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

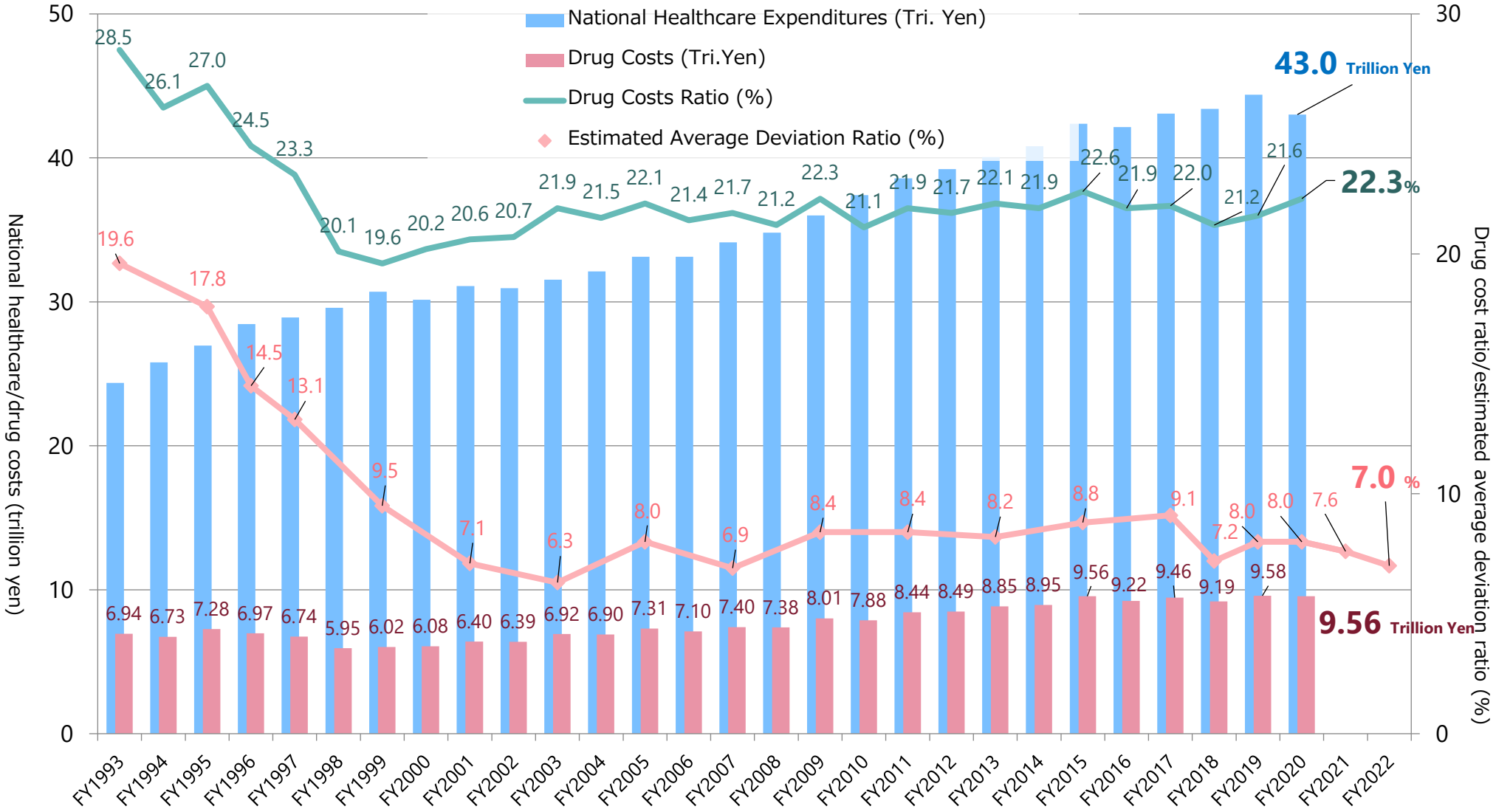
Health Insurance for Sustainable Universal Health Coverage in Japan

12th Joint Conference of Taiwan and Japan on Medical Products Regulation

Policy Planning division for Pharmaceutical Industry Promotion and Medical Information Management,
Health Policy Bureau, MHLW

Ministry of Health, Labour and Welfare of 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

Overview of Medical Service Regime in Japan

- 75 years or older
  10% copayment
  (Those with income comparable to current workforce have a copayment of 30%.
  Except for those whose income is comparable to the current workforce; those persons whose income is a certain level or higher must bear 20% of the medical costs (copayment) effective from October 1, 2022.)
- 70 to 74 years old
  20% copayment*
  (Those with income comparable to current workforce have a copayment of 30%)
- Start of compulsory education to 69 years old
  30% copayment
- Yet to start compulsory education
  20% copayment

Patient (insured)

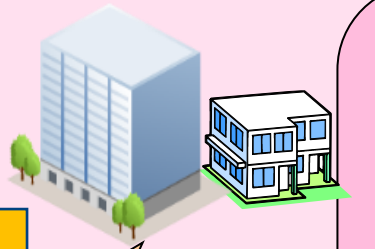
Copayment: 5 trillion yen

(2) Receive service & copayment

(3) Clinical service

Medical expenditure: ¥43 trillion

[Medical Service Regime]



Hospital:	8,205
(Number of beds:	1,500,057)
Clinic:	104,292
(Number of beds:	83,668)
Dental clinic:	67,899
Pharmacy:	60,171

* Numbers as of October 1, 2021
(Source: 2021 Survey of Medical Care Institutions)

* No. of pharmacies as of March 31, 2019
(Source: FY2019 Report on Public Health Administration and Services)

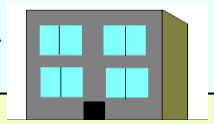
Insurance premium: ¥21.3 trillion

(1) Insurance contribution

(5) Payment

(4) Claims

Insurer



[Medical insurance system]

Administrative bodies

National
Prefectural
Municipal governments

Public funding

Public funding

Supportive contribution

Respective insurer

(Principle schemes)	(Number of insurers)	(Number of enrollment)
National Health Insurance	1,716	approx. 26 million
Japan Health Insurance Association administered health insurance	1	approx. 40 million
Association/union administered health insurance	1,388	approx. 29 million
Mutual aid association	85	approx. 9 million

* No. of insurers and enrollments as of March 31, 2021

Medical Care System for the Elderly Aged 75 and Over	47	approx. 18 million

* Number of those enrolled is as of the end of March 2021

Physician	339,623
Dentist	107,443
Pharmacist	321,982
Registered nurse	1.32 million
Public health nurse	67,000
Midwife	42,000

* No. of physicians, dentists, and pharmacists as of December 31, 2020
(2020 Survey of Physicians, Dentists and Pharmacists)

* No. of registered nurses, public health nurses and midwifes as of 2020
Statistics of the Nursing Division, the MHLW

Overview of the Current NHI drug price system

1. The drug price standard sets the price of drugs when they are paid by the medical insurance to health insurance medical institutions or health insurance pharmacies (health insurance medical institutions, etc.).

