9 th June 2011

Circular No. P07/2011

Dear Healthcare Professional,

Re: A European review of Pioglitazone-containing medicines

The EMA's Committee for Medicinal Products for Human Use (CHMP) started a European review of pioglitazone-containing medicines in March 2011 to investigate the signal of a possible increased risk of bladder cancer with pioglitazone.

The CHMP is currently reviewing all relevant data, including data from pharmacoepidemiological studies, non-clinical and clinical data, post-marketing reports of bladder cancer and published data to assess their impact on the balance of benefits and risks of these medicines. The Committee will now also assess the results of the French study and its potential impact on the use of these medicines across the whole EU. The CHMP will discuss this issue at their next meeting on 20-23 June 2011 and recommend appropriate actions as necessary.

Pioglitazone is used to treat type 2 diabetes in adults, particularly those who are overweight. Its main use is in patients who are not satisfactorily controlled with metformin or a sulphonylurea and can be used alone or in combination with other anti-diabetic medications including insulin. This review encompasses the centrally authorised pioglitazone-containing medicines; Actos, Glustin, Competact, Glubrava and Tandemact in all doses.

The French Medicines Agency (Afssaps) has decided to suspend the use of pioglitazone-containing medicines in France (Actos, Competact), while awaiting the outcome of the ongoing review on the benefits and risks of these antidiabetic medicines. This decision by the French authority follows receipt of results of a retrospective cohort study carried out in France which gave results that appear to suggest an increased risk of bladder cancer with pioglitazone. The French targeted epidemiological study is a retrospective cohort study conducted by the French

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health insurance (Caisse National d'Assurance Maladie) which followed antidiabetic patients taking antidiabetic medicines between 2006 and 2009.

The Medicines Authority will be participating 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 regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis

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