

Frequently Asked Questions Generics Tiered Pricing Framework

Tiered Pricing Framework (TPF)		
Generic Drug Category Description/Tier¹	% of Brand Reference Pricing	Notes
Tier 1: 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% of brand Products at this level may be reassessed after 2 years following their initial assessment ³	Option for jurisdiction to retain PLA or pricing agreement with brand if provides better value
Tier 2: Two generics	50% of brand	
Tier 3: Three or more generics	25% of brand (oral solid)² 35% of brand for all dosage forms other than oral solids (e.g., liquids, patches, injectables, inhalers, etc.)	
The pan-Canadian Select Molecules Effective April 1, 2018		
<p>The list of the 67 pan-Canadian Select Molecules and the associated prices, effective April 1, 2018, are published on Saskatchewan's Formulary website: http://formulary.drugplan.ehealthsask.ca/PDFs/April%202018%20-%20pan-Canadian%20Molecules%20new.pdf</p>		

¹The number of generic competitors on the Canadian market establishes tiered pricing. Tier changes are triggered by a change in the number of generic competitors in the Canadian market.

²Modified release products will be treated the same as regular tablets and capsules.

³After 2 years following the initial assessment, jurisdictions may 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.

TERMS AND ABBREVIATIONS FOR THE PURPOSES OF THE FAQs

Calculated Unit Price:	The price of a generic product as assessed by the pCPA Office.
Existing Generic Category:	A group of generic products which has been previously established through the TPF.
Exiting Manufacturer:	The manufacturer with a generic product DIN/NPN that is exiting the Canadian market.
Market Entrant:	New generic DIN/NPN entering the Canadian market or seeking listing on a public drug formulary.
Market Entry Assessment:	Assessment of a Market Entrant for a generic product which may result in a Tier change (Tier 1 → Tier 2 or 3, or Tier 2 → 3) and/or the associated price change for generic products which are currently listed or applying to be listed on a public drug formulary.
Market Exit Assessment:	Assessment of a Market Exit for a generic product, which has exited the Canadian market on or after April 1, 2018, which may result in a Tier change (Tier 3 → 1 or 2, or Tier 2 → 1) and the associated price change for the remaining generic products in the generic category.
Market Exit:	Generic DIN/NPN exiting the Canadian market through cancelled DIN/NPN status, dormancy, or discontinuation without supply (details included in this document).
New Generic Category¹:	A new group of generic products that has not previously existed in the TPF and is established in the TPF as a result of a Market Entry Assessment or Market Exit Assessment.
Not Assessable Product:	A generic product is deemed a Not Assessable Product when the DIN/NPN is listed in any jurisdiction prior to April 1, 2014, and is not part of an Existing Generic Category. The pCPA Office will provide a Suggested Submitted Price as a result of the submission.
pCPA Office:	pan-Canadian Pharmaceutical Alliance Office
Product Distribution:	Generic DIN/NPN's availability for sale and distribution, for example, as evidenced through available supply at a provincial wholesaler.
Submitting Manufacturer:	The manufacturer submitting a Market Entry or Market Exit form for assessment.

Suggested Submitted Price: The lowest generic DIN/NPN price listed in any jurisdiction across Canada.

TPF: Tiered Pricing Framework, also referred to as “The Framework”. The TPF includes Market Entry Assessments and Market Exit Assessments.

¹ Generic interchangeability is established at the jurisdictional level

EXPECTATIONS ON OR AFTER APRIL 1, 2018

The Framework requires that any generic DIN/NPN entering the Canadian market after April 1, 2014 and that any generic DIN/NPN exiting the Canadian market on or after April 1, 2018 is compliant with the following pricing Tiers:

- Tier 1 (Single Source/One generic at 85% of brand reference price) - jurisdictions will confirm if a Brand Product Listing Agreement exists; if so, then Tier 1 drops to 75%.
- Tier 2 (Dual Source/Two generics at 50% of brand reference price).
- Tier 3 (Multi Source/Three or more generics @ 25% of brand reference price) - oral solid dosage forms including modified release drugs.
- Tier 3 (Multi Source/Three or more generics at 35% of brand reference price) - non-oral solid dosage forms.
- pan-Canadian Select Molecule Price List:
<http://formulary.drugplan.ehealthsask.ca/PDFs/April%202018%20-%20pan-Canadian%20Molecules%20new.pdf>

Jurisdictions and manufacturers are expected to work in good faith to apply the Framework and to resolve any conflicts or disagreements, to the extent possible under each jurisdiction’s legislation.

