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Ministry of Health, Labour and Welfare

# Update of Drug Pricing System in Japan

Takafumi Yumoto

Section Chief

Economic Affairs Division

Health Policy Bureau

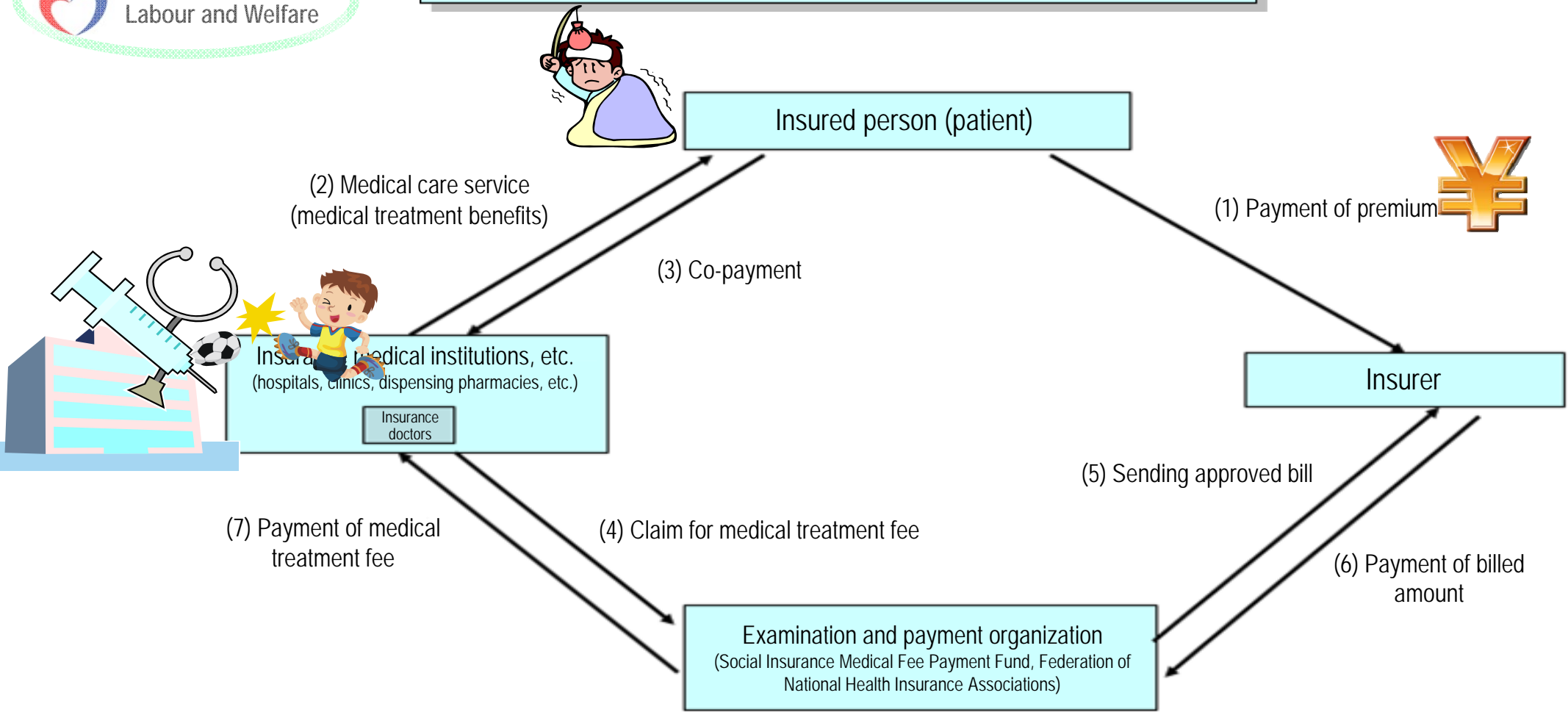
Ministry of Health, Labour and Welfare

# Outline of Today's presentation

1. Drug Pricing System in Japan
2. Reform of Drug Price System

# 1. Drug Pricing System in Japan

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.

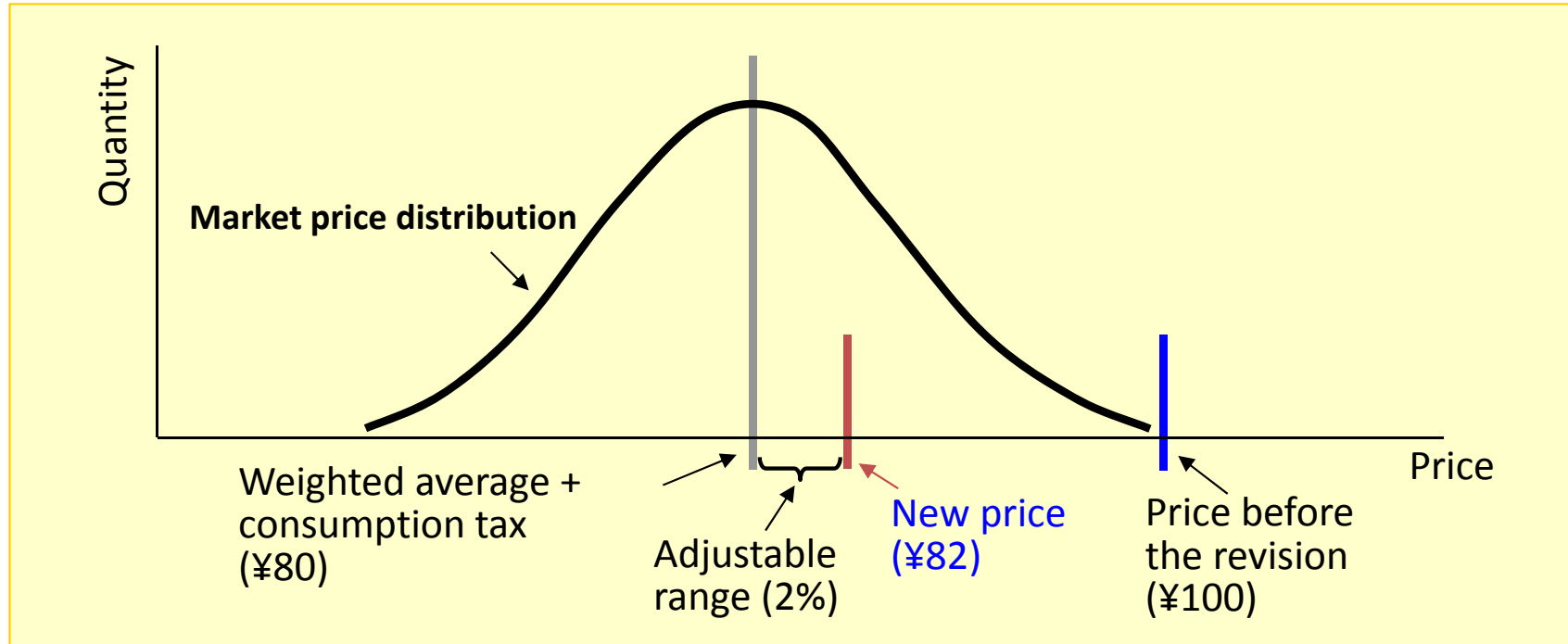
- Price table

- 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.

# Outline of current drug price standard system

1. The Drug Price Standard specifies the price of drugs when paid from medical insurance to authorized medical institutions or pharmacies operating under the health insurance program (insurance medical institutions).
2. The Drug Price Standard is announced by the Minister of Health, Labour and Welfare, based on “Drug Pricing Standards” issued by the Central Social Insurance Medical Council on February 10, 2016.
3. Prices specified by the Drug Price Standard is periodically revised based on the results of a survey (drug price survey) on the actual selling price (market price) to medical institutions and pharmacies.

