The Management of Taiwan's National Health Insurance Drug Reimbursement Scheme

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National Health Insurance Administration, Taiwan

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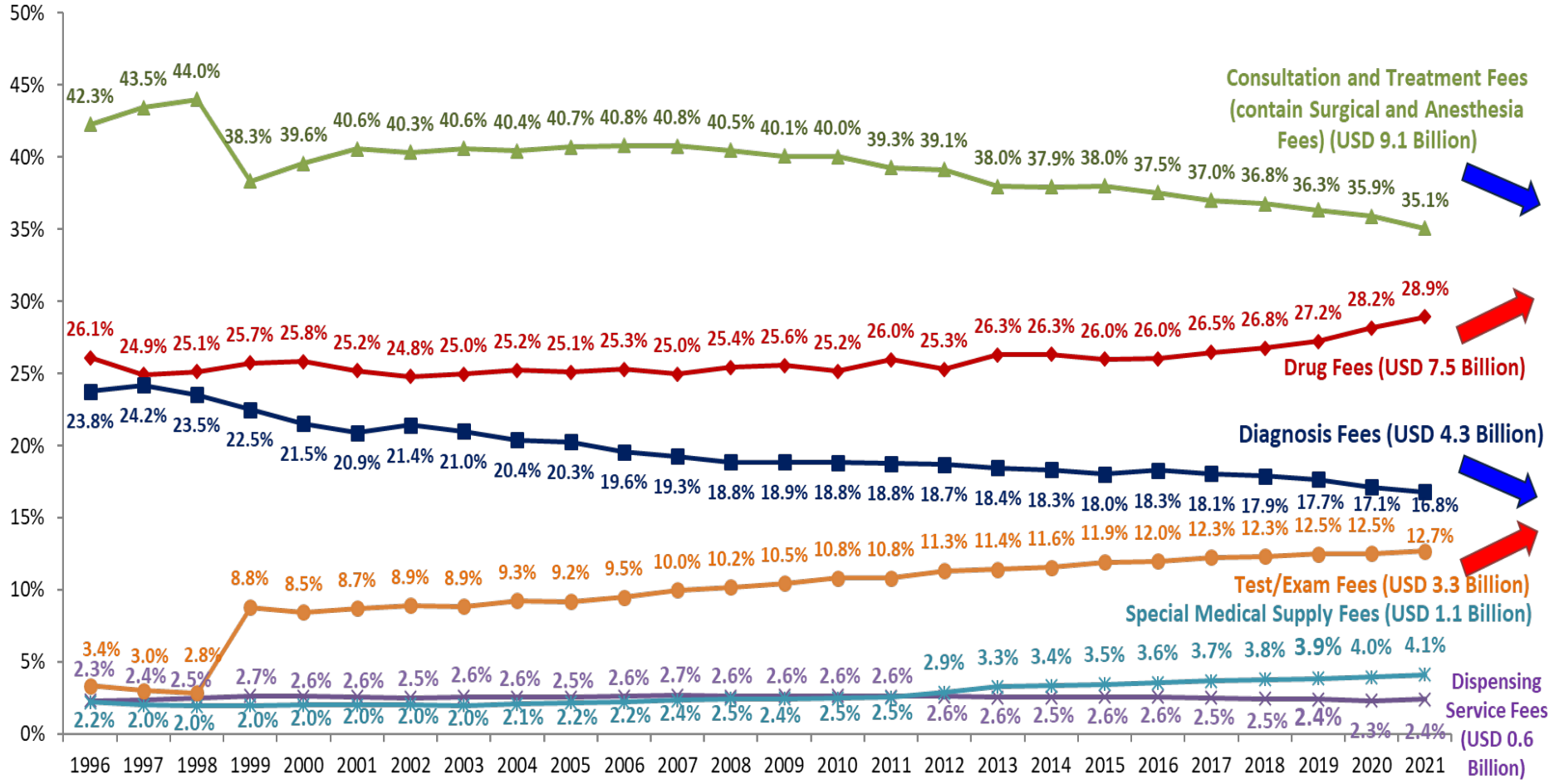
Outline

- Pharmaceutical Expenditure in Taiwan
- Principles and Procedures of drug listing
- Enhance Reimbursement Efficiency
- Conclusion