FAQS

1. Q: What products are subject to the Framework?

A: The Framework applies to any generic product, wherein the currently or previously available brand reference product was eligible for reimbursement by any jurisdiction.

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

A: The “Price Confirmation Process” is the centralized process to determine the price and tier of Market Entrants and Exits and their competitors. Manufacturers are requested to submit the TPF Pricing Confirmation Form by e-mail for all Market Entrants (including pan-Canadian Select Molecules) and Market Exits at pCPAGenericsOffice@ontario.ca.

The pCPA Office will verify that the Framework applies to the product, determine the appropriate price tier, and advise the Submitting Manufacturer, and all jurisdictions of the completed assessment.

The pCPA Office will provide notification to affected manufacturers when an assessment results in a Tier change.

3. 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 public drug plan formulary in any jurisdiction it is subject to the framework and must be submitted for price confirmation through the centralized process.

4. Q: What about biosimilars?

A: Biosimilars are outside the scope of the Framework.

5. Q: How is “competitor” defined for the purposes of assigning the appropriate tier within the TPF?

A: For the purposes of confirming the appropriate tier, “competitor” means any product that has a Notice of Compliance (with an associated DIN) and has:

- A “Marketed” or “Approved” Status on Health Canada’s Drug Product Database; and
- Supply available in the 12 months leading up to a submission in any jurisdiction as evidenced by product distribution, such as through provincial distributors/wholesalers.

Please note:

- Although Market Exit tests will not be applied in assigning the appropriate tier, if a product associated with a submitted Market Exit form (with a “Cancelled Post Market”, “Dormant”, or “Discontinued”

Health Canada Status) has failed the pCPA Office's Market Exit tests due to supply/sales exceeding benchmark values, the product will be counted a competitor.

- Assigning the appropriate tier within the TPF for products with a Natural Product Number (NPN) will take place on a case-by-case basis.

6. Q: How will the brand reference price be determined for the purposes of the TPF?

A: Apart from the exceptions outlined below, as of April 1, 2018, all jurisdictions will use Ontario's brand reference price for all New Generic Categories that are established on or after April 1, 2018.

- When an assessment *results in a tier change*, Existing Generic Categories established through the TPF prior to April 1, 2018 will use the established Ontario brand reference price (that which was used when the first generic triggered the TPF generic category), except for BC regulated 35% non-oral solids; this group of products will continue to use BC's brand reference price.
- When an assessment *does not result in a tier change*, Existing Generic Categories established through the TPF prior to April 1, 2018 will continue to use the previously established British Columbia brand reference price for British Columbia. For all other jurisdictions the previously established Ontario Brand Reference price will continue to apply.

Please note:

- The BC brand reference price is established with the price for the LCA drug comparator, as defined in the Drug Price Regulation B.C. Reg. 344/2012.
- New Brunswick cannot accept a calculated price that is higher than the listed unit price in any other jurisdiction in Canada.

7. Q: What happens if the brand reference product for the generic submission is not a benefit on the Ontario Drug Benefit Formulary?

