

**Medicinal products – List of marketing authorisations granted by the EEA EFTA States for the second half of 2019**

(2020/C 308/06)

**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 2019, at their meeting on 20 March 2020.

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Annex IV List of withdrawn marketing authorisations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

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## 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 2019:

EU-Number	Product	Country	Date of authorisation
EU/2/19/240	Afoxolaner Merial	Iceland	30.8.2019
EU/1/19/1398	Arsenic Trioxide Accord	Iceland	2.12.2019
EU/1/19/1398	Arsenic Trioxide Accord	Liechtenstein	31.12.2019
EU/1/19/1398	Arsenic Trioxide Accord	Norway	26.11.2019
EU/2/18/228	Arti-Cell Forte	Iceland	16.7.2019
EU/1/19/1382	Azacitidin Celgene	Iceland	29.8.2019
EU/1/19/1382	Azacitidin Celgene	Liechtenstein	31.8.2019
EU/1/19/1382	Azacitidin Celgene	Norway	8.8.2019
EU/1/19/1406	BAQSIMI	Iceland	30.12.2019
EU/1/19/1406	BAQSIMI	Liechtenstein	31.12.2019
EU/1/19/1397	Bortezomib Fresenius Kabi	Iceland	29.11.2019
EU/1/19/1397	Bortezomib Fresenius Kabi	Liechtenstein	31.12.2019
EU/1/19/1397	Bortezomib Fresenius Kabi	Norway	10.12.2019
EU/1/19/1365	Cufence	Iceland	9.10.2019
EU/1/19/1365	Cufence	Liechtenstein	31.8.2019
EU/1/19/1365	Cufence	Norway	12.8.2019
EU/1/19/1386	Deferasirox Mylan	Iceland	11.10.2019
EU/1/19/1386	Deferasirox Mylan	Liechtenstein	31.10.2019
EU/1/19/1386	Deferasirox Mylan	Norway	8.10.2019
EU/1/19/1370	Dovato	Iceland	19.7.2019
EU/1/19/1370	Dovato	Liechtenstein	31.8.2019
EU/1/19/1370	Dovato	Norway	04.07.2019
EU/1/19/1389	Epidyolex	Iceland	18.10.2019
EU/1/19/1389	Epidyolex	Liechtenstein	31.10.2019
EU/1/19/1389	Epidyolex	Norway	16.10.2019
EU/1/19/1392	Ervebo	Iceland	4.12.2019
EU/1/19/1392	Ervebo	Liechtenstein	31.12.2019
EU/1/19/1392	Ervebo	Norway	19.11.2019
EU/1/19/1374	Esperoct	Liechtenstein	31.8.2019
EU/1/19/1411	Evenity	Iceland	12.12.2019
EU/1/19/1411	Evenity	Liechtenstein	31.12.2019
EU/2/19/242	EVICTO	Iceland	27.8.2019

EU-Number	Product	Country	Date of authorisation
EU/2/19/242	EVICTO	Liechtenstein	31.8.2019
EU/2/19/242	EVICTO	Norway	13.08.2019
EU/1/19/1384	Giapreza	Iceland	29.8.2019
EU/1/19/1384	Giapreza	Liechtenstein	31.8.2019
EU/1/19/1384	Giapreza	Norway	25.09.2019
EU/1/19/1375	Grasustek	Iceland	24.7.2019
EU/1/19/1375	Grasustek	Norway	31.10.2019
EU/2/19/245	Gumbohatch	Iceland	29.11.2019
EU/2/19/245	Gumbohatch	Liechtenstein	31.12.2019
EU/2/18/226	HorStem	Iceland	16.7.2019
EU/1/17/1216	Imraldi	Norway	16.09.2019
EU/1/19/1390	Inbrija	Iceland	11.10.2019
EU/1/19/1390	Inbrija	Liechtenstein	31.10.2019
EU/1/19/1390	Inbrija	Norway	16.10.2019
EU/1/19/1396	Ivozall	Iceland	28.11.2019
EU/1/19/1396	Ivozall	Norway	26.11.2019
EU/1/19/1383	Lacosamid UCB	Iceland	3.9.2019
EU/1/19/1383	Lacosamid UCB	Liechtenstein	31.8.2019
EU/1/19/1383	Lacosamid UCB	Norway	18.10.2019
EU/1/19/1376	LIBTAYO	Iceland	19.7.2019
EU/1/19/1376	LIBTAYO	Liechtenstein	31.8.2019
EU/1/19/1376	LIBTAYO	Norway	05.8.2019
EU/1/19/1381	LysaKare	Iceland	26.8.2019
EU/1/19/1381	LysaKare	Liechtenstein	31.8.2019
EU/1/19/1381	LysaKare	Norway	12.8.2019
EU/1/18/1301	Mepsevii	Liechtenstein	31.8.2019
EU/2/19/247	Mirataz	Iceland	30.12.2019
EU/2/19/247	Mirataz	Liechtenstein	31.12.2019
EU/2/19/241	NASYM	Iceland	27.8.2019
EU/2/19/241	NASYM	Liechtenstein	31.8.2019
EU/2/19/241	NASYM	Norway	16.8.2019
EU/2/19/246	Neptra	Iceland	30.12.2019
EU/2/19/246	Neptra	Liechtenstein	31.12.2019
EU/2/19/244	Nobivac Myxo-RHD Plus	Iceland	4.12.2019
EU/2/19/244	Nobivac Myxo-RHD Plus	Liechtenstein	31.12.2019
EU/1/19/1364	Nuceiva	Iceland	18.10.2019

