



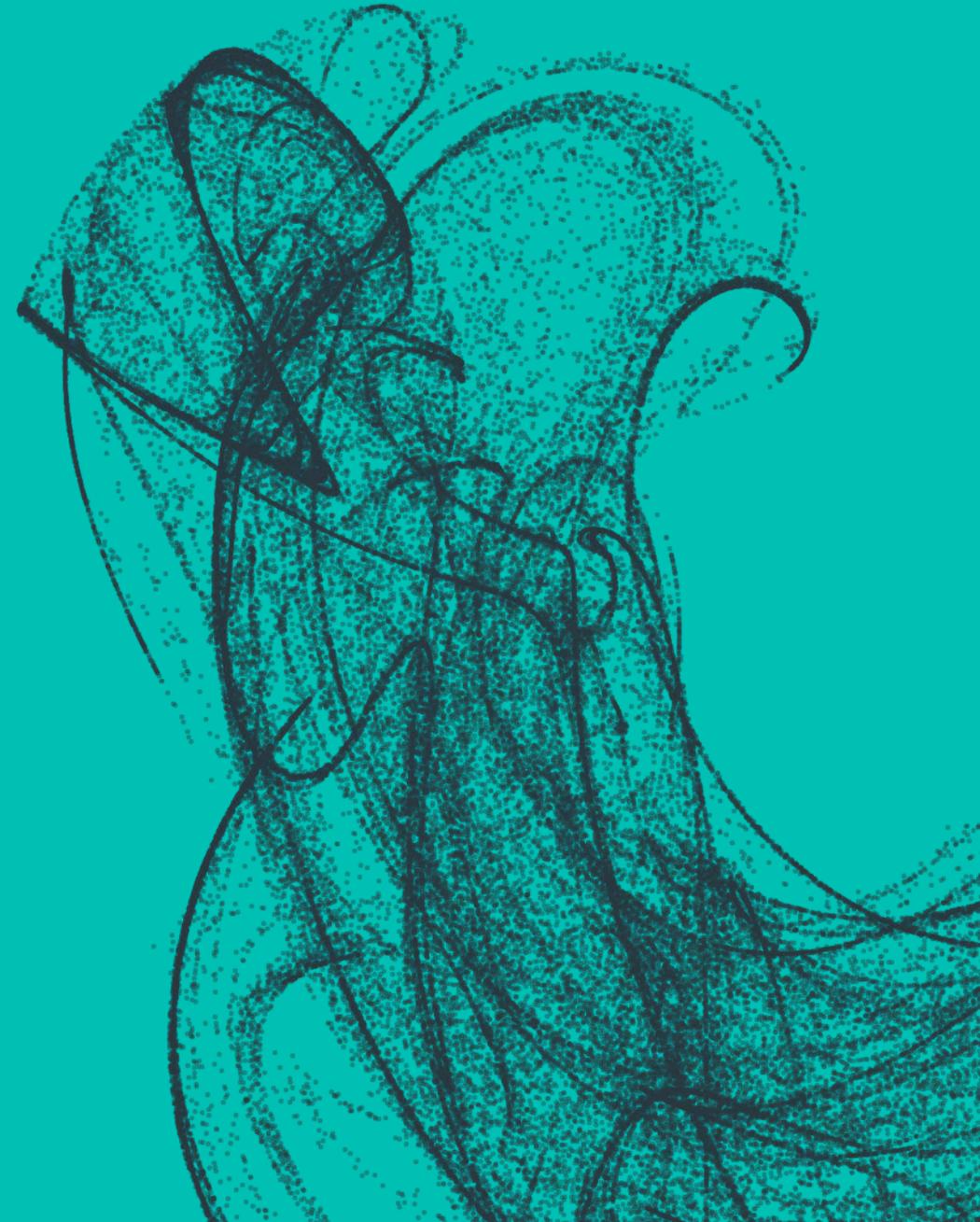
# Global Perspectives on Biosimilar Markets and Sustainability