A: If Ontario Brand Reference Price is not available, the following sequence of jurisdictions will be used to establish the brand reference price:

- 1) Alberta, 2) Saskatchewan, 3) British Columbia, 4) Manitoba, 5) Nova Scotia, 6) New Brunswick, 7) PEI, 8) Newfoundland & Labrador, 9) Yukon

8. Q: What happens if the brand reference price has increased after the first generic was assessed through the TPF?

A: The brand reference price is established when the first generic is assessed through the TPF. 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: If the current Brand Reference Pricing is not available in any jurisdiction, the historical Brand Reference Pricing as per the following sequence of jurisdictions will be used:

- 1) Ontario, 2) Alberta, 3) Saskatchewan, 4) British Columbia, 5) Manitoba, 6) Nova Scotia,
- 7) New Brunswick, 8) PEI, 9) Newfoundland & Labrador, 10) Yukon

If current or historical Brand Reference Pricing is not available in any jurisdiction of the New Generics Initiative, Quebec's current Brand Reference Pricing will be used. Further, if the current Quebec pricing is unavailable, Quebec's historical Brand Reference Pricing will be used.

10. Q: What happens in the event that the brand and the generics are currently listed at the same price?

A: The pCPA Office will conduct a historical analysis of the generic and brand prices to identify the appropriate brand reference price.

Please note: Ontario will continue to use the brand reference prices as determined under Ontario Regulation 201/96.

11. Q: How are product listing agreements addressed under the Framework?

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

12. Q: What is the Generic TPF Pricing Confirmation Form and where is it found?

A: A TPF Pricing Confirmation Form for Market Entrants (including pan-Canadian Select Molecules) or Market Exits must be filled out and returned to the pCPA Office for all Market Entry/Exit submissions. The TPF Pricing Confirmation forms can be found here:

<http://formulary.drugplan.ehealthsask.ca/PanCanadian.aspx>

The submission of a Market Entry/Exit Assessment means a manufacturer:

- a) Confirms that it is currently able to supply the product which it is submitting for an assessment at the distribution level in a quantity sufficient to meet the anticipated demand for the product in the jurisdiction in which it is listed; and
- b) Acknowledges that the pCPA Office and jurisdictions may undertake further action to confirm supply; and
- c) Accepts Terms & Conditions on the TPF Pricing Confirmation Form

13. Q: What happens after the pCPA Office completes the TPF assessment for a Market Entry or Exit submission?

A: The pCPA Office will notify jurisdictions, the Submitting Manufacturer (and competitors if there is a change in tier) of the assessed tier and price.

- For Market Entrants: all competitors currently listed at higher prices must adjust their prices to match the assessed price established through the TPF during jurisdictions' next regular/scheduled formulary updates.
- For Market Exits: all competitors currently listed will be given the opportunity to adjust their prices to match the assessed price point established through the TPF during jurisdictions' next regular/scheduled formulary updates.

14. Q: What if a manufacturer's Submitted Unit Price on the TPF Pricing Confirmation Form exceeds the pCPA Office's Calculated Unit Price?

A: If the manufacturer's Submitted Unit Price exceeds the pCPA Office's Calculated Unit Price, the manufacturer will have the opportunity to review the Calculated Unit Price and respond to the pCPA Office. In the case that the manufacturer declines the assessment, they are deemed "non-compliant" by the pCPA Office. "Non-compliant" products are subject to process outlined in Q#15.

15. Q: What is a "Non-Compliant Assessment"?

A: A "Non-Compliant Assessment" means any situation for any generic product wherein the manufacturer is not in agreement with the pCPA Office's Calculated Unit Price and will not provide their product to jurisdictions at the Calculated Unit Price. Non-compliant products may not be listed or may be delisted if a manufacturer does not comply with the established tier.

Jurisdictions will provide all manufacturers with generic products in a New or Existing Generic Category an opportunity to adjust prices according to the pCPA Office's assessment. If the price is not adjusted to match the pCPA's Calculated Unit Price it will be considered a "Non-Compliant Assessment" and the jurisdictions may be required, according to their policies/regulations/legislation to only fund the lowest cost alternative price.

When a submitting manufacturer is compliant with the pCPA Calculated Unit Price, competitors are expected to adjust their prices to pCPA's Calculated Unit Price. The manufacturer will be notified of the pCPA assessment by the pCPA Office (tier change) or by any jurisdiction. Tier/price changes for competitors will occur for a jurisdiction only when that jurisdiction undergoes a regular/scheduled formulary update. Jurisdictions commit to adherence to formulary submission deadlines and listing deadlines.

