



Drug Price Adjustments under Taiwan's Health Insurance System

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Outline

- Regulations regarding drug price adjustment
- Price and Volume Survey
- Principles of drug price adjustment
- Drug Expenditure Target (DET)
- Examples



Regulations Regarding Drug Price Adjustment

- **Article 46, National Health Insurance Act**
 - The Insurer should adjust drug prices based on prevailing market conditions; prices for drugs with patents, which have **expired for a year**, should start being lowered; gradual adjustment to reasonable prices should be done within **five years** based on **prevailing market conditions**.
 - The Competent Authority shall determine the operating procedure for the adjustment in the preceding paragraph as well as the relevant rules.
- **Drug Price Adjustment Scheme**
 - Promulgated by the Ministry of Health and Welfare (MoHW) on Oct. 2, 2013.



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- Regulations regarding drug price adjustment
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Price and Volume Survey (1)

➤ **Pharmaceutical Companies:**

- All the pharmaceutical companies selling drugs directly to the contracted medical care institutions shall declare to the Insurer the sales data of the previous season **within 20 days on the first month following the end of every season.**

➤ **Medical Care Institutions:**

- **General purchase data survey:** The contracted medical care institutions shall declare to the Insurer the purchase data of the previous season **within 20 days on the first month following the end of every season.**
- **Special purchase data survey:** The contracted medical care institutions shall declare items as well as follow the declaration time course as announced by the Insurer.



Price and Volume Survey (2)

- **Ad hoc Survey :**
 - When being reported as indicated by clear evidence **and** when the following criteria are met
 - Sales price is **50%** lower than reimbursement price.
 - More than **3 items** in the same group.
 - The total declared expenditure exceeds **100 millions**.
 - **Not basic price.**
 - **item of the same group** shall be surveyed and dealt.



Survey on Sales Data

- **Declare via internet:**
 - Pharmaceutical companies shall upload transaction data via internet.
- **Declaration system:**
 - Website: <https://med.nhi.gov.tw>



Undeclared or False Declaration (1)

- **False Declaration:** when any of the following condition is met
 - Did not declare **gifted** quantities or did not deduct **discounts** from the declared trading value.
 - Only declare transaction data from **part** of the contracted medical care institutions.
 - **Other** actions that may **influence** the **accuracy** or **integrity** of surveys.
- **Measures to deal with** undeclared or false declaration
 - Delisting
 - Price reduction
 - All items from the same drug license are dealt with together.



Undeclared or False Declaration (2)

- Principles regarding submission of new items listing and price adjustment
 - Drugs from the same license **can not submit** for listing until one year afterwards.
 - **Basic price can not be applied** until one year afterwards..

