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Improving healthcare decisions

THE EVOLUTION OF BIOSIMILAR MARKETS:

Key elements for long-term sustainability of the healthcare ecosystem

ISPOR 2022 Global HEOR Conference

Forum brought to you by the **ISPOR Special Interest Group on Biosimilars**

17th May 2022

Meet the speakers

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Conflicts of Interest Statements

- **Cate Lockhart**, PharmD, PhD. Executive Director at Biologics and Biosimilars Collective Intelligence Consortium (BBCIC)

  No conflicts of interest to disclose

- **Murray Aitken**, MBA. Executive Director at IQVIA Institute for Human Data Science

  Employee and shareholder of IQVIA Holdings Inc.

- **Jackie Vanderpuye-Orgle**, PhD. Vice President, HEOR and RWE at Parexel International (US)

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- **Anna Hyde**, MA. Vice President of Advocacy and Access at Arthritis Foundation

  No conflicts of interest to disclose

- **Teresa Barcina**, PharmD. PhD researcher at the Faculty of Pharmaceutical Sciences in KU Leuven (MABEL Fund)

  No conflicts of interest to disclose

AIM OF TODAY'S FORUM

- Share insights on the role biosimilar medicines play in supporting the long-term sustainability of the healthcare ecosystem
- Reflect on learnings extracted from the use of biosimilars in the U.S.
- Identify elements that may undermine the sustainability of off-patent biologic/biosimilar markets
- Provide a multistakeholder perspective on elements necessary to ensure sustainable markets

AGENDA

- U.S. Perspective (Lockhart)
- IQVIA Sustainability Framework (Aitken)
- Multistakeholder Objectives (Vanderpuye-Orgle)
- Patient Advocate’s Perspective (Hyde)

About the audience…

It's Time for a Poll!

- What is your work environment? Please select:

  a) Industry

  b) Regulatory agency/HTA agency

  c) Clinical practice/hospital/managed care/pharmacy management

  d) Academia

  e) Other

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Cate Lockhart

U.S. Perspective

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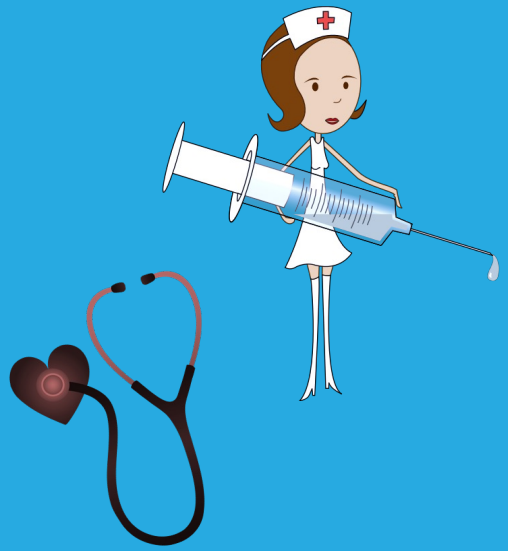
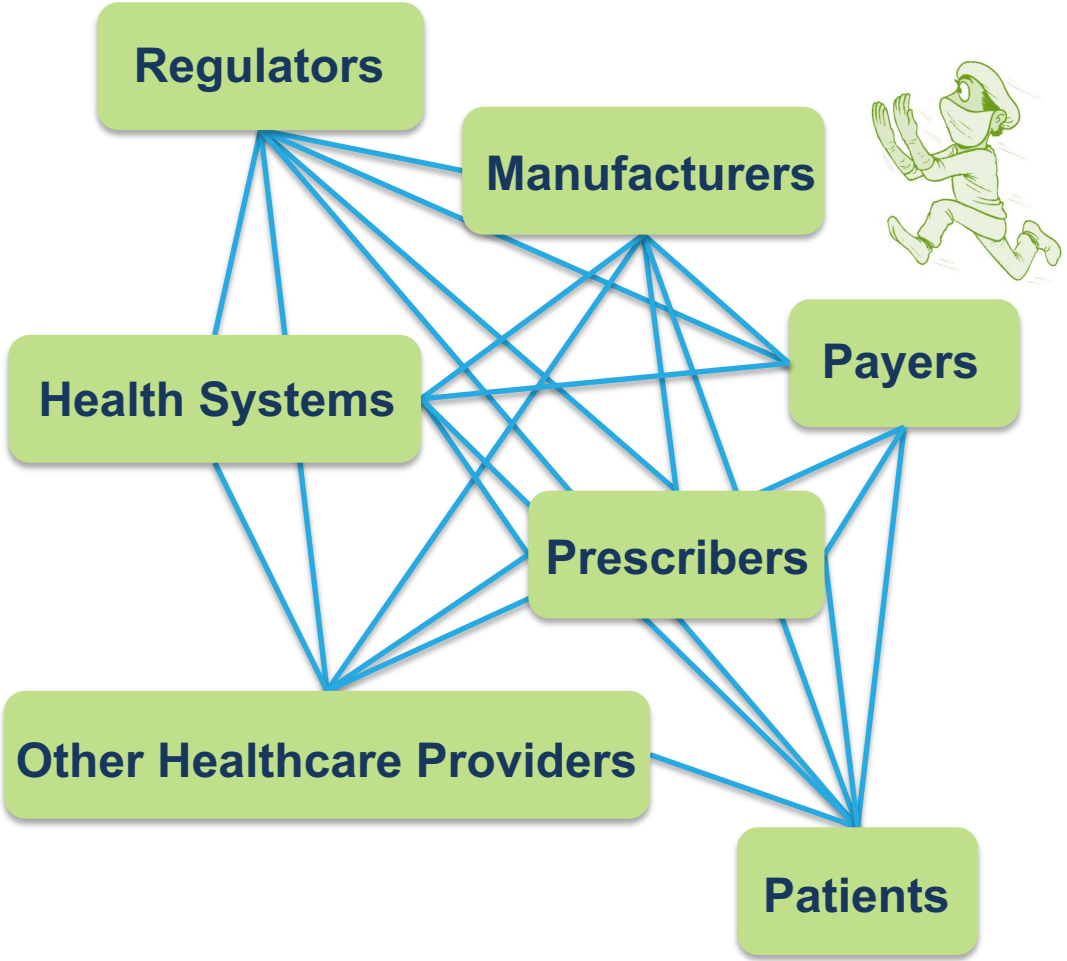
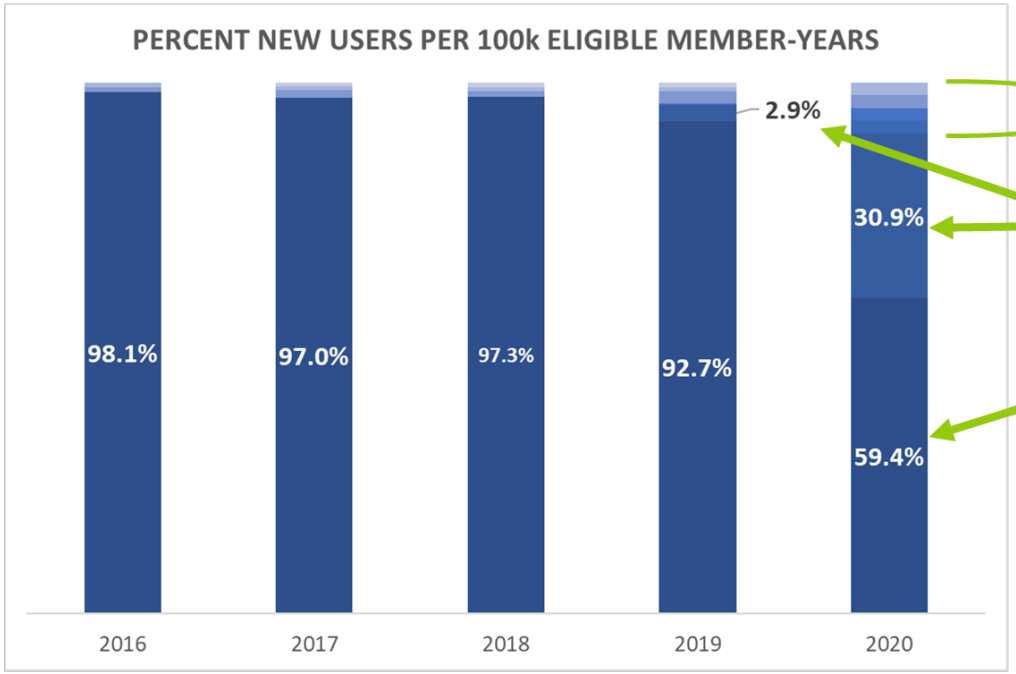


