Malta, 10 January 2008

Circular No. P01/2008

Dear Healthcare Professional,

Re: Recommendation for the Withdrawal of the Marketing Authorisation of Lumiracoxib-containing medicines

As stated in the latest Medicines Authority Circular on lumiracoxib, Circular P18/2007 issued on 22 November 2007, the Medicines Authority is hereby providing a further update on the benefit-risk profile of this medicinal product. The Committee for Medicinal Products for Human Use (CHMP) has finalized a review of available information on the safety of lumiracoxib and has concluded that the risks of these medicines are greater than their benefits. Therefore, the CHMP has recommended the withdrawal of their marketing authorizations in all Member States where they are approved. The only lumiracoxib-containing medicine currently licensed for marketing in Malta is Prexige®, which has been marketed since April 2007. The Medicines Authority has participated in these discussions held at the European Medicines Agency (EMEA) and is in agreement with the actions described in the attached **press release** and **Q & A document** issued by the EMEA. The CHMP's opinion has been forwarded to the European Commission for the adoption of a Decision which is legally binding. In the interim period the Medicines Authority has recommended the Licensing Authority to suspend the marketing authorisation of Prexige®. Furthermore, the Medicines Authority has held discussions with the Marketing Authorisation Holder of Prexige® (Novartis) to carry out a recall of Prexige® at a pharmacy level. Patients taking lumiracoxib-containing medicines are advised to contact their doctor who will recommend a change to other medicines. Further information can be obtained by calling us on 23439000 or sending an email to: postlicensing.mru@gov.mt

Medicines Authority
198, Rue D'Argens, Gzira, GZR 03 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 email: info.mru@gov.mt