International Federation on Ageing

Eye See You

An Educational Framework is the Missing Element in Canada's Biosimilars Discourse: A Brief Report

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Introduction

The development and commercialization of biosimilars is an emerging international trend attracting attention from not only governments but also professional associations and patient and advocacy organizations. The value proposition for biosimilars moves beyond the argument of cost reduction relative to the originator biologic drug and into the critical realm of ensuring treatments are safe and effective and address the needs of a diverse groups of stakeholders.

The evolution of biosimilars, while being a relatively recent phenomenon in Canada has demonstrated lessons internationally about safety, efficacy, and implementation policies. What is undeniable from peer-reviewed and gray literature is the critical importance of a sound educational framework for health care professionals and patients on the appropriate uses of biosimilars.

This report aims to inform future dialogue in the emerging field of ophthalmology biosimilars by exploring the critical elements in other therapeutic areas which lead to effective consultations between clinicians and their patients for the safe and appropriate use of biosimilars.

Background

Biologic drugs are produced in living cells and are the most advanced therapy available for many conditions.[1] As patents expire on originator biologic drugs, biosimilars engineered to be like their biologic reference product enter the market as less costly alternatives.[1] Worldwide, the biosimilars market value has been projected to reach $61 billion by 2025, with potential cost-savings dependent upon uptake rates in local markets.[2]

In 2006, the European Union (EU) endorsed the first policy and legal framework around the approval of biosimilars.[3] Since then, 58 biosimilars have been approved in a variety of therapeutic areas including rheumatology, oncology, gastroenterology, dermatology and endocrinology, with ophthalmology on the horizon.[4,5,6] Initial uptake of biosimilars in the EU market was marked by a paucity in confidence from health care professionals and a lack of patient awareness and education.[7] More recently the market has grown alongside improved professional and patient perceptions framed by the theory that increased industry competition will expand patient access to treatment, and release funds to support future innovation and research.[3] As the global market expands, EU experiences, guidelines and frameworks often inform the development of national policies and educational campaigns as evidenced in a selection of countries including Germany, the United Kingdom, Australia, and Japan.

In Canada, biologic medicines rank as the greatest expense in public drug plans.[8,9] Since biosimilars first entered the Canadian market in 2009, uptake has been slow in comparison to the EU, with only 18 biosimilars approved to date.[10,11] As the Patented Medicine Prices Review Board (PMPRB) forecasts a potential $1.8 billion annual health system savings with the emergence of more biosimilars, Canada is likely to take steps to improve uptake in the near future.[12]

Several recent policy developments at the federal and provincial levels have opened the door to increasing biosimilar uptake rates. At the federal regulatory level, the Canadian Agency for Drugs and Technologies in Health (CADTH) announced in May 2019 that the Common Drug Review (CDR) and the pan-Canadian Oncology Drug Review (pCODR) will no longer require evaluation of biosimilar drug submissions upon their approval from Health Canada.[13] Provincial policies enacted in British Columbia and Alberta have established mandatory protocols, such as non-medical switching from

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originator biologics to biosimilars, across several therapeutic areas including but not limited to oncology, rheumatology and endocrinology.[14,15]

Manitoba, on the other hand, has implemented a tiered biologics reimbursement policy while remaining provinces and territories (excluding Saskatchewan) have given biosimilars preferential listing for patients naïve to biologic treatments.[16] While such policy developments may aim to facilitate an expansion in the use of biosimilars in Canada, uptake rates remain low. A 2019 study of three commonly used biosimilars over a 2-year period found that just 4.2% of savings were realized in this market, which may not be a threshold of cost-savings to support further policy changes based on the economic argument alone.[17] Similar to the early stages of the EU biosimilar market, there is considerable resistance in public and professional spheres on pending policy changes, and the impact on current and future patients.[18]

To inform policies in Canada on biosimilars and to address concerns among stakeholders in dermatology, endocrinology, gastroenterology, rheumatology and ophthalmology, CADTH was engaged by the pan-Canadian Pharmaceutical Alliance (pCPA) in 2019 to convene a national multi-stakeholder engagement process. [19] Results from this process highlighted the provincial-specific biosimilar policy frameworks and the largely unresolved gap in professional confidence and patient education.[19] Stakeholders agreed that ongoing engagement and collaboration is necessary to develop appropriate responses to continuing concerns and knowledge gaps.[19] (See Appendix 1 for Summary of CADTH Consultation Findings)

