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 folic acid, the scientific conclusions are as follows:

Based on a review of relevant cases of anaphylactic reaction in the database of one MAH, based on temporality, possible alternative aetiologies, and sensitivity testing, the PRAC concluded that there was reasonable evidence of a causal association between anaphylactic reaction and use of folic acid. The evidence presented is considered sufficient to request an update of the Product Information for folic acid containing medicinal products. As no exposure data from clinical trials is available, the frequency should be stated as “not known”. 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 folic acid the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing folic acid 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 folic acid 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 Immune system disorders with a frequency **not known**:

anaphylactic reaction

Package Leaflet

- 4. Possible side effects

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

severe allergic reaction (anaphylactic reaction)

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	January 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	10 March 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	9 May 2018