

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

2026

Marketing Authorisations granted in Norway 01.01.2023 - 31.12.2023 (Table 1.)

The deadline for an exemption application is: 31.12.2026

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 01.01.2023- 31.12.2023

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 31.12.2026

| Product name | Active substance(s) | Marketing Authorisation Holders (MAHs) |
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| Firekol | Roflumilast | 2care4 Generics ApS |
| Daptomycin Accord Healthcare | Daptomycin | Accord Healthcare B.V. |
| Oxycodone Accord | Oksykodonhydroklorid | Accord Healthcare B.V. |
| Baclofen Accord | Baklofen | Accord Healthcare B.V. |
| Paracetamol/Codeine Accord | Paracetamol, Kodeinfosfathemihydrat | Accord Healthcare B.V. |
| Orlistat Accord | Orlistat | Accord Healthcare B.V. |
| Pazopanib Accord | Pazopanibhydroklorid | Accord Healthcare B.V. |
| Vinorelbine Accord | Vinorelbintartrat | Accord Healthcare B.V. |
| Melatonin AGB Pharma | Melatonin | AGB-Pharma AB |
| Obupro | Oksybutrokainhydroklorid | Agepha Pharma s.r.o. |
| Lunploro | Acetylene, Karbonmonoksid, Metan | Air Liquide Santé International |
| Veoplore | Helium, Karbonmonoksid | Air Liquide Santé International |
| Piperacillin/Tazobactam Antibiotice | Piperacillin, Tazobaktam | Antibiotice |
| Sugammadex Kalceks | Sugammadeksnatrium | AS Kalceks |
| Meropenem Kalceks | Meropenemtrihydrat | AS Kalceks |
| Pantoprazol Kalceks | Pantoprazolnatriumseskvihydrat | AS Kalceks |
| Clefirem | Teriflunomid | Bausch Health Ireland Limited |
| Iberoherb | Flytende ekstrakt av prydsløyfe, kamilleblomst, karvefrø, melisseblad, peppermynteblad, lakrisrot | Bayer AB - Solna |
| Melatonin Bluefish | Melatonin | Bluefish Pharmaceuticals AB |
| Emtricitabine/Tenofovir disoproxil Cipla | Emtricitabin, Tenofovirdisoproksilfumarat | Cipla Europe NV |
| Esomeprazol Cipla | Esomeprazolmagnesiumdihydrat | Cipla Europe NV |
| Rivaroxaban Cipla | Rivaroksaban | Cipla Europe NV |
| Foragen | Nitrofurantoin | CNX Therapeutics Ireland Ltd. |
| Salmeterol/flutikason ELC | Salmeterolxinafoat, Flutikasonpropionat | ELC Group s.r.o. |
| Dexmedetomidine EQL Pharma | Deksmedetomidinhydroklorid | EQL Pharma AB |

