For people, for life, for the future

Ministry of Health, Labour and Welfare

2018.7.3

Update of Drug Pricing System in Japan

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1. Drug Price Standard system

Ministry of Health, Labour and Welfare

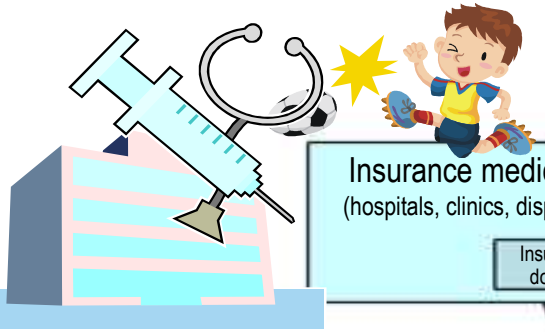
Conceptual diagram of health insurance treatment

Insured person (patient)

(1) Payment of premium

(2) Medical care service
(medical treatment benefits)

(3) Co-payment



Insurance medical institutions, etc.
(hospitals, clinics, dispensing pharmacies, etc.)

Insurance doctors

Insurer

(5) Sending approved bill

(7) Payment of medical treatment fee

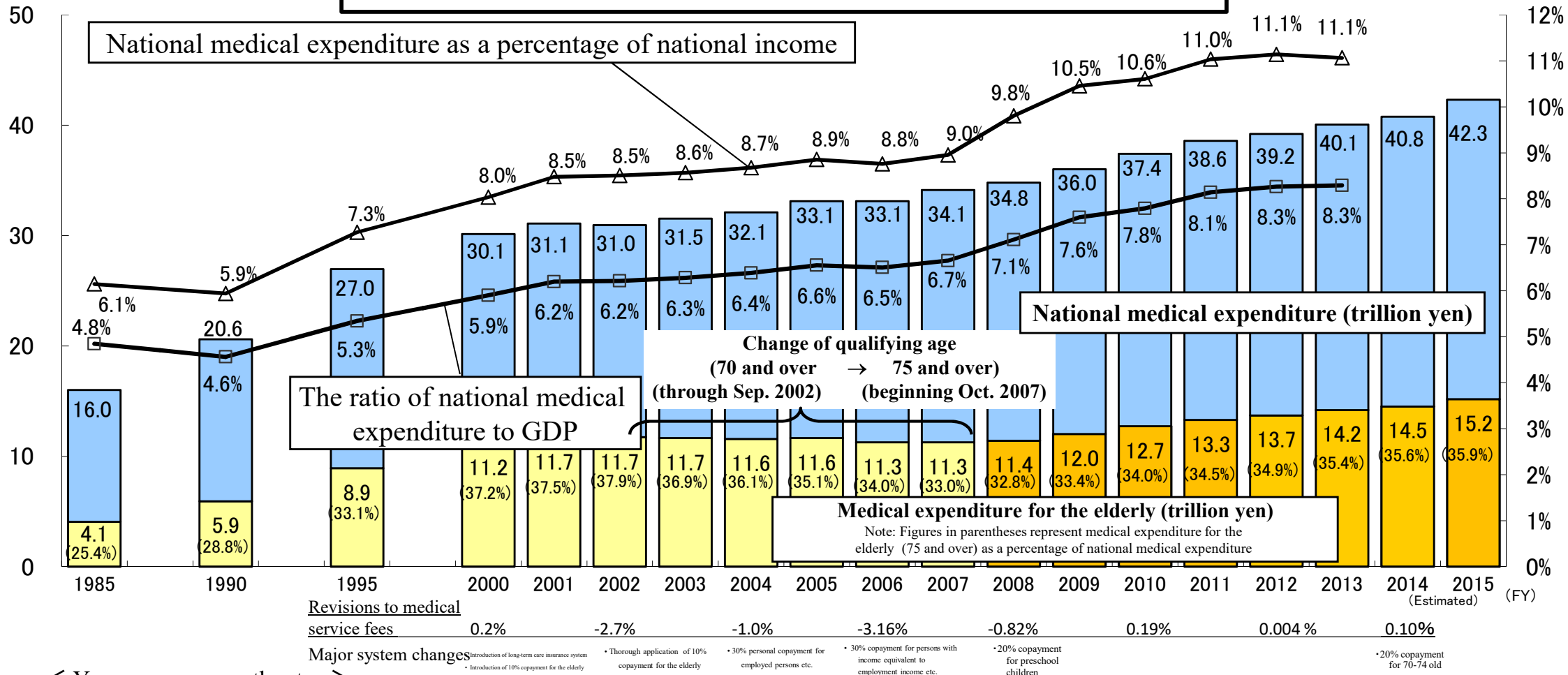
(4) Claim for medical treatment fee

(6) Payment of billed amount

Examination and payment organization
(Social Insurance Medical Fee Payment Fund, Federation of National Health Insurance Associations)

- 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.