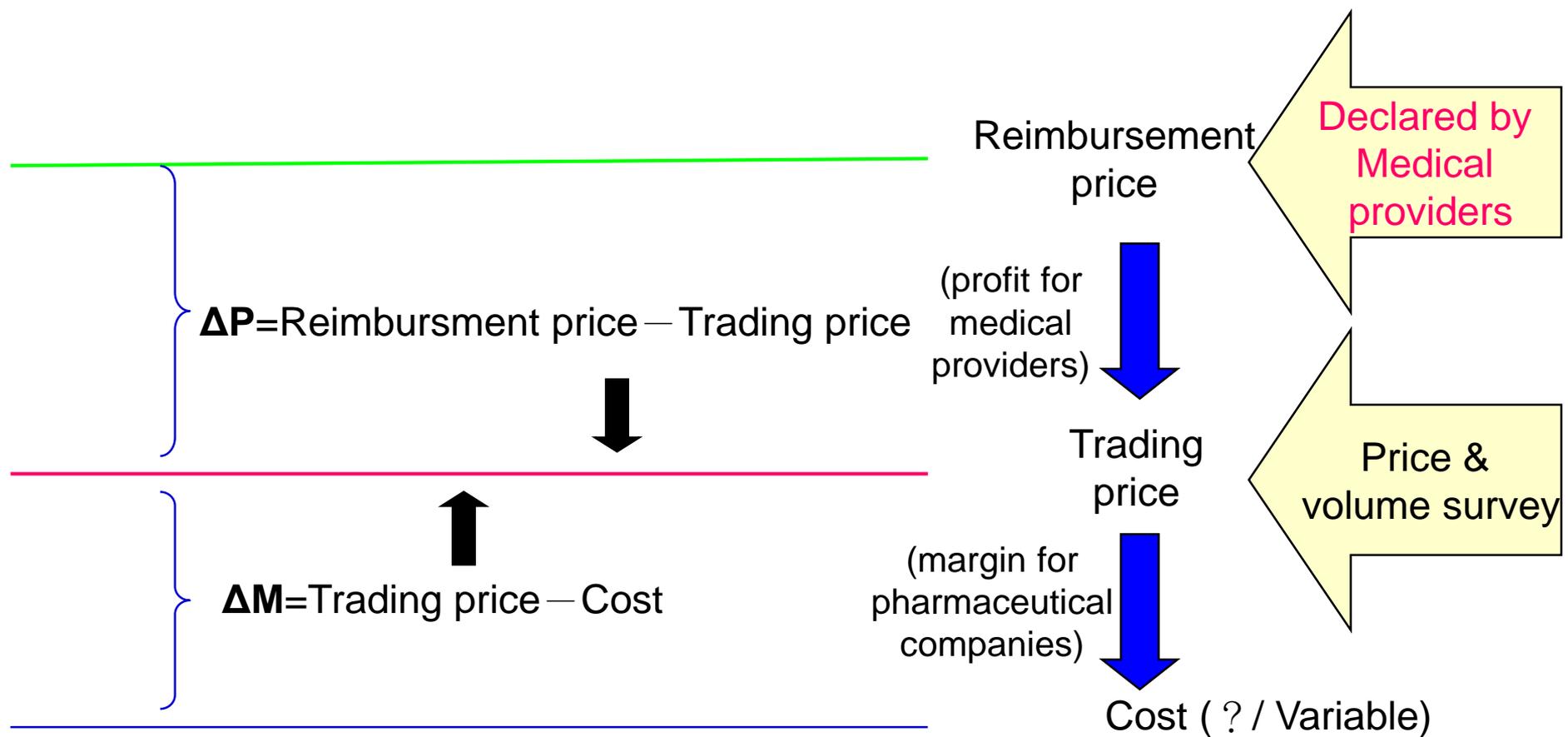


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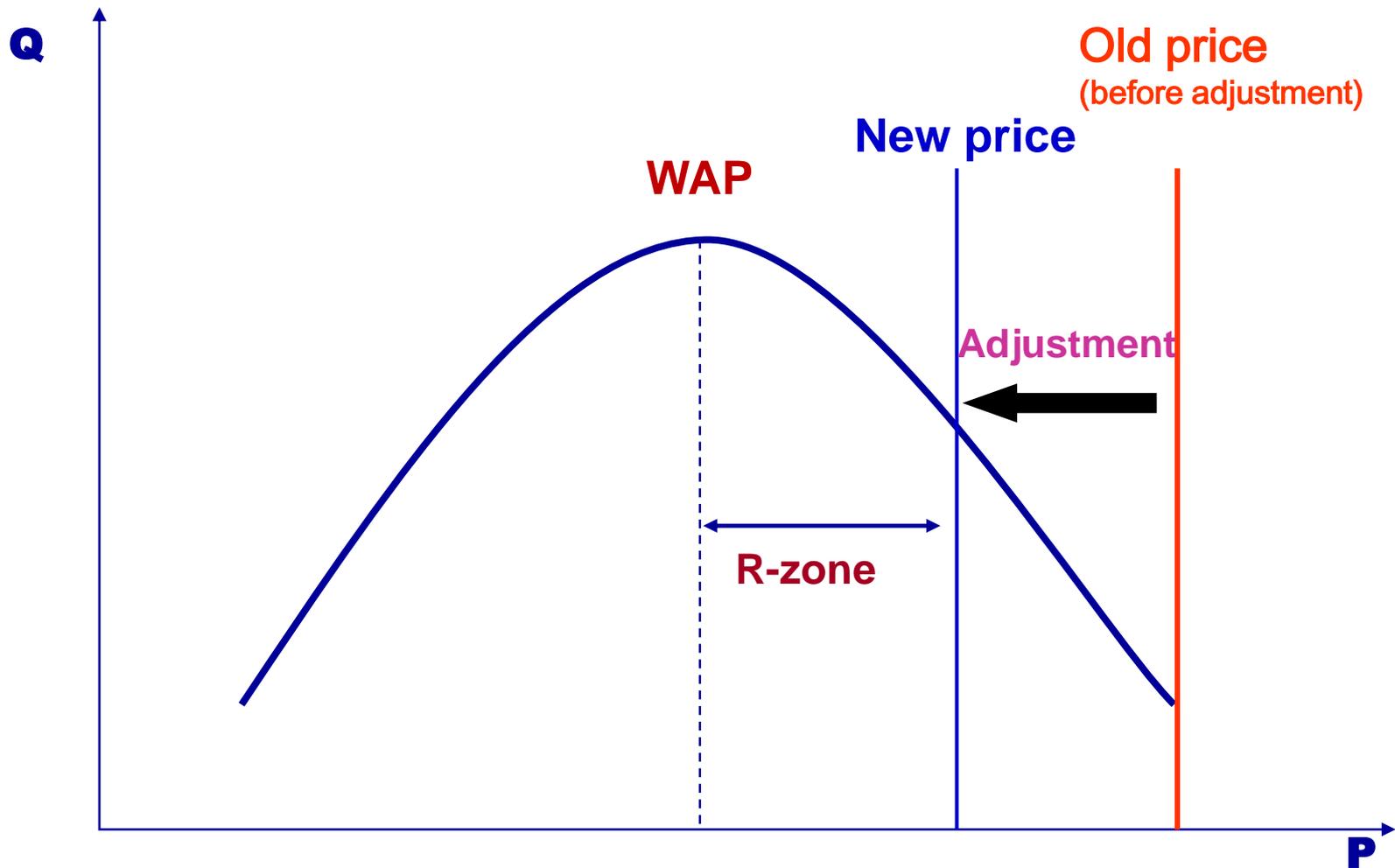


