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 etodolac, the scientific conclusions are as follows:

In view of available data on "acute generalised exanthematous pustulosis", and "fixed drug eruption", from the literature, and spontaneous reports, including in some cases a close temporal relationship, a positive de-challenge or re-challenge and in view of a possible class effect, the PRAC Lead Member State considers a causal relationship between etodolac and "acute generalised exanthematous pustulosis" and "fixed drug eruption", is at least a reasonable possibility. The PRAC Lead Member State concluded that the product information of products containing etodolac should be amended accordingly.

In view of available data on "anaphylactic reaction" from spontaneous reports, including in some cases a close temporal relationship and a positive de-challenge or re-challenge the PRAC Lead Member State considers a causal relationship between etodolac and "Anaphylactic reaction" is at least a reasonable possibility. The PRAC Lead Member State concluded that the product information of products containing etodolac 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 etodolac the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing etodolac 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 4.4

A warning should be amended as follows:

~~Skin reactions~~ **Severe cutaneous adverse reactions (SCARs)**

Serious skin reactions, ~~some of them fatal~~, such as exfoliative dermatitis, Stevens-Johnson syndrome **(SJS)**, toxic epidermal necrolysis **(TEN)**, and **acute generalised exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been** reported **in association with etodolac treatment** (see section 4.8). Patients appear to be at highest risk for these reactions early in the course of therapy**. Patients should be advised of the signs and symptoms of the severe cutaneous adverse reactions and should seek medical advice from their physician immediately when observing any indicative signs or symptoms. If signs and symptoms suggestive of these reactions appear, etodolac should be withdrawn immediately and an alternative treatment considered (as appropriate).**

If the patient has developed a severe cutaneous adverse reaction such as SJS, TEN or AGEP with the use of etodolac, treatment with etodolac must not be restarted in this patient at any time.

- Section 4.8

The following adverse reactions should be added under the SOC "Skin and subcutaneous tissue disorders" with a frequency "not known":

Acute generalised exanthematous pustulosis (AGEP)

Fixed drug eruption (FDE)

- Section 4.8

The following adverse reactions should be added under the SOC "Immune system disorder" with a frequency " not known"

Anaphylactic reaction

Package Leaflet

Section 2 - What you need to know before you use < product name >

Do not take <product name>

- **If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking <**product name**> or other painkillers (NSAIDs or acetylsalicylic acid)**

Warnings and precautions

This medicine can cause serious skin reactions. Stop using <product name> and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Section 4 – Possible side effects

Serious side effects:

Stop using < product name > and seek medical attention immediately if you notice any of the following symptoms:

- **A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis)(frequency not known).**

Other side effects:

not known (frequency cannot be estimated from the available data)

- **An allergic skin reaction, that may include round or oval patches of redness and swelling of the skin, blistering, and itching (Fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur. Fixed drug eruption usually reoccurs at the same site(s) if the medication is taken again.**

Section 4 – Possible side effects

Serious side effects:

Stop using < product name > and seek medical attention immediately if you notice any of the following symptoms:

- **sudden, severe allergic reaction with itching, hives, breathing difficulty, facial/throat swelling, lightheadedness, dizziness, fast heartbeat, sweating and loss of consciousness (anaphylactic reaction) (frequency not known)**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	January 2026 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	16 March 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	14 May 2026