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Public statement

Vylaer Spiromax

Withdrawal of the marketing authorisation in the European Union

On 9 January 2017, the European Commission withdrew the marketing authorisation for Vylaer Spiromax (budesonide / formoterol) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Teva Pharma B.V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Vylaer Spiromax was granted marketing authorisation in the EU on 19 November 2014 for treatment of asthma and chronic obstructive pulmonary disease (COPD). The marketing authorisation was initially valid for a 5-year period. Vylaer Spiromax was a duplicate of DuoResp Spiromax, which is marketed in several EU countries.

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Report (EPAR) for Vylaer Spiromax will be updated accordingly to indicate that the marketing authorisation is no longer valid.

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