



LUGANO – DUBLIN, 15th May 2007

SUSPENSION OF NIMESULIDE FROM THE IRISH MARKET, PENDING EU CHMP SCIENTIFIC REVIEW

On 15th May 2007 the Irish Medicines Board (IMB) has decided to suspend Nimesulide from the Irish Market and refer it to the EU Committee for Human Medicinal Products (CHMP) for a review of its benefit /risk profile. The decision is due to the reporting of six (6) cases to the IMB by the National Liver Transplant Unit, St Vincents Hospital, late last week. These cases occurred in the period from 1999 to 2006.

Helsinn, the originator of Nimesulide, shares the concern of the IMB for the safety of the Irish public and is co-operating fully with the measures being initiated. Liver damage is a rare adverse effect known of the therapeutical class of non-steroidal anti-inflammatories as described in the present Patient Information Leaflet of Nimesulide. The use of Nimesulide has been already reviewed by the European Medicines Agency (EMA) in 2003, confirming the positive benefit /risk profile when used in accordance with prescribing instructions. Helsinn will work with the IMB and the EU authorities to ensure a full comprehensive review of all the safety data is completed as soon as possible. This is particularly important because the clinical details of the cases have not been disclosed.

Nimesulide is a non-steroidal anti-inflammatory medicine that is authorized in more than 50 countries for the treatment of acute pain, the symptomatic treatment of painful osteoarthritis and for primary dysmenorrhoea. In the past 22 years Nimesulide has been used by approximately 500 million patients worldwide.

Nimesulide has been sold in Ireland under prescription since 1995 and in this period an estimated 5 million treatments have been prescribed.

Helsinn is a Swiss based group with 450 employees, present in Ireland since 1989, where it employs 220 people in manufacturing and sales activities.