11 July 2013
EMA/PRAC/411967/2013

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/1376

INN/active substance: hydroxyethyl starch

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

On 27 June 2013, the United Kingdom Competent Authority (MHRA) 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 MHRA 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) question by 5 August 2013:

Question

Considering your clinical experience, please provide your views on the benefits and risks of Hydroxyethyl starch medicinal products taking as well into account alternative medicinal products. Please also submit any data considered relevant in support of your views.