

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

2022

Marketing Authorisations granted in Norway 01.01.2019 - 31.12.2019 (Table 1.)
Marketing Authorisations granted 3 years exemption for sunset clause until 31.12.2022 (Table 2.)

The deadline for an exemption application is: 31.12.2022

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:

From the entry into force of the Veterinary Medicinal Products Regulation on 28 January 2022,
the sunset clause does not apply to veterinary medicines.

Table 1 - Marketing Authorisations granted in Norway 01.01.2019- 31.12.2019

Product name	Active substance(s)	Marketing Authorisation Holders (MAHs)
Benlysta	Belimumab	Abacus Medicine
Fulvestrant Accord	Fulvestrant	Accord Healthcare
Emtricitabine/Tenofovir disoproxil Accordpharma	Emtricitabin, Tenofovirdisoproksilfumarat	Accord Healthcare
Tenofovir disoproxil Accordpharma	Tenofovirdisoproksilfumarat	Accord Healthcare
Atomoxetine Accord	Atomoksetinhydroklorid	Accord Healthcare
Lunivia	Eszopiklon	Alfred E. Tiefenbacher
Dexmedetomidine Altan	Deksmedetomidinhydroklorid	Altan Pharma Limited
Melphalan Amring	Melfalanhydroklorid	Amring Farma SRL
Alfentanil Kalceks	Alfentanilhydroklorid	AS Kalceks
Dexmedetomidine Kalceks	Deksmedetomidinhydroklorid	AS Kalceks
Rocuronium bromide Kalceks	Rokuroniumbromid	AS Kalceks
Gadograf	Gadobutrol	Bayer AB - Solna
Pregabalin 1A Farma	Pregabalin	Billev Pharma ApS
Levomethadone hydrochloride dne	Levometadonhydroklorid	dne pharma
Okitask	Ketoprofen	Dompé farmaceutici SpA
Hevicain Spinal Tung	Bupivakainhydroklorid	EQL Pharma AB
Fentanyl Ethypharm	Fentanylsitrat	Ethypharm
Simmelan	Esketaminhydroklorid	Eurocept International B.V
Hydrokortison Norfri	Hydrokortison	Evolan Pharma AB
Diklofenakkalium Norfri	Diklofenakkalium	Evolan Pharma AB
Leverette	Levonorgestrel, Etinyløstradiol	Exeltis Healthcare S.L.

Anidulafungin Fresenius Kabi	Anidulafungin	FRESENIUS KABI NORGE AS
Dipyridamol Glenmark	Dipyridamol	Glenmark Arzneimittel
Atovaquone Glenmark	Atovakvon	Glenmark Arzneimittel
Tirosintsol	Levotyroksinnatrium	IBSA Farmaceutici Italia
Deltius	Kolekalsiferol	Italfarmaco S.p.A
Dimenhydrinat Karo Pharma	Dimenhydrinat	Karo Pharma AB
Amlodipine/Valsartan/Hydrochloro thiazide Krka	Amlodipinbesilat, Valsartan, Hydroklortiazid	KRKA, d.d. Novo mesto
Tamsulosin Krka	Tamsulosinhydroklorid	KRKA, d.d. Novo mesto
Bortezomib Krka	Bortezomibmannitolboronat	KRKA, d.d. Novo mesto
Dasatinib Krka	Dasatinib	KRKA, d.d. Novo mesto
Bronwel Natt	Legestokkroserot, tørrekstrakt, Limeblomst, tørrekstrakt, Smalkjempeblad tørrekstrakt	Kwizda Pharma GmbH
Libroxar	Buprenorfinhydroklorid, Naloksonhydrokloriddihydrat	Laboratoires SMB S.A.
Melphalan Medac	Melfalanhydroklorid	Medac - Gesellschaft für klinische Spezialpräparate
Sildenafil Medical Valley	Sildenafilsitrat	Medical Valley Invest AB
Entecavir Medical Valley	Entekavirmonohydrat	Medical Valley Invest AB
Erlotinib Medical Valley	Erlotinibhydroklorid	Medical Valley Invest AB
Ladiva	Bringebladet, tørrekstrakt	Medis GmbH
Mithraring	Etonogestrel, Etinyløstradiol	Mithra Pharmaceuticals S.A
Dasatinib Mylan	Dasatinib	Mylan AB
Sunitinib Mylan	Sunitinib	Mylan AB
Anidulafungin Mylan	Anidulafungin	Mylan AB
Cutaquig	Immunglobulin, normalt, humant	Octapharma AB
Adenuric	Febuksostat	Orifarm AS
Cyclogest	Progesteron	Orifarm AS
Zepatier	Elbasvir, Grazoprevir	Orifarm AS
Innovair	Beklometasondipropionat, Formoterolfumaratdihydrat	Orifarm AS
Seretide Diskus	Salmeterolxinafoat, Flutikasonpropionat	Orifarm AS
Duotrav	Travoprost, Timololmaleat	Orifarm AS
Velmetia	Sitagliptinfosfatmonohydrat, Metforminhydroklorid	Orifarm AS
Kaletra	Lopinavir, Ritonavir	Orifarm AS
Fyremadel	Ganireliks	Orifarm AS
Sevorane	Sevofluran	Orifarm AS
Fasenra	Benralizumab	Orifarm AS
Epivir	Lamivudin	Orifarm AS
Oftagel	Karbomer 974P	Orifarm AS
Epclusa	Sofosbuvir, Velpatasvir	Orifarm AS

