

## **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 linezolid, the scientific conclusions are as follows:

In view of available data on hypoglycaemia from clinical trial(s), the literature, spontaneous reports including in some cases a positive dechallenge and/or rechallenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between linezolid and hypoglycaemia is at least a reasonable possibility. The PRAC concluded that the product information of products containing linezolid should be amended accordingly.

In view of available data on black hairy tongue from the literature, spontaneous reports including in some cases a positive dechallenge and/or rechallenge and in view of a plausible mechanism of action the PRAC considers a causal relationship between linezolid and 'black hairy tongue' is at least a reasonable possibility. The PRAC concluded that the product information of products containing linezolid 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 linezolid the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing linezolid 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 4.8

The following adverse reaction should be added under the SOC ‘Metabolism and nutrition disorders’ with a frequency uncommon:

### Hypoglycaemia

The following adverse reaction should be added under the SOC ‘Gastrointestinal disorders’ with a frequency rare:

### Black hairy tongue

### Package Leaflet

- Section 4

Section 4 should be amended as follows:

#### Uncommon (may affect up to 1 in 100 people):

...

- Hyponatraemia (low blood sodium levels)
- Hypoglycaemia (low blood sugar)
- Kidney failure

...

#### Rare (may affect up to 1 in 1000 people):

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- ...
- Black discolouration of the tongue's surface, which appears hairy

### **Annex III**

#### **Timetable for the implementation of this position**

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Adoption of CMDh position:	December 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	25 January 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	26 March 2026