2025 제22차 국제연수과정

NHIS UHC GLOBAL ACADEMY

Drug Pricing Policy and Drug Pricing Negotiation

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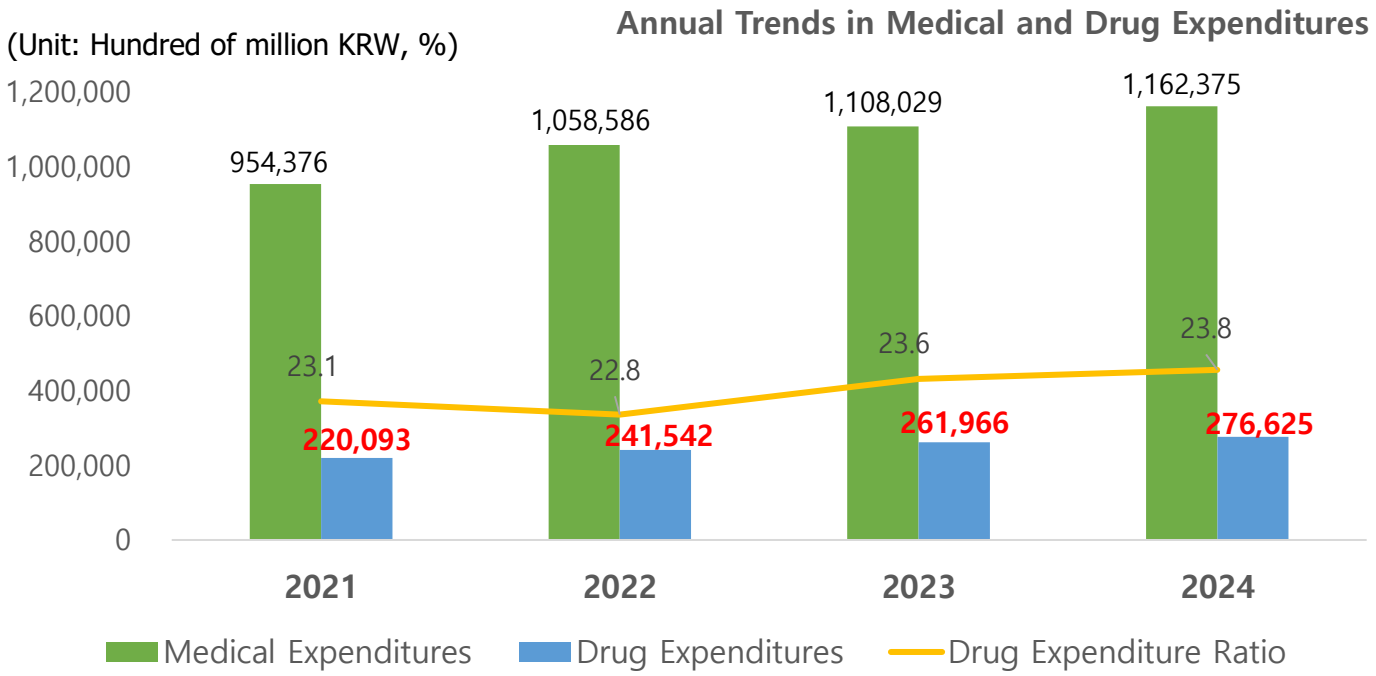
Contents

Current Status of Pharmaceutical Expenditures in Korea

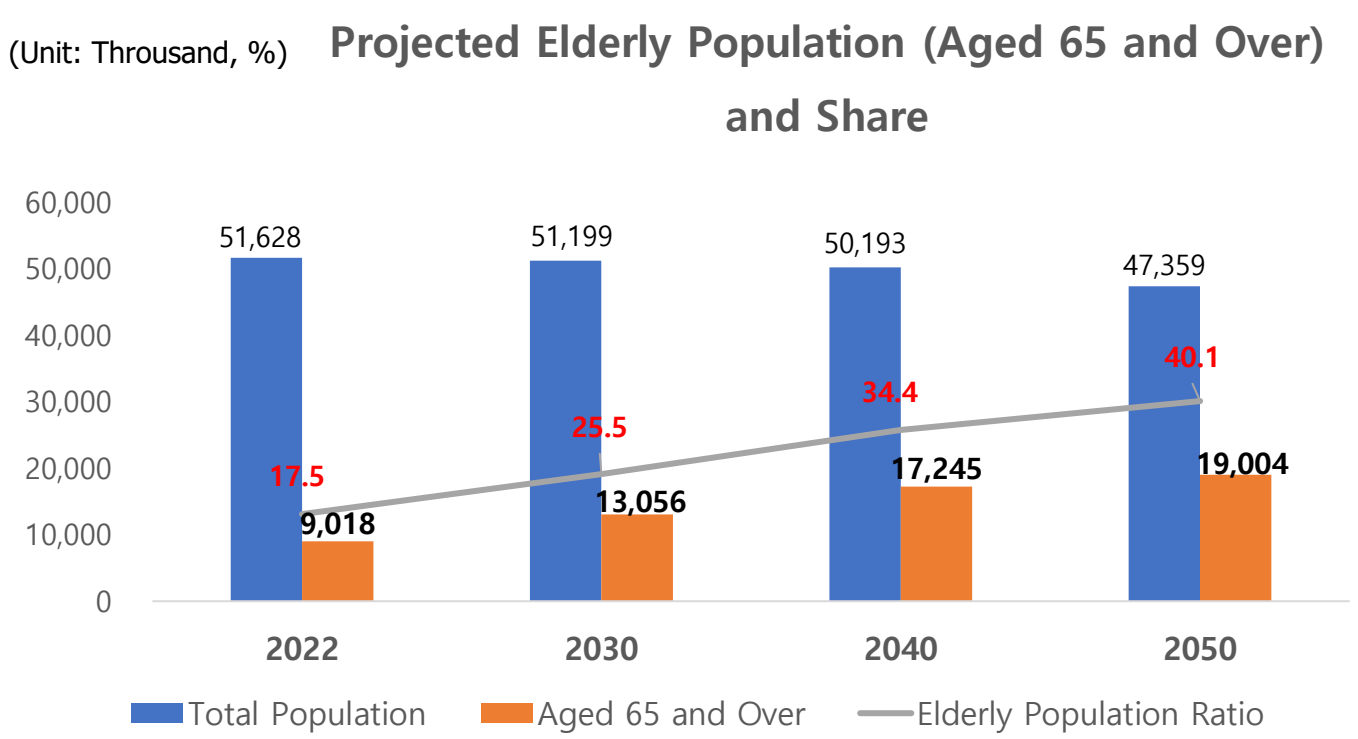
Health Insurance Drug Expenditure Status

