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 deoxycholic acid, the scientific conclusions are as follows:

Based on the review of post marketing data, there is sufficient evidence of a causal association between the occurrence of injection site hypoaesthesia and the use of deoxycholic acid. Therefore, the PRAC recommended to update section 4.8 of the Summary of Product Characteristics of deoxycholic acid to include the adverse reaction injection site hypoaesthesia with a frequency unknown. 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 deoxycholic acid the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing deoxycholic acid 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 deoxycholic acid 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 **<u>underlined and in bold</u>**, deleted text ~~strike through~~)

Summary of Product Characteristics

- Section 4.8

[The following adverse reaction should be added under the SOC General disorders and administration site conditions with a frequency unknown]

<u>Injection site: Hypoaesthesia</u>

Package Leaflet

- Section 4: Possible side effects

[The following adverse reaction should be added with a frequency "Not known: cannot be estimated from the available data"]

<u>Injection site reaction:</u>

- **<u>Reduced sense of touch or altered sensation in the cheek</u>**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	June 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	11 August 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	10 October 2018