NM16

IMS Health & Quintiles are now IQVIA™

The Impact of Biosimilar Competition in Europe

October 2019

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Slide 1

NM16 DEADLINE FIRST: EOB 29

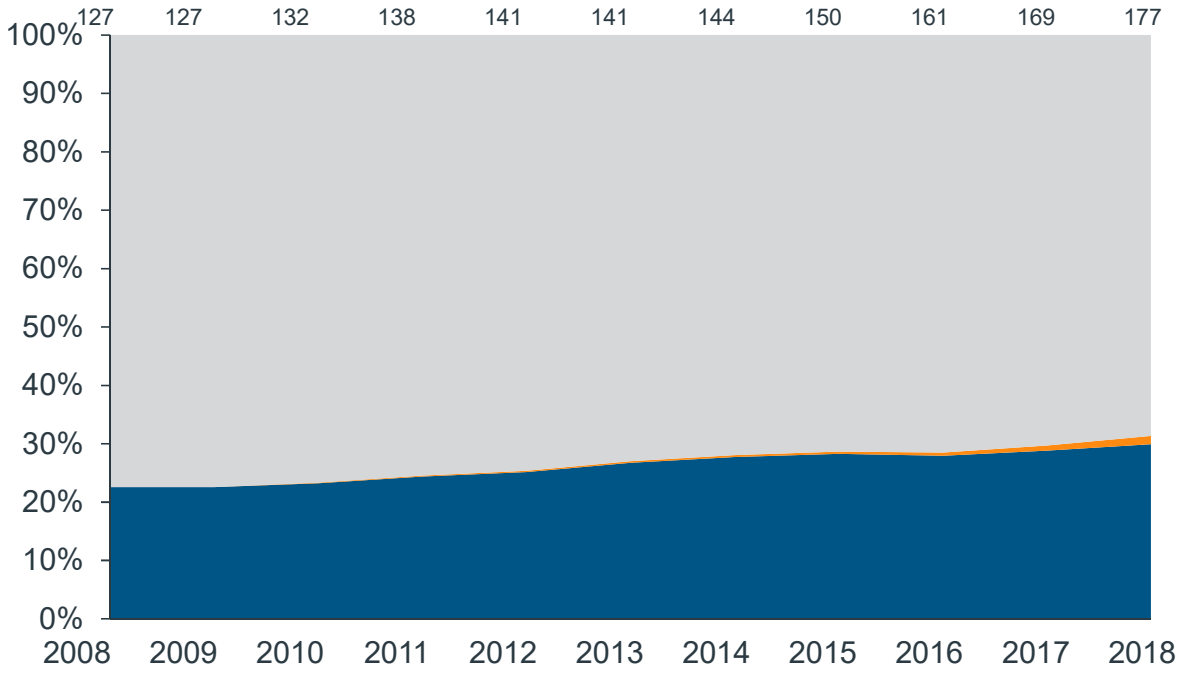
Newton, Max; 28/10/2019

Table of Contents

NM2

Biosimilar spending is nominal across Europe, but growing rapidly to counteract the impact of originator biologics

Proportion of European healthcare spending on biologic molecules 2008 – 2018 (LCEUR Bn)



Growth measure	Biologics	Biosimilars	Other
% market share	29.9%	1.5%	68.7%
YoY growth	8.3%	71.9%	1.3%
5yr CAGR	5.7%	40.2%	3.1%

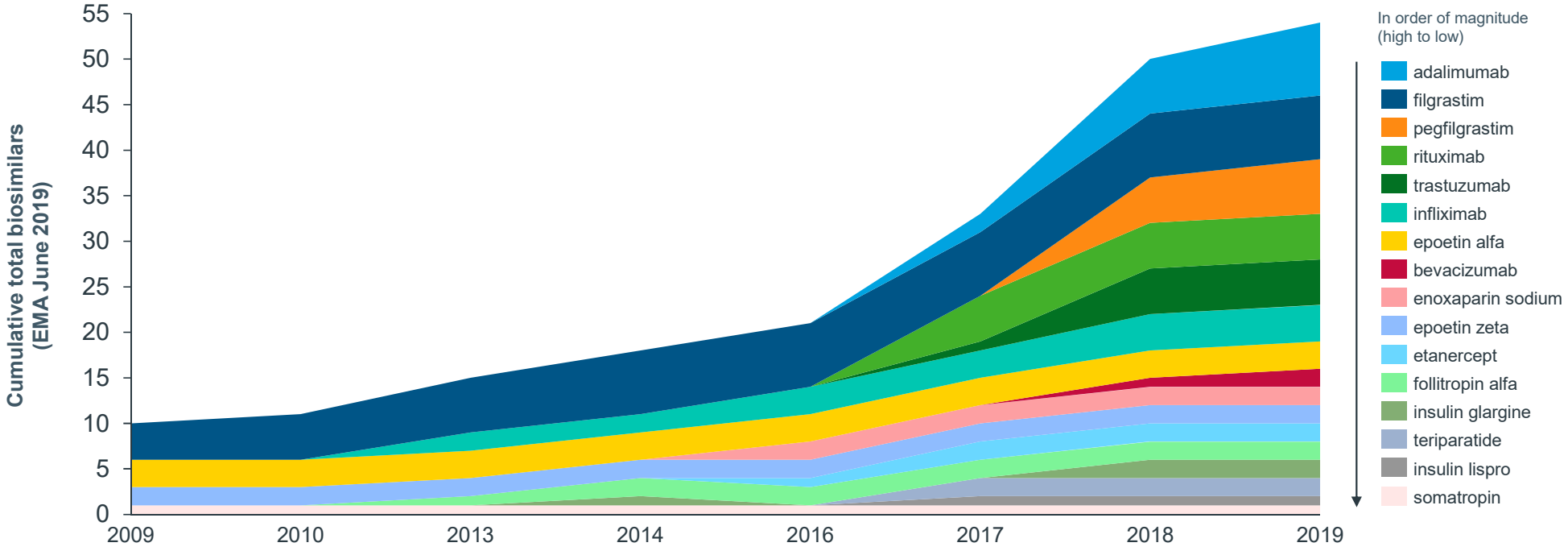
Source: IQVIA MIDAS MAT 2019 full year data; biologic split by IQVIA MIDAS definitions
Notes: YoY = year on year (2017 to 2018); 5 year CAGR growth between (2013 – 2018)

NM2 HEADLINE

Newton, Max; 28/10/2019

There are an increasing number of biosimilar medicines launched in Europe in the past 10-years

Biosimilar numbers and reference products



IQVIA Pipeline Intelligence – New Product Information insights Q2 2019; IQVIA Global Supplier & Association Relations analysis 2019

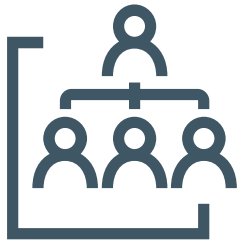
Why are biosimilars so important in Europe?

