

Position Statements for the Implementation of Oncology Biosimilars from the pan-Canadian Clinical Operations Working Group

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## Terms and Abbreviations

**Auto-substitution –** refers to a therapeutic substitution automatically executed by a pharmacist within an institution, through a documented policy.

**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.

CCO - Cancer Care Ontario is the principal cancer advisor to the Ontario government.

**Compounding label** – a label that contains all of the relevant information in order to compound the final product, without requiring any additional information for preparation (i.e., the label includes information such as the drug name, concentration, dose, and volume required for preparation).

**COWG** – Clinical Operations Working Group

**CPOE** – Computerized Physician Order Entry

**DIN** – Drug Identification Number

**EMR** – Electronic Medical Record

FDB – First Databank

**INN** – International Non-proprietary Name – The terms: INN, generic, and non-proprietary (common) name can be used interchangeably when referring to the naming of reference biologics and biosimilars in the context of Health Canada's Policy Statement on the Naming of Biologic Drugs. The interchangeable use of these terms does not supersede Health Canada's guidance that biosimilars are not generic versions of reference biologics.

LA/SA - Look-alike Sound-alike

MAR – Medication Administration Record

**pCPA** – the pan-Canadian Pharmaceutical Alliance is an alliance of all 13 Canadian provinces and territories, including three federal drug plans that collaborate to negotiate for brand name and generic drugs to achieve greater value for publicly funded drug programs and patients.

#### **PPO** – Pre-Printed Order

**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.





## Introduction

In Canada, therapeutic oncology biosimilars are expected to be implemented in late 2019. Although provincial cancer systems differ in the organization and delivery of cancer services, all need to assess the impact of biosimilars implementation, with special consideration given to the administration of these therapies.

The pan-Canadian Pharmaceutical Alliance (pCPA) and Cancer Care Ontario (CCO) have collaborated to lead the pan-Canadian Oncology Biosimilars Initiative (pCOBI), which is a cancer-specific strategy that recognizes the unique considerations for the implementation of oncology biosimilars.

The pCOBI has defined seven priority areas to facilitate the implementation of oncology biosimilars. One priority area is to assess whether oncology biosimilars may impact safety and workflow efficiency in the clinical setting.

A national Clinical Operations Working Group (COWG), comprised of oncology prescribers, oncology pharmacists and oncology nurses from across Canada, was established to evaluate the impact of implementing oncology biosimilars into clinical practice, and to support the consistency of implementation across provincial cancer systems where appropriate. The working group identified areas where the implementation of biosimilars might require changes in the clinical operations process flow (Appendix 1) to ensure safe and efficient usage of biosimilars. As a result, the working group has developed position statements aimed at guiding organizations' and jurisdictions' implementation of biosimilars throughout the entire clinical operations process flow.

The COWG worked to align position statements with Health Canada's nomenclature on the naming of biologic drugs:

"Health Canada has decided that biologic drugs, including biosimilars, will be identified by their unique brand name and non-proprietary (common) name, without the addition of a product-specific suffix. Both the brand name and non-proprietary name should be used throughout the medication use process so that biologics that share the same nonproprietary name can be distinguished by their unique brand names."<sup>1</sup>

In an ideal state, the COWG agreed that both the unique brand name and non-proprietary (common) name should be used throughout the medication use process (i.e., both drug names are to be included in the Computerized Physician Order Entry, Electronic Medical Record, and in the Medical Administration Record<sup>\*</sup>). However, this would require seamless technological capability throughout the medication administration cycle, requiring all jurisdictions and institutions to have advanced IT systems. Currently, this may not be feasible in every jurisdiction and/or institution, therefore the COWG developed all recommendations in view of this limitation.

\*Note: In the case of smart pumps, the COWG does not recommend that the brand name be included in stand-alone smart pumps, but supports including the brand name in

<sup>&</sup>lt;sup>1</sup> Health Canada. 2019. Notice to Stakeholders – Policy Statement on the Naming of Biologics Drugs <u>https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/biosimilar-biologic-notice-to-stakeholders-drugs-naming-of-biologics.html</u>





smart pumps that are fully-integrated electronically with other IT systems. Additionally, the COWG does not recommend including the drug brand name in the naming of regimens.

