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Ministry of Health, Labour and Welfare

# Current update in NHI policy and future directions

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# Outline

1. Drug Price Standard system
2. The reform of drug price system in FY2016
3. Emergency measures for drug price
4. Health Technology Assessment

# National Health Insurance Drug Price Standard

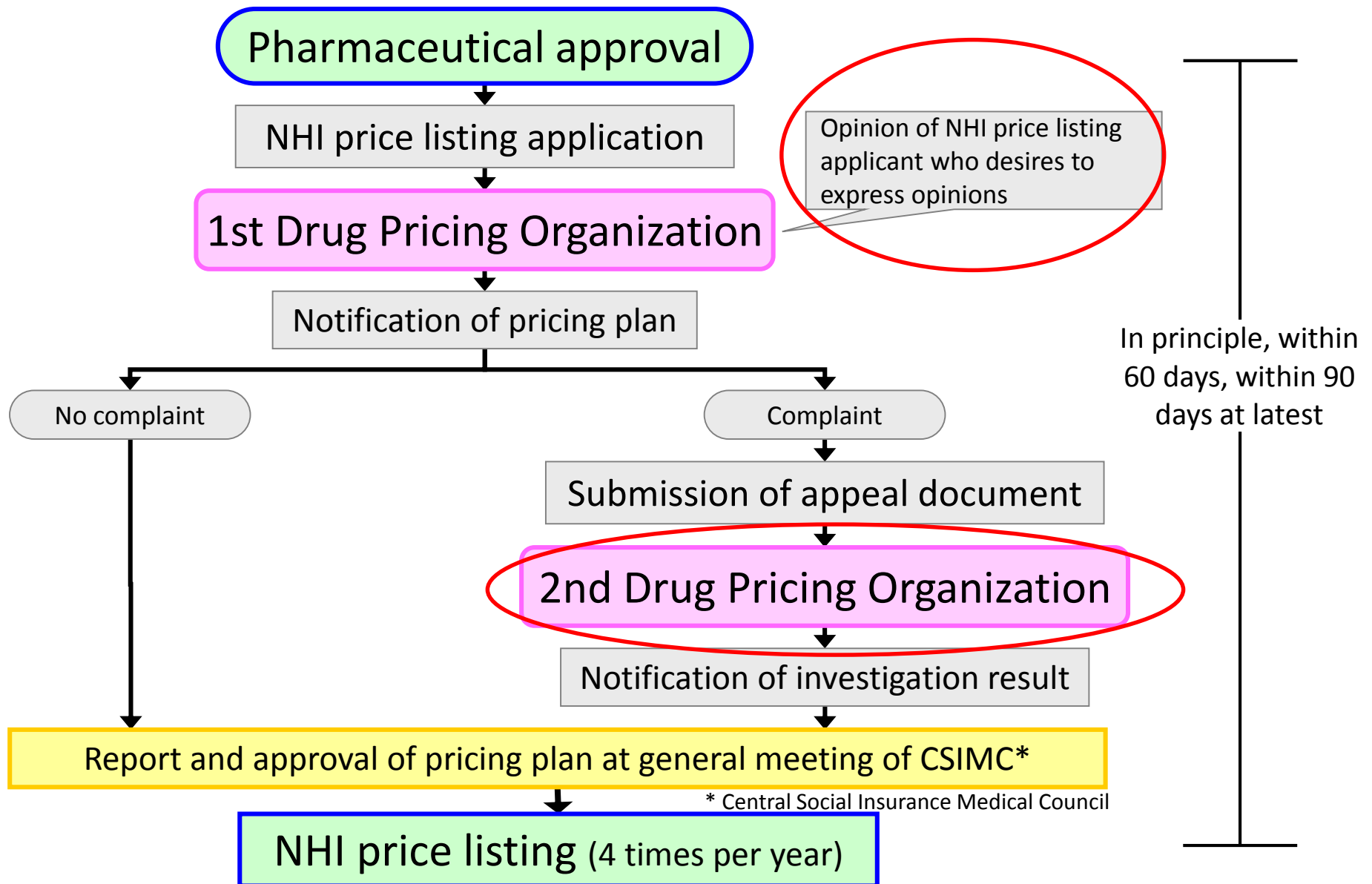
Items and prices of drugs usable in insurance-covered healthcare,  
specified by the Minister of Health, Labour and Welfare  
(common for all medical insurance systems, including health insurance, National Health Insurance (NHI), and various mutual aid systems)

- 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.