Balances spending

- Pharmaceutical spending is rapidly increasing, biosimilars counteract the rising cost of medicines

Allows new innovation

- Creating savings across healthcare systems frees up funds which can be spent on new, innovative medicines



Expands biologics access

- Cost and restrictions on biologics is often a limiting factor to patient access, biosimilars alter this paradigm

Agenda

+ Introduction and biosimilar outlook
+ **IQVIA report for DG GROW**
+ Key observations

Background

- This document sets out to describe the effects on price, volume and market share following the arrival and presence of biosimilar competition in the Europe*.
- It has been prepared as a set of indicators to monitor the impact of biosimilars in the European markets.
- It was prepared by IQVIA at the request of the DG Grow, with initial contributions from EFPIA, Medicines for Europe, and EuropaBio.
- Previous reports were published using 2014, 2015, 2016, and 2017 data, and this report uses full year 2018 data.
- EMA has a central role in setting the rules for biosimilar submissions, approving applications, establish approved indications and monitor adverse events, and if necessary issue safety warning. IQVIA have, when appropriate, quoted their information and statements.

*Europe: Austria, Belgium, Bulgaria, Czech, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, UK

IQVIA report for DG GROW

The Impact of Biosimilar Competition

- IQVIA has prepared as a set of indicators to monitor the impact of biosimilars in the European markets at the request of the European Commission services with initial contributions from EFPIA, Medicines for Europe, and EuropaBio.
- The report sets out to describe the effects on price, volume and market share following the arrival and presence of biosimilar competition in the EEA.

Observations by IQVIA

- In this document IQVIA suggests a number of key observations based on the data from the report.

Reading guide

- IQVIA has developed a simplified guide to read the report that has a broad set of KPIs for multiple countries.
- EPO and Austria are used as the example.

Previous reports were published using 2014, 2015, 2016, and 2017 data, and this report uses full year 2018 data.

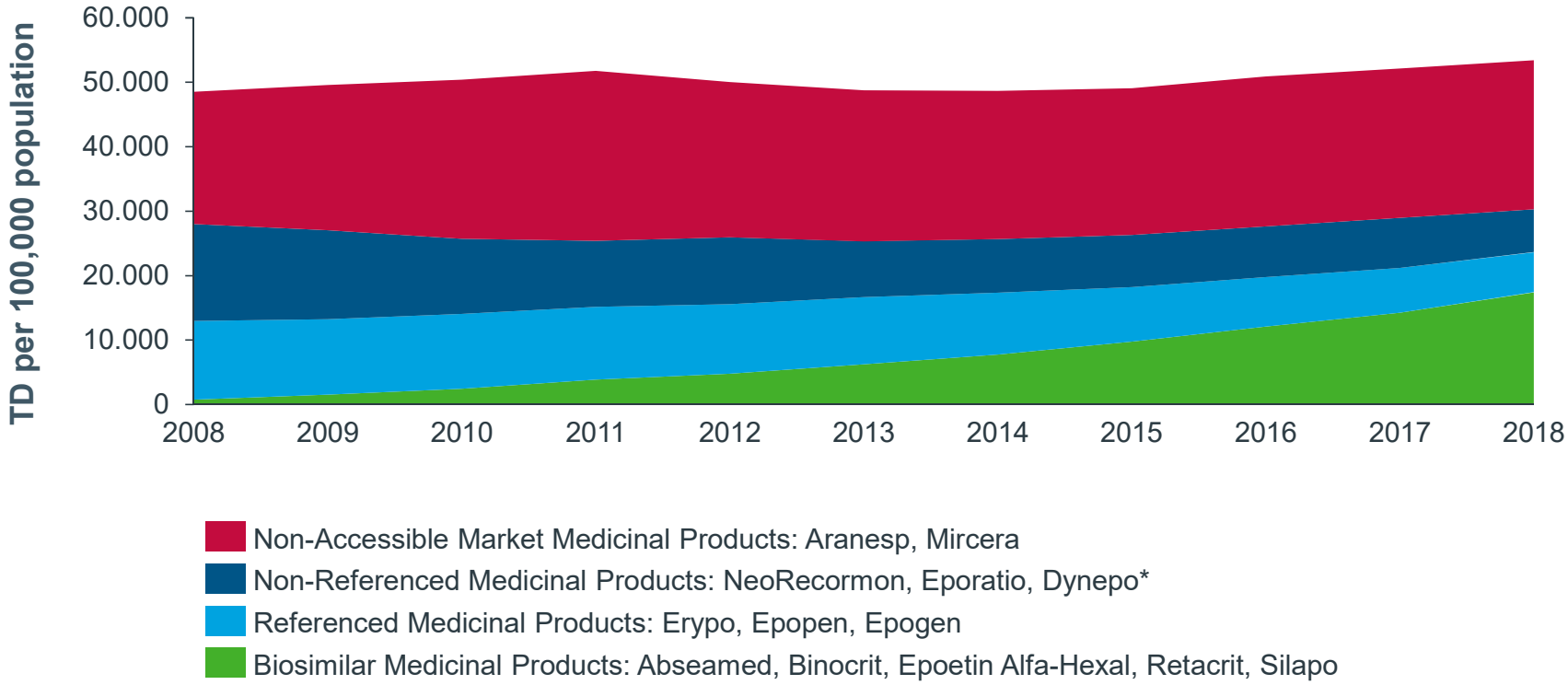
Countries included in the document are 23 European countries: Austria, Belgium, Bulgaria, Czech, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, UK

