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 allopurinol, the scientific conclusions are as follows:

Based on the review of data presented in this PSUSA, covering the period from 1 January 2017 to 31 December 2017, as well as cumulative data since the European birth date, the PRAC considers that the product information of medicinal products containing the active substance allopurinol should be updated as follows: update of section 4.8 of the SmPC to add angioedema and anaphylactic reaction with a frequency very rare. 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 allopurinol the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing allopurinol 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 allopurinol 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 skin and subcutaneous tissue disorders with a frequency very rare:

Angioedema

The following adverse reaction should be added under the SOC immune system disorders with a frequency very rare:

Anaphylactic reaction

Package Leaflet

- Section 4

Possible side effects very rare (may affect up to 1 in 10,000 people):

Serious allergic reaction which causes swelling of the face or throat

Possible side effects very rare (may affect up to 1 in 10,000 people):

Serious potentially life-threatening allergic reaction

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	September 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position :	3 November 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	2 January 2019