



For people, for life, for the future

Ministry of Health, Labour and Welfare

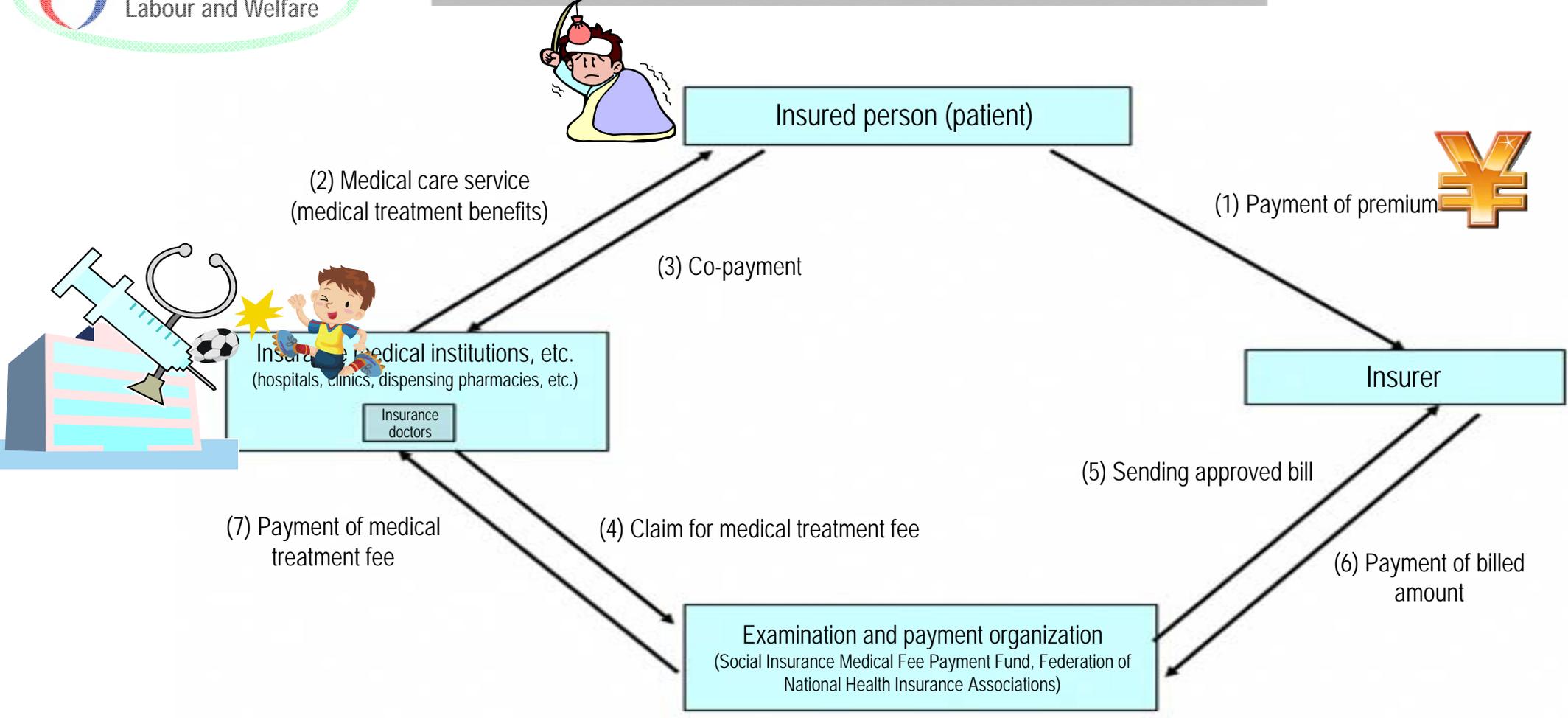
Drug Pricing System in Japan

Economic Affairs Division
Health Policy Bureau
Ministry of Health, Labour and Welfare

