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Ministry of Health, Labour and Welfare

# Update of Drug Pricing System in Japan

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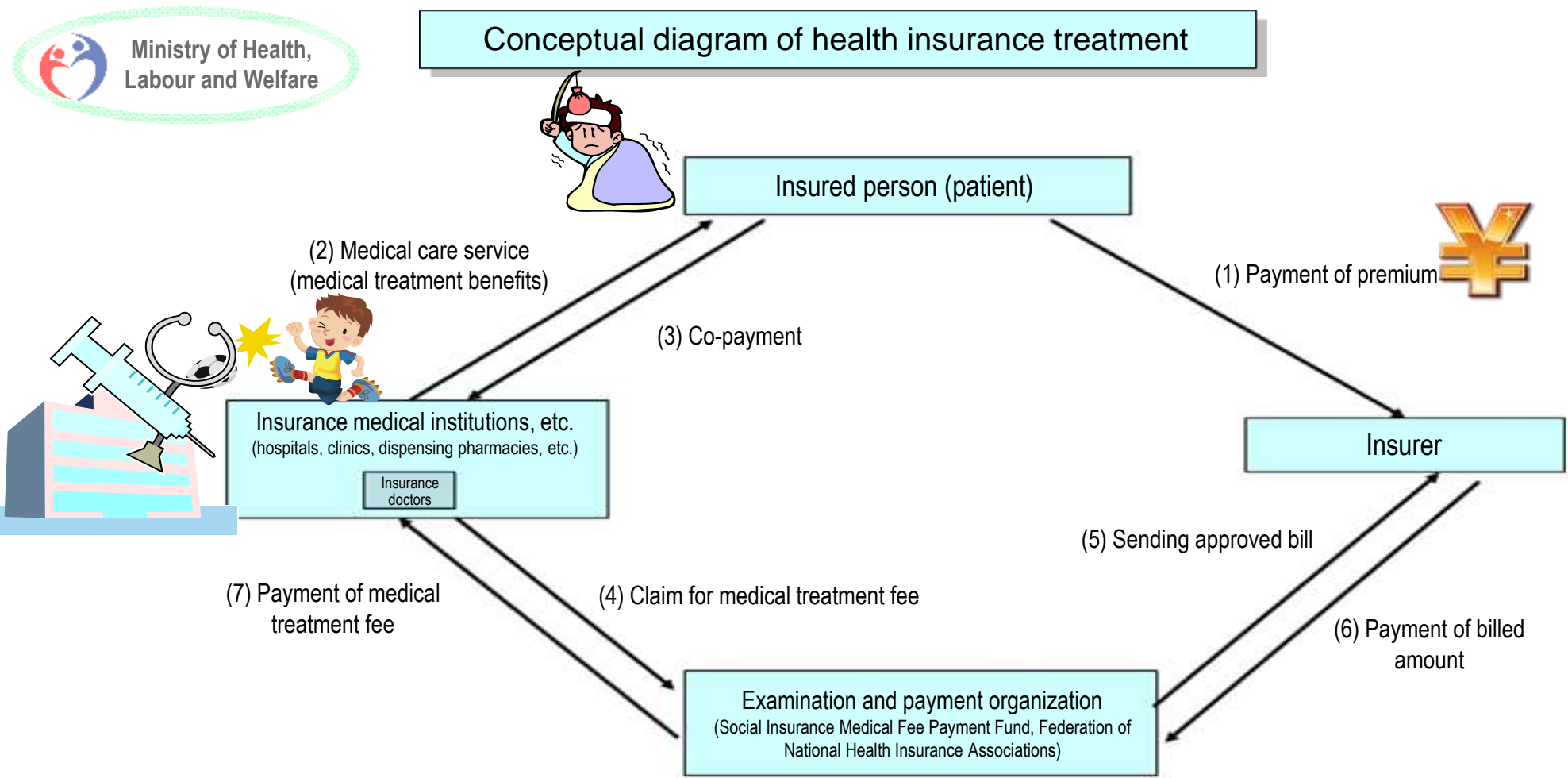
# Outline of Today's presentation

1. National Health Insurance and Drug Pricing System in Japan
2. Reform of Drug Price Standard
3. Health Technology Assessment

# 1. National Health Insurance and 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.

# Medical Services NOT Covered by Medical Insurance

- (1) A illness or injury either during work or commuting to or from the workplace
- (2) Services which are provided for conditions which are not regarded as illnesses
  - ① Normal pregnancy and delivery
  - ② Physical check-ups and associated tests
  - ③ Vaccinations etc.
- (3) Restrictions on unjust or unfair actions
- (4) The use of special drugs or special treatment methods

Insurance is not applied to the use of some special drugs or special treatment method which is not recognized as effective and appropriate by the medical community.

# Medicines listed in Drug Price Standard

- Drug Price Standard covers all medicines that are necessary for medication and dispensing by the National Health Insurance (NHI) .
  - ➔ Drugs for medical use approved by Pharmaceutical and Medical Device Act are listed in Drug Price Standard in principle .
- There are some Drugs NOT listed in Drug Price Standard
  - OTC
  - A part of drugs for medical use as follows:
    - Not suited for NHI such as Viagra

# 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.

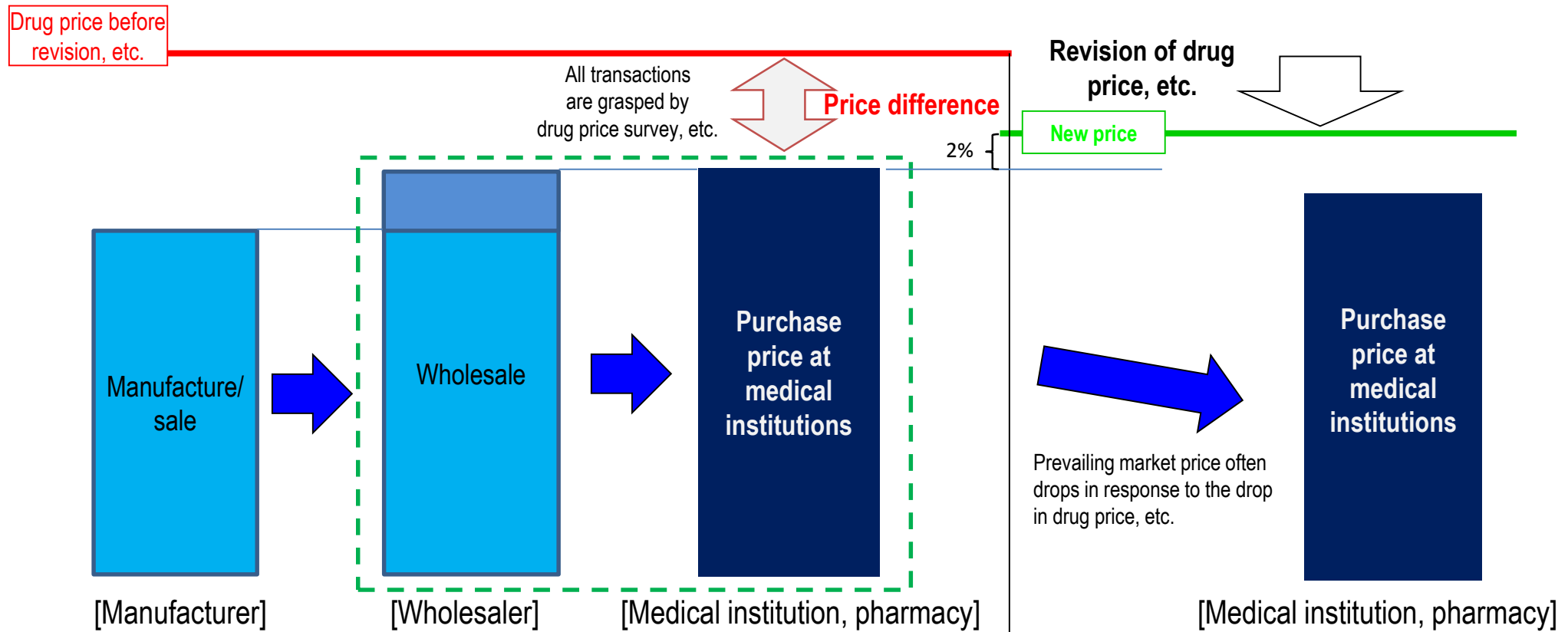
# Overview of Current Drug Pricing System

- 1 . *Drug Price Standard* defines price of medicines reimbursed in medical institutions and pharmacies by the National Health Insurance (NHI) .
- 2 . Minister of Health, Labour and Welfare announced “Rule of pricing medicines” on February 10, 2016 agreed by Central Social Insurance Medical Council (*Chuikyo*) .
- 3 . Price of medicines is periodically revised based on official survey of the actual sales price (market price) to medical institutions and pharmacies.



# 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.



# Outline of drug price survey

For items listed in the Drug Price Standard, the price is revised once every two years based on the market price. The market price survey carried out for this purpose is called the “drug price survey”. The drug price survey is one of the General Statistics Surveys that require approval by the Ministry of Internal Affairs and Communications based on the Statistics Act. Response from the survey subjects is voluntary.

## (1) Drug price main survey

The survey is conducted for all items listed in the Drug Price Standard (approx. 16,000 items) for the purpose of obtaining base data for revising the drug price.

For the selling side, a nationwide survey is conducted for all drug distributors in Japan (pharmacies, general distributors, wholesale general distributors) that directly supply medical drugs to medical institutions, etc.

For the purchase side, a survey is conducted on the purchase price for medical institutions, etc., selected at a certain rate.

