Current Update in NHI Policy and Future Directions

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Outline

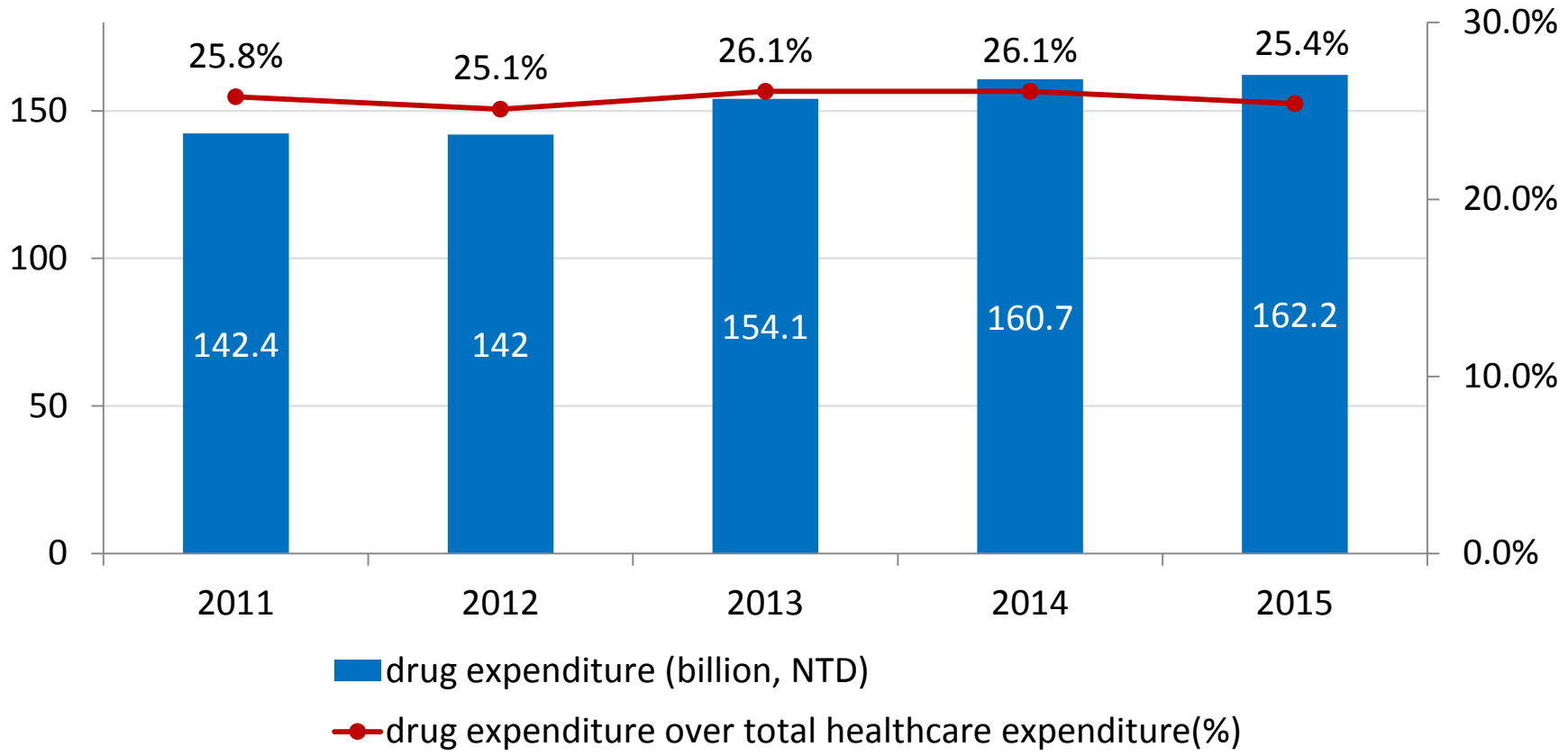
- Payment system and pharmaceutical expense
- Pharmaceutical Benefits and Reimbursement Schedule (PBRS)
- Health Technology Assessment in NHI
- Price Volume Agreement

