



The Value of Generic + Biosimilar M E D I C I N E S



CONFERENCE COVERAGE

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Biosimilars Canada
The Voice of Biosimilar Medicines in Canada

Significant strides have been made in increasing the utilization of generic prescription medicines in private sector drug benefits plans. Now it's time for biosimilars. That was a key message at the 2017 half-day conference in May in Toronto, where plan sponsors converged to hear about the best ways to ensure the sustainability of their benefits plans.

Though some concerns about generics still exist—namely, the notion that brand name drugs are somehow better—they've largely been embraced by employers, physicians, pharmacists and patients, according to Jake Thiessen, associate dean and professor emeritus at the University of Toronto's Leslie Dan Faculty of Pharmacy.

Biosimilars are the new kid on the block. They're medicines that have the potential to save thousands of dollars in drug costs per patient, but ones that need more widespread acceptance.

"Biosimilars are poised to provide tremendous value," said Jim Keon, president of Biosimilars Canada and the Canadian Generic Pharmaceutical Association. "These are exciting times for biosimilars, plan sponsors and patients."

However, getting biosimilars on the radar of plan sponsors is now the challenge. Though Europe has successfully adopted biosimilars in a number of countries for more than a decade, the medications—which are similar but not equivalent to biologic drugs—are still in the early days of adoption in Canada.

Keon said there's an opportunity for plan sponsors to improve the sustainability of their drug plans, but employers will need to be proactive. In the long run, the introduction of new cost-saving biosimilar products in Canada will depend on their level of uptake.

SESSION 1:

Generics and brand name drugs are interchangeable

Dr. Jake Thiessen
FOUNDING DIRECTOR,

UNIVERSITY OF WATERLOO'S SCHOOL OF PHARMACY



Jake Thiessen wants to dispel any lingering misconceptions about generic drugs. He said that though many plan sponsors have adopted mandatory generic substitution, people still tell him, "I've made up my mind. Don't confuse me with facts." Some also mistakenly perceive the generic medicines to be inferior to brand name medications, cheaper, second rate or not the real thing.

He also noted that many doctors who still write scripts for brand name drugs had gotten into that prescribing pattern years ago, unaware of what the standards are for generic medicines to be approved in Canada. And a lack of dialogue between patients and pharmacists can also lead to miscommunication about their comparative safety and effectiveness.

But "it's important to understand why they can be trusted," said Thiessen. "Canada has played a leading international role in the historical requirement for generic prescription medicines' specifications and bioequivalence."

He said Health Canada's mandate is as follows: to ensure that the Canadian public gets medicines that are safe, effective and of high quality. "What is Health Canada really saying?" he said. "That the public is getting originator and generic drugs that are equally safe, effective and of high quality." There is only one standard this agency uses in approving medicines.

Variability is normal

Thiessen said there are certain issues that come up when generics are discussed: excipients (inactive ingredients that are added to drugs) and the variability in health outcomes when taking generics.

"Many people are concerned about the potential difference in excipients," said Thiessen. But he noted that many aren't aware that excipients/additives are ubiquitous: vitamins contain them, as do natural food products and supplements. Even processed foods like ice cream typically contain the same additives as are generally found in

pharmaceuticals. "People are unaware that they're exposed to them all the time," he said.

As for variability, that's common as well. And Health Canada permits it, said Thiessen, as long as differences in a drug's absorption performance are within a confidence interval of 80 per cent to 125 per cent. "It's impossible for all capsules and tablets to be identical and to contain the same number of active ingredients stated on the label," he said. "It's impossible for all batches from the same manufacturer to be identical. This permitted variability is the same for both originator and generic manufacturers."

But that's okay. He said variability occurs even among patients taking the same brand name drugs. "Products and people are simply variable."

As for why a permitted variability of between 80 per cent and 125 per cent even exists, Thiessen drew an analogy between generic drugs and soccer. "You can't have a tiny soccer net because the goalie could lie down in front of it and nobody could score. It's the same thing when it comes to bioequivalent standards. They must be fair and sufficiently rigid; the conditions must be such that the originator can pass the test as well."

In the end, it comes down to quality control on the content of a medication and its performance. "The key is that the content requirements are identical for the originator and generic medicines," said Thiessen. And that clinical performance is the same.

Based on studies out of Canada, the U.S., Sweden and Taiwan, that is evident. All premier clinical effect studies have been unable to find a difference between originator and generic medicines that have been shown to be bioequivalent, according to Thiessen. "There is no evidence for superiority of brand name drugs to generic drugs," he said. "And, in keeping with the statement by Health Canada, bioequivalence translates into the same clinical response."

