

# Real-World Utilization of Sodium Zirconium Cyclosilicate in Hyperkalemia Management in Italy

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## INTRODUCTION

- **Hyperkalemia (HK)** is common in patients with chronic kidney disease (CKD) and heart failure (HF), especially those on renin-angiotensin-aldosterone system inhibitors (RAASi) [1,2].
- Fear of HK often leads to **discontinuation of RAASi** due to the risk of cardiac arrhythmias and mortality [3].
- New treatments, such as **sodium zirconium cyclosilicate (SZC)**, have been approved for managing HK. In Italy SZC is reimbursed since 2021 [4].

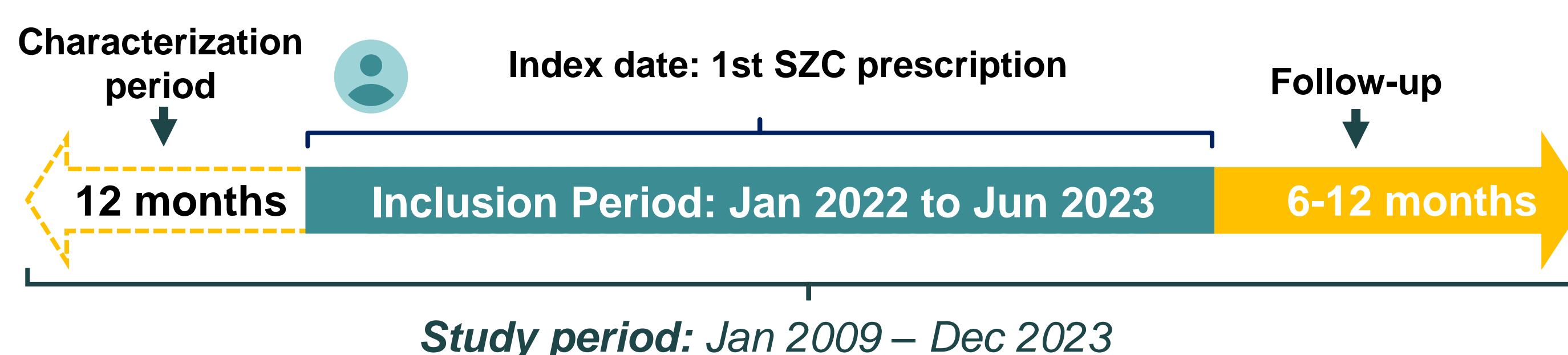
## OBJECTIVE

This study aimed to collect real-world data on the use of SZC for HK treatment and the related economic burden from the perspective of the Italian National Health Service (NHS) in a setting of real clinical practice.

## PATIENTS AND METHODS

**Data source:** A retrospective observational analysis of data from Italian Local Health Units (LHU), covering nearly 6 million health-assisted individuals.

**Study design and population:** Adults (≥18 years) with at least one prescription of SZC (ATC V03AE10) were included at the time of therapy initiation (index-date). Patients prescribed other K-binders or resins after the index-date were excluded.