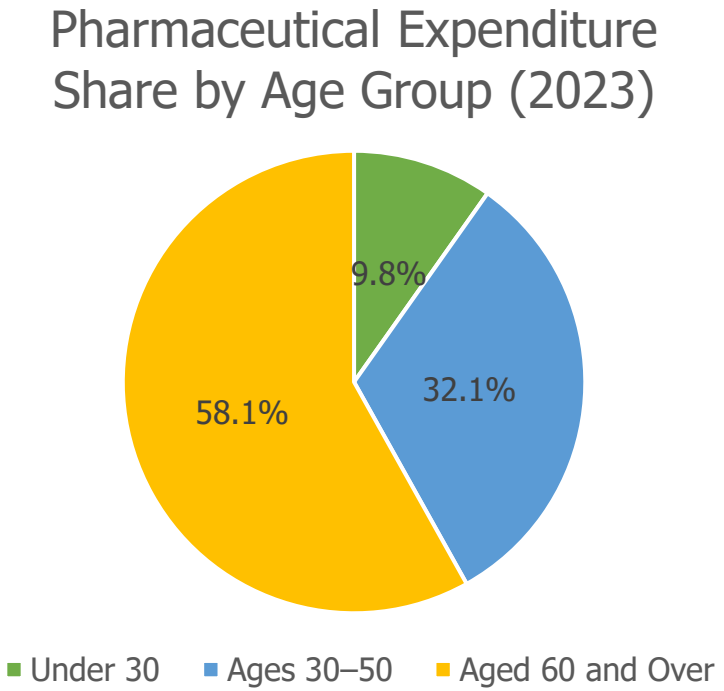
- 2024 drug expenditures: 27.7 trillion KRW
- Share of total medical expenses (2024): 23.8% of 116.2 trillion KRW
- The share of drug expenditures has remained stable at 23–24%, while the absolute amount has continued to increase by approximately 1.5–2 trillion KRW each year



Factors Contributing to Rising Pharmaceutical Expenditures (1)

- The proportion of individuals aged 65 and over increased from 17.5% in 2022 and is projected to reach 25.5% by 2030
- Pharmaceutical expenditures for the elderly account for 58.1% of total drug expenditure (as of 2023)





Factors Contributing to Rising Pharmaceutical Expenditures (2)

- Chronic disease medications account for 7.5 trillion KRW, representing 28.7% of total pharmaceutical expenditures
  - Anti-atherosclerotic agents (1st), antihypertensive drugs (3rd), and antidiabetic drugs (5th) rank among the highest in overall drug expenditures
  - Central nervous system (CNS) drugs, including dementia treatments, also represent a significant share, ranking 6th in total drug expenditures

< Top 6 Drug Class by Drug Expenditure>

Rank	2022	2023
1	**Antiatherosclerotic agent**	**Antiatherosclerotic agent**
2	Antitumor agent	Antitumor agent
3	**Antihypertensive drugs**	**Antihypertensive drugs**
4	**Antidiabetic drugs**	Anti-ulcer agent
5	Anti-ulcer agent	**Antidiabetic drugs**
6	**Other CNS drugs**	**Other CNS drugs**

Factors Contributing to Rising Pharmaceutical Expenditures (3)

- Rising Expenditures for Anticancer and Orphan Drugs
  - (Anticancer Drugs) In 2024, the number of patients receiving anticancer drugs increased by 2.7% compared to the previous year while expenditures rose by 15.8%
  - (Orphan Drugs) the number of patients grew by 13.0% year-on-year, accompanied by a 16.3% increase in total expenditures

< Number of Patients and Expenditures >

(Unit: Hundred of million KRW, thousand people, %)

		2022	2023	2024
Anticancer Drugs	Drug Expenditures (Growth Rate)	24,505 (12.9)	27,550 (12.4)	**31,901 (15.8)**
	Number of Patients (Growth Rate)	850 (6.3)	885 (4.0)	**908 (2.7)**
Orphan Drugs	Drug Expenditures (Growth Rate)	7,287 (14.0)	8,124 (11.5)	**9,446 (16.3)**
	Number of Patients (Growth Rate)	132 (4.3)	149 (13.2)	**168 (13.0)**

Factors Contributing to Rising Pharmaceutical Expenditures (3)

- Reimbursement Listing for Ultra-high-cost Drugs Such as One-time Treatments
  - Kymriah(tisagenlecleucel): 360,039,359 KRW (Included on April 2022) for acute lymphoblastic leukemia
  - Zolgensma(onasemnogene abeparvovec): 1,981,726,933 KRW (Included on August 2022) for spinal muscular atrophy
  - Luxturna(voretigene neparvovec): 325,800,000 KRW (Included on January 2024) for inherited retinal dystrophy

<Status of Major Ultra-high cost Drugs>

Rank	Product Name	Manufacturer	Reimbursement Cap
1	Zolgensma(onasemnogene abeparvovec)	Norvatis	1,981,726,933
2	Kymriah(tisagenlecleucel)	Norvatis	360,039,359
3	Luxturna(voretigene neparvovec)	Norvatis	325,800,000
4	Spinraza(nusinersen)	Biogen	92,359,131
5	Lutathera(lutetium Lu 177 dotatate)	Norvatis	22,104,660
6	Ultomiris(Ravulizumab)	AstraZeneca	18,846,039
7	Yervoy(Ipilimumab)	BMS	14,006,513
8	Cupistem(adipose derived mesenchymal stem cell)	Anterozen	13,490,000
9	Qarziba(dinutuximab beta)	Recordati	11,482,566
10	Ilaris(canakinumab)	Norvatis	11,029,469