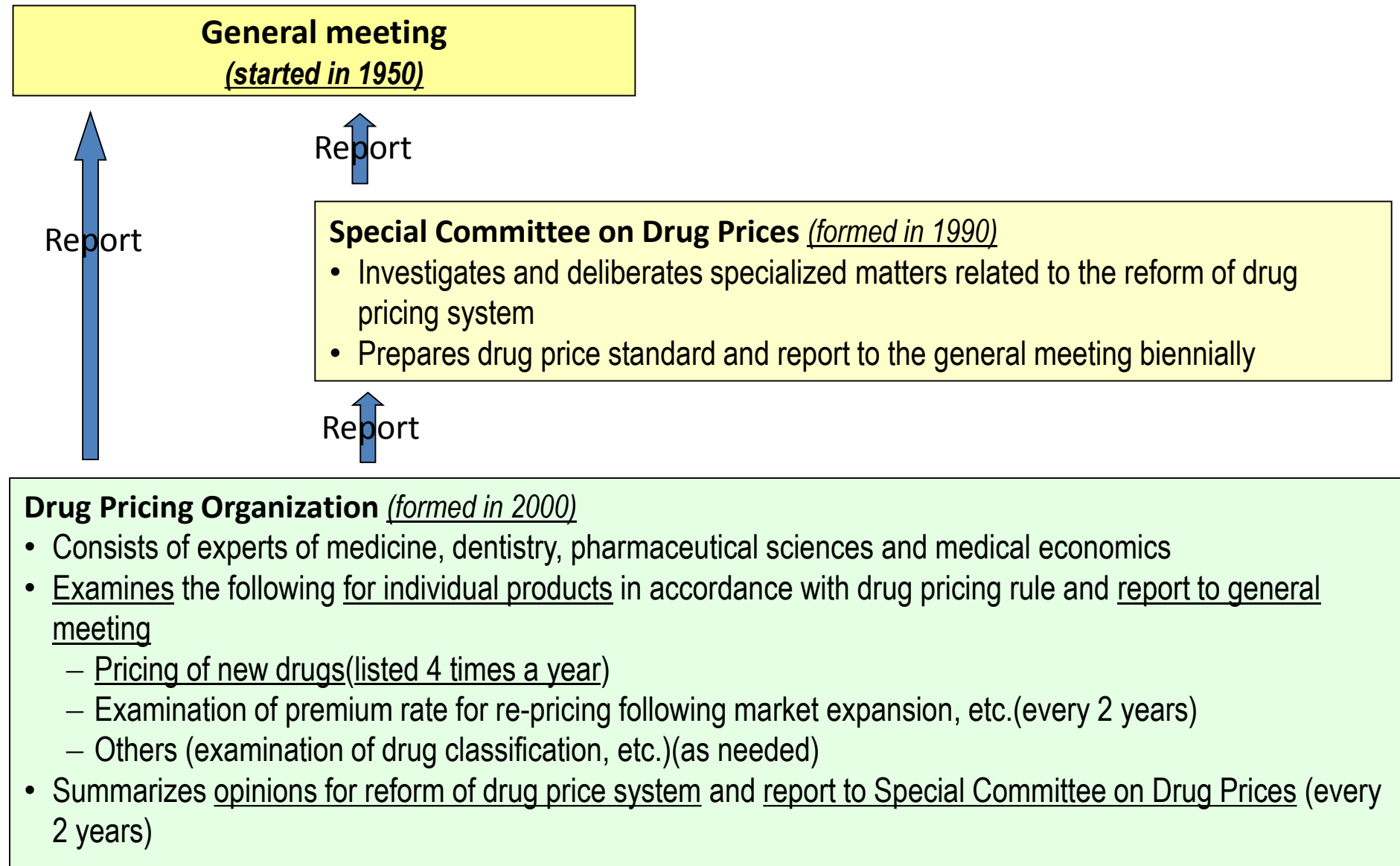
# Outline of current drug price standard system

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.

# New drugs price determination process



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

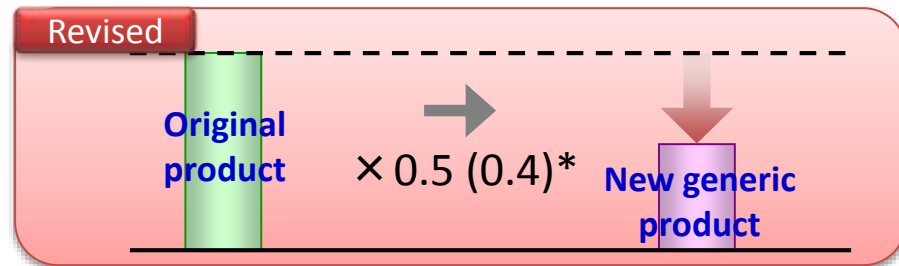
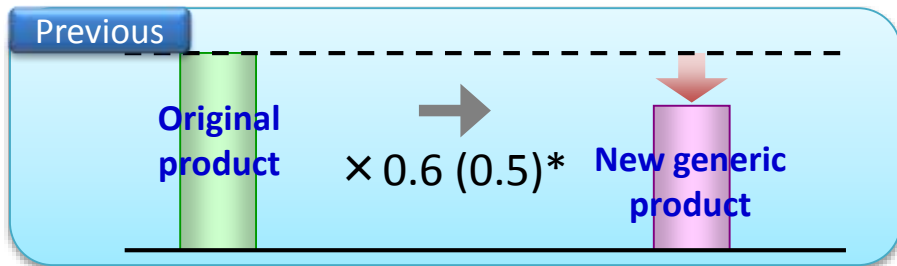