Subject: Selling side	Wholesaler	All	Approx. 6,000 objects
Purchase side	Hospitals	1/10 of all	Approx. 850 objects
	Clinics	1/100 of all	Approx. 1,000 objects
	Insurance pharmacies	1/30 of all	Approx. 1,900 objects

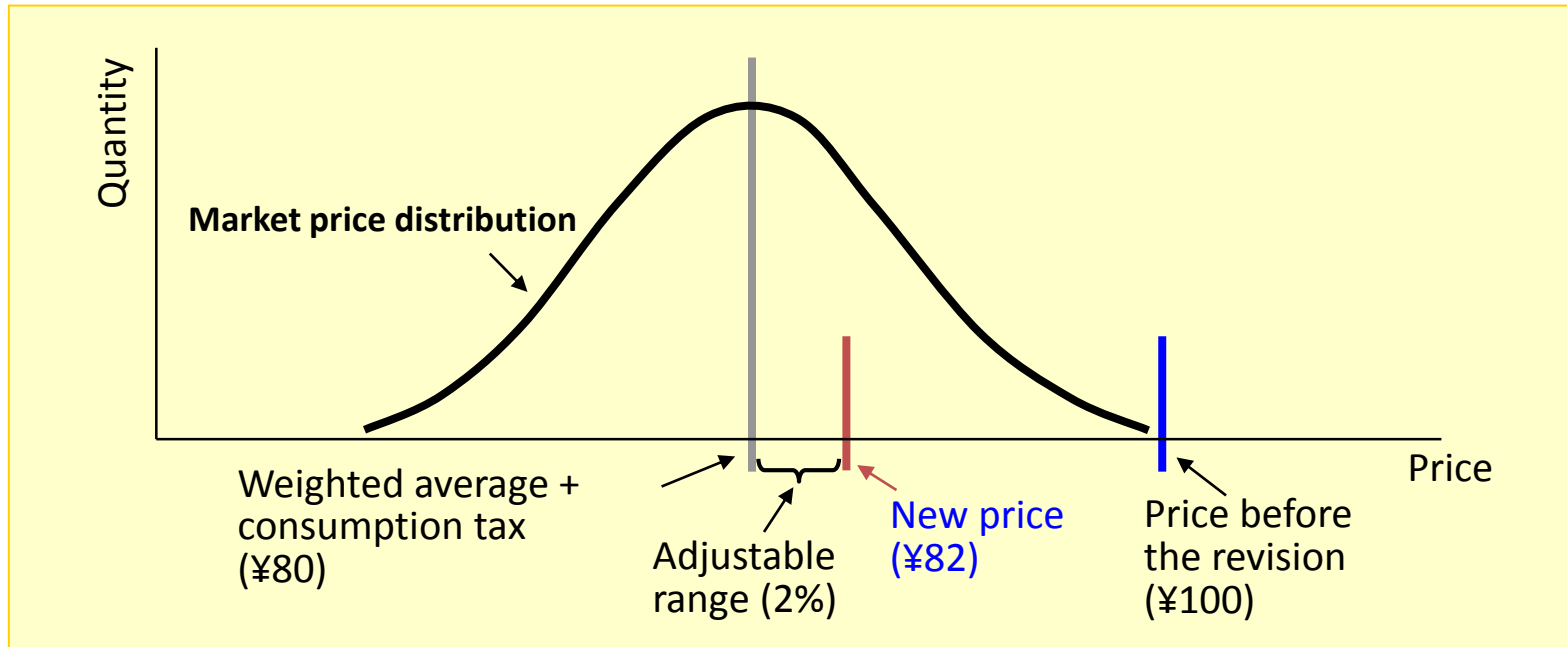
Period: Transactions within a month in the surveyed fiscal year (conducted for September in FY2015)

## (2) Time variation survey

Regularly conducted for the purpose of accurately understanding the market price and supplementing the data obtained by the main survey. The main purpose is to improve the reliability of the data obtained by the main survey. A self-administered survey, similar to the main survey.

Subject: Selling side	Wholesaler	Extraction	Approx. 1,600 objects
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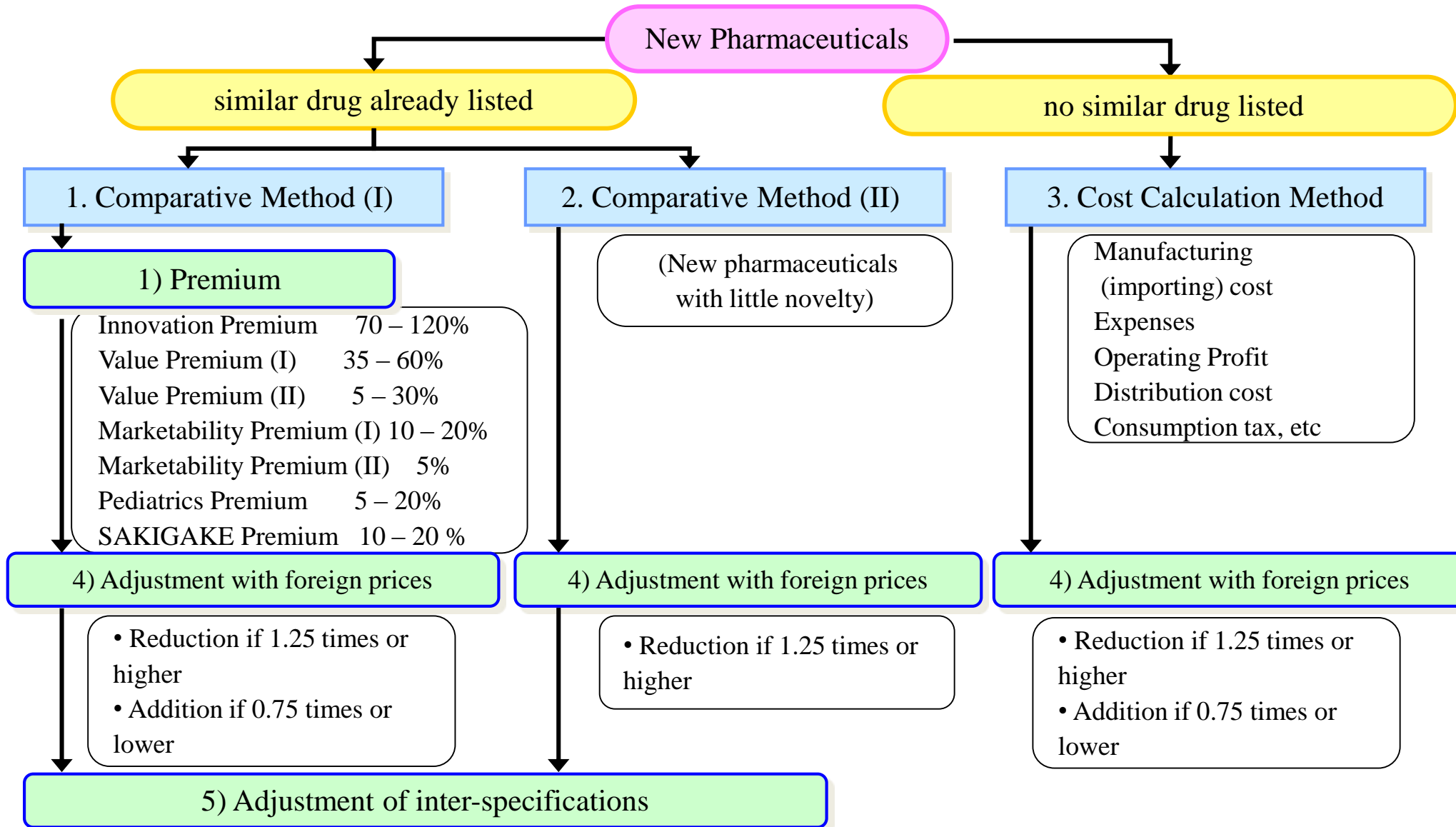
# Pricing method for listed drugs



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.

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

# Outline of Pricing New Pharmaceuticals





\* Kit materials with highly clinical values are to be further rewarded by 5%..

# Pricing Rule for New Pharmaceuticals

## Comparative method I

- When there is a comparable drug with same indication in the list, the daily price of a new medicine is to be equal to that of the comparable drug, to secure their fair competition in the market. **【Comparative Method (I)】**
  - comparable drug: a brand-name drug listed within the last 10 years without its generic drug listed basically.

1 tablet = 50 yen  
 3 tablets / day

1 tablet =  $X$  yen  
 2 tablets / day

**<Daily price equivalence>**  
 $50 \text{ yen} \times 3 \text{ tablets}$   
 $= X \text{ yen} \times 2 \text{ tablets}$   
 $X = 75 \text{ yen}$

Significant points of a comparable drug:

- 1) Indication
- 2) Pharmacological mechanism
- 3) Active ingredients and their structural formula
- 4) Route of administration, category of dosage form, dosage form and way of administration

- Premium is applied when a new pharmaceutical is proven to be highly useful.

Innovation Premium	70 – 120%	New mechanism of action, high efficacy or safety, and significant improvement in treatment
Value Premium	5 – 60%	High efficacy or safety, significant improvement in treatment, etc
Marketability Premium	5% or 10 – 20%	Orphan drugs, etc
Pediatrics Premium	5 – 20%	Pediatric indication/dosage/administration shown explicitly, etc
SAKIGAKE Premium	10 – 20%	The new listing drugs designated as a target of SAKIGAKE designation system

# Cost Calculation Method

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 +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.

# Pricing Rule for New Pharmaceuticals

Cost calculation method

- Price of new pharmaceuticals without similar drugs, is determined by the total cost of raw materials, manufacturing, etc. **【Cost Calculation Method】**

example	a) Cost of raw materials	(active ingredients, additives, containers, etc.)
	b) Labor cost	( = <u>3,818 yen</u> <sup>(*1)</sup> X labor hours)
	c) Manufacturing expenses	
	<hr/>	
	<b>d) Manufacturing cost</b>	
	e) Marketing, R&D cost	( $\leq$ (d + e + f) ) * <u>0.452</u> <sup>(*2)</sup> )
	f) Operating profit	( = (d + e + f) ) * <u>0.147</u> <sup>(*2)</sup> )
	g) Distribution cost	( = (d + e + f) + g ) * <u>0.073</u> <sup>(*3)</sup> )
	h) Consumption tax	( <u>8%</u> )

## Total= Price of a new pharmaceutical

(figures underlined: average coefficients of pharmaceutical industry (average of latest three years) is generally used)

Increase of up to 100% (200%) or decrease of up to 50% (50%) is applied to the operating profit, depending on the novelty, efficacy and safety compared with existing treatment.

