

**NOTICE AND DECISION ON THE CESSATION OF THE MARKETING
AUTHORISATION (“SUNSET CLAUSE”)**

2019

Marketing Authorisations granted in Norway 01.01.2016 - 31.12.2016 (Table 1.)
Marketing Authorisations granted exemption for sunset clause until 31.12.2019 (Table 2.)

The deadline for an exemption application is: 31.12.2019

Pursuant to § 16 of the Civil Services Act Marketing Authorisation Holders (MAHs) are hereby given notice that the Norwegian Medicines Agency is considering making a decision with regard to the cessation of the marketing authorisation for the below mentioned medicinal products:

Table 1 - Marketing Authorisations granted in Norway 01.01.2016- 31.12.2016

Product name	Marketing Authorisation Holders (MAHs)
Onytec	2care4
Traneksamsyre Accord	Accord Healthcare B.V.
Ezetimibe Accord	Accord Healthcare B.V.
Bleomycin Accord	Accord Healthcare B.V.
Caristenol	Accord Healthcare B.V.
Solifenacin Accord	Accord Healthcare B.V.
Bivalirudin Accord	Accord Healthcare B.V.
Ictady	Actavis Group PTC ehf
Clindamycin Actavis	Actavis Group PTC ehf
Iviverz	Actavis Group PTC ehf
Ictastan	Actavis Group PTC ehf
Prednisolon Actavis	Actavis Group PTC ehf
Tinguri	Actavis Group PTC ehf
Gitrabin	Actavis Group PTC ehf
Prespex	Actavis Group PTC ehf
Pemetrexed Actavis	Actavis Group PTC ehf
Solona	Actavis Group PTC ehf
Tadalafil Actavis	Actavis Group PTC ehf
Senziola	Actavis Group PTC ehf
Voriconazol Actavis	Actavis Group PTC ehf
Gabapentin Amneal	Amneal Pharma Europe Limited
Pantoprazol Amneal	Amneal Pharma Europe Limited
Duloxetine Amneal	Amneal Pharma Europe Limited
Raploc	Amomed Pharma GmbH
Voriconazole Aristo	Aristo Pharma GmbH
Zoledronic Acid Aristo	Aristo Pharma GmbH
Etoricoxib Aristo	Aristo Pharma GmbH
Dotagraf	Bayer AB

Eurican DAP	Boehringer Ingelheim Animal Health Nordics
Dutasteride Chemo Ibérica	Chemo Iberica, SA
Bosentan Cipla	Cipla (EU) Limited
Carbidopa/Levodopa Fair-Med	Fair-Med Healthcare GmbH
Duotrav	Farmagon
Imatinib Fresenius Kabi	Fresenius Kabi Deutschland GmbH
Paracetamol Galpharm	Galpharm Healthcare Limited
Flixonase	GlaxoSmithKline Consumer Healthcare AS
Carlosafine	Glenmark Pharmaceuticals Europe Limited
Lidotec	Grünenthal GmbH
Phybag	Guerbet
Rhemox Vet	Industrial Veterinaria S.A.
Dolerin	Karo Pharma AB
Amlodipin/Valsartan Krka	KRKA, d.d. Novo mesto
Rosuvastatin Krka d.d.	KRKA, d.d. Novo mesto
Olmesartan medoxomil/Hydrochlorothiazide Krka	KRKA, d.d. Novo mesto
Rasagilin Krka	KRKA, d.d. Novo mesto
Mayprep	Laboratoires Mayoly Spindler
Bivalirudin Reig Jofre	Laboratorio Reig Jofre
Palonosetron Reig Jofre	Laboratorio Reig Jofre
Bupredine vet	Le Vet Beheer B.V.
Pregabalin Medical Valley	Medical Valley Invest AB
Cinacalcet Medice	Medice Arzneimittel Pütter GmbH & Co KG
Tibelia	Mithra Pharmaceuticals S.A
Clozapine Mylan	Mylan AB
Medanef	Mylan AB
Bupremyl	Mylan AB
Solifenacin Mylan	Mylan AB
Bendamyl	Mylan Ireland Limited
Pemetrexed Mylan Pharma	Mylan S.A.S.
Tektrotyd	Narodowe Centrum Badán Jadrowych
Sandostatin LAR	Orifarm AS
Valcyte	Orifarm AS
Zocor	Orifarm AS
Concerta	Orifarm AS
Efexor Depot	Orifarm AS
Suprelorin	Orifarm AS
Zocor Forte	Orifarm AS
Calcioral D3	Orifarm AS
Equip FT	Orifarm AS
Porcilis Ery Parvo vet	Orifarm AS
Ezetimibe Orion	Orion Corporation
Ximaract	PharmaSwiss Ceska republika s.r.o.
Duloxetine Sandoz	Sandoz
Cinacalcet Sandoz	Sandoz