Basic terms used in the report

- **Accessible category**; products within the same ATC4 code including the following three product categories:
  - **Referenced Medicinal Product**: Original product, granted market exclusivity at the start of its life, exclusivity has now expired and the product has been categorised as referenced.
  - **Non Referenced Medicinal Product**: Original product, granted market exclusivity at the start of its life, exclusivity has now expired and the product has never been categorised as a Referenced Medicinal product, or may have been referenced but the referencing biosimilar has not been launched.
  - **Biosimilar Medicinal Product**: Product, granted regulatory approval, demonstrating similarity to the reference medicinal product in terms of quality characteristics, biological activity, safety and efficacy.
- **Non-accessible category:** Products within the same ATC4 code as the accessible category products, and are typically second generation version of biosimilar molecules; this category may include products with different dosing schedules and /or route of administration to those in the accessible category.
- **Total market**; includes both the Accessible and the Non-accessible product markets.

EPO market shows continued market growth in treatment days driven by growth of biosimilars

KPI example: Volume development



NM7

EPO market share has increased +5%, price remains unchanged, and total market volume share has grown +2% since 2017

KPI example: volume share, price evolution, and volume evolution

	Market share TD (2018)			Price per TD (2018/Yr before BS entry)			Volume TD (2018/Yr before BS entry)					
	Biosimilar vs Referenced product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	TD per capita	TD/capita (Yr before BS entrance)	First Recorded sales of Biosimilars
AU	80%	35%	23%	-40%	-42%	-30%	-2%	-3%	-25%	0.69	0.92	2008
BE	14%	9%	2%	-3%	-2%	2%	-31%	-23%	7%	0.56	0.52	2014
BU	100%	78%	50%	-1%	-33%	-20%	82%	19%	42%	0.34	0.24	2011
CZ	74%	38%	19%	-56%	-48%	-38%	299%	110%	204%	0.28	0.09	2011
DK	30%	8%	0%	-10%	-2%	-17%	-93%	-97%	-8%	0.44	0.48	2010
FI	100%	76%	12%	-47%	-43%	-27%	1541%	-47%	15%	0.38	0.33	2008
FR	62%	42%	16%	-35%	-34%	-33%	15%	-23%	5%	0.94	0.90	2009
DE	84%	73%	46%	-54%	-57%	-47%	75%	-3%	-5%	0.37	0.38	2007
GR	88%	87%	81%	-51%	-52%	-50%	393%	195%	109%	0.04	0.02	2008
HU	100%	56%	34%	-78%	-48%	-30%	52%	19%	-13%	0.31	0.36	2009
IE	98%	19%	7%	-33%	-34%	-21%	61%	-52%	-19%	0.40	0.50	2008
IT	79%	74%	61%	-16%	-14%	-10%	212%	89%	46%	1.21	0.83	2008
NL	60%	15%	3%	-51%	-44%	-35%	-84%	-68%	-38%	0.33	0.52	2009
NO	57%	13%	1%	314%	54%	-2%	-72%	-76%	11%	0.23	0.20	2008
PL	100%	84%	20%	-63%	-58%	-27%	4758%	19%	217%	0.09	0.03	2009
PT	93%	30%	21%	-79%	-79%	-65%	224%	139%	11%	0.49	0.45	2010
RO	95%	74%	44%	-58%	-52%	-43%	87%	-72%	-60%	0.12	0.30	2009
SK	100%	74%	56%	-60%	-57%	-52%	345%	60%	12%	0.50	0.45	2010
SL	62%	32%	11%	-47%	-52%	-49%	-41%	-46%	9%	0.57	0.52	2009
ES	70%	57%	35%	-31%	-31%	-20%	55%	-8%	-11%	0.62	0.69	2009
SE	93%	40%	26%	-29%	-40%	-30%	45%	13%	-2%	0.45	0.46	2008
CH	25%	7%	1%	-51%	-45%	-41%	-45%	-52%	15%	0.38	0.33	2009
UK	5%	3%	1%	-13%	-21%	-13%	110%	9%	44%	0.34	0.24	2009
EU	**74%**	**58%**	**33%**	**-31%**	**-33%**	**-27%**	**92%**	**10%**	**10%**	**0.53**	**0.49**	

Slide 13

NM7 add in anuimations to show focus by focus on the final column of each segment
Newton, Max; 28/10/2019

Caveats to the DG Grow report 2019

- The indicators are intending to give a broad overview of the uptake and the implications on price and volume evolution after introduction of biosimilar medicines. There are differences in perspective between payers, providers, and different types of manufacturers. In focusing on the payers there are a few key caveats that needs to be made in interpreting the results:
- **Pricing and discounts**: the report is based on publicly available LIST prices. Discounting occurs, especially in contracting with hospitals and in countries using tenders for biological drug procurement, which can lead to larger price fluctuations than is visible through the reported IMS data.
- **Approved indications and efficacy**: not all products in a specific product group in the accessible, non-accessible or total market have the same approved indications and can have differences in efficacy and individual patient outcomes. Biosimilars normally receive the same indications as the referenced products and are inferred expected to have similar the same safety and efficacy.
- **Volume estimates:** the pack volumes reported is based on IMS collected data which may have been unknowingly impacted by issues such as parallel exporting. The volumes have been converted to daily doses using the published World Health Organization (WHO) defined daily doses (DDD) which can introduce bias. Consumption measures are therefore not adjusted for clinical practice guidelines, patient characteristics, indications for which the molecule is used, or other factors that may result in different volumes utilised on a per patient treatment day basis.

