

# THE 20SENSE REPORT



Making sense of Canada's  
specialty pharmaceuticals market

SPOTLIGHT ON THE CANADIAN  
SPECIALTY PHARMACEUTICAL MARKET

JULY 2018 ISSUE 5

## A Broken System: The Ongoing Saga of Originator Biologics and Biosimilars

Biologic drugs offer hope and health to a large number of Canadians living with serious disorders. When these medicines first entered the market, prescribers and patients quickly recognized them as revolutionary and the industry followed suit.

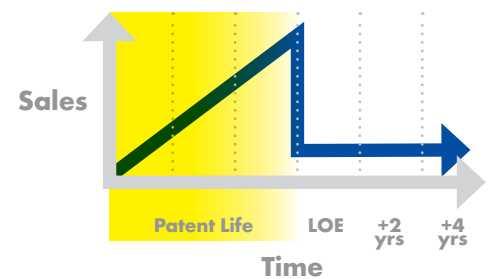
Today, biologics represent over 20% of the Canadian drug market<sup>1</sup> and the category shows no signs of slowing down. Great news for patients? It can be, as long as policies move forward to contain costs and balance the market. With the health system careening toward unsustainability, this needs to happen.

When “biosimilars” – drugs designed to deliver the same clinical benefits as existing biologics, but at a lower cost – came along, they offered a welcome path toward the more balanced, sustainable market we would all like to see. But that’s not what is actually happening. The traditional life cycle of a drug – patent protection, patent

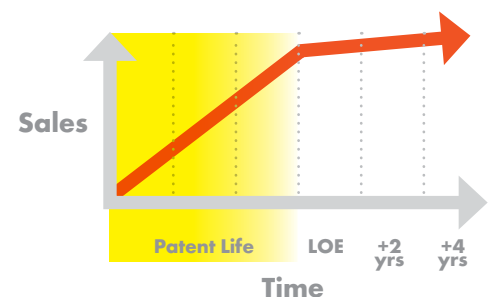
expiry, followed by high uptake of low-cost generics – has not played out in the biologic arena. It’s a new game with new rules and stakeholders have largely clung to the status quo, with the result that patients remain on the higher-priced and better-known originator molecules.

Consider infliximab, the highest-earning biologic in Canada with annual sales of about \$1.1 billion.<sup>2</sup> Six years after Remicade’s loss of patent, two biosimilar versions of infliximab have stepped in – but Remicade continues to dominate with a market share of over 95%.<sup>2</sup> The post-patent life of another popular biologic, etanercept, has followed a similar arc. Clearly, today’s market is not set up to give biosimilars their rightful place alongside originators. Why the resistance to change? For one thing, while biosimilars have no clinically meaningful differences from their corresponding originators,<sup>3</sup> they do not have the label of interchangeability. This leaves the power to switch in prescribers’ hands, and prescribers have largely stuck with →

### Product lifecycle: from brand to generic



### Product lifecycle: from originator biologic to biosimilar



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what they know. And why not? Patients are stable on their current biologic therapies, and most payers are still paying for the originator drugs and have not mandated a switch.

If we cannot save money on existing products after their patent expiry, we will not be able to pay for the new, disruptive therapies that move patient care forward.

Let's start by learning from isolated success stories such as filgrastim, a biologic used to correct some acute effects of cancer treatment. Two years post-launch, the filgrastim biosimilar has captured as much as 50% of the market share, by some estimates – simply because payers enacted listing changes favouring the biosimilar. With the right push, biologics for chronic conditions could follow a similar trajectory.

We can also take our cue from countries such as Norway, where biosimilars have seen price drops as great as 72%.<sup>4</sup>

The Canadian market has a place – and a need – for both originators and biosimilars. We must simply establish the right balance between the two. With the health care system under mounting pressures, the way forward is clear: follow the evidence and responsibly contain costs. Patients across the country are counting on it.

Despite the underwhelming performance of biosimilar products to-date, new biosimilars continue to enter the market. Clearly, manufacturers believe these products can earn their rightful place alongside originator molecules. And they can – if supported by forward-thinking policies and practices.

