24th October 2011

Circular No. P15 /2011

Dear Healthcare Professional,

Re: European Medicines Agency concludes that benefit-risk balance of angiotensin II receptor antagonists remains positive

Angiotensin II receptor antagonists (ARBs) have been authorised in the European Union since the mid-1990s for the treatment of hypertension. They are also used in the treatment of conditions such as heart failure and kidney disease in type 2 diabetics and for the prevention of strokes and heart disease.

Following the publication of a meta-analysis which showed a small increased risk of new cancers (particularly lung cancer) with ARBs compared with placebo and other heart medicines (7.2% versus 6%) the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has reviewed the possible link between the use of ARBs and the occurrence of new cancers and concluded that the evidence does not support any increased risk of cancer in patients using these medicines.

The CHMP reviewed all available data on the risk of cancer in patients taking ARBs, including the meta-analysis. It found that the evidence from the meta-analysis was weak, noting several problems with the quality of the data, specifically that patients in the trials were not followed up for long enough to clearly establish a link between ARBs and cancer, information on the risk of cancer before start of treatment was lacking, and there was a possibility of publication bias, whereby studies that showed a link with cancer were more likely to have been included in the analysis.

The CHMP also reviewed data from large population-based studies and more complete meta-analyses that did not have the same methodological problems as the original meta-analysis, and the

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results did not show an increased risk of cancer with ARBs. The safety of ARBs will be continuously monitored. The Committee's opinion has now been forwarded to the European Commission for the adoption of an E.U. wide decision.

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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