Overview of Today's Presentation

- National health insurance system
- Drug pricing system in Japan
- Price determination by comparable drugs
- Cost accounting system
- Various premiums
- Adjustment to average overseas price
- Premium for kits
- Calculation of prices of combination drugs

Conceptual diagram of health insurance treatment



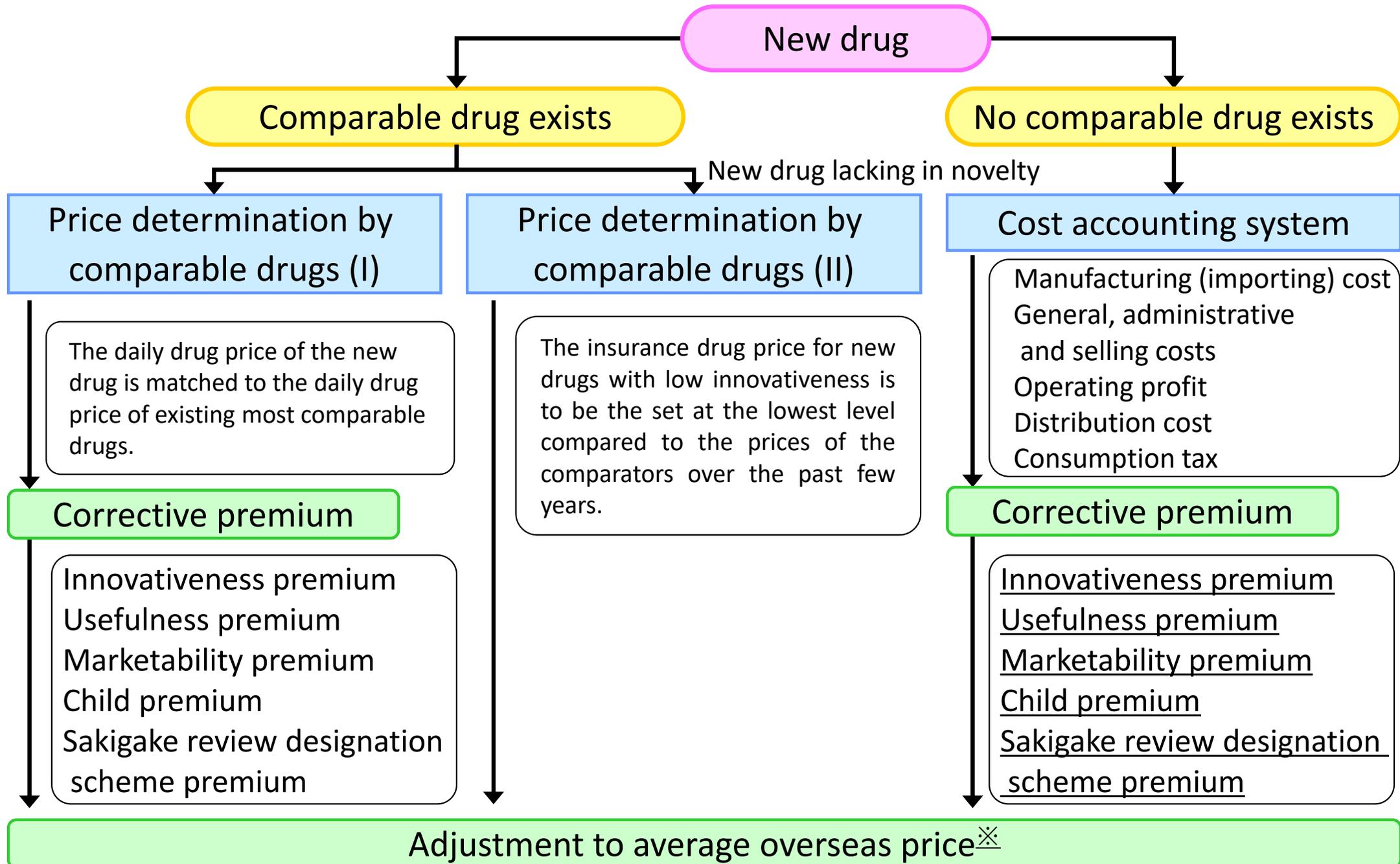
- Medical treatment fee is classified into medical, dental and dispensing fee.
- Specifically, medical fee is calculated by adding the scores given to individual medical actions that were provided, converting 1 point to 10 yen, in principle (so called, “fee-for-service system”).
- For example, when a patient is hospitalized for appendicitis, the first visit fee, hospital fee according to the number of days of hospitalization, surgery fee for appendicitis, test fee, drug fee, etc. are added. The insurance medical institution will receive the total amount less the co-payment charged to the patient from the examination and payment organization.

