厚生労働省 ひと、くらし、みらいのために Ministry of Health, Labour and Welfare

Japan's NHI Drug Price System

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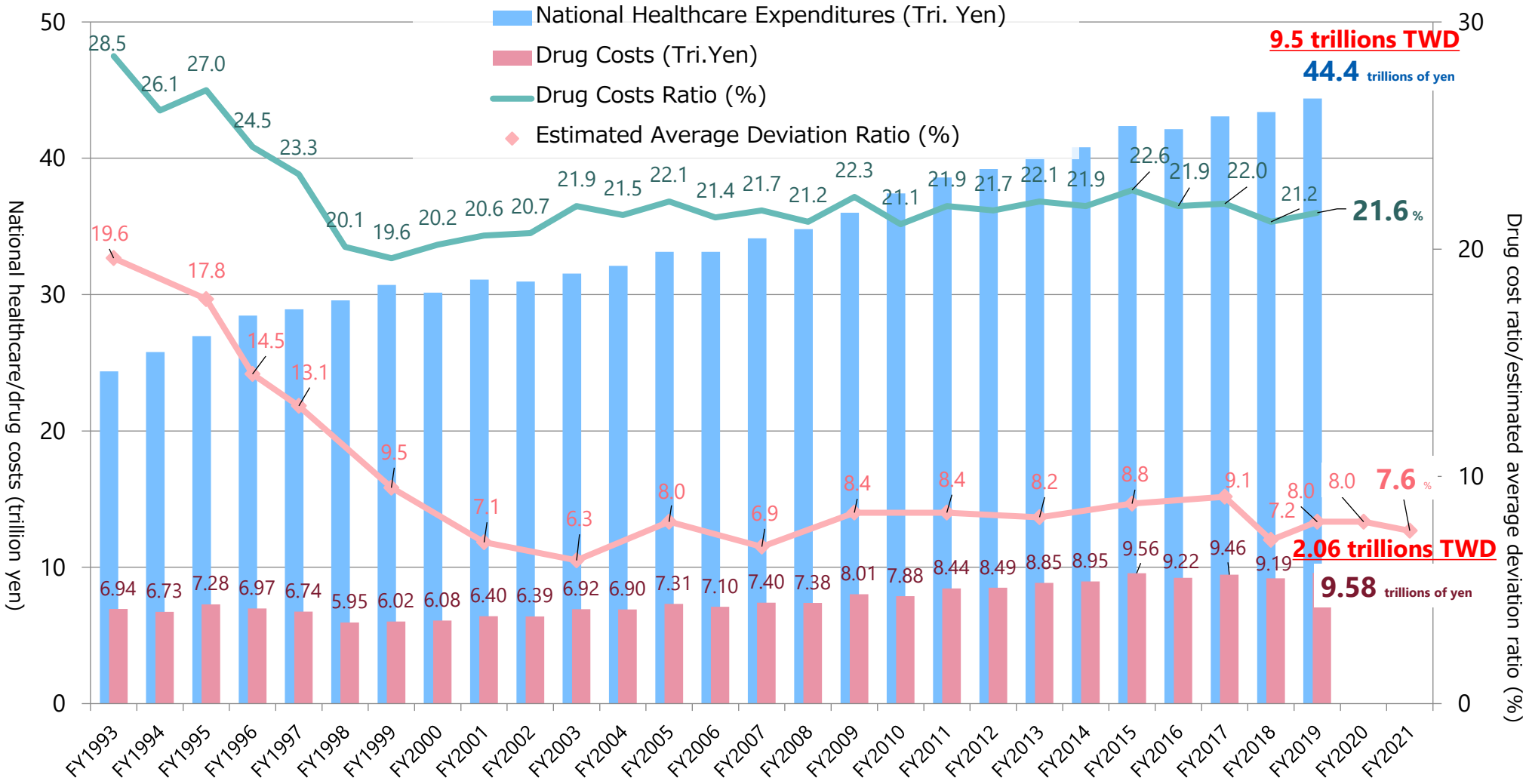
Basics

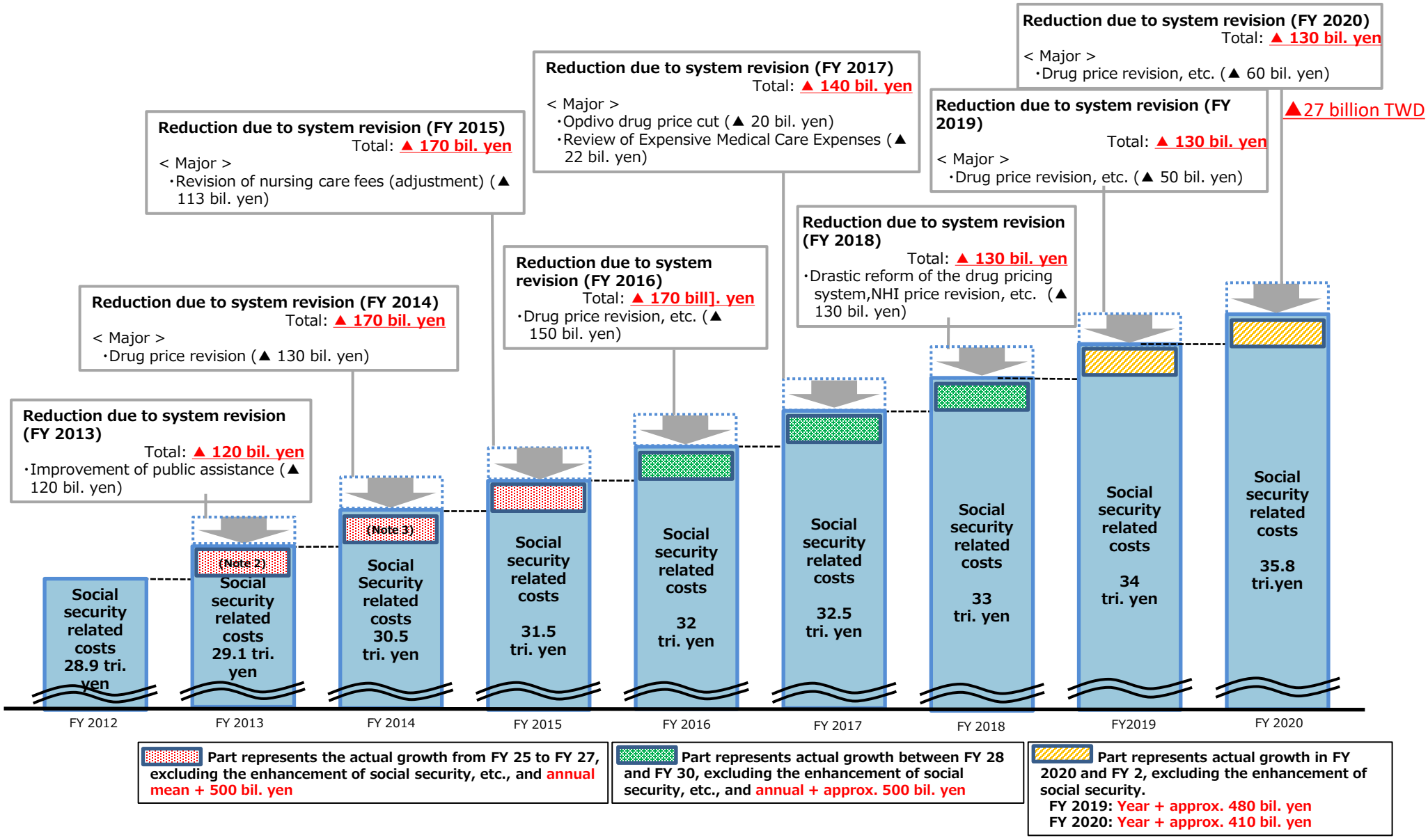
Q1:Why has the ratio of drug costs been maintained at about 20% in Japan?

Changes in National Healthcare Expenditures (NHE), Drug Costs, etc.



*The average deviation rate obtained in the drug price survey is regarded as the estimated deviation rate for the fiscal year.
*Estimated deviation rate in FY 2019 was deviation from the NHI price in April 2018
*Drug costs do not include those where drug costs such as DPC are calculated by including them in hospitalization fees

Recent Growth in Social Security Expenditure



Analysis of the Impact of Drug Price Revision, etc. on the Pharmaceutical Market (Drug Costs)

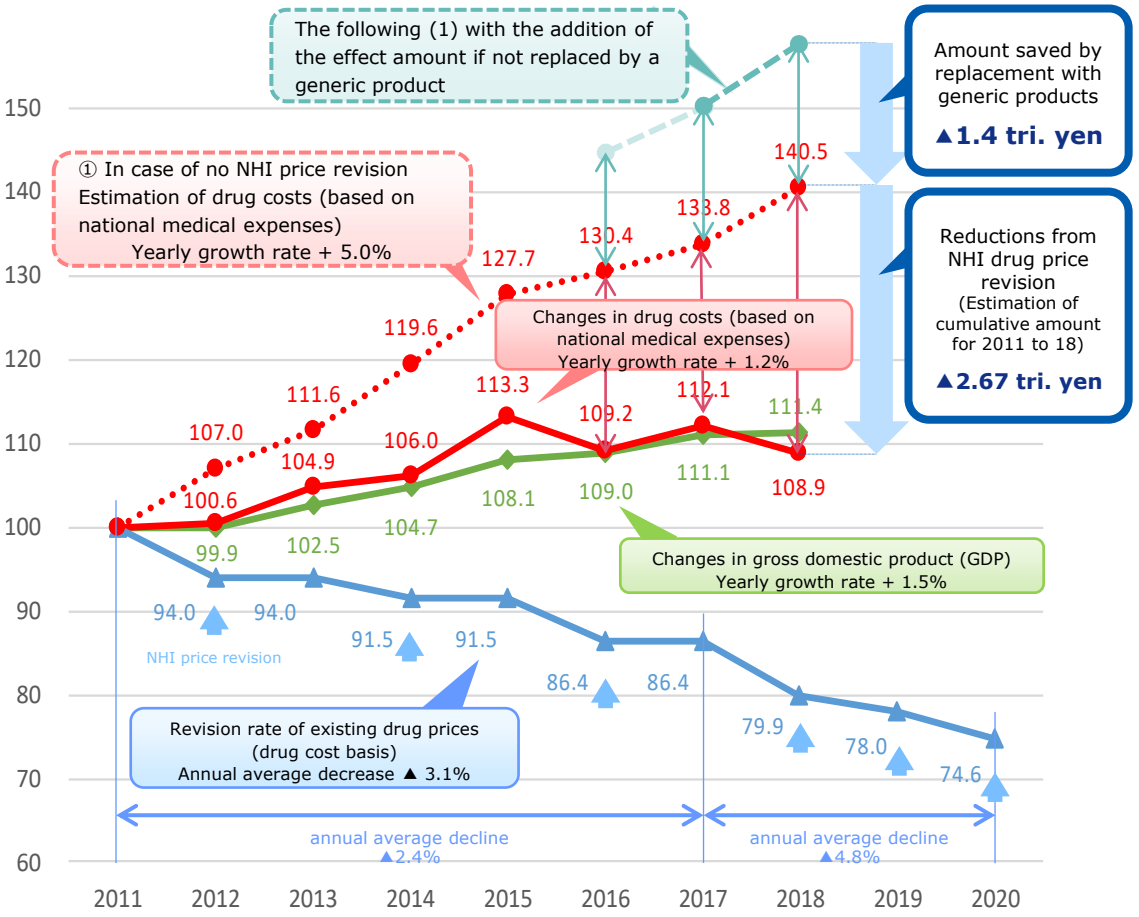
○ The growth rate of the drug market (drug costs) by 2018 was expected to increase by an annual average of 5.0% under the situation if the drug prices were not revised, but the biennial drug price revision suppressed the annual average increase to 1.2%.