The COWG reached consensus on each position statement through facilitated discussions. Scenario analysis was used as a method to problem-solve operational challenges: the COWG considered different clinical scenarios for each operational step, took these scenarios to their respective jurisdictions, and gathered further input as part of the consensus building process. Where applicable, these scenarios have been described to provide context to the recommendations. Additionally, the COWG identified barriers and enablers to implementation, which have been outlined for each operational step, and identified future directions for biosimilars implementation.





### Notes for the Reader

### Out of Scope for the COWG

The COWG recognizes the importance of clinician and patient education, clinical decisionmaking, funding and reimbursement policies, adjudication processes and systems, monitoring and evaluation, and reinvestment of cost-savings, however these were out-of-scope for this working group.

### **Biosimilars Terminology**

Throughout the position statement, the term INN (International Nonproprietary Name) is used. Health Canada has used the term non-proprietary (common) name, and individuals may be more accustomed to using the term "generic name". All of these terminologies can be used interchangeably when referring to the naming of reference biologics and biosimilars in the context of Health Canada's Policy Statement on the Naming of Biologic Drugs. The interchangeable use of these terms does not supersede Health Canada's guidance that biosimilars are not generic versions of reference biologics.

### Patient Safety

The COWG anticipates that biosimilars will not pose an increased risk to patient safety and that the typical processes that occur within a pharmacy department regarding patient safety issues (e.g., dealing with latex rubber stoppers in patients with a latex allergy) will continue with biosimilars implementation. The COWG also anticipates that any patient safety mitigation strategies that exist for two *different* biologics (not between a reference biologic and its biosimilar) will continue and will not be influenced by how biosimilars and reference biologics are handled.

### Jurisdictional and/or Institutional Implementation

The COWG recommends the position statements in this document as best practices for biosimilars implementation across Canada and encourages their uptake as they are relevant to safe and effective practices of care. The COWG recognizes that jurisdictions and institutions differ in their policies and procedures. As such, some jurisdictions and/or institutions may have additional requirements that must be satisfied, and therefore may not align entirely with these recommendations. The recommendations in this document are for guidance purposes only.





## **Executive Summary**

### Procurement

- Biosimilars are to be considered as look-alike, sound-alike (LA/SA) products for operational safety.
- Pharmacies are to use the unique Drug Identification Number (DIN), or item number to distinguish biosimilars from reference biologic drugs at procurement.
- Biologics and biosimilars are to be entered as separate drug database entries to allow for tracking utilization, financial impact, and other data.
- If the product is received from an international jurisdiction that does not use the same nomenclature, the product is to be entered as a separate drug entry using Canadian nomenclature.

### Receiving

- Biosimilars are to be considered as LA/SA products for operational safety.
- Similar to all drugs at the receiving stage, staff are to first look at the brand of the drugs received, and then confirm the order with the packing slip to prevent confirmation bias.

### Storing

- Biosimilars are to be considered as LA/SA products for operational safety.
- Auxiliary labels are to be placed on reference biologics and biosimilars. The auxiliary labels used for biosimilars are to follow LA/SA guidance.
- When storing biosimilars, LA/SA shelf-talkers and stop signs can be used to alert pharmacy staff.
- Pharmacies are to physically separate biosimilars from the reference biologic, and/or from similar looking products (either by physical location, refrigerator, or physical separation within the refrigerator). If the biosimilar is stored in the same refrigerator or physical location as the reference biologic, or similar looking products, then the biosimilar should not be stored in alphabetical order by international non-proprietary name (INN). The reference biologic and biosimilar could be kept in alphabetical order by <u>brand name</u>.







### **Regimen Building and Provider Prescribing**

- Treatment facilities are to only use one biologic brand for a specific indication and prescribers will
  not able to change the brand. Using only one brand for an indication allows for easier regimen
  building in both Computerized Physician Order Entry (CPOE) and pre-printed order (PPO) systems.
  Using only one brand for an indication will also facilitate correct identification of the brand being
  prescribed and dispensed for patient administration. This scenario will require:
  - 1. No changes needing to be made to existing regimens which to date, only display the INN.
  - 2. The creation of a documented policy, via delegated authority mechanisms, (within a health authority, cancer agency, or local institution) that clearly indicates the brand being used for an indication and any other policy considerations (e.g., new patients starting on a biosimilar vs. patients continuing therapy on the current brand). This could include, but is not limited to, an auto-substitution.
- If prescribers are able to choose a brand for an indication, this would require more complex regimen builds and increased prescriber knowledge of CPOE systems to prescribe the desired brand. Recommended regimen building options for this scenario are to:
  - 1. Only include one brand in the regimen (i.e. the reference biologic or one biosimilar). If the prescriber wants to change the default brand, they must manually add the desired brand and delete the default brand.
  - 2. Have a system that is capable of listing a default brand in the regimen, but an option for a physician to see additional brands and select one.
- Clinical documentation and verbal confirmation are not recommended to be used as an order for brand selection.

