



11th Joint Conference of Taiwan and Japan on Medical Products Regulation

Strategies on New Drug Reimbursement of Taiwan's NHI System

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Outline

- 1 Drug payment system of Taiwan NHI**
- 2 Drug listing and mark-ups for new drugs**
- 3 NHI Pharmaceutical Policy**



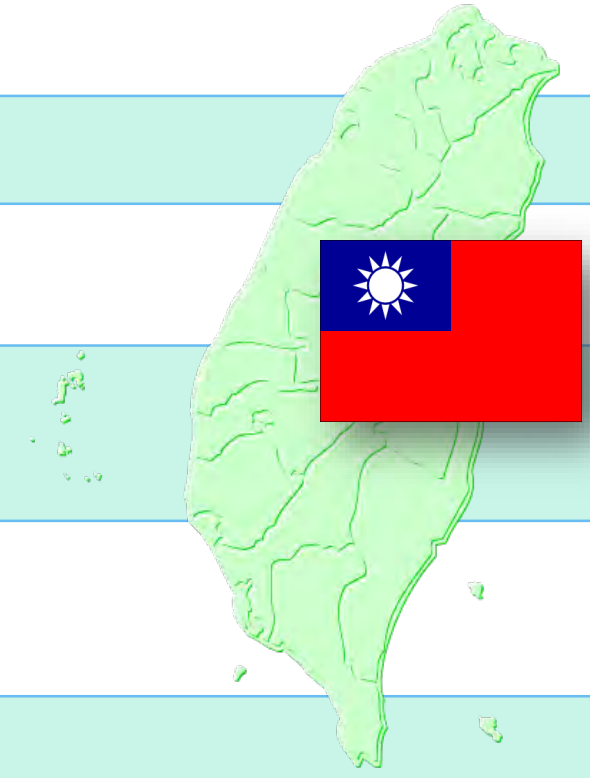
Drug payment system of Taiwan NHI



Profile of Taiwan

as of 2021

Population	23.38 million
Land area	36,197km ²
Aging (over 65)	16.85%
GDP per capita	US\$ 33,011
Crude birth rate	6.55 ‰
Crude death rate	7.83 ‰
Infant mortality	3.6 ‰
Maternal mortality(2020)	13.0 0/0000
NHE as % of GDP (2020)	6.69%
Life expectancy (2020)	84.7 (F) / 78.1(M)





Taiwan's Major Social Insurance Programs



Only 59% of the population was covered by these insurance plans in 1994, most of the uninsured were the children and the elderly.



NHI Characteristics

Coverage

Compulsory enrollment for all citizens and legal residents

Administration

Single-payer system
run by the government

Financing

Premiums

Providers

93.03% of healthcare providers contracted with NHI

Payment

Plural payment programs under **the global budget payment**

Privileges

Premium subsidies and co-payment waivers for **the disadvantaged**

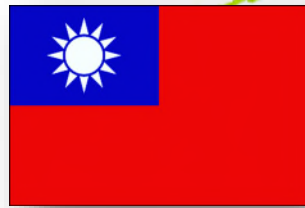


Numbeo Health Care Index

Taiwan has consistently ranked first in the Numbeo Health Care Index from 2019 to 2023.



[Health Care](#) > Index by Country



Health Care Index by Country

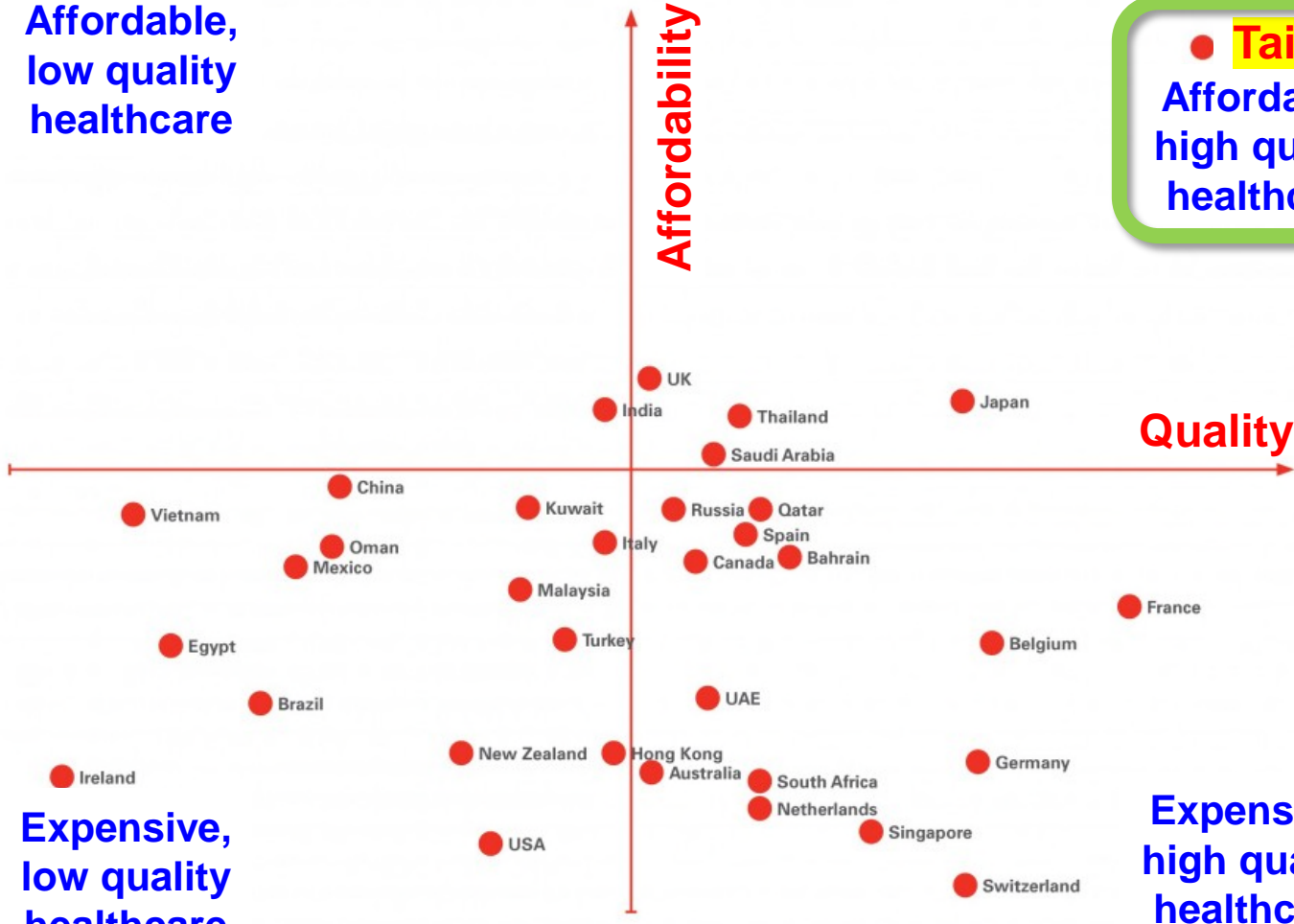
Rank	2019		2020		2021		2022		2023	
	Country	Health Care Index	Country	Health Care Index	Country	Health Care Index	Country	Health Care Index	Country	Health Care Index
1	Taiwan	86.22	Taiwan	86.71	Taiwan	86.39	Taiwan	86.4	Taiwan	85.9
2	South Korea	84.51	South Korea	81.97	South Korea	82.34	South Korea	82.7	South Korea	83.0
3	Japan	80.40	Japan	81.14	France	80.99	Japan	80.5	Japan	80.3



