Trends and Challenges in Reimbursement Decisions in Portugal: 2015-2023

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BACKGROUND

- Health Technology Assessment (HTA) has been an integral practice in Portugal since 1991, with the first national guidelines published in 1998 by INFARMED, the National Authority of Medicines and Health Products.

- In 2015, a major step forward was taken with the creation of the National Health Technology Assessment System (SiNATS), which introduced a structured and systematic process for evaluating the clinical and economic value of innovative therapies. This system aimed to improve health outcomes evaluation, ensure the long-term sustainability of the National Health Service (NHS), and optimize the use of public health resources.

OBJECTIVES

- The primary objective of this analysis is to provide a comprehensive overview of the reimbursement decisions in Portugal from 2015 to 2023 and identify trends in therapeutic areas, approval rates, and challenges in specific fields like oncology.

METHODS

- We conducted a comprehensive analysis of all the reimbursement decisions published by INFARMED from 2015 to 2023. Key variables assessed include therapeutic area, active substance, type of decision (approval or refusal) and year of decision.

RESULTS

- We analyzed a total of 494 official reimbursement decisions published by INFARMED, with 89% (439) resulting in approvals and 11% (55) in refusals (Figure 1).

- The top-4 therapeutic areas with the highest number of reimbursement decisions were oncology (37.9%), central nervous system (CNS) (9.3%), cardiovascular (8.5%), and anti-infectious (7.1%), together representing 63% of all decisions over this 9-year period.