2. The NHI drug price standard was announced by the Minister of Health, Labour and Welfare based on the "Standards for Drug Pricing" prepared by the Chuikyo on February 7, 1990.

3. The prices specified in the NHI drug price standard shall be periodically revised based on the results of investigation (drug price survey) of the actual sales price (market price) to medical institutions and pharmacies.

National Health Insurance Drug Price Standard

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)

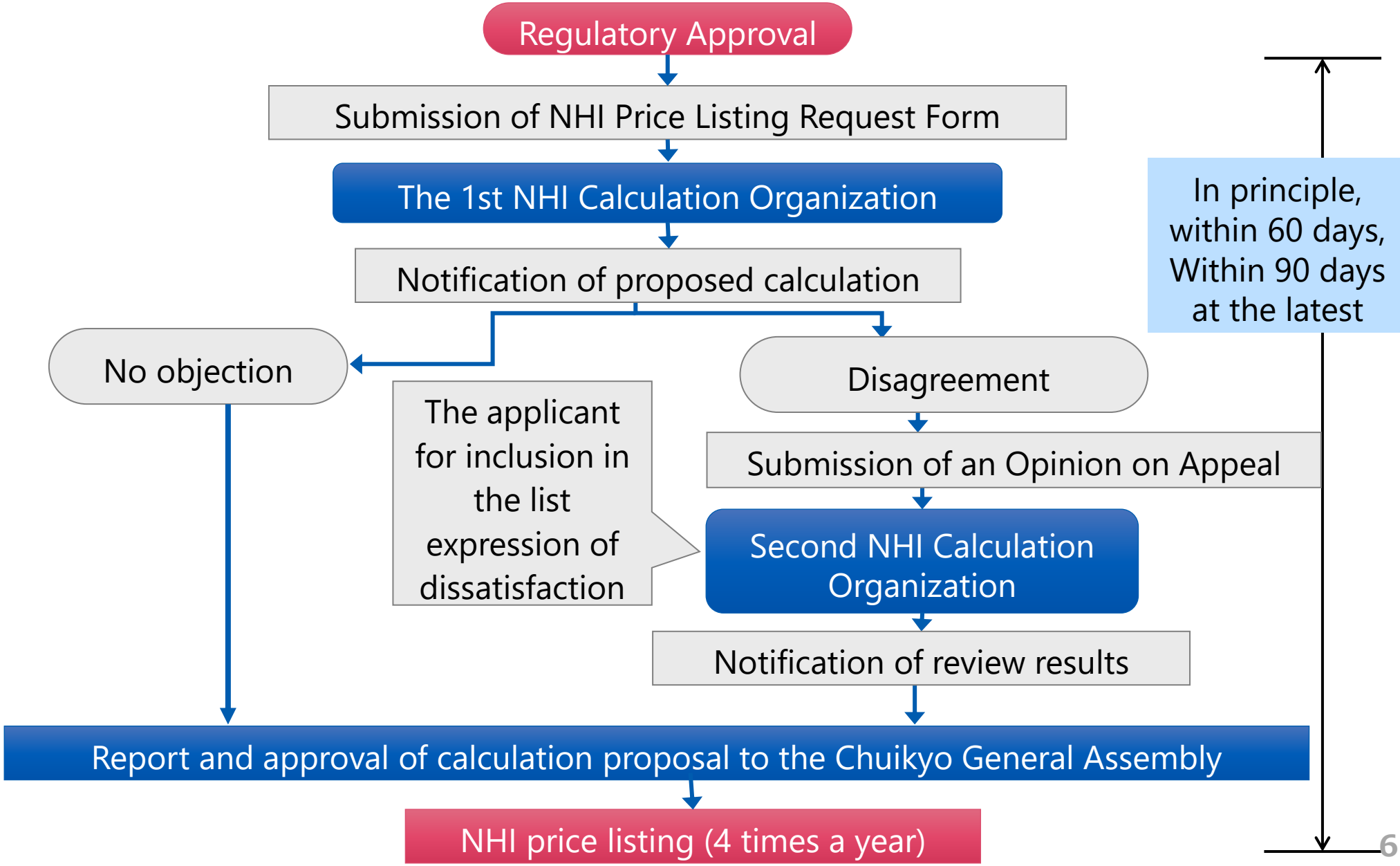
- Item list
  - A doctor or pharmacist operating under the health insurance program, in principle, must not use drugs other than “Drugs the Minister of Health, Labour and Welfare specifies”.
  - Items listed in the NHI Drug Price Standard are stipulated as “Drugs the Minister of Health, Labour and Welfare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

New Drug Price Calculation Method for New Drugs (Overall picture)



Drug Pricing Process

General Meeting (Chuikyo)
(established in 1950)

Reports

Reports

Special Committee on Drug Prices *(established in 1990)*
- Investigation and deliberation of technical matters related to drug price system reform
- Preparation of drug pricing standards once every 2 years and reporting to the General Meeting

Reports

Drug Pricing Organization *(established in 2000)*
- Members are experts in medicine, dentistry, pharmacology, and health economics.
- In accordance with the drug pricing standards and Regarding individual products examine the following and report to the general meeting
  - Calculation of new drugs, (quarterly listing)
  - Examination of premium rates for repricing for market expansion, etc. (every 2 years)
  - Other (consideration of drug classification, etc.) (as needed)
- Opinions on revision of drug pricing system, compile, report to the Special Committee on Drug Prices, (every 2 years)

Overview of FY 2024 NHI Drug Price System Reform

○In the reforms to the drug pricing system in FY 2024, actions will be taken based on the following points based on the Basic Policy 2023.

