

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

2023

Marketing Authorisations granted in Norway 01.01.2020 - 31.12.2020

The deadline for an exemption application is: 31.12.2023

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 01.01.2020- 31.12.2020

Product name	Active substance(s)	Marketing Authorisation Holders (MAHs)
Levetiracetam 1A Farma	Levetiracetam	1A Farma - København
Alphagan	Brimonidintartrat	2care4
Cordarone	Amiodaronhydroklorid	2care4
Cosopt	Dorzolamidhydroklorid, Timololmaleat	2care4
Cyklokapron	Traneksamsyre	2care4
Fludara	Fludarabinfosfat	2care4
Flutiform	Flutikasonpropionat, Formoterolfumaratdihydrat	2care4
Meropur	Menotropin, humant	2care4
Mycostatin	Nystatin	2care4
Norvasc	Amlodipinbesilat	2care4
Saflutan	Tafluprost	2care4
Venofer	Jern(III)polymaltose	2care4
Vepesid	Etoposid	2care4
Zyban	Bupropionhydroklorid	2care4
Curosurf	Fosfolipider og hydrofobe proteiner fra svinelunge	2care4
Forxiga	Dapagliflozinpropandiolmonohydrat	2care4
Gentamicin B. Braun	Gentamicinsulfat	2care4
Gonal-F	Follitropin alfa	2care4
Raxone	Idebenon	2care4
Srivasso	Tiotropiumbromid	2care4
Jevtana	Kabazitaxel	Abacus Medicine
Cyramza	Ramucirumab	Abacus Medicine
Imatinib Accord	Imatinibmesilat	Abacus Medicine
Kisqali	Ribosiklibsuksinat	Abacus Medicine
Raxone	Idebenon	Abacus Medicine
Cisatracurium Accordpharma	Cisatrakuriumbesilat	Accord Healthcare

Hydroxychloroquine sulfate Accord	Hydroksyklarokinsulfat	Accord Healthcare
Bicalutamide Accord	Bikalutamid	Accord Healthcare
Abacavir Accord	Abakavir	Accord Healthcare
Atropine Accord	Atropinsulfat	Accord Healthcare
Amlodipin Actavis	Amlodipinmesilatmonohydrat	Actavis Group PTC
Clopidogrel Actavis	Klopidogrelbesilat	Actavis Group PTC
Epirubicin Actavis	Epirubicinhydroklorid	Actavis Group PTC
Valsartan Actavis	Valsartan	Actavis Group PTC
Valsartan/Hydrochlorthiazid Actavis	Valsartan, Hydroklortiazid	Actavis Group PTC
Zolpidem Actavis	Zolpidemtartrat	Actavis Group PTC
Abboticin ES	Erytromycinytuksinat	Amdipharm Limited
Rivaroxaban Aristo	Rivaroksaban	Aristo Pharma
Arixobat	Natriumoksybat	Aristo Pharma
Eslicarbazepine acetate Aristo	Eslikarbazepinacetat	Aristo Pharma
Levetiracetam Aristo Pharma	Levetiracetam	Aristo Pharma
Ondansetron Aristo	Ondansetronhydrokloriddihydrat	Aristo Pharma
Noradrenalin Kalceks	Noradrenalintartrat	AS Kalceks
Fentanyl Kalceks	Fentanylsitrat	AS Kalceks
Dexmedetomidine B. Braun	Deksmedetomidinhydroklorid	B. Braun Melsungen
Lipidem	Triglyserider av middels kjedelengde, Soyaolje, rensed, Omega-3-syretriglyserider	B. Braun Melsungen
Tranexamic acid Baxter	Traneksamsyre	Baxter Holding
Furosemide Baxter	Furosemid	Baxter Holding
Natriumklorid-Glucos Baxter Viaflo	Natriumklorid, Glukosemonohydrat	Baxter Medical
Clarityn	Loratadin	Bayer
Remifentanil Reig Jofre	Remifentanilhydroklorid	Bioglan
Anidulafungin Reig Jofre	Anidulafungin	Bioglan
Lenalidomid Cipla	Lenalidomid	Cipla Europe
Carboplatin Ebewe	Karboplatin	EBEWE Pharma Ges.m.b.H Nfg.
Ezetimibe/Atorvastatin Egis	Atorvastatinkalsiumtrihydrat, Ezetimib	Egis Pharmaceuticals Public Limited Company
Fulvestrant Ever Pharma	Fulvestrant	EVER Valinject
Cabazitaxel Ever Pharma	Kabazitaxel	EVER Valinject
Fulvestrant Fresenius Kabi	Fulvestrant	Fresenius Kabi Norge
Imipenem/Cilastatin Fresenius Kabi	Cilastatinnatrium, Imipenemmonohydrat	Fresenius Kabi Norge
Rokuroniumbromid Fresenius Kabi	Rokuroniumbromid	Fresenius Kabi Norge
Gemcitabin Fresenius Kabi	Gemcitabinhydroklorid	Fresenius Kabi Norge
Vancomycin Fresenius Kabi	Vankomycinhydroklorid	Fresenius Kabi Norge
Levometaan G.L.	Levometaanhydroklorid	G.L. Pharma