Global Budget Payment System

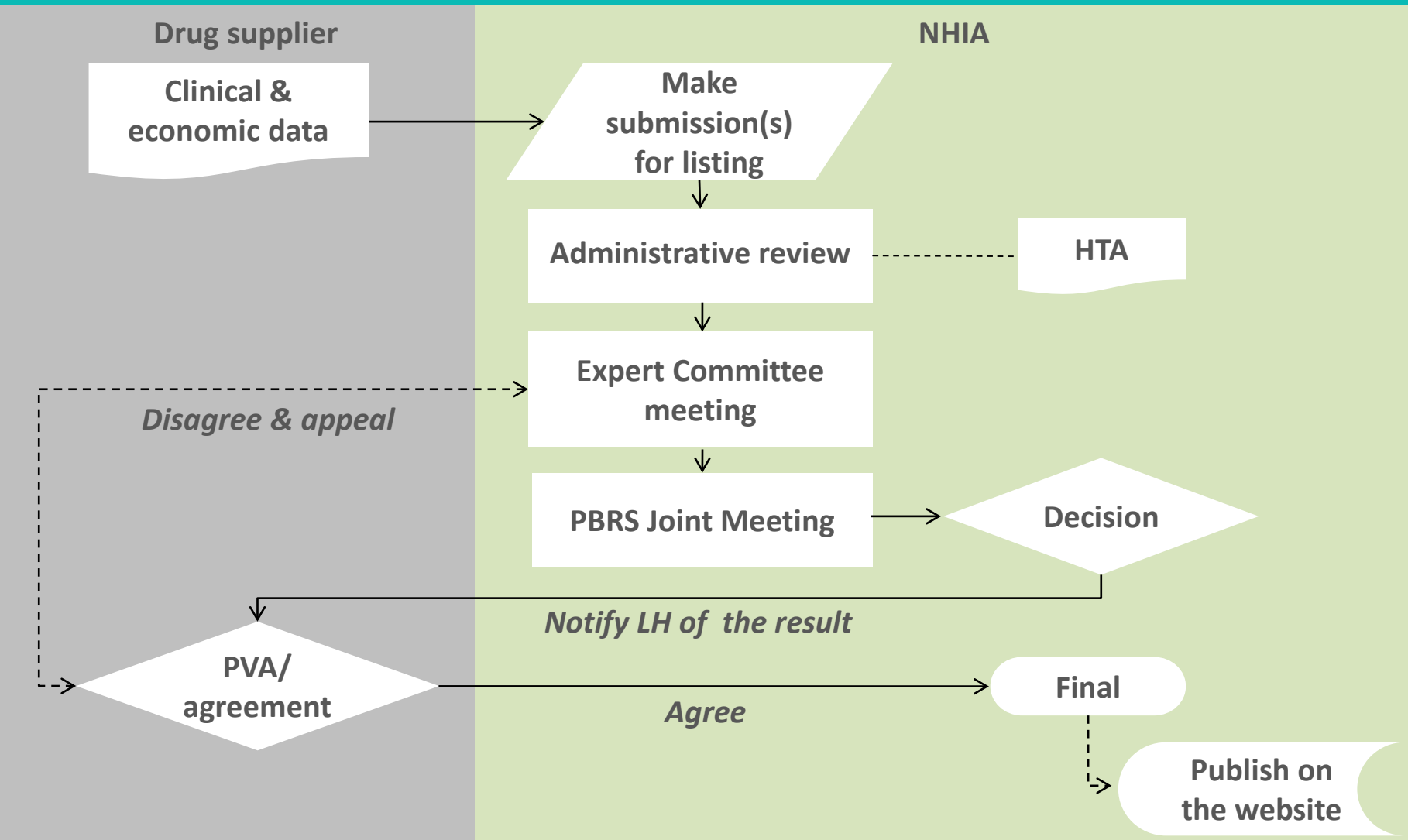
The global budget payment system was adopted to constrain the rapid growth in costs under the fee for-service model and institute a system of financial accountability.

Medical providers and payers negotiate overall caps on total medical payments with the NHI system prior to the beginning of a fiscal year based on a fixed volume and range of medical services.

Trend of NHI Drug Expenditures



Process for New Drug Listing Application



PBRS Joint Meeting

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

Two-level of Pricing & Reimbursement Decision

1. Expert committee: initial proposal
2. Stake Holder Committee: final decision

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 in drug indication or pre-utilization review is needed?

