The International Biosimilars Experience: Lessons for Alberta

2016 Institute of Health Economics Alberta Biosimilars Forum

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IMS INSTITUTE FOR HEALTHCARE INFORMATICS

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Agenda

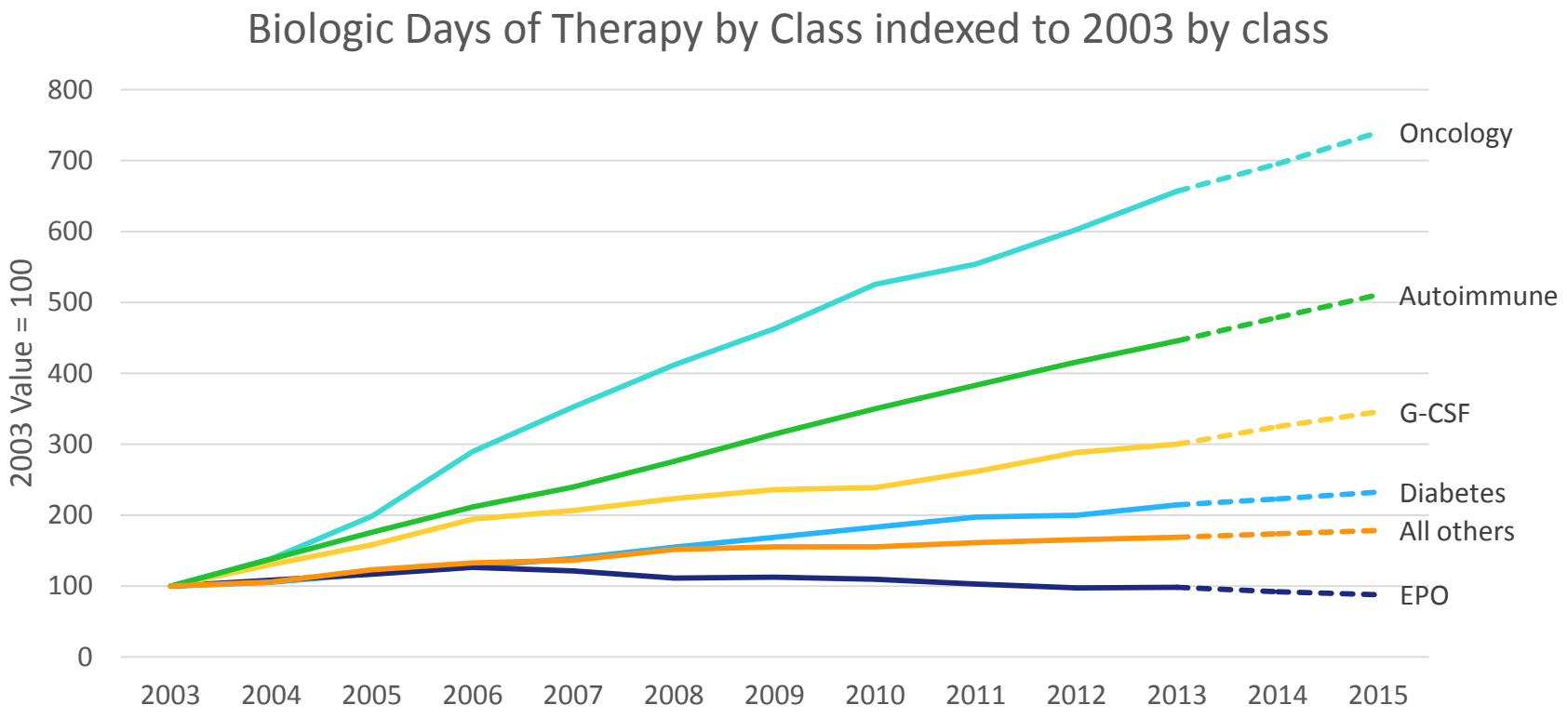
- Framing the biosimilar landscape
- Approaches taken to biosimilar access and reimbursement
- Outcomes achieved
- Considerations for Alberta

Framing the biosimilar landscape

- Role and use of biologics in treating patients is expanding
- Medicine costs have risen accordingly
- Innovation will extend the use of biologics over the next decade
- Manufacturers are aggressively pursuing development of a large number of biosimilar products

Evolution of biologic use

Dramatic increases in usage of biologics over 10 years



Source: IMS Institute for Healthcare Informatics, "Harbingers of Change" October 2014. Projected values for 2014, 2015

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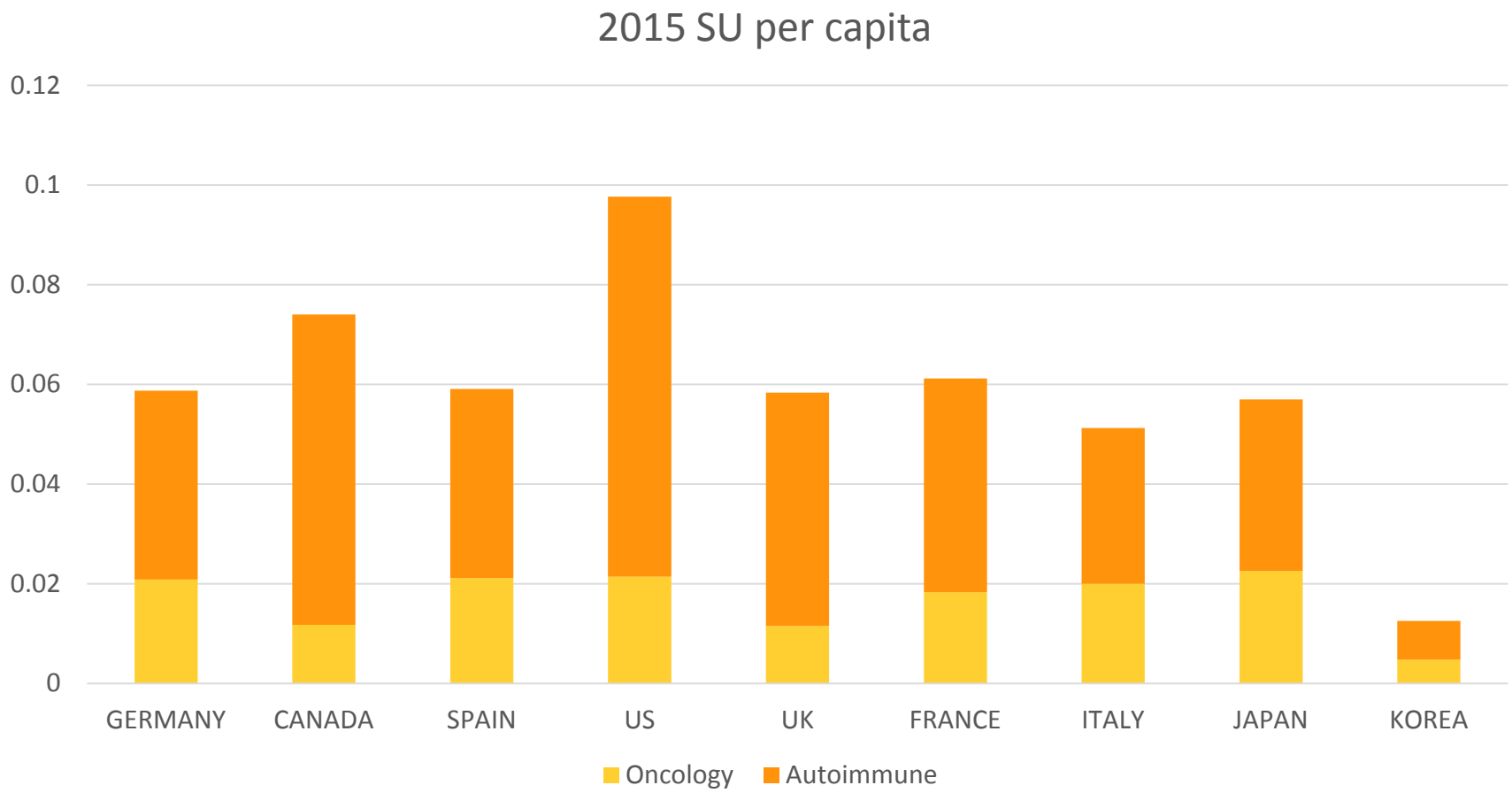
Oncology and autoimmune biologics use in 2015