# Generic drug pricing and price revision

## (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)

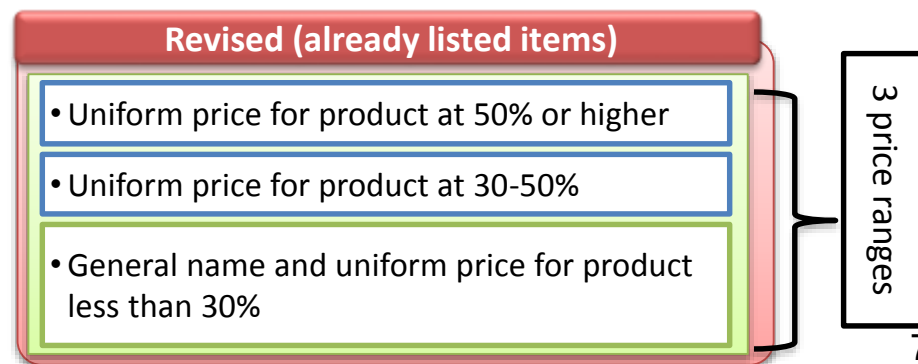
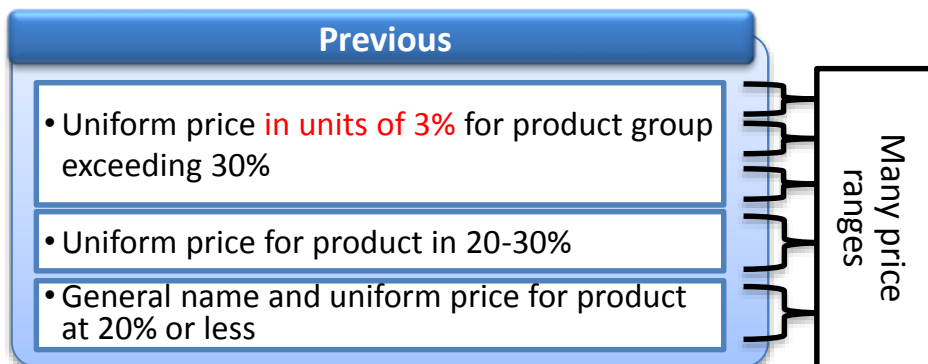