EU-Number	Product	Country	Date of authorisation
EU/1/19/1364	Nuceiva	Norway	18.10.2019
EU/1/18/1320	Onpattro	Liechtenstein	31.12.2019
EU/1/19/1388	Polivy	Liechtenstein	31.12.2019
EU/1/19/1379	Posaconazole Accord	Iceland	28.8.2019
EU/1/19/1379	Posaconazole Accord	Liechtenstein	31.8.2019
EU/1/19/1379	Posaconazole Accord	Norway	26.8.2019
EU/1/19/1380	Posaconazole AHCL	Iceland	27.8.2019
EU/1/19/1380	Posaconazole AHCL	Liechtenstein	31.8.2019
EU/1/19/1380	Posaconazole AHCL	Norway	12.8.2019
EU/1/19/1401	Qtrilmet	Iceland	18.11.2019
EU/1/19/1401	Qtrilmet	Liechtenstein	31.12.2019
EU/1/19/1401	Qtrilmet	Norway	6.12.2019
EU/1/19/1393	Quofenix	Iceland	30.12.2019
EU/1/19/1393	Quofenix	Liechtenstein	31.12.2019
EU/1/19/1400	Rhokiinsa	Iceland	5.12.2019
EU/1/19/1400	Rhokiinsa	Norway	17.12.2019
EU/1/19/1404	Rinvoq	Iceland	30.12.2019
EU/1/19/1404	Rinvoq	Liechtenstein	31.12.2019
EU/1/19/1387	Senstend	Iceland	4.12.2019
EU/1/19/1387	Senstend	Norway	4.12.2019
EU/2/19/243	Simparica Trio	Iceland	10.10.2019
EU/2/19/243	Simparica Trio	Liechtenstein	31.10.2019
EU/2/19/243	Simparica Trio	Norway	11.11.2019
EU/1/19/1369	Sixmo	Iceland	17.7.2019
EU/1/19/1369	Sixmo	Norway	15.7.2019
EU/1/19/1410	Spravato	Liechtenstein	31.12.2019
EU/1/19/1372	Striascan	Iceland	2.7.2019
EU/1/19/1372	Striascan	Liechtenstein	31.8.2019
EU/1/19/1372	Striascan	Norway	11.7.2019
EU/1/19/1377	Talzenna	Iceland	16.7.2019
EU/1/19/1377	Talzenna	Norway	15.7.2019
EU/1/19/1359	Trogarzo	Iceland	5.11.2019
EU/1/19/1359	Trogarzo	Liechtenstein	31.10.2019
EU/1/19/1359	Trogarzo	Norway	18.10.2019
EU/1/19/1371	Ultomiris	Iceland	22.7.2019
EU/1/19/1371	Ultomiris	Liechtenstein	31.8.2019

