



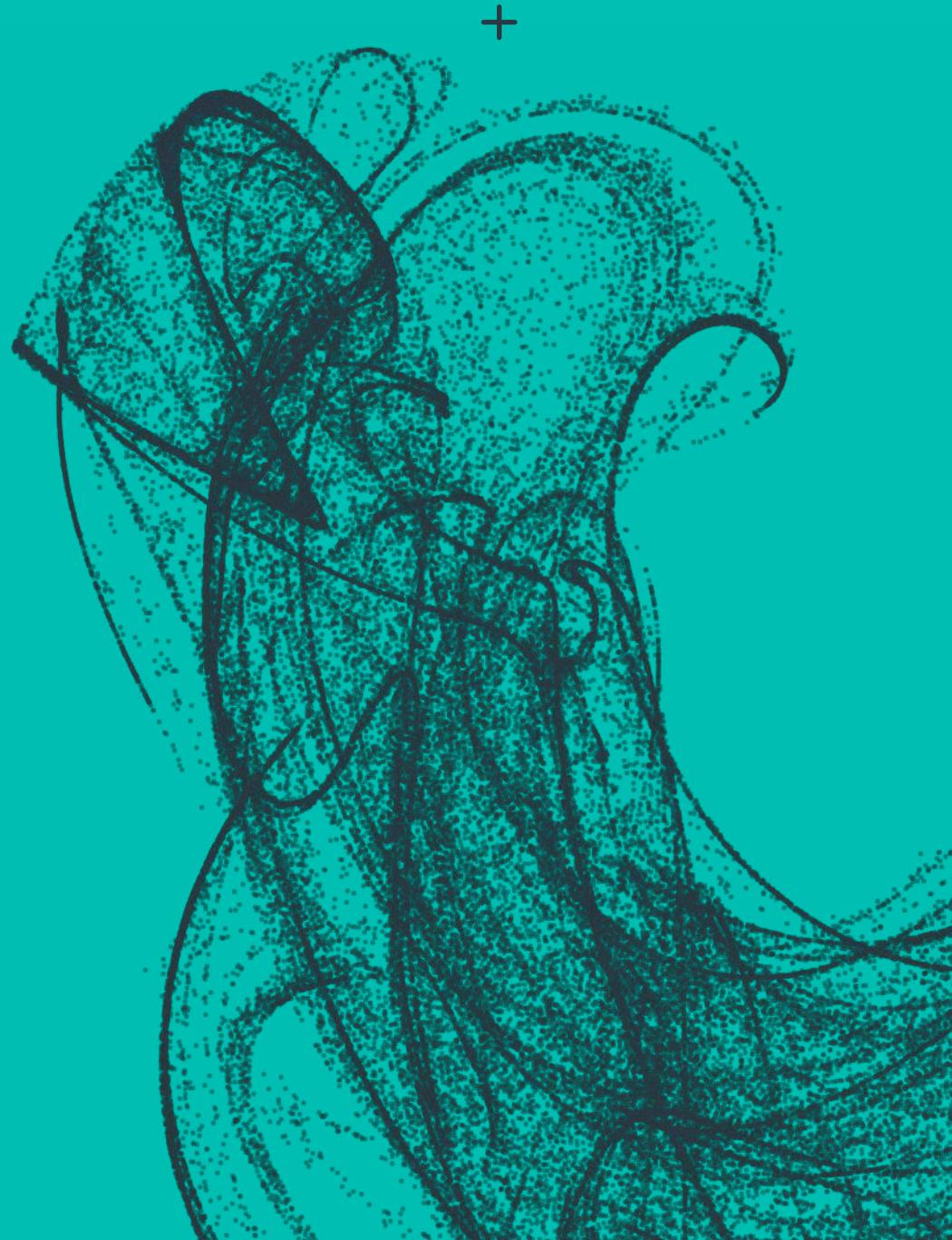
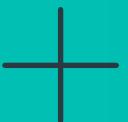
Global Perspectives on Biosimilar Markets and Sustainability

