

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

3. Term - 2017

Marketing Authorisations granted in Norway 01.09.2014 - 31.12.2014 (Table 1.)

Marketing Authorisations granted 3 years exemption for sunset clause until 31.12.2017 (Table 2.)

The deadline for an exemption application is: 31.12.2017

**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 01.09.2014 - 31.12.2014

Product name	Marketing Authorisation Holders (MAHs)
Esomeprazole Accord	Accord Healthcare
Bicacta	Actavis Group PTC ehf
Memantine Amneal	Amneal Pharma Europe Limited
Oroxine	Aspen Pharma Trading Limited
Mometasone Auden	Auden Mckenzie (Pharma Division) Ltd
Fipronil Beaphar vet	Beaphar B.V
Vinelle	CampusPharma AB
Nifedoz	Sandoz - København
Albumin Behring	CSL Behring GmbH
Xolipos	Dune Medicare ApS
Nimatek vet	Eurovet Animal Health BV
Ibuprofen Galpharm	Galpharm Healthcare Limited
Priorix Tetra	GlaxoSmithKline Biologicals S.A.
Ketokel vet	Kela N.V.
Linezolid Reig Jofre	Laboratorio Reig Jofre, S.A
Acilib	Meda - Asker
Formatris	Meda - Asker
Meropenem Medipha Sante	MEDIPHA SANTE SN
Cefimam vet	Norbrook Laboratories Ltd
Pestigon	Norbrook Laboratories Ltd
Diflucan	Orifarm AS
Lamictal	Orifarm AS
Naglazyme	Orifarm AS
Nimotop	Orifarm AS
Nitrolingual	Orifarm AS

Orgalutran	Orifarm AS
Stribild	Orifarm AS
Yellox	Orifarm AS
Zanedip	Orifarm AS
Crominet	Orifarm Generics A/S
Valganciclovir Sandoz	Sandoz - København

Table 2 - Marketing Authorisations granted 3 years exemption for sunset clause until 31.12.2017

Product name	Marketing Authorisation Holders (MAHs)
Klaximol	Amneal Pharma Europe Limited
Tekcis	Cis bio international
Carboplatin Ebewe	EBEWE Pharma Ges.m.b.H Nfg. KG
Etoposid Ebewe	EBEWE Pharma Ges.m.b.H Nfg. KG
Calciumfolinat Ebewe	EBEWE Pharma Ges.m.b.H Nfg. KG
Doxorubicin Ebewe	EBEWE Pharma Ges.m.b.H Nfg. KG
Budesonid/Formoterol Turbuhaler 160/4,5	Farmagon
Lansoprazol Medical Valley	Medical Valley Invest AB
Asolzyd	Mylan 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 31.12.2017.

If no written objections to the notice or exemption application(s) are submitted by the deadline 31.12.2017, the decision of cessation of the marketing authorization will come in to force by immediate effect and **without any further confirmation to the MAH.**