His message for plan sponsors: switching brand name drugs with generics is perfectly safe. ■

SESSION 2:

Snapshot of a drug plan: Ensuring sustainable plan design

Mark Jackson
PHARMACY CONSULTANT,
TELUS HEALTH



As a pharmacy consultant and a member of TELUS Health's pharmacy services team, Mark Jackson is well acquainted with drug plan management. Part of that includes carefully tracking which medications are big cost drivers—and resolving how to manage them. The results for 2016 were mixed: there's both positive news and concerning trends for private payers.

"Costs are continuing to increase," said Jackson. "There are an increasing number of claimants, and specialty drugs contributed to cost growth."

Jackson said specialty drugs account for 26 per cent of total drug costs, despite being less than 1 per cent of all claims. And these drugs cost \$10,000 or more per year, per person. "They've grown an average of 15 per cent per year since 2008," he said.

"Biologics went up 24.6 per cent last year. That's where the bulk of your growth in the high-cost drug area is happening."

On the plus side, Jackson said that claims for some specialty medications—such as hepatitis C drugs—have dipped a bit from a few years ago. "These are starting to stabilize," he said. Given that one top seller, the hep C drug Harvoni, costs \$58,608 per claimant annually, this is a welcome reprieve. Jackson said there has also been an overall decline in brand name drugs, although this has been offset by the number of drug claims increasing across Canada driving up plan sponsors' drug costs.

Jackson said drug usage data from TELUS Health—which adjudicates more than 12 million lives aged 0 to 64 years—reflect these trends. At TELUS, the eligible amount per cardholder (an employee who's covered) jumped significantly by 5.95 per cent, to \$445 in 2016—from \$420 in 2015, he said. "The increase per cardholder is increasing at a pretty significant rate."

And, the number of claims went up 0.1 per cent to 9.9 per cent in 2016, from 9.8 per cent in 2015, he said.

In terms of demographics, the cohorts with the highest rate of growth in drug claims were employees in their 20s and 30s, while those in their 50s had the highest percentage of drug claims. Jackson said claimants in their 30s are being prescribed medications to treat autoimmune conditions requiring tens of thousands of costly specialty drugs that can cost tens of thousands of dollars annually.

What's encouraging is that generics are making inroads. Jackson said that 79.2 per cent of TELUS's cardholders in 2016 had benefits plan designs that require generic substitution at some level. "The number of plans with generic substitution has been increasing," he said. "That trend is positive and encouraging, but we'd like to see it get higher."

But he pointed out that specialty drugs are eroding those successes. "Growth on the specialty side is exceeding the savings we're seeing on the generics side."

The drugs with the highest increases include immunomodulators, medications such as Humira and Enbrel that are used to treat autoimmune conditions such as psoriasis and rheumatoid arthritis. Claims for drugs used to treat multiple sclerosis, attention deficit hyperactivity disorder and narcolepsy are also rising. And medications for skin disorders are on the rise, too—accounting for 4.7 per cent of the total adjudicated amount in 2016 versus 4.2 per cent in 2015.

As for PCSK9 inhibitors—new medications that reduce bad levels of cholesterol with a price tag of \$10,000 to \$15,000 per year—their uptake has been slower than expected, said Jackson. "That's good news for payers." ■

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SESSION 3:

The benefits of biosimilars

Jim Keon
PRESIDENT,
BIOSIMILARS CANADA



Jim Keon is pretty passionate when it comes to biosimilars, biologic medications that are similar to originator drugs but cost much less. He sees biosimilars as a huge opportunity for plan sponsors that struggle with year-over-year drug plan cost increases—and face an uncertain future as more specialty drugs enter the market.

But he's also aware that, like any lesser known entity, biosimilars have a way to go before they're adopted in the same way the European market has embraced them. "This is a new area," said Keon, adding that pharmaceutical firms have moved into the biosimilars realm in recent years. To date, six biosimilars have been approved in Canada.

He knows education is a big piece of the equation, too. And that means debunking myths around the biologically derived drugs. "Biosimilars are not generics: generics are approved as bioequivalent," said Keon. "Biosimilars are not interchangeable. They're highly similar."

Keon said that data out of Europe also indicate that biosimilars are safe. The first approval of a biosimilar drug in the EU was in 2006. Since then, there have been more than 400 million patient days experience, he said.

And there have been no unexpected side effects from using biosimilars, he said. "The regulators have determined that they can be used safely and efficaciously."