International Federation on Ageing Roundtable

JUNE 28, 2022

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

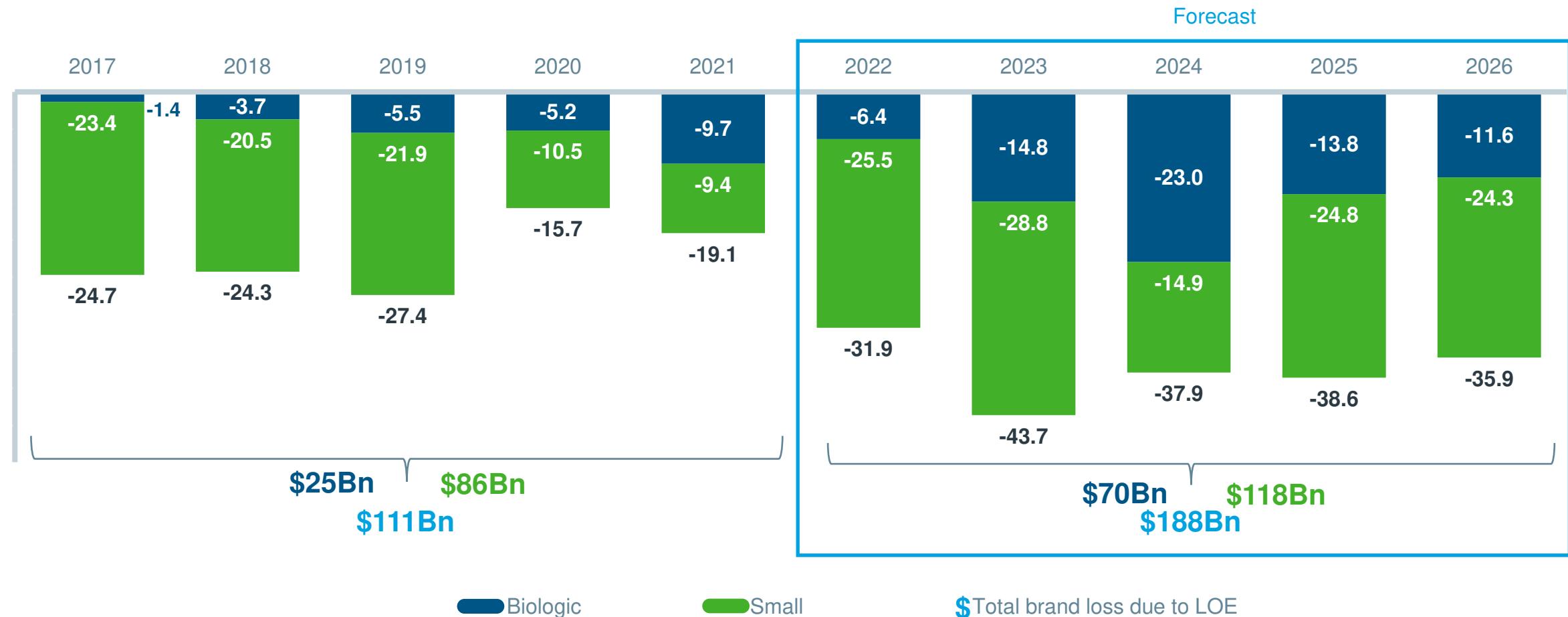
Spending and growth drivers 2016–2026 const US\$Bn



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



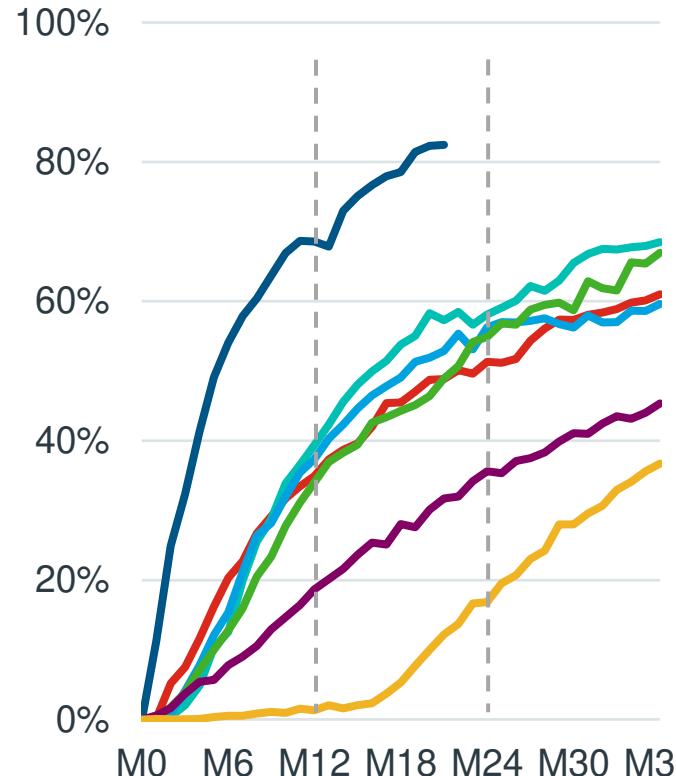
Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Nov 2021
The Global Use of Medicines 2022: Outlook to 2026. Report by the IQVIA Institute for Human Data Science

