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 terbinafine, the scientific conclusions are as follows:

In view of available data on Thrombotic thrombocytopaenic purpura from the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between terbinafine and Thrombotic thrombocytopaenic purpura is at least a reasonable possibility. The PRAC concluded that the product information of systemic products containing terbinafine 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 terbinafine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing terbinafine 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~~)

Summary of Product Characteristics

- Section 4.4

A warning should be amended as follows:

…

Haematological effects

Very rare cases of blood dyscrasias (neutropenia, agranulocytosis, thrombocytopenia, pancytopenia) have been reported in patients treated with [medicinal product]. Aetiology of any blood dyscrasias that occur in patients treated with [medicinal product] should be evaluated and consideration should be given for a possible change in medication regimen, including discontinuation of treatment with [medicinal product].

Cases of thrombotic thrombocytopenic purpura (TTP), some fatal, have been reported with terbinafine. TTP is characterised by thrombocytopenia and microangiopathic haemolytic anaemia and may be associated with neurological symptoms, renal dysfunction, or fever. If TTP is suspected, [medicinal product] should be immediately interrupted for diagnostic workup and treatment for TTP initiated. If TTP is confirmed, administration of [medicinal product] should be discontinued.

…

- Section 4.8

The following adverse reaction(s) should be added under the SOC 'Blood and lymphatic system disorders' with a frequency not known:

Thrombotic thrombocytopenic purpura

Package leaflet

Section 2

Please inform your doctor if you experience or have experienced any of the conditions described below.

…

A blood clotting disorder called thrombotic thrombocytopenic purpura (TTP) has been reported with terbinafine. Stop treatment immediately and see a doctor or go to hospital straight away, if you notice any symptoms of TTP mentioned in section 4, possible side effects.

…

Section 4

Not known side effects (frequency cannot be estimated from the available data):

- …
- **fever accompanied by bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness, confusion, yellowing of the skin or eyes (jaundice) – signs of medical condition called thrombotic thrombocytopenic purpura (TTP),**
- …

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	June 2026 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	9 August 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	8 October 2026