

What is the status of generic and biosimilar orphan drugs in Spain in 2024?

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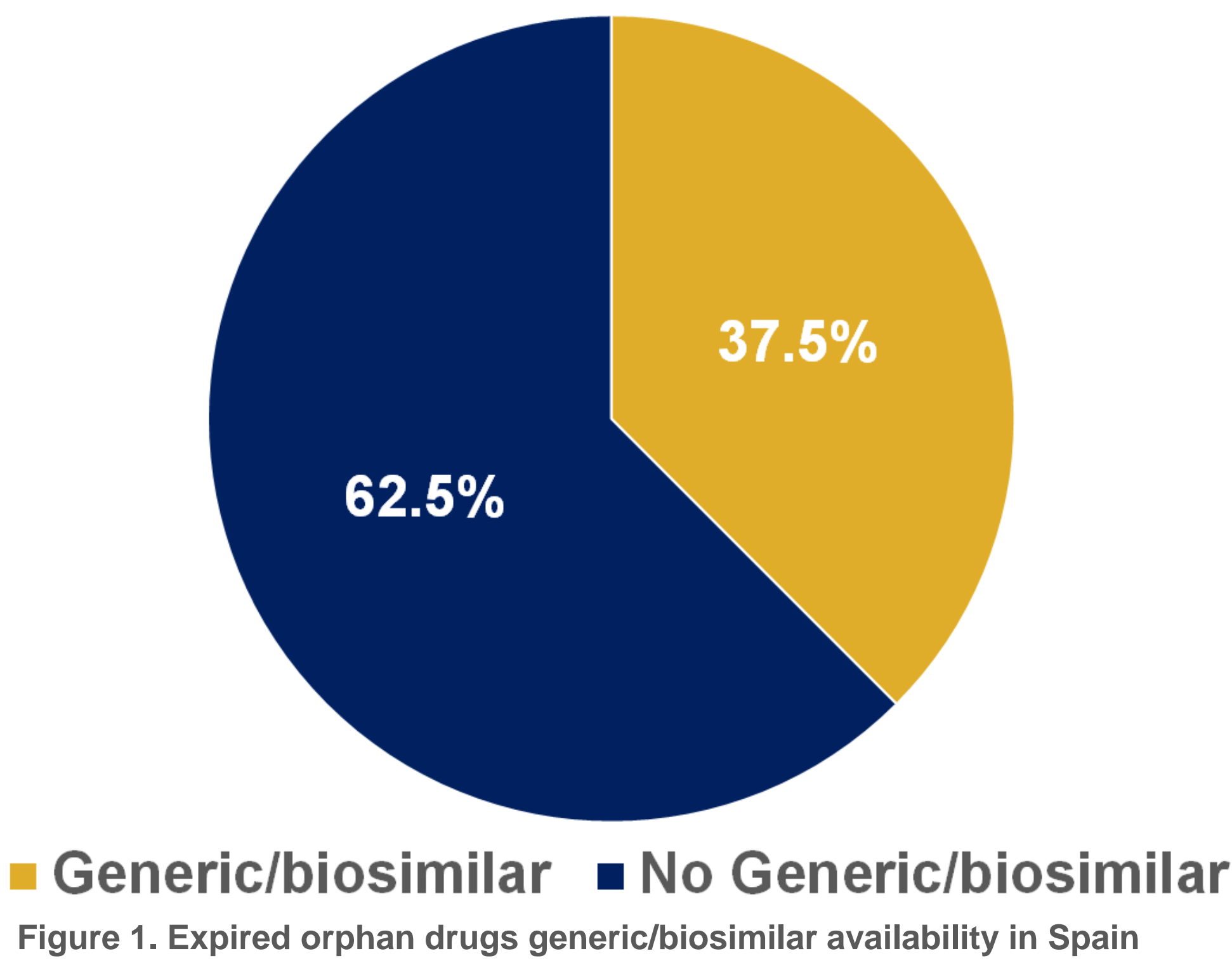
Objectives

The aim of this study was to investigate the availability of generic drugs in Spain for medications that initially had at least one orphan designation.

