



# Biosimilars: Evolution and trends

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Biosimilars promised the Moon but did not deliver

Were we expecting too much and is it time to be optimistic again?

**Historic estimation  
for 2011 (in 2007)**



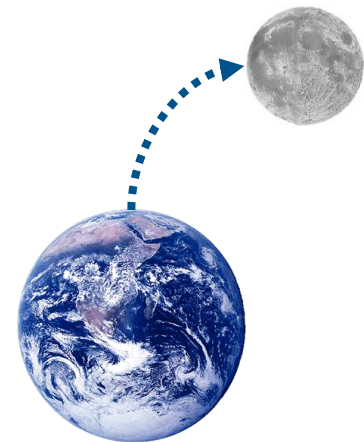
\$16BN

**Today's actual  
sales\***



\$0.6BN

**Forecast for  
2020**

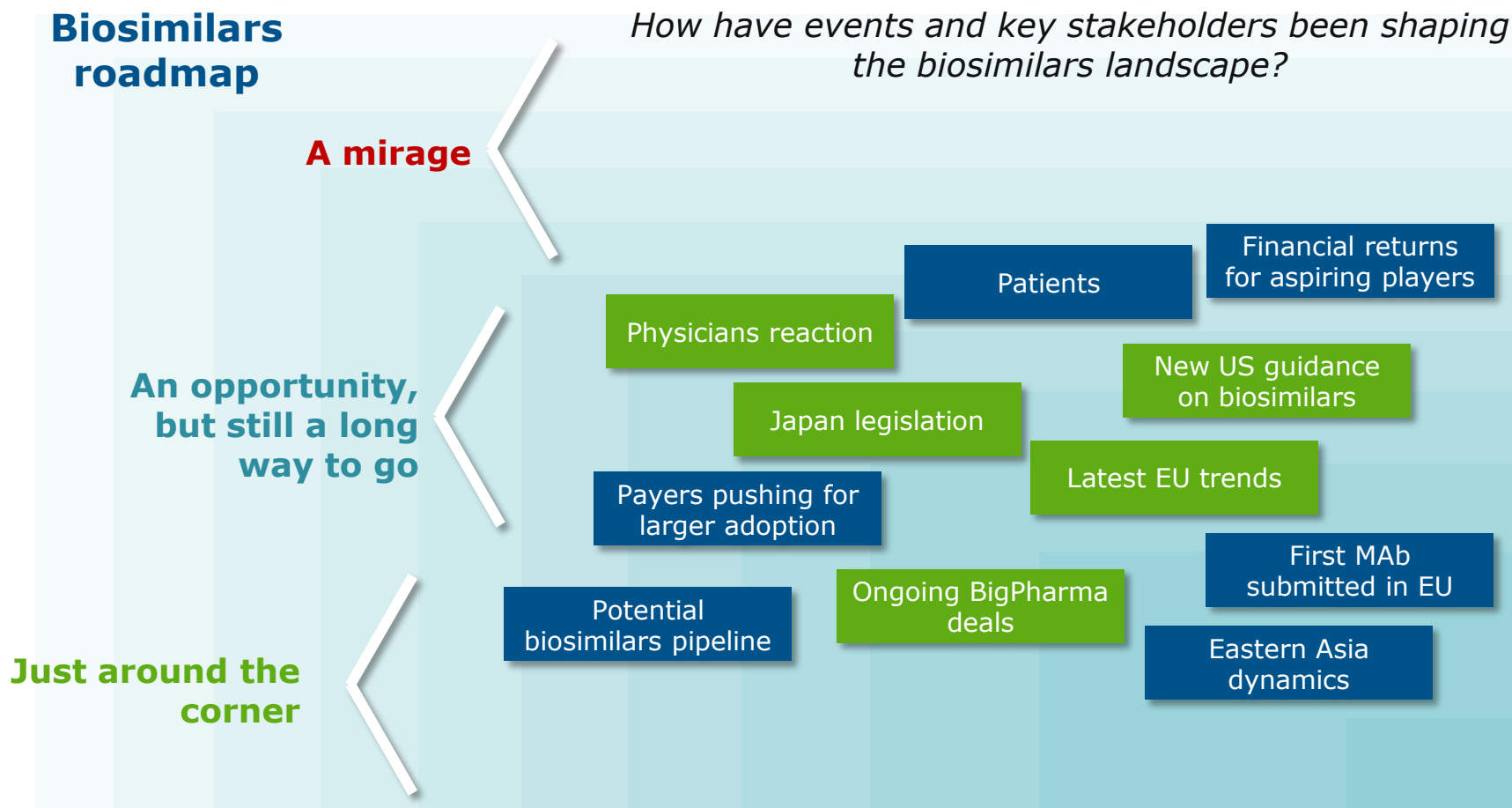


\$25BN

Source: Suzanne M. Sensabaugh. Biological generics: A business case (2007) Journal of Generic Medicines 4 , 186-199, \* MAT 03/2012

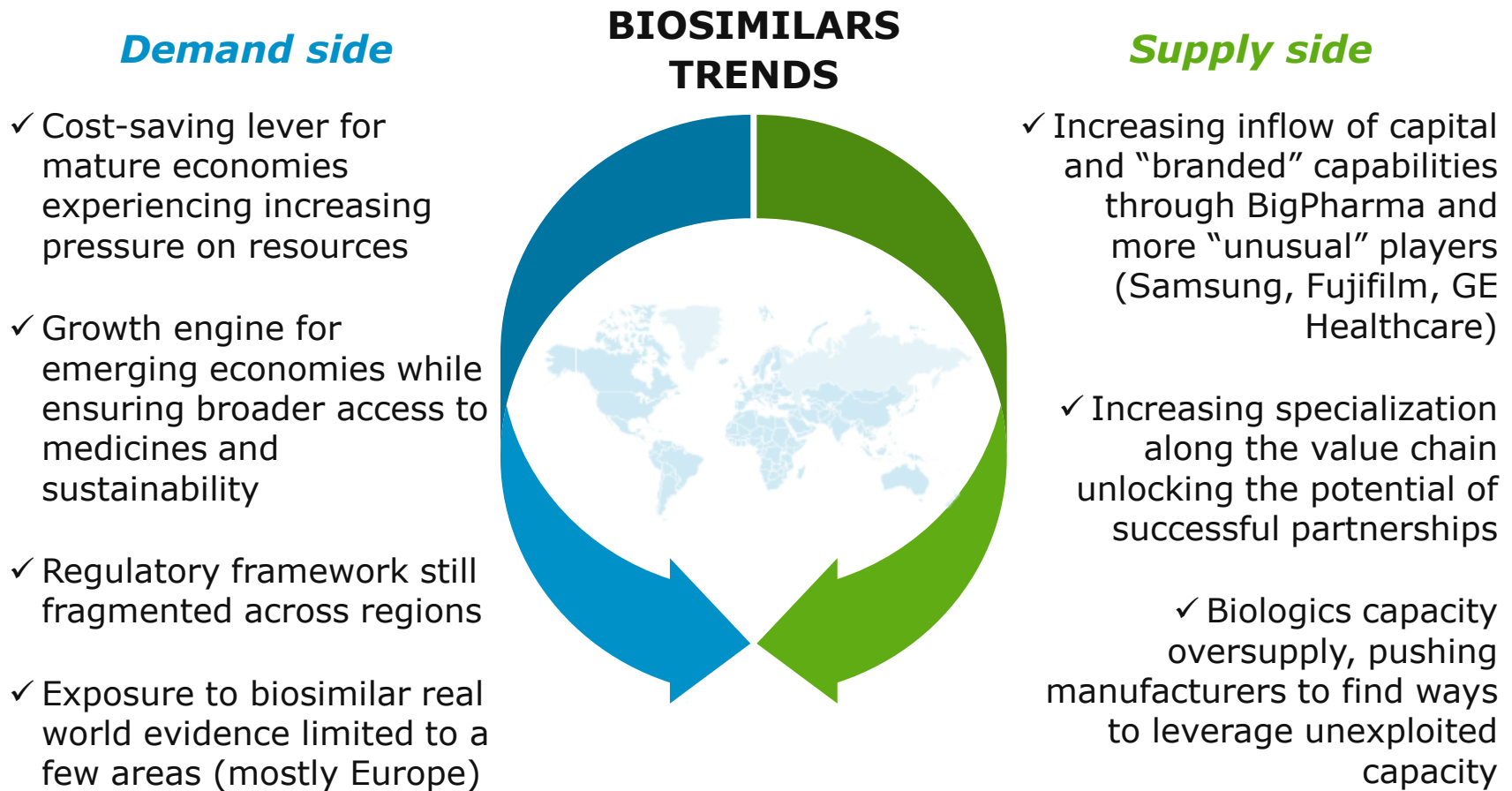
# Biosimilars are approaching a turning point

Positive moves are apparent, but still much has to change



This trend is supported both from demand and supply drivers

Mature economies look at them in the attempt to stem costs;  
emerging ones to ensure access and sustainable growth

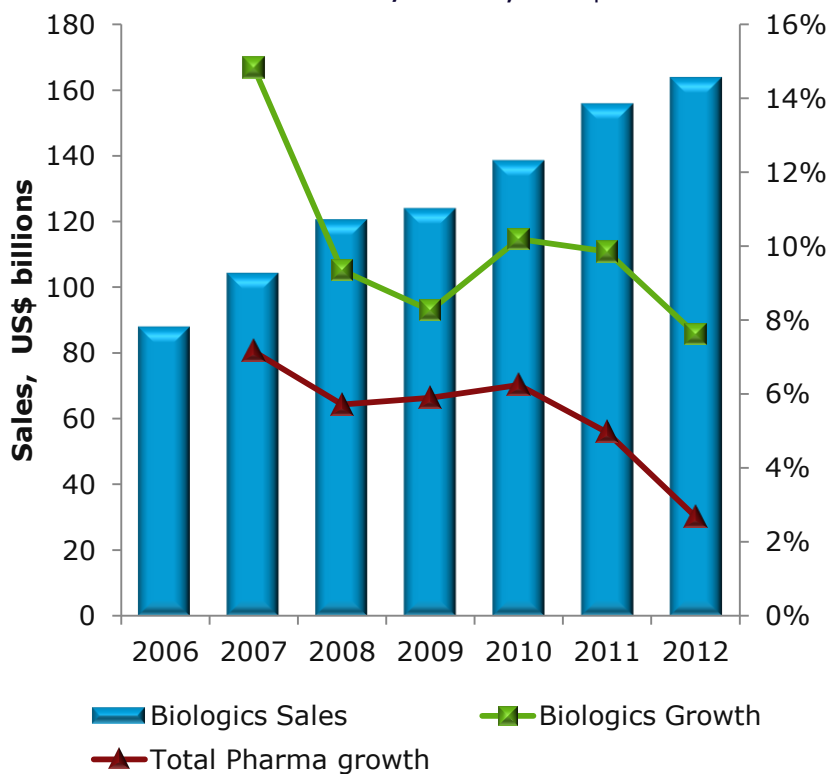


# Biologics growth is nearly double that of total pharma

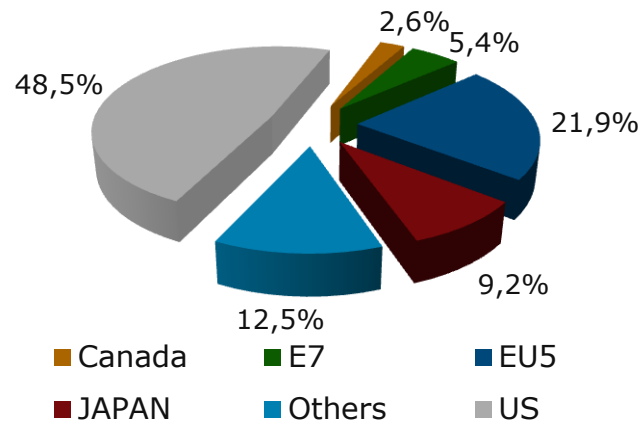
Such a trend is putting additional financial pressure on healthcare budget, whereas for PharmaCos represents a great opportunity

