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Outcome of review of new safety data on insulin glargine

Data from population-based studies and the scientific literature do not indicate an increased risk of cancer

On 30 May 2013, the European Medicines Agency completed a review of new data on the cancer risk with insulin glargine-containing medicines. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the data do not show an increased risk of cancer and that the balance of the medicine's benefits and risks remains unchanged.

What is insulin glargine?

Insulin glargine is an injectable insulin used to treat diabetes in patients aged two years or older.

Insulin glargine is a type of long-acting insulin. It is absorbed more slowly after injection than normal human insulin, and has a longer duration of action, but works in same way in helping to control blood glucose levels.

Insulin glargine has been authorised in the EU as Lantus and Optisulin since June 2000.

Why was insulin glargine reviewed?

In 2009, the publication of four registry studies raised concerns of a possible link between insulin glargine and cancer, particularly breast cancer. Following the publication, the CHMP carried out an in-depth review and concluded, in July 2009 that, due to some limitations in the way the studies were conducted, a link between insulin glargine and cancer could not be confirmed or excluded from the results. In addition, the Committee noted that the results of the studies were not consistent.

The CHMP requested that the company that markets the medicine provide further data. The company subsequently carried out further studies and submitted the results to the CHMP for review.

What data were included in this review?

The current review included data from three population-based studies. Two of these were cohort studies (studies that follow up and collect data from a particular patient population, known as a cohort): one study collected data from around 175,000 patients in northern Europe who were treated with insulin glargine, human insulin or combined insulin, while the other collected data from around

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140,000 patients in the United States. Both studies looked at the occurrence of breast, colorectal and prostate cancer with the various insulins.

The third study was a 'case-control' study conducted in Canada, France and the UK. This study compared 775 patients with diabetes who had breast cancer with a control group of patients with diabetes who did not have breast cancer. The aim was to establish whether there was any link between the insulins the patients were receiving and the occurrence of breast cancer. This study compared insulin glargine with human insulin and other types of insulin.

The review also included data obtained from a thorough search of studies in the scientific literature investigating the link between insulin glargine and cancer.

What are the conclusions of the CHMP?

Based on the assessment of the population-based studies, the CHMP concluded that overall the data did not indicate an increased risk of cancer with insulin glargine, noting that there is no known mechanism by which the insulin glargine would cause cancer and that a cancer risk has not been seen in laboratory studies.

As for all medicines, the Agency will continue to assess any new data that become available in this area, as part of the routine monitoring of the medicine.