

# Historical Products Policy

# Historical Products Policy

- 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<sup>st</sup>, 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:

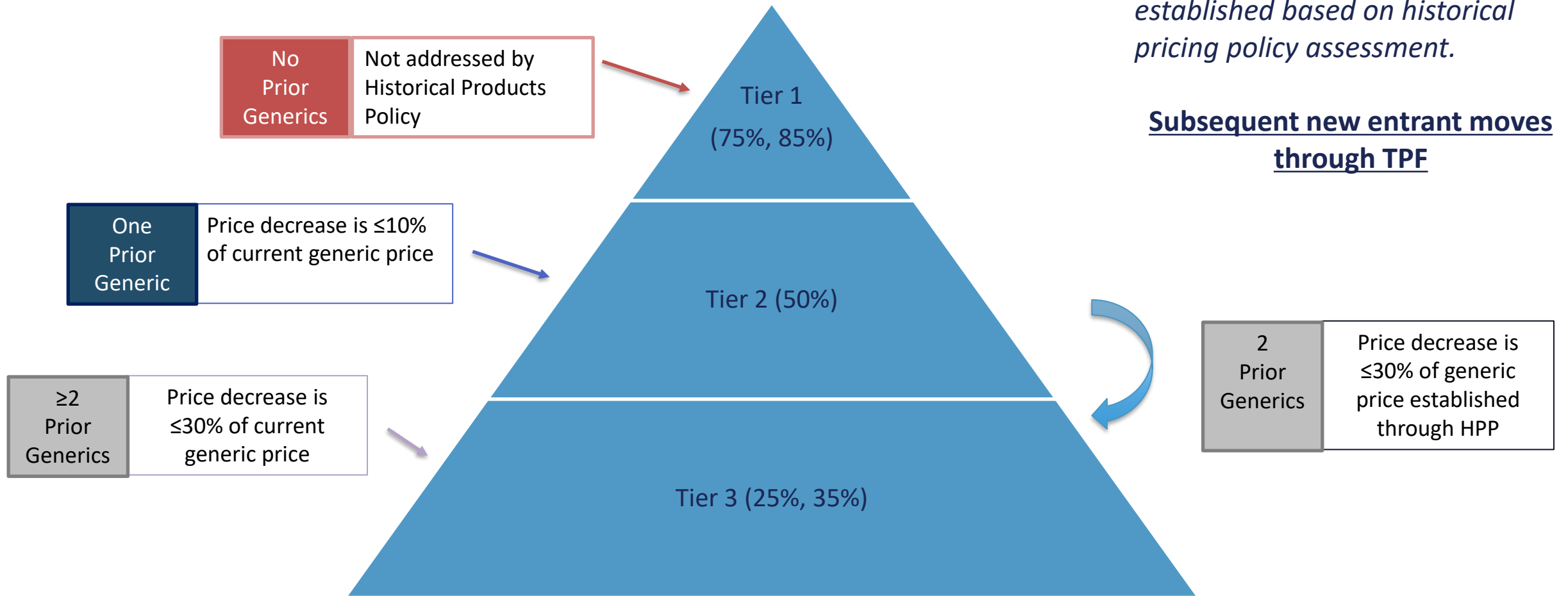
# of current generic competitors	Assessed Tier	Maximum Price Reduction
0	Tier 1	Not addressed by Historical Products Policy
1	Tier 2	Less than or equal to 10% <sup>1</sup>
2 or more	Tier 3	Less than or equal to 30% <sup>1,2</sup>

**(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 Entry: TPF & Historical Product Policy

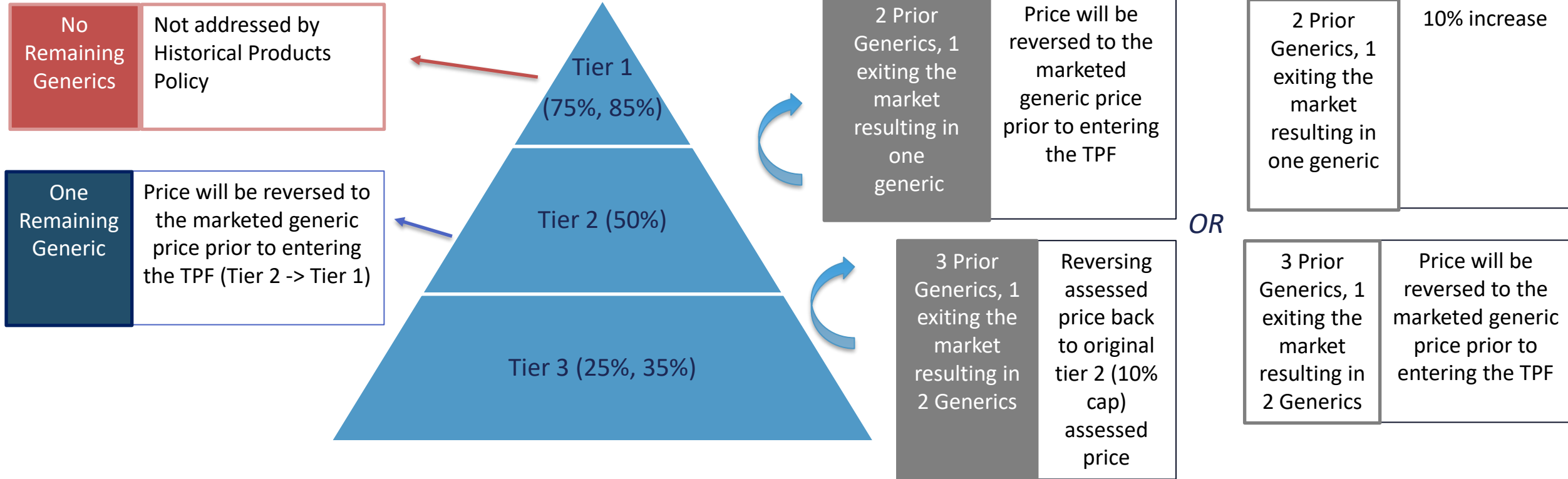
## New entrant brings price category into the TPF



\*arrows indicate new generic entrant

# Market Exit: TPF & Historical Product Policy

Subsequent exits can move through the TPF in 2 different ways depending on the scenario:



