4th October 2011

Circular No. P12/2011

Dear Healthcare Professional,

Re: European Medicines Agency starts review of orlistat-containing medicines

The European Medicines Agency (EMA) has started a review of the orlistat-containing anti-obesity medicines Xenical (orlistat 120 mg) and the over-the-counter-medicine Alli (orlistat 60 mg) with respect to the risk of liver reactions. The vast majority of liver injuries reported are not serious, and severe liver injury has been reported very rarely. Both Xenical and Alli are available in Malta.

Orlistat 120mg

The most recently submitted analysis of all cases of hepatic events reported with orlistat 120 mg between 8 August 2009 and 31 January 2011, identified a total of 21 suspected cases, of which 4 were cases of severe liver toxicity (one fatal case of hepatic failure, one case of hepatic failure leading to liver transplantation, one case of exacerbation of hepatitis and one case of hepatitis). Overall, between 1997 until January 2011 there were 21 cases of suspected serious liver toxicity for which a causal link to orlistat cannot be excluded. However, these cases do not provide strong evidence of a link to orlistat, as alternative explanations for liver injury are present in many of the cases. Furthermore, the number of cases needs to be considered in the context of cumulative usage of these medicines in 38 million patients.

Orlistat 60mg

During the period between May 2007 and January 2011 there were a total of 9 reports of suspected severe liver injury with orlistat 60 mg. In some cases other possible explanations for liver injury

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were present and some cases provided insufficient information to allow assessment. These 9 cases need to be considered in the context of cumulative usage of 11 million patients.

The EMA's Committee on Human Medicinal Products is now reviewing all relevant data on the risk of hepato-toxicity of orlistat-containing medicines and will issue an opinion on whether or not the marketing authorisations for these medicines should be revoked, suspended or changed. The Medicines Authority will give updated information in a timely manner on the association of severe liver toxicity with orlistat products. In the interim, healthcare professionals are encouraged to be vigilant and report any suspected adverse drug reactions with orlistat products to the Medicines Authority through the yellow-card scheme or online at http://www.medicinesauthority.gov.mt/pub/adr.doc or to the marketing authorisation holder.

The full **press release** issued by the EMA is 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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