

BIOSIMILAR SCORECARD 2020 **ITALY**

CONTRIBUTION OF BIOSIMILARS

MOLECULE	LEVEL OF COMPETITION <i>1=Low, 5=High</i>	PRICE EVOLUTION <i>1=Low, 5=High</i>	VOLUME DEVELOPMENT <i>1=Low, 5=High</i>
Anti-TNF			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 1
Adalimumab	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> 4	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 5	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 1
Infliximab	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 5	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 5	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 1
Etanercept	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> 4	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 5	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 1
Insulin Lispro	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 1	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 4	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 1
Insulin Glargine	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> 4	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 2	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 1
Rituximab	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 5	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 5	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 1
Trastuzumab	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 5	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 5	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 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
		<i>1=Low, 5=High</i>
Regulatory environment and clinical guidelines	Time from EMA approval to first biosimilars sales	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> 4
	Treatment guidelines for biosimilar use	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> 4
	Physician switching policies	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 5
	No biologic pharmacy substitution	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 5
Awareness and education	Comprehensive training /education for patient	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 3
	Comprehensive training /education for physician	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 3
Incentives	Patient incentives to promote biosimilar use	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 3
	Prescription quotas or financial incentives for providers that do not restrict physician choice	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 2
Pricing rules and dynamics	Originator price not subject to mandatory price cuts	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 5
	Molecule pricing not subject to reference price	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 5
Purchasing mechanisms	Length of contracts	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 5
	Tender timing relative to biosimilar availability	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 3
	Time from tender award to delivery	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 3
	Number of winners	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 5
	Winner decision criteria beyond price	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 3



BIOSIMILAR SCORECARD: ITALY

POSITIVE POLICY ELEMENTS

1. The central government has a clear position on promoting biosimilars with the intention of achieving savings from biosimilar competition.
2. An efficient tendering process, defined by national law, with a multi-winner tender approach is used when there are more than three biosimilars available.

POLICY CHALLENGES

1. Certain regions have poor uptake of the most cost efficient product and tendering processes result in high levels of complexity.
2. Incentives for investment in future innovation are at risk if savings from biosimilars are not achieved and are offset by “high growth” charges to the industry.

POTENTIAL POLICY SOLUTIONS

1. A national commitment to achieve target uptake levels, and increase recognition by all stakeholders of their shared responsibility to encourage biosimilars would be welcomed. Acknowledgment that the increased usage of biosimilars in Italy would contribute to the long term sustainability of biosimilars, and play a role in the sustainability of the Italian healthcare system.
2. Awarding multiple tender winners across more regions rather than a single winner can result in more manufacturers being willing to bid and therefore intensifying the level of competition in these regions, while promoting long term sustainability.
3. A system to provide consultation to regions with poor uptake of the most cost efficient products, in order to understand the issues and provide advice, could bring improved levels of savings to those regions.
4. Measures to ensure that regions effectively make the three winners available to prescribers should be pursued in order to support prescribers’ freedom, ensure the success of the multi-winner tender framework, and guarantee long-term competition.

Italy 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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