

FAQs
Biologics Policy Directions & pCPA Negotiations
April 2019

1. Are all pan-Canadian Pharmaceutical Alliance (pCPA) jurisdictions supportive of the contents of the Biologics Policy Directions & pCPA Negotiations document?

Yes. The pCPA, composed of all participating jurisdictions, jointly developed and endorse the contents of the document.

2. Do the Biologics Policy Directions change or impact the pCPA's objectives?

The overarching objectives of the pCPA remain unchanged and the Biologics Policy Directions are consistent with the objectives to:

- increase access to clinically-effective and cost-effective drug treatment options;
- achieve consistent and lower drug costs;
- reduce duplication of effort and improve use of resources; and
- improve consistency of decisions among public drug plans.

3. Does PMPRB modernization or CADTH/INESSS changes relating to the assessment of biosimilars impact pCPA's work on biologics?

The pCPA is supportive of the proposed PMPRB reforms to assist in lowering the cost of prescription drugs in Canada. The pCPA also supports implementation of a distinct, streamlined review process for biosimilars in the health technology assessments of CADTH/INESSS. The pCPA will continue to work collaboratively with PMPRB, CADTH/INESSS, and others to align processes within the Canadian drug approval process in order to enhance patient access to clinically-effective and cost-effective drug treatment options.

4. Is the September 2018 Biologics Policy Directions & pCPA Negotiations document final?

This document is the final product resulting from the formal consultation undertaken with the pharmaceutical manufacturing industry in March 2017. There are currently no plans to further modify the existing document. Further work in the biologics space and/or in response to market changes may result in the pCPA revisiting the document or creating supplementary documents as needed. This FAQs document offers clarification based on questions and feedback received from stakeholders after release of the 2018 Biologics Policy Directions & pCPA Negotiations document.

5. Could more clarity be provided regarding pCPA’s commitment to a unified process governing how biologic drugs, including biosimilars, will be considered for reimbursement by public drug plans? Can differing policy approaches still exist?

Although cross-jurisdictional differences in implementation and timelines may exist, all jurisdictions are committed to moving in a common broad direction, as outlined in the Biologics Policy Directions & pCPA Negotiations. While collective efforts through pCPA are aimed at increasing policy consistency across the country, there may be cross-jurisdictional differences given that Canada’s public drug plans are ultimately governed by existing jurisdictional legislation, regulations, and policies.

6. Can pCPA elaborate on and clarify Policy Direction #6 stating that “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”?

A transparent price is the price, or the component of the price, for a drug product that is made public.

As per Policy Direction 6, in order for offers to be considered, the transparent price component should at a minimum match the lowest public list price available in Canada. Policy Direction 6 does not state that all value must be offered through transparent pricing. Agreements for all biologics (including biosimilars) may have confidential components.

Policy Direction 6 was developed to support seeking the greatest benefit for all Canadians, while acknowledging each specific negotiation’s unique circumstances and respecting the pharmaceutical manufacturing industry’s limitations as they pertain to global pricing policies/considerations by allowing confidential pricing to remain a component of the negotiated value.

7. What are the process timeline expectations for each step in the negotiation process for biosimilars as compared to the standard negotiations outlined in the Brand Process Guidelines?

Biosimilars are subject to the standard negotiations timeline targets for each step in the negotiation process as outlined in the [pCPA Brand Process Guidelines](#). However, there is an opportunity for biosimilars negotiations to begin in parallel with the Health Technology Assessment (HTA) process given that the assessment conducted by HTA bodies will provide information to public payers on aspects related to stakeholder input, cost, and implementation considerations.

8. What information can the pharmaceutical manufacturing industry offer to help the pCPA?

The pCPA’s planning capability would benefit from the pharmaceutical manufacturing industry providing product pipeline details and best estimates as they pertain to the timing of product availability. This information can be sent directly to the pCPA Office via email pCPA@ontario.ca.

9. Will the Biologics Policy Directions impact access to innovative drugs?

The Biologics Policy Directions aim to support a vibrant, competitive, and sustainable market for biosimilars that ultimately works towards long-term sustainability of payers. Similar to when generic drugs were introduced, biosimilar drugs not only offer more options for treatment but also offer potential to bring significant savings which help to decrease drug budget pressures and improve funding availability for innovative drugs.

10. Why is the pCPA encouraging appropriate uptake of biosimilars?

Biologics represent a significant and increasing portion of total drug spending for both private and public payers at approximately 10% and 22% respectively in Canada according to 2016 data. Health Canada authorization of biosimilars meets the same high standards for quality, safety, and efficacy as all other biologic drugs and indicates no clinically meaningful differences in safety and efficacy between a biosimilar and its reference biologic drug. It is also recognized that to date, the use of marketed biosimilars in Canada is very low. Compared to many OECD countries, Canada is significantly behind in terms of timing of introduction and adoption rates of biosimilars (e.g., 0.2% in Canada in 2015 vs. 68% in Norway in 2013, vs. 85% in Scotland in 2016). The pCPA is interested in fostering and supporting a vibrant and competitive market for biosimilars to provide greater access and choice to prescribers and patients, through more drug product options, while also achieving improved value and supporting long-term sustainability for drug plans and individuals. It is also recognized that many countries around the world, including the United States, United Kingdom, and Australia, are also actively working on encouraging uptake of biosimilars.

11. Will negotiations for biologics with new indications also begin in parallel with the HTA process, similar to negotiations for biosimilar drugs?

Provided that HTA reviews of reference biologics, including new indications, generate details that the pCPA requires to begin negotiations (i.e. listing recommendations), negotiations for biologics with new indications will not begin in parallel with the HTA.