Use in Korea substantially lower than other major developed countries



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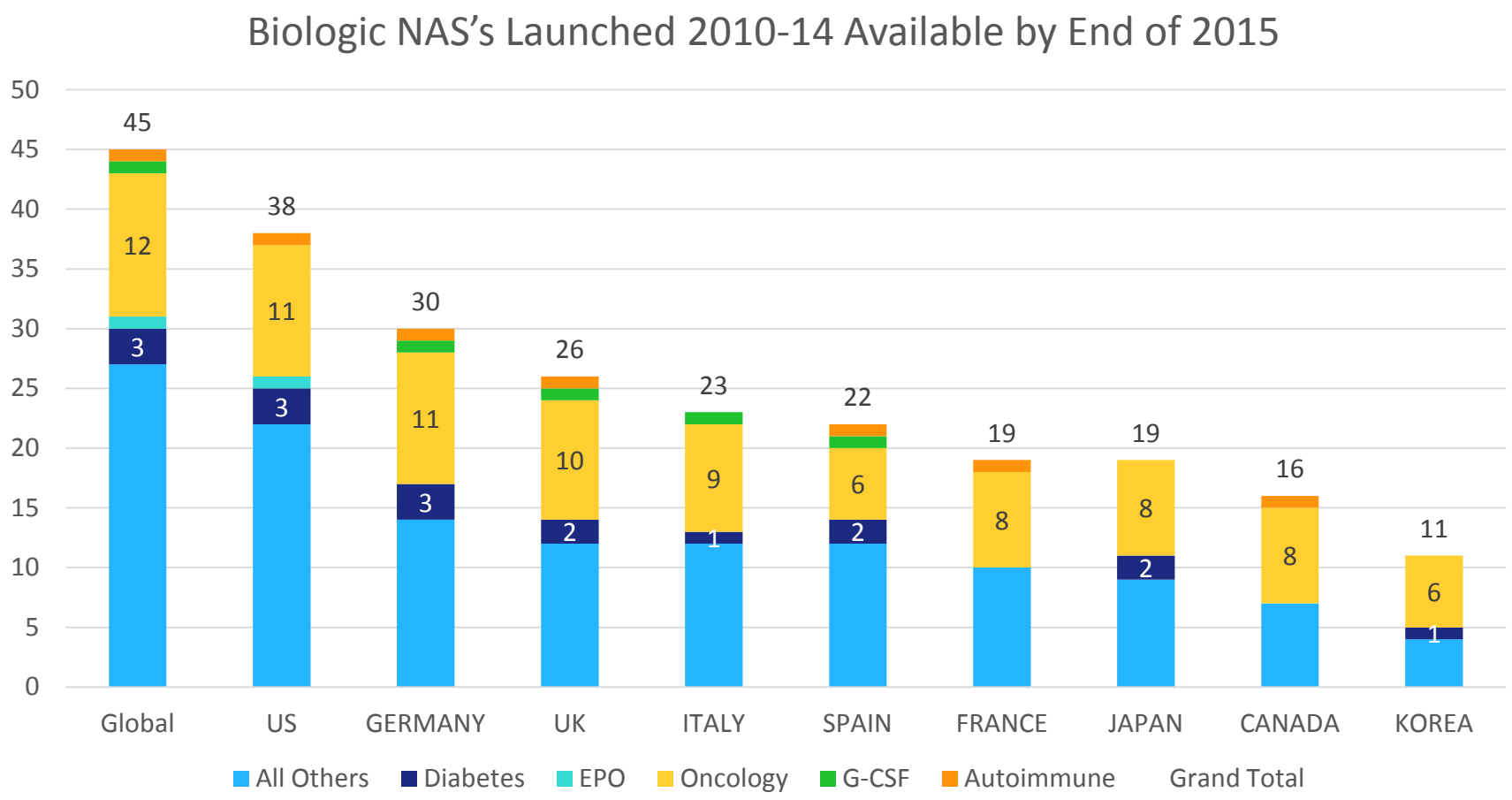
Availability of new biologics

