COMPASS NEWS TODAY

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Biosimilars Causing A Stir In The U.S. Market, Are You Ready?

Barriers to biosimilar uptake in the US temper optimistic predictions of accelerated biosimilars market growth.

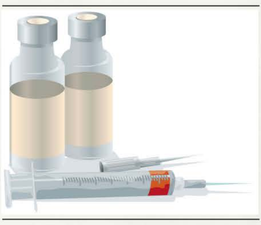
Wondering why the opening of the US market to biosimilars isn't resulting in a collective cheer or groan from the biopharmaceuticals industry? Despite the FDA approval of the first biosimilar drug, Zarxio, in the US earlier this month, the complex factors influencing the biologics market suggest that biosimilars will not overtake the market as rapidly as generics.

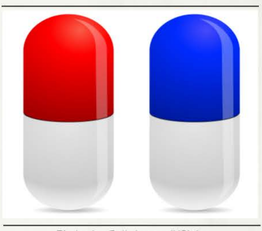
Biosimilars Disrupt Business For Biopharmaceutical Giants

Investors were unconcerned as the dip in Amgen's stock after Zarxio's approval rebounded a few days later after promising data was presented about their new biologic that lowers cholesterol. The California biotech giant has also invested in their own biosimilars. Companies like Merck, Hospira and Sandoz, are aggressively pursuing biosimilars seeking rapid growth in the biosimilars market. With the Zarxio entry into the US, optimism is tempered by factors such as a stable of new biologics and biobetters (drugs engineered to be more effective than the original) in the pipeline, barriers in the US market, and disappointing rates of biosimilar adoption observed in the European Union (EU).

Biosimilar Introduction In The US

While chemically synthesized small molecule drugs have stiff competition from synthetic copies, or generics; biologics, or drugs produced by a biologic process, have been hard to imitate. Biosimilars, copies of biologics, entered the EU once their approval process launched in 2007. FDA rules for the approval of biosimilars have only recently been defined in the US. Amgen's Neopogen brand, filgrastim, is used to prevent infection in immune-compromised cancer patients undergoing chemotherapy. Neopogen is the first of several biologics facing competition from a biosimilar as their US patents expire.





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Branded Biologics - Timeline For US Patent Expiration

Branded Biologic Drug	Company	Type	Year US Patent Expires
Enbrel	Amgen	Anti-TNF	2012
Avonex	Roche/Biogen Idec	mAb	2013
Rebif	Serono, Inc. & Pfizer Inc.	mAb	2013
Epogen	Amgen	ESP	2013
Procrit	Janssen	ESP	2013
Humalog	Lilly	Insulin analogue	2013
Remicade	Janssen	Anti-TNF	2013
Neulasta	Amgen	G-CSF	2013
Novolog	NovoNordisk	Insulin analogue	2014
Neopogen	Amgen	G-CSF	2015
Lantus	Sanofi	Insulin analogue	2015
Humira	AbbVie	Anti-TNF	2016
Rituxan/Mabethera	Roche/Biogen Idec	mAb	2018
Avastin	Genentech	mAb	2019
Herceptin	Genentech	mAb	2019

Once patents for these branded biologics expire, competition between generics, biobetters, and biosimilars expect to greatly increase within the next five years.

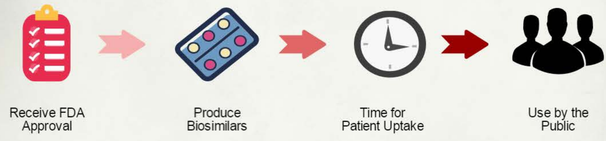
Market Growth Rate Defined By Payers, Physicians, and Patients

As the US market opens, predictions for biosimilars market growth are cautious. The rate of EU physicians and patients embracing biosimilars necessary to fuel growth has been slower than expected. While US payers, such as ExpressScripts, hail the arrival of biosimilars in the US saying Zarxio could save the US healthcare system $5.7 billion; prices for biosimilars in the EU have not been as deeply discounted as generics (25-30% vs. 50-80%).

A lack of familiarity may prevent physicians from suggesting biosimilar substitutions. Without deep price cuts, physicians and patients can weigh concerns about efficacy more heavily.

Since US pharmacists can't automatically substitute Zarxio for Neupogen because it is therapeutically similar, not equivalent, conversion from the branded biologic may be slow. US payers have no automatic incentives to substitute biosimilars. Moreover, adoption of biosimilar oncology drugs in the US requires a channel change from provider-administered channels to specialty pharmacies, which could cause a lagging patient response.

Nonetheless, Zarxio is a good US market entry choice, because the filgrastim biosimilar has achieved adoption in Europe at levels similar to a generic. In contrast, somatropin, used to treat a chronic condition in pediatric patients, has lagged in patient and physician support. Given the barriers to entry into the US market, Zarxio (the Sandoz version of filgrastim) is more likely to pay-off.



Approvals Needed To Ignite Biosimilars Market Growth

The overall outlook for biopharma remains strong with the introduction of biosimilars. The opening of the US market to biosimilars heralded by the Zarxio approval will take time to translate to adoption and cost savings for patients, payers and market growth for biosimilar manufacturers. Approval and acceptance of mAb and insulin analogue biosimilars in the EU, US and emerging markets will define the rate of the biosimilars market expansion over the next few years.

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