Methodology

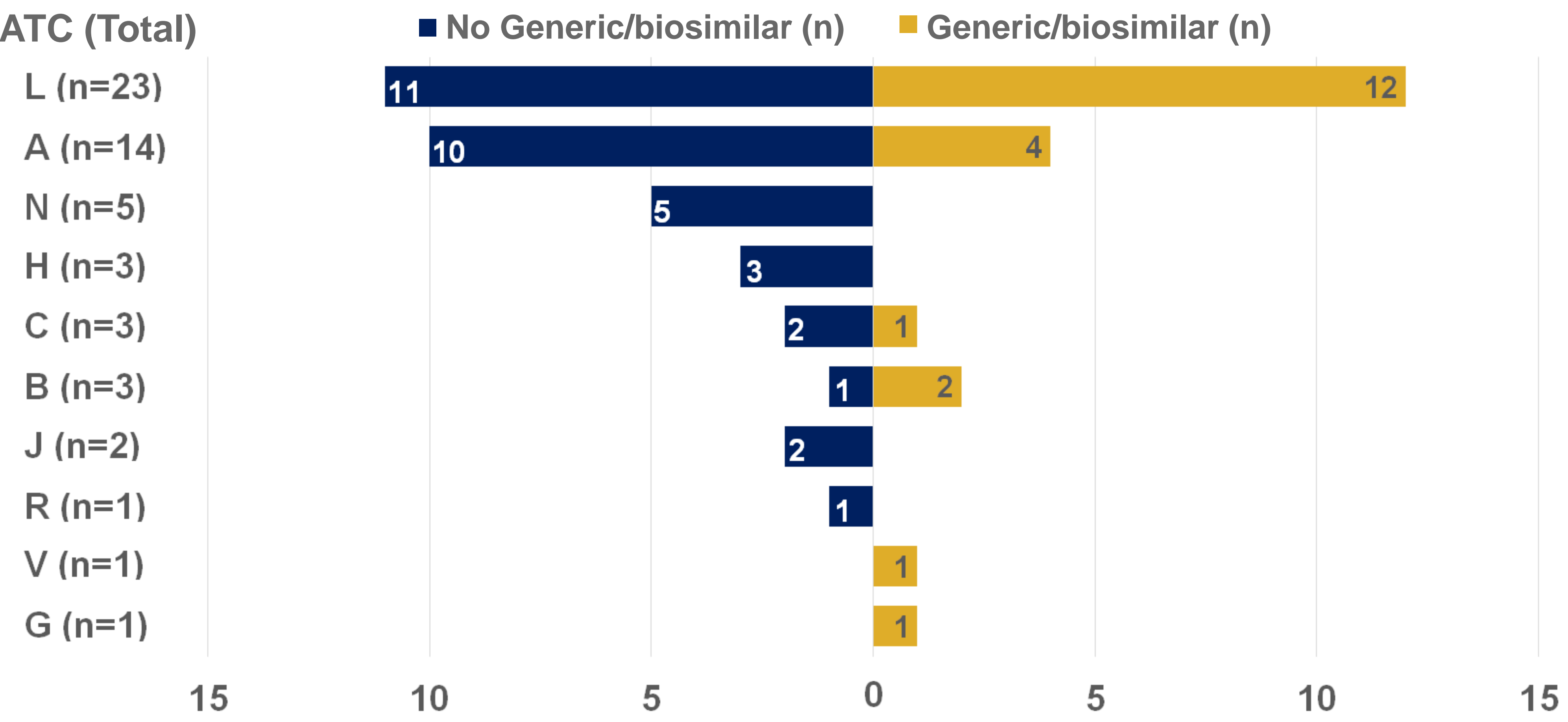
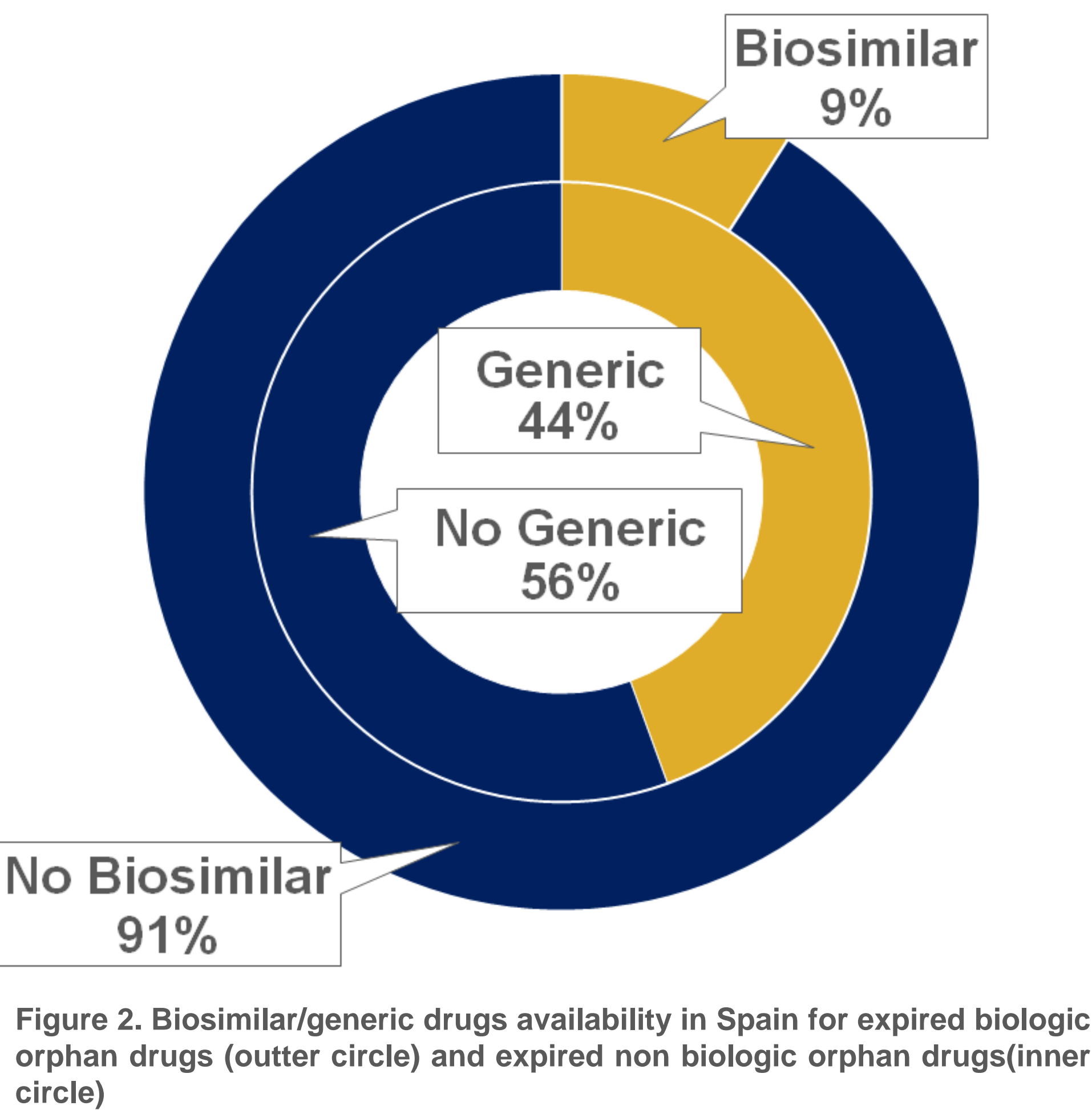
A systematic review was performed focusing on drugs with at least one expired orphan designation by EMA, that are available within the Spanish Health System, until June 2024. Also, the included drugs did complete the market protection granted by the EMA due to the orphan designation, as early withdrawal could introduce bias to the analysis The study analysed information from various sources including CIMA¹, BIFIMED², the Community Register of Orphan Medicinal Products for Human Use³, and drug Summary Product Characteristics⁴. A descriptive analysis based on availability of generic/biosimilar drug was performed and subgroup analysis of biologic drugs and Anatomical Therapeutic Chemical (ATC) groups were conducted.

