

THE 20SENSE REPORT



Making sense of Canada's
specialty pharmaceutical market

SPOTLIGHT ON THE CANADIAN
SPECIALTY PHARMACEUTICAL MARKET

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Patient Support Programs: A Tsunami is Rolling In



Tremors in PSP Land

PSPs have become, as the saying goes, part of the wallpaper.

Whether high touch or bare bones, PSPs are a must-have component of specialty medicine treatment. To understand how far PSPs have come and may evolve in the future, it's worth stepping back and revisiting why we have PSPs in the first place.

A couple of decades ago, as specialty drugs began pouring into the marketplace, gaps in the delivery of services came to light: Who would help the patient navigate the reimbursement maze? Who would deliver the medication to its final destination? Who would set up a treatment and lab testing schedule? Recognizing that the existing system couldn't absorb these new treatment requirements, manufacturers created PSPs to bridge the gaps.¹

The jury is in: PSPs work. Not only do they support patients through the logistics of treatment, but – depending on their design – they can help patients achieve better outcomes with their medication. In a study of over 10,000 Canadian PSP participants, those who received motivational phone calls from nurses were 72% less likely to stop treatment.² The bulk of evidence also suggests that PSPs improve clinical and humanistic outcomes, as well as containing health care use and costs.³

Clearly, PSPs are here to stay. At the same time, the ground they occupy has been shifting. Changes in the specialty drug sector are pushing PSPs into new areas of functionality, and they are being required to adapt little by little. Here are 4 pressure points you need to be aware of, now, in the PSP space.

An expanding specialty drug (and PSP) universe

Every year brings a spate of new and costly specialty medicines to the market, and the future promises more of the same. Specialty medicines accounted for 24% of total drug spend in 2014;⁴ four years later, the figure had climbed to 32%⁴ and is set to reach 52% by 2025.⁵

What specialty changes are we seeing? Biologics are branching out into new therapeutic areas, such as asthma, allergy and stroke.⁵ The biologic boom extends to biosimilar molecules: As of 2019, Canada approved 17 biosimilars,⁶ each requiring its own PSP. Sophisticated new cancer treatments, such as immunotherapy and gene therapy, have raised the average annual cost of cancer treatment from \$79,000 to \$150,000 between 2013 and 2017,⁴ with no ceiling in sight. With more specialty drugs coming to market, we can expect PSPs to follow suit.



CONTINUED FROM PAGE 1

Ethical guideline update

In this climate of relentless growth, it comes as no surprise that PSPs would experience, well, growing pains. Enter the Code of Ethical Practices, created by Innovative Medicines Canada to help the specialty medicine universe stay honest.⁷ In late 2019, amid media concerns that infusion fees paid to doctors by manufacturers could influence prescribing decisions,⁸ IMC amended Section 14 of the Code – the section that deals with PSPs. Slated to take effect in July 2020, the updated Section 14 states that “third parties cannot pay or provide a financial benefit to the prescribing HCP in the context of a PSP” except when the physician depends on such payments to ensure access to patients living in remote areas.⁹

Manufacturers and PSP vendors alike are working to understand the impact of this amendment and tweak their programs accordingly. How remote is remote, for example? What if a manufacturer does not belong to IMC? And the overarching concern: Will PSPs be able to maintain their high value to patients in the wake of the guideline changes?

Squeezed at the margins

In the model that emerged a decade ago, pharmacy and wholesale markups on drugs subsidized the PSP services offered by pharmacy vendors. In recent years, however, reductions and caps on markups have put a strain on the traditional model.

British Columbia’s public drug plan, for example, allows a markup of up to 5% for high-cost drugs – but the limit on certain hepatitis drugs fell from 5% to 2% as of March 2017.¹⁰ In Ontario, the maximum markup for high-cost drugs has held steady at 6% for the past four years, but a recently introduced clawback provision effectively brings the figure down to 5% over a 3-year period.¹¹ And with a \$30 limit on professional fees within public drug programs and a markup reduced down to 2% on about 30 drugs, Manitoba has taken an especially hard-line stand on markups.¹²

When you consider that the markups are divided among several players in the supply chain, coupled with tighter margins at the wholesale level, the math no longer works out. Manufacturers require increasingly sophisticated PSP services for their new products, while pharmacies and PSP vendors are expected to provide more with fewer resources – hardly a recipe for sustainability.