Principles of Drug Price Adjustment





Principles of Drug Price Adjustment



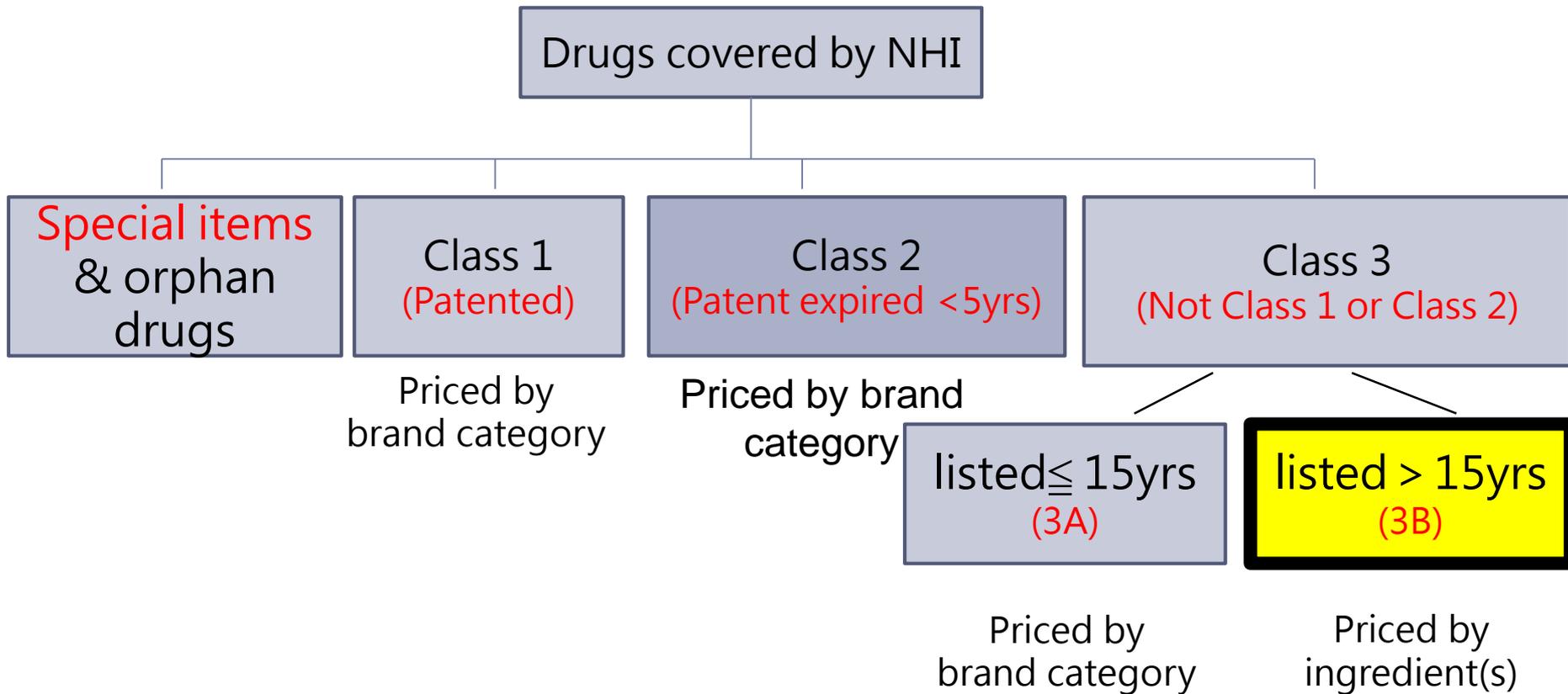


Principles of Drug Price Adjustment

- Adjust the reimbursement prices of drugs by referring to their actual transaction prices, so the reimbursement prices will **get closer to the market trading prices** .
- **Timely reflect** the market trading prices for off-patent drugs.



