EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 October 2017
EMA/PRAC/691743/2017

PRAC List of questions to be addressed by the Stakeholders

For hydroxyethyl starch (HES) containing medicinal products

Article 107i of Directive 2001/83/EC

Procedure number: EMEA/H/A-107i/1457

INN: hydroxyethyl starch

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On 17 October 2017, the Swedish National Competent Authority (MPA) notified the European Medicines Agency, in accordance with article 107i of Directive 2001/83/EC, informing on its consideration to suspend the marketing authorisations of hydroxyethyl starch (HES) - containing medicinal products.

The notification of the MPA triggering the procedure together with the scientific background is available on the webpage of the procedure.

In accordance with Article 107j(1) of the Directive 2001/83/EC, all stakeholders (e.g. healthcare professionals, patients' organisations or the general public) are invited to submit data relevant to the procedure, addressing the below Pharmacovigilance and Risk Assessment Committee (PRAC) list of questions by 16 November 2017:

Question

In view of the restrictions in place in the EU product information for medicinal products containing hydroxyethyl starch, please provide your views on the safe use of these products.