Changes in the Drug Pricing System

Optimization of Pharmaceutical Expenditures

- Measures to Optimize Pharmaceutical Expenditure (2006)
  - Selection and listing of drugs with high therapeutic and economic value
  - Negotiation procedures introduced for appropriate drug pricing, rationalization of pricing calculation standards
  - Enhancement of pharmaceutical quality and transparency in distribution to reflect actual transaction prices
  - Establishment of management mechanisms for the appropriate use of medicines

Before Implementation (Prior to December 2006)

- **Negative List System: All drugs were included in the reimbursement listing**
- **Prices determined by the Drug Evaluation Committee (HIRA)**

  - International Price Reference: Based on prices in **A7 countries** (U.S., U.K., Germany, France, Italy, Switzerland, Japan)
- **After patent expiration, original drugs were priced at 100% while generic drugs were priced at 80% of the original**

After Implementation (January 2007 Onwards)

- **Positive List System: Only cost-effective drugs are selectively listed for reimbursement**
- **Following a reimbursement appropriateness review by the Drug Reimbursement Evaluation Committee (HIRA), new drug prices determined through negotiations between the NHIS and pharmaceutical companies**

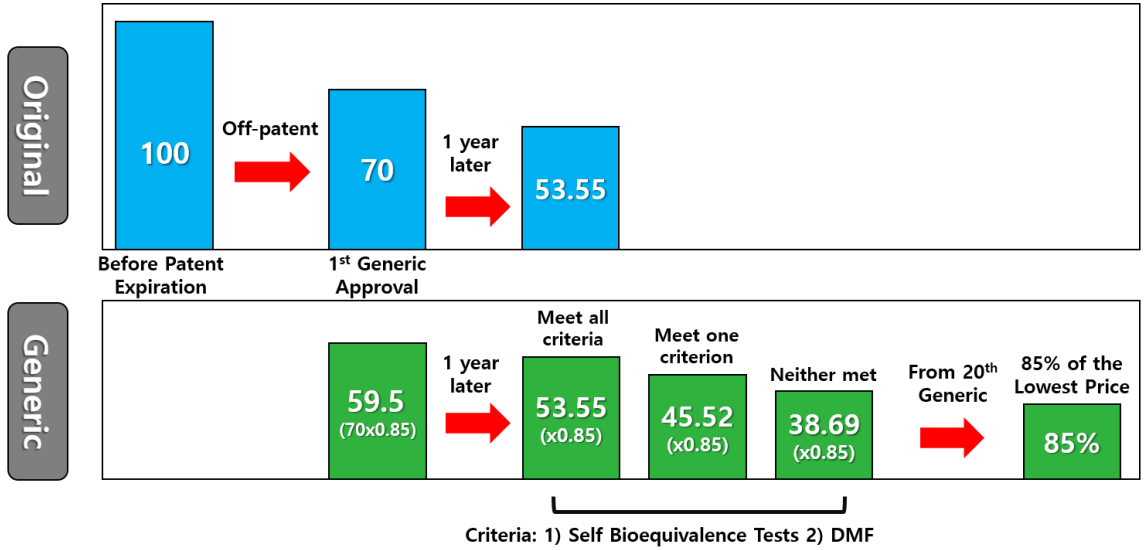
  - Pricing Considerations: Substitute drug prices, OECD price levels, and fiscal impact
- **After patent expiration, original drugs are priced at 80% of their pre-expiration price while generic drugs are priced at 68% of the original drug price**
- **Introduction of the Price-Volume Agreement System**

Changes to the Drug Pricing System

Year	Drug pricing & reimbursement policy
2000	Negative List System: Mandatory reimbursement listing for all drugs approved by MFDS 1) New drugs: ① (Significant improvement) A7 adjusted average price, ② (general) relative price vs. similar efficacy drugs 2) Generics: 1st–5th listings → 80% of original, 6th listing onward → 90% of lowest price
2006	Positive List System & Price Cap Negotiation 1) New drugs: Price negotiated between NHIS and pharmaceutical companies after proving ① clinical utility and ② cost-effectiveness 2) Patent-expired drugs: 20% reduction (80% of original) 3) Generics: 1st–5th listings → 68% of original, 6th listing onward → 90% of lowest price
2012	Generic Drug Same Price System 1) Patent-expired new drugs: 70% of original → 53.55% after 1 year 2) Generics: 59.5% of original → 53.55% after 1 year
2014	Policy to Strengthen Coverage for Four Major Critical Illnesses (① cancer, ② cardiovascular, ③ cerebrovascular, ④ rare diseases) 1) Introduction of risk-sharing agreements 2) Implementation of economic evaluation exemption system
2020	Generic Drug Same Price System + Differential Drug Pricing System 1) Differential pricing based on quality (bioequivalence tests, DMF-registered ingredients) and listing order 2) Negotiations reflecting ①quality and ②stable supply conditions for all drugs

Generic Drug Pricing Calculation (From July 2020)

- Differential Price Reduction System: Introduced in July 2020 to reflect drug quality and listing order in pricing
  - Patent-Expired Original Drugs: 70% of original price in the first year and reduced to 53.55% after one year
  - Generic Drugs: 59.5% of original price in the first year. Thereafter, 1) differential reduction based on satisfaction of quality criteria and 2) 85% of the lowest price applied to the 20th listed generic
  - (Evaluation Criteria 1) Possession of a bioequivalence test result report conducted directly by the pharmaceutical company independently or jointly
  - (Evaluation Criteria 2) In cases where finished pharmaceutical products are manufactured using active pharmaceutical ingredients listed in the MFDS'S Drug Master File (DMF) as the principal ingredient