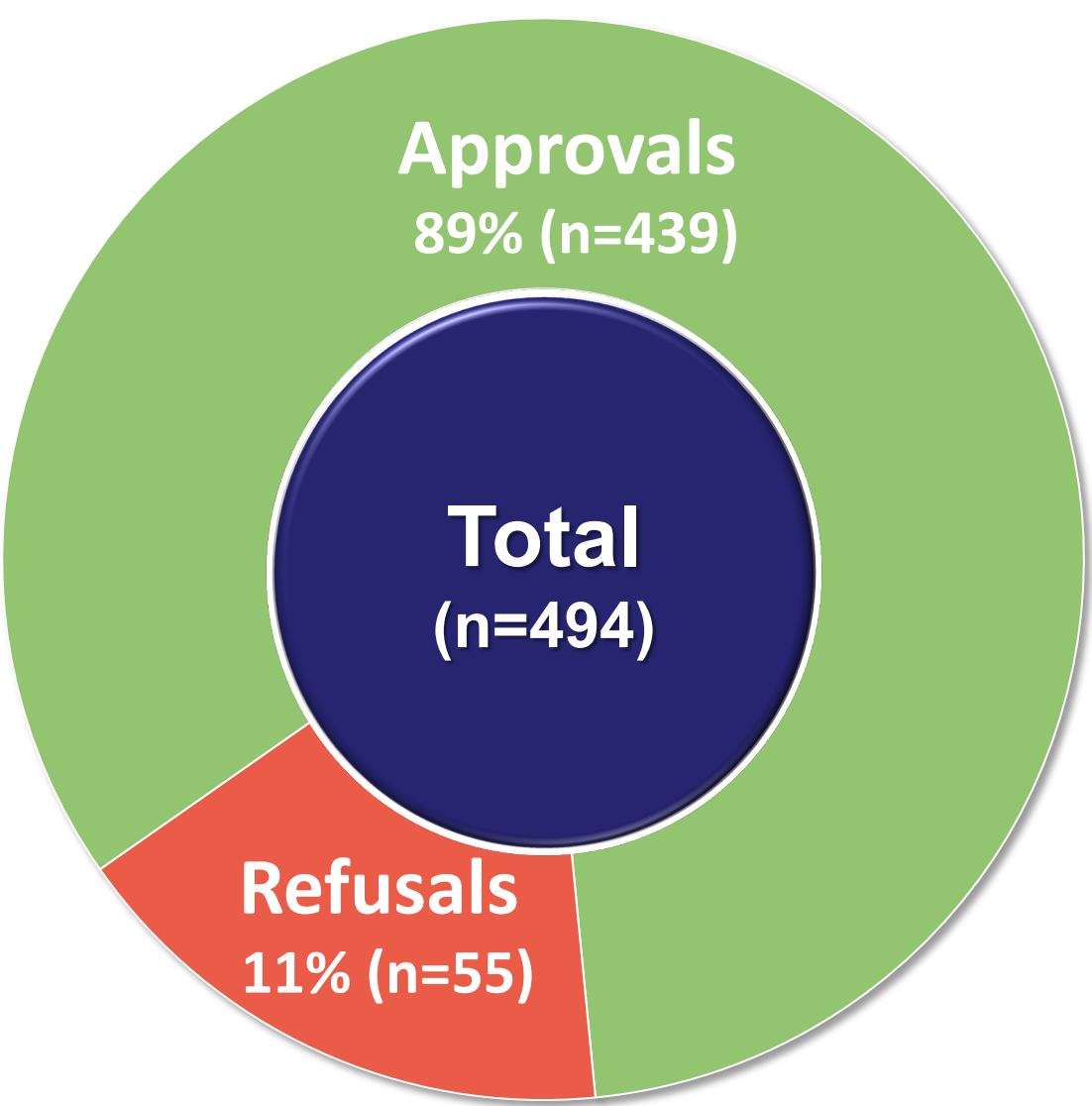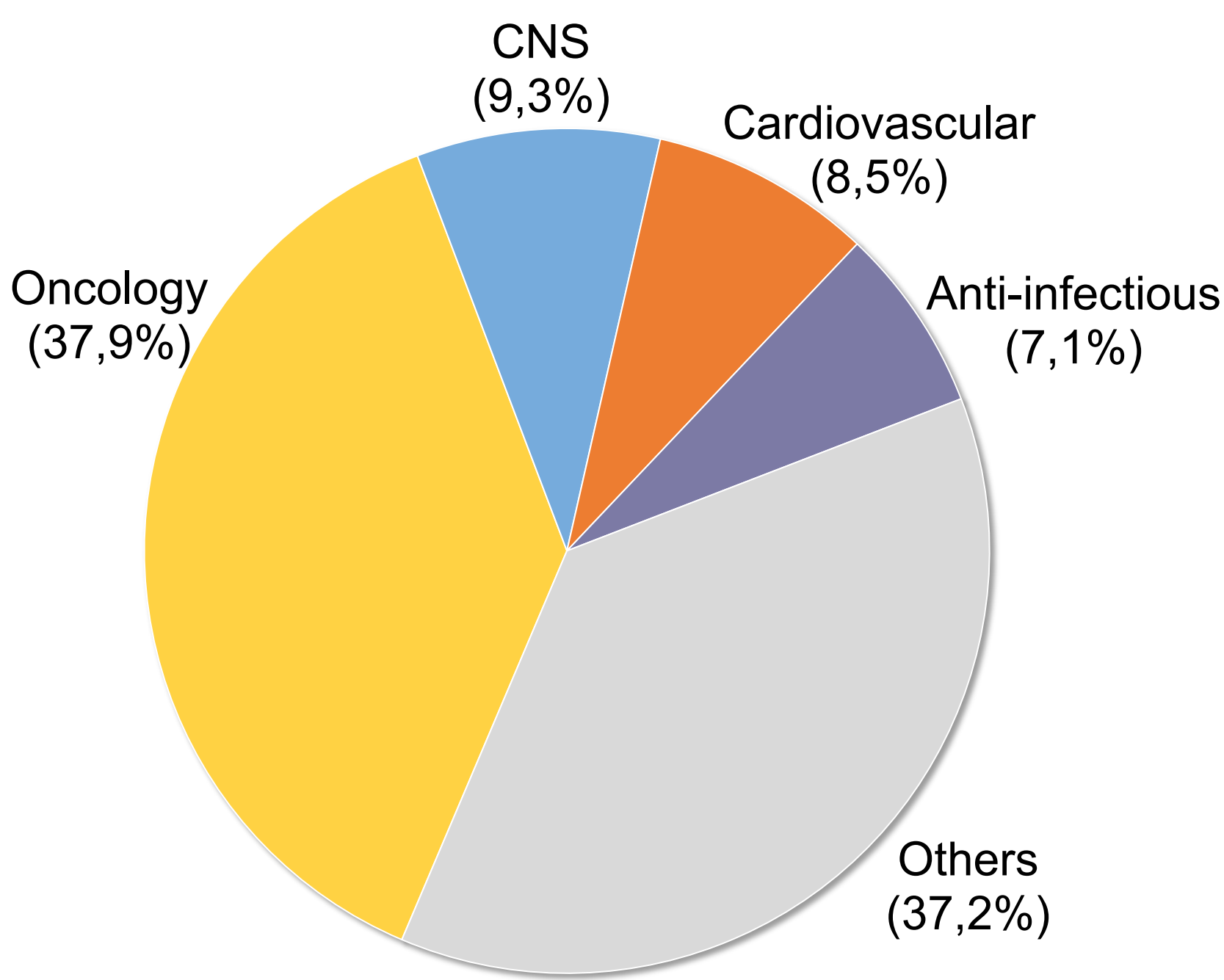**Figure 1**. Total reimbursement decisions, approvals and refusals rates