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

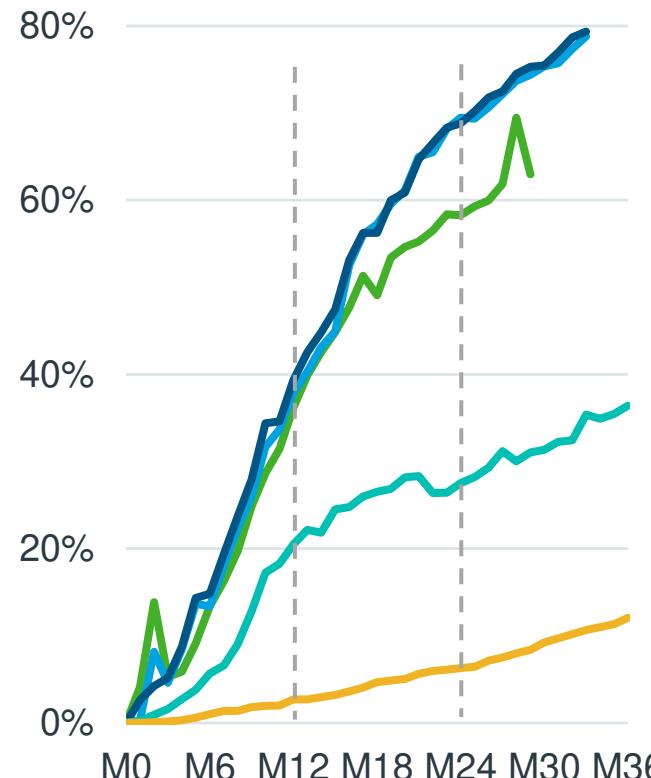
Biosimilar market averaging 40% after 12 months and likely 60% after 24



Europe biosimilar uptake rates
(months since launch, Treatment Days)

