16 September 2011
EMA/CHMP/477156/2011 Rev. 1
EMEA/H/A-36/1295
EMEA/H/A-36/1297
EMEA/H/A-36/1298

Questions and answers on the review of Novosis Goserelin, Goserelin Cell Pharm, Novimp and associated names (goserelin, 3.6 mg implant),

Outcome of a procedure under Article 36 of Directive 2001/83/EC as amended

The European Medicines Agency has completed a review of the clinical studies that were submitted as part of the marketing authorisation application of the hybrid (a type of generic) medicinal products Novosis Goserelin, Goserelin Cell Pharm, Novimp and associated names (goserelin, 3.6 mg implant). The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that these medicines have not be shown to be equivalent to the reference medicine (Zoladex) and therefore the marketing authorisation should be suspended until therapeutic equivalence has been demonstrated.

What is Goserelin?

Goserelin is used to treat patients with advanced prostate cancer. It is a copy of the natural hormone (luteinizing hormone-releasing hormone) that regulates many processes in the body. In prostate cancer it works by depriving prostate cancer cells of the male hormone testosterone on which they depend to grow and spread.

Goserelin is marketed as a hybrid of Zoladex under the names Novimp, Goserelin Cell Pharma, Novosis Goserelin and associated names.

Why was Goserelin reviewed?

Following an inspection, the German medicines regulatory agency found that the clinical studies performed as part of the marketing authorisation applications for some goserelin containing medicines were not conducted in accordance with Good Clinical Practice (GCP) and questioned whether their results could be relied on. The German medicines regulatory agency considered that a suspension of the marketing authorisation of the already authorised medicines was necessary as therapeutic equivalence with the reference medicinal product could not be guaranteed. On 16 March 2011, the German agency referred the matter to the CHMP so that the Committee could give its opinion on

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whether the marketing authorisations for Novosis Goserelin, Goserelin Cell Pharm, Novimp and associated names should be maintained, varied, suspended or withdrawn across the EU.

What are the conclusions of the CHMP?

Based on the evaluation of the studies that were submitted in support of the marketing authorisation application and the scientific discussion within the Committee, the CHMP concluded that therapeutic equivalence has not been demonstrated and as such the benefit risk balance for these hybrid products was considered negative. The marketing authorisation should therefore be suspended in all member states until the companies provide new studies showing therapeutic equivalence and being GCP compliant.

The European Commission issued a decision on 16 September 2011.