Metadon G.L.	Metadonhydroklorid	G.L. Pharma
Vagirux	Østradiolhemihydrat	Gedeon Richter
Avodart	Dutasterid	GlaxoSmithKline
Voltarol	Diklofenaknatrium	GlaxoSmithKline Consumer Healthcare
Fulvestrant Glenmark	Fulvestrant	Glenmark Arzneimittel
Pemetrexed Hexal	Pemetrekseddinatriumhemipentahydrat	Hexal
Xerodent	Epleysyre, Natriumfluorid	Karo Pharma
Simvastatin Krka	Simvastatin	KRKA Sverige
Lacosamide Krka	Lakosamid	KRKA, d.d. Novo mesto
Erlotinib Krka	Erlotinibhydroklorid	KRKA, d.d. Novo mesto
Rivaroxaban Krka	Rivaroksaban	KRKA, d.d. Novo mesto
Willfact	von Willebrandfaktor, human	LFB Biomedicaments
Fingolimod Lupin	Fingolimodhydroklorid	Lupin Europe GmbH
Enalapril/Hydrochlorothiazide Medical Valley	Enalaprilmaleat, Hydroklortiazid	Medical Valley Invest
Lenalidomid Medical Valley	Lenalidomid	Medical Valley Invest
Fingolimod Medical Valley	Fingolimodhydroklorid	Medical Valley Invest
Sunitinib Medical Valley	Sunitinibmalat	Medical Valley Invest
Amlodipine/Valsartan/ Hydrochlorothiazide Mylan Pharma	Amlodipinbesilat, Valsartan, Hydroklortiazid	Mylan
Sildenafil Mylan	Sildenafilsitrat	Mylan
Micafungin Mylan	Mikafungin	Mylan
Escitalopram Mylan	Escitalopramoksalat	Mylan
Caspofungin Mylan	Kaspofofunginacetat	Mylan Ireland
Rupafin	Rupatadinfumarat	NOUCOR HEALTH
Nuwiq	Simoktokog alfa	Orifarm AS
Synjardy	Empagliflozin, Metforminhydroklorid	Orifarm AS
Imfinzi	Durvalumab	Orifarm AS
Cerubidine	Daunorubicinhydroklorid	Orifarm AS
Flutiform K-haler	Flutikasonpropionat, Formoterolfumaratdihydrat	Orifarm AS
Cabometyx	Kabozantinib	Orifarm AS
Saizen	Somatropin	Orifarm AS
Kalydeco	Ivakaftor	Orifarm AS
Gazyvaro	Obinutuzumab	Orifarm AS
Tafinlar	Dabrafenibmesilat	Orifarm AS
Omnitrope	Somatropin	Orifarm AS
Malarone	Atovakvon, Proguanilhydroklorid	Orifarm AS
Palexia depot	Tapentadolhydroklorid	Orifarm AS
Kisqali	Ribosiklibsuksinat	Orifarm AS
Volibris	Ambrisentan	Orifarm AS
Zarzio	Filgrastim	Orifarm AS

