

## FREQUENCY AND CHARACTERISTICS OF ADVERSE DRUG REACTIONS TO ANTINEOPLASTIC AND IMMUNOMODULATORY MEDICATIONS IN THE METROPOLITAN AREA OF FLORENCE (ITALY)

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**Introduction:** Antineoplastic and immunomodulatory drugs (ATC code L\*) are largely used in clinical practice given their efficacy in prolonging patients' survival. However, adverse drug reactions (ADRs) are often observed in these subjects and could represent the first cause of therapy interruption and/or patient's hospitalization. In our Local Health Unit (USL Toscana Centro), ADRs related to drugs with ATC code L\* represent the 7th cause of Emergency Department (ED) admission. The aim of this research was to analyse the frequency and characteristics of ADRs related to this drug class.

**Methods:** We performed an analysis based on the National Pharmacovigilance Database, from January 1st to December 31st, 2016. We selected all ADRs related to ATC code L medications, and clustered the results considering the ADRs seriousness and specific ATC code L drug classes. Finally, we classified ADRs by System Organ Class (SOC) and Preferred Term (MedDRA).

**Results:** In 2016 we collected 2556 ADRs and, among them, 105 (4%) were related to drugs with ATC code L\*. Most of pharmacovigilance charts were reported by physicians (68%). Serious ADRs were 39 (38%), followed by not serious (55, 52%) and undefined ones (11, 10%). Among ATC code L\*, the most reported drug classes were: cytostatic medications (55%) and immunomodulators (30%). Among these, the most frequent active principles were: bevacizumab (17%), nivolumab (12%), vemurafenib (10%), pemetrexed (7%), and everolimus (5%). Regarding serious ADRs, the most frequently reported SOCs were: gastrointestinal disorders (n=10, 9,5%), skin and subcutaneous tissue disorders (n=10, 9,5%), general disorders and administration site conditions (n=7, 6,7%), cardiac disorders (n=6, 5,7%), blood and lymphatic system disorders (n=6, 5,7%), investigations(n=6, 5,7%), neoplasms benign, malignant and unspecified includes cysts and polyps (n=6, 5,7%), respiratory, thoracic and mediastinal disorders (n=6, 5,7%), vascular disorders (n=6, 5,7%), and infections and infestations (n=5, 4,7%).

**Conclusions:** ADRs related to antineoplastic and immunomodulatory drugs represent an important clinical and economic issue for Healthcare systems. This research provides a valid estimation of their frequency and seriousness in a large population from a representative Italian Local Health Unit.