\* When exceeding 10 brands

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

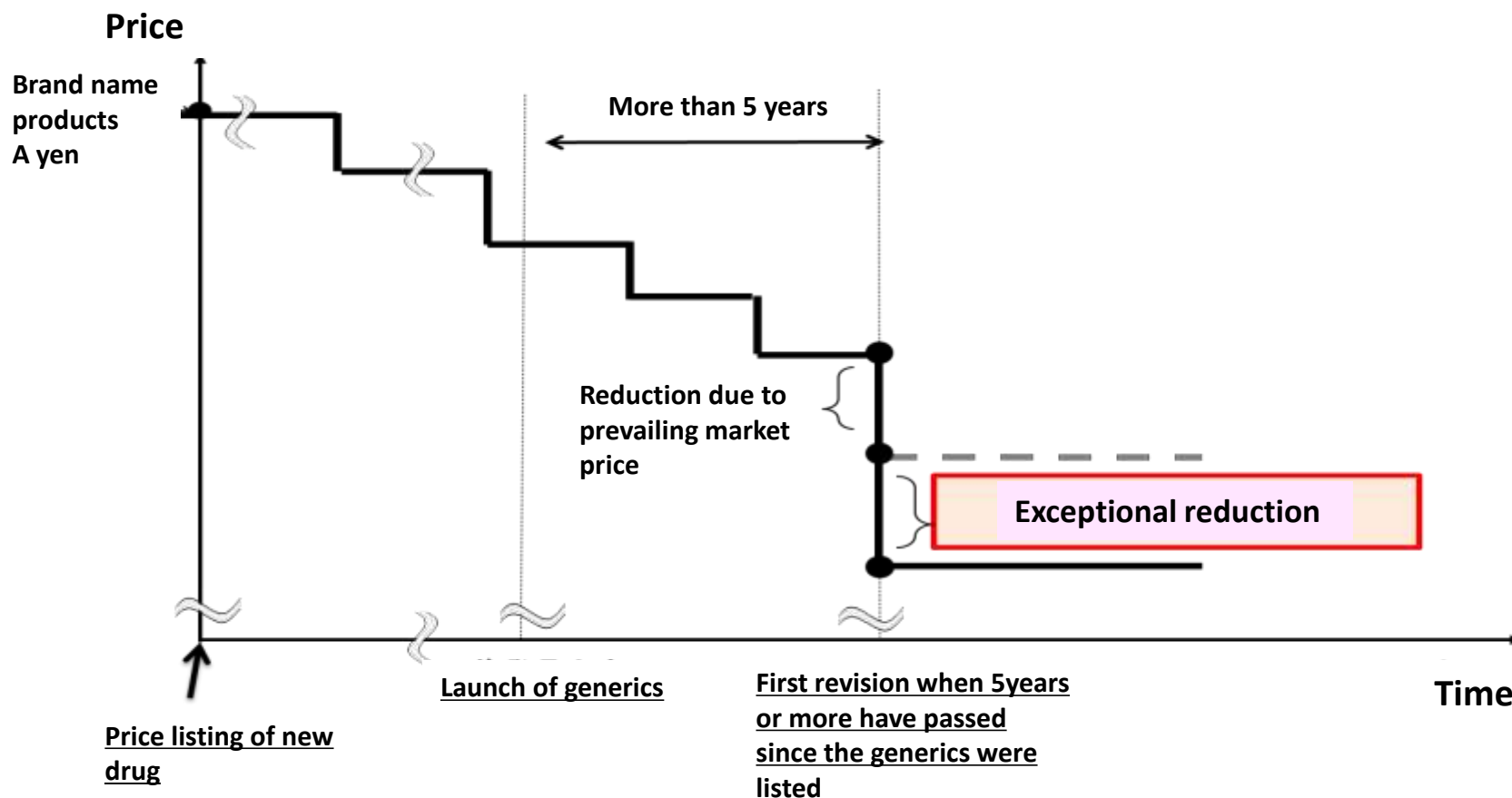
### Measure

- ◆ 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).



# 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

Amount calculated by the rules in Chapter 3, Section 1 for the listed item (drug price after normal drug price revision)

$$\times \frac{(\text{Average deviation rate for all listed item} - 2/100) \times 80/100}{5.41\%}$$



5.41%

(FY2014 4.94%)

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

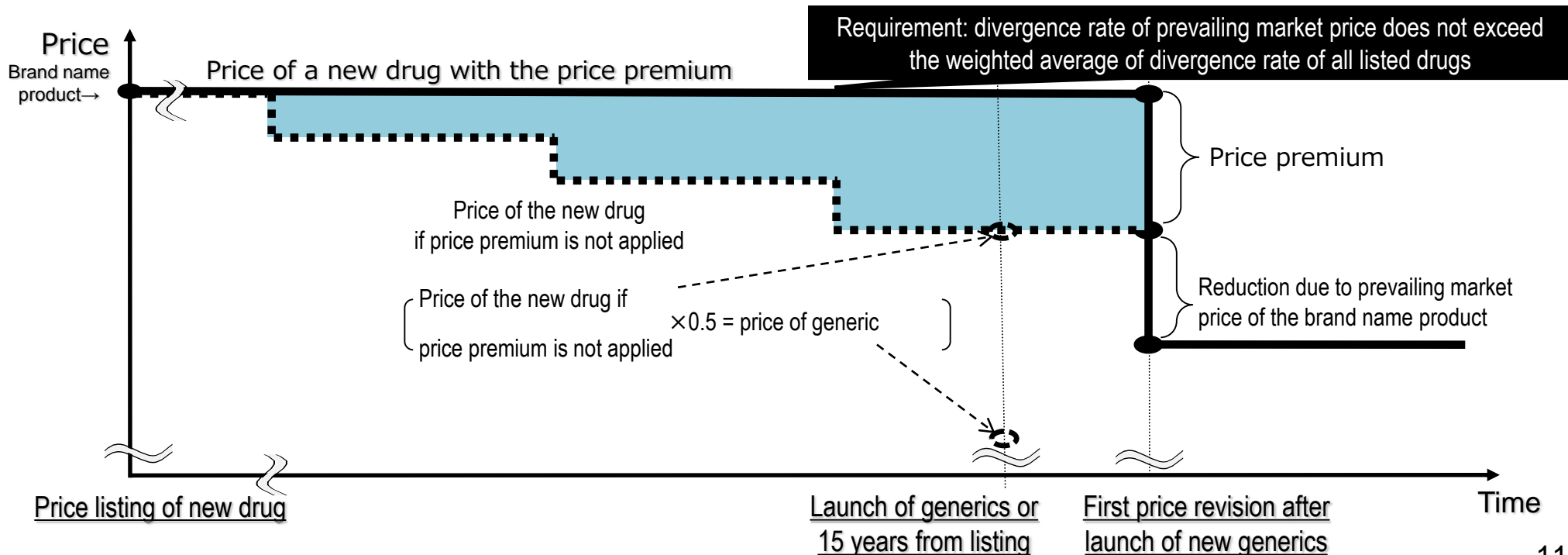
# 「Framework of the reform of drug price system in FY2016」

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

Continued trial implementation of price premium for promotion of new drug development and resolution of off-label use, etc.

