F13 Off Label: A Hope or a Liability? An Analysis of Cases in Oncology

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After attending this presentation, attendees will be aware of distributive justice concerns and their consequences on medical liability.

This presentation will impact the forensic science community by illustrating how off-label use provides a valuable treatment alternative (with scientific support) for cancer patients by reducing the time related to the duration of the trial and the final approval of the Ministry of health.

Off-label refers to the use in clinical practice of drugs already registered but used in situations that, owing to dosage, routes of administration, disease, or population are prescribed differently than the approved practice by the Ministry of Health. Very often these medicines are widely known, but new scientific evidence suggests their being used even in clinical situations not provided for in the Ministerial information sheet.

In Italy, the use of medicinal products for indications other than those authorized is regulated by specific laws.[1] One of the areas in which the off-label use of drugs is most prevalent is cancer; the proper use of off-label therapies can represent a real hope for cancer patients for both the prognosis and their quality of life.

A mapping of the Oncology Departments in Puglia, Italy, and Centralized Handling Units for the preparation of cytotoxic chemotherapy was conducted. In addition, the medical oncologists and the hospital pharmacists were provided with a specially formulated questionnaire. The responses were then analyzed according to statistical and descriptive canons.

The study revealed only a partial knowledge of the topic of off-label; therefore, an in-depth exploration of the field of study was conducted by analyzing the current situation at the Oncology Institute of Bari (IRCCS) in order to assess the diseases for which they are in greater demand, the reasons for which they are used, the authorization process adopted, the procedures put in place in order to safeguard patient health, and, at the same time, the responsibilities of the physicians and the hospital.

The requests for off-label therapies that had arrived at the pharmacy between 2011 and 2015 (85 cases) were examined. This study selected the two diseases for which such treatment was implemented (Hodgkin's lymphoma and small-cell lung cancer), and examined the medical records. Having identified the "formal" shortcomings, a specific procedure for the use of off-label drugs within the Oncology Institute of Bari was implemented.

Given a partial formal shortcoming (there was an adequate informed consent form in only 33% of the cases) that has currently been compensated for, the results obtained revealed very good use of off-label drugs; the therapy had positive effects either on the prognosis or on the quality of life. The sector with the most reassuring results was Hematology. All patients with Hodgkin's lymphoma treated in the last year with brentuximab vedotin + bendamustine achieved a complete remission of the disease.

In Italy, the topic off-label is still controversial. On the one hand, it can promote clinical trials by creating valid therapeutic alternatives for patients, often at lower cost and in a shorter time, and, for that reason, it would be implemented specially in research institutes (like the Oncology Institute of Bari); on the other hand, it must be carefully controlled to prevent a disproportionate use which may lead to complications, which are as important for patient health as for the liability of the physician and the hospital.

Reference(s):

1. Law no. 94/1998 and Law no. 296/2007, Art. 1, paragraph 796, letter Z – Financial law 2007.

Off-Label Drugs, Hodgkin's Lymphoma, Liability