

Spotlight on the Canadian Specialty Pharmaceutical Market



The
**Biologic
Plot
Thickens**

The new wave of biosimilars
presents us with an opportunity to do better

**Originator biologics
and biosimilars
by the numbers**

**Tug of War:
Can biosimilars and biologics
coexist harmoniously?**

**Alan Low
on B.C.'s
biosimilar policies**

By the Numbers

Originator biologics & biosimilars come out on top.

There's nothing modest about the biologic and biosimilar industry. Here are some figures that highlight the strength of this continually evolving ecosystem.

BIRD'S EYE VIEW

7

Number of biologics in the top 10 best-selling drugs in Canada, accounting for \$5.3B in annual sales.^{1,2}

2015

The year Health Canada approved the first biosimilar for a high-cost originator biologic.

31

Number of biosimilars approved in Canada, with a further 10 under review.¹

3.9%

Biosimilars' share of total Canadian biologic prescriptions as of June 2020.³

BIOLOGIC POWERHOUSE

\$1.1B

Annual sales of originator biologic Remicade (infliximab), the top-ranked drug in Canada by sales value.⁴

2%

Year-over-year growth of Remicade as of June 2020, 8 years after loss of patent.⁴

2015

Year that the first infliximab biosimilar, Inflectra, was approved by Health Canada; ³ other biosimilars have received NOC since that time.⁵

10.3%

Biosimilar share of the infliximab market as of November 2020,⁶ compared to a median uptake of 55% across OECD countries.³⁵

KINETIC ENERGY

\$930M

Annual sales of Humira (adalimumab), ranked #2 in Canada by sales value.⁴

8.5%

Humira's year-over-year growth as of June 2020.⁴

6

Number of adalimumab biosimilars expected to enter the market in early 2021.⁵

\$300M

Potential savings adalimumab biosimilar competition could generate for Canadian payers.⁵

BOLD STEPS IN BRITISH COLUMBIA

75%

Proportion of B.C. patients who successfully transitioned to biosimilars during Phase One and Two of B.C.'s Biosimilars Switching Initiative.⁷

\$127M

Estimated savings netted by the initiative as of August 2020.⁸

\$22M

Savings reported by Pacific Blue Cross in June 2020, after the private payer aligned with the initiative.⁹

2

Additional medications, Jardiance & Taltz, that BC Pharmacare was able to include in its formulary thanks to the savings from the initiative.¹⁰