Pharmaceutical Expenditure in Taiwan

Overview of Medical Expenditure

National Health Insurance Administration

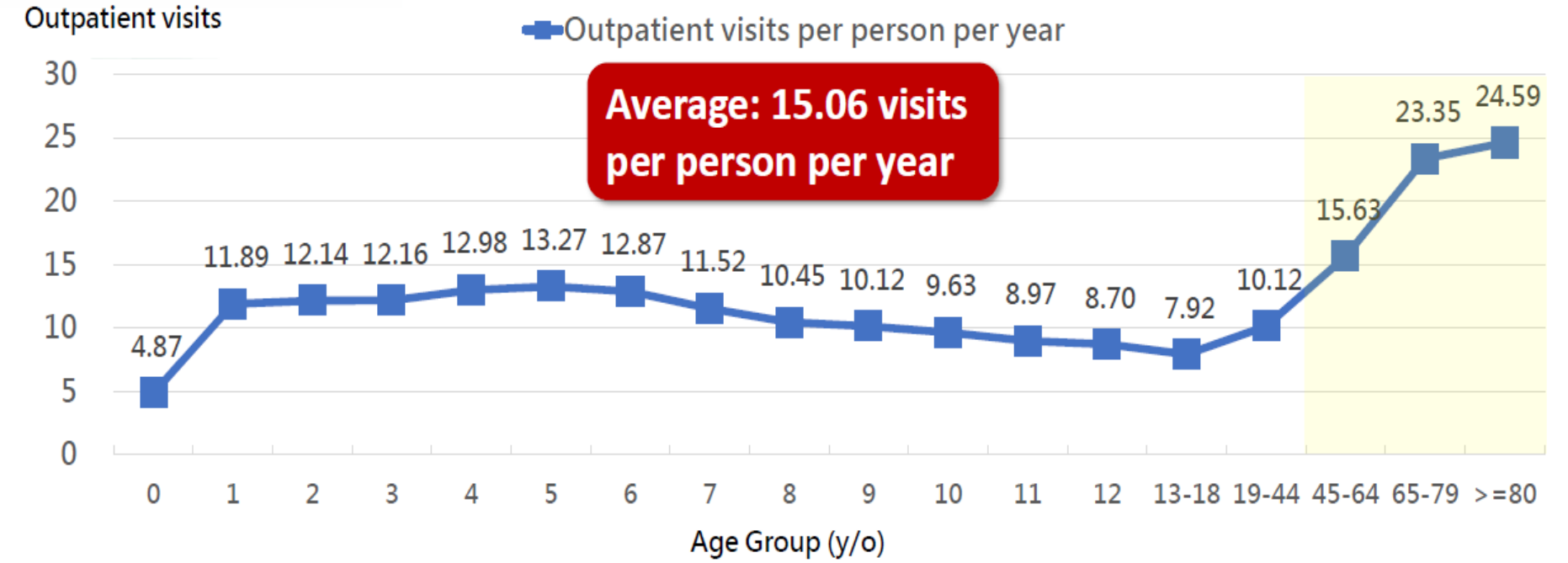


Hospitalization diagnostic fee (without examination fee) is including room charge, tube-feeding diet, radiotherapy, treatment fee, surgery, rehabilitation, blood/plasma, dialysis, anesthesia, psychotherapy, injection fee, etc.

Outpatient Medical Utilization in 2021

National Health Insurance Administration

- The number of outpatient visits is higher than national average among the groups aged >= 45 y/o.

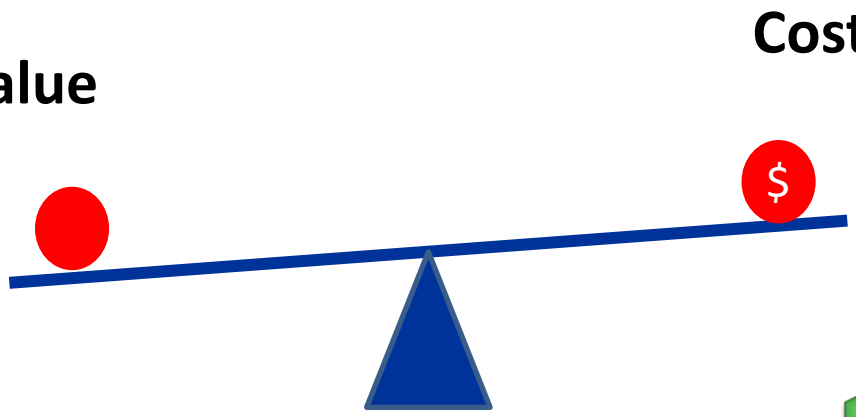


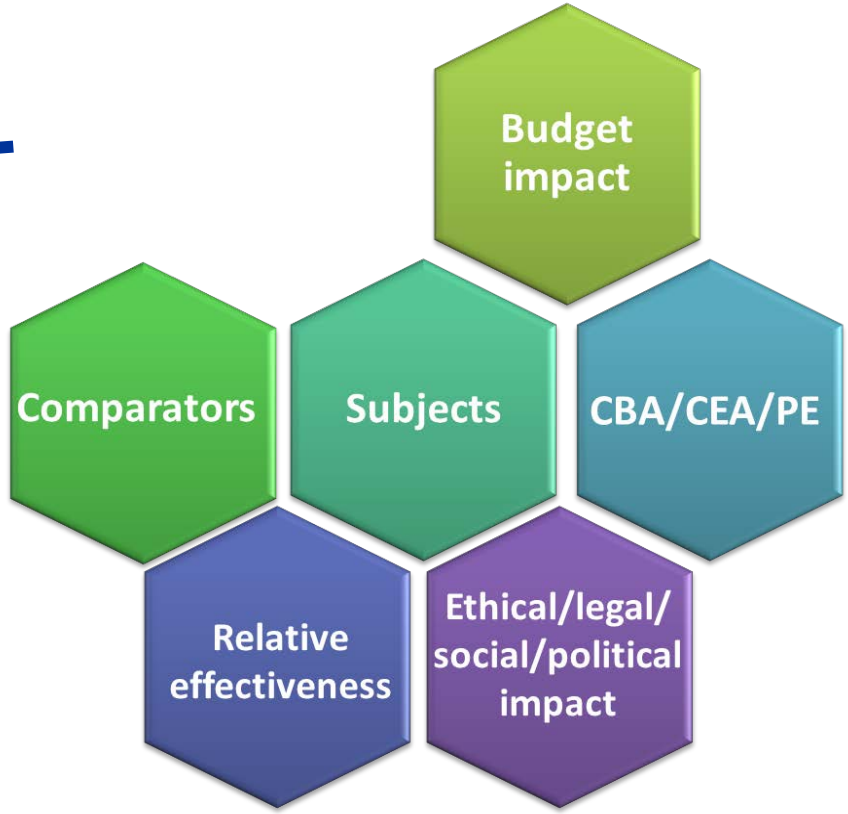
Note: 1. The figure is based on 2021 statistics, and the cases of administrative assistance were excluded.
2. The number of outpatient visits among 0-year-old persons might be underestimated due to age conversion.

