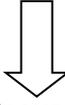


Frequently Asked Questions about the Pan-Canadian Generic Value Price Initiative Generic Pricing Framework and Centralized Price Confirmation Process

Pan-Canadian Pharmaceutical Alliance –Generic Pricing Framework ¹			
Category ² Description	% of Brand	Progression	Notes
New single source (i.e. only one manufacturer of a generic drug)	75% of brand if product listing agreement (PLA) or pricing agreement for brand exists in any jurisdiction Other single source: 85%	 As soon as another competitor begins selling its version of the drug in any jurisdiction, the price of the drug will drop to the next tier (i.e. 75% to 50% to 25%)	Option for province/territory to retain PLA or pricing agreement with brand if provides better value
Two generics	50%		
Three or more generics	25% Oral solid ⁴ 35% All dosage forms other than oral solids (e.g., liquids, patches, injectables, inhalers, etc.)		
Pan-Canadian 18% group – specific molecules negotiated with industry; may be new or existing drugs			
Pan-Canadian 18%	18%		

¹ This framework will be reassessed after 3 years.

² Price reduction to the next pricing tier is triggered by market entry of additional competitors.

³ After 2 years PTs will reassess continued listing of the single source product against international prices and the number of Notice of Compliance approvals that Health Canada has granted for the drug.

⁴ Modified release products, will be treated the same as regular tablets and capsules.

The Framework requires that any generic introduced after April 1, 2014 is compliant with the following pricing tiers:

- Tier 1 (Single Source/One generic @ 85% of brand reference price) - Provinces and territories will confirm if a Brand Product Listing Agreement exists; then Tier 1 drops to 75%.
- Tier 2 (Dual Source/Two generics @ 50% of brand reference price)
- Tier 3 (Multi Source/Three or more generics @ 25% of brand reference price) - oral solids or modified release drugs
- Tier 3 (Multi Source/Three or more generics @ 35% of brand reference price) - non-oral solids

Participating jurisdictions and manufacturers work in good faith to apply the Framework and to resolve any conflicts or disagreements.

1. Q: What products are subject to the Framework?
A: The Framework applies to any product that is equivalent with a current or previously available brand drug product, termed a “generic”, wherein the current or previously available brand drug product was eligible for reimbursement by any jurisdiction.

2. Q: What about products, such as oral solid cancer products and products for HIV and tuberculosis etc., that are not listed on all formularies but in some cases are reimbursed by public drug plans?
A: If a product is listed on the drug plan formulary in any province/territory (PT) it is subject to the framework and must be submitted for price confirmation through the centralized process.

3. Q: What about Subsequent Entry Biologics?
A: Subsequent Entry Biologics are outside the scope of the Framework.

4. Q: How is the term “competitor” defined under the Framework?
A: Within the Framework, the term “competitor” is any product that has a Notice of Compliance or Natural Product Number (NPN) that is marketed in any jurisdiction in Canada.

5. Q: What is the definition of “marketed”?
A: Within the Framework, the term “marketed” means a product that is available for sale in any jurisdiction.

6. Q: How is “marketed” defined for the purposes of confirming the appropriate tier?
A: For the purposes of confirming the appropriate tier, “marketed” shall be any product that:
 - a) is listed on any public drug plan formulary within any jurisdiction; or
 - b) has been submitted under the Price Confirmation Process; or
 - c) is available for sale in any jurisdiction as evidenced by product distribution through any provincial wholesalers.

7. Q: How will brand reference price be determined?

- A: All jurisdictions with the following exceptions will use Ontario as the reference price for brand products:
- a) British Columbia will use the price for the LCA drug comparator, as defined in the Drug Price Regulation B.C. Reg. 344/2012.
 - b) New Brunswick cannot accept a submitted unit price that is higher than the listed unit price in any other jurisdiction in Canada.
8. Q: What happens if the brand reference price has increased after the first generic was assessed under the Price Confirmation Process?
- A: The brand reference price is established when the first generic is assessed under the Price Confirmation Process. This established brand reference price will be used for all future assessments.
9. Q: What happens in the event that the brand is no longer marketed in Canada?
- A:
- a) For jurisdictions that reference the Ontario brand price, the centralized office will align with Ontario's approach in calculating a brand reference price for the product. If the Ontario approach cannot be used to calculate a price, the last known brand price from another participating jurisdiction will be used.
 - b) For jurisdictions that do not reference the Ontario brand price, the centralized office will use the British Columbia brand reference price as defined in the British Columbia Drug Price Regulation.
10. Q: What happens in the event that the brand and the generics are currently listed at the same price?
- A:
- a) For jurisdictions that reference the Ontario brand price, the centralized office will conduct a historical analysis of the generic and brand prices.
 - b) For jurisdictions that do not reference the Ontario brand price, the centralized office will use the British Columbia brand reference price as defined in BC Drug Plan Regulations.
 - o For a category established before April 2013, the brand price set in the Drug Price Regulation Schedule will be used.
 - o For a category established after April 2013, a historic price will be used if the brand price decreased more than 20% in the last two years before a generic drug is first assigned to the LCA category.
11. Q: How are product listing agreements addressed under the Framework?

A: Provinces and territories may retain pricing agreements with the brand product if they provide better value than the generic products. Provinces and territories commit to not actively seeking agreements with brand companies that would preclude generic entry.