# Market Exit: TPF & Historical Product Policy

Generic Competitors At HPP Establishment*	First HPP "Tier"	Highest # of Generic Competitors within HPP	Market Exit to # of Competitors	HPP M.EX. Scenario
1	2	2	1	PGP**
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**
2	3	3	1	10% increase over PGP**
≥3	3	>3	≥3	Not Eligible
≥3	3	≥4	2	PGP**
≥3	3	≥3	1	10% increase over PGP**
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

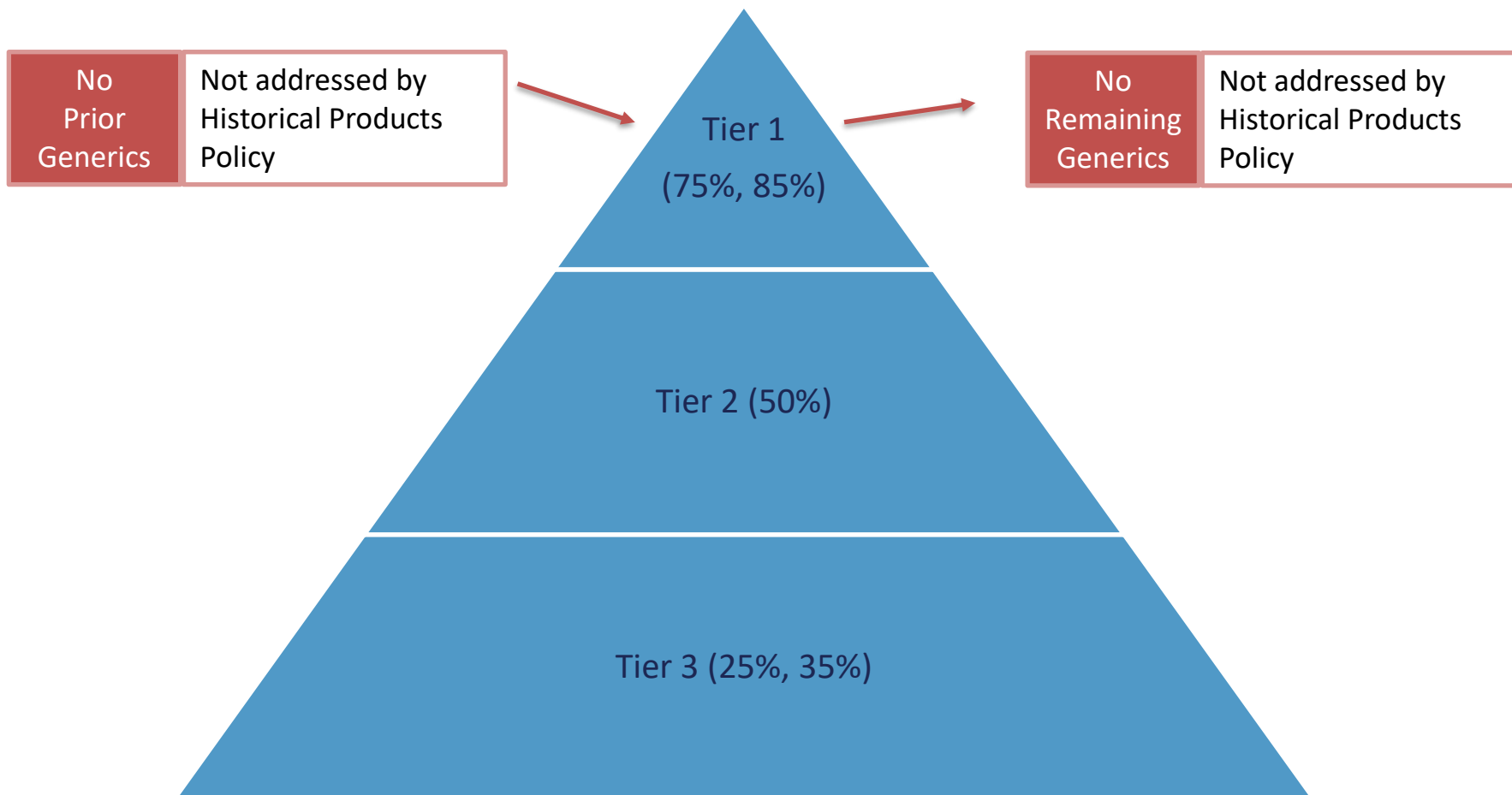
\*Excluding Submitted Product

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