\*1: Unit cost of labor: “Monthly Labor Survey” (MHLW), average of 2012-2014

\*2: Ratio of expenses/labor, marketing/administration cost, operating profit: “Handbook of Industrial Financial Data” (Development Bank of Japan), average of 2012-2014

\*3: Ratio of distribution cost: “Current Report of Pharmaceutical Industry ” (MHLW), average of 2012-2014

# Drug Price Determination Methods for new pharmaceuticals

## Adjustment with Average Foreign Price

- Drug prices calculated by Comparative Method (I) and Cost Calculation Method is adjusted in case of large disparity between average foreign price.

### 【Adjustment with Average Foreign Price】

1) average foreign price: average of US, UK, Germany and France

2) adjustment conditions:

a) 1.25 times or higher than average foreign price → Reduction\*

b) 0.75 times or lower than average foreign price → Addition

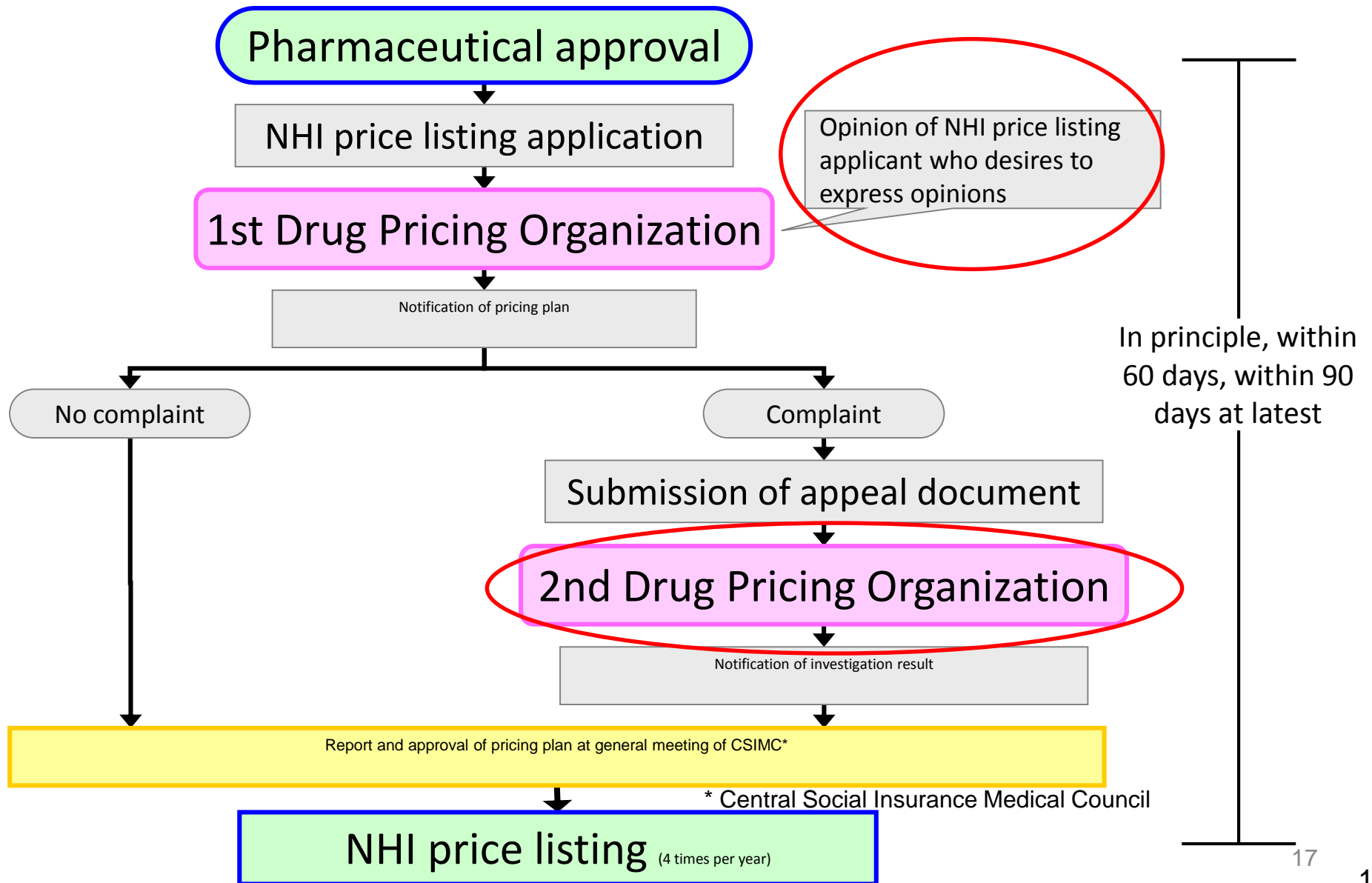
$$(1) \text{ 1.25 times or higher: } \left( \frac{1}{3} \times \frac{\text{Temporally calculated price}}{\text{average foreign price}} + \frac{5}{6} \right) \times \text{average foreign price}$$

$$(2) \text{ 0.75 times or lower: } \left( \frac{1}{3} \times \frac{\text{Temporally calculated price}}{\text{average foreign price}} + \frac{1}{2} \right) \times \text{average foreign price}$$

(Note: upper limit is as twice as the temporally calculated price)



# New drugs price determination process



# Timing of listing of new drugs

## ○ Basic rules

- Four times a year for new drugs  
(within 60 days in principle, within 90 days at the latest)
- Twice a year for report products and new kit products
- Twice a year for generics

## ● Timing of listing

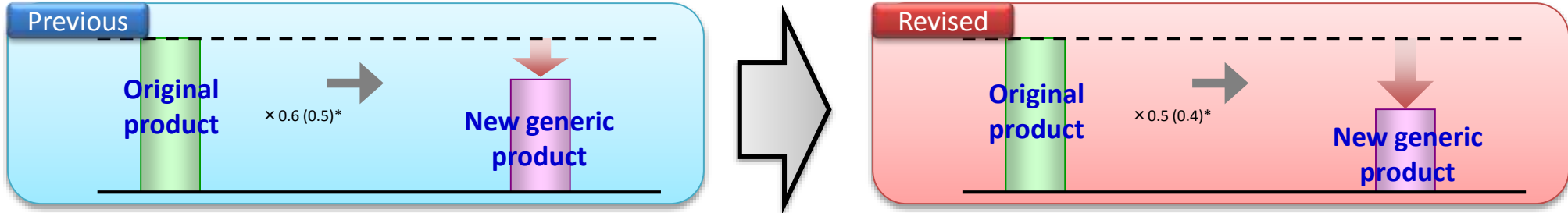
New drugs	4 times a year	February, May, August, November (corresponding to approval timing based on Pharmaceutical Affairs Law)
Report products New kit products	Twice a year	May, November
Generics	Twice a year	June, December

# Generic drug pricing and price revision

## (1) Price revision of generic drugs to be newly listed

### Measure

- ◆ It shall be “50% of the original product (for oral medicine, 40% if the number of brands exceeds 10)”.
- ◆ It shall be the same as before for biosimilar.(70% of the original product )  
(Both approved at a general meeting of the Central Social Insurance Medical Council on December 25, 2015)

