

Malta, 23 July 2009
Circular No. P13/2009

Dear Healthcare Professional,

Re: European Medicines Agency second update on safety of insulin glargine

Following review of all available information on a possible relationship between insulin analogues, in particular insulin glargine, and the risk of cancer, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the available data does not provide a cause for concern and that changes to the prescribing advice are therefore not necessary.

Concerns over a possible relationship between these medicines and cancer, in particular breast cancer, were raised by four recently published registry studies. The Committee carried out an in-depth review of these studies and their outcomes. Due to methodological limitations the studies were found to be inconclusive and did not allow a relationship between insulin glargine and cancer to be confirmed or excluded. In addition, the Committee noted that the results of the studies were not consistent.

The Medicines Authority has participated in these discussions held at the EMEA and is in agreement with the full [press release](#) 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.