Four Criteria of Pricing & Reimbursement

Safety and efficacy: by Taiwan's FDA

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

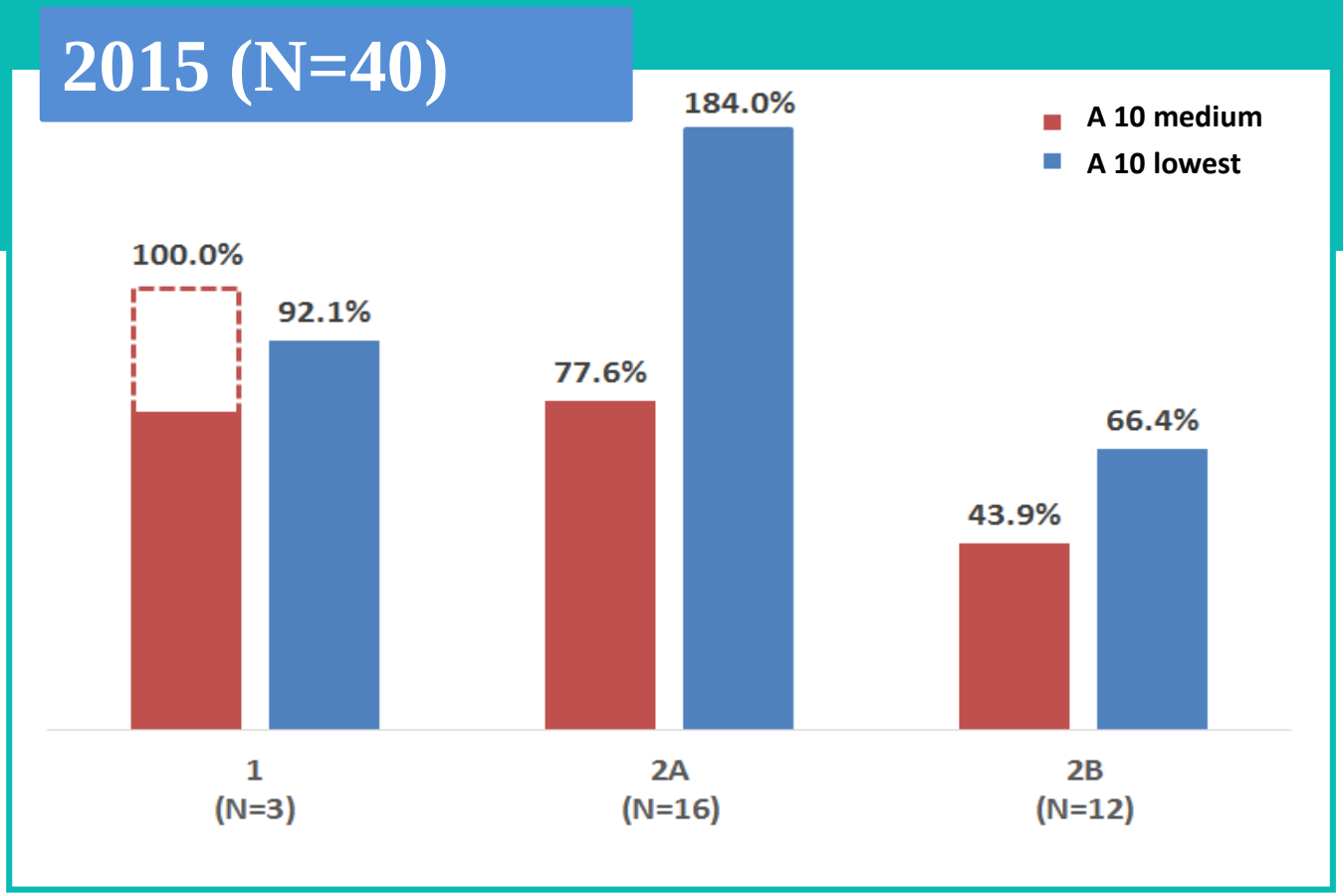
Pricing for New Drugs

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	• 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. Capped at A-10 median price	
2B	Me-too		

A-10 reference countries

Country	Source of Reference	Pricing Structure
US	Red Book (not official publication)	Wholesale price
Japan	Drug price baselines (official website)	Ex-factory price + wholesale premium + drugstore premium + value-added tax
UK	NHS Prescription Service (official website)	Ex-factory price + wholesale premium
Canada	Saskatchewan Formulary (official website)	Wholesale price
Germany	ROTE LISTE (official website)	Ex-factory price + wholesale premium + drugstore premium + value-added tax
France	Base des Médicaments et Informations Tarifaires (official website)	Ex-factory price + wholesale premium + drugstore premium + value-added tax
Belgium	Centre Belge d'Information Pharmacothérapeutique (official website)	Ex-factory price + wholesale premium + drugstore premium + value-added tax
Sweden	Farmaceutiska specialiteter i Sverige (official website)	Wholesale price + drugstore premium
Switzerland	Arzneimittel kompendium der schweiz (official website)	Ex-factory price +logistics premium (shared by wholesalers and drugstores) + value-added tax
Australia	Pharmaceutical Benefits Scheme (official website)	Ex-factory price + wholesale premium + drugstore premium + dispensing fees

Price of new drugs compared with A-10 reference countries



Exclude:

1) None of reference countries listed (N=6)
2) Only 1 reference countries listed, reimbursement price/ Price submitted by the supplier (N=1，87.8%)
3) Price submitted by the supplier 。(N=2，100%)

Why Need HTA ?

