



Pan-Canadian Oncology Biosimilars Summit

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Executive Summary

This report describes the significance of biologic/biosimilar medications and outlines the proceedings at the pan-Canadian Oncology Biosimilars Summit hosted by the pan-Canadian Pharmaceutical Alliance (pCPA) and Cancer Care Ontario (CCO). The summit took place in Toronto on November 16, 2018 and brought together patients, patient advocacy organizations, clinicians, healthcare administrators and government officials from nine provinces to discuss the opportunities and challenges of introducing oncology biosimilar medications (biosimilars) in Canada. These stakeholders were engaged to provide input which would help inform a pan-Canadian strategy for implementing biosimilars.

Biologic medications (biologics) are complex protein molecules created inside living cells and are used for treating various diseases, including cancers. Patents protect innovative biologics for a limited amount of time. In Canada, patents for some biologics are expiring and highly similar copies, known as biosimilars, are being developed. According to Health Canada, a biosimilar is not identical to a biologic medication, but based on approval standards, the two are highly similar, and there are no clinically meaningful differences in safety and efficacy.^{1,2,3}

The expected arrival of therapeutic oncology biosimilars in Canada offers the potential to bring significant savings to provincial cancer expenditures as biosimilars in other therapeutic areas are priced up to 47% lower than their reference biologic⁴. However, the adoption of biosimilars in the oncology setting requires multiple considerations to maintain high-quality care and patient outcomes. Provinces differ in their policy, reimbursement and delivery of cancer services in ways that may affect the consistent implementation of biosimilars across the country.

The pCPA's recently published "Biologics Policy Directions & pCPA Negotiations" document aims to develop and pilot a clear and consistent pan-Canadian approach that encourages appropriate use of biologics (both innovators and biosimilars) in support of a common pCPA mandate to enhance patient access to clinically relevant and cost-effective drug treatment options. This document applies to all biosimilars, non-oncology and oncology. Consequently, the pCPA and CCO partnered to develop a pan-Canadian oncology biosimilar implementation strategy with the summit being an engagement opportunity to kick-start this initiative.

At the summit, learnings were shared from the implementation of biosimilars in other jurisdictions and therapeutic areas. Jatinder Harchowal, Chief Pharmacist at the Royal Marsden Hospital, shared National Health Service England's implementation of rituximab biosimilar. He highlighted stakeholder engagement, education and information sharing, and supply chain management as the key drivers of success for biosimilars implementation and uptake.

¹ Health Canada. (2016, December 2). *Guidance Document: Information and Submission Requirements for Biosimilar Biologic Drugs*. Retrieved from <https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/information-submission-requirements-biosimilar-biologic-drugs.html>

² Health Canada. (2017, August 3). *Fact Sheet: Biosimilars*. Retrieved from <https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html>

³ ICH Expert Working Group. (2004). *ICH Harmonised Tripartite Guideline: Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process Q5E*.

⁴ Patented Medicines Prices Review Board. (2018, February 5). *Potential Saving from Biosimilars in Canada*. Retrieved from <https://www.pmprb-cepmb.gc.ca/view.asp?ccid=1304>

Among patients and clinicians, the common themes discussed throughout the event were education, communication, trust and confidence in biosimilars, monitoring and pharmacovigilance, and reinvestment of savings achieved from biosimilars implementation. Particular emphasis was placed on clinician-patient conversations; these will lead to more understanding, openness and acceptance, especially when it pertains to switching patients from a reference biologic to a biosimilar medication. Payers also addressed the importance of trust and confidence in biosimilars for successful implementation, but also stated the need for national decision making and discount maximization strategies. Furthermore, payers noted that decisions on biosimilar implementation need to consider the impact on pharmacy and clinic operations, the system's capacity for this change, and the cost of resources required to manage incremental workload and safety issues.

During the summit, a breakout group session offered additional engagement opportunities for participants to provide feedback on the proposed vision, goals, and strategic objectives for implementing biosimilars in Canada. Based on the feedback received from participants, the Oncology Biosimilars Initiative Team consolidated ten strategic objectives into seven discrete objectives. These strategic objectives will inform an Action Plan for the pan-Canadian Oncology Biosimilars Initiative. Following are the vision, goals, and revised strategic objectives that emerged from the summit.

Vision

Stakeholders across Canada have implemented an oncology biosimilar strategy that improves outcomes for patients, is evidence-informed, ensures appropriate quality and safety measures are in place, and facilitates access to innovative cancer treatments.

Goals

Stakeholder Engagement

- Collaborate with stakeholders so they participate in the development of a pan-Canadian oncology biosimilar strategy.

Quality & Safety

- Ensure that oncology biosimilars are safely implemented and that clinical and patient considerations are taken into account.

Evidence-informed Policy Approach

- Engage pan-Canadian partners to discuss pricing, implementation and usage strategies that are informed by the best practices⁵.

Sustainability & Value for Money

- Improve system sustainability and performance by facilitating the uptake of oncology biosimilars and ensuring stakeholders are benefiting from the transition.

Strategic Objectives

1. Engage stakeholders throughout the project to validate and inform ongoing work.

Important considerations: Stakeholders should be engaged throughout the planning and implementation process. Stakeholder working groups will be created to provide advice and guidance for the implementation of oncology biosimilars.

2. Adopt best practices and standardized approaches to prescribing, storing, preparing, labelling, dispensing, and administering oncology biosimilars. This requires addressing technical⁶ and logistical⁷ challenges of implementation.

Important considerations: A system-wide change management plan with clear communication strategies should be developed to promote consistency across jurisdictions. Stakeholders need to consider the impact on pharmacy and clinic operations, the system's capacity for this change, and the resources required to manage workload and safety issues.

⁵ Best practices seen in other jurisdictions (UK/Europe) who publicly fund multiple therapeutic oncology biosimilars.

⁶ For example, CPOE/EMR, smart pumps, pharmacy preparation and dispensing, and medication administration recording

⁷ Logistical considerations should also consider advanced warning for funding, standardized change management processes, policies, and procedures in advance of going live.

3. Develop comprehensive education programs for health professionals and patients.

Important considerations: Educational resources should be tailored to the target audience, focused on safety and efficacy, and rolled out before biosimilar implementation. It should be accessible, language appropriate and provided in various modalities. Patient advocacy organizations and clinicians were identified as trusted sources of information for patients. Furthermore, patients want to be assured that they will be monitored and that a long-term monitoring strategy will be in place.

4. Support the overall intent of creating a viable market for oncology biosimilars by developing reimbursement strategies that promote implementation and sustainability across Canada.

Important considerations: The market should allow for multiple biosimilars which may or may not include the reference biologic medication. It was felt that a guaranteed market share for manufacturers will incentivize them to enter and stay on the market. This allows jurisdictions to ensure a viable supply chain in case of drug shortages, supply interruptions or unexpected toxicities.

5. Develop clear guidance on clinical scenarios such as initiating, switching and generalizability.

Important considerations: There should be an option to switch a patient to other biosimilar alternatives or the reference biologic medication in case of adverse reactions. Clinician education is important; patients are more at ease if their prescriber is knowledgeable and confident about a biosimilar treatment plan.

6. Reinvest savings from oncology biosimilars back into the cancer system⁸, with the objective of optimizing health outcomes.

Important considerations: The savings offered by biosimilars should be reinvested into the cancer system (e.g., cancer drugs, staffing resources, technologies, cancer prevention strategies). Performance metrics should be developed to quantify and evaluate the system improvements achieved from biosimilar savings (e.g., incremental new therapies funded and patients treated). Cost savings could also be invested to directly support Strategic Objective 7, real-world evidence (RWE). The creation of a prioritization framework should help determine how to reallocate savings.

⁸ Cancer system defined to include drugs, resources (e.g. staff), technologies (e.g. Positron Emission Tomography), cancer prevention strategies.

7. Develop an evaluation and monitoring plan that includes the collection and generation of real-world evidence (RWE).

Important considerations: Real-world data should be collected to assess utilization, safety, and effectiveness of therapeutic oncology biosimilars. Consideration should be given to collecting baseline data on the biologic innovator product prior to the introduction of its biosimilar to most effectively compare the biosimilar and biologic innovator products. Additionally, patient-reported outcomes (related to switching, sequencing, downstream impact, etc.) and the net value of biosimilar adoption (cost savings vs. cost of adoption) should be assessed.

Abbreviations

CAPCA – Canadian Association of Provincial Cancer Agencies is an interprovincial association of provincial/territorial cancer agencies engaged in cancer control.

CCO – Cancer Care Ontario is the principal cancer advisor for the Ontario government.

CPOE – Computerized Physician Order Entry refers to the process of a healthcare professional entering medication orders and treatment instructions electronically.

CCC – Colorectal Cancer Canada is a national non-profit organization dedicated to increasing awareness of colorectal cancer, supporting patients, and advocating on their behalf.

HC – Health Canada is the federal regulator of drugs and health products in Canada.

IV – Intravenous

NAPRA – National Association of Pharmacy Regulatory Authorities is an association of provincial and territorial pharmacy regulatory bodies as well as the Canadian Forces Pharmacy Services. Members regulate the practice of pharmacy and operation of pharmacies in their respective jurisdictions.

OECD – Organization for Economic Cooperation and Development is a forum of 36 member countries that helps governments foster prosperity and fight poverty through economic growth and financial stability.

