Biosimilars:
US Payer Perspectives

A FirstWord Dossier Advisory report
Biosimilars: US Payer Perspectives

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Regulatory standards in the US are robust, but certain critical issues remain unresolved 37
Payers want biosimilars to be highly similar to the original product, and acknowledge that analytics will play a key role.

The pendulum has swung toward biosimilars having distinguishable names in the US, and for the most part, payers are in favour.

Payers have limited enthusiasm for the biosimilar labelling debate, suggesting they will work with whatever the FDA decides.

**Perceptions and views on critical market-shaping issues; interchangeability, automatic substitution and indication extrapolation**

Payer attitudes toward interchangeability have not changed significantly over the last 12 months, but lack of FDA progress on this issue is concerning.

As long as data from controlled clinical studies is generated which supports interchangeability, payers will have no issues switching patients.

While treatment-naive patients will be the initial focus for switching, some payers argue that established patients will need to be switched in order to make the big cost savings.

Concerns remain for pharmacy level substitution for biosimilars, with payers arguing that the practice is unlikely to be widely embraced in the early years of the US biosimilars market.

Payers want more information and education on indication extrapolation, and expect resistance from physicians when asked to use biosimilars with extrapolated indications.

**Commercialisation of biosimilars**

What has been US payer reaction to the commercialisation of the first biosimilar in the US?

Cost retains its crown as the number one driver of biosimilar adoption in the US, argue payers.

Payers argue that little has changed in terms of how payers will handle biosimilars, with many stating that they will continue to be treated like any other branded product.

Payers remain concerned about the ‘rebate trap’, but the legality of such practices remains to be established.

The new CMS rule on J codes for biosimilars has been widely criticised by payers, with many arguing individual J codes for biosimilars are warranted to protect patient safety.
Future challenges and opportunities for biosimilars

Payers predict that originator price competition could undermine the position of biosimilars in the US

Companies that develop biosimilars and have branded biologic businesses need to have a clear message to prevent physician confusion

Payer policies likely to become more aggressive in the future, but costs will play a significant role in coverage decisions

Price, quality and education remain critical to the success of the US biosimilars market

Appendix
Research objectives and methodology

Objectives

Following on from the April 2015 edition of Biosimilars: US Payer Perspectives, this FirstWord Dossier Advisory update provides an overview on how payers’ opinions on the core issues facing the US biosimilars market have changed over the past 12 months, along with insights on current thinking. Much progress has been seen in the US since early 2015, but a key question remains from a payer’s perspective; has enough progress been made?

In order to achieve this goal, FirstWord analysts conducted detailed secondary research into the US biosimilars market focusing on key developments in the past 12 months, including regulatory developments, policy changes, product approvals, and changes to the commercial landscape. Key questions that were asked during the course of the research included:

- How have the key drivers and resistors of biosimilar usage in the US evolved over the past year?
- Do payers agree with the current regulatory pathway for biosimilars in the US, and how do they perceive it changing moving forward?
- How do payers expect pricing dynamics within the US biosimilars market to evolve, and what are their expectations in relation to the pricing of originator biologics in response to biosimilar competition?
- How have payer views in relation to the key market-shaping issues of switching, automatic substitution, extrapolation of indications, and biosimilar naming changed over the past year?
- What are the critical success factors for the US biosimilars market, both from a biosimilar and originator biologic manufacturer perspective?
Methodology

This report summarises key findings from this secondary research, but focusses primarily on providing expert US payer insight into critical, potentially market-shaping issues. These insights were obtained from conducting 60-minute telephone interviews with 10 expert payers from the US who work at a variety of organisations, including Pharmacy Benefit Managers (PBMs), Managed Care Organisations (MCOs), Integrated Delivery Networks (IDNs) and regional health plans. All respondents were interviewed between January 27 and February 2, 2016, and they all received a financial incentive to take part in the research. To qualify, respondents had to meet the following screening criteria:

- Have between 5-30 years’ experience
- Be a pricing and reimbursement (P&R) or health economics expert
- Be responsible for developing, setting or administering medicine reimbursement schemes
- Be a primary decision-maker; key influencer or a voting/contributing member on a P&T (pharmacy and therapeutics) committee
- Have direct experience of making formulary decisions for biological therapies in at least two of the following areas: oncology, rheumatology, gastroenterology, dermatology, endocrinology, neurology, nephrology or fertility
- Have direct experience of assessing biosimilars for inclusion on formulary, either as part of a committee or as the lead decision-maker