The trial implementation of the price premium shall be continued as innovation through the development of drugs that contributes to the growth strategy is promoted, and new requests for unapproved and off-label drugs are publicly invited.

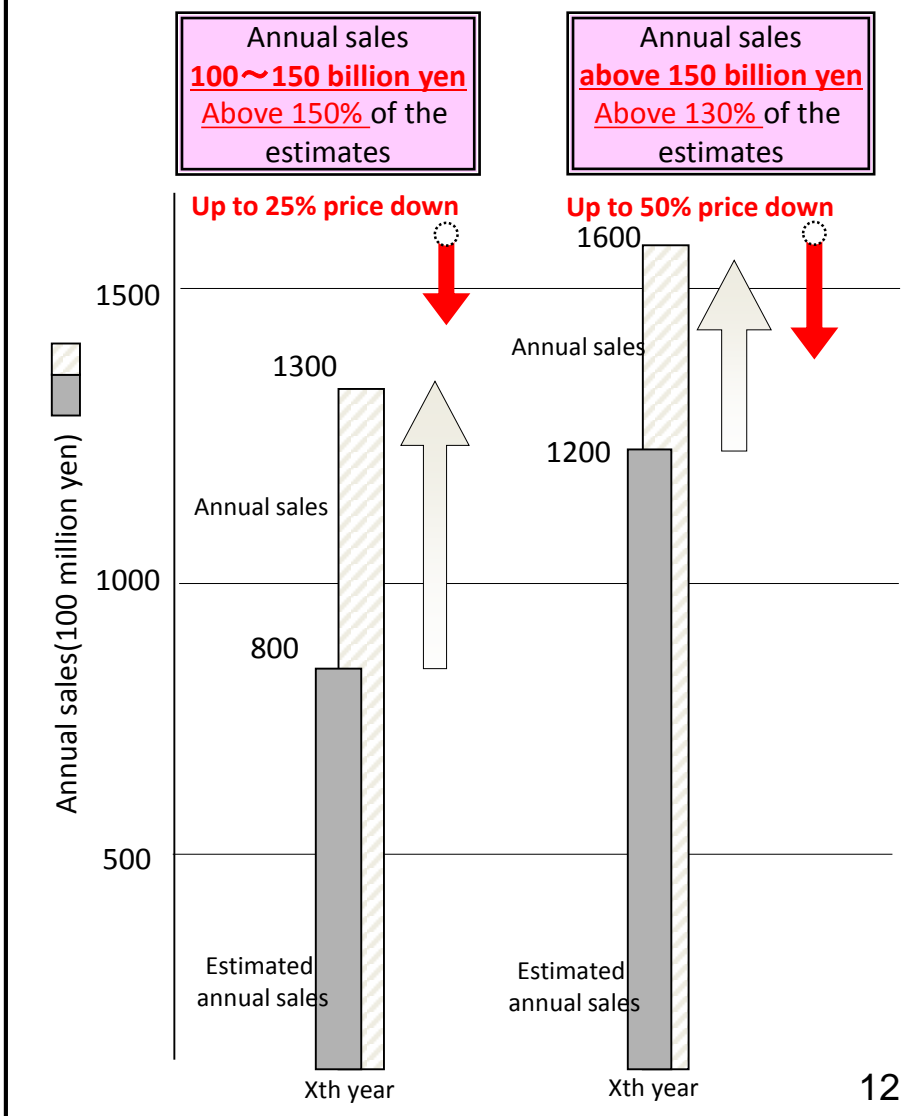
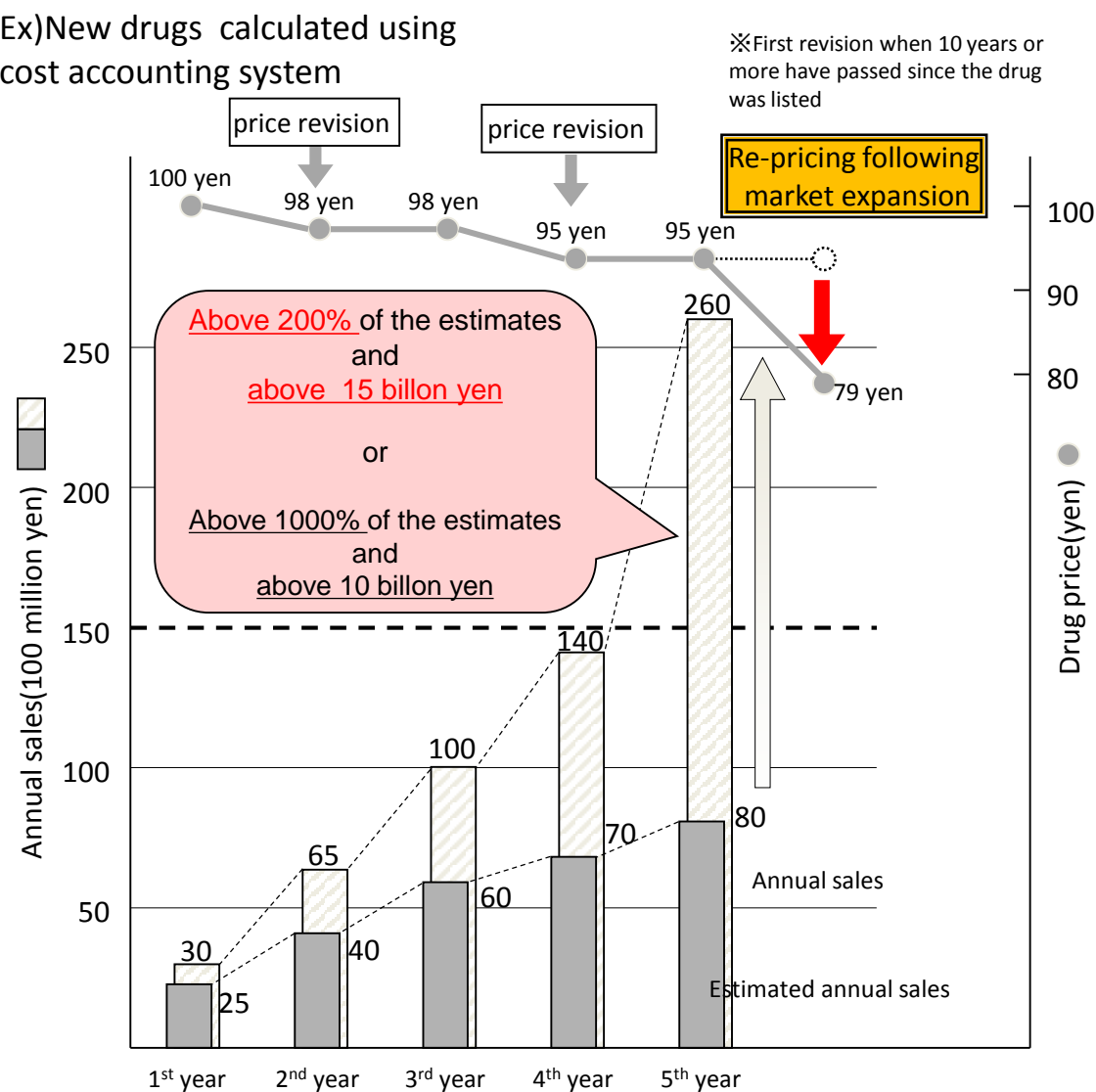
After the reform of drug price system in FY2016, we will confirm how far the development of unapproved and off-label drugs is proceeding and evaluate concrete results of R&D of new medicine. We will also examine how the premium system should be in the future.