ORA – Ontario Rheumatology Association is a professional organization that represents Ontario rheumatologists and promotes their pursuit of excellence in arthritis care through leadership, advocacy, education, and communication.

pCPA – Established in August 2010, the pan-Canadian Pharmaceutical Alliance (pCPA) conducts joint provincial/territorial/federal negotiations for brand name and generic drugs in Canada to achieve greater value for publicly funded drug programs and patients through the

use of the combined negotiating power of participating jurisdictions. The pCPA member jurisdictions include public drug plan and/or cancer agency participation from: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Québec, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland & Labrador, Yukon, Northwest Territories, Nunavut, Non-Insured Health Benefits (NIHB), Correctional Services of Canada (CSC) and Veterans Affairs Canada (VAC).

pCPA-GC – pan-Canadian Pharmaceutical Alliance Governing Council

RWE – Real-World Evidence. Real world data relates to patient health status and/or the delivery of health care routinely collected from a variety of sources. Real world evidence is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of real-world data.

SC – Subcutaneous

Common Terms

Biologic Medication (or biologic) – is a complex protein molecule created inside living cells with biotechnology. Biologics are used to treat diseases and medical conditions including cancer.

Biosimilar – is a drug demonstrated to be highly similar to a biologic drug that was already authorized for sale (known as the reference biologic drug). Biosimilars are approved based on a thorough comparison to a reference drug and may enter the market after the expiry of reference drug patents and data protection.

Equivalence – is the absence of a significant difference in the rate and extent to which the active ingredient in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of action when administered at the same dose under similar conditions in an appropriately designed study.

Generalizability (or extrapolation) – is often used to refer to the authorization of a biosimilar for indications where clinical studies were not done.

Interchangeability – products that are so alike that the drug is expected to have the same clinical result as the reference drug in any given patient. Decisions about interchangeability are made by provinces and territories. Drugs deemed interchangeable may be noted on the provincial Drug Benefit List.

Jurisdiction – refers to public drug plans from British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Québec, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland & Labrador, Yukon Territory, Northwest Territories, Nunavut, and Federal Drug Plans.

Reference Biologic – is the original biologic product to which a biosimilar refers to in its application for marketing approval.

Study End Points – in clinical trials, an event or outcome that can be measured objectively to determine whether the intervention being studied is beneficial. The endpoints of a clinical trial are usually included in the study objectives. Some examples of endpoints are survival, improvements in quality of life, relief of symptoms, and disappearance of the tumor.

Switching – generally refers to a one-time change from a reference biologic drug to a biosimilar but can also refer to a change from a biosimilar to a reference biologic or another biosimilar.

Background

Biologic medications (biologics) are complex protein molecules created inside a living cell. Biologics have become mainstays in the treatment of many types of cancer, including breast, gastrointestinal, lung, ovarian and other cancers. Patents protect innovative biologics for a limited amount of time. In Canada, patents for some biologics are expiring and highly similar copies, known as biosimilars, are being developed. A biosimilar that is approved by Health Canada (HC) is not necessarily identical to its reference biologic, but based on guidelines and approval standards for the pharmacokinetics, pharmacodynamics, safety and clinical efficacy of biologics the two are highly similar.^{9,10,11}

In 2016, biologics were the largest driver of drug spending growth, accounting for 15.9% of Canadian drug sales, or over \$3.6 billion.¹² The expected arrival of therapeutic oncology biosimilars in Canada offers the potential to bring significant savings to provincial cancer expenditures as biosimilars in other therapeutic areas are priced up to 47% lower than the reference product.¹²

A variety of approaches have been used to promote uptake of biosimilars worldwide, with different degrees of price reduction and market uptake observed. Compared to many Organization for Economic Co-operation and Development (OECD) countries, Canada is significantly behind in terms of adopting biosimilars (e.g., the adoption rate for biosimilar infliximab was 1% in Canada in 2016¹³ vs. 82% in Norway and 90% in Denmark in 2015¹⁴). This suggests that payer policies need to be carefully considered to optimize use and drive overall savings. Canadian provincial cancer systems differ in their policy, reimbursement and delivery environments in ways that may affect approaches to implementing oncology biosimilars. However, harmonized decision-making across jurisdictions should positively impact the emerging biosimilars market in Canada.

⁹ Health Canada. (2016, December 2). *Guidance Document: Information and Submission Requirements for Biosimilar Biologic Drugs*. Retrieved from <https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/information-submission-requirements-biosimilar-biologic-drugs.html>

¹⁰ Health Canada. (2017, August 3). *Fact Sheet: Biosimilars*. Retrieved from <https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html>

¹¹ ICH Expert Working Group. (2004). *ICH Harmonised Tripartite Guideline: Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process Q5E*.

¹² Patented Medicines Prices Review Board. (2018, February 5). *Potential Saving from Biosimilars in Canada*. Retrieved from <https://www.pmprb-cepmb.gc.ca/view.asp?ccid=1304>

¹³ Patented Medicines Prices Review Board. (2017, April). *Potential Savings from Biosimilars in Canada*. Retrieved from <https://www.cadth.ca/sites/default/files/symp-2017/presentations/april24-2017/Concurrent-Session-B4-Gary-Warwick.pdf>

¹⁴ OECD. (2017). *Health at a Glance 2017: OECD Indicators*. Paris: OECD Publishing. Retrieved from http://dx.doi.org/10.1787/health_glance-2017-en

The pan-Canadian Pharmaceutical Alliance (pCPA) is implementing a pan-Canadian biosimilar strategy with the goal of ensuring appropriate and cost-effective use of biologics (including biosimilars) across the country. The pCPA's recently published "Biologics Policy Directions & pCPA Negotiations" document aims to develop and pilot a clear and consistent pan-Canadian approach that encourages appropriate use of biologics (both innovators and biosimilars) in support of a common pCPA mandate to enhance patient access to clinically relevant and cost-effective drug treatment options. This document applies to all biosimilars, non-oncology and oncology, and its objectives are to:

- Encourage a harmonized approach to policies and review processes for biologics across all key stakeholders in Canada.
- Achieve the reduction of costs and to maximize access to effective treatments for Canadians.
- Increase awareness and confidence in the use of biosimilars through clinical evidence, education, and support for prescribers and patients.
- Promote appropriate uptake of biosimilars to enhance patient care and support drug plan sustainability.
- Facilitate post-market evaluation and monitoring of biologics in support of optimal use.

The development a cancer-specific strategy provides an opportunity to drive the acceptance and use of oncology biosimilars while considering the different environments in which cancer is treated with biologics. The pCPA has identified this as a key success factor in the overall biosimilars strategy and has partnered with Cancer Care Ontario (CCO) to provide pan-Canadian leadership on an oncology-specific biosimilars strategy.

As part of this strategy, the pCPA and CCO hosted the pan-Canadian Oncology Biosimilars Summit on November 16, 2018. The summit brought together patients, patient advocacy organizations, clinicians, health system administrators and government officials, with representatives from nine provinces, to discuss the challenges and opportunities of introducing therapeutic oncology biosimilars in Canada. Learnings from other jurisdictions and therapeutic areas were also shared to help shape best practice policies for oncology biosimilar implementation. The pCPA and CCO prepared draft strategic objectives which were vetted by an Advisory Committee comprised of clinicians, healthcare administrators and patient advocacy organization representatives. Stakeholders provided their feedback on the strategic objectives and insights for successful implementation of biosimilars in the oncology setting, to ensure that appropriate quality and safety measures are in place. The feedback received from the summit will be used to shape an Action Plan for the pan-Canadian Oncology Biosimilars Initiative. The vision, goals, and strategic objectives are outlined below.

Vision

Stakeholders across Canada have implemented an oncology biosimilars strategy that improves outcomes for patients, is evidence-informed, ensures appropriate quality and safety measures are in place, and facilitates access to innovative cancer treatments.

Goals

Stakeholder Engagement	Quality & Safety	Evidence-informed Policy Approach	Sustainability & Value for Money
<p>Collaborate with stakeholders so they participate in the development of a pan-Canadian Oncology Biosimilars Strategy.</p>	<p>Ensure that Oncology Biosimilars are safely implemented and that clinical and patient considerations are taken into account.</p>	<p>Engage pan-Canadian partners to discuss pricing, implementation and usage strategies that are informed by the best practices.</p>	<p>Improve system sustainability and performance by facilitating the uptake of Oncology Biosimilars and ensuring stakeholders are benefiting from the transition.</p>

Strategic Objectives

At the summit, stakeholders were divided into pre-assigned breakout groups and asked to provide feedback on ten proposed strategic objectives. Based on the feedback received from participants, the Oncology Biosimilars Initiative Team consolidated the ten strategic objectives into seven discrete objectives. Additionally, participants identified important issues for the pCPA and CCO to consider when operationalizing the strategic objectives.

1. Engage stakeholders throughout the project to validate and inform ongoing work.

Goals addressed: Stakeholder Engagement, Quality and Safety, Evidence-informed Policy Approach, Sustainability and Value for Money

Resources: CAPCA, Jurisdiction, pCPA-GC

Important considerations:

- This strategic objective was not discussed in a breakout session as it was inherent in the summit and across all other objectives.

2. Adopt best practices and standardized approaches to prescribing, storing, preparing, labelling, dispensing, and administering oncology biosimilars. This requires addressing technical¹⁵ and logistical¹⁶ challenges of implementation.

Goals addressed: Stakeholder Engagement, Quality and Safety

Resources: CAPCA, Jurisdictions, NAPRA

Important considerations:

- Standardization should be sought across jurisdictions and not left up to individual centres.
- A system wide change management plan may be beneficial. Plan should consider:
 - Conducting baseline assessments of computerized physician order entry (CPOE), pharmacy preparatory and dispensing, and medication administration recording systems.
 - Implementing policies, procedures and protocols prior to the arrival of biosimilars.
 - Ensuring sufficient personnel to modify IT systems, label, input warnings and track products for pharmacovigilance.
 - Having clear naming conventions for biologics to track the agent used and implementing an appropriate labelling system to identify whether a biosimilar or originator product was used.
 - Developing consistent communication policies and engagement strategies for all institutions and stakeholders (e.g., non-profit cancer groups, patient advocacy organizations, patient advisors).