Atarax	Hydroksyzinhydroklorid	Orifarm AS
Locoid	Hydrokortisonbutyrat	Orifarm AS
Prezista	Darunaviretanolat	Orifarm AS
Diane	Cyproteronacetat, Etinyløstradiol	Orifarm AS
Esmya	Ulipristalacetat	Orifarm AS
Tesavel	Sitagliptinfosfatmonohydrat	Orifarm AS
Biktarvy	Biktegravirnatrium, Emtricitabin, Tenofoviralfenamidfumarat	Orifarm AS
Toujeo	Insulin glargin	Orifarm AS
Atripla	Efavirenz, Emtricitabin, Tenofoviridisoproksilfumarat	Orifarm AS
Aimovig	Erenumab	Orifarm AS
Envarsus	Takrolimusmonohydrat	Orifarm AS
Ibrance	Palbociklib	Orifarm AS
Fortzaar	Losartankalium, Hydroklortiazid	Orifarm AS
Certican	Everolimus	Orifarm AS
Ecalta	Anidulafungin	Orifarm AS
Nucala	Mepolizumab	Orifarm AS
Norspan	Buprenorfin	Orifarm AS
Lanzo Melt	Lansoprazol	Orifarm AS
Tresiba	Insulin degludec	Orifarm AS
Symbicort Mite Turbuhaler	Budesonid, Formoterolfumaratdihydrat	Orifarm AS
Locoid Lipid	Hydrokortisonbutyrat	Orifarm AS
Elocon	Mometasonfuroat	Orifarm AS
Onglyza	Saksagliptinhydroklorid	Orifarm AS
Oribamide	Hydroksykarbamid	Orifarm Generics A/S
Prucalopride Orifarm	Prukalopridsuksinat	Orifarm Generics A/S
Betahistindihydroklorid Orifarm	Betahistindihydroklorid	Orifarm Generics A/S
Erlotinib Orion	Erlotinib	Orion Corporation - Espoo
Quetiapin Orion	Kvetiapinfumarat	Orion Corporation - Espoo
Cinacalcet Orion	Cinacalcethydroklorid	Orion Corporation - Espoo
Xenical	Orlistat	Paranova AS
Incruse Ellipta	Umeklidiniumbromid	Paranova AS
Everolimus Sandoz	Everolimus	Sandoz - København
Dronedaron Sandoz	Dronedaronhydroklorid	Sandoz - København
Dasatinib Sandoz	Dasatinib	Sandoz - København
Venlafaxin Sandoz	Venlafaksinhydroklorid	Sandoz - København
Sunitinib Sandoz	Sunitinib	Sandoz - København
Pemetrexed STADA	Pemetrekseddinatrium-hemipentahydrat	Stada Arzneimittel AG
Cinacalcet STADA	Cinacalcethydroklorid	Stada Arzneimittel AG
Oxycodone Substipharm	Oksykodonhydroklorid	Substipharm

Dexmedetomidine Teva	Deksmedetomidinhydroklorid	Teva B.V.
Dasatinib Teva B.V.	Dasatinib	Teva B.V.
Dasatinib Teva Pharma B.V.	Dasatinib	Teva B.V.
Dasatinib Teva	Dasatinib	Teva B.V.