Part of the challenge in Canada, said Keon, is regulatory approval. After being reviewed and authorized for sale by Health Canada, biosimilars then go through the Canadian Agency for Drugs and Technologies in Health (CADTH) to be reviewed for cost-effectiveness. "All of this takes

time, and all of it takes money. The additional CADTH review is costing lost savings significantly in terms of time lost," he said.

Keon said plan sponsors can play a role in ensuring this process changes. "Payer policies should insulate the biosimilar market against originator tactics, which will continue to evolve over time," he said. These policies include redesigning benefits plans and making biosimilars preferred products. "There is very little uptake without a preferential listing."

In the past 12 months in Canada, there have been \$6.3 billion in sales of biologic drugs. Conversely, biosimilars accounted for only \$13 million in sales.

He said patients who have been diagnosed with diseases necessitating a biologic drug can be prescribed a biosimilar. "We'd like to encourage the plans for the naive patients to use the biosimilar," he said.

Keon noted Green Shield Canada, which became the first benefits provider in Canada to list biosimilars as preferred products under its formularies.

He said British Columbia also recently decided to give preferred status to a biosimilar, Grastofil, used to boost white blood cells during chemotherapy, versus the originator biologic, Neupogen.

The key message Keon wanted to convey is that biosimilars can significantly increase patient access and help control drug plan costs. "These are very effective treatments. Biosimilars can help you continue with those treatments at competitive rates," he said. "The potential is still largely untapped, but I'm confident that it will grow and improve." ■

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SESSION 4:

Optimal listing strategies for biosimilars

Ned Pojskic
PHARMACY STRATEGY LEADER,
GREEN SHIELD CANADA



As a pharmacy strategy leader with Green Shield Canada, Ned Pojskic attends many biosimilar conferences. And he's been hearing a lot about the difficulties in bringing a greater number of biosimilars to Canada. It's something he'd like to see change.

"We have amazing new drugs coming to market," said Pojskic. "These are truly important therapies."

Pojskic also said there's a lot of misinformation around the medications, with all stakeholders concerned about safety. The mindset with often encounters is, *We don't understand, so let's stay away.*

But he said evidence has shown again and again that the drugs are safe and effective. "The reality is that any difference between originators and biosimilars is insignificant," he said. "They produce the same therapeutic effect in the human body. And that's ultimately what we care about."

Pojskic said that numerous studies have shown the high degree of safety in these medications. "Biosimilars can be used safely. We have 10 years of European experience to draw on. Over the last 10 years, the EU monitoring system for safety concerns has not identified any relevant difference in the nature, severity or frequency of adverse effects between biosimilars and their reference medicines."

He cited the large-scale, ongoing NOR-SWITCH study, which is assessing the safety and efficacy of switching from Remicade to the biosimilar treatment Reimsa in patients with rheumatoid arthritis, spondyloarthritis, psoriatic arthritis, ulcerative colitis, Crohn's disease and chronic plaque psoriasis. Findings released in 2016 indicated that a large number of patients were switched from biologic drugs to biosimilars, without any significant change in the rate of disease worsening.

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But he concedes that the Canadian landscape is challenging. Pojskic said there are three obstacles to successful biosimilar adoption in Canada: physician buy-in, issues around interchangeability and private payer policies.

Pojskic said physicians have shown a preference for originator drugs, a behaviour that acts as a barrier in getting biosimilar drugs to patients. He said two-thirds of rheumatologists in a recent survey indicated they would avoid using a biosimilar as initial therapy. Physicians need to be made aware of the safety profiles of these medications and to be exposed to biosimilar options, he said. "As familiarity with these products grows, so does acceptance."

On the interchangeability front, Health Canada has not deemed biosimilars as interchangeable, he said. But Pojskic is encouraged by activity in the U.S., which may influence Canadian health regulators down the road. Though the U.S. Food and Drug Administration (FDA) hasn't designated biosimilars as interchangeable, Pojskic said certain "states are laying groundwork so that when the FDA does shift position, they'll be ready to offer them as interchangeable."

Then there are private payers. "We've not seen the same type of commitment to biosimilars in the private payer space as we've seen in the public payer space," said Pojskic. He suggested that private payers should weigh listing biosimilars as preferred products and using originators only in exceptional circumstances, but extensive monitoring and support should accompany these decisions.

The bottom line is that private payers should capitalize on the opportunity biosimilars offer, said Pojskic. "The efficacy is the same. The safety is the same. The cost is less." ■

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