¹⁵ For example, CPOE/EMR, smart pumps, pharmacy preparation and dispensing, and medication administration recording

¹⁶ Logistical considerations should also consider advanced warning for funding, standardized change management processes, policies, and procedures in advance of going live.

- Provide advanced notice of funding policies to enable timely implementation; one month is insufficient.
- Jurisdictions should decide whether a biosimilar will be used and which one(s). The decision should not be left to prescribers. Having only one product available in a pharmacy may be beneficial.
 - Too many choices could increase dispensing errors.
 - Capacity may be an issue in some centres if too many products are available. However, carrying both the originator and a biosimilar could be necessary if the biosimilar is not used for all indications.
- Easily identifiable packaging, bar coding, and better format/vial size were noted as possible ways to improve ease of biosimilars adoption. Extended stability was also identified as a way to facilitate biosimilars adoption.

3. Develop comprehensive education programs for health professionals and patients.

Goals addressed: Stakeholder Engagement, Quality and Safety

Resources: CAPCA, Jurisdictions, Patient and Clinician National Associations, pCPA-GC

Important considerations:

- Education materials should:
 - Be created for health care providers and patients.
 - Be rolled-out prior to biosimilars implementation.
 - Be audience-specific.
 - Be tailored to deliver specific messages (i.e., different messaging for new starts vs. patients being switched).
 - Have consistent messaging.
 - Be clear and concise.
 - Focus on safety and effectiveness, not cost-savings.
 - Not be funded by industry.
- Various modes of education materials were welcomed. Patients felt it was important to have printed information sheets in multiple languages whereas health care providers preferred web-based information.
- Patients unanimously agreed that receiving consistent messaging from their health care team in a uniform way is most important (i.e., receiving the same message from their physician, pharmacist and nurse). Printed and web-based information should also be aligned with messaging from patients' health care team.
- Over the next 6 months, standardized education materials for clinicians should be developed to ensure consistent messaging to patients. Content should:
 - Include explanations of biosimilars and how they differ from generics.
 - Include the benefits of implementing biosimilars, and how clinicians can best educate their patients.
 - Discuss how real-world evidence will be collected and address uncertainties within and between biosimilar and originator batches.

- Patients want to be assured that they will be monitored and that long-term monitoring is in place.
 - Stakeholder education is needed to promote acceptance of biosimilars and cultivate social responsibility.
- 4. Support the overall intent of creating a viable market for oncology biosimilars by developing reimbursement strategies that promote implementation and sustainability across Canada.**

Goals addressed: Stakeholder Engagement, Quality and Safety, Evidence-informed Policy

Approach, Sustainability and Value for Money

Resources: CAPCA, pCPA-GC

Important considerations:

- In an ideal state, there would be multiple manufacturers on the Canadian market which may or may not include the innovator product. It was felt that a guaranteed market share is required to incentivize manufacturers to enter and stay on the market. For biosimilar brands subsequently entering the market, a rolling strategy to retender every 1-2 years was recommended. Within hospitals and clinics, only one product should be available because of practical concerns, like storage.
- Jurisdictions must ensure a viable supply chain while maintaining system flexibility to be able to quickly adapt in the event of supply interruptions, drug shortages, or unexpected toxicities.
- An 'overnight' switch to a biosimilar would likely offer greater uptake and sustainability than a 'slow go' (i.e., one indication at a time) approach.
- Promote transparency when discussing why patients are being switched to a particular drug (i.e., communicate that switches are being made as a result of achieving better value through negotiations).
- If a patient is unable to tolerate a biosimilar, cancer systems should be able to manage this on a case-by-case basis.

5. Develop clear guidance on clinical scenarios such as initiating, switching and generalizability.

Goals addressed: Stakeholder Engagement, Evidence-informed Policy

Accountabilities: CAPCA, Clinicians, Payers

Important considerations:

- Need to ensure that all relevant stakeholders are consulted when developing policies.
- Build in a clinical policy option for patients who have issues with biosimilars (e.g., adverse event) to switch back to the reference biologic drug.
 - Timing is important as there may be different implications when a patient is at the beginning or end of his/her treatment.

- It is important to consider patient stress when switching from the originator biologic to the biosimilar.
- Managing two systems concurrently (i.e., patients on biosimilars and patients on originator products) may cause medication errors due to storing dual inventory.
- Need to consider patients' concern about being on biosimilars for non-HC approved indications. There is a need to ensure clinicians are knowledgeable and able to communicate effectively on approved and non-approved indications.
- Biologic drugs used at the present time are not the same as those used in the original clinical trials because companies change their manufacturing process along the way.
- For the use of biosimilars for non-HC approved indications, the term 'generalizable' is preferred over 'extrapolate.'

6. Reinvest savings from oncology biosimilars back into the cancer system¹⁷, with the objective of optimizing health outcomes.

Goals addressed: Stakeholder Engagement, Sustainability & Value for Money

Accountabilities: CAPCA, Ministries of Health

Important considerations:

- It is important that cost-savings from biosimilars stay within the cancer system.
- Reinvestment activities should be transparent and communicated.
- Performance metrics need to be developed to quantify and evaluate the system improvements achieved from the biosimilar savings (e.g., incremental new therapies funded and patients treated).
- Develop a prioritization framework to help determine how to reallocate cost-savings.
- Leverage cost savings to invest in an infrastructure that enables effective RWE work.
 - Analyze real world evidence to ensure that biosimilars provide the same outcomes as their reference product (i.e., have registries in place to track adverse events).
 - There was some support for costs being shouldered by the pharmaceutical industry as opposed to using savings from biosimilars. However, there were concerns that adverse reaction reporting may be biased if manufacturers assumed total responsibility.

¹⁷ Cancer system defined to include drugs, resources (e.g. staff), technologies (e.g. PET), cancer prevention strategies.

7. Develop an evaluation and monitoring plan that includes the collection and generation of real-world evidence (RWE).

Goals addressed: Stakeholder Engagement, Sustainability & Value for Money

Accountabilities: Cancer Agencies, CAPCA, Jurisdictions

Important considerations:

- Collect real-world data to assess utilization, safety and effectiveness of oncology biosimilars.
- Collection of data and evaluation of RWE will be important to help confirm that outcomes are as expected and build confidence among stakeholders (e.g., patients, clinicians, healthcare administrators).
- Leverage experience of other jurisdictions (e.g., NHS and the EU).
 - Focus on where there are gaps in evidence not being addressed by other jurisdictions and target those areas to avoid duplication of effort. There was consensus that data from one province or jurisdiction could be used broadly to avoid repeat work; each province will not need to collect their own data.
- Establish evaluation criteria for choosing when to evaluate new biosimilars with RWE and which questions to address (e.g., should data be collected on the first biosimilar to market? Or biosimilars being used for off-label use? etc.).
- Establish a data collection plan, including what data elements to collect, who will collect the data, how long data will be collected, and how data will be synthesized to make informed decisions.
- Important to collect baseline data on the originator product prior to biosimilars introduction.
 - Comparative evidence is needed. Similar data needs to be collected for the biosimilar and the originator product in order to identify any changes in safety and efficacy.
 - Biosimilar manufacturers will be required to collect post-market data on their biosimilar as part of their Notice of Compliance requirements the same as all other biologic medications.
 - Post-market safety monitoring will also be conducted through existing adverse drug reaction reporting to HC. Adverse events in oncology are expected and common. Reporting should follow standard practice, as increased vigilance for biosimilar products compared to originators could produce biased results.
- Consider outcomes to study to address uncertainties that are important to stakeholders.
 - Some outcomes can be obtained from current routinely collected administrative data (e.g., utilization and uptake).
 - Need to develop capacity to assess other outcomes and questions that would be meaningful to patients, particularly patient reported outcomes and the impacts of switching, sequencing, downstream impact etc.
 - RWE may be especially relevant if provinces fund indications that are non-HC approved, and may require more data collection.
- Data collection and making policy decisions can happen simultaneously.
 - Thought should be given to net value of biosimilar adoption (cost savings vs. cost of change).

The pan-Canadian Oncology Biosimilars Summit

Welcome and Opening Remarks: Defining Scope

Presented by Scott Gavura

Director, Provincial Drug Reimbursement Programs, Cancer Care Ontario

Scott Gavura welcomed attendees to the pan-Canadian Oncology Biosimilars Summit and provided an overview of the work leading up to the event. CCO worked closely with pCPA to plan the summit and has begun mapping out a strategy for implementing oncology biosimilars. The goal of the summit was to gain participants' insight on how to successfully implement oncology biosimilars in Canada and to identify issues, concerns and opportunities related to execution. During the planning of the summit, a draft vision statement was developed to guide the work of CCO and the pCPA. The proposed vision for the pan-Canadian Oncology Biosimilars Strategy was:

“Stakeholders across Canada have implemented an oncology biosimilars strategy that improves outcomes for patients, is evidence-informed, ensures appropriate quality and safety measures are in place, and facilitates access to innovative cancer treatments.”

Mr. Gavura noted that throughout the day and following the summit, through a post-event survey, participants would be asked for their feedback on the proposed vision, goals, and strategic objectives.