- ➢ In order to enhance our country's drug discovery capabilities and eliminate drug lag/loss, NHI drug price measures will be taken to promote appropriate evaluation of the innovation of innovative new drugs.
- ➢ In order to solve the problem of stable supply mainly of generic products, we will promote the shift of the industrial structure of generic product companies and take measures for drug prices to ensure stable supply of products with high medical needs.

○By taking these measures for NHI drug prices and proceeding with further replacement of long-term listed products with generic products in an unconventional manner, we will promote a shift in our country's pharmaceutical industry from a model that relies on long-term listed products to a R & D-type business model with high drug discovery capabilities.

< Major reform items >

Evaluation of innovation, drug lag / Actions to eliminate drug loss

- Maintenance of drug prices during patent period for innovative new drugs (revision of PMP)
- Evaluation of new drugs promptly introduced to Japan (new premium)
- Promote pediatric medicinal product development
  (Evaluation of pediatric indications developed simultaneously with adults, enhancement of premiums at the time of listing/revision, etc.)
- Enhancement of usefulness evaluation, etc. of innovative new drugs
  (Enhancement of premium at listing/revision, etc.)
- Readjustment of repricing for market expansion (Exemption of similar products in certain areas)

Ensuring a stable supply of pharmaceuticals

- Evaluation of generic companies that can ensure stable supply
  (Evaluation based on company indicators for stable supply, etc.)
- Expand the scope of “basic drugs” that maintain drug prices
  (Period after NHI price listing: ≥ 25 years → ≥ 15 years)
- application of special measures to repricing unprofitable products
  (For products with discrepancy rates below a certain level [7.0%])

Review of health insurance benefits for long-term listed products

*Introduction of a system for selective medical treatment
(To be enforced from October 2024)

Major reform items in FY 2024 drug pricing reform

1 Elimination of drug lag/drug loss Evaluation of innovation in innovative drugs

(1)Evaluation of early introduction in Japan

- Evaluation of products that were introduced to Japan early in accordance with the Sakigake Premium (priority review products and products that meet the requirements such as within 6 months after the first approval in Europe and the US) (accelerated introduction premium)
- Increase in foreign price adjustment after listing, etc.

(2)Review of the Premium System for the Promotion of Innovative Drug Discovery and Resolution of Off-Label Use

- Maintenance of drug prices during the premium target period (abolition of premium coefficients by company category, etc.)
- Addition of target products (Pediatric drugs, rapid introduction premium)

(3)Evaluation at the time of NHI price listing of new drugs

- Enhancement of evaluation of usefulness premium
- Flexible judgment of premium rates such as marketability premium and pediatric premium

(4)Evaluation at the time of the NHI drug price revision

- Enhancement of premium at revision for addition of multiple efficacies (evaluation for each efficacy)
- Enhancement of evaluation of premium at revision for products qualifying for price maintenance premium (change of premium method)

(5)Evaluation of Medicinal Products for Pediatric Use

- Flexible judgment of premium rates; addition to the eligibility for price maintenance premium
- Increase in premium rate when the pediatric development plan is formulated at the same time as the adult development and approval is obtained

(6)Evaluation of innovation in new modalities

- Continued consideration will be given to improving the disclosure level under the cost calculation method.
- Assessment of new modalities including cellular and tissue-based products toward the next revision

(7)Other matters related to innovation evaluation

- Evaluation of products that are expected to be positioned as standard therapies
- Review so that G1/G2 products can be used as comparators

(8)Readjustment of repricing for market expansion

- Excluding the application of the previously specified areas as similar products (from 2024Q4)

(9)Handling of long-term listed products

- The revision rules will not be reviewed, but the status of substitution of generics, etc. will be verified and further measures on drug prices will be considered in light of the review of the way of health insurance benefits for long-term listed products.

(2) Focused on generic products Measures to ensure a stable supply of pharmaceuticals

(1)Company Approach to Ensure Stable Supply of Generics

- Introduction and evaluation of company indicators for stable supply, visualization of information related to stable supply
- Consolidate generic products of companies with higher ratings to prices different from the usual three price ranges
  (Drugs with assured stability A/B for which stability is assured within 5 years after listing)

(2)Price of generics at the time of new listing

- If there are more than 7 oral drugs to be simultaneously listed, multiply by 0.4 (current: more than 10)

(3)Enhancing price support systems

- Expand the scope of basic drugs from 25 years after listing to 15
- Repricing of unprofitable products was applied to all products requested by companies (for products with discrepancy rates below a certain level [7.0%])

(3) Other issues

(1)Drug distribution

- Issues in drug distribution including unevenly distributed drug price differences will be continuously discussed based on the results of discussions at related meetings.
- The adjustment range will be continuously examined based on the above examination.

(2)NHI drug price revision in a year without medical service fee revision

- Continued discussion (FY 2024, discussion to be started promptly)

(3)Handling of Expensive Drugs

- For products whose market size is expected to exceed 150 billion yen per year, the drug pricing method will continue to be discussed at the general meeting of Chuikyo prior to usual drug pricing.

< Verification of drug pricing reform, etc. >

- Analyze and evaluate the impact on drug development, such as the creation of innovative new drugs and the elimination of drug lags/drug losses, in cooperation with the pharmaceutical industry, and continue to discuss how drug prices should be for innovative new drugs.
- In order to ensure a stable supply of drugs, the validity, etc. of this corporate indicator and evaluation method will be verified, and the concept of companies that can ensure a stable supply and the handling of evaluation results in the drug price system will be continuously discussed.