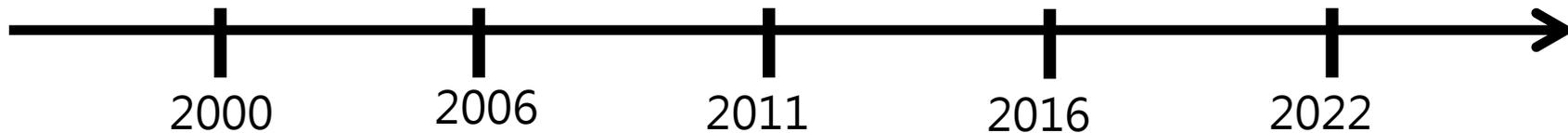
Framework of Drug Price Adjustment



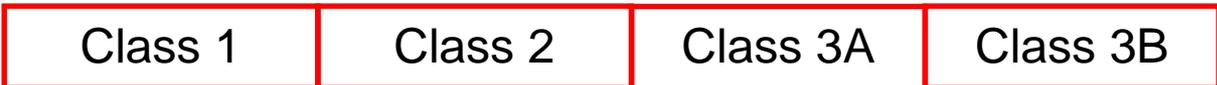


Framework of Drug Price Adjustment

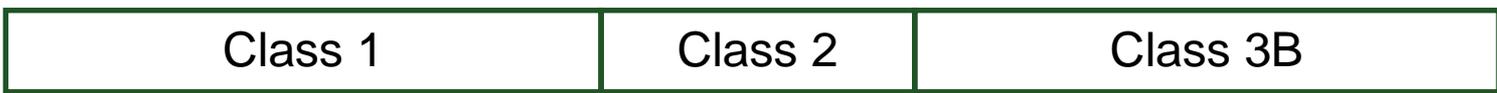
Patent expiration date



Item A



Item B



※Listed > 15yrs (Class 3 B): Determined by when the first item with the same ingredient(s) and dosage form is listed.



Time course of Drug Price Adjustment

Class	Range	Time course
Class 1	<ol style="list-style-type: none">1. Patented items2. Other items from the same group	<ol style="list-style-type: none">1. Once every 2 yrs2. Under DET program: When the expenditure target is exceeded
Class 2	<ol style="list-style-type: none">1. Items with patent expired <5yrs2. Other items from the same group	Once a year (by items)
Class 3	Items other than Class 1 or 2	<ol style="list-style-type: none">1. Once every 2 yrs2. Under DET program: When the expenditure target is exceeded



Drug Price Adjustment- Data Collection & Effective Date(1)

- **Data collection** of class **1 & 3** drugs
 - Sales data of pharmaceutical companies **within 1 year** after the latest price adjustment are collected.
 - If less than 1 year, data up to the time point of the price review are collected.
- **Effective date** of the new price after adjusting
 - Routine adjustment (once every 2yrs): as announced by the Insurer
 - Under DET program: The 1st day of the 1st month of the 2nd season in the next fiscal year (**April 1st**).



Drug Price Adjustment- Data Collection & Effective Date(2)

➤ Class 2 drugs

Season when the patent expires	Collection interval of sales data	Effective date of the new price
1 st season	The 3 rd & 4 th season of the previous year	Jun. 1 st
2 nd season	The 4 th season of the previous year and the 1 st season	Sep. 1 st
3 rd season	The 3 rd & 4 th season	Dec. 1 st
4 th season	The 2 nd & 3 th season	Mar. 1 st of the next year



Grouping

- **Same Group** : Drugs with identical **ingredients, content, specification** and **dosage form**.
- **Weighted average market trading price (WAP)**
 - $\frac{\Sigma(\text{Trading value of drugs within the same group and from the same license holder})}{\Sigma(\text{Trading volume})}$
- **Group weighted average market trading price (GWAP)**
 - $\frac{\Sigma(\text{Trading value of drugs in the same group})}{\Sigma(\text{Trading volume})}$



Price Adjustment-Class 1 (1)

