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EMA starts new review of hydroxyethyl-starch containing medicines

Studies show low adherence to restrictions aimed at reducing risks of kidney injury and death

The European Medicines Agency (EMA) has started a new review of medicines containing hydroxyethyl-starch (HES). These products are used for the management of hypovolaemia (low blood volume) caused by acute (sudden) blood loss, where treatment with alternative infusion solutions known as 'crystalloids' alone is not considered to be sufficient. HES medicines are given by infusion (drip) into a vein and are used as blood volume expanders to prevent shock following acute bleeding.

The review is triggered by results from two drug utilisation studies indicating that HES-containing medicines were being used outside their authorised uses, including in critically ill patients and those with sepsis and kidney injury despite restrictions introduced in 2013 to reduce the risks of kidney problems and deaths.[1]

The drug utilisation studies had been requested by EMA's Pharmacovigilance Risk Assessment Committee (PRAC) in 2013 as a condition to the marketing authorisations of these products, in order to verify adherence to the new restrictions.

The PRAC will review the results of these studies, and all other available data, and their impact on the benefit-risk balance of HES-containing medicines for infusion and issue a recommendation on whether their marketing authorisations should be maintained, varied, suspended or withdrawn across the EU.

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

More about the medicines

Infusion solutions containing HES are indicated for volume replacement and belong to the class of medicines known as colloids. There are two main types of medicines used for volume replacement:

[1] Information on the previous restrictions introduced in the EU can be found here.

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crystalloids and colloids. Colloids contain large molecules such as starch, whereas crystalloids, such as saline or Ringer's solutions, contain smaller molecules.

In the European Union, HES-containing medicines for infusion have been approved via national procedures and are available in the Member States under various trade names.

More about the procedure

The review of HES-containing medicines was initiated on 17 October 2017 at the request of the Swedish Medical Products Agency, under Article 107i of Directive 2001/83/EC.

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 HES-containing 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 position. The CMDh is a body representing EU Member States as well as Iceland, Liechtenstein and Norway. It is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.