26 October 2017
EMA/PRAC/691228/2017

PRAC List of questions

To be addressed by the marketing authorisation holders 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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The marketing authorisation holders for hydroxyethyl starch (HES) - containing medicinal products are requested to:

Question 1

Please provide an overview of the status of your marketing authorisation(s) for HES-containing product(s) in EU/EEA countries. Please use a table to provide information as follows:

Product name	Country	Strength	Dosage Form	Pack sizes authorised (marketed)	Date of launch	Marketing status

Question 2

Please submit sales and patient exposure data stratified per year and per EU member state during the last 10 years; i.e. from 2008 to 2017. The algorithm used to estimate patient exposure should be justified.

Question 3

Please submit and discuss all available data on the degree of adherence to the restrictions within the current product information for your HES-containing medicinal product(s). Discuss the impact on safety.

Question 4

Please submit a critical appraisal of new data from clinical studies (published or unpublished), that are relevant for the evaluation of the benefits and the risks of HES-containing medicinal products.

Question 5

In view of the evidence on the benefits and risks of your HES-containing medicinal product(s), please provide a justification for populations where the benefit-risk balance remains favourable.

This should include a discussion of measures needed to ensure a positive benefit-risk balance, including strengthening existing measures or introducing new measures. The feasibility of adherence to the measures in clinical practice should also be addressed.