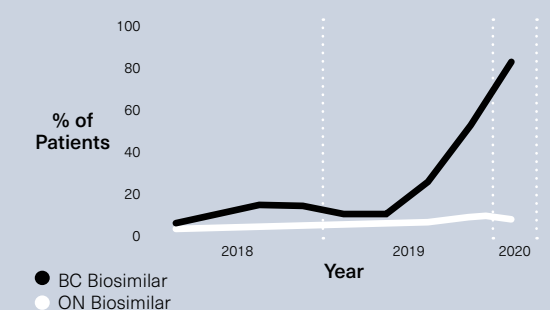
MEANWHILE, IN ONTARIO

35%

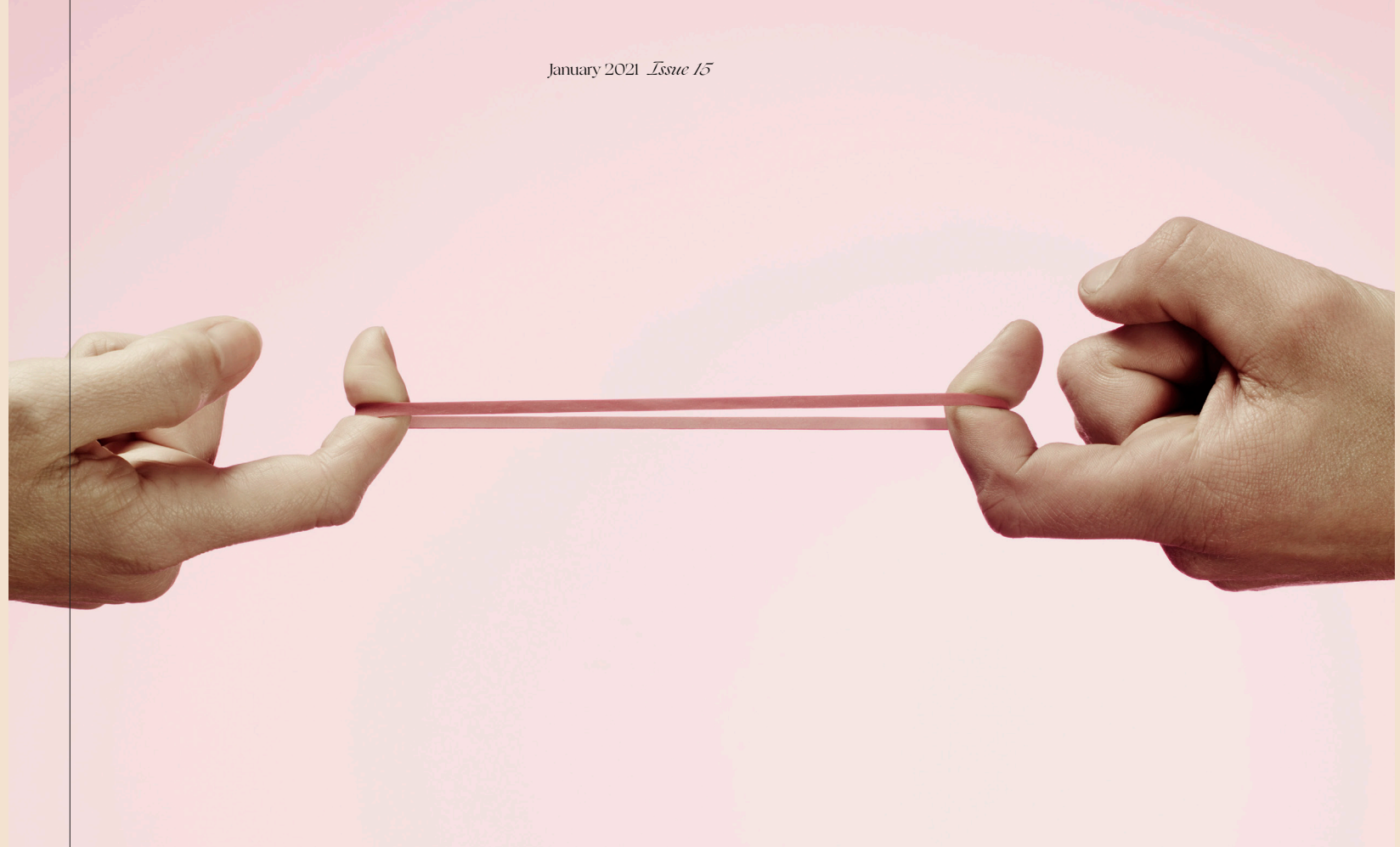
Expected proportion of infliximab and etanercept patients in Ontario who will be using a biosimilar product in early 2022, absent a provincial biosimilar policy.¹¹

THE IMPACT OF A SWITCHING POLICY ON BIOSIMILAR UPTAKE¹²

British Columbia Versus Ontario Biosimilar Uptake



Tug of War Biosimilars and biologics have yet to settle into harmonious coexistence



More than two decades after etanercept and infliximab launched the new era of biologic medicine,

biologics are riding a seemingly endless wave. They continue to expand their therapeutic reach, leaving prescribers with new polysyllabic names to learn every year, and dominate drug-spend in Canada. Between 2018 and 2019, expenditures for specialty medications (largely biologics) grew by 13.9%, compared to just 6.1% growth for non-specialty drugs,¹³ and the trend shows no signs of abating.

Since Canada approved the first biosimilar in 2009, these not-quite-generic drugs have offered a way to ease the cost crunch without compromising quality of care. That's the theory, anyway. More than a decade in, biosimilar uptake remains dramatically lower in Canada than in many other OECD countries.¹⁴ Sales of Remicade, the originator infliximab brand and highest-earning biologic in Canada, continue to grow at an annual rate of about 2%,¹⁵ even though the drug now has four biosimilar versions. Whether deep-rooted prescribing habits, unclear coverage policies, or lack of prescribing incentives are to blame, the hesitation around biosimilars represents a missed opportunity.