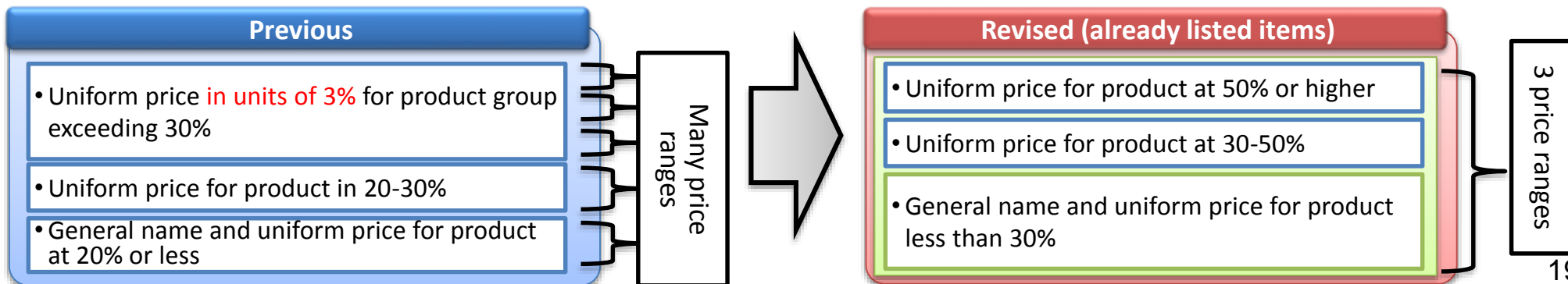


\* When exceeding 10 brands

## (2) Price revision of generic drugs already listed

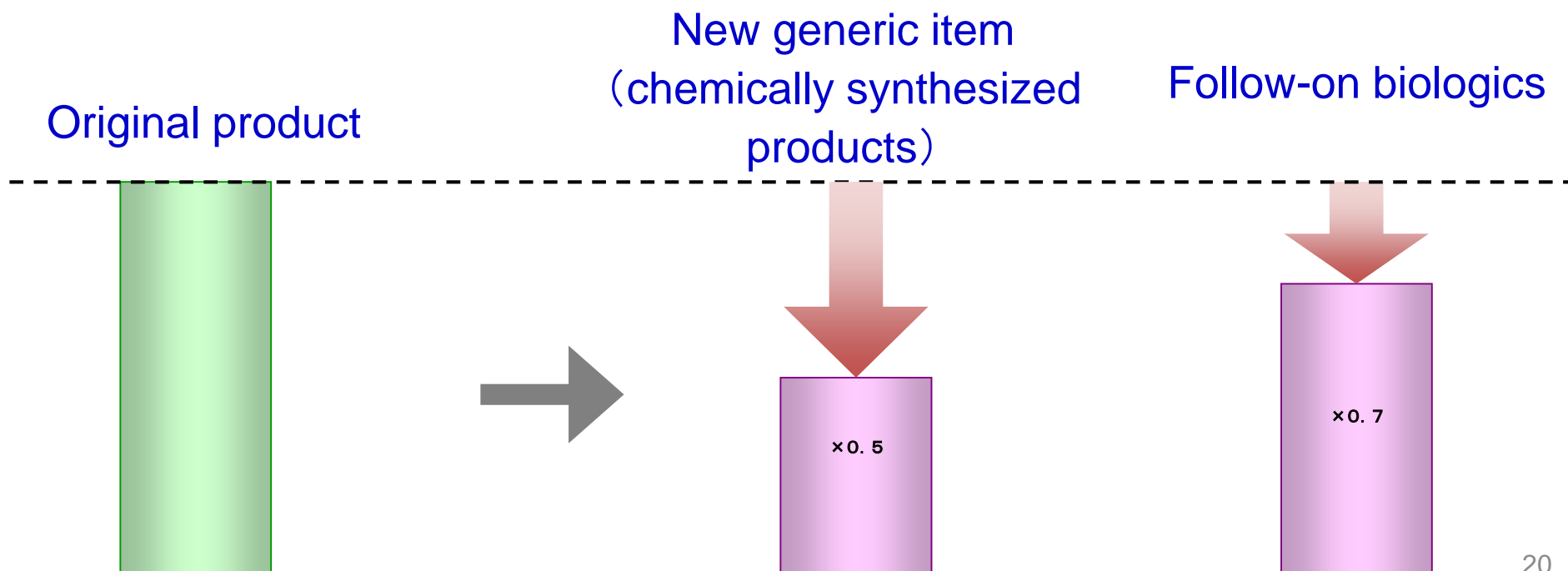
### Measure

- ◆ In the next drug pricing system reform, the drug price shall be calculated as below for all listed product groups where the composition, dosage form and specifications are the same, from the viewpoint of promoting the use of generic drugs  
(Approved at a general meeting of the Central Social Insurance Medical Council on December 25, 2013)
- (1) For a listed item whose calculated amount becomes below 30% of the maximum price, it shall be the weighted average for all relevant items (general name).
- (2) For a listed generic item whose calculated amount becomes 30% or more and below 50% of the maximum price, it shall be the weighted average for all relevant items (by brand).
- (3) For a listed generic item whose calculated amount becomes 50% or more of the maximum price, it shall be the weighted average for all relevant items (by brand).

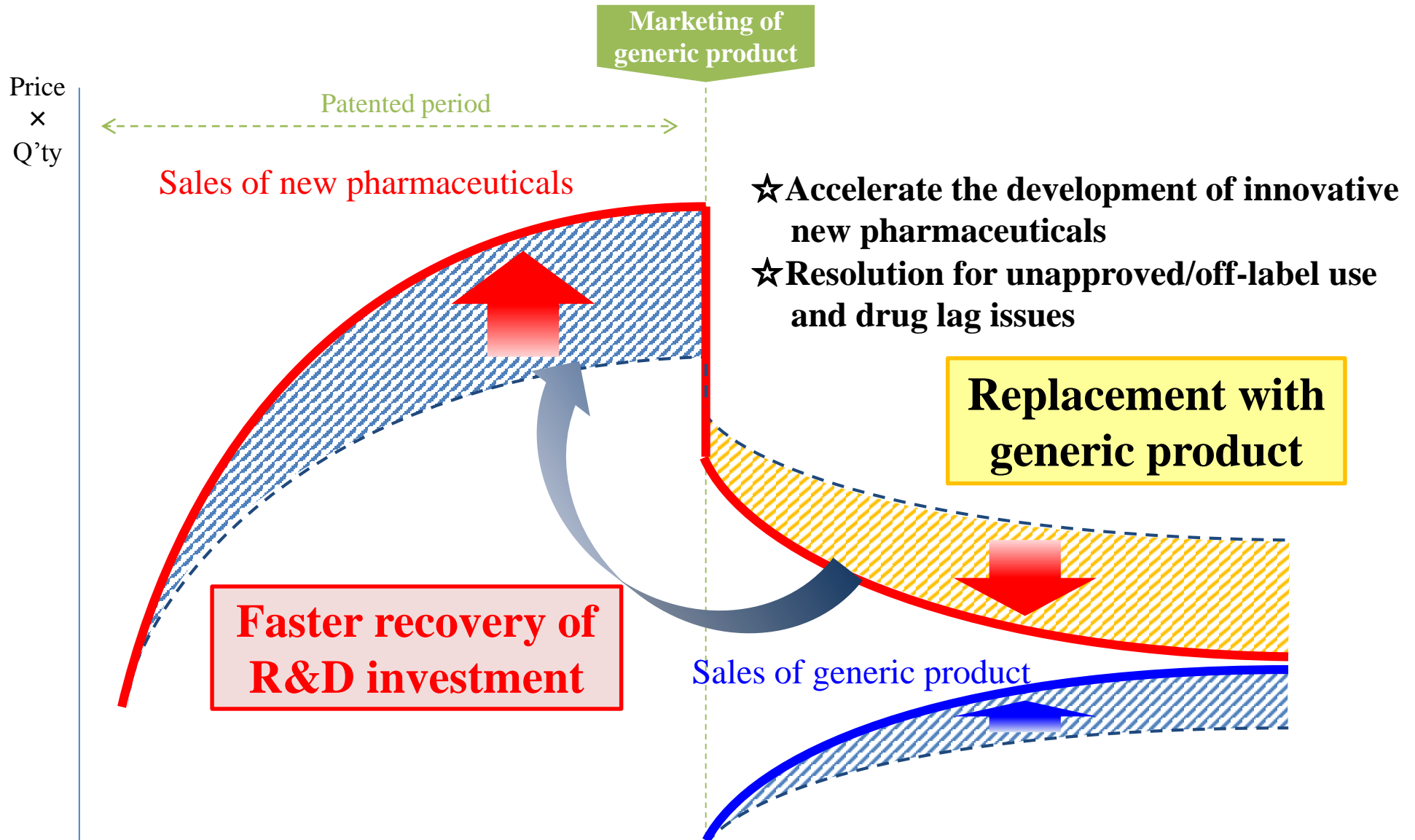


# The drug price of the follow-on biologics (biosimilars)

- 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



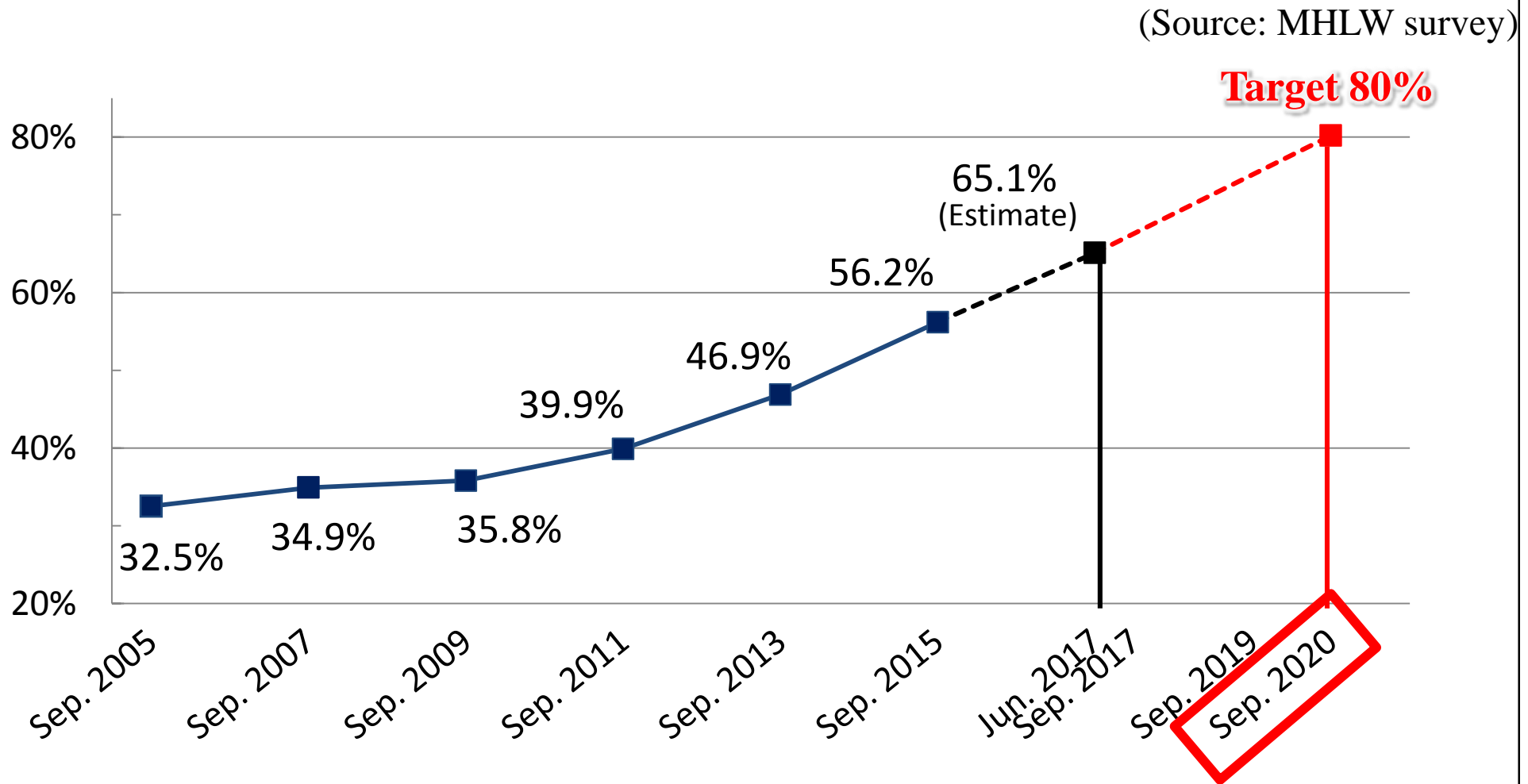
# Concept for new pharmaceuticals creation premium