### Verification

- In a treatment facility where the prescriber is not able to choose a brand for an indication, an autosubstitution policy should be clearly outlined. A collaborative, multidisciplinary team of clinicians should approve this auto-substitution policy prior to implementation of biosimilars.
- In a treatment facility where the prescriber is able to choose a brand for an indication, and where CPOE systems have character limitations that do not allow for the recommended Health Canada nomenclature, the brand should be documented in another area of the CPOE system that is accessible to all relevant staff.

### Preparation

- LA/SA products, including reference biologics and biosimilars, must have the DIN or manufacturer, lot and expiry recorded, regardless of whether institutions have an electronic or manual system.
- When using compounding labels, the DIN or manufacturer, lot and expiry should be recorded.

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### Labelling

- The label is to include both the INN and brand name.
- To best identify the product, the product is to be labelled first with its INN, followed by its brand name.

### **Nursing Administration**

- A provincial decision is to be made with respect to auto-substitutions to ensure consistency across the province, and to be appropriately prepared for intra-provincial patient movement. The actual auto-substitution will be implemented at the local level.
- Auto-substitution orders must be accessible by nursing to ensure that they can efficiently confirm if an auto-substitution has occurred. This will help reduce the effort needed to confirm the status of the order.
- The INN must always be visible, and match at all checkpoints: Label →CPOE/ Electronic Medical Record (EMR)/PPO → Smart Pump → Label → Medication Administration Record (MAR).
- Only the INN is required for the smart pumps, similar to the naming convention recommended for the CPOE, EMR, and PPO systems.
- The documentation of drug administration is to be recorded in a MAR, either manually or electronically, without the need to specify a brand.
- If the reference biologic has off-label administration evidence (e.g., infusion rate) that has been incorporated into clinical practice, these same practices may be used for the biosimilar in the same situations (e.g., first dose vs. subsequent doses).







## **Overview of Position Statements**

### Procurement, Receiving, and Storing

The following assumption was made:

• Procurement, receiving, and storing of biosimilars will be similar to the current processes for all medications.

### **Position Statements**

### Overarching Position

The COWG takes the position that biosimilars are to be considered as look-alike, sound-alike (LA/SA) products with respect to operational safety, as it applies to the areas of procurement, receiving, and storing.

### Procurement

- Pharmacies are to use the unique Drug Identification Number (DIN), or item number to distinguish biosimilars from reference biologic products at procurement.
- Biologics and biosimilars are to be entered as separate drug database entries to allow for tracking utilization, financial impact, and other data.
- If the product is received from an international jurisdiction that does not use the same nomenclature, the product is to be entered as a separate drug entry using Canadian nomenclature.
  - For example, if a product is received from the United States via the Special Access Program as biologic-xxyy, the product is to be entered as the INN without the 4-letter suffix.

### Receiving

• Similar to all drugs at the receiving stage, staff are to first look at the brand of the drugs received, and then confirm the order with the packing slip to prevent confirmation bias<sup>2</sup>.

### Storing

- Auxiliary labels are to be placed on reference biologics and biosimilars. The auxiliary labels used for biosimilars are to follow LA/SA guidance to enhance the operational safety when handling biosimilars.
  - Institutions are advised to refer to their policy for LA/SA drugs, or high-alert, drugs for appropriate auxiliary labels.
- When storing biosimilars, LA/SA shelf-talkers and stop signs can be used to alert pharmacy staff.

<sup>&</sup>lt;sup>2</sup> The tendency to process information by looking for, or interpreting, information that is consistent with one's existing beliefs.





 Pharmacies are to physically separate biosimilars from the reference biologic, and/or from similar looking products (either by physical location, refrigerator, or physical separation within the refrigerator), if possible. If the biosimilar is stored in the same refrigerator or physical location as the reference biologic, or similar looking products, it is recommended that the biosimilar not be stored in alphabetical order by international non-proprietary name (INN). The reference biologic and biosimilar could be kept in alphabetical order by <u>brand</u> <u>name</u>.