International Federation on Ageing Roundtable

JUNE 28, 2022

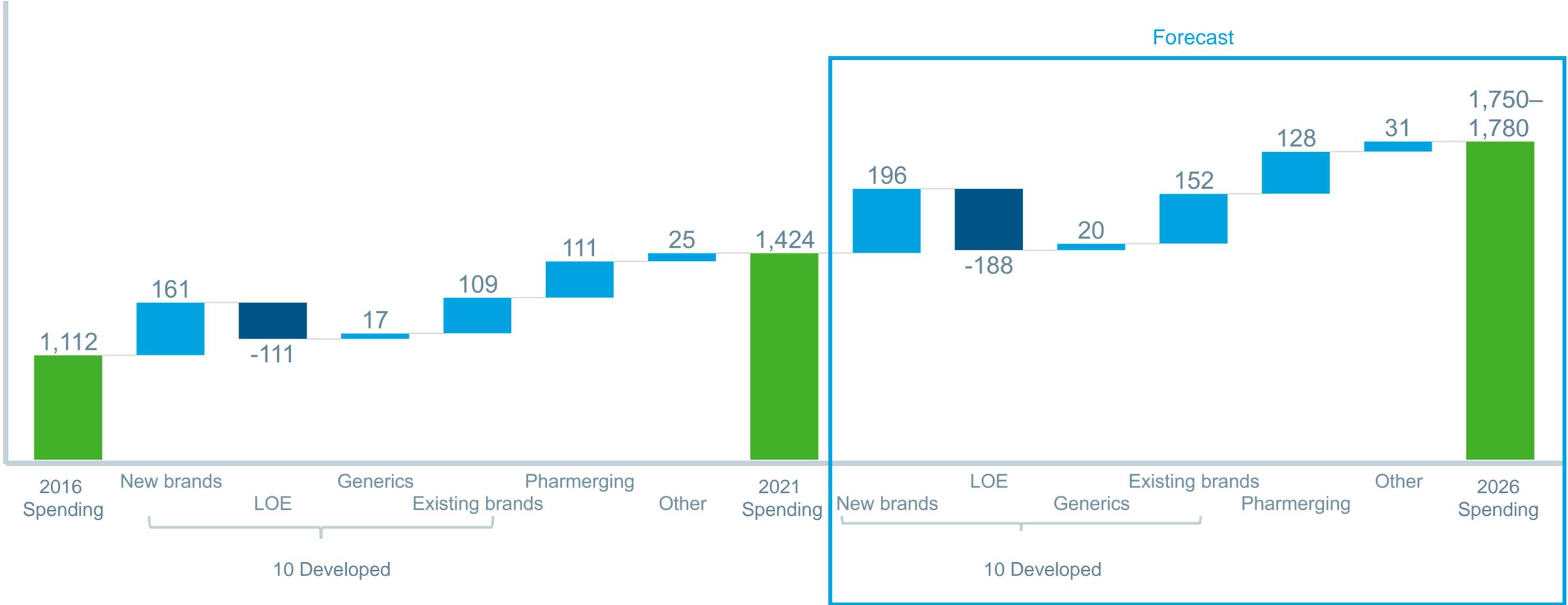
Murray Aitken, Executive Director

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# Demand for medicines to address unmet needs – excluding COVID-19 vaccines – is expected to reach almost \$1.8Tn by 2021

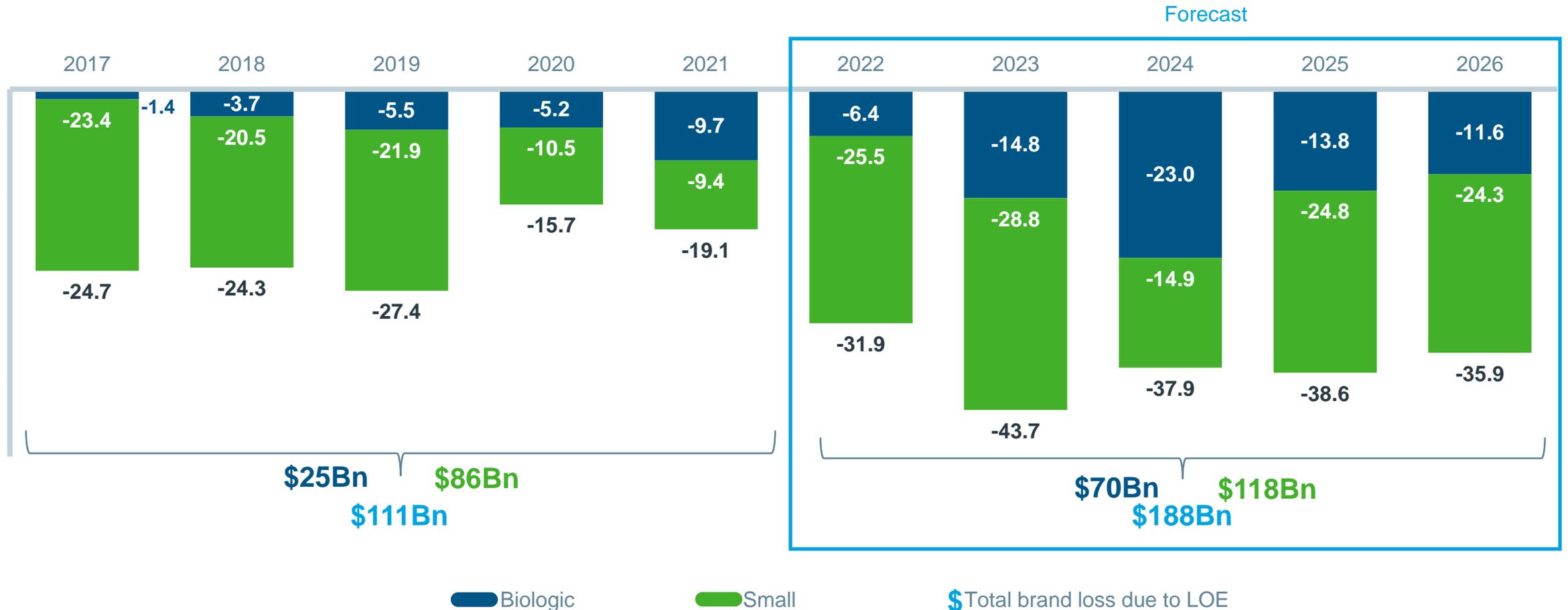
Spending and growth drivers 2016–2026 const US\$Bn



Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Nov 2021  
 The Global Use of Medicines 2022: Outlook to 2026. Report by the IQVIA Institute for Human Data Science