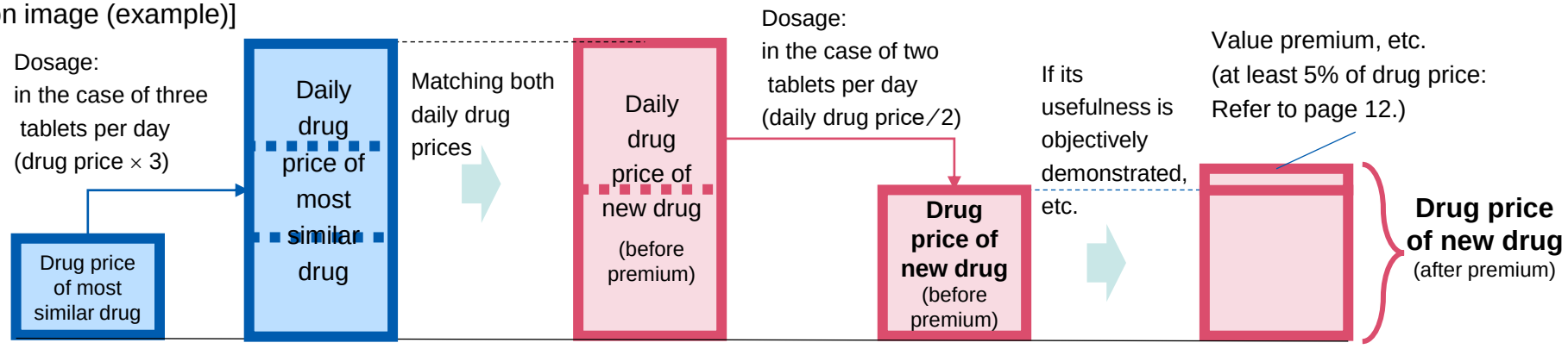
Similar Efficacy Comparative Method (I)

Calculation rule

- If there are similar drugs* to a new drug to be newly listed in the drug price standard, the daily drug price of the new drug shall be matched to that of the drug with the highest similarity (most similar drug) from the perspective of ensuring fair competition in the market.
- If it is objectively demonstrated that the new drug is more useful than the similar drug, a corrective premium shall be applied to the above amount.

*Similar drug: Those drugs having similarities in terms of (a) to (d); (a) indication and effect, (b) pharmacological action, (c) composition and chemical structural formula, and (d) administration route, dosage form category, and dosage form and dosing regimen

[Calculation image (example)]



Cost Calculation Method

- If there are no similar drugs, add up material costs, manufacturing expenses and other items.

(Example)

(1) Material costs	(Active ingredients, excipients, containers and boxes, etc.)
(2) Labor costs	(= 3,636[Note 1] × working hours)
(3) Manufacturing expenses	
(4) Product manufacturing (import) cost	
(5) Selling expenses, research expenses, etc.	((5)／((4) + (5) +(6)) ≤ 0.505[Note 2])
(6) Operating profit	((6)／((4) + (5) + (6)) = 0.166[Note 2])
(7) Distribution costs	((7)／((4) + (5) + (6) + (7)) = 0.071[Note 3])
(8) Consumption tax	(10%)
Total: Calculated drug price	

However, the upper limit of the selling, general, and administrative (SGA) ratio shall be 70% for chemical products with a degree of disclosure ≥ 80% and for biopharmaceuticals with a degree of disclosure ≥ 80% and in which only research and development expenses exceed the upper limit of the SGA ratio (50.6%) (limited to those with a peak market size of less than 5 billion yen).

For regenerative medicine products, the distribution cost shall be closely investigated for each item. If it is lower than the amount calculated by the average coefficient, the lower amount shall be used for calculation.

Note 1 Unit labor cost: “Monthly Labour Survey” and “General Survey on Working Conditions” (Ministry of Health, Labour and Welfare)
Note 2 Selling, general and administration expenses ratio operating profit margin: “Handbook of Industrial Financial Data” (Development Bank of Japan Inc.)
Note 3 Distribution cost ratio: “Statistics on Pharmaceutical Industry Report” (Economic Affairs Division, Health Policy Bureau, Ministry of Health, Labour and Welfare)
In principle, the above figures shall be the average coefficients in the pharmaceutical industry (averages over the last three years [2019 to 2021] obtained at the end of the previous fiscal year).

- If the new drug is found to be more useful than existing therapies, a corrective premium shall be applied to the above amount.
- However, the premium rate shall vary depending on the percentage of parts that can be disclosed by the drug pricing organization (degree of disclosure) out of the total product cost.

Amount of the premium = Total price (Price before premium) × Premium rate (0% to 120%) × Premium coefficient (0 to 1)

Degree of disclosure	80% or more	50% to 80%	Less than 50%
Premium coefficient	1.0	0.6	0

* Degree of disclosure = (Parts of the drug price that can be disclosed)／(Total product cost: (4), (5))

Adjustment premium at time of new drug listing

Innovation premium (70 ~ 120%)

Newly listed products that **meet all** the following requirements
(a) Have **clinically useful novel mechanism of action.**
(b) It has been objectively shown to have **high efficacy or safety** compared with similar drugs or existing therapies.
(c) The newly listed product has been objectively shown to **improve the treatment method** for the disease or injury targeted by the newly listed product.

Usefulness premium (I) (35 ~ 60%)

Newly listed products that **meet two of the three requirements** of the innovation premium

Usefulness premium (II) (5 ~ 30%)

Newly listed products * (a) to (c) that **meet any of the requirements** below are the same as the requirements for the innovation premium.
(a) It has a clinically useful novel mechanism of action.
(b) It has been objectively shown to have high efficacy or safety compared with similar drugs or existing therapies.
(c) The newly listed product has been objectively shown to improve the treatment method for the disease or injury targeted by the newly listed product.
(d) it has been objectively demonstrated to exhibit higher medical usefulness **compared to similar drugs or existing therapies due to its innovative formulation.**

Determined by the number of requirements met

*If more than one adjustment premium is applicable, the sum of the proportions of each premium shall be used for calculation. (For cellular and tissue-based products, the premium rate shall be adjusted according to the market size, etc.)

Marketability premium (I) (10 ~ 20%)

Orphan drug for which the efficacy/effectiveness related to the target disease, etc. is the primary efficacy/effectiveness

Marketability premium (II) (5%)

Products for which the primary efficacy/effectiveness corresponds to an efficacy separately specified as **products with a small market size**

Specified use premium (5 ~ 20%)

Products designated as **Specified drug**

Pediatric premium(5 ~ 20%)

Products for which the primary **efficacy/effectiveness** or the **dosage and administration** related to such efficacy **explicitly includes a pediatric efficasy**

Not calculated

Sakigake Premium (10 ~ 20%)

Products designated as **pioneering drugs** (including products designated under the old system)
< Developed in Japan first in the world > 【 New 】

Rapid introduction premium (5 ~ 10%)

Products that are introduced in Japan in an expedited manner in accordance with the above (products that meet the following requirements)
・Products under international development (e.g., implementation of global clinical trials)
・Priority Review Items
・Products for which application and approval are earlier than those in the US and Europe or within 6 months after the first application and approval in the US and Europe

Not calculated

*Not eligible for premium if comparator drug receives premium (With some exceptions.)

