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Drug Reimbursement & Drug Price Adjustment Under Taiwan's NHI System

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Outline

- The global budget system
- Principles and procedures of drug listing
- Price and volume survey and principles of drug price adjustment
- Managed entry agreements (MEAs)

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The Global Budget System

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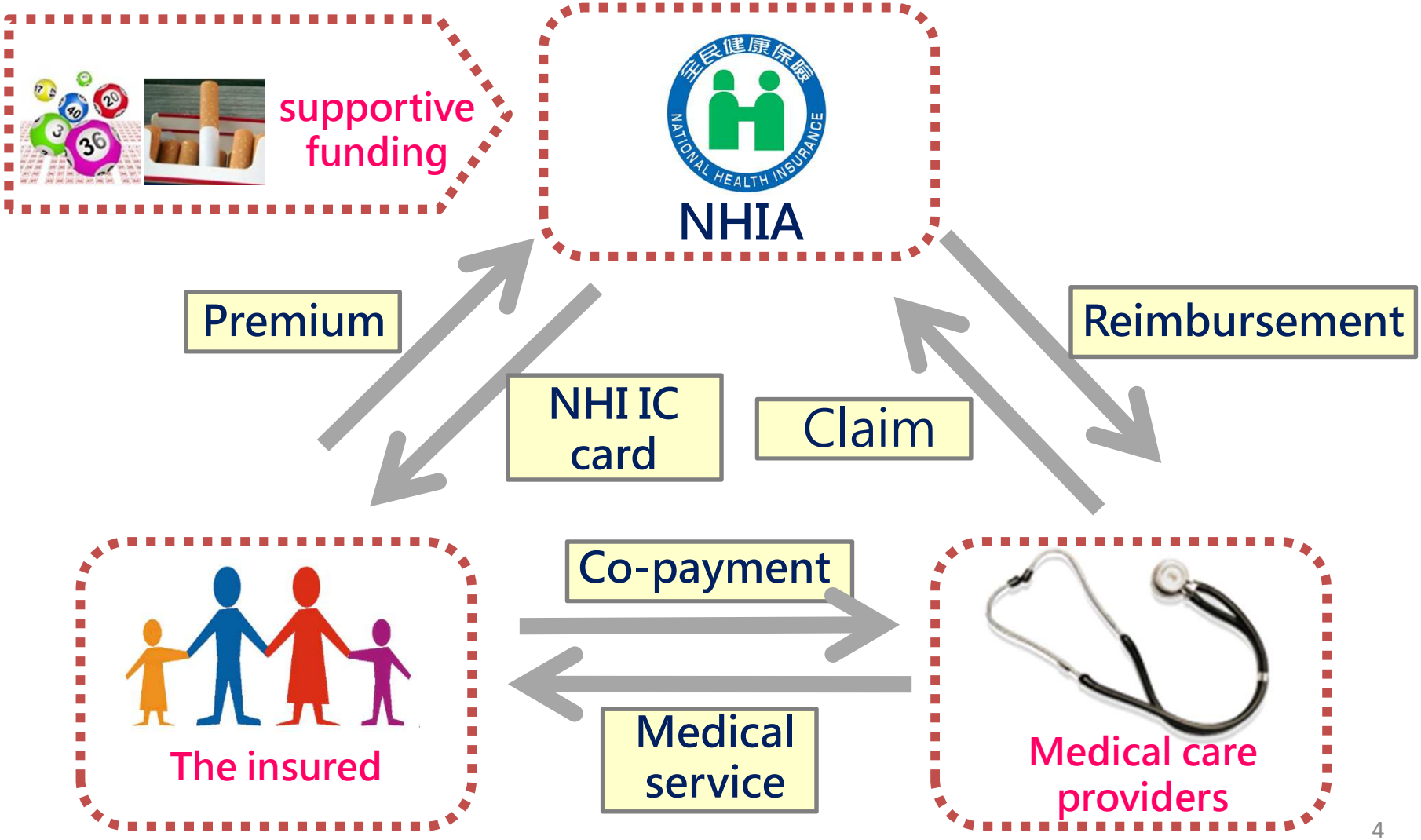
The Framework of NHI



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The Global Budget System

- The cap on overall expenditure：
  - Set annual budget
    - Prior to the beginning of a next fiscal year based on the estimation on medical costs and the amount of services.
  - Paid under a point-value scale
    - Point-value= (global budget/total amount of medical services)
    - Calculate retrospectively
  - Fluctuating point-value
    - When the service volume (actual expenditure) **exceeds the cap**, **the point-value will be reduced**.
  - Ensures that the overall expenditure stays under the cap.

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Decision of Annual Global Budget

MOHW

Figure out general parameters for the global budget

(Jan. ~ Apr.)

Executive Yuan

Approve the global budget parameters

(May.~ Jun.)

NHI Committee

Negotiate and allocate global budget

(Aug.~ Dec.)

Estimate budget based on actual spending

Review by National Development Council

Allocate expenditure based on approved budget

1. Target growth rate of each sector
2. Content of budget increase and expected benefit
3. Revise relevant formulas
4. Consult NHI committee

1. Payers ' willingness to pay
2. Financial consideration

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Principles and Procedures of Drug Listing

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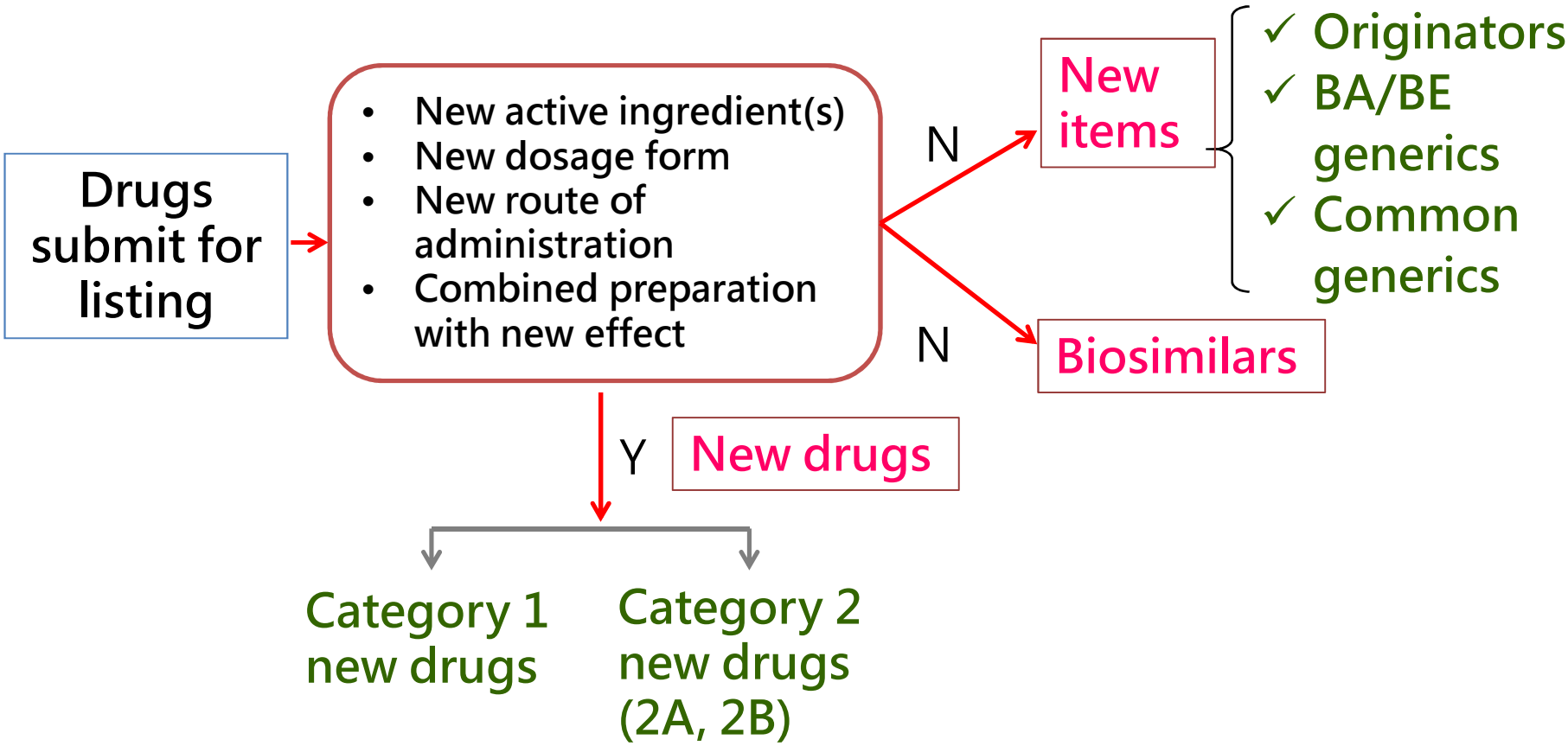
Classification of Drugs to be Listed



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Two-level Pricing Mechanism

1. Expert committee → initial proposal
2. Stake Holder Committee (PBRS Joint Meeting) → final decision

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Three decisions of Pricing & Reimbursement

1. Listing: Whether the new drug will be listed in pharmaceutical benefits scheme?
2. Pricing: How much will the new drug be paid?
3. Restriction: Whether the restriction on reimbursed indication or pre-utilization review is needed?

