27 February 2020
EMA/CHMP/88965/2020

CHMP List of questions

To be addressed by the marketing authorisation holder for Yondelis

Procedure under Article 20 of Regulation (EC) No 726/2004

Yondelis - EMEA/H/A-20/1493/C/0773/0060

Marketing authorisation holder(s): Pharma Mar, S.A.

INN/active substance: trabectedin

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Questions

The marketing authorisation holder (MAH) is requested to address the following questions:

Question 1

The MAH is requested to submit the full clinical study report of the trial 2012-004808-34 (OVC-3006).

Question 2

The MAH should provide an overview of all MAH-sponsored and non-MAH-sponsored clinical trials with Yondelis in an ovarian cancer indication, including information on current study status, baseline patient characteristics, number of patients recruited and planned, study questions addressed and results for each study endpoint.

Question 3

The MAH should provide the current marketing status worldwide in relation to the ovarian cancer indication.

Question 4

In light of all the available data and taking into consideration the results from trial 2012-004808-34, the MAH should explore and comment on the differences between study 301 and of study 3006 (including a tabulated comparison using the same metrics for patient / disease characteristics at the time of recruitment, including number of lines of treatment previously started, number of relapse / progression, cumulative anthracycline, taxane, platinum exposure, distribution of most important, established prognostic factors), and discuss the benefit-risk balance of Yondelis in the currently approved indication of ovarian cancer.