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:

The PASS final study report submitted by the MAHs complies with their obligation to perform a survey among health care professionals to evaluate their knowledge and attitudes on prescribing conditions of thiocolchicoside containing medicinal products, as imposed during the Article 31 procedure EMEA/H/A-1361.

The final results of the complementary drug utilization study using databases, which allows a dual approach to assessing the effectiveness of the risk minimisation measures imposed on thiocolchicoside containing medicinal products, are expected in 2019, and this new due date should be reflected in the conditions of the Marketing Authorisation.

Therefore, in view of available data regarding the PASS survey final study report, the PRAC considered that changes to the conditions of the marketing authorisation 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 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 product information.

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 change the following condition(s) (new text **underlined and in bold,** deleted text ~~strike through~~)

The following changes to the conditions of the marketing authorisation(s) of medicinal products containing the active substance thiocolchicoside concerned by the PASS final report are recommended:

The MAH(s) should provide ~~within the risk management plan submission, a protocol for~~ **results of** the drug utilisation study to characterise prescribing practices for the medicinal products during typical clinical use in representative groups of prescribers and to assess main reasons for prescription. Final study report by:	November ~~2017~~**2019**

Annex III

Timetable for the implementation of this position>

Timetable for the implementation of the position

Adoption of CMDh position:	February 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	07 April 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	06 June 2018