# Pricing method for listed drugs

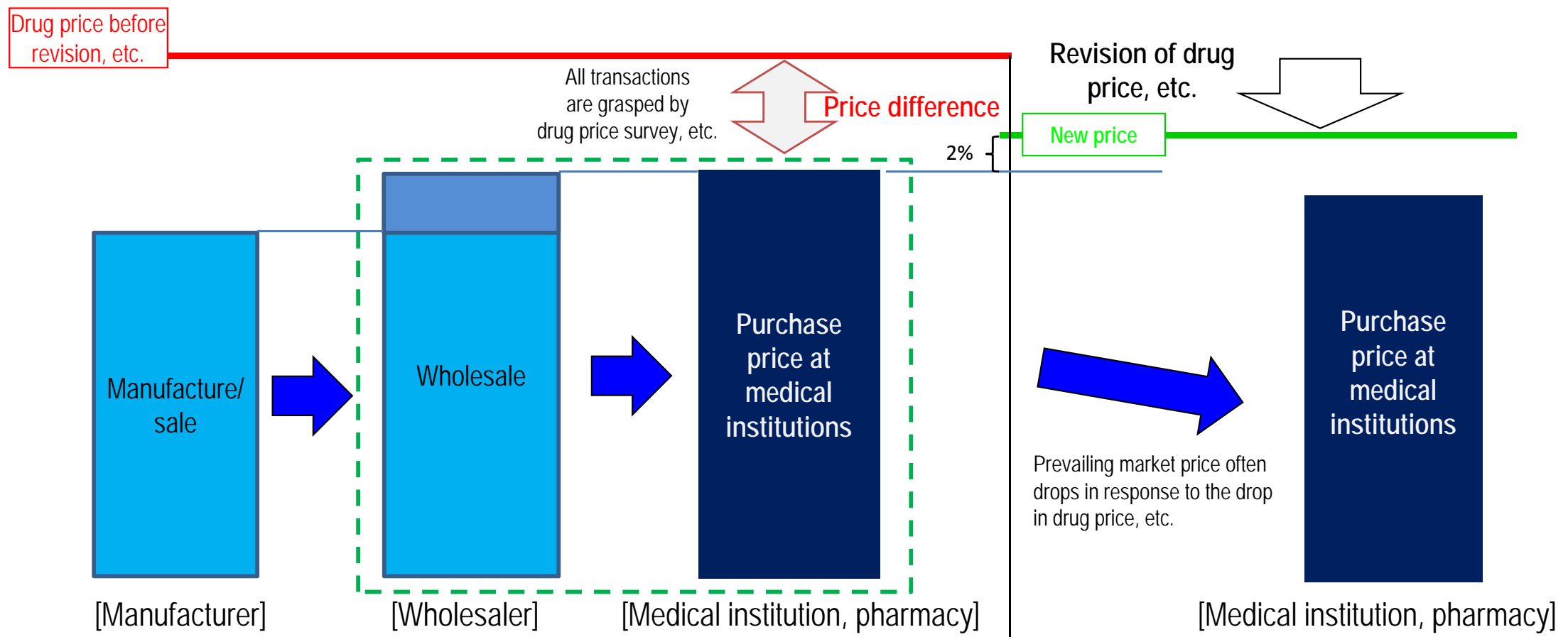


The new drug price is the weighted average of the wholesaler's selling price to medical institutions and pharmacies (market price excluding tax), with consumption tax added as well as the span of the adjustable range (2% of drug price before the revision) for stabilizing drug distribution.

$$\text{New drug price} = \left[ \text{Weighted average of selling price to medical institutions and pharmacies (market price excluding tax)} \right] \times \left( 1 + \text{consumption tax rate (incl. local consumption tax)} \right) + \text{Span of adjustable range}$$

# 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.

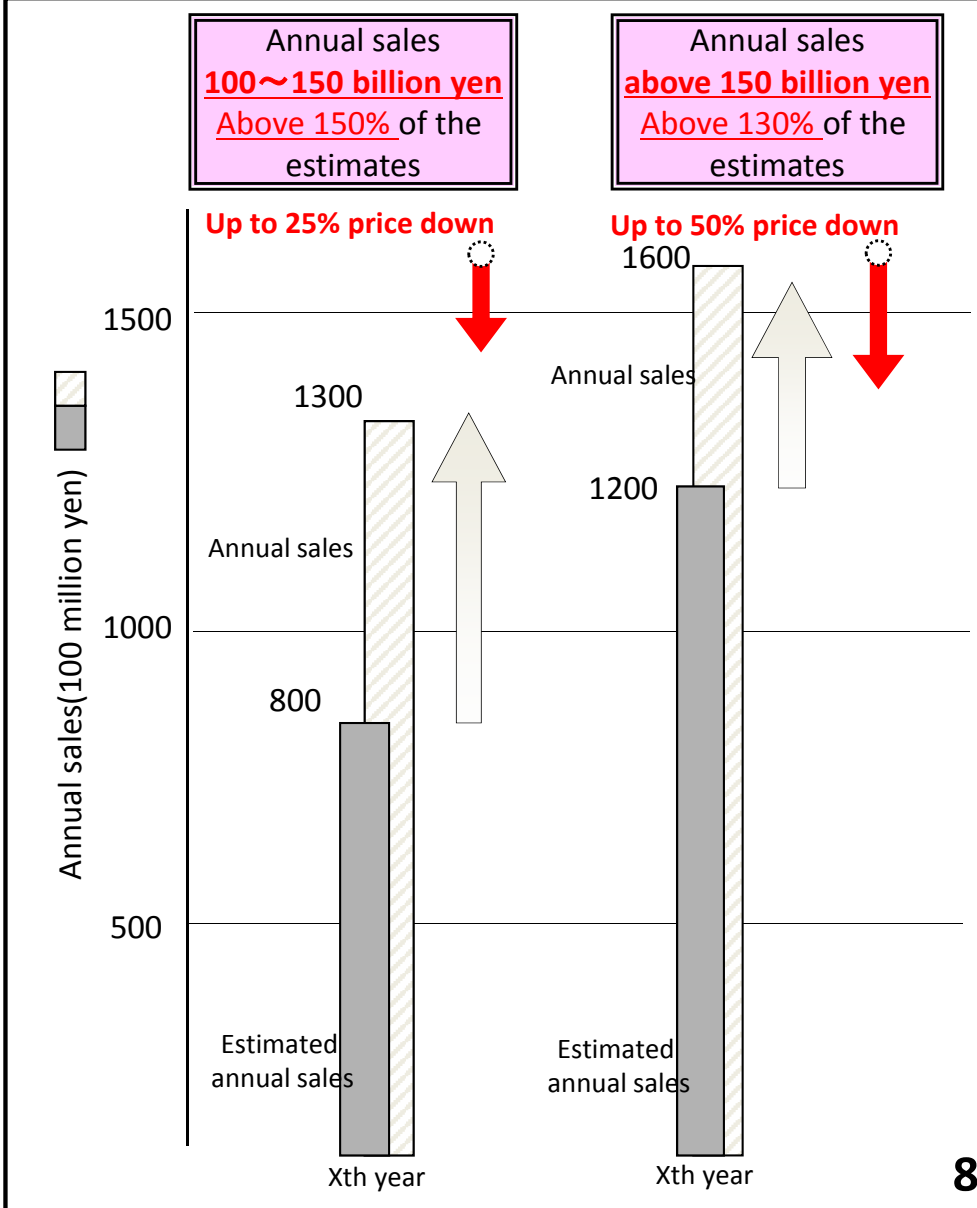
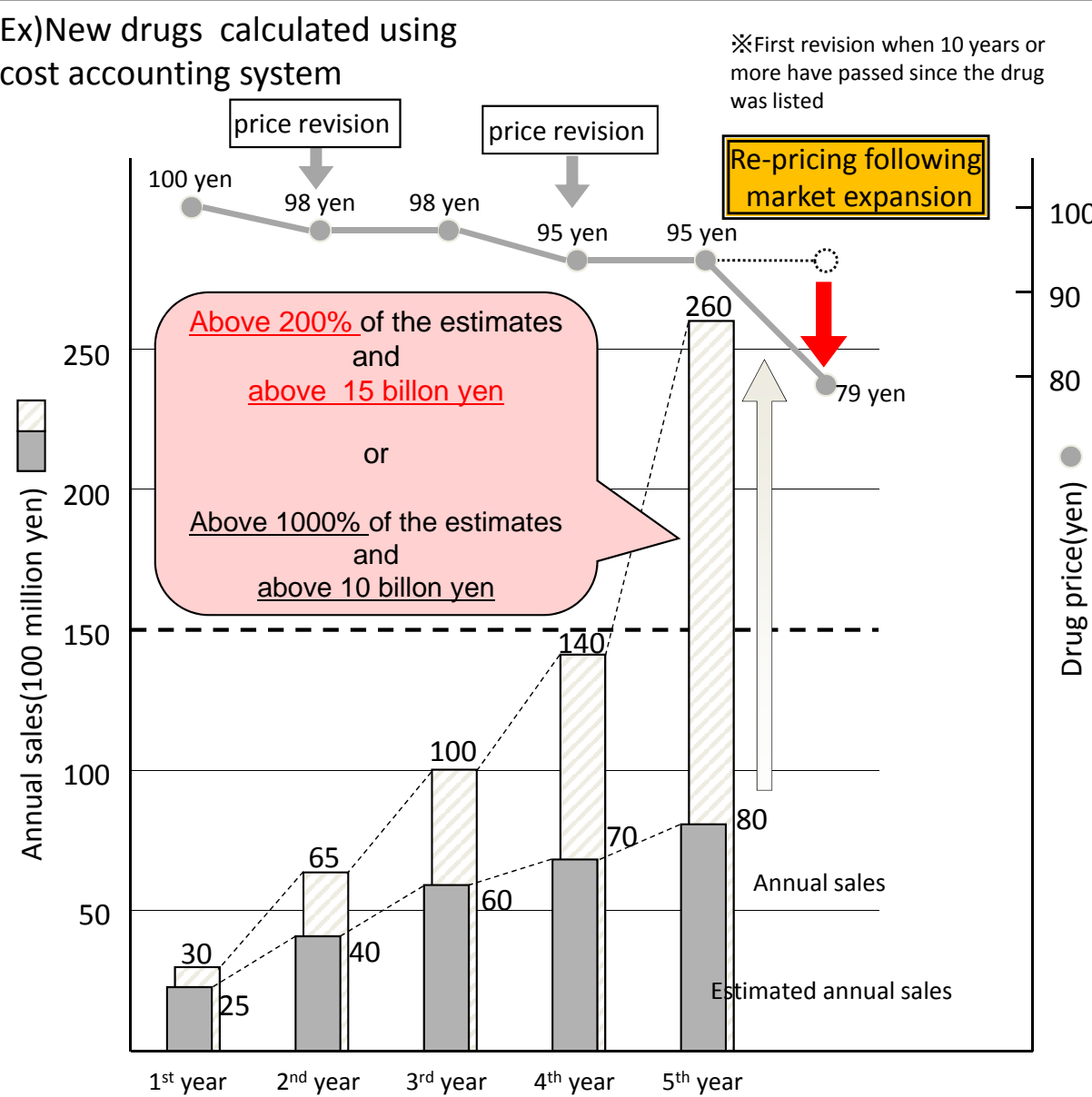




