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Start of review of medicines manufactured at Pharmaceutics International Inc., USA

The European Medicines Agency (EMA) has started a review of medicines manufactured by Pharmaceutics International Inc., USA. This follows an inspection in February 2016 conducted by the MHRA (the medicines regulatory agency in the United Kingdom) which highlighted several shortcomings in relation to good manufacturing practice (GMP).

Pharmaceutics International Inc. manufactures the centrally authorised medicine Ammonaps (sodium phenylbutyrate) and is also the registered manufacturing site for some other medicines that have been authorised through national procedures in the European Union (EU).

This inspection which was a follow-up to an inspection in June 2015 aimed to assess whether corrective measures agreed previously had been appropriately implemented. It found that shortcomings remained, which included insufficient measures to reduce the risk that traces of one medicine could be transferred to another (cross-contamination), as well as problems with the way data were generated and checked and deficiencies in the systems for ensuring medicines' quality (quality assurance).

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

There is no evidence that patients have been put at risk by this issue. However, as a precautionary measure, medicines from this site will no longer be supplied to the EU unless they are considered to be 'critical' to public health. Criticality will be assessed by national medicines regulatory agencies for their territories, taking into account alternatives and any impact of shortages on patients. In case where a medicine manufactured at this site is considered not critical in a member state it will no longer be supplied in this member state and any medicine remaining on the market will be recalled.

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More about the medicines

The list of medicines being reviewed is available on the EMA website.

Whereas Ammonaps is exclusively manufactured at Pharmaceutics International Inc., some of the other nationally authorised medicines may have more than one registered manufacturing site; therefore, the recommendation to recall will only apply to those products on the market that have been manufactured at Pharmaceutics International Inc.

Ammonaps is used to treat inherited diseases known as urea cycle disorders, where patients are not able to get rid of waste nitrogen from the body because they lack some enzymes.

Further information on Ammonaps can be found here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000219/human_med_000646.jsp&mid=WC0b01ac058001d124

More about the procedure

The review of has been initiated at the request of the European Commission under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.