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 teicoplanin, the scientific conclusions are as follows:

In view of available data on pancytopenia from the literature and spontaneous reports including 14 cases with close temporal relationship of which 1 case had probable causality and 13 pancytopenia cases with possible causality, and included 1 case of positive rechallenge and 10 cases of positive de-challenge) and in view of already known causal association of teicoplanin with other blood disorders, the PRAC considers a causal relationship between teicoplanin and pancytopenia is at least a reasonable possibility. The PRAC concluded that the product information of products containing teicoplanin should be amended 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 teicoplanin, the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing teicoplanin 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 teicoplanin 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 4.8

The following adverse reaction should be added under the SOC Blood and lymphatic system disorders with a frequency not known:

pancytopenia

Package Leaflet

- Section 4

The following adverse reaction should be added with a frequency not known:

low levels of all types of blood cells

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	June 2022 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	07 August 2022
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	06 October 2022