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Four Criteria of Pricing & Reimbursement

TFDA

Safety/efficacy/quality

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1. Relative effectiveness
2. CBA/CEA/PE
3. Budget impact analysis
4. Ethical/Legal/Social/Political Impact

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PBRS Joint Meeting

composed of stakeholders to ensure decision making for drug listing and reimbursement

Healthcare Providers	13	
Scholars and Experts	9	
The Insured	3	
Employer	3	
Health Regulatory Authority (MoHW)	1	
Drug Regulatory Authority (TFDA)	1	
The Suppliers	3	

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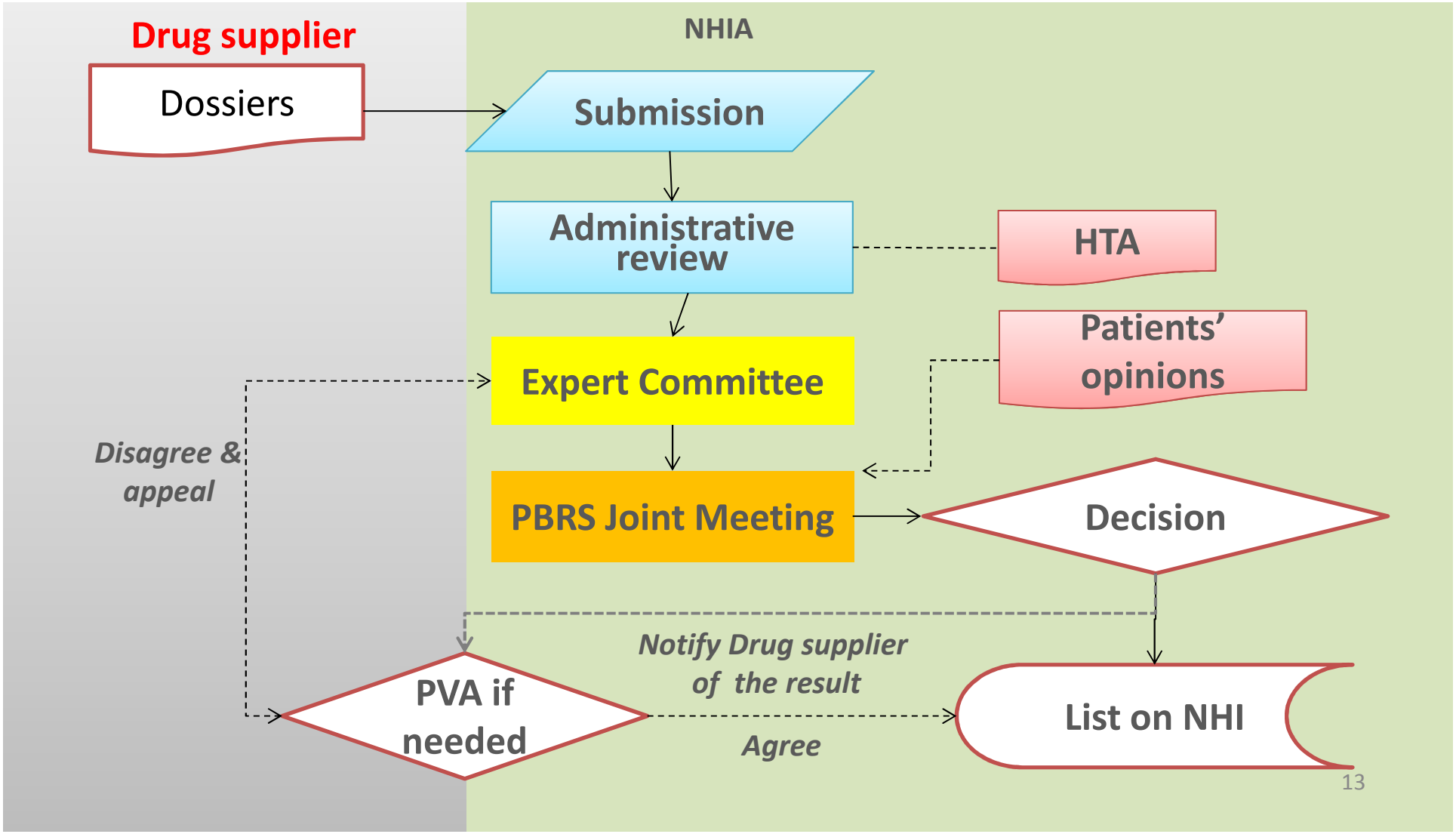
Pricing Process of New Drugs



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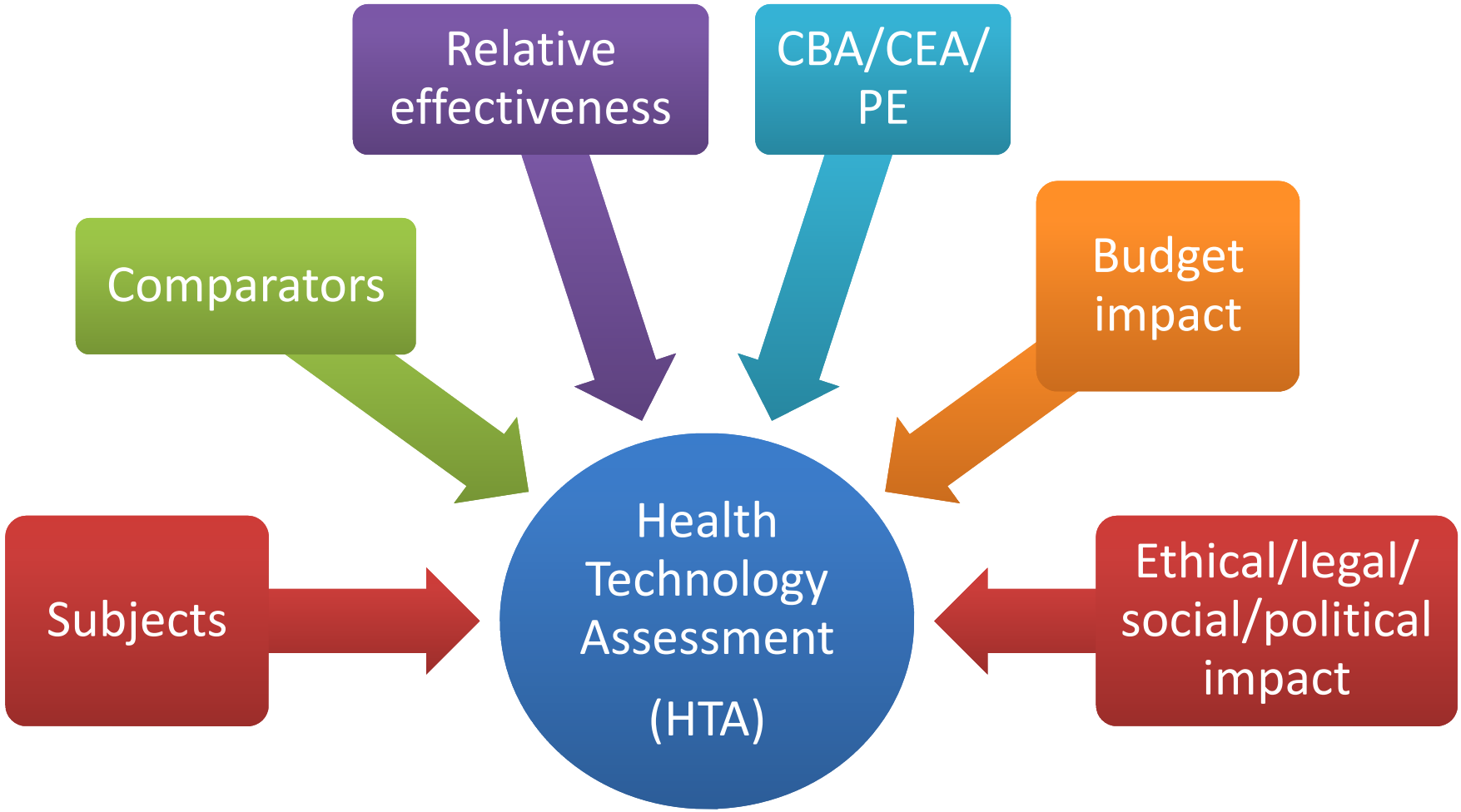
Value-based Pricing