Principles and Procedures of drug listing

Pay for Value

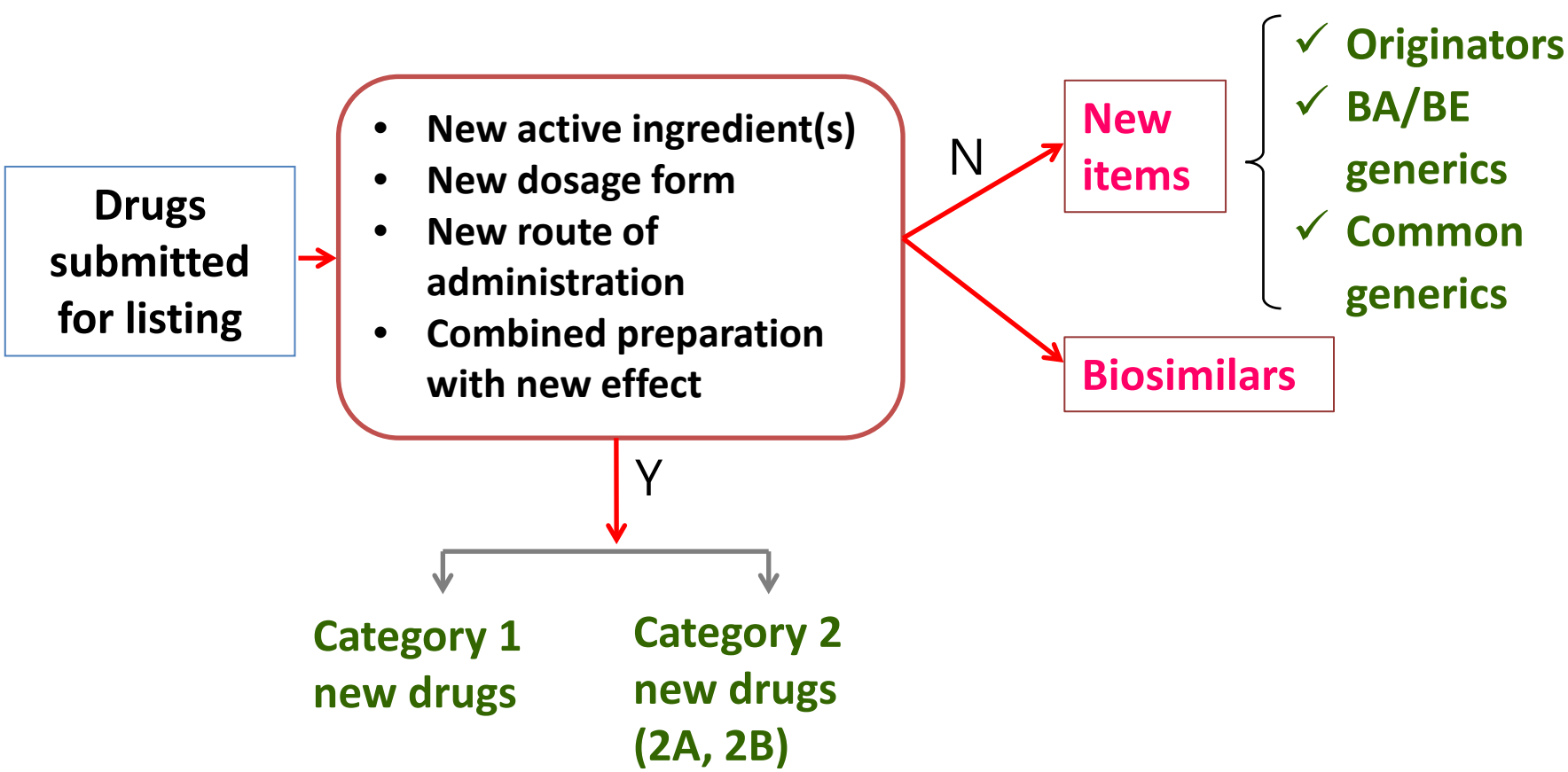
National Health Insurance Administration





Classification of Drugs Listed

National Health Insurance Administration



Pricing of New Drug

National Health Insurance Administration

Category		Pricing	Mark-ups
1	Breakthrough	Median price of A-10 countries	• 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 • 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.

Incentives in Pricing of New Drugs (1)

National Health Insurance Administration

☐To encourage local development of new drugs

Criteria	Mark-ups
Performing **domestic clinical trials**	10%
Conducting **domestic pharmaco-economic (PE) study**	Up to 10%

☐To encourage innovation

Criteria	Mark-ups
Superior therapeutic effects, better safety, favorable dosage forms of children's medications compared to the chosen comparators	Up to 15% for each criterion
Better convenience (ex: longer dosing interval, better route of administration, etc.)	Up to 15%

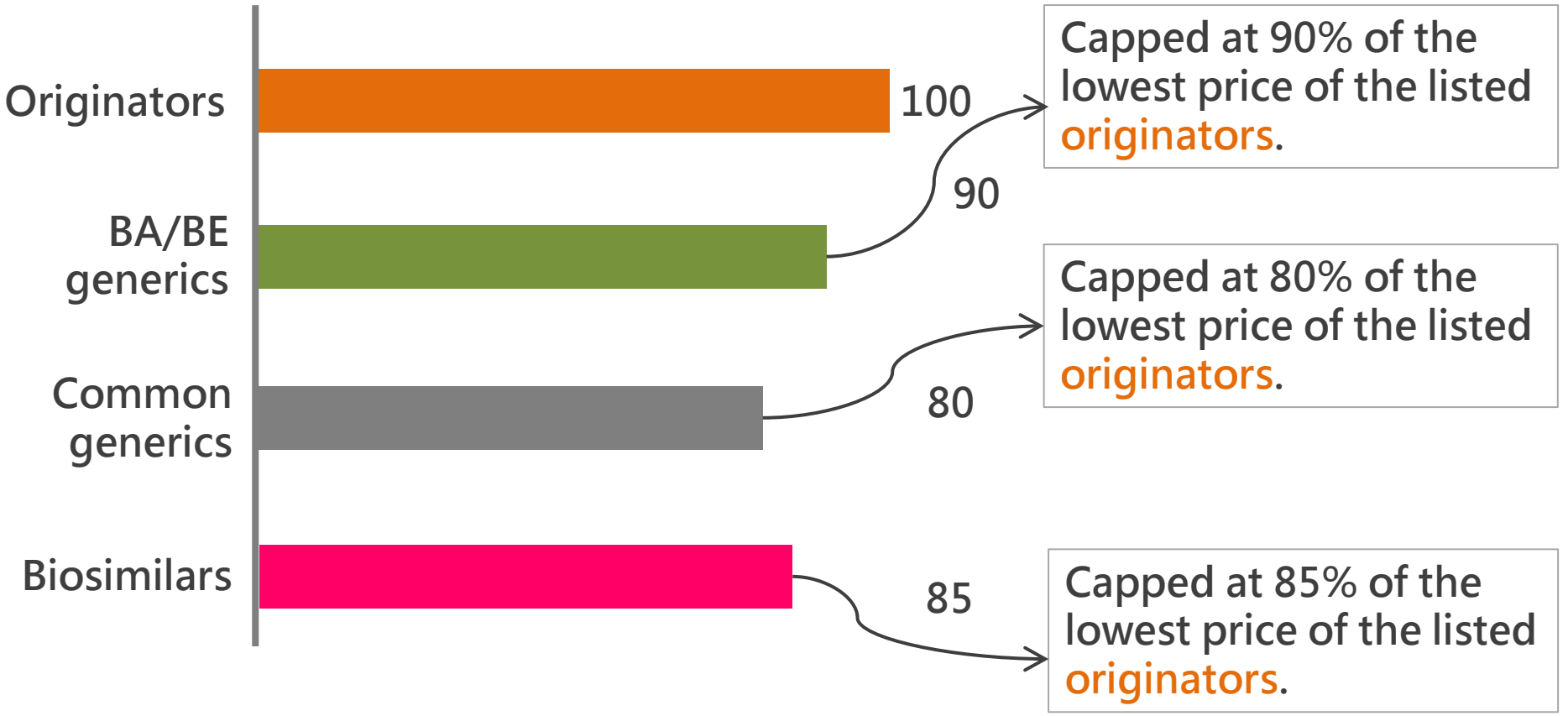
Incentives in Pricing of New Drugs (2)

