Economic impact of biosimilars in Spain (2020-2023): a retrospective analysis and lessons learned

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INTRODUCTION

- Consumption of biological medicines has significantly grown in the latest years, causing sharp increases in healthcare spending¹.
- The use of biosimilars, which are usually priced lower than their respective originals, contributes to the rationalisation and optimisation of pharmaceutical expenditure.
- The aim of this analysis was to retrospectively quantify the savings generated by the use of biosimilars in the Spanish National Health System (NHS) between 2020-2023. Additionally, these results were compared and contextualised with a previous published analysis².

METHODS

A budget impact model was developed to compare a hypothetical scenario without biosimilars (where biological medicines retain their original prices) against the current scenario, where **Figure 3.** Biosimilar market uptake in active substances dispensed at retail pharmacy (left) and hospital pharmacy (right) [2009-2019 data sourced from retrospective results of previous published analysis²].



biosimilars have entered the market and prices have decreased due to competition (Fig. 1).

Figure 1. Budget impact analysis structure and variables of the compared scenarios.



- The analysis was performed from a Spanish payer perspective (NHS) for the period 2020-2023.
- Medicines included were those with a commercialised biosimilar in 2020-2023: insulin, enoxaparin, epoetins, folitropin, somatropin, teriparatide, rituximab, trastuzumab, bevacizumab, filgrastim, pegfilgrastim, eculizumab, etanercept, infliximab, adalimumab and ranibizumab.

Consumption inputs

- Real-world consumption data (units) were obtained from official sources (Spanish Ministry of Health) for original and biosimilars of each active substance and analysed in terms of overall growth and biosimilar market uptake.
- Following methodology used in the previous published analysis, consumption for each active $^{-2}$

---Etanercept ---Infliximab ---Adalimumab ---Ranibizumab

- The use of biosimilar medicines has generated savings up to €5,789 million between 2020 and 2023, with yearly savings increasing throughout the period (Fig. 4).
- More than half of savings were generated by biosimilars of three active substances: adalimumab, infliximab and rituximab (Fig. 5).

Figure 4. Budget impact analysis results and scenario differences (€M).



substance was calculated in terms of defined daily dose (DDD)^{2,3}.

Price inputs

- In the scenario without biosimilars, prices of original medicines during their exclusivity period were assumed to be maintained over time.
- In the scenario with biosimilars, to estimate the actual purchase price of original and biosimilar medicines, all deductions and price changes occurring during the medicine lifecycle for the analysed period were included (Fig. 2).

INITIAL PRICING REFERENCE PRICE SYSTEM PUBLIC PROCUREMENT Interministerial Commission Regional Health Services, Ministry of Health hospitals, hospital groups, etc. for Drug Pricing Price variations Original price *Reference Price Order*⁵ Biosimilar price ----deductions required by law apply to Original price = Biosimilar price ----Tender price originals and biosimilars⁴ Manufacturers' bids **Ex-factory price Purchase price** (Hospital level) **Reference price**

In Spain, most biological medicines are dispensed at hospital pharmacies (12 of 16 included in our model) and purchased at regional or hospital level through public tenders in which drug

2020	2021	2022	2023
Scenario without biosimilars		Budget impact (difference	e between scenarios)
Scenario with biosimilars: orig	inator spending	Scenario with biosimilars:	biosimilar spending

Figure 5. Aggregated savings (2020-2023) generated by biosimilars of each active substance (€M) and share of total savings (%).



CONCLUSIONS

The use of biosimilars generated savings of €5,789M between 2020 and

Figure 2. Price regulation of biological medicines in Spain.

manufacturers offer commercial discounts. Biosimilars dispensed at retail pharmacies have a

fixed ex-factory or reference price and are not subject to further discounts.

RESULTS

- Most active substances consumption grew during the analysed period, with exceptions traceable to clinical or commercial reasons.
- Biosimilars' market uptake grew significantly during the period, reaching values over 75% in half of active substances included (Fig. 3).
- Price analysis revealed significant reductions in price after biosimilar ex-factory price and reference price reductions, reaching more than 50% combined in some cases.
- Commercial discount analysis showed that biosimilars often are associated with higher discount rates, reaching discount levels over 70%.

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2023 in the context of the Spanish NHS.

Biosimilars' uptake is increasing more rapidly in recent commercialised biosimilars, **pointing to**

an acceleration of uptake speed favoured by competition in the biologicals market, which also

causes **price reductions** in most active substances.

The results of the current analysis show **higher biosimilar uptake and higher price reductions**

than those estimated in the previous published study for the coincidental period (2020-2022)²,

leading to increased savings.

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Disclosures

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