# Shift in the quantity share for generic products and targets

**Volume share target**  
(Major policy 2017)

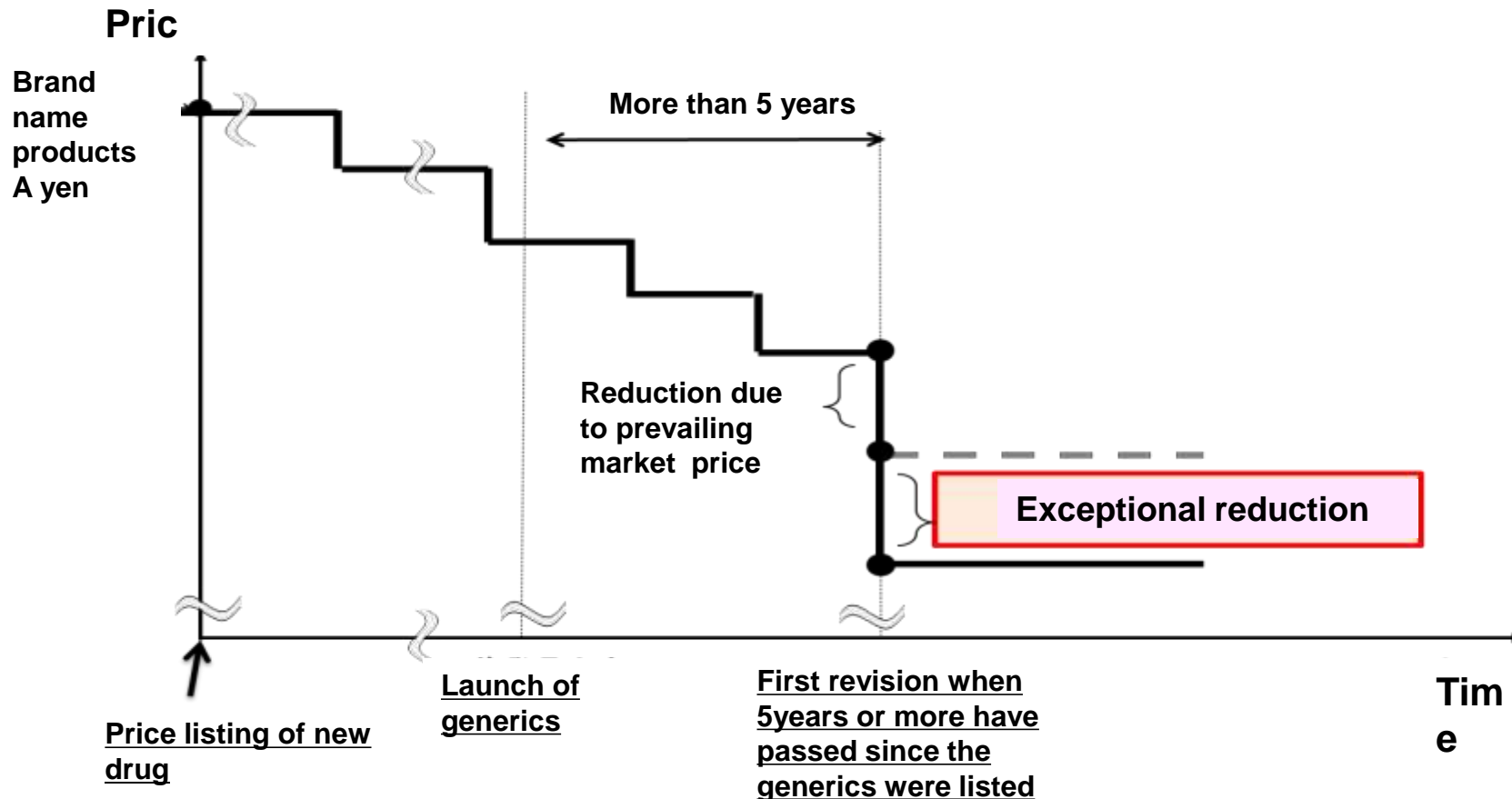
○ Achieving **80% by September 2020**, considering further promotion in order to archive the target as soon as possible.



Volume share means ratio of quantity of “generics” against quantities of “branded drugs with generics” and “generics”

# Revision of drug price that promotes replacement of drugs listed for a long time with generics

- ◆ “Exceptional reduction” shall be applied to individual brand name products that have not been appropriately replaced by generics even after 5 years of listing of these generics.
- ◆ The percentage of exceptional reduction is shown below.
  - Price reduction of brand name products with less than 30% of replacement rate by generics : 2.0%
  - Price reduction of brand name products with less than 50% of replacement rate by generics : 1.75%
  - Price reduction of brand name products with less than 70% of replacement rate by generics : 1.5%



# “Premium to promote the development of new drugs and eliminate off-label use” (1)

- Purpose

For new drugs for which generic drugs are not marketed and that satisfy certain requirements, **promotes solution of problems such as the pressing matter of off-label drugs** and **accelerates discovery of innovative new drugs**, by **temporarily delaying the reduction of drug prices based on the market price** for the period until generic drugs are marketed.

(Approved by Central Social Insurance Medical Council on December 21, 2011)



# “Premium to promote the development of new drugs and eliminate off-label use” (2)

## 1. Range of new drugs subject to the premium

Those that satisfy the requirements (1)-(3) below.

Excludes those containing compounding agent for internal medicine (excluding HIV drugs) to which a corrective premium was not applied at the time of NHI price listing and where 15 years have passed since NHI price listing or a generic drug is marketed.

(1) New drug for which no generic drug is marketed (up to 15 years after NHI price listing)

(2) Those where the deviation rate of the market price to the drug price does not exceed the weighted deviation rate average of all listed drugs

(3) Those marketed by a marketer that developed or is currently developing off-label drugs to which development is requested based on the results of deliberations at an Unlicensed Drugs Review Meeting, or that applied for items to which development was publicly invited and carried out or is carrying out activities toward development, or those marketed by a marketer that is carrying out research and development of “drugs that truly contribute to improving the quality of medical services” separately from such items

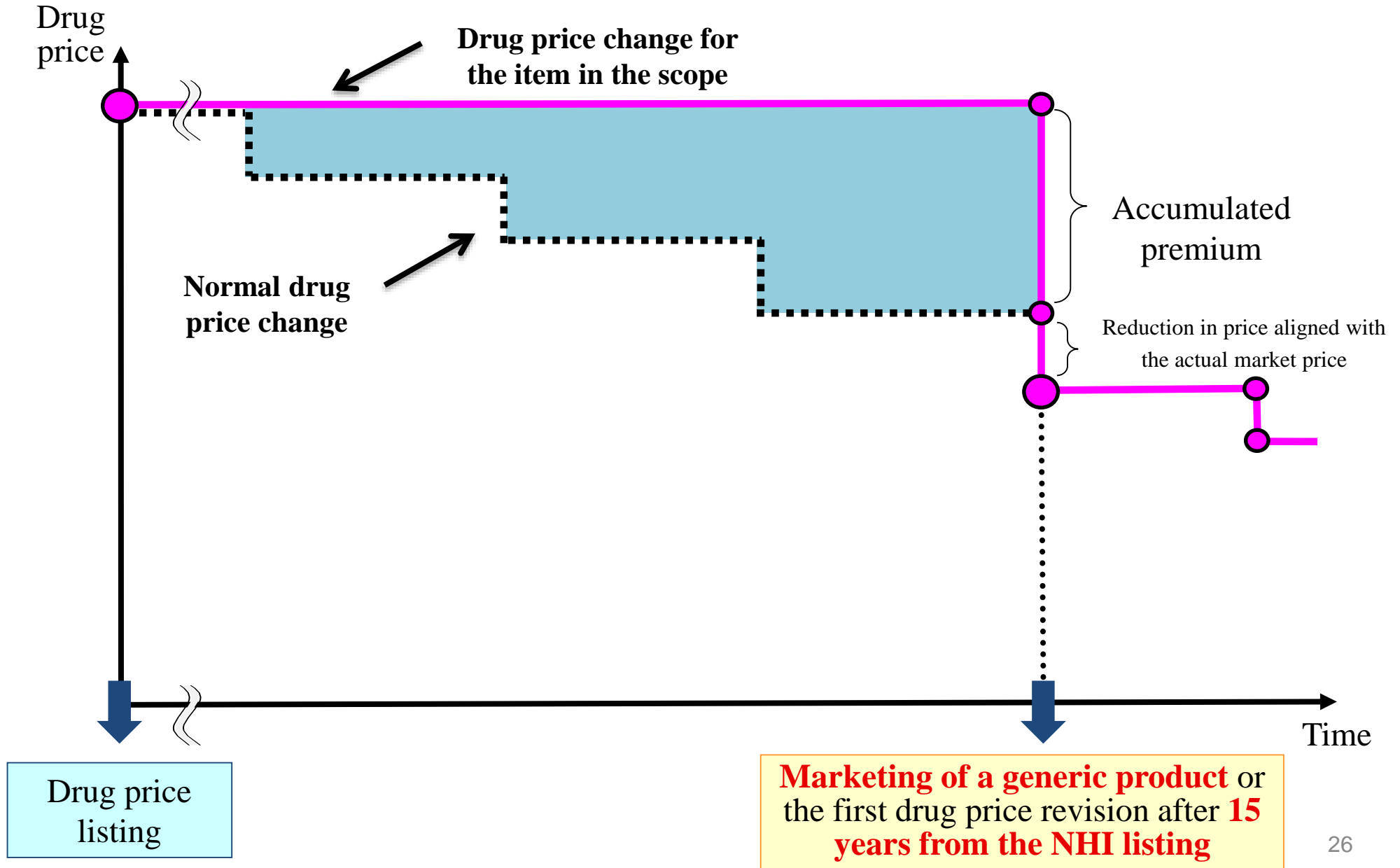
## 2. Formula

$$\left( \begin{array}{l} \text{Amount calculated by the rules} \\ \text{in Chapter 3, Section 1 for the} \\ \text{listed item (drug price after} \\ \text{normal drug price revision)} \end{array} \right) \times \frac{(\text{Average deviation rate for all listed item} - 2/100) \times 80/100}{5.41\%}$$

(FY2014 4.94%)

\* Limited to FY2014 revision, upper limit is 108/105 of the pre-revision drug price.

# Image of drug price change of a new pharmaceuticals given the Premium for promoting new pharmaceuticals creation



# 「Framework of the reform of drug price system in FY2016」

(approved in the general meeting of Central Social Insurance Medical Council on December 25,2015)

## II Price revision of drugs already listed

### 3. Basic drugs

The system named “Basic drugs” is designed to prevent the drug from being minimum-priced or being subject to the rule of re-pricing unprofitable products.

