Annex IV

Conditions to the marketing authorisation

Each marketing authorisation holder shall complete the below conditions, within the stated timeframe, and the competent authorities shall ensure that the following is fulfilled:

The MAH shall implement a controlled access program to ensure that HES solutions for infusion are only delivered to accredited hospitals / centres where healthcare professionals expected to prescribe / administer these medicinal products have been trained on their appropriate use. As a consequence, the MAH shall be responsible of: - delivering the training to all relevant HCPs prescribing / administering HES solutions for infusion through agreed training material. The training should be repeated on regular basis. - managing the accreditation system - ensuring HES solutions for infusion are only delivered to accredited hospital/centres, i.e where all relevant HCPs have been trained. Each MAH shall develop training materials according to the following core elements: • the risks related to the use of HES solutions for infusion outside the terms of the MA • a reminder of the indication, dose, duration of treatment and contraindications and the need to comply with the product information • the new additional risk minimisation measures. • the results from the DUSs The MAH should submit and agree with the National Competent Authorities: - the details of the controlled access program and the modalities of its implementation - the final training materials, including communication media and distribution modalities. These measures should be submitted with a risk management plan (RMP): The controlled access program should be effectively implemented at the latest:	Within 3 month from the Commission Decision. Within 9 month from the Commission Decision.
Each MAH of HES solutions for infusion shall perform a drug utilisation study to assess the effectiveness of the risk minimisation measures implemented as an outcome of this referral procedure.	

Protocol to be submitted for assessment by the PRAC: The final study report shall be submitted for assessment by the PRAC: The MAHs are strongly encouraged to collaborate to perform a joint study.	Within 3 months of the Commission decision. Within 24 months of the Commission Decision