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Review of Yondelis started

EMA's human medicines committee (CHMP) has started a review of the cancer medicine Yondelis (trabectedin), used to treat ovarian cancer (cancer of the ovaries) and soft-tissue sarcoma (a type of cancer that develops from the soft, supporting tissues of the body). The review started after a clinical study (OVC-3006) investigating the use of Yondelis in patients with ovarian cancer was stopped ahead of time, because an interim analysis of the results showed that, overall, patients treated with Yondelis plus pegylated liposomal doxorubicin (PLD, another cancer medicine) did not live longer than patients given PLD alone.

Although there were some differences in the types of patients enrolled in study OVC-3006 compared with those of the study on which the authorisation of Yondelis for ovarian cancer was based, study OVC-3006 also included patients for whom Yondelis would be indicated. EMA will therefore review the available data to assess whether the results from study OVC-3006 have an impact on the authorised use of Yondelis in patients with ovarian cancer.

This review does not cover the use of Yondelis for the treatment of soft-tissue sarcoma. While the review is ongoing, Yondelis can continue to be used for the treatment of both ovarian cancer and soft-tissue sarcoma, according to the authorised product information. Patients who have any questions about their treatment should speak to their doctor.

More about the medicine

Yondelis is used with pegylated liposomal doxorubicin to treat ovarian cancer that has relapsed (come back after previous treatment) and is sensitive to medicines containing platinum.

Yondelis is also used to treat adults with advanced soft-tissue sarcoma. It is used when the cancer had started to spread and treatment with anthracyclines and ifosfamide (other cancer medicines) have stopped working, or in patients who cannot be given these medicines.

More information about Yondelis is available here: ema.europa.eu/medicines/human/EPAR/yondelis.

More about the procedure

The review of Yondelis has been initiated at the request of the European Commission, under [Article 20 of Regulation \(EC\) No 726/2004](#).

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.