Table of Contents

During the research, 5 key observations were noted which have the greatest impact on the future of biosimilars in Europe

1. **Biosimilar competition has a significant potential to impact overall drug spend**

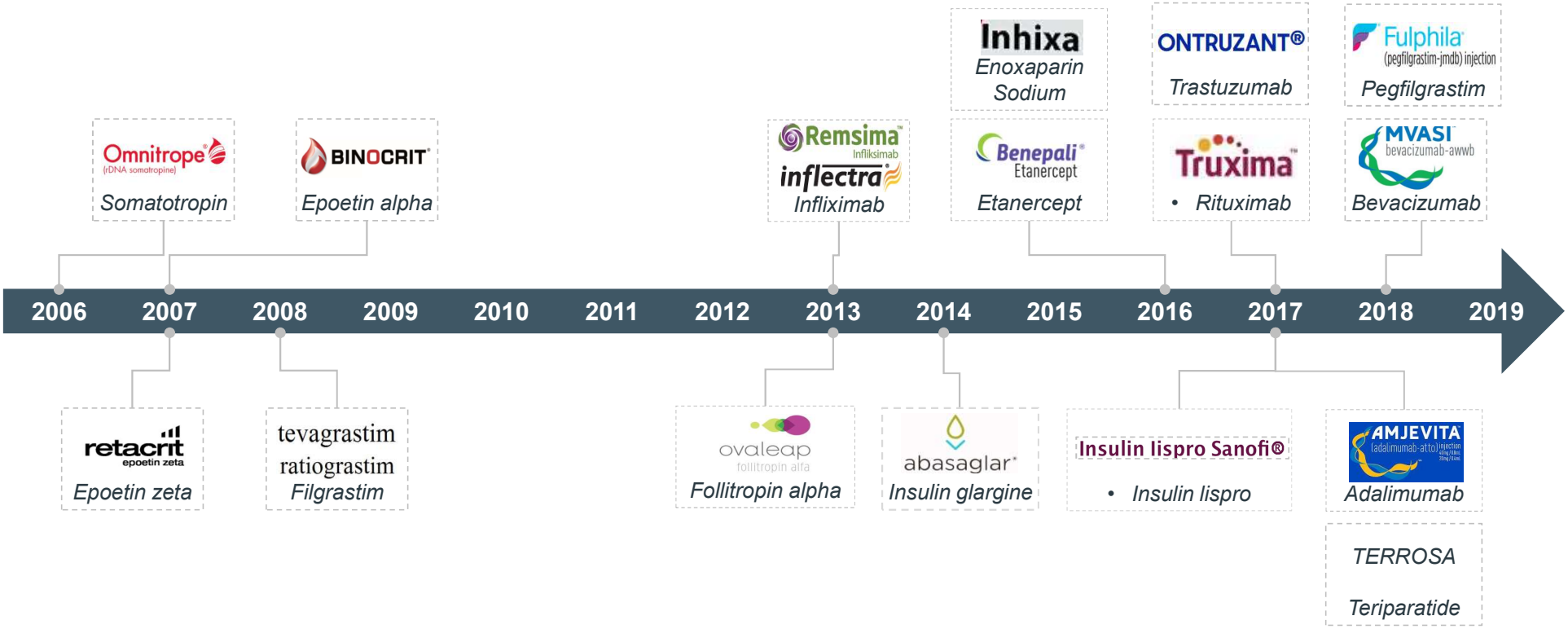
2. **Major products see fast uptake and large price reductions**

3. **Originator manufacturers have changed strategy to stay competitive**

4. **Access is not yet increasing for all molecules and in all countries after biosimilar introduction**

5. **More is needed to create a sustainable market for biosimilar manufacturers**

Biosimilars for 16 biologic molecules have been approved in Europe since 2006

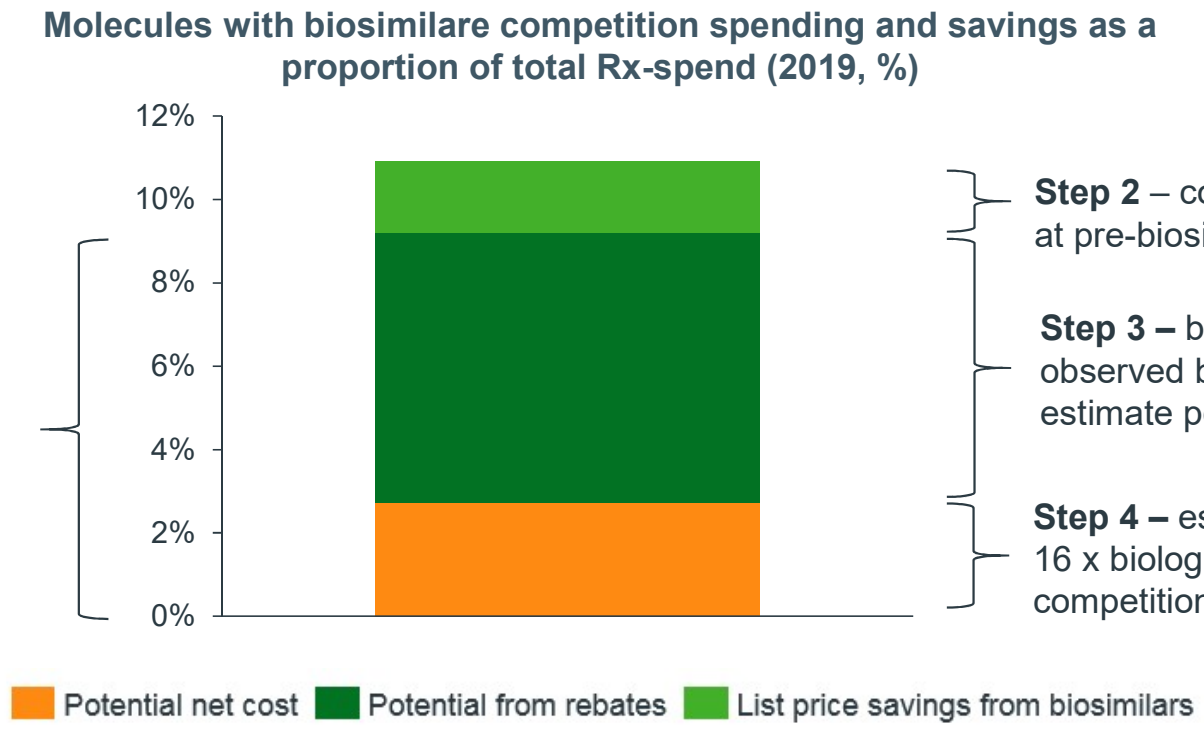


Note: Only the first biosimilar per molecule is presented; list of biosimilars per molecule is not exhaustive; total number of biosimilars currently approved by the EMA is 54
Sources: EMA list of approved biosimilars (June 2019); IQVIA analysis

