pCPA pan-Canadian Pharmaceutical Alliance

APP Alliance pancanadienne pharmaceutique

Biologics Policy Directions & pCPA Negotiations

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BACKGROUND

Over the last decade, biologic drugs (biologics) have become the treatments of choice for a range of conditions, particularly in the gastrointestinal, rheumatological, and metabolic space. Canada has among the world's highest prevalence rates of diseases that are responsive to biologics; many of these are chronic conditions that require lifelong treatment. While biologics can be life changing for many patients, they often come at a very high price. With costs that can exceed $25,000 per patient per year, biologics disproportionately impact and strain health expenditure budgets.

Unlike traditional chemically synthesized small molecule drugs, biologics are complex molecules produced in living systems. Biosimilar drugs (biosimilars) are analogous to generic drugs; however, unlike generic drugs they are not exact copies of their reference brand product due to their complex nature. Health Canada deems that the differences between biosimilars and their reference biologic drugs are not clinically meaningful in terms of quality, safety, and efficacy. Like generics, biosimilars are significantly less costly than their reference drugs, and accordingly represent an opportunity to provide a cost-saving alternative without compromising patient care. To date, the pan-Canadian Pharmaceutical Alliance (pCPA) has completed negotiations for six biosimilar drugs, and more negotiations are underway or anticipated in the near future.

The pCPA includes all Canadian provincial and territorial public drug plans as well as three federally administered public drug plans: Non-Insured Health Benefits (NIHB), Correctional Services Canada (CSC), and Veterans Affairs Canada (VAC). The pCPA's mandate includes enhancing patient access to clinically relevant and cost effective drug treatment options. It serves this mandate by conducting collective, expert-informed negotiations for drug products.

With the rapidly evolving market for innovative biologics and the emerging biosimilars market there is a need for a clear and consistent approach to guide negotiations for these drugs. Presented in this document is a set of policy directions for biologics, as they apply to pCPA negotiations, informed by First Principles (published April 1, 2016) and a consultative process with pharmaceutical industry associations, intended to guide and define the core features of the process that will govern how biologic and biosimilar products will be negotiated and considered for reimbursement by Canada's public drug plans.

While this document provides policy directions, it is important to note that these focus on the negotiation process that takes place between pharmaceutical manufacturers and the pCPA. Canadian public drug plans recognize that further policy development with respect to appropriate use of biologics and uptake of biosimilars will need engagement of stakeholders beyond the pharmaceutical industry, including patients and clinicians. A well supported, effective and sustainable Canadian biologics environment requires considerations beyond the negotiation process and the engagement of all stakeholders to deliver appropriate patient access.

For the purpose of this document, the term **biologics** refers to all drugs that are biologic in nature, including biosimilar drugs.

For the purpose of this document, the term **value** refers to components of negotiated agreements that contribute to the long-term financial health of public drug plan budgets, such that Canada's public drug plans can continue to offer a broad range of clinically effective drugs while also promoting long-term sustainability without compromising patient care.

The overarching goal and objectives of the pCPA with respect to biologics are as follows:

Goal:

To develop and pilot a clear and consistent pan-Canadian approach that encourages appropriate use of biologics in support of a common pCPA mandate to enhance patient access to clinically relevant and cost-effective drug treatment options.

Objectives:

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

FIRST PRINCIPLES & OPTIONS FOR NEXT STEPS

In April 2016, the pCPA took its first steps towards a pan-Canadian approach for biologics by releasing its first principles for Subsequent Entry Biologics (Biosimilars).

