THE BENEFITS ALLIANCE GROUP Better Advisors. Better Advice.™

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AdvisorsForum

EASTERN ROUNDTABLE

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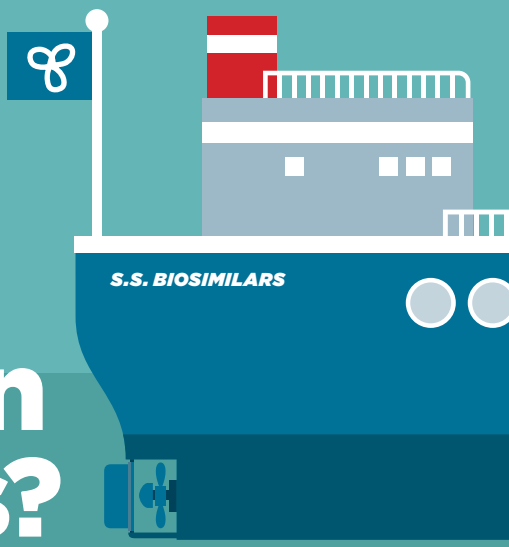
"We can proactively communicate and educate clients that in order to protect the integrity of your health and benefit plan in the long term, biosimilars have to be part of the solution."

Rob Green,
Green Benefits Group

UPFRONT

Are we missing the boat on biosimilars?



Canada's first major biosimilar drug appears to be having a rough start in the private group insurance industry. Meanwhile, it looks like much smoother sailing for public drug plans, which are going ahead with preferred listing status for Inflectra based on a price that's 47% less than the originator biologic, Remicade (which is Canada's number-one drug by purchases, with sales just shy of $1 billion in 2015[1]).

Why are most private plans not putting similar policies in place?

The answers touch on a myriad of issues that are unique to this sector of specialty pharmaceuticals, but one thing is clear: without listing policies from both public and private payers, biosimilars (also referred to as subsequent-entry biologics, or SEBs) may not be able to establish enough of a market in Canada. When you consider that patents on 15 originator biologics are set to expire by 2020,[2] this could mean significant missed opportunities for savings.

"There's an urgency to bring our clients up to speed on biosimilars," says Robert Houle, Vice-President of Capcorp Financial in Ottawa, Ontario, and a participant in the Eastern Roundtable for the *Advisors Forum* in November, 2016. "This also points to our role in advocacy, as members of The Benefits Alliance Group, by encouraging employers to lobby with organizations like the Business Council of Canada and Chambers of Commerce to raise awareness and generate public pressure on private payers."

Different approaches

In April 2016, the pan-Canadian Pharmaceutical Alliance (pCPA) released *First Principles for Subsequent Entry Biologics (SEBs)*, a document to guide its negotiations with manufacturers of biosimilars and, possibly, originator biologics.[3] The document includes the following statement:

"The introduction of an SEB must provide a reduction in the drug's ***transparent price*** *to benefit all Canadians."*

In other words, if manufacturers of biosimilars want their drugs to be included in public plans, they must provide a reduction in their transparent list price that is available to all Canadians—not just beneficiaries of public drug plans.

Only a few insurance carriers in Canada, however, can currently take advantage of pCPA's policy for biosimilars. Green Shield Canada (GSC), for example, has its own policy giving preferred listing status to biosimilars, for plan members not already taking the originator biologic. In the case of Inflectra in particular, that means that GSC pays the same price as public drug plans, which represents a 47% discount off the price of Remicade. For plan members starting treatment for rheumatoid arthritis, this translates into about $12,500 for the first year of Inflectra, compared to about $23,700 for Remicade.[4]

Meanwhile, a number of Canada's insurers and pharmacy benefits managers (PBMs) have taken a different approach. Well before pCPA negotiated its price for Inflectra and released its *First Principles* document, these providers opted to negotiate confidential agreements with the manufacturer of Remicade. Details of these agreements, including their duration, remain under wraps.

Bigger picture

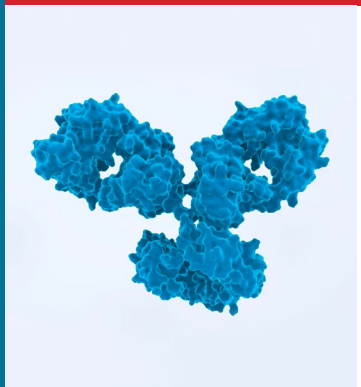
Should these confidential arrangements with the manufacturers of originator biologics take root, what happens to the biosimilar market in Canada? "Why would manufacturers of SEBs continue to invest in Canada, when they know they'll be undercut by private payers signing deals with originator products?" asks Ned Pojskic, pharmacy strategy leader at GSC and guest speaker at the Eastern Roundtable of the *Advisors Forum*. "We need to look at the long-term picture and see it as our responsibility to support SEBs, just like we support generics, to drive competitive market forces."

