AWTORITA' DWAR IL-MEDIĆINI

**Malta**, 1 July 2009

Circular No. P10/2009

Dear Healthcare Professional,

Re: European Medicines Agency update on safety of insulin glargine

The European Medicines Agency (EMEA) is looking into four recently published registry studies

investigating a possible relationship between insulin analogues, in particular insulin glargine, and the

risk of cancer. The studies were published on the Diabetologia website on 26 June 2009.

On the basis of the currently available data, a relationship between insulin glargine and cancer can

neither be confirmed nor excluded. However, the concerns raised by the four studies require further

in-depth evaluation. The Agency's Committee for Medicinal Products for Human Use (CHMP) will

perform a detailed assessment of the studies' results and any other relevant information.

Patients being treated with insulin glargine should continue their treatment as normal. At this time

there is no recommendation that treatment should be changed. Patients should, nevertheless, be

advised to consult their doctor in case of any concerns.

Further information will be provided once the CHMP has concluded its review.

The Medicines Authority has participated in these discussions held at the EMEA and is in agreement

with the full <u>press release</u> issued by the EMEA, 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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