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Public statement

Aerivio Spiromax

Withdrawal of the marketing authorisation in the European Union

On 4 October 2019, the European Commission withdrew the marketing authorisation for Aerivio Spiromax (salmeterol / fluticasone propionate) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Teva B.V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Aerivio Spiromax was granted marketing authorisation in the EU on 18 August 2016 for treatment of asthma and COPD.

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Public Assessment Report (EPAR) for Aerivio Spiromax will be updated to indicate that the marketing authorisation is no longer valid.

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