The Role of Education

As the development and implementation of biosimilars have significant implications for patient treatment and safety, evidence-based information and continuing education must be a high priority. Every patient and their family has the right to receive information and ask questions before procedures and alterations to treatment. Increasingly, there are scenarios where information is either not available or not conveyed about biosimilar treatment options and in some situations an originator biologic drug treatment may be rescinded.[18]

The safety, efficacy, and appropriateness of biosimilars and switching patients from originator biologics to biosimilars are decisions that impact the lives of patients and their families as well as health care professionals. Insufficient understanding of biosimilars poses risks to health care professionals in their decision-making and to patients relying on access to appropriate and effective treatments.

Biosimilar Policy

Regardless of the country and speciality the policy focus is on the treatment transition from the originator biologic to biosimilars. *New starts* and *switching* are the most common government policies often developed in consultation with professional associations and patient organizations. *New starts* involve the prescription of biosimilars to biologic treatment naïve patients upon commencement of treatment. Participants in the 2019 CADTH Consultation, as well as patients and professionals more broadly, report the least resistance to the new starts policy.[18,19]

Switching, however, involves changing the treatment of a patient currently undergoing therapy with an originator biologic to a biosimilar under defined parameters. Patients undergoing therapy with biologics

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are routinely apprehensive about changes to their treatment regimen.[18] Negative perceptions about switching to biosimilars have been shown in some cases to have severe effects on patient safety.[20]

Patients and representative associations in the EU as well as Canada have raised well-founded concerns about being switched from originator biologics to biosimilars without their knowledge, consultation, or consent.[18,19] Studies have reported that *switching policies* have the potential to cause confusion, mistrust and increased risk for the nocebo effect.[20] With reference to biosimilars the nocebo effect is defined as an unexplained, unfavorable therapeutic effect subsequent to a non-medical switch and often involves patient non-adherence based on negative perceptions of treatment.[21] The nocebo effect has also been associated with disease relapse, increased symptom burden, psychological distress, breakdown in trust of their health provider, and discontinuation in clinical trials or novel therapies.[22]

While some studies have shown that knowledge of and access to high-quality data, and subsequently appropriate patient-physician consultation can minimize the nocebo effect, evidence has not definitively shown that overcoming the nocebo effect is sufficient to eliminate negative patient outcomes.[20,22]

Professional associations in the EU have presented strong opposition to automatic switching, advocating for a joint decision-making approach between patients and health professionals.[18] There is, however, continuing debate about certain biosimilars and the lack of real-world evidence on multiple switching, an area particularly lacking in clinical studies.[18]

Without comprehensive understanding of the uses, implications, risks, and benefits of biosimilars, health care professionals are placed in an invidious position as they advocate for the best interests of their patients. Disclosure of all information and risks is essential for both clinicians and patients including the safety and efficacy of biosimilar treatments, and the patient's ability to access unfunded originator biologic medicines.[23]

Robust education and awareness-raising strategies have been shown in the EU experience to respond to the concerns of both patients and professionals. Effective guidelines and information campaigns targeting physicians, nurses, and pharmacists, have at times led health care professionals to support biosimilar treatment switching policies and recommend biosimilar treatments to their patients in clinical consultations.[24] Stakeholders in Canada support the development of such resources specific to therapeutic areas according to a standardized framework.[25]

Brief Regional and National Perspectives

The scientific community, decision-making entities and regulatory authorities have emphasized the importance of educational materials on biosimilars to establish trust and confidence among patients and health care professionals.[26] Several recurring themes are central to building such materials.

Patients report low awareness of biosimilar treatments, a high interest in participating in treatment decisions, and the evaluation of efficacy and safety over cost-effectiveness

Health care professionals, including physicians, pharmacists and nurses report low awareness of the fundamental concepts around biosimilars, clinical evidence for indication-specific use of biosimilars, and prescribing guidelines.[26]

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Europe

The European Commission (EC) and the European Medicines Agency (EMA)[i] have a distinct and critical role in providing recommendations around the development and implementation of biosimilars. The EMA assesses a majority of biologic and biosimilar manufacturer applications to ensure the biosimilar is highly similar to its originator biologic, and that there are no clinically meaningful differences between them in terms of safety, quality and efficacy.[27] Once EMA grants authorization to enter the market, each country formulates biosimilar policies independently.[27] The EC in collaboration with the EMA respond to gaps in information for both patients and professionals across Europe by producing educational resources, examples of which are outlined below.[27]

