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PRAC recommends suspending hydroxyethyl-starch solutions for infusion from the market

Review finds measures to protect patients have not been sufficiently effective

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has recommended the suspension of the marketing authorisations for hydroxyethyl-starch (HES) solutions for infusion across the European Union. These products are used as plasma volume replacement following acute (sudden) blood loss, where treatment with alternative products known as 'crystalloids' alone is not considered to be sufficient.

The review was triggered by results from two drug utilisation studies indicating that HES solutions are being used 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 in these patient populations.

In 2013, the PRAC had recommended restrictions on the use of HES solutions, including that they must no longer be used to treat critically ill patients or patients with sepsis, because of an increased risk of kidney injury and mortality seen in clinical trials. The Committee requested that further studies be carried out to verify adherence to these restrictions.

The PRAC has reviewed the results from the drug utilisation studies of HES solutions for infusion together with the currently available data on benefits and risks from clinical trials and observational studies and feedback received from stakeholders and experts. Based on this review, the PRAC has concluded that the restrictions introduced in 2013 have not been sufficiently effective. The Committee explored the possibility of introducing additional measures but concluded that such measures would be ineffective or insufficient.

In view of the serious risks that certain patient populations are exposed to, the PRAC has recommended the suspension of the marketing authorisations for HES solutions. Alternative treatment options are available.

The PRAC recommendation will now be sent to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh)[1] for consideration at its meeting on 22-25 January 2018.

[1] The CMDh is a medicines regulatory body representing the European Union (EU) Member States, Iceland, Liechtenstein and Norway.

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More about the medicines

HES solutions for infusion are used for the management of hypovolaemia (low blood volume) caused by acute blood loss, where treatment with alternative infusion solutions known as 'crystalloids' alone is not considered to be sufficient. They are given by infusion (drip) into a vein and are used as blood volume expanders to prevent shock following acute bleeding. They belong to the class of medicines known as colloids. Besides blood products, there are two types of medicines used for plasma volume replacement: crystalloids and colloids. Colloids contain large molecules such as starch, whereas crystalloids, such as saline or Ringer's solutions, are pure electrolyte solutions.

In the European Union, HES solutions 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 solutions for infusion 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 has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which has made a set of recommendations. The PRAC recommendations will now be sent 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.