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## 1. Background and Importance

The Portuguese National Pharmacy and Medicine Institute (INFARMED) implemented in 2015 a Digital Assessment Decision Support Tool (SiNATS) to maximize health gains and sustainability, monitor drug use and its equitable access, based in a pharmacotherapeutic/economic evaluation leading to a Public Financing Report (RAFP) that grants Early Access to Medicines (PAP).

## 2. Aim and objectives

To characterize drug requests (DR) evaluated by SiNATS in hospital setting.

## 4. Results

We enrolled 72 DR, 3 for stock and 69 per patient of which 75% were female with an average age of 51 years, prescribed mainly by Internal Medicine (38%), Pneumology (21%) and Gastroenterology (11%) departments.

The main DR and those with higher approval rate are mentioned on table 1:

DR	n	%	Clinical Justification	% of approvals
Nintedanib	13	18	Inefficacy of corticotherapy	92%
Upadacitinib	11	16	Failure to first line treatment	55%
Bulevirtide	6	9	Contra-indication to interferon	100%
Mepolizumab	6	9	First-line treatment	40%
Belimumab	5	7	Failure to first line treatment	40%
Tolvaptan	5	7	First-line treatment	100%

## 3. Materials and Methods

A 2-years retrospective study was conducted from 2022 to 2023 in an 800-bed hospital. DR's clinical, pharmaceutical and economic data were submitted on SiNATS digital platform to be evaluated by Infarmed (after the approval by the local drug and therapeutic committee), except those from Oncology department. The data was analyzed in an Excel 5.0 database.

Overall, approval rate was 75%. Rejections were mainly due to lack of compliance to PAP requirements (61%) namely because of the existence of alternative first line options (upadacitinib and mepolizumab) and RAFP already approved (33%) (belimumab and nintedanib).

The economic impact was 969.652€ per year, of which 667.238€ was related to approvals and 302.614€ to rejections.

## 5. Conclusions and Relevance

Our data shows a high percentage of approvals. However, upadacitinib for Crohn disease and mepolizumab for Eosinophilic granulomatosis with polyangiitis showed higher rates of rejection, due to the existence of alternative first line treatments options. Economic impact was high, showing the importance of the definition, by experts in the field, of utilization criteria on a National level, so clinicians and pharmacists, as a team, can optimize treatment outcomes in accordance with RAFP and international guidelines, while ensuring sustainability of public resources and enabling more patients to benefit from innovative therapies.

