HPR200

No Demand-Side Policies, No Expenditure Savings

LinkedIn

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1 INTRODUCTION

- The utilization of high-cost biopharmaceuticals, which consistently rank among the top in global pharmaceutical sales, imposes a growing financial burden on health insurance systems.
- To control pharmaceutical expenditure, various demand- and supply-side policies are frequently implemented.

2 OBJECTIVES

- This study aims to examine whether the introduction of biosimilars is associated with decreased prices of originators and, ultimately, total budget-saving, among 12 high-income countries across three continents (Europe, North America, and Asia).
- We also sought to compare and interpret biologics market dynamics within each country's policy context.

3 METHODS

Data Source | **IQVIA-MIDAS® database**

- Quarterly pharmaceutical sales data in hospital and retail sectors
- Sales volume data in Standard unit (SU)*
  *Number of counting units sold divided by standard unit factor
- Sales value data in Local Currency Dollars (LCD)**
  **Local currency sales converted to USD at constant exchange rates

Country Selection

Australia, Austria, Canada, France, Germany, Italy, Japan, Korea, Spain, Sweden, Switzerland, UK

- 12 high-income countries were selected for their economic status and data availability

Molecule Selection

- 4 Molecules with biosimilars introduced in 12 countries
- Belonged to L (Antineoplastic and Immunomodulating Agents) class in the WHO-ATC classification
- Selected specific dosage forms for price index comparison

Etanercept	Infliximab	Rituximab	Trastuzumab
50mg/ml*1ml	100mg	10mg/ml*50ml	150mg (Canada 440mg)

Market Dynamics Analysis

- Calculated prices by dividing sales value by sales volume
- Analyzed price and expenditure trends and their CQGRs
- Set biosimilar market entry point as the reference (0Q)

-4Q — 0Q — Q2 2020

Originator Fisher price index
Relative overall expenditures
→ **CQGRs** (Compound Quarterly Growth Rates)

Comprehensive Policy Review

- Explored key supply- and demand-side policies for biosimilars in 12 countries

Supply-side	Demand-side
Price-linkage / Tendering	Financial incentives / Education
Internal reference pricing	Prescribing guidelines
External reference pricing	Substitution / INN prescribing

4 RESULTS

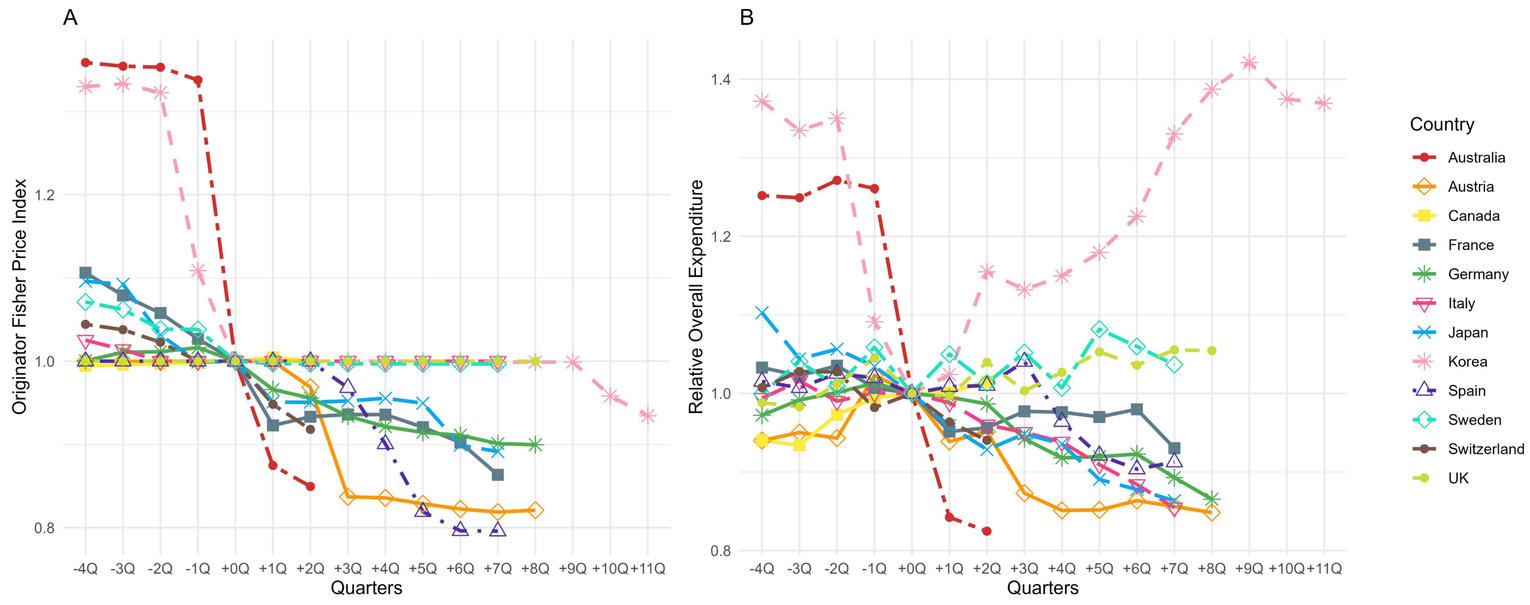

Figure 1. Biologics market dynamics trends for four biologics across 12 countries (from -4Q to Q2 2020). (A) Originator Fisher price index trends before and after the biosimilar introduction (setting the biosimilar entry point as +0Q, +0Q in each country = 1.00, selected dosage form only). (B) Overall expenditure (in relative value) trends before and after the biosimilar introduction (setting the biosimilar entry point as +0Q, +0Q in each country = 1.00).