A holistic view

Sandra Hanna, CEO of the Neighbourhood Pharmacy Association of Canada, gives a nuanced perspective on drug costs, pharmacy markups and provider sustainability.

“We know the challenges that high-cost drugs pose for payers and the potential strain of pharmacy markups on the system as a whole. At the same time, we need to consider the value pharmacists bring to the mix.

As stewards of drug expenditure, pharmacists can increase the use of more cost-effective alternatives and ensure patients get the best value from their prescribed medications. A cost-containment strategy that better leverages pharmacists’ holistic knowledge of the drug universe makes more sense than focusing on the small cost slice associated with markups.”

Public offering, Quebec style

Here’s a new twist: In September 2019, the Association québécoise de pharmaciens propriétaires (AQPP) announced its intent to deploy a province-wide PSP for the more than 2,000⁵ owner-pharmacists it represents.¹³ The effort grew out of perceived inequities in the flow of specialty drug prescriptions to Quebec pharmacists – like the fact that 38% of prescriptions for five top-selling specialty drugs fall into the hands of just five pharmacies.⁵

Lending regulatory weight to the initiative is 2016’s Bill 92, which states that manufacturers or wholesalers cannot confine the supply of medications to a limited number of pharmacies.¹³ In effect, the Bill protects patients’ rights to choose their own pharmacy to provide the services they need. If a community pharmacy lacks the infrastructure to provide specialty medicine services, AQPP intends to step in and fill the gap. Other provinces are watching.

These seismic shifts make it clear: PSPs must stretch to survive. For this to happen, stakeholders need to get creative. There are several ways this can happen.

One PSP Challenge, Four Big Ideas



Making sense of Canada's specialty pharmaceutical market



The two imperatives of PSPs – delivery of vital treatment support services and financial sustainability – exist in a state of mounting tension.

Changes in patient, prescriber and payer roles are already rumbling under this shifting terrain. By all appearances, a change in the whole model of specialty medicine care is on the way. [Here, we explore four possible PSP models of the future.](#)

Big Idea #1: The broad-spectrum PSP

The “one drug, one PSP” model yokes each PSP to a specific drug, but the industry has begun to question this paradigm. Instead of developing separate PSPs for each product, why not develop a PSP to cover all specialty medicines (or a whole drug class) within a therapeutic area?

One group, Biosimilars Canada, an association representing some of Canada’s biosimilar makers, has done just that. Earlier this year, the association launched its own PSP to provide support services for member pharmaceutical companies.¹⁴ Such drug-agnostic PSPs stand to lower costs and increase consistency across indications and products. Extending this idea to its logical conclusion brings us to the “universal PSP,” meaning a flexible PSP that can shape-shift to suit all comers.

In a variant of this approach, PSPs could make their services available across an open network of clinics, rather than tethering services to specific sites. Such an infrastructure would free up patients to select the clinics that are most convenient for them, and avoid having them move sites if their prescribed medications changes – as is the case today with some PSP models. On the flip side, an open-network model could consolidate services currently duplicated by several clinics in a single neighbourhood. The model would also make life easier for the vast number of patients being mandated to switch from originator biologics to biosimilars – especially in provinces such as Alberta and BC, which have recently instituted biosimilar switching policies.

One size fits all?

A year into Biosimilars Canada’s PSP program, **Jim Keon**, President of the association, weighs in.

“Some of our members already had PSPs in place, so they did not leverage this program. Right now, we have two biosimilars participating in the program, with more to come. We are open to non-member companies participating as well.

Though it’s still early days, feedback from payers and prescribers has been very positive. Stakeholders have been concerned about the proliferation of programs, which adds complexity and costs, and view this solution as a good one.

We mitigate costs through economies of scale, but more importantly, we provide a first-class PSP that patients can use with confidence. To account for differences between services that different companies [drug manufacturers] can tailor to their needs.”

Big Idea Snapshot

Big Idea 1: The broad-spectrum PSP

In this model, PSPs cover whole drug classes or therapeutic areas under a unified program.

Big Idea 2: Collaboration on PSPs

By working together, manufacturers can create joint PSPs that maintain high standards and contain costs through economies of scale.