"What I Need to Know About Biosimilar Medicines" is a leaflet written for patients on biosimilar medicines and describes:

1. Basic concepts of originator biologic and biosimilar medicines (i.e., what are they)
2. General processes of development and approval (i.e., why and how are biosimilars developed and approved)
3. Guidance on addressing the subject of switching treatment from an originator biologic to a biosimilar, in consultation with a physician or pharmacist[28]

Roles and responsibilities of patients and health care professionals in reporting biosimilar treatment and potential side effects are outlined in the leaflet, as are information sources for specific therapeutic areas including rheumatology and gastroenterology.[28] The leaflet together with an animated video are meaningful in the process of shared decision-making between patients and their health care professional.

"Biosimilars in the EU – Information guide for health care professionals" responds to technical concerns on the use of biosimilars addressing topics such as:

1. Biochemical descriptions of originator biologic and biosimilars
2. Descriptions of the regulatory framework and data requirements for biosimilar approval (i.e., how do clinical and comparability studies inform the development and approval process)
3. Patient safety standards and monitoring for originator biologic or biosimilar therapies
4. Introductory review of prescribing guidelines[29]

The leaflet concludes with an outline of the role of EU Member States in implementing policies on interchangeability, switching, and substitution, and encourages health care professionals to direct patients to additional sources of information about biosimilar therapies (including EMA and EC websites).[29]

The leadership provided at the regional level by the EC and the EMA indicates a collective commitment to education of both patients and health care professionals within the region. National and local initiatives are however critical to ensure a patient-centred approach to the transition from originator biologics to biosimilars should that be the most appropriate treatment regime.[30]

[i] The European Medicines Agency (EMA) protects and promotes human and animal health by evaluating and monitoring medicines within the European Union (EU) and the European Economic Area (EEA).

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Germany

Germany has a rigorous regulatory framework illustrated through the EMA approved and funded biosimilars in the country.[31,32] While the German biosimilar market may have developed beyond many of its neighbours biosimilar uptake has not met original forecasted targets.[31] One explanation for the below- target uptake can be found in the lack of clinical and patient education. In 2008, the Drug Commission of the German Medical Association endeavoured to address knowledge gaps and concerns particularly from health care professionals, citing the education of physicians as the most critical factor influencing market uptake of biosimilars.[33,34]

Several stakeholders including professional associations, patient organizations and national research authorities published clinical guidance and position statements to help build confidence among health care professionals in the use of biosimilars.[35] These resources tried to build consensus around common and critical themes that impact decisions:

1. Equivalence in the safety and effectiveness of biosimilar drugs compared with originator biologics
2. Lack of evidence that switching from the originator biologic to biosimilar drugs produces negative side-effects
3. Decisions around prescribing biosimilars should rest with the physician[35]

Given these concerns are generally echoed among stakeholders in the majority of countries venturing into the field of biosimilars, real-world evidence regarding treatment switching will play a pivotal role in the development of future policies. In a publication by Medicines for Europe (2019), which listed position statements on physician-led switching for biosimilars medicine, two-thirds were submitted by rheumatology-related associations representing the front-line clinicians and correspondingly the level of awareness and real-world experience in this field.[36]

The safety of patients should be a core value of biosimilar policy and in part informed by representative associations.[26] The European League Against Rheumatism (EULAR) has developed evidence-based recommendations to guide patient education in rheumatology centred around access to information on biosimilar safety at diagnosis and rendering support through in-person, telephone and/or online patient support programs (PSPs).[30]

Educational materials about biosimilars including leaflets, websites, and interactive fora (i.e., seminars, workshops or conferences) are disseminated by patient associations, medical societies, and pharmaceutical manufacturers to enable easy access to information.[37] However, the communication between a patient and their specialist (whether it be a rheumatologist or ophthalmologist) remains the forum where trust and confidence is built on the safety and effectiveness of appropriate treatment.[38]

United Kingdom

In the United Kingdom (UK), regulatory approval of biosimilars is also built upon the EMA framework. A 2014 biosimilars market report prepared on behalf of the European Biosimilars Group indicated that holistic consideration of education and understanding of biosimilars in the UK context is needed to establish a sustainable policy framework.[39]