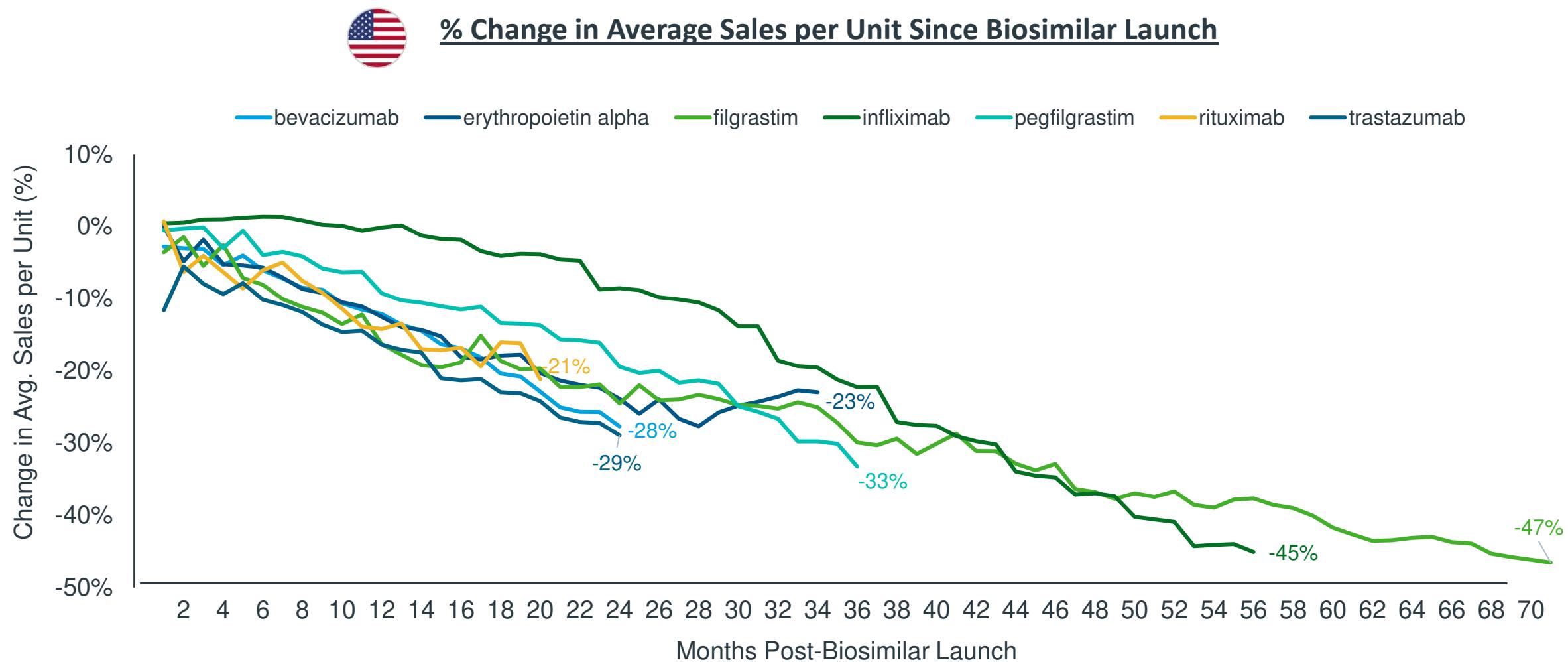


US biosimilar uptake rates
(months since launch, Treatment Days)



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

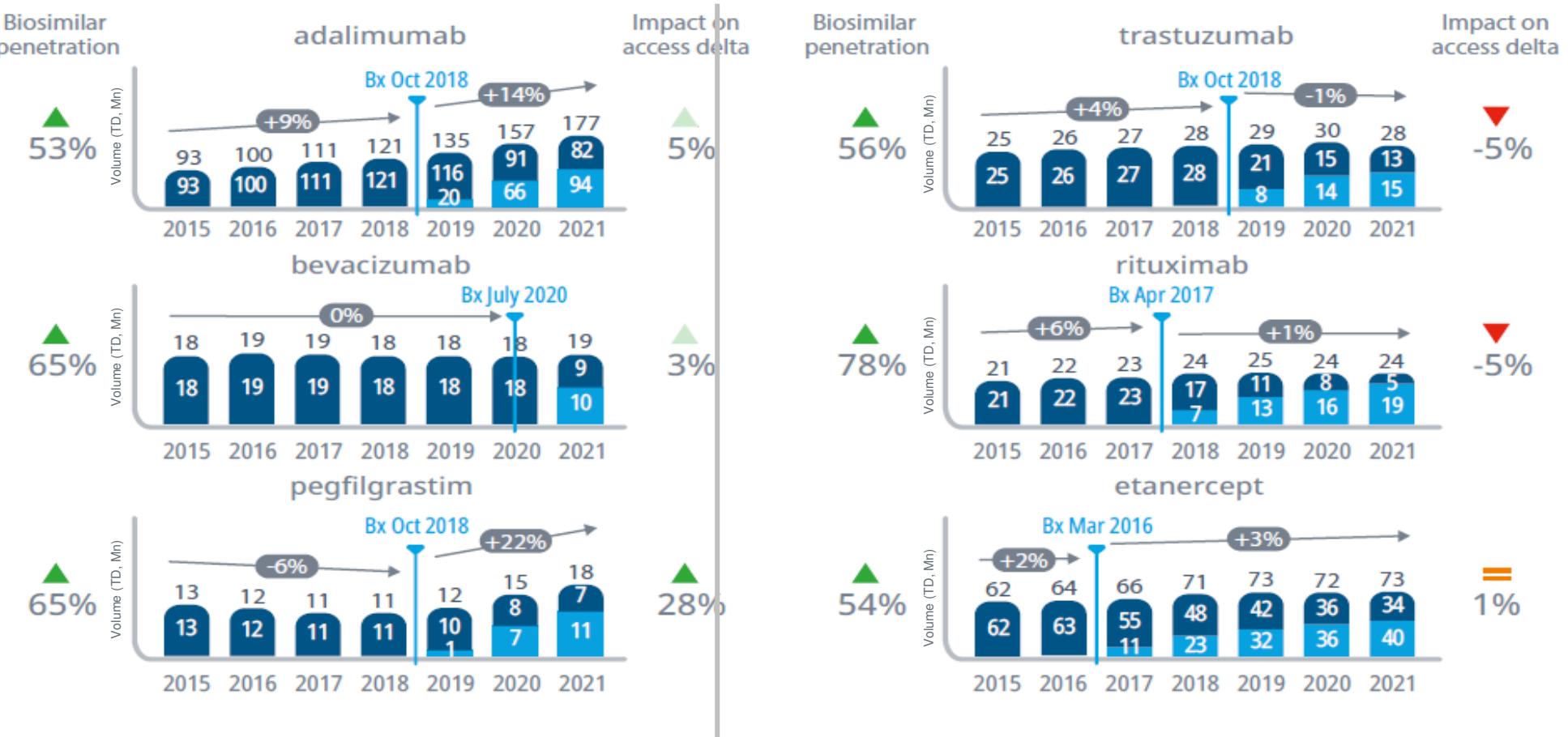
In the U.S. market, per unit prices are declining by 10-30% after two years



