EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency gives recommendations to deal with sterility assurance concerns for DepoCyte

Inspection finds manufacturing deficiencies

The European Medicines Agency has today agreed a number of precautionary measures to deal with manufacturing deficiencies which could affect the sterility of DepoCyte (cytarabine), an anti-cancer medicine used to treat lymphomatous meningitis. These measures are intended to protect patients from potentially harmful effects, while they also allow continued access to treatment for patients who have no suitable alternatives.

At present, there is no evidence of any microbial contamination of product on the market or risk to patients. However, the Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended, as a precautionary measure, that DepoCyte be recalled from all European Union countries where suitable alternative treatments are available. For patients already initiated on DepoCyte and for whom alternative treatments are not appropriate, it may be possible for doctors to request a supply of DepoCyte to continue the treatment. In EU countries without suitable therapeutic alternatives, DepoCyte will remain on the market, but with specific recommendations to monitor patients' safety, in particular for signs and symptoms of infection.

A question-and-answer document with detailed recommendations for healthcare professionals is available on the Agency's website. Healthcare professionals will be receiving a letter explaining the measures that will apply in their country.

DepoCyte is a prolonged release liposomal suspension for injection containing cytarabine for the intrathecal treatment of lymphomatous meningitis. This means it is administered by injecting it directly into the cerebrospinal fluid.

A recent inspection carried out jointly by France and the United Kingdom at the manufacturing site for DepoCyte in San Diego in the United States, Pacira Pharmaceuticals Inc, identified a number of manufacturing deficiencies. The findings relate to a lack of adequate sterility assurance in the manufacturing process. Following assessment of the available data, the CHMP concluded that these findings pose a theoretical risk of sterility failure, even though currently there are no data to indicate that there has been a negative impact on the finished product.

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Production and batch release of DepoCyte are currently on hold. New batches of DepoCyte will only be manufactured once all deficiencies have been resolved and a re-inspection has indicated the manufacturing site to be compliant with good manufacturing practice (GMP) requirements.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The inspection was conducted by the UK and French medicines regulatory agencies in July 2012.
3. DepoCyte has been authorised in the European Union since 11 July 2001 and is marketed in Austria, Belgium, Bulgaria, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom, as well as Iceland and Norway.
4. Lymphomatous meningitis is a condition in which cells from a lymphoma (a tumour in the lymphatic system) have spread to the spinal fluid and the meninges (the membranes that surround the brain and spinal cord).
5. Therapeutic alternatives include medicines containing non-liposomal cytarabine, methotrexate or thiotepa. It should be noted that not all alternative products are approved for intrathecal use. For further information on indications and posology of alternative treatments, the product information should be consulted.
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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