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

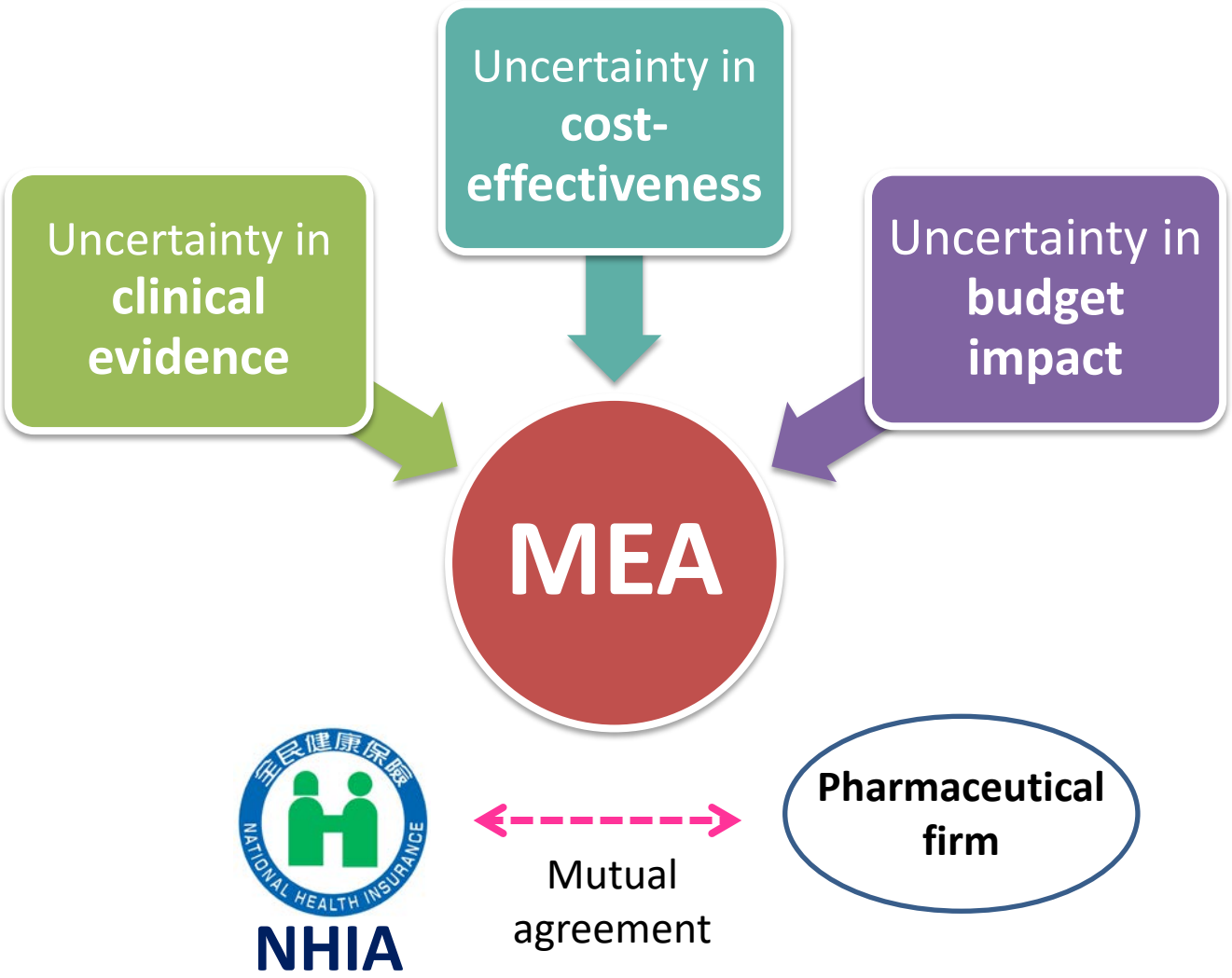
Principle of Pricing Generics and Biosimilars

National Health Insurance Administration



Managed Entry Agreement(MEA)

National Health Insurance Administration



MEAs Models in Taiwan

National Health Insurance Administration

- 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 insurer via refund/ payback.

Category	Mechanism of MEAs Models
1. Performance-based	1. Ensure the improvement in overall survival 2. Ensure the progression-free survival 3. Refund / payback based on response rate etc.
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.

New Drug Listing Time Course
(from submission to listing)

National Health Insurance Administration

Year of listing	No. of cases	No. of items	Minimum (month)	Average (month)	Maximum (month)	Median (month)
2013	19	26	4.2	7.8	12.9	7.7
2014	23	45	4.0	8.4	14.9	7.9
2015	22	40	6.3	11.5	22.0	10.0
2016	17	26	7.3	11.3	21.1	10.4
2017	29	50	7.3	12.0	31.3	8.9
2018	26	51	7.3	11.7	28.2	10.2
2019	33	51	3.7	11.5	19.1	10.6
2020	27	45	3.3	13.6	27.5	10.0
2021	25	39	4.4	11.6	19.0	11.6
Total	221	373	3.3	11.2	31.3	10.0

