

THE EARLY ACCESS PROGRAMME (EAP) IN PORTUGAL: A QUANTITATIVE AND QUALITATIVE ANALYSIS



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OBJECTIVE

This research aimed to analyse the EAP appraisals in Portugal in a quantitatively and qualitatively perspective.

CONCLUSIONS

The number of EAPs has increased over the years, allowing a better access to innovative healthcare solutions. However, the growth in the number of processes (specially in 2021), together with delays in HTA procedures, may result in bigger costs and block the access to innovation to patients that do not benefit from EAPs.

INTRODUCTION

- The Early Access Programme (EAP), created in September 2017 as part of the regulatory framework of the National Health Technology System (SiNATS), is the Portuguese strategy to allow patients to have access to new hospital drugs before the Health Technology Assessment (HTA) process is concluded.

METHODS

- An analysis of the EAPs published in the INFARMED's database until October 31st 2021 was performed.
- Several variables were taken under consideration, such as Therapeutic Area, Number of patients, Date, Target Population and Appraisal Outcome.

RESULTS

- Between 2017 and October 2021, there were 142 EAPs submitted, with an approval rate of 65,5% (93 EAPs) while 34,5% (49 EAPs) were denied. This approval rate is depicted in Figure 1.

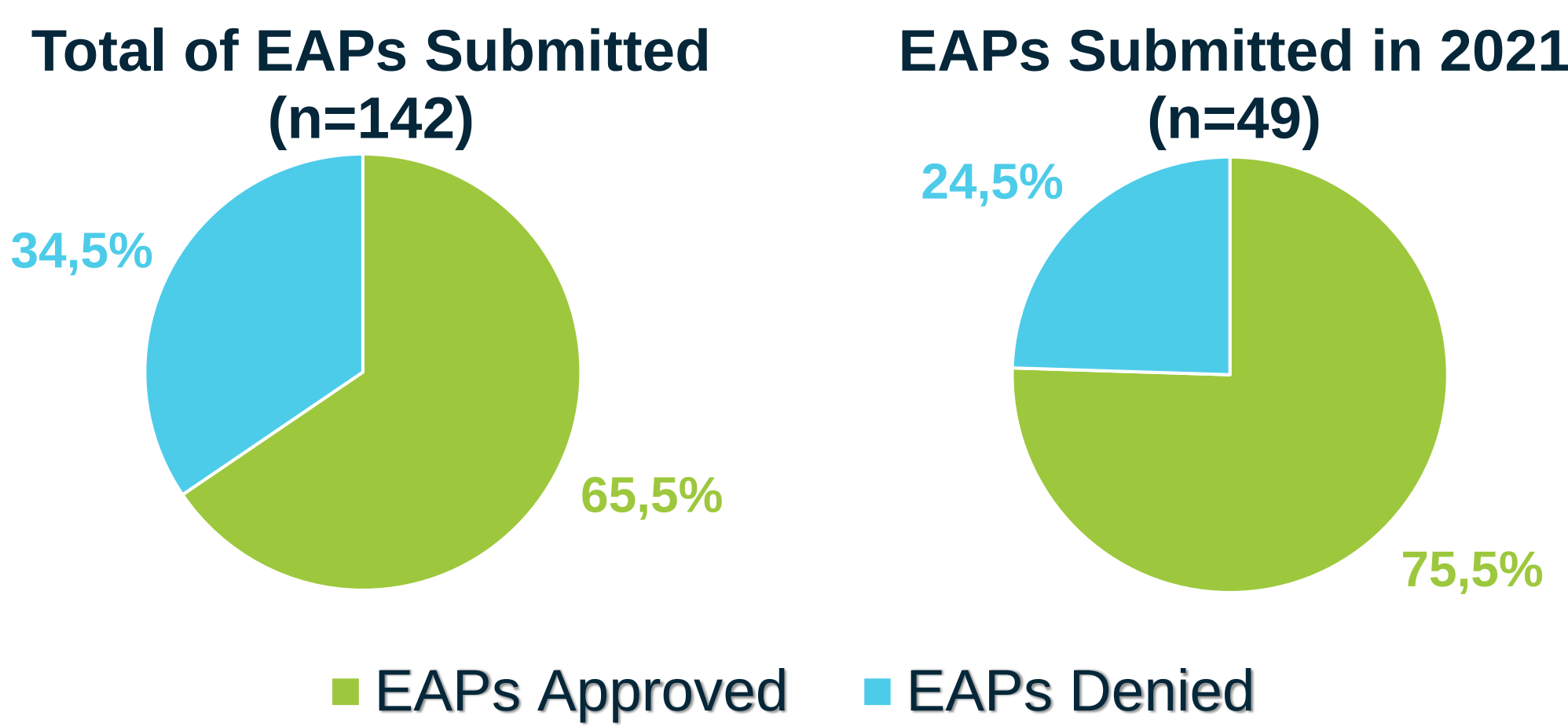


Figure 1. Approval rate of the total of EAPs submitted between 2017 and 2021, and approval rate of EAPs submitted just in 2021.