Only 1 in 4 recently launched new biologics are available in Korea



Source: IMS Institute for Healthcare Informatics, Dec 2015

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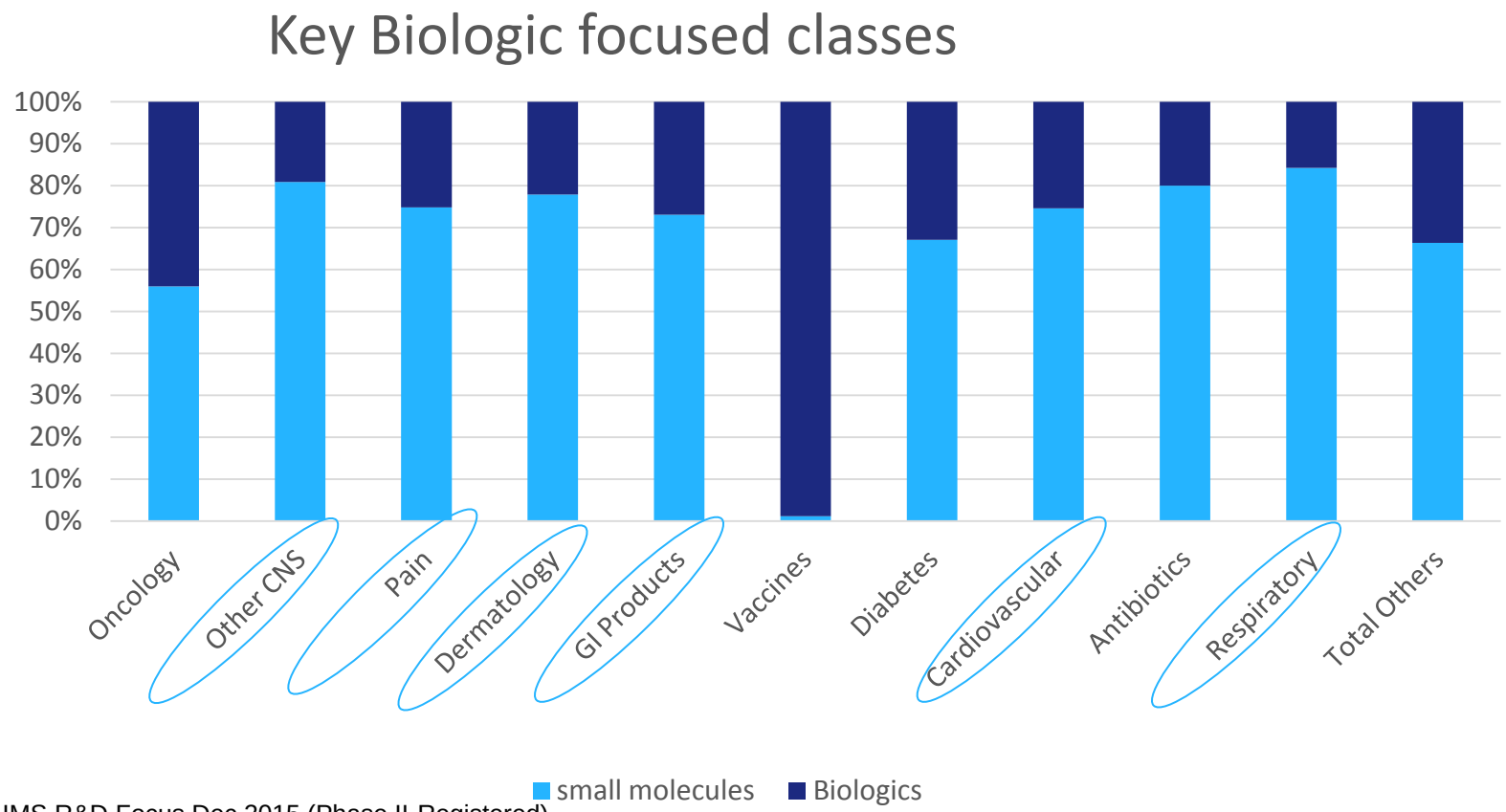
Pipeline of future biologics

Significant share of most major disease areas including several that have traditionally been small-molecule based



Source: IMS R&D Focus Dec 2015 (Phase II-Registered)

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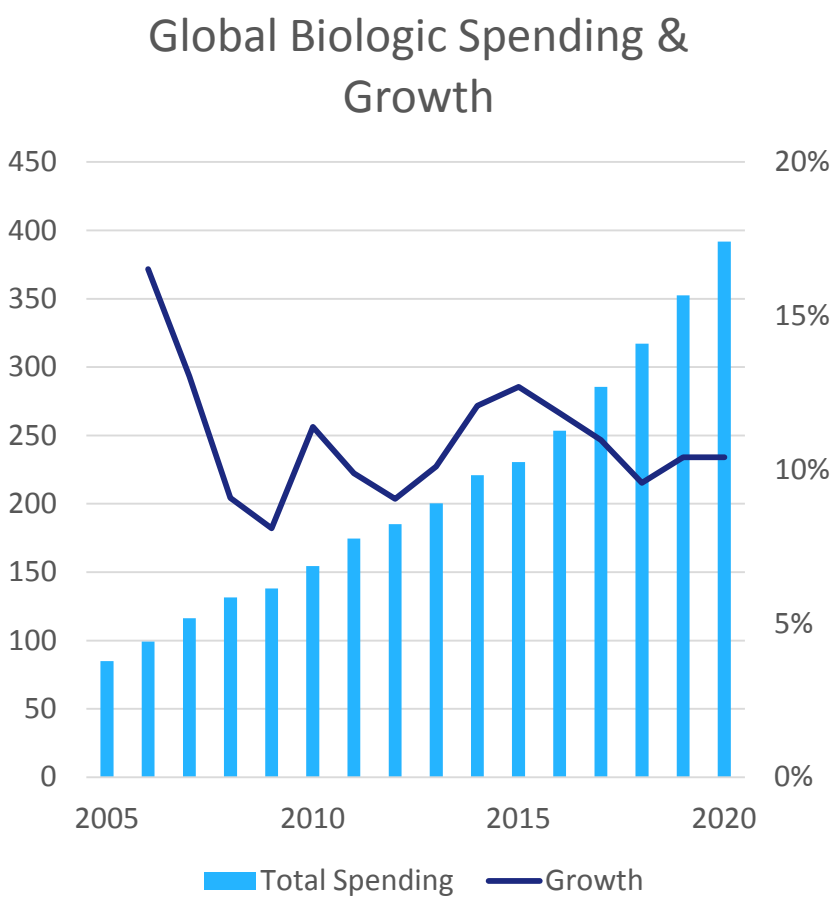
Spending on biologics

Forecast to reach about $400bn by 2020 globally



	2015 Spending US$BN	2016-20 CAGR
US	127.4	14.3%
GERMANY	12.8	4.7%
JAPAN	12.6	2.1%
FRANCE	8.3	2.1%
UK	6.9	7.8%
CANADA	6.0	3.2%
ITALY	4.8	7.1%
SPAIN	4.1	-0.3%
KOREA	1.6	5.8%