The pCPA received feedback on the first principles from Industry Associations, and through an iterative internal process developed a series of options that may be considered for inclusion in the policy directions and processes that will govern how negotiations for biologics will proceed. Understanding the need to work together with negotiating partners, the pCPA undertook consultations with Industry Associations on March 22, 2017 at the pCPA

FIRST PRINCIPLES

- Commitment to a pan-Canadian pCPA negotiation process
- Decisions informed by evidence
- Foster a competitive biologics market supporting long term cost reductions and sustainability
- Lower transparent pricing
- Pursuit of optimal value from all industry stakeholders

Office in Toronto. The goals of the consultations were to provide an initial presentation of the options under consideration, build mutual understanding of the options and their implications, and to receive preliminary feedback from the Industry Associations consulted. Options were presented in four major areas of discussion:

1) **Negotiation process:** how might negotiations through pCPA be approached for reference biologics and biosimilars as the market expands?
2) **Building value - pricing:** how might building value through pricing be approached?
3) **Building value - listing status:** how might building value through listing status be approached?
4) **Therapeutic equivalence:** how might transitioning (switching) between reference biologics and biosimilars be approached?

Presented herein is a summary of the key themes that arose both during the consultation sessions with industry association stakeholders, and from the supplementary feedback provided by industry associations and individual manufacturers over the months that followed. These themes are presented in the context of the four major areas of discussion.

1) Negotiation Process

Currently, the pCPA negotiates all biologics through its general process applied to all new brand market entrants. Through establishing a clearly defined process, the pCPA wishes to ensure a fair negotiating table for all biologic products negotiated.

The options related to the negotiation process presented for consideration include:

1. Status quo: consider all new biologics, including biosimilars, on an individual basis
2. Continue negotiating new reference biologics on an individual basis, but establish an expedited process for biosimilars and expanded indications
3. Expedite negotiations and listings where the greatest value is brought to the table
4. During negotiations for a biosimilar, do not consider offers on the reference biologic
5. During negotiations for a biosimilar, consider offers on the reference biologic based on value proposition

WHAT WE HEARD: Key Themes

- The negotiation process should be expedited, predictable, and systematic, combined with being flexible for each individual product

WHAT IT MEANS: Opportunities and Impacts

- As with the current process for brand negotiations, pCPA's approach to biologics should have elements that are standardized, but also adaptive to recognize the variability and uniqueness of individual circumstances.

- Biosimilar products, which have a streamlined Health Technology Assessment (HTA) review, present an opportunity to adjust the time to engage in negotiations.

- Predictability of process is greatly enhanced by establishing clear expectations on pCPA interaction with reference biologic and biosimilar manufacturers that is not product-specific.

2) Building Value - Pricing

In alignment to its mandate, pCPA seeks to negotiate price reductions on all drugs it considers, which directly supports drug plan sustainability. Furthermore, it is recognized that biologics cost more in Canada than in other Organisation for Economic Co-operation and Development (OECD) jurisdictions, and pCPA has already negotiated biologic products.

The options related to pricing presented for consideration include:

1. Status quo: continue to evaluate pricing on an individual basis
2. Establish a fixed pricing framework that includes both transparent and confidential pricing components
3. Establish a fixed pricing framework that includes both transparent and confidential pricing components, and considers number of market players
4. Provide expedited negotiations to offers including transparent price reductions
5. Mandate transparent price reductions as a precursor to opening negotiations with pCPA

WHAT WE HEARD: Key Themes

- Industry is supportive of individual pricing evaluations for drug products
- Industry is not supportive of implementing a Tiered Pricing Framework, similar in structure to that which exists for generic products, at this time
- Industry is not supportive of the entire value being provided through transparent pricing given:
    - Global and Canadian market dynamics;
    - Potential differences in indications; and
    - Product profiles

WHAT IT MEANS: Opportunities and Impacts

- Biosimilars are not deemed interchangeable with a reference product and therefore there is a continued place for individually negotiating instead of implementing a standard pricing framework.
- There should be an opportunity to negotiate value in addition to transparent pricing reductions.
- Assessment of value should consider longer term sustainability of public funding for all drugs rather than short term savings from any individual drug.

3) Building Value – Listing Status

Listing status is a lever that could be used to promote higher-value biologic products in the marketplace, directly supporting drug plan sustainability. It is recognized however, that market dynamics could be impacted by listing status.

