016
EU/2/97/004/050-053	Metacam	Norway	29.8.2016

ANNEX IV

List of withdrawn marketing authorisations

The following marketing authorisations have been withdrawn in the EEA EFTA States during the period 1 July-31 December 2016:

EU Number	Product	Country	Date of withdrawal
EU/1/00/137	Avandia	Iceland	12.8.2016
EU/1/03/258	Avandamet	Iceland	12.8.2016
EU/1/07/385	Focetria	Iceland	12.8.2016
EU/1/08/489	Opgenra	Iceland	14.7.2016
EU/1/08/489	Opgenra	Norway	11.8.2016
EU/1/08/489	Opgenra	Liechtenstein	31.8.2016
EU/1/08/500	Fablyn	Iceland	12.8.2016
EU/1/08/506	Celvapan	Iceland	7.12.2016
EU/1/08/506	Celvapan	Liechtenstein	31.12.2016
EU/1/08/506	Celvapan	Norway	21.12.2016
EU/1/09/518	PANTECTA Control	Iceland	7.10.2016
EU/1/09/518	PANTECTA Control	Norway	20.10.2016
EU/1/09/518	PANTECTA Control	Liechtenstein	31.10.2016
EU/1/09/563	ChondroCelect	Liechtenstein	31.8.2016
EU/1/09/563	ChondroCelect	Iceland	15.8.2016
EU/1/09/563	ChondroCelect	Norway	11.8.2016
EU/1/10/657	Prepandemic Influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Dia	Iceland	12.8.2016
EU/1/11/721	Paglitaz	Iceland	12.8.2016

EU Number	Product	Country	Date of withdrawal
EU/1/12/810	Krystexxa	Iceland	14.7.2016
EU/1/12/810	Krystexxa	Norway	6.7.2016
EU/1/12/810	Krystexxa	Liechtenstein	31.8.2016
EU/1/13/831	Capecitabine SUN	Iceland	13.7.2016
EU/1/13/831	Capecitabine SUN	Norway	6.7.2016
EU/1/13/883	Vitekta	Iceland	10.11.2016
EU/1/13/883	Vitekta	Liechtenstein	31.12.2016
EU/1/13/883	Vitekta	Norway	15.12.2016
EU/1/14/942	Clopidogrel/Acetylsalicylic acid Teva	Iceland	26.7.2016

ANNEX V

List of suspended marketing authorisations

The following marketing authorisations have been suspended in the EEA EFTA States during the period 1 July-31 December 2016:

EU Number	Product	Country	Date of suspension
EU/2/15/192	Velactis	Iceland	30.8.2016
EU/2/15/192	Velactis	Norway	29.8.2016
EU/2/15/192	Velactis	Liechtenstein	31.8.2016