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

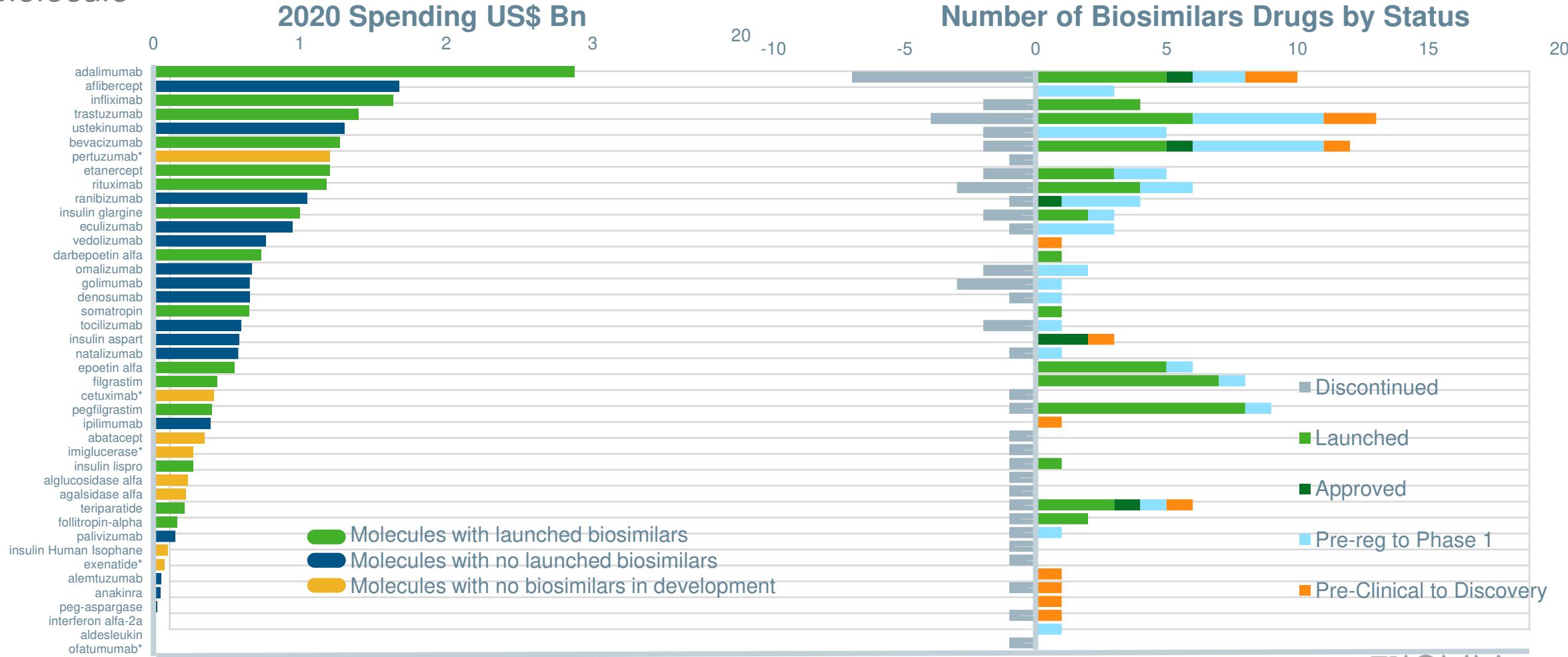
European markets are seeing growing, flat, and declining patient volumes