# “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.



# 「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

# Response to expensive drug

## Issues

### (1) Measures towards drug pricing reforms

#### (i) Response to large expansion of market scale due to additional indication, etc.

○ In the current drug price system, this situation that market scales are largely expanding because of additional indications and additional dosage and administration is not anticipated. In the first place, a system which can respond to these situations has to be established for the drug price system consisting of price determination by comparable drugs and cost accounting system.

#### (ii) Response to the drug with very large market scales

○ Furthermore, not only for the drug whose market largely expanded because of additional indications but also for the drug with very large market scales from the beginning of NHI listing, the following points are needed to be examined based on the compatibility between maintaining of universal health insurance coverage and promotion of innovation.

- Establishing the scheme to promote the optimal use of pharmaceutical products and optimize the benefit pertaining to drug under the cooperation between Pharmaceutical Safety and Environmental Health Bureau and Health Insurance Bureau
- In addition to drug pricing scheme based on the results of the examination on the experimental introduction of cost benefit assessment, the response considering not only the market scales but also the characteristics of the pharmaceutical products, the comparison with cost pertaining to the previous treatment, etc. is necessary.

# Response to expensive drug (continued)

## **(2) Current response**

### (i) Special response pertaining to drug price

○ In parallel with radical revisions of the issues mentioned above, special response pertaining to the drug (Opdivo) which could not make it in time of the examination of recalculation on price revision in 2016 and whose market largely expanded because of additional indications, etc. is need to be examined.

