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Does Short-Term Gain Lead to Longer Term Pain? The Case for Developing a Sustainable Biosimilar Marketplace

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Introduction/objective

- Biosimilars offer the potential for an estimated €11 to €33 billion of savings across the EU.[1]
- To facilitate biosimilar uptake, several mechanisms aimed at reducing the acquisition cost of biosimilars and encouraging biosimilar uptake have been implemented.[2] However, the mechanisms used vary across the EU and it is unclear which mechanisms contribute towards a sustainable biosimilar marketplace.
- This study presents a comparison of mechanisms implemented for biosimilars across five European markets and identifies initiatives that allow for a sustainable biosimilar practice.

Methods

- We collected publicly available information from regional and national authority websites combined with stakeholder interviews across the EU5 (France, Germany, Italy, Spain and the United Kingdom).
- We identified biosimilar policy mechanisms pertaining to key criteria including pricing and volume measures for each market. Each measure was catalogued as either positive, neutral or negative towards biosimilar sustainability.
- The similarities and differences across the EU5 were then determined to identify which mechanisms contribute towards a sustainable biosimilar marketplace.

Results

- All EU5 countries have biosimilar price reduction measures in place, either through:
  - Mandatory price discounts (France, Italy or Spain) and/or
  - National or regional tenders (all EU5 countries)
- All EU5 countries have biosimilar prescription targets in place, although with differing levels of enforcement. All EU5 markets have gainshare mechanisms in place. None of the EU5 countries have pharmacist incentives in place, with four countries having some form of physician incentives and only two countries (Germany and Spain) having patient incentives in place to encourage switching to biosimilars.

Table 1. Biosimilar pricing mechanisms

Pricing mechanisms		EU5 countries				
Pricing	Reimbursement process	No AMNOG	Same[a]	Same[a]	Same[a]	No HTA
	Mandatory First Biosimilar	Free pricing	-30%	-20%	-30%[b]	Free pricing
	Mandatory originator discount	None	<20%[c]	None	>20%[d]	None
Tendering	Criteria	Multiple factors	Only price	Only price	Multiple factors	Multiple factors
	Single or multiple winners permitted	Multiple	Multiple	Multiple	Mixed practices	Multiple
	Gain sharing in place	✓	✓[R]	✓	✓	✓

Table 2. Biosimilar volume targets

Decision-driver influence on access	EU5 countries				
Prescription targets	✓ R	✓ R	✓ R	✓	✓
Patient incentives	✓	✓	✗	✗	✗
Biosimilar initiation	Tx-naïve / Existing patients	Tx-naïve / Existing patients	Tx-naïve / Existing patients	Tx-naïve / Existing patients	HCP-led
INN prescription allowed	✗	✗	✗	✗	✗
Automatic substitution allowed	Inter-changeables	No	No	Yes, for treatment naïve	No

Key: Positive mechanism; Neutral mechanism; Negative mechanism; ✓ Present; ✗ Not present

Legend:
[a] compared vs originator; [b]40% for retail/30% for hospital products; [c] Fixed reference price; [d] >20% for retail/30% for hospital products; [R] regional

Tx: treatment; HTA: health technology assessment, AMNOG: Act on the Reform of the Market for Medicinal Products; INN: International Non-proprietary Names

Discussion and conclusions

We identified **four initiatives** that should be considered to **enable a sustainable biosimilar marketplace**:

A. A fair price level avoiding significant mandated discounting for biosimilars or originators.
B. Procurement practices avoiding price-driven, single-winner-based tendering systems.
C. Physician prescription targets to facilitate biosimilar uptake.
D. Biosimilar initiation in both treatment-naïve and continuing patients permitted.

Our results add to a growing body of literature on recognised challenges in the uptake of biosimilars, such as barriers to pricing and acceptance[3,4,5]. These four initiatives have implications relevant to policy-makers for future practice in a sustainable market. Continued efforts are needed to ensure optimisation and equality in uptake of biosimilars across Europe.

References

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