Drug Cost Reimbursement System

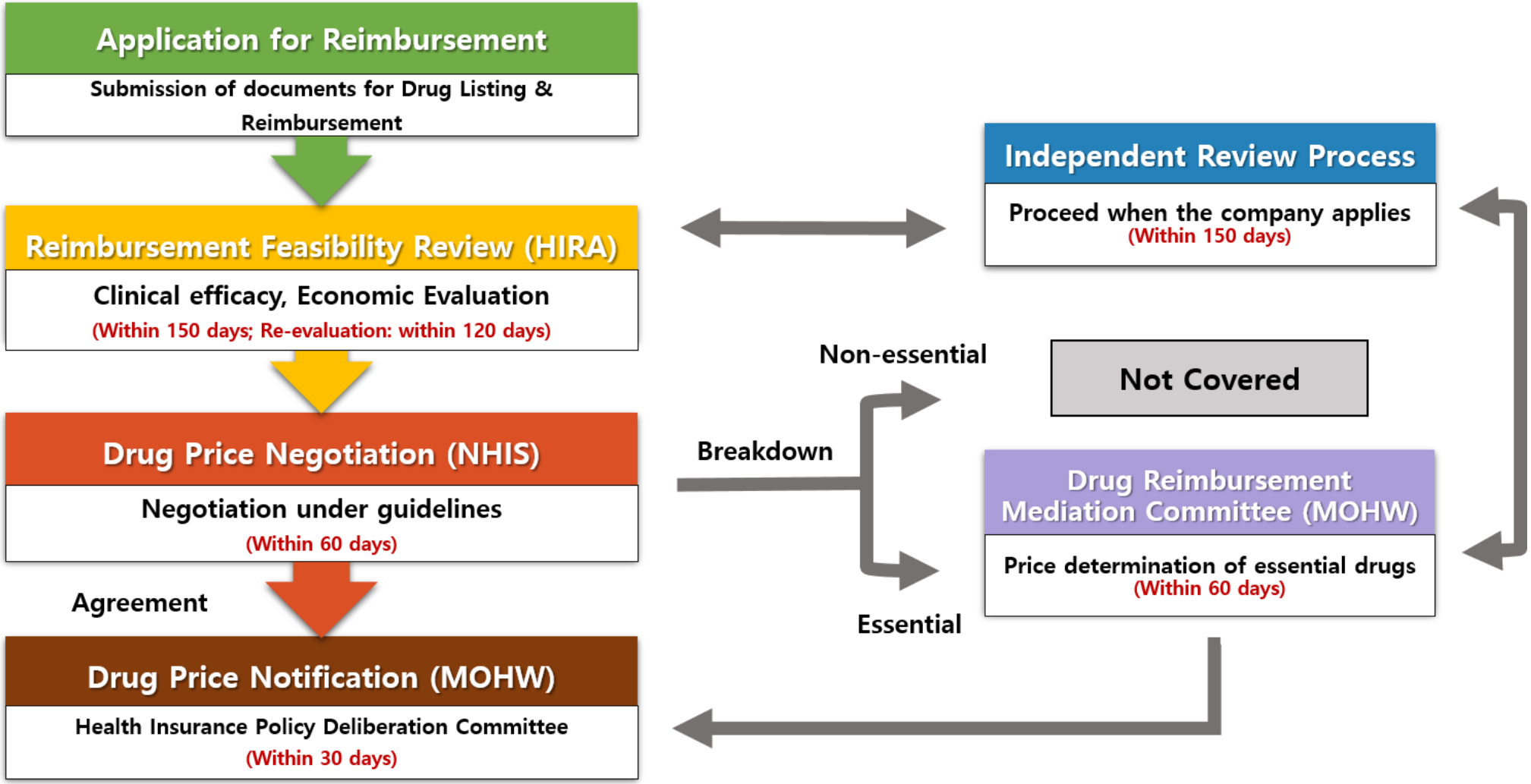
- Drug Cost Reimbursement Procedure
  - Medical care institutions (hospitals, pharmacies) provide medications to patients, who pay only their copayment
  - The institutions then claim the remaining cost as medical care benefit expenses from the NHIS
  - HIRA reviews the appropriateness of the claim. After review, the NHIS reimburses the medical care institutions

- Changes in the Drug Cost Reimbursement System

Government-set Price Reimbursement System (1977~1999)	• Claim and reimbursement based on government-set prices → When purchasing below the notified price, institutions retained the difference as profit • Set Price: Factory-gate price (reported by pharmaceutical companies) + 12% distribution margin
Actual Transaction Price-based Reimbursement System (1999.11.~)	• Claim and reimbursement based on actual purchase price within the maximum amount of the government-set prices → No profit margin from price differences, removing the incentive for low-price purchasing since reimbursement is based on the actual purchase price • Low-price purchase incentive (2010~): Incentives of up to 70% of savings provided to institutions purchasing below the maximum price

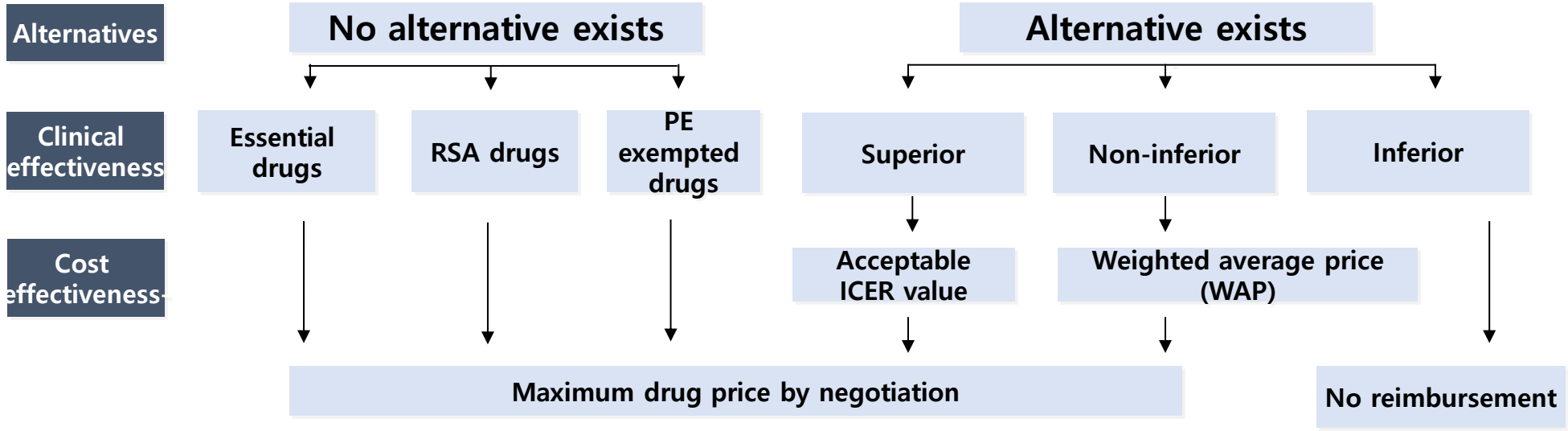
New Drug Pricing Negotiations

New Drug Reimbursement Listing Procedure



Evaluation Criteria for New Drugs(HIRA)