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| Levosimendan EQL Pharma | Levosimendan | EQL Pharma AB |
| Tranexkabi | Traneksamsyre | Fresenius Kabi Norge AS |
| Thiotepa Fresenius Kabi | Tiotepa | Fresenius Kabi Norge AS |
| Kidtrayze | Sinkklorid, Kobberkloriddihydrat, Mangankloridtetrahydrat, Natriumselenitt, Kaliumjodid | FRESENIUS KABI NORGE AS |
| Hydroxocobalamin G.L. Pharma | Hydroksokobalaminacetat | G.L. Pharma Gmbh |
| Sugammadex Glenmark | Sugammadeksnatrium | Glenmark Arzneimittel GmbH |
| Dabigatran etexilate Glenmark | Dabigatraneteksilatmesilat | Glenmark Arzneimittel GmbH |
| Lymecycline Glenmark | Lymesyklin | Glenmark Arzneimittel GmbH |
| Eltrombopag Glenmark | Eltrombopagolamin | Glenmark Arzneimittel GmbH |
| Voriconazole hameln | Vorikonazol | hameln pharma GmbH |
| Lacosamide hameln | Lakosamid | hameln pharma GmbH |
| Mycophenolate mofetil Hexal | Mykofenolatmofetil | Hexal A/S |
| Dimethyl fumarate Hexal | Dimetylfumarat | Hexal A/S |
| Meriofert | Menotropin | IBSA Farmaceutici Italia S.r.l. |
| Teriflunomide Krka | Teriflunomid | KRKA, d.d. Novo mesto |
| Dabigatran etexilate Krka | Dabigatraneteksilatmesilat | KRKA, d.d. Novo Mesto |
| Dapagliflozin Krka | Dapagliflozinpropylenglykolmonohydrat | KRKA, d.d. Novo Mesto |
| Sugammadex Aguettant | Sugammadeksnatrium | Laboratoire Aguettant |
| Elymbus | Bimatoprost | Laboratoires Thea S.A.S |
| Hydroxocobalamin Basi | Hydroksokobalaminklorid | Laboratorios Basi - Industria Farmaceutica, S.A. |
| Furosemide Basi | Furosemid | Laboratorios Basi - Industria Farmaceutica, S.A. |
| Fentanyl Basi | Fentanylsitrat | Laboratorios Basi - Industria Farmaceutica, S.A. |
| Zemograc | Omeprazol | Laboratorios Leon Farma, S.A. |
| Duloxetine Liconsa | Duloksetinhydroklorid | Laboratorios Liconsa, S.A. |
| Cristalmina | Klorheksidindiglukonat | Laboratorios Salvat, S.A. |
| Thiotepa medac | Tiotepa | Medac - Gesellschaft für klinische Spezialpräparate GmbH |
| Pirfenidon Medical Valley | Pirfenidon | Medical Valley Invest AB |
| Teriflunomide Medical Valley | Teriflunomid | Medical Valley Invest AB |
| Medimaa | Albumin, humant, som makroaggregater | Medi-Radiopharma Ltd. |
| Terbinafin Moberg Pharma | Terbinafinhydroklorid | Moberg Pharma AB |
| Ipratropiumbromid/Salbutamol Neutec | Ipratropiumbromidmonohydrat, Salbutamolsulfat | Neutec Inhaler Ireland Limited |
| Salbutamol Neutec | Salbutamolsulfat | Neutec Inhaler Ireland Limited |
| Fampridine Newbury | Fampridin | Newbury Pharmaceuticals AB |
| Clindamycin Noridem | Klindamycinfosfat | Noridem Enterprises Ltd. |
| Octaplasma | Plasmaproteinfraksjon, human | Octapharma AS |
| Xeplion | Paliperidonpalmitat | Orifarm AS |
| Retsevmo | Selperkatinib | Orifarm AS |
| Jyseleca | Filgotinibmaleat | Orifarm AS |
| Rybelsus | Semaglutid | Orifarm AS |
| Minjuvi | Tafasitamab | Orifarm AS |
| Wegovy | Semaglutid | Orifarm AS |
| Kyprolis | Karfilzomib | Orifarm AS |
| Diacomit | Stiripentol | Orifarm AS |
| Cosentyx | Sekukinumab | Orifarm AS |

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| Tukysa | Tukatinib | Orifarm AS |
| Apexxnar | Vaksine mot pneumokokkinfeksjon | Orifarm AS |
| Relistor | Metylnaltreksonbromid | Orifarm AS |
| Takhzyro | Lanadelumab | Orifarm AS |
| Aubagio | Teriflunomid | Orifarm AS |
| Amikacin Orifarm | Amikacinsulfat | Orifarm AS |
| Empliciti | Elotuzumab | Orifarm AS |
| Diacomit | Stiripentol | Orifarm AS |
| Myrelez | Lanreotidacetat | Orifarm AS |
| Flutide Nasal | Flutikasonpropionat | Orifarm AS |
| Xorox | Aciklovir | Orifarm AS |
| Inrebic | Fedratinibhydrokloridmonohydrat | Orifarm AS |
| TicoVac | Skogflåttencefalittvirus (TBE), inaktivert | Orifarm AS |
| Lumykras | Sotorasib | Orifarm AS |
| Plenadren | Hydrokortison | Orifarm AS |
| Alunbrig | Brigatinib | Orifarm AS |
| Salmeterol Orifarm | Salmeterolxinafoat | Orifarm Healthcare A/S |
| Remifentanil Orion | Remifentanilhydroklorid | Orion Corporation |
| Teriflunomide Orion | Teriflunomid | Orion Corporation |
| Lisdeksamfetamindimesilat Orion Pharma | Lisdeksamfetamindimesilat | Orion Corporation |
| Rivaroxaban Orion | Rivaroksaban | Orion Corporation - Espoo |
| Dabigatran etexilate Orion | Dabigatraneteksilatmesilat | Orion Corporation - Espoo |
| Tigecycline Panpharma | Tigesyklin | PANMEDICA |
| Vitamin C Pascoe | Askorbinsyre | PASCOE pharmazeutische Präparate GmbH |
| Frekidir | Sitagliptinhydrokloridmonohydrat | Pharmathen S.A |
| Dimethyl fumarate Pharmathen | Dimetylfumarat | Pharmathen S.A |
| Meropenem Qilu | Meropenemtrihydrat | QILU PHARMA SPAIN S.L. |
| Piperacillin/Tazobactam Qilu | Piperacillinnatrium, Tazobaktamnatrium | QILU PHARMA SPAIN S.L. |
| Cefazolin Qilu | Cefazolinnatrium | QILU PHARMA SPAIN S.L. |
| Galieve Forte | Natriumalginat, Natriumhydrogenkarbonat, Kalsiumkarbonat | RB Health Nordic A/S |
| Galieve Forte | Natriumalginat, Natriumhydrogenkarbonat, Kalsiumkarbonat | RB Health Nordic A/S |
| Nurofen | Ibuprofen | Reckitt Benckiser Healthcare (Scandinavia) A/S |
| Enzalutamide Sandoz | Enzalutamid | Sandoz A/S |
| Levotyroksinnatrium Sandoz | Levotyroksinnatrium | Sandoz A/S |
| Axitinib Sandoz | Aksitinib | Sandoz A/S |
| Aripiprazol STADA | Aripiprazol | Stada Arzneimittel AG |
| Forminet | Metforminhydroklorid | Stada Arzneimittel AG |
| Methylphenidate STADA | Metylfenidathydroklorid | Stada Arzneimittel AG |
| Viaredin | Sildenafilsitrat | Stada Arzneimittel AG |
| Losartan Stada | Losartankalium | Stada Arzneimittel AG |
| Trabectedin Stada | Trabektedin | Stada Arzneimittel AG |
| Levosimendan Stada | Levosimendan | Stada Arzneimittel AG |
| Dimethyl fumarate STADA | Dimetylfumarat | Stada Arzneimittel AG |

