EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 July 2013
EMA/PRAC/411968/2013

PRAC List of questions

To be addressed by the marketing authorisation holder(s) for hydroxyethyl starch (HES) - containing medicinal products

Article 107i of Directive 2001/83/EC

Procedure number: EMEA/H/A-107i/1376

INN/active substance: hydroxyethyl starch

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The marketing authorisation holders MAH(s) for hydroxyethyl starch (HES) - containing medicinal products are requested to:

Question 1

Provide the latest available evidence regarding the risks of mortality and renal injury associated with HES in all clinical settings.

Question 2

Discuss the pathophysiological mechanism of renal injury and increased mortality associated with HES including discussion in respect of capillary leakage and systemic inflammatory response in the various clinical settings.

Question 3

Provide any new evidence to demonstrate a positive balance of benefits and risks in any clinical setting.