Affordable and High Quality Healthcare in Taiwan

Affordability versus quality of healthcare

Affordable, low quality healthcare



Taiwan
Affordable, high quality healthcare

Good accessibility

Low cost

Short waiting times

Comprehensive population coverage

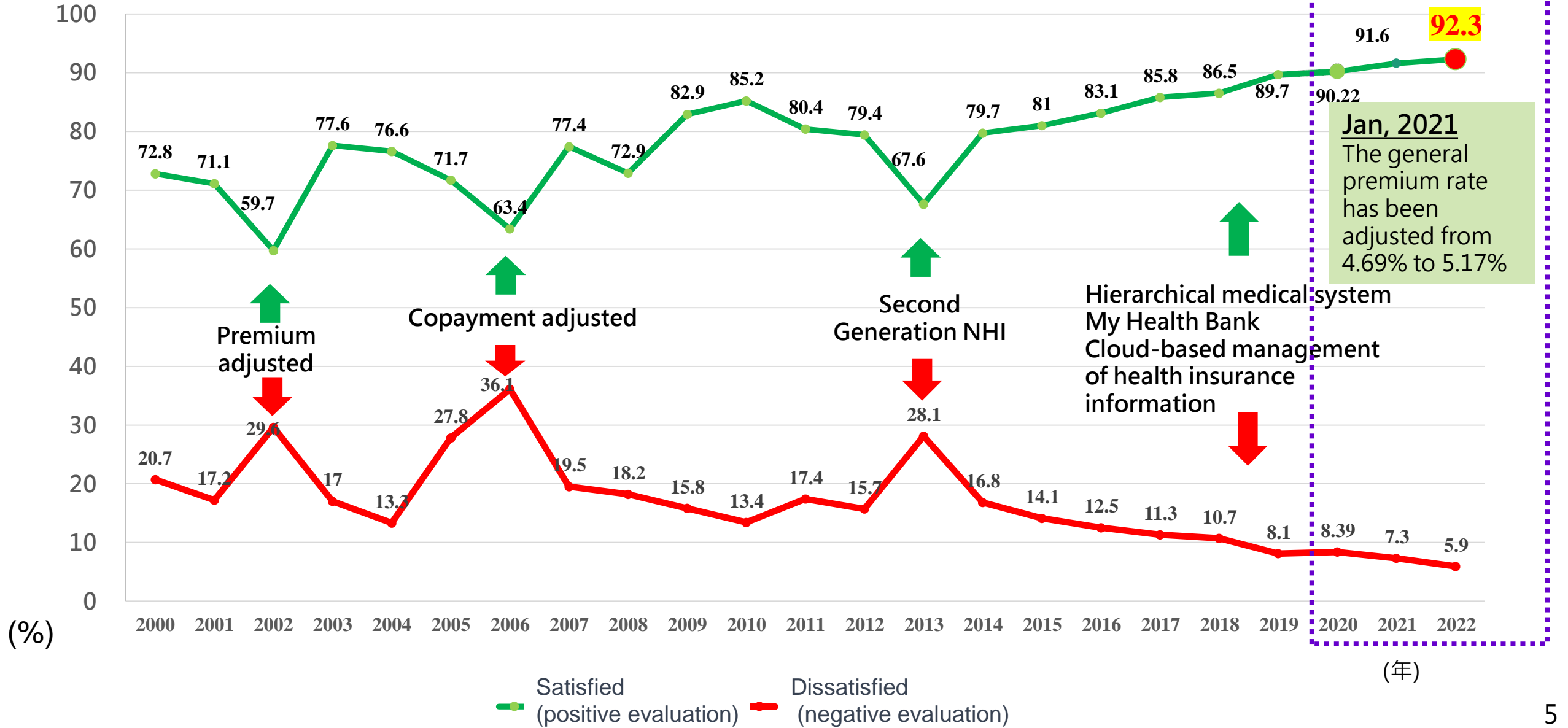
National data collection systems










Public Satisfaction Reached a Record High during the COVID-19 Pandemic

COVID-19 Pandemic



Types of Health Insurance

Country	National Health Service(UK) 	Social Insurance (Taiwan, Korea)  	Private Insurance (US) 
Financing	Government Budget Tax	Government collects Premium from the Insured	Insurance Company collects Premium from the Insured
Beneficiary	All Citizens	All Citizens	Private: Blue Crosses, Blue Shields, HMO Public: Medicare, Medicaid, SCHIP
 Challenges	<ul style="list-style-type: none"> Ageing Population Increased in medical demands 	<ul style="list-style-type: none"> Ageing Population Increased in medical demands Large insurance expenditures 	Attempts to ensure health coverage rights in Obama Care. The Obamacare was repealed because of the high cost.



Taiwan's Medical Utilization Higher but Expenses Lower than OECD Countries

Country	Medical utilization			
	Consultations (Per capita)	Hospital discharges (per 1000 inhabitants)	MRI exams (per 1000 population)	CT exams (per 1000 population)
OECD	6.8 [#]	146.2 [#]	79 [#]	155 [#]
United States	-	-	82.7 [*]	254.6
Canada	6.6 [#]	82.0 [#]	62.0 [#]	144.1 [#]
United Kingdom	-	127.2 [#]	-	-
Germany	9.5 [*]	252.5 [#]	149.9 [*]	150.0 [*]
Netherlands	8.4 [*]	89.8 [#]	58.6 [*]	113.9 [*]
Japan	12.4 [#]	130.7 [#]	-	-
Korea	14.7 [*]	179.8 [#]	71.7 [*]	250.0 [*]
Taiwan	13.4[*]	133.4[*]	37.1[*]	100.7[*]

Source :