Big Idea 3: A new centre of PSP gravity

This model shifts the driving force behind PSP development from manufacturers to payers and/or prescribers.

Big Idea 4: The turbo-charged PSP

Loading PSPs with value-added features (particularly deep data collection and mining) can boost their ROI and value to patients.

CONTINUED FROM PAGE 3

Big Idea #2: Collaboration on PSPs

Picture this: a group of manufacturers band together to build a shared PSP across a therapeutic area, such as rheumatoid arthritis or inflammatory bowel disease. They use a single PSP vendor (selected through a request-for-proposal process), which uses its own pharmacies to deliver services. The manufacturers also merge their distribution architecture, in line with, for example, the unified model offered today by the Canadian Pharmaceutical Distribution Network for hospital drug distribution.¹⁵

Such consolidation of resources would bring down costs, which manufacturers could split based on usage. To make the model work, participants would need to take full advantage of the economies of collaboration, which could include data sharing.

Big Idea #3: As new centre of PSP gravity

Who drives the creation and operation of PSPs? Manufacturers, of course. But does it have to be this way? Could PSPs' centre of gravity shift to another locus?

One could argue, for instance, that PSPs fill holes in the healthcare system, so the system should step up and support them. In a nod to this idea, Ontario's Ministry of Health and Long Term Care (MOHLTC) has suggested that provincial oversight and funding of private infusion clinics – often part of PSP service delivery – could help support high standards across these clinics.¹⁶

Prescribers, for their part, receive several indirect benefits from PSPs. Most PSPs handle the paperwork for patient enrolment and take charge of laboratory testing, lifting a sizable load off physicians' shoulders.⁵ PSPs also support treatment success by speeding up access and improving adherence, which prescribers recognize as a game changer. Dr. Thomas Walters, a pediatric gastroenterologist at SickKids Hospital in Toronto, has noted how manufacturer-sponsored PSPs have improved treatment outcomes and made his own job easier.¹⁷

What if prescribers exerted a more direct pull on PSP development? As an example, physicians have justifiable concerns about the logistics of interfacing with a different PSP for each drug. Based on such feedback, could PSP design be tailored to better meet prescribers' needs? In fact, this shift is already underway, with a number of stakeholders working closely with prescribers to pilot and test how such models might work, and drive increased benefit to their patients.

Big Idea #4: The turbo- charged PSP

Given the large investment in running a PSP, it makes sense to get the highest possible ROI from the effort. Data collection already plays an important role in today's PSPs, but there is room to go further – like ramping up data on health outcomes. The judicious use of technology could also help integrate PSP outputs with data from other sources, such as hospital data, claims data, and unstructured data within the health system, thus making the information more valuable to more people.

It goes without saying that such "fortified" PSPs would benefit all parties. Prescribers could better understand their patients' trajectories, including the pain points. Payers would gain insight into which drugs work for which patients, enabling them to allocate their resources even more equitably. These same insights could help manufacturers make informed business decisions and reduce strategic risk. Ideally, all the data would come together to help get patients on "the right drug at the right time."

The future of PSPs depends on bold, big-picture thinking. As stakeholders put their heads together, who knows what other ideas will bubble up? The next few years will be interesting.





Insights of a PSP Strategist: An Interview with Andrea de Jaray

As AstraZeneca's Group Patient Support Programs (PSPs) Strategy Lead, **Andrea de Jaray** views PSPs through a holistic, patient-centric lens. With over 10 years' experience working with PSPs, she has witnessed numerous changes within the PSP environment and continually seeks opportunities to "do things better." An early career as a registered nurse in a neonatal intensive care unit has given her first-hand knowledge of how PSPs can empower patients and families to play an active role in their care. In this interview, Andrea shares her perspective on PSPs of the present and consideration for the future.

Q: How has the PSPs landscape in Canada evolved over the past decade?

While PSPs have been evolving since their inception, the emergence of precision medicine and growing complexity in our healthcare system are facilitating a significant shift in how PSPs are developed and delivered.

Precision medicines differ from standard, one-size-fits-all therapies in that they enable the treatment of those who are most likely to benefit while avoiding 'trial and error prescribing.' The increasing prevalence of precision medicine and diagnostic testing is helping us to better target PSPs so we can provide the right medicine to the right patient at the right time. This principle informs every aspect of modern PSP design.

