12 July 2013
EMA/403074/2013

New review of hydroxyethyl starch-containing solutions for infusion started

The European Medicines Agency has started a new review of hydroxyethyl starch (HES)-containing solutions for infusion, following the suspension of the use of these medicines in the UK on 27 June 2013.

The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) had recommended in June 2013 that these medicines be suspended in the EU, following an assessment of available data which concluded that their benefits do not outweigh the risks of kidney injury and mortality. However, the process to implement the PRAC's recommendation across the EU has not yet begun since a number of marketing authorisation holders exercised their legal right to request a re-examination of the recommendation.

In the meantime, some Member States have taken action to suspend or limit the marketing or use of these medicines in their territories. In accordance with EU legislation this type of action currently requires that a review procedure be carried out. Consequently, the United Kingdom has requested the PRAC to start this review procedure, which will run in parallel with the re-examination of the PRAC's June 2013 recommendation.

The Agency invites all stakeholders (e.g. healthcare professionals, patients' organisations, the general public) to submit data relevant to this procedure. Full details are available under the 'data submission' tab.

More about the medicine

HES solutions are volume expanders used to replace lost blood volume in hypovolaemia (low blood volume caused by dehydration or blood loss) and hypovolaemic shock (a steep fall in blood pressure caused by drop in blood volume). They are used in critically ill patients including patients with sepsis (bacterial infection of the blood) or burn or trauma injuries, or patients who are undergoing surgery. HES solutions are given by infusion (drip) into a vein.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7129
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Infusion solutions containing HES belong to the class of colloids. There are two main types of volume expanders: crystalloids and colloids. Colloids contain large molecules such as starch, whereas crystalloids such as saline solutions contain smaller molecules. In the EU, HES-containing solutions for infusion have been approved via national procedures.

More about the procedure

This review of HES solutions for infusion has been initiated at the request of the UK medicines agency, MHRA, under Article 107i of Directive 2001/83/EC, also known as the urgent Union procedure.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. As these medicines are all authorised nationally, the PRAC recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh is a regulatory body that represents the EU Member States, responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.

In June 2013, the PRAC had adopted recommendations on HES solutions under Article 31 of Directive 2001/83/EC. A number of marketing authorisation holders have requested a re-examination of the recommendations. More information about this can be found here.