EU-Number	Product	Country	Date of authorisation
EU/1/19/1371	Ultomiris	Norway	17.7.2019
EU/1/19/1385	VITRAKVI	Iceland	5.11.2019
EU/1/19/1385	VITRAKVI	Liechtenstein	31.10.2019
EU/1/19/1385	VITRAKVI	Norway	18.10.2019
EU/1/18/1312	Xerava	Liechtenstein	31.12.2019
EU/1/19/1399	Xospata	Iceland	6.11.2019
EU/1/19/1399	Xospata	Norway	30.10.2019
EU/1/19/1366	Xromi	Iceland	19.7.2019
EU/1/19/1366	Xromi	Liechtenstein	31.8.2019
EU/1/19/1366	Xromi	Norway	17.7.2019

## 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 2019:

EU-Number	Product	Country	Date of authorisation
EU/1/14/944	Abasaglar	Iceland	28.8.2019
EU/1/14/944	Abasaglar	Liechtenstein	31.8.2019
EU/1/14/944	Abasaglar	Norway	16.8.2019
EU/1/12/794	ADCETRIS	Iceland	18.10.2019
EU/1/12/794	ADCETRIS	Norway	29.10.2019
EU/1/09/578	Adjupanrix	Iceland	29.8.2019
EU/1/09/578	Adjupanrix	Norway	12.8.2019
EU/1/17/1214	Bavencio	Liechtenstein	31.10.2019
EU/2/14/176	Bovela	Iceland	15.11.2019
EU/2/14/176	Bovela	Liechtenstein	31.12.2019
EU/2/14/176	Bovela	Norway	27.11.2019
EU/1/14/963	Brimica Genuair	Iceland	29.8.2019
EU/1/14/963	Brimica Genuair	Liechtenstein	31.8.2019
EU/1/14/963	Brimica Genuair	Norway	20.09.2019
EU/1/14/951	Busulfan Fresenius Kabi	Norway	15.07.2019
EU/1/14/974	Cerdelga	Iceland	30.12.2019
EU/1/14/974	Cerdelga	Liechtenstein	31.12.2019
EU/1/14/975	Clopidogrel ratiopharm	Iceland	15.11.2019
EU/1/14/975	Clopidogrel ratiopharm	Liechtenstein	31.12.2019
EU/1/14/975	Clopidogrel ratiopharm	Norway	9.12.2019
EU/1/13/890	Cometriq	Norway	3.07.2019
EU/1/14/980	Cosentyx	Iceland	10.9.2019
EU/1/14/980	Cosentyx	Liechtenstein	31.10.2019
EU/1/14/980	Cosentyx	Norway	18.09.2019
EU/1/17/1262	Crysvita	Iceland	27.12.2019
EU/1/17/1262	Crysvita	Liechtenstein	31.12.2019
EU/1/14/957	Cyramza	Iceland	10.10.2019
EU/1/14/957	Cyramza	Norway	3.10.2019
EU/1/14/964	Duaklir Genuair	Iceland	29.8.2019
EU/1/14/964	Duaklir Genuair	Liechtenstein	31.8.2019
EU/1/14/964	Duaklir Genuair	Norway	20.09.2019
EU/1/14/960	DUAVIVE	Iceland	15.11.2019