Who are the stakeholders for biosimilars in the United States?



U.S. PERSPECTIVE – TRASTUZUMAB SUCCESS

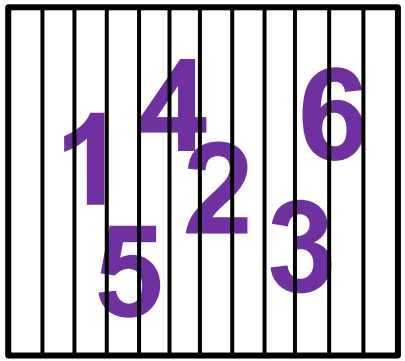


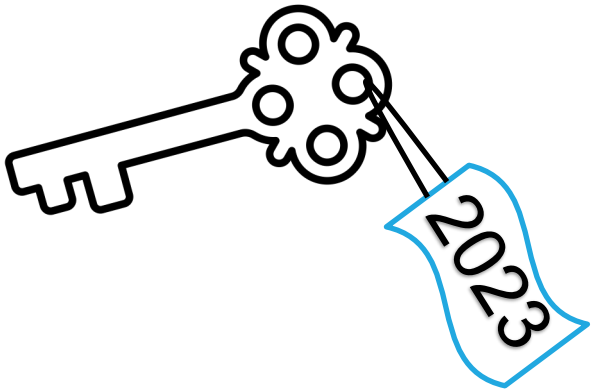
Note: For 2020, data up to 2/29/20 were analyzed. Data at the beginning of the year may reflect different utilization compared to the rest of the year due to coverage changes.

Adapted from Nam YH, et al. Poster presented at: AMCP Nexus 2021; October 19-21, 2021; Denver, CO.

U.S. PERSPECTIVE – ADALIMUMAB JAIL BREAK

Adalimumab Biosimilars



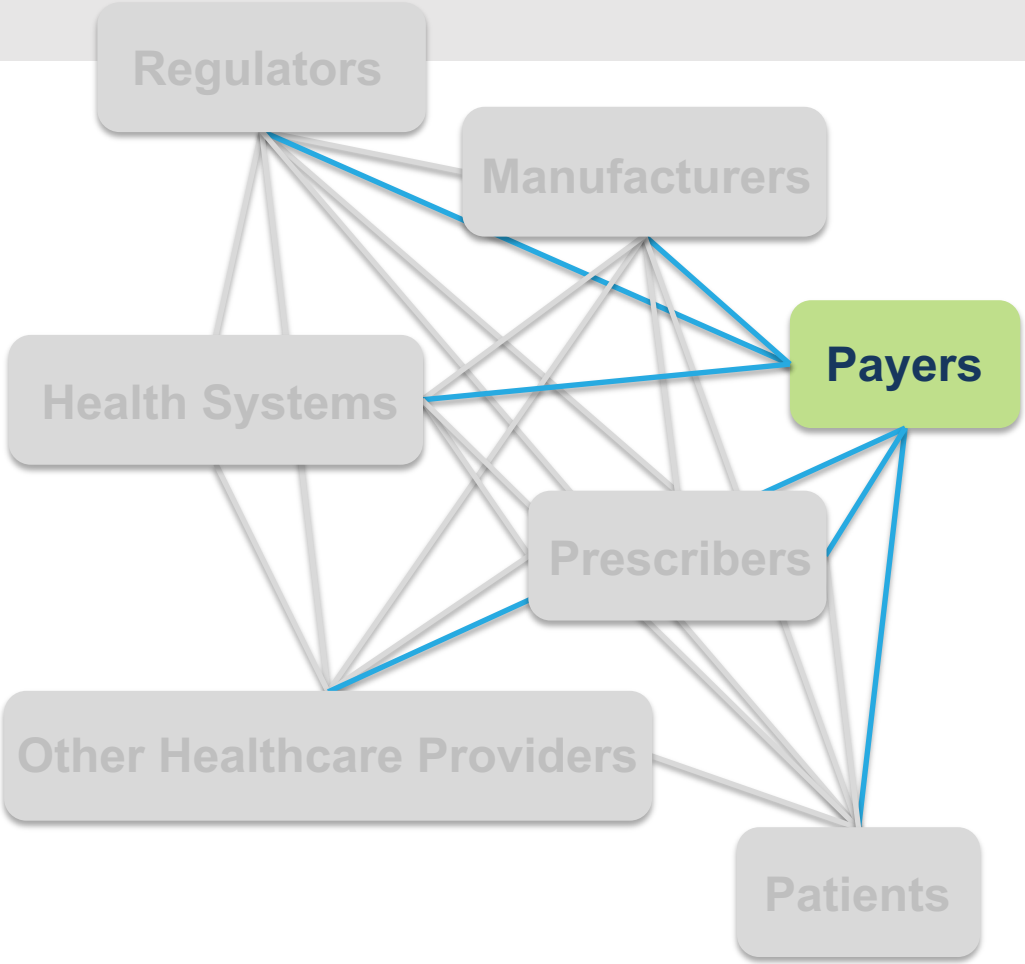


Adalimumab Reference (Humira®)