Interview questions were designed to evaluate how the US biosimilars market has changed during the past 12 months, as well uncover what the future of the US biosimilars marketplace could look like with regard to regulation, clinical development, commercialisation, pricing, reimbursement, and market access. Primary market research was complemented with in-depth secondary research across multiple, publicly available sources of information. Data from other FirstWord reports were also used, including FirstView’s Biosimilar Index.²

Payers believe that physician comfort in relation to prescribing biosimilars is growing, but originator misinformation tactics remain an issue

US payers believe that physician comfort in relation to their use of biosimilars is growing. Payers also mentioned that originator company tactics, including misinformation strategies, could have a negative impact on physician comfort and sentiment. According to payers, originator company misinformation tactics are likely to focus on giving physicians pause for thought in relation to the safety, efficacy and quality of biosimilars. The lack of US physician awareness and familiarity with biosimilars is in many ways playing into the hands of the originator companies. In contrast, a small number of payers believe that physicians are becoming more accepting of biosimilars, due to becoming more attuned to the costs of healthcare and how biosimilars could help.

“Physicians remain sceptical about biosimilars. They’ve not had enough exposure to them. For better or worse, physicians are influenced by their relationship with brand name manufacturers. As long as brand name manufacturers continue to have this relationship, most physicians will always be uncomfortable using biosimilars.”

Chief Pharmacy Officer; Pharmacy Benefits Manager

“Physicians don’t know enough about biosimilars. Very few physicians have had to make any decisions about biosimilars. For these reasons, I don’t believe physicians are at all comfortable about the prospect of having to use biosimilars.”

VP Strategic Analytics; Pharmacy Benefits Manager

“Physicians are becoming more tuned into biosimilars, that’s for sure. From this, I guess comfort levels are expected to grow. We only have one biosimilar in the US, and that’s in the oncology setting, so outside of oncology and perhaps rheumatology, comfort levels could be much lower.”

Pharmacy Director; Managed Care Organisation

“Physician acceptance remains key. There’s a lot of misinformation out there, and a lot of legislative efforts by the originators to put limitations on biosimilars. Keeping physicians happy is critical.”

Pharmacy Director; Pharmacy Benefits Manager

“I’m only basing this on my gut feel, as I don’t have any data to support this, but I think some physicians are becoming more accepting of biosimilars. Some of them will obviously understand the rationale, based on the potential for reduced cost for both the plan and for the member. But there will be others that will be more resistant and want to take a ‘wait and see’ attitude. But as physicians in this country become more comfortable with the idea and get experience with biosimilars, I think there will be more acceptance.”

Medical Director; Managed Care Organisation
Concerns remain for pharmacy level substitution for biosimilars, with payers arguing that the practice is unlikely to be widely embraced in the early years of the US biosimilars market.

Within the US, pharmacy level substitution is largely irrelevant for a significant proportion of the biologics market. Channels of reimbursement for biologics and other specialty products in the US could, therefore, influence the potential impact of pharmacy level substitution in the US. These channels can be grouped into two general forms, reflecting whether a product is financed under the pharmacy benefit (i.e. Medicare Parts C and D, plus commercial insurance plans), or the medical benefit (i.e. Medicare Part B). Medical benefit tends to cover infused products that are administered in a physician’s office, such as the oncology mAbs and certain anti-TNFs (e.g. Remicade). These products are reimbursed via a process often referred to as ‘buy and bill’. In the vast majority of cases, the patient does not collect the medicine from the pharmacy.

Pharmacy benefit tends to cover self-injected treatments for inflammatory conditions like RA, psoriasis, and MS (e.g. Humira, Enbrel, Avonex). These products are dispensed via specialty pharmacy (e.g. Accredo Health from Express Scripts), or retail pharmacy.

Payers have concerns about pharmacy level substitution for biosimilars, primarily from a patient safety perspective. Despite legislation that supports pharmacy level substitution being enacted in significant number of US states, payers don’t believe that it will happen in the short term. Interchangeable biosimilars, one of the key prerequisites, are unlikely to be approved in the short term, and the US market needs to get more experienced with biosimilars. Even when it is allowed, pharmacy level substitution for biosimilars is likely to be a tightly controlled process that involves the pharmacy, patient and physician. Certain indications will also be off-limits, such as conditions where loss of control could result in hospitalisation or death (e.g. oncology). A small minority of payers, mostly from PBMs, argue that substitution will become the norm, but even these pro-pharmacy level substitution payers argue that the process needs to be tightly controlled.

“My views remain the same as they did a year ago; I have concerns about this. Some products could be substituted easily. For example, where treatment failure doesn’t mean death or hospitalisation, biosimilars could be substituted for the originator product. In other areas, however, like ulcerative colitis and the treatment of oncology with monoclonals [mAbs], I’d say this was a very bad idea.”

Medical Director; Managed Care Organisation

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