As a trial implementation in the FY2016 drug pricing system reform, prices on those that meet all the requirements below will be fixed at that of a brand with biggest sales. The price will be maintained while they are authorized as basic drugs.

- ① 25 years or more passed after NHI price listing and each deviation rate of the market price to the drug price of a certain brand and drugs with same ingredient does not exceed the average deviation rate of all listed drugs.
- ② Having a multiplicity of uses ,for example, to be listed in general guidelines and widely used at medical institutions
- ③ drugs formerly subject to the rule of re-pricing unprofitable products

anti-pathogenic organism drugs and narcotic drugs forming the basis of health care for a long time

Profitable drugs are excluded from the basic drugs category. As for basic drugs, stable supply should be maintained while the prices are maintained.

# Subject of basic drugs at the reform of drug price system in FY2016

The prices of basic drugs will be fixed at that of a brand with biggest sales and the price will be unchanged while they are authorized as basic drugs.

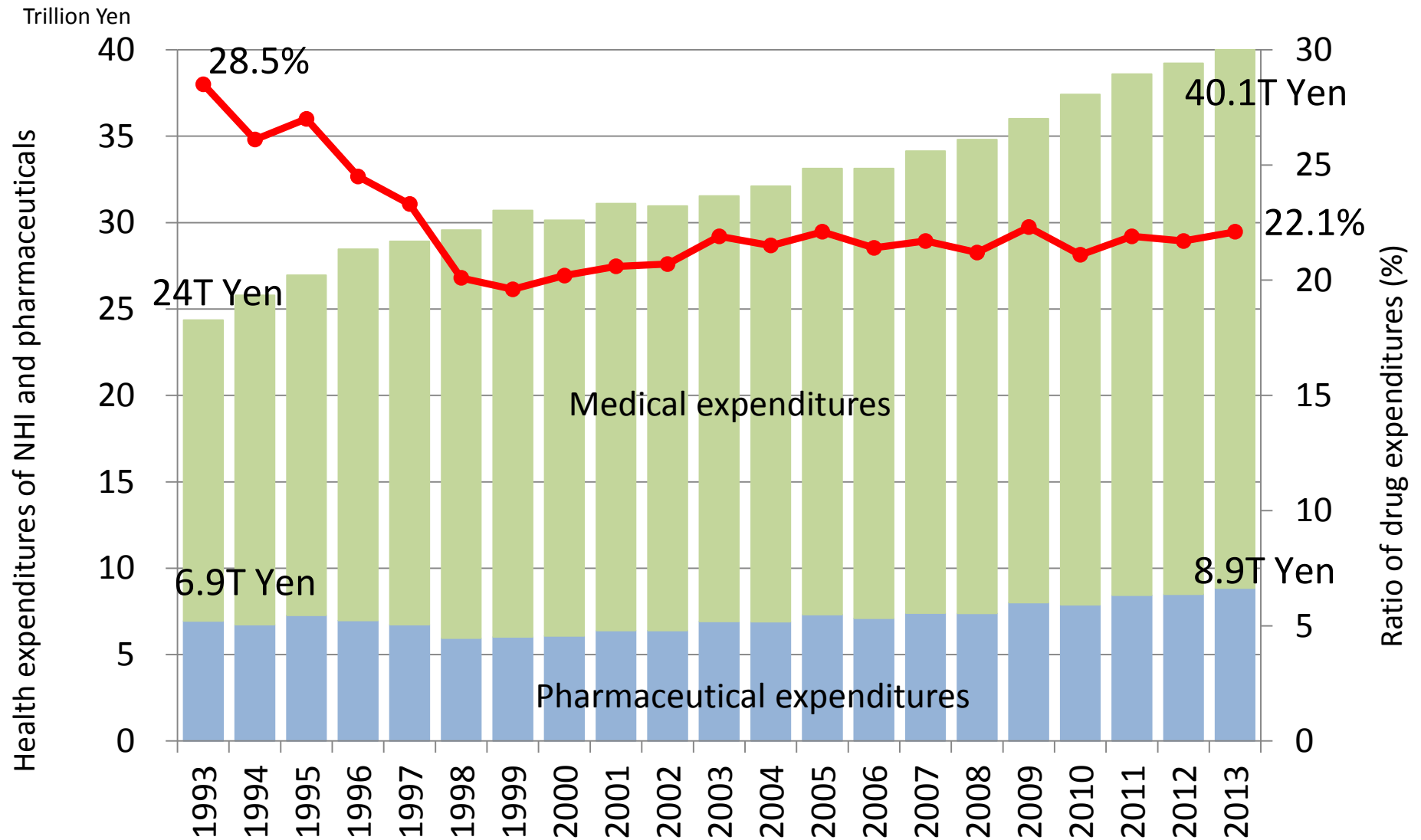
Subject: 134 ingredients 439 items

Category	Number of ingredients (Number of items)	Example	Main efficacy
pathogenic organism	51 (160)	AMOLIN FINE GRANULES EBUTOL Tablets Retrovir Capsules ARASENA-A for I.V. Infusion	various infections pulmonary tuberculosis etc HIV infection herpes simplex encephalitis etc
narcotic drugs	6 (15)	MS Contin MORPHINE HYDROCHLORIDE INJECTION	pain relief of cancer with severe pain pain relief or sedation when suffering from severe pain etc
Unprofitable products	77 (264)	HYDANTOL POWDER THYRADIN-S POWDER Endoxan PAM SOLDEM 3	epileptic fit congenital hypothyroidism multiple myeloma etc organophosphorus agent poisoning Rehydration when unable to intake orally etc

※ categorize as Unprofitable products when the drug can also be categorized into other categories

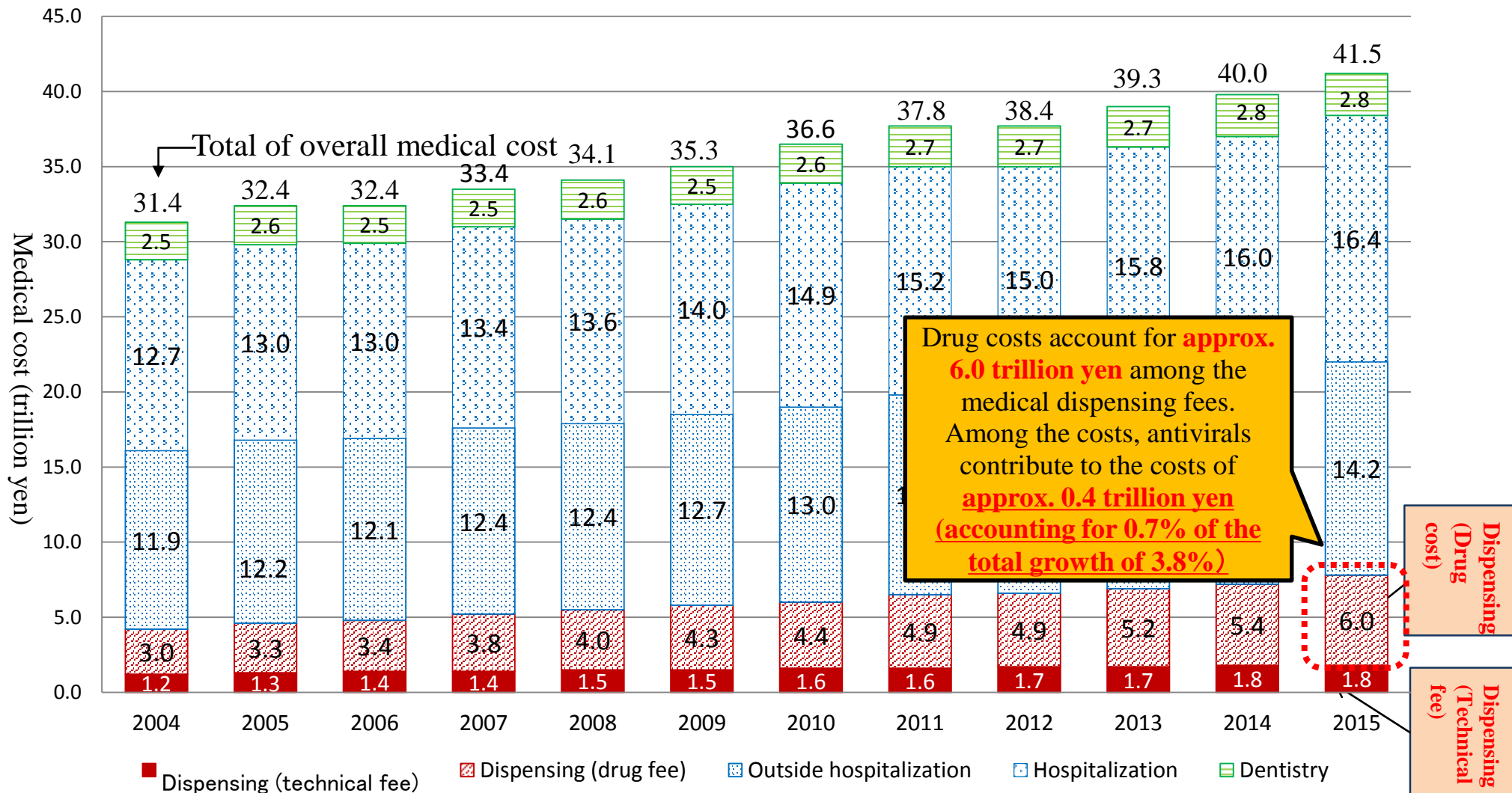
## 2. Reform of Drug Price Standard

# Yearly medical and pharmaceutical expenditures of NHI



# Shift in overall medical costs

The medical costs for fiscal 2015 reached 41.5 trillion yen with year-on-year increases by approx. 1.5 trillion yen (growth rate of 3.8%) from the previous fiscal year.



# Summary of Urgent Drug Price Revision for Fiscal 2016

## Background

- In recent years, a part of high-unit price anticancer drugs with extremely large market share have been marketed. Some of such drugs exceeded the initial prospect because of the extended indication/dosage and administration resulting in drastic expansion of the market share.
- Such drugs with huge market share expansion have been subject to repricing (drug price discount) conventionally done every two years. However, some may enjoy more than two years until repricing depending on the timing of the drug price listing. In reflection, the drug price was reviewed in fiscal 2016 as an emergency.

