

ANNEX IV

CONDITIONS OF THE MARKETING AUTHORISATIONS

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National Competent Authorities, coordinated by the Reference Member State where applicable, shall ensure that the following conditions are fulfilled by the Marketing Authorisation Holders:

PSURs

The MAHs should submit PSURs with a yearly periodicity. These PSURs should include a specific overview and analysis of the photosensitivity reactions including photoallergy reactions. These reactions should be presented cumulatively and for the period covered by the PSUR. Particular attention should be given to indication, dosage, time to onset, sun exposure and duration of treatment. The yearly PSUR should be submitted to the NCAs, for assessment.

Educational tools

The MAHs should implement the educational program for Healthcare Professionals that should be in accordance with the other RMM. The draft outlines of such programme will be submitted to the National Competent Authorities by the MAHs four weeks after notification of the Commission Decision. The complete programme will be agreed with the National Competent authorities.

Legal status

All ketoprofen medicinal products for topical use should be subject to medical prescription.

Direct Healthcare Professional Communication

A DHPC will be sent following adoption of the CHMP Opinion as per the agreed communication plan.

In view of the divergent outcomes on the effectiveness of the measures previously applied by some Member States, the CHMP considers that it is important for the Committee to review and conclude on the effectiveness of the measures that are now being recommended at Community level. Therefore the **MAHs should provide the following to the CHMP:**

Cumulative analysis of photosensitivity reactions

The MAHs are required within 3 years of the Commission Decision to submit to the CHMP a cumulative analysis of photosensitivity reactions including photoallergy reactions together with a report of the effectiveness of RMMs to be implemented following the Commission Decision.

Surveillance study of photocontact dermatitis leading to hospitalization in Europe with a special focus on topical ketoprofen and other topical NSAIDs, including evaluation of severe photosensitivity reactions

The MAHs should perform a Surveillance study of photocontact dermatitis leading to hospitalization in Europe with a special focus on topical ketoprofen and other topical NSAIDs to clarify the incidence of severe photosensitivity reactions associated with topical medications leading to hospitalisation in different geographic areas in Europe, to evaluate possible sequelae, and to assess the impact of risk minimisation strategies. The draft protocol should be submitted for review by the CHMP by 1st December 2010. The timelines for the study conduct and final report should be provided with the draft protocol for agreement by the CHMP. Updates on the progress of the study should be provided to the CHMP on a yearly basis.