- The number of EAPs submitted has been increasing, with 20 in 2018, 35 in 2019 and 36 in 2020, as seen in Figure 2. The present year of 2021, with already 49 submissions (and an above average approval rate of 75,5%, as shown in Figure 1), is following the trend, becoming the year with most EAP submissions.

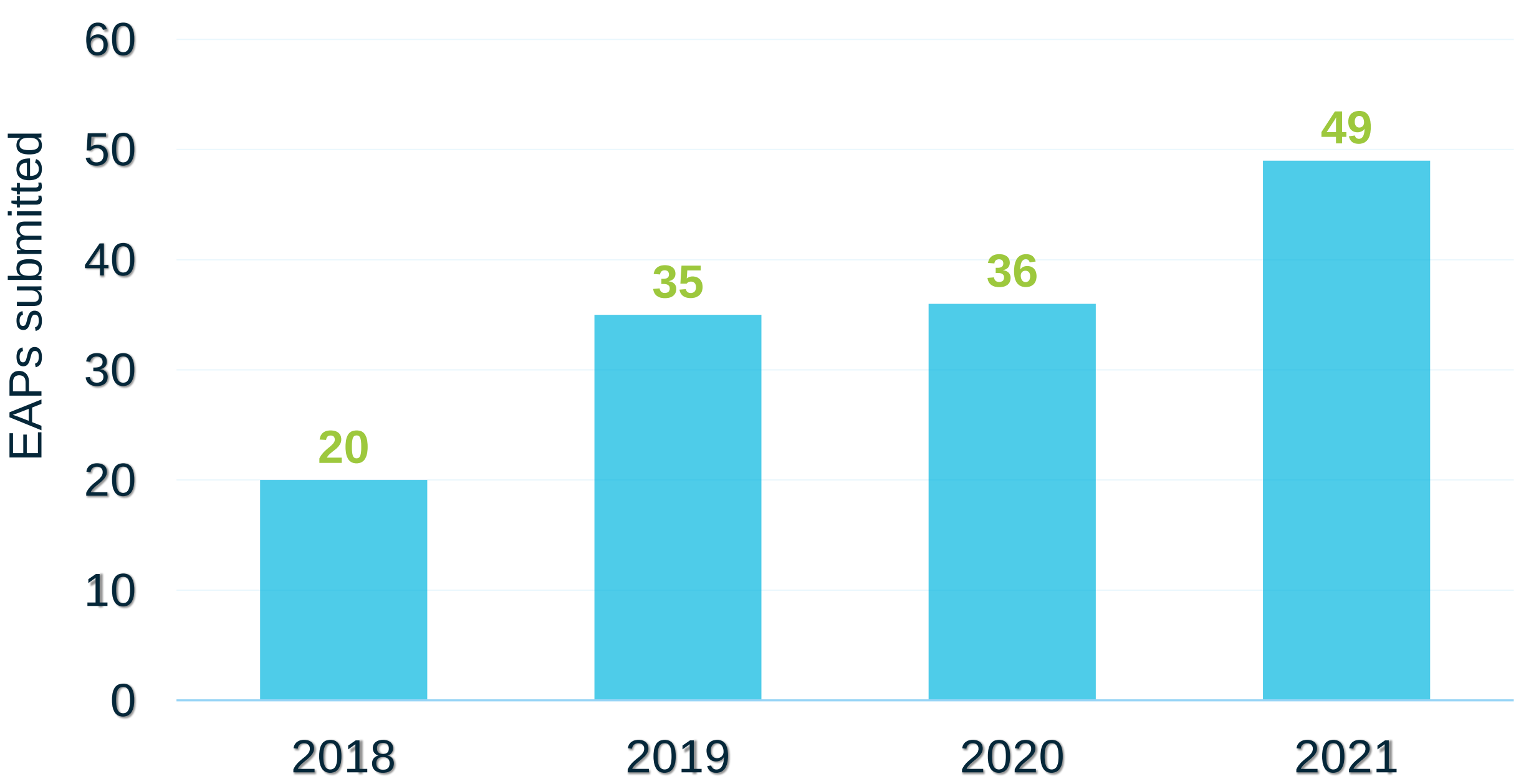


Figure 2. Number of EAPs submitted to INFARMED I.P. per year.

