24th October 2011

Circular No. P16 /2011

Dear Healthcare Professional,

Re: European Medicines Agency starts new review of cardiovascular risks of non-selective NSAIDs

The European Medicines Agency (EMA) is reviewing the latest available data on the cardiovascular safety of non-selective NSAIDS (non-steroidal anti-inflammatory drugs).

NSAIDS have been the subject of several European reviews in relation to gastrointestinal and cardiovascular safety and the occurrence of serious skin reactions. At the outcome of the last review on the cardiovascular safety of non-selective NSAIDs, in 2006, the Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the overall benefit-risk balance remained positive, but the possibility of a small increased risk of thrombotic events such as heart attacks or stroke with non-selective NSAIDs could not be excluded. This was particularly seen when NSAIDs were used at high doses and for long-term treatment. Further epidemiological studies were needed to obtain additional data on pertinent safety aspects of NSAIDs and therefore the Agency recommended in 2006 that the European Commission fund an independent epidemiological study to further explore the risk of gastrointestinal and cardiovascular toxicity of these medicines.

Since 2006, a number of new studies on the cardiovascular safety of NSAIDs have been published. Recently, results from the independent research project 'Safety Of non-Steroidal anti-inflammatory drugs' (SOS) funded by the European Commission under the 7th framework program to evaluate the safety of NSAIDs, have become available. The CHMP will now review the results of this meta-analysis thoroughly, together with any other available clinical data (including data from clinical trials and epidemiological studies) and post-marketing safety reports on non-selective NSAIDs, to clarify whether there is any need to update the opinion issued in 2006.

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Healthcare professionals are encouraged to maintain vigilance on this class of medications. Suspected adverse drug reactions may be reported using the Medicines Authority yellow card scheme or online at http://www.medicinesauthority.gov.mt/pub/adr.doc or to the marketing authorisation holder or their local representatives.

The Medicines Authority has participated in the discussions held at the EMA and is in agreement with the full **press release** issued by the EMA, attached here for your perusal.

Healthcare professionals are encouraged to check the Medicines Authority website regularly for product safety updates as these are issued on an ongoing basis.

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