IQVIA created a method to model biosimilar savings in 2019

Since introduction based on list price and net price assumptions

Step 1 – cost of 16 x molecules with biosimilar competition as a % of the total 2019 Rx spend



Step 2 – cost of 2019 volume at pre-biosimilar prices

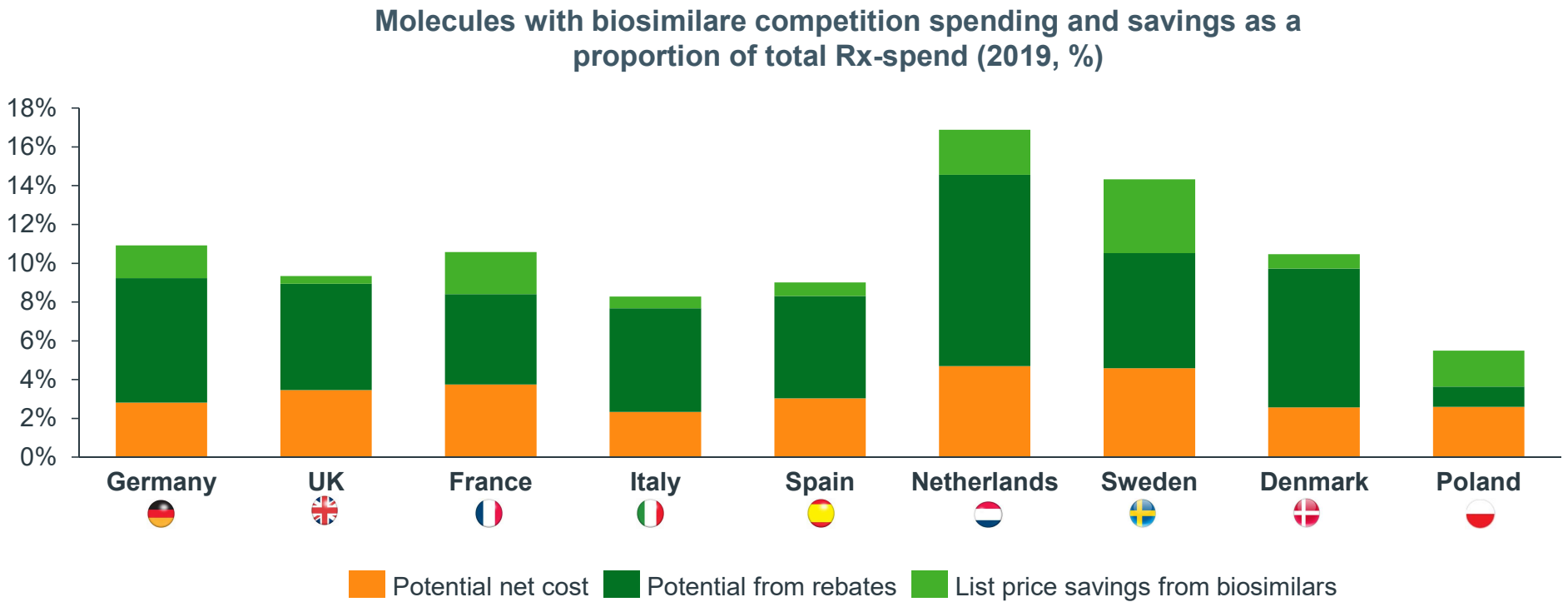
Step 3 – based on observed best net prices, estimate potential rebates

Step 4 – estimated cost of the 16 x biologics with biosimilar competition post-rebates in 2019

Source: Global Supplier & Association Relations model 2019; MIDAS Q2 2019, calculated using defined daily doses (DDD) for all 16 products with biosimilars available (excluding teriparatide, and bevacizumab due to lack of data); Assumptions based on net price based on IQVIA expertise; Countries included: EU5 + Netherlands, Denmark, Sweden

IQVIA has modelled a best estimate savings model for 2019

Since introduction based on list price and net price assumptions



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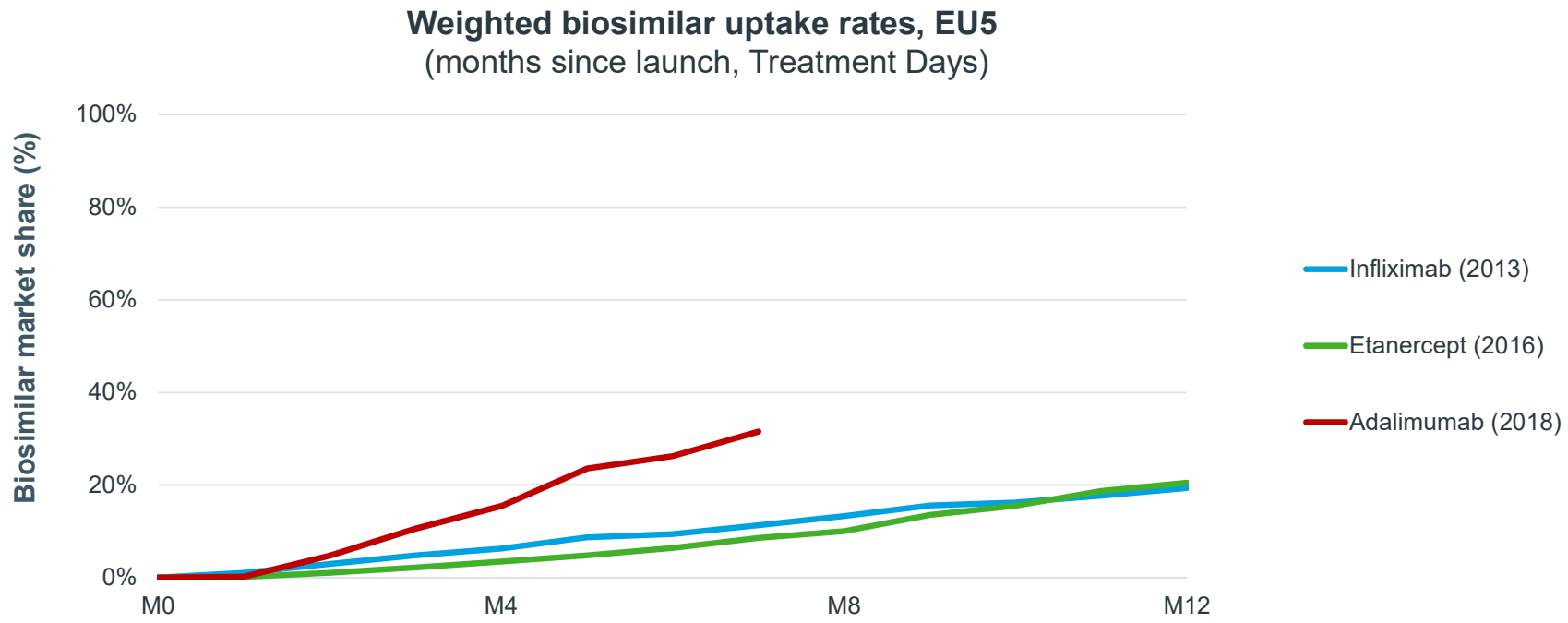
Major products see fast uptake and large price reductions

