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EMA to review Inductos

The European Medicines Agency (EMA) has started a review of Inductos, an implant used in patients with spinal disc problems and leg fractures. This follows an inspection by Dutch and Spanish authorities which found the manufacturing site for one of the components of Inductos (the absorbable sponge) to be non-compliant with manufacturing requirements.

The inspectors noted that the manufacturer, located in the United States, did not have adequate measures in place to prevent particle contamination of the sponges and called for importation of the products into the European Union (EU) to cease.

There is at present no indication of risk to patients linked to the inspection findings. Healthcare professionals using Inductos should follow the instructions in the product information as usual. As with any medicinal product, patients who have received Inductos implants should speak to their healthcare professional if they have any questions.

During the review of Inductos, stocks are expected to run low in the EU. The shortage (expected from end of October 2015) will be due to the import restriction and not patient safety concerns.

EMA's Committee for Medicinal Products for Human Use (CHMP) will now review the impact of the inspection findings on the product's overall benefits and risks and make a recommendation as to whether any changes are needed to its marketing authorisation.

The recommendation will then be sent to the European Commission for a final legally binding decision.

More about the medicine

Inductos is available as a kit for implant containing a powder, solvent and collagen sponge (or matrix). It is used during surgery in patients with damaged spinal discs or leg (tibia) fractures.

The active substance is dibotermin alfa, a protein that acts on the bone structure and helps with the formation of new bone tissue. The new bone tissue grows into the sponge, which is gradually degraded by the body.

Inductos was authorised centrally in the EU in September 2002.

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More about the procedure

The review of Inductos was initiated on 23 July 2015 at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004. It is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use. A CHMP opinion will be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

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