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

## 2. Term - 2017

Marketing Authorisations granted in Norway 01.05.2014-31.08.2014 (Table 1.)
Marketing Authorisations granted 3 years exemption for sunset clause until 31.08.2017 (Table 2.)

**The deadline for an exemption application is: 31.08.2017**

**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 01.05.2014-31.08.2014

| **Product name** | **Marketing Authorisation Holders (MAHs)** |
|---|---|
| Isotretinoin 2care4 | 2care4 |
| Taflotan | 2care4 |
| Mometasone Actavis | Actavis Group PTC ehf |
| Paracetamol Adare | Adare Pharmaceuticals Srl |
| Klobetasolpropionat Auden | Auden Mckenzie (Pharma Division) Ltd |
| Adaxio | Ceva Santé Animale |
| Dutasteride Cipla | Cipla Europe NV |
| Viazet | Egis Pharmaceuticals Public Limited Company |
| Hydroxyzine EQL Pharma | EQL Pharma AB |
| Levobupivacaine Fresenius Kabi | FRESENIUS KABI NORGE AS |
| Cisplatin Fresenius Kabi | Fresenius Kabi Oncology Plc |
| Bendamustine Intas | Intas Pharmaceuticals Limited |
| Latanoprost Mylan | Mylan AB |
| Norador vet | Norbrook Laboratories Ltd |
| Taurador vet | Norbrook Laboratories Ltd |
| Timosan | Orifarm AS |
| Cerubidine | Orifarm AS |
| Menveo | Orifarm AS |
| Voltarol | Orifarm AS |
| Rebetol | Orifarm AS |
| Nimenrix | Orifarm AS |
| Suprecur | Orifarm AS |
| Nevanac | Orifarm AS |
| Nanotop | ROTOP Pharmaka GmbH |
| Serelys | S.E.R.P Sales (UK) Limited |

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|---|---|
| Travoprost Sandoz | Sandoz - København |
| Brinzolamide Sandoz | Sandoz - København |
| Piperacillin/Tazobactam Stravencon | Stravencon Ltd. |
| Dutasteride Teva | Teva Sweden AB |
| Clavaseptin | Vetoquinol |
| Neoprinil | VIRBAC |

**Table 2 -** Marketing Authorisations granted 3 years exemption for sunset clause until 31.08.2017

| **Product name** | **Marketing Authorisation Holders (MAHs)** |
|---|---|
| Candesartan Actavis | Actavis Group PTC ehf |
| Enrotron vet | aniMedica GmbH |
| Arimidex | Farmagon |
| Lactulose Fresenius Kabi | Fresenius Kabi Austria GmbH |
| Buprenorphine G.L. Pharma | G.L. Pharma Gmb |
| Mometason Glenmark | Glenmark Generics Europe Limited - Middlesex |
| Remifentanil Hospira | Hospira UK Limited |
| Drosetil 28 | Laboratorios Leon Farma, S.A. |
| Axibal | Laboratorios Liconsa S.A. |
| Bonefurbit | Laboratorios Liconsa S.A. |
| Ibandronsyre Liconsa | Laboratorios Liconsa S.A. |
| Kefort | Laboratorios Liconsa S.A. |
| Licobondrat | Laboratorios Liconsa S.A. |
| Nucodran | Laboratorios Liconsa S.A. |
| Ratiban | Laboratorios Liconsa S.A. |
| Vinodran | Laboratorios Liconsa S.A. |
| Esmocard | Orpha-Devel Handels und Vertriebs GmbH |
| Curbisal | Pharbio Medical International AB |
| Revitonil | Pharbio Medical International AB |

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 31.08.2017.

If no written objections to the notice or exemption application(s) are submitted by the deadline 31.08.2017, the decision of cessation of the marketing authorization will come in to force by immediate effect and **without any further confirmation to the MAH.**