

# COMPASSIONATE DRUG USE: THE EXPERIENCE OF THE LECCE-ASL ETHICS COMMITTEE

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## Introduction

Compassionate drug use allows treatment with investigational drugs when there are no therapeutic alternatives. In Italy this is regulated by Ministerial Decree 08/5/2003. The Protocol must be submitted by the physician for the approval of the competent Ethics Committee. Compassionate use is authorized for individual patients.

## Purpose

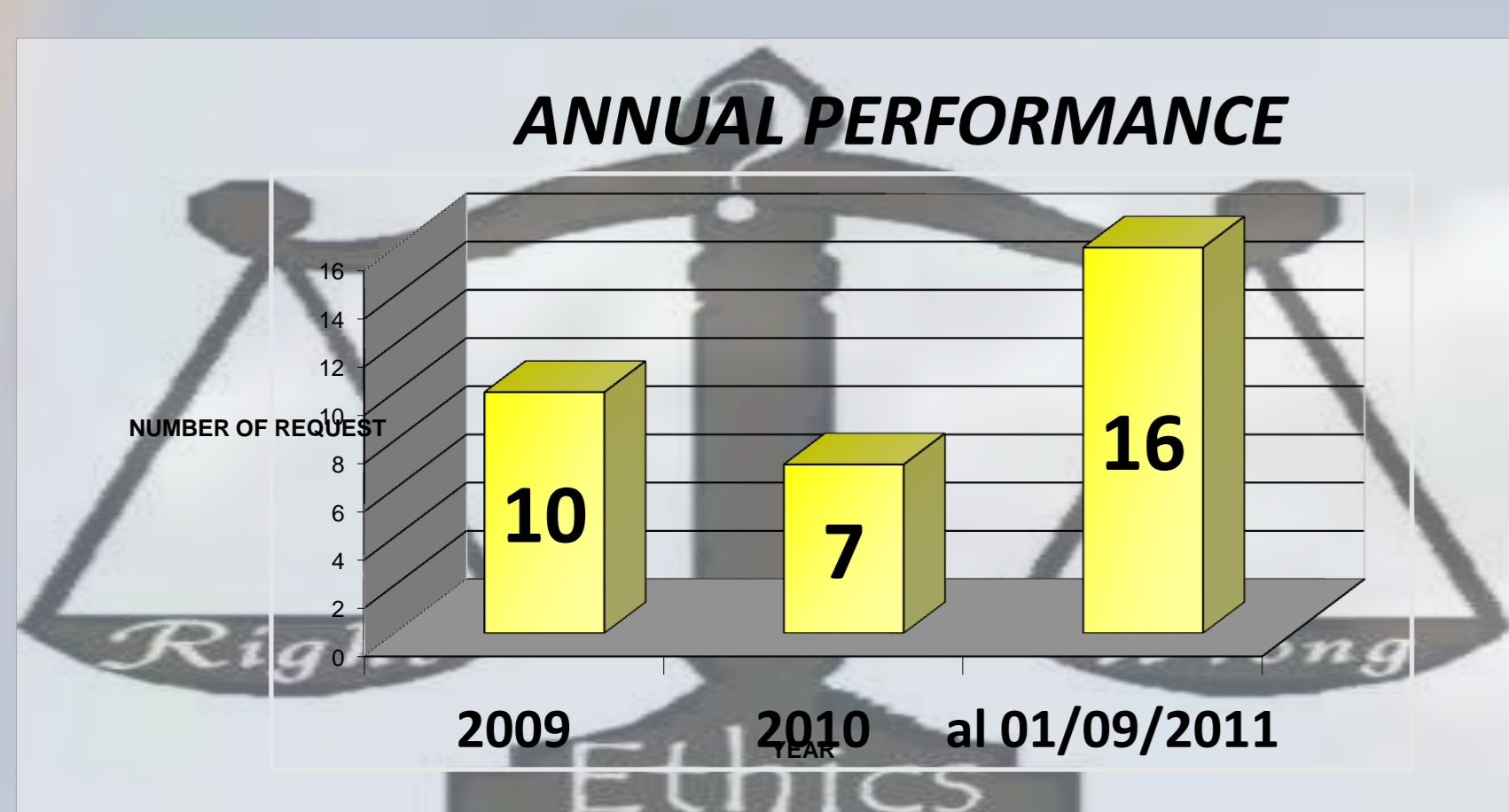
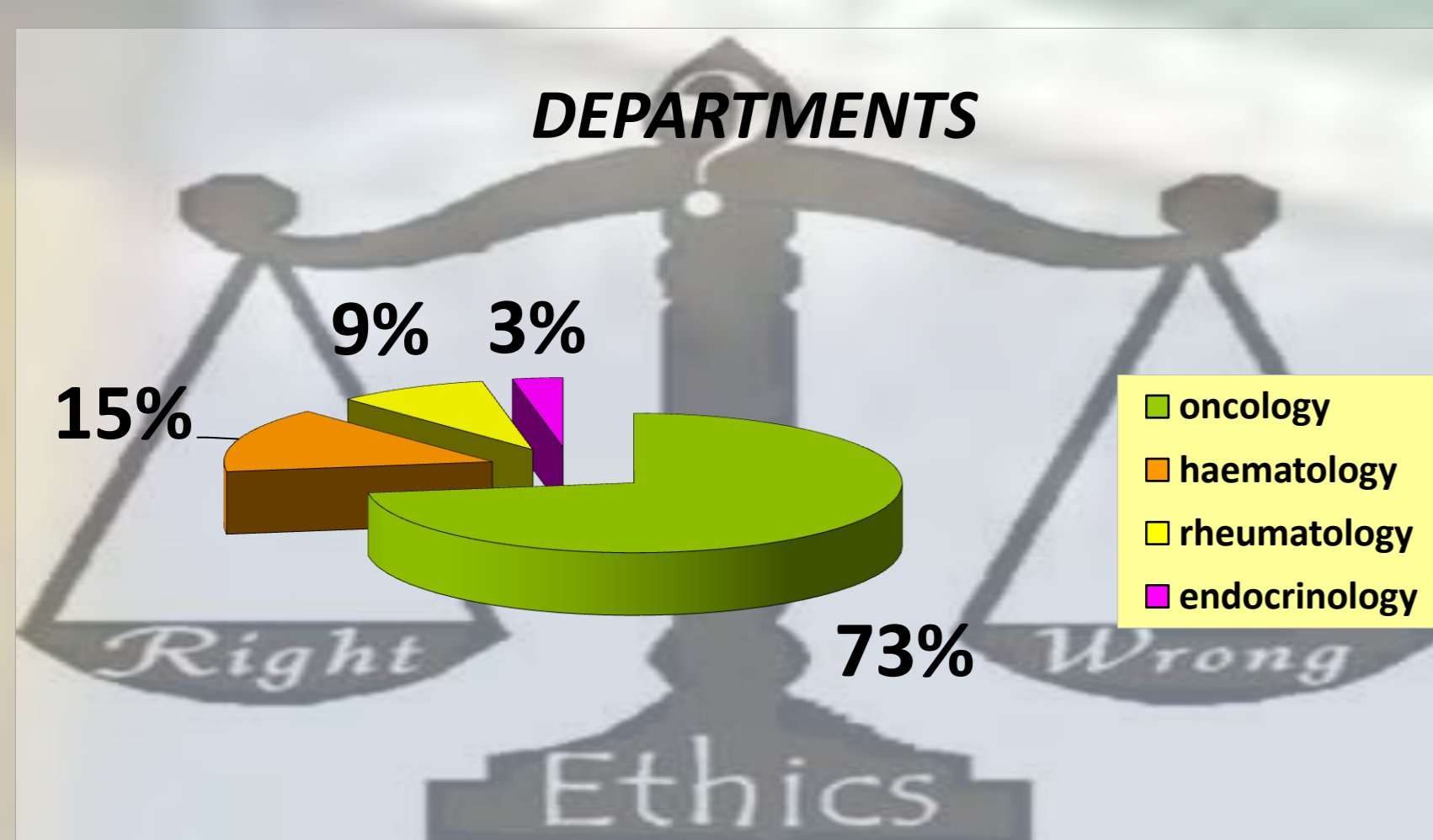
The increasing request for Compassionate Drug use stressed the need for the Asl-Lecce Ethics Committee to set up an electronic data base to highlight the epidemiology.

## Materials and Methods

The Scientific Secretariat of the Ethics Committee receives the request for compassionate drug use, verifies the completeness and examines the characteristics, and prepares documents for submission to the Ethics Committee. Once approved, it is recorded in an Excel database which shows the clinic, hospital ward, physician, the proposed drug use, name of the patient and date of approval.

## Results

The analysis included all data recorded from 01/01/2009 to 01/09/2011, from which it emerged that during this period 34 requests for compassionate drug use were submitted to the Ethics Committee, 10 of which were in 2009, 7 in 2010, and 16 in the first 9 months of 2011. Seventy-three percent of the requests came from the oncology ward, 15% from Haematology, 9% from Rheumatology and 3% from Endocrinology.



## Conclusions

Growing requests for compassionate drug use underline the need for doctors and patients to have access to innovative drugs when there are no therapeutic alternatives and no possibility of inclusion in clinical trials.

The monitoring system has made it possible to check that the drugs for which compassionate use was requested were then registered for that purpose by AIFA; and it will allow the Ethics Committee to propose to doctors the setting up of non-profit clinical trials when the request for compassionate drug use increases.

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