1. [#]: 2019, ^{*}: 2020, [★]: 2021 *

2. OECD data 2022, NHI data 2022, Taiwan household registration (戶政) data 2022 *

Country	Health expenditure	
	Health expenditure per capita (USD PPP)	% of GDP
OECD	4,087 [#]	8.8 [#]
United States	12,318.1	16.8 [#]
Canada	5,904.9	10.8 [#]
United Kingdom	5,387.2	12.8 [*]
Germany	7,382.6	12.5 [*]
Netherlands	6,189.7 [*]	11.2 [*]
Japan	4,665.6 [*]	11.0 [#]
Korea	3,913.7	8.4 [*]
Taiwan	1,900[*]	6.7[*]

Source :

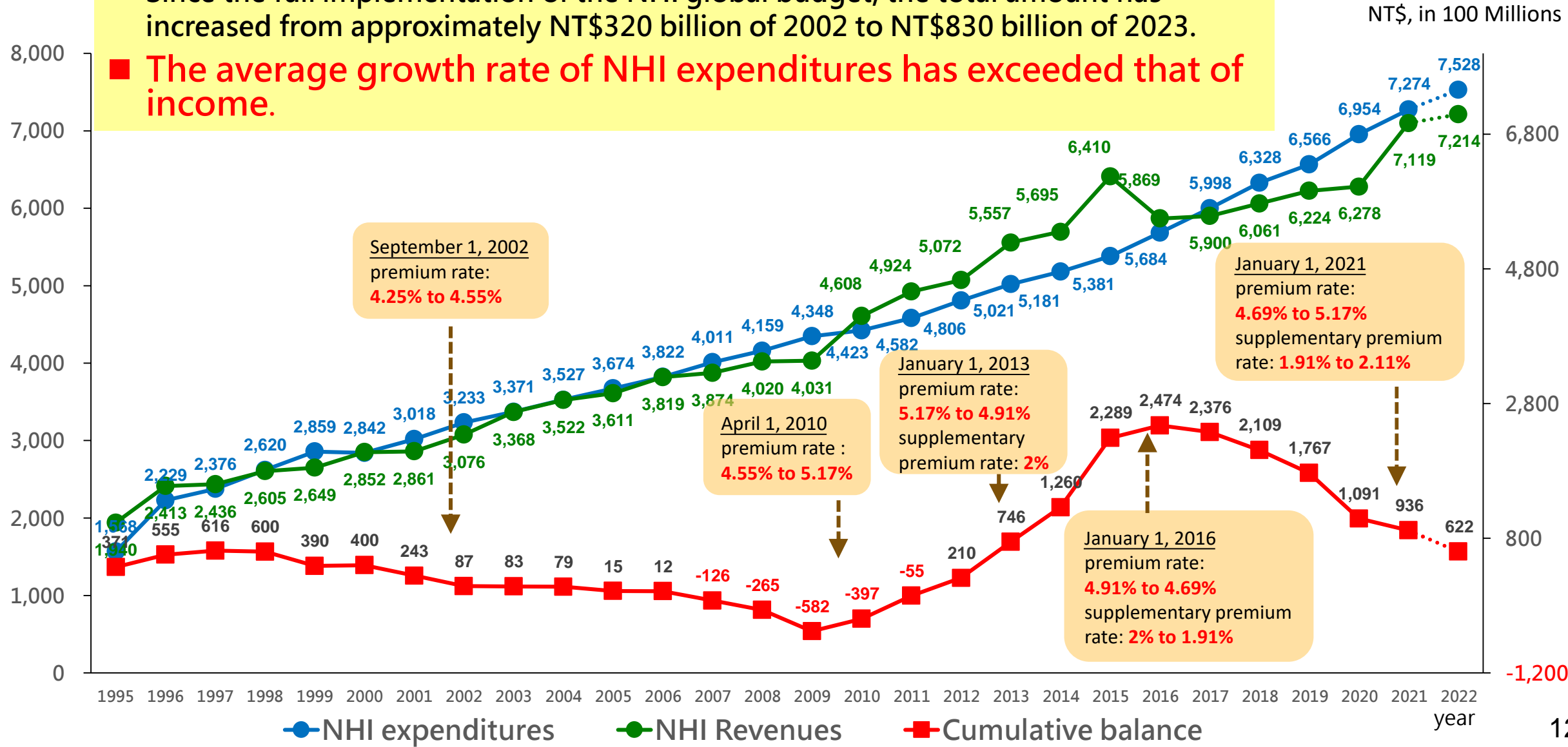
1. [#]: 2019, ^{*}: 2020, [★]: 2021 *

2. OECD data 2022, MOHW data 2022 *



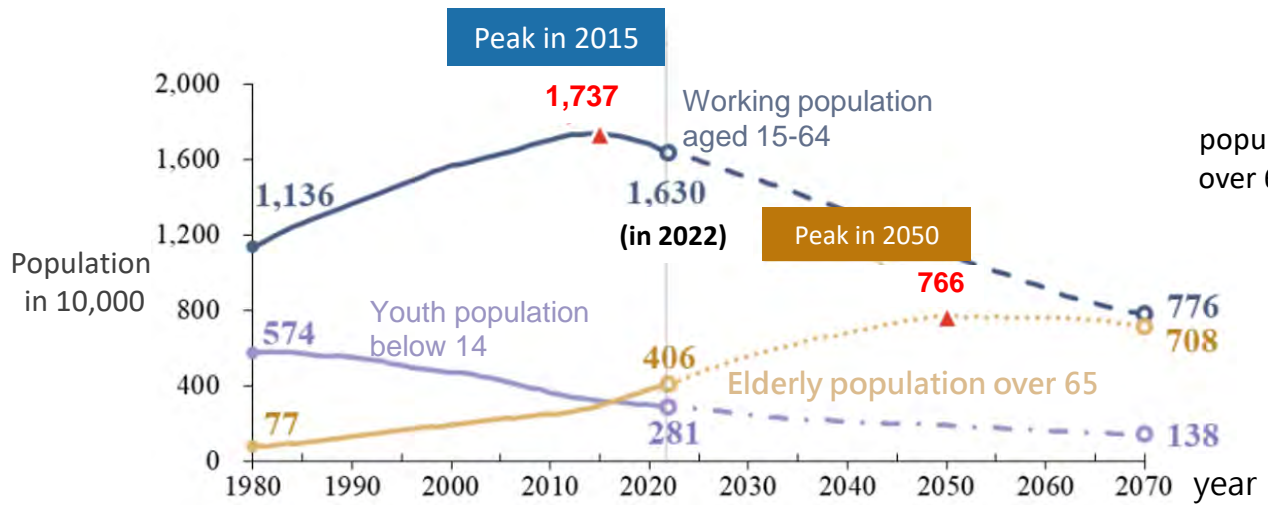
NHI Expenditure Constantly Growing

- Since the full implementation of the NHI global budget, the total amount has increased from approximately NT\$320 billion of 2002 to NT\$830 billion of 2023.
- The average growth rate of NHI expenditures has exceeded that of income.

