



BIOSIMILAR SCORECARD 2020 GERMANY

CONTRIBUTION OF BIOSIMILARS

MOLECULE	 LEVEL OF COMPETITION	 PRICE EVOLUTION	 VOLUME DEVELOPMENT
	1=Low, 5=High	1=Low, 5=High	1=Low, 5=High
Anti-TNF			5
Adalimumab	5	5	5
Infliximab	5	4	5
Etanercept	5	4	5
Insulin Lispro	4	3	3
Insulin Glargine	2	3	5
Rituximab	5	3	1
Trastuzumab	5	2	1
	<i>Indicator of the amount of competition based on the number of competitors and their respective market shares</i>	<i>Net price reduction from average price of the countries in scope 1 year before first biosimilar entry</i>	<i>Change in biologic volume since biosimilar entry</i>

SUSTAINABILITY SCORECARD

POLICY AREA	SUSTAINABILITY MEASURE	CURRENT COUNTRY STATUS
		1=Low, 5=High
 Regulatory environment and clinical guidelines	Time from EMA approval to first biosimilars sales	5
	Treatment guidelines for biosimilar use	4
	Physician switching policies	5
	No biologic pharmacy substitution	3
 Awareness and education	Comprehensive training /education for patient	4
	Comprehensive training /education for physician	4
 Incentives	Patient incentives to promote biosimilar use	3
	Prescription quotas or financial incentives for providers that do not restrict physician choice	4
 Pricing rules and dynamics	Originator price not subject to mandatory price cuts	5
	Molecule pricing not subject to reference price	1
 Purchasing mechanisms	Length of contracts	5
	Tender timing relative to biosimilar availability	5
	Time from tender award to delivery	5
	Number of winners	5
	Winner decision criteria beyond price	1

Considers only hospital contracts



BIOSIMILAR SCORECARD: GERMANY

POSITIVE POLICY ELEMENTS

1. Germany has succeeded in achieving acceptance of biosimilars with payers, providers and patients as an integral part of appropriate medicine use.
2. There is full reimbursement from day 1 at a price set by the company including immediate patient access to biosimilars.
3. Sick funds are used to achieving savings by open house contracts to achieve the best price for retail drugs.
4. Clinical guidelines adopted to encourage biosimilars to be used as first choice where appropriate.
5. The structure of hospital tendering by multiple buying groups and separate hospital chains allows for competition among several manufacturers to be maintained.

POLICY CHALLENGES

1. Germany is planning for biologic pharmacy substitution from Aug 2022. This may result in exclusive tenders in the future and could negatively impact biosimilar sustainability.
2. There is variability across Germany in the level of biosimilar uptake.
3. Use of fixed reimbursement price groups can lead to downward pressure on pricing which can be destabilizing to competitive markets and discourage manufacturer participation.
4. Reimbursement level for compounded biologics (retail and hospital) is linked to list price level, which provides incentive for the use of less cost-efficient options.

POTENTIAL POLICY SOLUTIONS

1. Ensure that there are clear interchangeability policies in place, not allowing for pharmacy level substitution without physician consent based on their assessment of optimal patient treatment.
2. Consider limiting the use of internal reference pricing especially when it is based on a small share of a market (e.g. less than 20%).
3. Implement measures to ensure that quotas are aligned across all regions.
4. Adapt clinical guidelines to ensure biosimilars are used as first choice.
5. Consider limiting use of “jumbo” reference price groups across multiple INNs when there is insufficient comparative clinical evidence regarding safety and efficacy.

Germany Biosimilar Scorecard prepared June 2020.

All analysis based on 12 months ending Q1 2020. In cases where information is unavailable, scores are left blank.

For information on methodology supporting the scorecard metrics and statements, please see the Appendix document at www.iqvainstitute.org/biosimilarscorecards

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