Rate of uptake of subsequent biosimilars has increased



Notes: Individual country launches normalised to M1; Market Share based on percent of treatment days; EU5 are UK, DE, FR, ES, IT
Source: IQVIA European Thought Leadership; IQVIA MIDAS MTH May 2019

For major new products, publications into the level of rebates show they reach high levels almost instantly

Regulatory Focus™ > News Articles > 11 > AbbVie Sees 80% Discounts in Nordic Market With New Humira Biosimilars

AbbVie Sees 80% Discounts in Nordic Market With New Humira Biosimilars

Posted 02 November 2018 | By Zachary Brennan

In the winner-take-all Nordic tender markets, AbbVie said it's seeing discounts of upwards of 80% from biosimilar competition for its blockbuster Humira (adalimumab).

"We're only two weeks into the launch of biosimilars [in the EU], four biosimilars have launched basically simultaneously – we've seen pricing in every single market, though it's not stabilized in every market," CEO Rick Gonzalez explained to investors on Friday's third quarter earnings call. He said AbbVie has seen price discounts in the range of 10% to 80%.

"The discounting has been on the higher end," Gonzalez said.

With the help of a substantial price reduction of 89 percent in some cases, AbbVie succeeded in driving competitors out of the market. As a result, at least seventy percent of Dutch patients continue to be treated with the original drug

According to: https://www.groene.nl/artikel/het-patent-gaat-voor-de-patient (translated)

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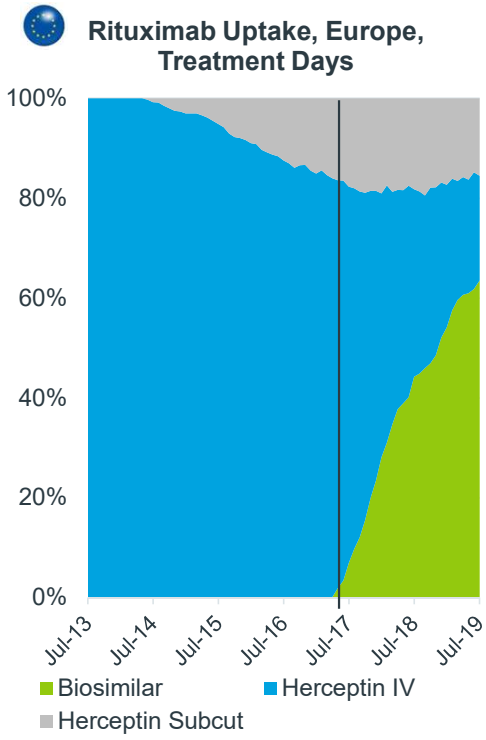
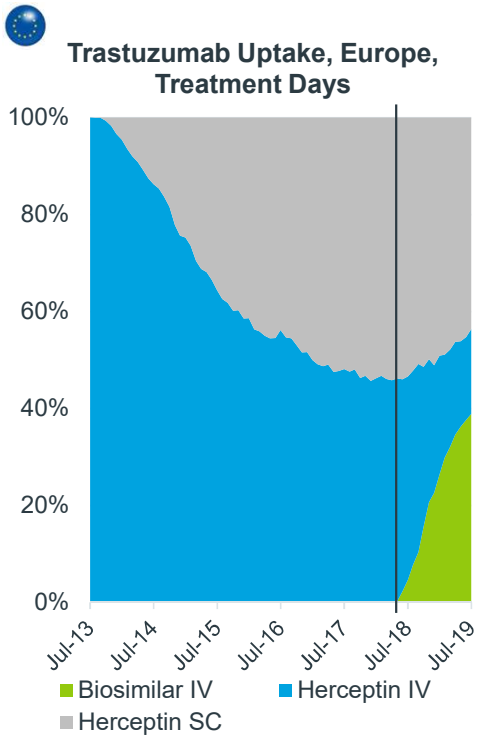
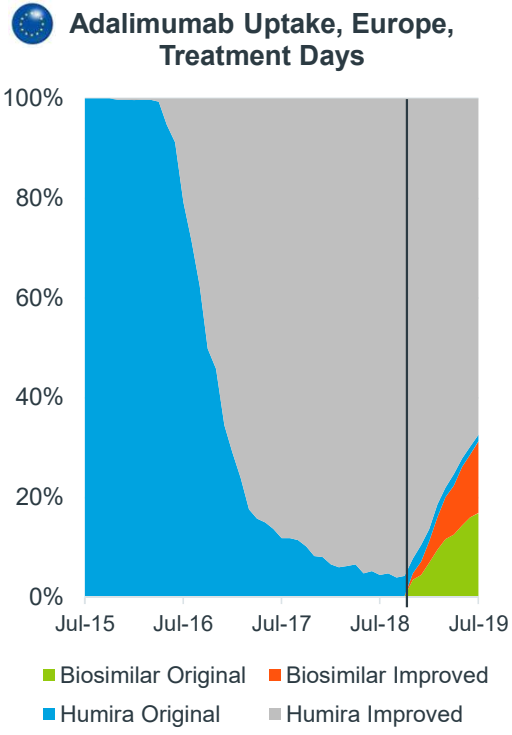
Originator manufacturers have changed strategy to stay competitive