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Incentives for Breakthrough New Drug

Category		Pricing	Mark-ups
1	**Breakthrough**	**Median price of A-10 countries**	• local clinical trials (10%) • local pharmaco-economic study (up to 10%) • better therapeutic effects (up to 15%) • greater safety (up to 15%) • more convenient (up to 15%) • pediatric preparations with clinical implications (up to 15%)
2A	Me-better	Capped at A-10 median price • lowest price in A10 • price in original country • international price ratio • treatment-course dosage ratio • a combination drug is priced at 70% of the sum of each ingredient's price, or at the price of the single active ingredient.	
2B	Me-too		

A-10 reference countries： Australia, Belgium, Canada, France, Germany, Japan, Sweden, Switzerland, US, UK.

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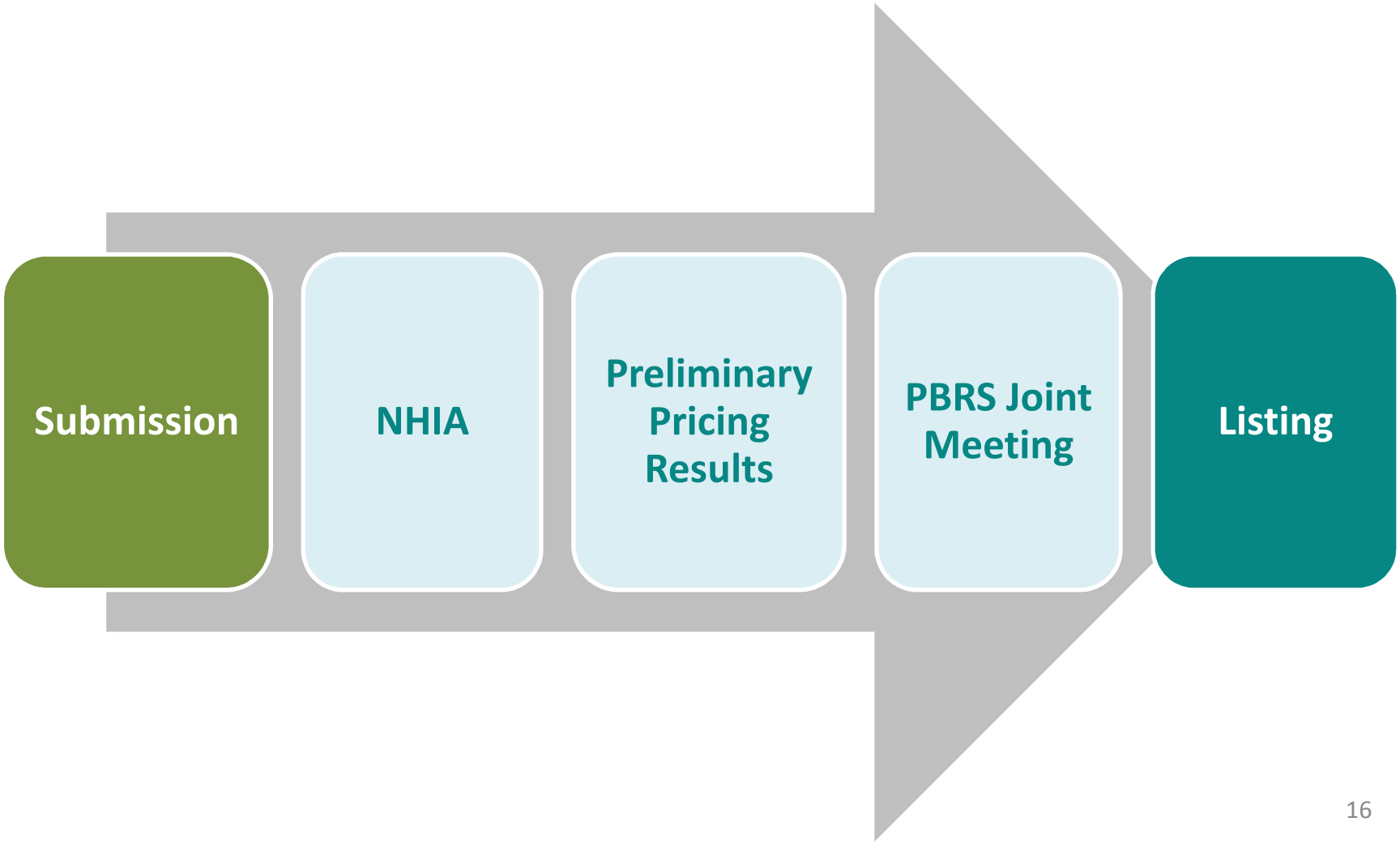
Pricing Process for Generics and Biosimilars



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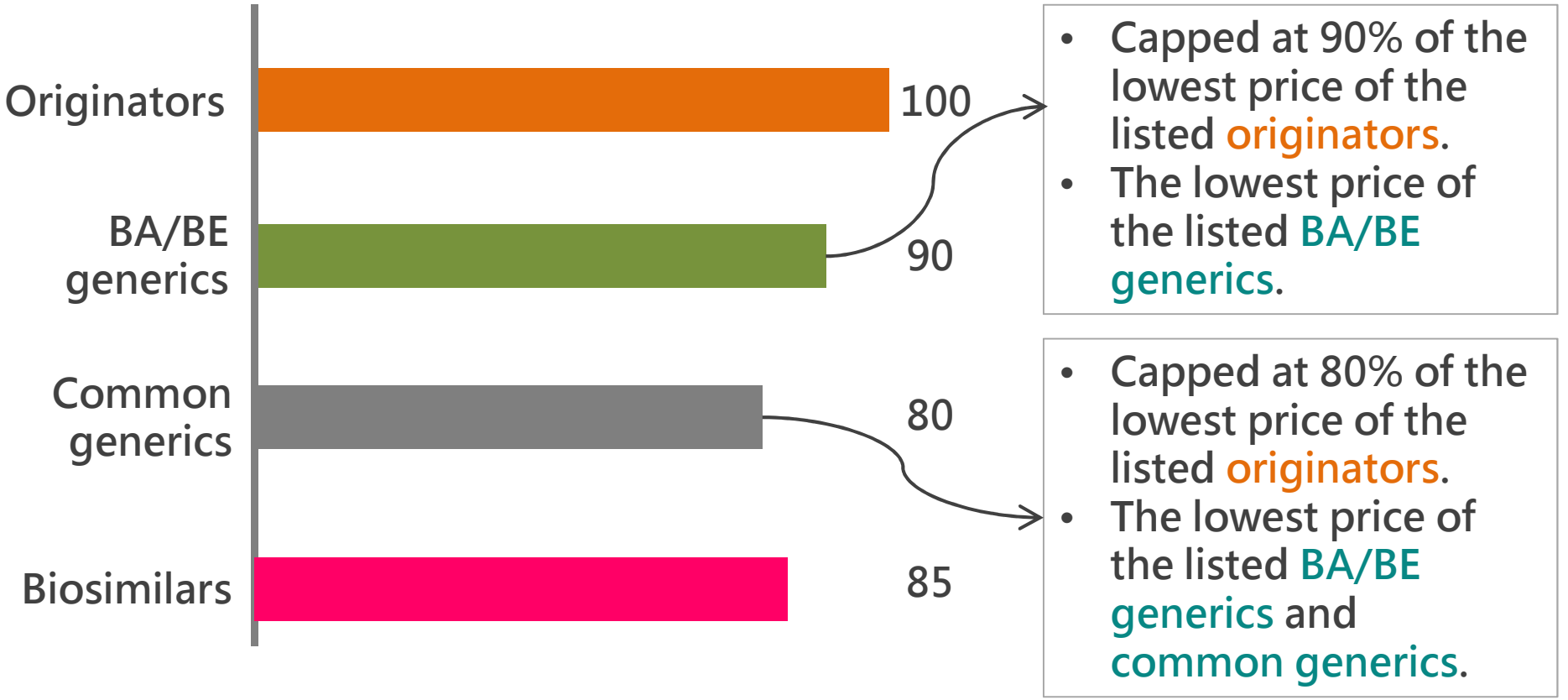
Principle of Pricing Generics