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The National Health System (NHS) in their *What is a Biosimilar* guidance handbook developed alongside industry, professional associations, patient organizations, and the National Institute for Health and Care Excellence (NICE) addresses the role of biosimilars in the health care system.[40] The handbook aims to support the safe, effective, and consistent use of biosimilars and responds to concerns such as:

1. Inherent variability in the structure of biologics
2. Difference between generic and biosimilar drugs
3. Extrapolation of indications
4. The European approval pathway for biosimilars[41]

Safety and efficacy concerns were reported as the most common reason for physicians not prescribing biosimilars.[42] As a result, the *educational campaign around biosimilars* focused on building confidence among patients and physicians based on real-world evidence and clinical studies.[43] The *Focus on Biosimilars* campaign launched in 2017 aimed to respond to the following questions:

1. Why should life science industry companies bring their clinical trials to the UK?
2. Why should NHS health professionals support clinical trials of biosimilar drugs?
3. Why should patients consider taking part in a clinical trial or switching programme?[43]

The campaign was largely web-based targeting physicians, pharmacists, and patients. Resources included video testimonies, general information about the biosimilars industry, links to relevant patient organizations, and information on clinical trials of biosimilars.[44]

Patient organizations such as the National Rheumatoid Arthritis Society have contributed to the development of the NHS What is a Biosimilar guide and provide supplementary supports to patients including instructional videos, position papers, fact sheets, and a Helpline inviting patients to share their experiences or concerns.[45]

Australia

In Australia, the Therapeutic Goods Administration (TGA) aims to align biosimilar regulatory frameworks to recommendations of EMA.[46] The Australian government has supported growth of the biosimilar market through the development of educational resources, including fact sheets and prescribing guidelines available on the Department of Health website.[47] An annual educational campaign, Biosimilar Awareness Week, aims to focus the national health discussion on increasing awareness and confidence in biosimilars among consumers and health care professionals.[48]

The government has also supported the creation of a national Hub for Biosimilar Education ("the Hub") through a grant awarded to the Generic Biosimilar Medicines Association (GBMA) in 2018.[49] The Hub houses resources targeting physicians, pharmacists, and patients in separate online portals, containing multimedia resources (video testimonials, interactive educational quizzes, and fact sheets/guidelines) that respond to common questions around biosimilar safety and quality, development, regulation, and substitutions.[49]

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For health care professionals, there are also template letters used to inform patients about the nature of changing treatment plans from originator biologics to biosimilars. Quarterly literature reviews are also published on the Hub with new research findings about:

1. Substitution and extrapolation of indications
2. Health outcomes
3. Perceptions among patients and professionals
4. National initiatives to increase biosimilar uptake[49]

Despite the solid production of educational materials, recent studies indicate that although the knowledge of health care professionals about biosimilars has been studied significantly, patient attitudes have received less attention.[50] In a small-scale study (n=132) of patients with rheumatoid arthritis 50% of respondents trusted their specialist to provide accurate and fulsome information about treatment options.[50]

Japan

In Japan, the Ministry for Health, Labour and Welfare (MHLW) alongside the Pharmaceuticals and Medical Devices Agency (PMDA) developed a regulatory framework for biosimilars based upon the EMA template in March 2009.[51,52] The MHLW and PMDA released the publication Guideline for the Quality, Safety, and Efficacy Assurance of Follow-on Biologics and explanatory Question & Answer that explored:

1. General principles of development and manufacturing
2. Comparability between biologics and biosimilars
3. Toxicity
4. Studies on clinical efficacy
5. Post-marketing surveillance[53,54]

Concerns over efficacy and safety of biosimilars persist among health care professionals, as real-world evidence has been particularly lacking in the Japanese context.[55] A 2016 study reported that although Japan was among the first to develop a biosimilar regulatory framework in 2009, only 4% of all clinical trials worldwide were based on Japanese data.[56] The significant need to develop educational resources has been framed around the requirement for clinical studies to reflect the Japanese population.[56]

Overall the development of a national educational strategy in Japan has been slow therefore physicians, pharmacists, and patients have a low awareness of biosimilars.[57] Furthermore, patient associations have not contributed to the creation of supportive educational resources in the oncology field specifically, and no information was found regarding other therapeutic areas.[57] Two major ongoing concerns are the lack of data specific to the Japanese population, and the need for educational programs on the concept of interchangeability and substitution of biosimilars, targeting physicians and patients concurrently.[58]

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Canada

Health Canada, the federal department that assesses the safety, efficacy, and quality of drugs and devices can authorize the use of biosimilars.[59] Although biosimilars is a relatively recent trend in Canada, government, health care professionals, NGOs including patient and advocacy organizations, private insurance providers and individuals are engaged in various policy conversations and debates, one being education.