Continue to introducing product enhancements and/or competing on prize







Infliximab – Remicade (MSD) winner in Finland based on lowest price (Jan 2017)

Etanercept – Enbrel (Pfizer) winner in Sweden based on lowest price (Oct 2017)

Adalimumab – Humira (Abbvie) winner in Norway based on lowest price (Nov 2018)

Source: IQVIA European Thought Leadership; IQVIA MIDAS MTH July 2019

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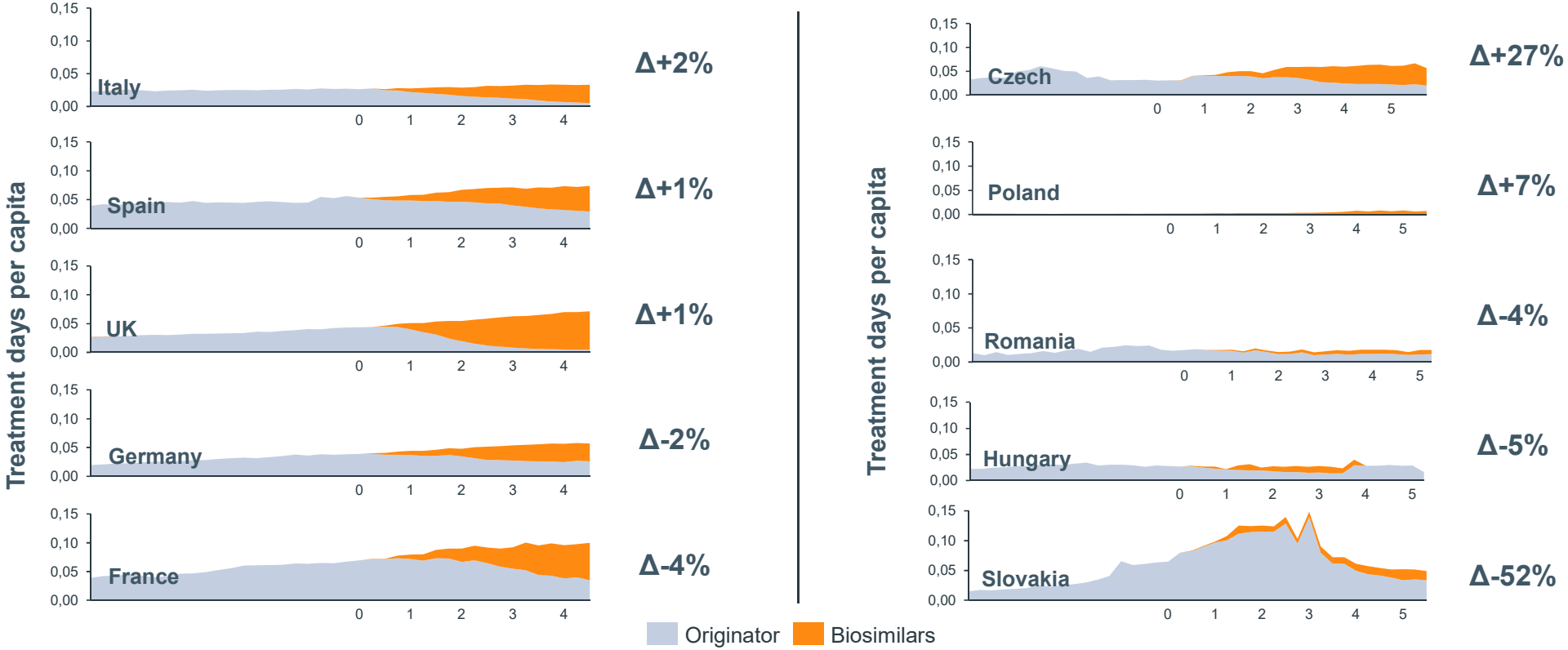
Access is not yet increasing for all molecules and in all countries after biosimilar introduction

