The Impact of Biosimilar Competition

Reading Guide

This example has been developed as a simplified guide to read the report that has a broad set of Key Performance Indicators for multiple countries.

EPO and Austria are used as the example.

Volume development

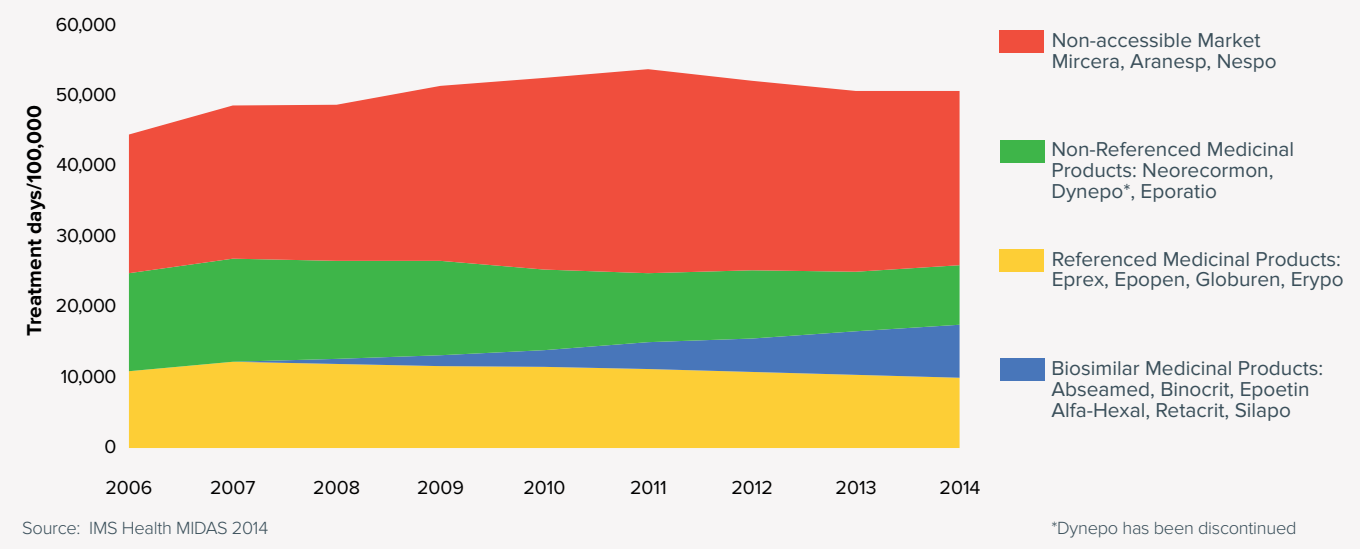
Chart *Epoetin Volume Development* shows volume development over time for the total European Economic Area (EEA). Volume is expressed in (WHO) DDDs as a proxy to be able to include different products.

The blue part of the chart shows the volume share of Biosimilar Medicinal Products (listed) which is currently at 15%. The yellow part shows volume share of Referenced Medicinal Products to the approved Biosimilar products which is currently at 20%.

After the introduction of Biosimilar Medicinal Products, the combined market of Referenced Products and Biosimilars has taken an increased share of 35% of the total market. The Non-Referenced Medicinal Products (green part of the chart) are other products with a largely similar profile to the Referenced Products, but have not been referenced. This category was affected by biosimilar entrance, which resulted in a loss of market share from 29% in 2007 to 17% in 2014. The Non-accessible market (red part of the chart) are the Pegylated (long acting) products, with 49% market share.

Overall the market grew until 2011. The slight volume drop in 2011 is largely explained by a safety warning from EMA that is described on page 4 of the report.

Epoetin volume development



Source: IMS Health MIDAS 2014

*Dynepo has been discontinued

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Approved indications

The table *Summary of EMA information for approved indications for Epoetin products* shows that the Biosimilar Medicinal Products receive the same indications as the Referenced Medicinal Products. It also shows that not all products are approved for all indications. However, indications are very different in patient populations; difference can be effective in limiting patient potential. Frequency of injecting can also vary and the implication of this might vary with patient type.

