The Impact of Biosimilar Competition

Five Observations by IMS Health

IMS Health has produced the report The Impact of Biosimilar Competition (based on 2014 figures) for the European Commission. The report has been published in December 2015. Input to the report was given by the European Generic medicines Association, the European Federation of Pharmaceutical Industries and Associations and and EuropaBio, the European Association of Bio-Industries. The report presents a set of Key Performance Indicators (KPIs) for European countries.

In this document IMS Health suggests five key observations based on the data.

1. Competition drives down the price

One of the key arguments for introduction of biosimilars is to drive down prices. The three established therapy areas with biosimilar competition show a consistent picture of reduced average prices in European Economic Area (EEA) countries (see Table 1).

The increased competition affects not just the price for the directly comparable product but also has an effect on the price of the whole product class. It can have an almost as large or even a larger impact on the total market price as it has on the biosimilar/reference product price.

Focusing on the 3 countries where we see the highest price reduction (see Table 2).

Other countries might have a similarly high reduction, which is not included in the data, through non-published discounting. Highest reduction may not be the same as the lowest price. The present price is also impacted by the starting price and the mix.

The countries with the highest reduction show reduction of 50-70%. In order to achieve long-term savings, there should be a competition with multiple players; however, too high short term savings might preclude this.

Table 1

	Price per TD (2014/Year before biosimilar entrance)		
	Biosimilar and Reference product	Accessible market	Total market
EPO	-28%	-33%	-27%
G-CSF	-19%	-10%	-28%
GH	-7%	-7%	-13%

Table 2

	Price per TD (2014/Year before biosimilar entrance)
	Total Market
Epoetins	
Slovakia	-61%
Portugal	-51%
Bulgaria	-51%
HGH	
Bulgaria	-72%
Slovakia	-71%
Romania	-59%
G-CSF	
Finland	-49%
Slovenia	-48%
Slovakia	-39%

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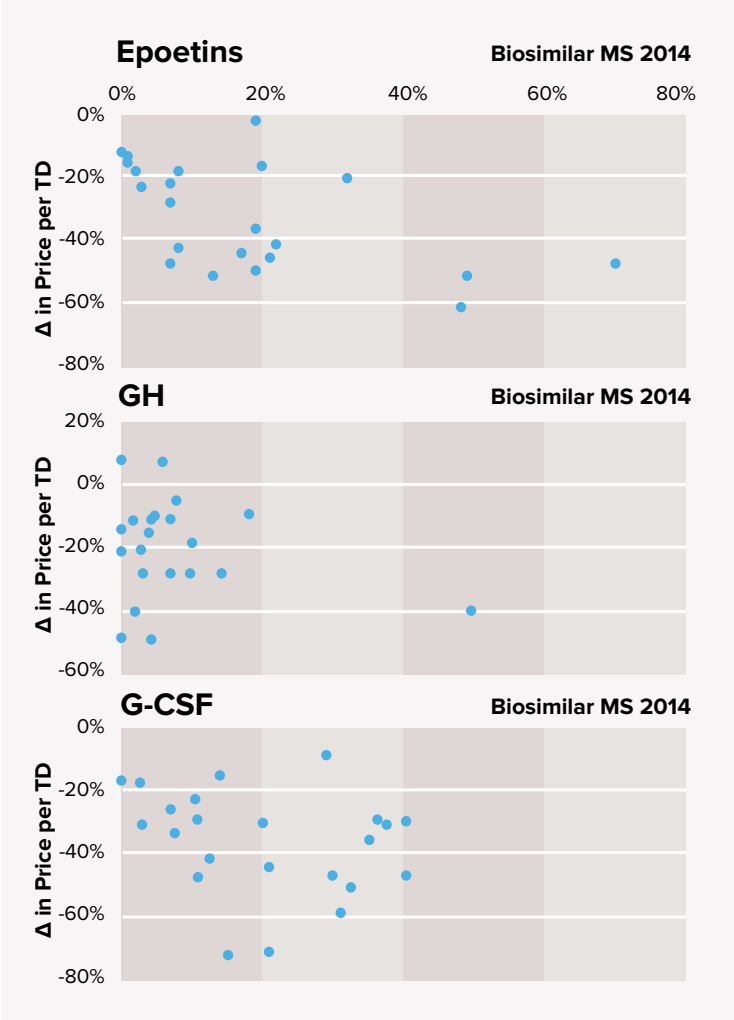
2. The correlation between biosimilars market share and price reduction is weak

The correlation between biosimilar market share and price reduction is weak, as can be seen by the three established biosimilar classes.



For the 3 classes we can see the same pattern; high savings can be achieved even if the share is low.

Price reduction can be achieved through price regulation interventions and/or commercial decisions of manufacturers.

Even if the biosimilar product does not end to be the product sold it is likely an essential step to generate a competitive environment, which leads to price reduction.

3. Competition can also influence the originator's behaviour

The originators have acted differently in many cases than what we have experienced for small molecules. Traditionally, behaviour has been that the originator has either maintained price or reduced price based on mandatory price regulations. *In the Biosimilar classes we have seen a multitude of different behaviours:*

- 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
- There is also a trend when originator companies are looking to launch biosimilar products

A part of the explanation for the changed behaviour in many cases can be that the product classes are hospital products. The hospital market is characterised by a rather strong competition, including on price, between the manufacturers.

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4. Lower prices has the most impact on usage (patient access) in countries with low initial usage

Some level of price-elasticity is expected to be observed for these products. The report however shows different levels of impact to lowered prices for different countries and different classes.

For Epoetins, we can see significant increases in consumption for countries with low starting volumes at time of introduction of biosimilars and at the same time volume reductions in countries with a high use based on safety warnings.

Lowered prices impact usage but we also need to be aware of other factors:

- New indications or restriction of indications (as the EPO safety warnings)
- General economic conditions imposing use restrictions
- Changes in diagnosing and prevalence of 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			
Romania	-42%	0.036	457%
Bulgaria	-51%	0.125	166%
Czech Rep	-44%	0.062	165%
Belgium	-12%	1.081	-52%
Austria	-36%	0.942	-28%
Germany	-45%	0.412	-25%
HGH			
Slovakia	-48%	0.044	98%
Czech Rep	-21%	0.060	82%
Poland	-39%	0.043	62%
G-CSF			
Romania	-59%	0.004	1621%
Bulgaria	-72%	0.001	1161%
Poland	-44%	0.010	474%

5. The product profile differences in classes 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.

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