# Example 1: Market Exit for Tier 1

New entrant brings price category into the TPF

Product exiting the established TPF category

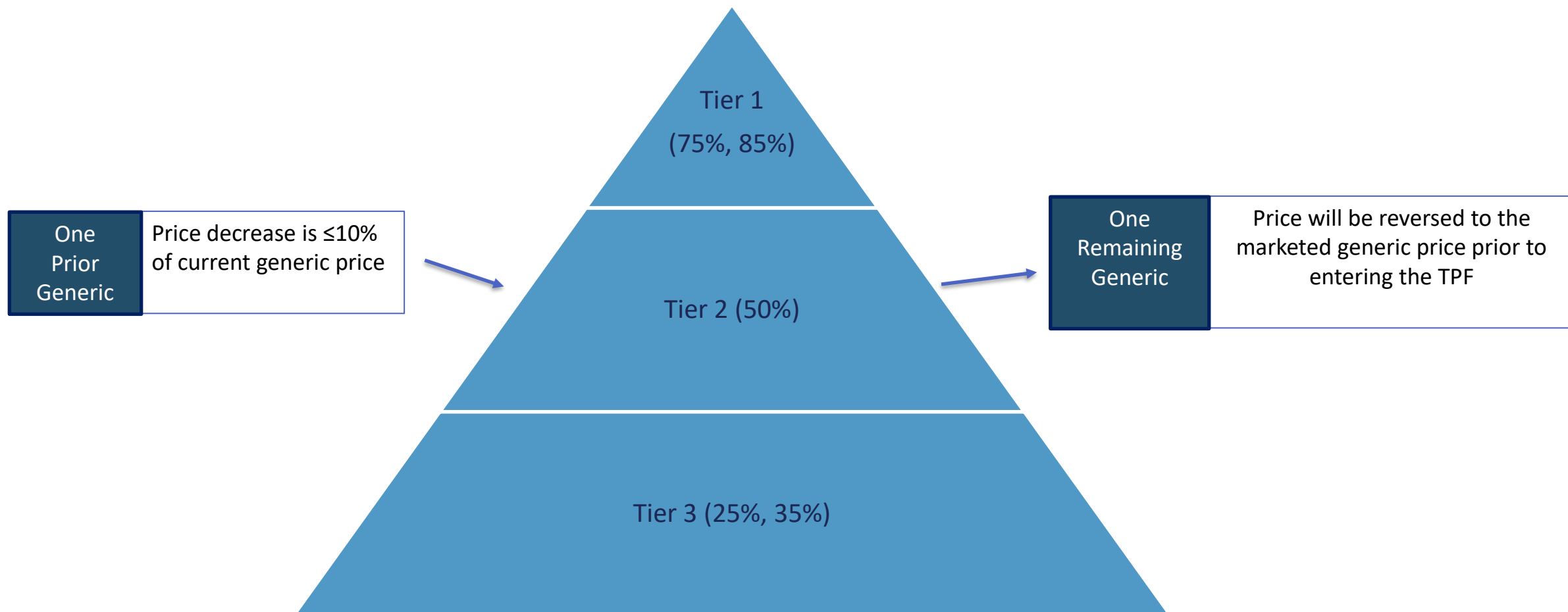




# Example 2A: 2 Marketed Generics, 1 Product Exits The Market

New entrant brings price category into the TPF

Product exiting the established TPF category

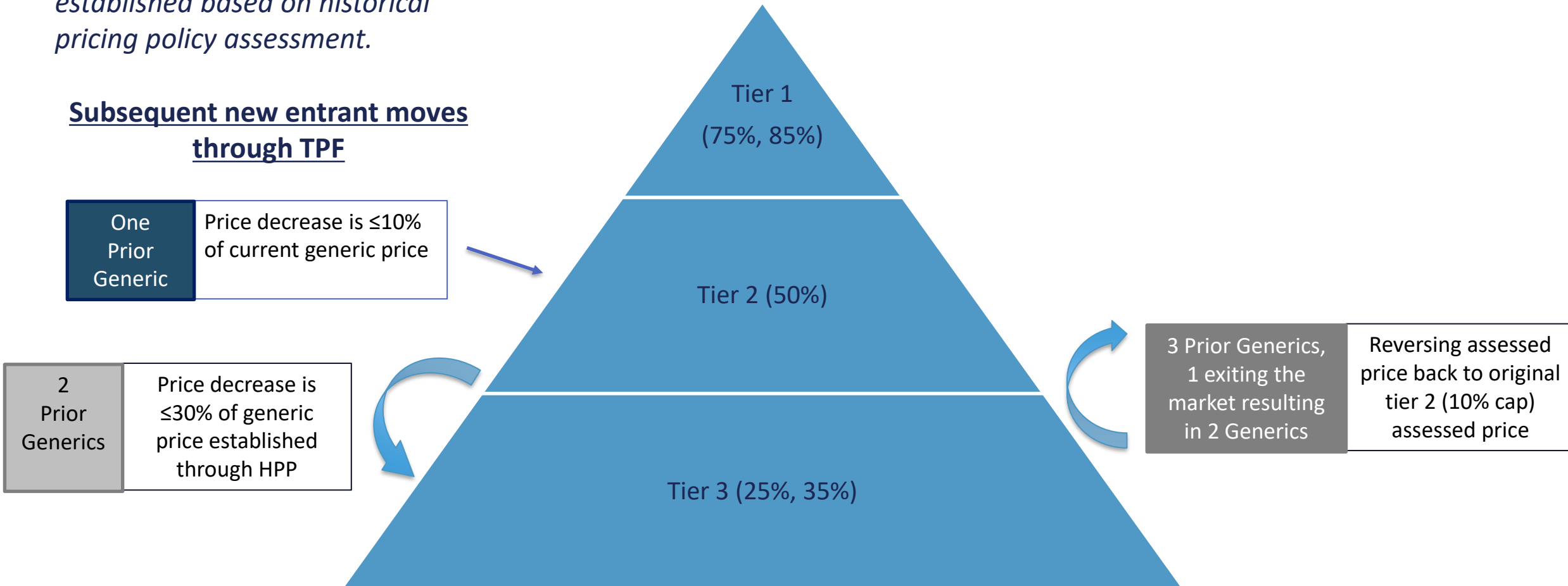


# Example 2B: 3 Marketed Generics, 1 Product Exits The Market

Pricing Category is already established based on historical pricing policy assessment.

