EVALUATION OF ACCESS TO OFF-LABEL NEW THERAPIES PHARMACOLOGICAL FIELD AND THE HOSPITAL AND ECONOMIC IMPACT

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BACKGROUND

The incorporation of new drugs in hospitals, for their special health, social and economic impact, are classified as High Impact Social and Economic Drugs and require a comparative analysis of their efficacy, safety and efficiency versus therapeutic alternatives available through multidisciplinary Committees of pharmacists and medical specialists for each drug (SAISE) to ensure homogeneous criteria in use in all health centers of the Conselleria de Sanitat of Valencia, ensuring equal access patients such treatments.

The SAISE establish guideline to authorize the use of off-label new therapies (OLNT)

PURPOSE

The aim of this study is to evaluate the process to approval the use of OLNT (requests allowed/denied treatments and time to obtain a resolution) and monthly cost of these treatments.

MATERIAL AND METHODS

Retrospective study that includes treatment requests received in the pharmacy service from January 2013 to April 2016 and evaluated in the corresponding SAISE.

The variables were: request date, service, drug, indication, outcome and date of the resolution and cost of treatment.

RESULTS

In the study period, 4704 requests were submitted in Pharmacy Service, of which 183 requests were processed as OLNT; 81,8% correspond to the oncology department, 12,7% to hematology, 3,3% to digestive medicine, 1,6% to internal medicine and 0,6 % to pediatrics.

The most requested treatments were 26,7% bevacizumab, 10,9% abiraterone, 6% nab-paclitaxel and regorafenib, 5% panitumumab and rituximab.

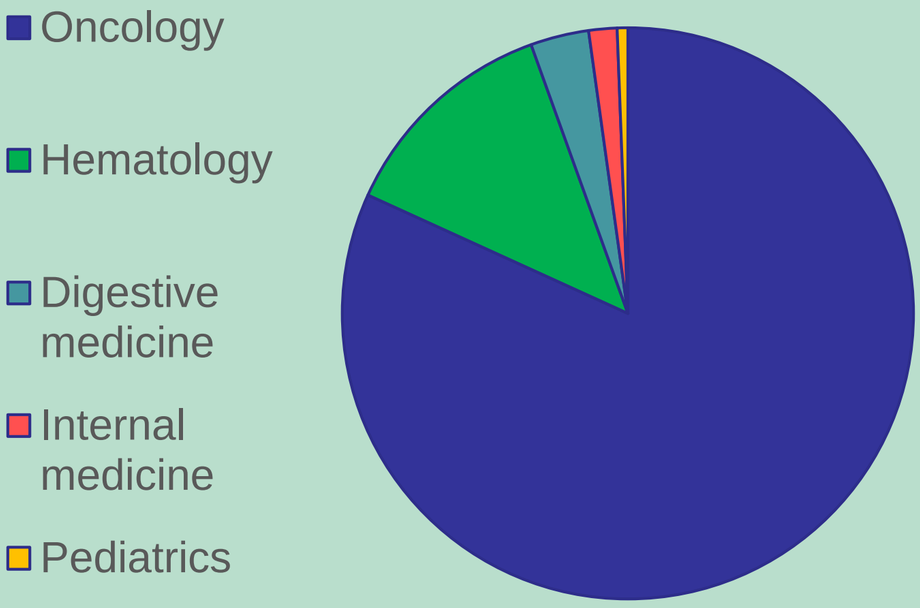
The most frequent pathologies were 21,8% colorectal cancer, 13.6% prostate cancer, 12,6% glioblastoma and 7,7% pancreas cancer.

24% of these requests were denied; 25% of Oncology,16% Hematology and 50% of digestive medicine. 90% were refused for insufficient information on the efficacy of treatment and the rest was for lack of information in the clinical report.

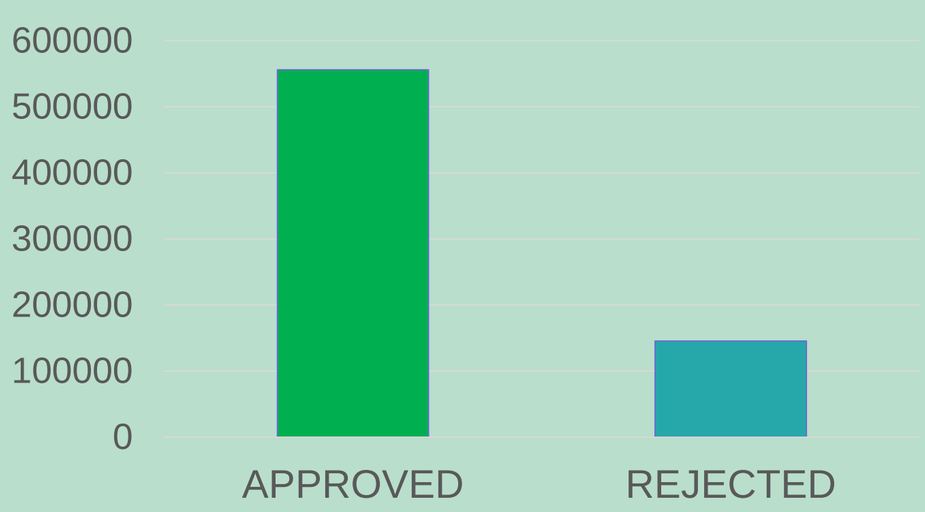
The monthly cost of approved request was 585.985 € and 145.690 € for the rejected.

The average time for resolution was 30 days (11-89 days).

REQUESTS



MONTHLY COST (€)



CONCLUSION

Due to the high cost of new drug therapies it is necessary to establish criteria to ensure that patients receive proper treatment and ensure the sustainability of the health system. Although it should be a faster process by the severity of some diseases.