Trends in Medical Expenditure



＜ Year-on year growth rates ＞

	1985 (S60)	1990 (H2)	1995 (H7)	2000 (H12)	2001 (H13)	2002 (H14)	2003 (H15)	2004 (H16)	2005 (H17)	2006 (H18)	2007 (H19)	2008 (H20)	2009 (H21)	2010 (H22)	2011 (H23)	2012 (H24)	2013 (H25)	2014 (H26)	2015 (H27)
National medical expenditure	6.1	4.5	4.5	−1.8	3.2	−0.5	1.9	1.8	3.2	−0.0	3.0	2.0	3.4	3.9	3.1	1.6	2.2	*1.8*	*3.8*
Medical expenditure for the elderly (75 and over)	12.7	6.6	9.3	−5.1	4.1	0.6	−0.7	−0.7	0.6	−3.3	0.1	1.2	5.2	5.9	4.5	3.0	3.6	*2.3*	*4.6*
National income	7.2	8.1	1.1	1.7	−2.2	−0.8	1.2	0.5	1.1	1.1	0.8	−6.9	−3.0	2.4	−0.9	0.7	2.9	−	−
GDP	7.2	8.6	1.8	0.8	−1.8	−0.7	0.8	0.2	0.5	0.7	0.8	−4.6	−3.2	1.3	−1.3	0.1	1.8	−	−

(%)

Note 1: National income and GDP are from "National economic accounting" published by Cabinet Office. Being used to compare the medical expenditure among OECD countries, total healthcare expenditure is a type of medical expenditure which covers wider areas such as preventative services and so on. The ratio of average medical expenditure of OECD countries to GDP was 9.3% in 2012.

Note 2: The national medical expenditure for FY2013 (and medical expenditure for the latter-stage elderly people (75 and over)) is an estimate. The estimate for FY2013 is made by multiplying the FY2012 national medical expenditure by the growth rate of the rough estimate of FY2013 medical expenditure (stated above in italics).

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”.

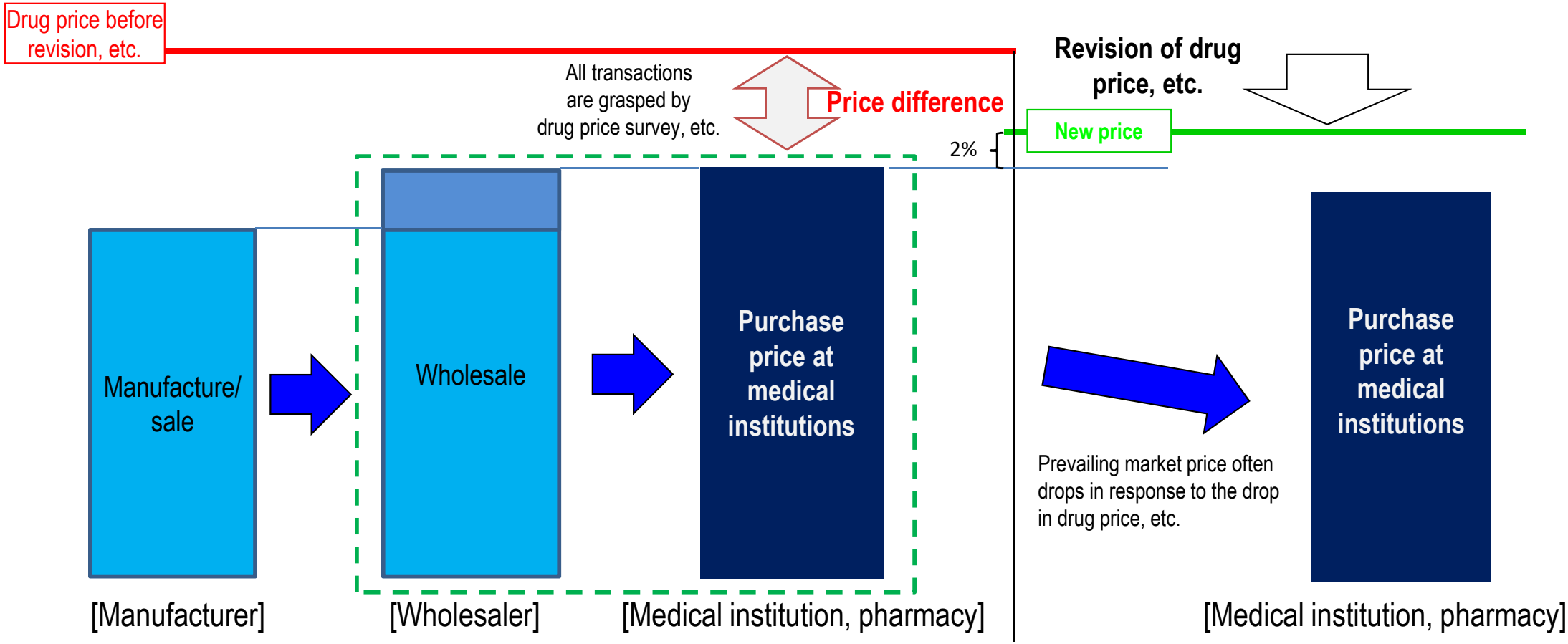
  = NHI Drug Price Standard specifies drugs usable in insurance-covered healthcare, and functions as an item list.

