Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for iron parenteral preparations, the scientific conclusions are as follows:

Based on the cumulative review of data from clinical trials and post-marketing settings the LMS considers that the evidence on causal association between the use of IV iron containing products and Influenza like illness is sufficient to update section 4.8 of the SmPC for all parenteral iron containing products. The Package Leaflet is updated accordingly.

The CMDh agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for iron parenteral preparations the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing iron parenteral preparations is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing iron parenteral preparations are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~)

Summary of Product Characteristics

4.8 Undesirable effects

The following adverse reaction(s) should be added under the SOC **General Disorders and Administration Site Conditions - *under frequency* "not known" *or product-specific frequency (if known)***

Influenza like illness whose onset may vary from a few hours to several days

Package leaflet

4. Possible side effects

Flu-like illness (*[product specific frequency to be inserted, if known]***) may occur a few hours to several days after injection and is typically characterised by symptoms such as high temperature, and aches and pains in muscles and joints.**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	August 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	04 October 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	03 December 2018