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

Quarter 2 - 2015

Marketing Authorisations granted in Norway 01.05.2012-31.08.2012

The deadline for an exemption application is: 31.08.2015

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:

Product name	**Marketing Authorisation Holders (MAHs)**
Fluvastatin Accord	Accord Healthcare Ltd.
Tolterodin Actavis	Actavis Group PTC ehf
Methotrexate Actavis	Actavis Group PTC ehf
Prilocard	aniMedica GmbH
Priligy	Berlin-Chemie AG
Bexepril	Chanelle Pharmaceuticals Manufacturing Ltd
Prospan	Engelhard Arzneimittel
Zoledronsyre Richter	Gedeon Richter Plc.
Flarin	Infirst Healthcare Limited
Procilis M1 ID	Intervet International BV
Kelactin vet	Kela Laboratoria NV
Tempora vet	Laboratoires SOGEVAL
Hydromed	MediLink
Zoledronsyre Medimpex	Medimpex UK Ltd
Lactulade	MIP Pharma GmbH
Valzydroc	Mylan AB
Candedoc	Mylan AB
Solamyl	Mylan AB
Losartan Mylan	Mylan AB
Vefamyl	Mylan AB
Fentanyl Mylan	Mylan AB
Lueva	N.V. Organon - Kloosterstraat
Clindamycin Orifarm	Orifarm Generics
Sildenafil Orifarm	Orifarm Generics
Rizatriptan Orifarm	Orifarm Generics
Tolterodin Pfizer	PFIZER AS
Zoledronsyre Sandoz	Sandoz
Elyria	Sandoz
Elyria 28	Sandoz
Gemcitabin Strides	Strides Arcolab International Limited
Paramax	Vitabalans Oy
Oxycodone Vitabalans	Vitabalans 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 31.08.2015.

If no written objections to the notice or exemption application(s) are submitted by the deadline 31.08.2015, the decision of cessation of the marketing authorization will come in to force by immediate effect and **without any further confirmation to the MAH.**