Exhibit 6: Patient access to molecules with biosimilar competition



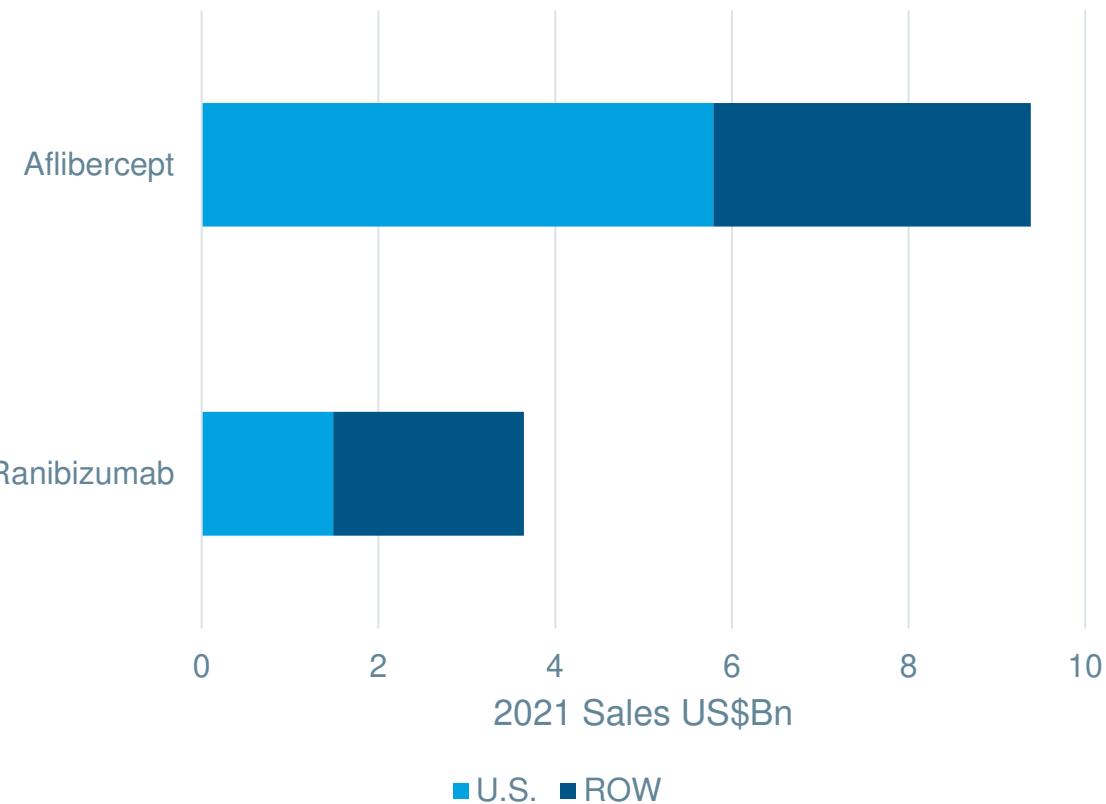
Biosimilars are launched, approved, or in development for 33 molecules in Europe, though at different levels of competition