Decision-making Processes:

1. **Assessment:** objective collection and evaluation of evidence
2. **Appraisal:** considers and weighs the summarized evidence in order to render a recommendation
3. **Decision**

The Content of HTA Report

1. Comparator
2. Relative effectiveness
3. Cost effectiveness
4. Budget impact analysis
5. Summary HTA reports from UK, Canada and Australia

Comparator

What are the existing treatment options?

- **Principle of selection → drug**
- **Clinical guideline**
- **Payment status**
- **Clinical practice**

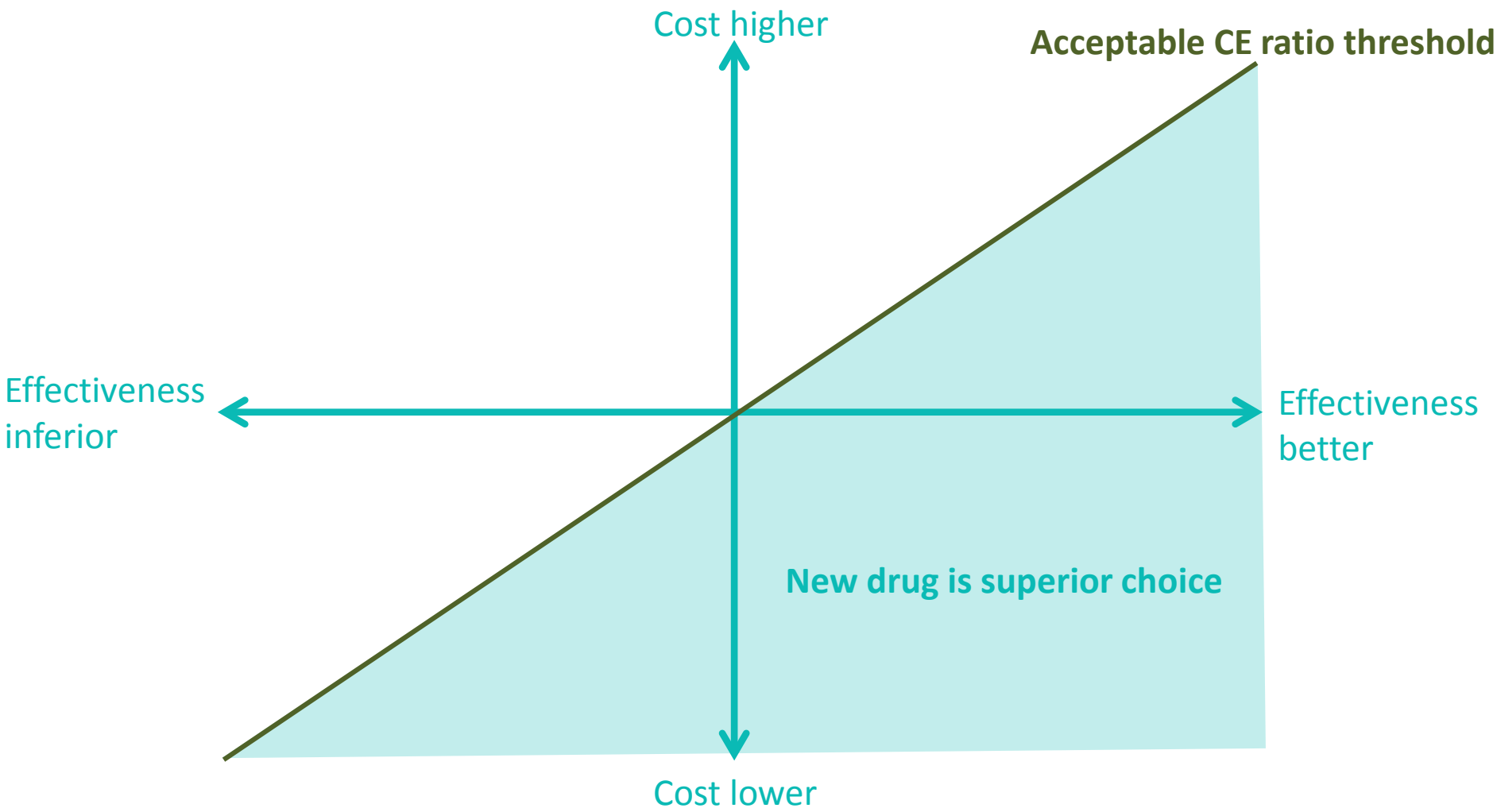
Relative Effectiveness

Is better than the existing option? What's better? How much better?

