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 thiocolchicoside, paracetamol thiocolchicoside the scientific conclusions are as follows:

In view of available data on risks from the literature, spontaneous reports including in several cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between thiocolchicoside in injectable formulations and Injection site reactions including Nicolau syndrome is at least a reasonable possibility. The PRAC concluded that the product information of products containing thiocolchicoside in injectable formulations should be amended accordingly.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for thiocolchicoside, paracetamol thiocolchicoside the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing thiocolchicoside, paracetamol thiocolchicoside is unchanged subject to the proposed changes to the product information

The CMDh recommends that the terms of the marketing authorisation(s) should be varied.

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 reactions should be added under the SOC General disorders and administration site conditions, with frequency not known:

- **Injection site reactions including pain, erythema, swelling around the injection site**
- **Embolia cutis medicamentosa (Nicolau syndrome)**

The following changes to the product information of medicinal products containing the active substance thiocolchicoside in injectable formulations are recommended (new text **underlined and in bold**, deleted text ~~strike through~~):

Package Leaflet

Section 4 Possible side effects

Not known: frequency cannot be estimated from the available data

Injection site reactions including injection site pain, reddening, swelling, hard lump, sores and bruising. This can progress to blackening and death of the skin and underlying tissues surrounding the injection site, that heal with scarring, also known as Nicolau syndrome.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	Feb 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	13 April 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	12 June 2025