Malta, 16th December 2010

Circular No. P19/2010

Dear Healthcare Professional,

Re: European Medicines Agency; Review of Somatropin containing medicines officially started

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has started a review of the safety of somatropin-containing medicines authorised centrally or by national procedures in the European Union (EU). The CHMP will look into all available data on somatropin to reassess the benefit-risk balance of these medicines. Somatropin is available in Malta and is marketed as Saizen click-easy, Humatrope, Norditropin SimpleXx and Genotropin.

While this review is ongoing, the CHMP confirms that there is no immediate concern. However, prescribers are reminded to strictly follow the indications and the approved doses. The maximum recommended dose of 50µg/kg weight/day for somatropin-containing medicines should not be exceeded.

Somatropin is a human growth hormone, manufactured using recombinant DNA technology. It is used to treat a number of conditions associated with a lack of growth hormone and short stature. This includes children who fail to grow due to a lack of growth hormone, Turner syndrome or chronic renal insufficiency.

This review was initiated further to information received from the French medicines agency on a long-term epidemiological study in patients treated during childhood for idiopathic lack of growth hormone and idiopathic or gestational short stature with somatropin-containing medicines. The study results

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suggest an increased risk of mortality with somatropin therapy compared with the general population. This study on the safety and appropriateness of growth hormone treatments is funded by the European Commission and conducted by an European consortium of paediatric endocrinologist, epidemiologists and biostatisticians, involving eight EU countries. The study is still ongoing and further results are expected in the future. Further updates on this review will be made as appropriate.

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

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