Product exiting the established TPF category

Subsequent new entrant moves through TPF

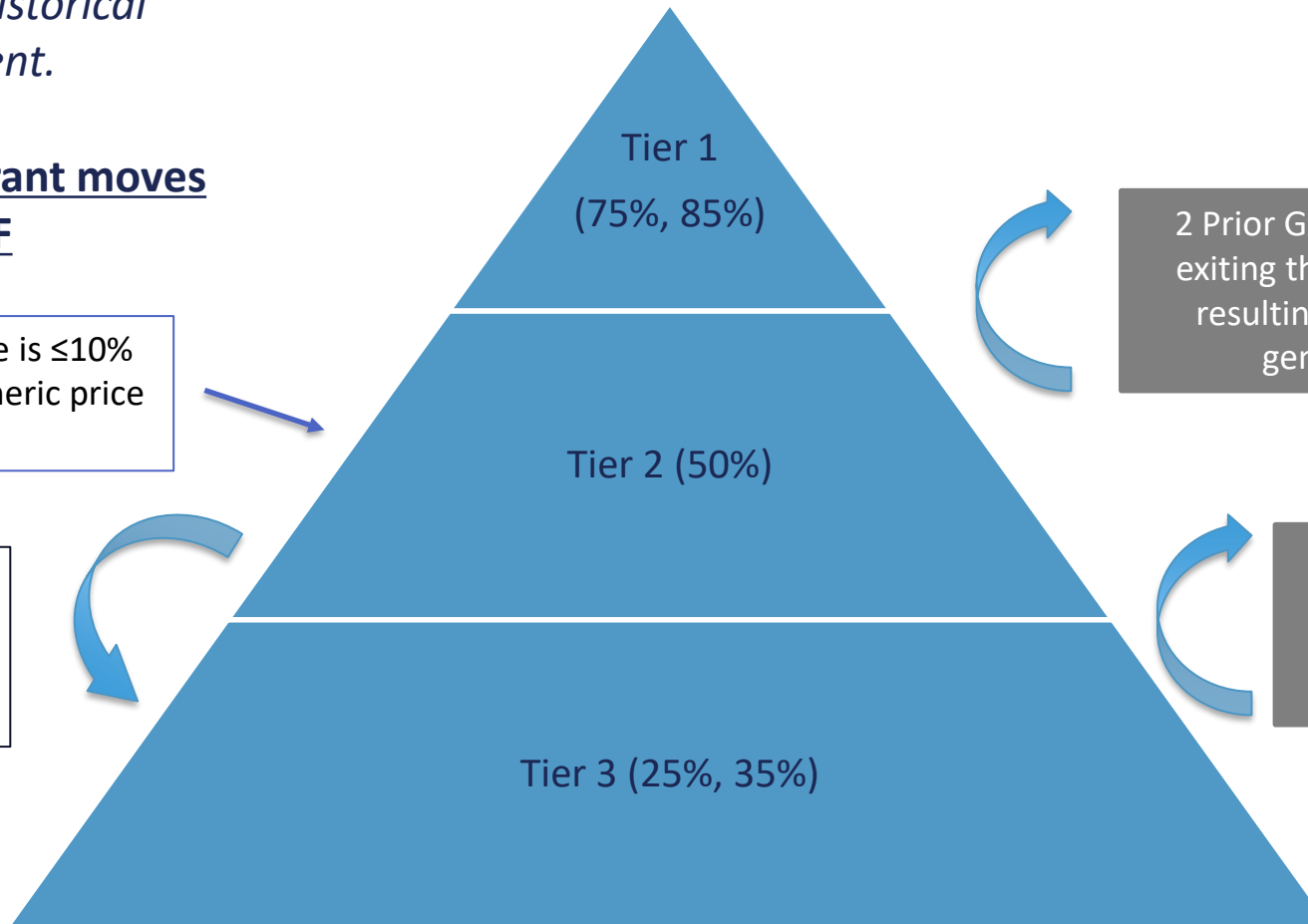


# Example 2C: Subsequent Market Exit

Pricing Category is already established based on historical pricing policy assessment.

## Product exiting the established TPF category

### Subsequent new entrant moves through TPF



One  
Prior  
Generic

Price decrease is ≤10%  
of current generic price

2  
Prior  
Generics

Price decrease is  
≤30% of generic  
price established  
through HPP

2 Prior Generics, 1  
exiting the market  
resulting in one  
generic

Price will be reversed to  
the marketed generic  
price prior to entering the  
TPF

3 Prior Generics,  
1 exiting the  
market resulting  
in 2 Generics

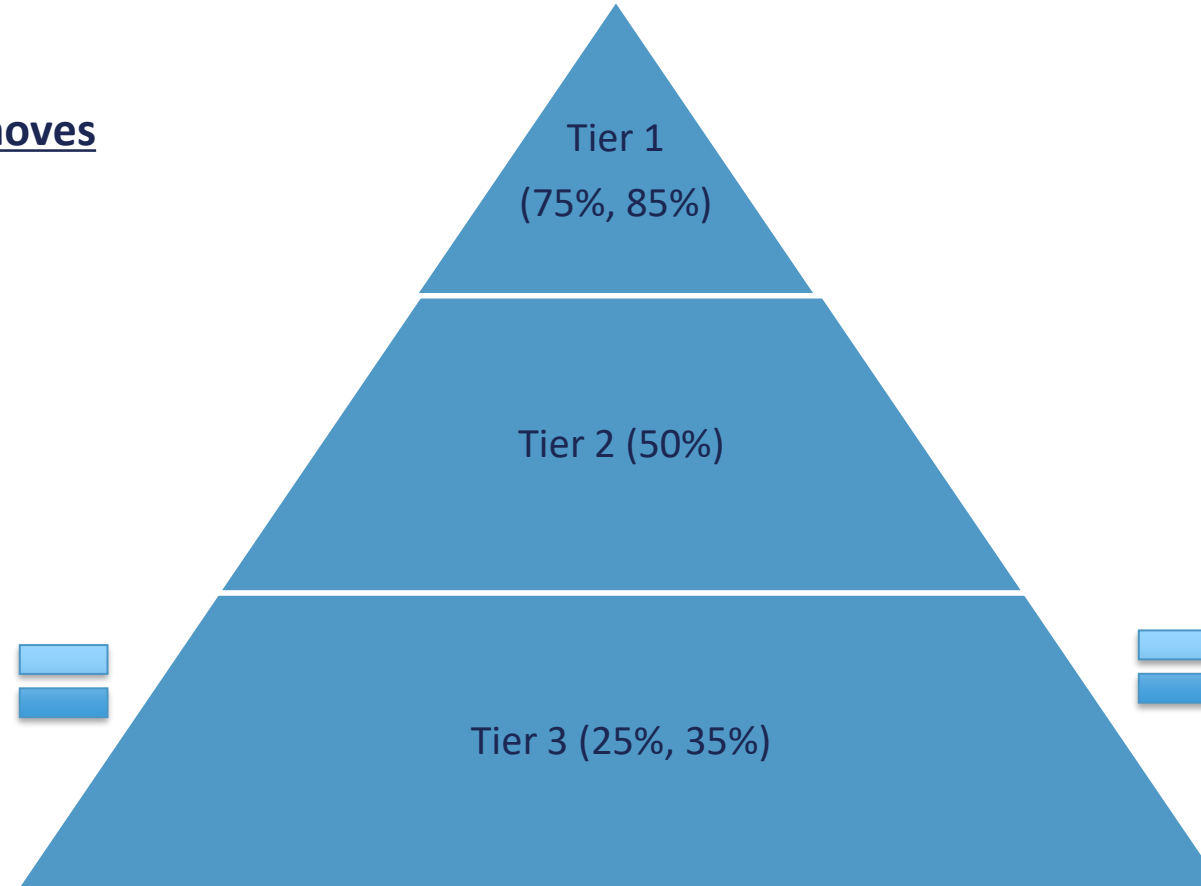
Reversing assessed  
price back to original  
tier 2 (10% cap)  
assessed price

# Example 2D: 3+ Marketed Generics, 1 Product Exits The Market

*Pricing Category is already established based on historical pricing policy assessment.*

