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 sotalol the scientific conclusions are as follows:

In view of available data on alopecia, hyperhidrosis and thrombocytopenia associated with sotalol use, including cases with a close temporal relationship and these adverse reactions are class effects of betablockers, the Lead Member State considers a causal relationship between sotalol and alopecia, hyperhidrosis and thrombocytopenia is at least a reasonable possibility.

Update of section 4.8 of the SmPC to add the adverse reactions alopecia, hyperhidrosis and thrombocytopenia 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 sotalol the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing sotalol 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 sotalol 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 reactions should be added under the SOC 'Skin and subcutaneous tissue disorders' with a frequency 'unknown':

- **Alopecia**
- **Hyperhidrosis**

The following adverse reaction should be added under the SOC 'Blood and lymphatic system disorders' with a frequency 'unknown':

- **Thrombocytopenia**

Package Leaflet

- Section 4

Other side effects

Not known (the frequency cannot be estimated from available data):

- **Hair loss**
- **Excessive sweating**
- **Abnormally low levels of thrombocytes, also known as platelets, in the blood.**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	April 2020 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	14 June 2020
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	13 August 2020