Presented by Michael Sherar, President and Chief Executive Officer, Cancer Care Ontario

Michael Sherar reiterated Mr. Gavura's welcoming remarks and extended his gratitude to the pCPA and patient and family advisors present at the summit. Dr. Sherar described the summit as an opportunity to work together to develop a unified strategy in implementing biosimilars for cancer patients across Canada. He acknowledged that the partnership of all stakeholders is critical in ensuring optimal uptake of biosimilars, best pricing, and excellent patient outcomes. As of 2019, Canada expects the first therapeutic oncology biosimilar to come to market. Biosimilars offer the opportunity for significant savings to cancer systems across Canada while delivering safe and effective patient care. Estimates suggest that \$800 million per year is spent on oncology biologic medications and approximately \$600 million of that, is expected to have biosimilar competition in the next few years. The adoption of biosimilars will provide critical savings that can be reinvested back into the health and cancer systems and allow for the opportunity to fund new and innovative therapies for patients across the country.

Presented by Mitch Moneo, Assistant Deputy Minister, BC Ministry of Health & Vice-Chair of the pan-Canadian Pharmaceutical Alliance Governing Council

Mitch Moneo welcomed attendees, thanked the summit's organizers for hosting the event and explained the pCPA's role in biosimilars implementation. The pCPA has fostered a collaborative relationship with the cancer agencies and is committed to a unified pan-Canadian approach to funding decisions for biologic drugs, including biosimilars. Mr. Moneo noted that Canada stands significantly behind other OECD countries in adopting biosimilars, both in the oncology and non-oncology spaces. Increases in biologics spending is unsustainable and appropriate adoption of biosimilars may offset some of the budget pressures. Optimal and appropriate use of biosimilars will maintain access to existing therapies, reduce costs, and allow for reinvestment in new and innovative therapies. Mr. Moneo explained that the pCPA has successfully negotiated prices for non-oncology biosimilars and does not foresee any differences for oncology biosimilar negotiations. However, he also mentioned that there will be some considerations that are unique to oncology biosimilars and input from the summit's participants will help shape the pCPA's considerations moving forward.

Mr. Moneo informed participants that the pCPA Office's Biologics Policy Directions document was introduced through webinars to industry and patient associations and is expected to be published in the next couple of months. This document indicated that all public drug plans (federal, provincial and territorial) share common goals including:

- Reducing costs and maximizing access to effective treatments for Canadians.
- Increasing awareness and confidence in biosimilars.
- Promoting appropriate uptake of biosimilars to enhance patient care and support drug plan sustainability.
- Facilitating post-market evaluation and monitoring of biologics in support of optimal use.

Lessons Learned from an International Perspective

Presentation by Jatinder Harchowal, Chief Pharmacist, Royal Marsden Hospital, England

Jatinder Harchowal presented the National Health Service (NHS) England's experience implementing oncology biosimilars. NHS England identified a need for a well-planned strategy to improve the uptake of oncology biosimilars as the previous implementation of non-oncology biosimilars showed extensive variation in uptake across England. A Commissioning Framework for Biological Medications was set-out to improve biosimilar uptake with the aim of "90% of new patients to be prescribed best value biological medicine within three months of launch of a biosimilar medicine, and at least 80% of existing patients within 12 months." Additionally, the Cancer Vanguard – a partnership between three local delivery systems to pilot and test new models of care – established the Pharma Challenge and invited pharmaceutical companies to submit proposals to improve the availability and delivery of cancer drugs. The Cancer Vanguard

selected Sandoz's proposal to improve biosimilars uptake through an education and engagement program ('Getting It Right First Time'). NHS staff worked collaboratively with Sandoz in a non-promotional manner to develop a robust implementation strategy. Sandoz and the Cancer Vanguard implemented education and engagement strategies to improve patient and clinician acceptance of biosimilars, which in turn influenced biosimilars uptake.

Using rituximab implementation as an example, Mr. Harchowal highlighted the key drivers for successful implementation of oncology biosimilars and shared preliminary implementation outcomes.

Key Drivers of Success

1. Stakeholder Engagement

The Cancer Vanguard engaged:

- Professional and patient groups to ensure consistent messaging across education materials about biosimilars.
- Clinicians (oncologists, nurses and pharmacists) to ensure their educational needs were met.
- Pharmacy and procurement staff to ensure updates were made to the electronic and manual systems involved in prescribing, administering and documenting biosimilar usage (e.g., for traceability).
- Pharmacy & Therapeutics Committee(s) to ensure that biosimilars were on the formulary.
- NHS Clinical Commissioners to demonstrate leadership in implementation.

2. Education and Information Sharing

Mr. Harchowal emphasized the importance of education and information sharing for the successful implementation of biosimilars. The Cancer Vanguard tailored education materials to both patients and clinicians and shared information as it became available.

Education

- For patients, the Cancer Vanguard prepared information sheets in collaboration with and endorsed by, patient advocacy organizations. These were made available for national use.
- For Clinicians, the Cancer Vanguard organized dedicated information sessions for all professions involved in biosimilar implementation.

Information Sharing

- As well as producing patient information leaflets, for trastuzumab, patients received a letter signed by their clinician before switching to a biosimilar, noting their clinician's confidence in the biosimilar's safety and efficacy. This letter offered patients an opportunity to voice their questions and concerns related to the switch.
- All stakeholders were kept informed of reinvestments made into the health system as a result of cost-savings from biosimilars.

3. Supply Chain Management

Mitigating supply chain issues were critical to ensuring successful implementation of biosimilars. As with all medications, there is an increased risk of drug shortages when a limited number of manufacturers are on the market. To address this concern, the NHS issued regional therapeutic tenders; the four main regions in England were each awarded products to help maintain the supply chain. This approach eliminated local (i.e., hospital) negotiations for additional discounts across the country.

Preliminary Outcomes

The NHS saw a rapid implementation of biosimilar rituximab with currently 98% uptake across the NHS. Before rolling out the rituximab biosimilar, the NHS collected real-world data about infusion reactions and therefore was able to compare patient experiences when on the originator versus the biosimilar. Despite rapid implementation, the NHS did not identify any practical nor clinical issues with the rituximab biosimilar.

Summary

Mr. Harchowal closed his presentation by noting that collaboration, system-wide leadership support, transparency and education were critical to the successful implementation of the rituximab biosimilar. As a result, the NHS planned to utilize the same approach when implementing future biosimilars. As an example, Mr Harchowal shared the initial data for intravenous trastuzumab biosimilar which showed an even quicker uptake of the biosimilar in the first three months compared to rituximab.

Highlights from the Question & Answer Session

Following Mr. Harchowal's presentation, the Q&A forum further explored:

Variability in Uptake Across the NHS

A participant asked why some centres previously had high biosimilars uptake while others did not. Mr. Harchowal attributed the variable uptake to lack of a national approach, incentive to change, and inadequate engagement. He reiterated that multi-stakeholder engagement was the foundation for promoting biosimilars' uptake.

Role of Industry

A participant inquired whether the Cancer Vanguard received any push-back for partnering with Sandoz. Mr. Harchowal explained that the partnership with Sandoz was not an issue as it was made clear from the beginning that Sandoz would work with the Cancer Vanguard in a non-promotional manner. Demonstrating their non-promotional partnership, Mr. Harchowal noted that successful contracts did not include Sandoz's product.

Information Sharing

Summit participants were interested in knowing patients' responses to the letter NHS sent out informing patients of a change in their treatment (i.e., patients switching from the originator to a biosimilar). Mr. Harchowal indicated that the majority of patients appreciated the letter, and only 5% of patients wrote back expressing concern. Patients had two common concerns:

- Patients on subcutaneous (SC) trastuzumab were interested in knowing if they would be switched to intravenous (IV) chemotherapy. Mr. Harchowal explained that patients on SC trastuzumab would not be switched to biosimilar IV trastuzumab.
- Patients wanted to know if they had the opportunity to switch back to the originator product if they were unhappy with the biosimilar. In the event patients were unhappy receiving the biosimilar, they had the option to switch back to the originator product. If patients did express this desire, Mr. Harchowal and his team took the time to investigate patients' specific concerns and ensured patients knew that they were being monitored throughout their treatment.

A patient advocate voiced concern for patients with metastatic breast cancer and inquired whether this population was among the 5% of unhappy patients. Mr. Harchowal agreed that many patients who expressed concern had metastatic breast cancer. He noted that assuring patients of biosimilars' safety and efficacy, and providing patients the option to switch back to the originator, eased most concerns. Furthermore, he explained that having this message supported and reiterated by clinicians and patient advocacy organizations aided in patient confidence in biosimilars. As a result, all patients were switched to the biosimilar except for one patient who remained on the originator product because she was in her last three months of treatment.

Subcutaneous Rituximab

Participants were interested in knowing the proportion of patients on SC rituximab and how this impacted biosimilar uptake and cost-savings. Mr. Harchowal highlighted that SC rituximab did not have a significant impact on biosimilar rituximab as SC rituximab only holds 10% of England's market. Furthermore, he explained that since SC rituximab was available 18 months before the biosimilar, the Royal Marsden made the conscious decision not to implement SC rituximab, though other hospitals did. He noted that horizon scanning and an unconvincing case made by clinicians to implement SC rituximab contributed to Royal Marsden's decision to not implement SC rituximab in preparation for the biosimilar's arrival.

Drug Pricing

A participant questioned whether the manufacturers of the originator product worked with NHS England on drug pricing. Mr. Harchowal stated that the originator company likely underestimated the success of the Cancer Vanguard initiative, and therefore when the tender was out, the originator manufacturer gave a very nominal discount, while the biosimilar manufacturer offered a discount in the region of 40-60%.

Tendering and Market Share

A participant inquired about the length of contracts issued. Mr. Harchowal noted that contracts in the NHS are either one or two years in length, with the option to extend. In the event their horizon scanning identified another biosimilar coming to market, a one-year contract would be issued to allow other manufacturers to bid for some of the business. Mr. Harchowal emphasized the importance of horizon scanning to plan the length of contracts.