By classification (originators, BA/BE generics, common generics orBiosimmilar)



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Price and Volume Survey and Principles of Drug Price Adjustment

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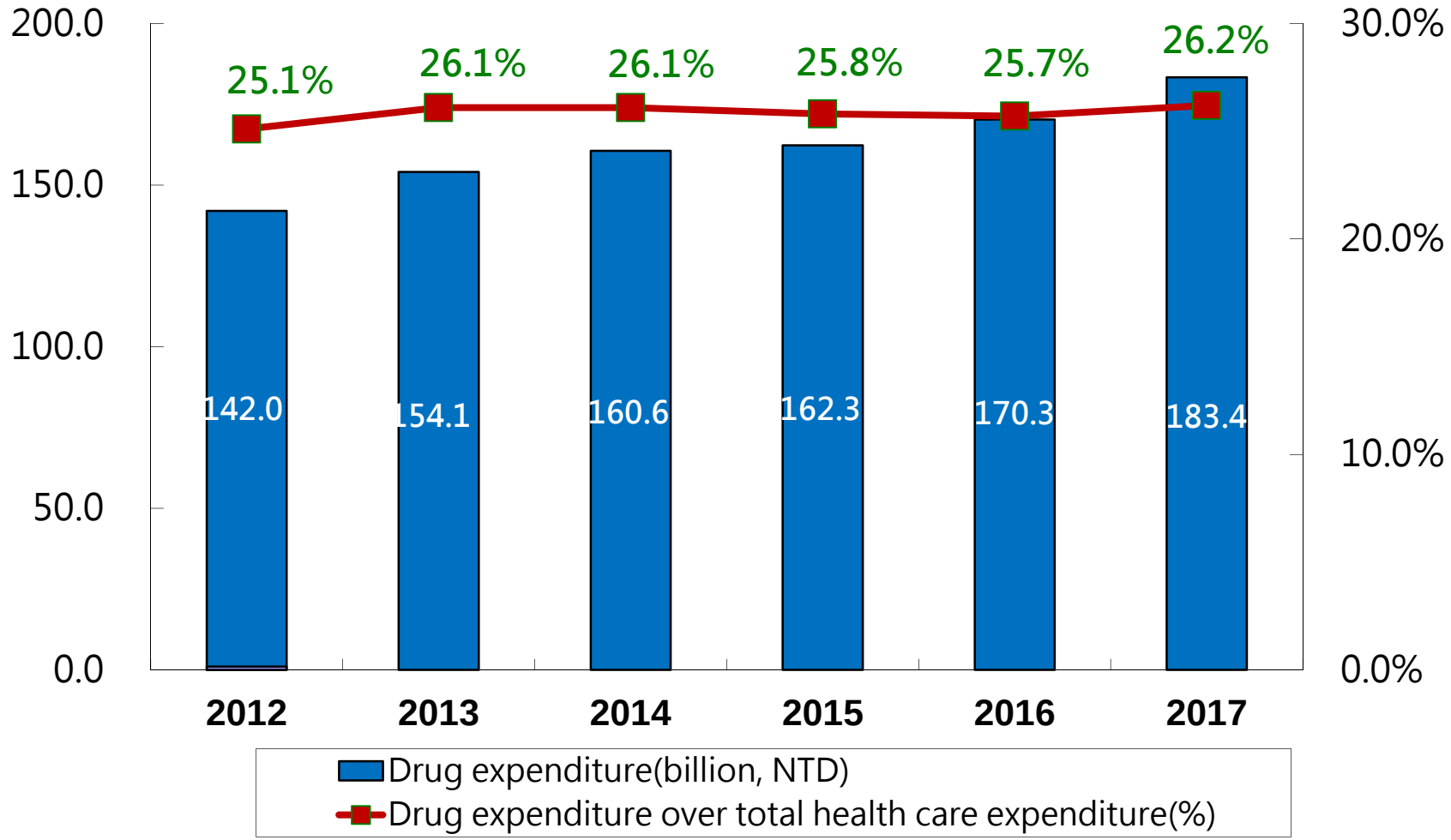
Trend of NHI Drug Expenditures



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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.

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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.

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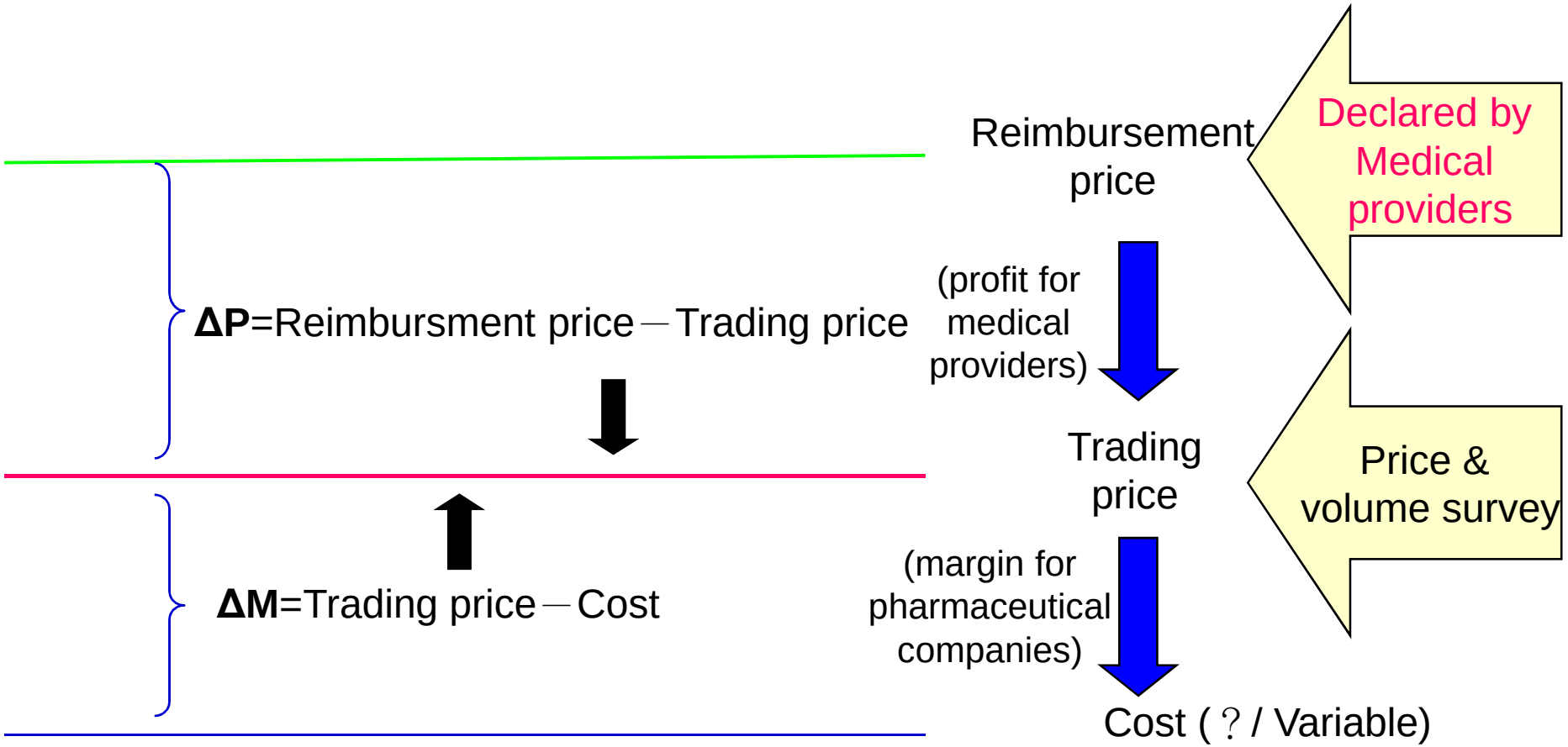
Principles of Drug Price Adjustment



