

Historical Products Policy (HPP)

The pCPA and CGPA have collaborated to develop a policy that addresses concerns regarding assessments for generic products whose brand reference product has been cancelled post-market.

This policy will come into effect on April 1, 2022.

It is a pilot program that will be reviewed on an ongoing basis to determine efficiency and effectiveness.

Historical Products Policy scope

The Tiered Pricing Framework will continue to be applied to all submitted generic assessments.

For generic products whose Brand Reference Product meets specific criteria, and who are in a drug category which has not previously undergone pCPA assessment, a maximum price reduction relative to existing generic pricing will be applied.

In order to be eligible for this maximum price decrease, the related Brand Reference Product:

- Must be classified as Cancelled Post-Market (CPM) according to the Health Canada Drug Product Database.
- CPM status must be effective on or before April 1, 2014.

Maximum Price Reduction

The TPF would apply however the **maximum decrease in price** relative to current generic prices would be as outlined below:

# of current generic competitors	Assessed tier	Maximum price reduction
0	Tier 1	Not addressed by Historical Products Policy
1	Tier 2	Less than or equal to 10% ¹
2 or more	Tier 3	Less than or equal to 30% ^{1,2}

¹ Assessed relative to the current generic price in the existing “sequence” of jurisdictions

² Not subject to “repeated” price decreases once Tier 3 price is established in TPF



Market Exit: TPF & Historical Product Policy

Generic competitors at HPP establishment ³	First HPP "Tier"	Highest # of generic competitors within HPP	Market exit to # of competitors	HPP market exit scenario
1	2	2	1	PGP ⁴
1	2	3	2	Roll back HPP Price Reduction (30%)
1	2	3	1	Roll back HPP Price Reduction (10%)
2	3	3	2	PGP ⁴
2	3	3	1	10% increase over PGP ⁴
≥3	3	>3	≥3	Not Eligible
≥3	3	≥4	2	PGP ⁴
≥3	3	≥3	1	10% increase over PGP ⁴
0		Any	Any	Not Eligible
Any	Any	Any	0	Not Eligible

If a market exit brings a generic category into the TPF, the regular TPF will apply.

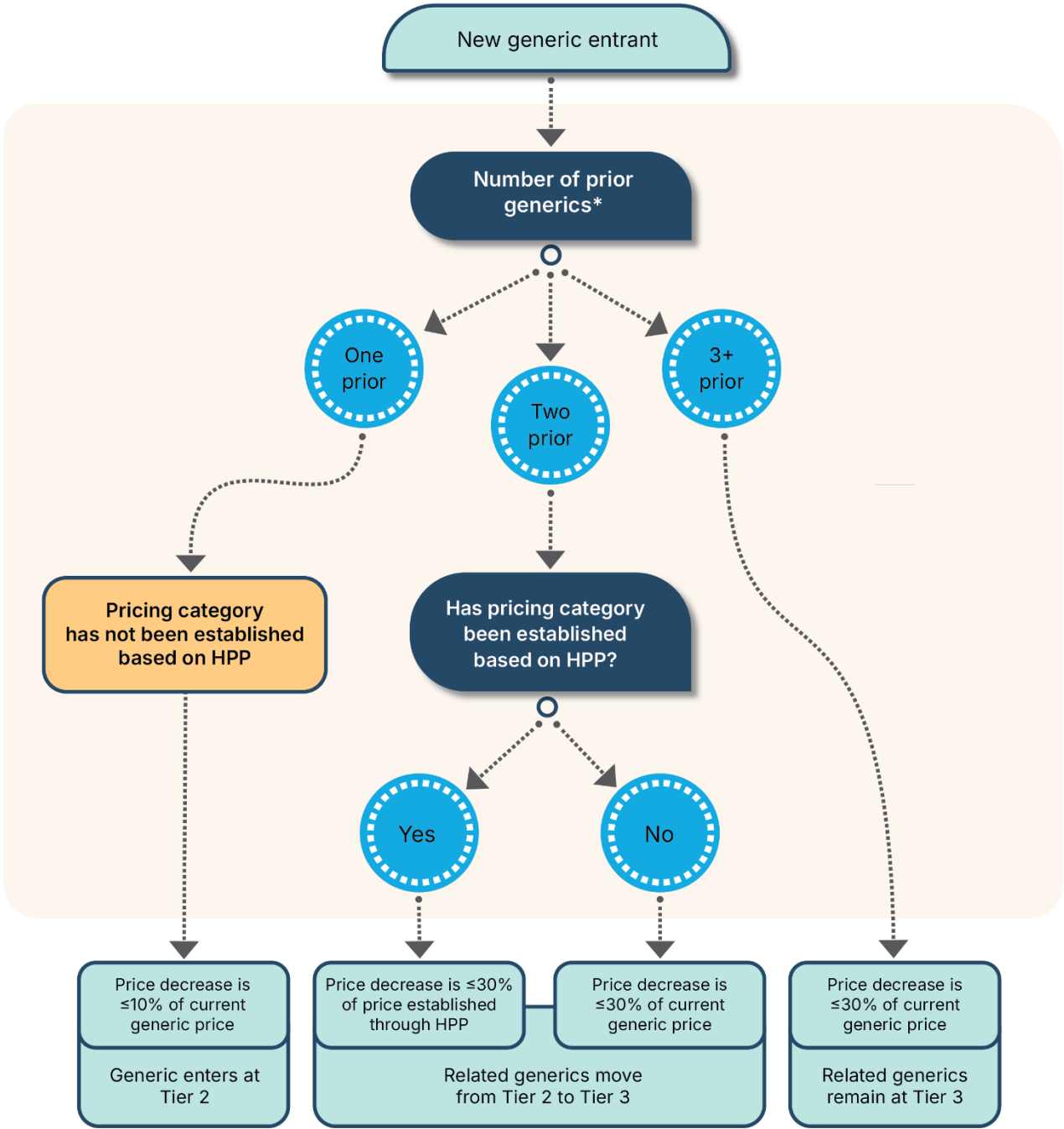
³ Excluding Submitted Product

⁴ Prior Generic Price (PGP): Marketed Generic Price prior to entering TPF, according to the sequence of jurisdictions