## Global market trends

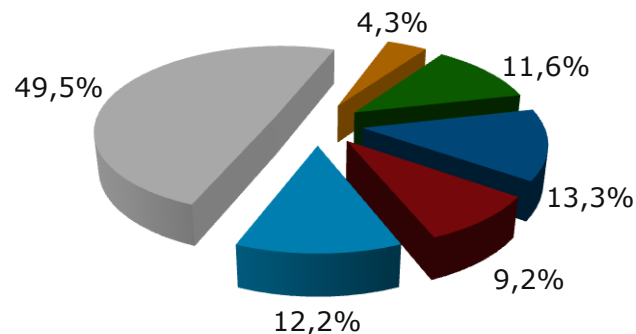
MAT 09/2012, US\$



## Biologics – Share of sales



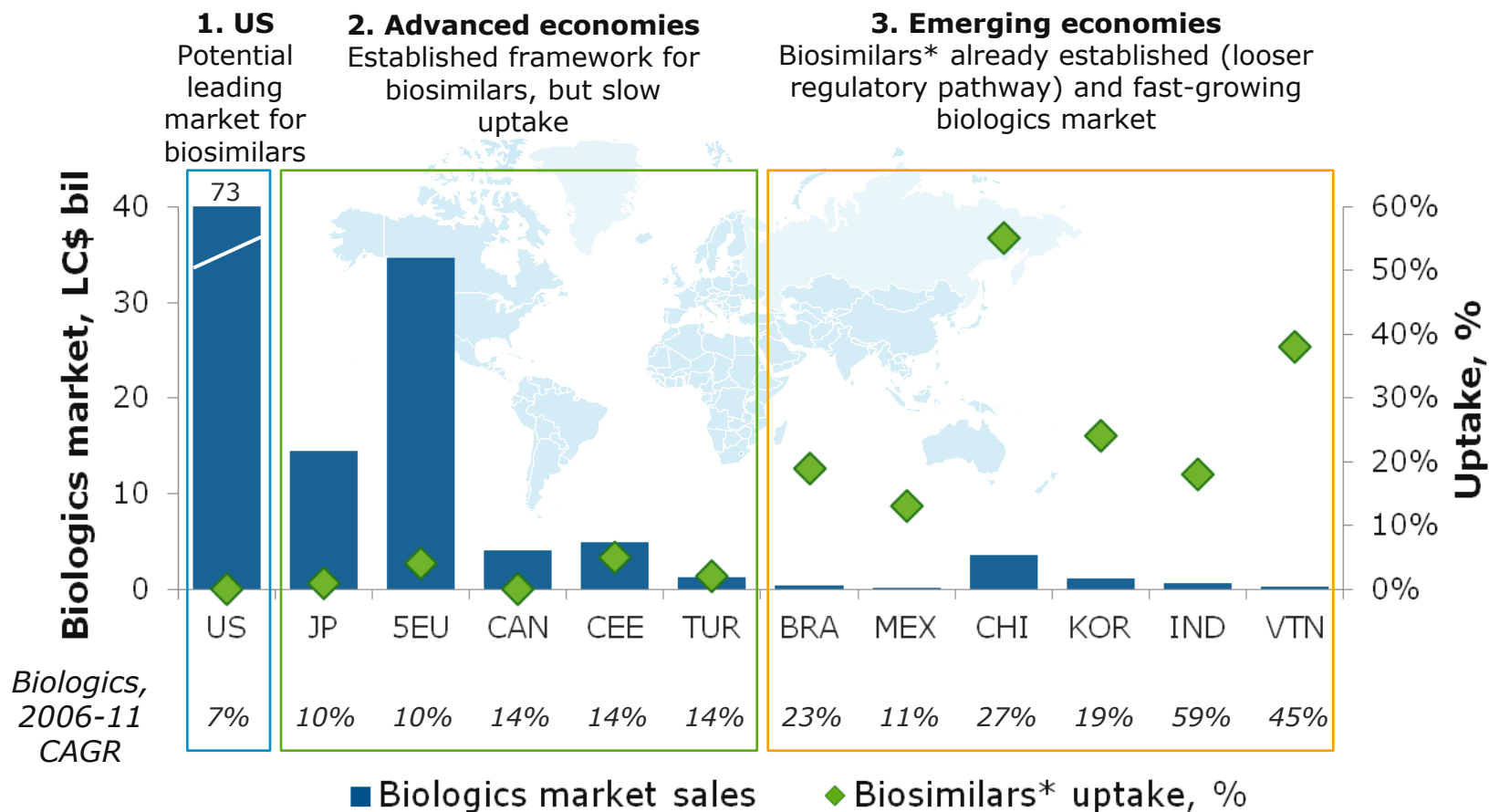
## Biologics – Share of growth



Source: IMS Health, MIDAS, MAT 09/2012

# Three geographical clusters arise

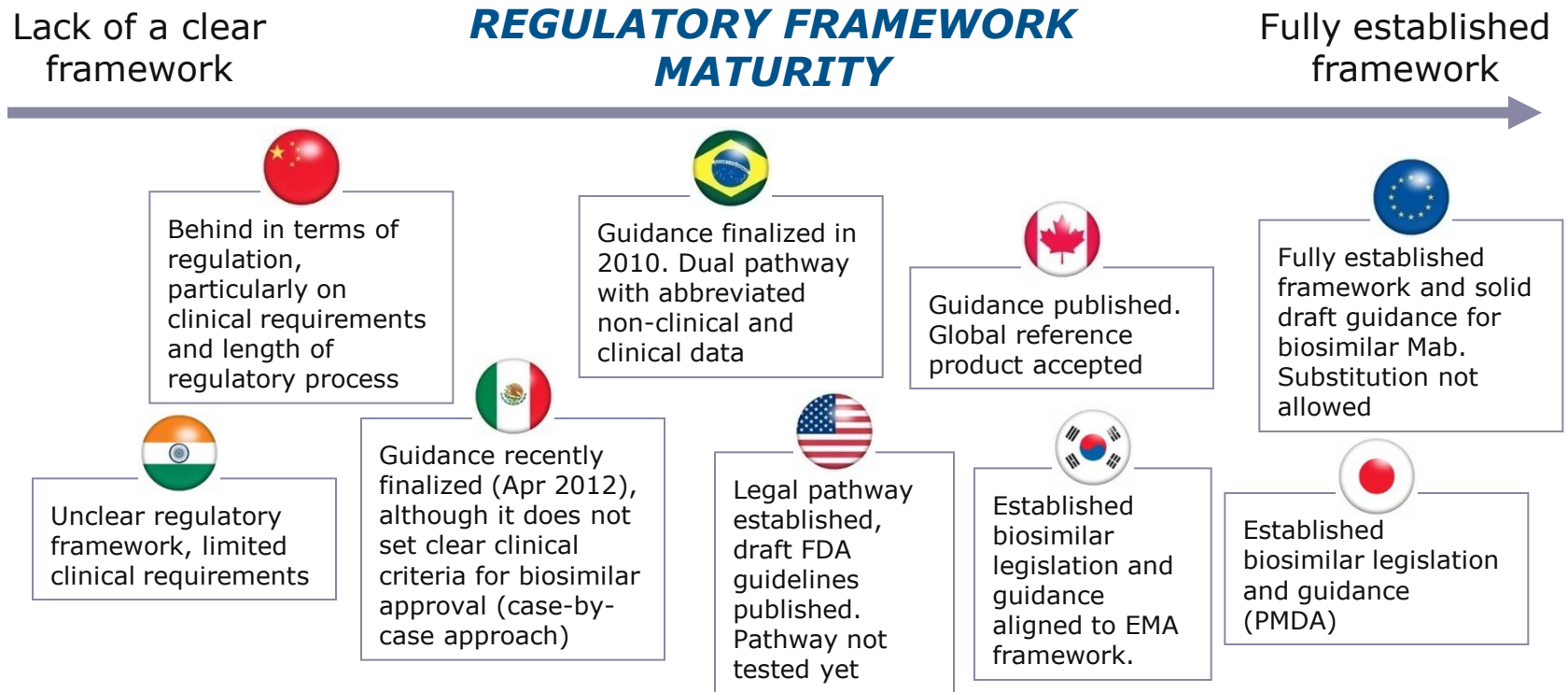
Emerging economies anticipated to be a potential growth driver due to local policies and “biosimilar” attitude



Source: IMS MIDAS, 2006-11, \*biosimilars in emerging economies have not gone through a thorough screening like in Europe