12. Q: What is the “Price Confirmation Process”?

A: The “Price Confirmation Process” is the centralized process to determine the price and tier of new generic products and their competitors. Saskatchewan is currently serving as the central office. Manufacturers are requested to submit the Tiered Pricing Confirmation Form by email for all new generic products at PCPAGenerics@health.gov.sk.ca. The Saskatchewan Drug Plan will verify that the Framework applies to the product, determine the appropriate price tier, and advise the manufacturer, competitors (in the case of a change in tier) and all participating jurisdictions.

13. Q: What is the Generic Tiered Pricing Confirmation Form and where is it found?

A: The Tiered Pricing Confirmation Form must be filled out and returned to the central office for all new generic product submissions. The Form can be found here: [Tiered Pricing Confirmation Form](#).

Submission of a Generic Pricing Confirmation Form means that the manufacturer:

- a) Confirms that it is currently able to supply the product in a quantity sufficient to meet the anticipated demand for the product;
- b) Accepts that jurisdictions may undertake to confirm supply; and
- c) Will advise jurisdictions within 5 business days should it anticipate a supply disruption for the product delineated on the Generic Pricing Confirmation Form and failure to do so will invalidate this submission form and may result in the delisting of the product.

14. Q: What happens after the central office completes the price confirmation process for a submitted product?

A: The central office notifies jurisdictions, the manufacturer (and competitors if there is a change in tier) of the assessed tier and price. All competitors that are currently listed at higher prices must reduce their prices to match the assessed price.

15. Q: What if a manufacturer’s Submitted Unit Price on the Generic Pricing Confirmation Form exceeds the pCPA’s Calculated Unit Price?

A: If the manufacturer’s Submitted Unit Price exceeds the pCPA’s Calculated Unit Price, the manufacturer will have the opportunity to review and accept the pCPA’s Calculated Unit Price.

16. Q: What if the number of competitors increases resulting in a change in the applicable Pricing Tier?

A: In the event that the number of competitors increases resulting in a change in the applicable Pricing Tier all manufacturers in the class will have the opportunity to review and accept the pCPA's Calculated Unit Price at the new Pricing Tier.

Example #1: Currently, Generic Competitor '1' and Generic Competitor '2' are marketed in Canada. Both are listed at 50% of brand. A new Generic Competitor '3' submits a Generic Pricing Confirmation Form to the central office. The central office will assess the submission and determine that the category now has three competitors. Therefore, the new compliant price is 25% of brand. The central office will communicate the new compliant price and tier to all three competitors.

In the event that Generic Competitor '3' chooses not to submit to a jurisdiction for listing at the compliant price, Generic Competitor '1' and Generic Competitor '2' must still reduce their price to 25% of brand in order to be compliant with the Framework.

17. Q: What is a "Non-Compliant Price"?

A: A "Non-Compliant Price" means any situation for any product wherein the manufacturer's Submitted Unit Price exceeds the pCPA's Calculated Unit Price and the manufacturer does not accept the pCPA's Calculated Unit Price.

18. Q: What is included in the Calculated Unit Price?

A: The final accepted price will represent the manufacturers "per unit" product price under the Framework should the product be listed in a jurisdiction, regardless of whether the brand product is currently listed. For greater certainty, the final reimbursement price may include upcharges and mark-ups as allowed by each jurisdiction's policies and regulations.

19. Q: Are manufacturers required to submit to individual jurisdictions for listing on a provincial formulary?

A: Yes. Manufacturers may make submissions for listing in individual jurisdictions based on the result of the price confirmation process. Jurisdictions may have additional submission requirements (e.g. other forms) that are required to be completed and submitted as part of a complete submissions package. Jurisdictions retain sole discretion over the final coverage decision of products.

20. Q: Are price increases considered under the Framework?

A: Approval or rejection of price increases by individual jurisdictions are not considered under the Framework.

21. Q: What happens when a product that has been assessed by the centralized office is already listed at a price higher than the pCPA's Calculated Unit Price in a jurisdiction?

A: Once a price confirmation form has been received and assessed by the centralized office, all competitors are expected to adjust the price to match the pCPA's Calculated Unit Price in all participating jurisdictions where the product is listed. If the price is not adjusted to match the pCPA's Calculated Unit Price it will be considered a non-compliant price.

22. Q: When are competitors expected to reduce their prices to the pCPA's Calculated Unit Price after a product has been assessed by the price confirmation process?

A: Competitors are expected to reduce their prices to the pCPA's Calculated Unit Price once they have been notified of the pCPA assessment by the pCPA office (tier change) or any participating jurisdiction (other situations).

23. Q: What about products that were listed in at least one participating PT prior to April 1, 2014?

A: The following is the process for products that were listed in at least on participating PT prior to April 1, 2014:

- Products/DINs will continue to be submitted to the central office.
- The central office will confirm that the product/DIN was listed in at least one participating PT prior to April 1, 2014.
- The central office will respond to the manufacturer advising that the product/DIN is not assessable under the Centralized Price Confirmation Process.
- The central office will provide to the manufacturer and jurisdictions a "suggested submitted price" that will typically be based on an analysis of prices available in other jurisdictions that currently list the product.
- Manufacturers will then submit their product/DIN to the jurisdiction in which they are seeking listing. Any existing jurisdictional policy, legislation, or regulations will apply.

This process will apply to specific products/DINs that were listed in at least one jurisdiction prior to April 1, 2014, and not pre-existing "categories" of generic drugs that were listed prior to the start of the Tiered Pricing Framework.