*Due to the annual NHI drug price revision since 2018, the annual average reduction rate doubled from ▲ 2.4% (2011–17) to ▲ 4.8% (2017–20)

○ In addition, the growth of drug costs has been further suppressed by optimization of long-listed products and promotion of the use of generic products.

1. Changes in drug costs (%) compared to 1.2011 (23)

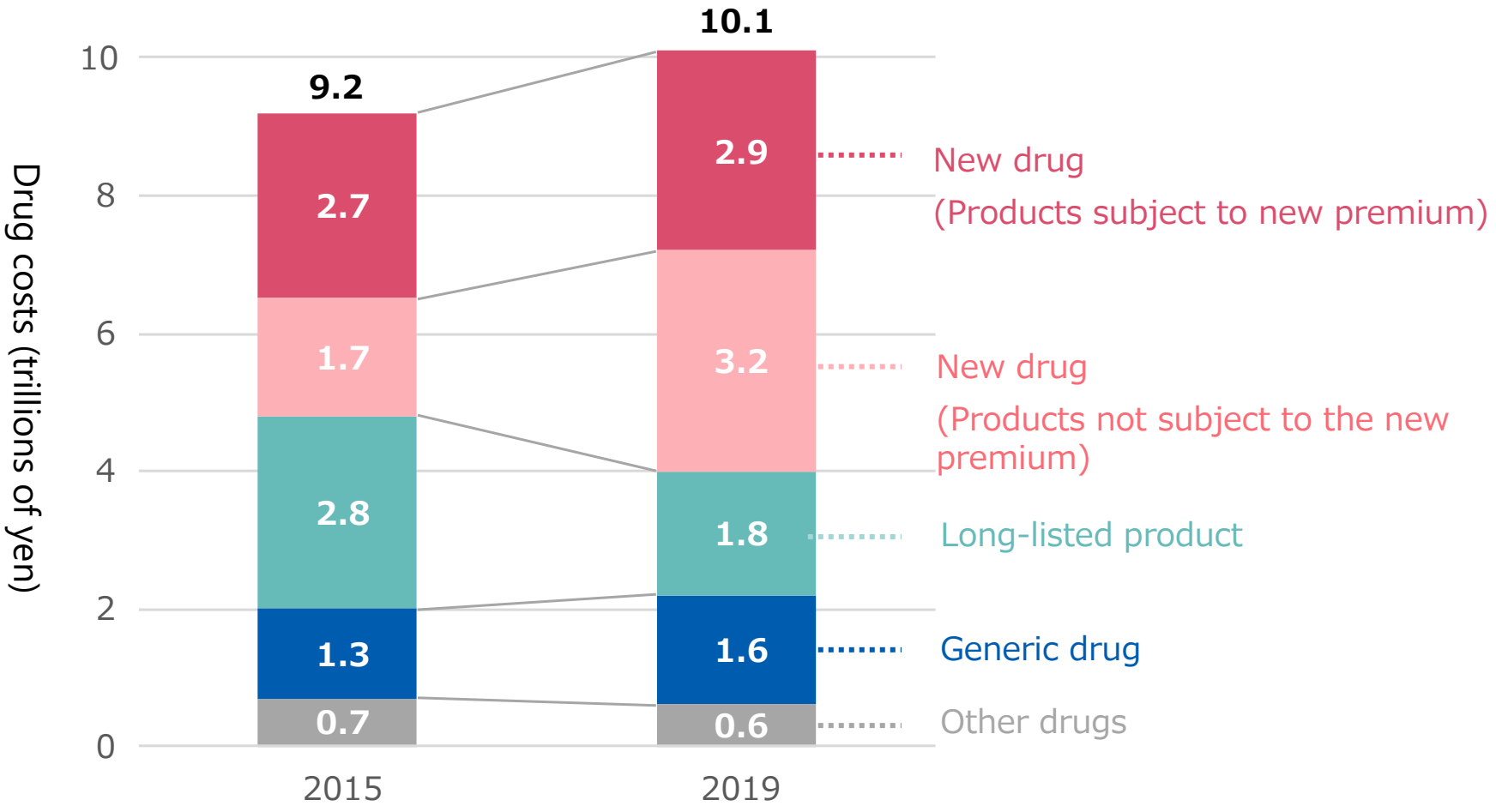
*For the drug cost/revision rate, the figure from "Chuikyo Drug-2 (3.8.4) " was used. For GDP, the figure from" Annual Estimate of National Accounts " by the Cabinet Office was used.



2. Amount of proper effects of medical expenses by replacement with generic products

Drug price survey Fiscal year¥	Generic Usage rate	Drug costs of the original product if it is not replaced with a generic product Difference from the drug costs of generic drugs
FY2017	65.8%	1.3 trillion yen
FY2018	72.6%	1.4 trillion yen
FY 2019	76.7%	1.62 trillion yen
FY 2020	78.3%	1.86 trillion yen

Estimate of Drug Costs



The results of drug price surveys in 2015 and 2019 were multiplied by 12 (annualized) to simply estimate the annual amount.

Items and prices of drugs usable in insurance-covered healthcare, specified by the Minister of Health, Labour and Welfare

(common for all medical insurance systems, including health insurance, National Health Insurance (NHI), and various mutual aid systems)

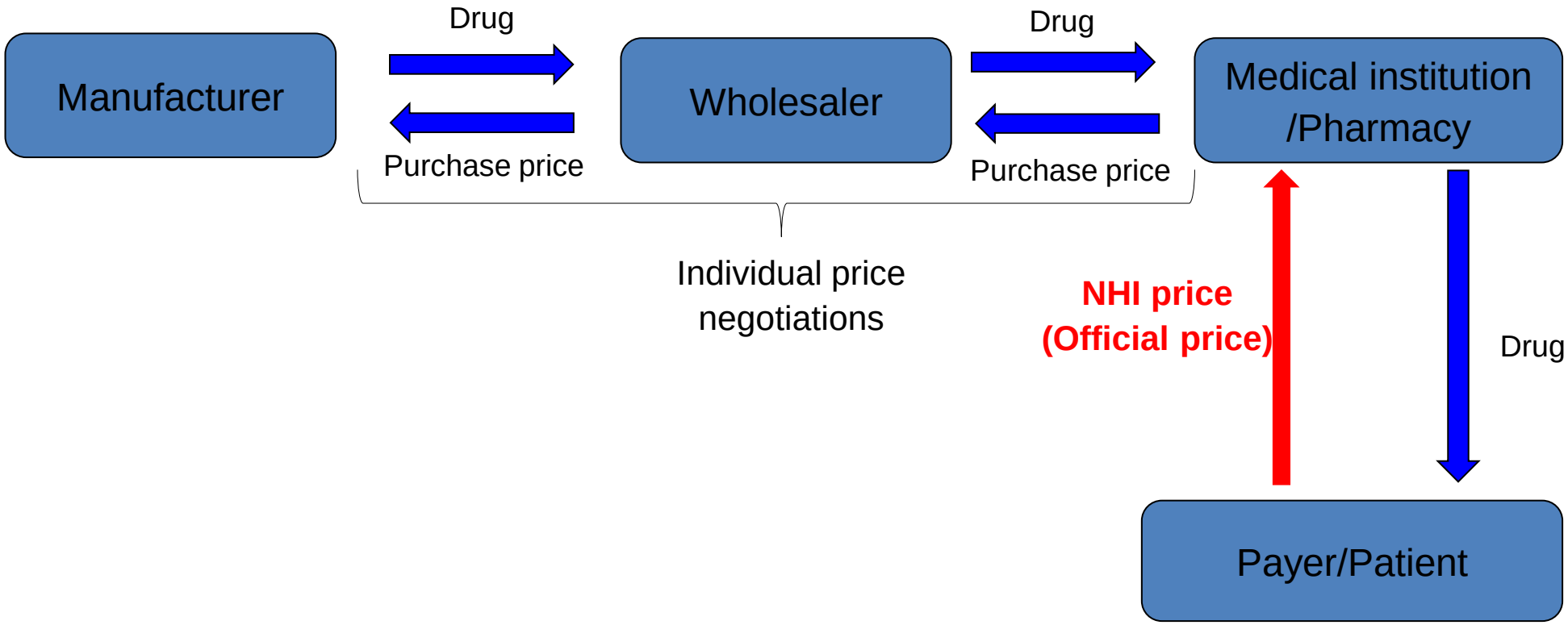
- Item list
  - A doctor or pharmacist operating under the health insurance program, in principle, must not use drugs other than “Drugs the Minister of Health, Labour and Welfare specifies”.
  - Items listed in the NHI Drug Price Standard are stipulated as “Drugs the Minister of Health, Labour and Welfare specifies”.

  = NHI Drug Price Standard specifies drugs usable in insurance-covered healthcare, and functions as an item list.
- Price table
  - When an authorized medical institution or pharmacy operating under the health insurance program makes insurance claims, the drug charge shall be calculated based on the price specified in the NHI Drug Price Standard.

  = NHI Drug Price Standard specifies the claimable amount of drugs used in insurance-covered healthcare, and functions as a price table.

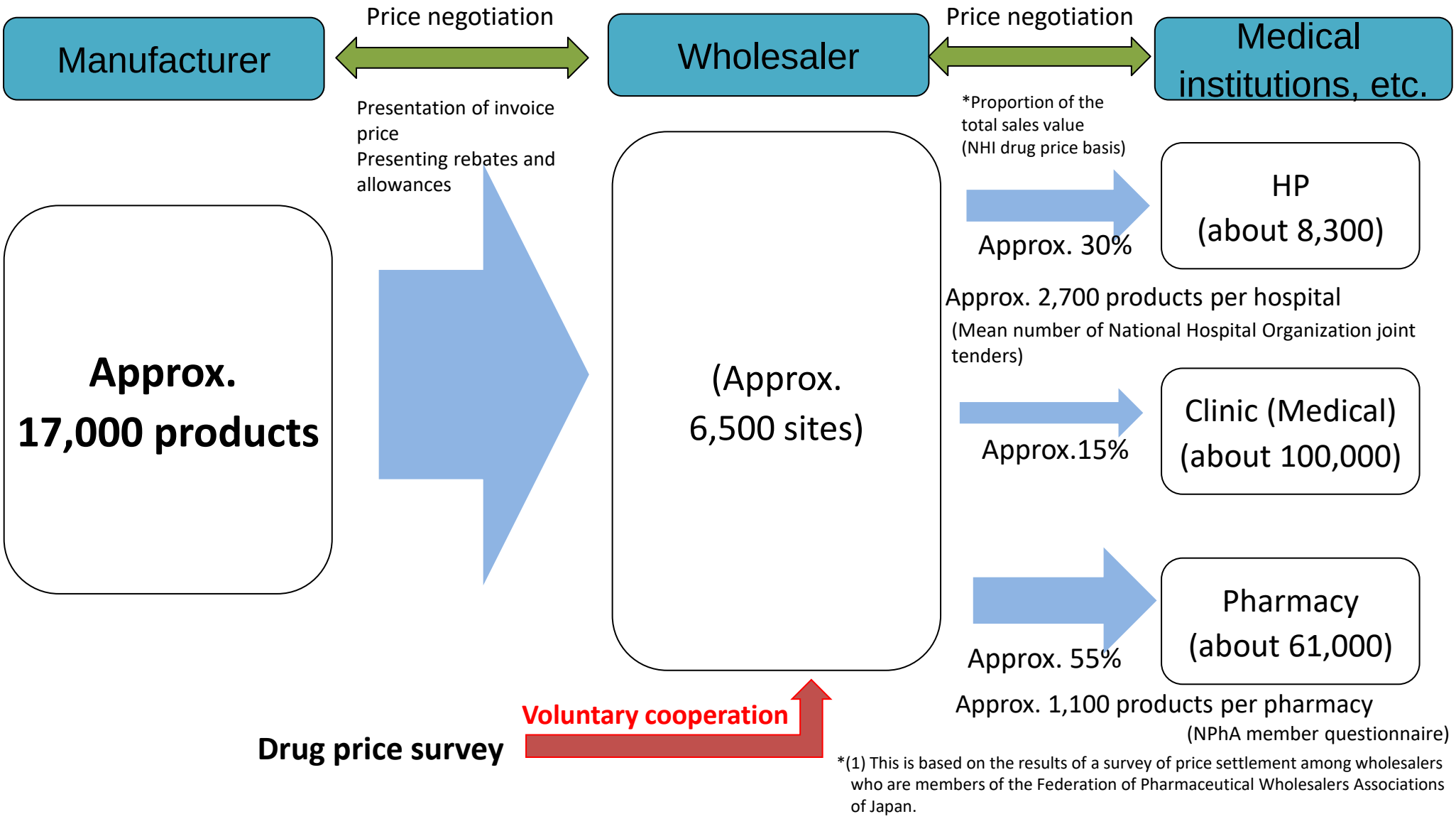
Current Pricing System (1)