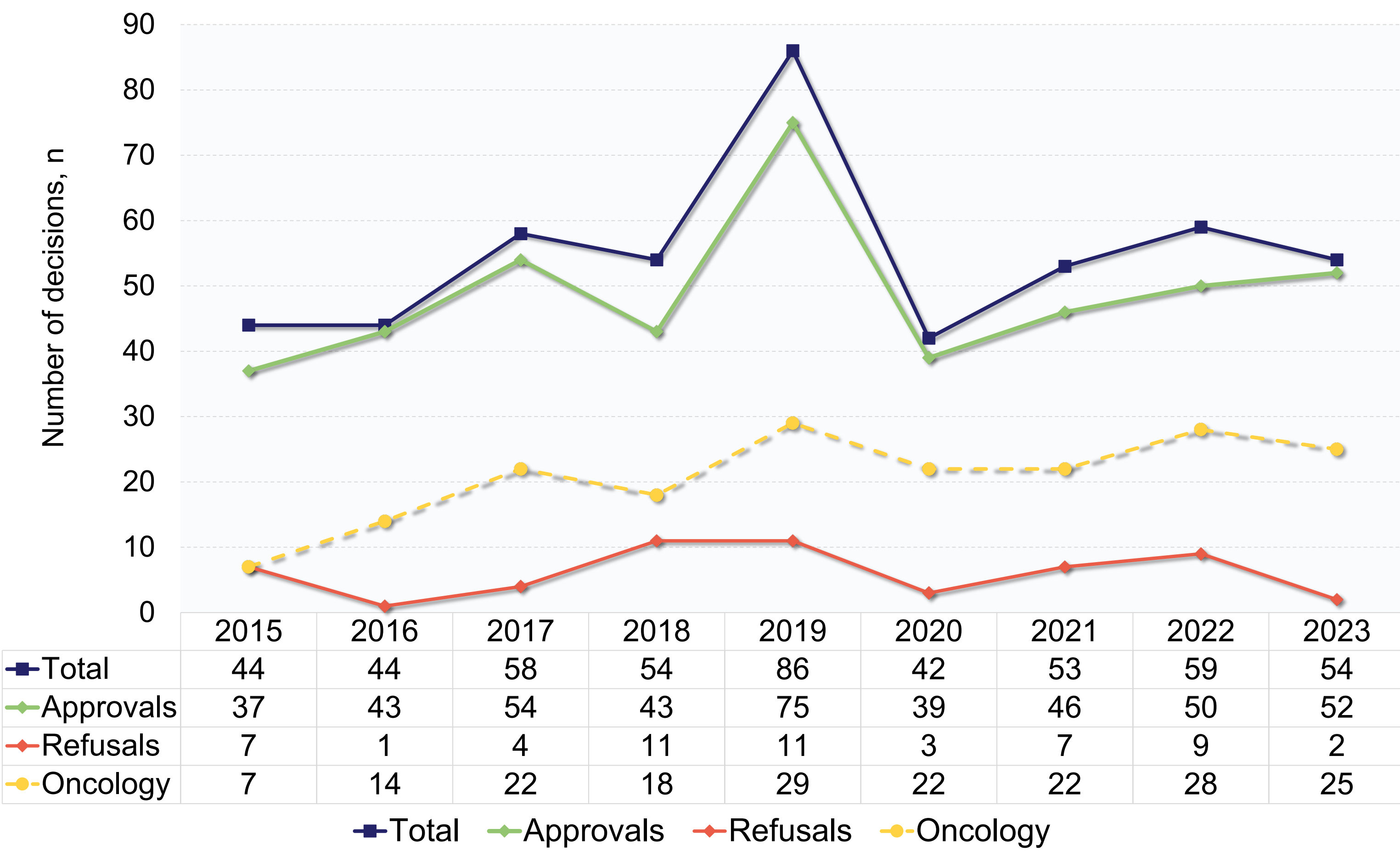**Figure 2**. Top-4 therapeutic areas with the highest number of reimbursement decisions