Summary of EMA information for approved indications for Epoetin products

		Classification				Indications					Patient Type		Frequency*	Route**	
Molecule	Product	Reference product	Biosimilar	Non-reference	Non-accessible	Anemia for Chemo-therapy patients	Anemia for patients with Chronic Kidney Disease	Preventing Anaemia in premature babies	Autologuos Blood Transfusion	Reduction of allogenic transfusion exposure in Orthopedic surgery	Adult	Paediatric		Subcutaneous	Intravenous
Epoetin alfa	Eprex	●				●	●		●	●	●	●	3x a week	●	●
	Epopen	●				●	●		●	●	●	●	3x a week	●	●
	Erypo	●				●	●		●	●	●	●	3x a week	●	●
	Globuren	●				●	●		●	●	●	●	3x a week	●	●
	Abseamed		●			●	●		●	●	●	●	3x a week	●	●
	Epoetin Alfa Hexal		●			●	●		●	●	●	●	3x a week	●	●
	Binocrit		●			●	●		●	●	●	●	3x a week	●	●

Selected KPIs

The first set of indicators is the *Market share TD 2014* calculated in treatments days/ DDDs. In Austria, Biosimilars represent 78% of Biosimilar + Referenced Products. If the Non-Referenced Medicinal Product also is included (total accessible market), the share of Biosimilar Medicinal Product is 30%. If it is Biosimilar Medicinal Product versus total market, it is 19%.

Selected KPIs to illustrate volume share, price evolution, and volume evolution in the EEA countries:

	Market share TD (2014)			Price per TD (2014/Year before biosimilar entrance)			Volume TD (2014/Year before biosimilar entrance)			TD per capita	First Recorded Sales of Biosimilar
	Biosimilar vs Reference product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Reference product	Biosimilar Accessible market	Total market	Biosimilar and Reference product	Biosimilar Accessible market	Total market		
AU	78%	30%	19%	-21%	-37%	-36%	20%	-9%	-28%	0.68	2008

The second set of indicators, *Price per TD (2014/Year before biosimilar entrance)*, shows price development per treatment day (DDD) comparing 2014 price with prices in the year before the first Epo Biosimilar Medicinal Product was launched (which is 2008 in the case of Austria). The volume weighted average price in 2014 vs. 2007 has fallen 21% for the Biosimilar Medicinal Product and Referenced Product, 37% for Biosimilar Accessible Market and 36% for the total market. This data illustrates that the competitive response or the price regulators response is to lower price also on other products as competition intensifies.

Selected KPIs to illustrate volume share, price evolution, and volume evolution in the EEA countries:

	Market share TD (2014)			Price per TD (2014/Year before biosimilar entrance)			Volume TD (2014/Year before biosimilar entrance)			TD per capita	First Recorded Sales of Biosimilar
	Biosimilar vs Reference product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Reference product	Biosimilar Accessible market	Total market	Biosimilar and Reference product	Biosimilar Accessible market	Total market		
AU	78%	30%	19%	-21%	-37%	-36%	20%	-9%	-28%	0.68	2008

The third set of indicators, *Volume TD (2014/Year before biosimilar entrance)*, shows the volume development in treatment days (DDDs) comparing 2014 versus the year before the first Epo Biosimilar Medicinal Product was launched (which is 2008 in the case of Austria).While the Biosimilar and the Referenced Product volume has grown 20%; the full accessible market volume decreased 9% and the total market volume decreased 28%.

Selected KPIs to illustrate volume share, price evolution, and volume evolution in the EEA countries:

	Market share TD (2014)			Price per TD (2014/Year before biosimilar entrance)			Volume TD (2014/Year before biosimilar entrance)			TD per capita	First Recorded Sales of Biosimilar
	Biosimilar vs Reference product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Reference product	Biosimilar Accessible market	Total market	Biosimilar and Reference product	Biosimilar Accessible market	Total market		
AU	78%	30%	19%	-21%	-37%	-36%	20%	-9%	-28%	0.68	2008

The last set of indicators, *TD per capita*, shows the usage per capita of the total market in 2014 which is 0.68 in Austria. The year with the *First recorded sales of Biosimilar* in Austria is 2008.

Selected KPIs to illustrate volume share, price evolution, and volume evolution in the EEA countries:

	Market share TD (2014)			Price per TD (2014/Year before biosimilar entrance)			Volume TD (2014/Year before biosimilar entrance)			TD per capita	First Recorded Sales of Biosimilar
	Biosimilar vs Reference product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Reference product	Biosimilar Accessible market	Total market	Biosimilar and Reference product	Biosimilar Accessible market	Total market		
AU	78%	30%	19%	-21%	-37%	-36%	20%	-9%	-28%	0.68	2008

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