## Originator Biologics with Biosimilars Approved in Canada

Year First Biosimilar Approved in Canada	Molecule	Originator Biologic & Approved Biosimilar(s)	1st NOC	Canadian Marketing Authority	Approx. Sales 2017 IQVIA \$M	2017 IQVIA Sales Rank	2016 IMS Sales Rank
2009	Somatropin	Genotropin <b>Omnitrope</b>	1996 09 <b>2009 04</b>	Pfizer <b>Sandoz</b>	N/A N/A	– –	– –
2015	Infliximab	Remicade <b>Inflectra Renflexis</b>	2001 06 <b>2015 01 2017 12</b>	Janssen <b>Pfizer Merck</b>	\$1,106 <b>\$16 N/A</b>	1 – –	1 – –
2015	Filgrastim	Neupogen <b>Grastofil</b>	1992 03 <b>2015 07</b>	Amgen <b>Apotex</b>	\$99 <b>N/A</b>	42 –	24 –
2015	Insulin Glargine	Lantus <b>Basaglar</b>	2002 04 <b>2015 09</b>	Sanofi-Aventis <b>Eli Lilly</b>	\$167 <b>\$3</b>	18 –	17 –
2016	Etanercept	Enbrel <b>Brenzys Erelzi</b>	2001 03 <b>2016 08 2017 04</b>	Amgen <b>Merck Sandoz</b>	\$322 <b>\$2.8 \$0.1</b>	5 – –	5 – –
2017	Insulin Lispro	Humalog <b>Admelog</b>	1996 10 <b>2017 11</b>	Eli Lilly <b>Sanofi-Aventis</b>	N/A <b>N/A</b>	– –	– –
2018	Bevacizumab	Avastin <b>Mvasi</b>	2005 09 <b>2018 04</b>	Roche <b>Amgen</b>	\$115 –	32 –	35 –
2018	Pegfilgrastim	Neulasta <b>Lapelga</b>	2004 03 <b>2018 04</b>	Amgen <b>Apotex</b>	N/A –	– –	– –
2018	Adalimumab	Humira <b>Hadlima</b>	2006 07 <b>2018 05</b>	Abbvie <b>Merck</b>	\$738 –	2 –	2 –



## Payer Be Aware

In a category marked by caution and conservatism, a private payer, Green Shield Canada (GSC) has enacted a couple of highly innovative policies for biologic drugs.<sup>5,6</sup> In this exclusive chat with 20Sense, Ned Pojskic, Leader, Pharmacy & Health Provider Relations at GSC, explains why GSC chose to take this bold step – and suggests a way forward for the biologic ecosystem.

### **20Sense: Can you briefly describe the biosimilar policies adopted by GSC?**

**Ned Pojskic:** In 2016, we introduced a policy whereby patients starting on a biologic only get coverage for the biosimilar (assuming one exists), barring exceptional circumstances. And in early 2018 we launched our Biosimilar Transition Program. It's the first program in the country that addresses transitioning for patients already on a biologic, as opposed to new starts. Under this new program, arthritis patients already on Remicade [infliximab] or Enbrel [etanercept] have the option to switch to the biosimilar versions of these drugs – or stay on the originators and pay the difference.

### **20Sense: What spurred GSC to adopt these policies?**

**NP:** Our company philosophy is to follow the evidence, which in this case is very clear: biosimilars do not compromise either efficacy or safety, and theoretical concerns

about increasing immunogenicity have not borne out. Fortunately our plan sponsors have stood behind us all the way, and it was vindicating to see public payers establish similar policies for new patients starting biologic therapy shortly after we introduced our 2016 program.

### **20Sense: What about the idea of letting people choose? Is this not a core value of our health system?**

**NP:** Canadian physicians have shown reluctance to rock the boat, so if we as payers maintain a totally open choice, we're simply going to funnel all uptake toward originators. The patient can always choose to pay more, but payer policies should rest on reason and evidence. This philosophy is part of a broader view that extends beyond any one drug or category. It's a rational approach to distributing scarce health resources in our society.

### **20Sense: Can we learn from the experience of other countries?**

**NP:** I think we can learn from European countries such as Norway and Sweden, where there's a greater focus on evidence and payers have taken a more aggressive stance. Payer policies have also driven down biosimilar costs in countries such as Norway, where we're seeing discounts of up to 75%. While it is true that these countries have single-payer systems for these drugs, some of their approaches could be adapted to the Canadian environment.

### **20Sense: What's your advice to payers operating in the biologic [originator and biosimilar] space?**

**NP:** At different points in their lives, patients sometimes move between public and private reimbursement, so ideally public and private payers should integrate their policies to facilitate such transitions. Above all, we payers need to keep presenting the evidence to doctors and policymakers. Sometimes it's just a matter of time before the message gets across.

