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 bupropion, the scientific conclusions are as follows:

Further to a cumulative review of reports of hyponatremia, including clinical trials, published literature and spontaneous data, the PRAC concluded that the risk of hyponatraemia has been identified based on 12 case reports, of which five reported a positive rechallenge and seven reported a positive dechallenge. The Committee agreed that amendments to the section 4.8 Undesirable effects of the Summary of Product Characteristics (SmPC) are warranted for inclusion of hyponatremia as a possible adverse reaction, with the frequency *'Not known'*.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing bupropion, were warranted.

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 bupropion the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing bupropion 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 bupropion are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that such marketing authorisations are varied accordingly.

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(s) should be added under the SOC Metabolism and nutrition disorders with a frequency **"Not known"**:

hyponatraemia

Package Leaflet

Possible side effects

The following adverse reaction(s) should be added with a frequency **"Not known"**:

blood sodium decreased (hyponatraemia)

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	September 2016 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position :	29 October 2016
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	28 December 2016