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

2. Term - 2016

Marketing Authorisations granted in Norway 01.05.2013-31.08.2013 (Table 1.)
Marketing Authorisations granted 3 years exemption for sunset clause until 31.08.2016 (Table 2.)

The deadline for an exemption application is: 31.08.2016

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 01.05.2013-31.08.2013

Product name	**Marketing Authorisation Holders (MAHs)**
Naproxen Actavis	Actavis Group hf.
Bicalutamid Actavis	Actavis Group PTC ehf
Diprivan	AstraZeneca
Xyloproct	AstraZeneca, AstraZeneca AS
Donepezil Aurobindo	Aurobindo Pharma Limited (Malta)
Simvastatin Aurobindo	Aurobindo Pharma Ltd (Storbritannia)
Sildenafil Bluefish	Bluefish Pharmaceuticals AB
Misoone	Exelgyn
Janumet	Farmagon
Nplate	Farmagon
Avandia	Farmagon
Fluorette	Fertin Pharma A/S
Octreotide Fresenius Kabi	Fresenius Kabi Norge AS
Donepezil Krka	KRKA Sverige AB
Carfelican vet	Le Vet Beheer B.V.
Carprosan vet.	Le Vet Beheer B.V.
Ketodine Vet	Le Vet Beheer B.V.
Fentanyl Meda	Meda
Anamex vet	Norbrook Laboratories Ltd
Kunstig tårevæske PVA	Ophtha AS
Advagraf	Orifarm AS
Aerius	Orifarm AS
Anafranil	Orifarm AS
Aprovel	Orifarm AS
Atrovent	Orifarm AS

Avodart	Orifarm AS
Canesten	Orifarm AS
Cordarone	Orifarm AS
Cymevene	Orifarm AS
Diprosalic	Orifarm AS
Inderal Retard	Orifarm AS
Isoptin Retard	Orifarm AS
Keppra	Orifarm AS
Lipitor	Orifarm AS
Lomudal Nasal	Orifarm AS
Madopar 50/200	Orifarm AS
Methotrexate	Orifarm AS
Mevacor	Orifarm AS
Nebcin	Orifarm AS
Norvasc	Orifarm AS
Onglyza	Orifarm AS
Orudis	Orifarm AS
Oxis Turbuhaler	Orifarm AS
Parlodel	Orifarm AS
Rebif	Orifarm AS
Remicade	Orifarm AS
Renagel	Orifarm AS
Ridaura	Orifarm AS
Rivotril	Orifarm AS
Sabrilex	Orifarm AS
Saizen click.easy	Orifarm AS
Sinemet Depot	Orifarm AS
Sinequan	Orifarm AS
Surmontil	Orifarm AS
Symbicort Turbuhaler	Orifarm AS
Ticlid	Orifarm AS
Zoladex	Orifarm AS
Zomig	Orifarm AS
Zomig Rapimelt	Orifarm AS
Zyloric	Orifarm AS
Zyprexa	Orifarm AS
Zyprexa Velotab	Orifarm AS
Zyvoxid	Orifarm AS
Tibolon Orifarm	Orifarm Generics
Atovaquone/Proguanil Orifarm	Orifarm Generics A/S
Xylofin	Orifarm Generics A/S
Xatral	Sanofi-aventis Norge
Brevoxyl	Stiefel Laboratories Ltd (Irland)

VetZin	Vepidan Aps
Colistimethate Xellia	Xellia Pharmaceuticals A. p. S
Torbugesic vet	Zoetis Finland Oy

Table 2 - Marketing Authorisations granted 3 years exemption for sunset clause until 31.08.2016

Product name	**Marketing Authorisation Holders (MAHs)**
Valaciclovir Amneal	Amneal Pharma Europe Limited
Ramipril Aurobindo	Aurobindo Pharma Limited (Malta)
Arkolamyl	Mylan AB
Ferion	Orion Corporation Orion Pharma
Nicodose Freshmint	Pierre Fabre Medicament
Nicodose Lakrismint	Pierre Fabre Medicament
Imipenem/Cilastatin Ranbaxy	Ranbaxy Ltd (UK)
Valsartan/Hydrochlorthiazid Ratiopharm	Ratiopharm GmbH
Pacligen	Sandoz
Cloriocard	Sandoz

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 31.08.2016.

If no written objections to the notice or exemption application(s) are submitted by the deadline 31.08.2016, the decision of cessation of the marketing authorization will come in to force by immediate effect and **without any further confirmation to the MAH.**