Another participant pointed out that Canada is a smaller market than the United Kingdom and may not have multiple biosimilars on the market. He asked how Canada should approach a situation where only one biosimilar was on the horizon. Mr. Harchowal suggested that having only one biosimilar on the market is not ideal and Canada may want to keep the originator on the market to ensure there are no long-term supply chain issues.

Reinvestment

Mr. Harchowal underscored that all savings were redistributed back to the Commissioners, and none was reinvested in the Royal Marsden Hospital for supporting the biosimilars work. These cost savings went to front-line patient care.

Real-World Evidence

One participant was interested in knowing what data NHS England was currently collecting for this initiative. Mr. Harchowal informed participants that he is the principal investigator on a study examining all patients who started their treatment on a biosimilar and those who were switched to the biosimilar from the originator. He stated that data about lymphoma patients would be available next year.

Setting the Stage: Opportunities and Challenges Implementing Biosimilars

Clinician Perspective

Presentation by Dr. Eitan Amir, Medical Oncologist, Princess Margaret Cancer Centre

Dr. Eitan Amir has given many talks on biosimilars across the country and shared what he has heard from clinicians¹⁸ about biosimilars. Three issues summarize clinicians' views:

- Do they work (effectiveness)?
- Are they safe?
- Why should we change? Change usually requires more work.

He highlighted that clinicians are not particularly interested in data on structural and functional similarity between a biosimilar and its reference product (part of the regulatory approval process). Instead, they are more interested in the clinical data of the drug, which is the drug's effectiveness and safety in a patient population (human clinical studies).

Dr. Amir outlined some differences in the clinical development of biosimilars and reference biologics which could present as areas of concern for clinicians:

Patient Population

- In clinical studies for a biosimilar, the patient population is required to be sensitive and homogenous. If a biosimilar proves effective in the indication studied, then it may be possible to extrapolate its effectiveness (efficacy) to other indications. Some clinicians are comfortable with this, while others are not.

Clinical Design

- Clinicians are more familiar with randomized clinical trials where an experimental drug is determined to be good or better than a previous standard of care. As part of the regulatory process, biosimilars are approved based on equivalence (and possibly non-inferiority) studies, which compare them to reference biologics. Clinicians are less familiar or knowledgeable about these types of comparative studies which causes some uncertainty.

Study End Points

- Frequently, clinicians debate what study endpoints are appropriate to approve a drug for use. They feel that the proposed study endpoints used for biosimilars (e.g. overall response rate, pathological complete response rate) are not always very good predictors of longer term outcomes like overall survival. While these endpoints can be reasonable estimates (or sensitive markers) about the effectiveness of a drug, clinicians do not use them routinely. Typical endpoints that are relevant for clinicians are overall survival and progression free survival.

¹⁸ Clinician could refer to a physician, registered nurse or pharmacist.

Extrapolation

- Some clinicians feel that extrapolation between indications may put patients at risk for the following reasons:
 - An oncology biologic has many mechanisms of action, and the net contribution of each one is not entirely clear. The exact mechanism may differ from patient to patient, from indication to indication or from early stage to late stage. As there is not a firm scientific grasp on this, a biosimilar may introduce another level of uncertainty if regulatory testing suggests different mechanisms of action. Clinicians may be less confident with the concept of extrapolation.
 - There is a lack of pharmacodynamic markers for many biologics creating a need to do large trials to determine how to assess outcomes. This will affect clinicians' willingness to extrapolate.

Regarding economic implications, clinicians acknowledge that biosimilars do provide savings coming to the market at a reduced price (i.e., 15-30% below current value). The presence of biosimilars will lead to competitive pricing which could, in turn, decrease the cost of the reference biologic. The availability of multiple biosimilars will also result in competition and reduce pricing even compared to market entry of the first biosimilar.

Dr. Amir concluded by saying that clinicians and payers are very experienced in deciding how to fund new drugs based on analyzing the cost-benefit trade-off. However, for biosimilars, this concept could prove challenging because clinicians are trading off cost-savings for uncertainty in safety and efficacy. This is not to say there is a difference in safety and efficacy, but that uncertainty exists and needs to be addressed. Unlike for new drugs with improved efficacy and increased cost, there are no societal thresholds for good value of biosimilars.

Payer/System Perspective

Presentation by Kathy Gesy, Canadian Association of Provincial Cancer Agencies

Kathy Gesy shared her perspectives as a payer and pharmacy director. As a payer, Ms. Gesy has extensive experience managing a continuously growing cancer drug budget. She noted that increases in expenditures are primarily due to new and more expensive drugs and therapies coming to market, expanded indications of current medications, use of drugs in combination with other therapies, and longer treatment durations. As such, the health care system is seeking measures to ensure oncology drug budgets can sustain this growth. Ms. Gesy identified some opportunities for cost-savings, including lower drug prices via pCPA negotiations, offsetting drug costs by prioritizing drugs or modifying sequencing therapies, and loss of patent exclusivity.

Biologic medications are an example of recent innovations that are consuming a large portion of the cancer drug budgets. Ms. Gesy emphasized that biosimilars present an opportunity to make room in the budget for new treatments. To successfully implement biosimilars, we need:

- Stakeholder confidence and acceptance.
- A national strategy for decisions on interchangeability, switching and indications for use to avoid duplication of efforts across jurisdictions.
- A national strategy to maximize discounts (e.g. rolling tenders).
- A reimbursement process that will ensure market uptake of biosimilars.

Alluding to her role as a pharmacy director, Ms. Gesy noted that decisions related to interchangeability, switching and reimbursed indications will impact pharmacy and clinic operations. Specifically, if funding policies allow both biosimilar and originator products to be available at one treatment centre for different indications, resources would be required to:

- Accurately identify between a biosimilar and originator product when prescribing and dispensing.
- Modify paper and electronically preprinted order sets, smart pumps, pharmacy software clinical management systems, and labelling procedures.
- Develop a system to track and monitor adverse events accurately (i.e., trace adverse events back to the correct product).
- Manage increases in workload associated with purchasing and inventory management.
- Accommodate additional storage requirements as the products would need to be stored separately.
- Absorb additional drug wastage costs as vials could not be shared between patients as often.
- Develop a continuous plan for staff and patient education.

Additionally, stocking both originator and biosimilar products poses new challenges when conducting medication reconciliation processes, which allow for assessing drug-drug interactions and documenting medication histories. Most critically, it increases the possibility of medical errors.

Overall, a piecemeal adoption of biosimilars may impede the successful integration of biosimilars into oncology clinics. Decisions on biosimilar implementation need to consider the impact on pharmacy and clinic operations, the system's capacity for this change, and the cost of resources required to manage incremental workload and safety issues.

Patient Perspective

Presentation by Pam Goldsilver, Patient Advisor, North York General Hospital

After Dr. Eitan Amir and Kathy Gesy shared the clinician, payer and system perspective, Pam Goldsilver, a Patient Advisor, moderated a discussion between the panel and the audience. Ms. Goldsilver kicked-off the discussion by emphasizing that communication and education will be essential to informing patients on biosimilars. Clinician-patient conversations will lead to more understanding, openness and acceptance, particularly when it pertains to switching patients from an originator product to a biosimilar.

Highlights from the Q&A Session

Ms. Goldsilver proceeded to open the floor for questions and started by asking the panel how to assure patients that biosimilars would be safe and effective when they are not identical copies of the originator. Dr. Amir commented that HC, as a federal regulatory body, is tasked to ensure the safety and efficacy of all drugs and their approval process should be considered the first step in assuring all stakeholders.

The Q&A forum underscored additional concerns related to:

Language

Representatives from patient advocacy organizations advocated for the use of language that redirects the focus on cost-savings to improved patient outcomes. These improvements would be due to potentially expanded access to current medications as well as funding new medications and technologies that are approaching. They also stressed the importance of ensuring that language does not imply interchangeability, given that HC has not deemed biosimilars as interchangeable with the originator product. It was later clarified by a representative from HC that the term interchangeability is a concept for small molecules only. Furthermore, HC does not declare small molecules interchangeable – that is left to the provinces. Health Canada has said that patients on biologics can be switched.

Interprovincial Migration

A patient advocate asked how to manage the interchangeability of biosimilars given that different biosimilars may be available in different provinces and patients travel across provinces for treatment. In response, Ms. Gesy noted that in a situation where the supply of an originator product was unavailable from its usual source, a company had imported the biologic drug from another county/manufacturing plant. In this case, the product was essentially a biosimilar because they were produced in different plants, in different countries, with similar processes. Patients were treated with these imported products, and there were no concerns from the patients or clinicians involved. As such, if a patient were to travel between provinces or countries for treatment, patients and clinicians should not be concerned whether the patient received the originator or the biosimilar.

Reinvestment

A healthcare administrator asked about reinvesting savings given that there is no assurance that savings will go back in the cancer system. Presenters noted that activities related to reinvestment are within each province's jurisdiction (ministries of health) and depends on their cancer program. Presenters highlighted that each year the annual oncology drug budgets continue to increase. As such, it is presumed that cost-savings are currently being reinvested into the cancer drug budget.

Role of Clinicians in Addressing the Strategic Objectives

Moderator: Dr. Leta Forbes, Cancer Care Ontario

Panellists: Dr. Henry Aaverns, Ontario Rheumatology Association; Dr. Gary Pansegrau, BC Cancer; and Dr. Bruce Colwell, Queen Elizabeth II Health Sciences Centre

Dr. Leta Forbes moderated a panel comprised of three clinicians who were invited to share their views on biosimilars implementation and uptake.