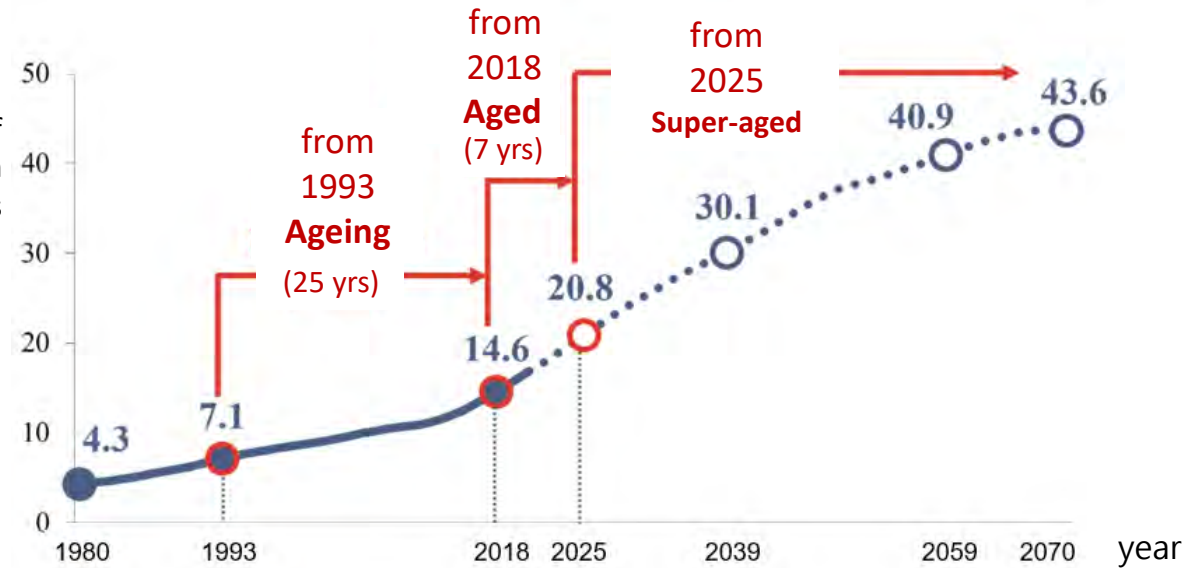




Rapidly Aged Population with Rising Medical Expenditures

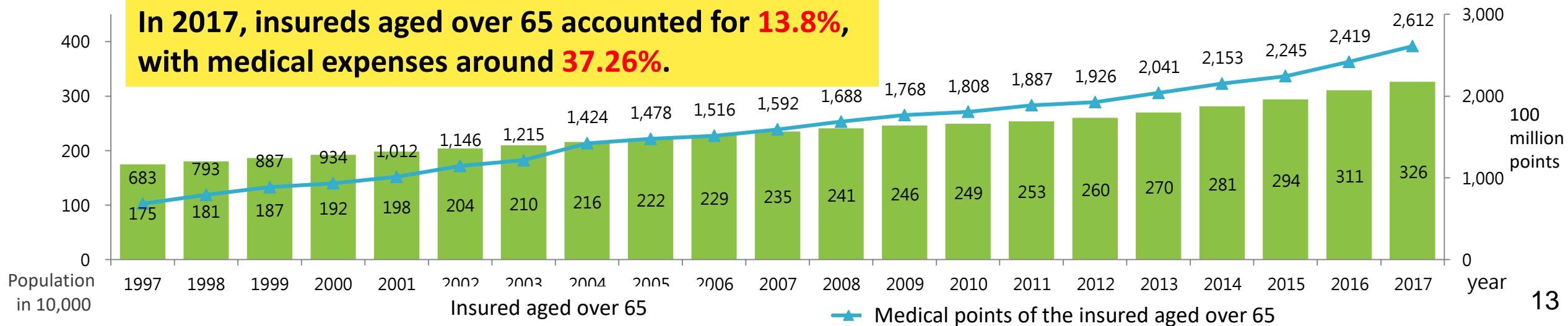


Population projection for Taiwan by the National Development Council in 2022



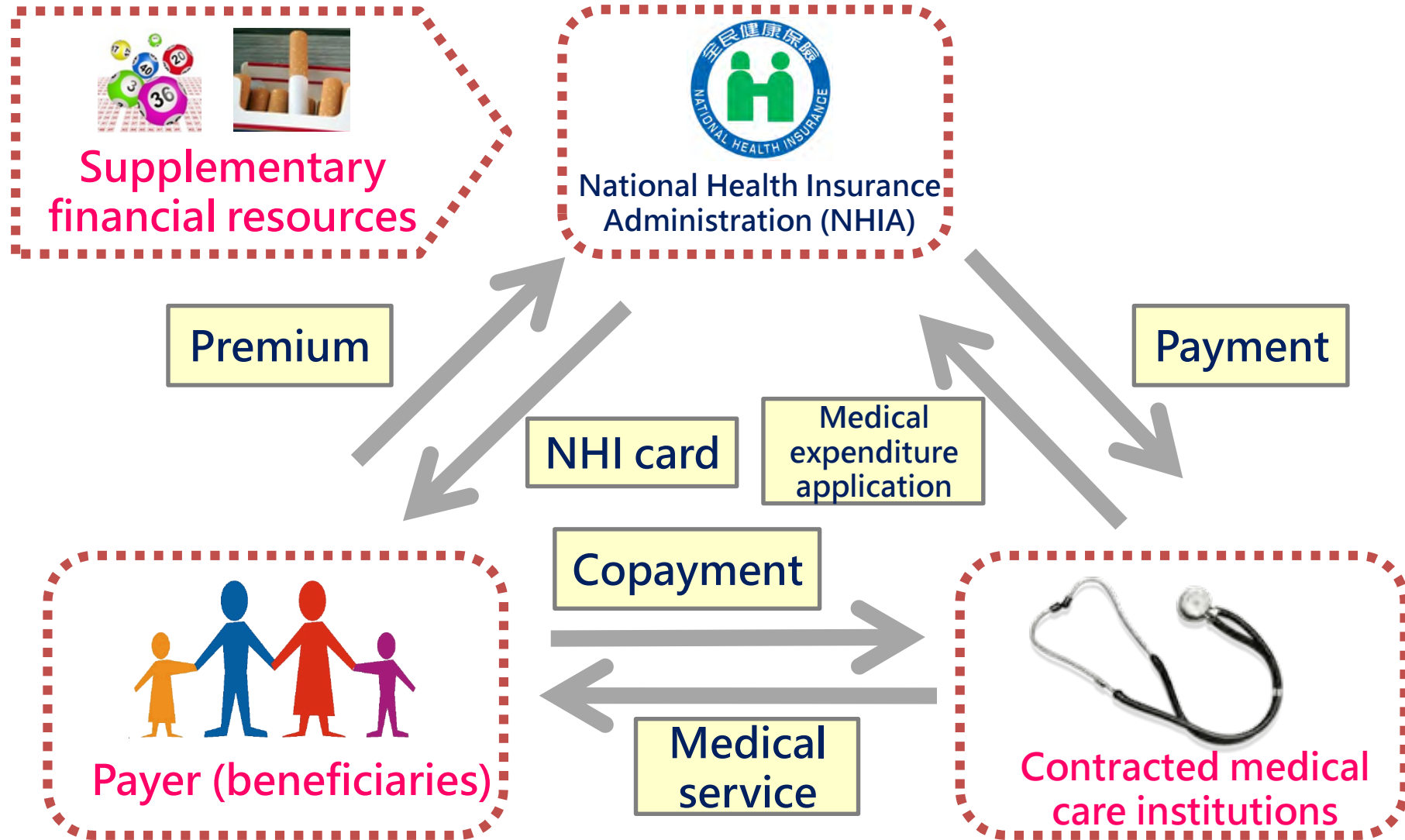
Population projection for Taiwan by the National Development Council