BBCIC Biologics & Biosimilars Collective Intelligence Consortium

U.S. PERSPECTIVE

Medical Benefit
vs
Pharmacy Benefit



U.S. PERSPECTIVE

2018 Survey

Specialty Pharmacy	Managed Care/ PBM
(n = 120)	(n = 180)

300 Surveys Collected

2020 Survey

Specialty Pharmacy	Managed Care / PBM	Other
(n = 24)	(n = 150)	(n = 163)

337 Surveys Collected

PRIME® AMCP Foundation

Greene et al. *J Manag Care Spec Pharm* 2019;25(8):904-12.

2021 Survey

Health Plan	PBM	IDN
(n = 33)	(n = 9)	(n = 9)

51 Surveys Collected

AmerisourceBergen Xcenda

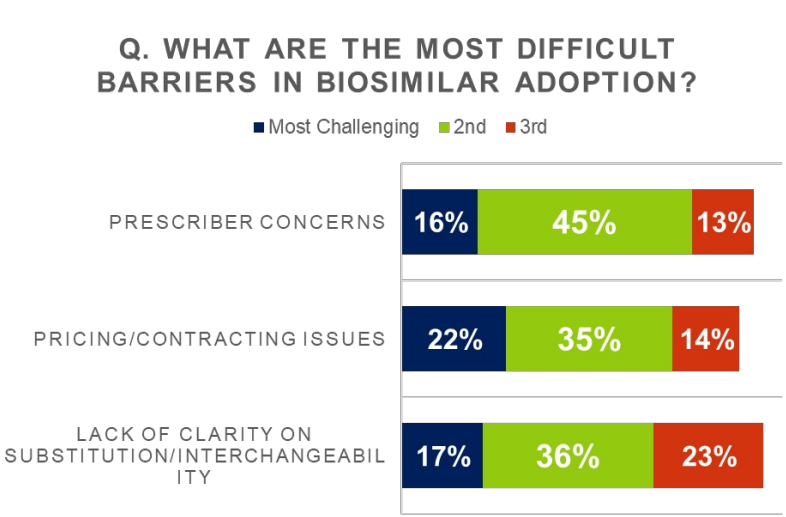
BBCC Biologics & Biosimilars Collective Intelligence Consortium

Hydery et al. Presented at AMCP Nexus 2021, Denver, CO.

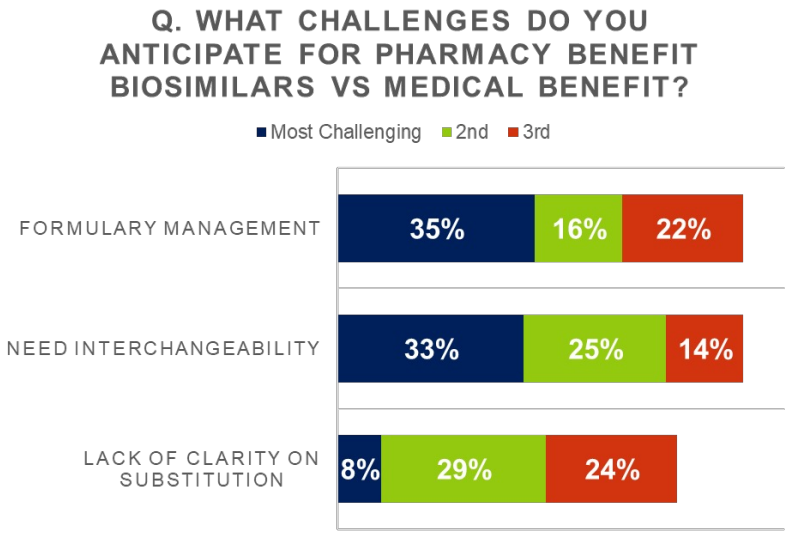
PBM = Pharmacy Benefit Manager
IDN = Integrated Delivery Network

U.S. PERSPECTIVE

2020 (n = 337)



2021 (n = 51)



Greene et al. *J Manag Care Spec Pharm* 2019;25(8):904-12.
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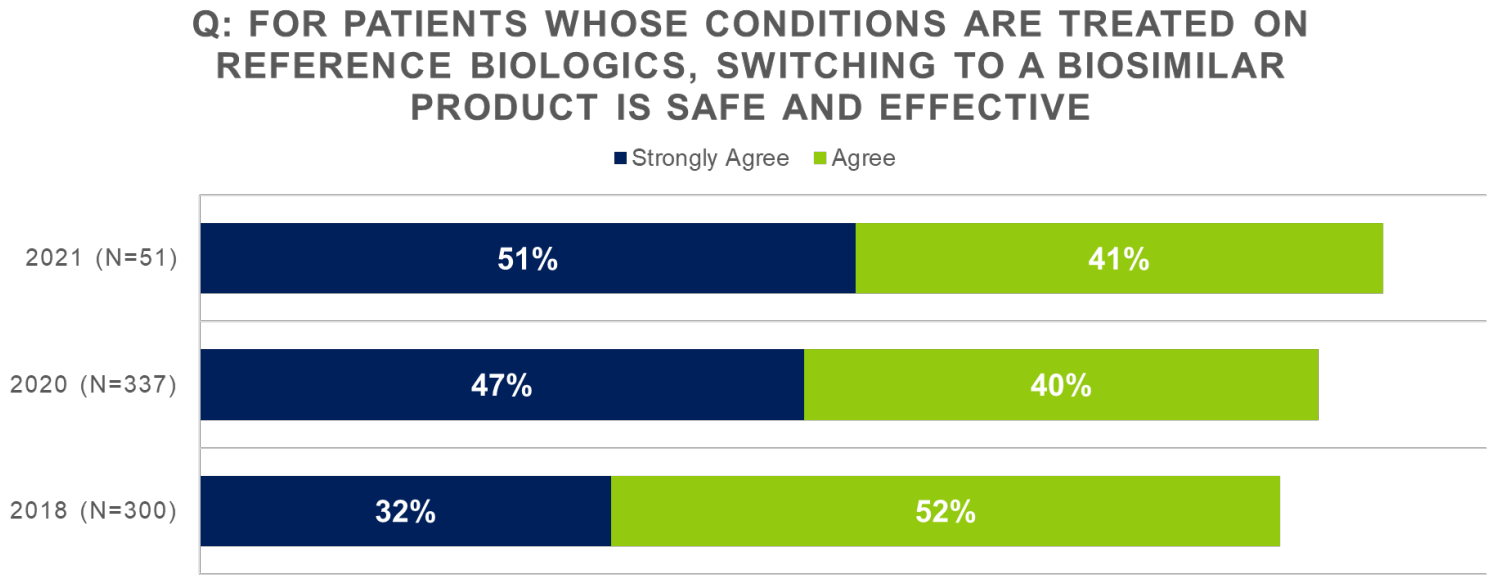
U.S. PERSPECTIVE



