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 fenspiride the scientific conclusions are as follows:

Based on the review of cumulative data from spontaneous reporting post-marketing, the PRAC considers that a causal relationship between the adverse drug reactions 'dysgeusia', 'headache', 'dyspnoea' and 'blood pressure increased' and fenspiride cannot be excluded and therefore recommends the update of section 4.8 of the SmPC to add these reactions with the frequency of 'unknown'. The package leaflet is updated in accordance.

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 fenspiride the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing fenspiride 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 fenspiride 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(s) should be added under the SOC Gastrointestinal disorders with a frequency **unknown**: **Dysgeusia**

The following adverse reaction(s) should be added under the SOC Nervous system disorders with a frequency **unknown**: **Headache**

The following adverse reaction(s) should be added under the SOC Respiratory, thoracic and mediastinal disorders with a frequency **unknown**: **Dyspnoea**

The following adverse reaction(s) should be added under the SOC Vascular disorders with a frequency **unknown**: **Blood pressure increased**

Package Leaflet

- Section 4
  - **Taste disorders**
  - **Headache**
  - **Increase of blood pressure**
  - **Difficulty in breathing**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	November 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	29 December 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	27 February 2019