None of this has prevented biosimilar development from forging ahead. All told, Health Canada has approved 31 biosimilars to date and has another 10 under review.¹ Rituximab, a popular biologic developed in 2000, has seen three biosimilar versions enter the market in 2019 and 2020.¹ Biosimilar action has also ramped up for bevacizumab, with the first biosimilar version appearing in 2018, the next one in 2019, and a further two in the approval queue.¹

In the community setting, biologics and biosimilars for chronic conditions are fighting to claim their turf, while biosimilars for oncology have been tumbling into the hospital arena, creating unexpected decision points for public policy-makers and hospital administrators. This feverish activity presents an opportunity to balance the market and inject savings into the system, while continuing to welcome innovator molecules that raise the treatment bar for patients. Here are some trends to watch for in this rapidly unfolding saga.

WHAT'S CHANGING IN THE COMMUNITY SETTING

The Big Switch

Despite strong evidence that biosimilars perform as well as originators, Canadian physicians have been slow to embrace them. Canadian law generally requires physicians to place their patients' best interests above cost containment,¹⁶ which could prompt more cautious physicians to keep stable patients on the originator molecule with the reasoning that what works doesn't need fixing. By the same token, traditional listing policies may not have the muscle to change prescribing practices.¹⁵ Patients, for their part, may succumb to the well-known nocebo effect, whereby negative expectations of biosimilars dampen their clinical effect.¹⁷

That said, British Columbia's Biosimilars Initiative is showing us what does work: mandatory switching policies. Launched in 2019, the program first focused on the blockbusters

Enbrel, Remicade and Lantus, requiring patients using these drugs for specific indications to switch to their biosimilar equivalents over phased periods. To date, the initiative has led 78% of patients to make the switch,¹⁸ resulting in \$97M savings¹⁹ that the province has reinvested in covering the drugs Jardiance and Taltz.²⁰ The program has now turned its attention to switching patients on Rituxan to a biosimilar counterpart, a move that is expected to save the province at least 30% in treatment costs.¹⁸

Alberta is enacting a similar switching policy for several biologics, though the pandemic delayed its original rollout date, which is now set for January 15, 2021.²¹ Manitoba is taking a slightly different approach, with a tiered reimbursement policy that gives preference to cost-effective biologics and biosimilars and places restrictions on switching.²²

Will Ontario and Quebec, the country's most populous provinces, follow suit? The time appears ripe for a move: In Quebec, despite lowest-price policies, the originator biologic Remicade accounted for 91% of infliximab

prescriptions,²³ speaking to the need for more decisive action. An INESSS report has made a strong case for the safety of biosimilar switches, an effort that should reassure skittish prescribers.²⁴

The stage is also set in Ontario, where only 16.7% of etanercept and infliximab users were treated with a biosimilar in the second quarter of 2019.²⁵ The province did give the go-ahead to a switching policy in February 2020,²⁶ though it has yet to announce a launch date or any details about the policy. Implementation cannot come soon enough: in the absence of a switch, an estimated 65% of patients on etanercept and infliximab will still be receiving the originator product by Q2-2022.²⁷

The momentum is also building among private payers, though the uneven playing field may slow the pendulum's arc.³ In late 2019, Pacific Blue Cross, British Columbia's largest provider of extended health benefits, aligned its biologic coverage criteria with the province's switching initiative. All but 1% of plan sponsors have opted into the new framework, to dramatic effect: between January and May 2020,

biosimilars accounted for 68% of total infliximab claims, compared to just 23% over the same period in 2019.²⁸ The change in etanercept biosimilar claims was still more pronounced – from 15% to 93%.²⁸ Best of all, the transition allowed plan sponsors and members to avoid \$22M in drug costs.²⁸ Several other private payers have put similar programs in place, while others are following Green Shield Canada's early lead with preferential listings for biosimilars.¹⁵

Molecule to Watch: Adalimumab

The original adalimumab product, Humira, has proven itself a versatile molecule with an ever-expanding list of indications. With annual sales of \$930M and 8.5% year-over-year growth, Humira generates more revenue in Canada than any other drug except Remicade.⁴ Not surprisingly, this standout performance has made adalimumab a prime target of biosimilar development. As it happens, several new adalimumab biosimilars are poised to enter the market in 2021 – at more or less the same time.

Adalimumab products in Canada¹

Type	Adalimumab brand	First NOC	Canadian Distribution
Originator	Humira	July 2006	Abbvie
Biosimilar	Hadlima	May 2018	Merck
Biosimilar	Idacio	October 2020	Fresenius Kabi
Biosimilar	Amgevita	November 2020	Amgen
Biosimilar	Hyrimoz	November 2020	Sandoz
Biosimilar	Hulio	November 2020	Mylan
Biosimilar	Adalimumab Injection	January 2021	Pfizer

While the molecule's future looks rosy, the story of infliximab biosimilars – a story of missed savings opportunities for both public and private payers – could easily repeat itself with adalimumab. As the onslaught of adalimumab biosimilars draws near, stakeholders have the opportunity to do better. The community pharmacy and patient support programs (PSPs), in particular, are poised for meaningful change.