# Biosimilars will play a significant role in contributing to lower spending on biologics that have lost exclusivity over the next 5 years

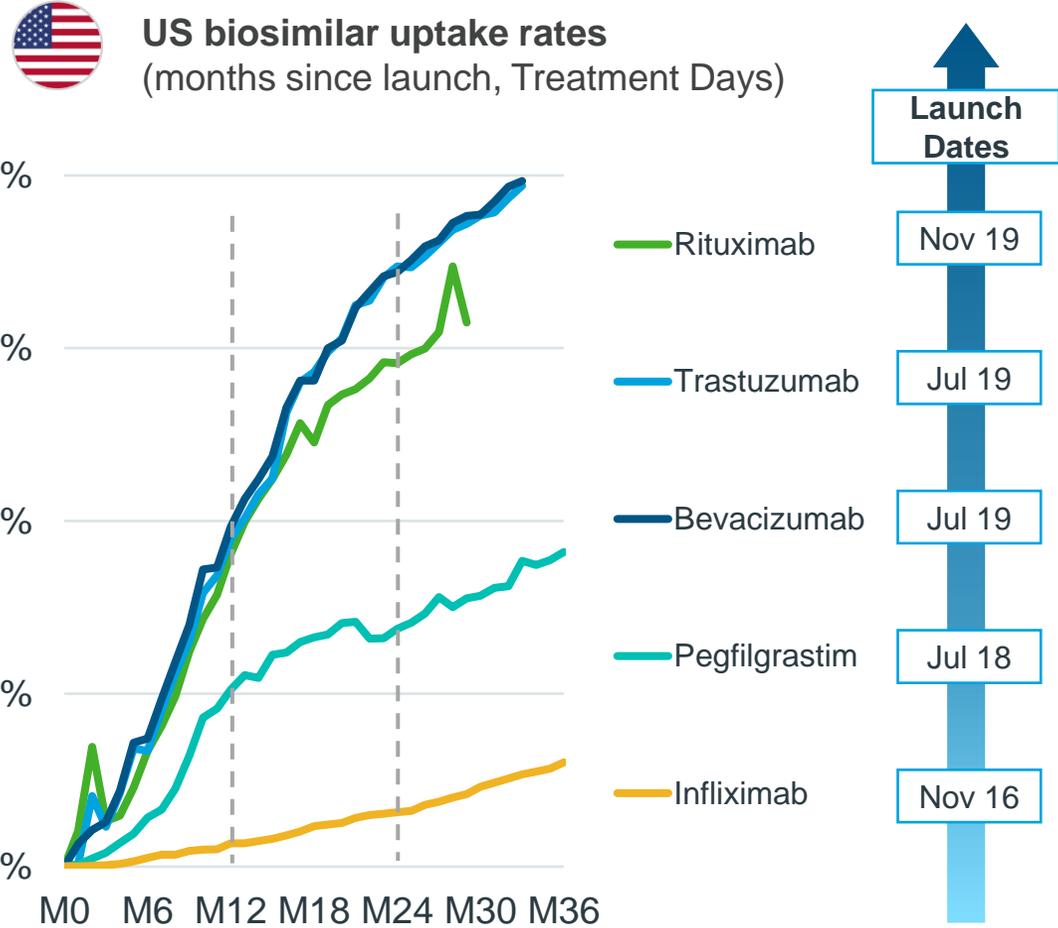
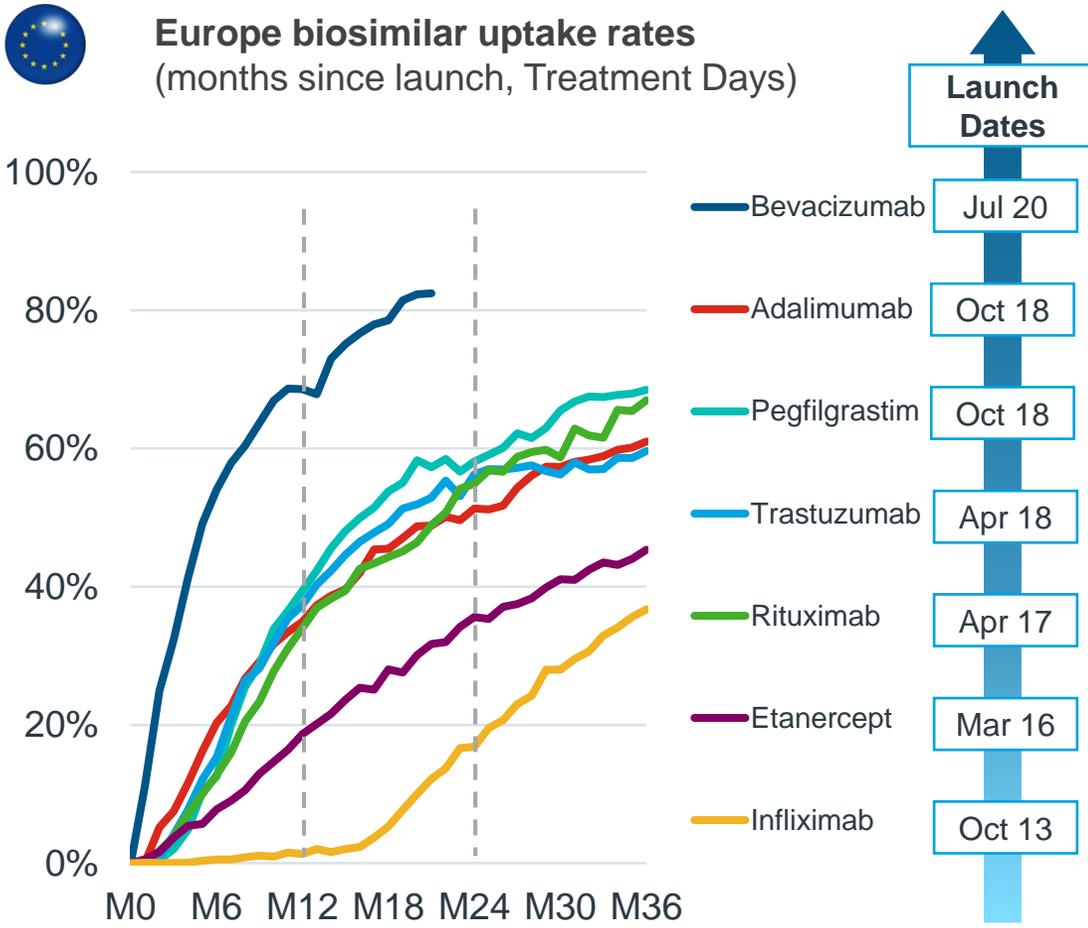
Developed markets impact of brand losses of exclusivity 2017–2026, US\$Bn



Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Nov 2021  
 The Global Use of Medicines 2022: Outlook to 2026. Report by the IQVIA Institute for Human Data Science

# Rate of uptake of subsequent biosimilars has accelerated as stakeholders become increasingly comfortable with biosimilars

*Biosimilar market averaging 40% after 12 months and likely 60% after 24*

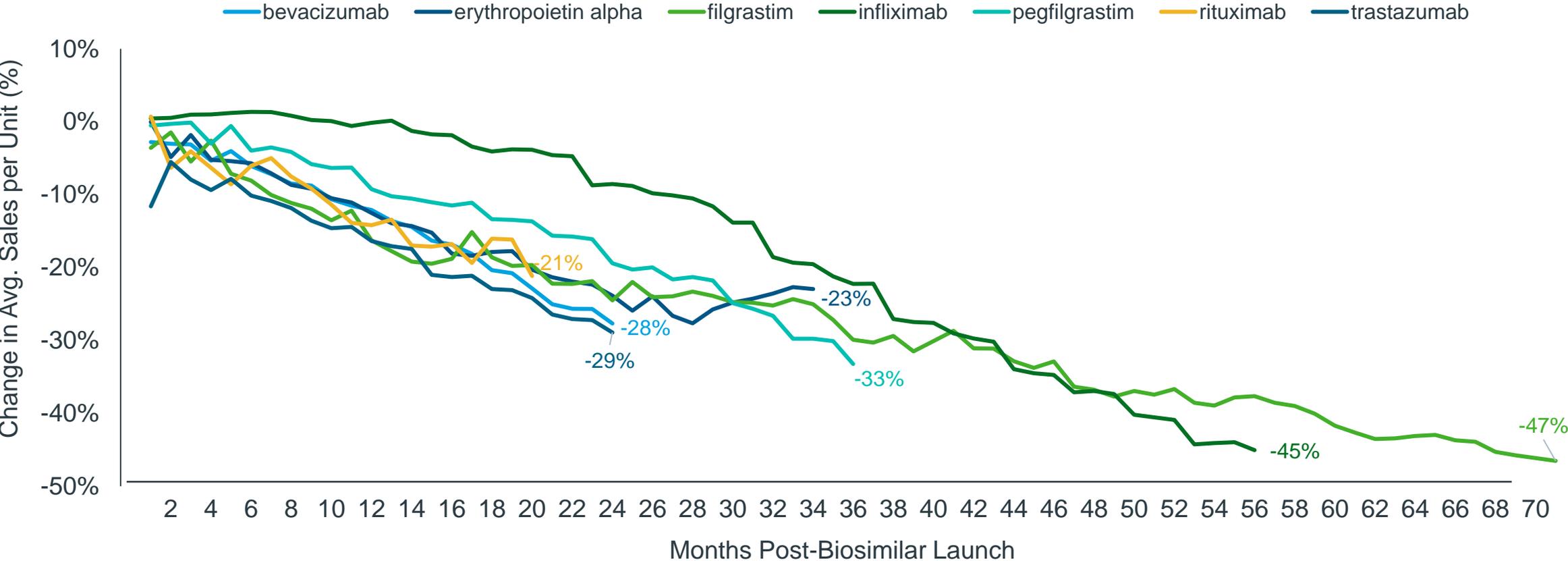


Notes: Includes subcutaneous formulations for rituximab, trastuzumab and infliximab  
Source: IQVIA European Thought Leadership; IQVIA MIDAS MTH Mar 2022

