EXPLORING HETEROGENEITY IN BIOSIMILARS DYNAMICS IN ITALY: RESULTS FROM THREE CHRONIC THERAPEUTIC AREAS

HPR17

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Introduction

Biosimilars are a fundamental player in ensuring sustainability of healthcare systems, providing a cost-effective alternative to branded biologics in the treatment of chronic systemic conditions. In recent years, the number of EMA-approved biosimilars has grown significantly and by 2022 a total of 18 originator products are experiencing direct competition after losing marketing exclusivity.[1] However, penetration of biosimilars may differ across therapeutic areas, under the influence of external factors like number of competitors, years of availability on the market, prescribers' attitude towards biosimilar products, and specific local policies.[2] Therefore, the introduction of biosimilars in clinical practice and the resulting direct competition with originator molecules may lead to different outcomes, potentially impacting other patent-protected molecules in the same class and therapeutic area. The objective of this study is to explore the impact of biosimilars' adoption in Italy, across three therapeutic areas, and its consequences on expenditure and potential savings for the NHS.

Methods

7 originators and 18 biosimilar products available in Italy were selected across three therapeutic areas and molecules' classes (14 TNF inhibitors or TNFi; 5 low molecular weight heparins or LMWH; 6 insulins). The analysis was extended to include branded molecules in the same therapeutic area still covered by patent to assess potential spill-over effects of competition between originators and biosimilars. Consumption data were extracted from IQVIA's proprietary database that collects Italian sales data across retail and hospital distribution channels. The analyses were conducted on year-to-year data from 2018 to 2022 regardless of originators' loss of exclusivity and market entry of biosimilars dates to standardize results across therapeutic areas. Sales volumes of in-scope molecules are expressed as total number of days of therapy estimated considering volumes sold (Days of Therapy, DoT), while net expenditure derives from IQVIA's Weighted Average Price, indicating net costs sustained by the NHS considering negotiated and tender discounts applied to Ex-Factory Prices. Penetration of biosimilars is defined as the share of biosimilar on the total molecule while market shares are defined as percentage of molecule over total market (including biosimilars, originators and other branded molecules within the therapeutic area). Reductions or increases over the considered timeframe are evaluated using Compound Annual Growth Rate (CAGR).

Results

TNF inhibitors

Penetration of TNFi biosimilars (n=11) was among the highest across selected therapeutic areas, with market shares in 2022 reaching 82% of total DoTs sold for adalimumab, 77% for etanercept and 95% for infliximab *(Figure 1A)*. Considering net expenditure, direct competition of biosimilars generated a maximum reduction of 29% for the NHS (adalimumab) and a minimum of 21% (etanercept) *(Figure 1B)*. The availability of biosimilars marginally affected adoption of patent-protected TNFis that only slightly decreased their market shares between 2018 and 2022 *(Figure 1C)*. However, market dynamics of the whole therapeutic area - including all patent-protected biologic products with at least one overlapping indication with originator molecules - indicate that despite a market growth of 11% in DoTs sold since 2018, biosimilars' adoption contributed to reducing net costs by 2%, liberating resources for innovative molecules *(Figure 1D)*.

Low molecular weight heparins

Since 2018, enoxaparin sodium biosimilars (n=4) consistently eroded originator's market shares and accounted for 77% of DoTs sold in 2022 *(Figure 2A)*. However, no contribution to net costs reduction was observed in the considered timeframe, as total expenditure increased from 147 M€ to 179 M€ *(Figure 2B)*. The analysis of the whole therapeutic area showed that shares of patent-protected low molecular weight heparins (LMWH) decreased from 19% in 2018 to 7% in 2022 following the introduction of biosimilars, with only a 1% reduction of total market volumes *(Figure 2C)*. However, no net costs reduction was observed in the considered timeframe, as expenditure remained constant *(Figure 2D)*.

Insulins

The lowest penetration was observed in the insulin class, where only one biosimilar is available for each originator molecule. Insulin aspart's biosimilar reached 1% of total DoTs in 2022, while adoption rate of insulin glargine did not exceed 15% of total DoTs and remained consistent in the considered timeframe. Insulin lispro's biosimilar, on the contrary, gained market shares, moving from 2% to 9% of total DoTs and net expenditure in 2022 *(Figure 3A-3B)*. The low adoption rate of biosimilar insulins could be attributable to distribution in the retail channel, with no competition induced by tendering procedures. Moreover, it is possible to observe an expenditure and consumption reduction in 2022 for the whole insulins' market with greater incidence of branded insulin (from 19% to 31% of total expenditure), with no appreciable variation related to biosimilars adoption *(Figure 3C-3D)*.

Conclusions

The analysis showed high variability in biosimilars' dynamics across selected therapeutic areas in Italy. High adoption rate and subsequent intra-molecule competition does not seem to consistently lead to a reduction of expenditure. Results indicate that the availability of multiple biosimilars on the market might positively influence their penetration, potentially resulting in a spill-over effect and a more efficient allocation of resources in the same therapeutic area, as observed for the TNFi class. However, further research is needed to extend the analysis and gather insights on peculiarities of each therapeutic area that hinder effective biosimilar uptake. In conclusion, with various biologic products expected to face patent expiry, there are still opportunities to enhance patients' access to biosimilars and to guarantee sustainability of NHS budgets.