➤ Equation for adjustment

(一) $WAP \geq (1-R) \times P_{old}$: No adjustment

(二) $WAP < (1-R) \times P_{old}$: Adjust as following

$$P_{new} = WAP + P_{old} \times R \quad (R : 15\%)$$

P_{new} : New reimbursement price after adjusting

WAP: Weighted average market trading price

P_{old} : Reimbursement price before adjusting



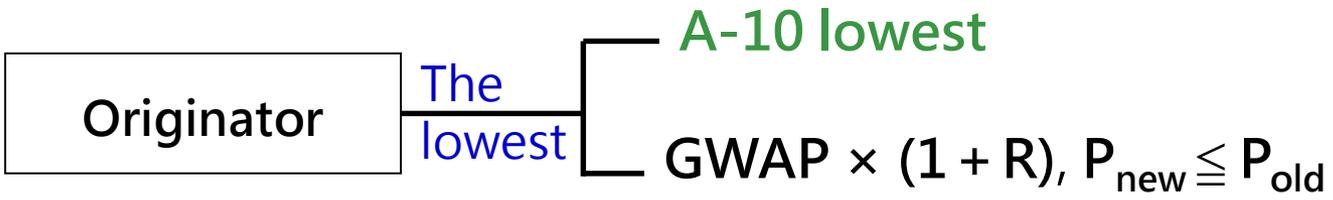
Price Adjustment-Class 1 (2)

- The **upper limit** of **adjustment range**: 40% (except under DET program)
- Set the **lowest price** within a **group**:
 - When the reimbursement price for an item after adjusting is **70%** lower than the **highest reimbursement price** within the same group, then its price shall be adjusted to 70% of the highest reimbursement price within the same group.
- **P_{new}** shall not be higher than **P_{old}**.
- **Generic** shall not be higher than **originator**.



Price Adjustment-Class 2

➤ Patent expired > 1 year



Items within the same group — Adjustment range based on originator
(If no originator is listed : $GWAP \times (1 + R), P_{new} \leq P_{old}$)

➤ Patent expired for 2~5 years



Items within the same group — Adjustment range based on originator
(If no originator is listed : $GWAP \times (1 + R), P_{new} \leq P_{old}$)

※ R=15% GWAP: Group weighted average market trading price



A-10 Reference Countries

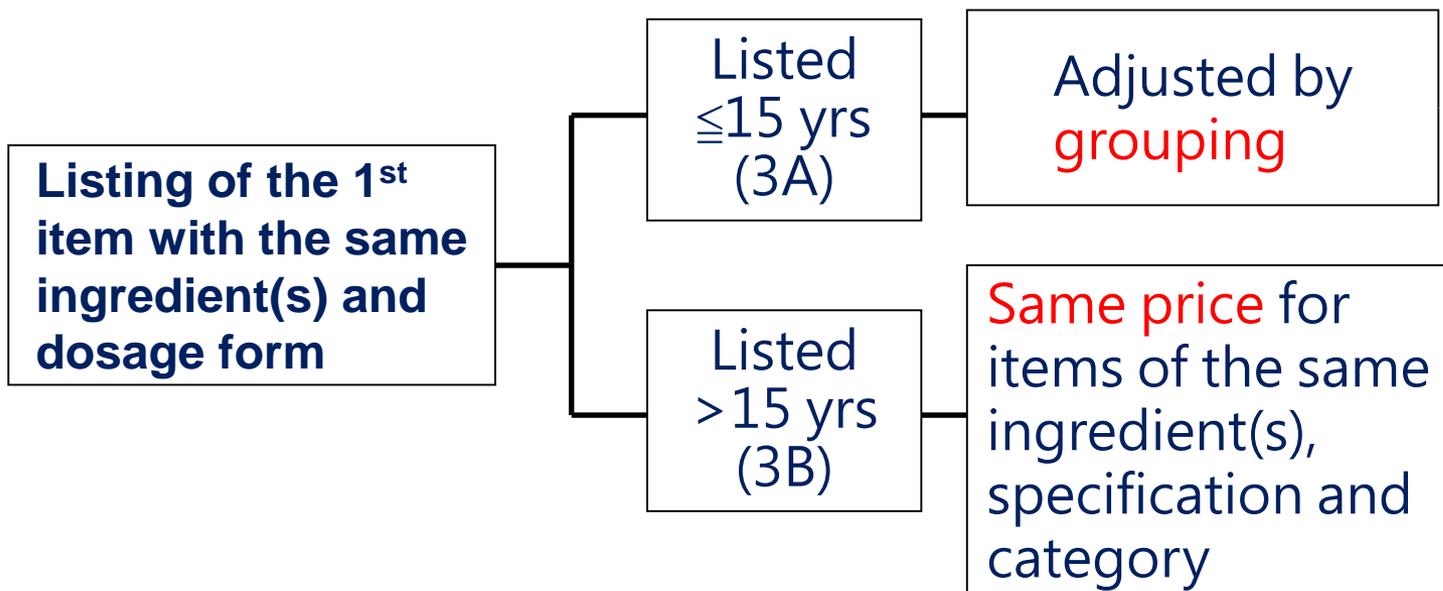
Country	Source of Reference
US	Red Book (not official publication)
Japan	Drug price baselines (official website)
UK	NHS Prescription Service (official website)
Canada	Saskatchewan Formulary (official website)
Germany	ROTE LISTE (official website)
France	Base des Médicaments et Informations Tarifaires (official website)
Belgium	Centre Belge d'Information Pharmacothérapeutique (official website)
Sweden	Farmaceutiska specialiteter i Sverige (official website)
Switzerland	Arzneimittel kompendium der schweiz (official website)
Australia	Pharmaceutical Benefits Scheme (official website)





