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 octenidine dihydrochloride / phenoxyethanol, the scientific conclusions are as follows:

Based on evidence from published literature reporting serious application site reactions including necrosis and scarring associated with the use of octenidine in low weight preterm neonates, an update to the product information is considered necessary for all products for cutaneous use (not applicable for vaginal use). Therefore a warning regarding the use of octenidine dihydrochloride /phenoxyethanol containing antiseptics in low weight preterm neonates has been included in the product information.

In addition, during the reporting period a safety signal including serious application site reactions following off-label use of octenidine dihydrochloride / phenoxyethanol in the eye was confirmed and categorised as an important identified risk. Therefore, a warning stating that use of octenidine dihydrochloride / phenoxyethanol in the eye should be avoided has been added to the product information.

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 octenidine dihydrochloride / phenoxyethanol the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing octenidine dihydrochloride / phenoxyethanol 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 octenidine dihydrochloride / phenoxyethanol are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that 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~~)

For all medicinal products for cutaneous use (not applicable for vaginal use):

Summary of Product Characteristics

- Section 4.4

A warning should be added as follows:

The use of octenidine aqueous solutions (0,1%, with or without phenoxyetanol), for skin antisepsis prior to invasive procedures has been associated with serious skin reactions in low weight preterm neonates.

Remove any soaked materials, drapes or gowns before proceeding with the intervention. Do not use excessive quantities and do not allow the <solution><gel> to pool in skin folds or under the patient or drip on sheets or other material in direct contact with the patient. Where occlusive dressings are to be applied to areas previously exposed to <product name>, care must be taken to ensure no excess product is present prior to application of the dressing.

Usage of <Product name> in the eye should be avoided.

Package Leaflet

- Section 2

Use with care in newborn babies, especially those born prematurely. <Product name> may cause serious skin lesions. Remove excess product and make sure that the <solution> <gel> does not remain on the skin longer than necessary (including materials with drips of the solution in direct contact with the patient).

Usage of <Product name> in the eye should be avoided. In case of contact with eyes, rinse immediately with plenty of water.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	September 2017 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	28 October 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	27 December 2017