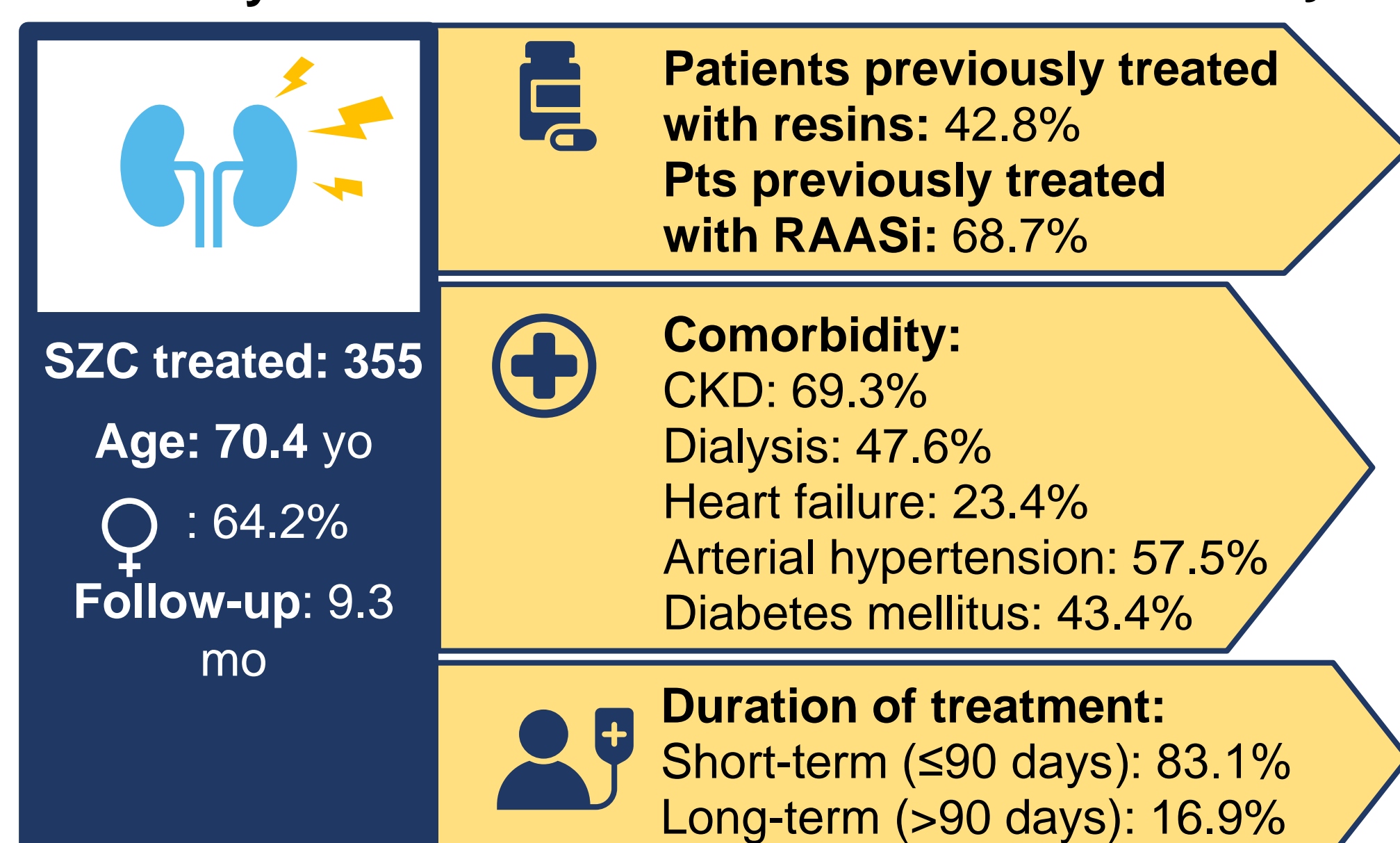
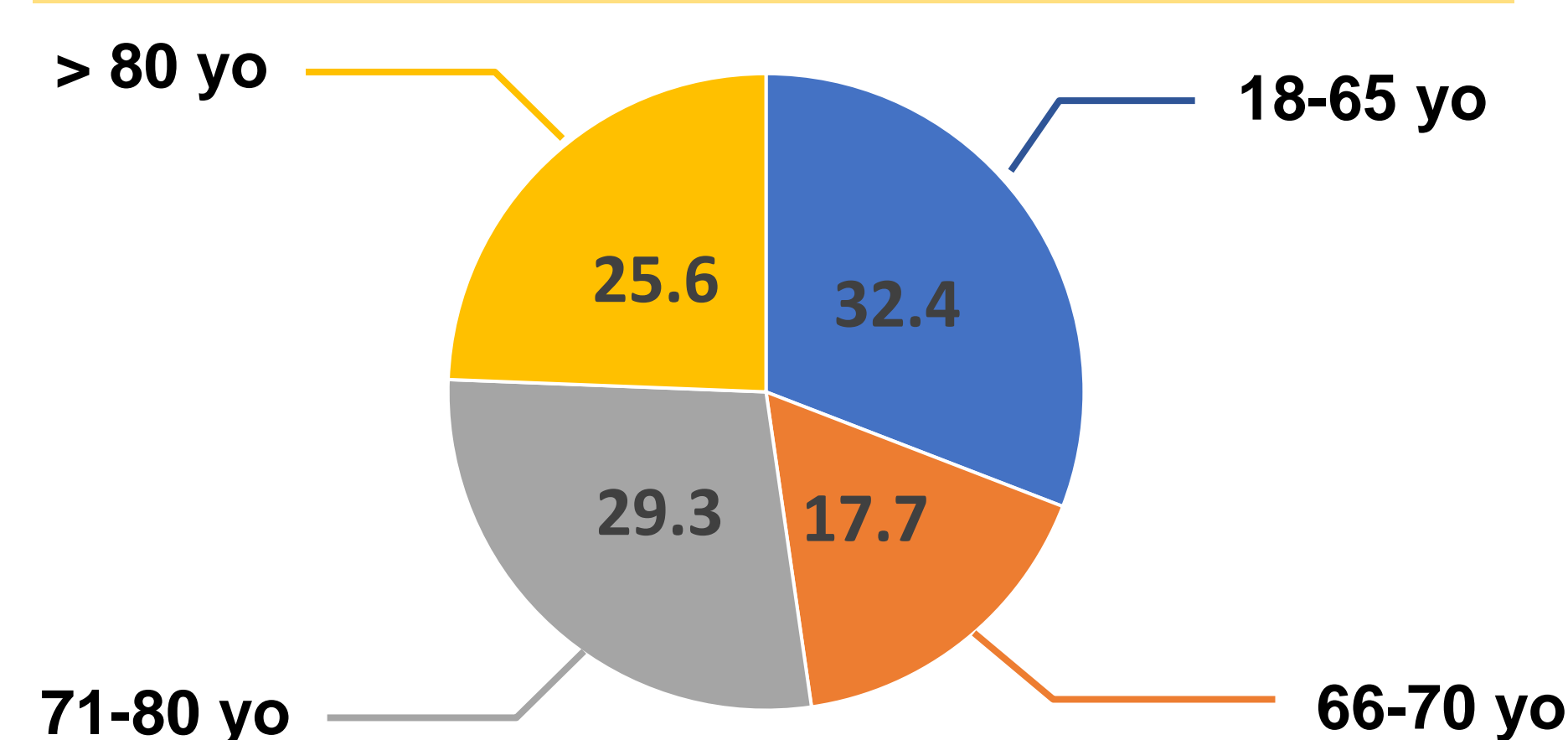
**Drug utilization:** The proportion of patients treated long-term and short-term was defined according to the frequency of those with a number of days covered respectively of >90 or ≤90, within a continuous treatment period ≥3 months evaluated using the Refill-Gap method, each supplied package is considered to cover 30 days, with an allowance for a grace period of 15 days. A subgroup analysis was performed on patients treated with RAASi at baseline or during follow-up to assess the rate of RAASi discontinuation between the long-term vs short-term SZC-treated. A logistic regression model was run to identify predictors of long-term treatment.