- Clinical Usefulness: whether alternative therapies exist, used for severe of life-threatening diseases or therapeutic benefit compared with exsting treatment
- Cost-effectiveness: whether it is highly priced compared to the existing alternatives
  - (superior) ICER(incremental cost effective ratio) derived from Pharmacoeconomic evaluation(PE)
  - (non-inferior) compare the weighted average price(WAP) with the alternatives
  - (PE exemption) lack of alternatives + life-threatening orphan drugs or anticancer drugs + insufficient evidence
- Budget Impact(number of patients, expenditure etc.), Reimbursement status(listed price, criteria) of other countries



New Drug Pricing Negotiations(NHIS)

Receipt of Price Negotiation Order

- ✓ Ministry of Health and Welfare → NHIS

※Negotiation period: 60 days from the day after receipt of order

Preparation for Negotiation

- ✓ Form a price negotiation team (up to 5 members)
- ✓ Notify the pharmaceutical company of the negotiation schedule and requirements
- ✓ Request submission of necessary materials from the company

Drug Price Negotiation

- ✓ Initial negotiation: Within 30 days
- ✓ Final negotiation: Within 60 days

※ Typically, 4–5 negotiation sessions in total

Report Negotiation Results

- ✓ Internal results report
- ✓ Submit final report to the Ministry of Health and Welfare

Notify Results

- ✓ HIRA
- ✓ Pharmaceutical company
  - If agreement is reached: Issue drug price agreement document
  - If negotiations fail: Send notification of negotiation breakdown

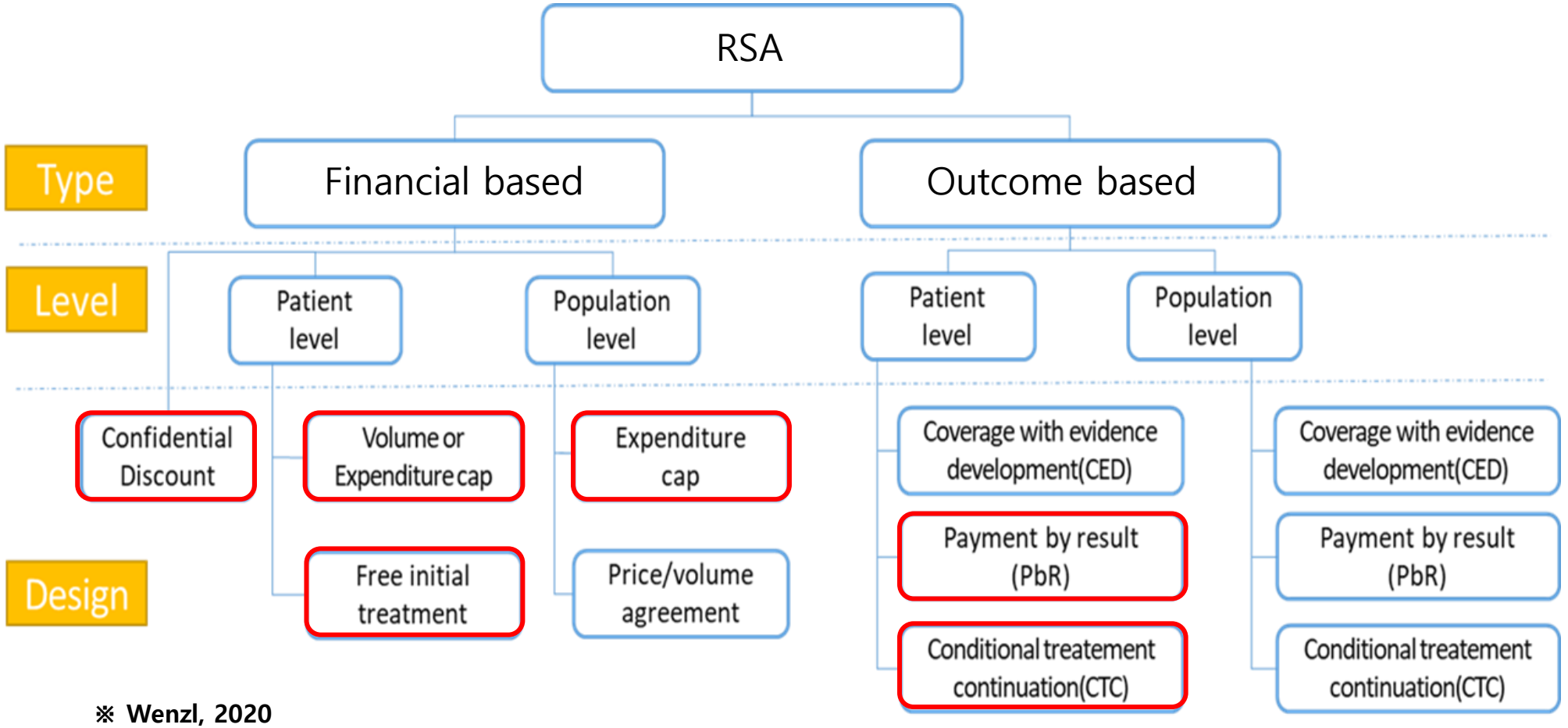
Considerations for Drug Price Negotiations

1. Evaluation data provided by the Drug Reimbursement Evaluation Committee (HIRA)
2. Impact on Insurance finance
3. Foreign prices, reimbursement status, and drug supply capacity
4. Patent status and domestic R&D investment costs
5. Company obligations (risk-sharing agreements)