- Under health insurance system in Japan, **NHI drug price (= insurance claim price/final retail price) is set uniformly across the country** like medical fees so that patients can receive medical care at the same price no matter where they live.
- On the other hand, **negotiations between medical institutions/pharmacies, wholesalers, and manufacturers are free trade** and purchasing prices are determined by individual price negotiations.



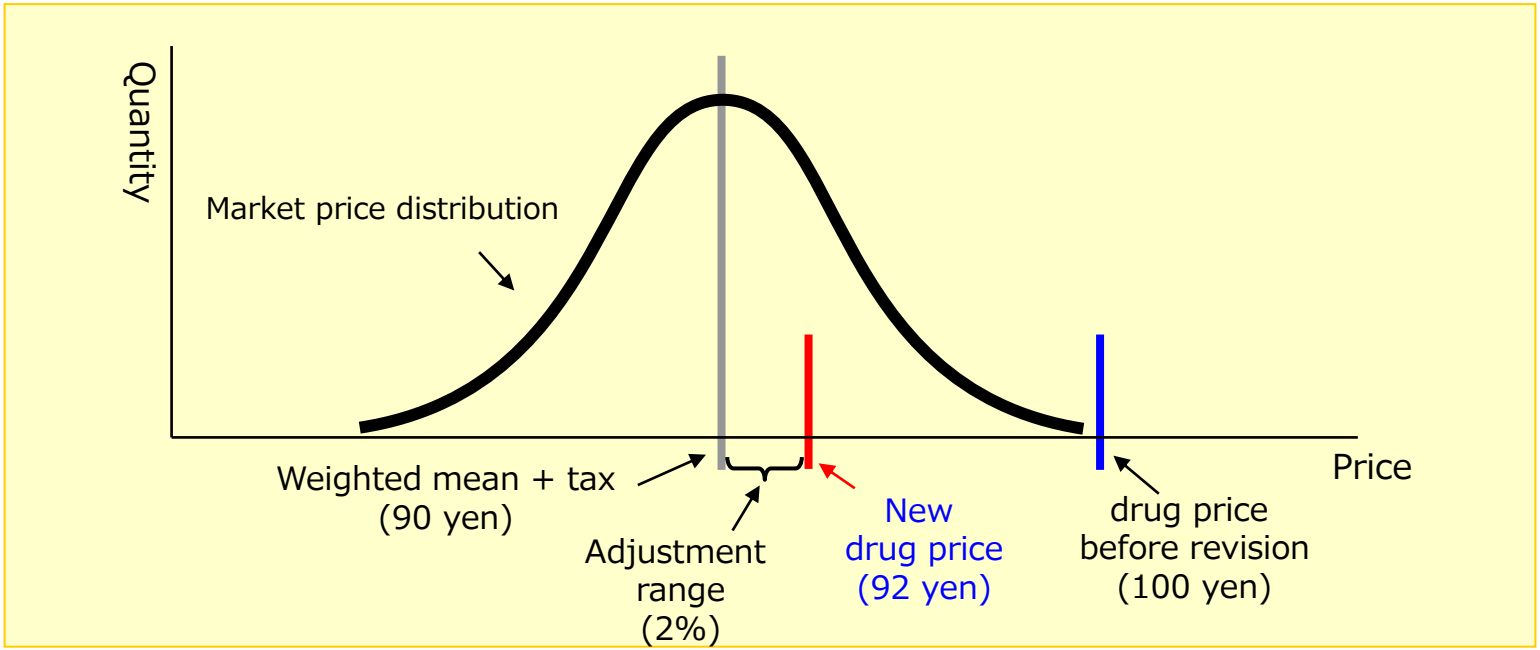
Current Pricing System (2)

○ About 17,000 prescription drugs are listed in the NHI drug price list, and wholesalers handle **many items.**



*(1) This is based on the results of a survey of price settlement among wholesalers who are members of the Federation of Pharmaceutical Wholesalers Associations of Japan.

NHI Drug Price Revision Based on Current Market Prices



The new drug price shall be the weighted average of the sales prices to wholesalers' medical institutions and pharmacies after adding the consumption tax and the adjustment range for the stabilization of drug distribution (2% of the drug price before revision).

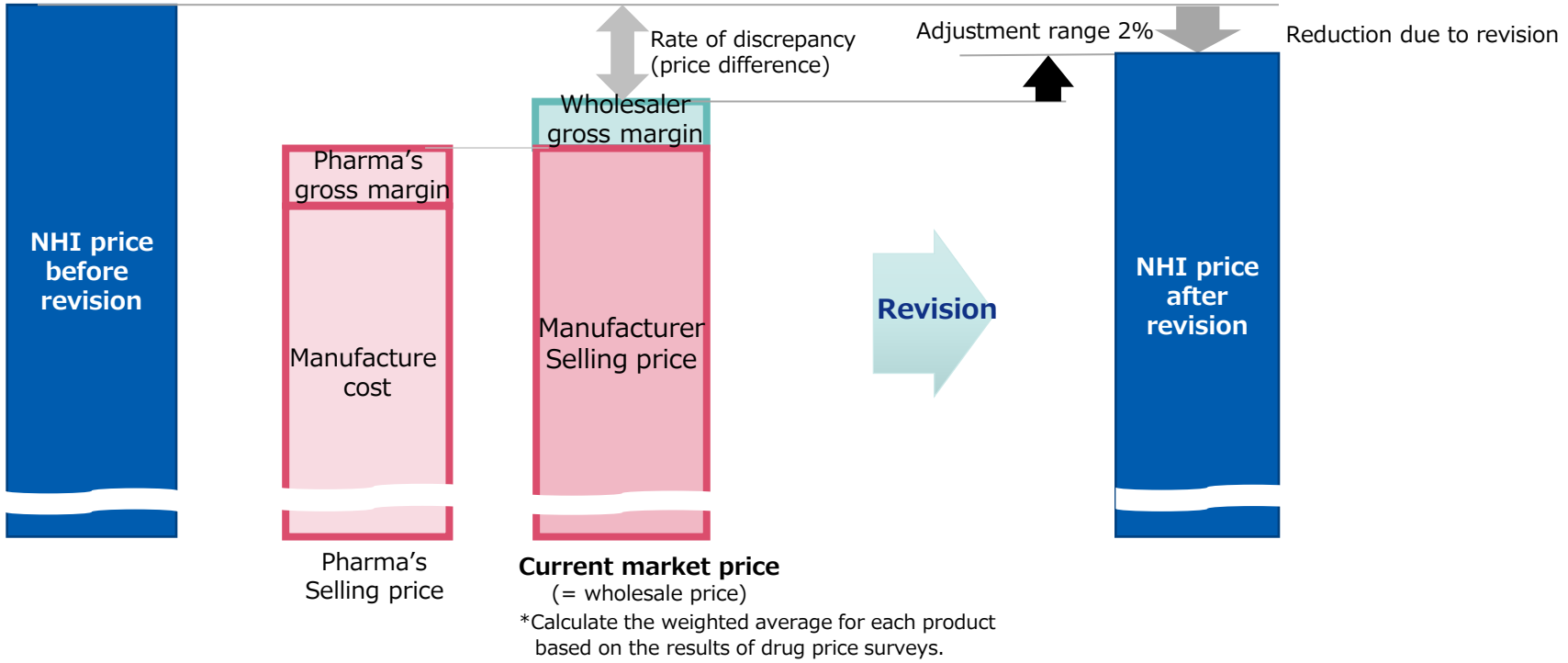
$$\text{New drug price} = \left[\begin{array}{c}\text{The sales price to medical institutions/pharmacies}\\ \text{Weighted mean (market price excluding tax)}\end{array}\right] \times (1 + \text{tax rate}) + \text{Adjustment range}$$

Image of Drug Price Revision

(weighted average of market prices with adjustment margin method)

At the time of drug price revision, the price (drug price) of drugs shall be revised to the weighted average of the current market price (*) of each product with the addition of an adjustment margin (However, the price before revision is the upper limit)

* Actual market price: the actual transaction price from wholesalers to medical institutions/pharmacies (wholesaler price)