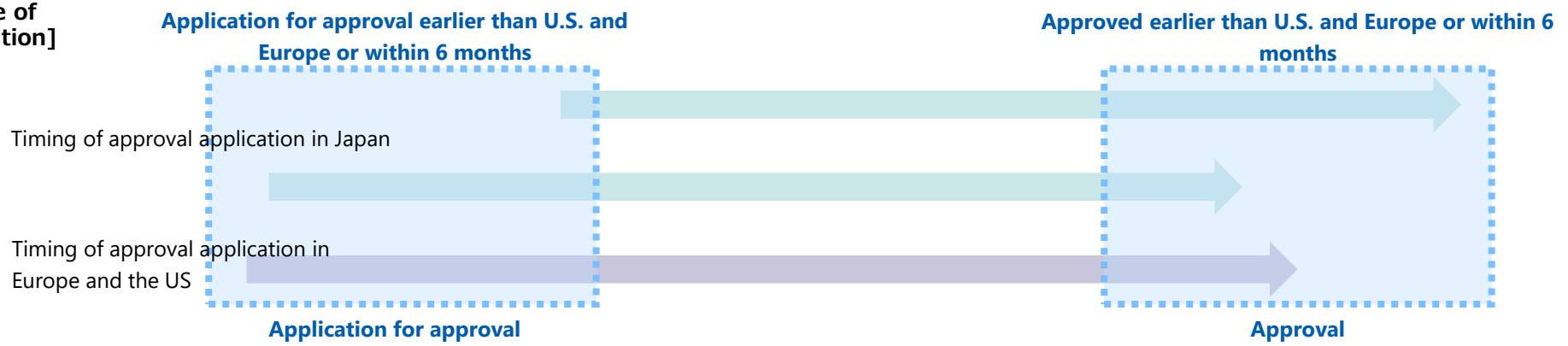
Evaluation of accelerated introduction to Japan (Rapid Introduction Premium)

(**New in FY 2024**)

Calculation Rules

- As a treatment in accordance with the Sakigake premium corresponding to pioneering drugs in the pharmaceutical affairs system, the **Rapid Introduction Premium** (A=5~10%) is applied to products that meet all of the following requirements at the time of new listing.
  - Products **developed by conducting global studies** or **developed by conducting clinical studies at the same time as or before overseas** in Japan
  - **Priority Review Items** in the Pharmaceutical and Medical Device Act
  - Products for which **application for approval is earlier than that in Europe and the US** or **within 6 months after the earliest application in Europe and the US** is approved for the indication
  - Products for which **approval is earlier than that in Europe and the US** or **within 6 months after the earliest approval in Europe and the US** is specified for the indication
- **Revision premium, correction premium for repricing for market expansion** shall be applied to products for which additional efficacy have been added satisfying the above requirements.

[Image of application]



Reference data

[Sakigake premium] (A =10~ 20%)

・Those designated as **pioneering drugs** in accordance with the Pharmaceutical and Medical Device Act (including products designated under the old system)

*Requirements for designation as a pioneering drug: (1) innovation of the therapeutic drug, (2) seriousness of the target disease, (3) extremely high efficacy for the target disease, (4) Intention/system for early development/application in Japan ahead of the world (application ahead of the world or within 3 months after the first application in other country)

Evaluation of early introduction in Japan

Outline of drug pricing reform

② **Foreign Average Price Adjustment After Listing** [Revision of Standards]

- The post-listing foreign average price adjustment shall be applied to products listed in FY 2024 and thereafter in addition to the current cost calculation method, **it shall also be applied to products priced with the similar efficacy comparison method (I).** Specifically, for drugs meeting all of the following requirements, a foreign average price adjustment shall be applied only once at the time of the drug price revision. Provided, however, that this shall be limited to the period until a generic product pertaining to the drug is NHI price listed or 15 years have elapsed since the date of NHI price listing.
- The price adjustment method will be in accordance with the rules for foreign average price adjustment at the time of listing, but **price increases** should be **up to 1.20 times the pre-revision drug price**, since it is necessary to consider the impact on increased burden on patioents, etc.

< Applicable drugs >

- products for which drug substance or drug product are imported
- Products for which no foreign price can be referred to at the time of NHI price listing
- Products for which any foreign price was posted for the first time after NHI price listing

[Outline of review]

	Current	After review	[Reference] Price adjustment at listing
Price adjustment	Reduction only	Reduction + **hike** *	Reduction + Increase *
Target product item	Only for Costing Items	Costing Items **Products with similar efficacy comparison method (I)**	Costing Items Products with similar efficacy comparison method (I)

*Increase only if foreign prices are in 2 or more countries

Evaluation of Medicinal Products for Pediatric Use

- Pediatric drugs were not eligible for the PMP by themselves, but they are now eligible for the PMP as a result of the present revision. (Includes products for which pediatric efficities were added after listing.)