12. Are all negotiations being expedited?

While negotiation for biosimilar drugs may begin in parallel with the HTA process, the pCPA is also improving negotiation timelines for all drugs that have received a new final HTA recommendation. The pCPA has published aspirational target timelines in the [pCPA Brand Process Guidelines](#) to improve transparency over the course of the coming years and demonstrate a commitment to continuous improvement and predictability of process.

13. Why would the pCPA not entertain additional value offers on reference biologics at any time considering that these offers would directly contribute to system savings and sustainability?

The pCPA has determined that offers for biologic drugs will be accepted at any time. However, to maintain transparency of process and encourage long-term fiscal sustainability, 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. Further, considering pCPA's objective to increase the appropriate uptake of biosimilars, offers for biologic drugs that seek to restrict or exclude biosimilar drugs will not be considered. Although accepting offers on reference biologics at any time could help achieve limited and short-term savings for jurisdictions, the pCPA's decision-making considers the impact of these decisions on the significantly greater and longer-term savings potential from a healthy biosimilars market. The pCPA recognizes that with the biosimilar market being new in Canada, accepting value offers on the reference biologic products would discourage biosimilars from entering the Canadian market.

14. If a new value offer for a reference biologic, which is being reimbursed by public drug plans, has been made before its corresponding biosimilar has been submitted to the HTA, would discussions and/or negotiations have to be stopped during the HTA review of the biosimilar?

In order to maintain the objective of not conducting concurrent negotiations on biosimilars and corresponding reference biologics, pCPA would only continue negotiations on the biosimilar product. For transparency, the timeframe during which a discussion on the reference biologic will not continue, includes when a corresponding biosimilar is under consideration by the HTA and pCPA processes (as outlined in the [pCPA Brand Process Guidelines](#)). Outside of the aforementioned timeframe, offers will be evaluated on a case-by-case basis, guided by the Biologics Policy Directions, and recognizing unique product-specific circumstances.

15. Would providing equal access to a reference biologic and its corresponding biosimilar be considered "restrictive" to the biosimilar?

Each case will have to be managed individually to take the unique opportunities and challenges into account. Case-by-case factors including supply considerations, unmet patient need, value proposition, and market dynamics would contribute to the evaluation of whether equal access to a reference biologic could be considered restrictive to the biosimilar.

16. Can the reference biologic be renegotiated at a later date and are there biosimilar market share triggers that would allow this to happen?

With a limited number of biosimilars currently available in the Canadian market, it is premature to implement a standard approach on how funding agreements on reference biologic products should be managed after a corresponding biosimilar entry. Upon improvement in appropriate biosimilar uptake in Canada, the pCPA will evaluate whether standard timeline expectations (i.e. a certain number of years), uptake metrics, or class-specific/product-by-product/case-by-case criteria

(especially with products that have multiple indications) can be established to provide more predictability.

17. How will second entry biosimilars be negotiated?

At this time, the pCPA expects the overall value to improve as more biosimilars become available. However, further consideration is required to establish a standardized approach and associated expectations. There has been some feedback from stakeholders to consider a pricing framework for biosimilars in the future.

18. Will all the provinces, territories, and federal drug plans enforce tiering?

Although all pCPA jurisdictions will not implement the same listing policies at the same time, Biologics Policy Direction 7 aims to improve transparency as to the available options being considered by the jurisdictions. Each public drug plan is responsible for providing drug coverage for their population and their autonomy to do so will not change. Moving forward, jurisdictions will continue to be guided by Health Canada's regulatory recommendations, health technology assessments and recommendations, and any other evidence or considerations to encourage the appropriate use of biosimilars.

19. Why is tiering being considered by jurisdictions?

Tiering offers an opportunity to evaluate product supply, a factor of particular importance for biologics, and relative value of drug products within a specific category or class. Tiering policies allow the pCPA to ensure that a given class or category of drugs is used in a cost-effective way. Tiering is intended to promote value while continuing to provide access and therapeutic choice for patients and their healthcare practitioners to both reference biologics and biosimilars.

20. Will all the provinces, territories, and federal drug plans enforce switching?

Although all pCPA jurisdictions will not implement the same listing policies at the same time, Biologics Policy Direction 8 aims to improve transparency as to the available options being considered by the jurisdictions. Each public drug plan is responsible for providing drug coverage for their population and their autonomy to do so will not change. Moving forward, jurisdictions will continue to be guided by Health Canada's regulatory recommendations, health technology assessments and recommendations, and any other evidence or considerations to encourage the appropriate use of biosimilars.

21. Are there any implementation differences being considered for oncology products?

Yes, implementation of oncology biosimilars across cancer agencies and hospitals will be different compared to experience to date with implementing non-oncology biosimilars. Unlike the biosimilars negotiated thus far by the pCPA, oncology biosimilars may be used exclusively in the hospital environment or ambulatory cancer clinic and must be integrated into specific protocols. Therefore,

oncology-specific considerations that are informed by consultations with clinician groups are being developed to address the unique characteristics and opportunities in this area.

22. How will relevant patient and clinician feedback be solicited, acquired, and incorporated into this document?

The Biologics Policy Directions document, with a specific focus on the negotiations process, was informed by pharmaceutical manufacturing industry consultation. The responses to the FAQs herein offer clarification based on questions and feedback received from stakeholders.

Separate policy development with respect to appropriate use of biologics, uptake of biosimilars, therapeutic area implementation details, and education, among other topics require engagement with stakeholders beyond the pharmaceutical manufacturing industry, namely patients and clinicians.

Formal feedback from patients and clinicians is typically obtained through patient groups and clinician groups via organized consultation or written feedback sent to the pCPA Office pCPA@ontario.ca. Jurisdictions continuously seek feedback from their patients and clinicians to inform formulary decisions made at the jurisdictional level, and the pCPA plans to also more formally engage the patient and clinician community further in the near future.