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Committee for Medicinal Products for Human Use (CHMP)

TOBI Podhaler

Tobramycin

Procedure No. EMEA/H/C/002155/PSUV/0015

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSURs for TOBI Podhaler, the scientific conclusions of PRAC are as follows:

The PRAC considers that the newly available data on efficacy are consistent with the known clinical efficacy and that the benefit-risk balance continues to be positive.

During the reviewed period, 1 new case of aphonia was reported. A total of three cases are available in Eudravigilance. The Marketing Authorisation Holder was requested to update the Product Information to include the adverse event “aphonia”, because:

- cases detailing the adverse event aphonia with a time to onset compatible with a causal relationship between aphonia and TOBI Podhaler have been reported,
- aphonia might be a more severe form of dysphonia which is listed according to the currently approved SmPC and the adverse event might be related to the active substance and is listed for tobramycin nebuliser solution TOBI 300 mg/5 ml (UK/H/0361/001).

Otherwise no new (potential) safety issue has been identified.

In view of available data regarding aphonia the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for TOBI Podhaler the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance tobramycin is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.