(**Red letters**: Revised part)

	At the time of new listing/at the time of initial regulatory approval		At the time of drug price revision/at the time of approval of additional efficity, etc.	
	Premiums to the calculated drug price	**Application of PMP**	**Premiums to the NHI drug price**	**Application of PMP**
Development of orphan drugs	○ Marketability premium (I) Marketability premium (II)	○ Item requirements	○	○ Item requirements
Pediatric Medicinal Product Development *Excluding those designated as special use drugs	○ Pediatric premium **Approval based on the pediatric development program ⇒ Premium rate increased**	× → ○	○ **Approval based on the pediatric development program ⇒ Premium rate increased**	× → ○
Development of Drug Products for Specified Use **(if specified for the pediatric category)**	○ special use premium	○ Item requirements Company indicators	○	○ Item requirements Company indicators

Products under development according to the pediatric development plan ⇒ Mitigate the reduction rate when repricing for market expansion is applied

Premium System for the Promotion of Innovative Drug Discovery and Resolution of Off-Label Use(Overall Summary)

(**Red letters**: Revised part)

Positioning of the system

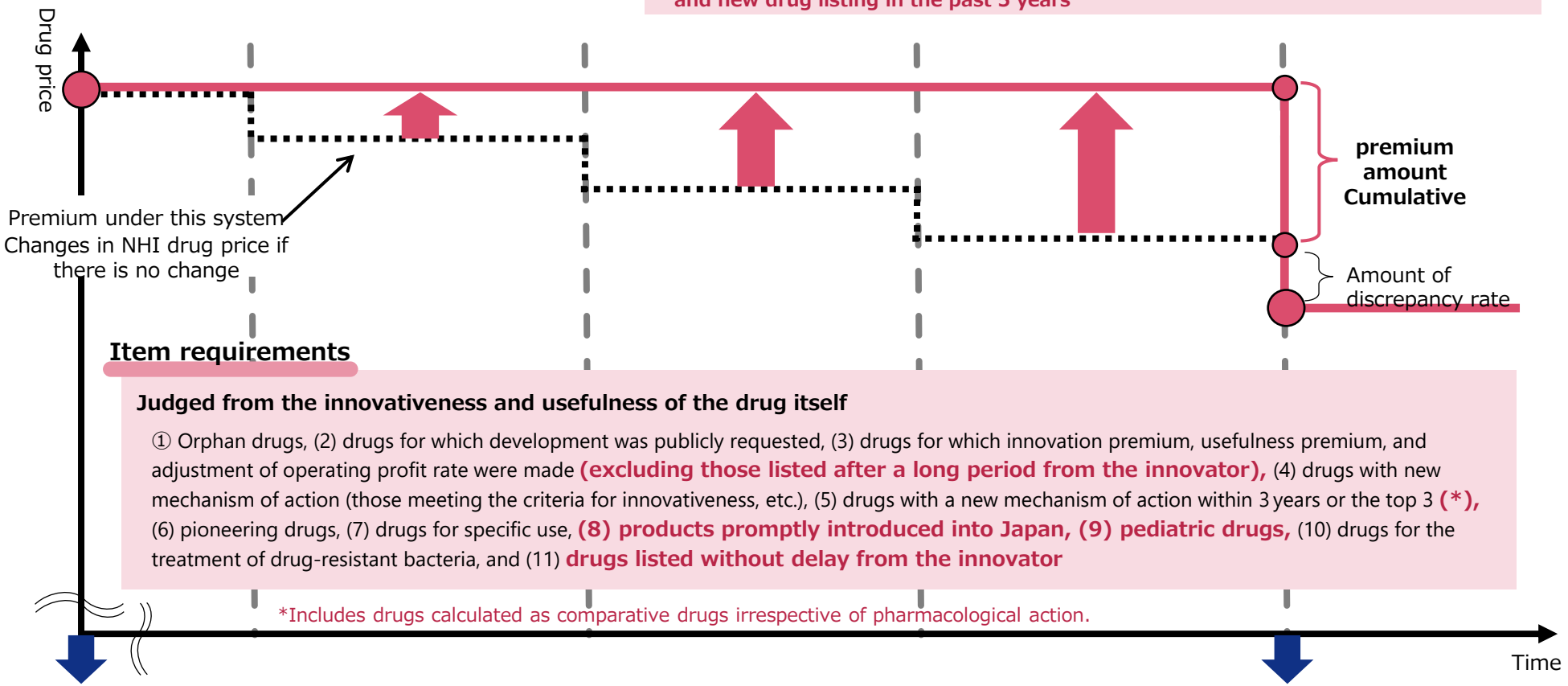
In order to promote the creation of innovative new drugs and the resolution of drug lag/loss, suspension of drug price reductions based on the actual market price of new drugs

Premium amount

○**Addition of the amount to maintain the pre-revision price**
○**However, products exceeding the average discrepancy rate shall not be added.**

Company requirements

○Appropriate response to development requests from MHLW
○**Has a track record of new drug development, including conduct of domestic studies and new drug listing in the past 5 years**



Item requirements

Judged from the innovativeness and usefulness of the drug itself

① Orphan drugs, (2) drugs for which development was publicly requested, (3) drugs for which innovation premium, usefulness premium, and adjustment of operating profit rate were made **(excluding those listed after a long period from the innovator),** (4) drugs with new mechanism of action (those meeting the criteria for innovativeness, etc.), (5) drugs with a new mechanism of action within 3 years or the top 3 **(*),** (6) pioneering drugs, (7) drugs for specific use, **(8) products promptly introduced into Japan, (9) pediatric drugs,** (10) drugs for the treatment of drug-resistant bacteria, and (11) **drugs listed without delay from the innovator**

*Includes drugs calculated as comparative drugs irrespective of pharmacological action.

Image of evaluation after NHI price listing

(**Red letters**: Revised part)

Evaluation at the time of NHI price listing (adjustment premium)

- Usefulness premium
- Marketability premium
- Pediatric premium
- Special use premium
- Sakigake Premium
- **Rapid Introduction Premium**

Evaluation at the time of drug price revision (premium at the time of revision)

- Listed products with additional efficacy/effectiveness for pediatric use, rare diseases, pioneering use or specific use
- Listed products whose true clinical usefulness has been verified after marketing
- **Listed products for which efficacy/effectiveness were added as a result of rapid introduction**

Evaluation of cellular and tissue-based products

- Medical usefulness that was not apparent at the time of initial approval when a product approved with conditions/limited term is approved again

(Evaluation of applicability of adjustment premium)

At the time of new approval

NHI price listing

NHI drug price revision

Newly eligible for the PMP
- **Pediatric Medicinal Products**
- **Products for rapid introduction**