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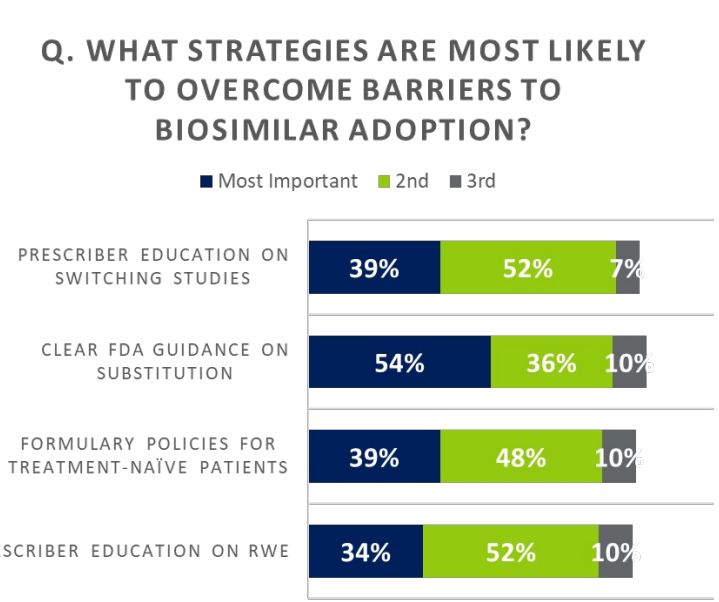
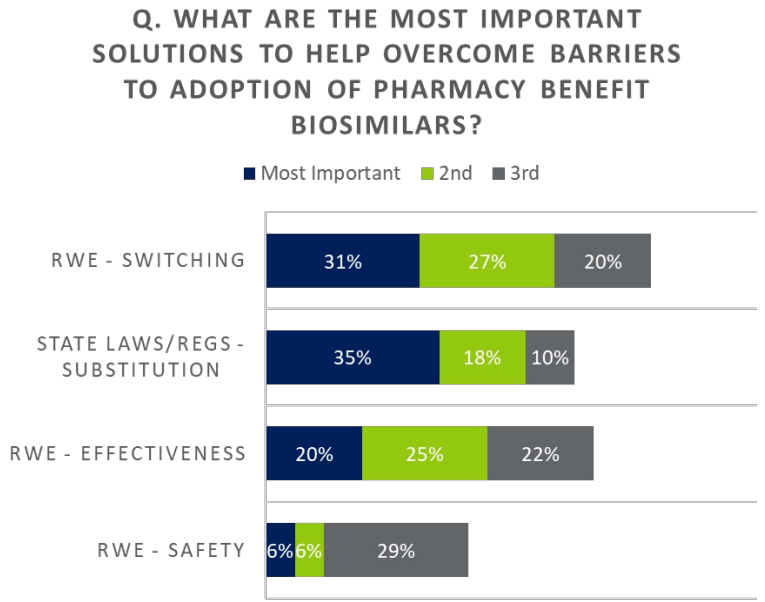
Hydery et al. Presented at AMCP Nexus 2021, Denver, CO.

U.S. PERSPECTIVE

2020 (n = 337)



2021 (n = 51)