### **20Sense: Any parting advice for biologic drug manufacturers?**

**NP:** For manufacturers of biosimilars, educate the payers to support new products and to understand they're not losing out by adopting forward-looking policies. For manufacturers of originators, avoid fear-mongering to preserve market share and take the long view: the more sustainable the market, the more room there is in benefit plans for new therapies coming to market.

**To learn more, listen to this GSC podcast on biosimilars featuring Ned Pojskic as well as patient advocate Cheryl Koehn:**

<https://www.greenshield.ca/en-ca/podcast/episode-7-biosimilars>

# Steering Your Ship to Shore

All stakeholders agree: biologics serve the public good, but the health system cannot support their indiscriminate use. Manufacturers need to think big and bold to achieve a rational – and *sustainable* – balance between originators and biosimilars. Here, we offer some guiding principles to help you stay the course.

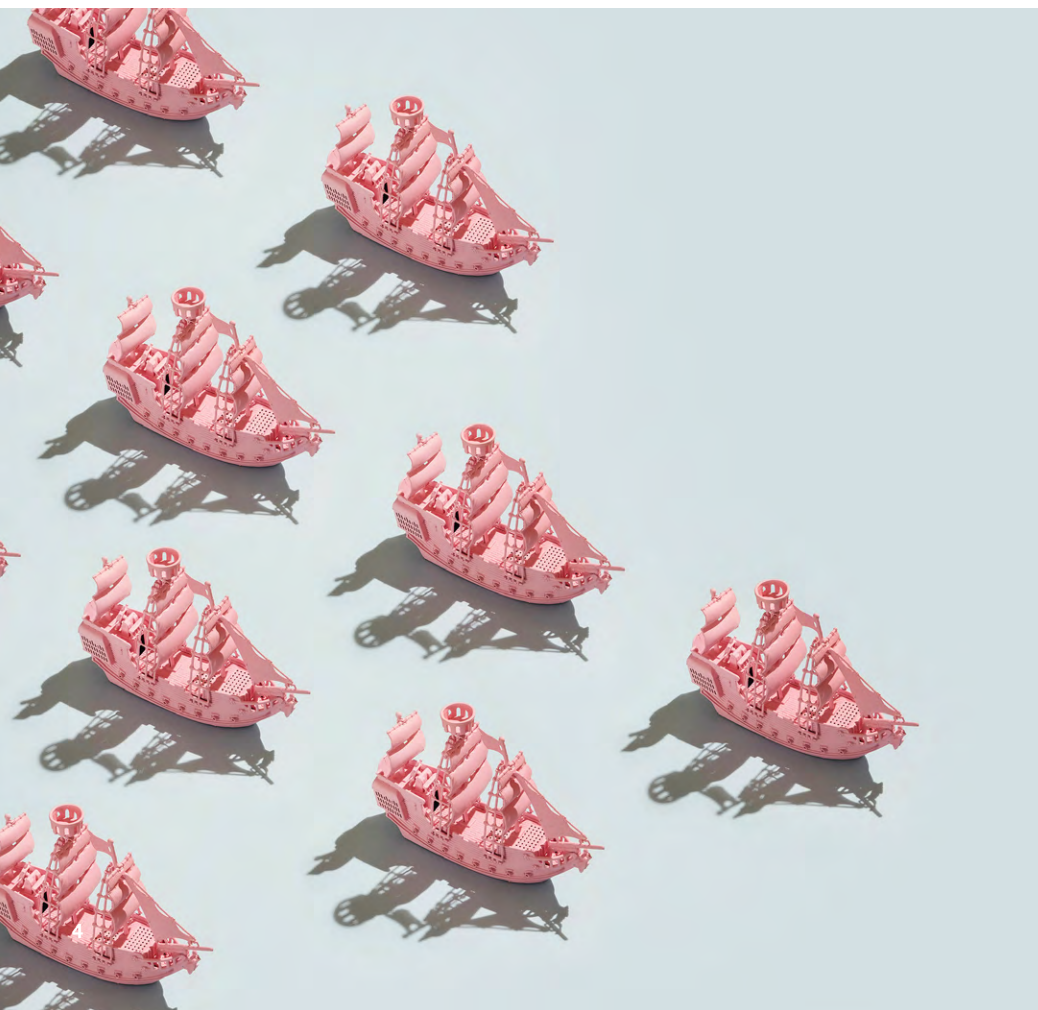
**Learn from other markets:** Get inspired from bold initiatives in other jurisdictions or areas of medicine. In Germany, for example, regional physician associations work with health insurance providers to establish biosimilar quotas.<sup>7</sup> Australia has launched a nation-wide Biosimilar Awareness Initiative to promote uptake, accompanied by extra price drops for publicly listed biosimilars.<sup>8</sup> Closer to home, Canadian Blood Services has set

up a transparent tendering process to help “right-price” the blood products it purchases, saving an estimated \$600 million over 5 years.<sup>9</sup> While this approach may seem foreign to today’s biologic market, we need disruptive thinking to break through the current impasse.