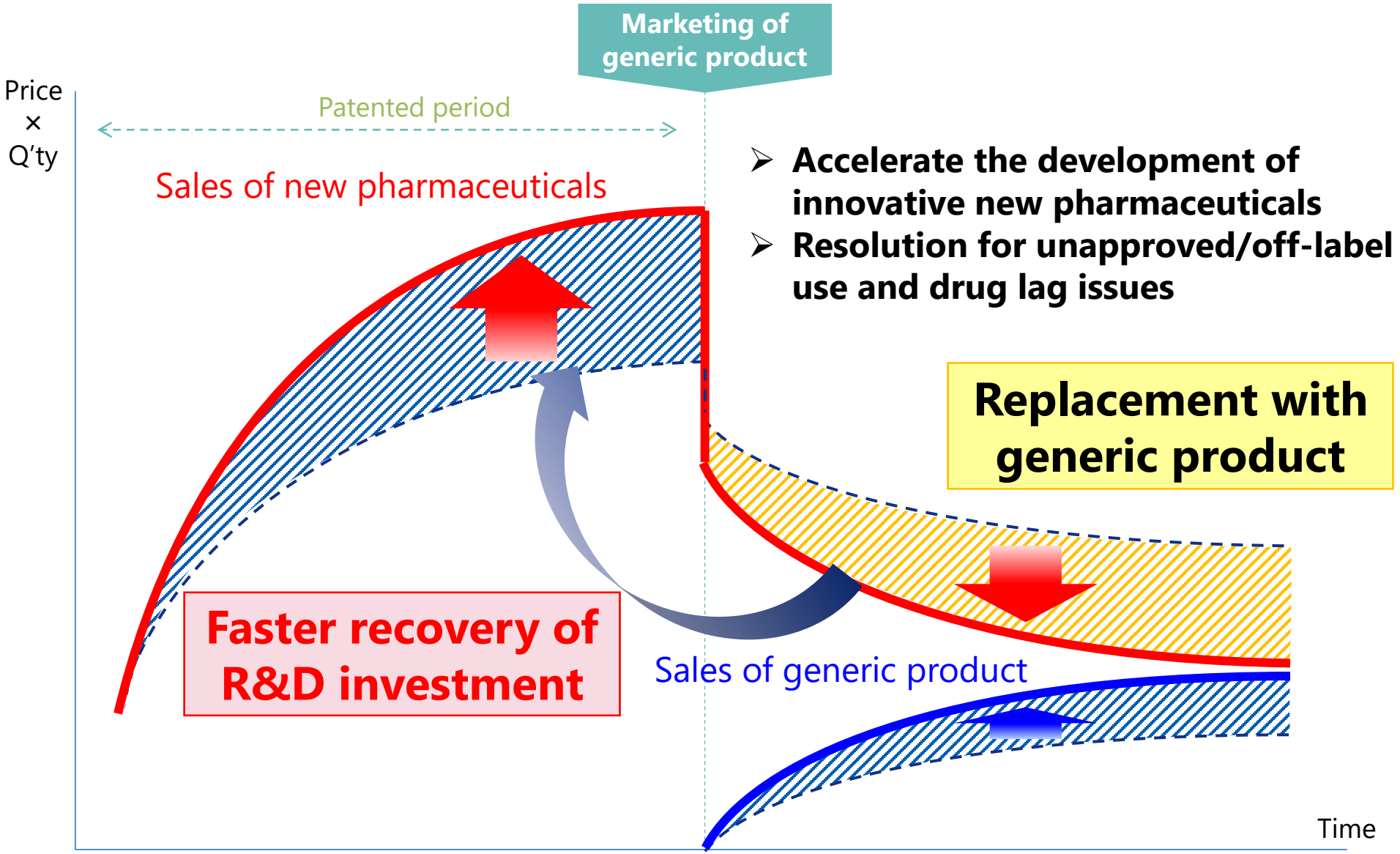
Quarterly repricing

Repricing for market expansion, etc.

Adjustment premiums for repricing based on market expansion

- Listed products with additional efficacy/effectiveness for pediatric use, rare diseases, pioneering use or specific use
- Listed products whose true clinical usefulness has been verified after marketing
- **Listed products for which efficacy/effectiveness were added as a result of rapid introduction**
- **Listed products under development based on the pediatric development plan**

Concept for new pharmaceuticals creation premium



Exception of Low-priced Drugs, etc.

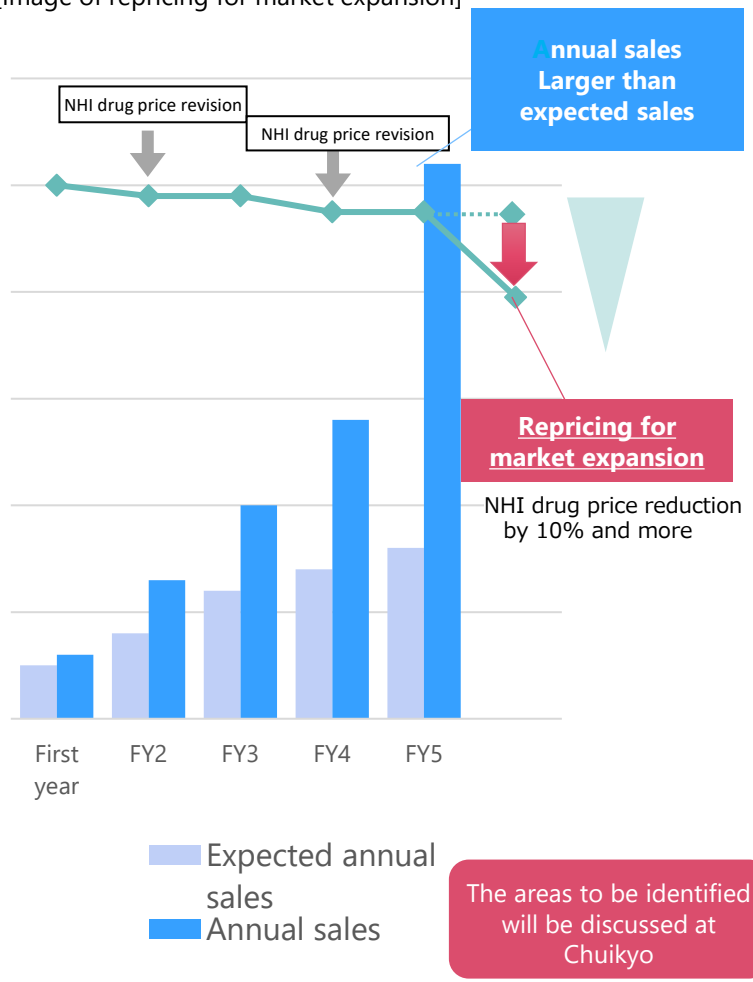
(1) Basic drugs	(Positioning of the system) • A system to support the drug price before the current recalculation of unprofitable products and the lowest drug price (Requirements of covered items) • Products with a high requirement for insured medical care • Products of which the efficacy and safety have been established as they have been widely used in clinical practice for a long period of time • Products that need to ensure the continuous and stable supply to the market (including repair of manufacturing facilities)
(2) Recalculation for unprofitable products	• Products with a high requirement for insured medical care • Products of which the minimum drug price has not been set, or which are unprofitable in the minimum drug price • Products difficult to be marketed continuously by the manufacturer due to significantly low drug price
(3) Minimum NHI price	• Price set for each dosage form regardless of ingredients to ensure the minimum cost of supply required for each dosage form