In 2017, insureds aged over 65 accounted for 13.8%, with medical expenses around 37.26%.





Health Insurance Framework in Taiwan





Drug Listing and Markup for New Drugs



Drug Fees Account for **10%** of the Total Budget of Central Government



用藥安全齊守護
把關資源顧健康

In 2022...

- **Total budget** of Taiwan's central government: **2.25 trillion** NTD
- **Global budget of NHI:** **809.6 billion** NTD
(**36%** of the total budget of central government.)
- **Drug fees:** **231.6 billion** NTD (**28.6%** of the global budget of NHI, **10%** of the total budget of central government.)

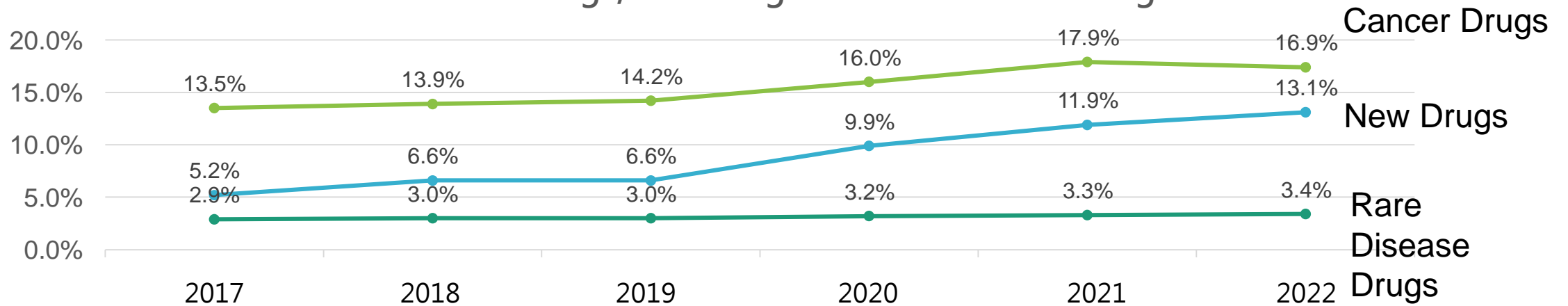




Increasing Resource Allocations for NHI Cancer Drugs/New Drugs/Rare Disease Drugs

➤ The share of cancer drugs, new drugs, and rare disease drugs expenditures has been increasing yearly. The global budget for 2022 is NT\$847.8 billion, with pharmaceutical expenditures totaling approximately NT\$231.6 billion. Among these, cancer drugs account for NT\$39.2 billion (16.9%), new drugs comprise NT\$30.3 billion (13.1%), and rare disease drugs amount to NT\$7.8 billion (3.4%).

Share of cancer drugs, new drugs and rare disease drugs



Notes : New drugs refer to the newly approved drugs within the past five years



Pricing of New Drug

Category		Pricing	Mark-ups
1	Breakthrough	Median price of A-10 countries	<ul style="list-style-type: none"> • domestic clinical trials (10%) • domestic 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 <ul style="list-style-type: none"> • lowest price in A10 • price in original country • international price ratio • treatment-course dosage ratio 	
2B	Me-too	<ul style="list-style-type: none"> • a combination drug is priced at 70% of the sum of each ingredient's price, or at the price of the single active ingredient. 	

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

Incentives in Pricing of New Drugs (1)

Domestic R&D encouragement

Criteria	Markup
Domestic implementation of clinical trials has reached a certain scale	10%
Domestic implementation of pharmacoeconomic (PE) clinical research	10%



Innovation encouragement

Criteria	Markup
Better effectiveness than price reference drugs	15%
Better safety than price reference drugs	15%
More convenient to use than price reference drugs	15%
Clinically significant pediatric preparations	15%

UP TO 80% EXTRA

Incentives in Pricing of New Drugs (2)

A new drug that demonstrates significant clinical value and is first introduced in Taiwan among the world