**HCRU and direct costs:** A descriptive analysis of healthcare resource utilization (HCRU) and costs associated with drug treatments, outpatient specialist services (OSS) and hospital admissions among patients treated with SZC was conducted. The subset of patients treated with RAASi was analyzed to evaluate costs by presence/absence of RAASi discontinuation.

## RESULTS

**Patient's characteristics:** Total 355 adults prescribed with SZC were included (mean age 70.4 years, 64.2% males). At index date, 23.4% had HF, 43.4% diabetes mellitus, 57.5% hypertension and 69.3% CKD (of which 47.6% on dialysis). Most SZC patients (83.1%) were treated short-term (≤90 days) while the remaining 16.9% were treated long-term (>90 days). Multivariate regression showed that dialysis predicted short-term treatment (data not shown).

**Demographics and clinical characteristics of patients prescribed with SZC:**



### Costs of overall SZC-treated patients (N=355)

As shown in **Fig. 1**, during the first 6 months of follow-up, the total mean healthcare cost per SZC patient was €7,943 for short-term treated patients and €6,647 for long-term treated patients.

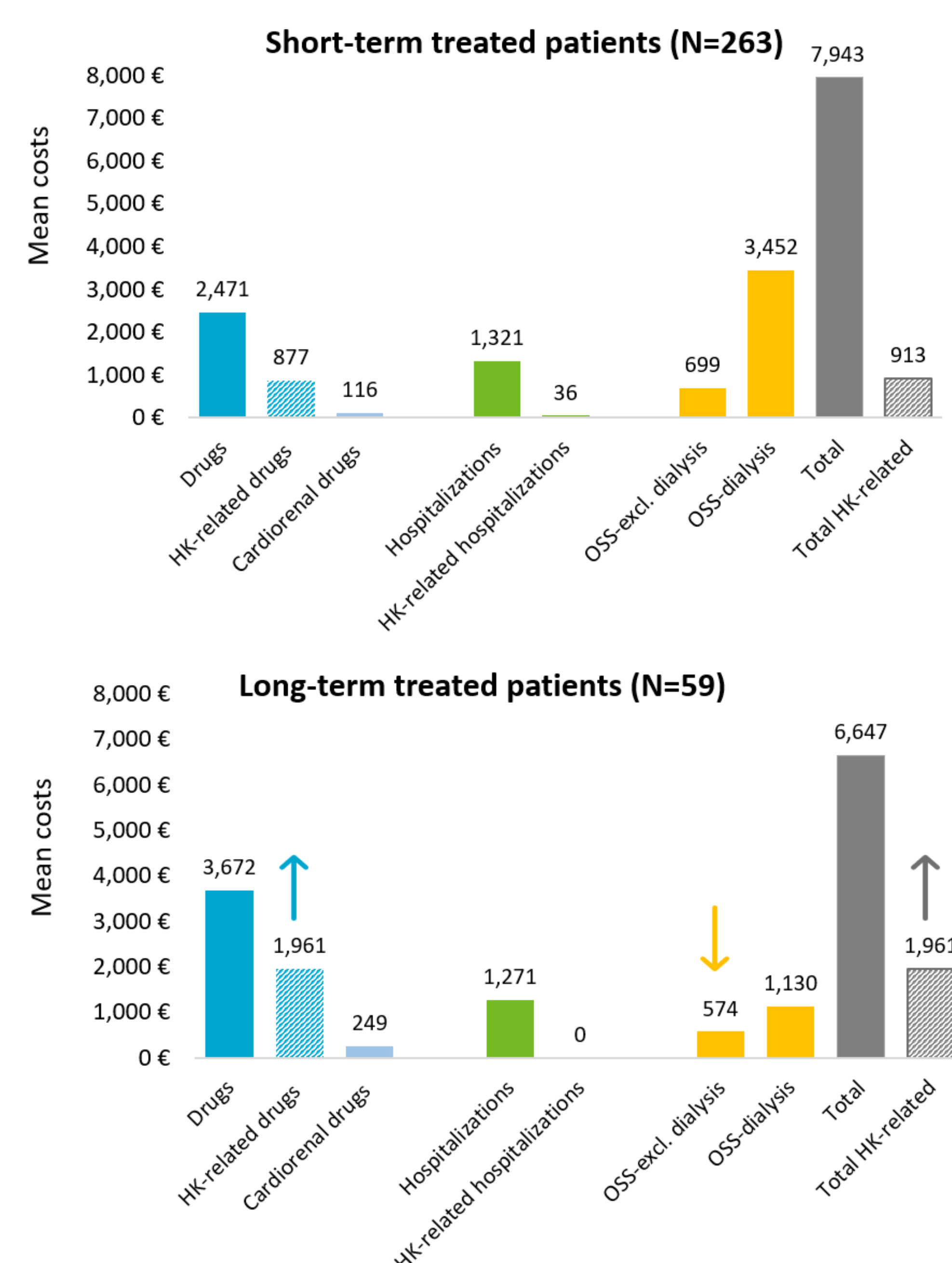


Fig. 1. Healthcare costs per patient/year short-term and long-term treated patients, total and by cost item.

### Subanalysis of SZC-treated patients with RAASi prescriptions at baseline or during follow-up (N=256)

The subanalysis on patients with RAASi at baseline or during follow-up showed that RAASi discontinuation was less prevalent in patients treated with SZC long-term than short-term (41.2% vs 56.6%, data not shown).

The mean cost was €6,908 for those who discontinued RAASi and €5,882 for those who did not (**Fig. 2**).