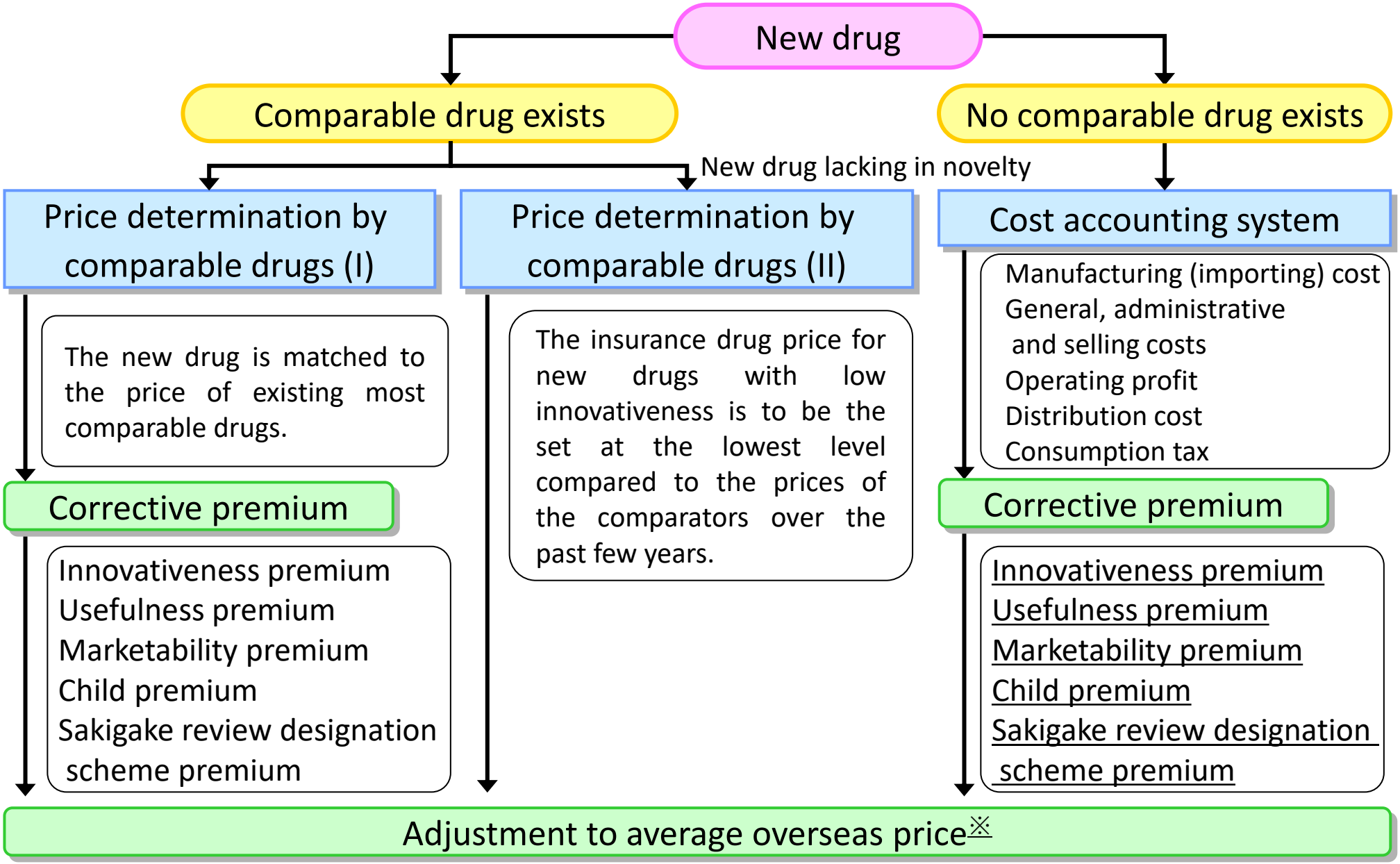
[Reference] Calculation method of weighted average of current market prices with adjustment margin method

$$\text{New drug price} = \left[\begin{array}{c}\text{The sales price to medical institutions/pharmacies}\\ \text{Weighted mean}\\ \text{(market price excluding tax)}\end{array}\right] \times (1 + \text{tax rate}) + \text{Adjustment range}$$

*Including local consumption tax

Adjustment range: The amount equivalent to 2% of the pre-revision price as **adjustment range to stabilize drug distribution**

New drug price determination method



※Only those to be priced with the cost accounting method or the comparator pricing method for which no drugs with similar pharmacological action exist

Price determination by comparable drugs(I)

- When there are comparable drugs, the daily drug price of the new drug is matched to the daily drug price of existing comparable drugs from the viewpoint of ensuring fair competition in the market.
  - A comparable drug shall be, in principle, a new drug within 10 years after NHI price listing and the drug price of generic drugs is not listed.

1 tablet = ¥50
3 tablets a day

=

1 tablet = ¥X
2 tablets a day

<Daily drug price matching>

¥50 × 3 = ¥X × 2

X = 75 yen

Comparable drugs refer to those similar in the following aspects.

A Efficacy and effect
B Pharmacological action
C Composition and chemical structure
D Dosage form, division and use

- For the relevant new drug, when higher efficacy is identifiable compared to comparable drugs, a corrective premium is applied to the above amount.

Innovativeness premium	70-120%	New action mechanism, high efficacy/safety, improvement of disease treatment method
Usefulness premium	5-60%	High efficacy/safety, improvement of disease treatment method
Marketability premium	5%, 10-20%	Orphan drug, etc.
Child premium	5-20%	Dosage and usage expressly includes those pertaining to children, etc.
Sakigake review designation scheme premium	10-20%	Pharmaceutical approval was obtained in Japan ahead of other countries, etc.

Price determination by comparable drugs(II)

- New drugs with little novelty shall be priced at the lowest price compared to prices of comparable drugs in the past several years.
  - New drugs with little novelty: Products meeting all of the following conditions
    - Out of scope of adjustment premium
    - 3 or more drugs with similar pharmacologic action
  - In principle, the amount shall be the lower of ① or ②.

    ① Average daily costs of comparable drugs listed in the past 10 years

    ② Lowest daily cost of comparable drugs listed in the past 6 years
  - ① Where ② and ③ exceed the "Price determination by comparable drugs (I) (daily drug price of the optimum comparable drug)",

    ④ Average daily costs of comparable drugs listed in the past 15 years

    ⑤ Lowest daily costs of comparable drugs listed in the past 10 years

    Calculate and make the lowest amount of ③ to ⑤.

Cost Accounting System

- If there are no comparable drugs, raw material costs, manufacturing costs, etc. will be accumulated.

(Example)

① Raw material costs (Active ingredient, excipients, containers, boxes, etc.)
② Labor cost (= 3,643 x working hours)
③ Manufacturing costs

④ Cost of products manufactured (imported)
⑤ Selling, research and other expenses ((5)/((4)+(5)+(6))≦ 0.507)
⑥ Operating Profit ((6)/((4)+(5)+(6))= 0.148)
⑦ Distribution costs ((7)/((4)+(5)+(6)+(7))= 0.075)
⑧ Tax (10%)

Total: Calculated price

However, for chemical products with a disclosure level of ≥ 80% and biopharmaceuticals with a disclosure level of ≥ 80% and research and development expenses alone exceeding the upper limit of the selling, general and administrative expense ratio (50.7%) (limited to those with a peak market size of less than 5 billion yen), the upper limit of the selling, general and administrative expense ratio is 70%

For cellular and tissue-based products, detailed examination shall be performed for each product item, and if the amount is lower than the amount calculated using an average coefficient, the amount shall be calculated using that amount.

- If the new drug is found to be more useful than the existing treatment, an adjustment premium will be applied to the above amount. However, the premium rate shall differ according to the proportion (degree of disclosure) of the part of the total product cost that can be disclosed by the Drug Pricing Organization.

Premium amount = Price total × Premium rate × Premium coefficient
(Price before Premium) (0~120%) (0.2~1)

Disclosure level	80% or more	50~80%	Less than 50%
Premium coefficient	1.0	0.6	0.2

* Disclosure level = (disclosable drug price part)/(total product cost)

Foreign Average Price Adjustment -1

- From the viewpoint of securing fair market competition, adjustments shall be made when the difference from foreign prices is large in the case of the cost calculation method and the similar efficacy comparison method for products without similar pharmacological actions.

1. Foreign average prices are the average of prices in the U.S. (Medicare/Medicaid), the U.K., Germany and France
   * If there are 2 or more foreign prices and the highest price is more than 2.5 times the lowest price, the average of the foreign prices excluding the highest price
   * If there are three or more foreign prices and the highest price is more than twice the average of the other prices, the average of the foreign prices calculated by regarding the highest price as twice the average of the other prices

2. Conditions for adjustment:
   ① For exceeding 1.25 times the foreign average price → Reduction adjustment
   ② For below 0.75 times the foreign average price → Raise adjustment

① > 1.25 fold

$$\left(\frac{1}{3} \times \frac{\text{Calculated value}}{\text{Foreign average price}} + \frac{5}{6} \right) \times \text{Foreign average price}$$

② Below 0.75 times

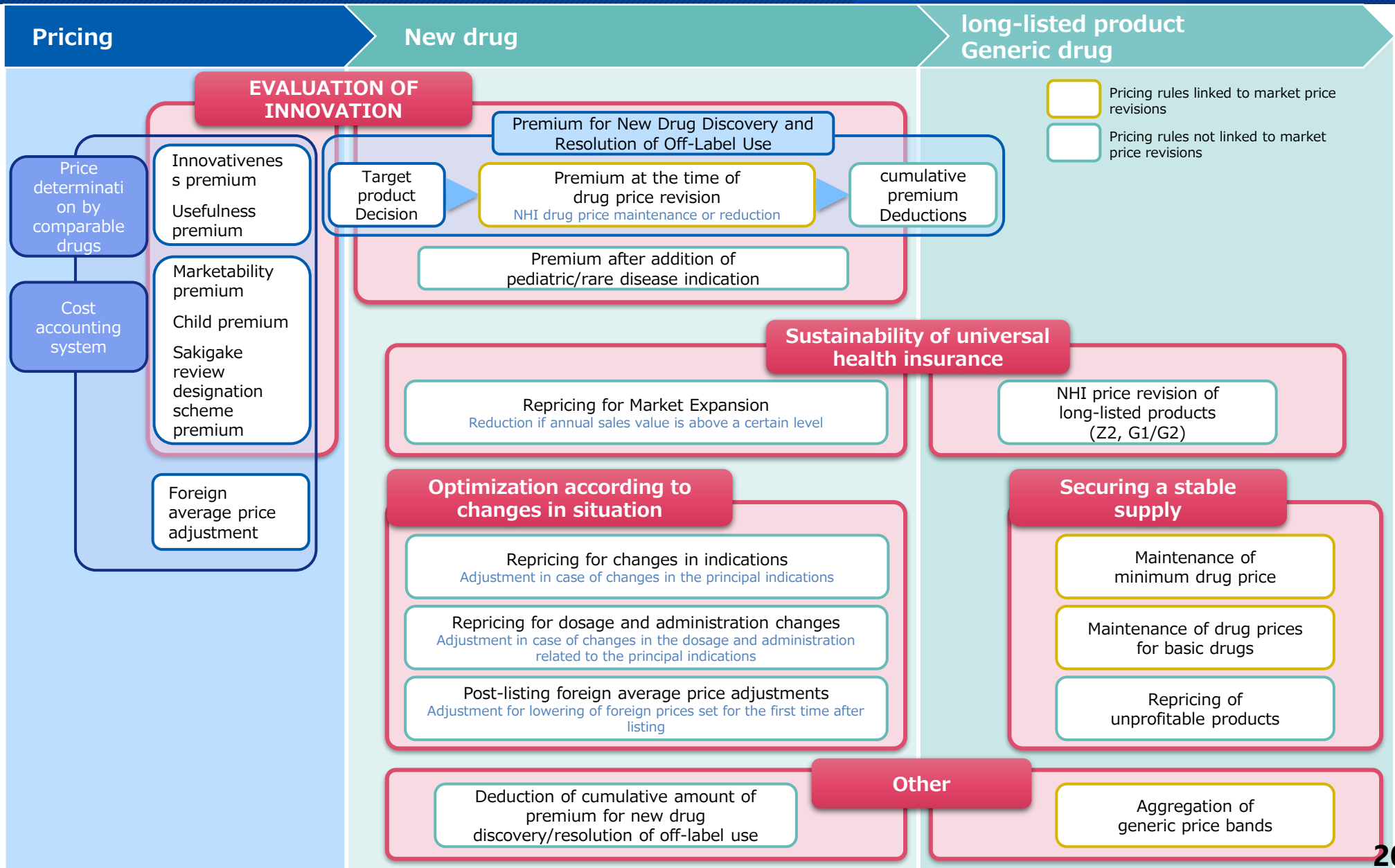
$$\left(\frac{1}{3} \times \frac{\text{Calculated value}}{\text{Foreign average price}} + \frac{1}{2} \right) \times \text{Foreign average price}$$

(Up to twice the calculated value)

Details

Q2: How is the transparency and predictability of the NHI drug price revision?