# In the U.S. market, per unit prices are declining by 10-30% after two years



## % Change in Average Sales per Unit Since Biosimilar Launch

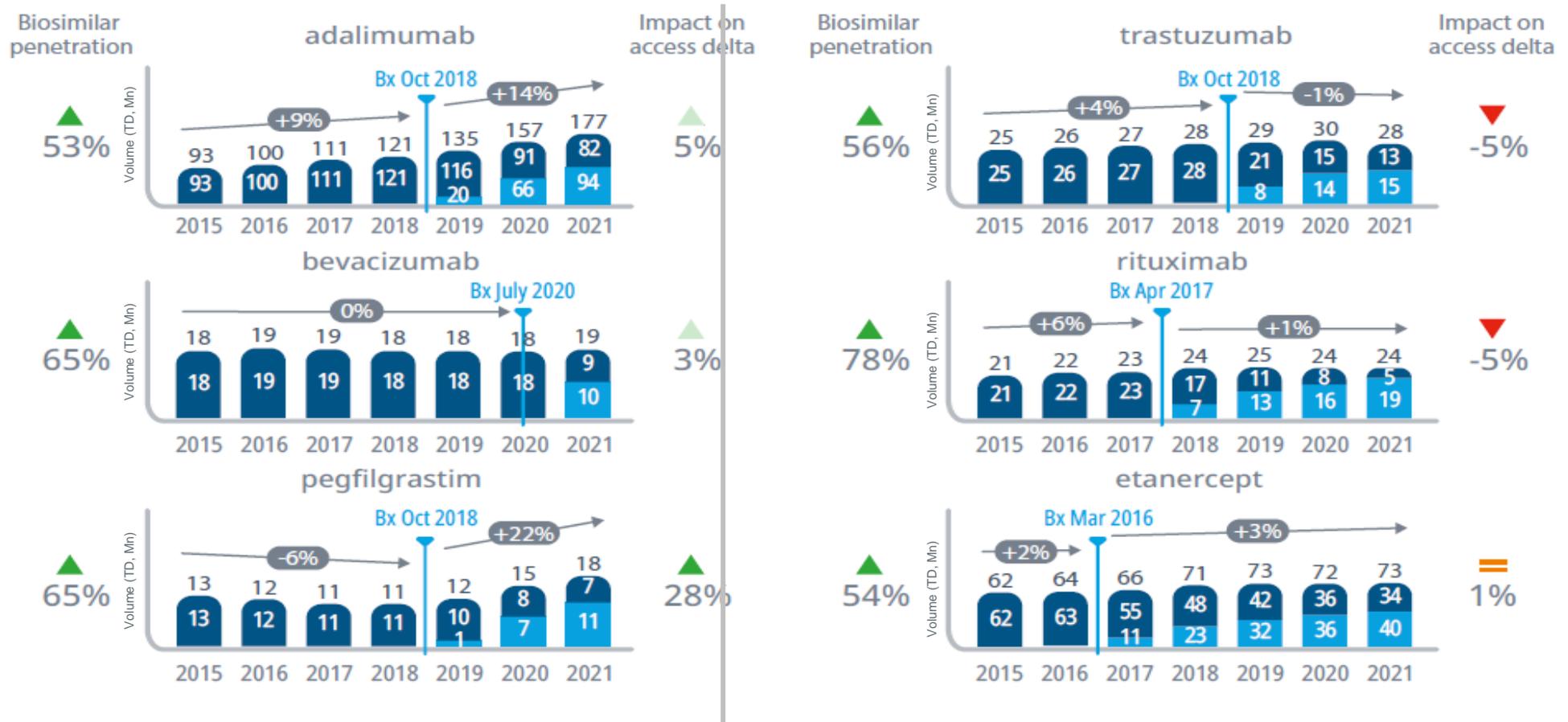


Source: IQVIA National Sales Perspective (NSP) data, US Market Access Strategy Consulting analysis

# While biosimilar penetration can be both rapid and significant, the overall increase in patient volumes does not always occur

