Some oncological treatments are used under off-label indications due to the lack of therapeutic alternatives. To authorize its use, an individualized benefit-risk assessment is needed, as well as an appraisal efficiency.

**AIM AND OBJECTIVES**

Analyze the safety of the off-label drugs prescriptions requested by the Oncology Service in patients who had received previous lines of treatment and in those who had not, so as to identify the importance of this factor when it comes to accept or decline these treatments.

**MATERIAL AND METHODS**

A retrospective observational study was conducted in a third level hospital, which included cancer patients with metastatic disease, treated with off-label medications, during the period December 2017 - January 2021.

The patients were grouped into two categories: pre-treated (received one or more lines of previous treatment) and not pre-treated (without previous treatment).

**RESULTS**

During the research period, treatment was requested for 121 patients, wereof 64 women (52.9%), with a mean age of 61.77 ± 11.18 years. 77 (63.64%) patients were pre-treated (mean of 1.88 previous lines of treatment) and 44 (36.36%) were not.

22 first-line patients (56.41%) experienced some type of toxicity which led to the treatment’s suspension, delay or dose reduction. In the pre-treated group, 41 patients (56.16%) endured toxicity. Data could not be obtained in a total of 9 patients (5 first-line, 4 pre-treated).

There is no statistically significant differences between these two categories. (p = 0.98)

**CONCLUSION AND RELEVANCE**

The toxicity that caused suspension, delay or dose reduction was similar in both groups, so we could conclude that the treatment line does not have an impact on the toxicity of these drugs, and, therefore, it should not be a factor to consider when evaluating these treatments.