ISPOR Warsaw 2019

The Implementation of Sustainable Biosimilar Policies to Increase Access to Biological Medicines in CEE Countries

27 March 2019

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The Implementation of Sustainable Biosimilar Policies to Increase Access to Biological Medicines in CEE Countries

Educational Symposium

Sponsored by Medicines for Europe

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The implementation of sustainable biosimilar policies to increase access to biological medicines in CEE countries

ISPOR Warsaw, 27 March 2019

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Objectives of the symposium

- In many countries high-priced original biological medicines are unavailable or reimbursement is restricted.
- The main value proposition of biosimilar medicines in these countries is not only to save money, but to increase patient access to treatment.
- To increase access for patients, there is a need for sustainable pricing and demand-side policies on biosimilar medicines.
- In this workshop, the panel and audience can discuss the implementation of sustainable biosimilar policies from the academic, payer, regulatory and industry perspectives.

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Panel

- Chair: **Rok Hren**, MSc, PhD; Assistant Professor, University of Ljubljana; Slovenia
- Speakers:
  - **András Inotai**, PharmD, PhD, DrHabil, Principal Researcher, Head of Pharmaceutical Policy Department - Syreon Research Institute, Hungary
  - **Marcin Czech**, PhD, MD, MBA, Head, Department of Pharmacoeconomics, Institute of Mother and Child, and Business School, Warsaw University of Technology, Warsaw, Poland, and former Deputy Minister of Health and Undersecretary of State, Poland
  - **Tomáš Tesař**, PharmD, PhD, MBA, Associate Professor, Union Health Insurance Fund, Slovakia
  - **Maarten Van Baelen**, PharmM, MBA, Market Access Director – Medicines for Europe

Value proposition of biosimilars in countries with resource constraints

András Inotai PharmD, PhD, DrHabil

Value proposition of biosimilars in countries with resource constraints

András Inotai PharmD, PhD, DrHabil

Assistant Professor,
Head of Pharmaceutical Policy Research

ISPOR Workshop
Warsaw, 27th March 2019

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

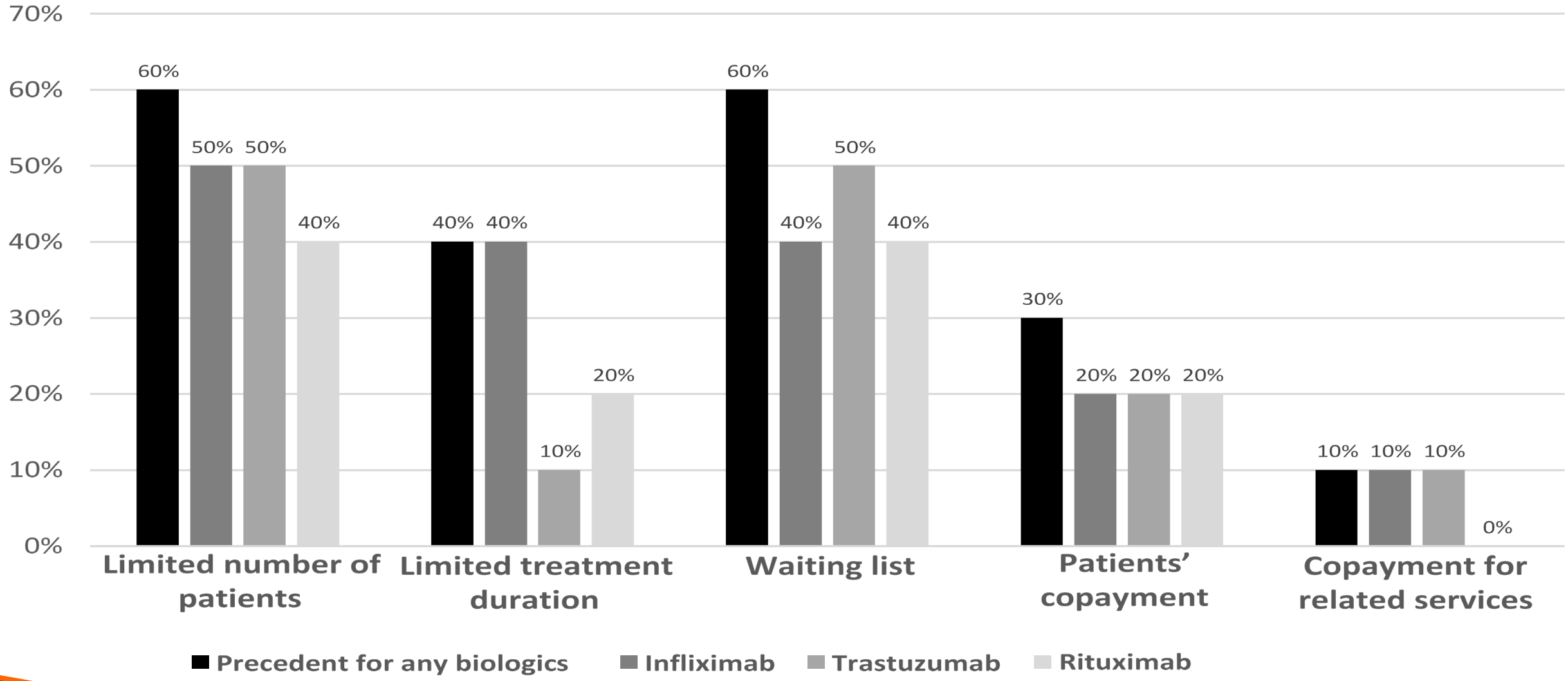
In lower income countries the **accessibility of patients to high cost biological medicines may be limited**, because sustainability of health care financing is facilitated by implementing volume limits, influencing