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| Efastad | Venlafaksinhydroklorid | Stada Arzneimittel AG |
| Ivermectin STADA | Ivermektin | Stada Arzneimittel AG |
| Adixemin | Lisdeksamfetamindimesilat | Stada Arzneimittel AG |
| Sildenafil STADA | Sildenafilsitrat | Stada Arzneimittel AG |
| Teriflunomide Stada | Teriflunomid | Stada Arzneimittel AG |
| Solifenacin/Tamsulosin STADA | Solifenacinsuksinat, Tamsulosinhydroklorid | Stada Arzneimittel AG |
| Desmopressin STADA | Desmopressinacetat | Stada Arzneimittel AG |
| Axitinib STADA | Aksitinib | Stada Arzneimittel AG |
| Sugammadex Stada | Sugammadexnatrium | Stada Arzneimittel AG |
| Azeflone | Azelastinhydroklorid, Flutikasonpropionat | Stada Arzneimittel AG |
| Eribulin STADA | Eribulinmesilat | Stada Arzneimittel AG |
| Losartan/Hydrochlorothiazide STADA | Losartankalium, Hydroklortiazid | Stada Arzneimittel AG |
| Tadalafil STADA Nordic | Tadalafil | STADA Nordic Aps |
| Testosterone undecanoate Teva | Testosteronundekanoat | Teva B.V. |
| Ticagrelor Teva | Tikagrelor | Teva B.V. |
| Desmopressin Teva B.V. | Desmopressinacetat | Teva B.V. |
| Fludarabin Teva | Fludarabinfosfat | Teva B.V. |
| Dimethyl fumarate Teva GmbH | Dimetylfumarat | Teva GmbH |
| Tranexamic acid Tillomed | Traneksamsyre | Tillomed Laboratories Limited |
| Midodrine Tillomed | Midodrinhydroklorid | Tillomed Pharma GmbH - Schönefeld |
| Hydrokortison Tiofarma | Hydrokortison | Tiofarma B.V. |
| Viagravil | Sildenafilsitrat | Upjohn EESV, Viatris Healthcare Limited |
| Ibuprofen/Paracetamol Viatris | Ibuprofen, Paracetamol | Viatris AS |
| Vancomycin Viatris | Vankomycinhydroklorid | Viatris Limited |
| Dymol | Azelastinhydroklorid, Flutikasonpropionat | Viatris Limited |
| Plerixafor Viatris | Pleriksafor | Viatris Limited |
| Lacosamide Vivanta | Lakosamid | Vivanta Generics s.r.o. |
| Kargluminsyre Waymade | Kargluminsyre | Waymade BV |
| Budesonid Zentiva | Budesonid | Zentiva k.s. |
| Tenofovir disoproxil Zentiva k.s. | Tenofovirdisoproksilfumarat | Zentiva k.s. |
| Dimethyl fumarate Zentiva | Dimetylfumarat | Zentiva k.s. |

If no written objections to the notice or exemption application(s) are submitted by the deadline 31.12.2026, the decision of cessation of the marketing authorization will come into force by immediate effect and **without any further confirmation to the MAH.**