New Roles for the Community Pharmacy

As this new wave of biosimilars approaches, the industry is quietly shifting gears. For a paradigm-disrupting development, we need look no further than the community pharmacy, where 73% of Canadians now access their biologic medications.¹⁵ And unlike infliximab, adalimumab comes in a prefilled syringe (PFS) formulation, which could mean more dispensing of biosimilar versions at community pharmacies.

While specialty pharmacies are here to stay and will continue to provide key services, Karine Matteau, head of biopharmaceuticals at Sandoz, sees an opportunity to “elevate the role of the pharmacist in the transition of thousands of patients to biosimilars.”¹⁵ This enhanced role could include nutritional counselling, side-effect management, and injection training certification.¹⁵ The day may even come when pharmacists have the authority to switch patients from one biosimilar to another – called biosimilar interchangeability – without involving a physician.

At the same time, it is easy to imagine the complications, at both the prescriber and pharmacy level, that the glut of adalimumab biosimilars could bring about. With so many biosimilars to choose from, doctors may settle into variable prescribing practices. Also, subtle differences in the ease of self-injecting the medication, like the size, shape or pressure of the injector, may swing patient preferences in unanticipated directions, which could feed back into prescription patterns. All this could make it challenging for community pharmacies to estimate demand and manage inventory, and for biologic manufacturers to size up their market opportunity.

PSPs in Flux

A big part of biologics' success depends on PSPs. Beyond handling such administrative tasks as reimbursement navigation, effective PSPs help promote treatment adherence and persistence, making them just as vital to biosimilars as

to originator biologics. In fact, there is a PSP mandate for every biosimilar – and it's not just a question of ticking a box. “As manufacturers of biosimilars, we are required by payers and provinces to prove we have a PSP that is equivalent to the originator,” Matteau explains.¹⁵

These high standards undoubtedly benefit patients. At the same time, the profusion of new market entrants could lead to a confusing quantity of PSPs. As a case in point, a single rheumatology website lists 21 PSPs, each with its own enrolment form²⁹ – and that's not even counting the adalimumab biosimilars in line for approval. As Matteau points out, “if there are [say] seven PSPs for a pharmacist and physician to understand, how is that sustainable?”¹⁵

A Suite of PSP Solutions

Manufacturers and PSP vendors alike have been grappling with the challenge of maintaining a strong patient focus while keeping costs under control. Here's what's been happening and what we can anticipate with PSPs for biologics:

- **Variable range:** Some PSPs have adopted a pared-down approach, focusing on the most essential services, while others are looking to differentiate through added value.
- **Feedback loop:** Forward-thinking PSPs are connecting more proactively with patients through tools such as surveys, using the feedback to improve their services.
- **High tech:** With Covid-19 having accelerated the need for contactless transactions, some PSP providers are ramping up the tech factor with such features as all-digital prior authorization.³⁰
- **New models – an area to watch:** PSPs that cover a whole drug class or therapeutic area,³¹ proposed by some stakeholders as a way to create synergies and contain costs for all stakeholders, have yet to come to fruition.

HOSPITAL SCENE

Meanwhile, biosimilars used in oncology treatment have been making inroads into hospital settings. In one of the most undercelebrated biosimilar success stories, biosimilars for filgrastim – a drug that counteracts the low neutrophil count resulting from some oncology therapies – have to date captured more than 85% of the filgrastim market.⁶

More recently, the proliferation of biosimilar versions of oncology blockbusters rituximab, trastuzumab and bevacizumab has highlighted the need for guidance on introducing such medications to the hospital setting. To this end, a group called the pan-Canadian Oncology Biosimilars Initiative has been working to expedite and harmonize the uptake of oncology biosimilars.³² If Cancer Care Ontario (CCO) data is any indication, these efforts are paying off. As an example, treatments with bevacizumab biosimilars have climbed from zero to about 750 between August 2019 and August 2020, surpassing the figures for the reference biologic along the way.³³ In B.C., patients already taking the bevacizumab reference drug can continue to do so, though they also have the option of switching to the biosimilar version in consultation with their doctors.³⁴

Biosimilars
still have a
lot *further*
to go.