- Systemic review
- Head-to-head comparison is preferred
- Indirect comparison is also accepted
- Outcome indicator
- Safety consideration
- Target population

Cost Effectiveness

How much to spend on the benefit? Is it worth?



Cost Effectiveness

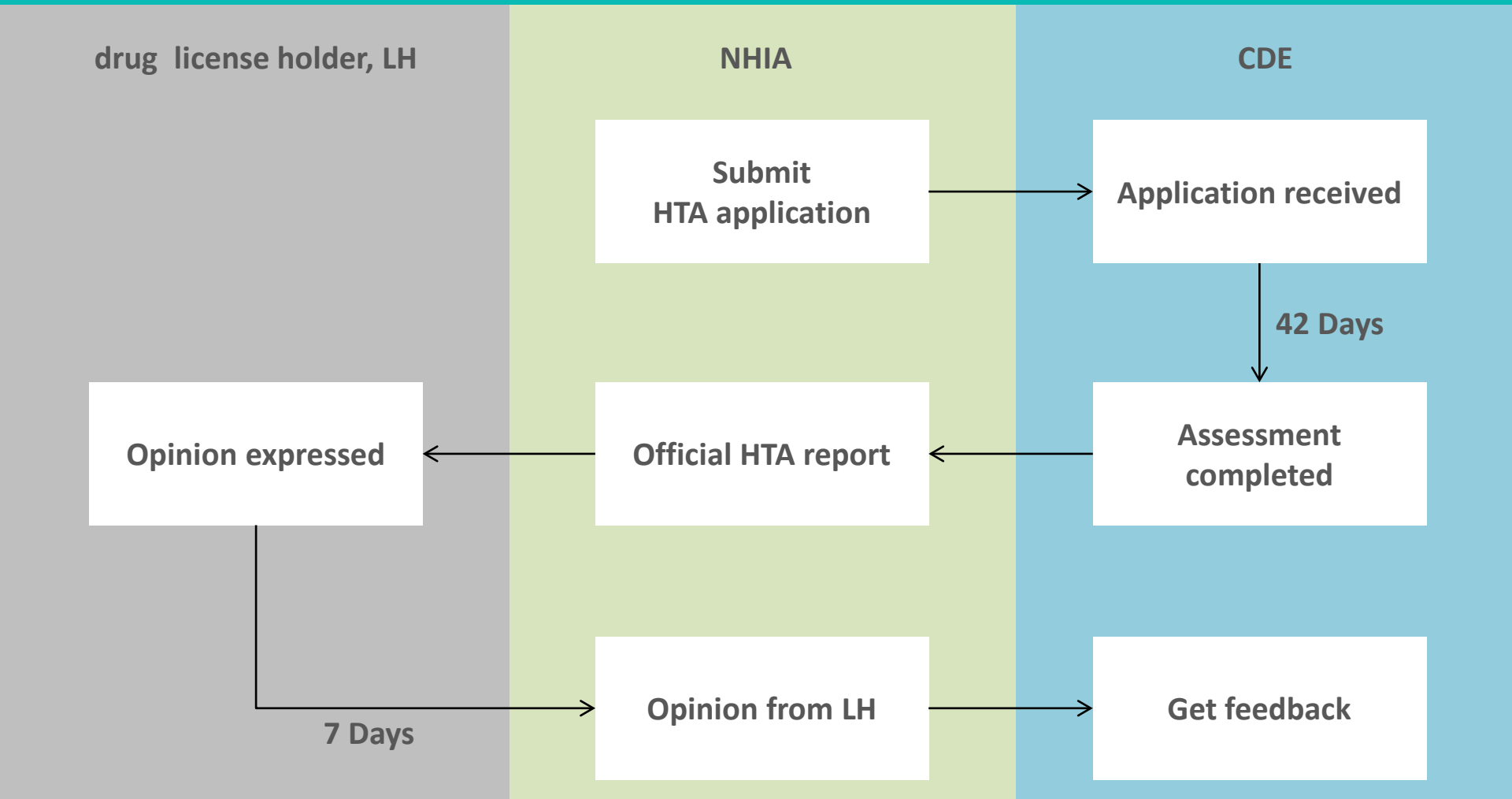
- Still in the stage of capacity building (lack of local clinical epidemiological data and cost data)
- CE result from UK, Canada and Australia as reference data
- Up to 10% price plus for conducting local PE study

Budget Impact Analysis

How much is the total expenditure? Is that affordable?

