

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

2025

Marketing Authorisations granted in Norway 01.01.2022 - 31.12.2022

The deadline for an exemption application is: 31.12.2025

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:

Marketing Authorisations granted in Norway 01.01.2022- 31.12.2022

Product name	Active substance(s)	Marketing Authorisation Holders (MAHs)
Clobazam 1A Farma	Klobazam	1A Farma A/S
Sebadrin	Efedrinhydroklorid	2care4 Generics ApS
Vitamine B1 Sterop	Tiaminhydroklorid	Abboxia AB
Pirfenidone Accord	Pirfenidon	Accord Healthcare B.V.
Lercanidipine Accord	Lerkanidipinhydroklorid	Accord Healthcare B.V.
Teriparatide Ambio Pharma	Teriparatid	Ambio Pharma Europe
Levosimendan Amdipharm	Levosimendan	Amdipharm Ltd
Amroliv	Ampicillinnatrium	Antibiotice
Xefal	Cefaleksinmonohydrat	Antibiotice
Tapentadol Aristo	Tapentadolfosfat	Aristo Pharma GmbH
Augermid	Midodrinhydroklorid	Aspire Pharma (Malta) Limited
Pregabalin Aurobindo	Pregabalin	Aurobindo Pharma (Malta) Limited
Desflurane Baxter	Desfluran	Baxter Medical AB
Abirateron Cipla	Abirateronacetat	Cipla Europe NV
Blomensy	Rivaroksaban	Egis Pharmaceuticals Public Limited Company
Caloket	Ketorolaktrometamol	EQL Pharma AB
Copneg	Glykopyrroniumbromid, Neostigminmetylsulfat	EQL Pharma AB
Glyronul	Glykopyrroniumbromid	EQL Pharma AB
Gepretix	Progesteron	Exeltis Healthcare S.L.
Hidrosun	Kalsifediolmonohydrat	Faes Farma
Zopiclone Dune	Zopiklon	Forza Advance Ltd.
Cabazitaxel Fresenius Kabi	Kabazitaksel	Fresenius Kabi Norge AS
Lacosamide Fresenius Kabi	Lakosamid	Fresenius Kabi Norge AS
Pantoprazole Gen	Pantoprazolnatriumsesquihydrat	Genilac Germany GmbH
Hevascol	Etiodisert olje	Guerbet
Noradrenalin hameln	Noradrenalinhydrogentartrat	Hameln Pharma Plus GmbH
Rivaroxaban Hexal	Rivaroksaban	Hexal A/S
Ketazed	Ketotifenhydrogenfumarat	Horus Pharma
Pirfenidon Koanaa	Pirfenidon	Koanaa Healthcare Spain, S.L.
Tapentadol Krka	Tapentadolmaleathemihydrat	KRKA, d.d. Novo mesto