Handling Multiples

How are multiple biosimilar entrants handled in the oncology space? The short answer: It depends. “It depends on the province, it depends on the jurisdiction, and different places have made different decisions,” says Helen Anderson of BC Cancer.³³ Here are some of the factors at play:¹

- **Decision points:** Some provinces make a top-down decision on which biosimilars to use, while others leave it to individual hospitals to make the decision.
- **Short list:** In Ontario, each hospital can select the biosimilars they want – as long as they're funded by CCO. The government does not guarantee a market share to any new entrants.
- **Fine points:** Without consistent and transparent guidelines, decisions on which biosimilar is listed at the hospital may depend on such fine points as reconstitution time, level of foaming in the vial – or even size of the exterior packaging.
- **Therapeutic inertia:** In practice, hospitals often find it most convenient to stick with the first biosimilar they selected, posing a challenge to new market entrants.

As of November 2020:⁶

Molecule	# of Approved Biosimilars	Biosimilar Market Share
Rituximab	3	9.2%
Trastuzumab	4	22.0%
Bevacizumab	2	55.6%

Source: IQVIA report: PharmaFocus 2024 Update. Canadian Drugstore and Hospital Audit. MAT November 2020

In short: biosimilars have made great strides but have a lot further to go. B.C.'s Biosimilars Initiative, boasting thousands of successfully and safely treated patients, has forged a path that other jurisdictions can follow. Payers such as Blue Cross and Green Shield Canada have demonstrated that biosimilar-first policies can work in the private sphere as well.

On the downside, uptake of biosimilars for major molecules continues to sputter, despite the requisite stakeholder consultations and body of reassuring data. Every day that goes by without biosimilar policies in place represents millions of dollars in lost savings. The opportunity to reinvest in biologic drug-spend and reinvest the savings into innovation and improved patient care lies within our grasp. What exactly are we waiting for?

Biosimilar *breakthrough*

Alan Low on the
impact of B.C.'s
biosimilar policies



Dr. Alan Low surely needs a separate closet for his numerous hats, which include frontline pharmacist, researcher, advisor, instructor, textbook author, corporate officer and previously hospital practitioner. A Clinical Associate Professor at the University of British Columbia, Alan coordinates and teaches the Pharmacy Practice Management and Leadership course as well as serves as a preceptor for pharmacy students. As Executive Director of Medicines Access Coalition BC (MedAccessBC), he works to improve B.C. residents' access to life-changing medicines. His deep expertise in biologics has given him the ear of policymakers and health professionals and made him a sought-after consultant and speaker.

Now that biosimilars have become part of the landscape in B.C., can you comment on how they are working for patients?

By and large they're performing very well and are offering the same clinical benefits as the matching originators, though some patients may have had unexpected responses. Most patients have adapted to biosimilars without any problems or complaints. Occasionally, a patient's negative beliefs about biosimilars can weaken the perceived response – the so-called nocebo effect. Separating out

actual from perceived negative effects can be difficult. It's important to educate health professionals on how to instill confidence in patients and avert misguided perceptions. Words have power!

Can you tell us about the British Columbia Biosimilars Initiative?

The idea behind the initiative, which was introduced in 2019, is to optimize public resources by switching patients from originator biologics to their biosimilar versions. It saves costs to the system and improves patient access to medications. As a direct result of the program, the B.C. government has been able to add new biologics and other advanced medications to its formulary, as well as covering new laboratory tests such as fecal calprotectin. The actual savings and impact to patients and the health system are yet to be reported.

How have physicians and patients responded to the program?

Most physicians and patients have embraced the program and made a smooth transition in rheumatologic conditions, less so in gastroenterology. A few doctors expressed concerns about the evidence for "non-medical" switches and about the lack of clarity in the special authorization process for staying on the originator biologic. Education and improved communication are helping to iron out these

challenges. To prepare patients for the program, I offered education sessions at my pharmacy and gave talks on behalf of various patient groups. In my experience, if a patient has trouble absorbing or accepting the change, continued education can help relieve anxieties and concerns, along with informing them of their options. People do not like to be forced into a treatment.

What role do patient support programs have in biologic treatment in B.C. and in particular with switches to biosimilars?

