



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Review of the manufacture of Baxter's peritoneal dialysis solutions initiated over potential presence of endotoxins in some batches

Interim recommendations issued to avoid acute shortages

The European Medicines Agency has been informed by Baxter that the problem of presence of endotoxins in peritoneal dialysis (PD) solutions has not been solved and that it cannot guarantee the production of endotoxin-free solutions from a production line at its Castlebar plant in Ireland in the short-term. As a consequence, the Agency's Committee for Medicinal Products for Human Use (CHMP), at the request of the European Commission, started a full review of the manufacture of Baxter's dialysis solutions at the affected plant.

In December 2010 healthcare professionals in the EU were advised that a small proportion of certain Baxter PD solutions (Dianeal, Extraneal and Nutrineal) manufactured at the plant could contain endotoxins, which may lead to adverse reactions in some patients undergoing peritoneal dialysis because of kidney failure. A recall of all potentially affected products was not possible because there were no replacements for these life-saving treatments. Healthcare professionals were provided with advice for management of patients using these potentially affected products.

There is a risk that patients who receive PD solutions that contain endotoxins may develop aseptic peritonitis. However the number of PD bags affected is likely to be very small and the overall risk to patients remains low. Patients and healthcare professionals should continue to look out for any symptoms that suggest the development of aseptic peritonitis (e.g. cloudy effluent seen in drain bag at the end of dialysis, abdominal pain, nausea, vomiting and possibly fever) and report any cases as soon as possible.

In order to make up for the shortfall in the supply of unaffected products, the CHMP considers that alternative Dianeal, Extraneal and Nutrineal solutions manufactured in other parts of the world (USA, Canada, Turkey and Singapore) can be imported into the European Union. These will promptly replace products from Castlebar in the coming months. This measure will minimise the use of PD solutions manufactured in Castlebar until the problem is completely solved.



In the meantime, batches of PD solutions manufactured in Castlebar will have to be released to meet patients' needs. The CHMP has therefore recommended that further safeguards be introduced into the procedures used for testing of PD solutions to minimise the risks for patients.

The CHMP also noted that the root cause of the presence of endotoxins needs to be fully identified and urgent action taken to rectify the problem. Baxter has informed the Committee that it will temporarily shut the manufacturing area in order to replace the majority of components of the manufacturing process to remove endotoxins from the production line at the Castlebar plant. This is expected to ensure the supply of new unaffected PD solutions for patients as soon as possible.

Once finalised, the Agency will communicate the outcome of the CHMP's review. Healthcare professionals will be sent updated advice, including information on new supplies from outside the EU as it becomes available. The EU regulatory system is intensively monitoring this issue on a continuous basis.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. A press release and a question and answer document on the previous review is available.
3. The procedure is being carried out under Article 31 of Directive 2001/83/EC.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu