pan-Canadian Pharmaceutical Alliance
Alliance pharmaceutique pancanadienne

Generics tiered pricing framework (TPF)

Frequently asked questions

Terms and abbreviations

Calculated unit price: The price of a generic product as assessed by the pCPA.

DIN: Drug identification number

Existing generic category: A group of generic products previously established through the TPF.

Exiting manufacturer: A manufacturer that is exiting their product(s) from the Canadian market as identified by drug identification number (DIN) or natural product number (NPN).

Market entrant: New generic DIN/NPN entering the Canadian market or seeking to list 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 to tier 2 or 3, or tier 2 to tier 3) and/or an associated price change for generic products that are currently listed or applying to be listed on a public drug formulary.

Market exit assessment: Assessment of a generic product that has exited the Canadian market on or after April 1, 2018 that may result in a tier change (tier 3 to 1 or 2, or tier 2 to tier 1) and an 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.

New Generic Category: 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/non-assessable product: A generic product is deemed not assessable 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 will provide a suggested submitted price.

NPN: Natural Product Number.

Product distribution: The availability of generic DIN/NPNs for sale and distribution, through available supply at a provincial wholesaler.

Product Listing Agreement: An agreement between a manufacturer and participating jurisdiction regarding the public funding of a drug.

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.

Line extension product: A new strength of a reference generic drug product formulation.

Historical products: Generic products with a brand reference product classified as cancelled post-market on the Health Canada Drug Product Database on or before April 1, 2014.

Q1: What products are subject to the TPF?

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

Line extensions of existing generic products may be processed through the line extension policy (see question 32) if a relevant brand reference product has not been marketed in Canada.

Q2: What is the price confirmation process?

A: The price confirmation process determines the price and tier of market entrants and exits and their competitors.

- Manufacturers submit the TPF pricing confirmation form found on the generics page of the pCPA website for all market entrants (including select molecules) and market exits via email to the pCPA.

- The pCPA verifies that the TPF applies to the product and determines the appropriate price tier. The pCPA advises the submitting manufacturer and all jurisdictions when the assessment is complete.
- The pCPA notifies affected manufacturers when an assessment results in a tier change.

Q3: What about products that are not listed on all formularies but might be reimbursed by public drug plans?

A: These products might include oral solid cancer products and those for HIV and tuberculosis, for example**.** If a product is listed on the public drug plan formulary in any jurisdiction, it is subject to the TPF and must be submitted for price confirmation through the centralized process.

Q4: What about biosimilars?

A: Biosimilars are outside the scope of the TPF.

Q5: How is "competitor" defined?

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

- Holds a marketed status on Health Canada's drug product database, or
- Holds an approved status on Health Canada's drug product database and
- Has supply available in the 12 months leading up to a submission in any jurisdiction. This availability is demonstrated by product distribution, such as through provincial distributors and wholesalers.

Note: A market exit assessment will not be applied in assigning the appropriate tier. However, 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's market exit assessment due to sales exceeding benchmark values, the product will be counted as a competitor.

The pCPA will assign the appropriate tier within the TPF for products with an NPN on a case-by-case basis.

Q6: How will the brand reference price be determined?

A: As of October 1, 2023, all jurisdictions will use Ontario's brand reference price for all new generic categories established on or after October 1, 2023, with the following exceptions.

- 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 (established when the first generic triggered the TPF generic category).
- 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 brand reference price. British Columbia will use the brand reference price for British Columbia. For all other jurisdictions, the previously established Ontario brand reference price will continue to apply.

Note: The British Columbia brand reference price is established with the price for the low-cost alternative drug comparator, as defined in the drug price regulation British Columbia Regulation 344/2012.

New Brunswick cannot accept a calculated price that is higher than the listed unit price in any other jurisdiction in Canada.

Q7: What happens if the marketed brand reference product is not a benefit on the Ontario drug benefit formulary or exceptional access program?

A: 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. Prince Edward Island
8. Newfoundland and Labrador
9. Yukon

10. Québec

Q8: What happens if the brand reference price has increased after the first generic was assessed?

A: Once the brand reference price is assessed through the TPF, the same price will be used for all future assessments.

Q9: What happens if the brand reference product is no longer marketed in Canada?

A: The historical product policy applies to generic products whose brand reference product meets specific criteria, and those in a drug category which has not previously undergone pCPA assessment. Recognizing the potential issues with using historical brand reference prices, these assessments are subject to a maximum price reduction relative to existing generic pricing. To be eligible for this maximum price decrease, the brand reference product must meet the following criteria:

- Be classified as cancelled post-market (CPM) according to the Health Canada drug product database.
- Have a CPM status effective on or before April 1, 2014.

See Question 10 for more information.

If the criteria for the historical product policy is not met, the historical price of the reference brand will be used to establish the brand reference price for the generic category as per the following sequence of jurisdictions:

1. Ontario
2. Alberta
3. Saskatchewan
4. British Columbia
5. Manitoba
6. Nova Scotia
7. New Brunswick
8. Prince Edward Island
9. Newfoundland and Labrador

10. Yukon
11. Québec

Q10: How does the pCPA apply the historical product policy?

A: For the historical products policy, a maximum price reduction will be applied for the assessment relative to currently marketed generic products in the price category. The maximum price decrease applied will be relative to the number of generic categories in the market and the tier in which the product enters the market. A maximum price reduction for a product assessed at tier 2 is 10%. For a product assessed as tier 3, the maximum price reduction is 30%. A product transitioning from tier 2 to tier 3 is 30%. For more information, please refer to the historical products policy examples document.

Current prices may vary by jurisdiction. The price used for pCPA assessment will be determined based on the existing sequence of jurisdictions:

1. Ontario
2. Alberta
3. Saskatchewan
4. British Columbia
5. Manitoba
6. Nova Scotia
7. New Brunswick
8. Prince Edward Island
9. Newfoundland and Labrador
10. Yukon
11. Québec

If more than one generic exists in the jurisdiction, the lower price of the two is used for the assessment.

If the standard TPF assessment results in a lower price than the maximum price reduction, a revised assessment will be applied, in which the maximum price decrease is applied.

Proportionate price decreases are assessed relative to existing generic pricing in the selected jurisdiction. If the pCPA assessment price for a market entry is higher than existing generic pricing in a specific jurisdiction, that jurisdiction is not expected to implement a price increase.

Q11: What happens if the brand and the generics are listed at the same price?

A: The pCPA 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.

Q12: How are product listing agreements addressed under the TPF?

A: The TPF does not affect the authority of any participating jurisdictions to make decisions with respect to coverage of drugs.

Q13: 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 for all market entry and exit submissions. The TPF pricing confirmation forms can be found on the generics page of our website.

The submission of a market entry or exit assessment means a manufacturer must do the following:

- Confirm it is currently able to supply the product being submitted 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.
- Acknowledge that the pCPA and jurisdictions may undertake further action to confirm supply.
- Accept terms and conditions on the TPF pricing confirmation form.

Q14: What happens after the pCPA completes the TPF assessment for a market entry or exit submission?

A: The pCPA 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. This adjustment would happen during the next formulary update for jurisdictions.

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. This adjustment would happen during the next formulary updates for jurisdictions.

Q15: What if a manufacturer's submitted unit price exceeds the calculated unit price?

A: If the manufacturer's submitted unit price exceeds the pCPA's calculated unit price, the manufacturer can review the calculated unit price and respond to the pCPA.

If the manufacturer declines the assessment, they are deemed "non- compliant" by the pCPA. "Non-compliant" products are subject to the process outlined in question 16.

Q16: What does non-compliant mean?

A: Non-compliant refers to any situation for any generic product where the manufacturer does not agree with the pCPA's calculated unit price and will not provide their product to jurisdictions at the calculated unit price. If a manufacturer does not comply with the established tier, non-compliant products may not be listed, or they may be delisted.

Jurisdictions will provide all manufacturers with generic products in a new or existing generic category an opportunity to adjust prices according to the pCPA's assessment. If the price is not adjusted to match the pCPA's calculated unit price it will be considered a non-compliant assessment. In this case, the jurisdictions may be required, according to their policies, regulations and/or legislation, to fund only 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 or by any jurisdiction. Tier or price changes for competitors will occur for a jurisdiction only when that jurisdiction undergoes a regular scheduled formulary update. Jurisdictions commit to adhering to formulary submission deadlines and listing deadlines.

Q17: What if the number of competitors increases?

A: If 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 then accept or decline, the pCPA's calculated unit price at the new pricing tier. If a manufacturer declines the assessment, they are deemed non-compliant by the pCPA. Non-compliant products may not be listed, or they may be delisted, if a manufacturer does not comply with the established tier or price.

Example:

Currently, two generic competitors are marketed in Canada. Both are listed at 50% of brand price. A third generic competitor submits a TPF pricing confirmation form to the pCPA. The pCPA assesses the submitting manufacturer's TPF pricing confirmation form and determines that the generic category now has three competitors. This means the new compliant price is 25% of brand price. The pCPA will communicate the new compliant price and tier to all three competitors.

If the third generic competitor chooses not to submit to a jurisdiction for listing at the compliant price, the two original generic competitors must still reduce their price to 25% of brand price with the next updated release of respective jurisdictional formulary updates. Jurisdictions commit to adherence to formulary submission deadlines and listing deadlines.

Q18: What is included in the calculated unit price?

A: The final accepted price will represent the manufacturer's per unit product price under the TPF 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.

Q19: Are manufacturers required to submit to individual jurisdictions for listing on a public drug plan?

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 as part of a complete submissions package. Jurisdictions retain sole discretion over the final coverage decision of products listed on public drug plan formularies.

Q20: What happens when a product that has been assessed by the pCPA is already listed at a price higher than the pCPA's calculated unit price in a jurisdiction?

A: Once a TPF pricing confirmation form has been received and assessed by the pCPA, 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.

Q21: What about products that were listed in at least one jurisdiction prior to April 1, 2014?

A: DINs/NPNs will continue to be submitted to the pCPA.