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

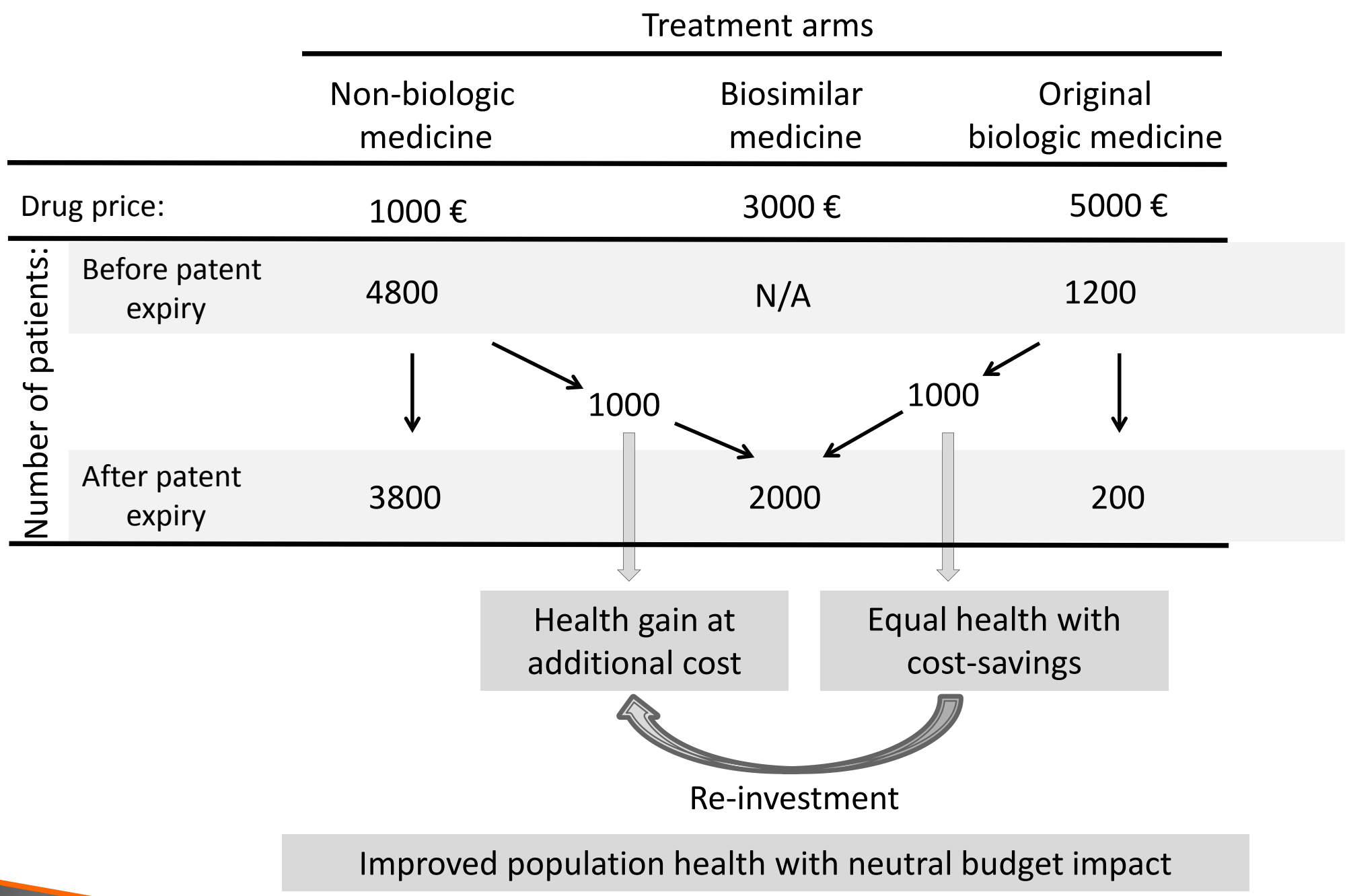


Ref: Inotai A et al. BioMed Research International. 2018. 9597362. 9.

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 ….

- … for treatment naive patients **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)
- … in maintenance therapy physicians prefer continuing the original therapy due to **hypothetical risks of immunogeneicity related to switching** to biosimilars

