

MINISTERO DELLA DIFESA
AGENZIA INDUSTRIE DIFESA
Stabilimento Chimico Farmaceutico Militare

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Annexes: =

SUBJECT: Withdrawal of an initial Marketing Application: Product reference H3800, Ketoconazole
AID SCFM 200 mg capsules -

TO : CHMP Chair: Dr Tomas Salmonson

Läkemedelsverket- Sweden
RIC@mpa.se

CC: CHMP Rapporteur: Dr. Patrick Salmon

Irish Medicines Board- Ireland
patrick.salmon@imb.ie

CHMP co-Rapporteur: Dr. Melinda Sobor

National Institute for Quality- and Organizational
Development in Healthcare and Medicines
Hungary
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European Medicines Agency
7 Westferry Circus | Canary Wharf | London E14
4HB | United Kingdom

Dear Sir,

We would like to inform you that, at this point of time, Agenzia Industrie Difesa- Stabilimento Chimico Farmaceutico Militare has taken the decision to withdraw the application for Marketing Authorization of Ketoconazole AID-SCFM 200 mg capsules, which was intended to be used for the treatment of Cushing's Syndrome.

This withdrawal is based on the following reasons:

- unresolved major issues for which the proposed time extension requested by the Applicant for providing the answers, was not accepted by CHMP;
- commercial reasons due to a granted Marketing Authorization for a similar product.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.
I agree for this letter to be published on the EMA website

Yours sincerely,

Florence, 20 Feb. 2015