Repricing for market expansion

(**Red letters**: Revised part)

If the annual sales value is larger than the expected sales value, the drug price will be reduced under certain conditions.

[Image of repricing for market expansion]



The areas to be identified will be discussed at Chuikyo

Repricing for market expansion	Annual sales	Projected sales ratio	Drug price reduction rate	
			Cost accounting Method	Similar drug Comparison method
Repricing at the time of NHI drug price revision	**More than 10 billion yen**	**10 times or more**	10~25%	-
	More than 15 billion yen	**2 times or more**	10~25%	10~15%
Repricing other than at the time of NHI price revision (Quarterly repricing)	**More than 35 billion yen**	**2 times or more**	10~25%	10~15%
Special case repricing for market expansion (at the time of revision/quarter)	**More than 100 billion JPY up to 150 billion JPY**	**1.5 times or more**	10~25%	
	More than 150 billion yen	**1.3 times or more**	10~50%	

*Products subject to special repricing for market expansion or products revised as similar products shall not be handled as products similar to products for special repricing for market expansion or products similar to products for special repricing for market expansion even if they fall under the category of products similar to products for special repricing for market expansion. **This applies one-time only during the period of 4 years from the day following the date of application of the revision.**

***Products corresponding to the areas previously specified by Chuikyo shall not be handled as products similar to products for repricing for market expansion or products similar to products for special case repricing for expansion**, even if they correspond to the requirements for products similar to products for repricing for market expansion or products similar to products for special case repricing for expansion.

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)

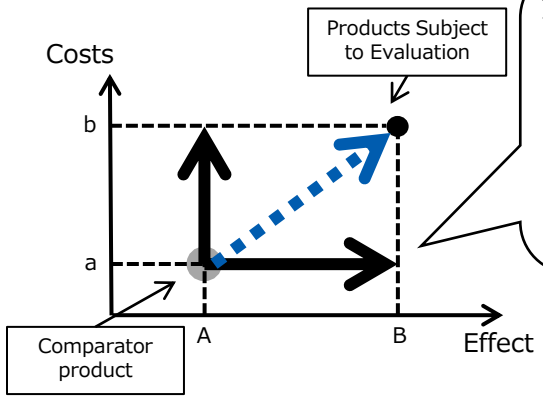
(* 1) Sponsored by the National Institute of Public Health

④ Overall Evaluation

(around Feb to Mar)

⑤ To cost-effectiveness assessments implement price adjustments based on

(Note)Periods in parentheses are standard intervals.

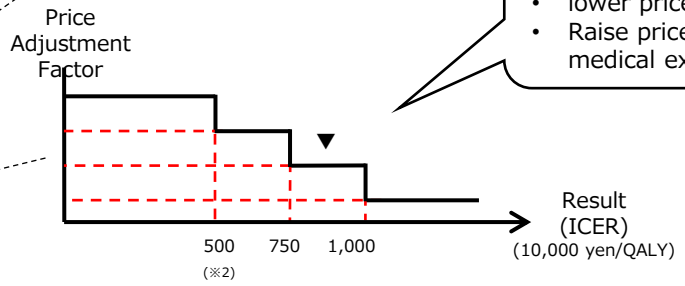


Analyze how much the cost and effect of the product subject to evaluation will increase compared to the comparator product (existing product).

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.

Mechanisms for optimizing drug costs for "high-cost drugs."

1. Optimization of drug prices

(Example.)

Foreign Average Price Adjustment

From the viewpoint of ensuring fair market competition, price adjustments will be made in the cost accounting method etc., when there is a large deviation from foreign prices at the time of NHI price listing .

Market expansion re-calculation,

The price is reduced at the time of NHI price revision, etc., when the annual sales amount exceeds a certain multiple of the projected sales amount.

Cost-effectiveness evaluation

The target of the evaluation is a pharmaceutical or medical device with a large market size or significantly high unit price, and the cost and effectiveness of the target item are analyzed in comparison with existing comparative technologies. The price of the subject item is adjusted according to the results of the evaluation.

2. Optimization of use

(Example.)

Guidelines for Promotion of Optimal Use

For drugs with innovative new mechanisms of action, the "Guidelines for the Promotion of Optimal Use" were developed, which indicate the requirements for patients and medical institutions regarding the use of such drugs. The contents based on the guideline are notified as points to be considered for insurance coverage.

Evaluation of innovation in new modalities

Outline of drug pricing reform

① Improvement of disclosure level by cost accounting method

- Improvement of disclosure level by the cost calculation method has been an issue for some time, and measures have been taken according to the disclosure level. However, considering the current situation that development of new drugs is often carried out by global emerging companies, and development and manufacturing are not completed within companies or group companies, and are carried out with involvement of various companies including outsourced companies, etc., **and therefore no particular review will be conducted in this NHI price revision and consideration will be made toward the next NHI price revision** as **reviewing with effectiveness is difficult** while avoiding the impact on drug lag/loss.
- Taking into account that the cost calculation method involves issues related to ensuring transparency, we will move forward with **considering specific measures for promoting pricing with the similar efficacy comparison method toward the next NHI price revision.**

② Evaluation of innovation in new modalities

- **Consideration toward the next NHI price revision** regarding the appropriate innovation evaluation for the drug price of innovative new drugs for which there are no similar drugs such as new modalities including cellular and tissue-based medicine products.