- 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.

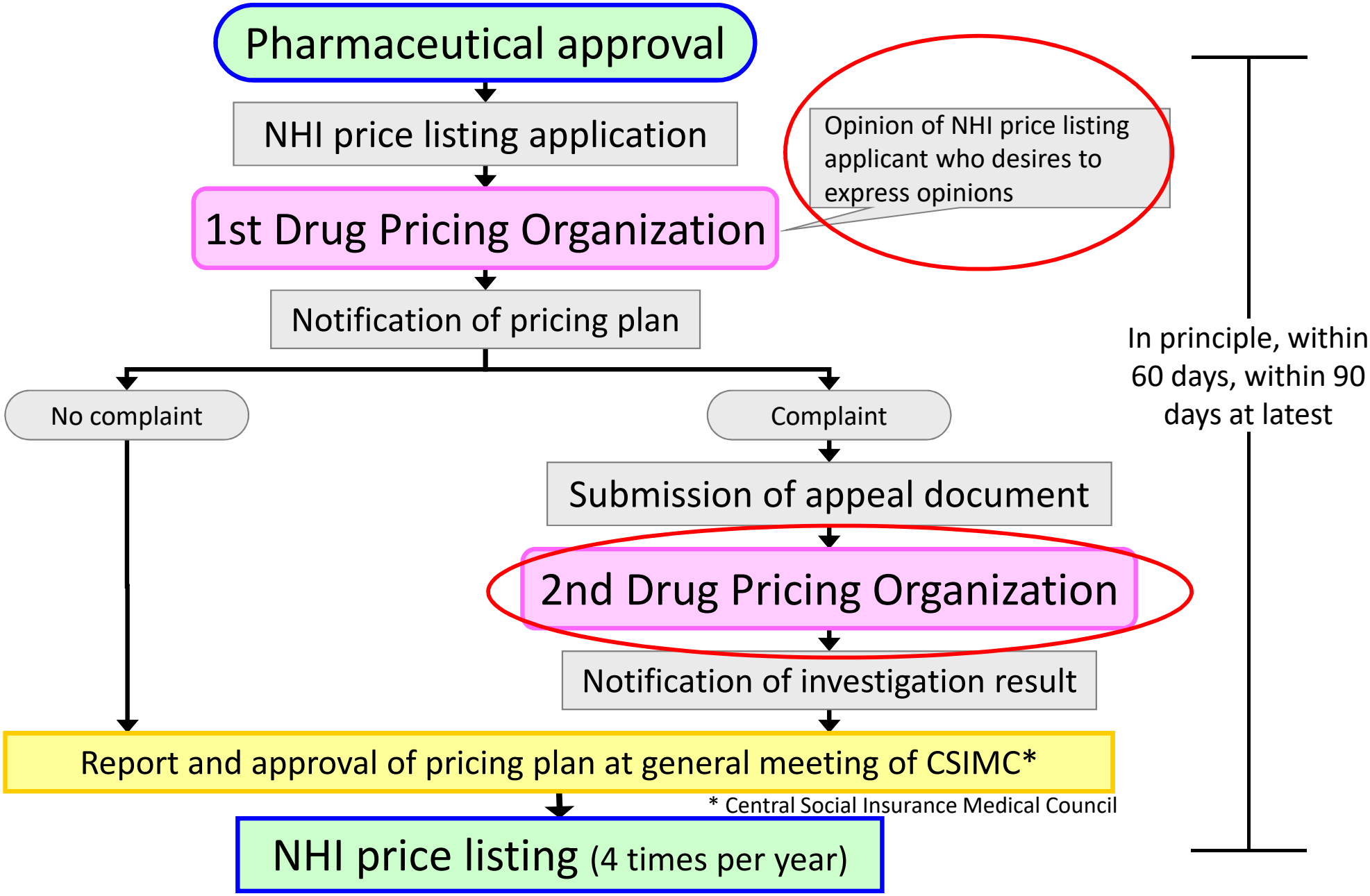
  = NHI Drug Price Standard specifies the claimable amount of drugs used in insurance-covered healthcare, and functions as a price table.

Revision of price of listed drugs

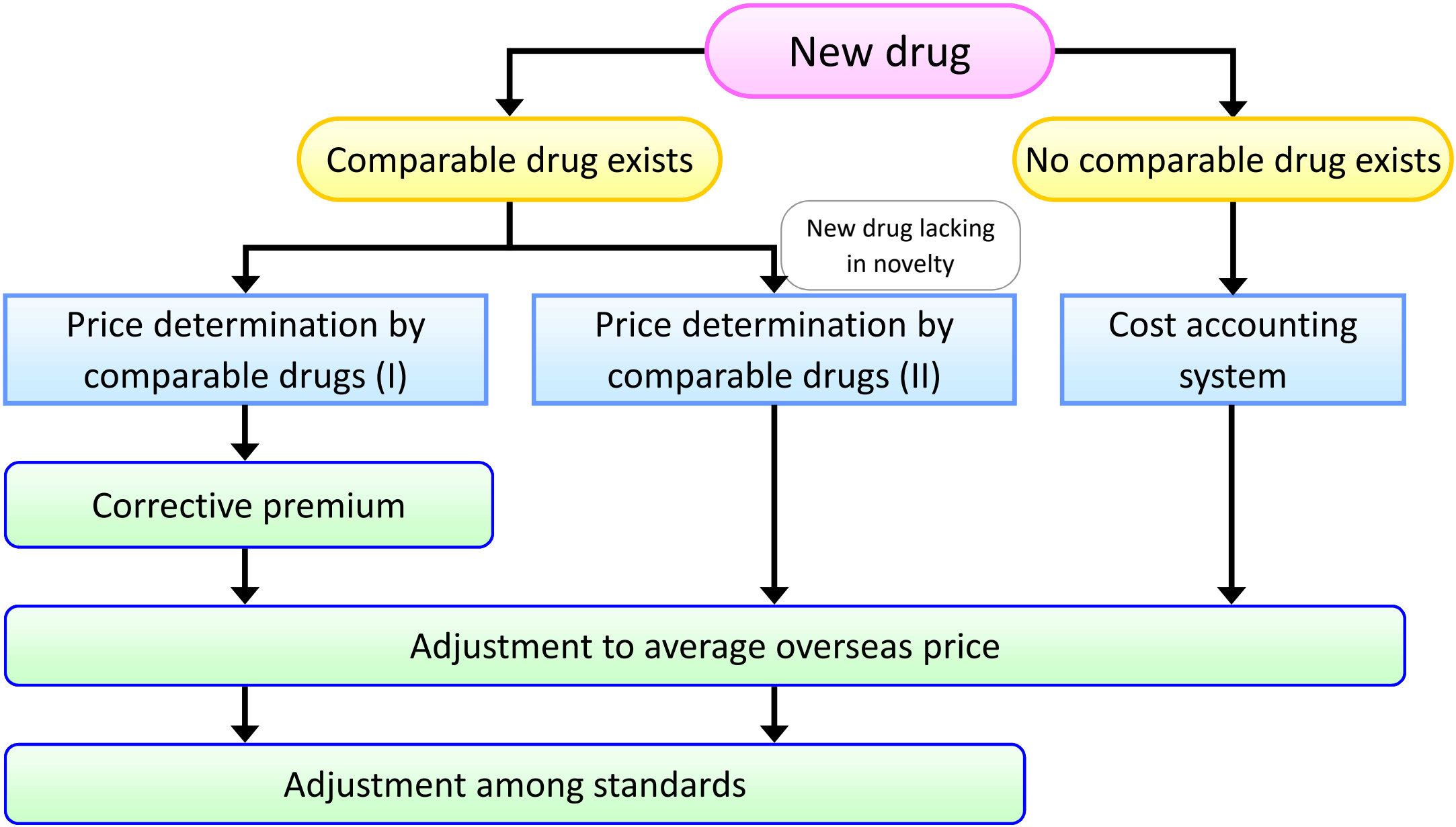
The actual purchase prices paid by medical institutions and pharmacies (prevailing market price) are surveyed (drug price survey) and the prices specified in the drug price standard are revised periodically based on the results of the survey.



New drugs price determination process



New drug price determination method



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.

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.