Product exiting the established TPF category

Subsequent new entrant moves through TPF



3+  
Prior Generics,  
TPF/HPP  
Established

No change from  
price already  
established in  
TPF/HPP



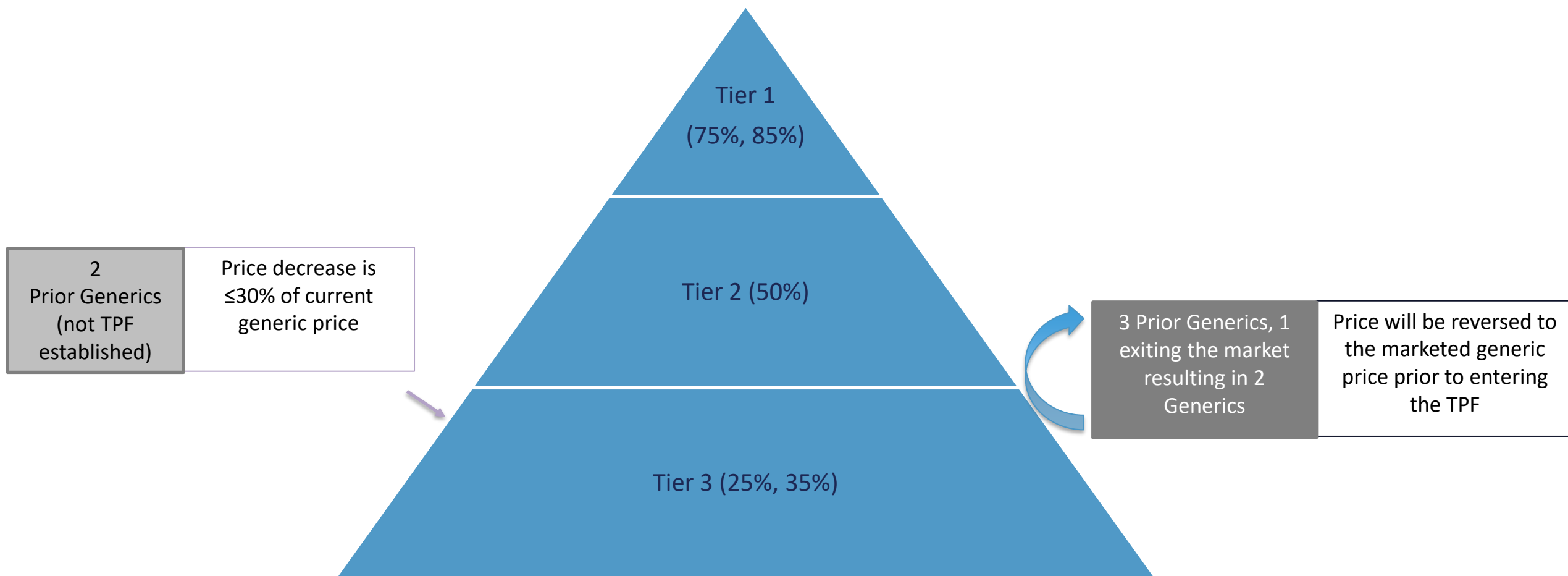
3+  
Prior Generics,  
TPF/HPP  
Established

Market exit will  
not apply if there  
is no TPF Tier  
Change as seen  
here

# Example 3A: 3 Marketed Generics, 1 Product Exits The Market

New entrant brings price category into the TPF

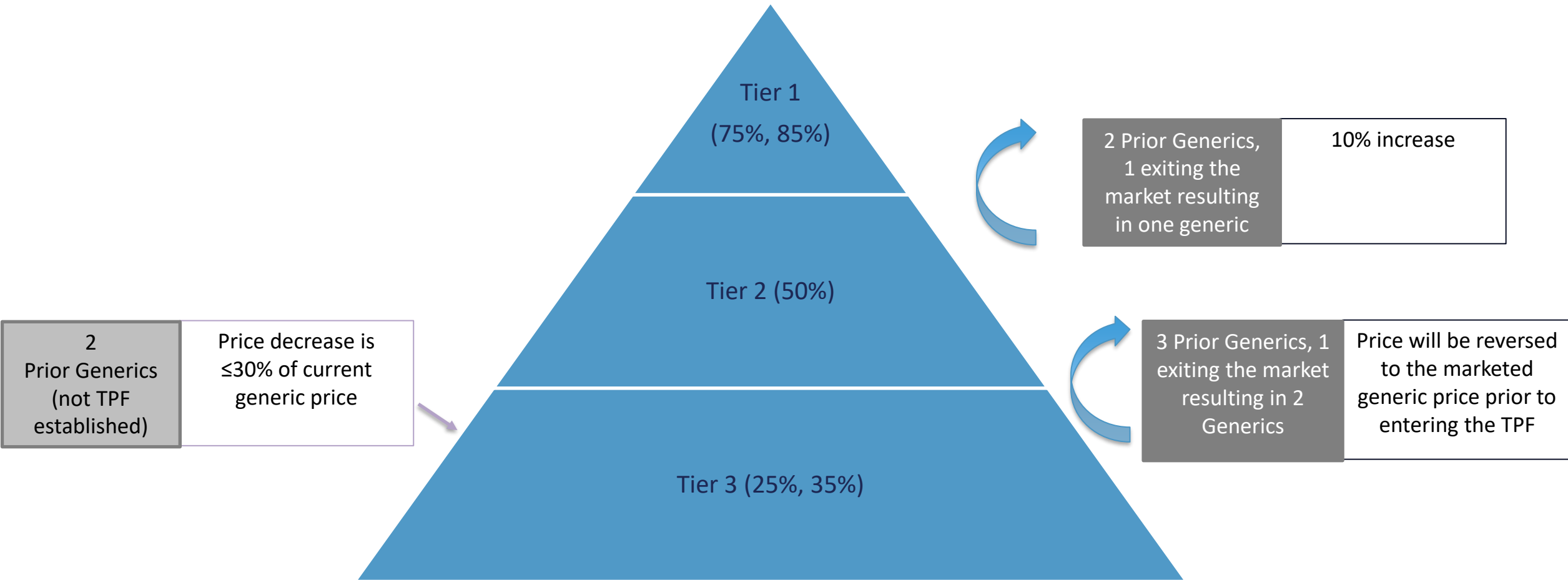
Product exiting the established TPF category



