

## **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 piroxicam, the scientific conclusions are as follows:

In view of the available data on the risk of fixed drug eruption (FDE) from numerous spontaneous reports and scientific literature, with positive re-challenge or confirmed allergy for piroxicam, the PRAC considers that a causal relationship between piroxicam and FDE is well supported, and concluded that the product information of products containing piroxicam 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 piroxicam the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing piroxicam 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 piroxicam 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**

Skin reactions

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

**Piroxicam should not be reintroduced in patients with history of piroxicam-related FDE. Potential cross reactivity might occur with other oxicams.**

### **Section 4.8**

unknown: **fixed drug eruption** (see Section 4.4)

## **Package Leaflet**

### **2. Before you take <piroxicam>**

**If you develop a rash or skin symptoms, you should stop taking <piroxicam> immediately, seek prompt medical advice and tell your doctor that you are taking this medicine.**

### **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**

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Adoption of CMDh position:	December 2020 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	24 January 2021
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	25 March 2021