- **Verification of financial forecast provided by new drug supplier**
- **Financial forecast include:**
  - **Total new drug expense in five years of listing**
  - **Substitution effect on other drug expense**
  - **Saving effect on other medical claims**

HTA Process for New Drug Listing Application



PVA Regulations in NHI-PBRS (1)

- **Article 41 Price volume agreement shall take effect if any of the following conditions is satisfied:**
  1. **A new drug for listing: a financial forecast provided by the drug supplier estimates that the sales volume of the new drug will exceed NT$200 million in any of the five years of listing.**
  2. **Extension of reimbursement scope of an existing drug: a financial forecast provided by the drug supplier estimates that the sales volume of the extension will exceed NT$100 million in any of the five years of extension.**
  3. **The actual expenditure of a drug which does not satisfy the above two conditions with a sales volume exceeding NT$200 million (new drug) or NT$100 million (extension of reimbursement scope) in any of five years after the new drug is listed for reimbursement or the reimbursement scope of an existing drug is extended.**

PVA Regulations in NHI-PBRS (2)

- **Article 42 The term of the price volume agreement is as follows:**

  The term of the price volume agreement is in principle for five years, but nonetheless is subject to reduction or extension as the case may be.

- **Article 43 If the price volume agreement is to be terminated, one of the following conditions shall be satisfied:**

  1. The agreement expires;

  2. The drug has been delisted; or

  3. Additional two or more drugs of the same ingredient(s) with different brands have been listed during the term of the agreement.

PVA Regulations in NHI-PBRS (3)

- **Article 44 The price volume agreement may be executed as follows:**
  1. **Rebating arrangements:**

     Set the cap of expenditure for each observation year. If any sales exceeded the cap in an observation year, the suppliers shall rebate a percentage of the expenditure to the insurer.
  2. **Price reduction arrangements:**

     Set the cap of expenditure for each observation year. If any sales exceeded the cap in an observation year, the reimbursement price shall be reduced.

PVA Regulations in NHI-PBRS (4)

3. Shared agreement:

Drugs of the same ingredient(s) with different brands or drugs in the same category of pharmacological effects share the same rebate or price reduction arrangement together. In the case of rebate, the amount of rebate shall be shared according to the ratio of the expenditure on each drug. In the case of price reduction, the adjustment of the price of each drug shall be based on the same ratio of reduction.

Article 45 The cap of expenditure shall be based on the financial forecast projected by the supplier (applicable number of persons multiplied by the projected annual amount) and calculated according to the tentative reimbursement price.

PVA Regulations in NHI-PBRS (5)

- Article 46　In the event of circumstances set forth in Subparagraph 3, Paragraph 1 of Article 41, if a drug of which the projected drug sales is not qualified for price volume agreement when the supplier makes submission but the actual drug expenditure has met the pre-conditions of price volume agreement in any of the following five years after the drug is listed or the reimbursement scope of an existing drug is extended becomes effective, the insurer shall notify the supplier to negotiate a price volume agreement before May 31 of the following year. (To be continued)

PVA Regulations in NHI-PBRS (6)

- In the event that the supplier fails to complete the price volume agreement within two months from the date of notification by the insurer for negotiation, the drug price shall be re-priced at 95% of the original reimbursement price which shall take effect on October 1 of the same year.
- If the price volume agreement fails to be concluded before the end of July in the following year of negotiation, the price shall be further reduced by 5%. The same principle shall apply to each of the following years with a 5% cut in each year until the price volume agreement is concluded or the price has been reduced for five consecutive years.

Issues to be concerned

- It takes time to build social consensus for choosing a ICER threshold as the listing criteria.
- Budget impact concern from healthcare providers
- Patient involvement in HTA and decision-making
- Performance-based Agreements
  - ✓ Payer pays for responders, pays stationary expenses for non-responders
  - ✓ Manufacturers payback for non-responders