Enhance Reimbursement Efficiency

The Registration Platform for Horizon Scanning

National Health Insurance Administration

Submission type

- ☐ New Drug
- ☐ Expansion of reimbursed indications

Claimed value of the new drug

- ☐ Breakthrough drug
- ☐ 2A
- ☐ 2B

New Drug Registration

- ☐ Expected indication
- ☐ Expected date of launch in Taiwan

Launched in Sep. 2020

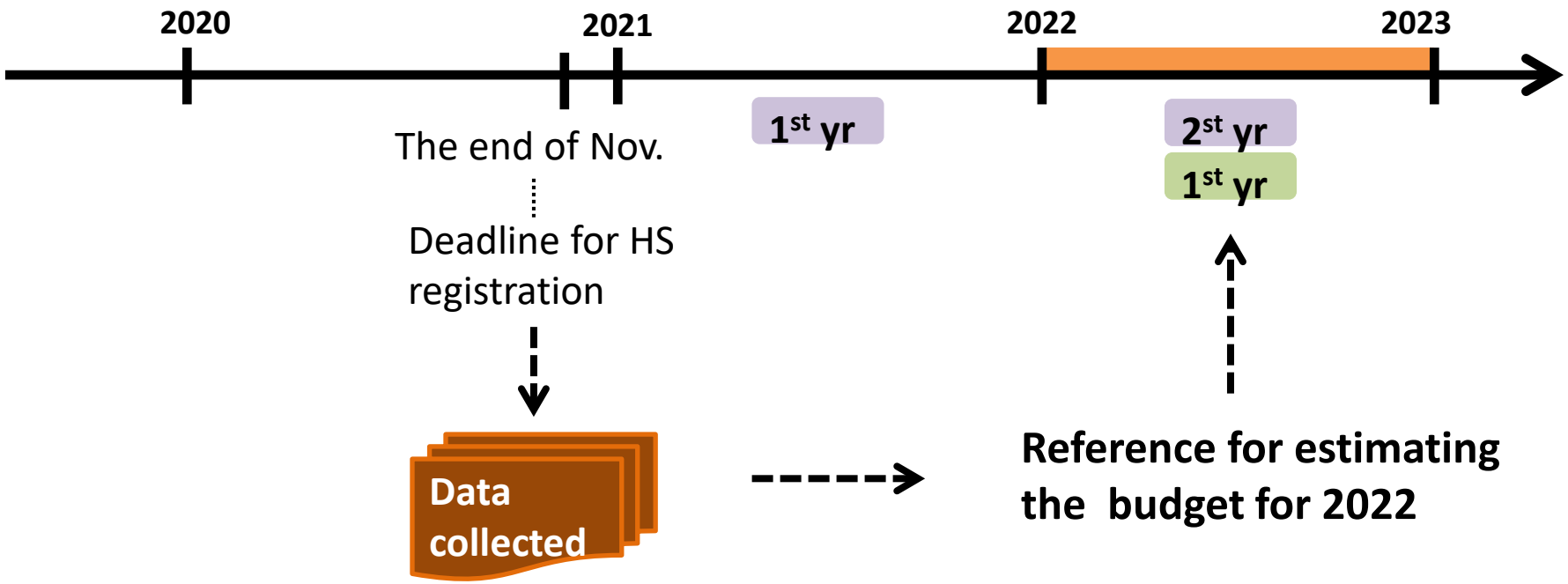
Submission for listing

- ☐ Type of Budget
- ☐ Expected date of submission
- ☐ Expected reimbursed indications
- ☐ Expected date of listing
- ☐ Suggested listing price
- ☐ Comparator
- ☐ Financial Forecast
  - ■ Target population for disease
  - ■ Target population for new drug
  - ■ New drug expenditure
  - ■ Replaced drug expenditure
  - ■ Budget impact
- ☐ MEA proposal or local PE

Horizon Scanning

National Health Insurance Administration

- ☐ New drug
- ☐ New reimbursed indication

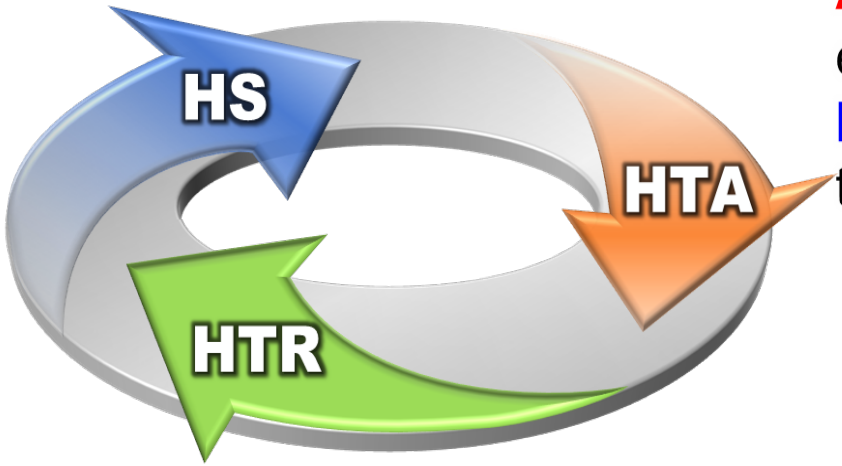


Precision Reimbursement for New Medical Technology

National Health Insurance Administration

Budgeting

Introduce **Horizon Scanning(HS)** to include new medical technologies that may be **included in the assessment when budgeting**.



Reimbursement

Use **Health Technology Assessment (HTA)** to estimate the **cost and benefit** of new technology to assist decision-making.