Price Adjustment-Class 3

Subcategories of Class 3





Price Adjustment-Class 3A (1)

The 1st item with the same ingredient(s) and dosage form has been listed ≤ 15 yrs

1. Set temporary price after adjusting

- GWAP as the target value of the temporary price
- Items within the same group ≤ 20 trading datas : Use item of other specifications with the highest sales volume in the previous year for calculating the target value (based on the conversion of specifications).
- **Temporary price after adjusting** = Min [Max [Min (WAP, target value $\times 1.05$), target value $\times 0.9$] , Pold]

If an item has no WAP, then the temporary price = target value



Price Adjustment-**Class 3A** (2)

2. Adjustment range and the maximum adjustment range

$$\text{Adjustment range (AR)} = (P_{\text{old}} - P_{\text{temp}}) / P_{\text{old}}$$

$$P_{\text{new}} = P_{\text{old}} \times [1 - \text{Min}(\text{AR} - 15\%, \text{AR}_{\text{Max}})]$$

★ Under DET program

$$P_{\text{new}} = P_{\text{old}} \times [1 - \underline{(\text{AR} - 3\% \text{ or } 5\%)}]$$

Items listed ≤ 4 yrs: 5%

Items listed > 4 yrs: 3%



Price Adjustment-**Class 3A** (3)

3. Same group, same license holder and same category : prices are adjusted to the price of the item with the **lowest price**.
4. Set the **lowest price** within a group :
 - $P_{\text{new}} < 60\%$ the highest reimbursement price : Adjusted to 60% of the highest reimbursement price within the same group, but $P_{\text{new}} \leq 2 \times P_{\text{old}}$. (e.g. $P_{\text{old}} = 100, P_{\text{new}} = 50 \rightarrow P_{\text{new}} = 60$; $P_{\text{old}} = 100, P_{\text{new}} = 20 \rightarrow P_{\text{new}} = 40$)
5. The price of **lower specification** shall not be higher than **higher specification** (same license holder).
6. The price of **Generic** shall not be higher than **originator** within the same group.



Price Adjustment-**Class 3B**

The 1st item with the same ingredient(s) and dosage form has been listed >15yrs

1. Set the **target value** of adjustment

- **GWAP** as the target value of adjustment for each individual item.
- The price of lower specification shall not be higher than higher specification.

2. **Equation** for adjustment

- $P_{\text{new}} = \text{Min} \left[\text{Target value} \times (1 + 15\%), \text{Maximum } P_{\text{old}} \text{ within the same group} \right]$



Price Adjustment-**Basic Price**

➤ For items complying with PIC/S GMP

Dosage Form	The lowest price in the dosage form
Tablets /Capsules	NT\$1.5 /Tab or Cap (standard packing /originators: 2 NT\$/Tab or Cap)
Oral solutions	NT\$25/Bot
Solutions for IV infusion (≥ 100 mL, < 500 mL)	NT\$22/Bot
Solutions for IV infusion (≥ 500 mL, < 1 L)	NT\$25/Bot
Solutions for IV infusion (> 1 L)	NT\$35/Bot
Injectables with penicillins/ cephalosporins /estrogens	NT\$25/Bot
Other Injectables	NT\$15/Amp or Vial
Suppositories	NT\$5/piece
Ophthalmic preparations	NT\$12 (NT\$4/Bot for daily-dose packaging eye drops)
Small package of granule/powder /suspension	6 NTD/pack
Ointment /Cream	10NTD