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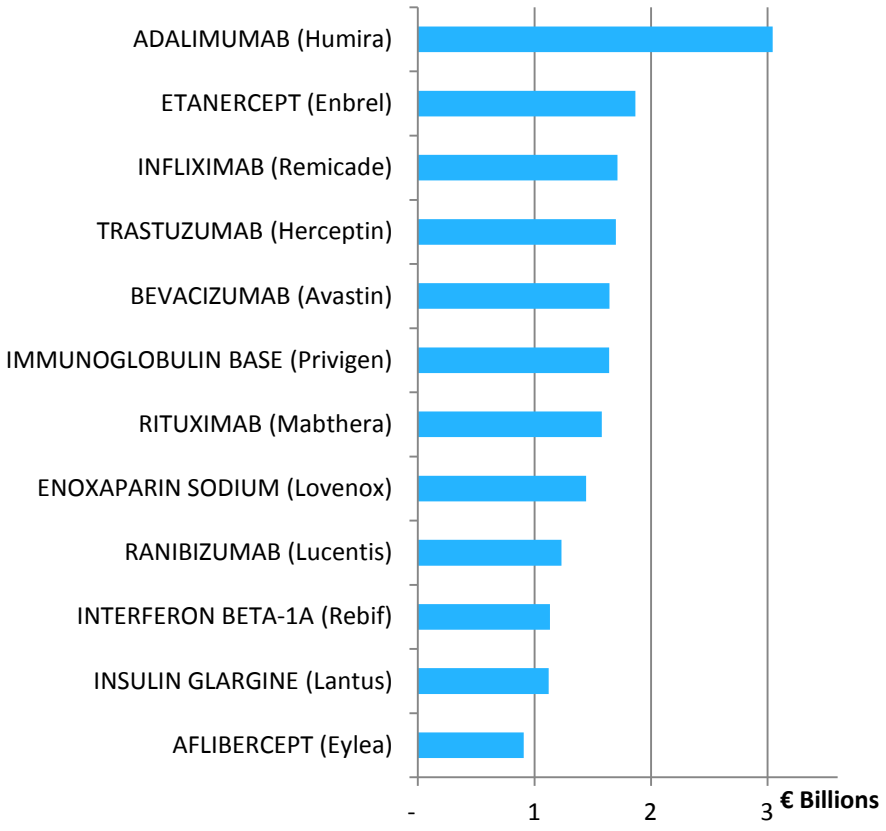
Loss of exclusivity drives biosimilar interest

Key products protection expired or losing protection by 2022



EU expiry date
2018
Expired
Expired
Expired
Expired
Expired
Expired
Expired
2016
Expired
Expired
2020

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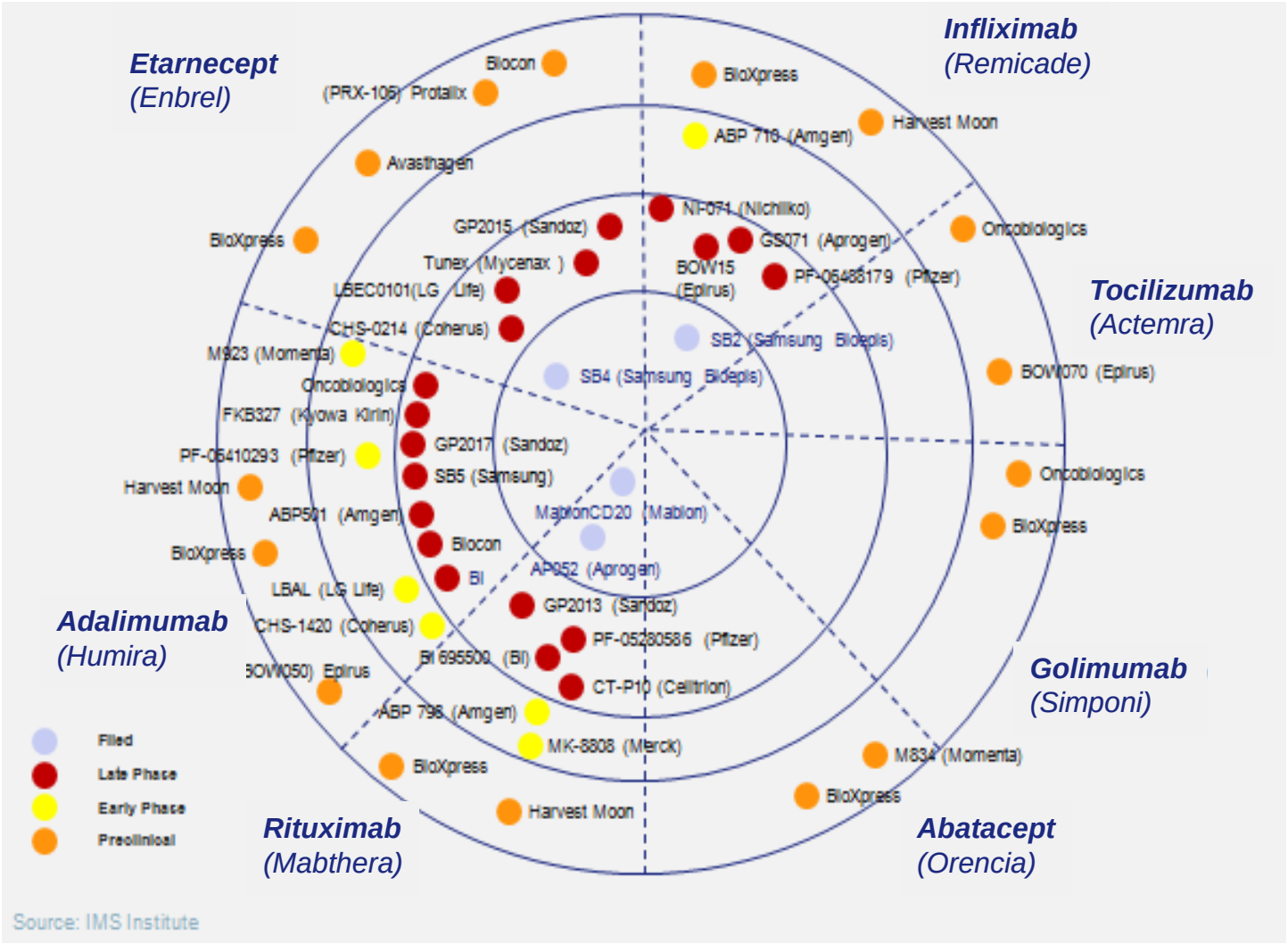
The biosimilars pipeline is extensive