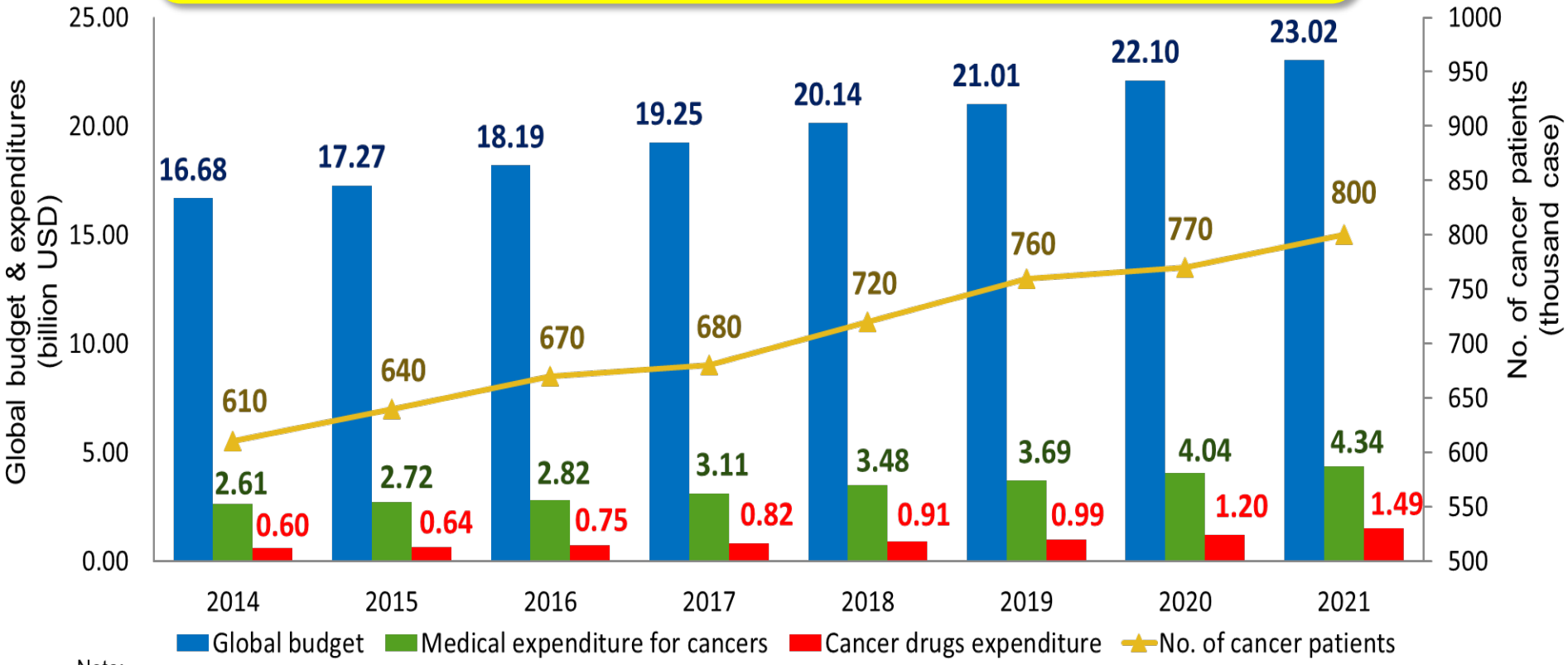
Reassessment

Carry out **Health Technology Reassessment (HTR)** on the paid items, extend coverage for effective items, limit the payment for non-benefit treatment. Use the resources for the **most effective treatment**.

Trends of Medical & Drug Expenditures for Cancer Therapy

National Health Insurance Administration

In recent years, growth rate of global budget is 4.4%, growth rate of cancer drug fees is 10.68%



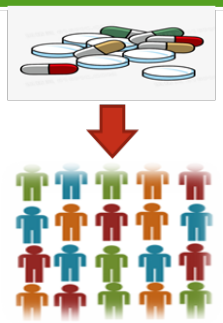
Note:

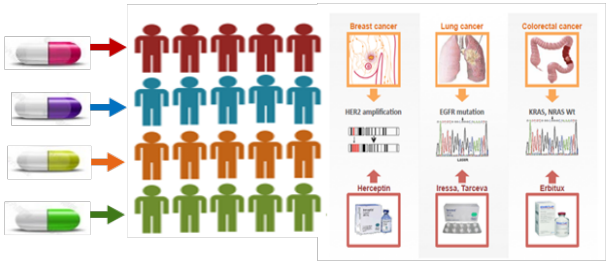
1. The insured patient's primary/secondary ICD codes indicating to cancer (C00-C97) were used to calculate for medical expenditures and no. of cases.
2. NHI reimbursed drugs' ATC code classified as L01~L02 were used to calculate for cancer drug expenditures.
3. Global budget was calculated by annual hospital & clinics departments.

NHI Policies of Precision Medicine

National Health Insurance Administration

One drug for all patients → **Targeted therapy Precision medicine** → **Precision health**





Frost & Sullivan's Visionary Healthcare program, 2017

➢ Facilitate reimbursement of drug companion diagnosis tests

- Reimburse 12 companion diagnosis tests for gene mutations of leukemia, breast cancer, lung cancer and colorectal cancer.

➢ Enhance precision medicine

- Collect treatment response & modify reimbursement by real-world evidence(RWE)
- Invite experts and medical associations to assist reviewing clinical guidance for cancer drugs

➢ Integrate medical information, and use AI review to improve cancer therapy

Establish Registration System of IO New Drugs

(Immuno-Oncology)

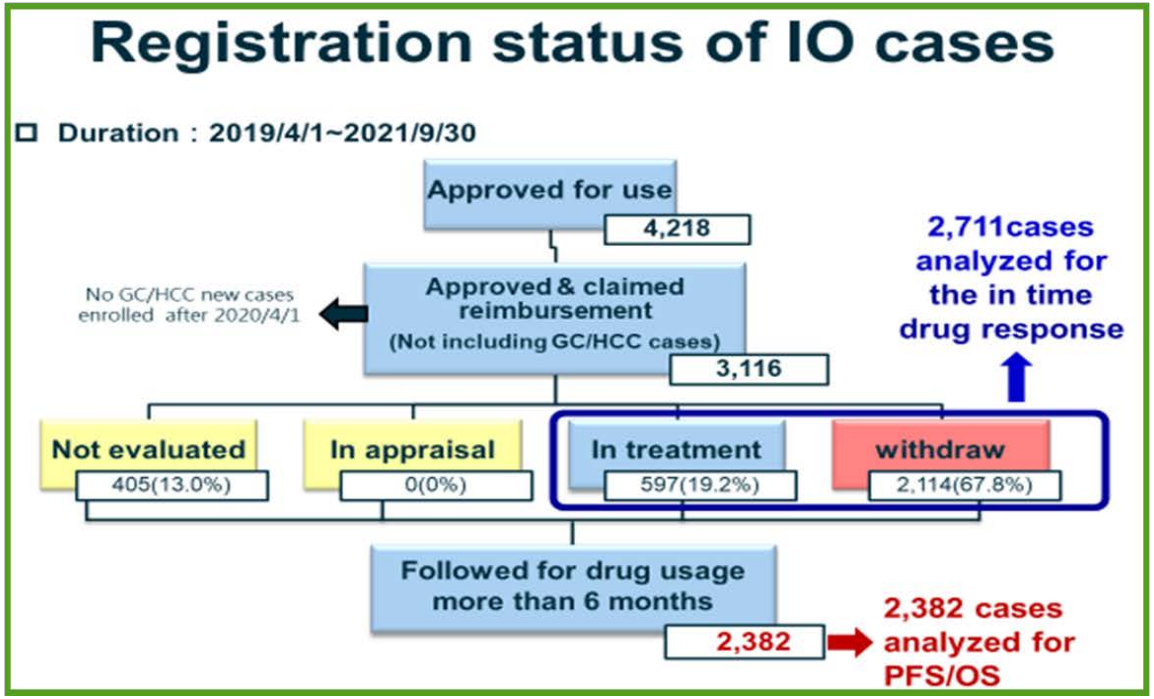
National Health Insurance Administration

Collect patient's data

Determine benefits of IO new drugs

Revise reimbursement restrictions

- Cancer type and stage
- **Gene mutation**
- **Biomarker test**
- **Adverse drug reaction**
- Drug response
- Withdraw reason



Value-Based Payment –

Immune Checkpoint Inhibitors, IO

National Health Insurance Administration

Art. 1.11078-PM 24933

European Review for Medical and Pharmacological Sciences 2021; 25: 6548-6556

Real-world results of immune checkpoint inhibitors from the Taiwan National Health Insurance Registration System