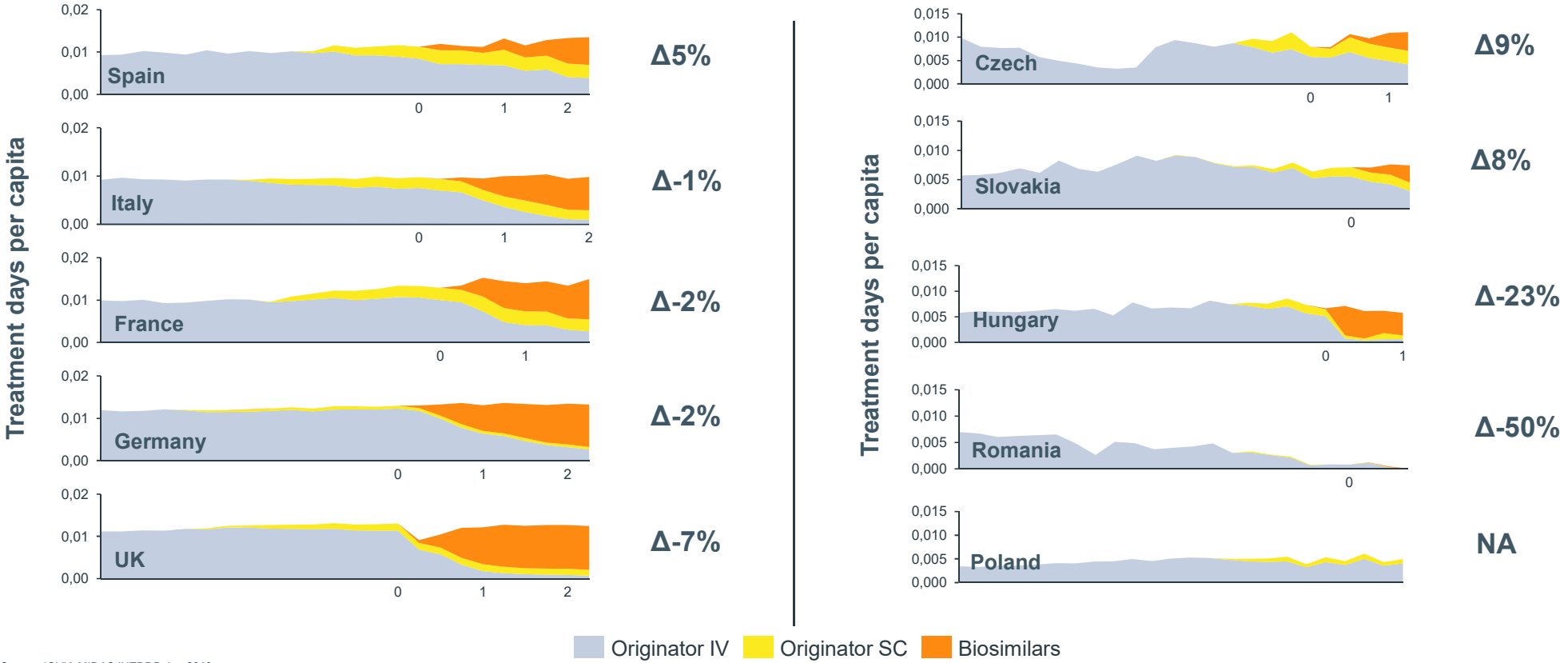
*Growth per Capita in treatment days for **infliximab** since biosimilar introduction*



Source: IQVIA MIDAS INTDDD Jun 2019,
Notes: Graphs display data from Q3 2013 – Q2 2019. Compound annual growth is calculated from the quarter before date of first sales within MIDAS (denoting biosimilar entry), to Q2 2019. Deltas subtract the organic growth of the biologic (3-year CAGR prior to biosimilar entry) to determine change in usage post-biosimilar entry. c

In oncology, countries with low access remain without biosimilars almost 2 years after launch

*Growth per Capita in treatment days for **rituximab** since biosimilar introduction*



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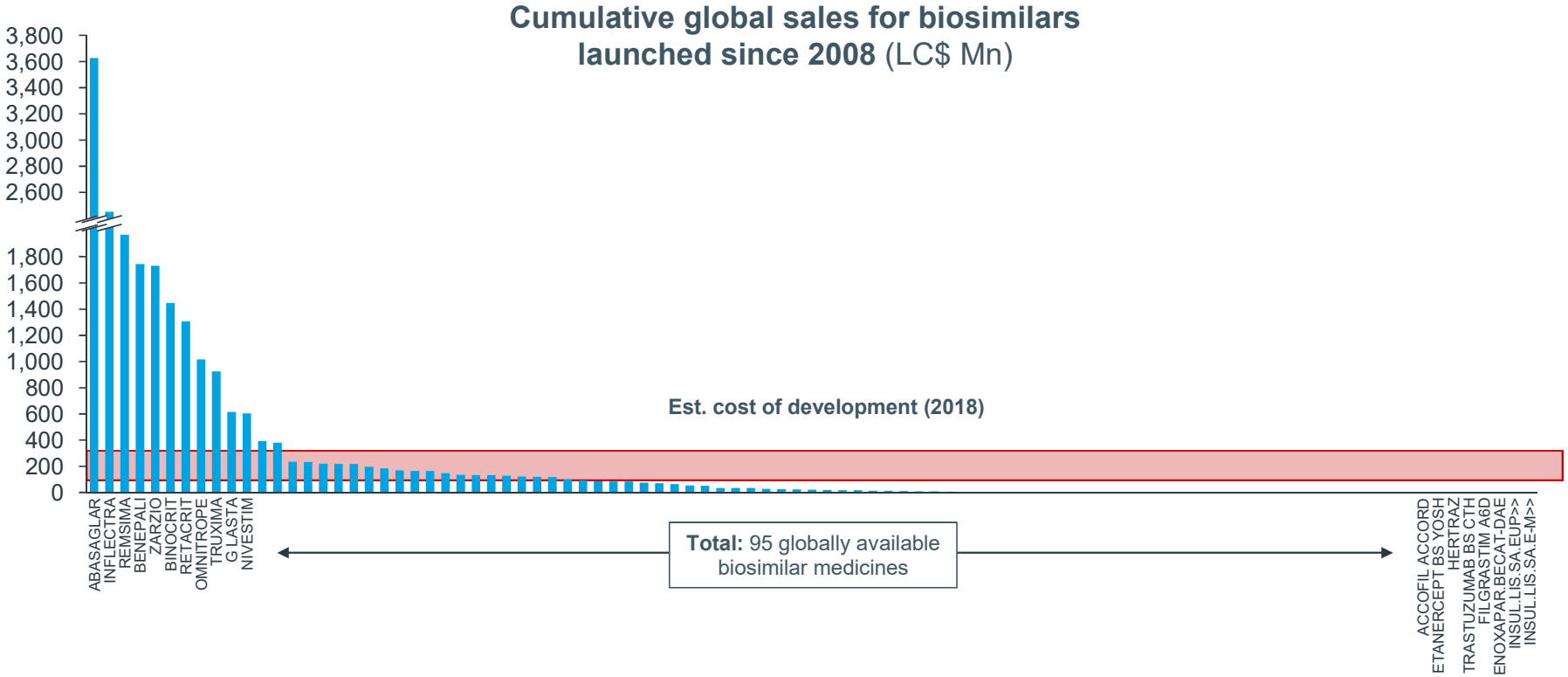
Return on Investment analysis



Source: IQVIA European Thought Leadership; MIDAS MAT 2019 Q2 data (2008 – 2019)

IMS Health & Quintiles are now IQVIA™

THANK YOU

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