

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

1. Term - 2016

Marketing Authorisations granted in Norway 01.01.2013-30.04.2013 (Table 1.)

Marketing Authorisations granted 3 years exemption for sunset clause until 30.04.2016 (Table 2.)

The deadline for an exemption application is: 30.04.2016

**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 01.01.2013-30.04.2013

Product name	Marketing Authorisation Holders (MAHs)
Crestor	2care4
Neupogen	2care4
Eligard	2care4
Clopidogrel Accord	Accord Healthcare Ltd.
Cytarabine Accord	Accord Healthcare AB
Actikerall	Almirall Hermal GmbH
Clopidogrel Aurobindo	Aurobindo Pharma (Malta) Limited - Floriana
Chanonil vet	Chanelle Pharmaceuticals Manufacturing Ltd
Prazitel Forte Vet	Chanelle Pharmaceuticals Manufacturing Ltd
Exitel Vet/Exitel Forte Vet	Chanelle Pharmaceuticals Manufacturing Ltd
Salmeson	ELPEN Pharmaceutical Co.Inc (SA), PharOS- Pharmaceutical Oriented Services Ltd.
Maxalt	Farmagon
Renvela	Farmagon
Ceftriaxon Fresenius Kabi	Fresenius Kabi Norge AS - Halden
Fludarabin Fresenius Kabi	Fresenius Kabi Oncology Plc
Mometason Galenpharma	GALENpharma GmbH
Lizam	Gedeon Richter Plc.
Letrozol Hetero	Hetero Europe, S.L.
Anastrozol Hetero	Hetero Europe, S.L.
Flimabend vet	KRKA, d.d. Novo mesto
Quiflox vet	KRKA, d.d. Novo mesto
Irbesartan/Hydrochlorothiazide Mylan	Mylan AB
Fipronil Norbrook	Norbrook Laboratories Ltd
Octroflex	NordicInfu Care AB
Seretide	Orifarm AS
Flixotide	Orifarm AS
Maxalt	Orifarm AS

Azzalure	Orifarm AS
Mirena	Orifarm AS
Cerazette	Orifarm AS
Valtrex	Orifarm AS
Vepesid	Orifarm AS
Memantin Orion	Orion Corporation - Espoo
Zoledronsyre Orion	Orion Corporation - Espoo
Farlutal Depot	Pfizer
Ezetimib Sandoz	Sandoz - København
Axor vet	Sogeval SA
Mitomycin Speciality European Pharma	Speciality European Pharma Limited
Esomeprazole Pharmaceutical Development Services	YES Pharmaceutical Development Services GmbH

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

Product name	Marketing Authorisation Holders (MAHs)
Epirubicin Accord	Accord Healthcare Ltd.
Ifenin	Actavis Group PTC ehf
Latanoprost Actavis	Actavis Group PTC ehf
Letrozol Actavis	Actavis Group PTC ehf
Simidon	Actavis Group PTC ehf
Venlafaxin Actavis	Actavis Group PTC ehf
Pravastatin Actavis	Actavis Group PTC ehf
Livazo	Kowa
Loncarti	Laboratorios Inibsa, S.A.
Metomylan	Mylan AB
Simvastatin Orion	Orion Corporation - Espoo
Alacare	Spirig Pharma Europe GmbH

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 30.04.2016.

If no written objections to the notice or exemption application(s) are submitted by the deadline 30.04.2016, the decision of cessation of the marketing authorization will come in to force by immediate effect and **without any further confirmation to the MAH.**