

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

3. Term - 2016

Marketing Authorisations granted in Norway 01.09.2013-31.12.2013 (Table 1.)
Marketing Authorisations granted 3 years exemption for sunset clause until 31.12.2016 (Table 2.)

The deadline for an exemption application is: 31.12.2016

**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 01.09.2013-31.12.2013

Product name	Marketing Authorisation Holders (MAHs)
Silgard	2care4
Candesartan/Hydroklortiazid Actavis	Actavis Group PTC ehf
Zerlinda	Actavis Group PTC ehf
Losartan/Hydrochlorothiazide Aurobindo	Aurobindo Pharma (Malta) Limited
Edicis	Cis bio international
Gudair	CZV - Porrino
Axiron	Eli Lilly Norge AS
Aricept	Farmagon
Baraclude	Farmagon
Carduran CR	Farmagon
Depo-Provera	Farmagon
Lodoz	Farmagon
Pepcidtwo	Farmagon
Zyrtec	Farmagon
Colineb	Forest Pharma B.V.
Nitroven	G. Pohl-Boskamp GmbH & Co.
Peptizole	Norbrook laboratories Limited
Intraseal	Norbrook Laboratories Ltd
Daxas	Orifarm AS
Detrusitol SR	Orifarm AS
Eviplera	Orifarm AS
Exelon	Orifarm AS
Gilenya	Orifarm AS
Incivo	Orifarm AS
Navelbine	Orifarm AS

Rapamune	Orifarm AS
Sprycel	Orifarm AS
Trusopt	Orifarm AS
Vimovo	Orifarm AS
Xarelto	Orifarm AS
Zypadhera	Orifarm AS
Eletriptan Pfizer	PFIZER AS
Simvastatin Rosemont	Rosemont Pharmaceuticals Ltd.
Finminette	Sandoz - København
Rubira	Sandoz - København
Tibocina	Sandoz – København
Nycoplus vitamin D3	Takeda AS
Ciqorin	Teva Pharma B.V
Omega-3-syre etylester Lypiad	Trygg Pharma AS
Nomixgen	Yara Praxair Holdning

Table 2 - Marketing Authorisations granted 3 years exemption for sunset clause until 31.12.2016

Product name	Marketing Authorisation Holders (MAHs)
Paclitaxel Accord	Accord Healthcare Ltd.
Montelukast Actavis	Actavis Group PTC ehf
Dolenio	Blue Bio Pharmaceuticals Ltd
Loprilin	Chemo Iberica , SA
Irinotecan Ebewe	EBEWE Pharma Ges.m.b.H Nfg. KG
Docetaxel Ebewe	EBEWE Pharma Ges.m.b.H Nfg. KG
Topotecan Ebewe	EBEWE Pharma Ges.m.b.H Nfg. KG
Oksykodon G.L. Pharma	G.L. Pharma GmbH
Celsior	Institut Georges Lopez-IGL
Atorvastatin Hexal	Hexal A/S
Valsartan Krka	KRKA Sverige AB
Oxycodon Lannacher	Lannacher Heilmittel Ges.m.b.H
Sedastop vet.	Le Vet B.V.
Detonervin vet.	Le Vet B.V.
Azithromycin Mylan	Mylan AB
Esomeprazol Mylan	Mylan AB
Sildenafil Mylan	Mylan AB
Sildenafil Orion	Orion Corporation - Espoo
Oxaliplatin Sandoz	Sandoz - København
Gemcitabin Sandoz	Sandoz - København
Gatonin	Teva UK Ltd

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 31.12.2016.

If no written objections to the notice or exemption applications are submitted by the deadline 31.12.2016, the decision of cessation of the marketing authorization will come in to force by immediate effect and **without any further confirmation to the MAH.**