Drugs **Exempted** from Routine Price Adjustment

- Drugs exempted from price adjustment
 - **Orphan drugs**
 - **Special drugs** (indicated by the Insurer)
- Reviewed and adjusted **once every 2 years:**
 - Refer to the **international price** of such drug or similar drug overseas
 - **Cost**-plus pricing for those without international price
- **Date of implementation for such price adjustment:** as announced by the Insurer



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DET Pilot Program

➤ Article 46, National Health Insurance Act

- In case the payment of expense exceeds the preset total of drug expense ratio target, exceeding the targeted amount, the Insurer shall adjust the drug expense payment and payment schedule for the following year.
- A 2-year DET Pilot Program was **first promulgated** by NHIA on Feb. 8th, **2013**. By Jul. 1st, 2015, NHIA announced that the program continue for another 2 years.
- The program was **amended** on Sep. 13th **2017** and it was announced that the program continue for another **3 years** from 2017 onwards.



How a Target Amount is Set

Target amount = Basal value × [1 + Growth rate(%)]

- **Basal value :**
 - The 1st year (2017): the target amount of 2016 (exclusive of the payment for drugs used in AIDS, Hepatitis C, Rare Diseases and Hemophilia)
 - From the 2nd year onwards: the target amount of the previous year
- **Growth rate (%) :**
 - The growth rate of the general part of the global budget (exclusive of the budget for Chinese medicine)



When the Payment Exceeds Target Expenditure

- When the **payment** of drug expense **exceeds** the target amount
 - The amount in excess shall be **payed by the budget** for the medical benefit payment for the current year .
 - The Insurer shall **adjust** the **drug expense payment** and **payment schedule** for the following year.



Price Adjustment under DET

	2013	2014	2015	2016
DET growth rate	4.528%	3.309%	3.481%	4.950%
Target amount (100M)	1,380.0	1,425.6	1,475.2	1,548.2
Payment (100M)	1,436.7	1,507.7	1,507.0	1,605.3
Amount adjusted (100M)	56.7	82.1	31.8	57.1
Effective date for new price	103.5.1 103.7.1	104.4.1	105.4.1	106.4.1
Adjustment range	3.9%	5.3%	2.1%	3.5%



Principles of Price Adjustment under DET program (1)

- Drugs in **Class 1 & 3** are subject to adjustment.
- **The amount in excess of the target amount** is shared among classes (Class 1, 3A and 3B), based on the proportion of the total amount adjusted in each class to the overall adjusted amount.
- Total amount adjusted in each class =
$$\sum_{\text{Each item}} \left[(P_{\text{old}} - P_{\text{temp}}) \times \text{volume} \right]$$



Principles of Price Adjustment under DET program (2)

Amount in excess of target **T**

Total amount adjusted in Class 1	A	\longrightarrow	$T \times \frac{A}{(A+B+C)} = \mathbf{A'}$
Total amount adjusted in Class 3A	B	\longrightarrow	$T \times \frac{B}{(A+B+C)} = \mathbf{B'}$
Total amount adjusted in Class 3B	C	\longrightarrow	$T \times \frac{C}{(A+B+C)} = \mathbf{C'}$

➤ Equation:

$$P_{\text{new}} = P_{\text{old}} - \left[(P_{\text{old}} - P_{\text{temp}}) \times (Y' / Y) \right]$$

e.g. $95 = 100 - \left[(100 - 80) \times (30 / 120) \right]$



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Example-Class 1

➤ **Class 1** $P_{\text{new}} = \text{WAP} + P_{\text{old}} \times R$ (R : 15%)

	P_{old}	WAP	$(1-R) \times P_{\text{old}}$	P_{temp}	P_{new}
w/o DET	17	6.6	14.45		10.2
w/ DET	17	6.6	14.45	9.1	15

w/o DET

1. $\text{WAP} < (1-R) \times P_{\text{old}} \rightarrow 6.6 < (1-15\%) \times 17 = 14.45$
2. $P_{\text{new}} = \text{WAP} + P_{\text{old}} \times R \rightarrow 6.6 + 17 \times 15\% = 9.1$
3. As the upper limit for Class 1 is **40%** $\rightarrow 17 \times (1 - 40\%) = \mathbf{10.2}$
 P_{new} shall not be lower than 10.2 $\rightarrow P_{\text{new}} = \mathbf{10.2}$

w/ DET (Suppose the adjustment ratio from DET=25%)

1. $\text{WAP} < (1-R) \times P_{\text{old}} \rightarrow 6.6 < (1-15\%) \times 17 = 14.45$
2. $P_{\text{temp}} = \text{WAP} + P_{\text{old}} \times R \rightarrow 6.6 + 17 \times 15\% = 9.1$
3. $P_{\text{new}} = 17 - \mathbf{[(17-9.1) \times 25\%]} = \mathbf{15}$