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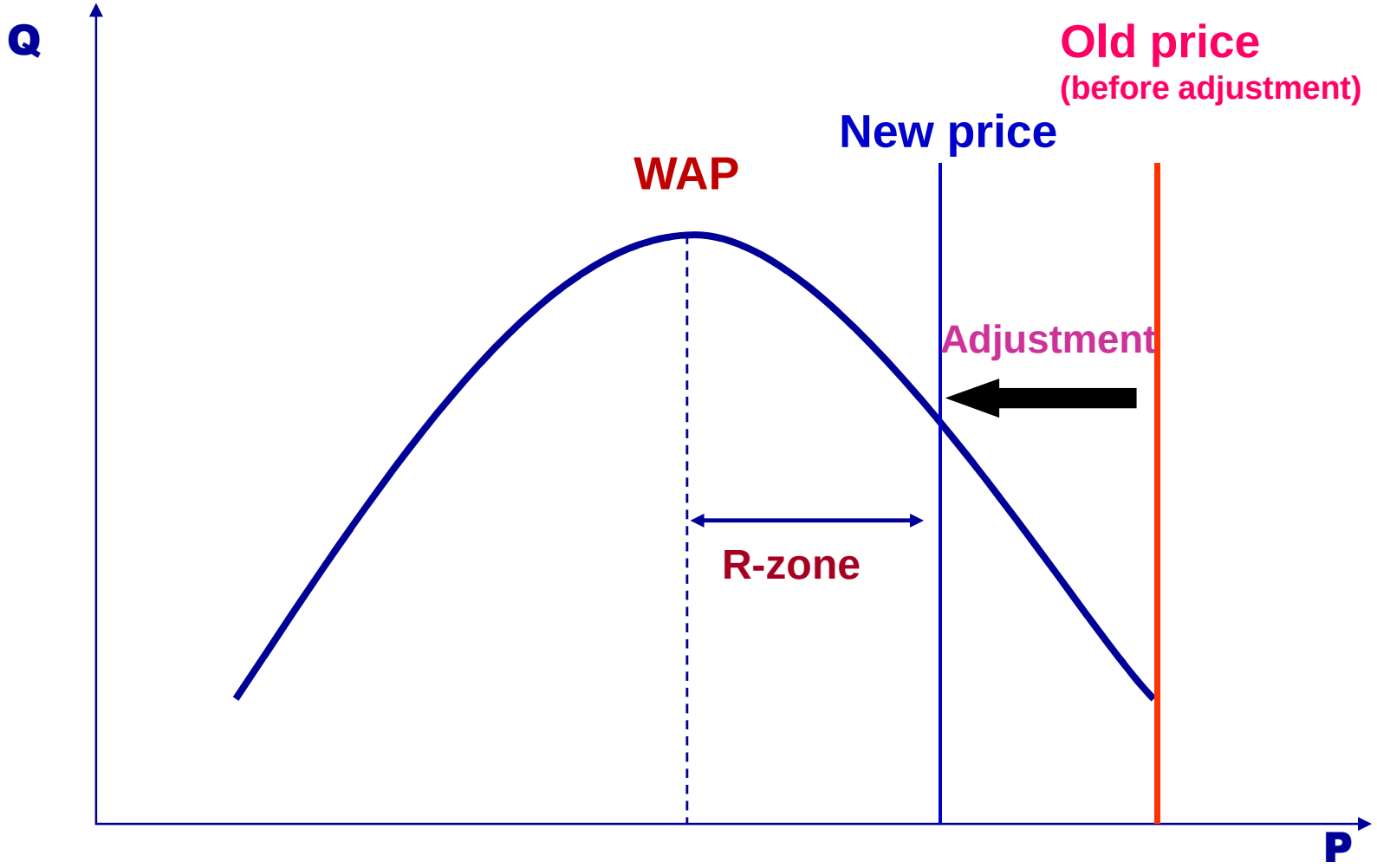
Principles of Drug Price Adjustment



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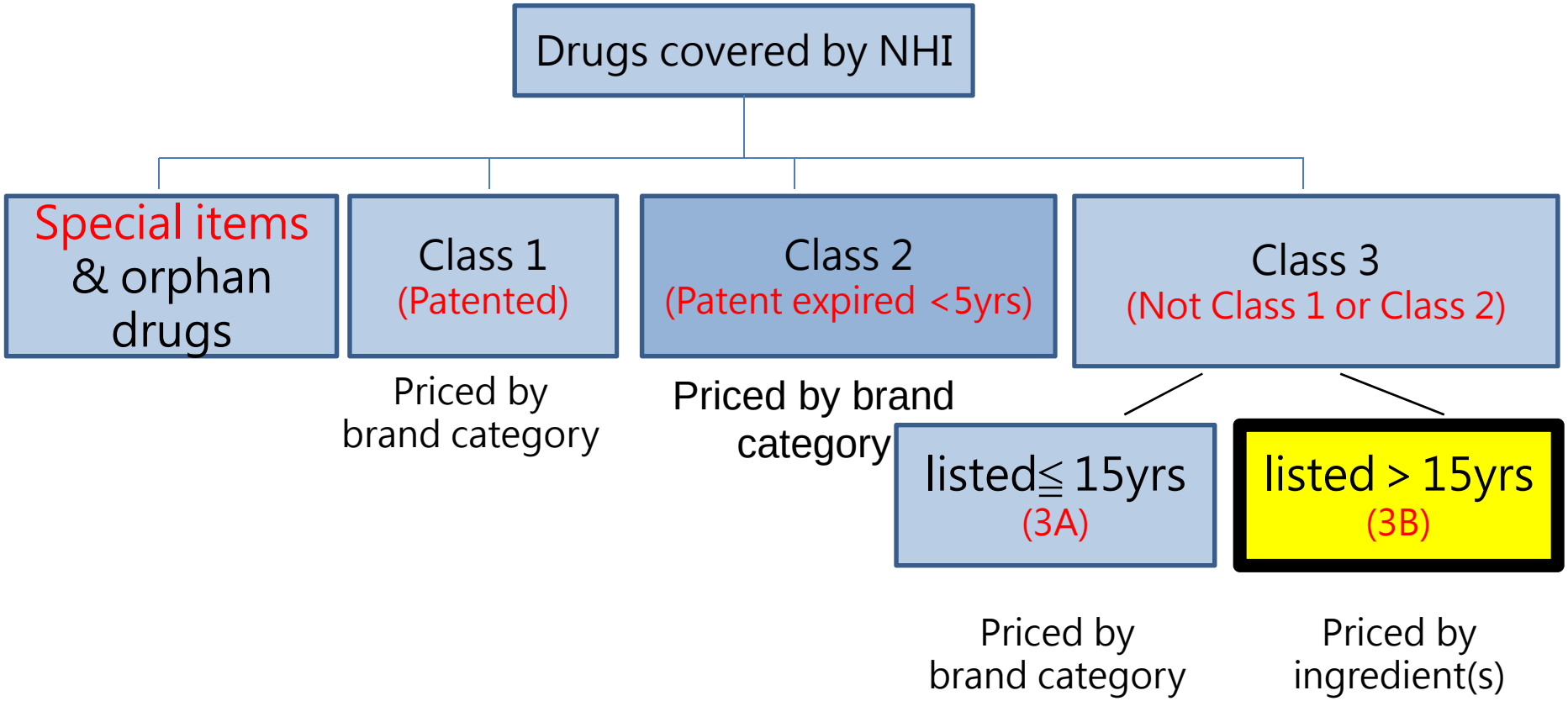
Framework of Drug Price Adjustment



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Time course of Drug Price Adjustment

Class	Range	Time course
Class 1	1. Patented items 2. Other items from the same group	1. Once every 2 yrs 2. Under DET program: When the expenditure target is exceeded
Class 2	1. Items with patent expired <5yrs 2. Other items from the same group	Once a year (by items)
Class 3	Items other than Class 1 or 2	1. Once every 2 yrs 2. Under DET program: When the expenditure target is exceeded

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Price Adjustment- Class 1 (1)

➢ Equation for adjustment

(一)WAP≧(1-R) × P_{old} : No adjustment

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

P_{new}=WAP + P_{old} × R (R : 15%)

P_{new} : New reimbursement price after adjusting
WAP: Weighted average market trading price
P_{old} : Reimbursement price before adjusting

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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.

