17 September 2020
EMA/CHMP/316556/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Deltyba

delamanid

On 17 September 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Deltyba. The marketing authorisation holder for this medicinal product is Otsuka Novel Products GmbH.

The CHMP adopted an extension to the existing indication as follows:[2]

> "Deltyba is indicated for use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) in adult**s** ~~patients~~**, adolescents and children with a body weight of at least 30 kg** when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability".

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

[2] New text in **bold**, removed text as ~~strikethrough~~

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