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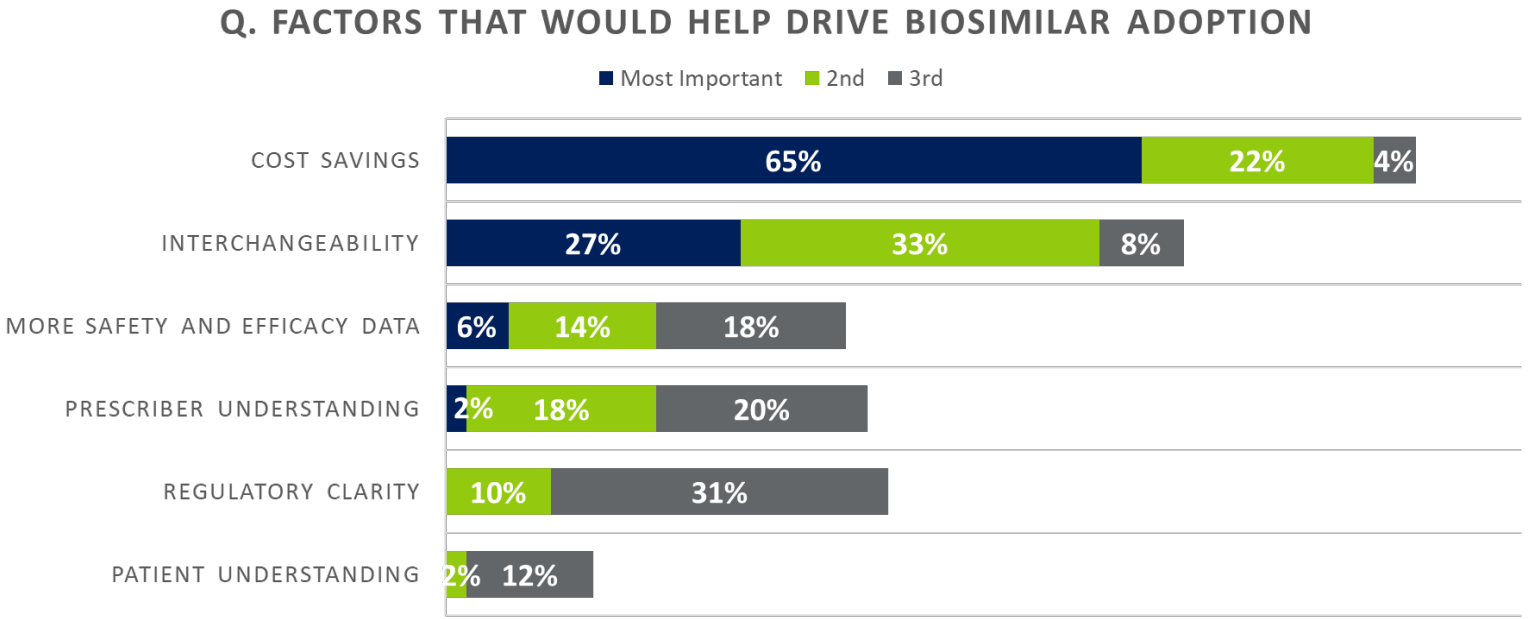
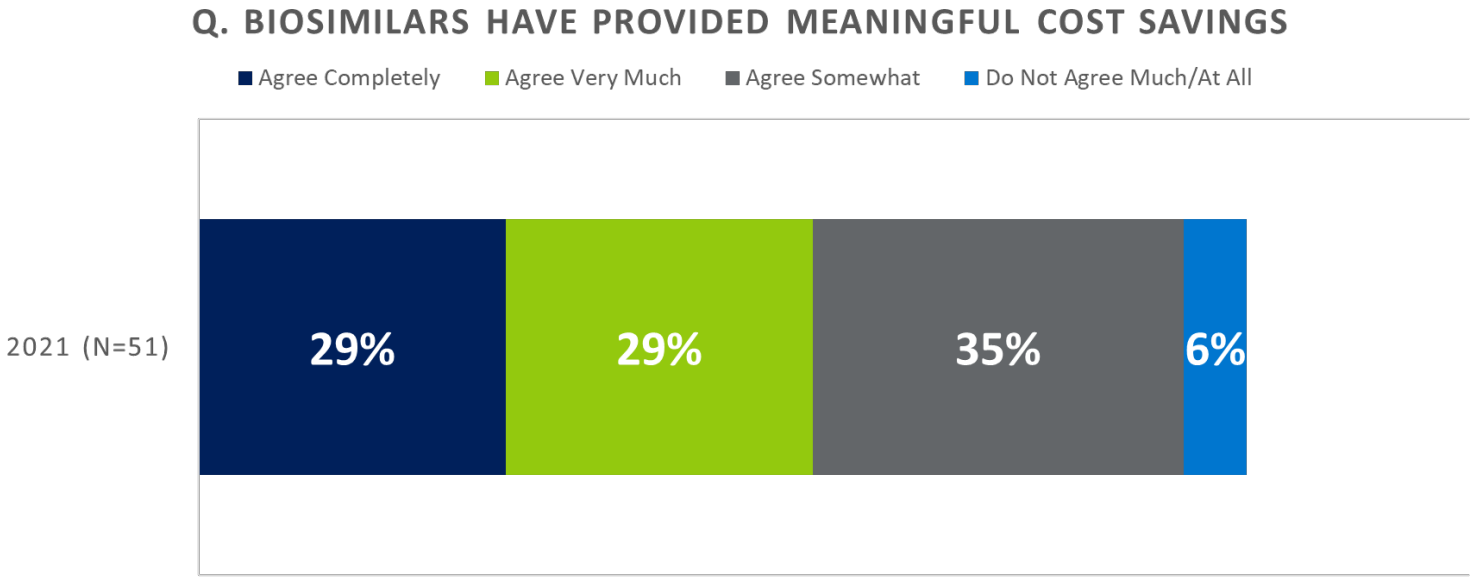
U.S. PERSPECTIVE



2021 (n = 51)

Hydery et al. Presented at AMCP Nexus 2021, Denver, CO.

U.S. PERSPECTIVE

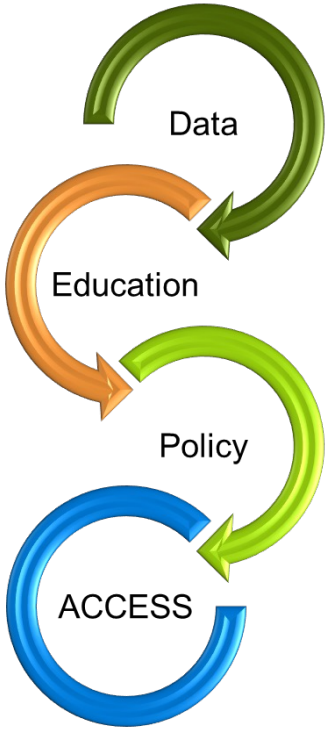


2021 (n = 51)

Hydery et al. Presented at AMCP Nexus 2021, Denver, CO.

U.S. PERSPECTIVE

- Patient
- Practitioner
- Payer
- Policymaker



- Interchangeability studies
- Switching studies
- HC resource utilization and cost implications
- Real-world evidence
- Models
- Clinical operations

- Clear regulatory guidance on substitution
- Formulary management
- Expanded Medicare/Medicaid policies
- Reduced cost sharing for patients

It's Time for a Poll!

- According to managed care pharmacy professionals, which of the following is **NOT** among the most important solutions to overcoming barriers to biosimilar adoption?

  a) Real-world evidence on product switching

  b) Clarity on laws and regulations regarding product substitution

  c) Real-world evidence on safety and effectiveness of biosimilars

  d) More clinical trials

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Murray Aitken

Methodologies to Evaluate Sustainability Risks

Definition of ‘biosimilar sustainability’

- Patient access
- Physician prescription choice
- Safety and high-quality biologics
- Needs of all stakeholders
- Healthcare budgets
- Healthy level of competition
- Healthy level of supply

*Biosimilar sustainability improves **patient access** and **physician prescription choice** of **safe and high-quality biologic medicines,** in a framework that considers the **needs of all stakeholders** (patient, healthcare professionals / providers, and manufacturers), provides a means to **manage existing healthcare budgets** while safeguarding a **healthy level of competition** and **supply.***

Source: IQVIA Institute for Human Data Science, Advancing Biosimilar Sustainability in Europe, 2018
Report: Spotlight on Biosimilars: Optimizing the Sustainability of Healthcare Systems. Report by the IQVIA Institute for Human Data Science, Jun 2021