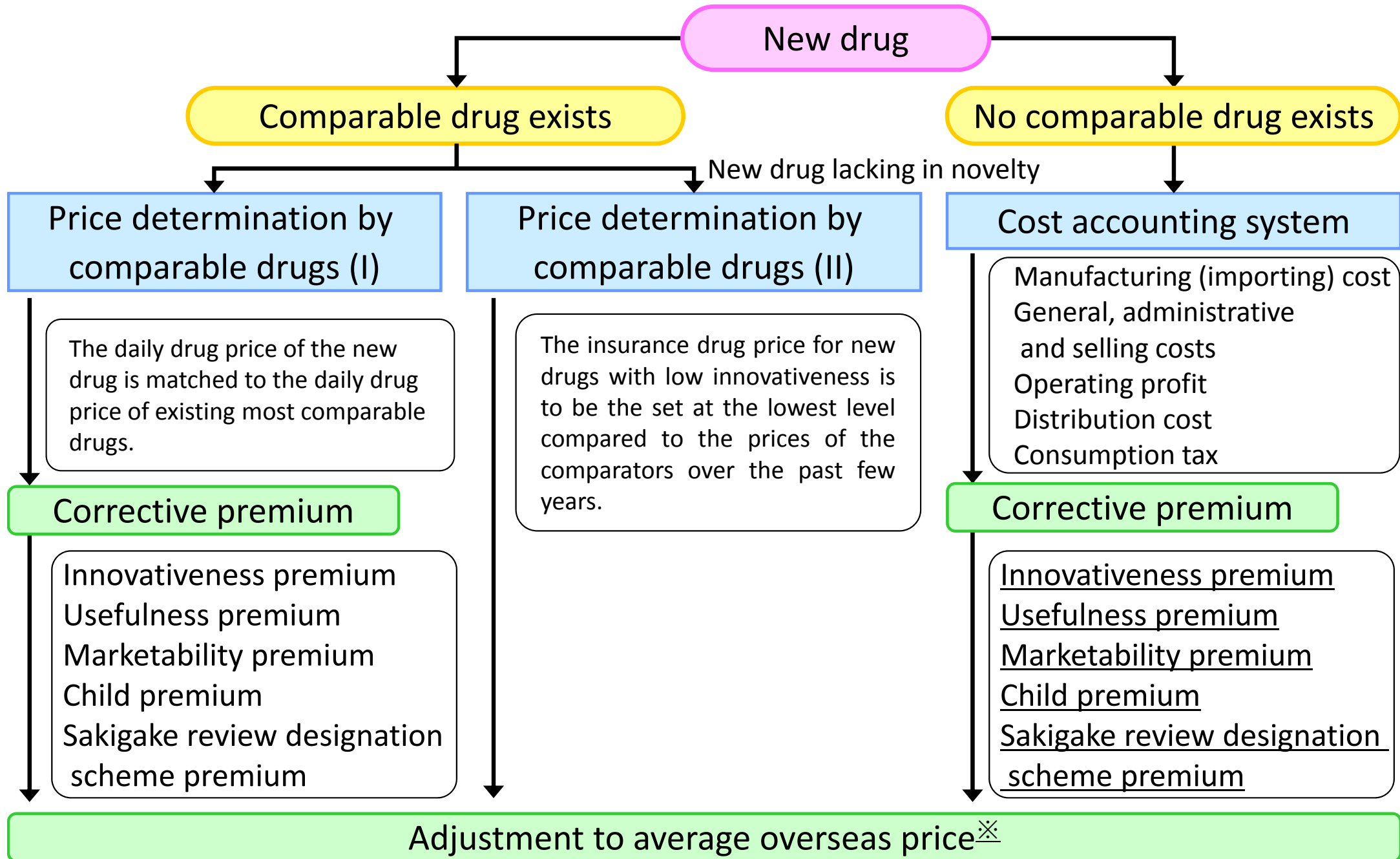
# “Re-pricing following market expansion” for the drugs with huge annual sales

**【Now (Previous)】**  
 Price will be reduced when annual sales of a drug exceed its estimated figure to some extent.

**【Revised】**  
 The drugs with huge annual sales will be treated as an exception of the current rule.





# 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

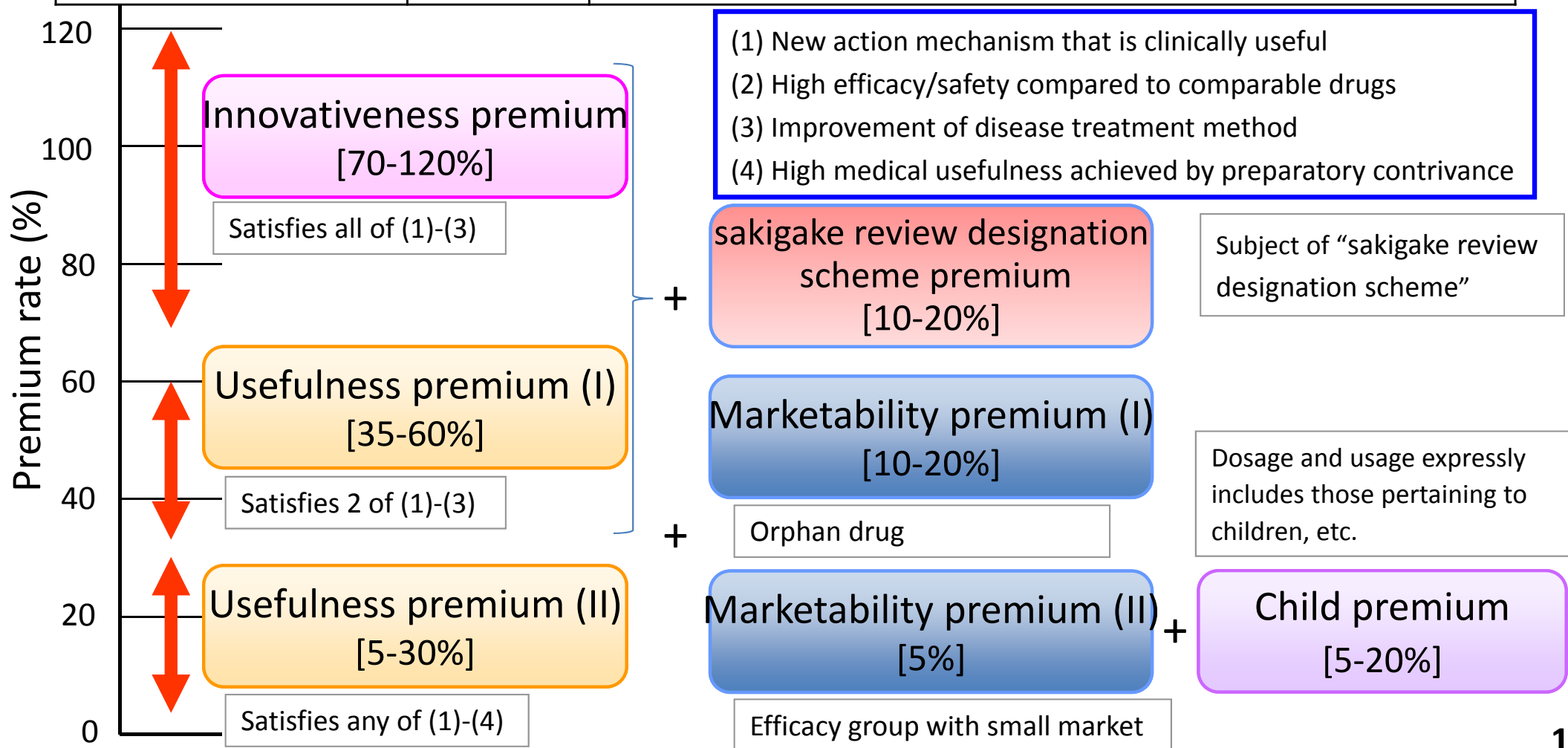
- For the relevant new drug, when higher efficacy is identifiable compared to comparable drugs, a corrective premium is applied to the above amount. [Innovativeness premium, usefulness premium, marketability premium, child premium, and sakigake review designation scheme premium]

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.

