

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 albendazole, the scientific conclusions are as follows:

In view of available data on hepatitis from spontaneous reports including in some cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers a causal relationship between albendazole and hepatitis is at least a reasonable possibility. The PRAC concluded that the product information of products containing albendazole should be amended accordingly.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for albendazole the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing albendazole is unchanged subject to the proposed changes to the product information

The CMDh recommends that the terms of the marketing authorisation(s) should be varied.

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~~)

For intestinal infections and cutaneous larva migrans indications: low-dose, short-term treatment:

Summary of Product Characteristics

- Section 4.4

A warning should be added as follows:

Influence on hepatic enzymes

Albendazole treatment has been associated with mild to moderate elevations of hepatic enzymes. Hepatitis cases have also been reported. Hepatic enzymes generally normalise on discontinuation of treatment. Individuals with hepatic impairment must seek medical advice before starting the treatment.

- Section 4.8

The following adverse reaction(s) should be added under the SOC Hepatobiliary disorders with a frequency uncommon:

hepatitis

Package Leaflet

Section 2

Only to be implemented in package leaflets where the occurrence of hepatitis is not described.

Cases with inflammation of the liver (hepatitis) have been reported.

Section 4

(..)

Uncommon: Inflammation of the liver

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	February 2026 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	12 April 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	11 June 2026