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

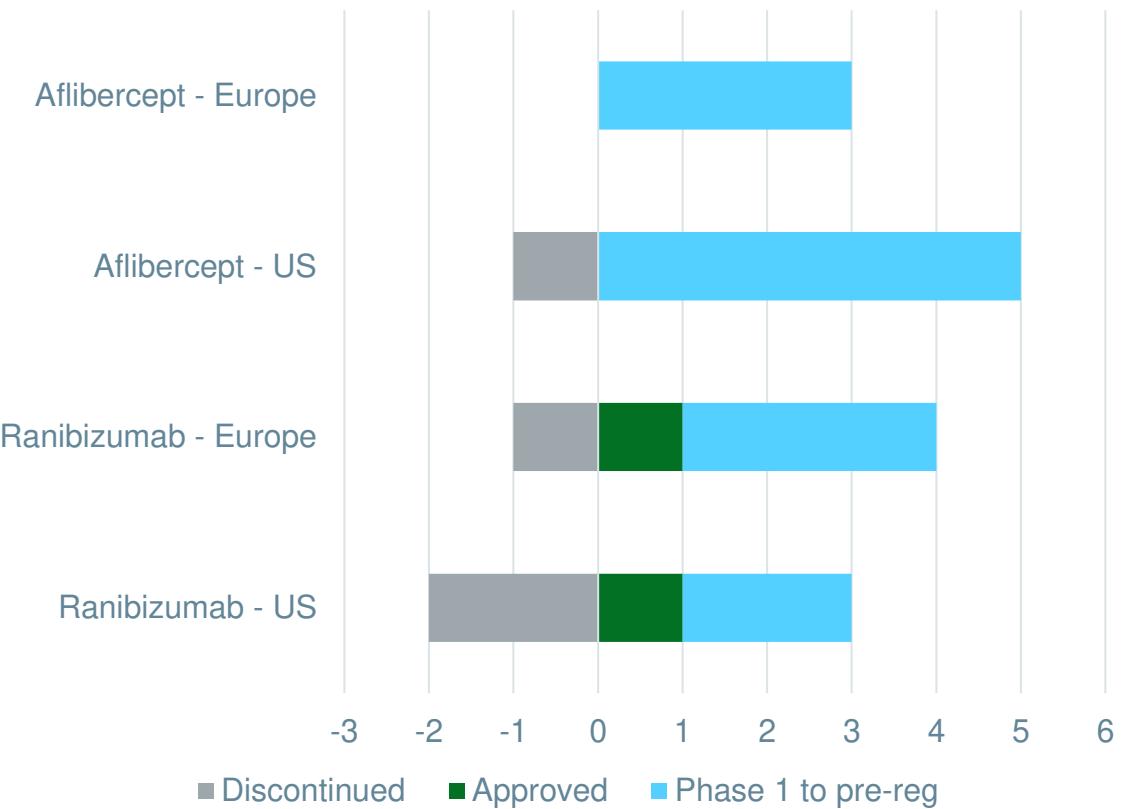


Ophthalmic biosimilars are in development for both the US and European markets

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

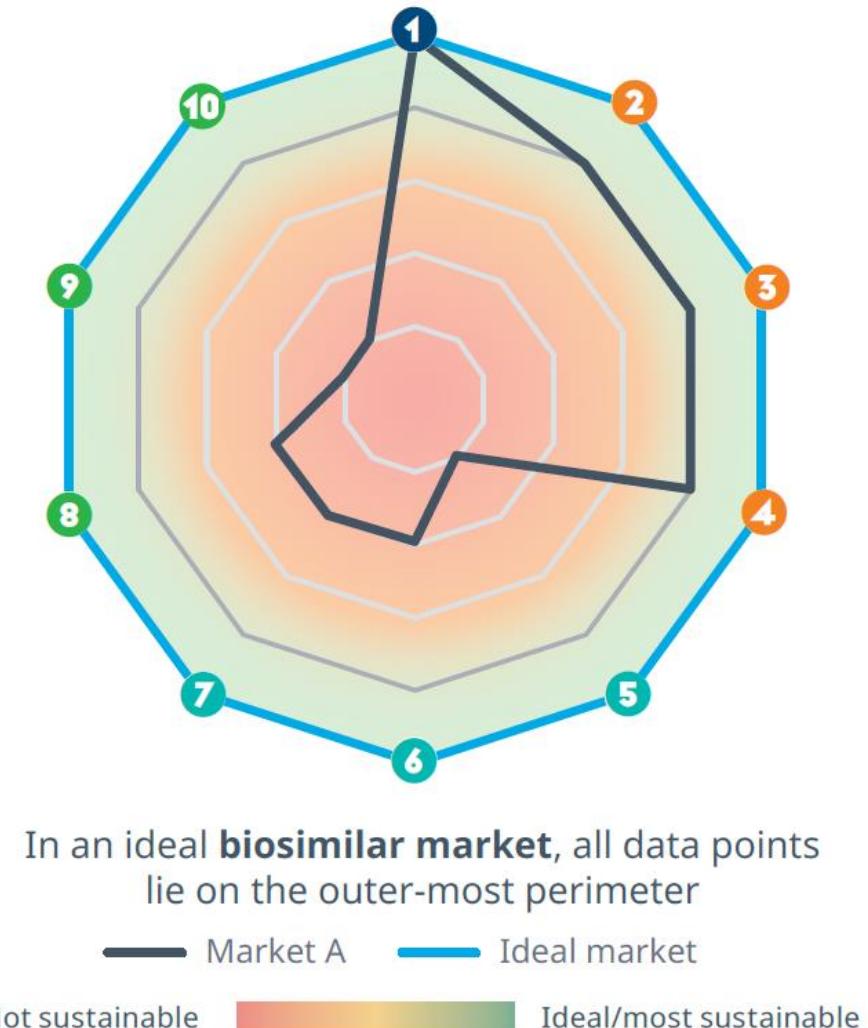
② **Regulatory and PMA pathway:** ensuring timely access to biosimilars following EMA approval
③ **Treatment guidelines:** recommending biosimilar use
④ **Switching and substitution policies:** at physicians' discretion while preventing automatic pharmacy substitution

