IRISH MEDICINES BOARD

# FAX

## IMPORTANT SAFETY INFORMATION – PLEASE READ

| | |
|---|---|
| **To:** All healthcare professionals, as addressed | **From:** Dr. Joan Gilvarry<br>Director of Human Medicines,<br>IMB. |
| **Fax number:** N/A | **Date:** 11th January, 2013 |
| **No. of pages:** 1 | **cc:** N/A |
| **Re:** **Tredaptive** (nicotinic acid/laropiprant) and PRAC recommendation for suspension | |

Dear Doctor/Pharmacist/Nurse,

Further to previous communications[1] on Tredaptive (nicotinic acid/laropiprant), the IMB is writing to inform you that following a thorough assessment of the benefits and risks of this medicine, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has concluded during its January 2013 meeting that the risks are greater than the benefits and has recommended that this medicine should be suspended.

The PRAC recommendation arises from review of the recent data from the HPS2-THRIVE study (Heart Protection Study 2-Treatment of HDL to Reduce the Incidence of Vascular Events) of Tredaptive (nicotinic acid/laropiprant). Preliminary results from HPS2-THRIVE have failed to show a beneficial effect of Tredaptive on the reduction of major vascular events. The study also showed a significant increase in the incidence of some types of non-fatal serious adverse events in the group that received Tredaptive. These events fall within the following categories: blood and lymphatic, gastrointestinal, infections, metabolism, musculoskeletal, respiratory and skin. Consequently the balance of risks and benefits is no longer considered to be favourable.

Therefore, in the light of the latest study data, the PRAC recommended that the marketing authorisation of this medicine should be suspended. The PRAC recommendation will be considered by the Agency's Committee for Medicinal Products for Human Use, which will adopt a final scientific opinion at the next CHMP meeting of 14-17 January 2013. Further to the EMA and IMB's previous communication published on 21 December 2012[1], the final CHMP opinion, together with full advice for patients and healthcare professionals, will be made public. You will receive a letter with detailed information on the appropriate actions to be taken including details of the suspension of availability. Further information on the background to this issue is available from the IMB/EMA websites (www.imb.ie /www.ema.europa.eu).

Yours sincerely,

Joan Gilvarry

**Dr. Joan Gilvarry, MB, FRCPI**
**Director of Human Medicines**

1. IMB Website Notice on initiation of referral, December 21st and MSD DHPC dated January 3rd available at www.imb.ie
2. PRAC highlights 11th January 2013 available at www.imb.ie and www.ema.europa.eu.