They've been both a help and a hindrance. When a patient is transitioning from an originator to a biosimilar, they have to deal with both the old PSP and the new one, which can cause confusion. PSP coordinators are restricted in what they can say about treatment, so the patient may not get the full picture. Logistics can get especially complicated for patients on infused drugs, who may have to move to a different infusion centre with different care providers. An idea gaining currency is the universal PSP, which would streamline enrolment and make life easier for both physicians and patients.

How are multiple biosimilars being handled at the pharmacy?

The ideal is to have all the biosimilar options in stock, so patients coming in with a prescription can receive the prescribed medication on the spot. Realistically, not all pharmacies can bear the costs of such a model. Even if a pharmacy has limited stock, advance communication between prescriber and pharmacy can facilitate just-in-time dispensing: the pharmacy gets a heads-up on the prescription and can order it while the patient is taking care of enrollment and reimbursement.

What is the pharmacy's role in choosing which biosimilar molecule is dispensed?

At the moment there is no interchangeability policy for biosimilars. If the prescribing physician selects a particular biosimilar version, prescribed by its trade name, the pharmacist has no authority to switch it to another brand, even though it is the same molecule. On the other hand, if the prescription just states the molecule or chemical name of the biologic, the pharmacist can select which biosimilar version to use, after consulting with the patient. Tools such as PharmaNet and real-time adjudication allow pharmacists to find out which medications the patient has been receiving in addition to which biosimilars are covered and what each copay is, so they can guide patients to choose the most cost-effective or preferred options.

Do you anticipate the interchangeability rules to change at some point?

We need studies proving that the pharmacokinetic properties of the various biosimilars corresponding to a single originator aren't too far apart, and that clinical efficacy and safety are

within defined limits. Once we have this data, I expect that many biosimilars will become interchangeable with the originator biologic and other biosimilars.

Do patients themselves have a say in biosimilar selection?

With brand-name and generic drugs, the current public system covers the lowest-cost alternative, and patients who prefer a more expensive brand-name version have the option of paying the difference. This is not the case with biosimilars right now: patients either agree to the biosimilar covered by the public payer or they pay 100% out of pocket, or some may be able to receive coverage through their private health plan. I hope the future will bring more choice to patients taking biosimilars, perhaps with copays to account for differences in cost where the patient can pay the difference from the biosimilar to the originator biologic if they prefer.

Where do you see the biosimilar conversation going in the next 6 to 12 months in B.C. and the rest of Canada?

Right now, pharmacists can't make any changes to biologic or biosimilar prescriptions without contacting the prescribing doctor. We have frontline contact with patients, who often tell us about their preferences of self-injectors and syringes, but we can't act on this knowledge without contacting the prescriber. I think regulations will open up and give more scope for pharmacists to use clinical judgment. I would love to see certification programs for pharmacists in the area of biologic and specialty drugs.

This year, we expect to see multiple biosimilars for adalimumab enter the market. Any thoughts about the complexities this may bring?

More choice is always a good thing for patients. Sometimes the choice comes down to the injector pen, and the competition will likely encourage innovation in this regard. A competitive market also encourages payers to negotiate better prices. There is always a risk of problematic business practices that could put pressure on prescribers, but we have mechanisms, such as oversight from PharmaCare and professional regulatory Colleges, to prevent this from happening.

What advice would you have for manufacturers of biosimilar products?

It would be useful for manufacturers to approach payers and policymakers as a group, to help promote a patient-centred and cooperative paradigm. Collaboration can also help avoid heavy-handed policies that stand in the way of patient care. I encourage manufacturers to not only work with pharmacists, but also involve patient advocacy groups in the push toward fair market solutions. Thanks to my work with MedAccessBC, a group devoted to removing barriers to accessing and receiving medicines, we have seen policy changes as a result patient advocacy, I can attest to the power of such organizations.

*More
choice is
always
good
for patients.*

On the reading list

[Forced To Switch: Canadian Biosimilar Experience Gastrointestinal Society Survey Report](#)

[INESSS: Safety of switching biologics and their interchangeability](#)

[Market access for biosimilars in Canada still below OECD average](#)

[Ontario's closed-door plan to switch to biosimilars garners mixed reactions](#)

[B.C. expands use of biosimilars to offer coverage for more treatment options](#)

[The Law and Ethics of Switching from Biologic to Biosimilar in Canada](#)

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THE 20SENSE REPORT

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