EU-Number	Product	Country	Date of authorisation
EU/1/14/960	DUAVIVE	Liechtenstein	31.12.2019
EU/1/14/960	DUAVIVE	Norway	9.12.2019
EU/1/14/972	Duloxetine Lilly	Iceland	28.8.2019
EU/1/14/972	Duloxetine Lilly	Liechtenstein	31.8.2019
EU/1/14/972	Duloxetine Lilly	Norway	30.8.2019
EU/1/14/983	Exviera	Iceland	10.10.2019
EU/1/14/983	Exviera	Norway	18.10.2019
EU/1/09/601	Firdapse	Iceland	30.8.2019
EU/1/09/601	Firdapse	Liechtenstein	31.8.2019
EU/1/09/601	Firdapse	Norway	18.9.2019
EU/1/14/958	Harvoni	Iceland	29.8.2019
EU/1/14/958	Harvoni	Liechtenstein	31.8.2019
EU/1/14/958	Harvoni	Norway	16.8.2019
EU/1/14/945	IMBRUVICA	Iceland	16.7.2019
EU/1/14/945	IMBRUVICA	Liechtenstein	31.8.2019
EU/1/14/945	IMBRUVICA	Norway	2.7.2019
EU/1/09/531	Instanyl	Iceland	23.7.2019
EU/1/09/531	Instanyl	Liechtenstein	31.8.2019
EU/1/09/531	Instanyl	Norway	16.7.2019
EU/1/15/994	Kengrexal	Iceland	27.12.2019
EU/1/15/994	Kengrexal	Liechtenstein	31.12.2019
EU/1/14/965	Ketoconazole HRA	Iceland	5.9.2019
EU/1/14/965	Ketoconazole HRA	Liechtenstein	31.8.2019
EU/1/14/965	Ketoconazole HRA	Norway	12.8.2019
EU/1/14/955	Lymphoseek	Iceland	18.10.2019
EU/1/14/955	Lymphoseek	Norway	25.9.2019
EU/1/14/959	Lynparza	Iceland	10.10.2019
EU/1/14/959	Lynparza	Norway	18.10.2019
EU/1/14/962	Moventig	Iceland	9.10.2019
EU/1/14/962	Moventig	Norway	31.10.2019
EU/1/09/591	Multaq	Iceland	9.10.2019
EU/1/09/591	Multaq	Norway	21.10.2019
EU/2/14/177	Nexgard Spectra	Iceland	15.11.2019
EU/2/14/177	Nexgard Spectra	Liechtenstein	31.12.2019
EU/2/14/177	Nexgard Spectra	Norway	27.11.2019
EU/1/16/1094	Ninlaro	Iceland	18.10.2019

EU-Number	Product	Country	Date of authorisation
EU/1/14/979	Ofev	Iceland	18.10.2019
EU/1/14/979	Ofev	Norway	21.10.2019
EU/2/14/170	Osurnia	Iceland	22.7.2019
EU/2/14/170	Osurnia	Liechtenstein	31.8.2019
EU/2/14/170	Osurnia	Norway	16.7.2019
EU/1/14/981	Otezla	Iceland	30.8.2019
EU/1/14/981	Otezla	Liechtenstein	31.8.2019
EU/1/14/981	Otezla	Norway	28.9.2019
EU/1/16/1089	Pandemic influenza vaccine H5N1 AstraZeneca	Norway	8.7.2019
EU/2/14/175	Porcilis PCV M Hyo	Iceland	9.10.2019
EU/2/14/175	Porcilis PCV M Hyo	Norway	14.10.2019
EU/1/14/977	Rasagiline ratiopharm	Iceland	21.10.2019
EU/1/14/967	Rezolsta	Iceland	28.8.2019
EU/1/14/967	Rezolsta	Liechtenstein	31.8.2019
EU/1/14/967	Rezolsta	Norway	16.8.2019
EU/1/14/970	RIXUBIS	Iceland	5.12.2019
EU/1/15/992	Saxenda	Iceland	27.12.2019
EU/1/15/992	Saxenda	Liechtenstein	31.12.2019
EU/1/14/969	SCENESSE	Iceland	5.12.2019
EU/1/14/969	SCENESSE	Liechtenstein	31.12.2019
EU/1/14/969	SCENESSE	Norway	6.12.2019
EU/1/14/978	Senshio	Iceland	6.11.2019
EU/1/14/978	Senshio	Liechtenstein	31.10.2019
EU/1/14/978	Senshio	Norway	21.11.2019
EU/1/14/952	Sevelamer carbonate Winthrop	Iceland	15.11.2019
EU/1/14/952	Sevelamer carbonate Winthrop	Liechtenstein	31.12.2019
EU/1/14/952	Sevelamer carbonate Winthrop	Norway	27.11.2019
EU/2/14/179	Suvaxyn CSF Marker	Iceland	15.11.2019
EU/2/14/179	Suvaxyn CSF Marker	Liechtenstein	31.12.2019
EU/2/14/179	Suvaxyn CSF Marker	Norway	27.11.2019
EU/1/14/961	Tadalafil Mylan	Iceland	28.8.2019
EU/1/14/961	Tadalafil Mylan	Liechtenstein	31.8.2019
EU/1/14/961	Tadalafil Mylan	Norway	12.8.2019
EU/1/13/902	Translarna	Iceland	28.8.2019
EU/1/13/902	Translarna	Liechtenstein	31.8.2019

