Access to Biosimilars in EU Expected to Continue to Outpace US and Canada

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Biosimilar experts from across the EU continued to show how rapidly biosimilars have gained market share, in contrast to US and Canadian markets.

Keith Ridge, chief pharmaceutical officer at NHS England, told attendees of the 16th annual Biosimilar Medicines Conference in London on Thursday that the UK has seen increasing uptake of rituximab, infliximab and etanercept biosimilars, particularly in London. For instance, a biosimilar for infliximab, which came to market in March 2015 is now used by about 80% of patients on the medicine in the UK.

The increasing uptake of the lower-cost alternatives to expensive biologics is important for the UK, Ridge noted, saying the government health service spends £17.4 billion ($24.3 billion) on medicines per year and that amount is growing. He noted that the incoming Humira (adalimumab) biosimilars, which are hitting the UK market this autumn, will save the country £100 million ($140 million) per year. In the US, by contrast, adalimumab biosimilars are expected in 2023.

Per Troein, vice president at IQVIA, also noted how Denmark and Norway are good examples of countries that have increased their uptake of infliximab biosimilars quickly because of their use of a tender system to pay for the medicines.

Such tender systems may explain at least part of the gap in the differences between the uptake of biosimilars in the EU and the US, though doctors' and payers' familiarity and ability to switch patients to biosimilars were also discussed as factors.

Justin Stebbing, professor of cancer medicine and oncology at Imperial College London, questioned if companies moving forward will have to run the types of large clinical studies currently needed to further prove how biosimilars are comparable to their reference products. He predicted that in two

years' time, such clinical studies may not be run, barring an unforeseen "nasty event" that results in a biosimilar being pulled from the EU market.

But the lingering question for Stebbing, which he said he grapples with daily, is how to explain to cancer patients what switching them to a biosimilar version of a medicine means, or if he should even try to explain the switch since the medicines are so similar.

Gustaf Befrits, a health economist with the Stockholm County Council in Sweden, noted that all the patients taking infliximab in Stockholm were switched to a lower-cost biosimilar in just two months, and very few expressed a negative opinion of the switch, though all patients were informed of the decision.

A review study published last month, cited at the conference, noted that data on biosimilars to date suggest that switching from a reference product to a biosimilar "is not inherently dangerous, and that patients, healthcare professionals, and the public should not assume that it is problematic."

Brian Lehman, a consultant with US-based Humana Pharmacy Solutions, and David Willows, chief innovation and marketing officer at Canada's Green Shield, meanwhile, lamented the slower uptake of biosimilars in North America.

In the US, nine biosimilars are approved, but just three have come to market and the market share of only one biosimilar has been substantial. Both Lehman and Willows also noted fewer incentives for payers and insurers to help encourage a shift to biosimilars.

Carol Lynch, president of Sandoz US, said she thought patent litigation is currently the biggest hurdle to biosimilar access in the US. The US Supreme Court last year ruled that biosimilar developers would not have to wait an additional six months after approval to launch their products, though that additional clarity has yet to help increase uptake.

Of the top 10 biologics by sales in the US and EU, patent protection on all but three has expired in the EU, whereas US patent protection on only three of 10 has expired, according to IQVIA's Troein.

As for as predictions for the next 10 years, Troein said he expects discounts in the EU between 25% and 70% off the original list price will be common and result in "significant volume increases." The issues of safety, switching and extrapolation – all of which were question marks when biosimilars first came to market in the EU 12 years ago – "will largely be gone."

In the US, meanwhile, savings from biosimilars over the next decade are expected to amount to more than $50 billion, but FDA approval does not mean market access and questions continue to linger with education and disputing anti-biosimilar rhetoric.

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Regulatory Affairs Professionals Society (RAPS)
5635 Fishers Lane, Suite 550
Rockville, Maryland 20852

P **+1 301 770 2920**
F +1 301 841 7956
Email: **raps@raps.org**