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Public statement

Iblias

Withdrawal of the marketing authorisation in the European Union

On 3 September 2019, the European Commission withdrew the marketing authorisation for Iblias (octocog alfa) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Bayer AG, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Iblias was granted marketing authorisation in the EU on 18 February 2016 for treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency).

The marketing authorisation was initially valid for a 5-year period. The product had not been marketed in the EU since 2018.

The European Public Assessment Report (EPAR) for Iblias will be updated to indicate that the marketing authorisation is no longer valid.

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