### Additional Information

Enabler for procurement, receiving, and storing of biosimilars

• The COWG encourages Health Canada to mandate barcoding on all unit of use vials and advocates that the Pharmaceutical Industry provide distinct packaging to ensure appropriate drug identification through procurement, receiving and storing.

#### Barriers for procurement, receiving, and storing of biosimilars

- Limited capacity of IT systems (used in procurement and receiving) to adhere to the nomenclature for tracking reference biologics and biosimilars will impact staff's ability to clearly view what brand is being procured and received.
- Similar packaging of the reference biologic and biosimilar will increase the potential for errors in receiving and storing products.
- Multiple brands will increase workload for inventory management.
- Storing more brands will increase storage needs, which may increase costs and/or require more pharmacy space.

### Operational safety issue for procurement, receiving, and storing of biosimilars

• The primary operational safety issue will be ensuring that products are kept in their correct location. Enacting processes and policies used to manage LA/SA products are recommended when managing reference biologics and biosimilars.

### **Regimen Building and Provider Prescribing**

When reviewing these areas of the clinical operations process flow, two scenarios were considered:

Scenario 1: Treatment facilities are to only use one biologic brand for a specific indication and prescribers are not able to change the brand.

Scenario 2: Treatment facilities do not specify which biologic brand should be used for an indication and prescribers are able to choose a brand.

In addition, the following assumptions were made:

• All regimen builds will be dependent upon jurisdictional policy. Each jurisdiction will also determine policies for how biosimilars will be used when initiating and switching patients.





• Regimen/protocol taxonomies for systemic therapy currently do not exist with international or national standards. As such, it was assumed that a regimen/protocol taxonomy will not be developed for biosimilars.

### **Position Statements**

- The COWG recommends that institutions implement Scenario 1 to allow for easier regimen building in both Computerized Physician Order Entry (CPOE) and pre-printed order (PPO) systems. Using only one brand will also facilitate correct identification of the brand being prescribed and dispensed for patient administration. This scenario will require:
  - 1. No changes needing to be made to existing regimens which to date, only display the INN.
  - 2. The creation of a documented policy, via delegated authority mechanisms, (within a health authority, cancer agency, or local institution) that clearly indicates the brand being used for an indication and any other policy considerations (e.g., new patients starting on a biosimilar vs. patients continuing therapy on the current brand). This could include, but is not limited to, an auto-substitution.
- If a treatment facility were to choose Scenario 2, this would require more complex regimen builds and increased prescriber knowledge of CPOE systems to prescribe the desired brand. Recommended regimen building options for Scenario 2 are to:
  - Only include one brand in the regimen (i.e. the reference biologic or one biosimilar). If the prescriber wants to change the default brand, they must manually add the desired brand and delete the default brand.
  - 2. Have a system that is capable of listing a default brand in the regimen, but an option for a physician to see additional brands and select one.
- If an institution moves forward with Scenario 2, an individual drug within a regimen is to be named first by its international non-proprietary name (INN), followed by its brand name.
- The COWG does not recommend that clinical documentation be used as an order for the selection of a brand; verbal confirmation is also not recommended.

### Additional Information

### Enablers for regimen building and provider prescribing

- Drug databases like the First Databank (FDB) Canada should use Health Canada's naming convention for biologics to ease implementation of biosimilars.
- CPOE and Electronic Medical Record (EMR) systems should utilize up-to-date drug databases to ensure that the most recent data is available for these systems.

### Barriers for regimen building and provider prescribing

• The use of CPOE/EMR and/or PPOs varies within jurisdictions. This may cause confusion if the orders are not easily communicated to all of the clinicians that are involved in the care of a patient on a reference biologic or biosimilar.





 If an institution moves forward with Scenario 2, regimens (electronic or paper-based) will need to be updated or created with each arrival of a new brand resulting in increased workload.

### Operational safety issues for regimen building and provider prescribing

- Depending on the scenario and option(s) chosen by a jurisdiction or institution, the
  operational risks of prescribing the incorrect brand or selecting the incorrect brand for
  preparation may either increase or decrease. The COWG has identified the following
  potential safety issues:
  - Scenario 1:
    - Potential increased risk of patients' receiving incorrect brand due to picking/mixing error.
  - Scenario 2:
    - Potential decreased risk of picking/mixing error by the pharmacy as the specific brand would be indicated on the script.
    - Potential increased risk of error at the point of order entry if a physician wanted to change the brand.
    - In a paper-based system, including all regimens may overcrowd the PPO and potentially detract from other important information.
    - Some CPOE and EMR systems are unable to accommodate both INN and brand names, impacting the display of the brand being prescribed. See Verification for documentation process.
    - Use of PPOs present additional risk when more options for selection are available. Clear communication must be in place so that all members of the healthcare team are aware of what is being prescribed to the patient.

