

Notice Information: - 3rd Party Publications
14 June 2013

Part 1. Product Information

a) Title: PRAC recommends suspending marketing authorisations for infusion solutions containing hydroxyethyl-starch

b) Product Name/Type: Infusion solutions containing hydroxyethyl-starch (HES)

Part 2. Problem/Issue

a) Problem/Issue: The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has concluded following a review of the available evidence that the benefits of infusion solutions containing hydroxyethyl-starch (HES) no longer outweigh their risks and therefore recommended that the marketing authorisations for these medicines be suspended.

The PRAC recommendation will be considered by the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).

Part 3. Enquiries

a) All enquiries should be made to: For full EMA statement please refer to link below:

PRAC recommends suspending marketing authorisations for infusion solutions containing hydroxyethyl-starch