Malta, 25 September 2007

Circular No. P13/2007

Dear Healthcare Professional,

Re: Benefit-Risk Profile of Nimesulide-containing Systemic Medicinal Products

Following the suspension of the marketing authorization of all nimesulde-containing medicinal products by the Irish competent authority in May 2007, as a result of reports received on serious side effects affecting the liver, the Committee for Medicinal Products for Human Use (CHMP) had initiated assessment of the hepatic safety of the above-mentioned medicinal product. Following the completion of this review, the CHMP has concluded that the benefit risk balance of nimesulide-containing systemic medicinal products is still positive, however, duration of treatment should be only for 15 days and as a consequence all packs containing more than 30 doses should be removed from the market in all Member States. The Medicines Authority has participated in these discussions held at the European Medicines Agency (EMEA) and is in agreement with the attached **press release** and **Q & A document** issued by the EMEA. Further to this, the European Commission will shortly publish a Decision which is legally binding in all Member States and to be implemented by all Marketing Authorisation Holders holding a license for nimesulide-containing systemic medicinal products.

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