Life Cycle of Drugs and Current Drug Pricing Rules (Overall Image)



Premium for Promotion of New Drug Discovery and Resolution of Off-Label Use: Addition of Target Products, etc.

Positioning of the system

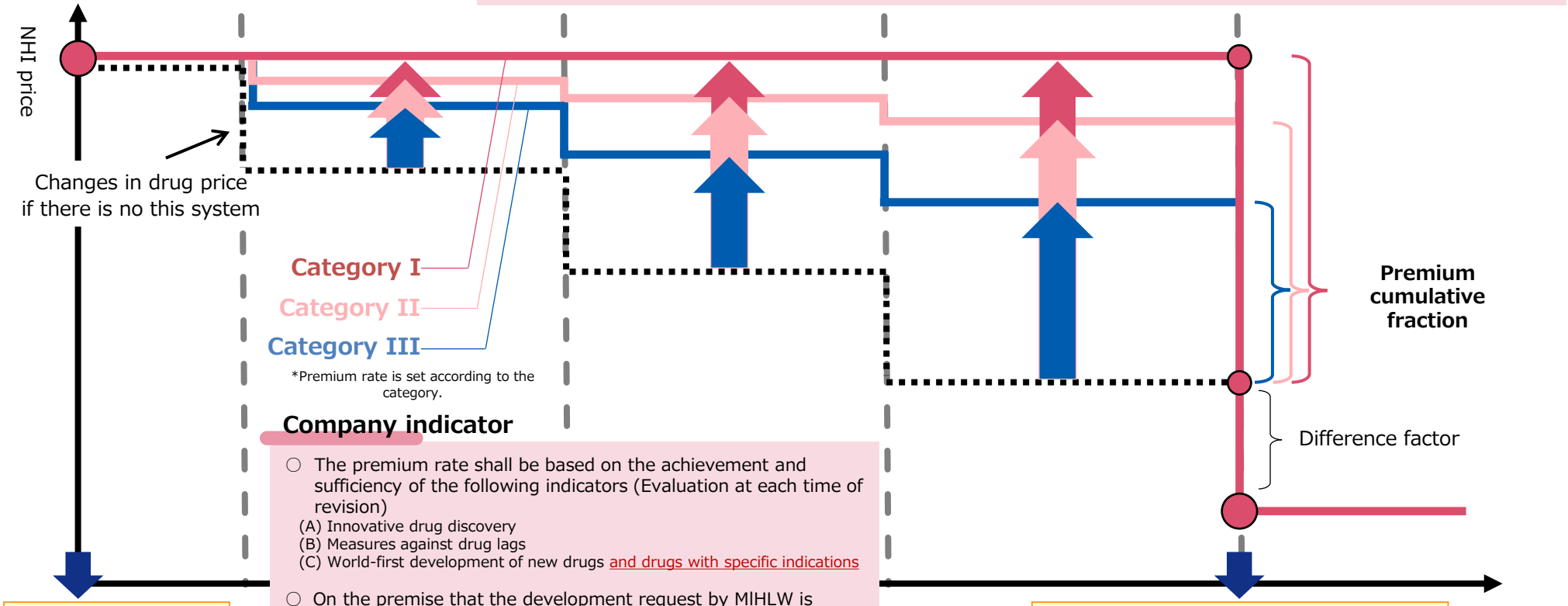
To efficiently and effectively promote the creation of innovative new drugs, a suspension of drug price reduction based on current market prices of new drugs without generics

item requirement

*Red was revised

Judgement focusing on innovativeness and usefulness of the drug itself

① Drugs for which the innovation premium, utility premium, and operating profit margin adjustment have been applied (including drugs with additional indications equivalent to these premiums), ③ Products publicly offered for development, ③ Orphan drugs, ④Drugs with novel mechanisms of action (Only those that are found to be innovative and useful in reference to the standards.), ⑤ Drugs with novel mechanisms of action that are within 3 years or within the third rank from drugs with novel mechanisms of action are products eligible for the premium or products meeting the standards, ⑥ Pioneering drugs, ⑦ Drugs for specific use, and ⑨ Drugs for the treatment of drug-resistant bacteria



Company indicator

○ The premium rate shall be based on the achievement and sufficiency of the following indicators (Evaluation at each time of revision)
(A) Innovative drug discovery
(B) Measures against drug lags
(C) World-first development of new drugs and drugs with specific indications

○ On the premise that the development request by MIHLW is appropriately responded

*The premium amount will be capped according to the discrepancy rate.

Review of the Premium to Promote the Development of New Drugs (Requirements for Companies, etc.)

- ○ Add vaccines and therapeutic drugs newly approved for COVID-19 (in the past 5 years) to the company indicators for the PMP (4 points for one product)
- ○ position “pioneering drugs ” and“ drugs for specific use ” as corporate indicators
- ○ Category III was expanded (changed to 2 points or less) in consideration of the balance of the number of companies in relation to the premium coefficient for the PMP.

*Red letters and red boxes were revised

< Company indicators >

	Description of the indicator	
A-1	Domestic studies (including multi-regional clinical trials including Japan) (Number of studies conducted) (Phase II and subsequent studies)	Top 25% 4 pts Moderate 50% 2 pt
A-2	Number of listed ingredients *1 (past 5 years)	Top 25% 4 pts Moderate 50% 2 pt
A-3	Enrollment performance of innovative new drugs (past 5 years)	2 pts with results
A-4	Past listing of drugs for the treatment of drug-resistant bacteria (past 5 years)	2 points for one product
A-5 Newly established	Drugs for the treatment of COVID-19, etc. (past 5 years)	4 points for one product
B-1	Products publicly offered for development (No. of development starts) (past 5 years) (excluding B2 minutes)	2 points for one product
B-2	Products publicly offered for development (number of approvals obtained) (past 5 years)	2 points for one product
C-1	World-first development of new drugs (number of products) (past 5 years)	2 points for one product
C-2 Newly established	Drug development for specific application (number of products) (past 5 years) (except for A-4 minutes)	2 points for one product

< Classification method >

Category	I	II	III
Range	Top 25% *	Other than I and III	Not more than 2 pt ~~Minimum score~~
addition coefficient	1.0	0.9	0.8

* Regarding A -5, it includes vaccines only if it is used for the treatment or prevention of the infection caused by the novel coronavirus and the therapeutic or preventive effect against the infection caused by the novel coronavirus has been clarified by the regulatory review.

* For C -1, the designated number of Pioneering Medicinal Product.

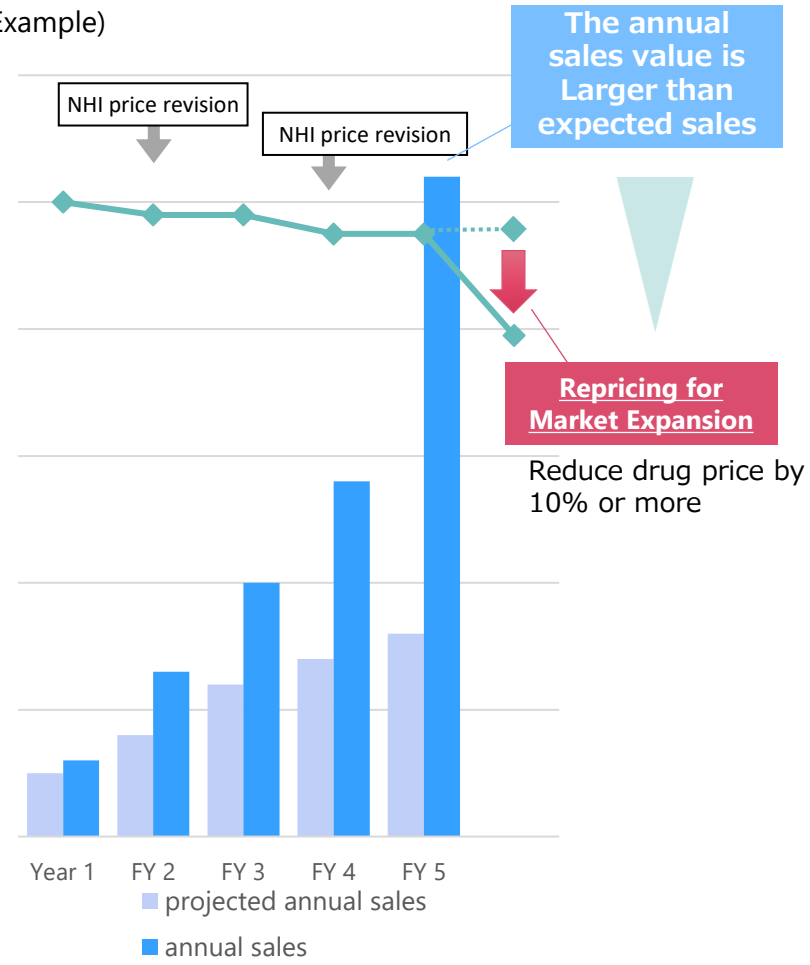
* Regarding C -2, it is the designated number of drugs for specific use.

Repricing: Handling of Similar Products of Products Subject to Repricing for Market Expansion

Products (including products subject to reduction as similar products) for which drug prices have been reduced as a special case for repricing for market expansion shall be excluded from the reduction as similar products for repricing for market expansion (including special cases for repricing for market expansion) only once for a period of four (4) years from the day following the application of the reduction.

[Image of repricing for market expansion] Drug price reduction in case the annual sales value exceeds a certain multiple of the expected sales value, etc.

(Example)



*Red: Part to be reviewed

Repricing for Market Expansion		Standard amount	Projected sales ratio	NHI price reduction rate	
				Cost accounting system	Price determination by comparable drugs
At the time of the drug price revision repricing	If the annual sales value exceeds a certain multiple of the expected sales value, etc., the price will be further reduced at the time of the drug price revision.	**Over 10 billion yen**	**≥ 10 times**	10~25%	-
		Over 15 billion yen	**≥ 2 times**	10~25%	10~15%
Repricing at times other than drug price revision (quarterly repricing)	For products for which additional indications, etc. have been approved, the price shall be revised according to the above formula taking advantage of the opportunity for new drug listing (4 times a year) only for products with a market size exceeding 35 bil. yen.	**Over 35 billion yen**	**≥ 2 times**	10~25%	10~15%
Special case repricing for market expansion (At the time of revision/quarterly)	Special case concerning handling of products with extremely large annual sales value	**100 ~ 150 billion yen**	**≥ 1.5 times**	10~25%	
		Over 150 billion yen	**≥ 1.3 times**	10~50%	