## Outline of emergency revision standard

### (1) Drugs in scope

A: Products with **additional indication in the period of Oct. 2015-Mar. 2016**

B: Sales prospect for the fiscal 2016 (drug price basis) would exceed **100 billion yen** with at least **10 times** the prospect sales

### (2) Calculation

The formula for **repricing for market expansion applicable for special cases** will be applied to review the price.

(Reference: outline of repricing for market expansion applicable for special cases)

(1) Annual sales exceeds 100 billion yen but not more than 150 billion yen with at least 1.5 times the prospect sales

→ Max reduction by 25%

(2) Annual sales exceeds 150 billion yen with at least 1.3 times the prospect sales → Max reduction by 50%

## Item in the scope of emergency revision

Item in scope	Sales prospect*	Drug price before revision	Revised drug price	% change
Opdivo (Ono Pharmaceutical)	At listing: 3.1 billion yen Fiscal 2016: > 150 billion yen	20 mg/bottle 150,200 yen 100 mg/bottle 729,849 yen	75,100 yen 364,925 yen	▲50% ▲50%

\* At the time of listing: Prospective sales by the manufacturer at the peak demand at the time of drug price listing (2nd year) (listed on Sep. 2, 2014)

Fiscal 2016: Estimated by MHLW with consideration for distribution expenses, consumption tax, price disparity rate, and possible indication extension in future based on the annual sales estimated by the manufacturer (126 billion yen)

Notified on: Nov. 24, 2016 Applied on: Feb. 1, 2017

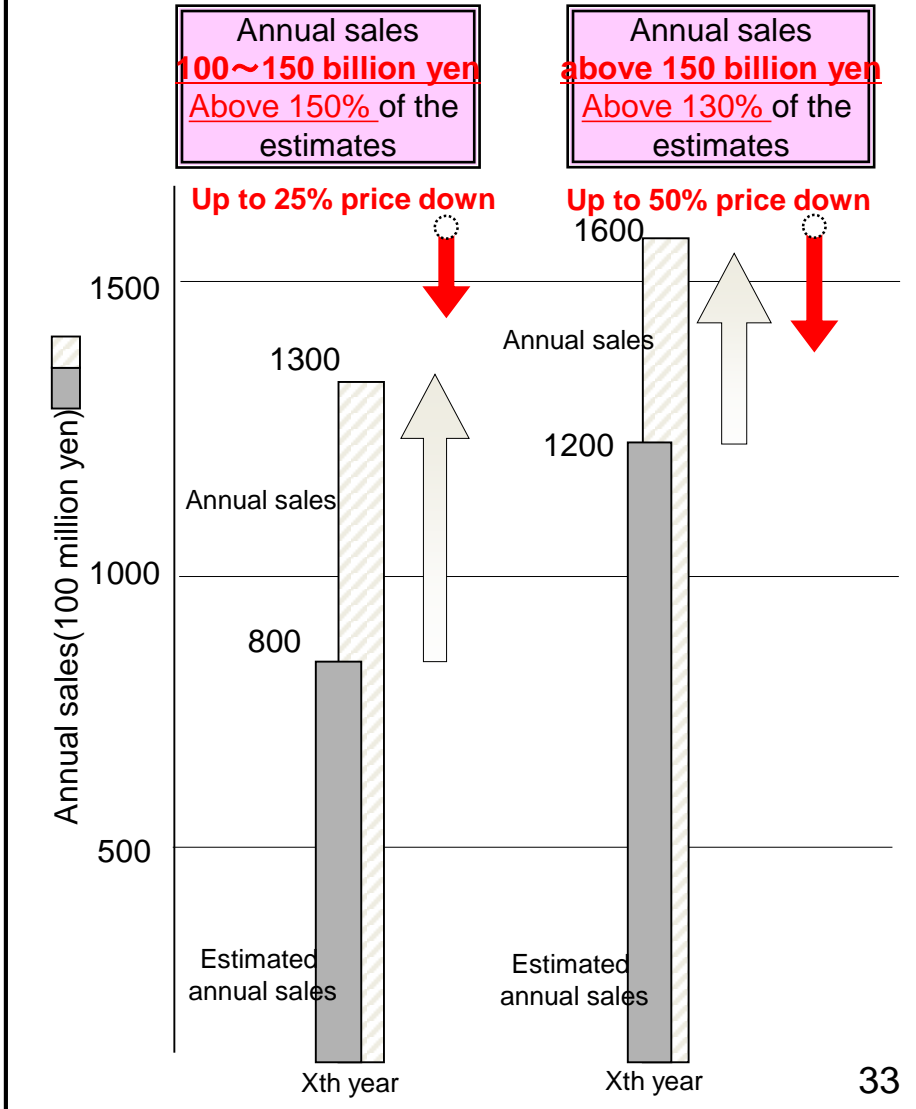
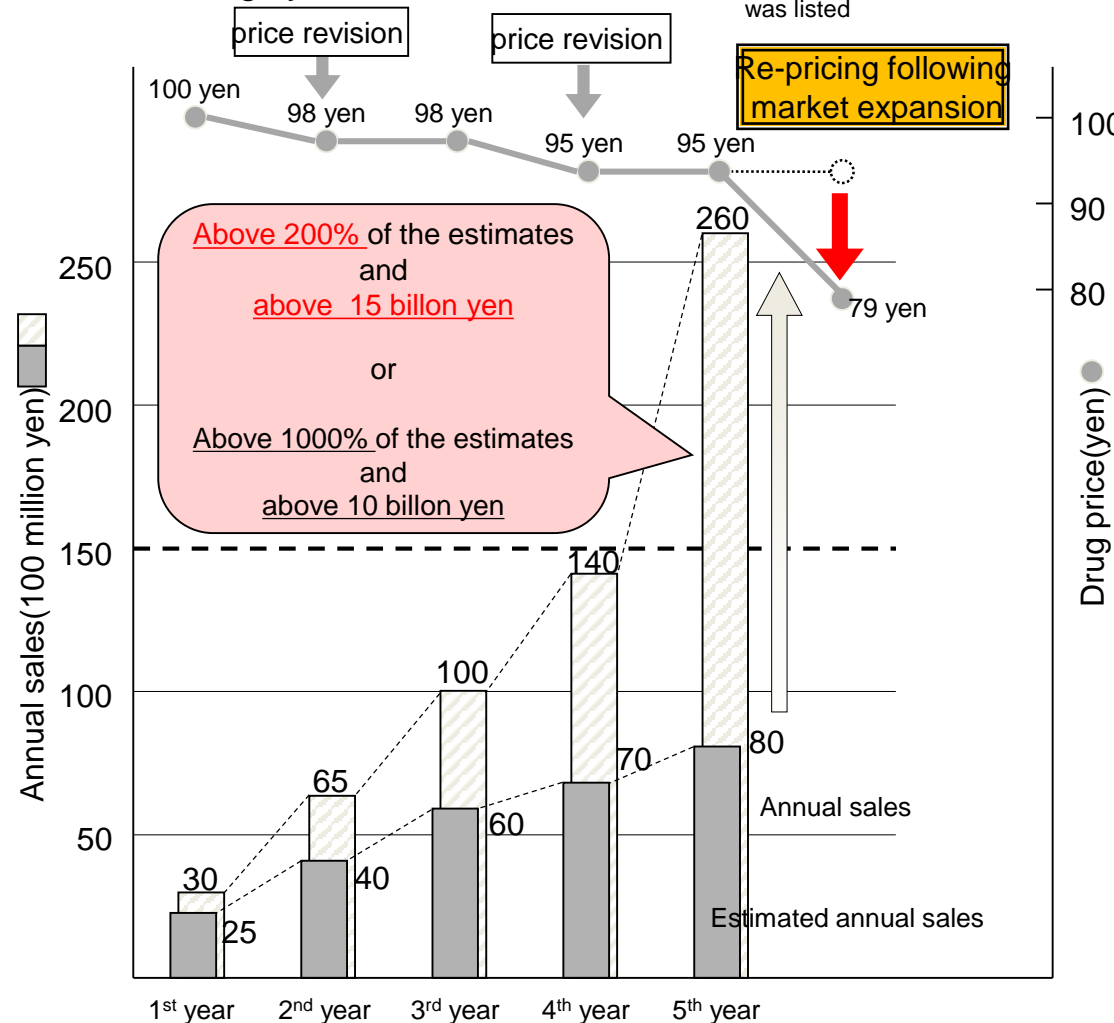


# “Re-pricing following market expansion” for the drugs with huge annual

**【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.

Ex) New drugs calculated using cost accounting system



# Reform plan for fundamental reform of the drug pricing scheme (December 20, 2016) ①

Recently, there have been innovative and extremely highly priced pharmaceutical products appearing on the market, but the current drug pricing system has been unable to flexibly respond to these pharmaceutical products, and there are concerns about the impact that it will have on the burden placed on the Japanese people and the finances of the medical insurance system.

From the perspective of balancing the “sustainability of the universal healthcare system” and the “promotion of innovation,” and “reducing the burden placed on the Japanese people” and “improving the quality of healthcare,” which will benefit the Japanese people, the following will be undertaken towards a drastic reform of the drug pricing system while emphasizing PDCA.

## 1. Drastic Reform of the Drug Pricing System

(1) In order to enable responses to changes in circumstances after insurance listings and to enable a prompt response to the expansion of markets beyond a given size that accompany additional indications, etc., opportunities for new drug listings will be utilized to their maximum extent, and drug prices will be reviewed four times per year.

# Reform plan for fundamental reform of the drug pricing scheme (December 20, 2016) ②

(2) In order to timely reflect the market price in drug pricing and suppress the burden placed on the Japanese people, drug price survey will be conducted annually and will cover all products, and drug prices will be revised based on the results.

To this end, in addition to the drug price survey currently being conducted biennially, a survey will be conducted for major businesses in the year in between, and drug prices for products with major price discrepancies (See Note) will be revised.

(Note) A conclusion will be reached on the specifics within the next year.

In addition, with regards to the drug price survey, the accuracy of the results of the survey and the survey methods, etc. will be verified, and based upon this, we will consider reviewing the drug price survey themselves, reaching a conclusion within the next year.