# The global regulatory framework is still quite heterogeneous

Some key emerging markets still lag behind in terms of regulatory guidance



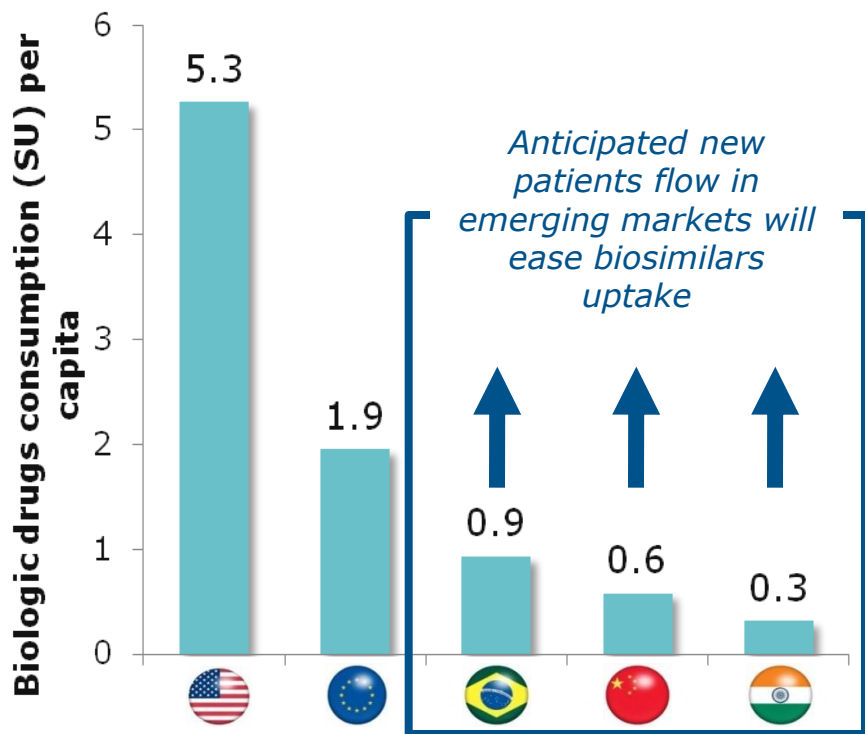
## Current hurdles to global biosimilar market

Patient ethnicity, Opportunity to leverage evidence from other geographies, PK testing, Clinical testing requirements, Interchangeability

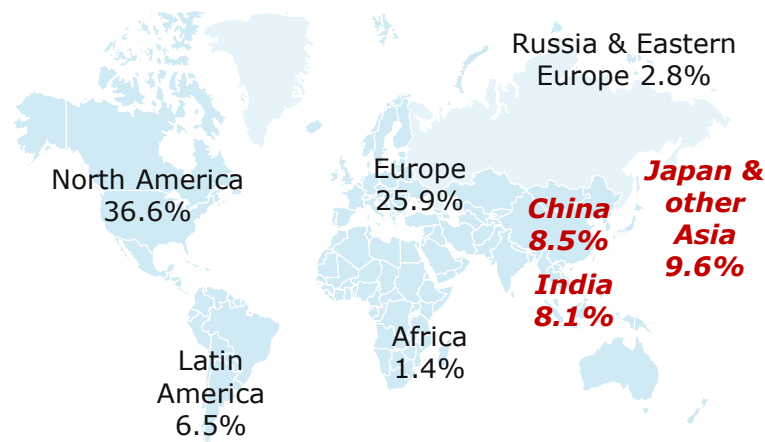
Biologic market is still at its early stage in emerging markets

Bioclusters are rapidly emerging in the major Asian emerging markets and will fuel growth of the biopharmaceutical sector in this area

### Future market potential for biologic drugs\*



### Concentration of Global Biopharmaceutical Manufacturing



- **Bioclusters** are **emerging in Eastern Asia**, driven by local government-led initiatives (South Korea, China)
- Based on BioPlan's Top 1000 Global Biopharmaceutical Facilities Index™ (Index considers variables such as overall fixed capacity, manufacturing-related employment, number of commercial and clinical biological products)

Source: IMS MIDAS, MAT Q4 2010, OECD 2010



# In Europe, biosimilar uptake exhibits different paces

A few countries have reached or approached the maturity stage

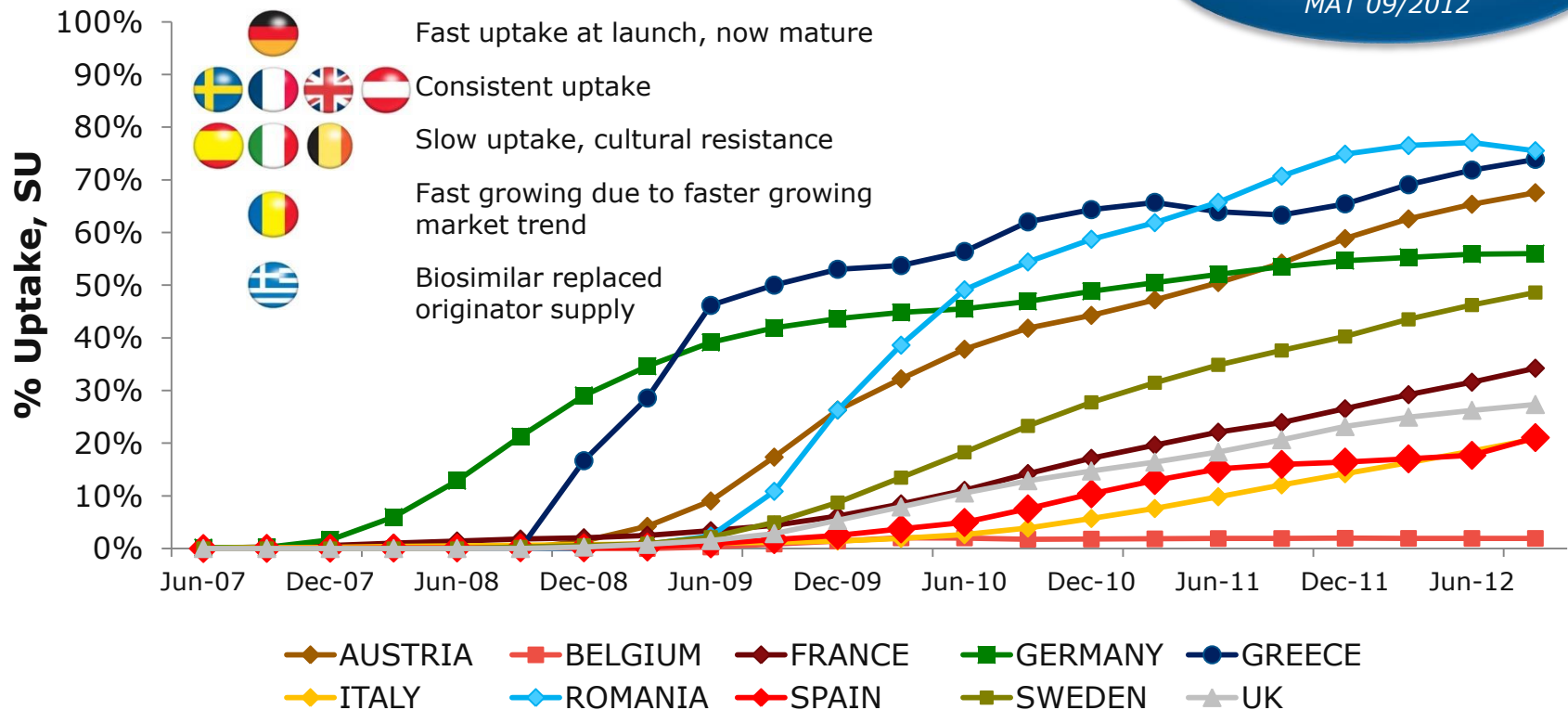
## Biosimilar uptake across Europe

MAT 06/2007 - 09/2012 (Volumes, SU)

Total 10 countries

314M €

MAT 09/2012



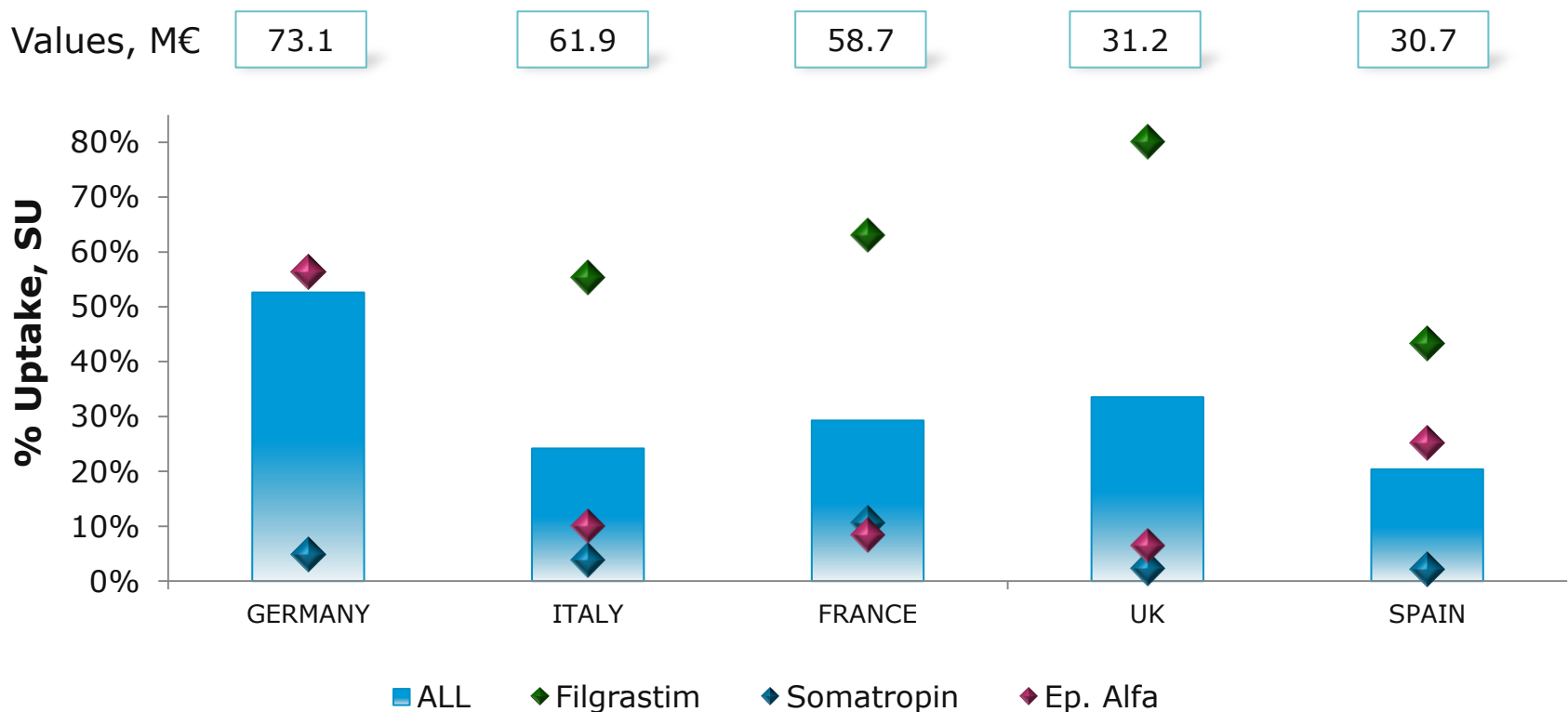
Source: IMS MIDAS, MAT 09/2012

Similar variations can be observed at therapy area level

Biosimilar filgrastim resembles generic performance in some countries (UK, France, Germany)