Results



The study found that out of the total 56 drugs analysed, only 21 (37.5%) have generic/biosimilar versions available (figure 1). Notably, only 1 of the 11 (9%) biologic drugs have biosimilars available. In contrast, among the 45 non-biologic drugs, 20 (44%) have generics (figure 2).

In terms of ATC codes, Group L, which includes antineoplastic and immunomodulating agents, comprised half of the studied drugs, with 52% of them having generic/biosimilar alternatives. This group also accounts for more than half of the generics (12 out of 21). Other ATC groups with available generics include Group A (4 generics), Group B (2 generics) and Groups C and G with 1 generic each (figure 3).



ATC codes: A, ALIMENTARY TRACT AND METABOLISM; B, BLOOD AND BLOOD FORMING ORGANS; C, CARDIOVASCULAR SYSTEM; G, GENITO URINARY SYSTEM AND SEX HORMONES; H, SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS; J, ANTIINFECTIVES FOR SYSTEMIC USE; L, ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS; N, NERVOUS SYSTEM; R, RESPIRATORY SYSTEM; V, VARIOUS.

Figure 3. Biosimilar/generic orphan drugs availability in Spain by ATC codes.

Conclusions

The study reveals a low availability of generic drugs and biosimilars for orphan medications in Spain. It highlights the need to study the prices evolution for these drugs to determine if, despite the low availability of generic alternatives, prices are decreasing over time. Such a trend could facilitate the adoption of new orphan drugs without significantly increasing the overall cost for the System.