(3) In order to promote the creation of innovative new drugs, the pricing premium system for the promotion of new drug development and the resolution of off-label use will be given a drastic and zero-based review, and by fully implementing cost-effectiveness evaluations including raising the price of drugs with high cost-effectiveness, innovation will be evaluated by appropriately identifying the drugs that are truly effective, promoting investment in research and development.

In order to fully implement cost-effectiveness evaluations, in addition to basing it on expert knowledge, the method of implementation including organizations / systems from a third party perspective will also be considered, and a conclusion will be reached within the next year.

# Reform plan for fundamental reform of the drug pricing scheme (December 20, 2016) ③

## 2. Future Initiatives in Conjunction with the Reform

(1) Thoroughly ensure the accuracy and transparency of the drug price calculation method. Specifically, while taking into consideration the high confidentiality of the information for the pharmaceutical companies, the clarification of the basis for drug price calculations and the enhanced transparency of the drug price calculation process will be considered, and a conclusion will be reached. In addition, particularly for highly priced drugs, improvements to methods for adjusting foreign prices will be considered, such as getting a more accurate grasp of foreign prices while taking into consideration differences in systems, and a conclusion will be reached.

(2) The business status of parties involved who will be impacted by the reform of the drug price system will be swiftly grasped, and based on the results, a response will be considered as needed, and a conclusion will be reached.

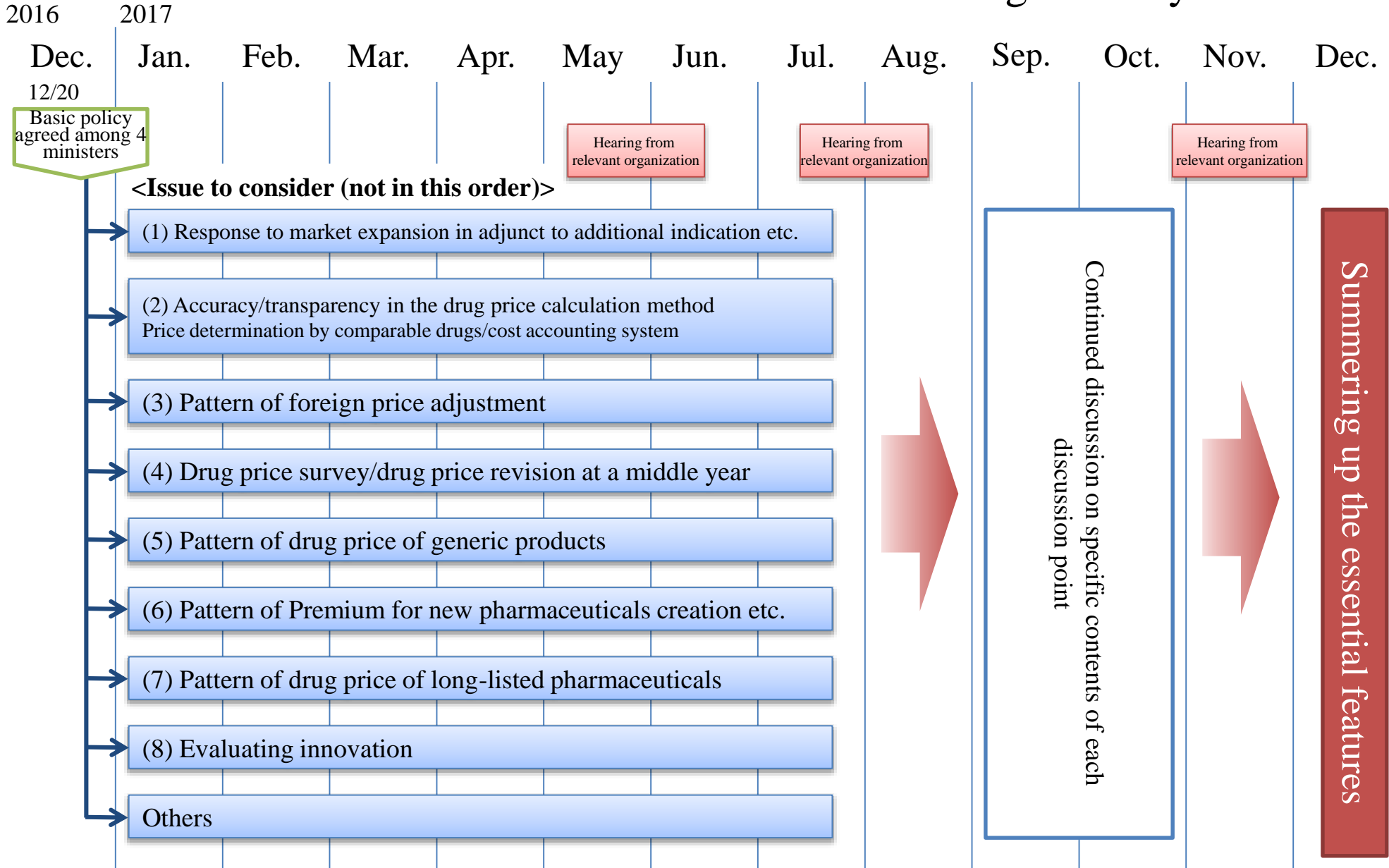
# Reform plan for fundamental reform of the drug pricing scheme (December 20, 2016) ④

(3) With regards to Japan's pharmaceutical industry, in order to switch from a model that is dependent on long-listed products to an industrial structure with more extensive drug discovery capabilities, the enhancement of measures to support the research and development of innovative biopharmaceuticals and biosimilars will be considered, as well as the support of venture companies and promoting the competitiveness of generic drug companies in the market, and a conclusion will be reached.

(4) In order to ensure the stable distribution of pharmaceutical products, the efficiency of distribution will be increased while taking the business statuses into consideration, improvements in distribution will be promoted, and appropriate approaches to the profit structure will be made to accompany the market environment. In particular, in order to promote the appropriate formation of prices, effective measures for promoting single item unit price contracts and early settlement of terms will be considered, and a conclusion will be reached.

(5) For new medical technologies with established evaluations, measures for promptly providing them to the Japanese people will be considered based on cost-effectiveness, and a conclusion will be reached.

# Review Schedule for Radical Reform of the Drug Price System



\* This is the schedule at the time of preparation and can be subject to alteration depending on discussions and circumstances onward.  
 \* Extracted the items to be reviewed at Drug Price Expert Committee from the items listed in the "Basic policy towards radical innovation of drug price system"

# 3. Health Technology Assessment

# 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.

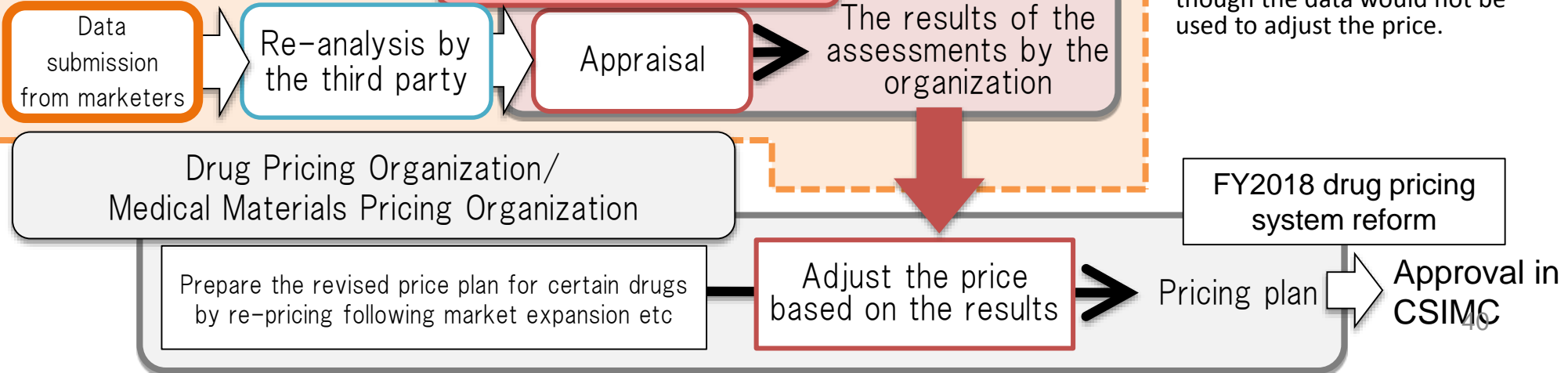
## <Discussion at Central Social Insurance Medical Council(CSIMC)>

- 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)>

### Rules of the cost-effectiveness assessment

※specify the subjects at the beginning of FY2016





# Summary of the selection criteria and Target Drugs/Medical Devices

## <Selection criteria for already listed items>

- [1] Exclusion criteria
    - a) Designated rare intractable disease, hemophilia and HIV infections
    - b) Request, etc., for the development based on the Review Committee on Unapproved Drugs, etc.
  - [2] Selection criteria
    - a) Drugs listed for fiscal years 2012 to 2015, whose price was determination by **similar efficacy comparison method**, meeting either of the following criteria.
      - i) **The premium rate is the highest.**
      - ii) **The expected peak sales is the highest** among drugs for which a premium of 10% or more was approved.
    - b) Drugs listed for fiscal years 2012 to 2015, whose price was determination by **cost calculation method**, meeting either of the following criteria.
      - i) **The profit premium rate is the highest.**
      - ii) **The expected peak sales is the highest** among the items for which a premium of 10% or more is approved.
- \* **Including pharmacological analogues** of the drugs selected based on these criteria.

(Also for newly listed items meeting the similar criteria , data submission is requested for future review, but not for price adjustments. )

	Drugs (7 items)	Medical Devices (5 items)
similar efficacy (functional category) comparison method	Sofosbuvir	Kawasumi Najuta Thoracic Stent Graft System
	Ledipasvir Acetate/Sofosbuvir	Activa RC
	Ombitasvir Hydrate/ Paritaprevir Hydrate/Ritonavir	Vercise DBS System
	Daclatasvir Hydrochloride	
	Asunaprevir	
cost calculation method	Nivolumab	J-tec Autologous Cultured Cartilage
	Trastuzumab Emtansine	Sapien XT

**Thank you for your attention  
with heart-warming hospitality.**