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Price Adjustment- Class 2

➢ Patent expired ≦ 1 year

Originator — The lowest:
- A-10 lowest
- GWAP × (1 + R), $P_{new} \leqq P_{old}$

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

➢ Patent expired for 2~5 years

Originator — GWAP × (1 + R), $P_{new} \leqq P_{old}$

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

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

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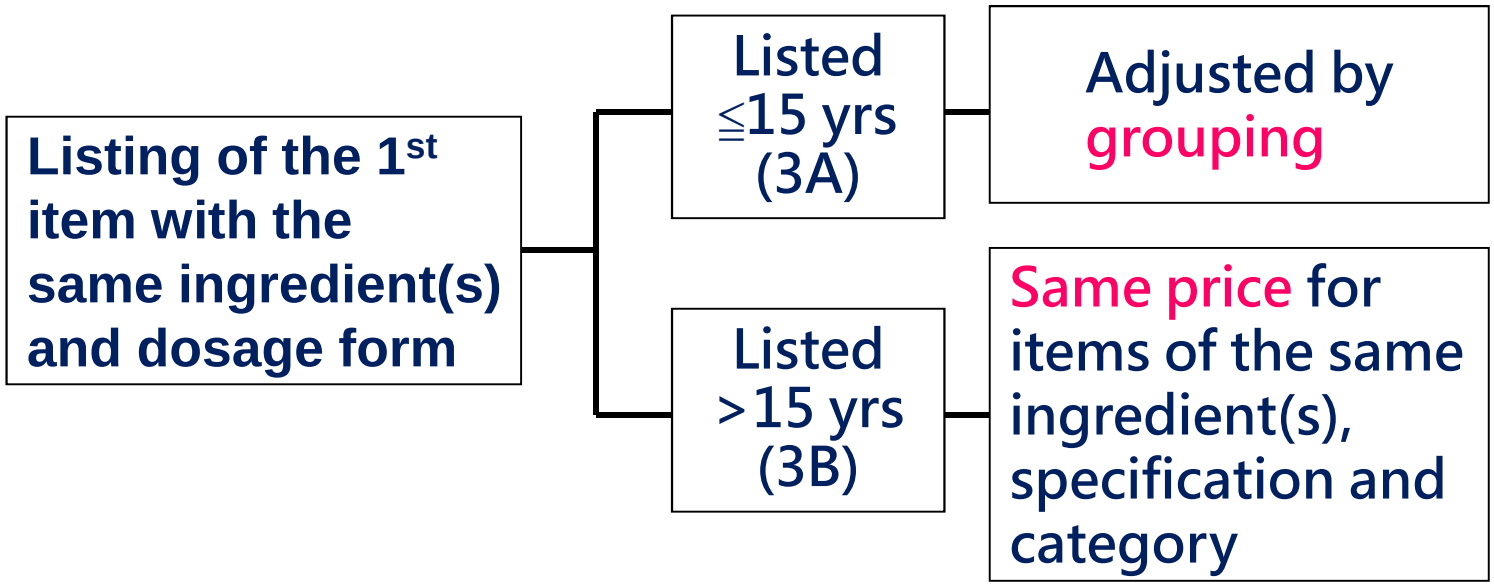
Price Adjustment- Class 3

Subcategories of Class 3



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Price Adjustment- Class 3A (1)

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

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×1.05),target value×0.9〕,Pold】

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

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Price Adjustment- Class 3A (2)

2. Adjustment range and the maximum adjustment range

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

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

★Under DET program

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

Items listed ≦4yrs: 5%

Items listed >4yrs: 3%

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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_{new} <60% the highest reimbursement price ：Adjusted to 60% of the highest reimbursement price within the same group, but $P_{new} \leqq 2 \times P_{old}$. (e.g. $P_{new\ highest}$=100, P_{new} =50 → P_{new} = 60；P_{old} =100, P_{new} =20 → P_{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.

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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_{new} = Min【Target value×(1 + 15%), Maximum P_{old} within the same group)】**

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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, <1L)	NT$25/Bot
Solutions for IV infusion (>1L)	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

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DET Pilot Program

- Article 62, 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.
- DET Pilot Program was first promulgated by NHIA on Feb. 8th, 2013.
- The program was amended on Sep. 13th 2017 and it was announced that the program continue for another 3 years from 2017 onwards.

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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)

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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=

$$\sum_{\text{Each item}} \left[(P_{old} - P_{temp} \times volume \right]$$

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Principles of Price Adjustment under DET program (2)

Amount in excess of target **T**

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

➢ Equation:

$$P_{new} = P_{old} - 【(P_{old} - P_{temp}) \times (Y'/Y)】$$

e.g. 95 = 100 – 【(100 – 80) × (30/120)】

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Price Adjustment of Drugs for Treating Rare Diseases and Special Items

- Article 24, Drug Price Adjustment Scheme
  - Drugs for treating rare diseases and special items are subject to price adjustment every 2 years based on:
    - Median price in A-10 countries (of the drug itself or its similar product)
    - Cost

Managed Entry Agreements (MEAs)

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Managed Entry Agreements (MEAs)

- New technologies being listed under agreements made between the suppliers and the insurer.
- Various risk-sharing models involved.
- To increase the accessibility of new drugs to patients, to cope with uncertainties in the efficacy of new drugs and to control budget impact.

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Examples of MEAs Models

- Financial-based：
  - Price-volume agreements
  - Expenditure-capping
  - Dose-capping
  - Conditional discounts
  - Rebate
- Performance-based：
  - Outcome guarantees
  - Risk-sharing
  - Coverage with evidence development
  - Conditional treatment continuation
  - Cost-sharing

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Drugs with MEAs

- High-cost
- Uncertainty in cost-benefit
- Uncertainty in therapeutic value

Ex: immuno-oncology agents

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MEAs Models Under Planning in Taiwan

- Any one (or more than one) of the models be chosen on a case by case basis.
- Mutual share of drug expenditure between the supplier and the insured via refund payback.

Category	Mechanism of MEAs Models
1. Performance-based	1. Ensure the improvement in overall survival 2. Ensure the delay in progression-free survival 3. Refund payback based on therapeutic effect
2. Financial-based	1. Fixed-rate refund payback 2. Free doses 3. Payback for co-prescribed drugs
3. Mutual share by negotiation	Mutual share of refund payback among pharmaceutical products with the **same ingredient or pharmacological category**.

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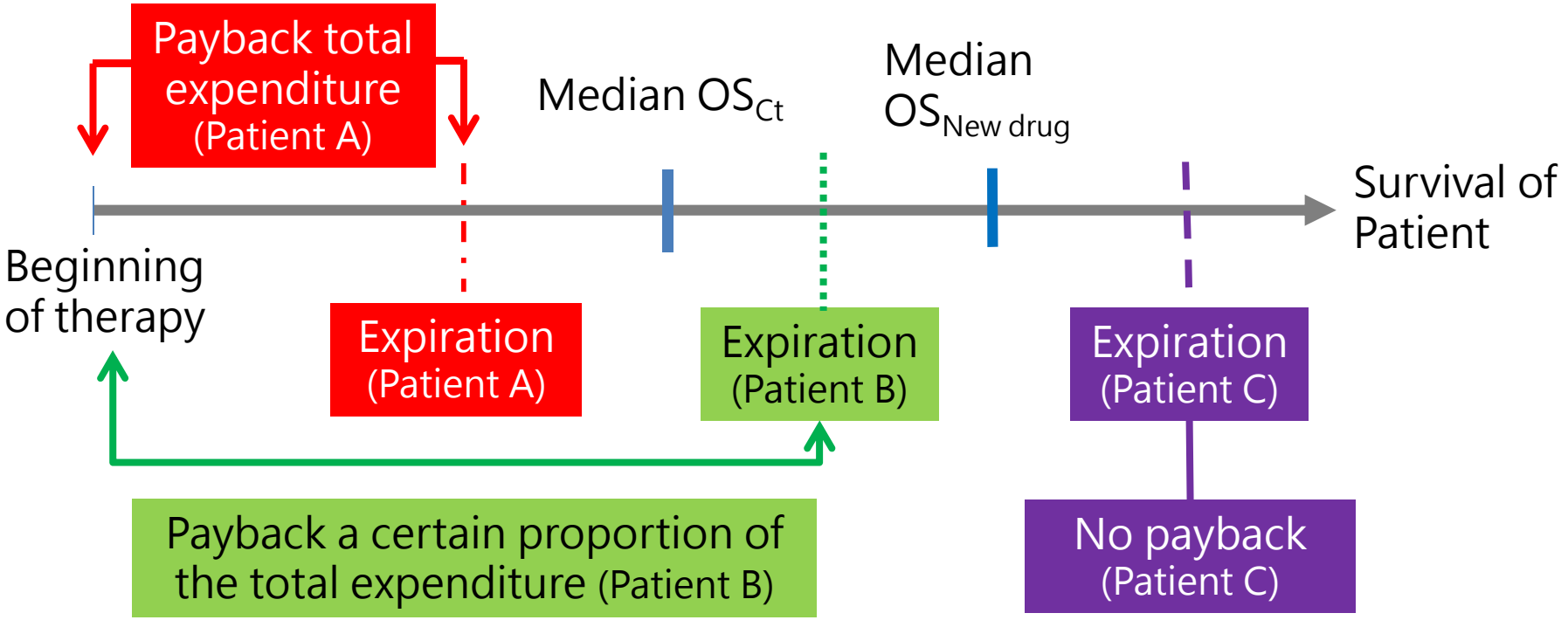
Performance-based (1) -Ensure the Improvement in Overall Survival (OS)

