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 gabapentin, the scientific conclusions are as follows:

PRAC reviewed the available post marketing safety data regarding the adverse reaction agitation. PRAC concluded that a causal association is established taking into account that a temporal relationship could be established with the start of gabapentin and the onset of agitation, positive de-challenge and positive re-challenge. Therefore the term has been included in section 4.8 of the SmPC. PRAC also reviewed the medical literature and the post marketing safety data regarding the signal of anaphylaxis. Based on this review information has been included on anaphylaxis in sections 4.4 and 4.8 of the SmPC. The package leaflet has been updated accordingly.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products gabapentin, 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 gabapentin the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing gabapentin 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 gabapentin 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 4.4

Anaphylaxis

Gabapentin can cause anaphylaxis. Signs and symptoms in reported cases have included difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment. Patients should be instructed to discontinue gabapentin and seek immediate medical care should they experience signs or symptoms of anaphylaxis.

- Section 4.8

The following adverse reaction should be added under the SOC Immune system disorders with a frequency 'not known': **anaphylaxis**

The following adverse reaction should be added under the SOC Psychiatric disorders with a frequency 'uncommon': **agitation**

Package leaflet

PIL section 4:

Frequency not known: anaphylaxis (serious, potentially life threatening allergic reaction including difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment)

frequency uncommon: agitation (a state of chronic restlessness and unintentional and purposeless motions)

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	October 2016 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	26 November 2016
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	25 January 2017