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 nimesulide (systemic formulations), the scientific conclusions are as follows:

In view of available data on risk of fixed drug eruption (FDE) from the literature, spontaneous reports including in some cases a close temporal relationship, a positive re-challenge, plausible TTO, confirmed allergy for nimesulide, the PRAC considers a causal relationship between nimesulide (systemic formulations) and FDE is at least a reasonable possibility. The PRAC concluded that the product information of products containing nimesulide (systemic formulations) should be amended 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 nimesulide (systemic formulations) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing nimesulide (systemic formulations) 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 nimesulide (systemic formulations) 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 4.4 (**to be implemented in the existing warning on skin reactions, if any**)

A warning should be added as follows:

Skin reactions

Cases of fixed drug eruption (FDE) have been reported with nimesulide.

Nimesulide should not be reintroduced in patients with history of nimesulide-related FDE (see section 4.8).

- Section 4.8

The following adverse reaction should be added under the SOC **Skin and subcutaneous tissue disorders** with a frequency **unknown**:

Fixed drug eruption (see Section 4.4)

Package Leaflet

2. What you need to know before you take X **(this section 2 should be amended only if similar information is not already included.)**

Warnings and precautions

Do no take or tell your doctor before taking X

- **If you have ever developed fixed drug eruption (round or oval patches of redness and swelling of the skin, blistering, hives and itching) after taking nimesulide.**

4. Possible side effects

Frequency unknown

Fixed drug eruption (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	February 2022 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	10 April 2022
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	9 June 2022