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The implementation of sustainable biosimilar policies to increase access to biological medicines in CEE countries

Maarten Van Baelen, Market Access Director

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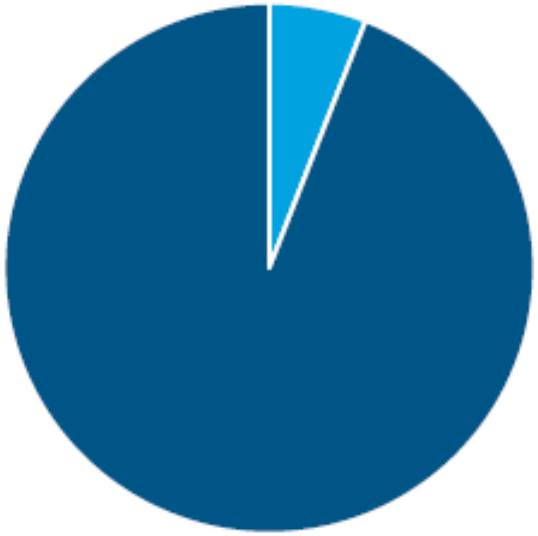
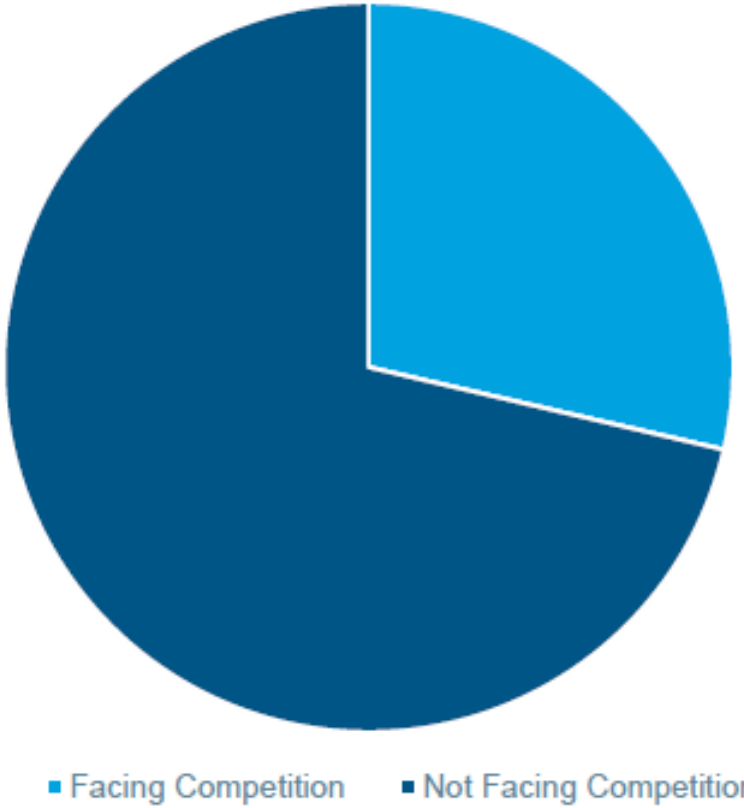
The share of the EU biotech market subject to biosimilar competition has increased from 9% to 29% over the past five years