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 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

- When there are comparable drugs with similar efficacy, 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. [Price determination by comparable drugs (I)]
 - 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.

 =  <Daily drug price matching>
 $¥50 \times 3 = ¥X \times 2$
 $X = 75 \text{ yen}$

1 tablet = ¥50
 3 tablets a day

1 tablet = ¥X
 2 tablets a day

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, usefulness premium, marketability premium, child premium, and sakigake review designation scheme premium]

| | | |
|--|------------|---|
| 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)

- The price of new drugs with low innovativeness is set at the lowest level compared to the prices of its comparators over the past few years [price determination by comparable drugs (II)].
 - New drugs with low innovativeness: All the following conditions must be met:
 - The drug is not subject to a corrective premium
 - There are at least 3 drugs with similar pharmacological action
 - In principle, the price is set at A or B, whichever is lower.
 - A. Average daily drug price of comparable drugs that have been included in the NHI price list in the past 10 years
 - B. The lowest daily drug price of comparable drugs that have been included in the NHI price list in the past 6 years
 - If the prices A and B are higher than “C. Drug price calculated by the price determination by comparable drugs (I) (daily drug price of the most comparable drug),” then the following prices are also calculated:
 - D. Average daily drug price of comparable drugs that have been included in the NHI price list in the past 15 years
 - E. The lowest daily drug price of comparable drugs that have been included in the NHI price list in the past 10 years

The price is set at the lowest of C to E.

Cost accounting system

Add up material cost, manufacturing expenses, etc., if there is no comparable drug

Calculated drug price

Manufacturing
(importing) cost

Material cost

Personnel expenses

Manufacturing expenses

Sales cost,
research cost, etc.

Operating profit

Distribution cost

Consumption tax

Operating profit varies drastically in the range from **-50% to 0%**, depending on the level of novelty, efficacy, or safety compared to the existing therapy.

In principle, in case of exceeding the average coefficient for the pharmaceutical industry, calculation is performed using a coefficient.

Cost accounting system

- If there is no comparable drug, add up material costs, manufacturing expenses, etc.

(Example)

| | |
|------------------------------------|---|
| A. Material costs | (active ingredient, excipient, container/box, etc.) |
| B. Labor costs | (= 3,643 ^{Note 1} × working hours) |
| C. Manufacturing expenses | |
| <hr/> | |
| D. Manufacturing (importing) cost | |
| E. Sales cost, research cost, etc. | $(E/(D + E + F) \leq 0.507^{\text{Note 2}})$ |
| F. Operating profit | $(F/(D + E + F) = 0.148^{\text{Note 2}})$ |
| G. Distribution cost | $(G/(D + E + F + G) = 0.075^{\text{Note 3}})$ |
| H. Consumption tax | (10%) |

Total: Calculated drug price

However, the upper limit of the selling and administrative cost ratio shall be 70% for chemical products with a degree of disclosure $\geq 80\%$ and for biopharmaceuticals—where research and development expenses alone exceed the upper limit of the selling and administrative cost ratio of 50.7%—with a degree of disclosure $\geq 80\%$ (provided that the peak market size is <5 billion yen).

For cellular and tissue-based products, the distribution cost shall be determined for each product based on detailed investigation. If it is lower than the price calculated using the average coefficient, it should be used in the subsequent calculation.

Note 1) Unit labor cost: "Monthly Labor Statistics Survey" and "Comprehensive Survey on Working Conditions" (Ministry of Health, Labour and Welfare)
 Note 2) General administrative and selling cost ratio, operating profit margin: "Handbook of Industrial Financial Data" (Development Bank of Japan)
 Note 3) Distribution cost ratio: "Pharmaceutical Industry Survey 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 of the last 3 years (2015 to 2017) obtained at the end of the previous fiscal year)

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

$$\text{Amount of the premium} = \text{Total price} \times \text{Premium rate} \times \text{Premium coefficient}$$

(Price before adding the premium) (0~120%) (0.2~1)

| | | | |
|----------------------|-------------|----------|------|
| Degree of disclosure | $\geq 80\%$ | 50 – 80% | <50% |
| Premium coefficient | 1.0 | 0.6 | 0.2 |

* Degree of disclosure = (Sections of drug price that can be disclosed) / (Total product cost)

Examples of expenses that are not allowed to be included in the cost accounting system

Question 53-5: What are the examples of expenses that are not allowed to be included in the cost accounting system?

(Answer) The examples of expenses that are not allowed to be included are the following:

<Manufacturing cost>

- Expenses for packaging, etc., excluding the immediate container/package of the relevant drug

<General administrative and selling costs>

- Expenses for basic research, non-clinical studies, and clinical studies for indications not directly related to the approved indications
- Expenses for non-clinical studies and clinical studies not included in the application package
- Contract research expenses for clinical studies that exceed the amount appropriate for the number of study subjects
- Food and drink expenses, venue expenses that are considered to be higher than necessary, and a large amount of rewards, out of the expenses required for holding study meetings, etc.
- Expenses for materials for information provision and promotion of understanding of diseases, etc. not limited to the use of the relevant drug
- Expenses for outsourcing that do not arise if outsourcing is not used, such as expenses for selecting and establishing contracts with contractors (expenses for outsourced operations and labor costs, etc. that arise even if they are performed by the company, are allowed to be included)

March 26, 2020

Q & A for “Drug Pricing Standards”

Simulation of drug price calculation by cost accounting system (virtual example)

| | | Item name | Price per unit (in yen) | Rationale, etc. | |
|--|---|---|---------------------------|---|---|
| Manufacturer (factory price: 445.10 yen) | Total product cost (380.10 yen) | D. Product manufacturing cost (20.00 yen) | A. Material cost | 112.00 | • Active ingredient, excipient, container, box, etc. |
| | | | B. Labor cost | 20.30 | • Tableting, box packing, etc. • Calculated by the unit labor cost (3,643 yen) × working hours |
| | | | C. Manufacturing expenses | 67.70 | • Utilities cost, testing cost, etc. |
| | E. General administrative and selling costs (sales cost, research cost, etc.) | | 180.10 | • Research and development expenses (clinical trials, post-marketing surveillance expenses, etc.)*, expenses for materials for promotion of proper use, etc. • $E / (D + E + F) \leq$ average general administrative and selling cost ratio (50.7%) • However, it may exceed the upper limit if there is a valid reason, such as the number of patients being very small. | |
| | F. Operating profit | | 65.00 | • $F / (D + E + F) =$ average operating profit margin (14.8%) • However, it shall be corrected in the range of -50% to 0% depending on the degree of innovativeness, etc. | |
| Wholesaler | G. Distribution cost | | 33.50 | • $G / (D + E + F + G) =$ average distribution cost (7.5%) | |
| | H. Consumption tax | | 47.90 | • $(D + E + F + G) \times$ consumption tax (10%) | |
| Calculated drug price | | | 526.50 | | |

* How to add up research and development expenses

Research and development expenses per unit =

Total research and development expenses

Expected sales quantity over the depreciation period (approximately 10 years based on the re-examination period)

Coefficients for calculation of prices of new drugs

Refer to Chuikyo Total-2-1
2 . 5 . 1 3

● Unit labor cost

| | 2016 | 2017 | 2018 |
|--|---------|---------|---------|
| Total cash salary (yen) *1 A | 510,807 | 475,388 | 509,625 |
| Actual working hours (hours) *2 B | 158.8 | 157.3 | 156.5 |
| Labor cost per hour (yen/hour) *3 C | 3,217 | 3,022 | 3,256 |
| Statutory welfare expenses (%) *4 D | 15.1 | 15.1 | 15.1 |
| Unit labor cost (yen/hour) *5 E | 3,703 | 3,478 | 3,748 |
| Average unit labor cost from 2016 to 2018 (yen/hour) | 3,643 | | |

*1 "Monthly Labor Statistics Survey" (Employment, Wage and Labour Welfare Statistics Office, Director-General for Statistics and Information Policy, Ministry of Health, Labour and Welfare)
"Total cash salary" based on the scale 0 (≥30 people) and sex T (men and women combined) for pharmaceutical industry (E165) in the annual report of nationwide survey

*2 "Monthly Labor Statistics Survey" (Employment, Wage and Labour Welfare Statistics Office, Director-General for Statistics and Information Policy, Ministry of Health, Labour and Welfare)
"Total actual working hours" based on the scale 0 (≥30 people) and sex T (men and women combined) for pharmaceutical industry (E165) in the annual report of nationwide survey

*3 $C = A / B$

*4 "General Survey on Working Conditions" (Wage and Labour Welfare Statistics Office, Director-General for Statistics and Information Policy, Ministry of Health, Labour and Welfare)
"Statutory welfare expenses" according to "Manufacturer-material related" in "Table 33. Percentage of labor expenses other than cash salaries to cash salaries by industry and corporate scale (3-1)"

*5 $E = C \times (1 + D / 100)$

● General administrative and selling cost ratio

| | 2016 | 2017 | 2018 |
|---|------|------|------|
| General administrative and selling cost ratio (%) *6 | 50.8 | 50.7 | 50.6 |
| Average general administrative and selling cost ratio from 2016 to 2018 (%) | 50.7 | | |

● Operating profit margin

| | 2016 | 2017 | 2018 |
|---|------|------|------|
| Operating profit margin (%) *7 | 14.0 | 15.3 | 15.0 |
| Average operating profit margin from 2016 to 2018 (%) | 14.8 | | |

● Distribution cost ratio

| | 2016 | 2017 | 2018 |
|---|------------|------------|------------|
| Sales (yen) *8 A | 15,771,689 | 15,474,246 | 16,419,264 |
| Sales cost (yen) *9 B | 14,640,643 | 14,314,297 | 15,158,496 |
| Distribution cost ratio (%) *10 C | 7.2 | 7.5 | 7.7 |
| Average distribution cost ratio from 2016 to 2018 (%) | 7.5 | | |

*6 "Selling and general administrative cost" according to "1.5.6 Pharmaceuticals" in "Table 1" of "Handbook of Industrial Financial Data" (Development Bank of Japan)

*7 "Operating profit and loss" according to "1.5.6 Pharmaceuticals" in "Table 1" of "Handbook of Industrial Financial Data" (Development Bank of Japan)

*8 "Sales" according to Wholesaler in "Table 8 Statement of profit and loss (including divisions other than those related to drugs)," in "Pharmaceutical Industry Survey Report" (Economic Affairs Division, Health Policy Bureau, Ministry of Health, Labour and Welfare)

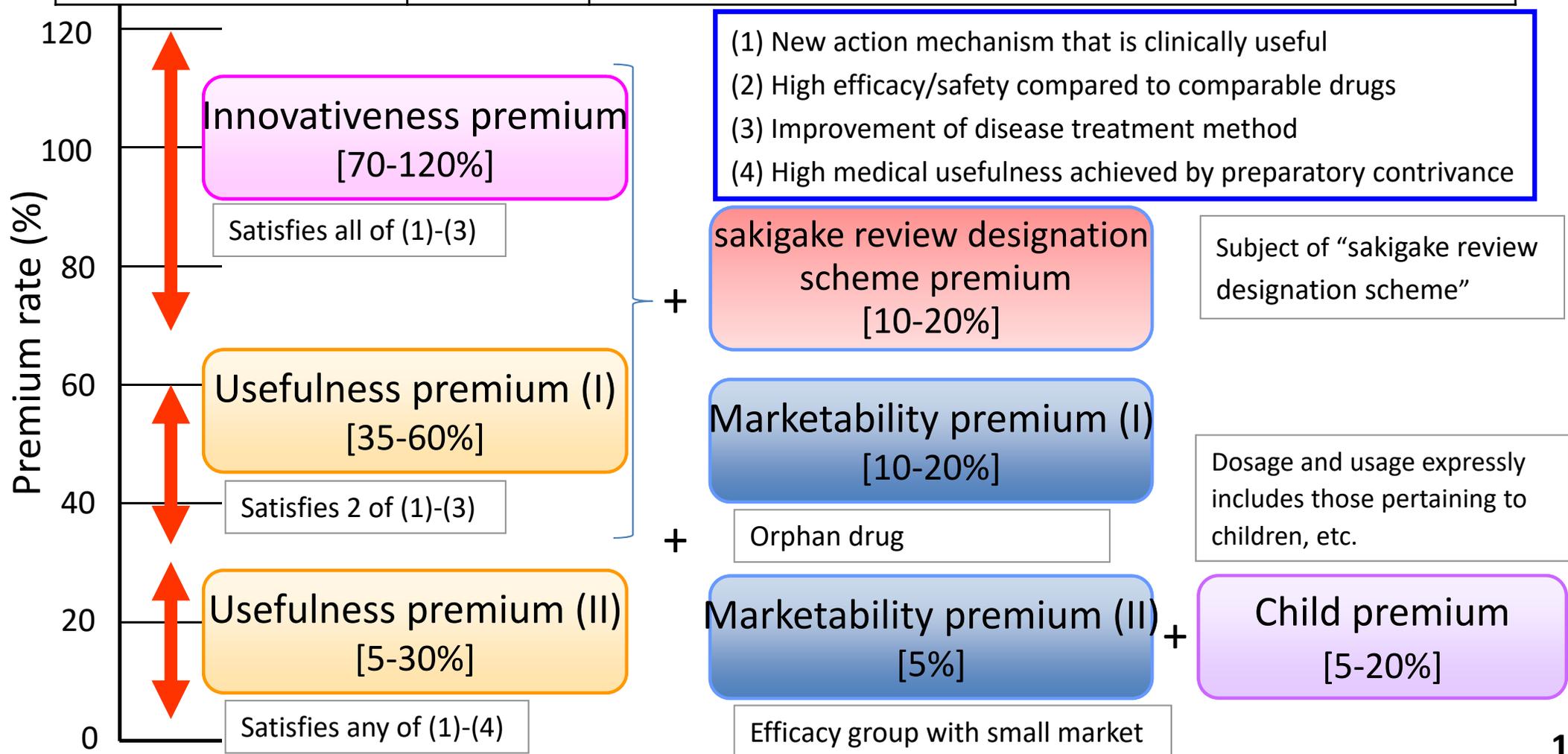
*9 "Sales cost" according to Wholesaler in "Table 8 Statement of profit and loss (including divisions other than those related to drugs)," in "Pharmaceutical Industry Survey Report" (Economic Affairs Division, Health Policy Bureau, Ministry of Health, Labour and Welfare)