# 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.



# 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.

# 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.

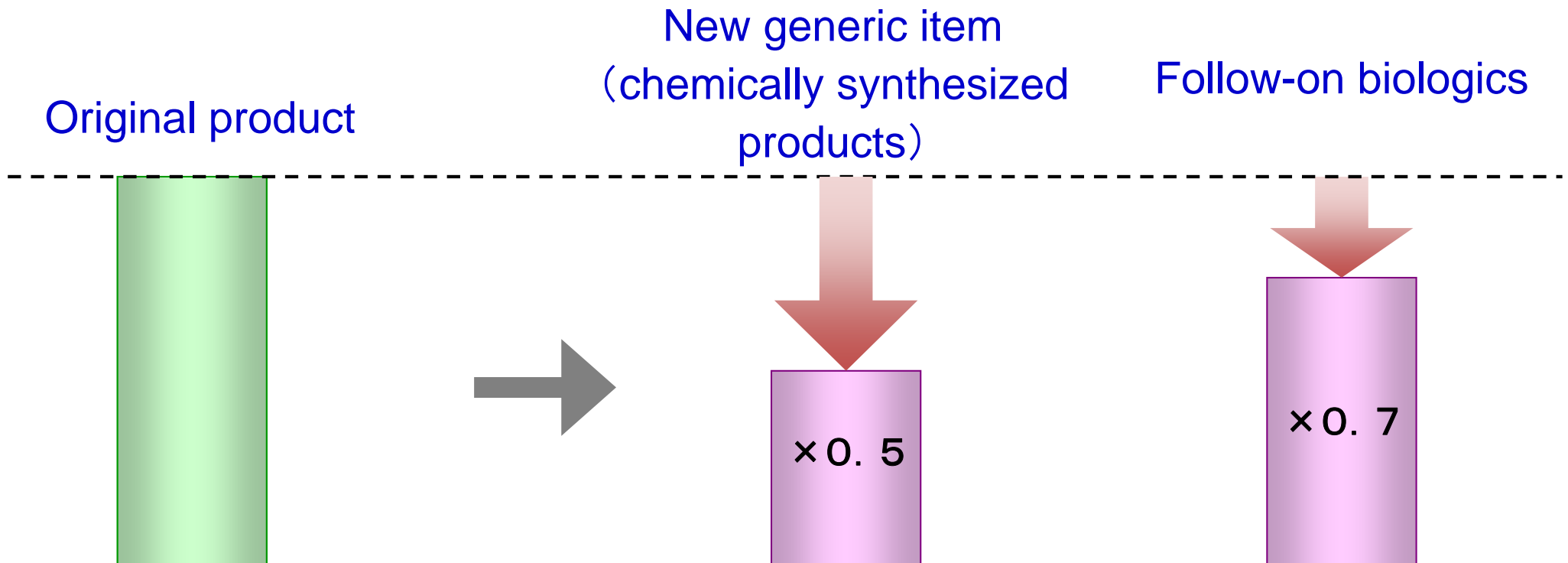
To solve the problem about unapproved and off-label drugs, the items whose development were requested to the private or public sectors, and satisfy all the requirements below, should be excluded from the adjustment.

- 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.

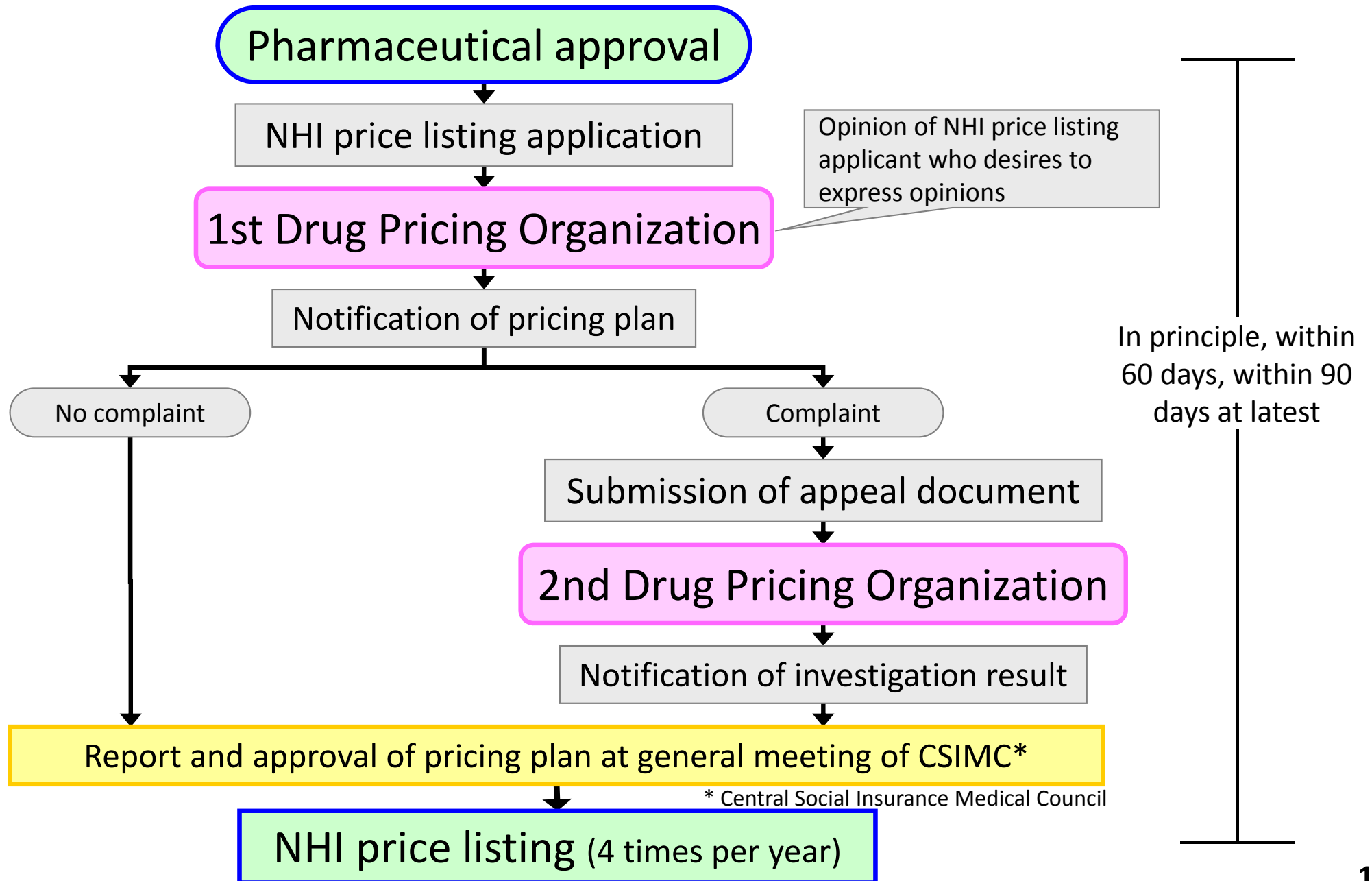
Exception: The development costs the manufactures and retailers shouldered are not considered to exceed certain level.