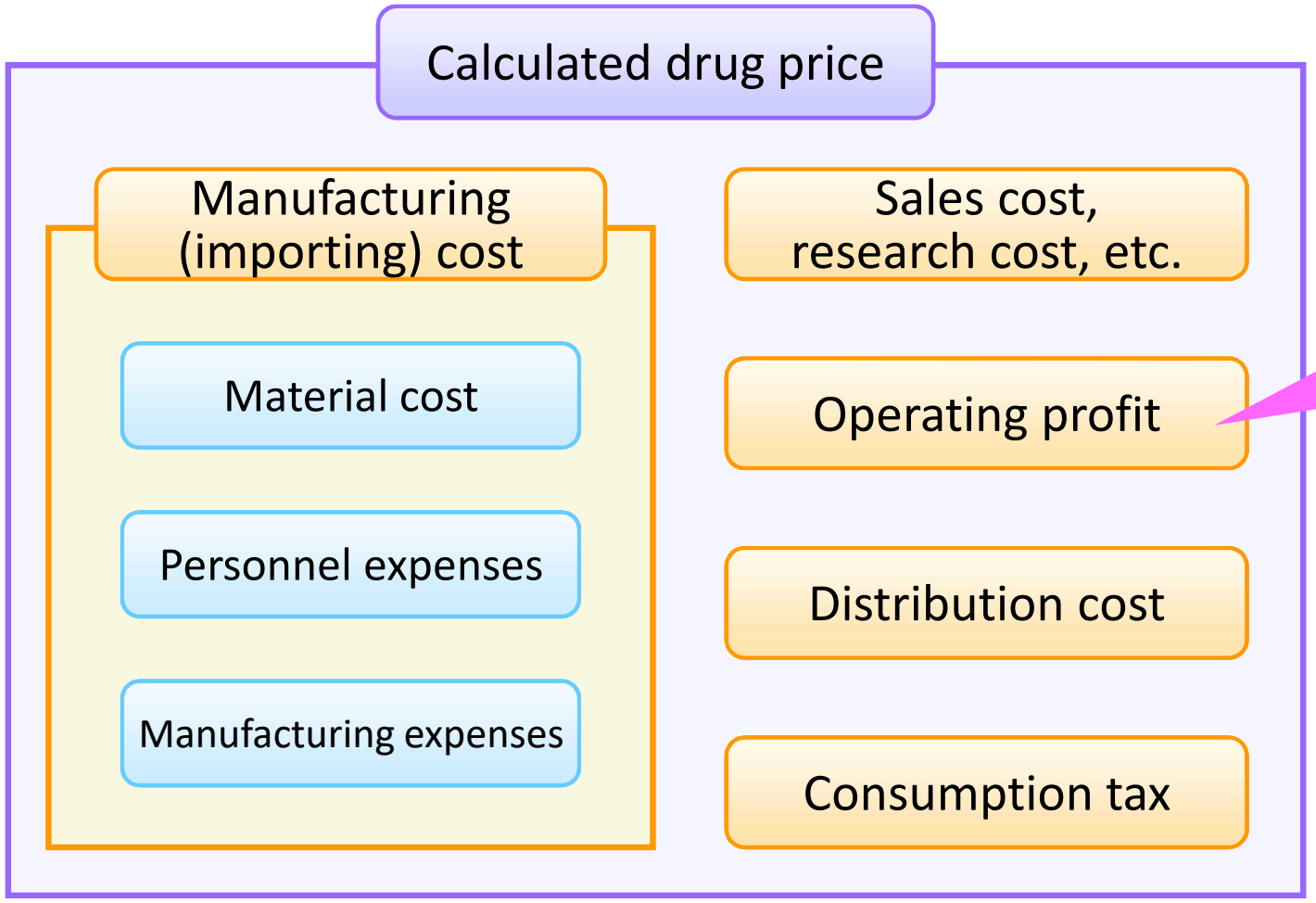
A Efficacy and effect
B Pharmacological action
C Composition and chemical structure
D Dosage form, division and use

- 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, 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.

Cost accounting system

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



Operating profit varies drastically in the range from **–50% to +100%**, 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.

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) When above 125%

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

(2) When below 75%

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

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.

The drug price of the follow-on biologics (biosimilars)

- Case of follow-on products of biotechnology

  : **0.7 multiplication of the drug price of the original product**

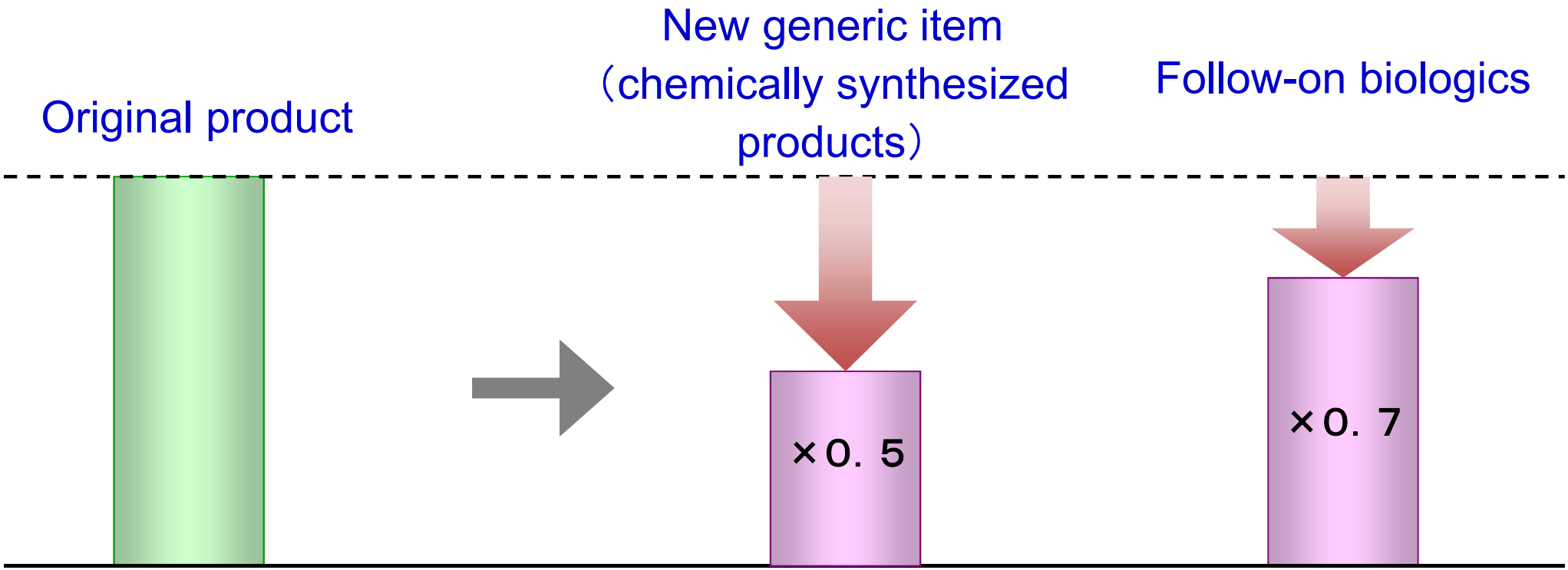
  ※If the medicine is more than 10 items, 0.6 multiplied

  ※Depending on the degree of clinical trial, up to 10% addition is allowed

- Case of chemically synthesized products

  : **0.5 multiplication of the drug price of the original product**

  ※If the medicine is more than 10 items, 0.4 multiplied



2. The reform of drug price system in FY2018

Basic Policy for Fundamental Reform of the Drug Pricing System (Overview Version)

(Decided by the related Chief Cabinet Secretary, Minister of State for Economic and Fiscal Policy, Minister of Finance, and Minister of Health, Labour and Welfare on December 20, 2016)

Achievement of both "Sustainability of the universal healthcare system" and "Promotion of innovation" to realize "Reduction of public financial burden" and "Improvement in the quality of medical care"

Response to a market expansion after drug price listing

○ **In order to promptly respond to a market expansion beyond a certain extent associated with an additional indication, etc., utilize the new drug listing opportunity (four times a year) to review the drug price.**

Drug price survey and drug price revision in the in-between year

○ **In addition to a drug price revision every two years, also conduct a drug price survey in the in-between year for all products, and based on the survey results, conduct a drug price revision for products with large price discrepancies.**

Evaluations of innovation (Review of the premium for new drug development and elimination of off-label drug use and introduction of cost-effectiveness evaluations)

○ **In order to promote the discovery of innovative new drugs, fundamentally review, on a zero basis, the premium for new drug development and elimination of off-label drug use.**

○ **Along with this, introduce full-scale cost-effectiveness evaluations, including a price increases for drugs with high cost-effectiveness. (Also consider the modality of implementation, including organization and system.)**

◆ Future efforts in line with reform

- Thorough implementation of accuracy and transparency of the drug price calculation method
- Improvement of the foreign price adjustment method

- Expeditious understanding of stakeholders' actual business situation and necessary action

- Prompt provision of new health technologies

- Transformation from a model depending on long-listed products to an industrial structure with stronger drug discovery capabilities
- Expansion of strategies/measures to support the R&D of innovative biopharmaceuticals and biosimilars
- Promotion of support for venture companies and market competition of generic manufacturers

- Improvement of distribution efficiency, promotion of distribution improvements, and appropriate responses to the profit structure associated with the market environment
- Promotion of unit price-based by-product contracts and promotion of early price settlements

Discussions regarding the Fundamental Reform of the Drug Pricing System

○ Based on the "Basic Policy for Fundamental Reform of the Drug Pricing System" (December 20, 2016), the Special Committee on Drug Prices initiated specific discussions in January 2017 and held 16 meetings throughout the year until December. Meetings to hear the opinions of the related industries were held three times.