# Example 3B: Subsequent Market Exit

New entrant brings price category into the TPF

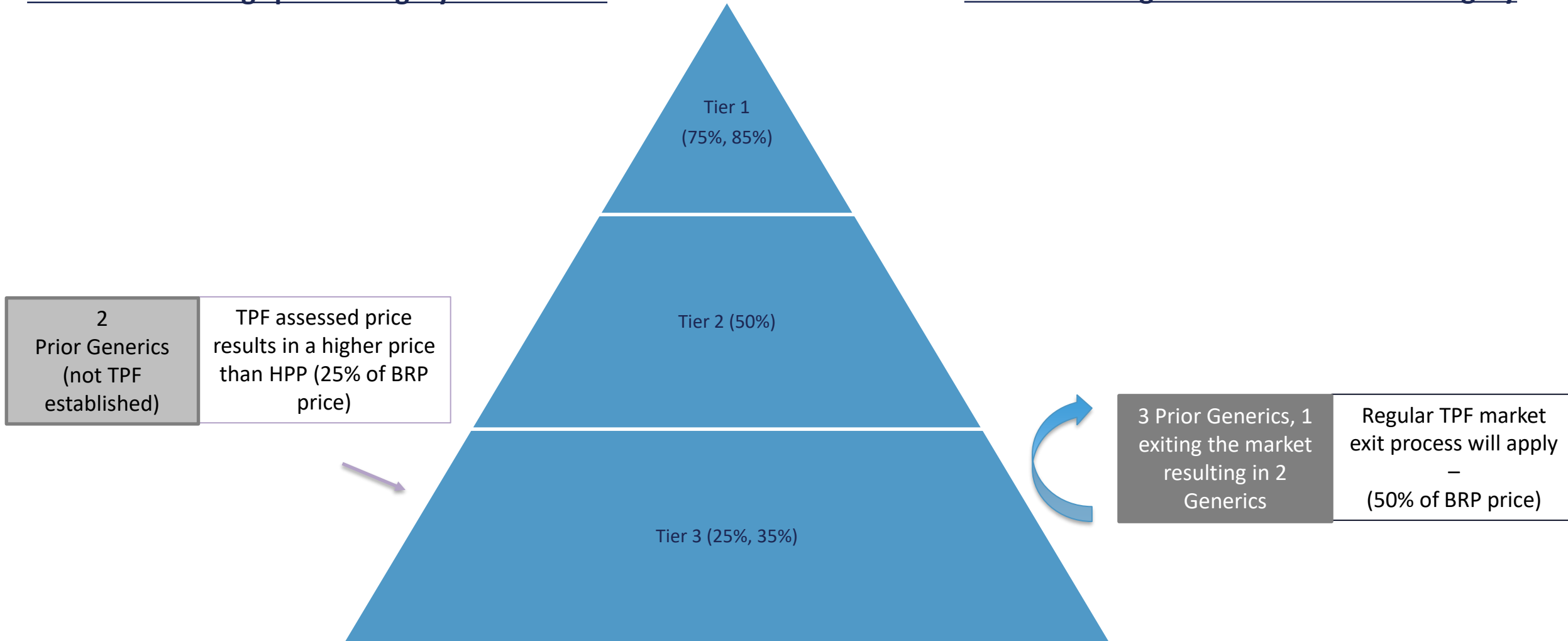
Product exiting the established TPF category



# Example 4A: When TPF Results in a Higher Price than HPP

New entrant brings price category into the TPF

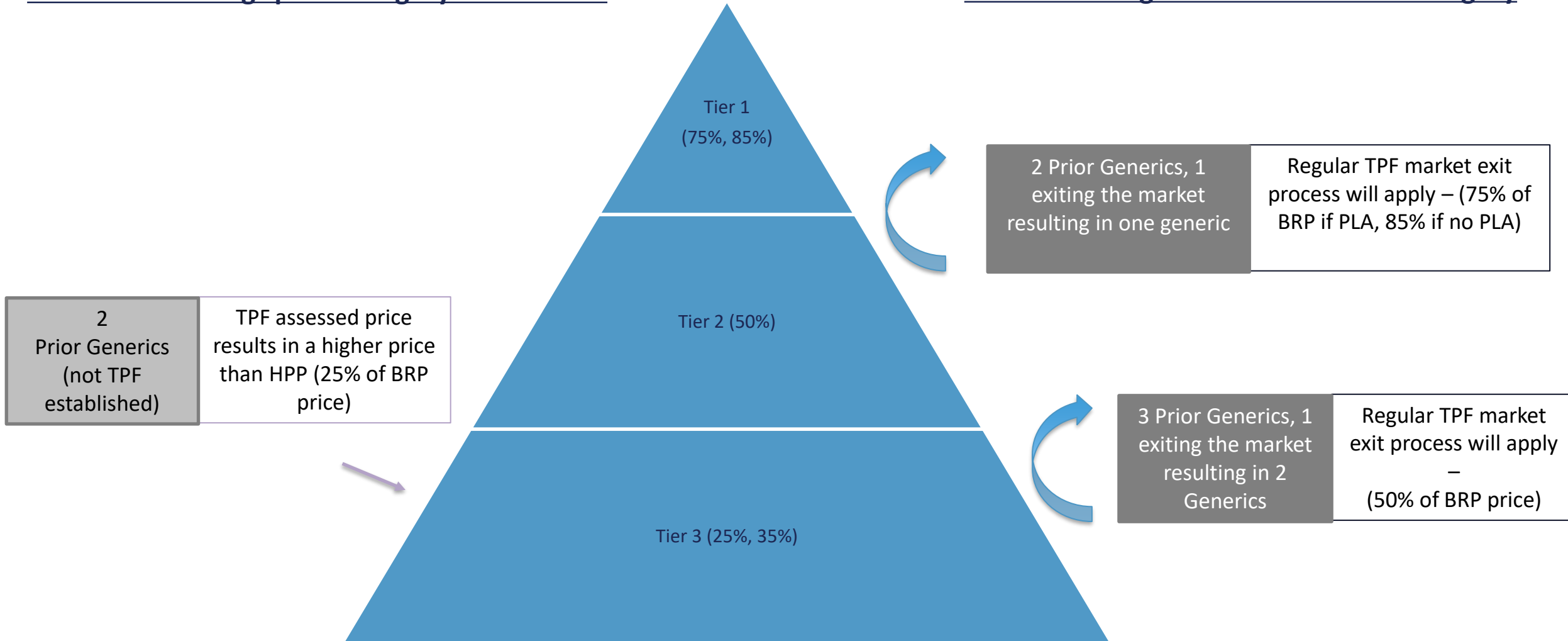
Product exiting the established TPF category



