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 for the non-interventional imposed PASS final report for the medicinal product(s) containing the active substance thiocolchicoside and concerned by the PASS final report , the scientific conclusions are as follows:

In view of the available data regarding the PASS final study report, the benefit risk balance of Thiocolchicoside containing medicinal product(s) remains unchanged. The referral condition is considered fulfilled; therefore, the inclusion of thiocolchicoside-containing medicinal products in the List of medicinal products under additional monitoring is no more 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 the results of the study for the medicinal product(s) containing the active substance thiocolchicoside and concerned by the PASS final report , the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) mentioned above is unchanged subject to the proposed changes to the conditions of the marketing authorisation(s).

The CMDh reaches the position that the marketing authorisation(s) of the products concerned by this PASS final report should be varied.

Annex II

Conditions to the Marketing Authorisation(s)

Changes to be made to the conditions of the marketing authorisation(s) of medicinal product(s) containing the active substance thiocolchicoside concerned by the non-interventional imposed PASS final report

The marketing authorisation holder(s) shall remove the following condition(s) (new text **<u>underlined and in bold</u>,** deleted text ~~strike through~~)

- ~~The condition to submit the results of an imposed non-interventional PASS is fulfilled. The inclusion of thiocolchicoside-containing medicinal products in the List of medicinal products under additional monitoring is no more warranted.~~

Annex III

Timetable for the implementation of this position

Timetable for the implementation of the position

Adoption of CMDh position:	February 2020 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	12 April 2020
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	11 June 2020