Value proposition of biosimilars in countries with resource constraints

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Off-patent medicines: objectives of pharmaceutical policies

- *Disinvestment aspect:* Reduce health care expenditure without compromising health outcomes → **sustainability of health care financing**
- *Investment aspect:* Increase population health gain by improved patient access without increasing health expenditure → **health improvement**

Ref: Kaló Z, Holtorf AP, Alfonso-Cristancho R, Shen J, Ágh T, Inotai A, Brixner D. Need for Multicriteria Evaluation of Generic Drug Policies, Value in Health 2015. 18. 346-351.

Opportunity for the investment aspect of biosimilars in Eastern European countries

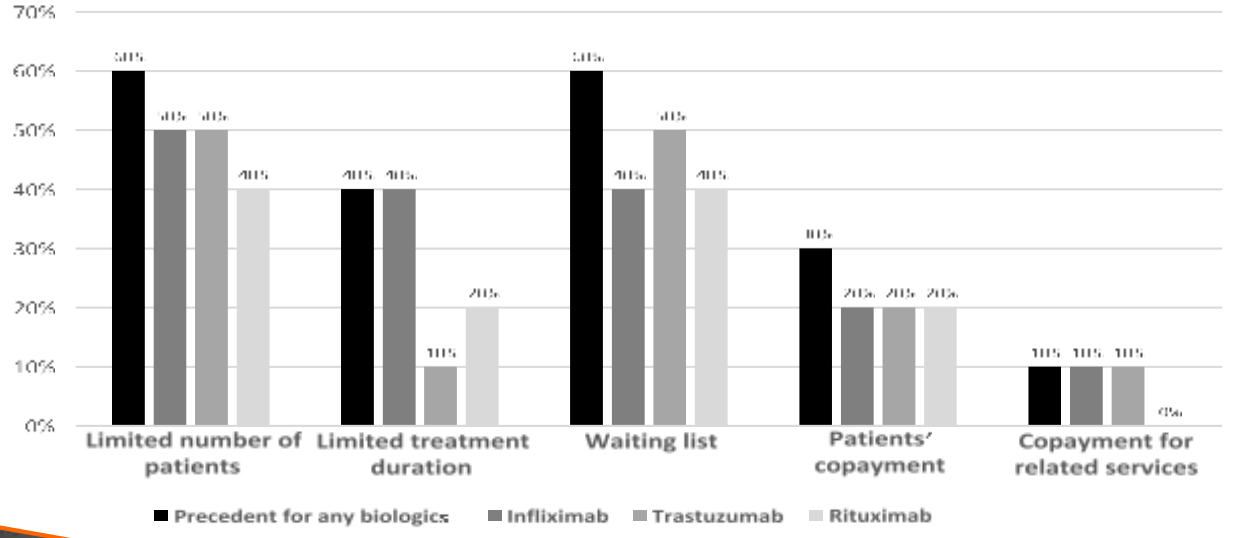
In lower income countries the **accessibility of patients to high cost biological medicines may be limited**, because sustainability of health care financing is facilitated by implementing volume limits, influencing

1. prescribers:
   - **financing protocols** to allow presciptions only for subgroup of patients
   - volume limit for individual prescribers or health care **institutions**
   - **second-line reimbursement** only after the first-line therapy fails
   - **prescription is limited** to selected centers
2. patients:
   - **waiting lists**
   - limited treatment **duration**
   - significant **copayment for** biological **medicines or related services**
   - significant **travel time and costs** to prescribing centers
3. manufacturers:
   - **delayed reimbursement**
   - **price-volume agreement**

Biosimilars at lower price can improve patient access

Ref: Inotai A et al. BioMed Research International. 2018. 9597362. 9.