Source: IMS Institute

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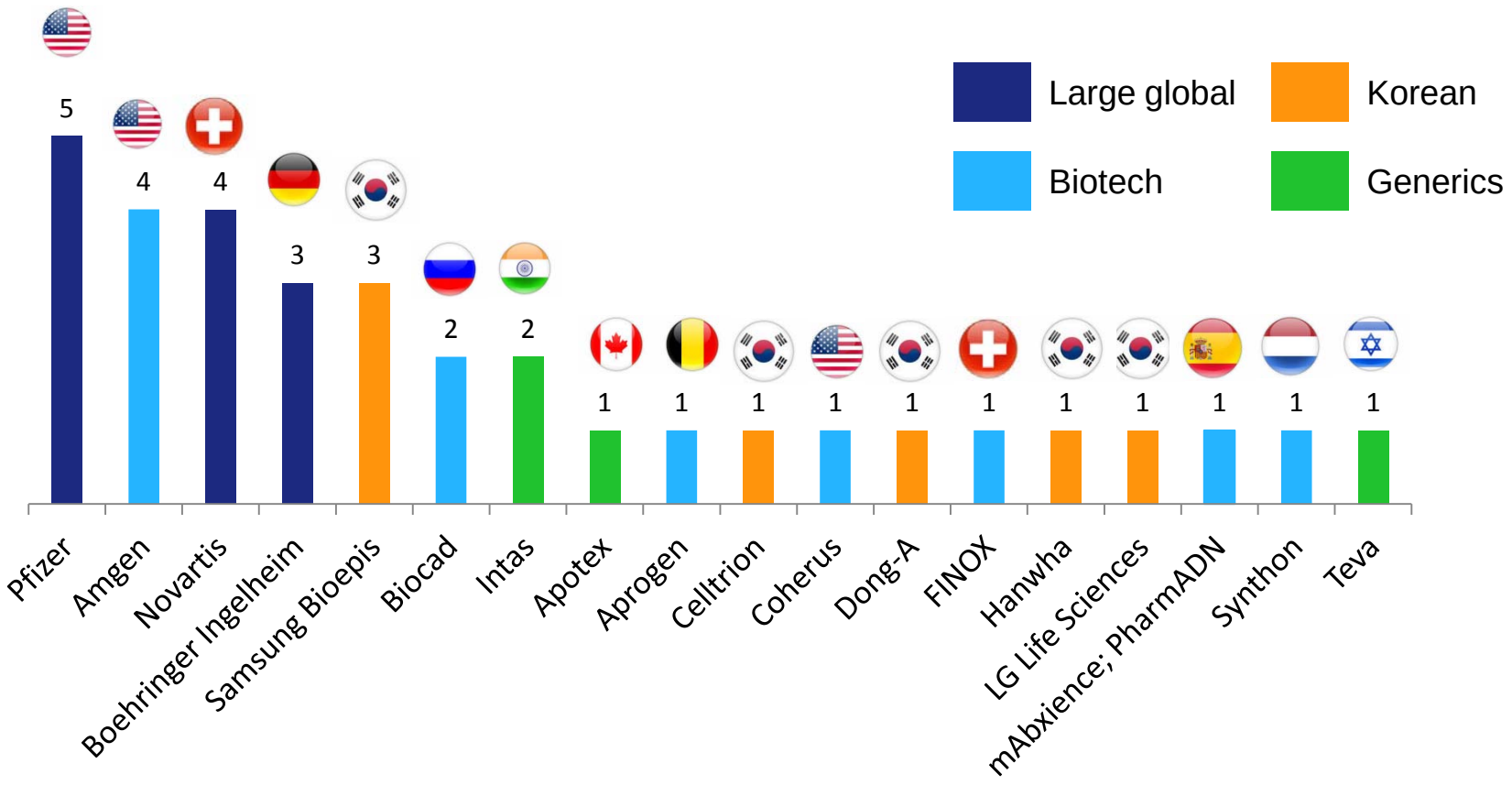
A diverse set of companies are investing in biosimilar development

Number of products in registration, pre-registration, and phase III



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Approaches taken to biosimilar access and reimbursement

- Four major elements of access and reimbursement
- Wide variation across countries
- Stakeholder role differs

Major elements of access and reimbursement

Pricing and reimbursement approach

- Price level of originator after biosimilar entry
- Price level of biosimilar relative to originator
- Pricing mechanisms applicable to both originators and biosimilars

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Examples:
- "Free pricing" for biosimilars, but major discount vs. originator medicine expected (Germany)
- "Free pricing" for biosimilars but included under and indirectly controlled by PPRS regulation (UK)
- In retail setting, biosimilar pricing at 25-35% lower than innovator's original price and mandatory price cut of 15-20% of originator medicine (Italy)
- Mandatory discount of 25% for biosimilar vs. originator's reimbursement price (Poland)
- Inclusion of biosimilar and originators in reference pricing groups (multiple)

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Procurement of biosimilars

- Use of tenders
- Scope of tenders (national, regional, local)

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Examples:
- Regional tenders for originator/biosimilar medicines only if considered interchangeable – for EPO but not G-CSF, inflximab (UK)
- Regional/local tenders for originators and biosimilars for naïve patients; direct purchasing from manufactureres for patients already under treatment (Spain)
- Specific procurement lot for originator medicine for existing patients, but provincial tender (Tuscany) for all infliximab patients (Italy)

Prescribing decisions related to biosimilars

- Initiation, switching
- Education programs for prescribers and patients
- Nature, magnitude and operation of incentives provided to prescribers

Examples:

- NICE recommendation to start treatment with the cheapest option; no national rule on switching; Clinical Commissioning Groups encurange use of biosimilars but physicains have flexibility; some NHS trusts pilot efforts with hospitals to enforce limited switching (UK)
- Quotas for biosimilars set by regional physician associations in conjunction with sick funds; physician bears responsibility for initiation/switching (Germany)
- Non-binding quotas in place for some regions (Italy)
- Treatment switching for infliximab explicitly permissable (Poland)

Dispensing of biosimilars

- Automatic substitution of biosimilar
- Pharmacy flexibility

Examples:
- Automatic substitution at point of dispensing not possible (multiple)
- If branded biologic or biosimilar is not unavailable, consultation with prescribing clinician required (multiple)
- If biosimilar is “bio-identical” (e.g. manufactured by the same company) it can be substituted (Germany)

