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Public statement

Picato

Withdrawal of the marketing authorisation in the European Union

On 11 February 2020, the European Commission withdrew the marketing authorisation for Picato (ingenol mebutate) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, LEO Laboratories Ltd, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Picato was granted marketing authorisation in the EU on 15 November 2012 for treatment of actinic keratosis. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2017.

This withdrawal is without prejudice to the outcome of the pending referral procedure on Picato under Article 20 of Regulation (EC) No 726/2004.

The European Public Assessment Report (EPAR) for Picato will be updated to indicate that the marketing authorisation is no longer valid.

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