Rheumatology

Dr. Henry Aaverns started the conversation by sharing his experience of infliximab biosimilar implementation. Uptake of the infliximab biosimilar was slower than expected and could likely be attributed to:

- Deep-rooted prescribing habits
- Lack of clinician incentive to prescribe the infliximab biosimilar
- Unclear insurance policies

Dr. Aaverns identified gain-sharing and clear insurance policies as ways to improve infliximab biosimilar uptake. Reinvesting savings from infliximab biosimilar implementation into patient care, such as insuring lab tests needed for therapy (currently paid out-of-pocket by patients), could incentivize clinicians to prescribe the infliximab biosimilar. Additionally, setting out clear co-payment assistance policies like those for the originator infliximab product would alleviate clinicians' concerns around patient access.

Oncology

Oncologists focused their discussion on education, trust and confidence in biosimilars, and pharmacovigilance. Oncologists feel that they lack knowledge of biologics and biosimilars, but know that their patients will look to them as the expert. As such, a carefully planned education program will help clinicians discuss biosimilars with patients. Oncologists stated that it was important for education to be delivered appropriately through peer-to-peer education, and for professional and patient advocacy organizations to contribute to the development of educational materials. Coordinated and consistent messaging among clinicians and patient advocacy organizations would also help improve trust and acceptance of biosimilars.

Oncologists feel that improved transparency around the drug review process would further cultivate their trust and confidence in biosimilars. For example, while HC's approval process for biosimilar medications is rigorous, knowing the qualifications of the individuals making these decisions at HC would improve clinicians' trust in biosimilars.

Lastly, clinicians discussed the importance of pharmacovigilance. They emphasized that prior to biosimilar market entry good baseline data must be collected to compare outcomes pre- and post- biosimilar implementation. Based on UK's experience, it was recommended to invest in data collection infrastructure, given that current systems are not capable of capturing RWE.

Role of Patient Advocacy Organizations in Addressing the Strategic Objectives

Moderator: Deborah Maskens, Kidney Cancer Canada

Panellists: Denis Morrice, Ontario Rheumatology Association; MJ DeCoteau, Rethink Breast Cancer; and Barry Stein, Colorectal Cancer Canada

Deborah Maskens moderated a panel of advocates from three Patient Advocacy Organizations.

To start the conversation, Denis Morrice discussed patients' difficulty accessing specialty drugs stemming from their high costs. Patients have difficulty accessing drugs due to private insurance policy changes including increasing deductibles, requests for prior authorizations for medications, denials of coverage, and delisting of drugs. Connecting his concern of patient access to oncology, Mr. Morrice stated that public payer financial sustainability is essential for continued and improved access to care.

Patient advocates also emphasized the importance of open communication with their members. The Ontario Rheumatology Association (ORA) posted an official position statement about switching on their website along with frequently asked questions as a way in which the organization could communicate with its members and clarify any outstanding questions about biosimilars. Additionally, the ORA acknowledged that education on biosimilars would be an iterative process and they would continue to share information with its members as it became available.

Among the oncology patient advocates, Mr. Stein and Ms. DeCoteau reported that their organizations conducted patient surveys to engage their members. Mr. Stein noted that Colorectal Cancer Canada (CCC) conducted a patient survey to provide feedback to pCODR on the bevacizumab biosimilar and Ms. DeCoteau stated that Rethink Breast Cancer conducted a high-level survey to assess patients' knowledge of biosimilars. Mr. Stein and Ms. DeCoteau reported some of their insights at the summit. Their surveys addressed several common themes:

Education

- Surveyed patients identified a significant need for education. Despite efforts made by the patient advocacy organizations, many patients surveyed had not heard of biosimilars and were interested in learning more. Specifically, among patients surveyed by CCC, patients reported that education would need to be ongoing until sufficient RWE was available to confirm that the medications were proving to be as safe and effective as expected.

Confidence

- Surveyed patients wanted to know that their physician was confident in the use of biosimilars and that they were safe and effective. Consistent messaging of biosimilars by patient advocacy organizations, oncologists and pharmacists would help assure patients that they are receiving the best treatment. Oncology patient advocacy representatives noted that unlike rheumatology, oncology drugs can influence survival time, and it is essential that physicians are confident in biosimilars and the treatment they are providing their patients.

Monitoring

- Surveyed patients wanted to be assured that their side-effects (if any) would be followed up on. Mr. Stein noted that having an appropriate naming system in place will help to track adverse events.

Reinvestment

- Surveyed patients wanted savings from biosimilars implementation to be reinvested into cancer care. Among patients with metastatic cancers, biosimilars implementation was of particular interest if reinvested savings would improve access to treatment.
- When summit participants asked the panellists to share their views on where money should be reinvested in the cancer system, panellists noted that there was an expectation to reinvest savings into the oncology drug budget, cancer prevention, and treatment access issues (i.e., access to oral chemotherapy medications) in jurisdictions across Canada.

Final Recommendations for Future Directions

Presented by Scott Gavura, Director, Provincial Drug Reimbursement Programs, Cancer Care Ontario

Mr. Gavura presented feedback received from the breakout session. He shared participants' suggestions on how to revise the strategic objectives and highlighted important areas for consideration for implementation of each strategic objective¹⁹. Mr. Gavura reiterated that the intent of the event was to start thinking about how Canada will implement oncology biosimilars and to start a dialogue with stakeholders about oncology biosimilars. He noted that the success of biosimilars implementation will only work with continued stakeholder engagement.

Mr. Gavura reminded participants that CCO and the pCPA would be sending out a post-event survey where participants could provide any additional feedback they may have.

Wrap-Up, Acknowledgements and Closing

Presented by Sang Mi Lee, Senior Pharmacist, pan-Canadian Pharmaceutical Alliance

Sang Mi Lee thanked the Advisory Committee, CCO, and the pCPA Office. She also thanked participants for their participation and level of engagement – their insights will not only help inform the strategic objectives for oncology, but also the pCPA's work outside of oncology. Finally, Ms. Lee acknowledged that although pharmaceutical manufacturers were not present at the event, they are an important stakeholder. She informed participants that the pCPA had scheduled meetings with individual manufacturers for the end of November 2018 which would provide an opportunity for the pCPA to inform industry of the summit's proceedings, and for industry to share their initial thoughts on oncology biosimilars implementation.

¹⁹ Participants' feedback and critical considerations can be found on pgs.11-16.

Appendices

Appendix 1: Oncology Biosimilars Summit Advisory Committee Members

1. Eitan Amir, Medical Oncologist, Princess Margaret Cancer Centre
2. Elizabeth Baugh, CEO, Ovarian Cancer Canada
3. Darryl Boehm, Director of Pharmacy, Saskatchewan Cancer Agency
4. Barry Stein, President and CEO, Colorectal Cancer Canada
5. Jenn Gordon, Director of Operations, Canadian Breast Cancer Network
6. Leta Forbes, Provincial Head, Systemic Treatment, Cancer Care Ontario
7. Marc Geirnaert, Director, Provincial Oncology Drug Program, Cancer Care Manitoba
8. Deb Maskens, Co-Founder, Kidney Cancer Canada & Can Certainty Coalition
9. M.J. DeCoteau, President, Rethink Breast Cancer
10. Elizabeth Lye, Scientific Advisor, Lymphoma Canada

Appendix 2: Oncology Biosimilars Summit Agenda (Nov 16, 2018)

Time	Activity
8:00am–8:45am	Registration & Networking (with light breakfast, coffee & tea)
8:45am–9:00am	Welcome and opening remarks: Defining scope Scott Gavura, Cancer Care Ontario Michael Sherar, Cancer Care Ontario Mitch Moneo, Ministry of Health, Government of British Columbia
9:00am–9:45am	Lessons learned from an international perspective / Discussion Q&A Jatinder Harchowal, The Royal Marsden NHS Foundation Trust
9:45am-10:00am	Break and light snack
10:00am-10:45am	Setting the stage: Opportunities and challenges implementing biosimilars <ul style="list-style-type: none"> • Pam Goldsilver, Patient Advisor • Dr. Eitan Amir, Princess Margaret Cancer Centre • Kathy Gesy, Canadian Association of Provincial Cancer Agencies
10:45am-11:00am	Q & A and Discussion
11:00am-11:20am	Review work plan recommendations / Discussion Q&A Jessica Arias, Cancer Care Ontario <ul style="list-style-type: none"> • Stakeholder Engagement • Quality and Safety • Evidence Informed Policy Approach • Sustainability and Value for Money
11:20pm-12:20 pm	Breakout sessions Review recommendations and provide feedback
12:20pm – 1:00pm	Lunch
1:00pm-1:45pm	Full group discussion/Report back: Future Directions for Biosimilar Drug Implementation Scott Gavura, Cancer Care Ontario
1:45pm-2:00pm	Break and light snack
2:00pm -2:40pm	Role of clinicians in addressing strategic objectives Panel Moderator: Dr. Leta Forbes, Cancer Care Ontario <ul style="list-style-type: none"> • Dr. Henry Averns, Ontario Rheumatology Association • Dr. Gary Pansegrau, BC Cancer • Dr. Bruce Colwell, Queen Elizabeth II Health Sciences Centre
2:40pm-3:25pm	Role of patient advocacy organizations in addressing strategic objectives Panel Moderator: Deborah Maskens, Kidney Cancer Canada <ul style="list-style-type: none"> • Denis Morrice, Ontario Rheumatology Association • MJ DeCoteau, Rethink Breast Cancer • Barry Stein, Colorectal Cancer Canada
3:25pm – 3:45pm	Final Recommendations for future directions Scott Gavura, Cancer Care Ontario
3:45pm – 4:00pm	Wrap up, Acknowledgements, and Closing Sang Mi Lee, pan-Canadian Pharmaceutical Alliance

Appendix 3: Summit Speakers Biographies



Scott Gavura is Director of the Provincial Drug Reimbursement Programs Unit at Cancer Care Ontario. In that role, Scott is responsible for the strategic management of CCO's cancer reimbursement programs, including the New Drug Funding Program, the Evidence-Building Program, the Case-by-Case Review Program, the PET Access Program, and the Out-of-Country Review Program.