Jan. 11	Responses to market expansions associated with additional indications, etc.
Jan. 25	Modality of foreign price adjustment
Feb. 8	Drug price surveys
Feb. 22	Accuracy and transparency of the drug price calculation method (comparator price method)
Mar. 15	Drug price survey and drug price revision in the in-between year
Mar. 29	Drug price survey
Apr. 12	Accuracy and transparency of the drug price calculation method (cost calculation method)
Apr. 26	Modality of the drug prices of generics
May 17	Opinion-hearing from the related associations
May 31	Modality of the drug prices of long-listed drugs
Jun. 14	Modality of the premium for new drug development and elimination of off-label drug use
Jun. 28	Evaluations of innovation
Jul. 26	Summary of discussions up to now (1)
Aug. 9	Summary of discussions up to now (2)
Sept. 13	Opinion-hearing from the related associations
Oct. 27	Other matters
Nov. 22	Fundamental reform of the drug pricing system (Draft)
Nov. 29	Opinion-hearing from the related associations
Dec. 13	Fundamental reform of the drug pricing system (Draft) (Part 2)

→ December 20: Summarized the Outline for the Fundamental Reform of the Drug Pricing System

Fundamental Reform of the Drug Pricing System

● Based on the "Basic Policy for Fundamental Reform of the Drug Pricing System" (December 20, 2016), achieve both "Sustainability of the universal healthcare system" and "Promotion of innovation" to realize "Reduction of public financial burden" and "Improvement in the quality of medical care."

New drugs

Fundamental review of the premium for new drug development and elimination of off-label drug use

- **Target products:** To be narrowed down based on the **innovativeness and usefulness**
- **Corporate index:** **Premium in accordance with the level of achievement of the corporate index** (development of innovative new drugs, etc.)

Prompt response to the market expansion due to additional indications, etc.

- **Target:** **35 billion yen or higher***
- **Frequency:** **4 times a year** (at the time of new drug listings)

*A reduction of the drug prices according to the re-pricing rule following market expansion

Review of the evaluation of new drug innovation

- **Scope of premium (new drugs with no comparators)**

Premium for the operating profit → **Premium for the entire drug price**

(Setting the premium rate based on the degree of disclosure of the manufacturing cost breakdown)

Review of foreign price adjustments

- **US reference price list**

Manufacturer's suggested retail price

→ **Price list in the publish health insurance system**

Introduction of cost-effectiveness evaluations

- **Trial introduction**

Price adjustments will be **conducted** for 13 target products **in April 2018**.

- **Full-fledged introduction**

Technical problems will be summarized and **a conclusion will be reached by the end of FY2018**.

Long-listed drugs and generics

Review of the prices of long-listed drugs

- **Target:** **Long-listed drugs for which 10 years have passed** since a generic was launched
- **Review method:** Step-by-step reduction **based on the generic price**

Consolidation of the generic price

- **Target:** **Generics for which 12 years have passed** since they were launched
- **No. of price ranges:** In principle, **1 price range**

Annual drug price survey and annual drug price revision

- **Scope:** In consideration of the status of the price revision of all products, the government will take the initiative to improve drug distribution and **decide on the scope by the end of FY2020**.

Future Considerations

● **Supplementary comments attached to the report concerning the FY2018 medical fee revision (excerpt)**

(Fundamental reform of the drug pricing system)
16 Based on the "Outline for the Fundamental Reform of the Drug Pricing System," continue discussing the necessary actions and measures upon verifying the impact of the fundamental reform of the drug pricing system on the stakeholders.
In addition, continue to discuss how to handle basic drugs.

● **Outline for the Fundamental Reform of the Drug Pricing System Appendix (Approved at the Chuikyo on December 20, 2017) (excerpt)**

II. Appropriate evaluations of innovation
1. Fundamental review of the premium for new drug development and elimination of off-label drug use
2) Corporate requirements and corporate index
○ Since the corporate index is to be introduced for the first time on this occasion, in the FY2018 revision, the disparity among companies due to the scope of Classifications I and III and differences in the premium will be limited, and after the FY2018 revision, pharmaceutical companies' efforts and the results of innovative drug development and drug lag elimination will continued to be examined in terms of whether they are appropriate as evaluation criteria while taking into consideration the actual situation surrounding new drug development, etc. in order to discuss the review of and reflection onto the next or later revision.