Example-Class 2

➤ Class 2

- Patent expired > 1 year

Category	P _{old}	GWAP	A-10 lowest	GWAP*1.15	P _{temp}	Adjustment range (AR)
Originators	650	590	620	678.5	620	4.6%
Generics	520	590			496	

Originators

$$P_{\text{new}} = \min \left[(\text{GWAP} \times 1.15), \text{A-10 lowest} \right]$$
$$= \min \left[(590 \times 1.15 = 678.5), 620 \right] = 620$$

Generics

1. AR of originator = $(650 - 620) / 650 = 4.6\%$
2. $P_{\text{new}} = P_{\text{old}} \times (1 - \text{AR of originator}) = 520 \times (1 - 4.6\%) = 496$



Example-Class 2

➤ Class 2

- Patent expired for 2~5 years

Category	P _{old}	GWAP	GWAP*1.15	P _{new}	Adjustment range (AR)
Originators_5mg	620	527	606.05	606	2.3%
Generics_5mg	496	527		484	
Generics_2.5mg	275	200	230	230	

Originators_5mg

$$P_{\text{new}} = \text{GWAP} \times 1.15 = 527 \times 1.15 = 606$$

Generics_5mg

1. AR of originator = $(620 - 606) / 606 = 2.3\%$

2. $P_{\text{new}} = P_{\text{old}} \times (1 - \text{AR of originator}) = 496 \times (1 - 2.3\%) = 484$

Generics_2.5mg

Since there's no originator in the same group,

$$P_{\text{new}} = \text{GWAP} \times 1.15 = 200 \times 1.15 = 230$$



Example-Class 3

➤ Class 3A

	P_{old}	WAP	GWAP	P_{temp}	AR	AR_{Max}	P_{temp} (DET)	P_{new}
w/o DET	17	6.6	10.2	9.18	46%	32.5%		11.7
w/ DET	17	6.6	10.2	9.18	46%		9.6	15.1

w/o DET

- $P_{temp} = 9.18$ (WAP < target value $\times 0.9 \rightarrow$ target value $\times 0.9 = 10.2 \times 0.9 = 9.18$)
- $AR = (P_{old} - P_{temp}) / P_{old} = (17 - 9.18) / 17 = 46\%$
- $P_{new} = P_{old} \times \left[1 - \min(AR - 15\%, AR_{Max}) \right]$
 $= 17 \times \left[1 - \min(46\% - 15\% = 31\%, 32.5\% \text{ (p.43)}) \right] = 17 \times (1 - 31\%) = 11.7$

w/ DET (Suppose listed ≤ 4 yrs; adjustment ratio from DET = 25%)

- The calculation of P_{temp} 及 AR is the same as in the case w/o DET
- $P_{temp} (DET) = P_{old} \times \left[1 - (AR - 3\%) \right] = 17 \times (1 - 43\%) = 9.6$
- $P_{new} = 17 - \left[(17 - 9.6) \times 25\% \right] = 15.1$



The Maximum Adjustment Range

Adjustment range (AR)	The maximum adjustment range
AR < 15%	No adjustment
15% ≤ AR < 20%	2.5%
20% ≤ AR < 25%	7.5%
25% ≤ AR < 30%	12.5%
30% ≤ AR < 35%	17.5%
35% ≤ AR < 40%	22.5%
40% ≤ AR < 45%	27.5%
45% ≤ AR < 50%	32.5%
50% ≤ AR < 55%	37.5%
AR > 55%	40%



Example-Class 3

➤ Class 3B

	P_{old}	WAP	GWAP	Weighted average price	P_{temp}	P_{new}
w/o DET	3.8	2.05	2.25			2.58
w/ DET	3.8	2.05	2.25	3.1	2.58	2.97

w/o DET (Suppose the Maximum P_{old} within the same group = 3.8)

$$P_{new} = \min \left[(GWAP \times 1.15), \text{Maximum } P_{old} \text{ within the same group} \right] \\ = \min \left[2.25 \times 1.15 = 2.58, 3.8 \right] = \mathbf{2.58}$$

w/DET (Suppose P_{old} differs among items in the same group; adjustment ratio from DET = 25%)

$$1. P_{temp} = \min \left[(GWAP \times 1.15), \text{Maximum } P_{old} \text{ within the same group} \right] \\ = \min \left[2.25 \times 1.15 = 2.58, 3.8 \right] = 2.58$$

$$2. P_{new} = 3.1 - \left[(3.1 - 2.58) \times 25\% \right] = \mathbf{2.97}$$