Scott's background includes roles focused primarily on evaluating the effectiveness and value of new drugs. He is a Registered Pharmacist and holds both Bachelor of Science in Pharmacy and Master of Business Administration degrees from the University of Toronto.



Dr. Michael Sherar is President and CEO of Cancer Care Ontario, a role he was appointed to in 2011. From 2006 to 2011, he was the provincial agency's Vice-President, Planning and Regional Programs, leading the development of Regional Cancer Programs, including capital planning for cancer services across the province.

Dr. Sherar is an Affiliate Scientist at the Techna Institute University Health Network where he carries out research and development of minimally invasive thermal therapy technologies for cancer including radiofrequency ablation. Dr. Sherar received a BA in Physics from Oxford University in 1985 and his PhD in Medical Biophysics from University of Toronto in 1989.



Mitch Moneo assumed the role of Assistant Deputy Minister, Pharmaceutical Services Division in 2017. Prior to his current appointment, Mitch was the Executive Director of the Division's PharmaCare Information, Policy and Evaluation Branch where he was responsible for guiding the development, evaluation and research of pharmaceutical policies that support equitable and sustainable patient access to effective drug therapies. A key accomplishment was the drafting of BC's Pharmaceutical Services Act, a comprehensive legislative framework for the one-billion dollar BC PharmaCare program.

In addition to his role at the Ministry, he currently serves as a director on the board of the Canadian Agency for Drugs and Technology in Health; is vice-chair of the pan Canadian Pharmaceutical Alliance (pCPA) governing council; and is a member of the Drug Safety and Effectiveness Network steering committee.



Jatinder Harchowal has been a hospital pharmacist for over 25 years. He is currently Chief Pharmacist and a Clinical Director in the Royal Marsden Hospital (RMH), a world leading cancer hospital, leading a team of 140 staff to ensure patients receive the most up to date medicines in the safest way. Jatinder is also the medicines lead for the RM Partners West London Cancer Alliance - a programme designed to test new and innovative pathways to improve the earlier diagnosis of patients with cancer and recently led on a programme to introduce biosimilar Rituximab safely and consistently in oncology. Jatinder is currently the Chair of the Royal Pharmaceutical Society's Hospital Expert Advisory Group and the London Chief Pharmacists Group.

Jatinder has been a Chief Pharmacist for over 14 years in various hospitals including Brighton and Ealing. Jatinder has previously worked in a number of different pharmacist roles in various hospitals across London, including Barts, King's College and Charing Cross Hospitals. He qualified in 1991 with a Bachelor in Pharmacy Degree and became a member of the Royal Pharmaceutical Society. Jatinder obtained an MSc in Clinical Pharmacy Practice in 1996 from London and completed Diploma in Management Studies in 2000 with the Kingston University. Jatinder is a current Health Foundation fellow and has recently completed the Health Foundation's Masters in Leadership and Quality Improvement programme (Generation Q).



Pam Goldsilver practiced as an Occupational Therapist, both as a clinician and in administration until she retired in late 2008. Pam was diagnosed with breast cancer in November 2005. She completed all her treatment, including hormone therapy in mid-2011. Pam serves as a board member at Sprint Senior Care and is a Patient and Family Advisor with North York General Hospital (NYGH). Previously, she co-chaired the Patient and Family-Centred Advisory Council at NYGH. Through this involvement, Pam participated in numerous committees to inform decision-making, including the Quality of Care committee, Choosing Wisely committee, and hiring panels for executive and director positions at NYGH.

In addition to her work with Sprint Senior Care, Pam is widely involved with other health organizations. This includes volunteering as a peer support volunteer at WellSpring, providing feedback and inform Health Quality Ontario, and participating in the Brokered Dialogues project at Choosing Wisely Canada.



Dr. Eitan Amir is a Medical Oncologist at Princess Margaret Cancer Centre in Toronto and an Associate Professor in the Department of Medicine at the University of Toronto. He serves as the Cancer Care Ontario Systemic Therapy Lead for Toronto Central South and as the Vice-Chair of the Cancer Research Ethics Board at University Health Network. Dr. Amir completed his medical training at the University of Manchester, UK. He then completed a PhD in Clinical Epidemiology at the University of Toronto. Dr. Amir has over 200 peer-reviewed publications as well as numerous published abstracts and book chapters.



Kathy Gesy was the Director of Oncology Pharmacy Services for the Saskatchewan Cancer Agency for many years. In this role, Kathy was responsible for pharmacy operations and managed the provincial cancer drug budget. Nationally, Kathy was active on a number of committees, including chair of pan-Canadian Oncology Drug Review's Provincial Advisory Group, a member of the pan-Canadian Pharmaceutical Alliance leading national oncology drug pricing negotiations and several CAPCA committees related to drug safety, drug shortages and national alignment of cancer drug program implementation. Kathy recently retired in June 2018, but has continued to support the Cancer Agency, CAPCA, and the Canadian Agency for Drugs and Technologies in Health in various capacities.



Jessica Arias is a Program Manager with Cancer Care Ontario's Provincial Drug Reimbursement Programs Unit. In this role, Jessica is responsible for the strategic planning and financial management of the program which includes data management, forecasting public drug expenditures, implementation of policy and process improvement activities, and planning program initiatives.



Dr. Leta Forbes began her career as a Medical Oncologist at the Durham Regional Cancer Centre in Oshawa Ontario in 2004. Her administrative career started in 2007 as the Head of Medical Oncology and the Regional Quality Lead for Cancer Care Ontario. In 2011 she became the Chief and Medical Director of Oncology and continued this role until March of 2018. Since 2016 she has been the Head of Systemic Therapy at Cancer Care Ontario and together with a dedicated CCO team, is responsible for the oversight of the quality, safety, access and funding of systemic treatment in Ontario. Dr. Forbes has had a medical practice in the communities of Oshawa, Peterborough and Cobourg and continues to see patients with breast and gynecological cancers in Oshawa.



Dr. Henry Avern was a consultant rheumatologist for 12 years in the UK and then moved to Kingston, Ontario where initially he was Director of Clinical Skills. He left the division of rheumatology and joined the department of family medicine, and at the same time moved in to the community.

Dr. Avern has been involved in improving healthcare to aboriginal communities on a National basis, and has been President of the Ontario Rheumatology Association for the last three years. Outside medicine his main interests are brewing beer and fishing.



Dr. Gary Pansegrau is a Medical Oncologist with a focus on breast cancer and melanoma, and is the Associate Medical Director at BC Cancer Vancouver. Previously, Dr. Pansegrau served as the Department Head for Medical Oncology and the Regional Medical Director for BC Cancer Surrey. Since 2013 he has been the Chair of the BC Cancer Priority and Evaluation Committee.



Dr. Bruce Colwell received his undergraduate degree at Mount Allison University in 1983, and his medical degree from Dalhousie University, in Halifax, Nova Scotia, in 1987. After a rotating internship, he worked for two years prior to doing his residency in internal medicine in Halifax completing in 1993. He then did Medical Oncology subspecialty training at the University of Calgary. He joined the staff of the Queen Elizabeth II Health Sciences Centre in Halifax in the Division of Medical Oncology in 1995. He is currently an Associate Professor of Medicine at Dalhousie University.

During his career he started the Residency Training Program in Medical Oncology and was Program Director from 1999 to 2012. During that time he was a member of the Royal College of Physicians and Surgeons of Canada's nucleus committee for medical oncology as well as the examination committee. He has been involved in clinical research that has led to several publications including the New England Journal of Medicine. He is a member of the GI, Breast and Sarcoma tumor site groups. He is Chair of the Gastrointestinal Tumor Site Group. He is a member of NSHA Drugs and Therapeutics Committee and chairs the Oncology Therapeutics Subcommittee for that same group. He is President of the Canadian Association of Medical Oncology Committee. He has an interest in biosimilars, GI, and breast cancers, and resident education.



Deborah Maskens, is a kidney cancer patient and patient advocate. Her current roles include Vice-Chair of the International Kidney Cancer Coalition (IKCC). Along with another patient, she Co-Founded Kidney Cancer Canada in 2016 and played an active leadership role for 10 years. During this time she focused on advocacy, health technology assessment, patient support and navigation.

In 2016, Deb was awarded the Canadian Governor General's Meritorious Service Medal, Canada's highest award for her dedication and professionalism in patient advocacy and volunteer service.



Denis Morrice is the Executive Director of the Ontario Rheumatology Association. He is a founding member of the Best Medicines Coalition and a representative of the Canadian Epilepsy Alliance. Denis serves as a board member on the Pharmaceutical Advertising Advisory Board. He is also a committee member for the Federal Multi-Stakeholder Steering Committee on Drug Shortages and the Patient Advisory Committee for the Ontario Best Practices Research Initiative. Previously, Mr. Morrice was a member of the Stakeholder Advisory Committee on Marijuana Medical Access Regulations, the Canadian Cochrane Collaboration Network, the Institute for Musculoskeletal Health and Arthritis/CIHR, the Canadian Arthritis Network/NCE, and the Canadian Joint Replacement Registry. Mr. Morrice passionately believes that: “Those affected by a decision should be involved in making that decision.”



M.J. DeCoteau is Founder and Executive Director of Rethink Breast Cancer, the young women’s breast cancer movement. Rethink seeks to bring relevant awareness to 40s-and-under crowd, foster a new generation of young and influential breast cancer supporters, and respond to the unique needs of young women going through breast cancer.