Table 2 - Marketing Authorisations granted 3 years exemption for sunset clause until 31.12.2022

Product name	Active substance(s)	Marketing Authorisation Holders (MAHs)
Heparin Leo	Heparinnatrium	2care4 ApS
Traneksamsyre Accord	Traneksamsyre	Accord Healthcare B.V.
Bleomycin Accord	Bleomycinsulfat	Accord Healthcare B.V.
Caristenol	Tolterodintartrat	Accord Healthcare B.V.
Abacavir/Lamivudine Accord	Abacavir/Lamivudin	Accord Healthcare B.V.
Voriconazol Accordpharma	Voriconazol	Accord Healthcare B.V.
Ictady	Tenofoviridisoprosil	Actavis Group PTC ehf
Ifenin	Ibuprofen	Actavis Group PTC ehf
Zerlinda	Zoledronsyremonohydrat	Actavis Group PTC ehf
Carboplatin Actavis	Karboplatin	Actavis Group PTC ehf
Esomeprazol Actavis	Esomeprazolmagnesiumdihydrat	Actavis Group PTC ehf
Irinotecan Actavis	Irinotekanhydrokloridtrihydrat	Actavis Group PTC ehf
Oxaliplatin Actavis	Oksaliplatin	Actavis Group PTC ehf
Paclitaxel Actavis	Paklitakel	Actavis Group PTC ehf
Prednisolon Actavis	Prednisolon	Actavis Group PTC ehf
Stemflova	Terlipressinacetat	Alliance Pharma (Ireland) Ltd
Ramipril Aristo	Ramipril	Aristo Pharma GmbH
Xyloproct	Lidokain/hydrokortisonacetat	Aspen Pharma Trading Limited
Naropin	Ropivakainhydrokloridmonohydrat	Aspen Pharma Trading Limited
Amipred	Aminosyrer	B. Braun Melsungen
Ximaract	Cefuroksimnatrium	Bausch + Lomb Ireland
Fluconazol Bluefish	Flukonazol	Bluefish Pharmaceuticals AB
Casenlax	Makrogol	Casen Recordati, S.L
Epaxal	Hepatitt A-Virus (inaktivert, virosom)	Crucell Italy S.r.l
Estroka	Østriol	Dr. Kade Pharmazeutische Fabrik GmbH
Docetaxel Ebewe	Docetaxel	EBEWE Pharma Ges.m.b.H Nfg. KG
Salmeton	Salmeterolxinafoat/flutikasonpropiona	ELPEN Pharmaceutical Co.Inc
Atosiban Ever Pharma	Atosibanacetat	EVER Valinject GmbH
Topogyne	Misoprostol	Exelgyn

Imatinib Fresenius Kabi	Imatinib	Fresenius Kabi Deutschland
Addex-Kaliumklorid	Kaliumklorid	Fresenius Kabi Norge AS
Postinor	Levonorgestrel	Gedeon Richter Plc
Buprenorphine Glenmark	Buprenorfin	Glenmark Arzneimittel GmbH
Atorvastatin Hexal	Atorvastatinkalsiumtrihydrat	Hexal A/S
Amlodipin/Valsartan Krka	Amlodipinbesilat/Valsartan	KRKA, d.d. Novo mesto
Rosuvastatin Krka d.d.	Rosuvastatinkalsium	KRKA, d.d. Novo mesto
Olmesartan medoxomil/ Hydrochlorothiazide Krka	Olmesartanmedoksomil/ Hydroklortiazid	KRKA, d.d. Novo mesto
Rasagilin Krka	Rasagilinhemitartrat	KRKA, d.d. Novo mesto
Palonosetron Reig Jofre	Palonosetronhydroklorid	Laboratorio Reig Jofre
Synaze	Azelastinhydroklorid/ flutikasonpropionat	Meda - Asker
Lastin	Azelastinhydroklorid	Meda - Asker
Medanef	Metylfenidathydroklorid	Mylan AB
Bupremyl	Buprenorfin	Mylan AB
Irbesartan/Hydrochlorothiazide Mylan	Irbesartan/hydroklortiazid	Mylan AB
Metomylan	Metoprololsuksinat	Mylan AB
Esomeprazol Mylan	Esomeprazolmagnesium	Mylan AB
Letrozol Mylan	Letrozol	Mylan AB
Tibelia	Tibolon	Novalon S.A.
Pantoprazol Oresund Pharma	Pantoprazolnatriumsesquihydrat	Oresund Pharma ApS
Concerta	Metylfenidathydroklorid	Orifarm AS
Efexor Depot	Venlafaksinhydroklorid	Orifarm AS
Maxalt	Rizatriptanbenzoat	Orifarm AS
Carduran CR	Doksazosinmesilat	Orifarm AS
Depo-Provera	Medroksyprogesteronacetat	Orifarm AS
Valtrex	Valaciklovirhydroklorid	Orifarm AS
Vepesid	Etoposid	Orifarm AS
Anafranil	Klomipraminhydroklorid	Orifarm AS
Aprovel	Irbesartan	Orifarm AS
Atrovent	Ipratropiumbromidmonohydrat	Orifarm AS
Canesten	Klotrimazol	Orifarm AS
Cordarone	Amiodaronhydroklorid	Orifarm AS
Cymevene	Ganciklovirnatrium	Orifarm AS
Diprosalic	Betametasondipropionat/salisylsyre	Orifarm AS
Isoptin Retard	Verapamilhydroklorid	Orifarm AS
Keppra	Levetiracetam	Orifarm AS
Lomudal Nasal	Natriumkromoglikat	Orifarm AS
Methotrexate	Metotreksat	Orifarm AS
Nebcin	Tobramycinsulfat	Orifarm AS