### Verification

When reviewing this area of the clinical operations process flow, the following two scenarios were considered:

Scenario 1: A prescriber works at an institution that has implemented an autosubstitution policy and is unable to choose a brand for an indication.

Scenario 2: A prescriber works at an institution where there is no auto-substitution policy and is able to choose a brand for an indication.

In addition, the following assumptions were made:

- The verification procedure will remain the same regardless of the drug prescribed.
- Off-label use of a reference biologic or its biosimilar will depend on individual jurisdictional policy.





### **Position Statements**

- In a treatment facility where the prescriber is not able to choose a brand for an indication, an auto-substitution policy should be clearly outlined. A collaborative, multidisciplinary team of clinicians should approve this auto-substitution policy prior to the implementation of biosimilars.
- In a treatment facility where the prescriber is able to choose a brand for an indication, and where CPOE systems have character limitations that do not allow for the recommended Health Canada nomenclature, the COWG recommends that the brand be documented in another area of the CPOE system that is accessible to all relevant staff.

### **Preparation**

The COWG did not explore scenarios when discussing the preparation of a biosimilar. Instead, the COWG discussed the tools used to document and enable safety checks in the preparation of systemic therapy.

The following assumptions were made:

- Biosimilars are to be considered LA/SA products for the operational safety of a clinic. The preparation of a biosimilar will follow the same process as any LA/SA product.
- Biosimilars will continue to have the same format as their reference biologic the same vial sizes, concentrations and administration instructions.
- In the case of inadvertent administration of a biosimilar brand for a reference biologic brand, there is no expected patient safety risk because the biosimilar brand has been deemed safe and effective by Health Canada.

### **Position Statements**

- The COWG recommends that LA/SA products, including reference biologics and biosimilars, must have the DIN or manufacturer, lot and expiry recorded, regardless of whether institutions have an electronic or manual system.
  - When using compounding labels, the DIN or manufacturer, lot and expiry should be recorded.

### Labelling

When reviewing this area of the clinical operations process flow, the following two scenarios were discussed:

Scenario 1: There are no changes made to the label.

Scenario 2: There are changes made to the label.





### Position Statements

- The COWG recommends that the label include both the INN and brand name.
- The COWG recommends labelling the product first by its INN followed by its brand name to best identify the product.

### Additional Information for Verification, Preparation and Labelling

### Enablers for verification, preparation, and labelling

- The implementation of a clear auto-substitution policy will allow for proper documentation of the ordered brand. This will allow for a safe preparation process that will ensure traceability of the products, and an accurately labelled final product.
- Education will be required to ensure the auto-substitution is clear and understood.

### Barriers for verification, preparation, and labelling

- Limited capacity of CPOE, EMR, and pharmacy information systems to display the full INN and brand names of reference biologics and biosimilars could result in an incomplete match between the CPOE or EMR, and the labelled product.
- The lack of legislation for barcodes on the unit of use (vial) may pose a barrier, especially among sites using intravenous (IV) automation or IV workflow solutions.

### Operational safety issues for verification, preparation, and labelling

- LA/SA guidance should be used when handling reference biologics and biosimilars. Many standards of care currently use these concepts and as such should be maintained when preparing and labelling biosimilars.
- If labels are truncated and the entire INN and brand name are not visible, institutions are to wrap text, or enter the brand name in a separate field so that both names are visible on the label.

### **Nursing Administration**

When reviewing this area of the clinical operations process flow, the following scenario was discussed:

A prescriber works at an institution that has implemented an auto-substitution policy and is unable to choose a specific brand.

*Note:* This scenario could include a model whereby a patient is seen at one cancer centre and then receives treatment at another institution that is closer to home. In this geographical model of care, the assumed change in location is intra-provincial. Patients who receive treatment in another province will be governed by that province's funding policies.

In addition, the following assumptions were made:





- Based on previous recommendations made by the COWG:
  - There will be no changes made to the regimens, therefore only the INN is to be included in the CPOE, EMR or PPO.
  - The label will include both the INN and brand name.
- The CPOE, EMR or PPO, Smart Pump and Medication Administration Record (MAR), need to be reconciled with the label to complete the independent double check.