### Biosimilar uptake across TA/Countries

MAT 09/2012 (Volumes, SU)

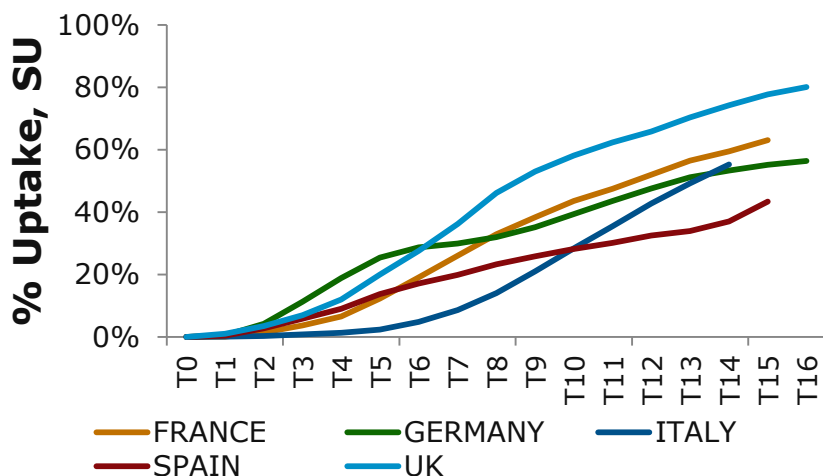


Source: IMS MIDAS, MAT 09/2012

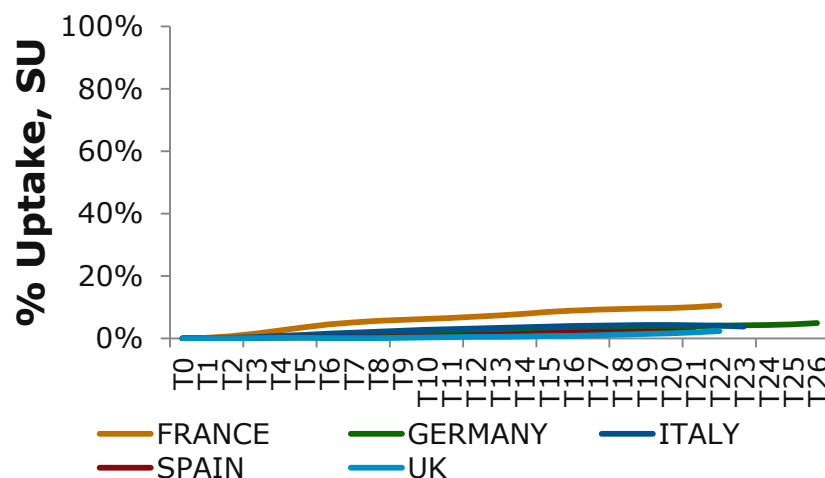
# Commodity or differentiated?

Stakeholder landscape – payer-driven vs. multiple influencers – and treatment cycle are the key determinants

**Filgrastim uptake**  
**SU 09/2012, quarterly**  
*Commodity market*



**Somatropin uptake**  
**SU 09/2012, quarterly**  
*Differentiated market*



- ✓ Payer-driven market access (e.g. Tender, step-wise algorithms)
- ✓ Price-driven competition
- ✓ Acute treatment and/or frequent cycling among therapies

- ✓ Complex stakeholder landscape with higher physician influence
- ✓ Competition based on multiple marketing levers
- ✓ Chronic treatment and/or long therapeutic cycles

Source: IMS MIDAS, 09/2012

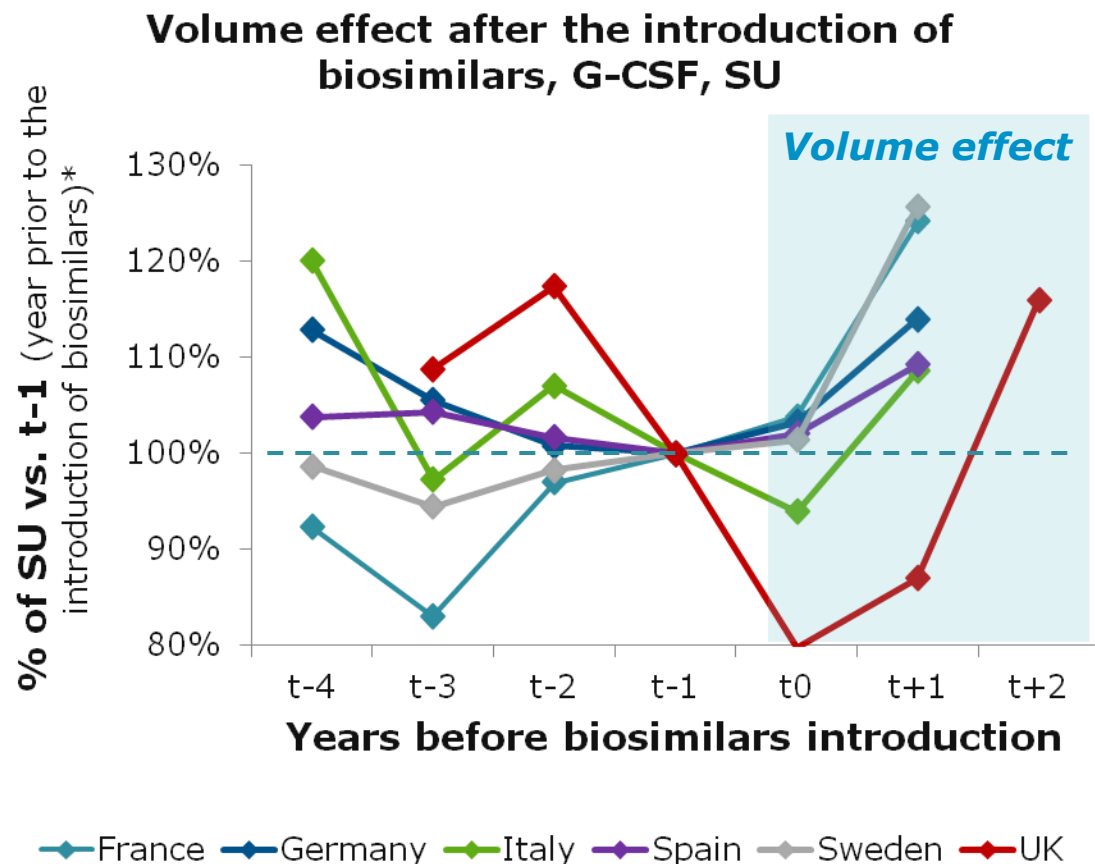
# Biosimilars have in some cases generated expanded access

As shown by G-CSFs, biosimilars improve access to therapies based on efficacy and costs

## UK case study



- Physicians moved G-CSF back in 1<sup>st</sup> line cancer treatment due to lower biosimilars cost
- G-CSF prevents hospital readmission due to infections
- The volume effect has both created new market and cannibalized the share of follow-on products (e.g. peg-filgrastim)



Source: IMS MIDAS, MAT Q4 2010, NHS. \*t-1 =100%, t0 = year of biosimilars introduction

# Although the opportunity for volume expansion is therapy area (and geography) dependent

- Largest volume expansion potential undoubtedly in **pharmerging**, but probably at a much lower price point
- **Europe** has lower and also variable biologic uptake relative to US
- **US** has highest penetration of biologics/head – least volume expansion potential?
- Volume expansion potential will also be affected by introduction of new, better innovative therapies (eg pertuzumab, Roche)

**Human Growth Hormone** and other **orphan drug biologics** show typically show high percentage of available patients treated

Erythropoetins for oncology

**Erythropoietin** for renal dialysis

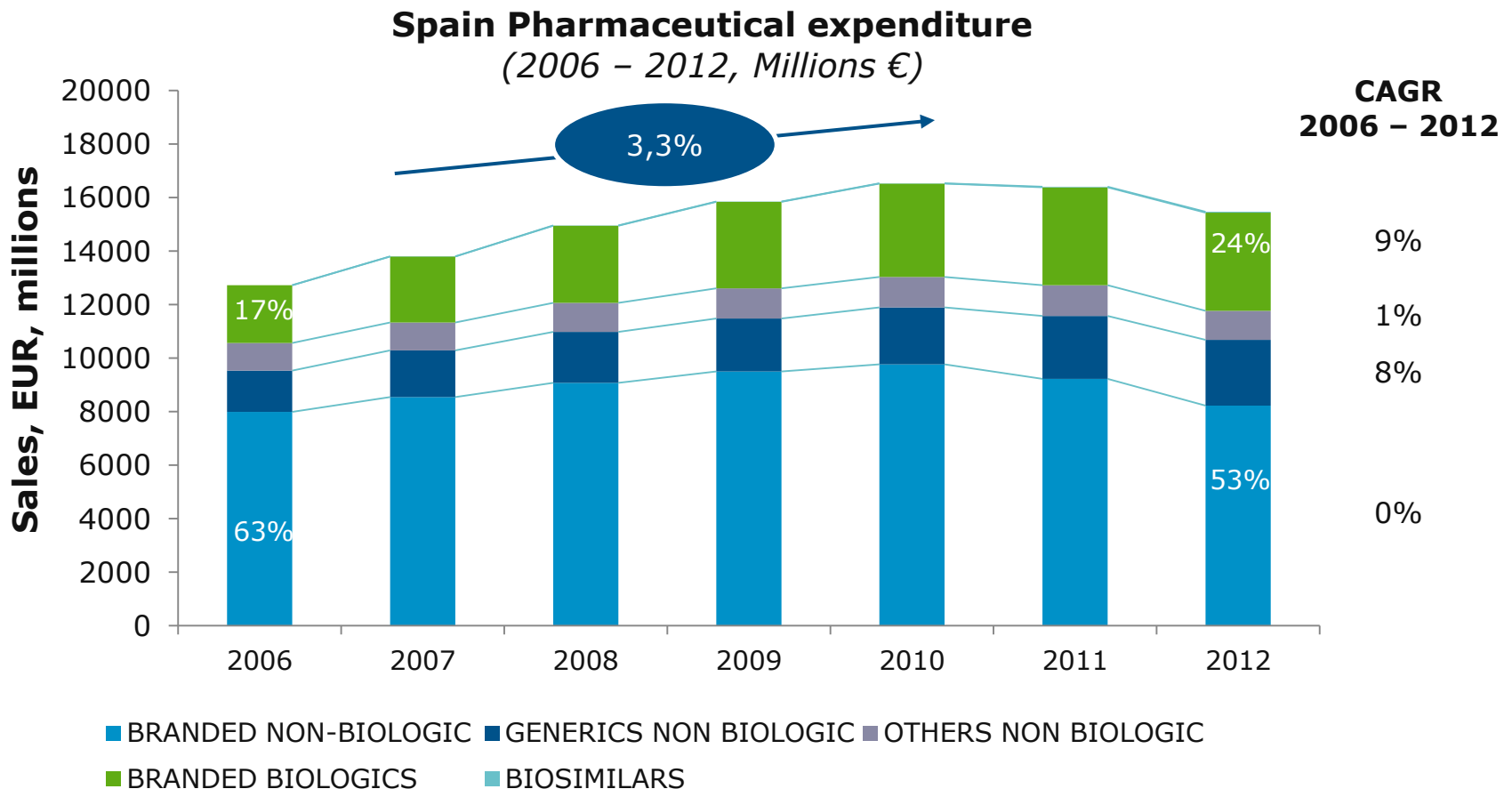
**Oncological biologics** always have the competitive threat of innovation to reduce volume for biosimilars