### (ii) Handling for promoting optimal use.

○ The examination is ongoing under the cooperation between Pharmaceutical Safety and Environmental Health Bureau and Health Insurance Bureau. Handling of the guidelines (GL for promoting optimal use) in the health insurance system to promote the optimal use of the pharmaceutical product with a novel mechanism of action is needed to be examined.



# Emergency measures for drug price (i)

## 1. Background

- Recently, the innovative drugs with high unit price and very large market scales such as some anticancer drugs have arisen. Some of them are the drugs whose markets largely expand than originally anticipated due to the additional indications and additional dosage and administration.
- On the other hand, basically, price revision is conducted once in 2 years according to drug price survey. A sudden and substantial change of this rule will significantly damage the predictability of the management in pharmaceutical corporations. Therefore, in principle, we establish the system which can respond to these circumstances towards the price revision in the fiscal year 2018.
- However, for the drug whose market largely expands beyond initial expectation because of additional indications and additional dosage and administration, because to maintain this drug price until the drug revision in the fiscal year 2018 greatly impacts health insurance finance, we will take emergency measures.

## 2. Issues and specific measures

- This emergency measure is for the response of the rules other than that of the past price revision, and it is appropriate to respond to a limited range of the drugs based on the concept of conventional scheme.
- Thus, in this emergency measure, the target drugs are as follows: (1) the drug with long period from its market expansion to next price revision; (2) the drug with significant degree of market expansion.  
Specifically, for (1), the target drug is the drug with the duration until next revision is more than 2 years and whose additional indications, etc. was approved in between the following month of the month in which drug price survey was conducted to the time of price revision; and for (2), the drug whose annual sales in the fiscal year 2016 are more than 100 billion yen (requirement of the market scale in repricing for market expansion (exception)) and the annual sales are 10-fold or more of forecasted annual sales at the time of NHI listing (the most severe applicable requirement of the ratio of market expansion for repricing for market expansion).
- Also, because the price survey was not conducted, the forecasted total sales of each corporation were used for confirmation of the market scales.
- Based on the above, measures will be taken as follows.

# Emergency measures for drug price (ii)

[Criteria of the emergency revision of drug price in the fiscal year 2016]

(1) The drug price shall be revised for the following drugs:

- a. The drug listed in the NHI price list whose partial change of indications and dosage and administration was approved between October 2015 and March 2016
- b. The drug listed in the NHI price list whose company forecasted annual sales (drug price basis) in the fiscal year 2016 are more than 100 billion yen and the company forecasted annual sales are 10-fold or more of the forecasted annual sales at the time of NHI listing

(2) Calculation method for emergency measures

- When emergency measures are taken, based on the fact that the measures themselves are not included in the current rules, and drug price survey will not be conducted in this fiscal year, it is reasonable to use the existing concepts as much as possible. The concept of repricing for market expansion according to the existing pricing rules shall be applied.
- However, because drug price survey is not conducted in this emergency measure, the company declared total sales, etc. (forecasted total sales, etc. in the fiscal year 2016) shall be used at a maximum as the total sales in calculation formula.
- Based on the above, measures will be taken as follows.

[Criteria of the emergency revision of drug price in the fiscal year 2016]

- (2) Drug price will be revised to the price calculated by the formula designated in Annex 6-2 in the Criteria of Drug Pricing (approved by Central Social Insurance Medical Council on February 10, 2016). In the calculation, the company forecasted annual sales (drug price basis), etc. shall be used as annual sales.  
 $\alpha$  (corrected additional rate) shall not be applied(\*) .

\*  $\alpha$  (corrected additional rate): The corrected additional rate which is calculated in the method of usefulness premium (II) for the drug listed in the NHI price list. In this case, the true clinical utility of the drug listed in the NHI price list has been directly verified by additional indications pertaining to children or rare diseases, etc. or by the accumulated survey results after marketing.

\*  $\alpha$  (corrected additional rate) in the repricing for market expansion shall not be applied based on the following reason: This response is an emergency measure with consideration of the impact on the health insurance finances and the drug price will be reviewed again in the fiscal year 2018 (refer to 3. Emergency measures in relation to the revision in the fiscal year 2018.

# Emergency measures for drug price (iii)

## (3) Timing of implementation of drug price revision in the emergency measures

- In consideration of the impact on the health insurance finances, it is necessary to revise the drug price as soon as possible.
- At the same time, from the viewpoint of smooth implementation in medical practices such as inventory control in the medical institutions etc., the duration between the notification and application of price revision should be 2 months or longer.
- Based on the above, measures will be taken as follows.

[Criteria of the emergency revision of drug price in the fiscal year 2016]

(3) Drug price revision shall be notified sometime in November 2018 and applied from February 1, 2017.