Reference Prices for Drug Price Negotiations

1. Results of economic evaluation from the Drug Reimbursement Evaluation Committee (HIRA)
2. Total medication costs of substitute drugs
3. Foreign reimbursement prices or adjusted prices
   - (Target countries) OECD member nations (+Taiwan, Singapore)
   - (Adjusted price) Reflects factory-gate prices, adjusted for value-added tax and distribution margins where pricing systems differ
4. Price ratio between the negotiated drug and its substitutable counterparts in foreign markets
5. For domestically developed new drugs, reflect the actual R&D costs incurred during development

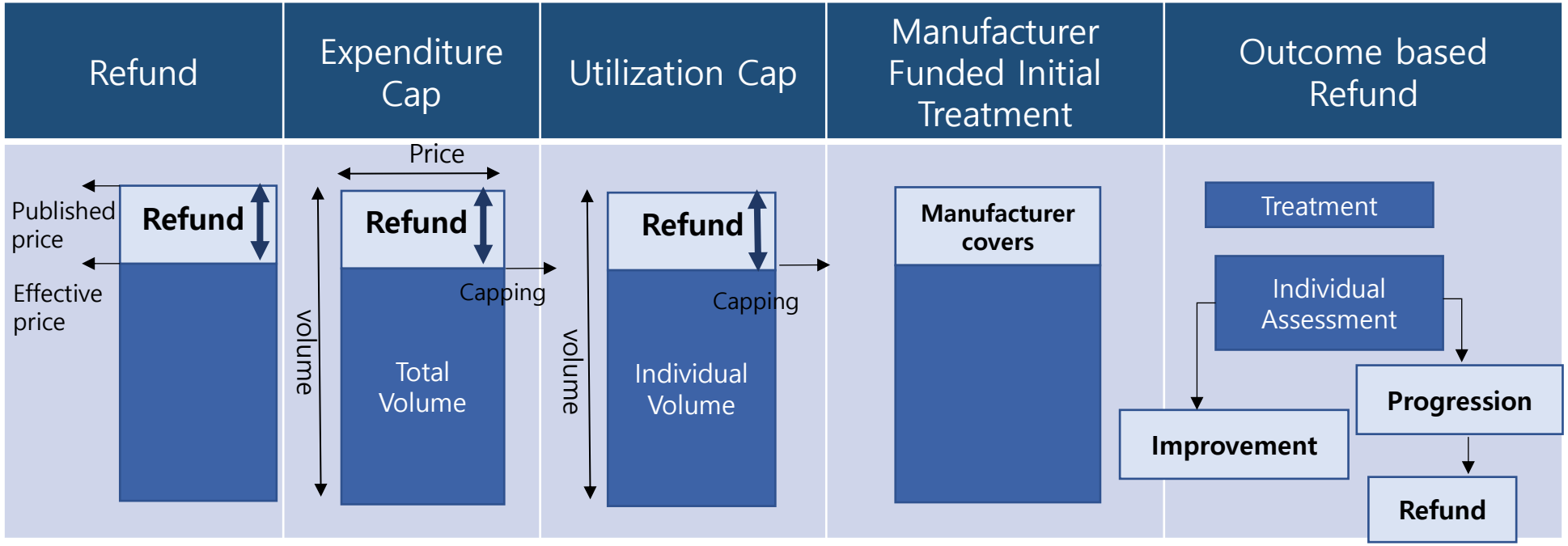
Risk-Sharing Agreement(RSA) Types



※ Wenzl, 2020

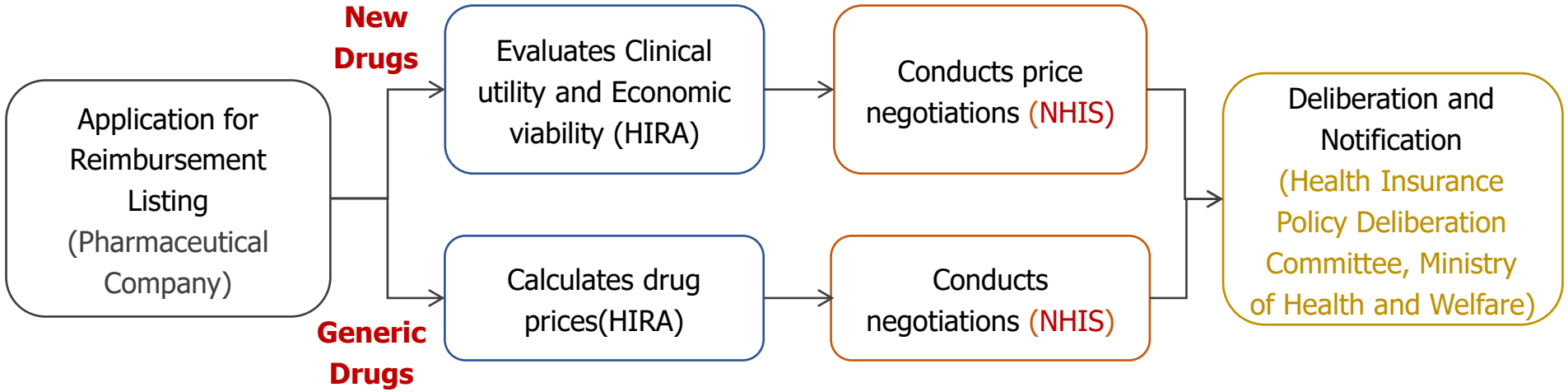
Risk-Sharing Agreement for New Drugs (2014~)

- Definition: Insurance benefit granted under conditions where the pharmaceutical company shares part of the uncertainty regarding therapeutic effectiveness and financial impact
- Target Drugs: Anticancer drugs and rare disease treatments used for life-threatening conditions with no alternative therapies
- Financial-Based Types: Refund, total expenditure cap, patient-level utilization cap, manufacturer funded initial treatment
- Outcome-Based Types: Conditional continued treatment, outcome-based refund



Negotiations for Generic Drugs

- Background for Introduction
  - Detection of NDMA (a probable human carcinogen classified by WHO IARC) in Valsartan (2018) and Ranitidine (2019)
  - Raised the need for pre- and post-market management of all reimbursed drugs in quality and supply stability including generics
- Negotiation Details
  - Negotiations focus on medical benefit–related factors such as stable supply and quality control (Price cap (drug price) is not subject to negotiation)
  - Agreements limited to drugs available for supply at the time of listing ⇒ preventing "blind listings" of drugs not yet in production
  - Pharmaceutical companies are obligated to ensure product quality and supply continuity with recovery measures required if problems arise.