It is worth noting that Health Canada delegates the authorization of interchangeability and policies on switching between originator biologics and biosimilars to the provinces and territories.

Canadian provinces and territories are responsible for managing, organizing and delivering health care services for their residents, and expected to meet national standards set out under the *Canada Health Act*. Biosimilar policies and information are developed and executed with provincial specificity including:

- Public health benefit plan funding
- Availability of reference biologics and biosimilars and their prescription guidelines
- Recommendations for consulting with patients on their therapy plan
- Processes for switching, if applicable, and referral information for patient support programs available for originator biologic and biosimilar drugs
- Additional national and international educational resources about biosimilar[60]

In Canada, educational resources addressing concerns about biosimilars are produced by the government, insurance providers, professional organizations, and patient associations. Biosimilar biologic drugs in Canada: Fact Sheet produced by Health Canada targets both patients and health care professionals and explores:

- Types of clinical studies to support the use of biosimilars
- Authorization of indications, interchangeability and switching of biologics and biosimilars
- Processes to monitor the safety of biosimilars and report adverse reactions
- Naming and labelling conventions of biologic and biosimilar drugs
- Alignment with international regulatory frameworks of biosimilars

In Canada, PSPs are funded by manufacturers of the biologic medicine, which is unique when compared to international settings.[61] As part of these programs, biologic medicines can be administered in infusion clinics which are often exclusive to a particular medicine.

As PSPs are generally medicine-specific, switching from an originator biologic to a biosimilar may require a change in treatment location and caregiving team. This presents important considerations for patients such as building trust and confidence in their new support team, ensuring that information about their health and medical history is appropriately and accurately relayed by their treating physician (i.e., other health complications, dosing schedule, and medication history and allergies), and the location, accessibility, and availability of the infusion centre.

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Recent alternatives to PSPs are insurer case management (ICM) programs which are not medicine-specific and aim to provide a single point of contact for patient inquiries and support through a case manager.[62]

Patient Advocacy

Several patient associations have led awareness strategies and produced educational resources on biologics and biosimilars. Since biosimilars in rheumatology were introduced in 2014, the Canadian Rheumatology Association and the Canadian Arthritis Patient Alliance have been strong voices in the development of evidence-informed position statements and educational resources.[63,64] It is worth emphasizing that high-quality evidence behind originator biologics and biosimilars, including the safety and effectiveness of switching, is abundant in the rheumatology space in Canada and abroad. This partly explains patient and physician confidence in their use. Unfortunately, this is not the same case for many other disease areas and, as a result, not all therapeutic specialties support biosimilar initiatives in the same way as the rheumatology field.

The Gastrointestinal Society is one of the leaders in the gastroenterology sphere who has worked with patient and professional associations, industry, provincial governments, and regulatory bodies to support evidence-based and patient-centered biosimilar policies.[65] The Canadian Gastroenterology Association, while supporting new starts for patients naïve to biologics, does not recommend non-medical switching for patients stable on biologic treatment and automatic substitution.[66] Similarly, in response to Alberta's Biosimilar Initiative, gastroenterologists in the province do not support non-medical switching for patients with Irritable Bowel Disease treated with the originator biologic as it may lead to avoidable surgeries for hundreds of patients.[67]

In Quebec the regulatory body "*Institut national d'excellence en santé* (INESSS)" for evaluating the cost-effectiveness of drugs and health technologies, concluded that evidence on safety and efficacy of switching from originator biologics to biosimilars varies among therapeutic areas, particularly raising concerns in gastroenterology and oncology.[68] Regardless of the therapeutic area, the Quebec College of Pharmacists also does not support non-medical switching without a thorough consultation with the prescribing physician, and does not support switching between biosimilar medicines given a lack of longitudinal clinical evidence.[68]

In addition to patient advocate organizations, the Biosimilars Working Group a diverse group of national and international non-profit organizations and registered charities collaborate to increase education among various stakeholders and advocate for robust and informed research, with the goal of ensuring the best outcomes for patients.[69]

Educational materials and other resources produced by patient advocates (rheumatology and gastroenterology) include summaries of biologics and biosimilars in print and digital formats, detailed descriptions of provincial and territorial biosimilar policies, position statements and studies as they relate to non-medical switching from originator biologics to biosimilars.[63,65]