- For generic categories that have not been established through the TPF, the pCPA will confirm that the DIN/NPN was listed in at least one jurisdiction prior to April 1, 2014.
- The pCPA will advise the manufacturer that the DIN/NPN is a not assessable product under the TPF.
- The pCPA will provide the manufacturer and jurisdictions a suggested submitted price based on an analysis of the lowest listed DIN/NPN price listed in any jurisdiction across Canada.
- 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. (See Question 19.)

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

Q22: Are price increases considered under the TPF?

A: Price increases are considered under the TPF only as part of the market exit assessment process, when one or more competitors have left the market and a market exit assessment may result in a tier change (tier 3 to 2 or 1, or tier 2 to 1).

Q23: Will jurisdictions still consider price increase requests outside of the market exit assessment process?

A: Generic products that have applied through the market exit assessment process, and have successfully been granted a tier change as a result of one or more competitor(s) leaving the market, are not eligible to apply for further price increases. Price increase requests for generic products not affected by the TPF may be considered by jurisdictions as per current established jurisdictional processes.

Q24: How does the pCPA become aware of a change in the number of competitors, specifically when one or more exits the market?

A: The pCPA is made aware of changes in competitors through the market exit assessment process. See question 25 for more details.

Q25: What triggers a market exit assessment?

A: A 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. Market change triggers taking place prior to April 1, 2018 are not eligible.

Q26: Which Health Canada status changes are eligible for pCPA 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:

- Health Canada's Drug Product Database (cancelled post market status or dormant status)
- Drug Shortages Canada (discontinued status, no reversal of decision status, no remaining supply)

Q27: Which generic categories are exempt from market exit assessments?

A: The pan-Canadian Select Molecules are exempt from market exit assessments. However, pan-Canadian Select Molecules will be reviewed by the pCPA on a case-by-case basis for ladder inclusion.

See the generic drugs page of our website.

Q28: How does the pCPA evaluate market exit assessment?

A: Once a status change occurs in one of the resources outlined in question 26 (on or after April 1, 2018), the pCPA will seek confirmation through a market exit confirmation form from the exiting manufacturer. A jurisdiction can also request the pCPA initiate a market exit form. The exiting manufacturer will have five business days to respond to the market exit confirmation form. The manufacturer will need to establish that there is no intention to re-enter the Canadian market within one year of the date they completed the form.

At the time of market exit confirmation, if it is determined there is intention to re-introduce the generic products in the Canadian market within one year of the date the manufacturer completed the market exit confirmation form, the pCPA will not proceed with recommending delisting to jurisdictions. The pCPA will require the manufacturer to provide the anticipated date of market re-entry or exit and may check back at a later date to confirm this position.

Once the pCPA receives a completed market exit confirmation form, it will conduct a sales test on the exiting DIN/NPN. If the DIN/NPN does not pass the sales test, the first eligible date for re-application will be three months from the date the sales test did not pass.

Flexibility to pass applications that fail the sales test in a small number of drug plans, or that have market share history close to a relevant sales threshold, could be allowed after the circumstances are reviewed.

Q29: What is a sales test?

A: A sales test is used to confirm the market exit of a drug. The sales test looks at the following factors:

- Maximum historical market share.

- Relevant sales threshold.

The maximum historical market share is assessed in each evaluated time period for the drug product exiting the market (by drug plan and month) as a percentage of total drug category volume.

Market share is evaluated in each time period from April 1, 2015 to present-day, 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%

A drug will be evaluated by jurisdiction and time period, over the previous six months, to determine if it exceeds the relevant sales threshold. If it does exceed the sales threshold, it will not pass the sales test.

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.

Q30: What happens when a drug passes a sales test?

A: Once the exiting DIN/NPN passes the sales test, the remaining competitor DINs/NPNs in the generic category are eligible for TPF assessment.

The pCPA 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.

Q31: 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 when they know that the DIN/NPN will be returning to the Canadian market. The manufacturer will re-submit to the TPF to be assessed prior to listing on formularies.

Q32: How does the line extension policy work?

A: A line extension is a new strength of a generic drug product formulation sold by the manufacturer that contains the same active ingredient or ingredients in the same dosage form. The policy is intended to proportionally price new submissions of generic line extension products to currently marketed generic strengths.

Three scenarios have been identified that may arise when a line extension is marketed. The pCPA will determine which scenario the line extension belongs to and will use the following algorithms for pricing:

- Equal pricing: Assessment of line extension strength price is equal to marketed strengths.
- Simple proportionality: Price of line extension strength price is proportional to marketed strengths/units.
- Complex proportionality: Price of line extension strength price is proportional to:
    - Average of two neighbouring strengths per milligram, if line extension strength is bracketed by marketed strengths (“in-between” strengths).
    - Price per milligram of closest strength, if line extension strength is not bracketed by market strength (“book end” strength).

If the reference strength has been previously assessed through the TPF, the TPF assessed price is used. If the anchor strength has not been previously assessed through the TPF, use the list price in the jurisdictions according to the following MOU sequence of jurisdictions:

1. Ontario
2. Alberta
3. Saskatchewan
4. British Columbia

5. Manitoba
6. Nova Scotia
7. New Brunswick
8. Prince Edward Island
9. Newfoundland and Labrador
10. Yukon
11. Québec

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