# 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

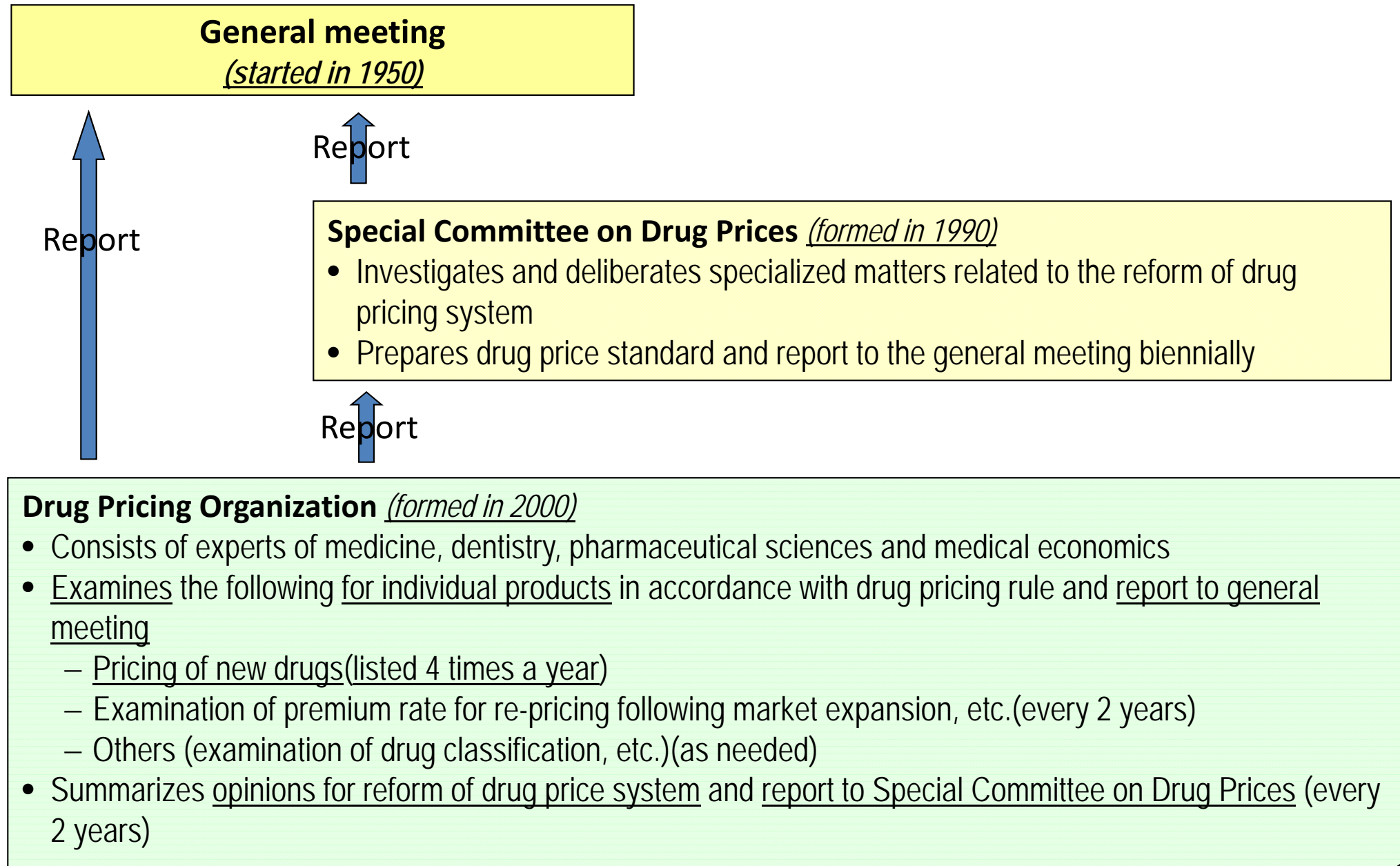


# New drugs price determination process





# Organizations of Central Social Insurance Medical Council involved in drug pricing



## 2. The reform of drug price system

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

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

- |  |  |
|--|--|
| <ul style="list-style-type: none"><li>• Thorough implementation of accuracy and transparency of the drug price calculation method</li><li>• Improvement of the foreign price adjustment method</li></ul> | <ul style="list-style-type: none"><li>• Transformation from a model depending on long-listed products to an industrial structure with stronger drug discovery capabilities</li><li>• Expansion of strategies/measures to support the R&amp;D of innovative biopharmaceuticals and biosimilars</li><li>• Promotion of support for venture companies and market competition of generic manufacturers</li></ul> |
| <ul style="list-style-type: none"><li>• Expeditious understanding of stakeholders' actual business situation and necessary action</li></ul>  | <ul style="list-style-type: none"><li>• Improvement of distribution efficiency, promotion of distribution improvements, and appropriate responses to the profit structure associated with the market environment</li><li>• Promotion of unit price-based by-product contracts and promotion of early price settlements</li></ul>   |
| <ul style="list-style-type: none"><li>• Prompt provision of new health technologies</li></ul>  |  |

# 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 17 meetings throughout the year until December. Meetings to hear the opinions of the related industries were held three times.

<b>Jan. 11</b>	Responses to market expansions associated with additional indications, etc.	<b>Jun. 14</b>	Modality of the premium for new drug development and elimination of off-label drug use
<b>Jan. 25</b>	Modality of foreign price adjustment	<b>Jun. 28</b>	Evaluations of innovation
<b>Feb. 8</b>	Drug price surveys	<b>Jul. 26</b>	Summary of discussions up to now (1)
<b>Feb. 22</b>	Accuracy and transparency of the drug price calculation method (comparator price method)	<b>Aug. 9</b>	Summary of discussions up to now (2)
<b>Mar. 15</b>	Drug price survey and drug price revision in the in-between year	<b>Sept. 13</b>	Opinion-hearing from the related associations
<b>Mar. 29</b>	Drug price survey	<b>Oct. 27</b>	Other matters
<b>Apr. 12</b>	Accuracy and transparency of the drug price calculation method (cost calculation method)	<b>Nov. 22</b>	Fundamental reform of the drug pricing system (Draft)
<b>Apr. 26</b>	Modality of the drug prices of generics	<b>Nov. 29</b>	Opinion-hearing from the related associations
<b>May 17</b>	Opinion-hearing from the related associations	<b>Dec. 13</b>	Fundamental reform of the drug pricing system (Draft) (Part 2)
<b>May 31</b>	Modality of the drug prices of long-listed drugs	<b>Dec. 20</b>	Outline for the Fundamental Reform of the Drug Pricing System (Approved at the Chuikyo)

# 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 foreign price adjustments

- **US reference price list**  
Manufacturer's suggested retail price  
→ **Price list in the publish health insurance system**

### 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)

### 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**.

# Handling of market expansion following addition of indications etc.

## Direction of reform

(Provisional translation by PhRMA)

- Drugs with additional indications etc. of which the market has expanded over and above a certain level shall be revised in price taking maximum advantage of the (four times a year) new drug listings.

### <Scope of drugs for data extraction>

- In order to capture products with market expansion over and above a certain level, the market size of the following products shall be identified through the National Database (NBD).

	Drugs for data extraction	Notes
(1)	Drugs with additional indications etc.	To identify those of which the market has expanded substantially due to the addition of indications etc.
(2)	Products for which on listing the sales in the second fiscal year were projected to be at least 10 billion yen <sup>*1</sup> or 15 billion yen <sup>*2</sup>	To identify those of which the market has expanded substantially since marketing over the initial projection

\*1 Cost calculation method, \*2 Comparator pricing method

Market size over a two-year period to be identified for (1) and (2) respectively

### <Drugs subject to repricing>

- Those of the above drugs that correspond to the conditions for the current repricing for market expansion rule (including special cases) shall be repriced in accordance with the current method. However, since quarterly repricings will impose a tremendous burden on medical institutions, pharmacies and pharmaceutical companies, as the certain level of market expansion, drugs with annual sales in excess of 35 billion yen shall be targeted.

- In addition, the (four times a year) new drug listings shall also be used for repricing for dosage and administration changes.

# Annual drug price surveys and revisions

## Direction of reform

(Provisional translation by PhRMA)

### <Scope of application of drug price survey>

- To control the national burden through the timely reflection of market prices in NHI prices, all-product drug price surveys shall be conducted in the off-year of the biennial drug price revision (the 'drug price revision off-year') based on extraction of survey subjects from all drug wholesalers including major companies. Prices shall be revised on the basis of the results.

### <Scope of applicable products>

- From the perspective of reducing the national burden while continuing to establish the infrastructure for the proper conduct of drug price surveys, it is valid to set the scope of applicable products as widely as possible. To this end, ahead of FY 2021\* the government shall take initiatives to improve drug distribution through proactively promoting single-product, single-price contracts, early price settlements and the correction of negative primary margins on sales so as to maintain stable drug distribution.

\* Since a consumption tax hike is scheduled for FY 2019, which shall involve the price revision of all products, the initial drug price revision off-year shall be FY 2021.