The options related to the listing status presented for consideration include:

1. Status quo: consider listing status on an individual basis
2. List all biologics equitably to promote choice and market competitiveness
3. Preferentially list all biosimilar products relative to their reference biologic
4. Establish tiered listing status framework
5. Delist products where higher value alternatives exist
6. List biologics with limited reimbursement levels
7. Enforce a period of market certainty following listing of a new biologic; do not accept unsolicited value offers during this period

WHAT WE HEARD: Key Themes

- Industry is supportive of:
  - Equitable listing
  - Preferential listing
  - Maximizing access to available treatment options
  - Improving access
  - Respecting physician and patient choice

WHAT IT MEANS: Opportunities and Impacts

- An environment that supports increased number of treatment options is beneficial to patient care
- Approaches to formulary listing are currently variable across therapeutic areas and across jurisdictions and listing status should continue to be adaptive to individual circumstance

4) Therapeutic Equivalence

Biosimilars are not identical to reference biologics. However, Health Canada deems the differences not clinically meaningful in terms of quality, safety, and efficacy. Promoting transitions from reference biologics to their biosimilars may provide a mechanism for creating value in support of plan sustainability.

The options related to the negotiation process presented for consideration include:

1. Ensure that both reference biologics and biosimilars are available through government funded plans, and allow patients and their health care providers to choose which product is used
2. Incent naïve patient starts and transitioning of stable patients to biosimilar drugs in consultation with their health care providers
3. Public plans preferentially cover biosimilar drugs

WHAT WE HEARD: Key Themes

- Industry is supportive of:
  - Health Canada's position on switching
  - Preferential listing for a product presenting best value

WHAT IT MEANS: Opportunities and Impacts

- Appropriateness of transitioning and/or preferential listing will vary by individual circumstance

SYNTHESIS

Based on the learnings gleaned through consultation with industry associations, and from the pCPA's experience to date in negotiating for biologic drug products, it is evident that all stakeholders would benefit from clear and consistent policy directions governing how these products will be considered for reimbursement by Canada's publically funded drug plans. The pCPA, at this stage, has developed a set of policy directions for biologics, as they apply to pCPA negotiations to guide and define the core features of the process that will be undertaken for each biologic drug product. Recognizing that Canada's public drug plans are ultimately governed by jurisdictional legislation, regulation, and policies, the implementation of agreements between manufacturers and jurisdictions may be subject to cross-jurisdictional differences, and each drug plan will retain the right to implement formulary tools as deemed appropriate by their leadership.

BIOLOGICS POLICY DIRECTIONS & pCPA NEGOTIATIONS

The following Biologics Policy Directions, as they apply to pCPA Negotiations, have been informed by the collective experience of the pCPA and the breadth of inputs received through consultation with stakeholders.

1. The pCPA[1] is committed to a unified, pan-Canadian process governing how biologic drugs, including biosimilars, will be considered for reimbursement by Canada's publically funded drug plans.

2. Biologic drugs will be considered on an individual basis, in their market context.

3. Negotiation for biosimilar drugs will begin in parallel with the HTA process.

4. Offers for biologic drugs will be accepted at any time; however, offers for biologic drugs currently reimbursed by public drug plans will not be discussed during the time that a corresponding biosimilar is under consideration by the HTA and pCPA processes.

5. Offers for biologic drugs that seek to restrict or exclude biosimilar drugs will not be considered.

6. Offers for (1) biologic drugs for which biosimilars are reimbursed, or (2) new biosimilar drugs will not be considered unless the offer includes a transparent list price reduction to the lowest public list price.

7. Tiered listings[2] for biologic drug products may be implemented in therapeutic areas where appropriate.

8. Switching of patients from a reference biologic molecule to a biosimilar may be implemented.

[1] The pCPA includes all of Canada's provincial and territorial publicly funded drug plans, as well as three federal drug plans through Correctional Services Canada, Non-Insured Health Benefits, and Veterans Affairs Canada

[2] Where a number of biologic drug products exist in a therapeutic space, those biologic drugs may be tiered. That is, authorization for of some biologic drug products will be gated based on evidence that other products have been used first, at the discretion of the reimbursing drug plan.