

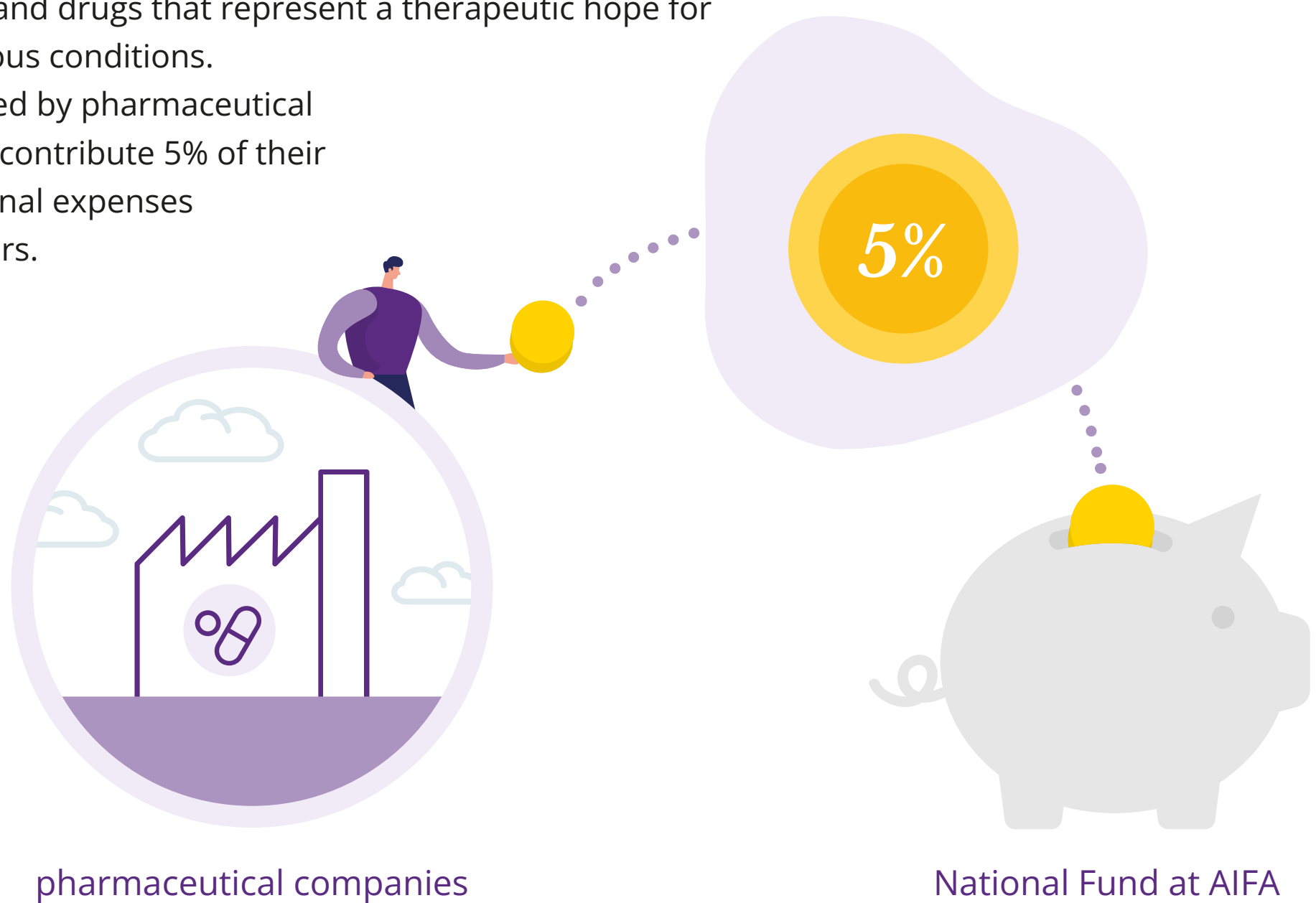
# Evolution of the utilization of the AIFA 5% Fund for orphan drugs and rare diseases

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## Background

Since 2003 law 326 established the creation of a National Fund at AIFA to be used for the acquisition of orphan drugs for treatment of rare diseases and drugs that represent a therapeutic hope for specific and serious conditions. The fund is funded by pharmaceutical companies, who contribute 5% of their annual promotional expenses directed at doctors.



## Objective

The analysis aims to understand the evolution of the utilization and allocation of economic resources for the so-called AIFA 5% from 2010 to 2022.

## Materials and methods

The information available in the 'transparent administration' section of the AIFA website was examined to understand the allocation and expenditures of resources for the AIFA 5% Fund. Yearly economic parameters such as initial budget, allocation, total expenditure, and final balance were considered. Through OSMED reports (A systematic analysis of drug prescription in Italy in terms of consumption, expenditure, types of medications, and user characteristics), the 10 drugs with the greatest impact and the number of patients treated were also identified. Concession acts (They are documents from the public administration that authorize the use of resources for a specific service.) of 2021 – 2022 were also considered to conduct a further examination regarding the fund's expenditure.