This echoes pCPA's position: "the pCPA will encourage a competitive environment that includes SEB market growth and is conducive to long-term cost reductions and sustainability." That could include agreements with manufacturers of originator biologics as well, but only if they "provide at least similar overall value compared to the SEB, and must include similar or better transparent price reductions."[3]

Getting the word out

Members of the *The Benefits Alliance Group Advisors Forum* unanimously agree that advisors can do more to educate clients. "How many advisors, let alone employers, know about the 47% discount off Remicade? I don't think most realize the discount is that big, and that it applies to private plans," says Paul Crossdale, President of Morrow Crossdale & Associates Inc. in Unionville, Ontario.

WHAT ARE BIOSIMILARS?



A biosimilar, also referred to as a subsequent-entry biologic (SEB), is a biologic medication that comes to market after the patent expires for the originator biologic. In Canada, that means biosimilars may arrive 10 to 15 years after the launch of the originator.

Like all biologics, biosimilars use living organisms. Manufacturing, storage and distribution are therefore highly complex. They are administered by injection (which patients can often do themselves) or by infusion at dedicated clinics.

Both originator biologics and biosimilars can dramatically improve the lives of the small percentage of plan members for whom traditional, chemical drugs provide little or no benefit. People with advanced rheumatoid arthritis, for example, can avoid disability leave.

"We can proactively communicate and educate clients that in order to protect the integrity of your health and benefit plan in the long term, biosimilars have to be part of the solution," agrees Rob Green, President and lead consultant, Green Benefits Group in Burlington, Ontario. "If government has already mandated that biosimilars come into play, I feel we have to hear more from the private side as well."

"If every carrier did what Green Shield did, Remicade would have to be market competitive. There would be no individual deals," adds Lio Spagnuolo, Managing Partner and COO at Penmore Benefits Inc. in Concord, Ontario.

Client education must also go beyond price, as advisors can help dispel misconceptions regarding the safety and effectiveness of biosimilars (see sidebar). "It's not unlike the education we do for generics," notes David McCulloch, Partner at Leystone Insurance & Financial Inc. in Ottawa, Ontario. "Once we educate clients about efficacy and safety, and the fact that the savings are there for the long term, then they will realize that covering biosimilars is the right thing to do. And that these agreements with the manufacturers of the original biologics don't seem to be the right thing to do."

Where are the savings?

Another question begs to be asked: where are the savings from the agreements for Remicade? "Right now it seems that all the savings are going into carriers' pools, because we're certainly not seeing any direct cause and effect for clients," says Jim Kilgour, President at Advanced Benefits Consulting in Waterloo, Ontario. "It may still be too soon to see the impact, but do we simply trust that carriers will manage their pools appropriately? There needs to be more accountability for our clients."

Even as biosimilars secure their place on private drug plans, it will take time for savings to filter down to plan sponsors and plan members. In part because the market is in its infancy in Canada, and in part because savings will be indirectly realized through pooling or stop-loss charges, and reduced co-pays for plan members. As well, more clinical proof is required before people already taking the originator biologic can switch to a biosimilar (see sidebar).

"Unlike with mandatory generics, where we can save money off the top, the thunder is not going to be there right away with SEBs. Which is why it's all the more important for advisors

SAFETY, SIMILARITY & SWITCHING

Since biologic drugs are made with living cells, biosimilars cannot be identical to originator biologics. They do not have to be identical in their chemical structure, however, to be as safe and effective. Knowing this, regulatory agencies around the world, including Health Canada, use degrees of similarity to assess the safety and effectiveness of a biosimilar. For example, a growing number of long-term studies comparing Inflectra and Remicade show no clinically significant differences in health outcomes.