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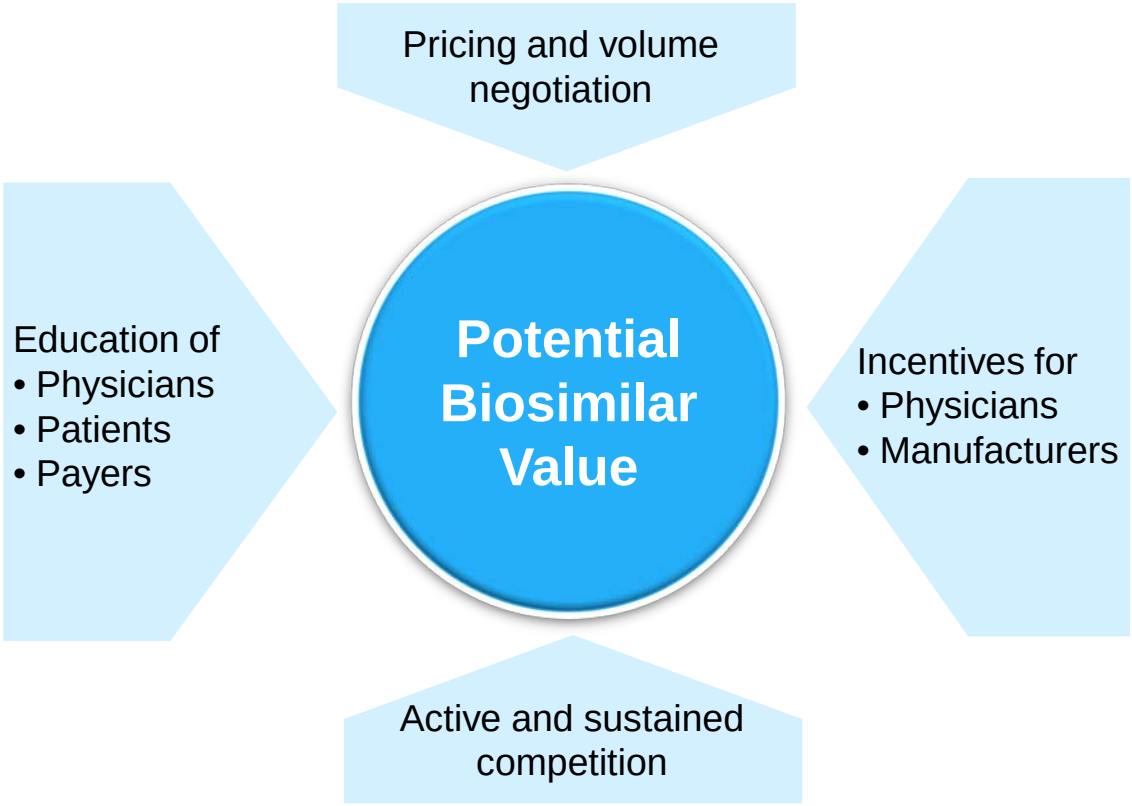
Drivers of differences across health systems

Examples

- Culture of small molecule brands generics
- Culture of biologics use
- Strength of clinical evidence/ champions
- Organization of healthcare – level of decision-making and fragmentation
- Organization of purchasing – linkage to clinicians, budget-holders
- Culture of “Incentives” to the prescriber – positive and negative

Multiple factors customized to the health system will determine how much value biosimilars will provide

Unlocking the Potential of Biosimilar Medicines



Source: IMS Health, IMS Consulting Group, Jan 2016

Outcomes achieved

The Impact of Biosimilar Competition

- IMS 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, EGA, 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.
- This first report is based on full year 2014 data; the second on 2015 data. The objective thereafter is to annually publish the previous year's updated indicators.

Five Observations by IMS Health

- In this document IMS Health suggests five key observations based on the data from the report

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Observation one:
Competition drives down the price (1)

Prices before discounts and rebates

	Price per TD/Year before Biosimilar entrance		
	Biosimilar and Reference product	Accessible market	Total market
EPO	-33%	-34%	-26%
G-CSF	-32%	-32%	-23%
GH	-19%	-13%	-13%
Anti-TNF	-8%	-8%	-4%

The increased competition affects not just the price for the directly comparable product but also the price of the whole product class

Observation one: Competition drives down the price (2)

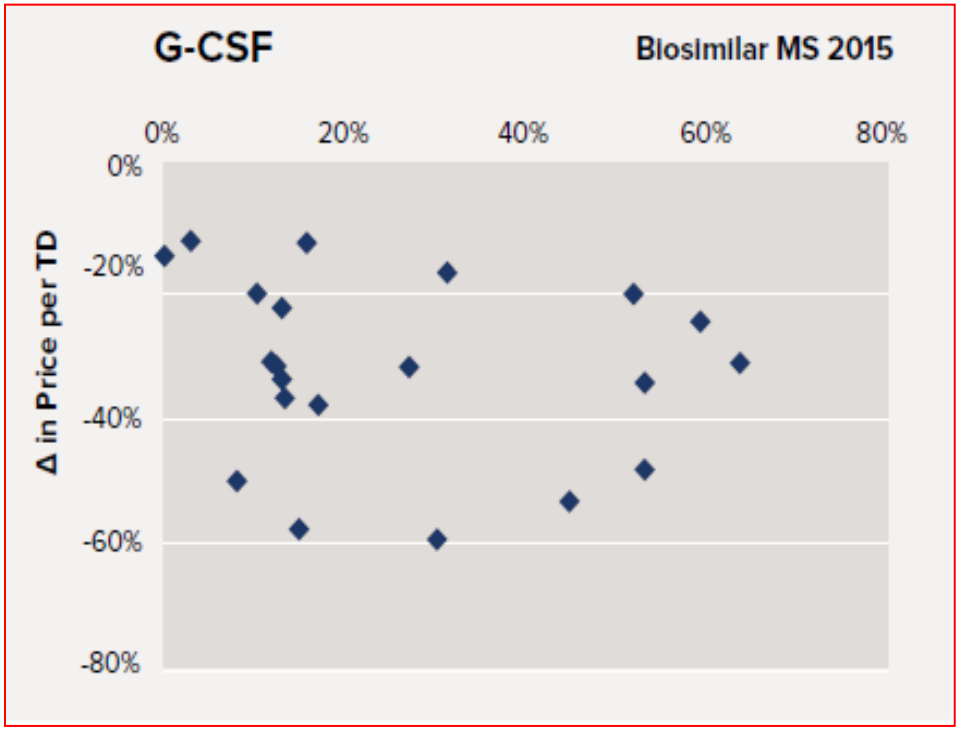
The countries with the highest reduction show reduction of 50-70%