Post-Listing Price Management

Post-Listing Drug Price Management System

System	Criteria	내용
Adjustment of Price Cap for Price-Volume Agreement	Financial impact	- If the claim amount increases beyond an agreed threshold compared to the projected claim amount at listing or the previous year's claim, - Drug price reduced through negotiation with the NHIS
Adjustment of Price Cap for Drugs with Expanded Scope of Reimbursement	Financial impact	- Reduce the ceiling price to account for additional fiscal burden from expanded indications - Reduction based on the HIRA formula or negotiation with NHIS
Adjustment of Price Cap Based on Actual Transaction Price	Weighted average of actual transaction prices	- Based on claims data from medical care institutions submitted to the NHIS - If the weighted average price is lower than the current price cap, the price is adjusted downward to match the weighted average price
Administrative Disposition for Rebate Violations	Rebate amount and frequency	- Price reduction or suspension of reimbursement depending on the number of violations - For essential drugs, a penalty is imposed

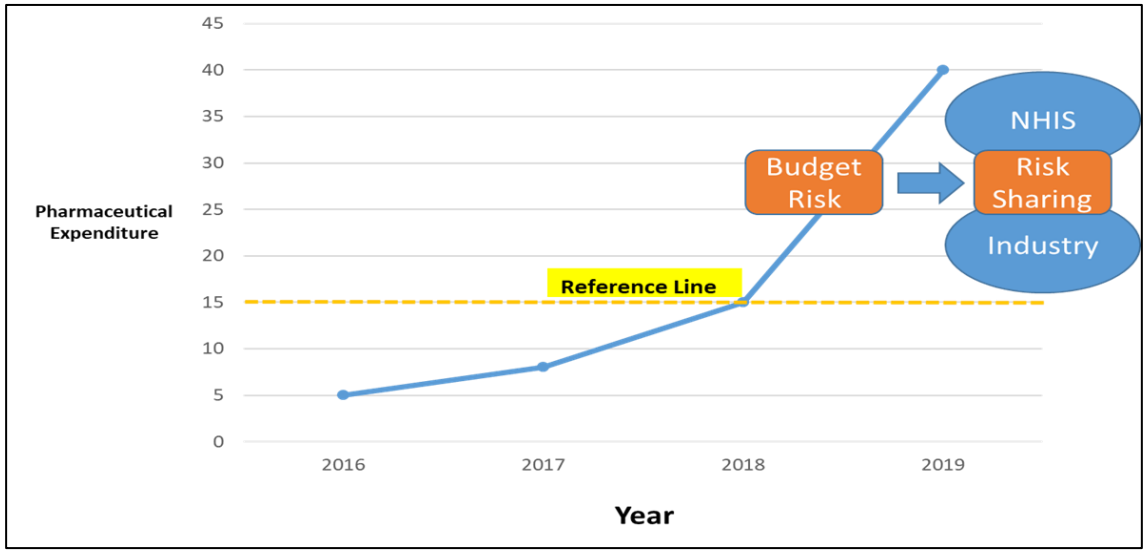
※ Rebate: The act of a pharmaceutical company providing money, goods, or hospitality to medical institutions or physicians to induce prescriptions

Price-Volume Agreement

- (About) Implemented to adjust drug prices when a sharp increase in usage imposes a financial burden on health insurance funds.
- Health insurance finances are public resources funded by the insured, making the sustainability of the system essential.
- When drug usage rises sharply, pharmaceutical company profits increase, but the NHIS faces higher expenditures.

  The PVA ensures shared financial responsibility between the NHIS and pharmaceutical companies.
- The PVA helps reallocate resources to other treatment areas and encourages appropriate drug use.

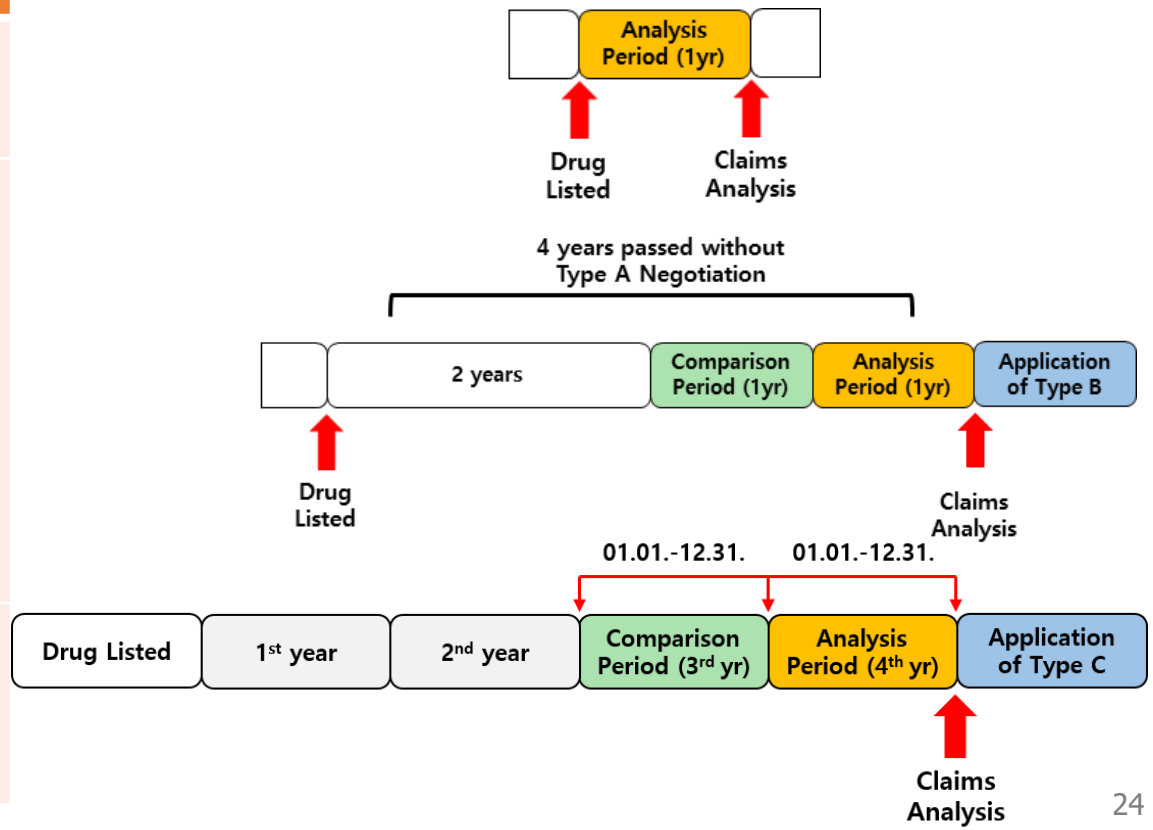
  When expenditures concentrate on certain drugs, funds for other medical services may become insufficient