Dupixent	Dupilumab	Orifarm AS
Livostin	Levokabastinhydroklorid	Orifarm AS
Dovato	Dolutegravir, Lamivudin	Orifarm AS
Vosevi	Sofosbuvir, Velpatasvir, Voksilaprevir	Orifarm AS
Alecensa	Alektinibhydroklorid	Orifarm AS
Holoxan	Ifosfamid	Orifarm AS
Braftovi	Enkorafenib	Orifarm AS
Maviret	Glekaprevir, Pibrentasvir	Orifarm AS
Darzalex	Daratumumab	Orifarm AS
Evotaz	Atazanavirsulfat, Kobicistat	Orifarm AS
Kyntheum	Brodalumab	Orifarm AS
Yervoy	Ipilimumab	Orifarm AS
Accofil	Filgrastim	Orifarm AS
Verzenios	Abemasiklib	Orifarm AS
Mektovi	Binimetinib	Orifarm AS
Keytruda	Pembrolizumab	Orifarm AS
Activelle	Østradiolhemihydrat, Noretisteronacetat	Orifarm AS
Adalat Oros	Nifedipin	Orifarm AS
Aerius	Desloratadin	Orifarm AS
Akynzeo	Netupitant, Palonosetronhydroklorid	Orifarm AS
Anoro	Umeklidiniumbromid, Vilanteroltrifenat	Orifarm AS
Calcigran Forte	Kalsiumkarbonat, Kolekalsiferol	Orifarm AS
Champix	Vareniklinterat	Orifarm AS
Cholestagel	Kolesevelam	Orifarm AS
Copegus	Ribavirin	Orifarm AS
Creon 10000	Lipase, Amylase, Protease	Orifarm AS
Creon 25000	Lipase, Amylase, Protease	Orifarm AS
Creon 25000	Lipase, Amylase, Protease	Orifarm AS
Cyramza	Ramucirumab	Orifarm AS
Dalacin	Klindamycinhydroklorid	Orifarm AS
Digoxin DAK	Digoksin	Orifarm AS
Diovan	Valsartan	Orifarm AS
Esmeron	Rokuroniumbromid	Orifarm AS
Exelon	Rivastigmin	Orifarm AS
Fampyra	Fampridin	Orifarm AS
Gonal-F	Follitropin alfa	Orifarm AS
Grazax	Allergenekstrakt av gresspollen fra Timotei	Orifarm AS
Imovane	Zopiklon	Orifarm AS
Instanyl	Fentanylisitat	Orifarm AS
Jakavi	Ruxolitinibfosfat	Orifarm AS