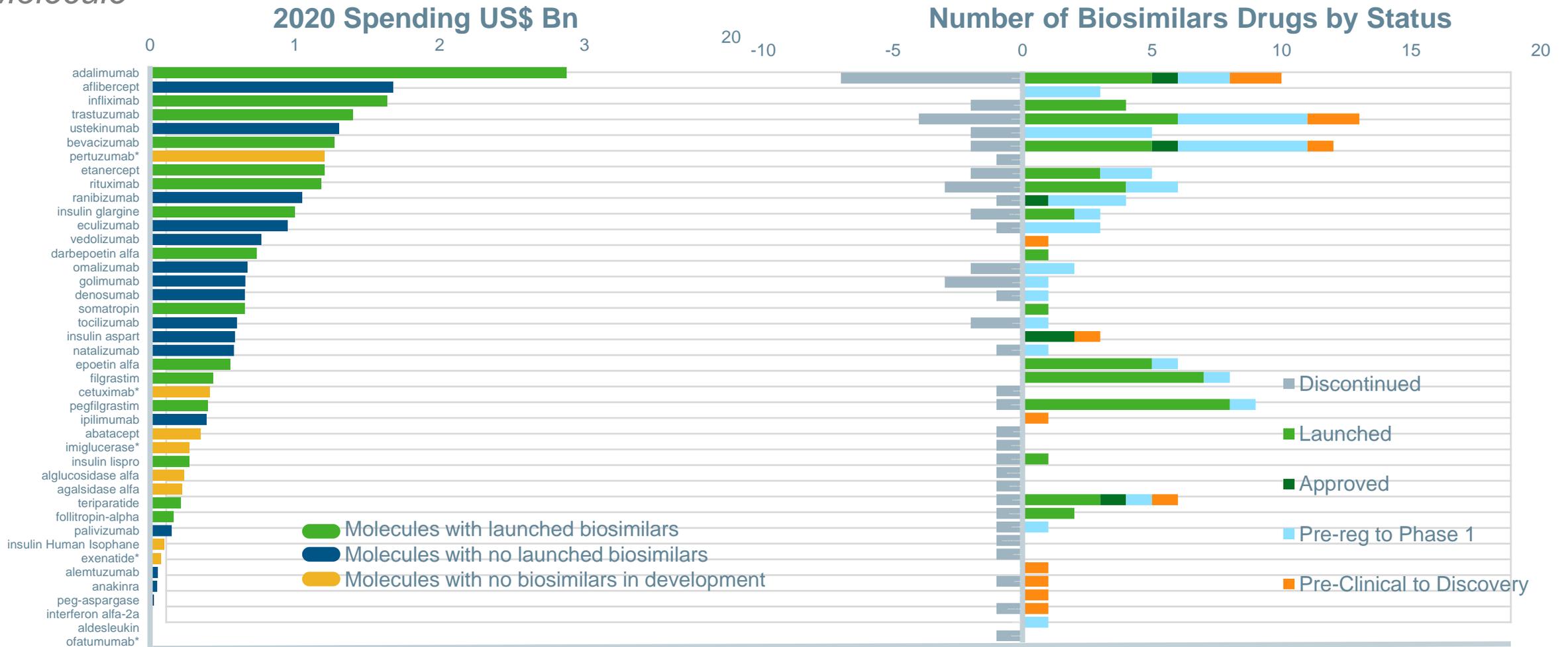
*European markets are seeing growing, flat, and declining patient volumes*

**Exhibit 6: Patient access to molecules with biosimilar competition**



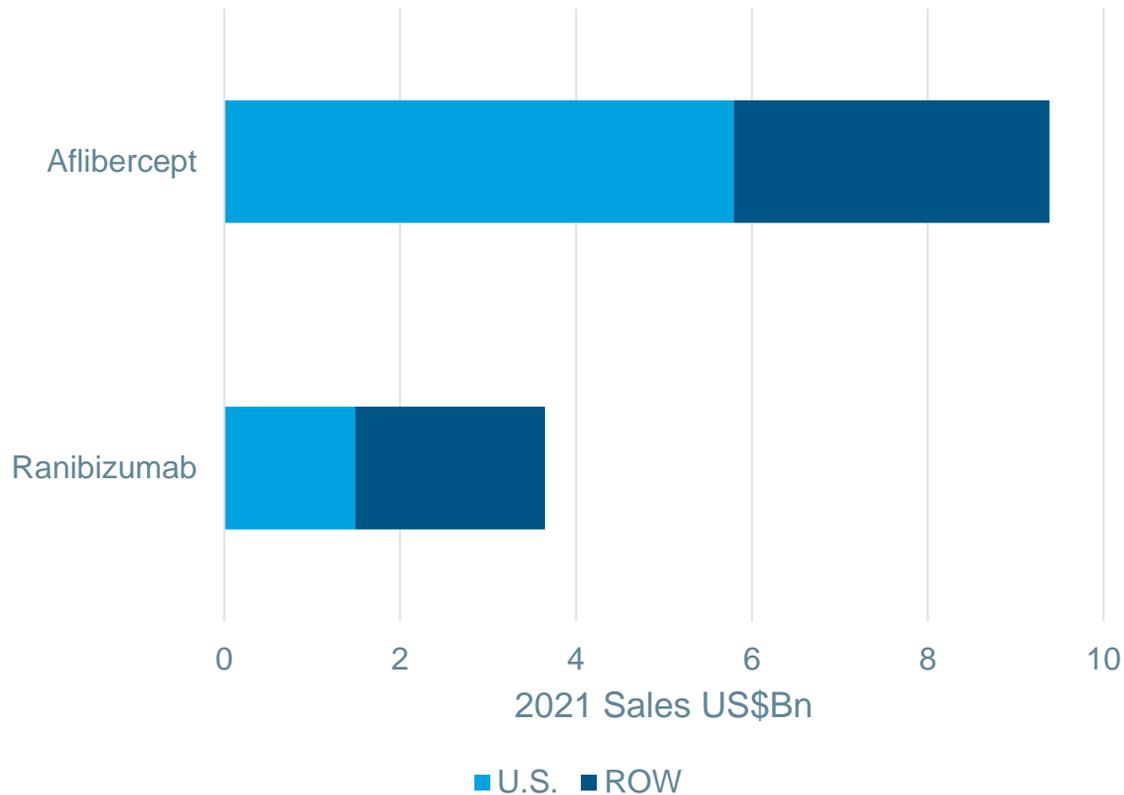
# Biosimilars are launched, approved, or in development for 33 molecules in Europe, though at different levels of competition

Current Total Molecule Spending and Approved, Launched and Pipeline Biosimilar Products for the Molecule