**Oncological biologics** in some European countries (eg UK) show significantly lower levels of use than elsewhere on cost grounds

**Filgrastim has already shown price elasticity**

**Biologics for autoimmune** show highly variable levels of use across patient populations, driven by access in Europe (>5% of patients to >30% across Europe\*)

In Spain, biologics represent one of the major cost drivers  
 However, biosimilars still represent a minimal portion of the total market



Source: IMS MIDAS, MAT 09/2012

# Payers and policy-makers are rising as biosimilar advocates

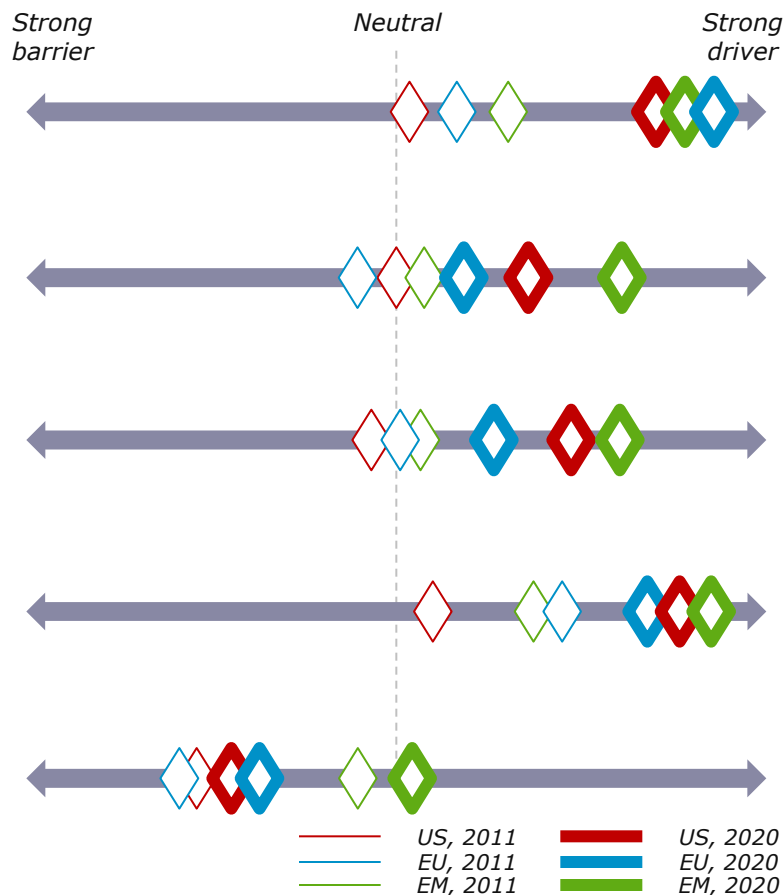
Biosimilar strategies and business models will be another critical factor to shape the future scenario

## Stakeholder drivers

<b>Payer / Government</b>	<ul style="list-style-type: none"> <li>• Increasing pressure on public/private budgets</li> <li>• Ensure safety and clinical efficacy of biosimilars</li> <li>• Leverage macroeconomic growth through biosimilars (EM)</li> <li>• Broaden access to life-saving drugs</li> </ul>
<b>Patient</b>	<ul style="list-style-type: none"> <li>• Broad access to life-saving / disease-modifying drugs</li> <li>• Safety profile of biosimilar drugs</li> <li>• Access to affordable therapies (EM, partly US)</li> </ul>
<b>Physician</b>	<ul style="list-style-type: none"> <li>• Safety and clinical efficacy concerns</li> <li>• Need to build learning curve on biosimilars</li> <li>• Different influence depending on therapy area (likely to be higher for the new wave)</li> </ul>
<b>Aspiring player</b>	<ul style="list-style-type: none"> <li>• Massive capital invested on biosimilars</li> <li>• BigPharma bringing in R&amp;D and manufacturing capabilities as well as brand equity</li> <li>• Growing specialization along the value chain (CRAMS providers) and availability of new leading technologies</li> </ul>
<b>Originator</b>	<ul style="list-style-type: none"> <li>• IP challenges to delay/block biosimilar entry (e.g. Enbrel in US)</li> <li>• Timely implementation of lifecycle management strategy (e.g. Roche with HER2 franchise)</li> <li>• Leverage dual brand strategies / licensing in developing markets</li> </ul>

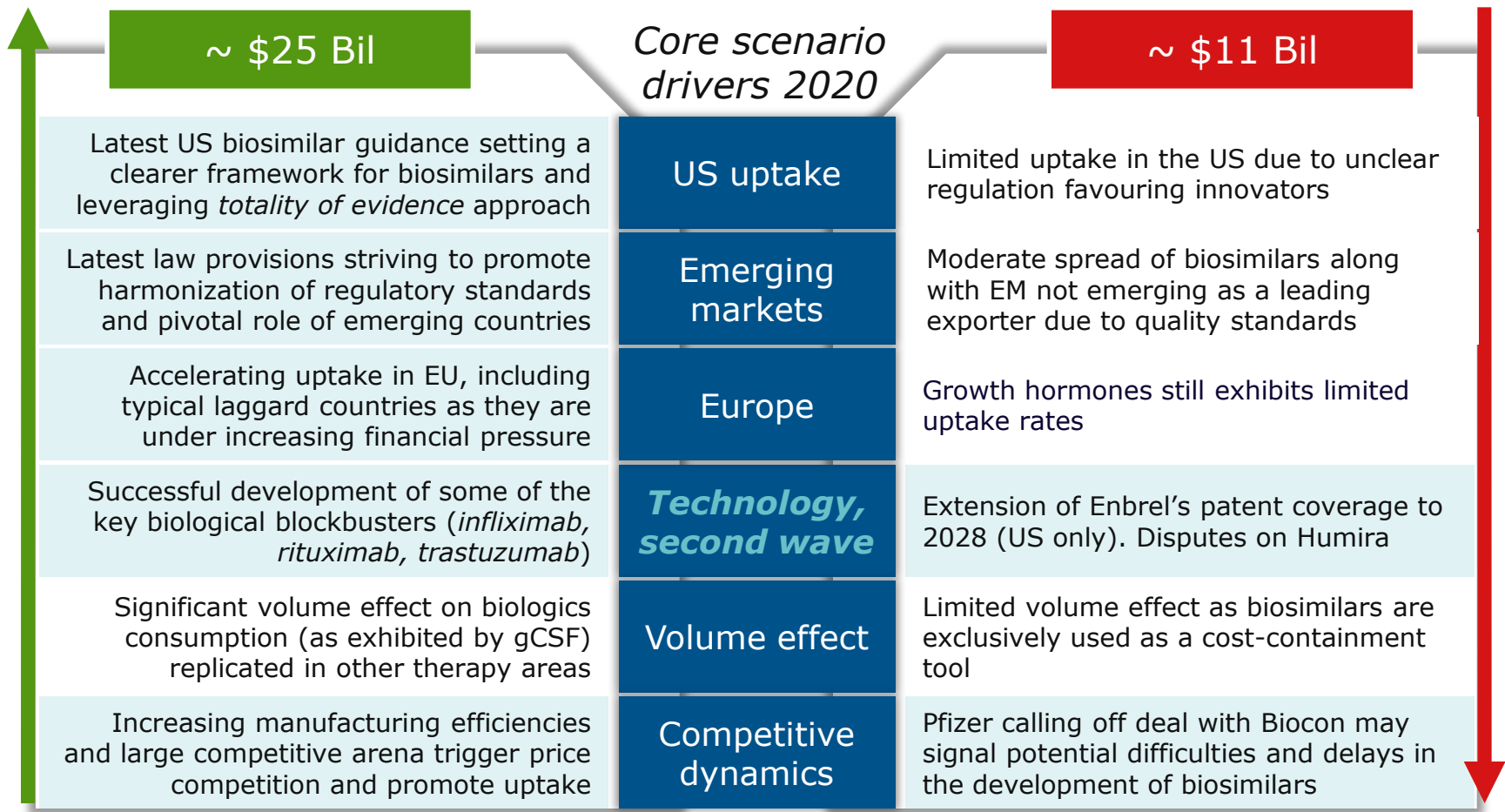
EM = emerging markets

## Impact on biosimilars market



Overall these events lean closer to the \$25 billion 2020 scenario

The verdict on the new wave of biosimilars will act as a cornerstone for this market