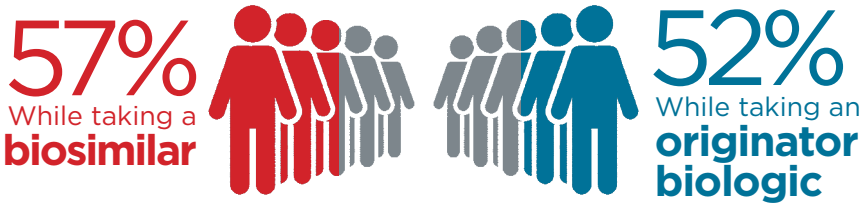
It's also important to keep in mind that, over time, originator biologics are not the same as they were when launched. This reflects their unique nature as well as adjustments in production, and regulators monitor this as well to ensure differences do not affect effectiveness or safety.

Can people safely switch from an originator biologic to a biosimilar, as they can do from a traditional brand-name drug to a generic? It's too soon to know. Health Canada currently recommends leaving such decisions to the discretion of physicians and patients, and do not support automatic substitutions. Public plans are, however, keeping a close eye on the results of ongoing clinical studies.

For example, the highly anticipated, government-funded NOR-SWITCH study in Norway is monitoring 482 patients taking biologics for a year, about half of whom were switched to a biosimilar. Preliminary data, released in November 2016, show that switching is not harmful. Final results are expected in 2017.

EQUALLY GOOD RESULTS

After 54 weeks, patients who reported their rheumatoid arthritis had measurably improved*



Source: PLANETRA Study (2013)
*"Measurably improved" refers to the ACR scoring system developed by the American College of Rheumatology and used universally in clinical studies. In this case, the statistic refers to a score of ACR20, which means patients reported a 20% improvement in their condition.

"It may still be too soon to see the impact, but do we simply trust that carriers will manage their pools appropriately? There needs to be more accountability for our clients."

Jim Kilgour, Advanced Benefits Consulting

to make sure clients understand the bigger picture," says Doug Calow, President of Calow Benefit Partners Inc. in Barrie, Ontario.

To help bring that picture into focus, members of *The Benefits Alliance Group* can advocate on behalf of clients by raising the following questions with carriers and PBMs:

- **What is your policy for biosimilars, especially now that the pan-Canadian Pharmaceutical Alliance requires that its negotiated lower list prices be available to all Canadians? How are we taking advantage of this?**
- **What savings can plan sponsors expect to see in terms of stop-loss pool rates?**
- **For agreements between providers and manufacturers of originator biologics, do price reductions match or surpass what's negotiated by the pCPA? Does the lower price for the originator biologic apply only to new claims, or for existing claims as well? Are plan members benefiting through lower co-pays?**
- **How can advisors and their clients evaluate which approach—a policy to support biosimilars or agreements with originator biologics—is better for them?**
- **Do the manufacturers of biosimilars provide patient support programs that are comparable to those provided by manufacturers of originator biologics?**

MARKET SNAPSHOT

23%

Biologics' share of **prescription purchases in Canada**

2%

Biologics' share of **prescriptions dispensed**

Source: QuintilesIMS, Canadian Drug Stores and Hospital Purchases and Canadian CompuScript. Year ending December 2015.

ON THE RADAR

The Eastern Roundtable of *The Benefits Alliance Group Advisors Forum* meeting included a workshop that explored a wide range of drug-plan management strategies—looking beyond the cost savings, into possible unintended impacts on plan members' experiences and health outcomes. Our advisors zeroed in on three areas of concern.

Caps: high health risk

Drug plan caps appear to present a simple option to minimize the risk of cost upswings for plan sponsors. After plan members reach the cap (ranging from $10,000 to as low as $2,000), they move on to catastrophic coverage from a public plan. In Ontario, for example, the Trillium program is available.

Unfortunately, the transition can be a "nightmarish experience for plan members," says Laurie Sobie, Partner at Bell Financial in Toronto, Ontario. Why? Because public plans must execute their step-by-step process to confirm eligibility. When criteria are not met, coverage may be limited to lower-cost traditional drugs, and only after these treatments are proven ineffective does coverage finally become available for higher-cost treatments.

Since these employees are likely suffering from serious conditions, the resulting interruptions to treatment can cause irreversible harm. "Employers then have to deal with the fallout of lower productivity, increased absenteeism and possibly disability leaves. Not to mention the impact on retention as word gets out," stresses Sobie. "We need to research the public plans and get the facts out, not only to clients but also to advisors who are recommending these caps."

Specialty PPNs: any savings?