- Prices shall be revised for all products for three consecutive years from FY 2018 to FY 2020. Therefore, the specific scope of applicable products shall be set during 2020 taking comprehensive account of identified market price trends, the status of price gaps ('yakkasa') and the impact of these revisions on wholesalers, medical institutions and pharmacies during this period.

### (Ref.) Scope of applicable products and impact on healthcare expenditure (estimates\*)

- |   |                         |
|---|-------------------------|
| a) Products with a price discrepancy rate of 2 times or higher the average<br>(approximately 3,100 products, approximately 20% of all products)   | ▲ 50 ~ 80 billion yen   |
| b) Products with a price discrepancy rate of 1.5 times or higher the average<br>(approximately 5,000 products, approximately 30% of all products) | ▲ 75 ~ 110 billion yen  |
| c) Products with a price discrepancy rate of 1.2 times or higher the average<br>(approximately 6,600 products, approximately 40% of all products) | ▲ 120 ~ 180 billion yen |
| d) Products with a price discrepancy rate of over 1 times the average<br>(approximately 8,100 products, approximately 50% of all products)        | ▲ 190 ~ 290 billion yen |

\* The estimates were calculated from the FY 2015 drug price survey data on the assumption that half to three-quarters of the price discrepancies that occurred during the previous two years would occur in the drug price revision off-year.

# Revision of price maintenance premium

## Direction of reform

(Provisional translation by PhRMA)

### <Product requirements>

- In applying the premium to on-patent new drugs etc., eligible products shall be limited to the following that have genuine innovativeness/utility so as to identify properly and evaluate the innovation of genuinely useful drugs and promote R&D investment.

Scope of application	Eligible products	
*New drugs with no generic launches	Orphan drugs	
	Products publicly offered for development	
	Products awarded premiums	Innovation, Utility I or II
		Operating profit adjustment
Verification of genuine clinical utility		
* In such cases, new drugs for which 15 years have passed since listing	Drugs with a novel mechanism of action etc. (only those with innovativeness/utility) etc.	

\* Details given on following page

- In addition, in view of the following issues, the product requirement for the price discrepancy rate to be the average or below shall be withdrawn:
  - (1) That it is not necessarily an indicator for the evaluation of innovativeness/utility
  - (2) That it leads to prices remaining at a high level through the setting of high invoice prices



# Revision of price maintenance premium

## Direction of reform

(Provisional translation by PhRMA)

- Innovativeness/utility criteria such as the following shall be set out for drugs with a novel mechanism of action and such drugs shall be limited to those fulfilling any of these criteria.

### Proposed criteria

**Demonstration of efficacy against diseases not adequately responsive to current therapies through the novel mechanism of action**

That following the demonstration of efficacy etc. in clinical studies that include cases that are inadequately responsive to or intolerant of standard therapies for the respective disease (only industry-sponsored clinical trials conducted with the objective of obtaining initial approval and for which the target number of cases inadequately responsive to or intolerant of standard therapies has been pre-set,) it is explicitly stated in the Indications, Precautions and Clinical Studies sections that the drug can be administered to these patients.

**Demonstration through comparative studies of supremacy over current therapies through the novel mechanism of action**

That clinical studies (only industry-sponsored clinical trials conducted with the objective of obtaining initial approval based on the hypothesis of verifying supremacy) have been conducted in which current therapies for the target disease (only those valid as therapeutic modalities in Japan) were set as the control (excluding placebos) and in which the primary endpoint was met through demonstration of supremacy of the agent over the current therapies.

In addition, post-marketing clinical studies conducted on the disease specified on initial approval shall be handled similarly.

**No other drugs available with the indications acknowledged through the novel mechanism of action**

Agents for which at the time of regulatory approval no products were available with matching indications and effects and that offered the first therapeutic option for the target disease; or that clearly expand the scope of treatable cases to a greater extent than current drugs with similar indications and effects.

- In addition to the above, the following products shall be eligible for the PMP since their level of innovativeness/utility is deemed to be equivalent to that of first-in-the-class products.
  - Those listed within three years of the listing of a drug with a novel mechanism of action (only up to the third-in-the-class) of which
  - The drug with a novel mechanism of action has been awarded a premium or correspond to the above criteria.

# Revision of price maintenance premium

## Direction of reform

(Provisional translation by PhRMA)

- The specific categorization of the company indicators based on the total respective points shall be as follows.
- Further, given that the company indicators are to be newly introduced, in the FY 2018 revision it shall be ensured that inter-company differentials arising from the difference in the scope and premium coefficient of Categories I and III are limited. For subsequent revisions too, and with reference to the status of new drug development etc., there shall be ongoing examination of the validity of these indicators for evaluating the initiatives and performance of pharmaceutical companies in respect of the development of innovative new drugs and elimination of drug lags, and their revision or the reflection of the findings in the respective revisions shall be discussed.

### <Company indicators>

	Details			
A - 1	Domestic studies (including global studies including Japan) (no. conducted) (Phase II ~)	Top	25%	4 pts
		Median	50%	2 pts
A - 2	New drug listing performance (no. of listed ingredients) (past 5 years)	Top	25%	4 pts
		Median	50%	2 pts
B - 1	Products publicly offered for development (no. of starts) (past five years) (excluding B - 2)	2 pts per product		
B - 2	Products publicly offered for development (no. of approvals) (past 5 years)	2 pts per product		
C	First-in-the-world new drug developments (no. of products) (past 5 years)	2 pts per product		

The A - 1 figures are those as at the end of September 2017 and the values of other indicators are the figures up to that date.

In addition, the A - 1 figures are per ingredient and include additional indications. (Studies underway for several indications for one ingredient are counted as '1'.)

The no. of studies conducted for A - 1 include products such as HIV agents for which applications for approval based solely on the results of overseas studies are exceptionally permitted.

The number of products referred to in C is the number designated under the *sakigake* review designation scheme.

### <Categorization>

Category	I	II	III
Scope	Top 25%*	Other than I and III	Minimum no. of points
Premium coefficient	1.0	0.9	0.8

\* Where there are several companies in the top 25<sup>th</sup> percentile of company indicator points, companies with the respective points shall be handled as Category I, with the ceiling set at the number of companies within the respective points percentile that do not exceed 30% of the total number of PMP-eligible companies.

### <Handling of medical ventures>

Companies fulfilling the following criteria shall be placed in Category II.

- Is an SME  
(A company with 300 or fewer employees or stated capital of 300 million yen or less)
- The share-holding or capital contribution of another corporation does not exceed 1/2 of the total no. of shares or total capital
- The share-holding or capital contribution of several corporations does not exceed 2/3 of the total no. of shares or total capital
- Has only one ingredient eligible for the PMP and has posted no current profits or did so but had no business income in the fiscal preceding the year of the respective product approval (only over the past five years)

# Revision of price maintenance premium scheme (overall image)

(Provisional translation by PhRMA)