When information of discounts are available, it suggest that similar levels are present in more markets

Epoetins	Price per TD 2015 / Year before Biosimilar entrance
Portugal	-61%
Slovakia	-52%
Poland	-49%
G-CSF	
Slovakia	-59%
Bulgaria	-58%
Slovenia	-50%
HGH	
Finland	-47%
Poland	-47%
Slovakia	-31%
Anti-TNF	
Sweden	-21%
Bulgaria	-19%
Denmark	-15%

Observation two: The correlation between biosimilars MS and price reduction is weak

- High savings can be achieved even if the share of biosimilars is low.
- Reduction can be achieved through price regulation and/or commercial decisions
- ***Biosimilar product s are likely an essential step to generate a competitive environment, which leads to price reduction***



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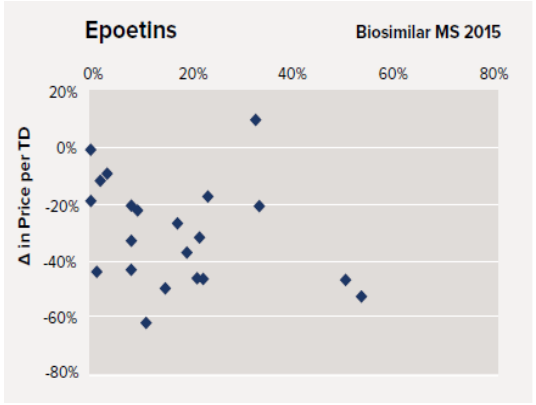

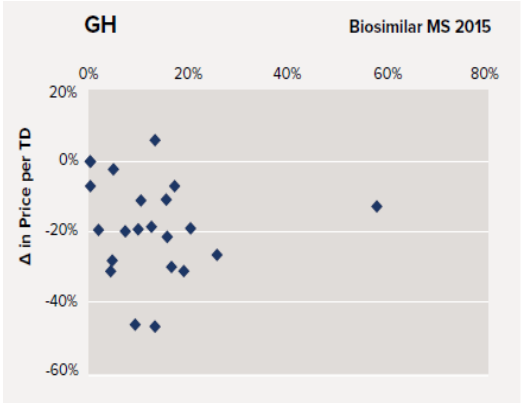

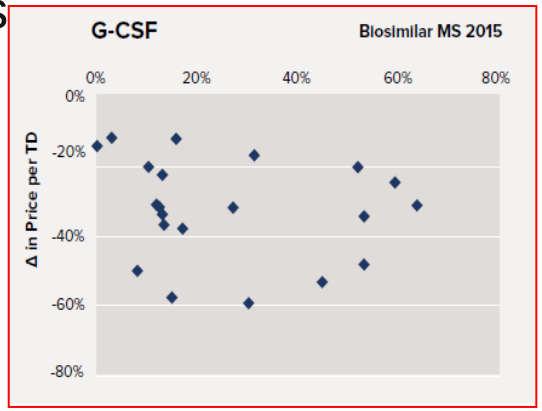

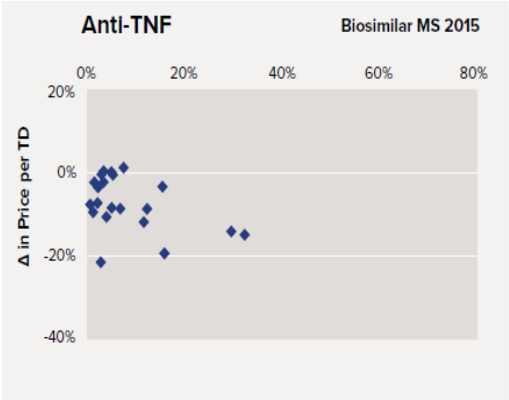

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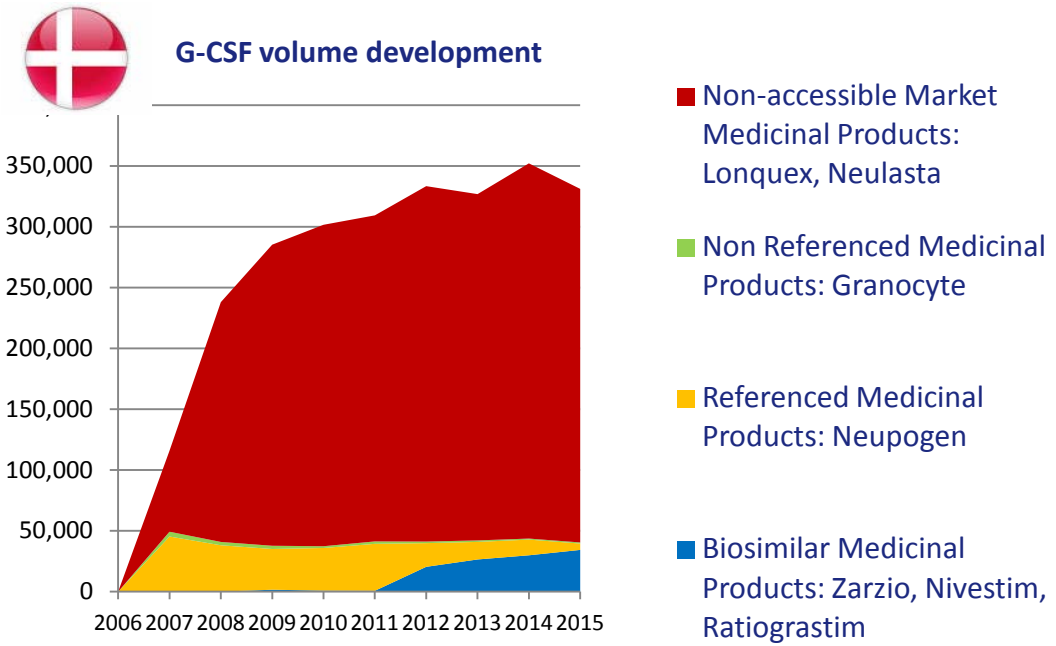
Observation three: Competition can also influence the originator's behaviour

- Originators launching innovative long-acting/pegylated products without a price premium versus the short-acting, changing the treatment paradigm and therefore usage pattern
- Originators effectively reducing the price levels
- Originator companies are looking to launch biosimilar products