VI. Future considerations
○ For the next revision, examine the evaluations of innovation in terms of whether or not it is necessary to evaluate the innovativeness and usefulness due to additional indications, etc.
○ For the next revision, examine the ideal time period until the step-by-step price reduction of long-listed drugs based on (1) the replacement rate to generics, (2) status of generic launches, and (3) responses to stable supply, among other things, after the price reductions of long-listed drugs on this occasion.
○ Upon examining the impact of the fundamental reform of the drug pricing system this time, such as review of the premium for new drug development and elimination of off-label drug use and review of the drug price of long-listed drugs, on the development, manufacture, distribution of drugs, when deemed necessary, consider the necessary measures for the next revision.

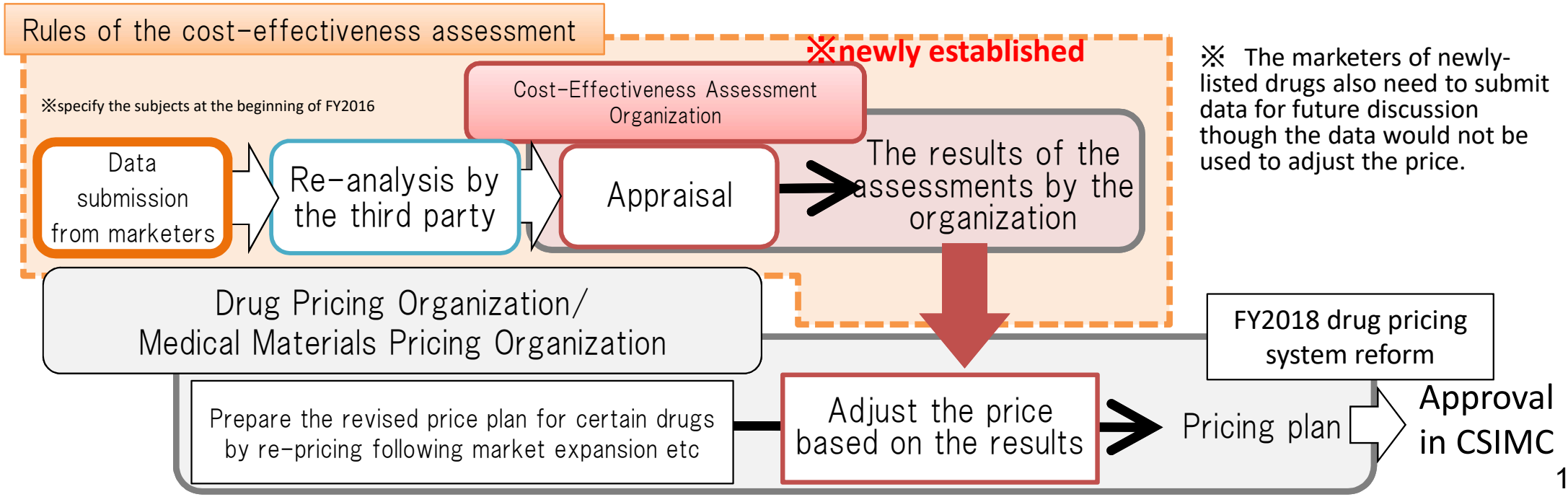
Trial implementation of the cost-effectiveness assessment

- We established "Special Committee on Cost-Effectiveness Assessment" as a branch of Central Social Insurance Medical Council ,out of concern for fiscal impact of growing expensive healthcare technologies. In the FY2016 drug pricing system reform, the cost-effectiveness assessment shall be introduced on a trial basis to evaluate medicine and medical instruments.

＜Discussion at Central Social Insurance Medical Council(CSIMC)＞

2012.5	Establishment of "Special Committee on Cost-Effectiveness Assessment" Discuss the relevant drugs,analytical method, and the use of the assessments etc,referring to overseas cases, on about once a month basis
2014.4～2015.11	Examine specific drugs and report the problems to the general meeting.Discuss each issue.
2015.12	Summarize how the cost-effectiveness assessment should be implemented on a trial basis.
2016.4	Trial implementation of the cost-effectiveness assessment

＜The flowchart of the trial implementation of the cost-effectiveness assessment (Outline)＞



※ The marketers of newly-listed drugs also need to submit data for future discussion though the data would not be used to adjust the price.