- $OS_{New\ drug}$ < **Median** OS_{Ct} : payback total drug expenditure
- $OS_{New\ drug}$ > **Median** OS_{Ct} : payback a certain proportion of the total drug expenditure



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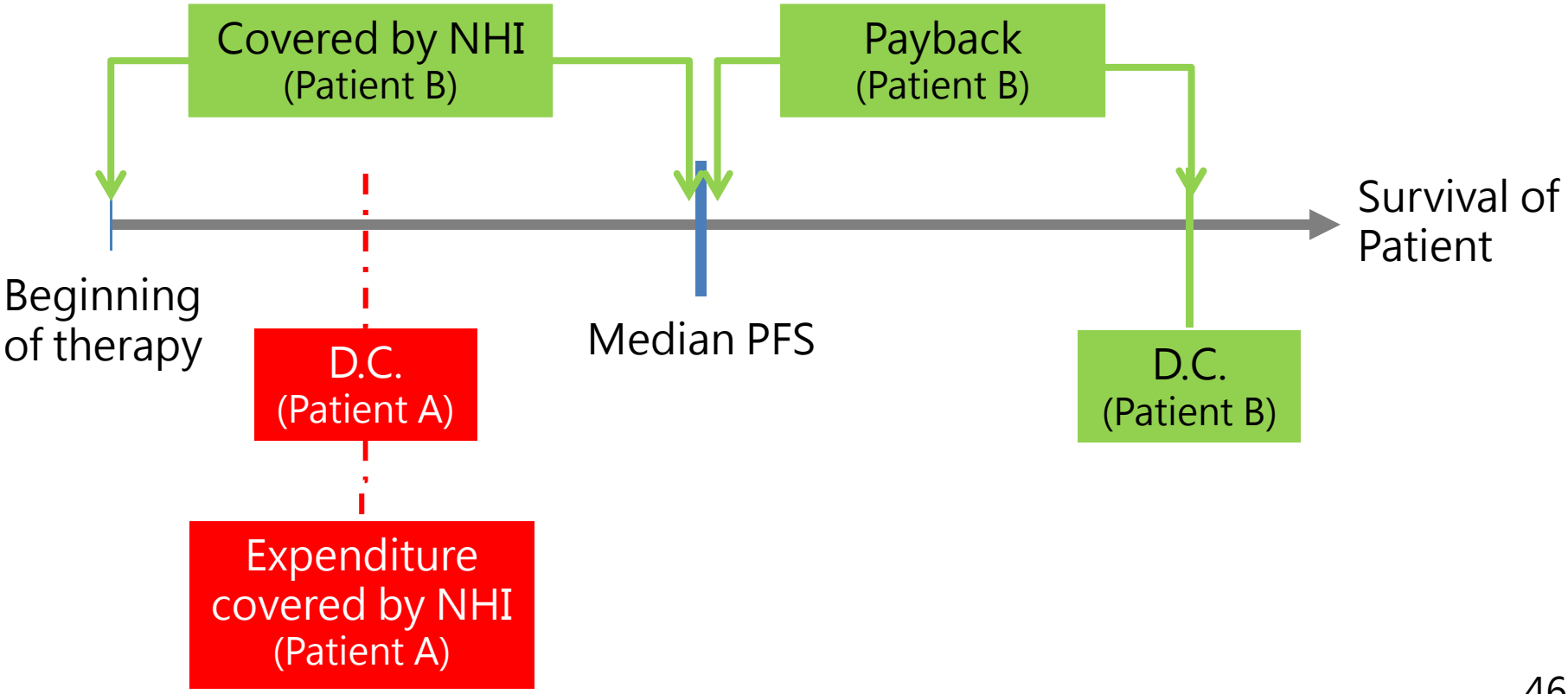
Performance-based (2) -Ensure the Delay in Progression-free Survival (PFS)

- **Payback the expenditure generated beyond the median PFS.** (NHI covers expenditure generated within the median PFS)



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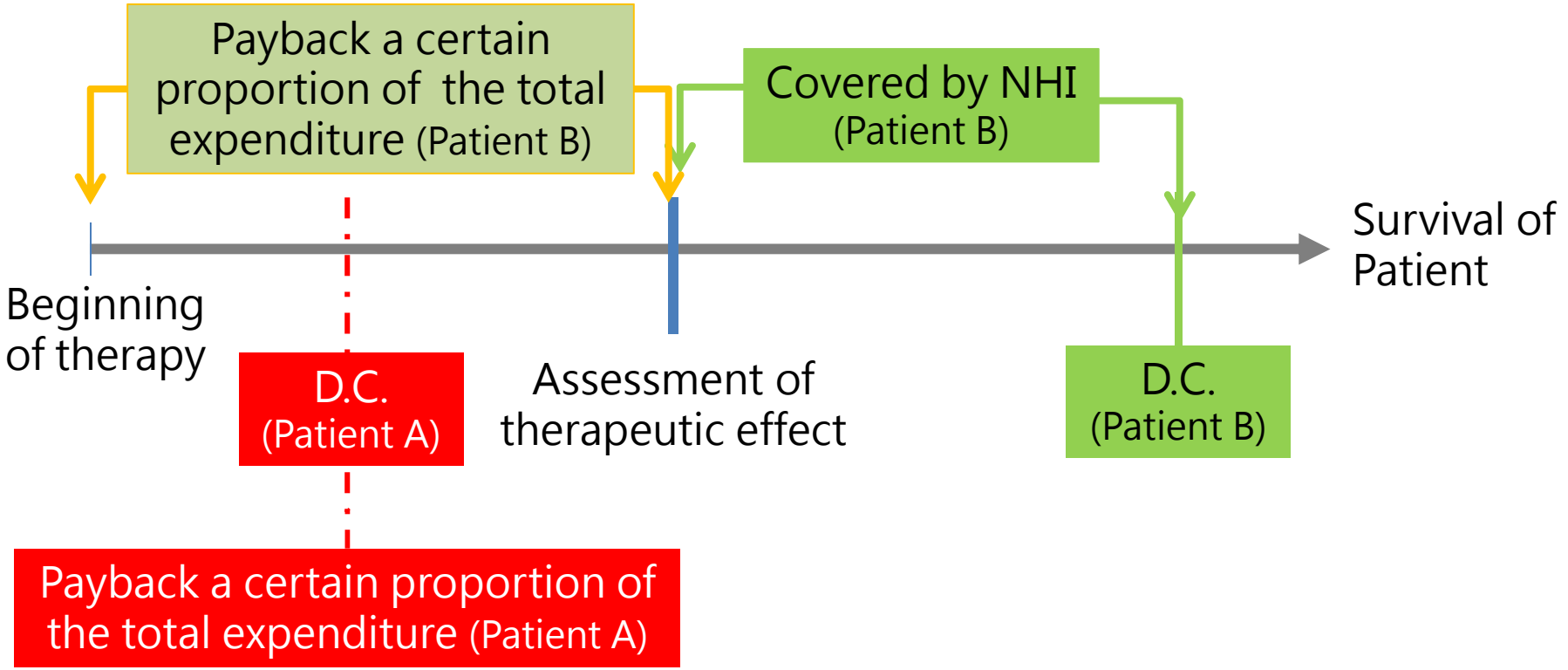
Performance-based (3) -Refund Payback Based on Therapeutic Effect

- Payback a certain proportion of the total expenditure generated before assessment of therapeutic effect.