Kiovig	Immunglobulin G, humant	Orifarm AS
Klyx	Dokusatnatrium, Sorbitol	Orifarm AS
Kreon 10000	Lipase, Amylase, Protease	Orifarm AS
Kreon 25000	Lipase, Amylase, Protease	Orifarm AS
Lantus SoloStar	Insulin glargin	Orifarm AS
Marcaine	Bupivakainhydroklorid	Orifarm AS
Maxalt Rapitab	Rizatriptanbenzoat	Orifarm AS
Mirena	Levonorgestrel	Orifarm AS
Monoket OD	Isosorbidmononitrat	Orifarm AS
Mozobil	Pleriksafor	Orifarm AS
Nasonex	Mometasonfuroatmonohydrat	Orifarm AS
Nebido	Testosteronundekanoat	Orifarm AS
Neotigason	Acitretin	Orifarm AS
Neurontin	Gabapentin	Orifarm AS
Nexavar	Sorafenibtosylat	Orifarm AS
Nexplanon	Etonogestrel	Orifarm AS
Norcuron	Vekuroniumbromid	Orifarm AS
Ofev	Nintedanibesilat	Orifarm AS
Omacor	Omega-3-syreetylestere 90	Orifarm AS
Pegasys	Peginterferon alfa-2a	Orifarm AS
Pentasa	Mesalazin	Orifarm AS
Pradaxa	Dabigatraneteksilat	Orifarm AS
Prograf	Takrolimusmonohydrat	Orifarm AS
Promixin	Kolistimetatnatrium	Orifarm AS
Rectogesic	Glyceryltrinitrat	Orifarm AS
Renitec	Enalaprilmaleat	Orifarm AS
Renvela	Sevelamerkarbonat	Orifarm AS
Replagal	Alfa-galaktosidase	Orifarm AS
Requip	Ropinirolhydroklorid	Orifarm AS
Reyataz	Atazanavirsulfat	Orifarm AS
Rhinocort Turbuhaler	Budesonid	Orifarm AS
Risperdal	Risperidon	Orifarm AS
Serevent Diskus	Salmeterolxinafoat	Orifarm AS
Sifrol	Pramipeksoldihydrokloridmonohydrat	Orifarm AS
Simbrinza	Brinzolamid, Brimonidintartrat	Orifarm AS
Soolantra	Ivermektin	Orifarm AS
Spiriva	Tiotropiumbromid	Orifarm AS
Sprycel	Dasatinibmonohydrat	Orifarm AS
Stalevo	Levodopa, Karbidopa, Entakapon	Orifarm AS
Stilnox	Zolpidemtartrat	Orifarm AS
Stivarga	Regorafenib	Orifarm AS
Stocrin	Efavirenz	Orifarm AS

Subutex	Buprenorfinhydroklorid	Orifarm AS
Synarel	Nafarelinacetat	Orifarm AS
Tevagrastim	Filgrastim	Orifarm AS
Toviaz	Fesoterodinfumarat	Orifarm AS
Xagrid	Anagrelidhydroklorid	Orifarm AS
Xeloda	Kapecitabin	Orifarm AS
Zemplar	Parikalsitol	Orifarm AS
Zofran	Ondansetron	Orifarm AS
Zyloric	Allopurinol	Orifarm AS
Betamethasone Orifarm	Betametasonnatriumfosfat	Orifarm Generics
Glycerylnitrat	Glyceryltrinitrat	Orifarm Healthcare
Nycoplus Calcigran	Kalsiumkarbonat, Kolekalsiferol	Orifarm Healthcare
Amlodipin/Valsartan Orion	Amlodipinbesilat, Valsartan	Orion Corporation
Amlodipin/Valsartan/Hydrochl orothiazide Orion	Amlodipinbesilat, Valsartan, Hydroklortiazid	Orion Corporation
Menovag	Østradiolhemihydrat	Orion Corporation
Sitagliptin Orion	Sitagliptinhydrokloridmonohydrat	Orion Corporation
Orionox Depot	Oksykodonhydroklorid	Orion Corporation
Glucosamine Owlpharma	Glukosaminsulfatkaliumklorid	Owlpharma - Consulting, Lda.
Pankaine Spinal tung	Bupivakainhydroklorid	PANPHARMA
Gentamicin Panpharma	Gentamicinsulfat	PANPHARMA
Vancomycin Pfizer	Vankomycinhydroklorid	Pfizer AS
Fingolimod Pharmathen	Fingolimodhydroklorid	Pharmathen S.A
Alacare	5-aminolevulinathydroklorid	photonamic GmbH & Co. KG
Tiotropium ProPharma Group	Tiotropiumbromid	ProPharma Group Netherlands B.V.
Fluoxetin ratiopharm	Fluoksetinhydroklorid	ratiopharm GmbH
Ranitidin ratiopharm	Ranitidinhydroklorid	ratiopharm GmbH
Venlafaxin ratiopharm	Venlafaksinhydroklorid	ratiopharm GmbH
Glitinum	Matrem	Sana Pharma Medical AS
Cabazitaxel Sandoz	Kabazitakselmonohydrat	Sandoz
Terbinafin Sandoz	Terbinafinhydroklorid	Sandoz
Bortezomib Sandoz	Bortezomibmannitolboronat	Sandoz
Rivaroxaban Sandoz	Rivaroksaban	Sandoz
Azacidine Sandoz	Azacididin	Sandoz
Ticagrelor Sandoz	Tikagrelor	Sandoz
Isotretinoin Sandoz	Isotretinoin	Sandoz
Atomoxetine Sandoz	Atomoksetinhydroklorid	Sandoz
Rimcure	Rifampicin, Isoniazid, Pyrazinamid	Sandoz
Tenofovir disoproxil Sandoz	Tenofovirdisoproksil	Sandoz
Valsartan/Hydrochlorothiazide Sandoz	Valsartan, Hydroklortiazid	Sandoz

