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 oxytocin, the scientific conclusions are as follows:

A review of 9 publications during the reporting period, assessing the causality between oxytocin and anaphylaxis, indicate that allergic sensitisation to latex allergens constitutes a significant risk factor for triggering severe systemic reactions after the infusion of oxytocin and that particular attention in managing delivering women suffering from latex allergy is needed.

Therefore, considering the seriousness of anaphylaxis and in view of the data presented in the reviewed PSUR(s) for oxytocin, PRAC considered that changes to section 4.4 of the product information of medicinal products containing oxytocin are warranted. 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 oxytocin the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing oxytocin 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 oxytocin 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 4.4

Anaphylaxis in women with latex allergy

There have been reports of anaphylaxis following administration of oxytocin in women with a known latex allergy. Due to the existing structural homology between oxytocin and latex, latex allergy/intolerance may be an important predisposing risk factor for anaphylaxis following oxytocin administration.

Package Leaflet

Section 2

Warnings and precautions

Latex allergy

The active substance in <product name> might cause a severe allergic reaction (anaphylaxis) in patients with latex allergy. Please tell your doctor if you know you are allergic to latex.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	March 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	05 May 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	04 July 2018