*10 $C = (A - B) / A \times 100$

Usefulness premium

* Usefulness premium for the case where high usefulness, etc., is identified compared to comparable drugs

| | | |
|------------------------|------------|---|
| 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. |



Adjustment to average overseas price

- For either price determination by comparable drugs (I) or cost accounting system, an adjustment is made if the deviation from the overseas price is large. [Adjustment to average overseas price]

1. Average overseas price (AOP): Average of prices in the US, UK, Germany and France

(Make adjustment if there is a large discrepancy among overseas prices)

2. Adjustment requirement:

(1) When above 125% of AOP → Downward adjustment

(2) When below 75% of AOP → Upward adjustment

$$(1) \text{ When above 125\%} \quad \left(\frac{1}{3} \times \frac{\text{Calculated value}}{\text{AOP}} + \frac{5}{6} \right) \times \text{AOP}$$

$$(2) \text{ When below 75\%} \quad \left(\frac{1}{3} \times \frac{\text{Calculated value}}{\text{AOP}} + \frac{1}{2} \right) \times \text{AOP}$$

The upper limit is 200% of the calculated value.

To solve the problem about unapproved and off-label drugs, the items whose development were requested to the private or public sectors, and satisfy all the requirements below, should be excluded from the adjustment.

- ① The latest date a drug was approved in any of the 4 countries is more than 10 years before the approval date in Japan.
- ② AOP is less than one third of the calculated value.

Exception: The development costs the manufactures and retailers shouldered are not considered to exceed certain level.

Calculation of prices of kit products

- Kit products: Products combining the drug and its method of administration (e.g., drugs in prefilled syringes)
- Calculation method:

Price of the drug included in the relevant kit calculated by the usual drug pricing rules for newly listed drugs

+

Material cost required for manufacturing and marketing of the portion that contributes to features of the kit product, other than the drug

- Premium for highly useful kit products:
A premium (A = 5%) is added to the price calculated as above if the relevant kit product meets one of the following requirements compared to cases where existing products (excluding existing kit products) are administered to patients (provided that the structure or function of the kit is innovative compared to existing kit products).
 - A. Reduces the risk of infection
 - B. Reduces the risk of dispensing errors
 - C. Allows taking prompt measures during an emergency
 - D. Improves the quality of treatment

Exceptions for new ethical combination drugs

For new ethical combination drugs* that are regarded as combinations of existing single agents or contain active ingredients not included in the NHI price list (those lacking in novelty), the prices are calculated by the following method (this does not apply to anti-HIV drugs or combination drugs for injection or external use with adequate clinical studies or apparent clinical benefits):

- Calculation method

- 1) All components are in-house products

⇒ Sum of “drug prices of in-house products” for the components $\times 0.8$

- 2) Components include in-house products and those from other companies

⇒ Whichever is lower

Sum of “drug prices of in-house products $\times 0.8$ ” and “drug prices of brand-name drugs of other companies $\times 0.8$ ”

Sum of “drug prices of in-house products $\times 0.8$ ” and “lowest drug prices among generic drugs of other companies”

- 3) All components are products from other companies

⇒ Sum of “lowest drug prices of products from other companies”

- 4) When the product contains an active ingredient not included in the NHI price list (those lacking in novelty)

⇒ The price is calculated assuming that the relevant combination drug does not contain an active ingredient not included in the NHI price list.

In any case, the drug price shall not be lower than that of the existing products of each components (each single agents). For new ethical combination drugs, for which a combination of single agents that are not combined in clinical practice is regarded as a comparator (excluding anti-HIV drugs), the drug price shall be less than the total daily drug price of each single agents.

* Exceptions shall be applied to a new ethical combination drug containing more than 3 components—including those that are not covered in the NHI price list as single agents—if existing combination drugs—containing the relevant components as well as other components of the given new ethical combination drug—have been included in the NHI price list. The given existing combination drug shall then be treated as a single agent.