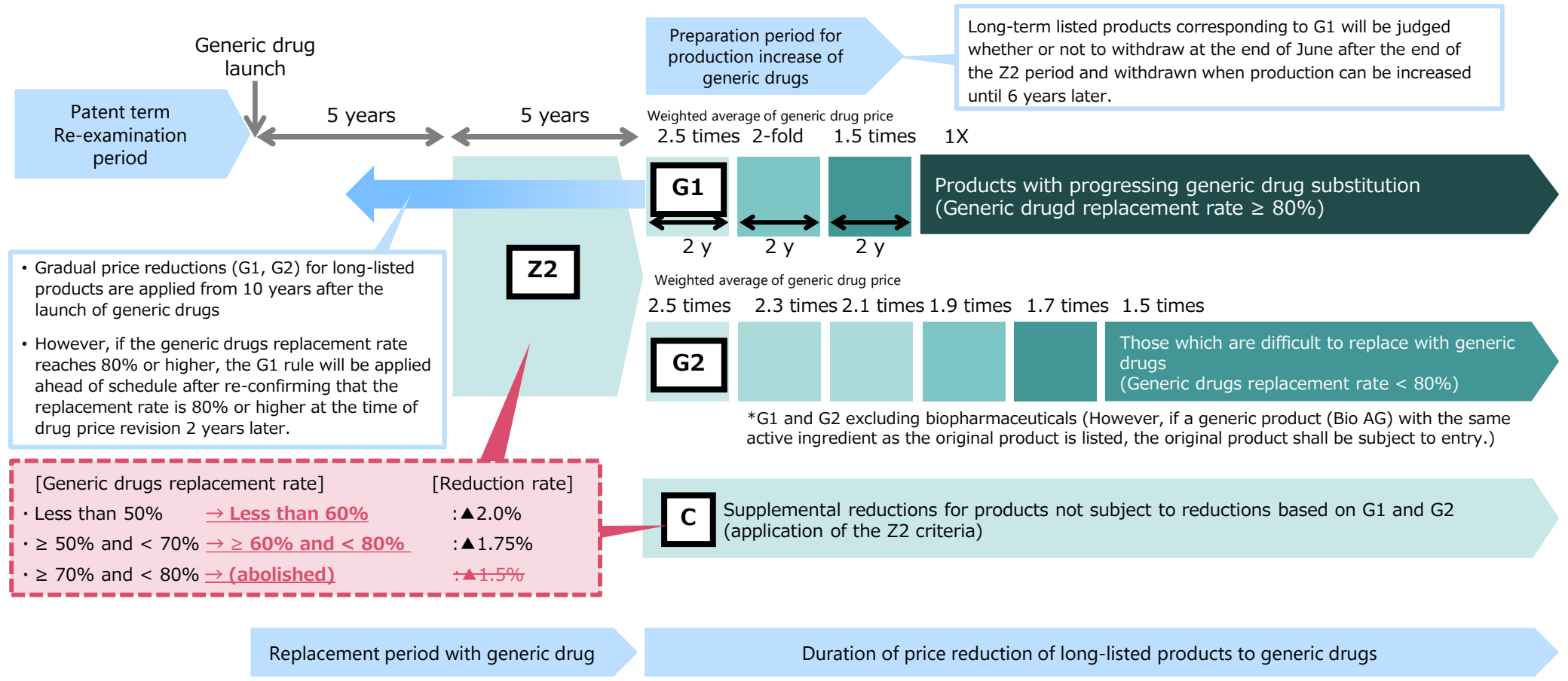
* Products subject to repricing for special case expansion or products similar thereto shall not be handled as products similar to repricing for market expansion or products similar to repricing for special case expansion even if they correspond to products similar to products similar to products for repricing for market expansion of other products **only once during the period until the day four years elapse from the day following the date of application of the respective revision.**

Revision of Price of Long-Listed Products: Optimization of Price of Long-Listed products (Review of Z2, etc.)

From the viewpoint of further optimizing the drug price of long-term listed products, the reduction rates by the replacement rate to generic products will be reviewed for special reduction (Z2) and supplemental reduction (C).

*Red letters/red boxes: Readjustment part

[Overview of optimization of long-term listed products]



Drug Price Reduction for Original Drugs for which Replacement with Generic Drugs has not Progressed (Special reduction (Z2))

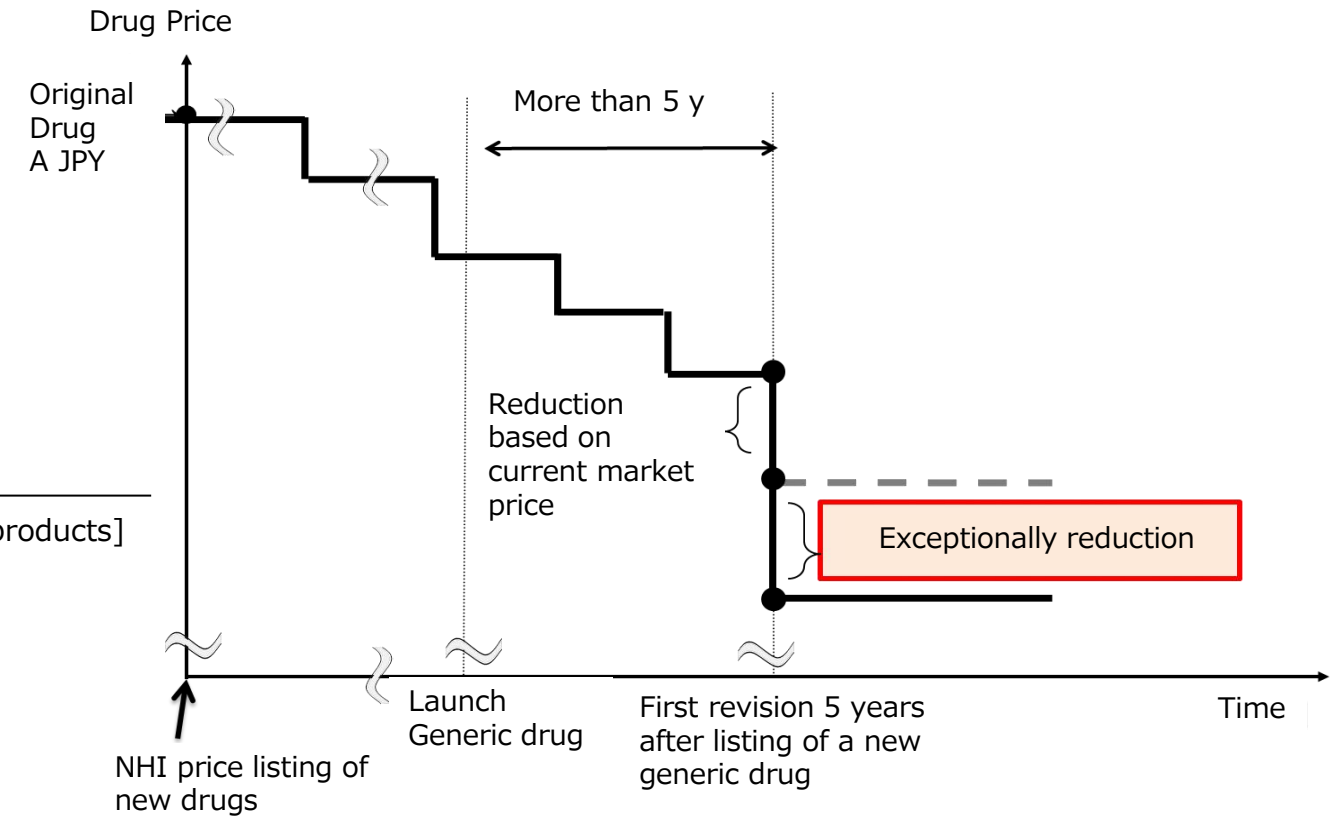
At each price revision for which 5 years have passed, but 10 years have not passed since the first generic drug was listed, original drugs for which the replacement rate to generic drugs is less than 80% shall be exceptionally reduced from the revised price based on the current market price according to the replacement rate.

< Reduction range >

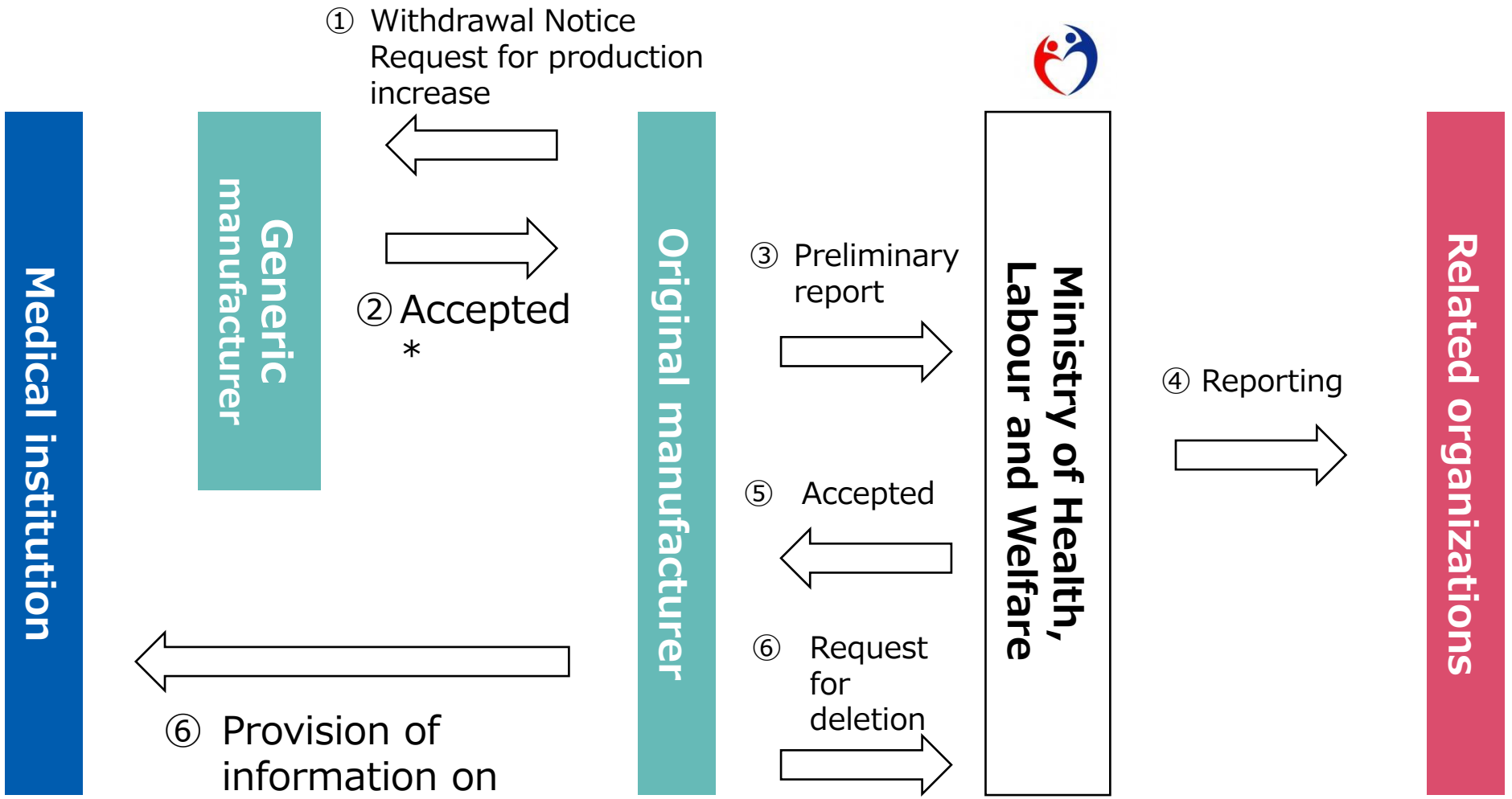
Generic drug replacement rate
- 50% Less than : ▲2.0%
- 50 ~ 70% Less than : ▲1.75%
- 70 ~ 80% Less than : ▲1.5%

< Replacement rate >

$$\frac{\text{[Number of generics]}}{\text{[Number of original products with generic products]} + \text{[Number of generic products]}}$$



Discontinuation Scheme for Long-Term Listed Products (G1)



*Generic manufacturers shall accept the withdrawal including the timing (within 6 years).