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 or decline the pCPA's Calculated Unit Price at the new Pricing Tier. In the case that the manufacturer declines the assessment, they are deemed "non-compliant" by the pCPA Office. Non-compliant products may not be listed or may be delisted if a manufacturer does not comply with the established Tier/price.

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 TPF Pricing Confirmation Form to the pCPA

Office. The pCPA Office will assess the Submitting Manufacturers TPF Pricing Confirmation Form and determine that the Generic Category now has three competitors. Therefore, the new compliant price is 25% of brand. The pCPA 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 with the following formulary update in order to be compliant with the Framework. Jurisdictions commit to adherence to formulary submission deadlines and listing deadlines.

17. 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.

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

A: Yes. Manufacturers are required to 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 listed on public drug plan formularies.

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

A: Once a TPF Pricing Confirmation Form has been received and assessed by the pCPA Office, all competitors are expected to adjust their price to match the pCPA's Calculated Unit Price in all jurisdictions, including where the product was listed prior to pCPA assessment. If the price is not

adjusted to match the pCPA's Calculated Unit Price it will be considered non-compliant. Generic products deemed non-compliant through the TPF may be delisted from public drug plan formularies.

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

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

- DINs/NPNs will continue to be submitted to the pCPA Office.
- For Generic Categories that have not been established through the TPF, the pCPA Office will confirm that the DIN/NPN was listed in at least one jurisdiction prior to April 1, 2014.
- The pCPA Office will respond to the manufacturer advising that the DIN/NPN is a Not Assessable Product under the Tiered Pricing Framework.
- The pCPA Office will provide the manufacturer and jurisdictions a "Suggested Submitted Price" that will be based on an analysis of the lowest listed DIN/NPN price listed in any jurisdiction across Canada.
- As explained in Q#18, manufacturers must then follow the appropriate submission requirements when seeking listing on a public drug plan formulary. Any existing jurisdictional policy, legislation, or regulations will apply.

For further clarity, this process applies in situations where a generic product was already listed in one or more jurisdictions prior to April 1, 2014; however, it is now seeking listing on another public drug plan formulary.

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

A: Price increases are only considered under the Framework under the Market Exit Assessment process, when one or more competitors have left the market and a Market Exit Assessment would result in a tier change (Tier 3 to 2 or 1, or Tier 2 to 1).

22. Q: Will jurisdictions still consider price increase requests outside of the Market Exit Assessment process?

A: Generic products which have applied through the Market Exit evaluation process and have successfully been granted a tier change as a result of 1 or more competitor(s) leaving the market are not eligible to apply for further price increases. Price increase requests for generic products that are not affected by the TPF may be considered by jurisdictions as per current established jurisdictional processes. A central process for price increase applications is being contemplated for potential implementation effective April 1, 2019.

23. Q: How does the pCPA Office become aware of a change in the number of competitors, specifically when one or more exits the market?

A: Either generic manufacturers or the pCPA jurisdictions may notify the pCPA Office of an eligible Health Canada status change taking place on or after April 1, 2018.

24. Q: What triggers a Market Exit Assessment?

A: The eligibility evaluation conducted by the pCPA Office for the “Market Exit” Assessment is triggered when the number of competitors in a Generic Drug Category changes as a result of a product exiting the market on or after April 1, 2018. There is no retroactivity, therefore market change triggers taking place prior to April 1, 2018, are not eligible.

25. Q: Which Health Canada status changes are eligible for pCPA Office consideration and what are the sources of this information?