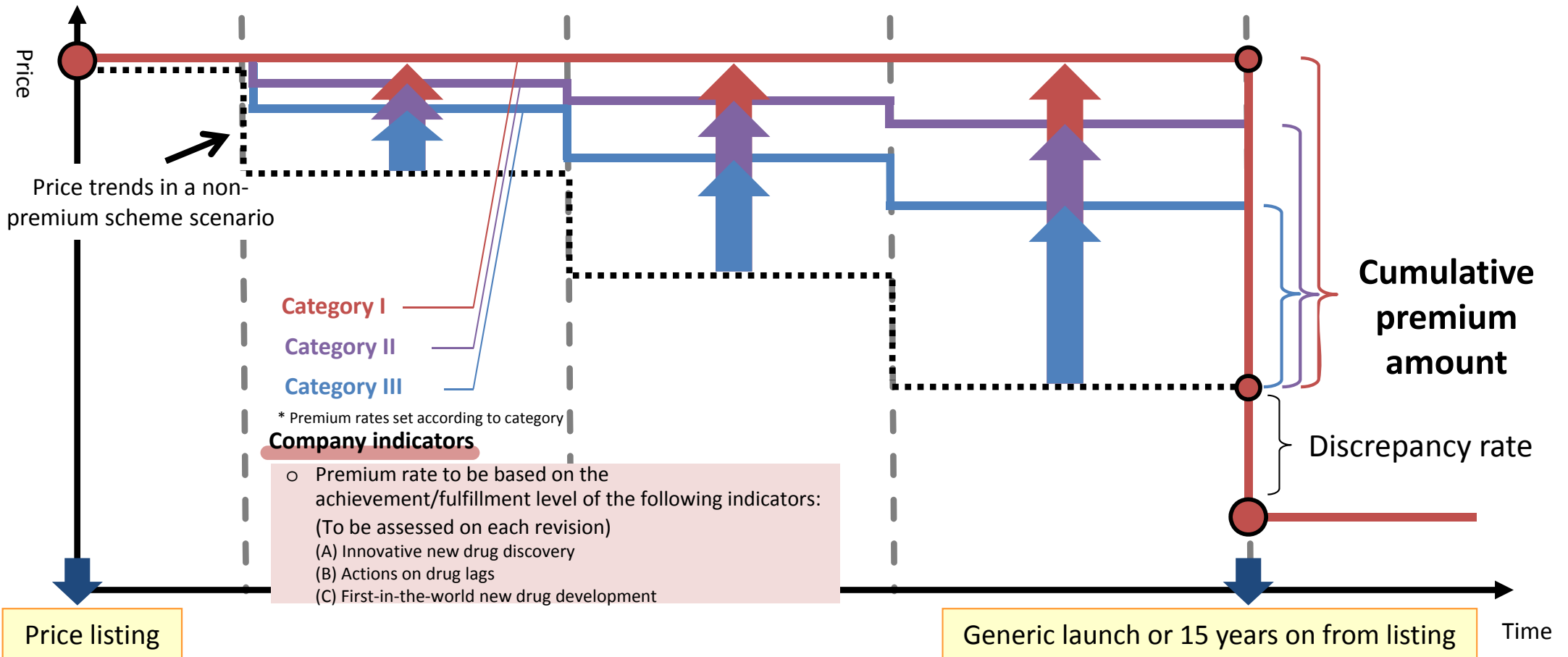
## Position of scheme

- Institutionalization to be discussed following fundamental revision to establish an efficient and effective mechanism for the promotion of breakthrough new drug discovery.

## Product requirements

- Decision based on intrinsic drug innovation and utility

Limited to drugs awarded an innovation/utility premium and operating profit rate adjustment, orphan drugs, products publicly offered for development and drugs with a novel mechanism of action (only those deemed under the pricing rules to have innovation and utility) etc.



\* Ceiling premium amounts also set according to the discrepancy rate

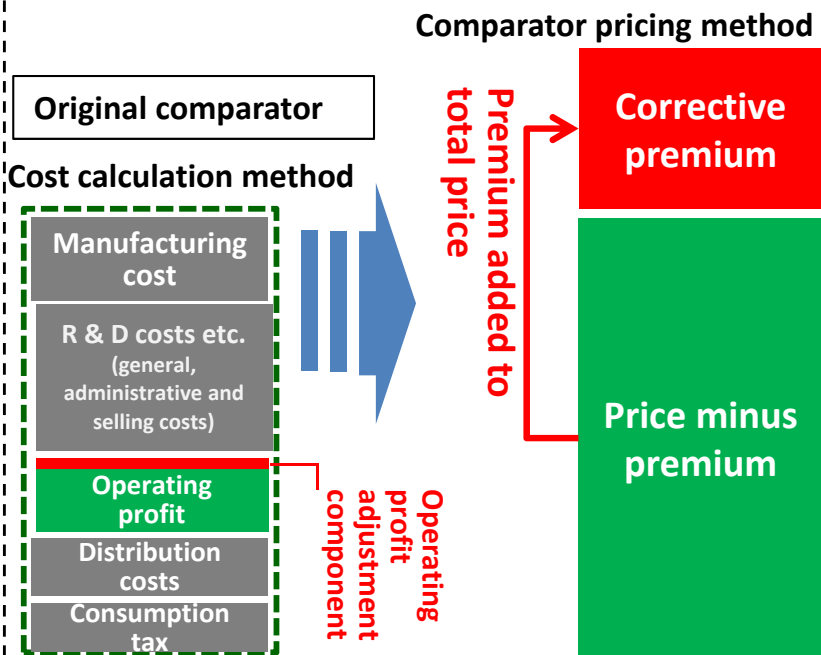
# Evaluation of innovation

(Provisional translation by PhRMA)

## Direction of reform

- To ensure that the innovation of innovative drugs is properly evaluated, with the cost calculation as well as the comparator pricing method, premiums shall be applied to the total price (the calculated price minus the premium).

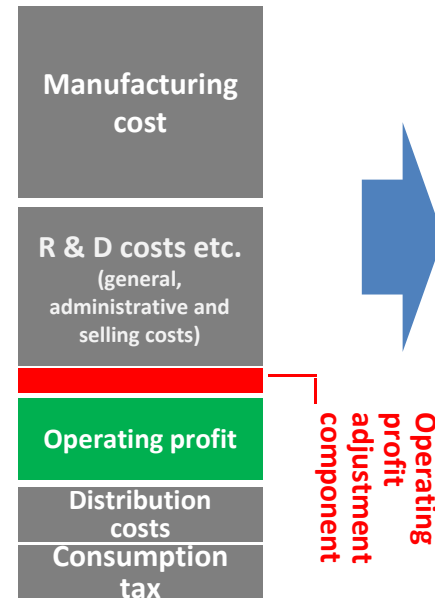
**Ref.** Even with the comparator pricing method, prices are originally based on the cost calculation method



Adjustment of operating profit only

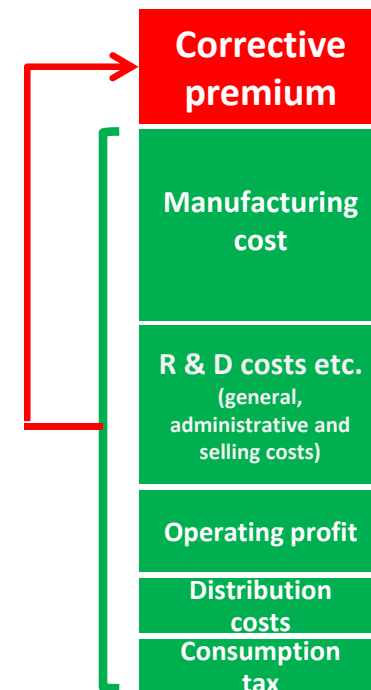
## Current

Cost calculation method



## Revised

Premium added to total price



# Evaluation of innovation

(Provisional translation by PhRMA)

## Direction of reform

- To promote the transparency of drug pricing, premium rate differentials shall be set for the cost calculation method according to the percentage of manufacturing cost items disclosable by the Drug Pricing Organization (the disclosure level)\*

$$\text{Premium} = \text{total price} \times \text{premium rate} \times \text{premium coefficient}$$

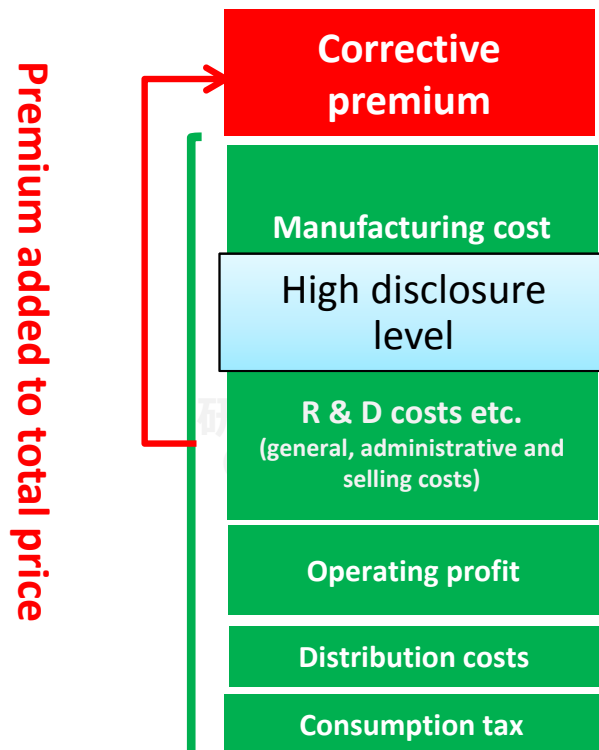
(price minus premium) (0 ~ 120%) (0.2 ~ 1)

Disclosure level	80% ~	50~80%	< 50%
Premium coefficient	1.0	0.6	0.2

\* Disclosure level = (disclosable price components) ÷ (manufacturing cost)