Criteria for the sustainable market

ACCESS TO BIOLOGICS

1. Significant increase to biologics since biosimilar entry*

REGULATORY AND PMA

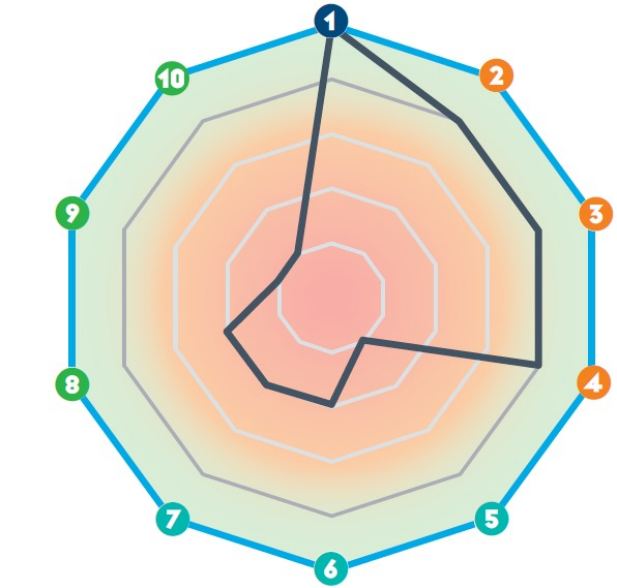
2. **Regulatory and PMA pathway:** ensuring timely access to biosimilars following EMA approval
3. **Treatment guidelines:** recommending biosimilar use
4. **Switching and substitution policies:** at physicians' discretion while preventing automatic pharmacy substitution

COMPETITIVE PRESSURE

5. **Level of competition:** high level of competition with multiple players
6. **Pricing rules and dynamics:** prices driven by competition only
7. **Procurement:** systems which support competition and drive uptake in the market

INCENTIVES

8. **Patient benefits:** effective benefits encouraging biosimilar use
9. **Provider and prescriber benefits:** effective benefits supporting biosimilar usage
10. **Awareness and education:** strong awareness of biosimilar benefits and sustainable practices across stakeholder groups



In an ideal **biosimilar market**, all data points lie on the outer-most perimeter

Market A — Ideal market

Not sustainable — Ideal/most sustainable

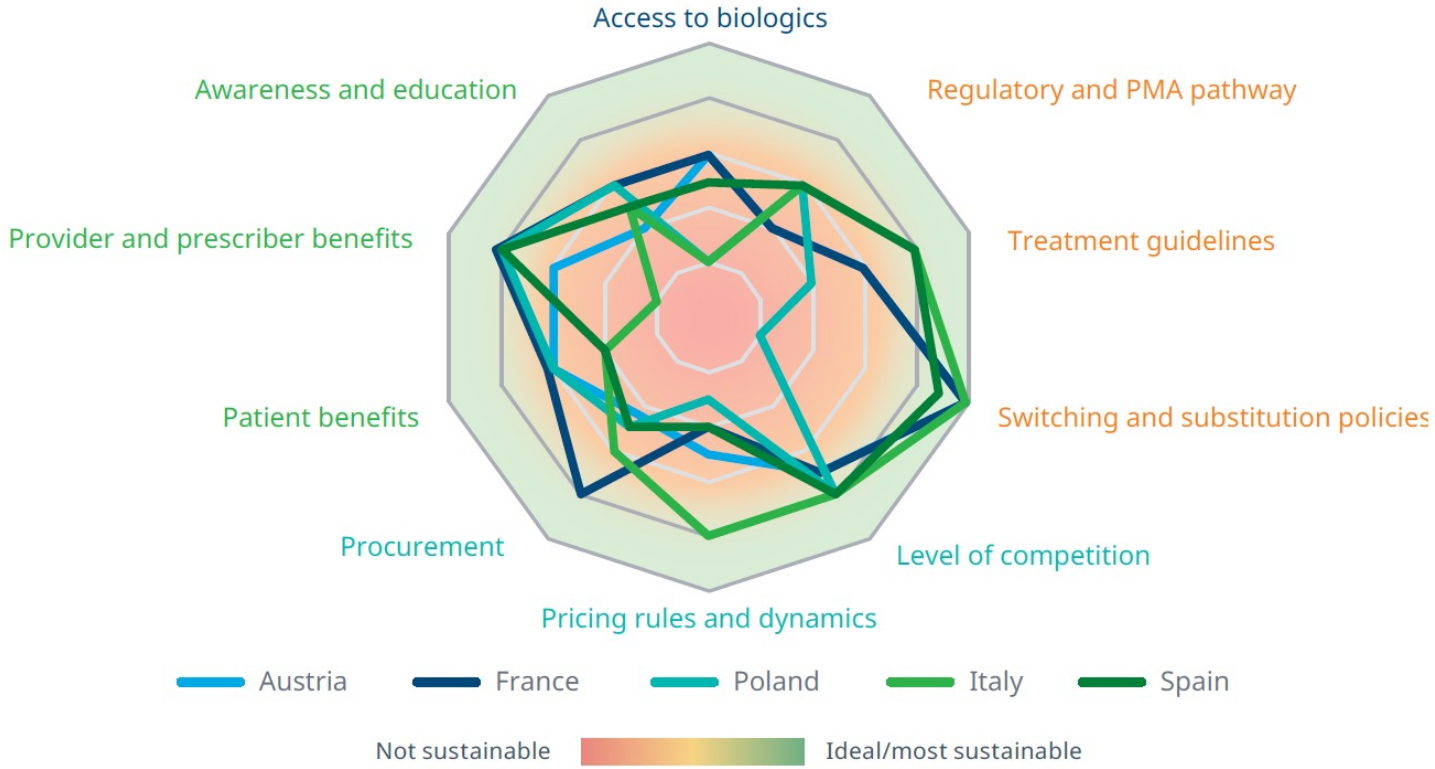
*Defined as >25% increase in DDD per capita

Report: Spotlight on Biosimilars: Optimizing the Sustainability of Healthcare Systems. Report by the IQVIA Institute for Human Data Science, Jun 2021

