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Public statement

ATryn

Withdrawal of the marketing authorisation in the European Union

On 22 December 2018, the European Commission withdrew the marketing authorisation for ATryn (antithrombin alfa) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Laboratoire Francais du Fractionnement et des Biotechnologies, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

ATryn was granted marketing authorisation in the EU on 28 July 2006 for prophylaxis of venous thromboembolism in surgery of patients with congenital antithrombin deficiency. The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2011. It was then granted unlimited validity in 2016. The product had not been marketed in the EU since 2015.

The European Public Assessment Report (EPAR) for ATryn will be updated to indicate that the marketing authorisation is no longer valid.

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