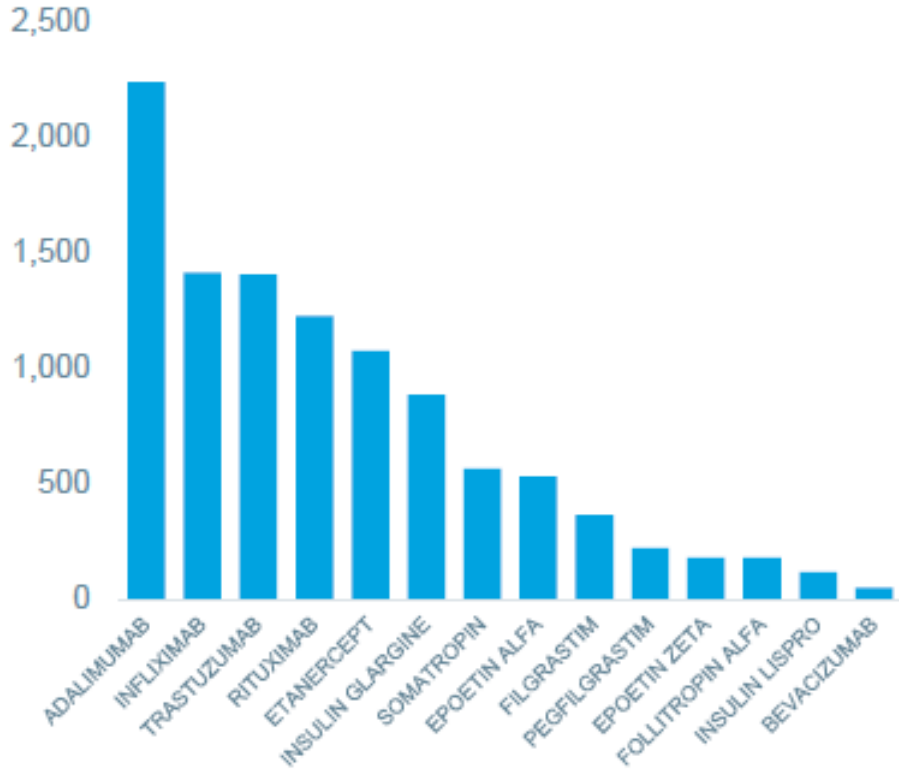
2013: €23.1Bn



2018: €36.4Bn

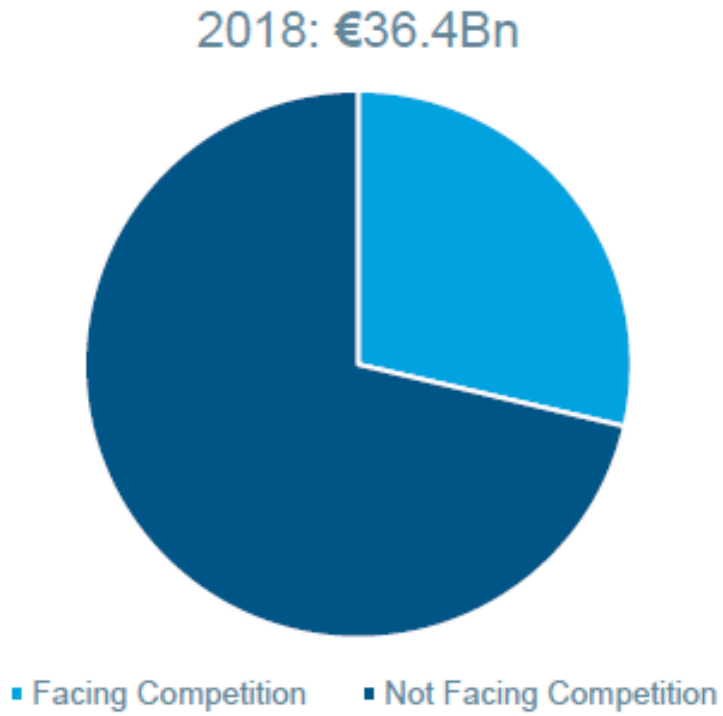


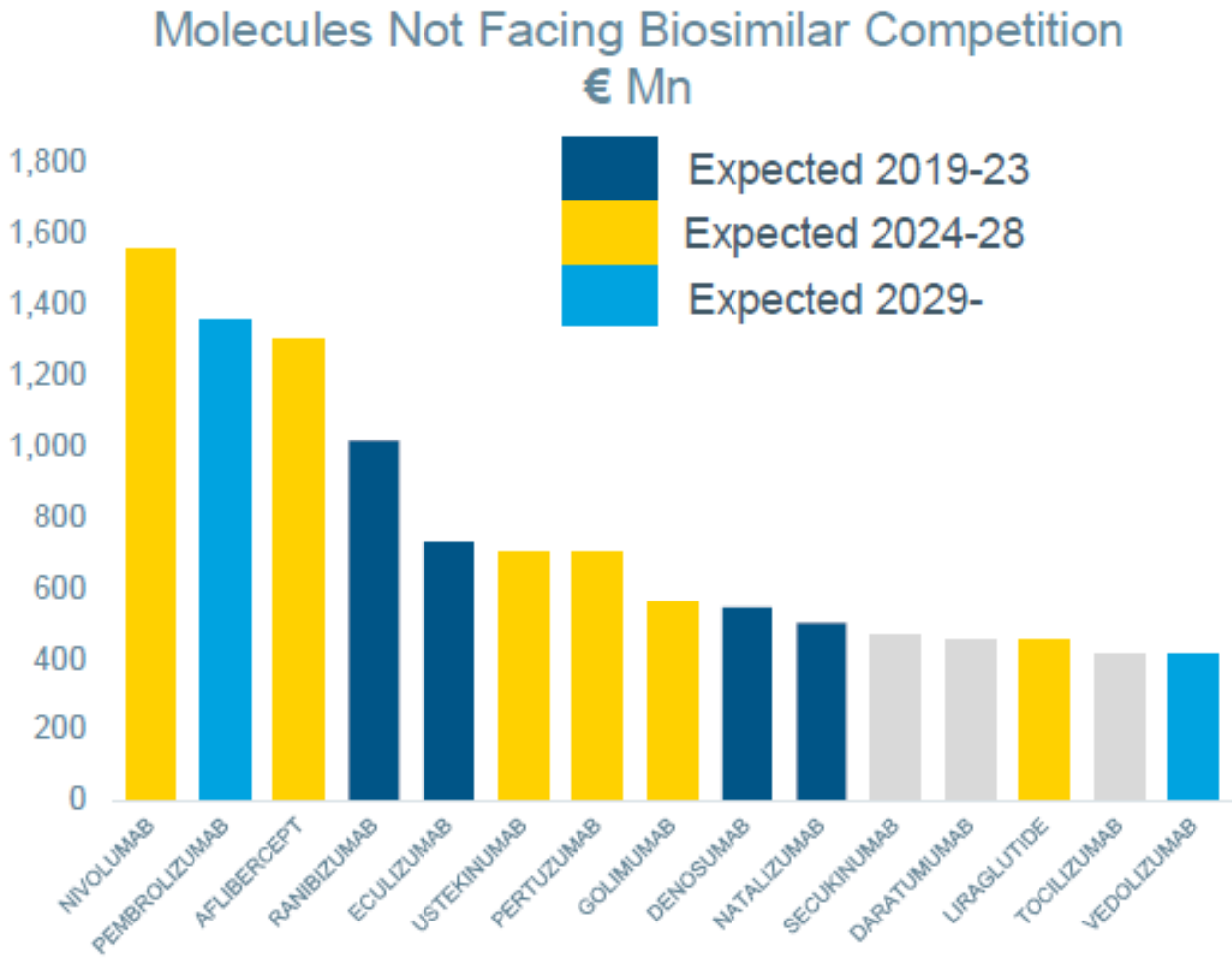
Molecules Facing Biosimilar Competition € Mn



Source: IQVIA MIDAS, Dec 2018

Near-term new biosimilar opportunities are smaller than in the past





Source: IQVIA MIDAS, Dec 2018

Chart Note: Molecules can be facing competition in some countries and not facing it in others as of the end of 2018. Some molecules not shown in the chart to the right

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Thank you!

Questions?

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