European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency 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.

Insulin glargine is a long-acting insulin analogue, authorised in the European Union (EU) as Lantus and Optisulin, for the treatment of adults, adolescents and children aged six years or above with diabetes, when treatment with insulin is required.

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.

Because of the limitations of the existing evidence, the Committee has requested the marketing authorisation holder, Sanofi-Aventis, to develop a strategy for generation of further research in this area. In addition the Committee is exploring possibilities for cooperation with academia to generate further information.

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Notes:

1. A press release informing about the safety concern was published in June: http://www.emea.europa.eu/humandocs/PDFs/EPAR/Lantus/40847409en.pdf
2. The articles are available online here: http://www.diabetologia-journal.org/cancer.html
3. Insulin analogues, such as insulin glargine, are substances that are similar to human insulin, but with some modifications that change properties such as the way the insulin is absorbed after injection or its duration of action.
4. Insulin glargine is available as Lantus and Optisulin in all 27 EU Member States. Both medicines have been authorised in the European Union since June 2000.
5. More information on Lantus and Optisulin is available in the European Public Assessment Report EPAR. For Lantus, please see: http://www.emea.europa.eu/humandocs/Humans/EPAR/lantus/lantus.htm; For Optisulin, please see: http://www.emea.europa.eu/humandocs/Humans/EPAR/optisulin/ optisulin.htm
6. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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