Is the speed of biosimilar penetration related to demand-side polices?

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Introduction

- The introduction of biosimilars for high-priced biologics contributes to a reduction in pharmaceutical expenditures
- The extent of cost-saving impact is directly proportional to the speed of biosimilar penetration in the market, which is influenced by factors like polices

Objective

- This study aims to examine the correlation between market penetration speed and demand-side polices across 8 high-income countries

Methods

✓ Biologics

Infliximab **Rituximab** **Trastuzumab**

- 3 biologics whose biosimilars were launched as early as 2012 and had expanded to all eight study countries by 2018

✓ Countries

France Germany Italy Japan

Korea Spain Sweden UK

✓ Data source

IQVIA™

- Data period from October 2012 to June 2020 (39 quarters)
- Utilized the quarterly sales volume of originators and biosimilars
- Sales data were quantified in standard units (SU)*

*number of standard "dose" units sold

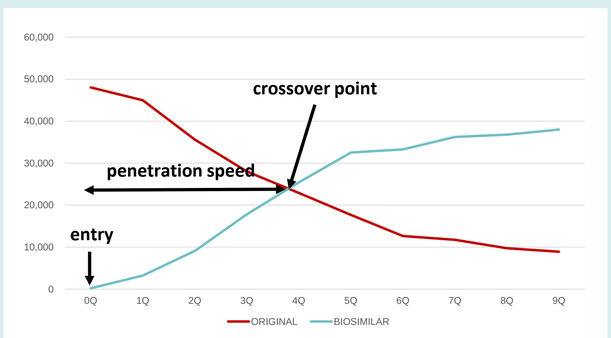
✓ Analysis

- **Observation period**

Equal duration starting from the entry point (0Q) of each biosimilar

Infliximab	21Q
Rituximab	9Q
Trastuzumab	7Q

- **Market penetration speed**



→ Correlation between biosimilar penetration speed and demand-side policies was analyzed by assessing the implementation of five policies

Results

Table. 1 Time (in quarters) to reach the crossover point and the number of biosimilars surpassing originators' sales

	Countries	N[a]	Time to reach the crossover point (crossover quarter[b])			
			Average	Infliximab	Rituximab	Trastuzumab
High	United Kingdom	3	4	6 (Q3 2016)	3 (Q1 2018)	3 (Q1 2019)
	Sweden		4.67	8 (Q1 2017)	4 (Q1 2019)	2 (Q1 2019)
	Italy		5	8 (Q1 2017)	4 (Q3 2018)	3 (Q2 2019)
Middle	France	3	6	13 (Q2 2018)	3 (Q3 2018)	2 (Q1 2019)
	Spain		8.33	13 (Q2 2018)	7 (Q2 2019)	5 (Q4 2019)
Low	Germany	0-1	7	1 (Q2 2015)	X (12Q)[c]	X (8Q)[c]
	Japan		34.67	X (84Q)[c]	6 (Q3 2019)	X (14Q)[c]
	Korea		41	X (81Q)[c]	X (21Q)[c]	X (21Q)[c]

[a]Number of biosimilars with market sales volume exceeding those of corresponding originators
[b]The time to reach crossover (in quarters) is the point at which the biosimilar sales volume surpasses that of the originator after market entry, with the actual quarter indicated in parentheses
[c]linear regression analysis was used to estimate the expected time at which the biosimilar and originator sales volumes would intersect

- Countries were classified into 3 groups based on the biologics that achieved market crossover **(Table 1)**
- High, Middle: Group with all 3-biologics crossed / Low: 0-1 biologics crossed **(Table 1)**
- High and Middle groups were separated based on the median of the time taken to reach the crossover point (5Q) **(Table 1)**
- The fastest country to reach crossover point was the UK (4Q), while the slowest country was South Korea (41Q) **(Table 1, Figure 1)**
- In Germany, classified as a low group, the average time to reach the crossover point was only 7Q due to active demand-side policies **(Table 1, 2)**