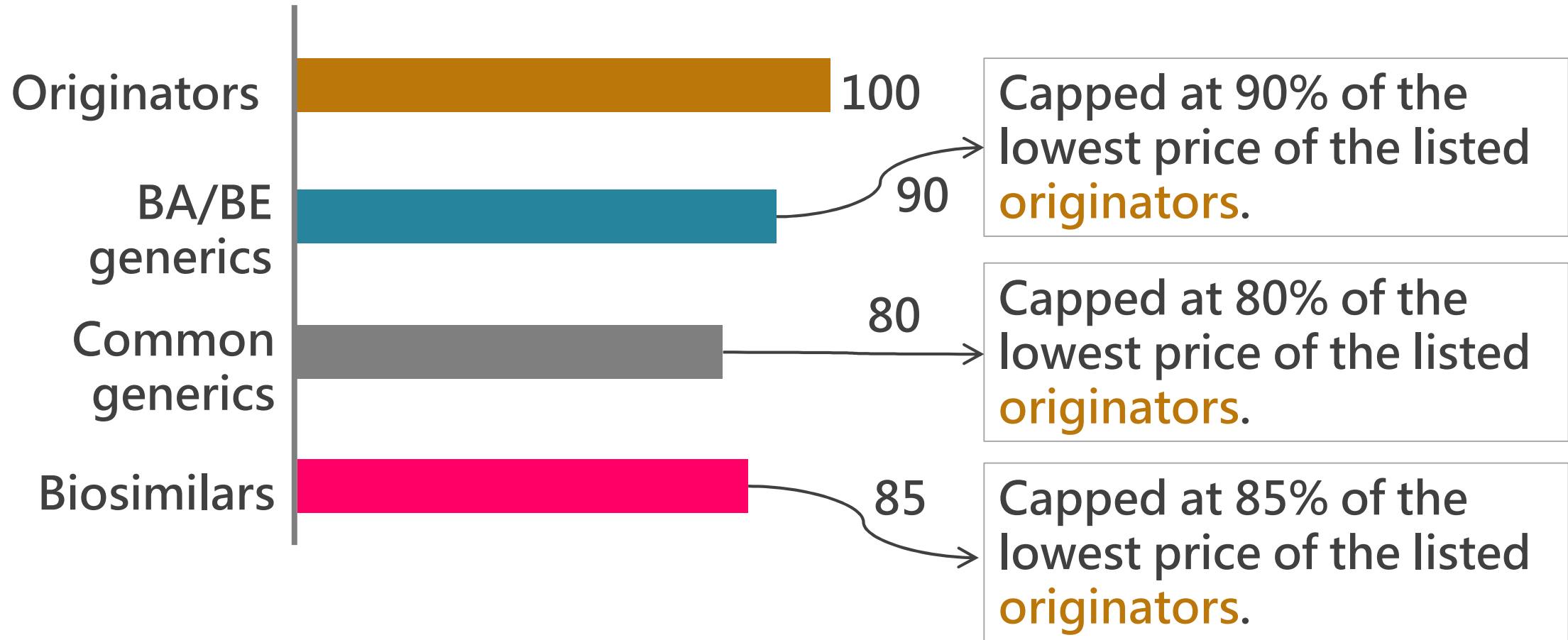
Based on actual transaction price

Cost calculation method

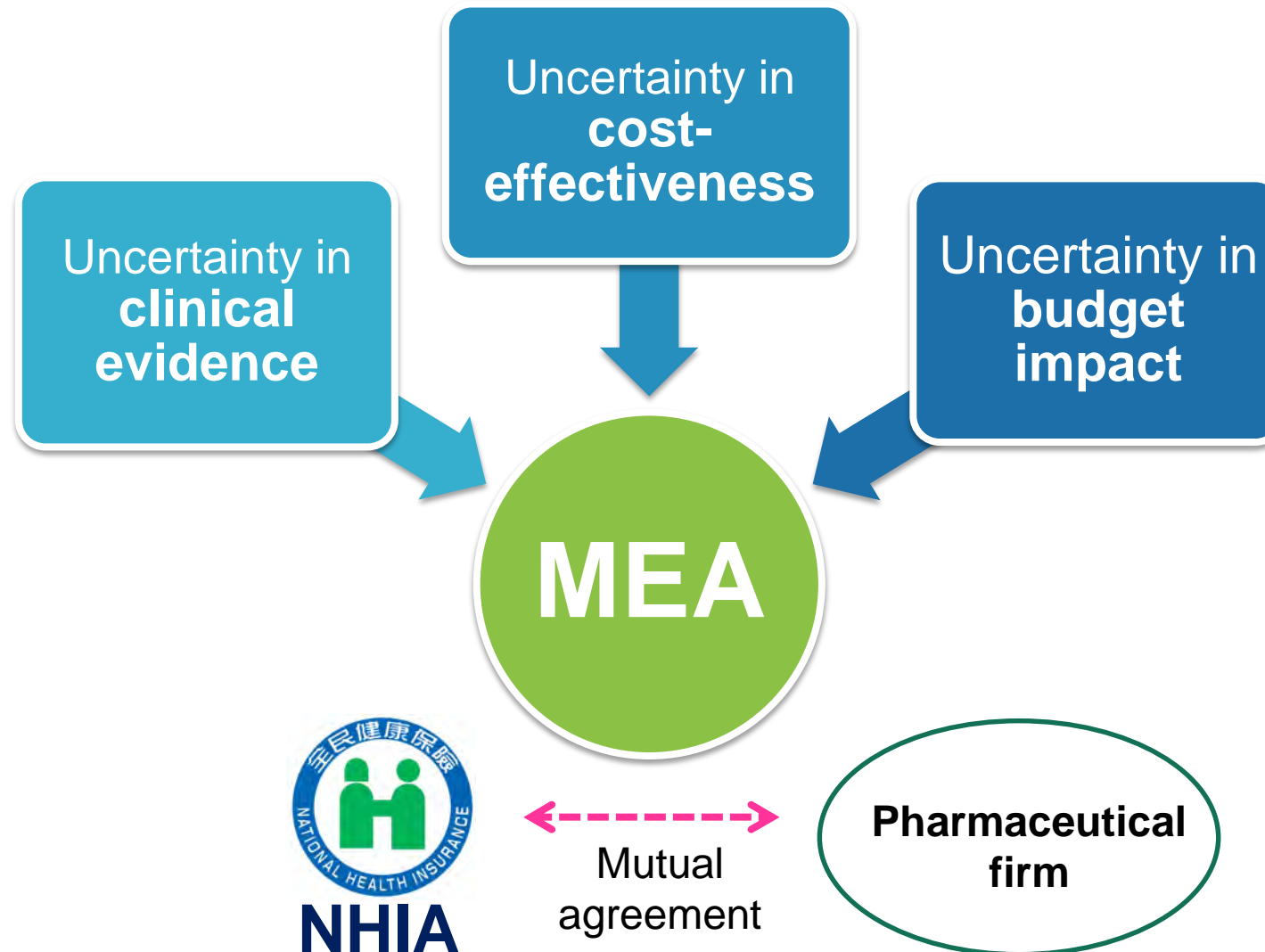
The listing prices of A-10 countries of the new drug and its comparators