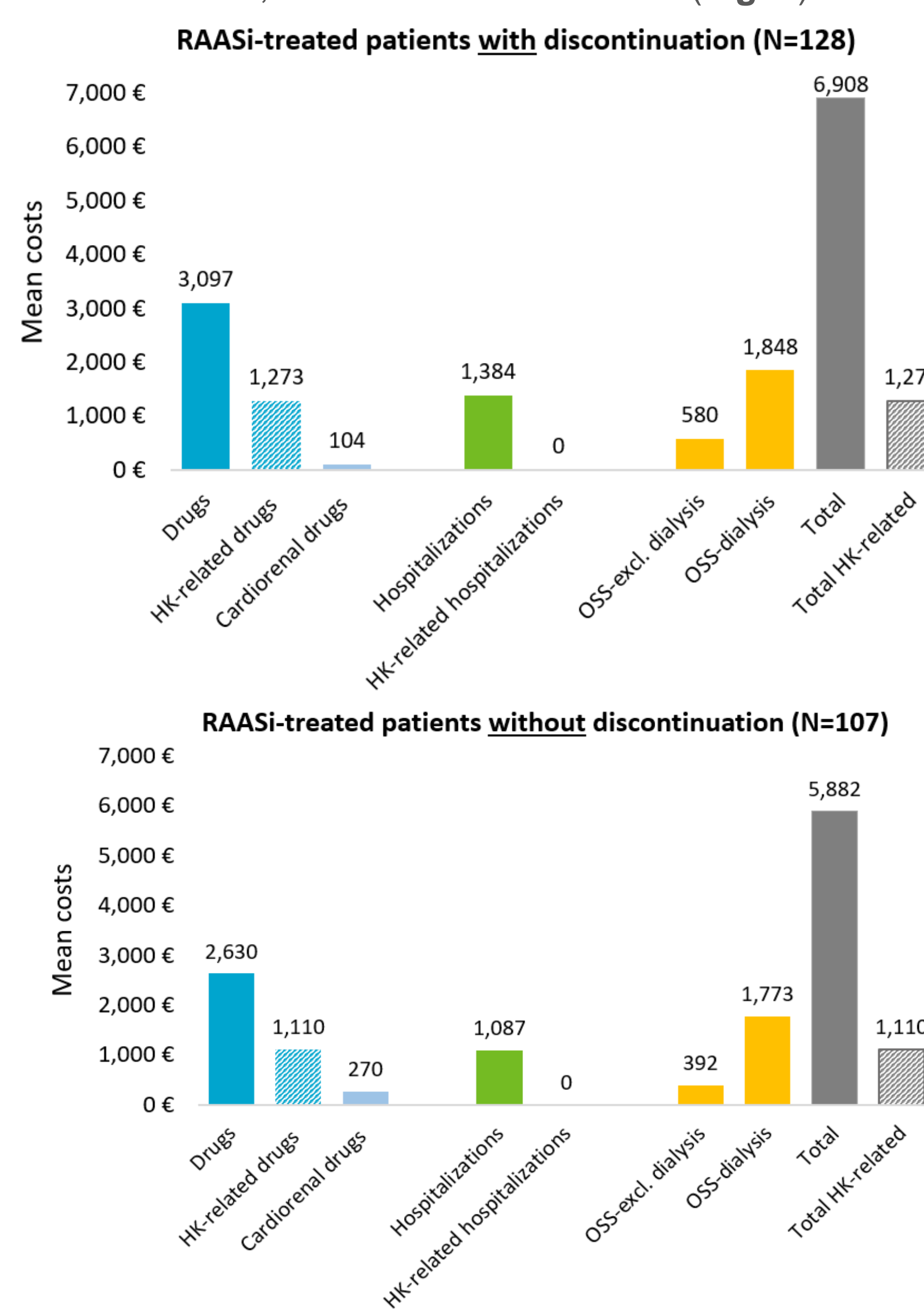


Fig. 2. Healthcare costs per patient/year by RAASi discontinuation.

## CONCLUSIONS

This study provided insights into the Italian real-world use of SZC, revealing that:

- the largest majority of the patients (83%) received a short-term treatment with SZC and only 17% of patients were treated for ≥90 days;
- patients with hyperkalemia undergoing long-term treatment with SZC were less likely to interrupt therapy;
- lastly, patients on long-term treatment with SZC appeared to experience significant clinical benefits from RAASi therapy, which, in turn, results to be associated with a reduction in the economic burden related to hospitalizations and outpatient services.

## REFERENCES

1. Dunn JD, et al. The burden of hyperkalemia in patients with cardiovascular and renal disease. Am J Manag Care. 2015;21:s307-s315.
2. Karaboyas A, et al. Hyperkalemia excursions are associated with an increased risk of mortality and hospitalizations in hemodialysis patients. Clin Kidney J. 2021;14:1760-1769
3. Agiro A, et al. Real-World Modifications of Renin-Angiotensin-Aldosterone System Inhibitors in Patients with Hyperkalemia Initiating Sodium Zirconium Cyclosilicate Therapy: The OPTIMIZE I Study. Adv Ther. 2023;40(6):2886-2901.
4. Agenzia Italiana del Farmaco (AIFA) - Determina 30 agosto 2021: Riclassificazione del medicinale per uso umano «Lokelma». Available at: <https://www.gazzettaufficiale.it/eli/id/2021/09/09/21A05289/sg>

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