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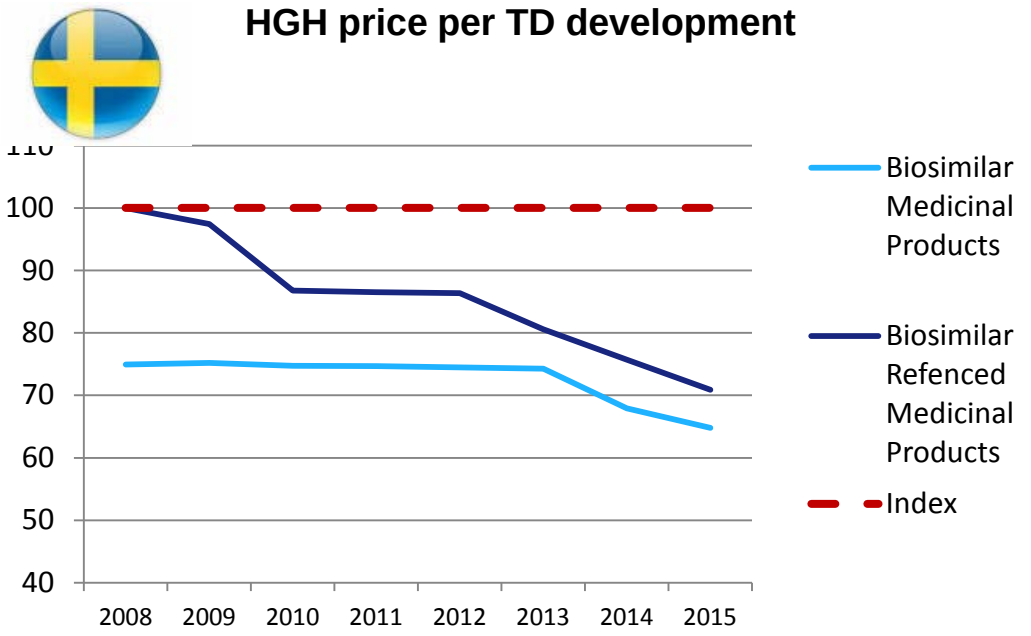

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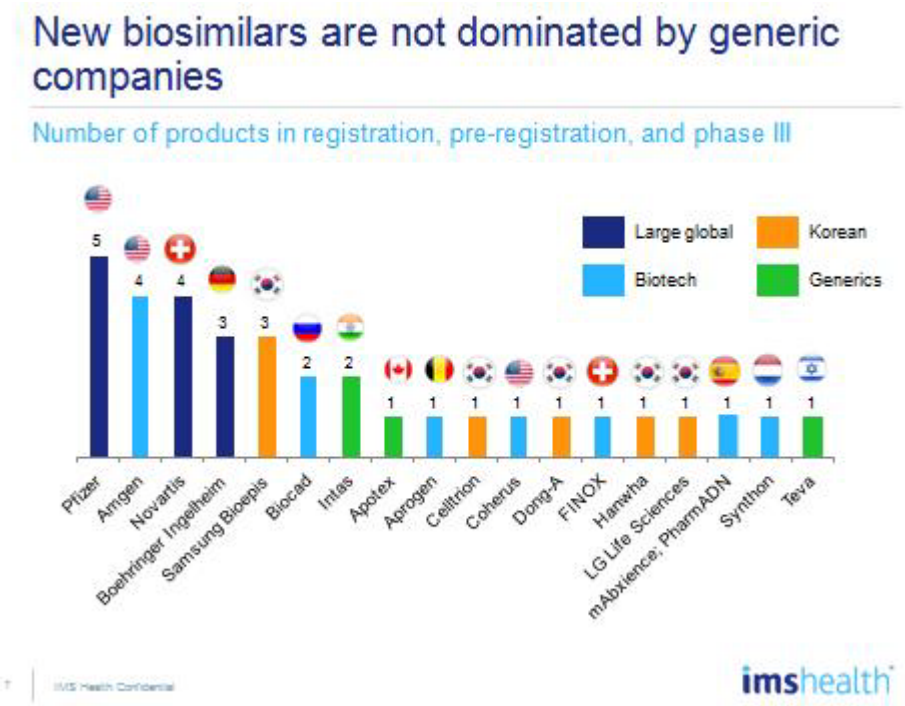

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Observation four: Lower price has the most impact on usage in countries with low initial usage

Lowered prices impact usage but;

- New indications or restriction of indicat (as the EPO safety warnings)
- General economic conditions
- Changes in diagnosing and prevalence diseases

- ***In countries which used to have low usage/availability in the classes the price reductions seem to have a significant impact on the increased access.***

	Price per TD/ Year before Biosimilar entrance	TD per capita (Year before Biosimilar entrance)	Volume TD 2014/ Year before Biosimilar entrance
Epoetins HGH			
Romamia	-27%	0.024	177%
Czech Rep	-20%	0.060	54%
Poland	-47%	0.043	78%
G-CSF			
Romania	-48%	0.004	498%
Bulgaria	-58%	0.001	1016%
Slovakia	-59%	0.004	371%
Anti-TNF			
Bulgaria	-19	0.099	131%
Czech Rep	-12%	0.232	53%
Slovakia	-8%	0.492	78%

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Observation five: The product profile differences can explain differences in impact on the KPIs

- The differences in approved indications are relatively small for HGH and G-CSF, somewhat larger for EPO and the largest for Anti-TNF
- As a result, different products are used for different indications which impact the patients for which they compete in the class. This is most obvious in Anti-TNF.
- Frequency of administration and mode of administration also impact the competition within a class:
  - We can see the differences in frequency impacting both for EPO and G-CSF but mainly for selected patients (for example patients recovering at home after a chemotherapy cycle)
  - The main differences are seen in Anti-TNF between a more frequent subcutaneous injection in home treatment and or a less frequent intravenous infusion in a hospital setting
  - User friendliness of device, simpler preparation or no need for refrigeration has mainly been a differentiator for Growth Hormones
- ***There are relevant product differentiations in all four classes which impact the product mix.***

Why so large variations between classes?

- **Length of treatment** - short treatment cycles makes issues of switching less urgent
- **Patient administration** - administration by health care professionals simplifies switching
- **Potential for innovation in class** - clinically meaningful improvements can cause significant differences in impact
- **Clinical evidence/ champions** - combination of the strength of clinical data and the existence of well informed champions promoting the use

Considerations for Alberta

What's important from the health system perspective?	• Safety, quality, reliable supply of medicines • Appropriate use for patients • Sustainable improving health system
What should be the role reimbursement policy?	• Marketplace that is competitive and sustainable • Reinforcement of appropriate use • Role of stakeholders in patient care decision-making • Allocation of available funds
How will you know if the policy is working?	• Explicit measureable goals • Ability to capture relevant information • Interpretation

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