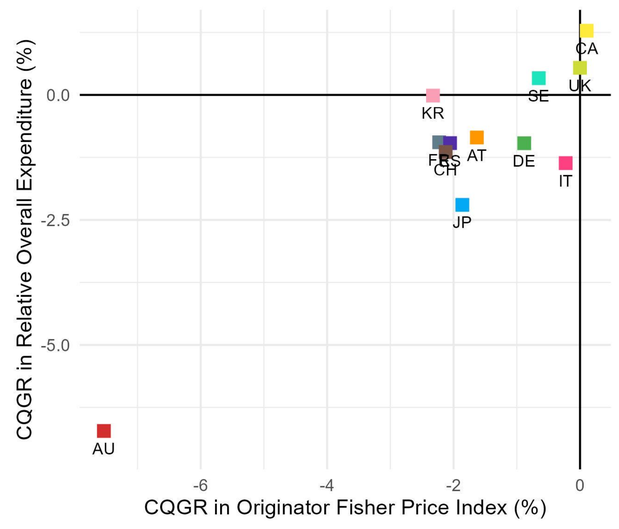

Figure 2. CQGRs in originator Fisher price index and relative overall expenditure trends across 12 countries (selected dosage form only for originator Fisher price index).

- Following biosimilar entry, the originator Fisher price index declined in all countries except Canada and the UK, where it remained stable (**Figure 1**).
- Most countries experienced a gradual decline in relative overall expenditure, but Canada, Sweden, and the UK saw an increase, while Korea showed a notable rebound at the biosimilar entry (**Figure 1**).
- The average CQGR for the originator Fisher price index across 12 countries was -1.78%, varying widely by country, from -7.53% in Australia to 0.11% in Canada (**Figure 2**).
- The average CQGR for relative total expenditure in 12 countries was -1.08%, ranging from -6.72% (Australia) to 1.28% (Canada) (**Figure 2**).
- Australia saw the sharpest declines in both metrics, while Canada and the UK had the highest CQGRs, showing no decrease (**Figure 2**).

- Seven countries with the largest declines in the originator Fisher price index—Australia, Austria, France, Japan, Korea, Spain, and Switzerland—adopted price-link policies, suggesting these contributed to lower originator prices (**Figure 2, Table 1**).
- In most of them, overall expenditures decreased after biosimilar entry, due to demand-side policies like financial incentives (**Figure 2, Table 1**).
- Japan and Korea, which did not adopt effective demand-side measures, displayed different results from each other.
- In Japan, strict price regulation, shown by the lowest price ratio in **Figure S1,** led to direct price cuts and indirect expenditure reductions.
- Conversely, Korea, with less stringent supply-side measures, showed a significant rebound in expenditure, consistent with previous studies (**Figure 1, Table 1**).

Table 1. Key supply- and demand-side policies for biosimilars in 12 countries

		AU	AT	CA	FR	DE	IT	JP	KR	ES	SE	CH	UK
Supply-side Policy	Price-linkage	O	O	X	O	X	O	O	O	O	X	O	X
	Tendering	O	O	X	O	O	O	X	△[a)]	O	O	O	O
	Internal reference pricing	O	O	X	O	△[b)]	X	X	X	O	X	X	X
	External reference pricing	X	X	X	X	X	O	X	X	X	X	X	X
Demand-side Policy	Financial incentives[c)]	O	O	X	O	O	O	△[d)]	X	△[e)]	O	O	O
	Information and education	O	O	O	O	O	O	△[f)]	X	O	O	O	O
	Prescribing guidelines and recommendation	O	O	X	O	O	O	X	X	O	O	O	O
	Biosimilar substitution (pharmacy level)	△[g)]	X	△	X[h)]	△[i)]	X	X	X	X	X	X	X
	International nonproprietary name (INN) prescribing	O	X	X	△[j)]	X	X	X	X	X	X	O	X

NOTES: AU = Australia, AT = Austria, CA = Canada, FR = France, DE = Germany, IT = Italy, JP = Japan, KR = South Korea, ES = Spain, SE = Sweden, CH = Switzerland, UK = United Kingdom, O = Applicable, X = Not applicable, △ = Partially or historically applicable

[a)] Applicable only in public hospitals (6% of total)
[b)] Applicable in a few molecules
[c)] If either an incentive to prescribe or an incentive to dispense was applied, we marked it with an "O"
[d)] Applicable in general hospitals covered by Japan's Diagnostic Procedure Combination (DPC) system. (55% of total)
[e)] Applicable in some regions
[f)] The Ministry of Health Labour and Welfare provides educational resources about biosimilars.
[g)] Biosimilar substitution is allowed when the prescriber does not mark "brand substitution not permitted" on the prescription, and the pharmacists should consult with the patients before substitution.
[h)] A regulatory framework for the introduction of biosimilar substitution was implemented in 2014, but there was no biosimilar substitution in practice, and biosimilar substitution was abolished in the 2020 Social Insurance Law.
[i)] Automatic substitution is allowed for some products from the same manufacturer, but legislation is expected to be implemented in 2022.
[j)] The pharmacist should consult with the prescriber before dispensing.

5 CONCLUSIONS

- In most countries, the biosimilar entry led to a decline in the originator Fisher price index and relative total expenditures.
- The countries with the largest CQGR reductions in the originator Fisher price index adopted price-link policies. Most of them experienced overall expenditure reduction by implementing demand-side strategies that foster biosimilar adoption.
- Biosimilar introduction, when supported by active demand-side along with supply-side policies, achieved greater reductions in originator prices and total expenditures, compared to biosimilar introduction without effective policies.

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