

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

1. Term - 2017

Marketing Authorisations granted in Norway 01.01.2014-30.04.2014 (Table 1.)
Marketing Authorisations granted 3 years exemption for sunset clause until 30.04.2016 (Table 2.)

The deadline for an exemption application is: 30.04.2017

Please be aware that this notice also applies to the products granted exemption for sunset clause, after the provisions came into force in Norway January 2013.

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 01.01.2014-30.04.2014

Product name	Marketing Authorisation Holders (MAHs)
Diklofenak/Misoprostol Actavis	Actavis Group PTC ehf
Libéo	Ceva Santé Animale
Equipramox vet	Continental Farmaceutica
Brilique	Farmagon
ReoPro	Farmagon
Vimovo	Farmagon
Xarelto	Farmagon
Etoposid Fresenius Kabi	Fresenius Kabi Oncology Plc
Topotecan Fresenius Kabi	Fresenius Kabi Oncology Plc
Paracetamol-Koffein Orion	Galpharm Healthcare Limited
Afamcivir	GlaxoSmithKline Consumer Healthcare A/S
Alkybend	Helm AG
Gemcitabin Hetero	Hetero Europe, S.L.
Rocuronium Hospira	Hospira UK Limited
Porceptal Vet	Intervet International BV
Carprofen Krka	KRKA, d.d. Novo mesto
Veclavam vet	Norbrook Laboratories Ltd
Artelac	Orifarm AS
Desferal	Orifarm AS
Inovelon	Orifarm AS
Lamisil	Orifarm AS
Meropur	Orifarm AS
Pradaxa	Orifarm AS
Provera	Orifarm AS
ReoPro	Orifarm AS

Sildenafil Pfizer	Orifarm AS
Vidaza	Orifarm AS
Xgeva	Orifarm AS
Xiapex	Orifarm AS
Zoely	Orifarm AS
Cetirizin Orifarm	Orifarm Generics
Mirtazapin Orion	Orion Corporation
Midazolam Orpha	Orpha-Devel Handels und Vertriebs GmbH
Isteranda	Sandoz - København
Voriconazole Sandoz	Sandoz - København
Zolmitriptan sanofi-aventis	Sanofi-Aventis Norge AS
Valganciclovir Teva	Teva Pharma B.V

Table 2 - Marketing Authorisations granted 3 years exemption for sunset clause until 30.04.2016

Product name	Marketing Authorisation Holders (MAHs)
Valsartan Hydrochlorothiazide Amneal	Amneal Pharma Europe Limited
Clopidogrel Amneal	Amneal Pharma Europe Limited
Baycox Ovine	Bayer Animal Health GmbH
Sevikar Comp	Daiichi Sankyo Europe GmbH
Rigevidon	Gedeon Richter France
Drosinetta 28	Gedeon Richter Ltd
Drosinetta	Gedeon Richter Ltd
Kylnetta 28	Gedeon Richter Ltd
Valsartan/Hydrochlorothiazide Krka	KRKA Sverige AB
Escitalopram Orion	Orion Corporation - Espoo
Paricalcitol Hospira	PFIZER AS
Valsartan/Hydrochlorothiazide Teva	Ratiopharm GmbH
Montelukast Sandoz	Sandoz - København
Latanoprost Sifi	SIFI SpA
Alendronat Unimedica (Endret navn fra Bonasol)	Unimedica AB
Heparine Leo	Orifarm AS

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 30.04.2017.

If no written objections to the notice or exemption application(s) are submitted by the deadline 30.04.2017, the decision of cessation of the marketing authorization will come in to force by immediate effect and **without any further confirmation to the MAH.**