Tramadol/Paracetamol Sandoz	Sandoz - København
Atomoxetine Sandoz	Sandoz - København
Hedera Helix Sanofi	SANOFI-AVENTIS NORGE AS
Bisolhelix	SANOFI-AVENTIS NORGE AS
Cinacalcet Teva	Teva Sweden AB
Bortezomib Teva	Teva Sweden AB
Braltus	Teva Sweden AB
Vistaprep	Tillotts Pharma AB
Cefaseptin	Vetoquinol Scandinavia AB
Effipro Comp	VIRBAC
CANIGEN DHPPi/L	VIRBAC
Clarvivo	Weifa AS
Equest vet	Zoetis Finland Oy
Versican Plus P	Zoetis Finland Oy
Versican Plus DP	Zoetis Finland Oy
Versican Plus DHP	Zoetis Finland Oy

Table 2 - Marketing Authorisations granted exemption for sunset clause until 31.12.2019

Heparin Leo	2care4 ApS
Ifenin	Actavis Group PTC ehf
Simidon	Actavis Group PTC ehf
Venlafaxin Actavis	Actavis Group PTC ehf
Bicalutamid Actavis	Actavis Group PTC ehf
Candesartan/Hydroklortiazid Actavis	Actavis Group PTC ehf
Zerlinda	Actavis Group PTC ehf
Montelukast Actavis	Actavis Group PTC ehf
Carboplatin Actavis	Actavis Group PTC ehf
Cetirizin Actavis	Actavis Group PTC ehf
Esomeprazol Actavis	Actavis Group PTC ehf
Irinotecan Actavis	Actavis Group PTC ehf
Oxaliplatin Actavis	Actavis Group PTC ehf
Paclitaxel Actavis	Actavis Group PTC ehf
Paracetamol Actavis	Actavis Group PTC ehf
Quetiapin Actavis	Actavis Group PTC ehf
Vinorelbin Actavis	Actavis Group PTC ehf
Valaciclovir Amneal	Amneal Pharma Europe Limited
Ramipril Amneal	Amneal Pharma Europe Limited
Paroxetin Amneal	Amneal Pharma Europe Limited
Diprivan	Aspen Pharma Trading Limited
Xyloproct	Aspen Pharma Trading Limited
Naropin	Aspen Pharma Trading Limited
Clopidogrel Aurobindo	Aurobindo Pharma
Amiped	B. Braun Melsungen

Flexbumin	Baxalta Innovations GmbH
Advantage vet	Bayer Animal Health GmbH
Fluconazol Bluefish	Bluefish Pharmaceuticals AB
Casenlax	Casen Recordati, S.L
Exitel Vet	Chanelle Pharmaceuticals Manufacturing Ltd
Zantel	Chanelle Pharmaceuticals Manufacturing Ltd
Epaxal	Crucell Italy S.r.l
Gudair	CZV - Porrino
Adequanin vet	Daiichi Sankyo Altkirch SARL
Estrokad	Dr. Kade Pharmazeutische Fabrik GmbH
Docetaxel Ebewe	EBEWE Pharma Ges.m.b.H Nfg. KG
Stellamune One vet	Elanco Animal Health - Danmark
Salmeson	ELPEN Pharmaceutical Co.Inc
Maxalt	Farmagon
Janumet	Farmagon
Aricept	Farmagon
Baraclude	Farmagon
Carduran CR	Farmagon
Depo-Provera	Farmagon
Pepcidtwo	Farmagon
Zyrtec	Farmagon
Addex-Kaliumklorid	Fresenius Kabi Norge AS
Postinor	Gedeon Richter Plc
Atorvastatin Hexal	Hexal A/S
Aquavac ERM Oral vet	Intervet International BV
siDonepezil Krka	KRKA Sverige AB
Atorvastatin Krka	KRKA Sverige AB
Flimabend vet	KRKA, d.d. Novo mesto
Quiflox vet	KRKA, d.d. Novo mesto
Synaze	Meda - Asker
Buquel	Meda - Asker
Lastin	Meda - Asker
Letrozol Medical Valley	Medical Valley Invest AB
Anastrozol Medical Valley	Medical Valley Invest AB
Irbesartan/Hydrochlorothiazide Mylan	Mylan AB
Metomylan	Mylan AB
Esomeprazol Mylan	Mylan AB
Letrozol Mylan	Mylan AB
Selegilin Mylan	Mylan AB
Carboplatin Mylan	Mylan Ireland Limited
Misoone	Nordic Group BV
Takipril	Nordic Group BV
Octroflex	NordicInfu Care AB
Setofim	Norgine BV