At 22, after losing her mother to a 4-year battle with breast cancer, Ms. DeCoteau was hard pressed to find relevant information that was not scary and overwhelming about her own risk factors. She quickly realized that young people were in the dark about breast cancer simply because they weren’t being targeted by awareness campaigns and other efforts. By 2001 she had brought together a group of Canada’s most innovative, energetic, and creative minds to found Rethink Breast Cancer, putting young people concerned about and affected by the disease in the spotlight for the very first time.

In its first year, the charity secured the exclusive Canadian rights to the world-famous Fashion Targets Breast Cancer campaign. By 2004, Ms. DeCoteau was featured in *Maclean’s* magazine’s Honour Roll as one of the top 10 Canadians making a difference.

Today, Ms. DeCoteau remains responsible for the overall direction, management, strategy, and creative vision of a growing Rethink Breast Cancer. Rethink’s small but dynamic team of dedicated staff and volunteers have continued to pave the way for the young women’s breast cancer movement, creating ground-breaking new resources, campaigns, events, research, and advocacy initiatives to bring much-needed support and attention to the cause.



Barry D. Stein has been a member of the Bar of Quebec since 1981 and has devoted a significant portion of his practice to labour law and health and administrative law. Barry is a founding member of the Canadian Partnership Against Cancer National Colorectal Cancer Screening Network and is the President of Colorectal Cancer Canada (CCC). Under Barry's stewardship, CCC has developed national awareness and educational programs, as well as support programs for patients and their families. Barry has been a key advocate for population based colorectal cancer screening initiatives, patient and physician education and multidisciplinary health professional consensus statements and guidelines. He is a survivor of metastatic colorectal cancer and actively represents the interests of cancer patients by speaking both within Canada and internationally.



Sang Mi Lee is a Senior Pharmacist at the pan-Canadian Pharmaceutical Alliance (pCPA) Office, supporting the Canadian provincial, territorial, and federal public drug programs to strengthen collaboration and achieve better value for brand and generic drugs. She is a leader in providing technical expertise as well as policy, clinical and analytical advice about drug funding recommendations and pan-Canadian negotiations. She also participates on various national advisory committees to support the mandate of the Office. Sang Mi previously worked for the Ontario Public Drug Programs and held various roles, including manager of the Exceptional Access Program

Appendix 4: Breakout Session Questions on the Proposed Strategic Objectives

Breakout Table 1

Strategic Objective #1: Jurisdictions to adopt best practices in prescribing, preparation, labelling, dispensing, and administering biosimilars.

AND

Strategic Objective #2: Technical (e.g., IT) challenges of implementing biosimilars should be addressed, as to not limit preferred strategies when implementing biosimilars.

Goals Addressed

- Stakeholder Engagement
- Quality & safety

Breakout Session Questions

1. When considering the safe and effective delivery of systemic treatment from prescribing, dispensing, labelling to administration, how would you ensure the right product selection where a biosimilar exists throughout this process? What are the implementation challenges in particular, as it relates to your information systems?
 - a. Use a templated PPO or CPOE – what modifications are required at a prescriber level to allow for right product selection
 - b. Use an electronic pharmacy system for inventory, verification and dispensing – what modifications are required at a regimen build, preparation and dispensing/labelling level to allow for right product selection
 - c. For nursing verification and administration – what modifications are required to ensure right product selection at time of administration

Six months after the introduction of biosimilar drugs in Dr. M's centre, she would like to review the cohort of the patients who have received this for toxicity and tolerability in a retrospective review.

2. When considering information management needs in the systemic treatment process from adjudication, traceability, brand options, auditing, etc, what are the needs when considering the implementation of biosimilars?

Optional (if time permits):

3. Is there anything that would facilitate easier adoption of biosimilars as it applies to this process flow? (e.g. manufacturer information on extended stability, improved packaging, increased vial sizes to reduce wastage)

Breakout Table 2

Strategic Objective #3: Comprehensive education programs for health professionals and patients should be developed.

Goals Addressed

- Stakeholder Engagement
- Quality & safety

Breakout Session Questions

Objectives

1. Discuss the educational needs of health care providers, patients and caregivers as they relate to biosimilars (e.g. indication, efficacy, side effects, convenience/cost).
2. Strategize on the approach to deliver the education programs across Canada for health care providers, patients and caregivers.
3. Develop an implementation plan that is both immediate (in the next 6 months) and long-term (12 – 18 months).
4. Identify stakeholders that need to be engaged in the development and delivery of the education programs.

Questions

General:

1. Do you agree that this should be a strategic objective of the Oncology Biosimilars Action Plan? Would you modify this in any way?

Objective 1

- What are the learning objectives of the educational programs (e.g. provide drug information, comprehensive approach)?
- Who should the educational programs target?
- What topics should be addressed (PROMPT: pharmacology/pharmaceutics, policy on switching/substitution, indication for curative vs. palliative, efficacy data and extrapolation to other indications, side effects and monitoring)

Objective 2

- Who should be responsible for delivering the educational programs (local, provincial, national)?
 - At each of the levels, describe the roles and responsibilities [PROBE: Who are the stakeholders (e.g. academic institutions, CCO and other cancer agencies, professional organizations, Health Canada, pCPA, etc)]
- How should the educational programs be structured? Is it a one-time event that is delivered online or via paper format when new drugs are marketed or funded? Is it an ongoing program with annual requirements? Is it mandatory training or left as a professional development process?

- How should the educational programs be delivered (online vs. cpd events vs. printed materials)

Objective 3

- In the next 6 months, what needs to be developed and implemented to enable the successful adoption of a biosimilar?
- In the next 12 – 18 months, what needs to be developed and implemented to enable the successful future of biosimilars in Canada?

Objective 4

- Who do we need to engage to implement our plan?
 - Health care provider education
 - Patient and caregiver education

Breakout Table 3

Strategic Objective #4: Pricing and reimbursement policies are designed, based on best practices, to maximize opportunities for cost-savings. (e.g., drug supply chain risks, market share, etc.)

AND

Strategic Objective #5: Jurisdictions should adopt consistent policies related to pricing and reimbursement for oncology biosimilars.

AND

Strategic Objective #6: Oncology biosimilar implementation strategies should support the overall intent of creating a viable market for biosimilars.

Goals Addressed

- Stakeholder Engagement
- Evidence-informed Policy Approach
- Sustainability & Value for Money

Breakout Session Questions

1. Do you agree that this should be a strategic objective of the Oncology Biosimilars Action Plan? Would you modify this in any way?
2. What are key considerations with regards to reimbursement of oncology biosimilars (e.g., shortages, # products)
3. Should we aim to keep the innovator product on the market?
4. What number of biosimilars is feasible to implement at the hospital, provincial, and national level? How do you propose we manage biosimilar brands that subsequently enter the market?

5. What national initiatives will be required to ensure consistent reimbursement policies across the jurisdictions and how will they be monitored?

Breakout Table 4

Strategic Objective #7: Develop clear policies regarding clinical scenarios (e.g., initiating, switching, generalizability).

Goals Addressed

- Stakeholder Engagement
- Evidence-informed Policy Approach

Breakout Session Questions

1. Do you agree that this should be a strategic objective of the Oncology Biosimilars Action Plan? Would you modify this in any way?
2. What considerations should be made when initiating a patient on a biologic product; when switching a patient from reference product to biosimilar?
3. In what scenario should a patient be switched vs. kept on the reference product?
4. Bevacizumab biosimilar has been approved for colorectal indications. Currently, the reference product is also indicated for ovarian and cervical cancer. Are you supportive of using biosimilars in non-Health Canada approved indications? Please highlight any challenges or considerations.
5. What terminology should be used when considering use of a biosimilar for a non-Health Canada approved indication? (e.g., generalize, extrapolate)

Breakout Table 5

Strategic Objective #8: Cancer systems commit to re-investing savings from oncology biosimilars back into the cancer system.

Goals Addressed

- Stakeholder Engagement
- Sustainability & Value for Money

Breakout Session Questions

1. Do you agree that this should be a strategic objective of the Oncology Biosimilars Action Plan? Would you modify this in any way?
2. Do you feel that all savings should be reinvested to the cancer system or a proportion? Are there other areas to reinvest?
3. How do you think savings should be re-invested into the cancer system (e.g., innovations, local level, education)

Breakout Table 6

Strategic Objective #9: Real-world Evidence should be collected to assess the utilization and confirm the clinical effectiveness and safety of oncology biosimilars.

Goals Addressed

- Stakeholder Engagement
- Sustainability & Value for Money

Breakout Session Questions

1. Do you agree that this should be a strategic objective of the Oncology Biosimilars Action Plan? Would you modify this in any way?
2. How soon after the start of public funding would you expect to see outcomes data related to biosimilars? (Outcomes can apply to utilization, uptake, survival and safety).
3. What other clinical outcomes related to biosimilars would be of interest?
4. How do you propose clinical outcomes (such as survival and safety), utilization and budget impact (savings) be used for decision-making?
 - a. Note for facilitator/scribe: We may need some prompts about what we mean by “how”? Do we mean how these endpoints can be acted upon depending on the results? Or do we mean how as in what process can we use (through pERC/pCPA or through OSCCD or directly as part of built in PLA)?

5. In thinking about a potential monitoring plan for biosimilars, are there any features specific to monitoring biosimilars that would differ from monitoring other non-biosimilar cancer drugs? (A monitoring plan would include a framework to collect real-world data, generate real-world evidence, conduct analysis, and disseminate / use findings).
6. If there are minimal resources to support monitoring of biosimilars, how should decisions be made regarding which biosimilars should be monitored?

Strategic Objective #10: Stakeholders to be engaged throughout the implementation of oncology biosimilars to validate and inform ongoing work.

This objective was not discussed in a breakout session. It was embedded in the summit's activities and as part of all other strategic objectives.