Losartan/Hydrochlorothiazide Sandoz	Losartankalium, Hydroklortiazid	Sandoz
Donepezil Sandoz	Donepezilhydroklorid	Sandoz
Efluelda	Influensa A-virus (H1N1), inaktivert, splittvirus, Influensa A-virus (H3N2), inaktivert, splittvirus, Influensa B-virus (Victoria-slektslinje), inaktivert, splittvirus, Influensa B-virus (Yamagata-linje), inaktivert, splittvirus	Sanofi Pasteur
Rabies-Imovax	Rabiesvirus, stamme Wistar PM/WI 38-1503-3M, inaktivert	Sanofi Pasteur Europe
Biorphen	Fenylefrinhydroklorid	Sintetica GmbH
Melphalan Sun	Melfalanhydroklorid	Sun Pharmaceutical
Imacillin	Amoksicillintrihydrat	Teva B.V.
Apixaban Teva	Apiksaban	Teva GmbH
Rivaroxaban Teva	Rivaroksaban	Teva GmbH
Deferasirox Teva	Deferasiroks	Teva GmbH
Tenofovir disoproxil Teva	Tenofovirdisoproksilfumarat	Teva Pharma
Atorvastatin Teva	Atorvastatinkalsium	Teva Sweden
Bicalutamide Teva	Bikalutamid	Teva Sweden
Pravastatin Teva	Pravastatinnatrium	Teva Sweden
Emtricitabin/Tenofovirdisoproxil Tillomed	Emtricitabin, Tenofovirdisoproksilfumarat	Tillomed Pharma
Azacidin Tillomed	Azacidin	Tillomed Pharma
Zeldox	Ziprasidonhydrokloridmonohydrat	Upjohn EESV
Maltofer	Jern(III)polymaltose	Vifor France
Rayaldee	Kalsifediolmonohydrat	Vifor Fresenius Medical Care Renal Pharma France
Amlodipine Vitabalans	Amlodipinbesilat	Vitabalans Oy
Bisoprolol Vitabalans	Bisoprololfumarat	Vitabalans Oy
Citalopram Vitabalans	Citalopramhydrobromid	Vitabalans Oy
Ibumax	Ibuprofen	Vitabalans Oy
Lopacut	Loperamidhydroklorid	Vitabalans Oy
Metformin Vitabalans	Metforminhydroklorid	Vitabalans Oy
Oxycodone Vitabalans	Oksykodonhydroklorid	Vitabalans Oy
Paramax	Paracetamol	Vitabalans Oy
Paramax Comp	Paracetamol, Kodeinfosfathemihydrat	Vitabalans Oy
Tramadol Vitabalans	Tramadolhydroklorid	Vitabalans Oy
Zolpidem Vitabalans	Zolpidemtartrat	Vitabalans Oy
Bortezomib Waverley	Bortezomib	Waverley Pharma Europe Limited
Vancomycin Xellia	Vankomycinhydroklorid	Xellia Pharmaceuticals
Ezetimibe Zentiva	Ezetimib	Zentiva k.s.
Azacidine Zentiva	Azacidin	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 31.12.2023

If no written objections to the notice or exemption application(s) are submitted by the deadline 31.12.2023, the decision of cessation of the marketing authorization will come in to force by immediate effect and **without any further confirmation to the MAH.**