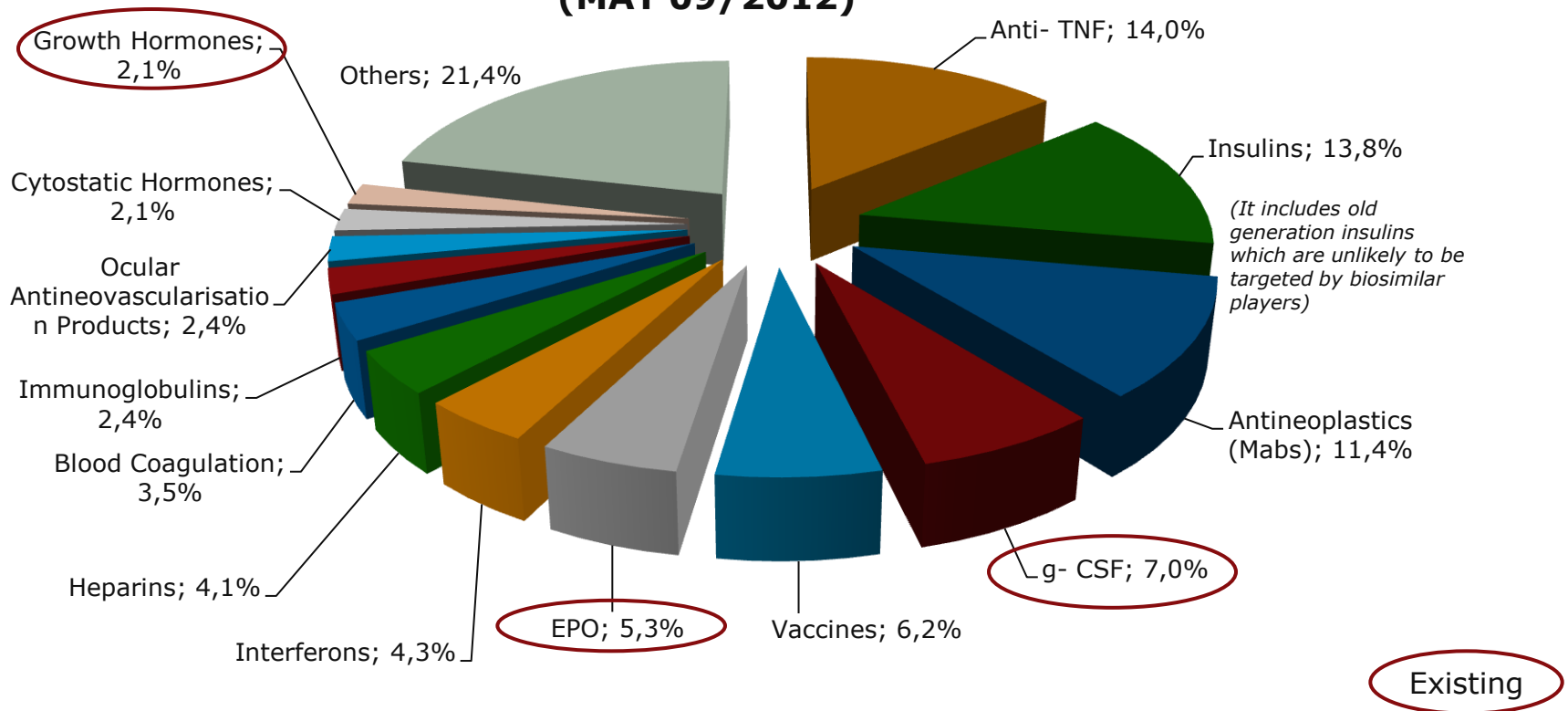




Among the new TAs, anti-TNF and MAb are the key ones

Along with insulins, another key investment area for biosimilar players, they account for more than 40% of the overall biologic market

**Top Biologic Therapy Area, Global Sales  
(MAT 09/2012)**

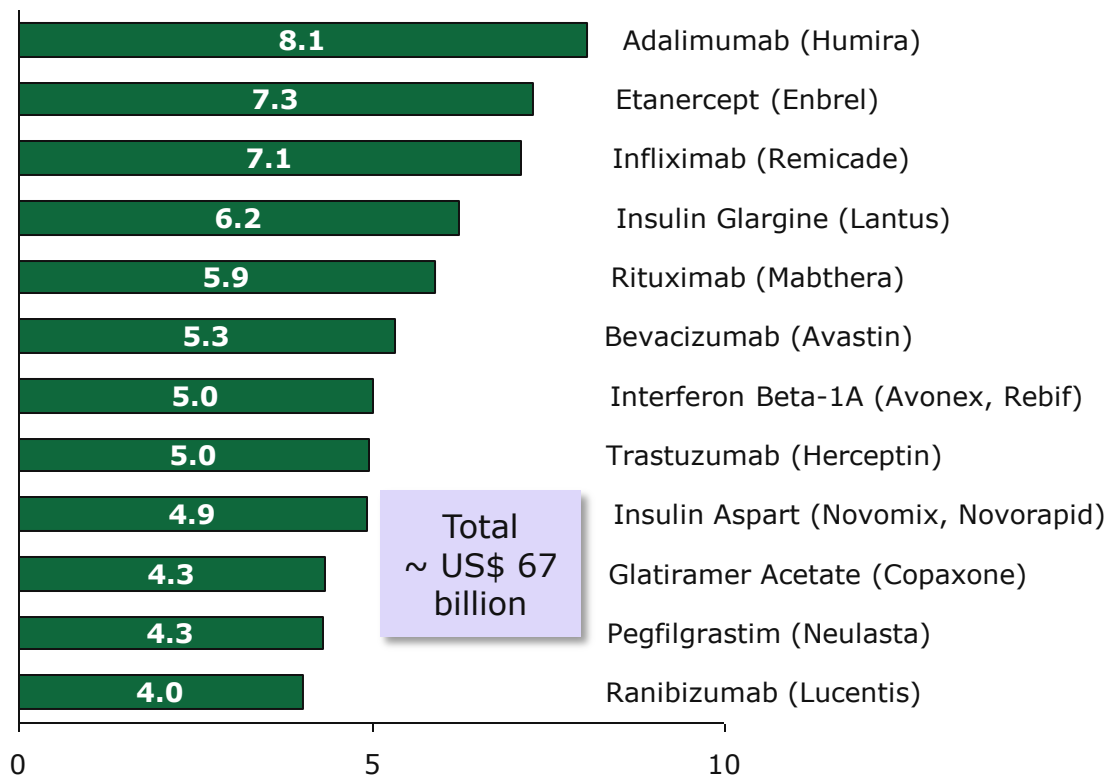


Source: IMS MIDAS, 09/2012

# Twelve compounds will present a US\$ 67 billion opportunity

All these products will lose patent protection by 2020, but Enbrel whose US patent has been extended until 2028

## Global Sales (MAT 09/2012), US\$ billion



EU expiry date	US expiry date
2018	2016
2015	2028 (extended)
2014	2018
2014	2014
2013	2016
2019	2017
2012	Expired
2015	2015
2014	2019
2017	2015
2015	2014
2016	2016

*Not considered existing biosimilars such as Epoetin Alfa expired in EU, but still patent protected in US*

Source: IMS MIDAS, 09/2012, IMS Patent focus

# Monoclonal antibodies dominate the biosimilars pipeline

## Biosimilars pipeline by class

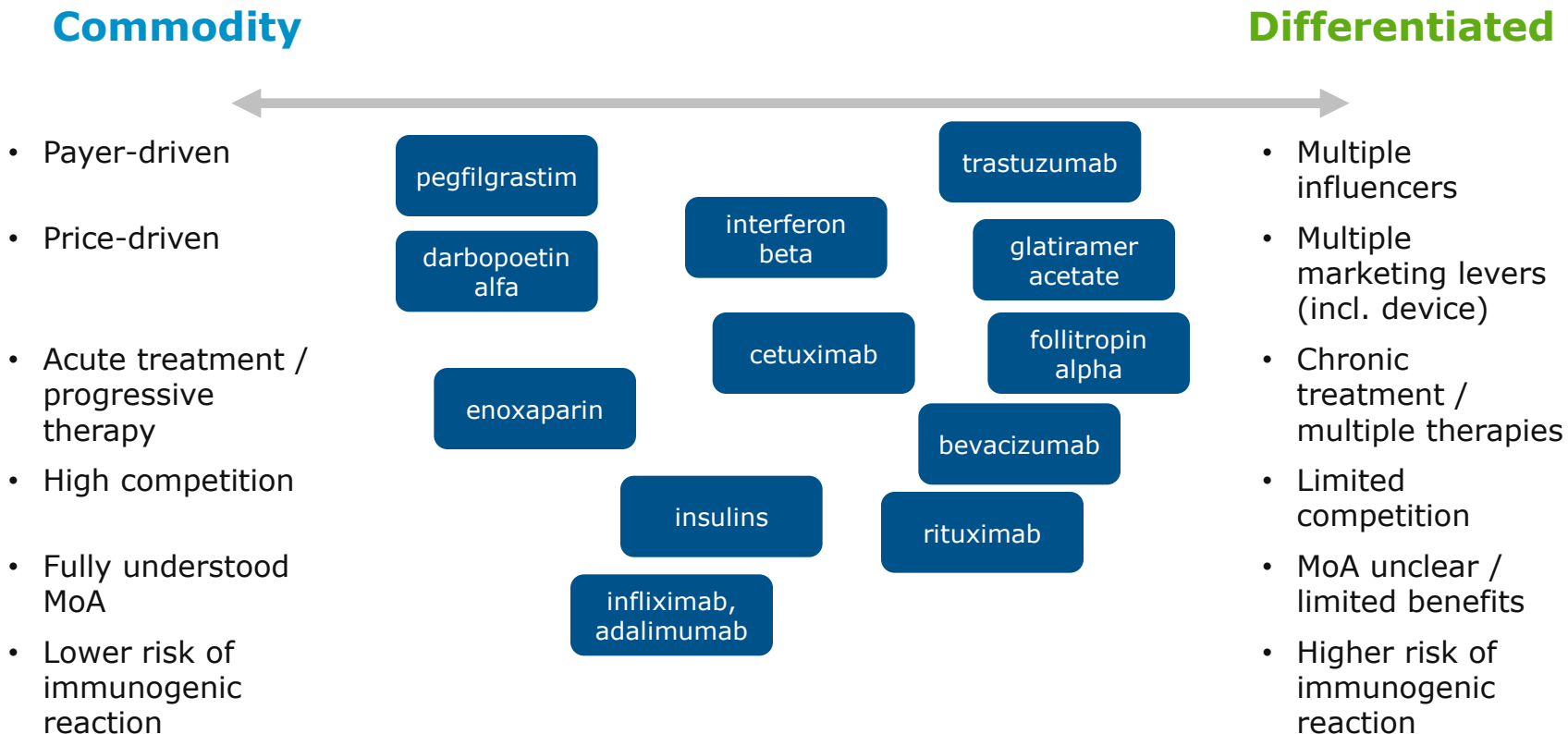
Class	Preclinical	Phase I	Phase II	Phase III	Prefiling/Pending
mAb immunomodulators	55	4	4	2	1
Cytotoxic Mabs	28	5	1	3	0
Other hormones (excl. insulins)	19	3	1	6	0
G-CSF	16	1	3	6	1
Insulin	14	4	3	3	1
Others (enzymes, BCF)	15	3	2	0	3
Interferons	14	3	3	1	1
Erythropoietin	14	1	1	5	0
Immunomodulators	8	1	1	2	1
<b>Total</b>	<b>183</b>	<b>25</b>	<b>19</b>	<b>28</b>	<b>8</b>