Interestingly, workshop participants initially perceived that preferred

provider networks for high-cost specialty drugs do little in terms of savings, even though one of the conditions for providers is lower mark-ups on the drugs. "We're not being told anything about reduced mark-ups. Carriers are telling us more about how these PPNs provide better plan member care," says Bill Zolis, Senior Employee Benefits Consultant at Penmore Callery Group in Whitby, Ontario.

So where do these savings go? "There may be savings to the carrier, but unfortunately not directly to employers," says Rob Green of Green Benefits Group. "As we continue to get clients to shift to PPNs, hopefully predictable claims charges will come down. The huge benefit is employers will not have to decrease drug coverage to their staff."

Spending accounts: employer beware

More plan sponsors appear to be considering healthcare spending accounts (HCSAs) instead of traditional health benefit plans. While this appears to be an attractive solution to manage costs and provide flexibility, our advisors warn about possible long-term negative impacts on plan member experience and health outcomes.

Like drug plan caps, HCSAs do not necessarily protect against unexpectedly high costs. Having said that, HCSAs can play a more important role, especially as an add-on to traditional plans, by incentivizing positive behaviours. For example, if employees get a flu shot, they get more funds in their HCSA.

WELLNESS

Vaccinations a potential win-win

One in three people will be blindsided by an episode of shingles in their lifetime—and 60% will still be of working age.[5] The extremely painful rash emerges suddenly, and affected employees report missing 27 hours of work on average, plus another 34 hours of reduced productivity.[6] Even worse, one in three will also suffer from postherpetic neuralgia, a type of severe chronic pain that can persist for more than a year and that requires chronic medications to manage, possibly including antidepressants.

Consider those costs to the employer, then consider that it costs only about $175 for a single vaccination that will prevent or significantly reduce the severity of shingles.

Similar cases can be made for vaccinations that prevent hepatitis A and B, pneumococcal disease and certain cancers caused by the human papilloma virus (HPV)—and of course, for flu shots. Indeed, coverage for adult vaccinations not covered by public plans is a simple way to inject value into wellness strategies in the workplace.

Adjudicators tell us vaccine coverage typically accounts for less than one percent of drug-plan spending, yet despite the dividends barely half (52%) of benefit plans opt for this benefit.[7] According to the *2015 Sanofi Canada Healthcare Survey*, just 31% of plan sponsors believe their plans cover vaccinations not covered by public drug plans. And in another survey, 53% of plan sponsors without coverage say they would have included it if it had been offered, while 46% need a greater understanding or more information before making up their minds.[8]

Among employers with coverage, four out of five (80%) recommend this benefit to other plan sponsors.

Once in the benefit plan, "it's definitely worthwhile to promote as part of your wellness program," says

Jim Kilgour of Advanced Benefits Consulting. "Many people can relate to the threat of shingles because they know someone who had it. They know it can be totally debilitating."

Members of the *Advisors Forum* also suggest promoting coverage for travel vaccines to generate employee interest and appreciation. Since travel vaccines may be required for personal vacations, coverage is a simple way for employers to communicate that they care about their employees. And of course coverage will also be valued if the travel is for business. ●

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The Benefits Alliance Group, Canada's largest group of independent benefits advisors, is pleased to produce *Advisors Forum* as part of its commitment to serve as a strong national advisory voice, providing tools for members to advocate on behalf of clients. To help achieve this objective, The Benefits Alliance Group has partnered with Pfizer Canada and Merck Canada in order to learn more about emerging trends in pharmaceuticals, and their implications for private benefit plans. A sincere thank you to the members of The Benefits Alliance Group who contributed their insights and calls to action as participants in the Eastern Roundtable of the inaugural *Advisors Forum* session in November 2016.

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The Benefits Alliance Group is comprised of 34 member firms with more than 150 advisors administering over 7,200 plans, with $700 million in group insurance premiums and more than $3.1 billion in retirement plan assets.

Members of the Eastern Roundtable, from left: **Gil McGowan**, The Benefits Alliance Group, **Richard York**, Merck Canada Inc., **Bill Zolis**, Penmore Callery Group, **Lio Spagnuolo**, Penmore Benefits Inc., **Rob Green**, Green Benefits Group, **David McCulloch**, Leystone Insurance & Financial Inc., **Robert Houle**, Capcorp Financial, **Paul Crossdale**, Morrow Crossdale & Associates Inc., **Douglas Calow**, Calow Benefit Partners Inc., **Jim Kilgour**, Advanced Benefits Consulting, **Laurie Sobie**, Bell Financial, **Connie Wong**, Pfizer Canada Inc.

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