- Approval rates varied significantly across therapeutic areas, considering oncology treatments (including new active substances and indications), the approval rate was 84.5%, while anti-infectious treatments achieved a 100% approval rate.

Table 1. Approval and refusal rates in the top-4 therapeutic areas with the highest number of decisions

Therapeutic Area	Approvals, n (%)	Refusals, n (%)	Total decisions, n
Oncology	158 (84.5%)	29 (15.5%)	187
CNS	42 (91.3%)	4 (8.7%)	46
Cardiovascular	37 (88.1%)	5 (11.9%)	42
Anti-infectious	35 (100%)	0	35

- Additionally, from the 439 positive reimbursement decisions, 36% were in oncology. Among all negative decisions, oncology accounted for the highest percentage, representing 53% of total refusals (29 out of 55) within this therapeutic area.

- Looking closely at oncology, the average number of total reimbursement decisions increased by 35% after 2020. From 2015 to 2019, oncology accounted for around 31% of total reimbursement decisions (an average of 18 decisions per year), compared to 47% from 2020 to 2023 (an average of 24 decisions per year).

Figure 3. Number of total reimbursement decisions, approvals, refusals and in Oncology, per year 2015-2023

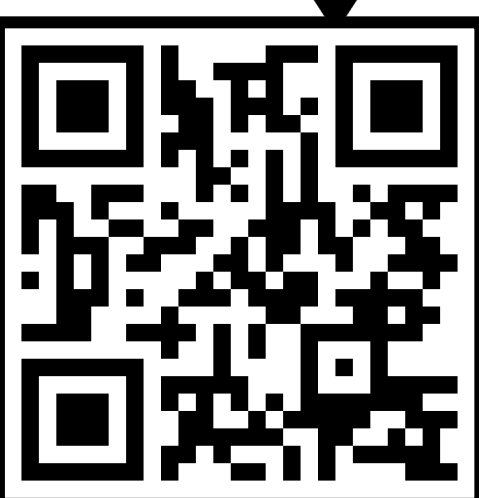|	2015	2016	2017	2018	2019	2020	2021	2022	2023
Total	44	44	58	54	86	42	53	59	54
Approvals	37	43	54	43	75	39	46	50	52
Refusals	7	1	4	11	11	3	7	9	2
Oncology	7	14	22	18	29	22	22	28	25

- Taking a deeper look at therapeutic indications, excluding oncology, the top-5 with the highest number of reimbursement approvals were: Diabetes mellitus (15 approvals); Dyslipidemia (14 approvals); HIV/AIDS (13 approvals); Hypertension (12 approvals) and Multiple sclerosis (11 approvals).

CONCLUSION

- This analysis offers valuable insights into reimbursement decisions made by INFARMED in Portugal from 2015 to 2023.

- Oncology reimbursement decisions have increased, emerging as the most frequently evaluated therapeutic area, particularly after 2020. This reflects global trends in the pharmaceutical industry pipelines and highlights a strong commitment to give patient access to innovative cancer treatments.

- Nonetheless, oncology remains one of the most challenging areas to obtain a positive reimbursement decision, as evidenced by the high rate of refusals.

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