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Public statement

Docetaxel Zentiva

Withdrawal of the marketing authorisation in the European Union

On 25 April 2022, the European Commission withdrew the marketing authorisation for Docetaxel Zentiva (docetaxel) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Zentiva, k.s., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Docetaxel Zentiva was granted marketing authorisation in the EU on 20 April 2007 for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma and head and neck cancer. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2011.

Docetaxel Zentiva is identical to Taxotere, which is authorised in the EU to treat breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma and head and neck cancer.

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Public Assessment Report (EPAR) for Docetaxel Zentiva will be updated to indicate that the marketing authorisation is no longer valid.

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