Annex III

Amendments to relevant sections of the Product Information

Note:

These amendments to the relevant sections of the Summary of Product Characteristics and package leaflet are the outcome of the referral procedure.

The product information may be subsequently updated by the Member State competent authorities, in liaison with the Reference Member State, as appropriate, in accordance with the procedures laid down in Chapter 4 of Title III of Directive 2001/83/EC.

MAHs of HES solution for infusion should amend the product information (insertion, replacement or deletion of the text, as appropriate) to reflect the wording as provided below, and in conjunction to the Scientific conclusions:

SUMMARY OF PRODUCT CHARACTERISTICS

[This statement below should be added in a black box at the top of the SmPC.]

Contraindications
Do not use in sepsis, renal impairment, or critically ill patients.
See section 4.3.

[...]

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

7. OTHER SPECIAL WARNING(S):

[This statement below should be strongly emphasised (e.g. capitalized, bold letters or use of colours), the visual details of the warning on the outer and immediate packaging should be agreed with NCAs and be subject to a user test taking into account the "Guideline on the Readability of the labelling and package leaflet on medicinal products for human use" within 1 month from the Commission Decision.]

DO NOT USE IN SEPSIS, RENAL IMPAIRMENT, OR CRITICALLY ILL PATIENTS. SEE ALL CONTRAINDICATIONS IN THE SMPC.

[...]

PACKAGE LEAFLET

[This statement below should be added in a black box at the top of the package leaflet.]

Warning
Do not use in sepsis (severe generalised infection), renal impairment, or critically ill patients.
See situations in which this product should never be used in section 2.