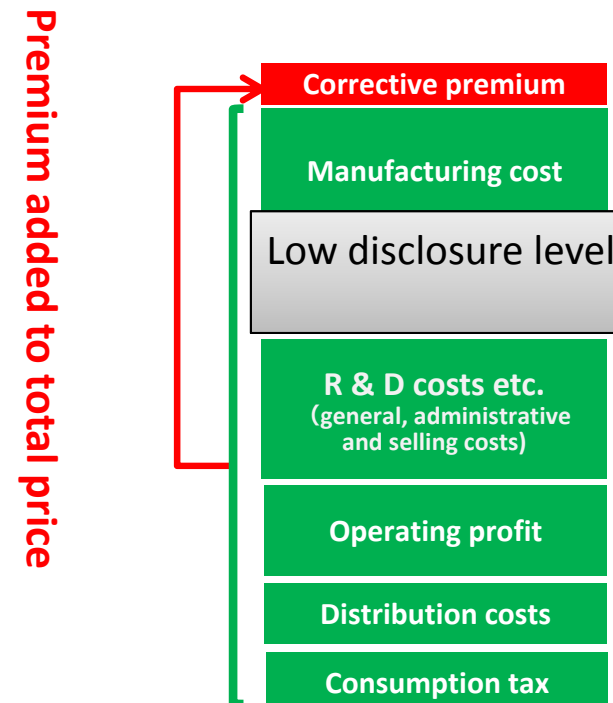
### High disclosure level

Premium = total price x premium rate x premium coefficient 1.0



### Low disclosure level

Premium = total price x premium rate x premium coefficient 0.2



\* All prices pre-FPA adjustment

# Revision of prices of long-listed products etc.

## Direction of reform

(Provisional translation by PhRMA)

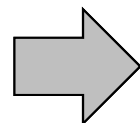
### <Outline of scheme>

- To promote a shift from an LLP-dependent industry structure to one with greater drug development capability, LLPs shall be positioned as follows and their prices revised at the respective timings.
  - (1) The generic substitution timing shall be up to ten years after generic launch
  - (2) The timing of the reduction of LLP prices to the generic level shall be ten years on from generic launch

### <Generic substitution timing: revision of the Z2 rule>

- The Z2 rule for generic substitution timing shall be maintained. However, in view of the government target for the achievement of an 80% volume-based generic share by September 2020, the criteria for the three substitution rate categories under this rule shall be revised as follows.

Substitution criteria (current)	Reduction rate
50% ~ 70%	▲ 1.5%
30% ~ 50%	▲ 1.75%
< 30%	▲ 2.0%

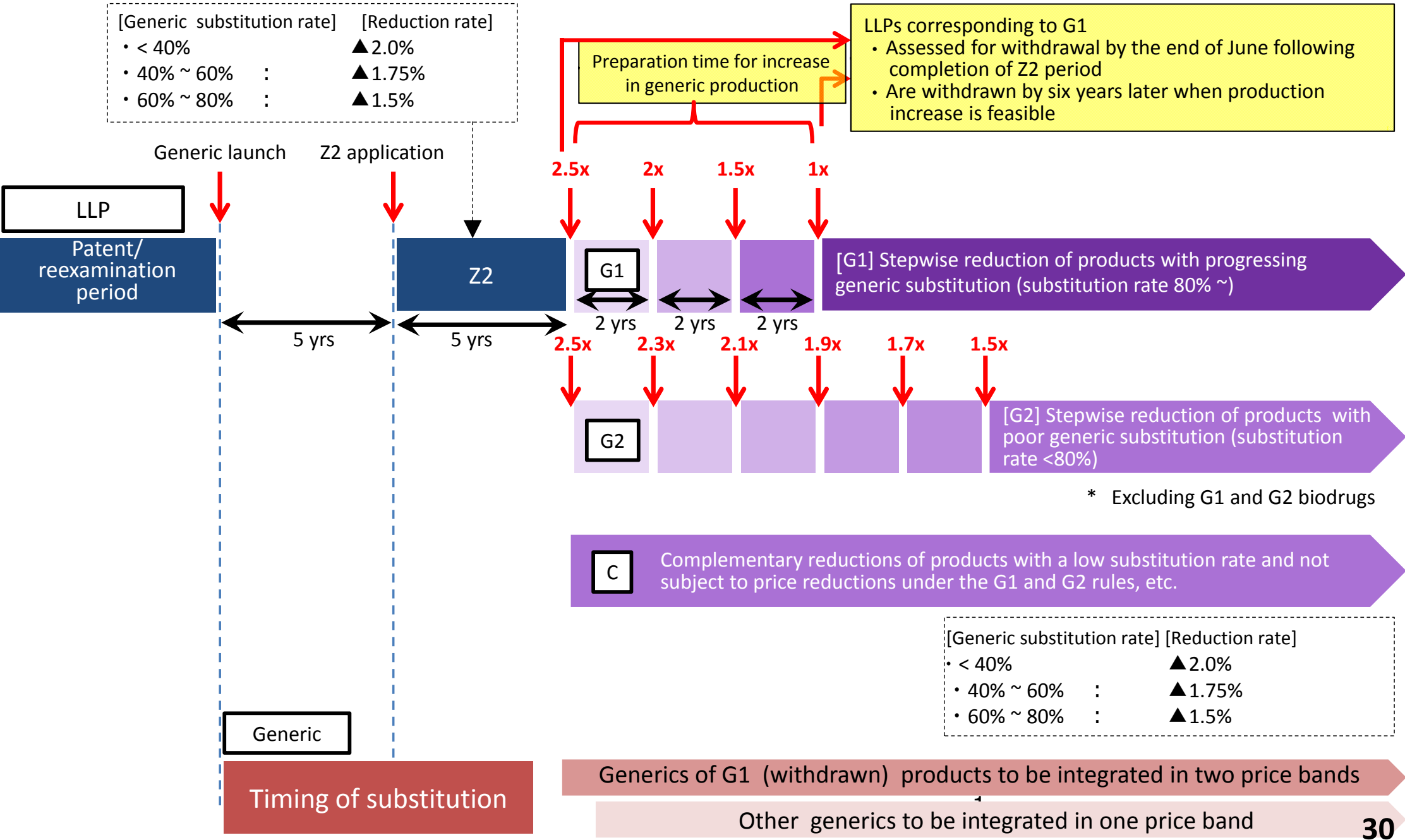


Substitution criteria (revised)	Reduction rate
60% ~ 80%	▲ 1.5%
40% ~ 60%	▲ 1.75%
< 40%	▲ 2.0%

### <Timing of reduction to generic price : introduction of new scheme>

- A new scheme for reducing the prices of LLPs shall be introduced based in principle on their categorization as follows:
  - (1) Products with progressing generic substitution (80% or above) **(G1)**
  - (2) Products with poor generic substitution (less than 80%) **(G2)**

# Revision of prices of long-listed products etc. (overall image)



# Revision of foreign price adjustment

## Direction of reform

(Provisional translation by PhRMA)

### <Reference price list>

- In the US the RED BOOK prices are currently referenced. However,
  - (1) Some have taken the view that, being a list of the manufacturers' recommended prices (free prices), the RED BOOK is inappropriate for comparative use in drug pricing decisions in Japan, a country that has official prices.
  - (2) Whereas others have take the view that, being the world's largest drug discovery country, it is not valid to exclude the US from the reference countries.
- In view of these points, the price lists ASP and NADAC\* used for the US public healthcare schemes Medicare and Medicaid shall be referenced.

### <Scope of applicable new drugs>

- Currently, FPA is applied both to drugs priced with the cost calculation and the comparator pricing methods. However, to assure fair market competition, FPA shall not be applied in the comparator pricing of new drugs but shall be applied to the following:
  - (1) New drugs to be priced with the cost calculation method
  - (2) New drugs to be priced with the comparator pricing method for which no drugs with similar pharmacological action exist

\* ASP : Medicare Part B Drug Average Sales Price  
NADAC : National Average Drug Acquisition Cost



# Re: NADAC and ASP

## Overview

	ASP	NADAC
Overview	<ul style="list-style-type: none"> <li>● Average sales price of in-house prescription drugs to medical centers</li> <li>● Reimbursement price for Medicare Part B coverage (hospital outpatient services etc.)</li> </ul>	<ul style="list-style-type: none"> <li>● Average cost for acquisition of in-house prescription drugs by dispensing pharmacies</li> <li>● Used as basis for Medicaid reimbursement prices</li> </ul>
Applicable drugs	Drugs principally used as part of treatment administered by physicians in clinics that are not reimbursed on a flat-fee basis.	Products included in the CMS outpatient prescription drug list or new products approved as outpatient prescription drugs by the CMS under the provisions of Section 1927 of the Social Security Act.

\* Extract from data distributed to Expert Advisors of the Expert Committee on Drug Pricing on August 9 2017

## Comparison with RED BOOK

	ASP/NADAC (New reference price lists)	RED BOOK (Reference price list used to date)
No. of listed products *	19 products	55 products
Price relative to RED BOOK (average)	0.77	—

\* New drugs listed in Japan April 2016 ~ August 2017 for which US RED BOOK prices were available at the time of listing (55 products in total)

# 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.