Sustainability scorecard metric definitions

POLICY AREA	METRIC	SUSTAINABILITY MEASURE (5: sustainable; 1: not sustainable)
Regulatory environment and clinical guidelines	• Time from EMA approval to first biosimilars sales	• Biosimilar average time to first sales from EMA approval: 5: 0-5 months; 4: 5–8 months; 3: 8–11 months; 2: 11–14 months; 1: >14 months
	• Treatment guidelines for biosimilar use	• 5: Multiple publications and guidelines on recommended biosimilar use; 4: Some publications on recommended biosimilar use; 3: Accept EMA guidelines/ no official position on biosimilars or papers to support use; 2: Against biosimilar use; 1: Strongly against biosimilar use
	• Physician switching policies	• Is a switch to biosimilar allowed at physician's discretion? 5: Yes; 3: Switching not allowed from biosimilar to biosimilar; 1: No
	• No biologic pharmacy substitution	• Is biologic pharmacy substitution allowed in the retail and hospital prescription setting? 5: No; 3: With limitations/no stringent enforcement; 1: Yes
Awareness and education	• Comprehensive training / education for patient	• 5: Comprehensive training or education provided in a country, or historic acceptance; 3: in between; 1: No training or education provided in a country
	• Comprehensive training / education for physician	
	incentives to e biosimilar use	• 5: Incentives in place to encourage biosimilar use; 3: No significant incentives available; 1: Incentives in place to encourage use of the originator
	tion quotas or l incentives for rs that do not physician choice	• 5: Existence of incentives or quotas that do not restrict physician choice (similar incentives across molecules and regions); 1: formal quotas and financial incentives restricting choice
	or price not subject latory price cuts	• 5: Yes; 1: No - forced originator price cuts in place
	e pricing not subject ence price	• 5: No - competition drives pricing; 1: Yes
	of contracts	• Between 12 and 24 months: (less than 12 months: the patients may be switched treatment too often etc.), or variable; 1: shorter than 12 months or longer than 24 months
	iming relative to ar availability	• 5: Tender opens when biosimilar enters the market; 3: Variable; 1: Tender opens before biosimilar enters market
Purchasing mechanisms	• Time from tender award to delivery	• 5: 4–6 months; 3: 2–4 months; 1: <2 months or >6 months
	• Number of winners	• Total number of active winners in a country: 5: Consistently award multiple winners; 3: Usually a single winner, but more would be allowed 1: Strictly single winner
	• Winner decision criteria beyond price	• 5: Yes, the most economically advantageous tender offers win; 3: Some, but limited; 1: None beyond price

Unique footprints of markets



Source: IQVIA PMR analysis and MIDAS data Q4 2020
Notes: Analysis includes national level perspectives only. Regional breakdown is included within the appendix for 3 regions for both Italy and Spain where areas within the analysis may differ to the national picture.
Report: Spotlight on Biosimilars: Optimizing the Sustainability of Healthcare Systems. Report by the IQVIA Institute for Human Data Science, Jun 2021

Methodologies to assess sustainability risk

- Definition of biosimilar sustainability requires multi-stakeholder considerations
- Criteria that are measurable in a combination of quantitative and qualitative assessments can be applied at a country or sub-national level to assess sustainability
- Markets have unique characteristics and sustainability profiles that change over time
- Sustainability risk should also be linked to measures of biosimilar penetration and concentration, pricing dynamics and patient access levels

It’s Time for a Poll!

- How applicable are the discussed sustainability elements to the U.S. market environment? Please rate (scale 1-10):

It’s Time for a Poll!

- In your experience, what approaches are being pursued by policy-makers to improve the level of sustainability?

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Jackie Vanderpuye-Orgle

Biosimilars market sustainability and the healthcare ecosystem

Elements of a sustainable healthcare ecosystem

- "…not everyone means the same thing when they speak about 'sustainable health care'." [Muzyka et al. 2014]
- There are various schools of thought but there are also common themes across stakeholders

Long-term strategic perspectives and innovation	Disease prevention and health promotion	Quality	Institutionalization of social and ecological environmental concerns	Institutional accountability and individual responsibility
• Keeping financial costs under control • Enacting enabling policies with long-term perspectives • Advancing effective therapies and improving services	• Emphasizing comprehensive patient-centered primary care and chronic disease management • Fostering a satisfactory environment for healthcare workforce	• Defining and tracking appropriate quality standards and performance indicators • Facilitating health equity and parity • Investing in advancements in data infrastructure and digital solutions	• Addressing broader socio-economic and cultural determinants of health • Addressing environmental contributing factors • Understanding interdependencies	• Prioritizing transparency in decision making and driving efficiencies • Empowering patients and enabling them to take ownership of their health

Muyzka, D.; Hodgson, G.; Prada G. The Inconvenient Truths about Canadian Health Care. Available online: http://www.conferenceboard.ca/cashe/research/2012/incnveneient_thruths.aspx
Fischer, M. Fit for the Future? A New Approach in the Debate about What Makes Healthcare Systems Really Sustainable. Sustainability 2015, 7, 294-312. https://doi.org/10.3390/su7010294

Biosimilars and a sustainable healthcare ecosystem

Through lower-priced therapies and more treatment options, biosimilars may result in:

Drivers include

- Safety
- Efficacy
- Effectiveness
- Reimbursement
- Stakeholder perceptions
  - Competition
  - Prices
  - Market share

Competition

Expanded access

Cost savings

Headroom for innovation

Health system sustainability

Estimates of the benefits of the biosimilars in the US

Potential for significant health system savings

- US cost savings of $54 bill from 2017 – 2026
- About 3% of total estimated biologic spending
- Range of $24 bill - $150 bill depending on:
  - Biosimilar price relative to reference biologic
  - Market share
- Potential savings per biologic class will depend on: sales, degree of competition, and timing of entry

Biosimilar Price Relative to Reference Biologic	Biosimilar Market Share Assumption						
	20%	25%	30%	35%	40%	45%	50%
50%	$60	$75	$90	$105	$120	$135	$150
55%	$54	$67	$81	$94	$108	$121	$135
60%	$48	$60	$72	$84	$96	$108	$120
65%	$42	$52	$63	$73	$84	$94	$105
70%	$36	$45	$54	$63	$72	$81	$90
75%	$30	37	$45	$52	$60	$67	$75
80%	$24	$30	$36	$42	$48	$54	$60

The promise of biosimilars and the benefits to the healthcare ecosystem can only be attained if we have a thriving and sustainable biosimilars market with a level playing field

Mulcahy, A. W., Hlavka, J. P. and Case, S. R. (2018). Biosimilar Cost Savings in the United States: Initial Experience and Future Potential. Rand Health Q 7(4): 3.