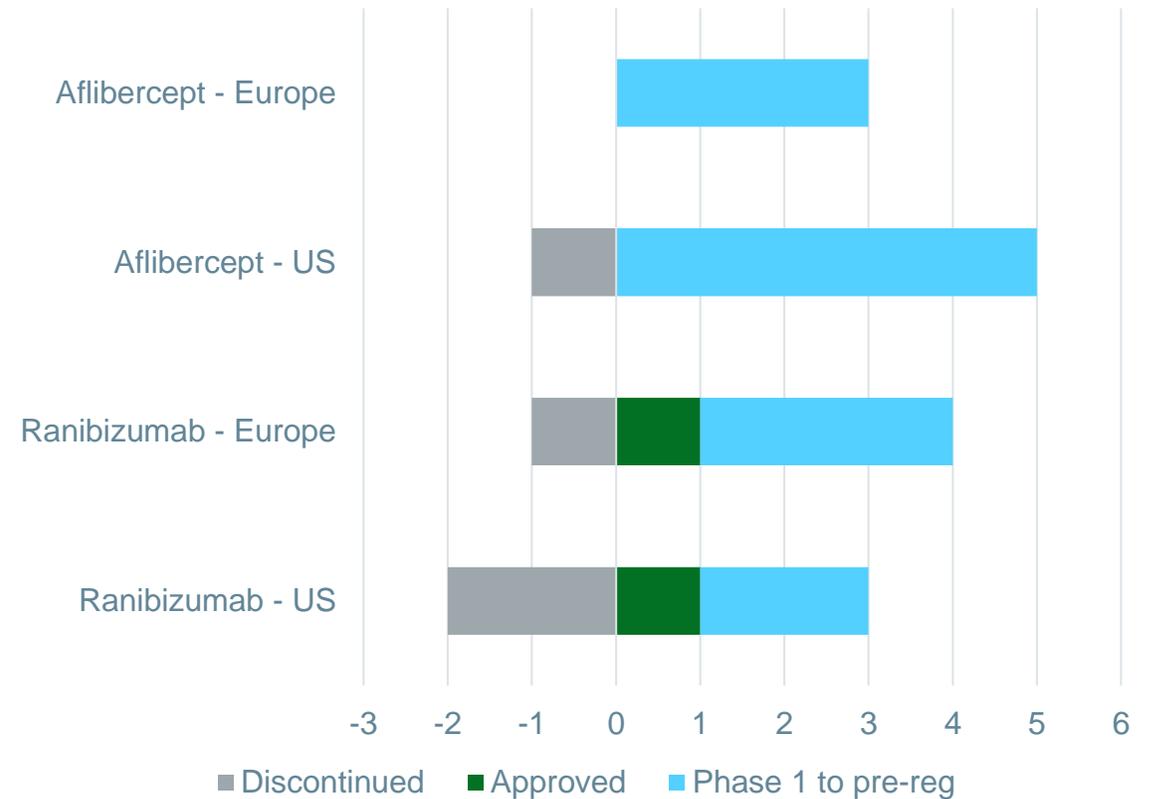


# Ophthalmic biosimilars are in development for both the US and European markets

## 2021 Net Reported Sales US\$ Bn



## Number of Biosimilars Drugs by Status



# Biosimilar sustainability includes multiple elements that work together to bring multi-stakeholder benefits

*Biosimilar sustainability is key to stakeholders unlocking both historic and future benefits*



*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** (patients, 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

# 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

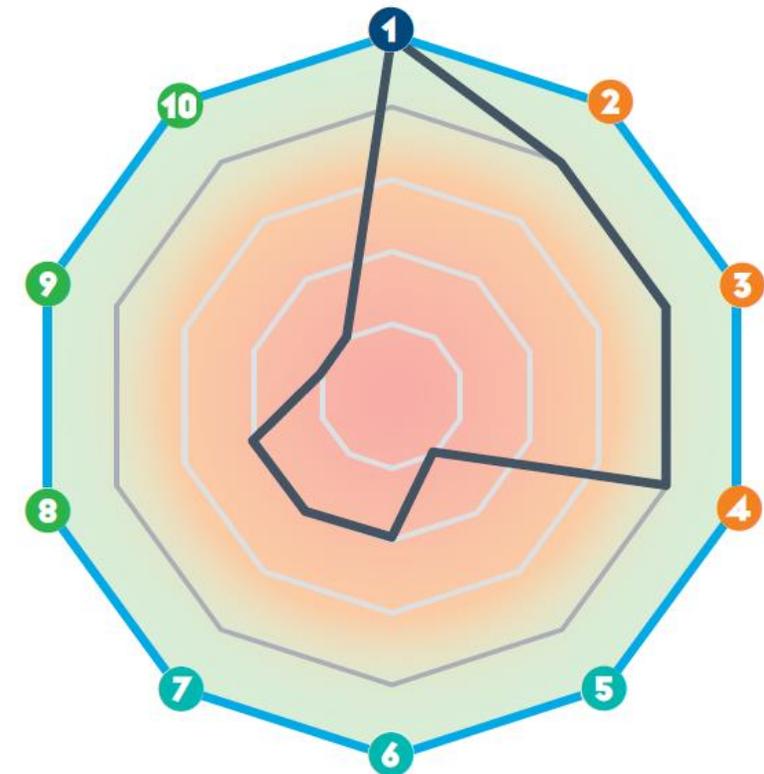
- 5 **Level of competition:** high level of competition with multiple players
- 6 **Pricing rules and dynamics:** prices driven by competition only
- 7 **Procurement:** systems which support competition and drive uptake in the market