EU-Number	Product	Country	Date of authorisation
EU/1/13/902	Translarna	Norway	26.8.2019
EU/1/14/971	TREVICTA	Iceland	6.12.2019
EU/1/14/971	TREVICTA	Norway	4.12.2019
EU/1/14/940	Triumeq	Iceland	21.10.2019
EU/1/14/940	Triumeq	Norway	16.8.2019
EU/1/14/956	Trulicity	Iceland	29.8.2019
EU/1/14/956	Trulicity	Liechtenstein	31.8.2019
EU/1/14/956	Trulicity	Norway	25.9.2019
EU/1/07/440	Tyverb	Iceland	9.10.2019
EU/1/07/440	Tyverb	Norway	21.10.2019
EU/1/14/954	Vargatef	Iceland	29.8.2019
EU/1/14/954	Vargatef	Liechtenstein	31.8.2019
EU/1/14/954	Vargatef	Norway	2.9.2019
EU/1/07/423	Vectibix	Iceland	9.10.2019
EU/1/07/423	Vectibix	Norway	21.10.2019
EU/1/14/982	Viekirax	Iceland	18.10.2019
EU/1/14/982	Viekirax	Norway	18.10.2019
EU/1/14/941	Vizamyl	Iceland	28.8.2019
EU/1/14/941	Vizamyl	Liechtenstein	31.8.2019
EU/1/14/941	Vizamyl	Norway	12.8.2019
EU/1/14/984	Xadago	Iceland	9.10.2019
EU/1/14/947	Xultophy	Iceland	21.10.2019
EU/1/14/947	Xultophy	Norway	7.8.2019
EU/1/14/986	Xydalba	Iceland	12.12.2019
EU/1/14/986	Xydalba	Liechtenstein	31.12.2019

## 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 2019:

EU-Number	Product	Country	Date of authorisation
EU/1/13/853/006-014	Remsima	Iceland	5.12.2019
EU/1/15/1043/003-006	Nucala	Iceland	28.8.2019
EU/1/15/1043/003-006	Nucala	Norway	31.7.2019
EU/1/17/1216/009	Imraldi	Iceland	30.8.2019
EU/1/17/1220/002	Tecentriq	Iceland	30.8.2019
EU/1/17/1220/002	Tecentriq	Norway	26.8.2019
EU/1/12/782/006	Kalydeco	Norway	17.12.2019

## 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 2019:

EU-Number	Product	Country	Date of withdrawal
EU/1/16/1122	Aerivio Spiromax	Iceland	21.10.2019
EU/1/16/1122	Aerivio Spiromax	Norway	29.10.2019
EU/1/07/390	Altargo	Iceland	28.8.2019
EU/2/99/017	Bovalto Ibraxion	Iceland	16.7.2019
EU/1/14/939	Daklinza	Iceland	13.12.2019
EU/1/15/1077	Iblias	Iceland	10.9.2019
EU/1/15/1077	Iblias	Liechtenstein	31.10.2019
EU/1/15/1077	Iblias	Norway	3.9.2019
EU/2/17/208	Ingelvac PCV FLEX	Norway	23.08.2019
EU/1/19/1357	Kromeya	Liechtenstein	31.12.2019
EU/1/19/1357	Kromeya	Norway	17.12.2019
EU/1/16/1143	Lartruvo	Iceland	26.8.2019
EU/1/16/1143	Lartruvo	Liechtenstein	31.8.2019
EU/1/16/1143	Lartruvo	Norway	5.8.2019
EU/1/13/847	MACI	Iceland	6.11.2019
EU/1/16/1100	Palonosetron Hospira	Iceland	2.7.2019
EU/1/16/1100	Palonosetron Hospira	Norway	23.8.2019
EU/1/13/849	Somatropin Biopartners	Norway	26.8.2019
EU/1/16/1131	Thorinane	Iceland	6.11.2019
EU/1/09/552	Topotecan Teva	Norway	23.08.2019
EU/1/16/1121	Zalmoxis	Iceland	18.10.2019
EU/1/16/1121	Zalmoxis	Norway	30.10.2019

## 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 2019:

EU-Number	Product	Country	Date of suspension