Source: FirstWord September 19<sup>th</sup> 2012

Among the core areas, anti-TNF are at higher risk of erosion

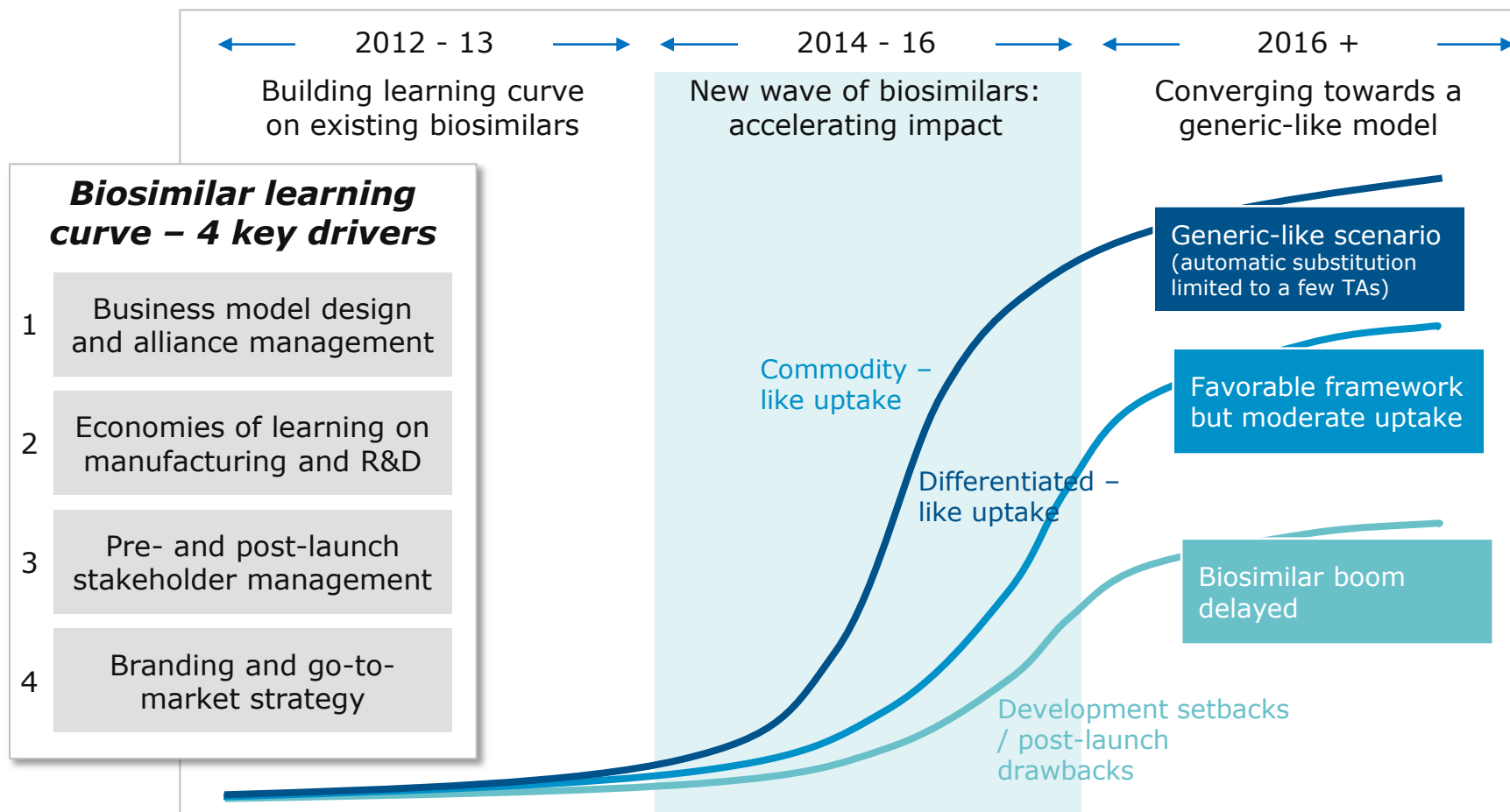
Uptake patterns will vary across geographic clusters, e.g. biosimilar insulins may perform better in emerging countries

### Positioning of upcoming biosimilars



# The next wave will be pivotal to determine future scenarios

The way the industry as a whole will pave the way to it and continue building the learning curve will shape the uptake through 2020



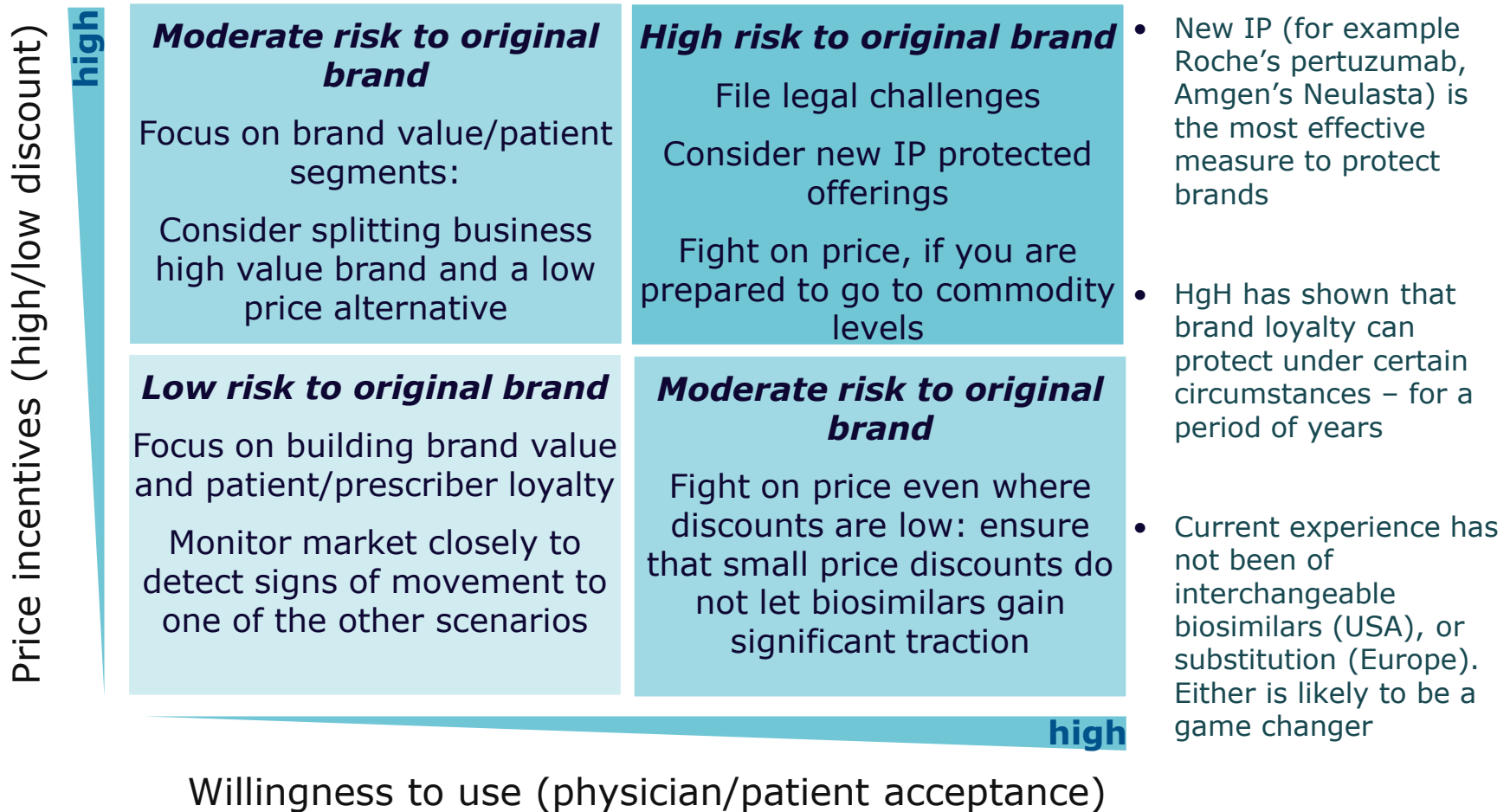
Biosimilars have been a hot topic in the last 12-18 months

The landscape is becoming over-populated. Is there a market for everybody?



