

Malta, 18 February 2005
Circular. No. P03/2005

RE: CELECOXIB (Celebrex® / Onsenal®); ETORICOXIB (Arcoxia®); VALDECOXIB (Bextra®/Valdyn®) and Parecoxib (Prexige®); and cardiovascular safety

Dear Healthcare Professional,

Following the finalisation of the class referral of COX-2 inhibitors by the Committee for Medicinal Products for Human Use (CHMP) and the subsequent statement on the **contra-indication** of celecoxib, valdecoxib, etoricoxib and parecoxib, in patients with established ischaemic heart disease and/or cerebrovascular disease. The Medicines Authority is of the opinion that the advice provided for the COX-2 inhibitors is appropriate and the increased cardiac safety concerns have been well implemented in section 4.3 of the Summary of Product Characteristics. The Medicines Authority would like to inform prescribers to follow carefully the latest recommendations, which the CHMP has made in the attached [press release](#), and modified Summary of Product Characteristics issued on these products.

Yours truly,

Dr John J Borg PhD
Post-Licensing Director