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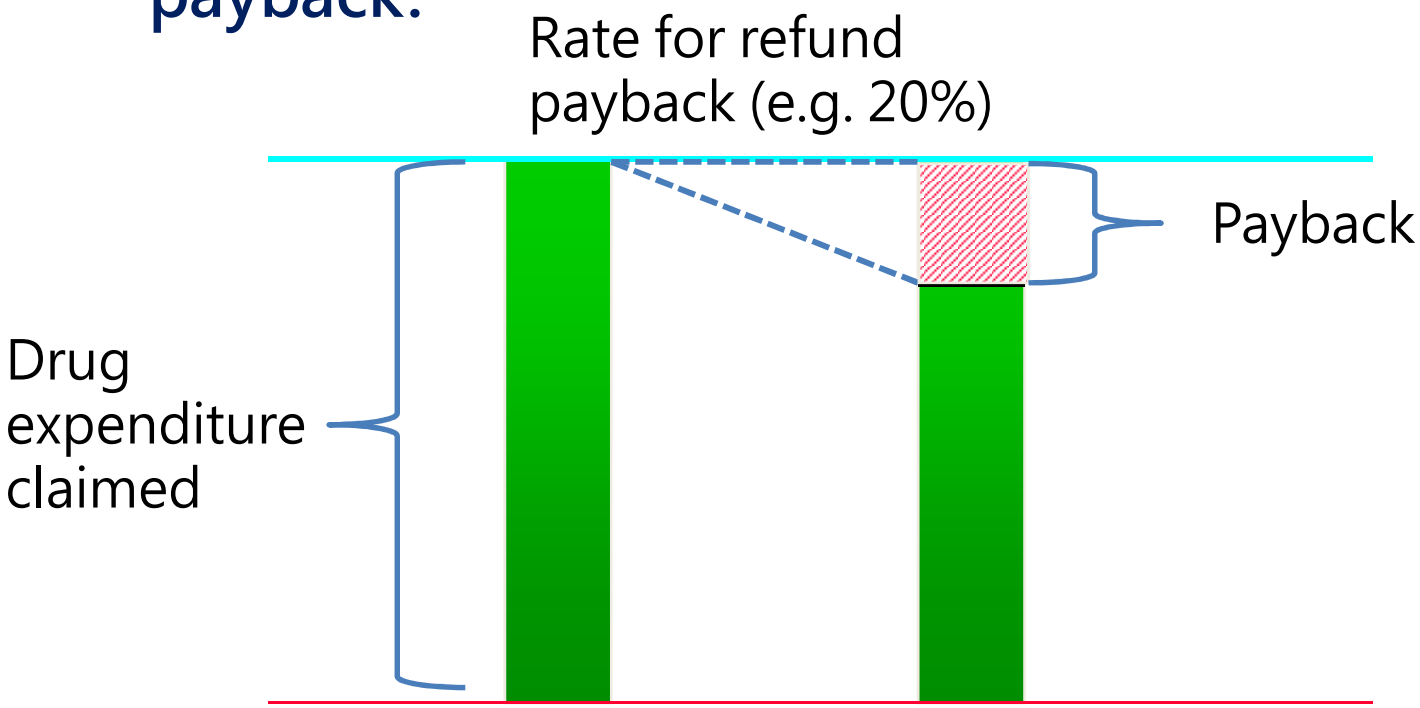
Financial-based (1)- Fixed-rate Refund Payback

- A supplier shall propose a fixed rate for refund payback.



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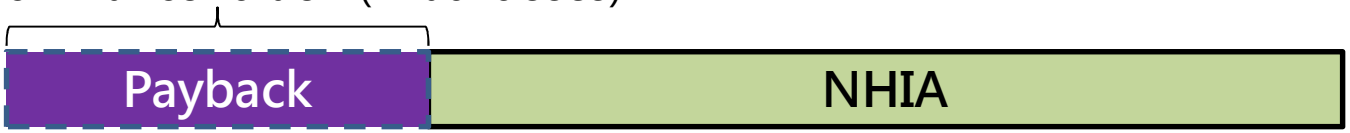
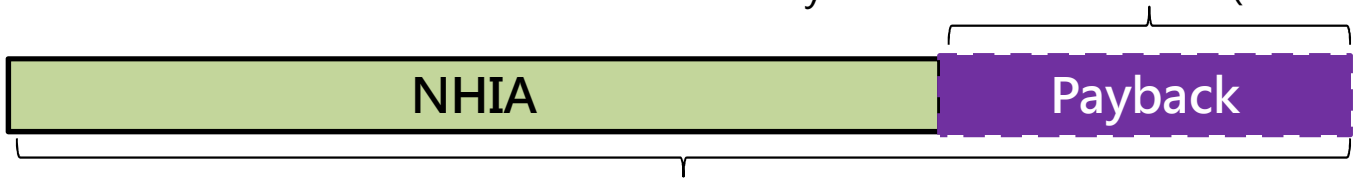
Financial-based (2)-Free Doses

- **A supplier shall pay for initial doses or additional doses used for the treatment.**
  - 🕮 Ex: Suppose that a supplier is willing to pay for the initial doses used in the first 2 months and the average treatment duration in the clinical trial is 10 months → equals to 20% refund payback (=2/10=20%)

☆ Payback with condition (Initial doses)



☆ Payback with condition (additional doses)



☆ Payback with condition: Involves negotiation with the supplier depending on different products (e.g. total cost)

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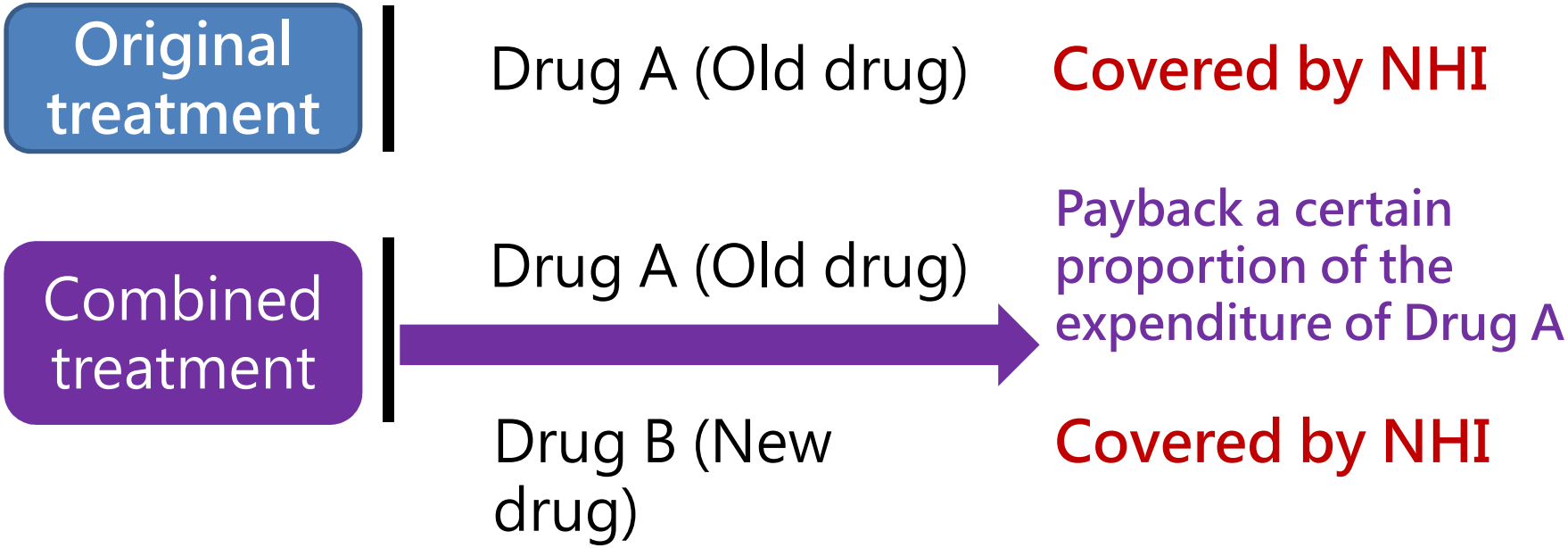
Financial-based (3)- Payback for Co-prescribed Drugs

- If a new drug has to be used in combination with other drugs, the new drug supplier shall payback a certain proportion of the expenditure generated from the other drugs.



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Points of Consideration Regarding Implementation of MEAs

- Fairness of the agreements：
  - Controversies may arise as the proposals differ among different companies or different products.
  - Taiwan has not yet adopted ICER threshold.
- How to present in the PBRS Joint Meeting：
  - MEAs are confidential.
  - We need to conceal the contents of the agreements and win the trust from the PBRS Joint Meeting.

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THANK YOU FOR YOUR ATTENTION