S.-T. HSIEH[1], H.-F. HO[2], H.-Y. TAI[2], L.-C. CHIEN[1], H.-R. CHANG[1], H.-P. CHANG[2], Y.-W. HUANG[2], J.-J. HUANG[2], H.-J. LIEN[2], L.-Y. HUANG[1], P.-C. LEE[3,4]

Following a year of data collection and analysis, the real-world ORR and PFS in Taiwan were 24.0% and 2.9 months, respectively. Experts agreed that, compared to regorafenib, payment benefits were limited while producing the same clinical status. As of March 2020, no HTA agen-

ODAC Opposes Ongoing FDA Approval of Nivolumab for HCC in Patients Pretreated With Sorafenib

April 30, 2021

Sara Karlovitch

The FDA's Oncologic Drug Advisory Committee voted 5 to 4 against the continued accelerated approval of nivolumab for the treatment of patients with hepatocellular carcinoma who were previously treated with sorafenib.

The FDA's Oncologic Drug Advisory Committee voted 5 to 4 against the continued accelerated approval of nivolumab for the treatment of patients with hepatocellular carcinoma who were previously treated with sorafenib.[1]

FDA

Real world evidence (RWE) application in Taiwan

- **In February 2020**, Taiwan National Health Insurance suspended the payment of Nivolumab for hepatocellular carcinoma and Penbrolizumab for gastric cancer with reference to RWE and other scientific evidence.
- **In April 2021**, The US FDA's ODAC voted against the approval of Nivolumab for HCC patients and Penbrolizumab for the treatment with gastric cancer.

Note: Published by European Review for Medical and Pharmacological Sciences on November 15th, 2021

Value-Based Payment –

Directing Antivirus Agent, DAA

National Health Insurance Administration

The analysis of big data from the Taiwan National Health Insurance Research Database revealed that **advanced HCC(Hepatocellular Carcinoma) patients on sorafenib benefited from DAAs as a treatment for HCV(Hepatitis C Virus) infection. Patients whose HCV infection was cured had better OS(Overall Survival).**

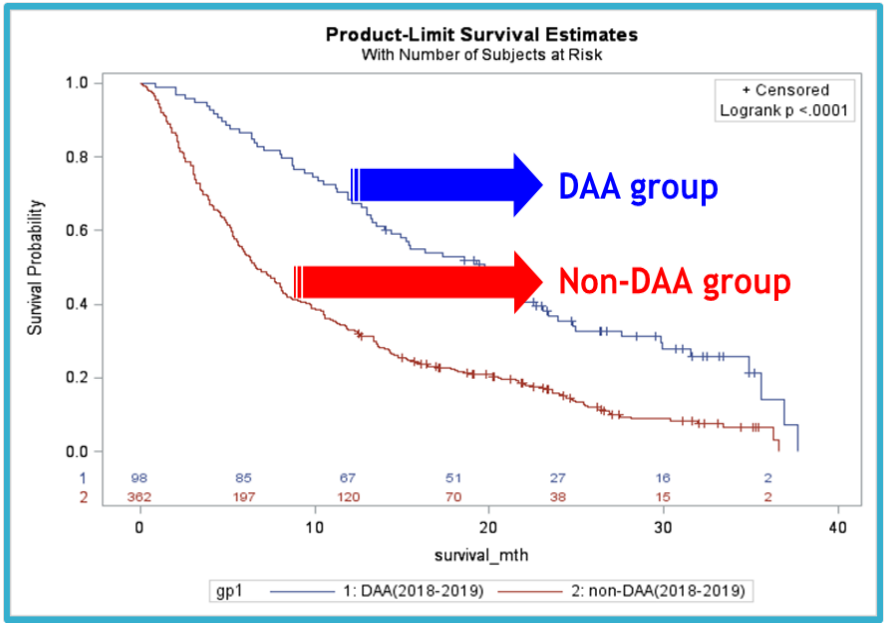
European Review for Medical and Pharmacological Sciences 2021; 25: 7543-7552

Effects of direct-acting antiviral therapy for patients with advanced hepatocellular carcinoma and concomitant hepatitis C—A population-based cohort study

H.-Y. TSAI[1], H.-P. CHANG[2], C.-J. CHEN[2], W.-L. HSU[1], L.-Y. HUANG[1], P.-C. LEE[3,4]

[1]Division of Health Technology Assessment, Center for Drug Evaluation, Taipei, Taiwan
[2]National Health Insurance Administration, Ministry of Health and Welfare, Taipei, Taiwan
[3]Director of General, National Health Insurance Administration, Ministry of Health and Welfare, Taipei, Taiwan
[4]Department of Surgery, College of Medicine, National Cheng Kung University, Taipei, Taiwan

■Kaplan-Meier survival analysis between DAA group (n=98) and non-DAA group (n=362) in 2018-2019 (matched 1:4)



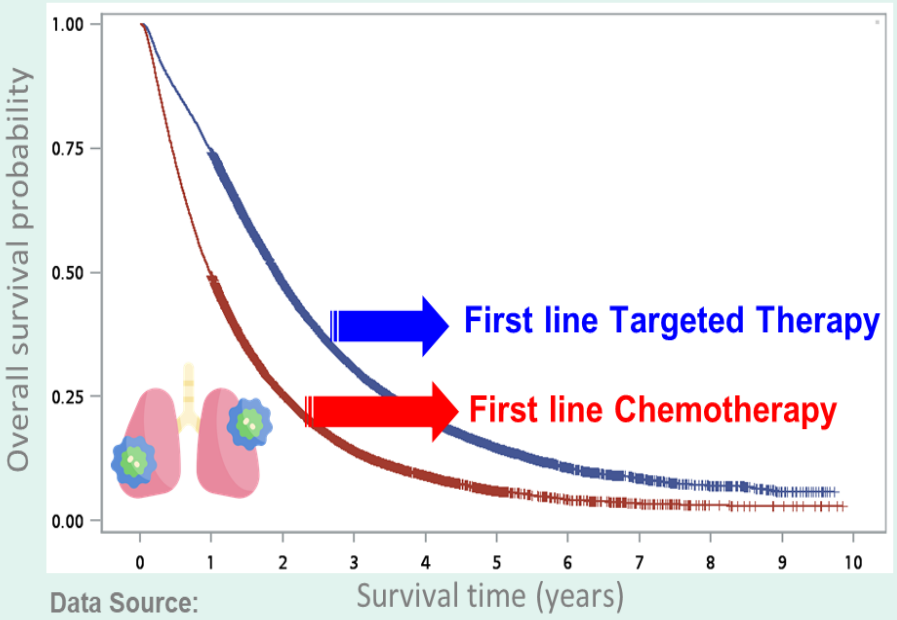
Note: Published by European Review for Medical and Pharmacological Sciences on December 2021

Real World Study in Taiwan -
Effectiveness of Targeted Therapy in Cancer

National Health Insurance Administration

EGFR mutation positive NSCLC

The median overall survival for **first-line targeted therapy** group is **better than chemotherapy** group.