Evidence from access restrictions related to biologics in 10 CEE countries

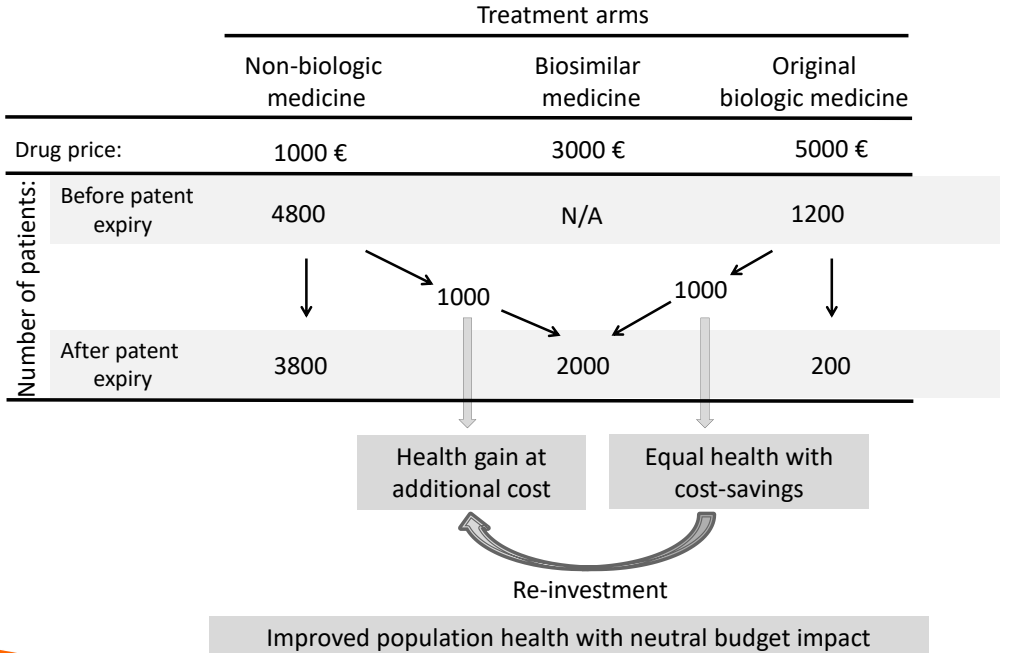


Ref: Inotai A et al. BioMed Research International. 2018. 9597362. 9.

Value proposition of biosimilar medicines

	Originator is reimbursed without access limits to patients	Originator is reimbursed with access limits to patients	Originator is not reimbursed
Value proposition	• savings in drug budget	• no increase in drug budget • improved patient access • health gain	• potential increase in drug budget • health gain
Decision context	Disinvestment	Re-investment of savings	Investment

Ref: Inotai A, Csanádi M, Vitezic D, Francetic I, Tesar T, Bochenek T, Lorenzovici L, Dylst P, Kaló Z. Policy Practices to Maximise Social Benefit from Biosimilars. Journal of Bioequivalence & Bioavailability. 2017. 9. 467-472.



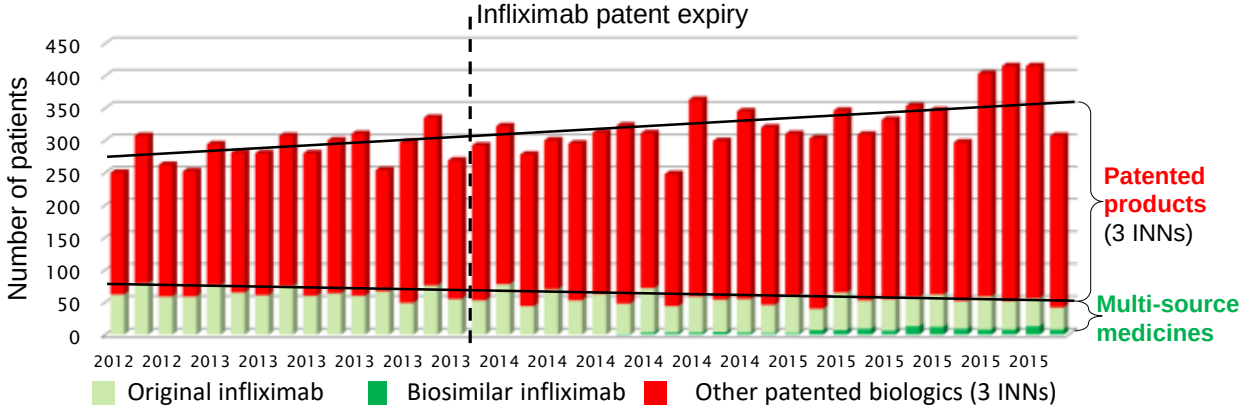
Ref: Inotai A, Csanádi M, Vitezic D, Francetic I, Tesar T, Bochenek T, Lorenzovici L, Dylst P, Kaló Z. Policy Practices to Maximise Social Benefit from Biosimilars. Journal of Bioequivalence & Bioavailability. 2017. 9. 467-472.

Investment to health: Does it happen in lower income countries?

Not really, because ….

- … <u>for treatment naive patients</u> **physicians prefer** prescribing **therapies with no biosimilar alternative**
  - due to hypothetical concerns related to **indication extrapolation**
  - to avoid **risk of (being forced to) switching** patients to biosimilars
  - as biosimilars and other patented biologicals are in the **same treatment line** in financing protocols (i.e. first line therapy)
- … <u>in maintenance therapy</u> physicians prefer continuing the original therapy due to **hypothetical risks of immunogeneicity related to switching** to biosimilars

Suboptimal biosimilar medicines policy in access-restricted environment



Success of biosimilar medicines policies	Fulfilled?
Share of biosimilars is significant?	no
Share of multi-source biologics is increasing?	no
Share of still patented biologics is decreasing?	no

Marki K, Csanadi M, Harsanyi A Inotai A. The effect of biosimilar infliximab on the treatment pattern of patient treated with biologics. ISPOR Hungary Chapter 10th Annual Conference

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Poll: What are the key barriers for biosimilar utilization in your healthcare system?

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Poll: What is the balance in your healthcare system between maximising short term gains of biosimilars versus creating a sustainable biosimilar market for sustained benefit?