Figure 1. ***TNFi class***

A) Biosimilar and originators penetration (DoT); B) Biosimilars and originators penetration (net expenditure €); C) Therapeutic area market shares (DoT); D) Therapeutic area market shares (net expenditure €)

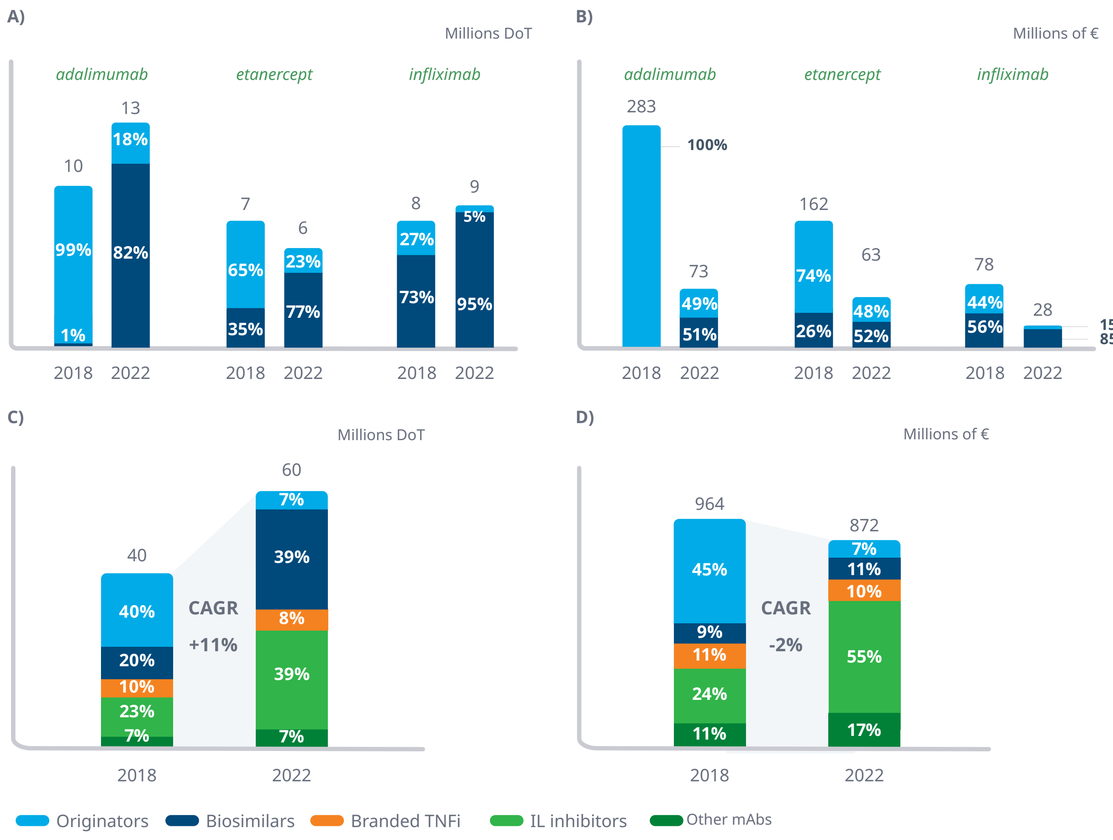


Figure 2. ***LMWH class***

A) Biosimilar and originators penetration (DoT); B) Biosimilars and originators penetration (net expenditure €); C) Therapeutic area market shares (DoT); D) Therapeutic area market shares (net expenditure €)