# Example 4B: When TPF Results in a Higher Price than HPP

## New entrant brings price category into the TPF

## Product exiting the established TPF category

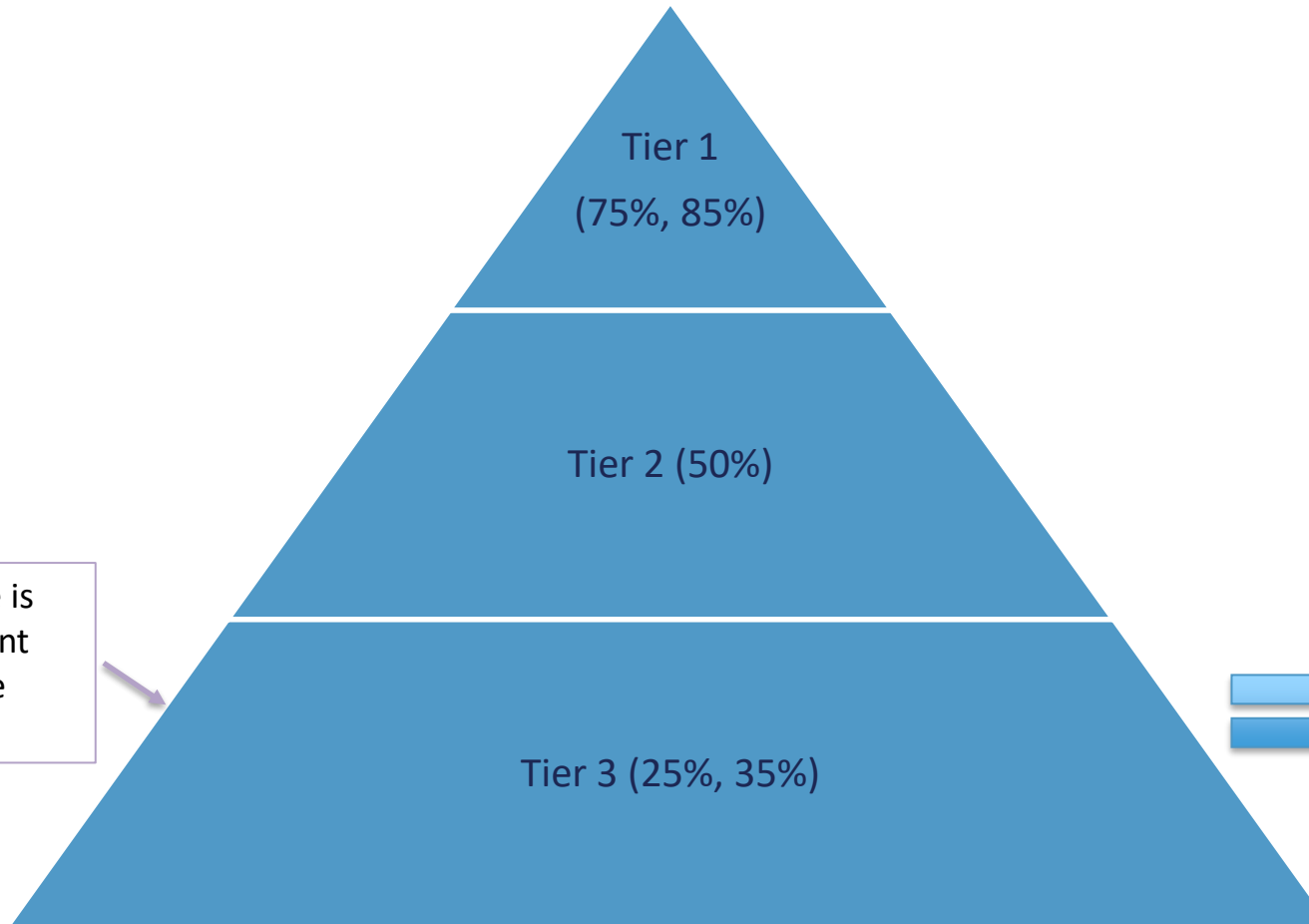




# Example 5: 3+ Marketed Generics, 1 Product Exits The Market

New entrant brings price category into the TPF

Product exiting the established TPF category



≥3  
Prior Generics  
(not TPF  
established)

Price decrease is  
≤30% of current  
generic price

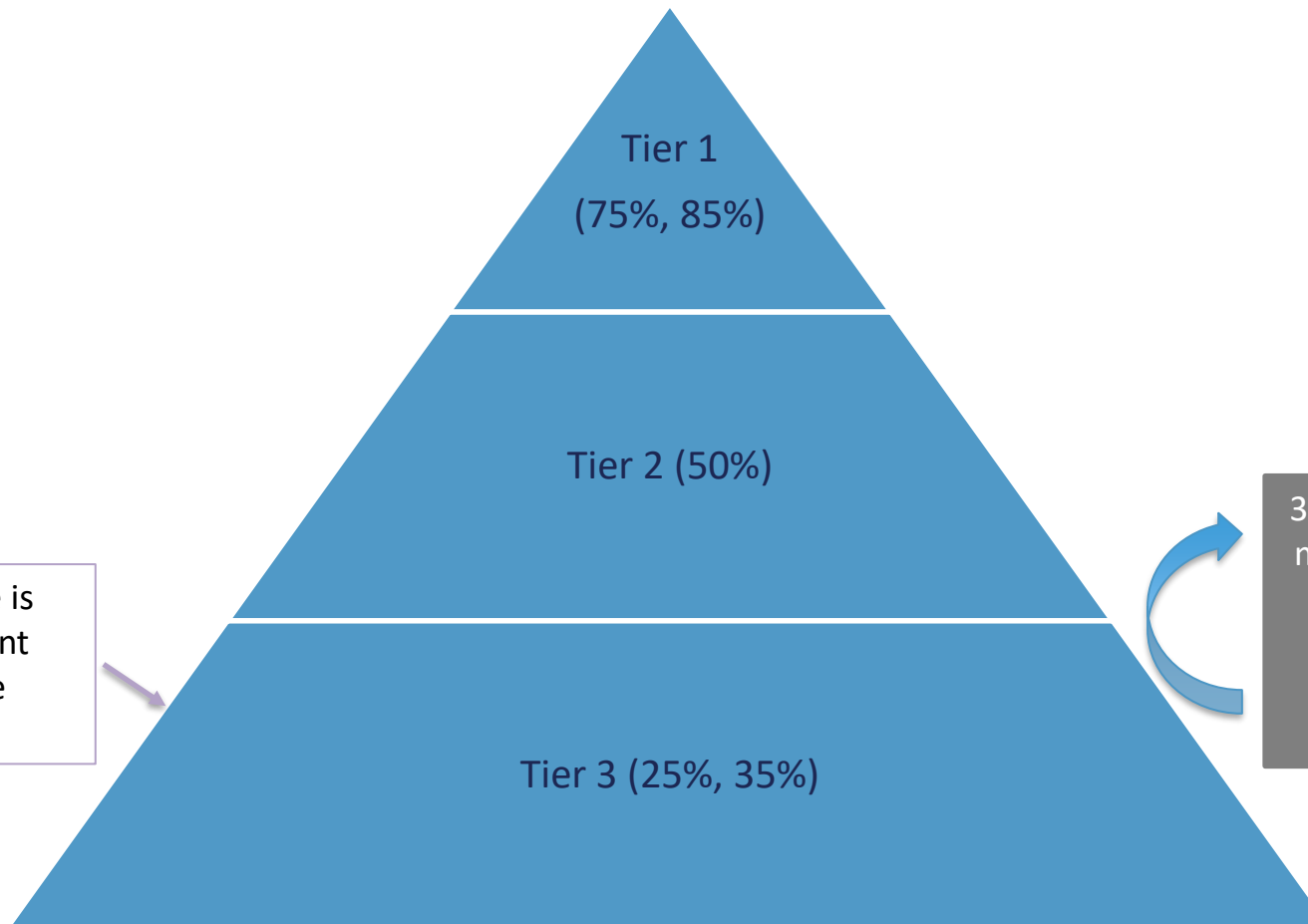
3+  
Prior Generics,  
TPF/HPP  
Established

