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Public statement

Apealea (paclitaxel)

Withdrawal of the marketing authorisation in the European Union

On 9 February 2024, the European Commission withdrew the marketing authorisation for Apealea (paclitaxel) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Inceptua AB, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Apealea was granted marketing authorisation in the EU on 20 November 2018 for the treatment of ovarian cancer. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2023.

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European Public Assessment Report (EPAR) for Apealea will be updated to indicate that the marketing authorisation is no longer valid.

Therapeutic alternatives are available throughout the European Union. Patients taking Apealea or participating in a clinical trial are advised to consult their doctor.

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