This analysis relies on publicly available data, to address this limitation interviews with AIFA's executives have been carried out for a better understanding of the evolution of the Fund.

## Analyzed documents

### AIFA Financial statements

YEAR	Allocation to the Fund	Utilization of the Fund
2015	€ 17.861.000	€ 15.000
2017	€ 17.831.000	€ 6.722.000
2020	€ 16.304.000	€ 25.838.000
2021	€ 10.713.000	€ 40.441.000,00
2022	€ 13.152.000	€ 33.235.000,00

### OSMED reports

A systematic analysis of drug prescription in Italy in terms of consumption, expenditure, types of medications, and user characteristics

YEAR	Top 10 drugs with the greatest impact on the AIFA 5% Fund	Patients with access to the AIFA 5% Fund
2017	€ 13.465.742	60
2020	€ 38.400.000	1361
2021	€ 29.983.008	1010
2022	€ 10.030.861	799

### Concessions Acts

Documents from the public administration that authorize the use of resources for a specific service

YEAR	Utilization of the Fund	Patients with access to the AIFA 5% Fund
2021	€ 31.971.907	830
2022	€ 44.895.922	1.006

## Results

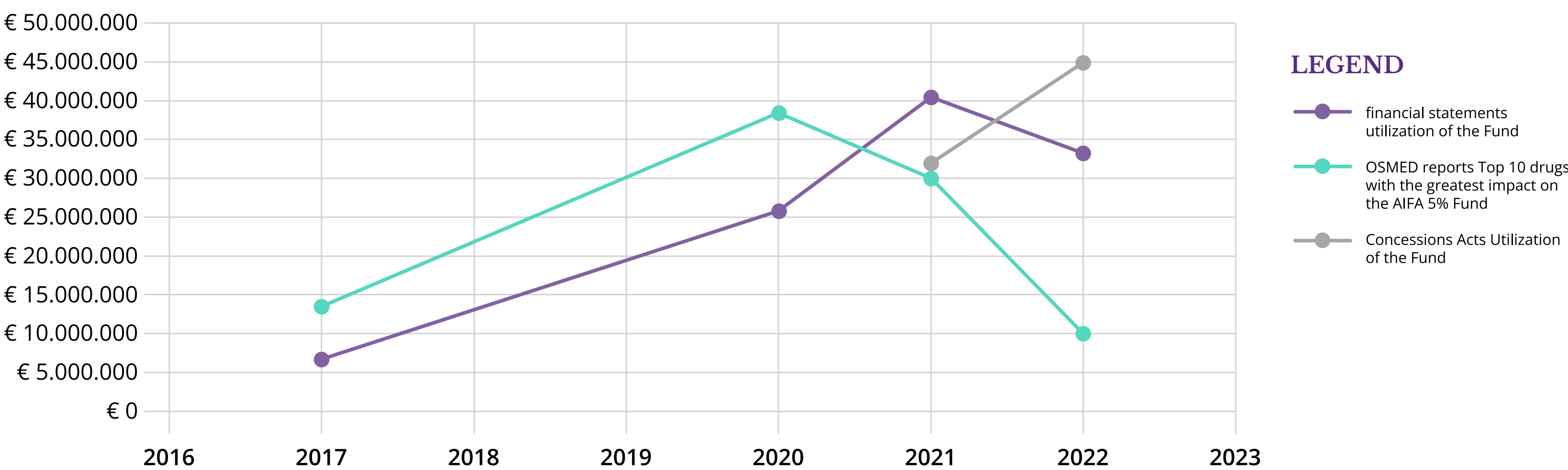
The analysis conducted among the official documents provided detailed information regarding the evolution of the Fund.

Inconsistencies regarding the annual fund expenditure and the number of patients with access to the Fund have been identified. For example, in 2020, according to the financial statements, the expenditure was €25,837,093, while that reported in the OSMED reports was €38,400,000. In 2021, according to the OSMED reports, the number of those with access to the fund is 1010, while the concession acts report a number of access equal to 830.

In 2021, AIFA decided to temporarily suspend the activities related to the fund to initiate a simplification and optimization of the system.

One of the reasons given by AIFA for the suspension was the Fund had only 8.5 million € in available resources, differing significantly from the €159,352,000 reported at the end of 2020 in the financial statement.

## Expenses of the Fund



### LEGEND

- financial statements utilization of the Fund
- OSMED reports Top 10 drugs with the greatest impact on the AIFA 5% fund
- Concessions Acts Utilization of the Fund

## Bibliography

- AIFA financial statements for years 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021 (B), 2021 (FS) and 2022
- OSMED reports for years 2015, 2016, 2017, 2018, 2019, 2020, 2021 and 2022
- Concession Acts for years 2021 and 2022

## Conclusions

The analysis reveals discrepancies in the published data, and interviews conducted indicate that these are due to the financial statement including only unspent resources, excluding the committed ones. This fact could potentially lead to confusion about the actual availability of the fund.

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