

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:

In view of the available data on the risk of fixed drug eruption (FDE) from spontaneous reports and scientific literature, including cases with positive rechallenge or confirmed allergy for meloxicam, it is considered that a causal relationship between meloxicam and FDE is at least a reasonable possibility. The product information of meloxicam containing products 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 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 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 meloxicam.

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

Section 4.8

SOC "Skin and subcutaneous tissue disorders", frequency "not known":

fixed drug eruption (see Section 4.4)

Package Leaflet

Section 2

Warnings and precautions

Talk to your doctor or pharmacist before taking <product name>:

• If you have ever developed fixed drug eruption (round or oval patches of redness and swelling of the skin that usually recurs at the same site(s), blistering, hives and itching) after taking meloxicam or other oxicams (e.g. piroxicam).

Section 4 (possible side effects)

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

- A distinctive cutaneous allergic reaction known as fixed drug eruption, that usually recurs at the same site(s) on re-exposure to the medication and 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:	March 2023 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	12 May 2023
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	13 July 2023