Increasing complexity in the Canadian healthcare system, including the patient journey, has made it important to engage with key stakeholders like patient groups, public and private payers, physicians and medical institutions, so we can better support patients as they navigate the healthcare system.

Q: How is technology helping facilitate changes?

Technology is helping us to create more efficiencies, to communicate more quickly and effectively with patients and physicians, and ultimately to deliver better patient care.

While PSPs of the past heavily relied on email and fax to communicate, today's online PSP platforms give stakeholders real-time information that can help patients start treatment more quickly.

Through healthcare apps that inform and empower patients to play an active role in their treatment, and physician portals that provide a complete view of their patient's journey, PSPs are equipping both the patient and health providers with critical information. I believe the movement towards digital connectivity with payers will also continue to drive expedited access and timely decisions.

We're seeing public payers increasingly focused on enhancing the patient experience through digital record keeping enabled by PSPs. For example, the Ontario Government's SADIE [Special Authorization Digital Information Exchange] portal makes it easier to fast-track exceptional access for Ontario Drug Benefit recipients by providing patients with relevant information.

CONTINUED FROM PAGE 5

Looking forward, I'm also excited about the growing application of artificial intelligence and machine learning to help better understand disease states and lead into predictive medicine. These data points give clinicians and payers a powerful lens on the patient experience, which they can use to improve treatment and access decisions.

Q: Can you tell us more about how PSPs intersect with precision medicine?

As more precision medicines come to market, PSPs have become more targeted and frequently include the facilitation of diagnostic testing, such as biomarker or tumor testing. PSPs can now provide faster and more efficient support to physicians who need test results to make treatment decisions.

Given the pace of change you describe, how can PSPs keep up?

With the Canadian healthcare system in a state of flux, many treatment and policy decisions may not fully consider the patient experience. PSPs need to evolve accordingly to ensure the patient doesn't get lost.

What role does data play in PSP programs?

Collection of data is an important part of the PSP value proposition – but not just any data. Modern PSPs are designed to collect real-world data (RWD), which evaluates how a treatment performs in a broad population outside a controlled clinical trial environment.

RWD are increasingly being used by payers to make reimbursement and pricing decisions – often linked to the real-world value delivered by an innovative medicine. As such, collection and security of patient data are becoming more important than ever.

More broadly, PSP data will need to communicate more and more with other data sets and systems, which will require

“The increasing prevalence of precision medicine and diagnostic testing is helping us to better target PSPs so we can provide the right medicine to the right patient at the right time.”

the healthcare system and industry to agree on a unified approach. While Canada still has a fragmented ecosystem of data collection, we are seeing some efforts to simplify, streamline and centralize at a provincial level. That being said, many silos still exist with continued challenges in working towards national alignment.

What value do PSPs add to patients and physicians?

PSPs aim to support both the patient and multidisciplinary healthcare team as a whole. Navigating the specialty care environment is complex and can be overwhelming for patients dealing with a difficult diagnosis like cancer. PSPs can help empower patients with education, knowledge and support mechanisms that allow them to play a more active role in their own care. Along with helping to coordinate appointments, lab tests and drug reimbursement, PSPs can inform patients about alternative access vehicles (such as not-for-profit programs) and other community resources.

Providing this support to patients can also alleviate some of the pressure and time-burden on prescribing physicians and allied healthcare providers. By the same token, PSPs generally have mechanisms to provide physicians with vital information about aspects of treatment, such as patient adherence and drug reactions. This holistic view of the patient experience can help inform treatment decisions.

Any special considerations for PSPs for two growing areas of specialty medicine – biosimilars and oncology drugs?

Biosimilars are entering the market at a cost differential, so I believe their PSPs need to prioritize must-have over nice-to-have services while keeping the patient experience at the forefront

With oncology treatments – or any other treatment involving a multi-disciplinary team – we need to ensure PSPs complement rather than duplicate care. To give a simple example, you wouldn't want a patient to get an appointment reminder call from the tertiary hospital on one day and the same call from the PSP the following day.

If a manufacturer is setting up a new PSP, what can they do to “get it right” from the start?

