

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 benazepril , the scientific conclusions are as follows:

In view of available data on psoriasis aggravation from the literature, spontaneous reports including in some cases a close temporal relationship and a positive de-challenge, the PRAC considers a causal relationship between benazepril and psoriasis aggravation is at least a reasonable possibility. The PRAC concluded that the product information of products containing benazepril 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 benazepril the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing benazepril 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 benazepril 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 4.8

The following adverse reaction should be added under the SOC Skin and subcutaneous tissue disorders with a frequency “unknown”:

SOC: Skin and subcutaneous tissue disorders

Psoriasis aggravation

Frequency

Unknown

Package Leaflet

Section 4

Frequency not known (cannot be estimated from available data): **aggravation of psoriasis (skin disease that causes red, itchy scaly patches, most commonly on the knees, elbows, trunk and scalp)**

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	July 2021 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	5 September 2021
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	4 November 2021