Apixaban Krka	Apiksaban	KRKA, d.d. Novo mesto
Zamisept	Heksamidindiisetionat	Laboratoires Thea S.A.S
Xilmac	Amoksicillinnatrium, Kaliumklavulanat	Macure Pharma ApS
Vinorelbin medac	Vinorelbintartrat	Medac Gesellschaft für klinische Spezialpräparate mbh
Carbomedac	Karboplatin	Medac Gesellschaft für klinische Spezialpräparate mbH, Hamburg
Fampridin AXiromed	Fampridin	Medical Valley Invest AB
Fesoterodine Medical Valley	Fesoterodinfumarat	Medical Valley Invest AB
Abirateron Medical Valley	Abirateronacetat	Medical Valley Invest AB
Medirax	Midazolamhydroklorid	Medir B.V.
Ticagrelor Newbury	Tikagrelor	Newbury Pharmaceuticals AB
Teriflunomide Newbury	Teriflunomid	Newbury Pharmaceuticals AB
Sugammadex Noridem	Sugammadexnatrium	Noridem Enterprises Ltd.
Juluca	Dolutegravirnatrium, Rilpivirinhydroklorid	Orifarm AS
Jemperli	Dostarlimab	Orifarm AS
Triumeq	Dolutegravir, Abakavir, Lamivudin	Orifarm AS
Pneumovax	Vaksine mot pneumokokkpolysakkarid	Orifarm AS
Poteligeo	Mogamulizumab	Orifarm AS
Vocabria	Kabotegravir	Orifarm AS
Suliqua	Insulin glargin, Liksisenatid	Orifarm AS
Opsumit	Macitentan	Orifarm AS
Alvesco	Ciklesonid	Orifarm AS
Metex	Metotreksatdinatrium	Orifarm AS
Rekamby	Rilpivirin	Orifarm AS
Itulazax	Allergen av bjørkepollen	Orifarm AS
Phesgo	Pertuzumab, Trastuzumab	Orifarm AS
Flixotide	Flutikasonpropionat	Orifarm AS
Victoza	Liraglutid	Orifarm AS
Differine	Adapalen	Orifarm AS
Lynparza	Olaparib	Orifarm AS
Lokelma	Natriumzirkoniumsyklosilikate	Orifarm AS
Rozlytrek	Entrektinib	Orifarm AS
Ninlaro	Iksazomibsitrat	Orifarm AS
Epiduo Forte	Adapalen, Benzoylperoksid	Orifarm AS
Vazkepa	Ikosapentetyl	Orifarm AS
Libtayo	Cemiplimab	Orifarm AS
Vocabria	Kabotegravir	Orifarm AS
Tecentriq	Atezolizumab	Orifarm AS
Xylocaine	Lidokainhydrokloridmonohydrat	Orifarm AS
Acarizax	Allergen av husstøvmidd	Orifarm AS
Calquence	Akalabrutinib	Orifarm AS
Pifeltro	Doravirin	Orifarm AS
Utrogestan	Progesteron	Orifarm AS
Bosulif	Bosutinibmonohydrat	Orifarm AS
Bavencio	Avelumab	Orifarm AS

Pacofarst	Paracetamol, Kodeinfosfathemihydrat	Orifarm Generics A/S
Sertraline Orifarm	Sertralinhydroklorid	Orifarm Generics A/S
Nomigrin	Sumatriptansuksinat, Naproksennatrium	Orion Corporation - Espoo
Orimelan	Melatonin	Orion Corporation - Espoo
Thiopental Panpharma	Tiopentalnatrium-natriumkarbonat	Panpharma S.A.
Sugammadex Qilu	Sugammadeksatrium	QILU PHARMA SPAIN S.L.
Flurbiprofen Reckitt Benckisser	Flurbiprofen	Reckitt Benckiser Healthcare (Scandinavia) A/S
Fulvestrant Reddy	Fulvestrant	Reddy Holding GmbH
Fingolimod Reddy	Fingolimodhydroklorid	Reddy Holding GmbH
Sugammadex Reddy	Sugammadeksatrium	Reddy Holding GmbH
Sitagliptin/Metformin Reddy	Sitagliptinhydrokloridmonohydrat, Metforminhydroklorid	Reddy Holding GmbH
Treprostinil Reddy	Treprostinil	Reddy Holding GmbH
Teriflunomide Sandoz	Teriflunomid	Sandoz - København
Epistatus	Midazolammaleat	SERB S.A.
Merkaptopurin Silver	Merkaptopurinmonohydrat	Silver Pharma S.L.
Fingolimod STADA	Fingolimodhydroklorid	Stada Arzneimittel AG
Pazopanib Stada	Pazopanibhydroklorid	Stada Arzneimittel AG
Gefitinib STADA	Gefitinib	Stada Arzneimittel AG
Tilamir	Levetiracetam	Stada Arzneimittel AG
Pirfenidone STADA	Pirfenidon	Stada Arzneimittel AG
Rivaroxaban STADA	Rivaroksaban	Stada Arzneimittel AG
Fulvestrant Stada	Fulvestrant	Stada Arzneimittel AG
Sunitinib STADA	Sunitinib	Stada Arzneimittel AG
Tapentadol STADA	Tapentadolfosfat	Stada Arzneimittel AG
Sorafenib STADA	Sorafenibtosylat	Stada Arzneimittel AG
Rivaroxaban STADA	Rivaroksaban	Stada Arzneimittel AG
Piperacillin/Tazobactam STADA	Piperacillinnatrium, Tazobaktamnatrium	Stada Arzneimittel AG
Etraga	Azacididin	Stada Arzneimittel AG
Meropenem Steriscience	Meropenemtrihydrat	Steriscience B.V.
Gabapentin Strides	Gabapentin	Strides Pharma (Cyprus) Limited
Ampitar	Ampicillinnatrium	Tarchominskie Zakłady Farmaceutyczne "Polfa" Spolka
Abirateron Teva	Abirateronacetat	Teva B.V.
Metformin Teva B.V.	Metforminhydroklorid	Teva B.V.
Venlafaxin Teva	Venlafaksinhydroklorid	Teva B.V.
Cabazitaxel Teva B.V.	Kabazitaksel 2-propanol	Teva B.V.
Trabectedin Teva	Trabektedin	Teva B.V.
Pirfenidon Teva	Pirfenidon	Teva GmbH
Apixaban Teva GmbH	Apiksaban	Teva GmbH
Meropenem Thrive	Meropenemtrihydrat	Thrive Pharma Ltd
Caspofungin Tillomed	Kaspofunginacetat	Tillomed Pharma GmbH - Schönefeld
Levosimendan Tillomed	Levosimendan	Tillomed Pharma GmbH - Schönefeld
Misbadi	Dabigatraneteksilatmesilat	Towa pharmaceutial Europe S.L.

