05 February 2018
EMA/58494/2018
EMEA/H/C/002399

Public statement

Libertek

Withdrawal of the marketing authorisation in the European Union

On 11 January 2018, the European Commission withdrew the marketing authorisation for Libertek (roflumilast) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, AstraZeneca AB, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Libertek was granted marketing authorisation in the EU on 28 February 2011 for treatment of chronic obstructive pulmonary disease (COPD).

The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period.

Libertek was a duplicate of Daxas, which is marketed in several EU countries. The marketing authorisation holder will maintain the marketing authorisation for Daxas.

The European Public Assessment Report (EPAR) for Libertek will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact