

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 dextran, the scientific conclusions are as follows:

Based on the strengths of evidence from spontaneous reports on maternal hypersensitivity reactions, published literature and data on possible biological mechanism it is sufficient to conclude on the causal relationship of foetal bradycardia with maternal hypersensitivity reactions following the use of IV iron parenteral preparations. During the hypersensitivity reaction compromised maternal oxygenation may lead to foetal hypoxia that compensatory may result in foetal bradycardia, however other pathophysiological mechanisms cannot be excluded. Therefore, recommendation that the unborn baby should be carefully monitored during intravenous administration of parenteral iron containing medicinal products to pregnant women due to possible occurrence of foetal bradycardia as a consequence of a hypersensitivity reaction in the mother should be added in the section 4.6 of the SmPC for all intravenous iron containing medicinal products irrespective of the amount of data regarding foetal bradycardia currently available.

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 dextran the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing iron dextran 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 dextran 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

- Section 4.6

Foetal bradycardia may occur following administration of parenteral irons. It is usually transient and a consequence of a hypersensitivity reaction in the mother. The unborn baby should be carefully monitored during intravenous administration of parenteral irons to pregnant women.

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	July 2019 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	08/09/2019
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	07/11/2019