Azzalure	Orifarm AS
Cerazette	Orifarm AS
Valtrex	Orifarm AS
Vepesid	Orifarm AS
Anafranil	Orifarm AS
Aprovel	Orifarm AS
Atrovent	Orifarm AS
Canesten	Orifarm AS
Cordarone	Orifarm AS
Cymevene	Orifarm AS
Diprosalic	Orifarm AS
Isoptin Retard	Orifarm AS
Keppra	Orifarm AS
Lipitor	Orifarm AS
Lomudal Nasal	Orifarm AS
Methotrexate	Orifarm AS
Nebcin	Orifarm AS
Orudis	Orifarm AS
Oxis Turbuhaler	Orifarm AS
Parlodel	Orifarm AS
Rebif	Orifarm AS
Remicade	Orifarm AS
Ridaura	Orifarm AS
Rivotril	Orifarm AS
Sabrillex	Orifarm AS
Surmontil	Orifarm AS
Ticlid	Orifarm AS
Zomig Rapimelt	Orifarm AS
Zyprexa Velotab	Orifarm AS
Daxas	Orifarm AS
Eviplera	Orifarm AS
Gilenya	Orifarm AS
Creon 10000	Orifarm AS
Creon 25000	Orifarm AS
Curosurf	Orifarm AS
Cyklokapron	Orifarm AS
Fleet Phospho-soda	Orifarm AS
Fungoral	Orifarm AS
Ipstyl	Orifarm AS
Micardis	Orifarm AS
MicardisPlus	Orifarm AS
Microgynon	Orifarm AS
Purinethol	Orifarm AS
Rocaltrol	Orifarm AS

Spersadex comp	Orifarm AS
Spersallerg	Orifarm AS
Vfend	Orifarm AS
Xalatan	Orifarm AS
Altifex	Orifarm Generics
Tibolon Orifarm	Orifarm Generics
Xylofin	Orifarm Generics
Memantin Orion	Orion Corporation
Simvastatin Orion	Orion Corporation
Recofol	Primex Pharmaceuticals Oy
Valsartan/Hydrochlorothiazid Ratiopharm	Ratiopharm GmbH
Cetirizin ratiopharm	ratiopharm GmbH
Diclofenac ratiopharm	ratiopharm GmbH
Fentanyl ratiopharm	ratiopharm GmbH
Loratadin ratiopharm	ratiopharm GmbH
Naso	ratiopharm GmbH
Pacligen	Sandoz - København
Finminette	Sandoz - København
Rubira	Sandoz - København
Tibocina	Sandoz - København
Oxaliplatin Sandoz	Sandoz - København
Gemcitabin Sandoz	Sandoz - København
Cloriocard	Sandoz - København
Irinotecan Seacross	Seacross Pharmaceuticals
Losartan Teva	Teva Pharma B.V.
Alendronat Teva	Teva Sweden AB
Citalopram Teva	Teva Sweden AB
Epirubicin Teva	Teva Sweden AB
Ketokonazol Teva	Teva Sweden AB
Letrozol Teva	Teva Sweden AB
Losartan Teva	Teva Sweden AB
Losartan/Hydrochlorothiazide Teva	Teva Sweden AB
Quetiapine Teva	Teva Sweden AB
Simvastatin Teva	Teva Sweden AB
Sumatriptan Teva	Teva Sweden AB
Gatonin	Teva UK Ltd
Mitomycin Vygoris	Vygoris Limited

If the information on the marketing status for the products in this list is inaccurate: the appropriate information must be provided to the Norwegian Medicines Agency no later than 31.12.2019

If no written objections to the notice or exemption application(s) are submitted by the deadline 31.12.2019, the decision of cessation of the marketing authorization will come in to force by immediate effect and **without any further confirmation to the MAH.**