Market exit will  
not apply if there  
is no TPF Tier  
Change as seen  
here

# Example 6: 3+ Marketed Generics, Product(s) Exits The Market Resulting in Tier Change

New entrant brings price category into the TPF

Product exiting the established TPF category



≥3  
Prior Generics  
(not TPF  
established)

Price decrease is  
≤30% of current  
generic price

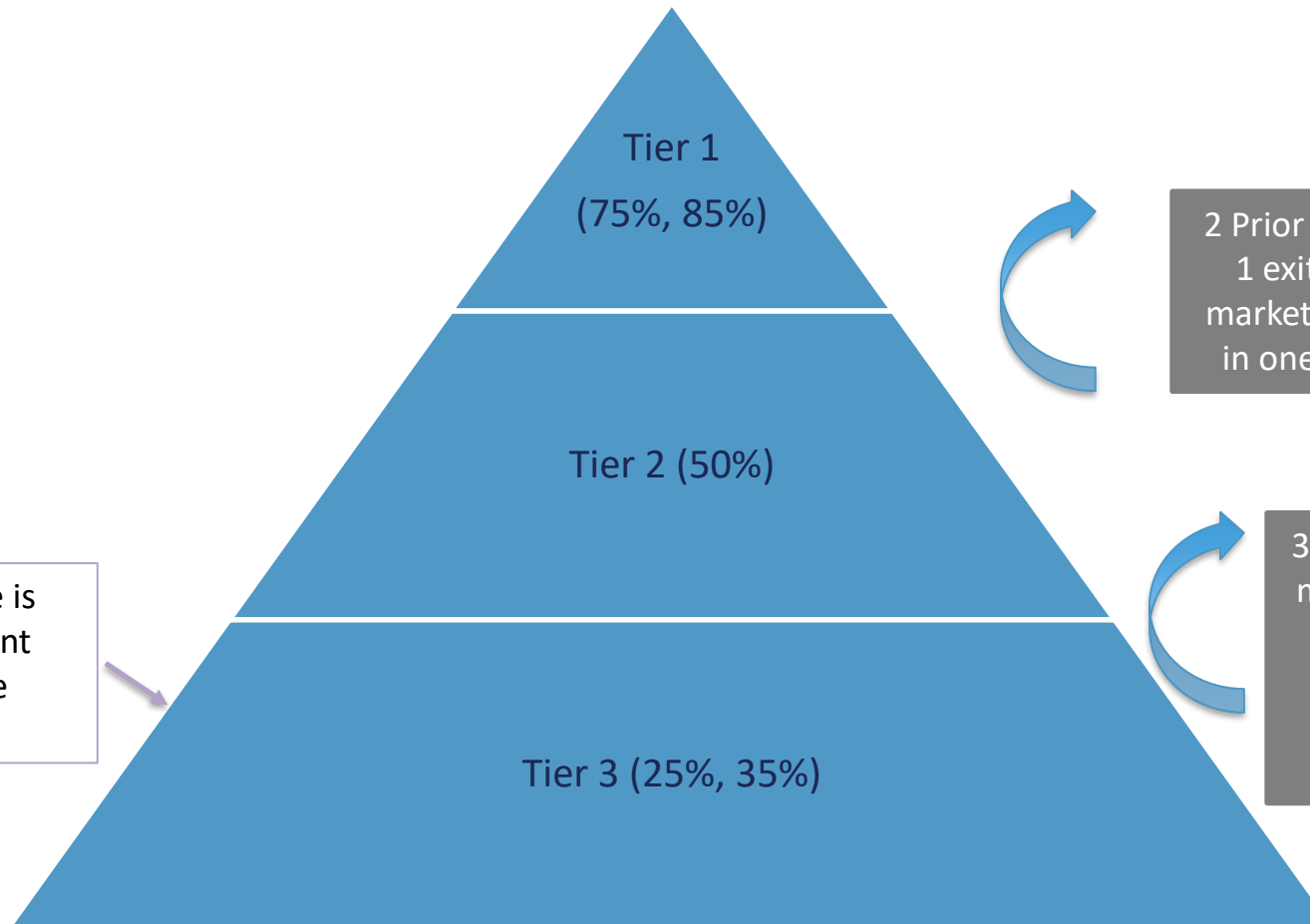
3+ Prior Generics,  
multiple generics  
exit the market  
resulting in 2  
competitors

Price will be reversed  
to the marketed  
generic price prior to  
entering the TPF

# Example 7: 3+ Marketed Generics, Product(s) Exits The Market Resulting in Tier Change

New entrant brings price category into the TPF

Product exiting the established TPF category



2 Prior Generics,  
1 exiting the  
market resulting  
in one generic

10% increase

3+ Prior Generics,  
multiple generics  
exit the market  
resulting in 2  
competitors

Price will be reversed  
to the marketed  
generic price prior to  
entering the TPF

≥3  
Prior Generics  
(not TPF  
established)

Price decrease is  
≤30% of current  
generic price

# Example 8: Market Exits that Establish TPF Category

Market Exits brings price category into the TPF:  
Regular TPF will apply

