



EMEA REFERRAL PROCEDURE ON NIMESULIDE

London-Lugano, 25th May 2007, The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), started a review of systemic formulations of nimesulide-containing medicinal products due to concerns over serious liver problems. This follows the suspension of the marketing authorisations in Ireland for all nimesulide-containing products by the Irish Medicines Board on 15 May 2007.

Products containing nimesulide are approved in a number of Member States for the treatment of acute (short-term) pain, symptomatic treatment of painful osteoarthritis and primary dysmenorrhoea (period pains).

The CHMP is now looking at the available scientific data on nimesulide to reach a scientific opinion in July 2007 on whether the marketing authorisations for nimesulide should be maintained, changed, suspended or revoked in the Member States where it is marketed.

The review was initiated under Article 107 (2) of Directive 2001/83/EC as amended.

Helsinn will provide the CHMP with all the data available, and is confident that this in-depth analysis will lead to the conclusion that the marketing authorisations for nimesulide should be maintained, confirming the outcome of a similar review performed in 2003.

Nimesulide is a prescription product and must be used in compliance with indications and contra-indications, and as all other NSAIDs, it should be used for the shortest possible treatment period.

About nimesulide

Nimesulide is one of the most used non-steroidal anti-inflammatory drugs in EU.

Present on the market since 1985, nimesulide containing products are currently available in around 50 countries. To date 500 million courses of treatment have been made in 22 years of marketing. Summary for a correct use of nimesulide:

Indications: treatment of acute pain, symptomatic treatment of osteoarthritis and primary dysmenorrhoea. *Target population:* adults. *Posology:* 100mg b.i.d.

Treatment duration: should be used for the shortest possible duration, as required by the clinical situation.



About HELSINN HEALTHCARE

HELINN HEALTHCARE SA, a privately owned pharmaceutical group with headquarters in Switzerland, is the worldwide licensor of nimesulide. HELSINN's core business is the licensing of pharmaceuticals in therapeutic niche areas. The company's business strategy is to in-license early stage new chemical entities and complete their development from the performance of pre-clinical/clinical studies and CMC development to the attainment of market approvals in strategic markets (U.S. and Europe). HELSINN's products are eventually out-licensed to its marketing partners for distribution. The active pharmaceutical ingredients and the finished dosage forms are manufactured at HELSINN's cGMP facilities and supplied worldwide to its customers.

For more information about HELSINN, please visit the company's Web site at www.helsinn.com.

Contact person at HELSINN, Switzerland

Massimo Tosi, M. Chem. Pharm., Senior Manager, Commercial Operations

Tel: +41 (0)91-985-21-14 mto@helsinn.com

Mobile: +41 (0) 79 701 49 61