Delphi panel - Multistakeholder perspective on biosimilars market sustainability

Rationale

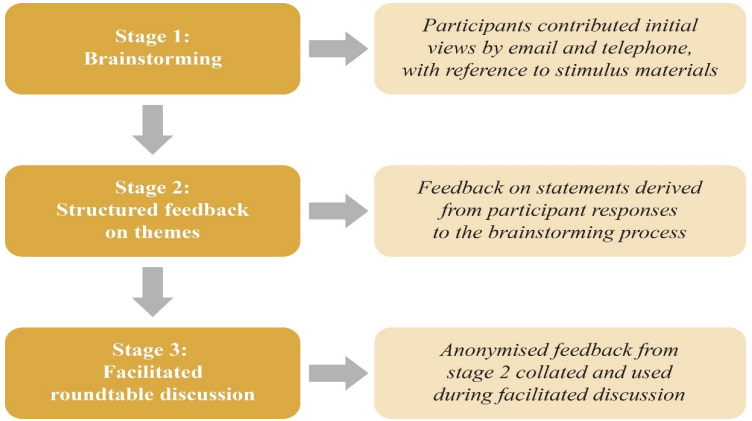
- Biosimilars have the potential to positively impact healthcare systems and budgets
- To realize this potential, stakeholders need to balance competition and supply chain security to foster a sustainable biosimilars market
- There is significant variation in the policies for pricing, procurement, and use of biosimilars in the EU

Objective

- To establish a multistakeholder definition of biosimilar market sustainability
- To further identify components of a sustainable biosimilar market
- To identify drivers and risks of a sustainable biosimilar market

Methods

- A modified Delphi process
- 11 participants *(1 patient advocate, 1 oncologist, 1 rheumatologist, 2 hospital pharmacists, 2 procurement pharmacists, 1 national payer, 2 policy advisers, 1 manufacturer)*
- 7 European countries



Vulto A. G., Vanderpuye-Orgle J., van der Graaff M, Simoens S. R. A., Dagna L., Macaulay R., Majeed B., Lemay J., Hippenmeyer J., and Gonzalez-McQuire S. (2020). Sustainability of Biosimilars in Europe: A Delphi Panel Consensus with Systematic Literature Review. Pharmaceuticals 2020, 13, 400.

Consensus statement on biosimilar market sustainability

- **A multistakeholder definition of biosimilar market sustainability**
  - A sustainable biosimilar market means that ...

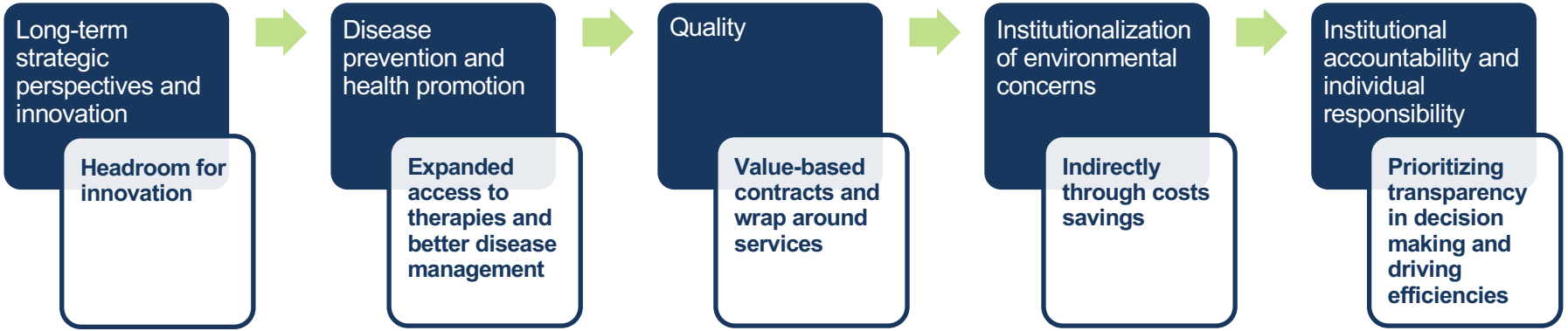
    "All stakeholders, including patients, benefit from appropriate and reliable access to biological therapies. Competition leads to a long-term predictable price level, without compromising quality, while delivering savings that may be reinvested."
- **Three key components:**
  - Delivers tangible and transparent benefits to the healthcare system
  - Addresses the needs of all stakeholders
  - Requires collaboration across stakeholders

Drivers and risks: Competition and incentives

1. Competition is more effective for achieving long-term predictable price level than regulation	
Increased competition leads to more rapid price reduction and, if procurement policies contribute to business continuity, a sustained lower price level	CONSENSUS*
There is a need to develop better prospective indicators to warn about potential risk of *de facto* monopoly	CONSENSUS*
2. There needs to be incentives for investment in future biosimilars	
Continued investment in biosimilar development and market entry is important to generate competition for biological therapies for which no biosimilar is currently available and, to a lesser extent, therapies with biosimilars already available	CONSENSUS*
3. Governments and pricing bodies need to drive incentives	
These bodies need to supply incentives that enable enough suppliers to survive free market onslaught; this may assure the continuity of long-term competition and sustainable discounts from originator biological therapy price levels	CONSENSUS*

Future outlook

- **Biosimilars have a key role in facilitating a sustainable health system both directly and indirectly**



- **In principle health system sustainability is feasible but there is a lot of work that needs to be done:**
  - Drive a consensus on how sustainability is defined for the different archetypes of health systems
  - Identify drivers/levers to facilitate sustainability and optimal pathways for collaboration within health systems

It’s Time for a Poll!

- Efficiency of treatments will probably lead to higher costs and contribute to financial instability in the long run

  a) True

  b) False

4

Anna Hyde

A patient advocate's perspective on sustainability

Patients are a critical stakeholder in driving biosimilars uptake

- Patient perception and comfort is derived from:
  - Their health care provider
  - FDA stamp of approval
  - Peer-to-peer support and real-world evidence

What is the value proposition to the patient?

- Lower out-of-pocket costs
- Lower administrative burden

……..***Which can benefit the entire system through***

- Direct benefits such as lower drug costs overall and greater access, leading to greater medication adherence
- Indirect benefits such as greater employee presenteeism

Understanding barriers to help drive uptake

- Our data show that patients may not take a biosimilar if:

  - They do not know about them or are unfamiliar
  - Their doctor has not talked about biosimilars as a treatment option
  - They fear biosimilars will not work as well and have concerns about interchangeability
  - They may not have easy access through their formulary or the out-of-pocket cost is not significantly lower

Combining our data with what else we know is happening in the market…

Barriers to uptake fall into four main categories:

1. A lack of incentives to the patient
2. Communication bias or misinformation
3. Inherent fear of “the new”
4. Formulary access challenges

What are the needs moving forward?

- Education and communication that is tailored to where the patient is in their disease journey and flows through the health care provider
- Consensus around terms and phrases we use for biosimilars
- Communication around transitions that emphasizes buy-in and bottom-up feedback
- Realization of the value proposition
- Patient engagement through the drug development process

It's Time for a Poll!

- According to your experience, please **rank** the relevance of the following barriers to biosimilars uptake:

  a) Lack of incentives to the patient

  b) Communication bias or misinformation

  c) Inherent fear of "the new"

  d) Formulary access challenges

Thank You!

Q&A

Contact: teresa.barcina@kuleuven.be

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