Price-Volume Agreement

- Drugs are classified into Types A, B, and C according to the characteristics of negotiated drugs.
- Drugs for which an expected claim amount was agreed upon during new drug price negotiations are generally managed as Type A or Type B.

Type	Applicable to
Type A	Drugs whose claimed amount increased by 30% or more compared to the expected amount agreed upon during price negotiations
Type B	- Drugs whose annual claimed amount increased by 60% or more, or by 10% and at least 5 billion KRW, compared to the previous year after adjustment under Type A - Drugs not adjusted under Type A and for which four years have passed since the initial listing. For the same product group, 1) claim amount increased by 60% or more compared to the previous year or 2) increased by 10% or more and by 5 billion KRW or more
Type C	Drugs not classified as Type A or B where the annual claimed amount increased by 60% or more, or by 10% and 5 billion KRW or more, compared to the previous year



Negotiations to Expand the Scope of Use

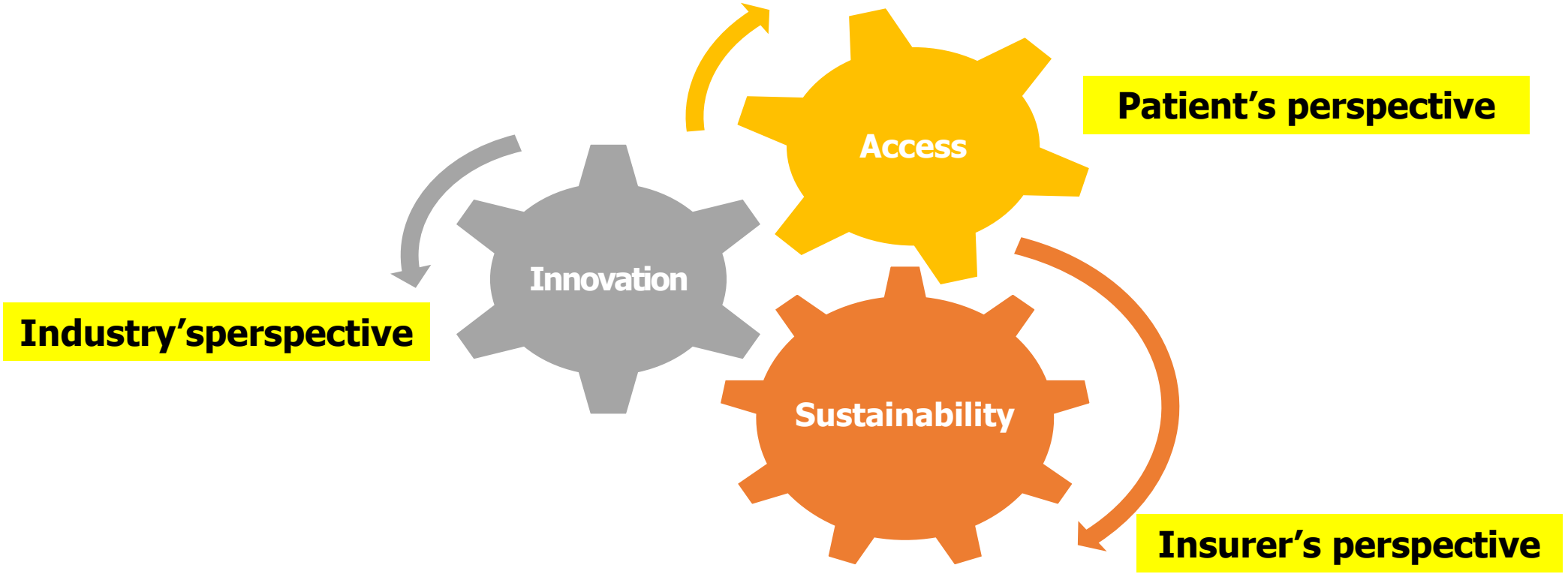
- Adjust the maximum drug price to reflect additional financial impact when expanding the scope of use (e.g., adding new indications), thereby improving patient access to necessary treatments.
- Dual Management System between the HIRA and the NHIS
- HIRA handles cases with a minor financial impact (under 10 billion KRW), by calculating and reducing the maximum drug price.
- For drugs under risk-sharing agreements (RSA) or cases with additional financial impact exceeding 10 billion KRW, the NHIS and pharmaceutical companies conduct negotiations to determine the maximum drug price and expected claim amount.

Expanded reimbursement

	Expansion coverage < 10 billion KRW & Non-RSA drugs	Expansion coverage ≥ 10 billion KRW or RSA drugs
Drugs		
Management	HIRA	NHIS
Negotiation	Maximum drug price	Maximum drug price Expected claims amount
Process	**Calculation**	NHIS-company **negotiation**

Conclusion

- Korea's health insurance drug expenditures continue to rise steadily, driven by population aging, the increasing prevalence of chronic diseases, and growing expenditure on high-cost medications.
- Efforts aim to strike a balance between ensuring patient access to treatments, maintaining the financial sustainability of the health insurance system, and providing appropriate compensation for pharmaceutical innovation.



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