

18 May 2017 EMA/CHMP/269250/2017 Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion<sup>1</sup> (post authorisation)

## Izba

travoprost

On 18 May 2017, 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 Izba. The marketing authorisation holder for this medicinal product is Novartis Europharm Ltd.

The CHMP adopted a new indication as follows:

"Decrease of elevated intraocular pressure in paediatric patients aged 3 years to < 18 years with ocular hypertension or paediatric glaucoma."

For information, the full indications for Izba will be as follows<sup>2</sup>:

"Decrease of elevated intraocular pressure in adult patients with ocular hypertension or openangle glaucoma.

Decrease of elevated intraocular pressure in paediatric patients aged 3 years to < 18 years with ocular hypertension or paediatric glaucoma."

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.



<sup>&</sup>lt;sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>&</sup>lt;sup>2</sup> New text in bold