## 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

\*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



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

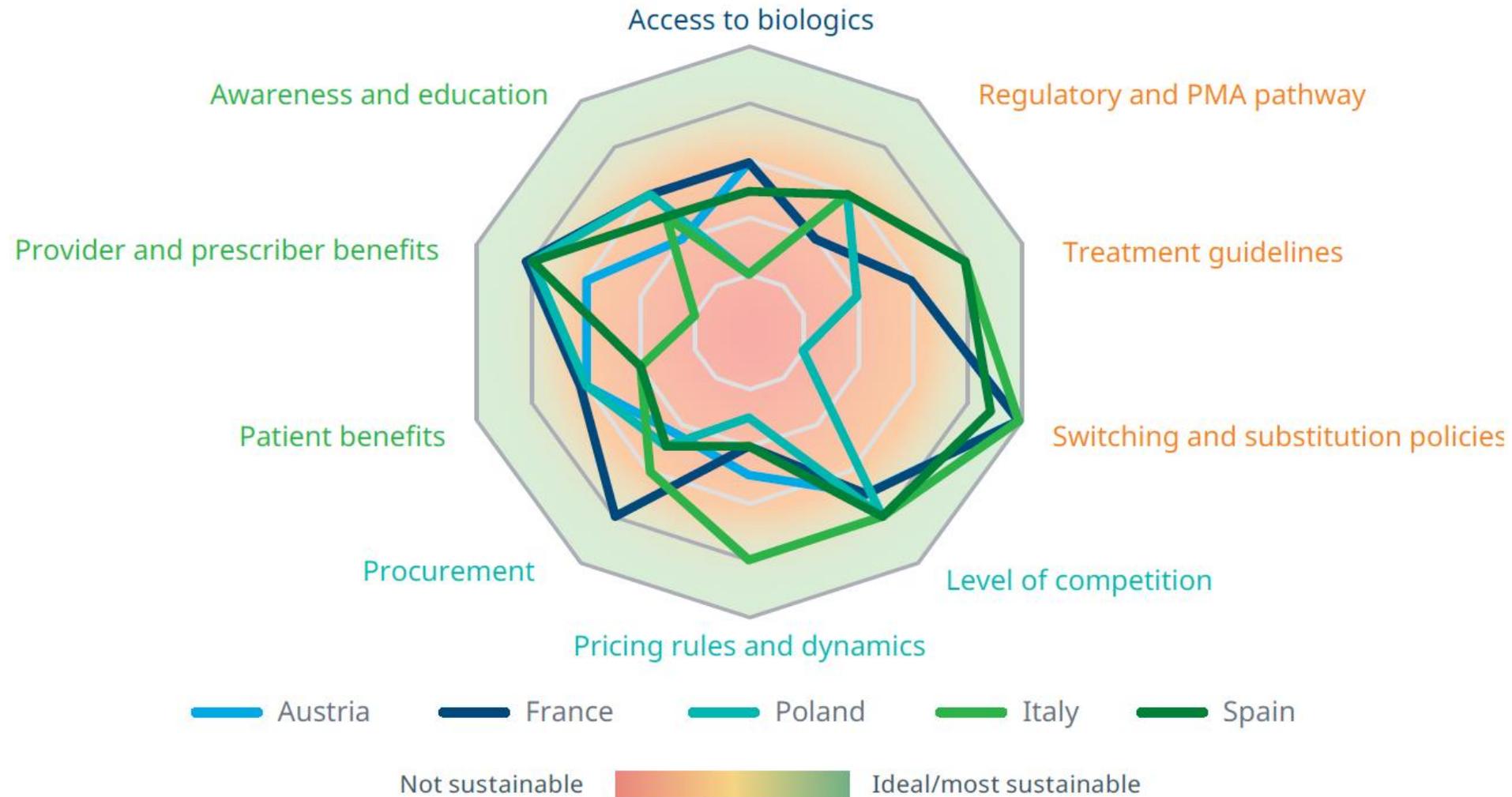
— Market A — Ideal market

Not sustainable — Ideal/most sustainable

# These criteria can be assessed on qualitative and quantitative bases

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	incentives to similar use	• 5: Incentives in place to encourage biosimilar use; 3: No significant incentives available; 1: Incentives in place to encourage use of the originator
	• 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	quotas or incentives for at 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
	• 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	price not subject to price cuts	• 5: Yes; 1: No - forced originator price cuts in place
	• 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	pricing not subject to price	• 5: No - competition drives pricing; 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	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
	• Comprehensive training / education for physician		eligibility relative to availability	• 5: Tender opens when biosimilar enters the market; 3: Variable; 1: Tender opens before biosimilar enters market
			tender award to	• 5: 4-6 months; 3: 2-4 months; 1: <2 months or >6 months
			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

# Each market – or subnational market – has a unique footprint



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

# Summary

- Biosimilars are an essential element of sustainable healthcare systems, with significant potential contribution to competitive markets
- Defining 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