- So far, Oncology represents more than 50% (78 EAPs) of the total number of EAPs submitted, registering a 45% denial rate. This is represented in the graph below (Figure 3), along with the same comparison for other therapeutic areas.

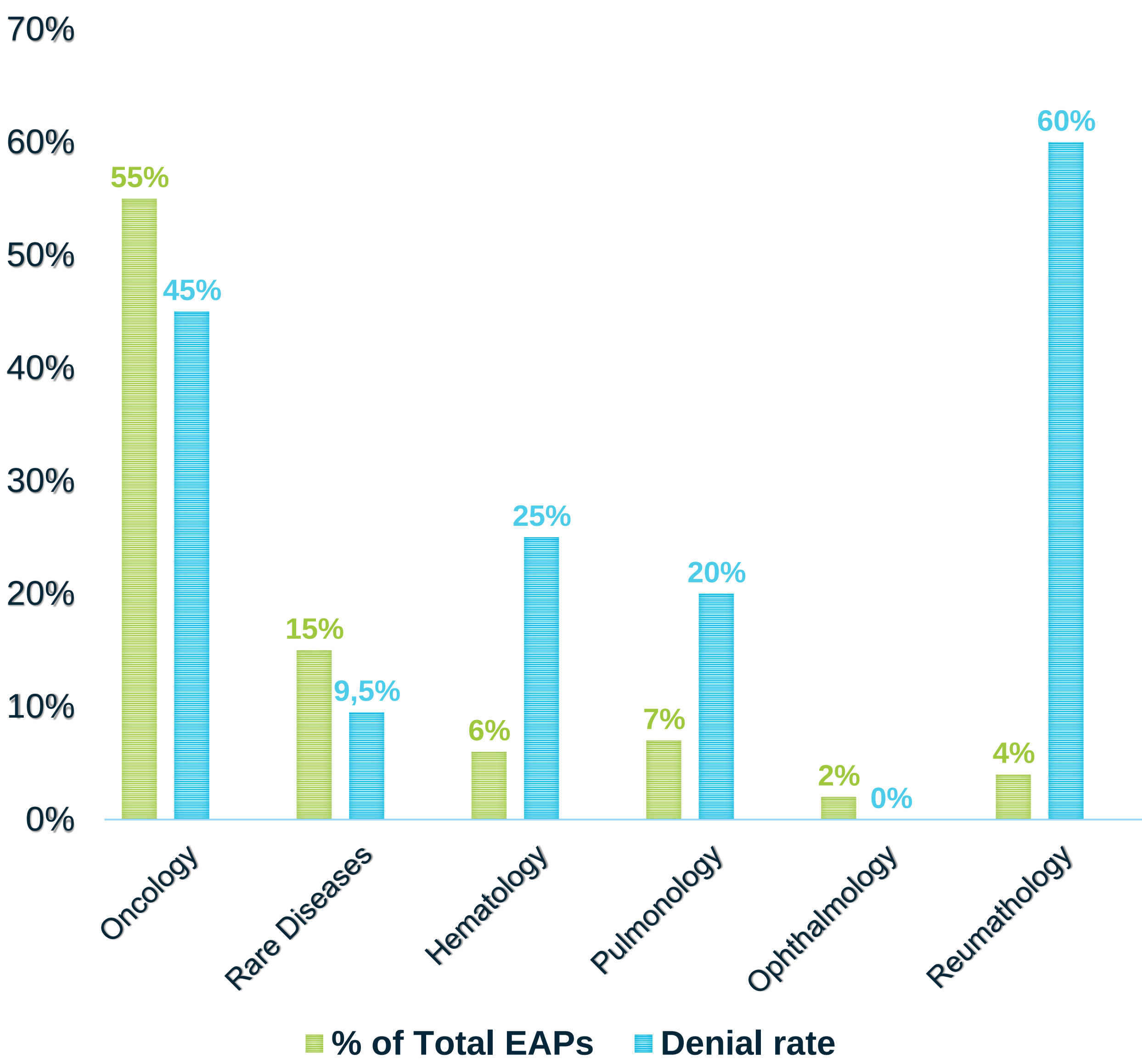


Figure 3. EAPs submitted per therapeutic area, and their respective denial rates.

- Since 2017, more than 1300 patients benefited with the Early Access Programme and approximately 20% of EAPs included pediatric patients.

Disclosure

All authors are employees of Bayer Portugal.

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