# 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 meloxicam, the scientific conclusions are as follows:

Pancreatitis

A total of 25 cases of pancreatitis were retrieved, cumulatively, since the initial marketing authorisation of meloxicam. The preferred terms (PT) of the Standardized MedDRA Query for the cases retrieved were, pancreatitis (14 events, including 7 serious events), pancreatitis acute (8 serious events), and pancreatitis haemorrhagic (3 serious events).

In addition, pancreatitis is an already identified risk for other drugs from the same class (piroxicam, tenoxicam).

In view of the above, in order to reflect the risk of pancreatitis, an update of the summary of product characteristics (SmPC) of meloxicam is recommended. Such identified risk should be added into the "Gastrointestinal disorders" System Organ Class (SOC) in summary of product characteristics and in section 4.8 with a frequency 'not known'. The package leaflet should be updated accordingly.

Therefore, in view of available data regarding meloxicam, the PRAC considered that changes to the product information of medicinal products containing meloxicam, were warranted.

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 meloxicam the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing meloxicam 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 meloxicam are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that such marketing authorisations are varied accordingly.

# 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 reaction should be added under the SOC 'Gastrointestinal disorders' with a frequency 'not known':

**pancreatitis**

**Package leaflet**

Section 4 Possible side effect

**Pancreatitis (inflammation of the pancreas)**

## Annex III

## Timetable for the implementation of this position

## Timetable for the implementation of this position

| | |
|---|---|
| Adoption of CMDh position: | March 2017 CMDh meeting |
| Transmission to National Competent Authorities of the translations of the annexes to the position: | 6 May 2017 |
| Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder): | 5 July 2017 |