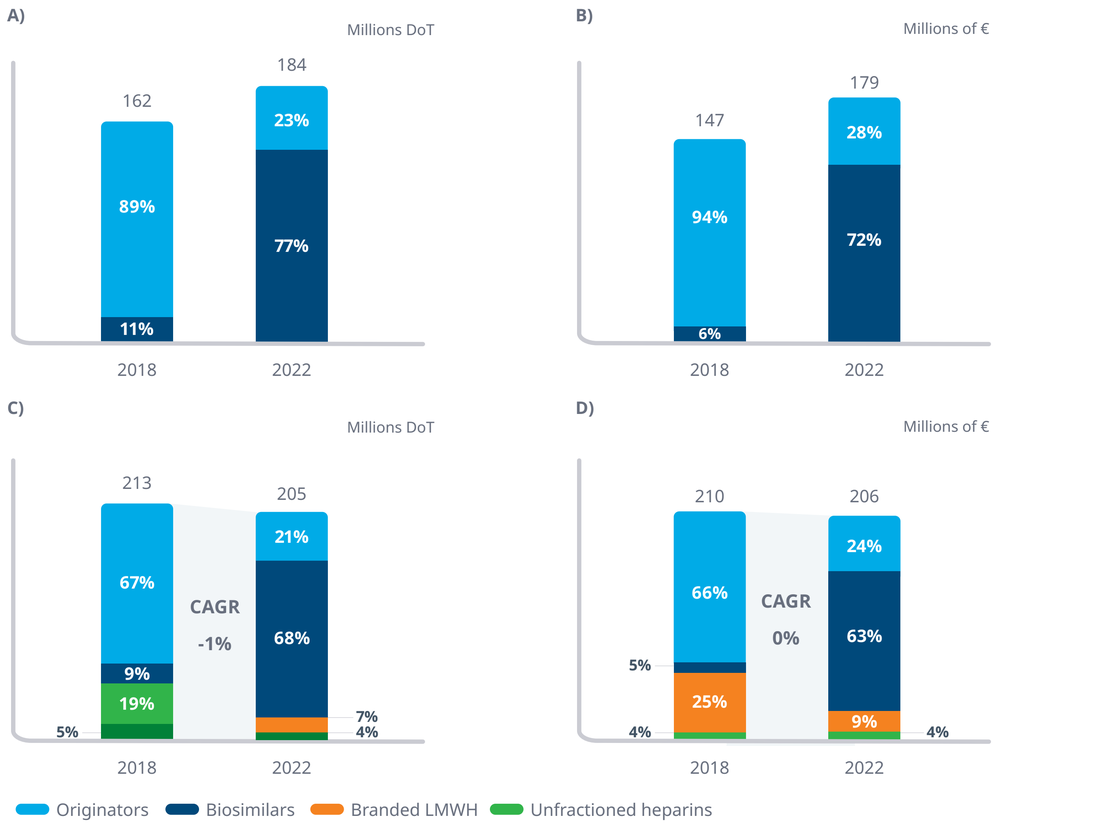
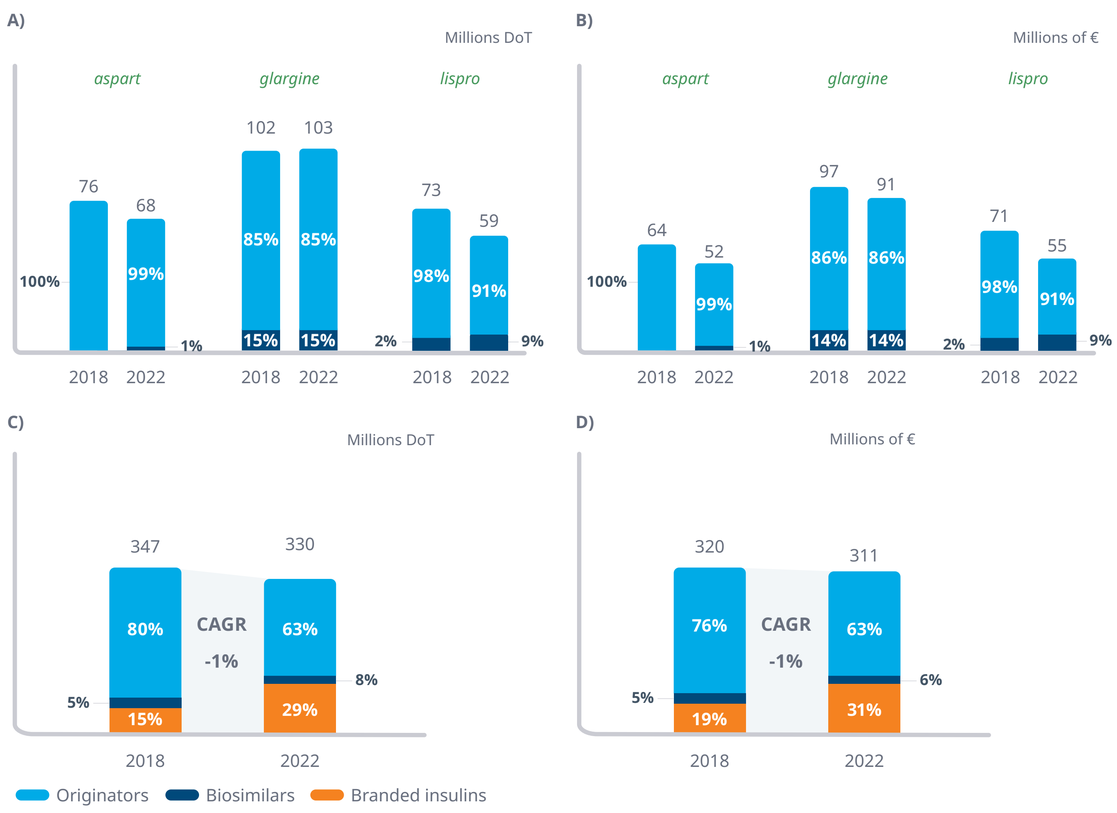


Figure 3. ***Insulin class***

A) Biosimilar and originators penetration (DoT); B) Biosimilars and originators penetration (net expenditure €); C) Therapeutic area market shares (DoT); D) Therapeutic area market shares (net expenditure €)



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