When setting up a PSP, full understanding of the patient experience – in the current environment and foreseeable future – is critical. PSPs must have the agility to respond to changes in the ecosystem while continuing to support patients. The more time allowed for design, challenge and pressure testing, the better.

What will the PSP of the future look like?

In the coming years, PSPs will need to accommodate the expanding roles of healthcare providers such as pharmacists and evolve with policy changes that impact the flow of treatment. That said, we need to ensure future PSPs maintain a strong patient focus. No matter what changes are in store, we can't lose sight of the patient experience.

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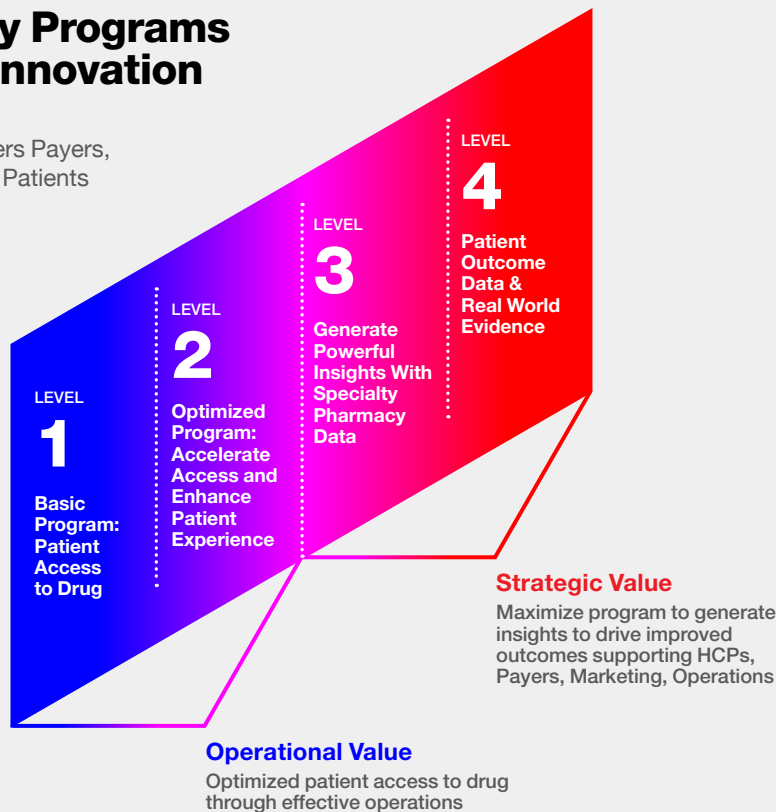
Checking in on the Levels: Where are Canada's PSPs Today?

Two years ago, 20Sense published an infographic describing four levels of PSP.¹⁸ Since that time, manufacturers have redoubled their efforts to reach levels 3 and 4. In collaboration with payers, patients and PSP providers, they are exploring opportunities to generate actionable data from their PSPs, including data to support outcomes-based reimbursement agreements.¹⁹ Patient data generated by PSPs – such as disease scores, safety, and adherence patterns – yields unparalleled insights into a treatment's value, enabling stakeholders to make informed decisions about treatment, reimbursement and strategy.²⁰

Basic PSP programs work well. Advancing through the levels makes them work even better. Higher-level PSPs yield a greater ROI and, above all, greater value to patients.

Specialty Programs Driving Innovation

For Manufacturers Payers,
Prescribers and Patients



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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.

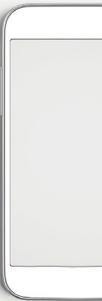
[Updated Code of Ethical Practices sets the bar higher](#)

[Drug maker urges patients to speak out as Alberta, Ontario consider switch to cheaper biosimilars](#)

[Innovative Medicines Canada bans members from paying doctors fees for IV infusions](#)

[The Association Québécoise des Pharmaciens Propriétaires \(AQPP\) sets to launch a patient support program offering](#)

[Biosimilars makers in Canada to launch patient support program](#)



Upcoming Issues

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

- Exploring opportunities for outcomes-based agreements with specialty pharmaceuticals
- Genetic-testing, specialty therapies and the growing complexity of specialty treatment
- Patient support programs: a ready infrastructure for health-outcomes data collection?

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.

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