Principle of Pricing Generics and Biosimilars



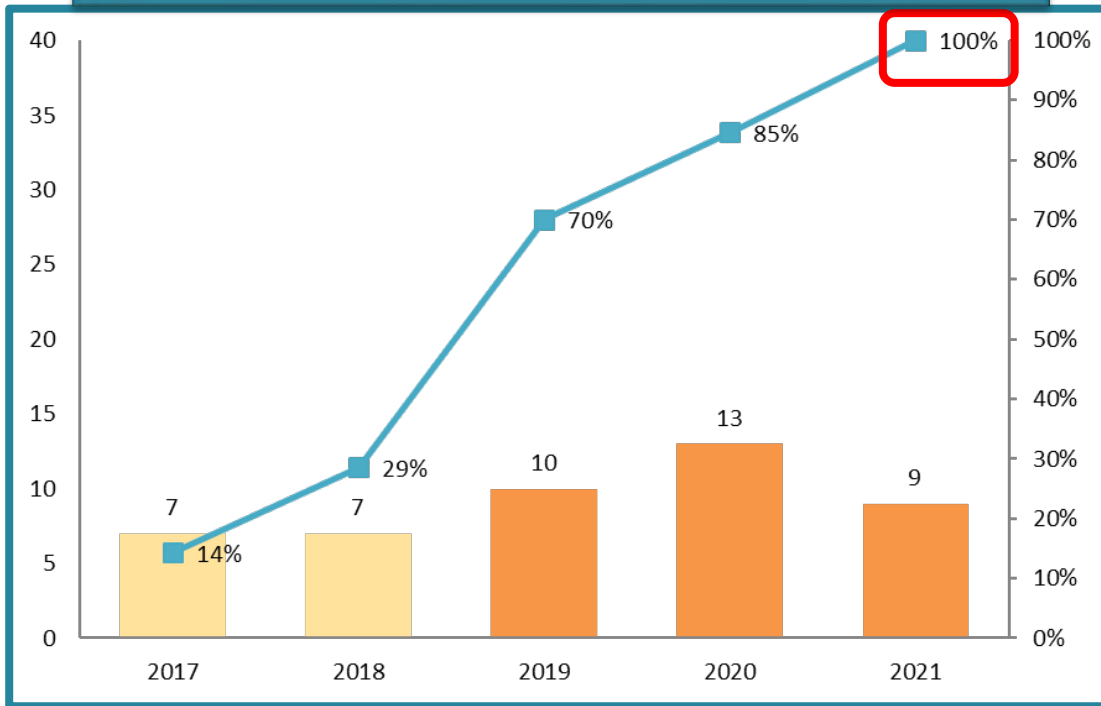
Managed Entry Agreement(MEA)



Introduce multiple negotiating and bargaining system

The **Managed Entry Agreement (MEA)** mechanism has been introduced since 2010. As of 2021, All new cancer drugs have signed MEAs, and nearly **20%** of cancer drugs have signed MEAs when expanding benefits.

Proportion of new cancer drugs signed MEA



Performance-based MEA

Financial-based MEA

Co-sharing MEA

- Provides payment terms based on specific therapeutic outcomes
- Improve overall survival
- slow disease progression
- Clinical efficacy repayment

- Focus on overall cost control
- Fixed discount plan
- Medication Assistance Program
- Drug matching plan

Set up a repayment plan shared by each drug with the same ingredient or the same AHFS/DI

Notes:

- 1) Calculated based on the number of new drug ingredients received in the current year.
- 2) The MEA has been implemented since 2019. From 2017 to 2018, the displayed data is the proportion of MEA signed when the drug's subsequent expansion of the payment scope.



NHI Pharmaceutical Policy

Cost-effectiveness Analysis: Prospective Planning for Precise Reimbursement

Making a Budget: **Horizon Scanning**

Introduction of **Horizon Scanning**, making potential NHI-covered items in a possible list while **making a budget**.

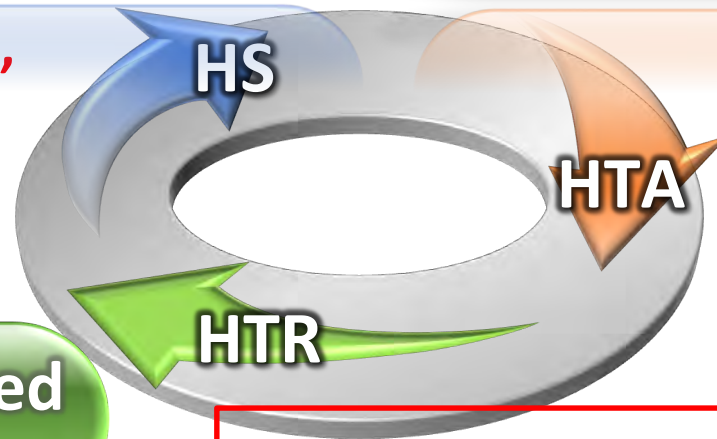
Reassessing the NHI-covered items: **HTR**

Reassess the NHI-covered items (**HTR, Health Technology Reassessment**).

- Effective: additional reimbursement;
- Ineffective: the reimbursement restricted; **resources reallocated to more beneficial items**.

New Drugs and New Technologies included into NHI : **HTA**

Use **Health Technology Assessment (HTA)** in order to make **cost-effectiveness analysis** for the purpose of policy-making.



Multiple risk-sharing models (including **Conditional Listing):**

For rare disease drugs with **unmet medical needs**, temporary payments are still made through negotiated agreements, even though the number of clinical trial cases is small or the trial period is short, and safety is yet to be observed. Additionally, a case registration system is established to regularly evaluate efficacy and cost-effectiveness, revise rare disease payment regulations in a rolling manner, and accelerate the introduction of new drugs and promote precision medication.



Health Technology Assessment (HTA)

National Health Insurance Act
Article 42

The Insurer may first conduct a **medical technology evaluation** (that is **HTA**) before drafting the medical service items and fee schedule in the preceding paragraph

for whom?



How many treatments we can use?



Is the new treatment better?

Relative effectiveness



How much will it cost? Does it worth?

Cost effectiveness



Can National Health Insurance afford it if included in scope of benefits?

Budget impact

Adjusting Drug Pricing according to Real World Evidence (RWE)

Markup if drug is valid

The reimbursed course of treatment was determined to extend up to 2 years for patients responsive to the medication
(Complete/partial response, CR/PR)

Patients having **stable disease (SD)** responded to those drugs have been extended to pay

- Formulate payment priorities
- Unmet medical need
 - Incremental cost-effectiveness ratio (ICER)
 - Budget impact



Repay if drug is ineffective

Gastric and liver cancer indications, as it shows no significant benefits compared with the existing treatments suspend applications from new patients. patients who are already under the treatment can continue until disease progression

The response rate to cancer immunotherapy is only about 20% on average. Adjust the price with reference to the drug prices in the ten countries

Continue to evaluate the response rate of patients and make performance-based MEA



Conditional listing Case

Ingredients	Coverage	Reimbursement Date
Pemigatinib	Intrahepatic cholangiocarcinoma	Jul 1th, 2023
Tepotinib	Metastatic non-small cell lung cancer	Jul 1th, 2023
Dinutuximab beta	Neuroblastoma	Aug 1th, 2023

By promoting the Conditional listing, speed up the reimbursement of new drugs.

Gene therapy medicine for treating SMA- **Zolgensma** (Onasemnogene abeparvovec)

Mechanism

Gene therapy involves intravenous infusion of an adeno-associated virus (AAV) vector carrying a normal SMN gene segment, which is then introduced into the patient's cells to produce SMN protein, achieving therapeutic effects for the treatment of Spinal Muscular Atrophy (SMA).