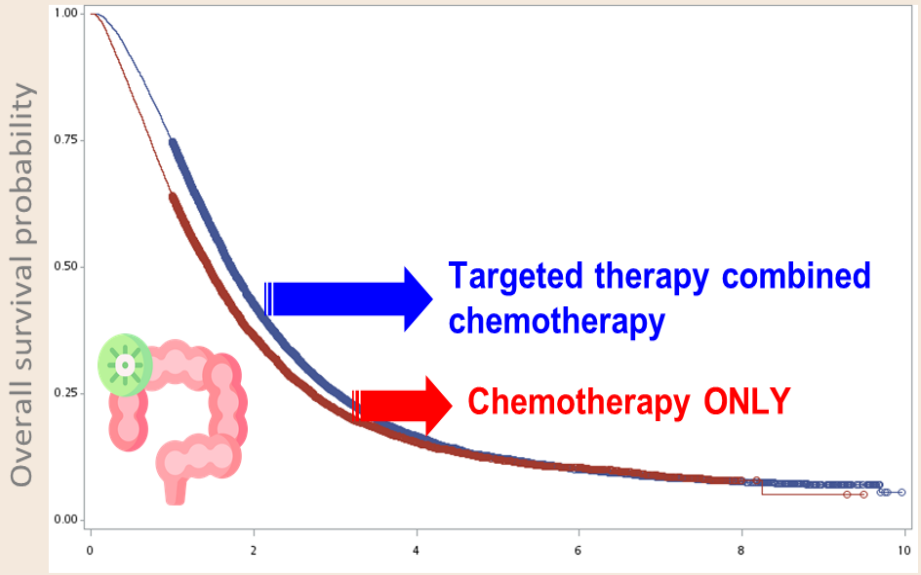


Data Source:
1. 2002-2019 Cancer Registration Database
2. 2002-2020 Taiwan National Health Insurance Research Database (NHIRD)

Note:
1. EGFR = epidermal growth factor receptor
2. NSCLC = non-small cell lung cancer

Stage IV Colorectal Cancer

The median overall survival for **targeted therapy combined chemotherapy** group is **better than chemotherapy only** group.



Data Source:
1. 2002-2019 Cancer Registration Database
2. 2002-2020 Taiwan National Health Insurance Research Database (NHIRD)

Positive Feedback Cycle of Reimbursement

National Health Insurance Administration

Budget

- Allocate sufficient budget
- Horizon Scanning

Products

- Value-based pricing
- Increase patients' access to new drugs
- Risk-sharing mechanism

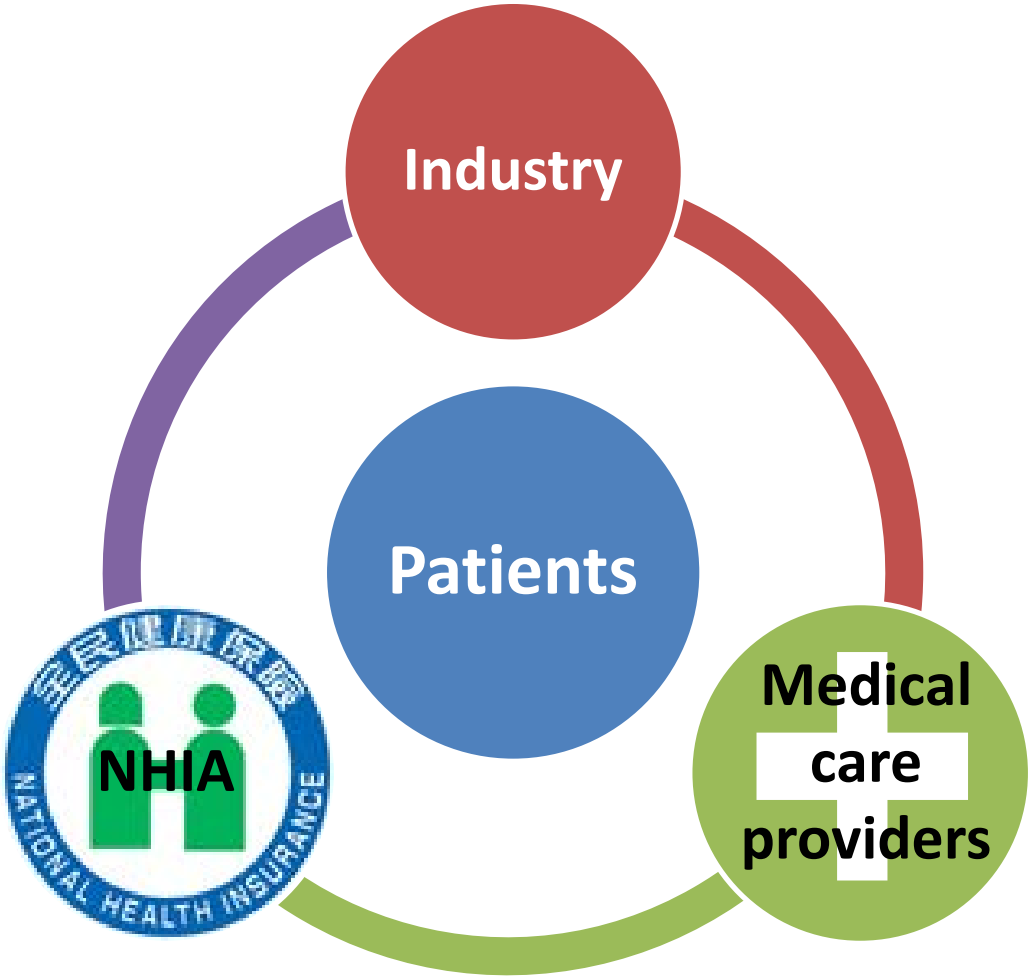
Pay for Value

Patients

- Collection of RWE
- HTR
- Revision of reimbursed indication

Patient-Centered Heath Care

National Health Insurance Administration



Thank you for your kind attention!