Orudis	Ketoprofen	Orifarm AS
Oxis Turbuhaler	Formoterolfumaratdihydrat	Orifarm AS
Parlodel	Bromokriptinmesilat	Orifarm AS
Rebif	Interferon beta-1a	Orifarm AS
Remicade	Infliksimab	Orifarm AS
Ridaura	Auranofin	Orifarm AS
Rivotril	Klonazepam	Orifarm AS
Sabrillex	Vigabatrin	Orifarm AS
Surmontil	Trimipraminmaleat	Orifarm AS
Ticlid	Tiklopidinhydroklorid	Orifarm AS
Daxas	Roflumilast	Orifarm AS
Eviplera	Emtricitabin/Rilpivirinhydroklorid/ Tenofoviridisoproksilfumarat	Orifarm AS
Gilenya	Fingolimodhydroklorid	Orifarm AS
Creon 25000	Lipase/Amylase/Protease	Orifarm AS
Curosurf	Fosfolipider og hydrofobe proteiner fra svinelunge	Orifarm AS
Fungoral	Ketokonazol	Orifarm AS
Ipstyl	Lanreotidacetat	Orifarm AS
Microgynon	Levonorgestrel/Etynyløstradiol	Orifarm AS
Purinethol	Merkaptopurin	Orifarm AS
Rocaltrol	Kalsitriol	Orifarm AS
Spersallerg	Antazolinhydroklorid/ Tetryzolinhydroklorid	Orifarm AS
Vfend	Vorikonazol	Orifarm AS
Xalatan	Latanoprost	Orifarm AS
Altifex	Feksofenadinhydroklorid	Orifarm Generics
Tibolon Orifarm	Tibolon	Orifarm Generics
Simvastatin Orion	Simvastatin	Orion Corporation
Caspofungin Orion	Kaspofungin	Orion Corporation - Espoo
Pemetrexed Orion	Pemetrekseddinatrium	Orion Corporation Orion Pharma, Espoo
Valsartan/Hydrochlorothiazid Ratiopharm	Valsartan/Hydrokloridtiaizid	Ratiopharm GmbH
Cetirizin ratiopharm	Cetirizindihydroklorid	ratiopharm GmbH
Loratadin ratiopharm	Loratadin	ratiopharm GmbH
Naso	Xylometazolinhydroklorid	ratiopharm GmbH
Finminette	Drospirenon/Etynyløstradiol	Sandoz - København
Rubira	Drospirenon/Etynyløstradiol	Sandoz - København
Tibocina	Tibolon	Sandoz - København
Oxaliplatin Sandoz	Oksaliplatin	Sandoz - København
Gemcitabin Sandoz	Gemcitabinhydroklorid	Sandoz - København
Irinotecan Seacross	Irinotekanhydrokloridtrihydrat	Seacross Pharma (Europe) Ltd.

Mitomycin Substipharm	Mitomycin	Substipharm
Gatonin	Gabapentin	Teva B.V.
Losartan Teva	Losartankalium	Teva Pharma B.V. / Teva Sweden AB
Cinacalcet Teva	Cinacalcet	Teva Sweden AB
Bortezomib Teva	Bortezomibmannitolboronat	Teva Sweden AB
Braltus	Tiotropiumbromid	Teva Sweden AB
Alendronat Teva	Natriumalendronatmonohydrat	Teva Sweden AB
Citalopram Teva	Citalopramhydrobromid	Teva Sweden AB
Epirubicin Teva	Epirubicinhydroklorid	Teva Sweden AB
Ketokonazol Teva	Ketokonazol	Teva Sweden AB
Letrozol Teva	Letrozol	Teva Sweden AB
Losartan/Hydrochlorothiazide	Losartankalium/Hydroklortiazid	Teva Sweden AB
Simvastatin Teva	Simvastatin	Teva Sweden AB

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 31.12.2022

If no written objections to the notice or exemption application(s) are submitted by the deadline 31.12.2022, the decision of cessation of the marketing authorization will come in to force by immediate effect and without any **further confirmation to the MAH.**