Treatment and indications

Single-dose IV injection

Treatment for patients under 6 months old, diagnosed with SMA through genetic testing, and have 2 or 3 copies of the SMN2 gene.

approximately 9 to 10 newborns will be diagnosed each year*

*Taking into account domestic literature and expert opinions, the incidence rate of SMN1 gene abnormalities in newborns (7.1/100,000) is estimated to be used as a, with a screening rate of 80% to 90%.

Inclusion in NHI coverage

- high price
- Actively negotiate with pharmaceutical companies
- Included in NHI coverage from August 1, 2023.

Sign **managed entry agreements based on the performance or financial results** with manufacturer.



Accelerating Inclusion of New Drugs

NEW

Speeding up Process

- ✦ Discussing a parallel review mechanism with the FDA for specific drugs, accompanied by CDE HTA reports

Improving simulation model for budget estimation

- ✦ Using horizon scanning to estimate budget
- ✦ Setting priorities for new drug inclusion based on healthcare needs

Managing and accelerating drug pricing process

- ✦ Strictly control the time for drug manufacturers to supplement and resubmit proposals
- ✦ Negotiate with manufacturers 9 months in advance for MEA renewal

Set up a diversified risk-sharing model

- ✦ Negotiating installment payments and performance-based repayment methods with manufacturers

Optimizing HTR

- ✦ Planning transparent guidelines for HTR operations

NEW

New Drugs



Change of drug reimbursement regulations

NEW

Ask for budget increase

- ✦ Strive for injections of drug price adjustment funds
- ✦ Strive for budget support for temporary payments
- ✦ Study independent budgets or funds for new drugs
- ✦ Collaborate between NHI and commercial insurance
- ✦ Getting additional support from tobacco surcharge funds

Managing and accelerating drug pricing

- ✦ Starting from November 2022, drug manufacturers are allowed to present at the first expert meeting.
- ✦ Facilitating payments for the Initial launch of new drug in Taiwan.

Conditional Listing

- ✦ In response to the urgent clinical needs but with uncertain efficacy and safety of new drugs, the NHIA will negotiate with drug manufacturers for diversified risk-sharing, temporarily payment for 2 years, and collect real-world data for review.

NEW



Health for All and NHI Sustainability

**HEALTH FOR ALL
NHI SUSTAINABILITY**

Holistic
Health Care

Medical
Equal Rights



Efficiency &
Quality

Care for the
Disadvantaged

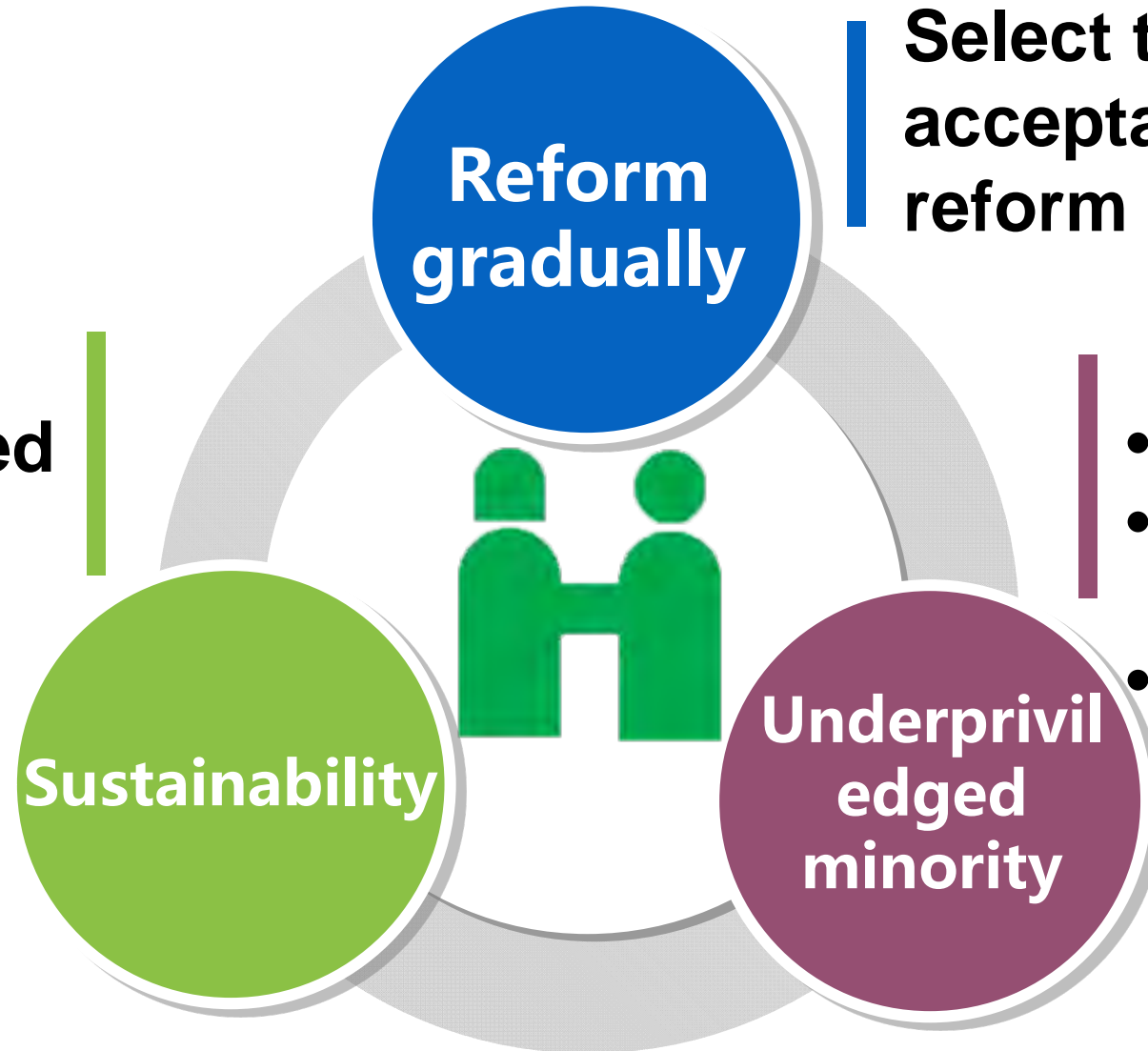
Beyond Hospital to Community

Beyond Healthcare to Health

Beyond Quality to Value

Sustainable Development for National Health Insurance in Taiwan

Maximize the therapeutic benefit of limited medical resources.



Select the most acceptable plan to reform in sequence.

- Severe illness
- people are not affected.
- Provide assistance to those with financial difficulties.



***Thank you
for your kind attention!***