**Create innovative agreements:** Encourage health technology assessors and payers to develop fair, evidence-based agreements that facilitate patient access to cost-effective products within a best-practice framework. Don’t be afraid to consider outside-the-box approaches, such as outcomes-based agreements that tie reimbursement to results. Innovation in reimbursement may take time and patience, but it benefits all parties.

**Understand the new rules:** The influencers have changed. While physician attitudes can make or break an originator or biosimilar, pharmacists who cannot order automatic substitutions to biosimilars – hold less sway than they do with generic drugs. Payers, meanwhile, play a larger role than ever. You need to tailor your commercialization strategy to today’s key players.

**Make the most of your data:** Are you gathering data from specialty pharmacies, from patient outcomes databases, and from your patient support program? More to the point, are you extracting full value from it? To maximize patient impact and grow your brand, you need to align the captured data to your brand’s marketing strategy.



<sup>1</sup> Adapted from CADTH Biosimilars Environmental Scan: Biosimilars – Regulatory, Health Technology Assessment, Reimbursement Trends, and Market Outlook, January 2018, and IMS 2016 sales figures.

<sup>2</sup> Adapted from IQVIA Canadian Pharmaceutical Industry Review 2017.

<sup>3</sup> Government of Canada. Fact sheet: biosimilars. <https://bit.ly/2L61bup>

<sup>4</sup> Gabi Online. Huge discount on biosimilar infliximab in Norway. <https://bit.ly/2KXqema>

<sup>5</sup> Green Shield Canada subsequent-entry biologic policy announcement, April 20, 2016: <https://bit.ly/2MZgPrV>

<sup>6</sup> Green Shield Canada biosimilar transition program announcement, March 8, 2018: <https://bit.ly/2u1kK0h>

<sup>7</sup> Health Canada Strategic Policy Branch. Biosimilars: International awareness and uptake initiatives. March 20, 2017.

<sup>8</sup> Measures to support generic and biosimilar medicines uptake. <https://bit.ly/2ucpPBZ>

<sup>9</sup> Canadian Blood Services as a model for national pharmacare. April 15, 2015. <https://bit.ly/2KUGOzP>



## What We're Reading

We find that the following articles provide great insight into the specialty pharmaceuticals market. Follow us on LinkedIn where we're sharing our thoughts on these topics and many more.

[CADTH Biosimilars: Regulatory, Health Technology Assessment, Reimbursement Trends, and Market Outlook](#)

[GSC Episode 7 - Biosimilars... to switch or not to switch](#)

[WEBINAR: What Is a Biosimilar? The Current Biologics and Biosimilars Landscape in Canada](#)

[Top 10 Updates on Canadian Market Access, Exclusivity and Pricing Issues \(including biosimilars\)](#)

[CADTH Drugs for the Management of Rheumatoid Arthritis: Clinical Evaluation](#)

[Rising biosimilar uptake touted amid 'continuously evolving' evidence for safety, efficacy](#)

[INESSS Evaluation of Biosimilars](#)

## Upcoming Issues

In upcoming issues of *The 20Sense Report*, we'll take a deeper dive into:

- The patient perspective on specialty pharmaceuticals
- Specialty pharmaceuticals and data, key areas for insight maximization
- Patient support programs: exploring opportunities for outcomes-based agreements

Is there an issue you'd like us to address? Do you have a question you'd like us to answer?

We welcome your suggestions for topics you'd like *The 20Sense Report* to cover.

Are you looking to make better sense of the specialty pharmaceuticals market?

Contact us at:  
[info@20Sense.ca](mailto:info@20Sense.ca)  
[www.20Sense.ca](http://www.20Sense.ca)  
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20Sense helps pharmaceutical manufacturers and specialty service providers more effectively enter and compete in Canada's complex specialty pharmaceuticals market by optimizing data, insights and programs that deliver better outcomes for patients and value for payers.

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