

## **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 ketorolac (systemic formulations), the scientific conclusions are as follows:

In view of available data on anastomotic leakage from the literature, the PRAC considers a causal relationship between ketorolac (systemic formulations) and anastomotic leakage is at least a reasonable possibility. The PRAC concluded that the product information of products containing ketorolac (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 ketorolac (systemic formulations) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing ketorolac (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 ketorolac (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

A warning should be added as follows:

Gastrointestinal effects:

[...]

**NSAIDs, including ketorolac, may be associated with increased risk of gastro-intestinal anastomotic leak. Close medical surveillance and caution are recommended when using ketorolac after gastro-intestinal surgery.**

[...]

#### **Package Leaflet**

Section 2: What you need to know before you take [product]

**Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before receiving/taking/using [product name], as [product name] can sometimes worsen wound healing in your gut after surgery.**

### **Annex III**

#### **Timetable for the implementation of this position**

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Adoption of CMDh position:	March 2023 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	14 May 2023
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	13 July 2023