AWTORITÀ DWAR IL-MEDIĊINI

27th October 2010

Circular No. P15/2010

Dear Healthcare Professional,

Re: The European Medicines Agency recommends use of fibrates as second-line treatment

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of the four fibrates bezafibrate, ciprofibrate, fenofibrate and gemfibrozil continue to outweigh their risks in the treatment of patients with blood lipid disorders. However, doctors should no longer prescribe them to newly-diagnosed patients with blood lipid disorders as first-line treatment, except for patients with severe hypertriglyceridaemia or patients who cannot take statins. In Malta marketing authorisations exist for bezafibrate as Bezalip and Befibrat and for fenofibrate as Lipanthyl.

Fibrates are a class of medicines that have been in use for many years to lower level of lipids such as triglycerides and cholesterol in the blood. They were first subject to a Europe-wide review in 2005, when the CHMP's Pharmacovigilance Working Party reviewed their benefits and risks because of limited evidence of their long-term benefits in reducing cardiovascular risks. At that time the Working Party concluded that these medicines continued to have a place in the treatment of lipid disorders but should not be used as first-line treatment.

The current review by the CHMP was initiated at the request of the United Kingdom, because a number of marketing authorisation holders of the four fibrates had questioned the conclusions of the Pharmacovigilance Working Party. The UK therefore referred the matter to the CHMP for adoption of a Europe-wide recommendation whether the existing marketing authorisations should be maintained or changed.

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The Committee confirmed the conclusions of the Pharmacovigilance Working Party and recommended that fibrate-containing medicines should not be used as first-line treatment, except in patients with severe hypertriglyceridaemia and in patients who cannot use statins. For fenofibrate, the Committee noted additional new data and recommended that it can also be used together with a statin in some circumstances when a statin on its own has not been enough to completely control blood lipid levels.

The CHMP's opinion has been sent to the European Commission for the adoption of a binding decision throughout the European Union.

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. A **question-and-answer** document with more information about the outcome of this assessment is also available.

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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