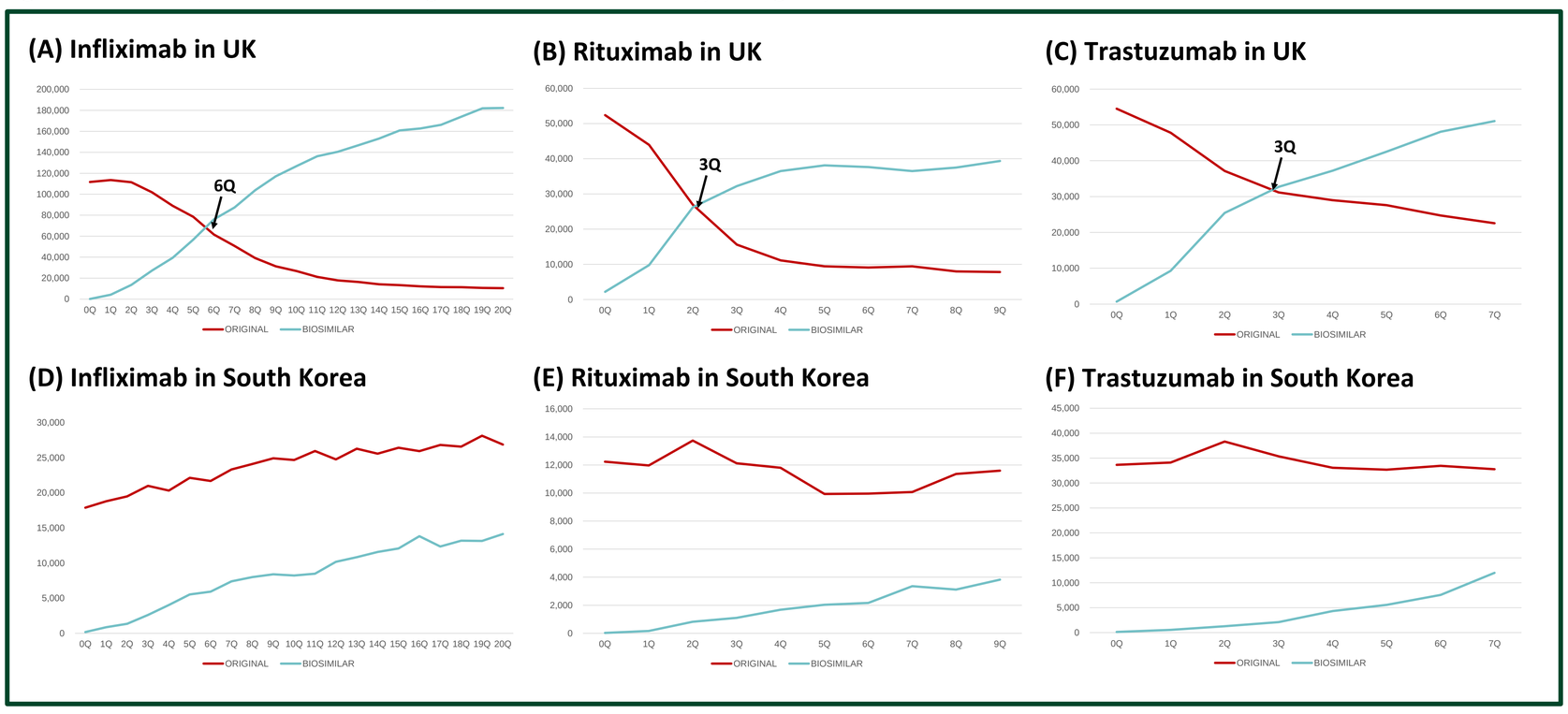
- High group (Italy, Sweden, and the UK) had four or more high-implementation demand-side policies aimed at promoting biosimilars **(Table 1, 2)**
- Middle group (France and Spain) had only two or fewer such policies **(Table 1, 2)**
- Low group consisted of countries where only zero or one biologic achieved market crossover **(Table 1, 2)**
- It included Germany, Japan, and Korea, with Korea having implemented no demand-side policies related to biosimilars **(Table 1, 2)**

Table. 2 Levels of policy implementation by country

	Demand-side polices				
	Financial Incentives	Prescribing guidelines	Prescription budget	Prescription quota	Information and education
Sweden	O	O	O	O	O
Italy	O	O	O	O	O
UK	O	O	O	X	O
Germany	O	O	Δ	Δ	O
France	O	O	X	Δ	O
Spain	Δ	O	Δ	Δ	O
Japan	O	X	X	X	Δ
Korea	X	X	X	X	X

Implementation Levels: O = High implementation (applied to all biosimilars and clearly defined policies), Δ = Moderate implementation (partially applied or indirectly implemented policies), X = Low implementation (policies not specified or stated as not implemented).

Figure. 1 Quarterly sales volumes of originators and biosimilars by biologics after the introduction of biosimilars in South Korea and the UK



Conclusions

- The countries where biosimilars have penetrated dominantly tend to have actively implemented demand-side policies.
- Conversely, countries with slower biosimilar market penetration tend to show the opposite trend.
- This underscores the importance of demand-side policies in enhancing biosimilar penetration speed.
- To further utilize biosimilars, it is important to implement demand-side polices effectively.

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