Historical Products Policy (HPP) entry process

When the TPF pricing grants a better price for a market entry, the TPF takes precedence to the HPP – please refer to the [Tiered Pricing Framework \(TPF\)](#) entry process. An [accessible version of this flowchart](#) is available.

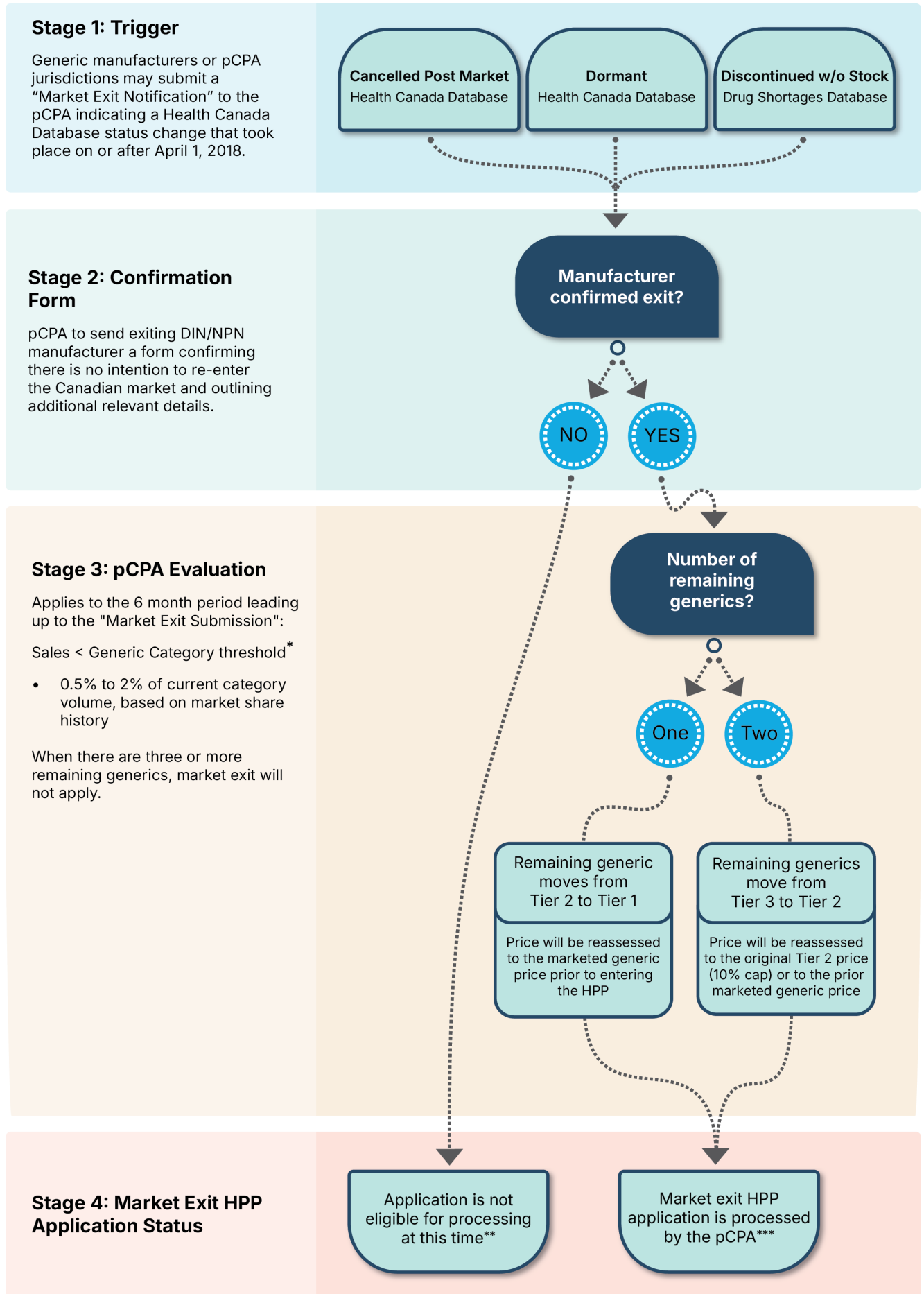


*If no prior generics, HPP does not apply - please refer to the TPF process for single-source generics



Historical Products Policy (HPP) exit process

The following exit process will occur in cases where the pricing category has already been established based on the HPP. Otherwise, refer to the [Tiered Pricing Framework \(TPF\) exit process](#). An [accessible version of this flowchart](#) is available.



* Generic Category: All products with same active ingredient, strength, and brand reference product.

** Requesting manufacturer may re-apply. Confirmation from Stage 2 may not be needed as part of the re-application process for previously confirmed MFRs ("no" at stage 3).

*** The pCPA will process the submitted market exit form and will recommend delisting of an exiting DIN/NPN to all jurisdictions.