Special Case for Low-Priced Drugs: Basic Drugs

Calculation rules

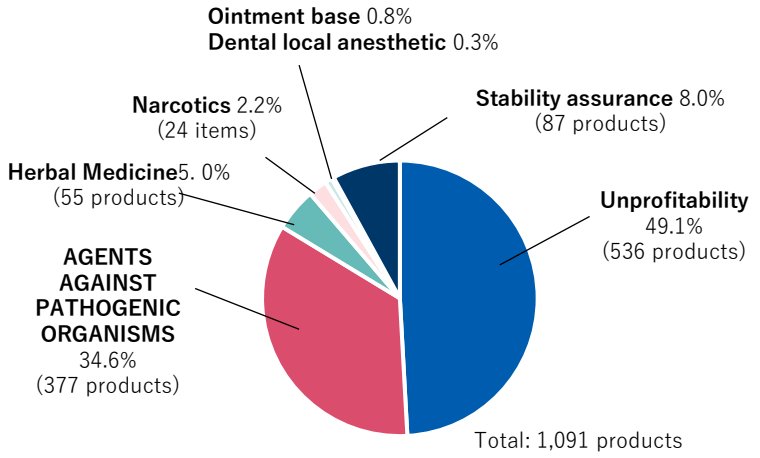
*Red: Part to be reviewed

- It is necessary to ensure a continuous and stable supply of drugs that are of high medical needs. However, for some drugs that have been NHI price listed for a long period of time, the continuous and stable supply has become difficult due to increases in manufacturing costs, decreases in market prices, etc.
- For this 2016 reason, drugs that meet all of the following requirements are handled as basic drugs under the drug pricing system, and the prices are consolidated to the brand with the highest sales volume in order to secure a stable supply.
  - ① It has a well-established medical position and is widely used in clinical practice.
  - ② Listed in the NHI price list for at least 25 years, and the discrepancy rate for any ingredient or brand is equal to or less than the average discrepancy rate for all products
  - ③ Products previously repriced as unprofitable products, drugs against pathogenic organisms, narcotics for medical use, herbal drugs, ointment bases, or dental local anesthetics
- **In addition, following the FY 2022 drug price system reform, products which are given high priority among drugs requiring stable assurance,** (Items in Category A. Except before the end of Period Z.) and **will be handled as basic drugs** under certain requirements.

*For the revision, ensure consistency with other rules, such as excluding brand-name products, etc. within 6 years from G1.

Number of ingredients and product items of basic drugs (as of the revision in FY 2022)

Category	Ingredient count	Number of items
Unprofitability	166 components	536 products
Pathogenic organism	98 components	377 products
Narcotic	9 components	24 products
Herbal Medicine	46 components	55 products
Ointment base	3 components	9 products
Dental local anesthetic	1 component	3 products
Stability assurance	8 components	87 products
Total	331 components	1,091 Products



*In cases falling under more than one category, the cases are classified into the upper category, excluding those related to drugs for which stable assurance is required.

Special Case of Low-Priced Drugs: Repricing of Unprofitable Products/Minimum Drug Price

Calculation rules (repricing of unprofitable products)

The amount calculated with the cost calculation method (up to the minimum amount including similar drugs) shall be revised for drugs deemed to be of high medical needs by the health insurance and for which the marketing authorization holder cannot continue the marketing of the drug due to its extremely low price (only when all similar drugs with the same ingredient specifications apply).

*the operating profit margin will be capped at 5/100

[**Reference**] **Number of ingredients and products for repricing of unprofitable products** (Revised in 2022)

Ingredient count	Number of items
131 components	440 items

Calculation rules (minimum price)

Revisions shall be made so that the price is not lower than the “minimum price ” set as the lower limit of drug prices for each category such as tablets and injections, regardless of ingredients.

[Reference] Examples of the minimum price: 5.90 yen for tablets (1 tablet), 6.50 yen for powder (1 g), 70 yen for injection (100 mL 1 bottle), etc. (the minimum price is set for a total of 36 categories)

Generic Drug Price Range

Calculation rules

○ For all similar products with the same composition, formulation category and specifications, the price ranges shall be aggregated by weighted average for each of the following categories.

(1)Generic drugs for which the calculated amount is **50% or more** of the highest price

(2)Generic drugs for which the calculated value is ≥ **30% and < 50%** of the highest price

(3)Generic drugs for which the calculated value is **less than 30%** of the highest price

* However, after the market price revision, **when the price is higher than before the revision due to belonging to a category higher than the category assigned at the time of the previous revision,** in, **weighted average is calculated by including the categories assigned at the time of the previous revision.** When the price of a product is not elevated to a category higher than the category assigned at the time of the previous revision, and **When the price of the product is elevated from the pre-revision price, the weighted average for the product concerned shall be re-applied.**

*Generic products pertaining to G1/G2 products are **integrated into one price band in principle** at the drug price revision after 12 years have passed after the first generic product launch pertaining to the G1/G2 product (However, if there are products whose drug prices are higher than before the revision due to aggregation, the weighted average shall be calculated for the products whose drug prices before the revision are lower than or higher than the weighted average. In the event that G1 originators are withdrawn from the market, generic products of one or more companies that respond to increased production and whose combined generic production volume exceeds 50% of all generic products shall be put into a separate price band.)

[Image of calculation] * Examples other than G1/G2

Q3:How are expensive drugs evaluated?

Cost-Effectiveness Evaluation System (Summary)

○The cost-effectiveness assessment system was introduced in April 2019 based on the discussion at Central Social Insurance Medical Council.
○Drugs and medical devices with a large market or a significantly high unit cost will be evaluated. However, this does not apply to rare diseases for which there are no sufficient treatment methods (e.g., designated intractable diseases) or products exclusively for pediatric use.
○The evaluation results are not used to determine the acceptability of insurance reimbursement but are used for price adjustment after listing in the insurance (supplement of the drug price system).
○In the future, the system will be improved, and case studies will be accumulated to discuss the ideal form of the system and how to utilize it.

[Cost-effectiveness evaluation procedure]

① Product Designation
(Designate drugs, etc. with a large market size

(2) Analysis by Company (-BL Feb - Sep (270 days))
Pre-analysis discussion (decision on framework of analysis, etc.), company analysis

③ Public analysis
(Verification) (March (90 days) to reanalysis (June (180 days)) (* 1)

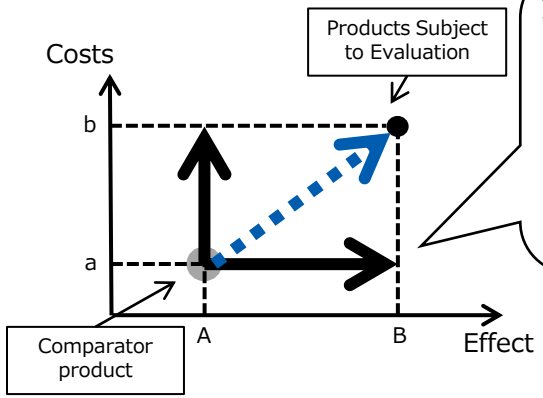
(* 1) Sponsored by the National Institute of Public Health

④ Overall Evaluation

(around Feb to Mar)

⑤ To cost-effectiveness assessments implement price adjustments based on

(Note)Periods in parentheses are standard intervals.

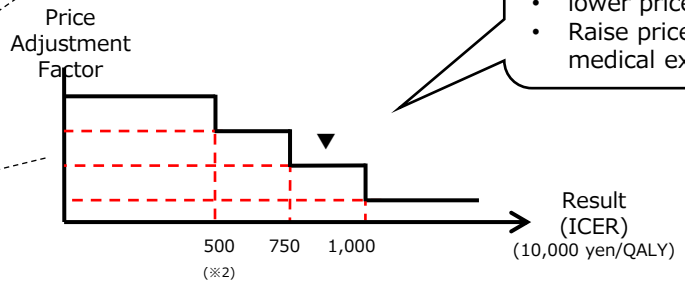


Analyze how much the cost and effect of the product subject to evaluation will increase compared to the comparator product (existing product).

Incremental cost-effectiveness ratio (ICER) = b-a (how much costs will increase) / B-A (increase in efficacy)

* Calculate the cost required to prolong 1-year survival in a healthy state.

In comprehensive evaluation, factors requiring consideration such as rare diseases, children, and anticancer drugs should be taken into consideration (* 2)



Adjust the price of the target product according to the evaluation results (* 3)
- lower prices for items with poor cost-effectiveness
- Raise prices for items, etc. that lead to a decrease in medical expenses

(* 2) For anticancer drugs, etc., a higher standard than usual (7.5 million yen/QALY) will be used.
(* 3) Price adjustment range includes utility premium etc.

Guidelines for Promotion of Optimal Use (Requirements for target patients, setting of medica institutions-physicians)

For innovative and expensive drugs and cellular and tissue-based products, the use is optimized as follows.

- The pharmacological action and safety profile of drugs with innovative new mechanisms of action may be clearly different from those of existing drugs, and therefore the **Guidelines for Promotion of Optimal Use** was prepared showing the requirements for target patients and for medical institutions and physicians to use them. The contents based on the guideline were notified as points to consider for insurance application.
- Until sufficient information on efficacy and safety is accumulated, (1) **Use in patients who are expected to benefit strongly from the drug.** and (2) **Use at medical institutions meeting certain requirements so that necessary actions can be taken promptly when adverse reactions occur.**

< Number of Guidelines to Promote Optimal Use > *As of September 2021

	Total	Drug		Regenerative medicine products	
		New	Amend ments	New	Amend ments
FY 2016	3	3			
FY 2017	7	2	5		
FY 2018	12	4	7	1	
FY 2019	12	3	8	1	
FY 2020	11	2	8		1
FY 2021	13	4	5	3	1

< Flow of preparation >

Approval review (PMDA/MHLW) → **Approval** → Insurance listing procedure (MHLW) → **Insurance Coverage** → Cost-effectiveness assessments (MHLW)

(Within 60 days after approval in principle or within 90 days at the latest)

Examination of the optimal GLs (MHLW, PMDA, relevant academic societies, etc.) → **GLs formulation** → (Continuously reviewed. Revise as appropriate)

(Reference) Example of guidelines: Kymriah Intravenous Infusion

- Regenerative medicine products used for the treatment of relapsed or refractory leukemia, etc. Lymphocytes collected from the patient will be genetically modified and then intravenously administered to the patient. Approximately 34 million yen per patient (applicable on May 22, 2019)
- With the cooperation of academic societies and 8 medical associations, the optimal use promotion GL was prepared in parallel with the regulatory review, and the requirements for medical institutions and physicians, patients, etc. to be treated was specified. (Approved on March 26, 2019, issued on May 21, 2019)