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



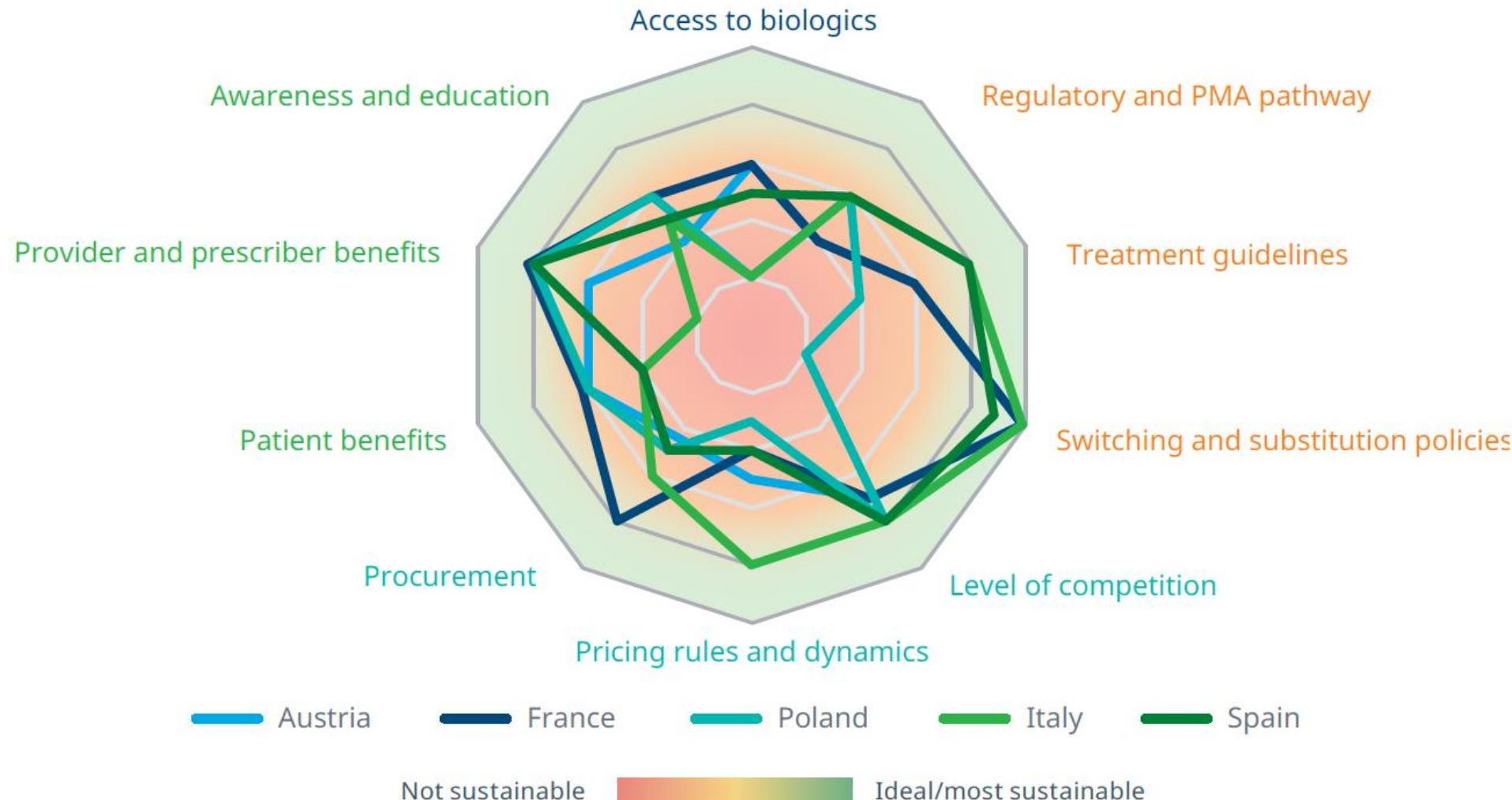
*Defined as >25% increase in DDD per capita

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

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	ntives 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	rice 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	cing 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	tracts	• 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		ing relative to availability	• 5: Tender opens when biosimilar enters the market; 3: Variable; 1: Tender opens before biosimilar enters market
			ender 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.

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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