A: A manufacturer or a jurisdiction may apply for a Market Exit Assessment when a generic DIN/NPN has exited the market as evidenced by a status change on or after April 1, 2018 on one more of the following sources:

- a) Cancelled Post Market Status (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>)
- b) Dormant Status <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>)
- c) Discontinued status, “no” reversal of decision status, and no remaining supply (<https://www.drugshortagescanada.ca/search?perform=0>)

26. Q: Which Generic Categories are exempt from Market Exit Assessments?

A: The select 67 pan-Canadian Molecules are exempt from Market Exit Assessments, which can be found here: <http://formulary.drugplan.ehealthsask.ca/PDFs/April%202018%20-%20pan-Canadian%20Molecules%20new.pdf>

27. Q: How does the pCPA Office evaluate Market Exit Assessment?

A: Once a status change occurs in one of the resources outlined in Q#25 on or after April 1, 2018, the pCPA Office will seek confirmation through a “Market Exit Confirmation Form” from the exiting manufacturer. The exiting manufacturer will have 5 Business Days to respond to the Market Exit Confirmation Form, establishing that there is no intention to re-enter the Canadian market within 1 year of the date the manufacturer completed the Market Exit Confirmation Form. If it is confirmed that at the time of market exit confirmation, there is intention to re-introduce the generic products in the Canadian market within 1 year of the date the manufacturer completed the Market Exit Confirmation Form:

- The pCPA Office will not proceed with recommending delisting to jurisdictions; and
- The pCPA Office requires the manufacturer’s (anticipated) date of market re-entry or exit; and
- The pCPA Office may re-initiate contact at a later date to re-confirm this position.

Once the pCPA Office receives a completed “Market Exit Confirmation Form” — confirmation of a generic DIN/NPN market exit and no intention to re-enter the Canadian Market within 1 year of the date the manufacturer completed the Market Exit Confirmation Form — from the exiting manufacturer, the pCPA Office will conduct a supply test and sales test, and the exiting DIN/NPN must pass both tests. If an exiting DIN/NPN does not pass both tests, the first eligible date for re-

application will be six (6) months after the most recent time period (i.e. month) in which the both tests were not passed.

a) Supply Test: Confirm that there has not been supply available anywhere in Canada at the distribution level over a six (6) months period leading up to a Market Exit Submission;

b) Sales Test¹:

- 1) Assess the maximum historical market share in each evaluated time period for the drug product which is exiting the market (by drug plan & month) as a percentage (%) of total drug category volume
 - Market share is evaluated in each time period from April 1, 2015 to present based on quantity of units dispensed
 - Maximum historical market share is used to determine the relevant sales threshold for the exiting drug product

Historical Maximum Market Share	Market Share Threshold by Drug Plan/Time Period
≥ 20%	< 2%
≥ 10% - > 20%	< 1%
< 10%	< 0.5%

- 2) By jurisdiction & by time period, evaluated over the past six months:
 - If the exiting drug product exceeds the relevant sales threshold in any assessed time period or drug plan, it will not pass the Sales Test.

¹Applications which fail the sales test in a small number of drug plans or due to a market-share history which is close to a relevant sales threshold may be referred to a CGPA-pCPA working group. This process will result in delays for affected applications.

Once the exiting DIN/NPN passes the pCPA checks, the remaining competitor DINs/NPNs in the Generic Category are eligible for TPF assessment by the pCPA Office.

The pCPA Office will process the submitted Market Exit TPF Pricing Confirmation Form and will recommend delisting of exiting DIN/NPN to all jurisdictions and provide the new assessed tier/price.

Eligibility for Market Exit assessments is further outlined in the [Market Exit TPF Eligibility Flowchart](#).

28. Q: How will the pCPA be notified about generic product market re-entry, triggering the TPF?

A: For products that have gone through a Market Exit assessment and have been delisted from the public formularies in all jurisdictions, the manufacturer must notify the pCPA Office when they know that the DIN/NPN will be returning to the Canadian market and re-submit to the TPF to be assessed prior to listing on formularies.

The pCPA may monitor public sales data and wholesale records to verify market entry and issue a TPF Market Entry assessment if sales increase or supply is available.

Jurisdictions have sole discretion over the final coverage decision of drug product(s) and the above processes outlined in this document will not supersede any existing legislation and/or policies in jurisdictions.