< List of applicable drugs/regenerative medicine products >

Drug	Indications
Nivolumab (Opdivo Intravenous Infusion)	Malignant melanoma, non-small cell lung cancer, renal cell carcinoma, classical Hodgkin lymphoma, head and neck cancer, gastric cancer, malignant pleural mesothelioma, esophageal cancer, and MSI-High colorectal cancer
Pembrolizumab (Keytruda Injection)	Malignant melanoma, non-small cell lung cancer, classical Hodgkin lymphoma, urothelial carcinoma, MSI-High solid cancer and colorectal cancer, head and neck cancer, renal cell cancer, esophageal cancer, breast cancer
Avelumab (Bavencio Intravenous Infusion)	Merkel cell carcinoma, renal cell carcinoma, urothelial carcinoma
Durvalumab (Imfinzi I.V. Infusion)	Non-small cell lung cancer, small cell lung cancer
Atezolizumab (Tecentriq I.V. Infusion)	Non-small cell lung cancer, breast cancer, small cell lung cancer, hepatocellular carcinoma
Alirocumab (Praluent Subcutaneous Inj.)	Familial hypercholesterolaemia, hypercholesterolaemia
Evolocumab (Repatha Subcutaneous Inj.)	Familial hypercholesterolaemia, hypercholesterolaemia
Dupilumab (Dupixent Subcutaneous Inj.)	Atopic dermatitis, bronchial asthma, chronic sinusitis
Omalizumab (Xolair Subcutaneous Inj.)	seasonal allergic rhinitis
Baricitinib (Olumiant Tablets)	atopic dermatitis

Drug	Indications
galcanezumab Emgality Subcutaneous Injection	Prevention of migraine attacks
Fremanezumab (Ajovy Subcutaneous Injection)	Prevention of migraine attacks
Erenumab (Aimovig Subcutaneous Injection)	Prevention of migraine attacks
Upadacitinib (Rinvoq Tablets)	Atopic dermatitis

Regenerative medicine products	Indications or performance
Human (autologous) bone marrow-derived mesenchymal stem cells (Stemirac Injection)	Improvement of neurological symptoms and functional impairment associated with spinal cord injury
Tisagenlecleucel (Kymriah Intravenous Infusion)	B-cell acute lymphoblastic leukemia, diffuse large B-cell lymphoma
Axicabtagene ciloleucel (Yescarta I.V. Infusion)	Large B-cell lymphoma
Lisocabtagene maraleucel (Breyanzi IV Injection)	Large B-cell lymphoma, follicular lymphoma
Teserpaturev (Delytact Injection)	malignant glioma

Reference

Summary of FY 2022 NHI Price Revision

1. Timing

Official Gazette Notification : Friday, March 4, 2022
Actual Date of implementation : Friday, April 1, 2022

2. Major revisions

○ Based on the results of the drug price survey, the drug price standard was fully revised.

○ Calculated with the weighted average of current market prices with adjustment margin method based on the "Standard for NHI Drug Pricing " (approved by Central Social Insurance Medical Council on February 9, 2022)

○ The revision rate was ▲ 1.35% (Of which, the market price revision was ▲ 1.44% *, the special response for insurance coverage for infertility treatment was + 0.09%) on the basis of medical expenses * ▲ 6.69% on the basis of drug expenses

○ Drugs listed in the NHI drug price list (announced number) are as follows

	Internal Drug product	Note:projectile	external medicine	dental agent	combination Total
Announcement Number	7,740	3,523	2,081	26	13,370

[Reference] Weighted average of current market price with adjustment margin method

$$\text{NHI price} = \left(\text{The average purchase price per drug pricing unit of the listed product at insurance medical institutions, etc. (weighted average of the current market price without tax)}\right) \times (1 + \text{tax rate } (0.10)) + \text{Adjustment range}$$

*Including local consumption tax

Adjustment range: The adjustment range to stabilize the drug distribution and the amount equivalent to 2% of the pre-revision price

(Reference) (1)

I Revision of price of long-listed products

Note:The numbers of products in the table are based on the numbers in public notices (the same for the following slides).

1. Subject of drug price reduction (Z2) for original drugs for which generic substitution has not progressed (product list: Appendix 1 -1)

	Generic substitution rate		Total
	Less than 60%	60% to 80%	
Ingredient count	30 components	28 components	58 components
Number of items	66 products	71 products	137 products

2. Subject of reduction to generic price (G1/G2/C) of long-term listed products for which 10 years have passed since generic listing (product list: Appendix 1 -2)

Category			Ingredient count	Number of items
G1 (including those to be brought forward)			109 ingredients (18 ingredients * and)	267 products (54 products *)
G2 (including those subject to acceleration)			104 ingredients (1 ingredient *)	192 products (9 products *)
C	Generic substitution rate	Less than 60%	139 components	319 products
		60% to 80%	113 components	223 products
	Total of C		252 components	542 products
Total			465 components	1,001 Products

*Number of Products Included in G1/G2 Accelerated

3. Products for which the generic drugs replacement rate exceeded 80% in the fiscal year 2020 or 2022 revision (excluding 2.): 23 ingredients and 59 products (product list: Attachment 2)

II Premium at the time of revision of listed products

○**Target product** (Product list: Attachment 3)

	Pediatric Use	Rare Diseases	Pioneering Medicinal Product	Specific Use	True Clinical Benefit	Total
Ingredient count	10 components	15 components	1 component	0 component	0 component	26 components
Number of items	29 items	39 items	1 Product	0 items	0 items	69 items

(Reference) (2)

III Repricing for market expansion

○**Target product** (Product list: Attachment 4)

	Repricing for Market Expansion	Repricing for market expansion (special case)	Repricing for dosage and administration changes
Ingredient count	17 components	4 components	2 components
Number of items	78 products	6 products	2 products

IV Generic drug price range

1. Generic price band (excluding 2.)

Note:The price may be the same between price bands due to the processing of the minimum price, etc. (Same for 2.)

Number of price range	Ingredient specification quantity	Number of ingredient specifications per price against the highest price		
		Less than 30%	30%~50%	Not less than 50%
1	886	13	163	710
2	173	83	168	92
3	54	52	54	48
4	1	1	1	1

2. Generic drug price range for G1/G2 products

1) Generic drugs for G1 products to be withdrawn from the market

Number of price range	Ingredient specification quantity
1	1
2	3

2) Generic drugs for G1 products and generic drugs for G2 products that will not be withdrawn from the market

Number of price range	Ingredient specification quantity
1	645
2	135

V. Basic drugs

1. Basic drugs (excluding 2.) (Product list: Attachment 5)

Note:If falling under more than one category, classify into the upper category

Category	Ingredient count	Number of items
Unprofitability	166 components	536 products
Pathogenic organism	98 components	377 products
Narcotic	9 components	24 items
Herbal medicine	46 components	55 products
Ointment base	3 components	9 products
Dental local anesthetic	1 component	3 products
Total	323 components	1,004 Products

2. Basic drugs for drugs to ensure stable disease (List of products: Attachment 5)

Category	Ingredient count	Number of items
The original drug is a G1/G2 product	6 components	67 items
Other than the above	2 components	2 products
Total	8 components	69 items

(Reference) (4)

VI Unprofitable item repricing

1. Products unprofitable and for which drug prices have been raised or maintained

Target ingredients: 131 ingredients

Number of products: 440 products

2. Major products

Note:General-purpose specification if there are

Ingredient name	Specification unit	Pre-revision price	Price after revision	Remarks
Quercus Fruit	10 g	11.00 yen	22.00 yen	crude drug
Glucose	1 bag of 5% 500 mL	177 yen	221 yen	Infusion
Basic solution for intravenous hyperalimentation	1 bag of 250 mL	306 yen	398 yen	Infusion
Spiramycin Acetate	1 tablet of 200 mg	42.40 yen	52.60 yen	Antibiotics
Propranolol Hydrochloride	0.1% 2 mL 1-tube	81 yen	122 yen	Antiarrhythmic agents

VII Premium for New Drug Development and Resolution of Off-Label Use

1. Premium (List of Products Subject to Product Quality Review and Companies: Attachments 6 and 7)

Note:If falling under multiple categories, classify into the upper category (Other requirements include (6) pioneering drugs, (7) drugs for specific use, and (8) drugs for the treatment of drug-resistant bacteria, but none of them correspond to (7).)

Requirements	Ingredient count	Number of items
① Premium product	87 components	162 products
② Products publicly offered for development	13 components	23 products
③ Orphan drug	187 components	277 products
④ Drugs with a novel mechanism of action meeting the standards	42 components	69 items
⑤ Within 3 years from a drug with a novel mechanism of action and within 3 ranks, the first product is a product eligible for premium or a product meeting the standards	20 components	40 items
Total	348 components	571 items

○Number of companies in each company category (Percentage of companies in each category in parentheses)

	Category I	Category II	Category III	Total
Number of companies	22 companies (24%)	47 companies (52%)	21 companies (23%)	90 companies (100%)

○Premium for the PMP: Approximately 52 billion yen

2. Deduction of cumulative amount of the PMP received to date (List of target products: Appendix 8)

○Deductions

Number of ingredients: 65 ingredients

Number of products: 145 products

○Deductions for PMP: Approximately 86 billion yen

2021 Drug Price Survey Results (1)

1. Mean discrepancy rate 7.6%

※ $$Mean\ discrepancy\ rate = \frac{Total\ of\ (Current\ drug\ price \times Volume) - Total\ of\ \ (market\ price \times Volume)}{Total\ of\ \ (Current\ drug\ price\ \times Volume)}$$

2. Percentage of generic drugs in volume 79.0%

※ $$Percentage\ of\ generid\ drugs\ in\ volume = \frac{(Volume\ of\ generic\ drugs)}{(Volume\ of\ Original\ drugs\ with\ generic\ drugs)\ +\ (Volume\ of\ generic\ drugs)}$$

3. Amount of proper effect on medical expenses by replacement with generic drugs (annual estimation) 1,924.2 billion yen

Of which, the amount of proper effect on medical expenses by replacement with biosimilars (annual estimation) 48 billion yen (21.8% of total amount of biosimilars)

* The amount of reasonable effect on medical expenditure is calculated by the following formula assuming that the corresponding original drug is individually traded for all of the generic drugs.

$$The\ amount\ of\ reasonable\ effect\ on\ medical\ expenditure$$
$$= Total\ of\ \{\ (current\ drug\ price\ of\ original - current\ drug\ price\ of\ generic\ drug) \times volume\ of\ generic\ product\}$$

※ $$Volume\ of\ Biosimilar = \frac{Total\ of\ \ (Current\ drug\ price\ of\ Biosimilar \times Volume)}{Total\ of\ \ (Current\ drug\ price\ of\ Original\ \times Volume) + Total\ of\ \ (Current\ drug\ price\ of\ Biosimilar \times Volume)}$$

4. Settlement rate (NHI price basis) 94.1%

*Settlement rate (NHI price basis) is based on the results of the Survey on the Status of Price Settlement (for September 2021)

2021 Drug Price Survey Results (2)

5. Survey object and recovery rate

(1) Sales side survey

All sales offices, etc. of drug wholesalers that sell drugs to insured medical institutions and pharmacies are covered.
Number of objects to be inspected 6,476 objects (86.1% recovery)

(2) Purchase side survey

① Hospitals extracted from the total number of hospitals with an extraction rate of 1/20 by the stratified random sampling method were targeted.
Number of objects to be inspected 410 objects (72.9% recovery)

② Clinics extracted with 1/200 extraction rate by the stratified random sampling method from the total number of clinics are included.
Number of objects to be inspected 512 objects (74.2% recovery)

③ Pharmacies extracted from the total number of health insurance pharmacies with an extraction ratio of 1/60 by the stratified random sampling method are included.
Number of objects to be inspected 1,017 objects (81.3% recovery)

6. Proportion in each field

Classification		Number of items	Proportion of drug price base to total	Quantity ratio to total
Original drug	No generic drugs	2,363	59.9%	15.1%
	Generic drug present	1,721	16.5%	14.3%
Generic drug		6,171	16.8%	50.3%
Other items		3,115	6.8%	20.2%