IQVIA INSTITUTE FOR HUMAN DATA SCIENCE

BIOSIMILAR SCORECARD 2020
ROMANIA

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			1
Adalimumab	1	N/A	1
Infliximab	4	N/A	1
Etanercept	1	N/A	1
Insulin Lispro	N/A	N/A	N/A
Insulin Glargine	1	3	5
Rituximab	1	N/A	1
Trastuzumab	1	N/A	1
	Indicator of the amount of competition based on the number of competitors and their respective market shares	*Net price reduction from average price of the countries in scope 1 year before first biosimilar entry*	*Change in biologic volume since biosimilar entry*

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	2
	Treatment guidelines for biosimilar use	3
	Physician switching policies	5
	No biologic pharmacy substitution	5
Awareness and education	Comprehensive training /education for patient	3
	Comprehensive training /education for physician	3
Incentives	Patient incentives to promote biosimilar use	2
	Prescription quotas or financial incentives for providers that do not restrict physician choice	3
Pricing rules and dynamics	Originator price not subject to mandatory price cuts	1
	Molecule pricing not subject to reference price	1
Purchasing mechanisms	Length of contracts	5
	Tender timing relative to biosimilar availability	3
	Time from tender award to delivery	3
	Number of winners	1
	Winner decision criteria beyond price	1

BIOSIMILAR SCORECARD: ROMANIA

POSITIVE POLICY ELEMENTS

1. Romania allows contracts to be re-opened at the time of biosimilar entry, although this has not yet been applied in practice.
2. There is rising awareness about biosimilar medicines.

POLICY CHALLENGES

1. There is no biosimilar quota or guidance in place for prescribers.
2. The reimbursement system allows a premium of 20% for referenced product over the biosimilar price which artificially limits the incentives for payers or physicians to consider switching to the biosimilar.
3. Treatment guidelines do not provide clear guidance to physicians on switching decisions.
4. Patient access to biologics in general is very poor.

POTENTIAL POLICY SOLUTIONS

1. Creating incentives for prescribers to use biosimilars would contribute to their uptake.
2. Making use of the option to re-open tender contracts at the time of biosimilar entry would contribute to faster competition.
3. Removal of the 20% premium for referenced product would provide incentives for biosimilar use.
4. Reengineering the growth agreement with industry to incorporate savings from biosimilars would contribute to their sustainability.
5. Establishing a predictable set of tender rules for reopening tenders at the time of biosimilar entry would encourage greater participation by manufacturers in competitive tenders.
6. Consider expanding or granting earlier access for patients to biologics when clinically justified.

Most biosimilar use is reimbursed via tender procedures, the Sustainability Scorecard scores do not consider retail segment. Other sections of the document include considerations for all the biosimilar segment.

Romania 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.iqviainstitute.org/biosimilarscorecards

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