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

Quarter 3 - 2015

Marketing Authorisations granted in Norway 01.09.2012-31.12.2012 (Table 1.)

The deadline for an exemption application is: 31.12.2015

Note: 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. Please see product listed in table 2 in this document. The deadline for an exemption application is also her 31.12.2015.

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 01.09.2012-31.12.2012

Product name	Marketing Authorisation Holders (MAHs)
Irbesartan Accord	Accord Healthcare Ltd.
Atorvastatin Actavis	Actavis Group PTC ehf
Rosytona	Actavis Group PTC ehf
Candesartan/Hydrochlorothiazide Tiefenbacher	Alfred E. Tiefenbacher (GmbH & Co. KG)
Chiana-Olje	Bio-Diät Berlin GmbH
Irbesartan Bluefish	Bluefish Pharmaceuticals AB
Chanspot Vet	Chanelle Pharmaceuticals Manufacturing Ltd
Vancomycin FarmaPlus	FarmaPlus AS
Capecitabine Fresenius Kabi	Fresenius Kabi Oncology Plc
Fipronil Krka	KRKA, d.d. Novo mesto
Fyperix vet	KRKA, d.d. Novo mesto
Benakor vet.	Le Vet Beheer B.V., Le Vet Pharma B.V.
Edluar	Meda - Asker
Iradier	MEDICAL VALLEY
Dolatramyl	Mylan AB
Lymecycline NRIM	NRIM Limited
Diprasorin	Orion Corporation - Espoo
Ropinirol Orion	Orion Corporation - Espoo
Docetaxel Pfizer	PFIZER AS
Alpha Marine Vibject	Pharmaq AS
Alpha Marine Vibrio	Pharmaq AS
Capecitabine Arrow	PharOS- Pharmaceutical Oriented Services Ltd
Oxycodone Depot Sandoz	Sandoz - København, Sandoz A/S
Ibandronsyre SUN	Sun Pharmaceutical - Nederland
Terlipressin SUN	Sun Pharmaceutical - Nederland

Table 2 – Products previously granted a 3 year exemption for sunset clause.

Product name	**Marketing Authorisation Holders (MAHs)**
Carboplatin Accord	Accord Healthcare Ltd.
Losartan Actavis	Actavis Group hf.
Mirtazapin Actavis	Actavis Group PTC ehf
Doxazosin Actavis	Actavis Nordic A/S
Gabapentin Actavis	Actavis Nordic A/S
Glimepirid Actavis	Actavis Nordic A/S
Lactulose Arrow	Arrow Generics Limited
Sumatriptan Aurobindo	Aurobindo Pharma Limited
Afluria	bioCLS GmbH
Ovarelin	Ceva Santé Animale
Inflexal V	Crucell Italy S.r.l
Salofalk	Dr. Falk Pharma GmbH
Fludarabin Ebewe	EBEWE Pharma Ges.m.b.H Nfg. KG
Epirubicin Ebewe	EBEWE Pharma Ges.m.b.H Nfg. KG
Erwinase	EUSA Pharma SAS
Infanrix Polio	GlaxoSmithKline AS
Fludarabinphosphat Hospira	Hospira UK Limited
Nobilis Marexine CA 126	Intervet International B.V.
Glucosamin Jemo	Jemo-pharm AS
Mirtin	KRKA Sverige AB
Montelukast Krka	KRKA Sverige AB
Quetiapine Krka	KRKA Sverige AB
Flexove	Laboratoires Expanscience
Hipracox dw	Laboratorios Hipra.S.A.
Novopulmon Novolizer	Meda - Asker
Vivoret	Meda - Asker
Valaciclovir Mylan	Mylan AB
Natriumklorid Noridem	Noridem Enterprises Ltd.
Sterilt vann Noridem	Noridem Enterprises Ltd.
Kaliumklorid Noridem	Noridem Enterprises Ltd.
Nesin	Novartis Norge AS
Menjugate Set	Novartis Vaccines and Diagnostics S.r.l
Diclofenackalium Orifarm	Orifarm Generics (3)
Enanton Depot Dual	Orion Corporation
Ketipinor	Orion Corporation
Latanoprost ratiopharm	Ratiopharm GmbH
Metformin Rosemont	Rosemont Pharmaceuticals Ltd.
Finasterid Sandoz	Sandoz - København
Metformin Sandoz	Sandoz - København
Piperacillin/Tazobactam Sandoz	Sandoz - København
Mirtazapin Sandoz	Sandoz - København
Topiramat Sandoz	Sandoz - København

Avaxim	Sanofi Pasteur MSD
Pentavac	Sanofi Pasteur MSD
Varivax	Sanofi Pasteur MSD
Viatim	Sanofi Pasteur MSD
Xatral OD	Sanofi-Aventis Norge
Donepezil Synthon	Synthon BV
Cenesid	Teva Sweden AB
Uvadex	Therakos (UK), Limited
Fenecin	Weifa AS
Duramune Puppy DP + C vet	Zoetis Finland Oy
Vangrab	Zoetis Finland Oy
Duramune Bb vet	Zoetis Finland Oy
Suvaxyn M.hyo - parasuis vet	Zoetis Finland Oy

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 31.12.2015.

If no written objections to the notice or exemption application(s) are submitted by the deadline 31.12.2015, the decision of cessation of the marketing authorization will come in to force by immediate effect and **without any further confirmation to the MAH.**