Icatibant Universal Farma	Ikatibantacetat	Universal Farma S.L
Enoxaparin Ledraxon	Enoksaparininnatrium	Venipharm
Apixaban Viatriis	Apiksaban	Viatriis Limited
Icatibant Viatriis	Ikatibantacetat	Viatriis Limited
Pemetrexed Viatriis	Pemetreksed	Viatriis Limited
Vildagliptin/Metformin Viatriis	Vildagliptin, Metforminhydroklorid	Viatriis Limited
Dutasteride/Tamsulosin Viatriis	Dutasterid, Tamsulosinhydroklorid	Viatriis Limited
Cabazitaxel Viatriis	Kabazitaksel	Viatriis Limited
Sunitinib Vivanta	Sunitinibmalat	Vivanta Generics s.r.o.
Pirfenidone Vivanta	Pirfenidon	Vivanta Generics s.r.o.
Deksamfetamin Waymade B.V.	Deksamfetaminsulfat	Waymade BV
Trientine Waymade	Trientindihydroklorid	Waymade BV
Cloxacillin XGX Pharma	Kloksacillinnatrium	XGX Pharma ApS
Iricryn	Bimatoprost	Zakłady Farmaceutyczne Polpharma S.A.
Dimaz	Dorzolamidhydroklorid	Zakłady Farmaceutyczne POLPHARMA S.A.
Tidimaz	Dorzolamidhydroklorid, Timololmaleat	Zakłady Farmaceutyczne Polpharma S.A
Bitifrin	Bimatoprost, Timololmaleat	Zakłady Farmaceutyczne Polpharma S.A
Emylif	Riluzol	Zambon SpA
Rosuvastatin Zentiva	Rosuvastatinkalsium	Zentiva k.s.
Ticagrelor Zentiva	Tikagrelor	Zentiva k.s.
Paracetamol Zentiva	Paracetamol	Zentiva k.s.
Abiraterone Zentiva	Abirateronacetat	Zentiva k.s.
Fampridin Zentiva	Fampridin	Zentiva k.s.
Bupropion hydrochloride Zentiva	Bupropionhydroklorid	Zentiva k.s.
Pemetrexed Zentiva	Pemetrekseddinatriumhemipenta-hydrat	Zentiva k.s.

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 31.12.2025

If no written objections to the notice or exemption application(s) are submitted by the deadline 31.12.2025, the decision of cessation of the marketing authorization will come in to force by immediate effect and **without any further confirmation to the MAH.**