In the emerging field of ophthalmology biosimilars, it is acknowledged by the scientific community and decision-makers worldwide that there is a persisting gap in knowledge.[70] The CADTH consultation, while being informed by ophthalmologists, failed to answer several fundamental questions about the use of ophthalmology biosimilars and the education needs of patients. Fighting Blindness Canada references biosimilars in ophthalmology in a recent White Paper proposing health system benefits of potential cost-savings.[71] However, a great deal more resources are required for both patients and

health care professionals when compared to the standard of existing educational resources regarding biosimilars in rheumatology. In the absence of such resources, there have been concerns in the public sphere around the rights of patients alongside their health care professionals to make informed decisions around their treatment with biosimilars in other therapeutic areas.[72]

Effects of COVID-19

At the time of writing this document, the COVID-19 pandemic has impacted timelines of biosimilar policies under development across Canada. For instance, the Alberta government has moved the deadline for mandated non-medical switching for all patients on an originator biologic from 1 July 2020 to 15 January 2021.[15]

Furthermore, many clinics providing care for chronic diseases have been shut down in an effort to prevent community spread of COVID-19, leading to a disruption in services available to patients that have been switched from originator biologics to biosimilars. As a result, many patients do not report experiencing side effects and adverse events as a result of the treatment switch, as they avoid high-risk areas of infection such as infusion clinics or medical settings.

Conclusion

Biosimilars in ophthalmology in Canada are on the horizon. Now is the time to strategically plan and act to ensure the education requirements of health care professionals, patients and their families are firmly in place and inform policy development, and not lag behind.

Framed around the goal of enabling informed consultations and decision-making between patients and health care professionals, international biosimilar experiences and to a lesser extent those in Canada provide evidence-based guidance and insight to build an educational framework that serves to inform the debate options on policy and practice.

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Appendix 1 – Summary of CADTH Consultation

Over a period of about 6 months, CADTH's multi-stakeholder engagement process included key informant interviews, an in-person consultation, and an online survey to solicit feedback that may inform biosimilar policy options. Although key informant interviews were not made public, the online surveys and in-person consultation reports provide clear insights into stakeholder concerns:

1. Policy Framework
   There is an overwhelming preference for the "New Starts" policy option, in which newly diagnosed patients can be prescribed biosimilars. The "Controlled Switching" policy option garnered greatest attention and opposition as it mandates patients to switch from current biologic reference drug to a biosimilar drug within a set timeframe. Switching policies raised several concerns among stakeholders:
   - Removal of the prescribing decision from the patient-provider relationship;
   - Introduction of significant stresses for physicians working to balance the care of existing patients with a new framework requiring additional visits and increased monitoring;
   - Creation of anxiety in stable patients who now face the possibility of receiving treatment in a new facility and coverage from a new patient support program (PSP);
   - Potential impact to the method of delivery of their biologic, which demonstrated an educational gap, given that biosimilar is required to have the same administration route as its reference biologic; and
   - Importance of providing focused and tailored education materials to clinicians and patients, and that biosimilar PSPs offer the same level of care as those offered by the reference biologic manufacturer.

   Furthermore, stakeholders underlined the need for real-world evidence (RWE) in the Canadian context. It was generally agreed that current Canadian-based clinical trial data were insufficient to drive policy change. Moreover, these data are needed to establish appropriate policy exceptions, particularly in the case of originator biologic-biosimilar medicine switching.

2. Reimbursement and Reinvestment
   There is a preference for harmonization across provinces of biosimilar reimbursement schemes, savings should be reinvested in patient care such as PSPs.

3. Monitoring
   A neutral third party should provide robust, ongoing, and transparent monitoring of biosimilar treatment outcomes, with input derived from patients as well as clinicians.

4. Education
   Standardized and consistent evidence-based educational messaging is essential both for patients and clinicians. Stakeholders agreed that professional associations are essential in educating clinicians, and that bias-free (i.e., non-industry) organizations would effectively reach patients.

The importance of patient and clinician engagement is evident throughout each of the concerns raised by participants in the consultation. Patients must be aware of the availability of safe and effective treatments; they must be able to make informed choices regarding their health alongside their health care providers and they must be able to inform ongoing monitoring of treatment outcomes. Without informed voices contributing in a sustained way, the advancements in biosimilar initiatives will be driven purely by economics rather than a collective patient-centred approach.

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