

Malta, 4 November 2005

Circular No. P19/2005

Dear Healthcare Professional,

Re: Cardiovascular and gastrointestinal safety and serious skin reactions with non-selective NSAIDs (Non-Steroidal Anti-Inflammatory Drugs)

Following the Medicines Authority's last statement¹ regarding safety concerns related to non-selective NSAIDs, the assessment of all available data on the non-selective NSAIDs² at a European level has been finalised. The Medicines Authority has participated in these discussions held at the European Medicines Agency (EMA) and is of the opinion that the advice and recommendations provided in the attached **press release** issued by the EMA is opportune and appropriate. The Medicines Authority assures healthcare professionals and patients that NSAIDs remain important treatments for arthritis and other painful conditions, and that NSAIDs are being continuously monitored. Furthermore, the Medicines Authority will implement consistent product information for the different non-selective NSAIDs as recommended in the EMA's press release.

¹ MA Statement P15/2005 (2 August 2005): Non-selective NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) and cardiovascular safety

² The non-selective NSAIDs currently included in the European review include: Diclofenac, Etodolac, Ibuprofen, Indomethacin, Ketoprofen, Meloxicam, Nabumetone, Naproxen, Nimesulide and Piroxicam.