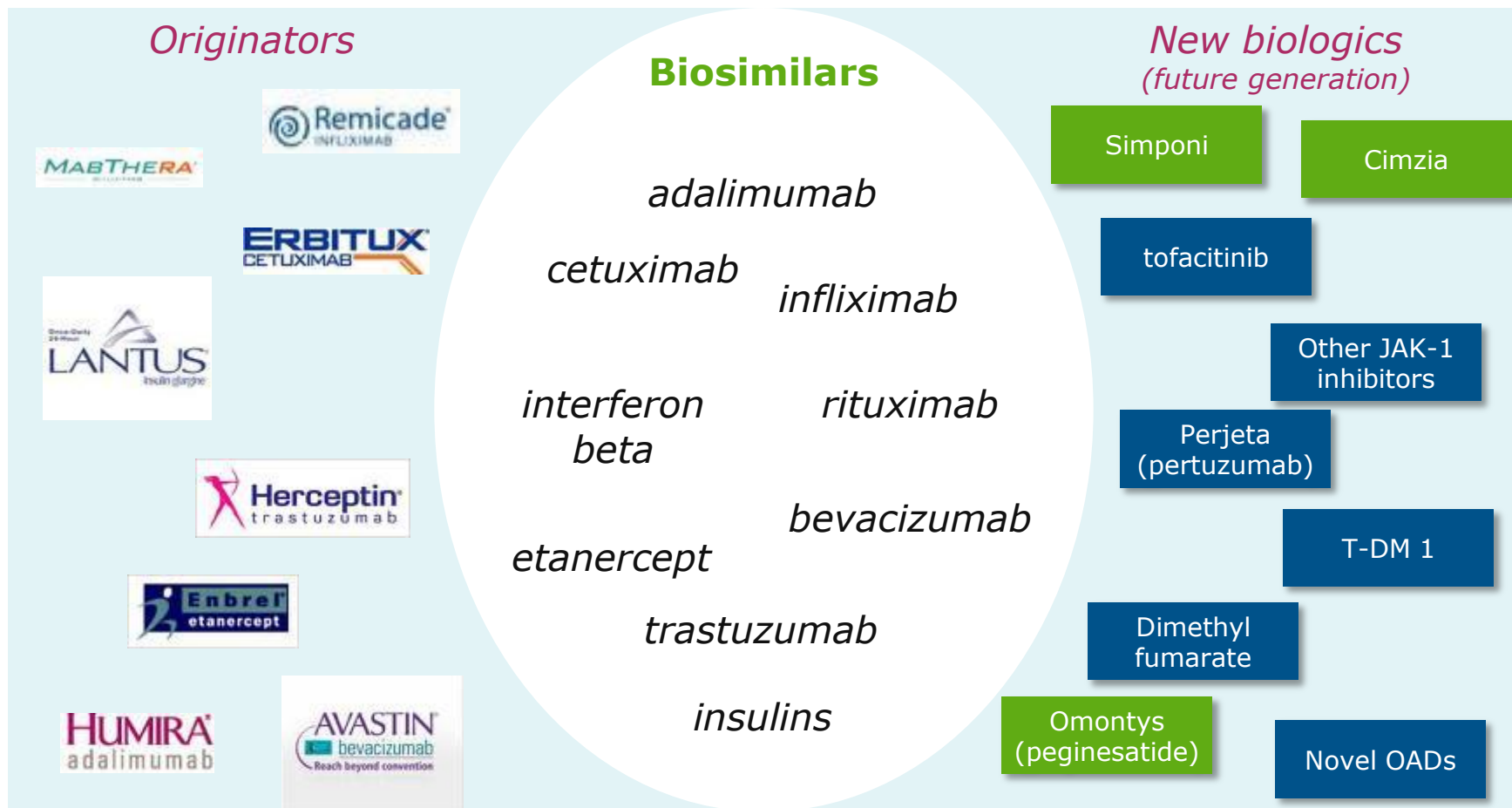
\*CRAMS, Contract Research and Manufacturing Services \*\* Based on press release news

# Original manufacturers will employ a range of defence approaches to contain the impact of biosimilars



# New biologics represent a threat for upcoming biosimilars

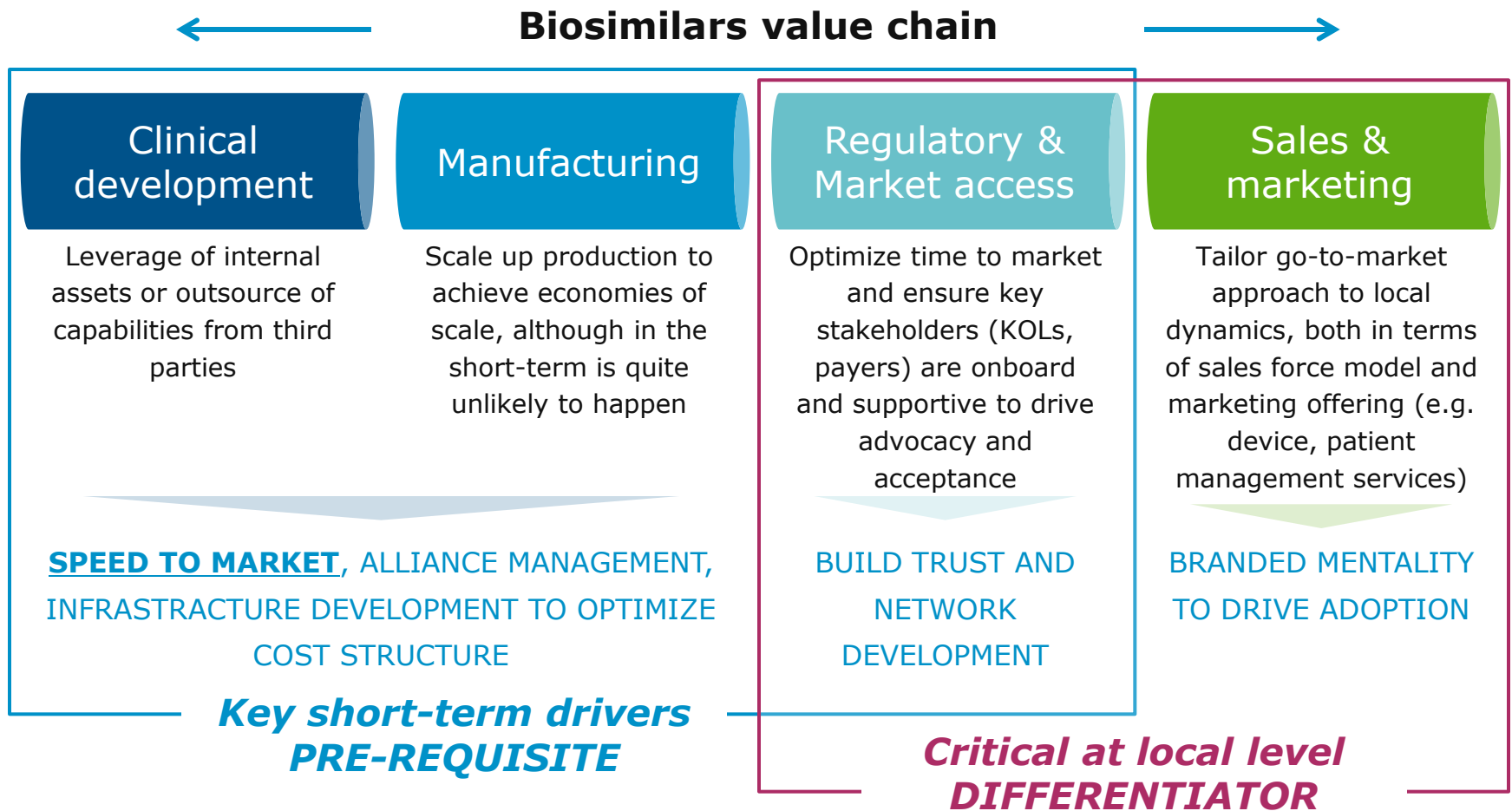
When engaging stakeholders, the biosimilar value proposition should include both the originator and follow-on biologics in the same TA





As biosimilars are mainly copies, speed to market remains key

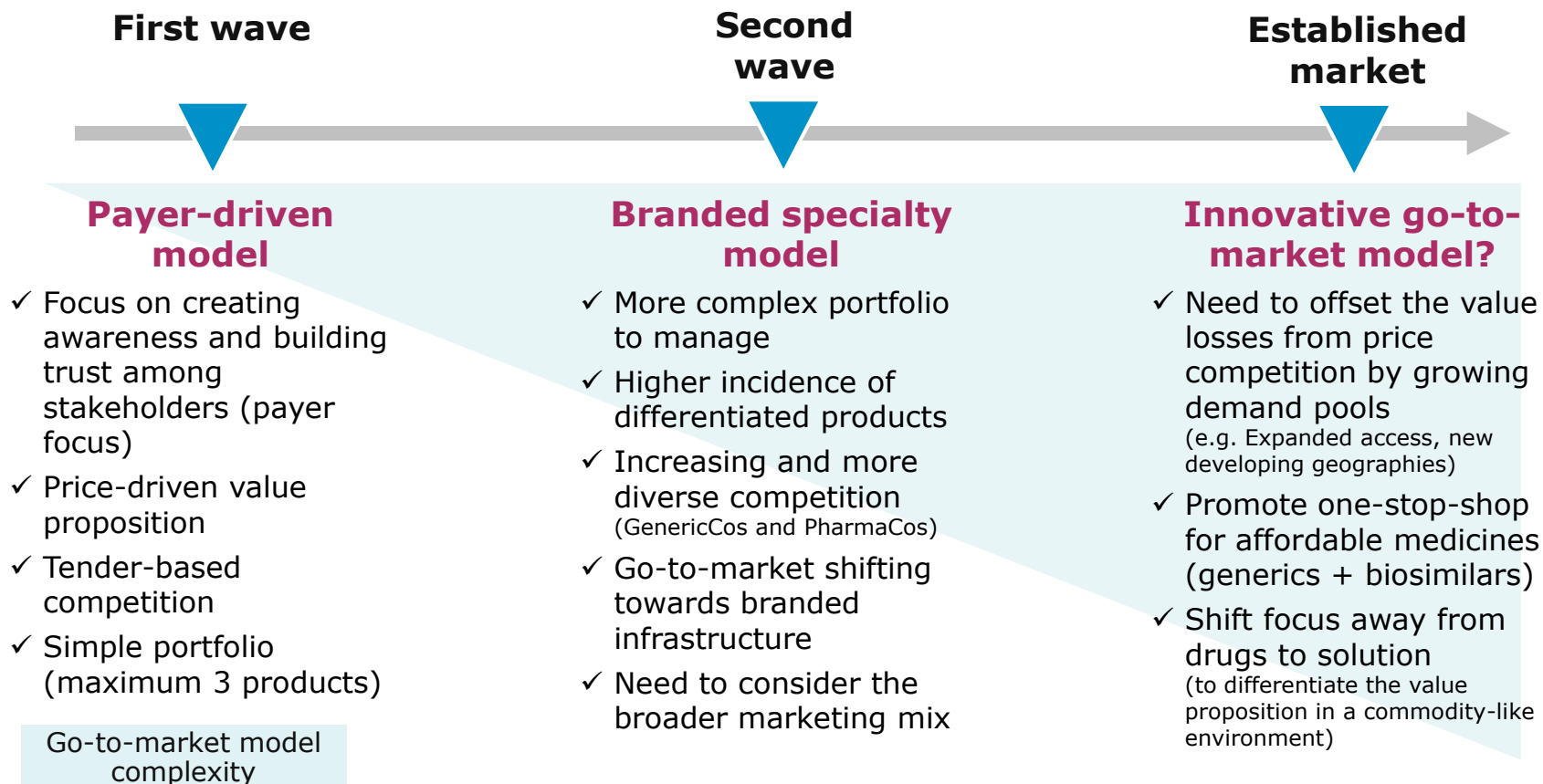
Going forward, while the scientific aspects will remain a basic pre-requisite, commercial models could drive differentiation at local level



# Go-to-market models are soon expected to transform

The evolving competitive arena and more complex biosimilars portfolios to manage will drive the transition

## *Biosimilar go-to-market evolution*





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