### **Position Statements**

- The COWG recommends that:
  - A provincial decision be made with respect to auto-substitutions to ensure consistency across the province, and to be appropriately prepared for intra-provincial patient movement. The COWG acknowledges that the actual auto-substitution will be implemented at the local level.
  - The auto-substitution orders must be accessible by nursing to ensure that they can efficiently confirm if an auto-substitution has occurred. This will help reduce the effort needed to confirm the status of the order.
  - The INN must always be visible, and match at all checkpoints: Label  $\rightarrow$  CPOE/EMR/PPO  $\rightarrow$  Smart Pump  $\rightarrow$  Label  $\rightarrow$  MAR.
  - Only the INN is to be used in the smart pumps, similar to the naming convention recommended for the CPOE, EMR, and PPO systems.
  - The documentation of drug administration is to be recorded in a MAR, either manually or electronically, without the need to specify a brand.
  - If the reference biologic has off-label administration evidence (e.g., infusion rate) that has been incorporated into clinical practice, these same practices may be used for the biosimilar in the same situations (e.g., first dose vs. subsequent doses).

### Additional Information

### Enablers for nursing administration

- A clear auto-substitution policy implemented at the institution would ensure that nurses are able to reconcile the order and the product to be administered.
- A thorough committee (e.g., Pharmacy and Therapeutics) submission that includes information for off-label infusion rates for biosimilars that are the same as the reference biologic will ensure seamless administration changes.

### Barriers for nursing administration

• Different IT systems (such as CPOE or EMR systems) may store auto-substitution orders in different areas of the patient's chart, increasing the effort to find the order.

### Operational safety issue for nursing administration

• If an independent double check process at your institution includes confirming the drug's brand, this information will be clearly indicated on the label. An institutional policy that clearly





indicates which brand is being used must be documented in an accessible location in a patient's chart to help clarify the remainder of the medication management process.

## **Future Directions**

- Advocating for Health Canada to mandate unique barcodes on products will help the validation of products at the procurement, receiving, storing, and preparation stages of the clinical operations process flow.
- Evolving IT systems that are able to display both INN and brand names (i.e. increase character length allowed within a field) will allow for clearer prescribing, if an institution chooses to change all regimens.
- CPOE/EMR systems that are updated to accommodate advanced prescribing will better allow for an institution with prescriber choice, to select the intended brand being prescribed.
- Ensuring IT systems can document orders from an auto-substitution policy in an obvious location of the patient chart will increase ease of product verification for all clinicians.
- Considering how institutions may manage additional biosimilars of the same drug entering the market will help identify whether the recommendations in this position statement need to be modified.
- Evaluating strategies for truncated labelling post-implementation will address any human factor issues that may arise from wrapping text (e.g., overcrowded label, small font).
- Quality evaluation of biosimilar implementation by the multidisciplinary team should be done at the local level.
- Sharing learnings and/or unintended consequences between jurisdictions within 6 months of implementation will allow for appropriate evaluation of these position statements.

## Conclusion

The COWG provided recommendations for each stage of the clinical operations process flow to assist with biosimilars implementation, taking into consideration the complicated steps associated with systemic therapy. Additionally, the COWG addressed enablers and strategies to mitigate operational risks and/or barriers to ease implementation and encourage consistency across the country. Finally, the COWG recognized that some issues are outstanding, and/or require follow-up and have thus outlined future directions for institutions to be cautious of, as biosimilars enter the Canadian market.





## Appendix 1. Clinical Operations Process Flow







## Appendix 2. Resources

#### Health Canada's Policy Statement for Naming Biologics, including Biosimilars

Health Canada. 2019. Notice to Stakeholders – Policy Statement on the Naming of Biologic Drugs. <u>https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/biosimilar-biologic-notice-to-stakeholders-drugs-naming-of-biologics.html</u>

### Institute for Safe Medication Practices' Look-Alike, Sound-Alike Risk Reduction Steps

Institute for Safe Medication Practices. ISMP Medication Safety Alert. 2009; 14(5): p.5.

### **Checklist for Safer Chemotherapy Practice**

Dobish R, Shultz J, Neilson S, Raven A, Chambers CR. Worksheets with embedded checklists support IV chemotherapy safer practice. J Oncol Pharm Pract. 2014; 22(1):142-150.