## (4) Other

- In this emergency measure, it is also necessary to give the pharmaceutical corporations the opportunity for submitting a dissenting opinion about drug pricing.  
In addition, the drug pricing in this emergency measure is nothing more than applying the annual sales to the given formula. Therefore, the drug pricing shall not be examined by the pricing organization.

[Criteria of the emergency revision of drug price in the fiscal year 2016]

(4) The pharmaceutical corporations can submit a dissenting opinion about calculated drug price.

## 3. Emergency measures in relation to the revision in the fiscal year 2018

- In the revision in the fiscal year 2018, drug price system will be reviewed to be able to respond to the innovation as well as maintaining the sustainability of health insurance and also to respond to the circumstance in which the market scales largely expand because of additional indications, etc.
- Also, in the revision in the fiscal year 2018, after the total sales calculation based on the assumption without the adjustment of this price reduction according to the drug price survey in the fiscal year 2017, repricing of the target pharmaceutical products of this emergency measure according to the revision of the drug price system in the fiscal year 2018 will be conducted separately.

# Emergency price revision in the fiscal year 2016

General meeting-2,  
Central Social Insurance  
Medical Council  
Nov. 16, 2016

## 1. Target items

[Criteria of the emergency revision of drug price in the fiscal year 2016]

(1) The drug price shall be revised for the following drugs:

- a. The drug listed in the NHI price list whose partial change of indications and dosage and administration was approved between October 2015 and March 2016
- b. The drug listed in the NHI price list whose company forecasted annual sales (drug price basis) in the fiscal year 2016 are more than 100 billion yen and the company forecasted annual sales are 10-fold or more of the forecasted annual sales at the time of NHI listing

- Ministry of Health, Labour and Welfare extracted the drug which applies to the requirement in a. above and confirmed with the manufacturer if the relevant drug applies to the requirement in b. above. The manufacturer replied that the following products applied to the requirement b.

Product name	Manufacturer name
Opdivo intravenous infusion 20 mg Opdivo intravenous infusion 100 mg	ONO PHARMACEUTICAL CO., LTD

- We suggest conducting the emergency price revision in the fiscal year 2016 for the relevant product.

## 2. Calculation

[Criteria of the emergency revision of drug price in the fiscal year 2016]

(2) Drug price will be revised to the price calculated by the formula designated in Annex 6-2 in the Criteria of drug pricing (approved by Central Social Insurance Medical Council on February 10, 2016). In the calculation, the company forecasted annual sales (drug price basis), etc. shall be used as annual sales.

$\alpha$  (corrected additional rate) shall not be applied.

- Company forecasted annual sales of Opdivo intravenous infusion that apply to (1) were announced to be 126 billion yen in invoice price (shipped price) basis. In consideration of distribution cost, consumption tax, the rate of deviation as well as additional indications in the future, the total sales are estimated to be more than 150 billion yen (drug price basis) in the fiscal year 2016 (see next page <Reference>).

On the contrary, if it is calculated according to (2), the drug price will be as follows:

Product name	Current drug price	Calculated drug price	Rate of change
Opdivo intravenous infusion 20 mg	150,200 yen	75,100 yen	-50%
Opdivo intravenous infusion 100 mg	729,849 yen	364,925 yen	-50%

# Handling of the guidelines for promoting optimal use in the health insurance

## 1 Handling of the guidelines for promoting optimal use in the health insurance

- The Manager of Medical Economics Division, Insurance Bureau, Ministry of Health, Labour and Welfare will notify the content of the guidelines for promoting optimal use for the pharmaceutical products whose guidelines will be prepared as points of concern in the insurance coverage (notification of points of concern).
  - \* In this fiscal year, the pharmaceutical products whose guidelines for promoting optimal use are experimentally prepared are Opdivo intravenous infusion and Repatha subcutaneous injection (including similar drugs of these products)
- In the notification of points of concern, guidelines for promoting optimal use will not be cited as it is. The mere general information etc. will be omitted from the content of the guidelines and necessary amendment etc. from the viewpoint of the following (i) to (iii) will be made, and then items that are necessary for health insurance system shall be specifically described:
  - (i) Ensuring the effectiveness of guidelines for promoting optimal use
  - (ii) Insurance coverage based on the economic efficiency and the characteristics of pharmaceutical products
  - (iii) Physician's discretion in the clinical practice

## 2 Procedures before the issue of the notification of points of concern

- Following the establishment of the guidelines for promoting optimal use, the contents mentioned above shall be promptly discussed in the general meeting of Central Social Insurance Medical Council, and the notification of points of concern shall be issued.
  - \* The final draft for Opdivo intravenous infusion is planned to be prepared by the end of this year
- Transitional period shall be exercised because the time from the issue to the application of the notification of points of concern is necessary from the viewpoint of inventory control in the medical institutions etc.

# 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.

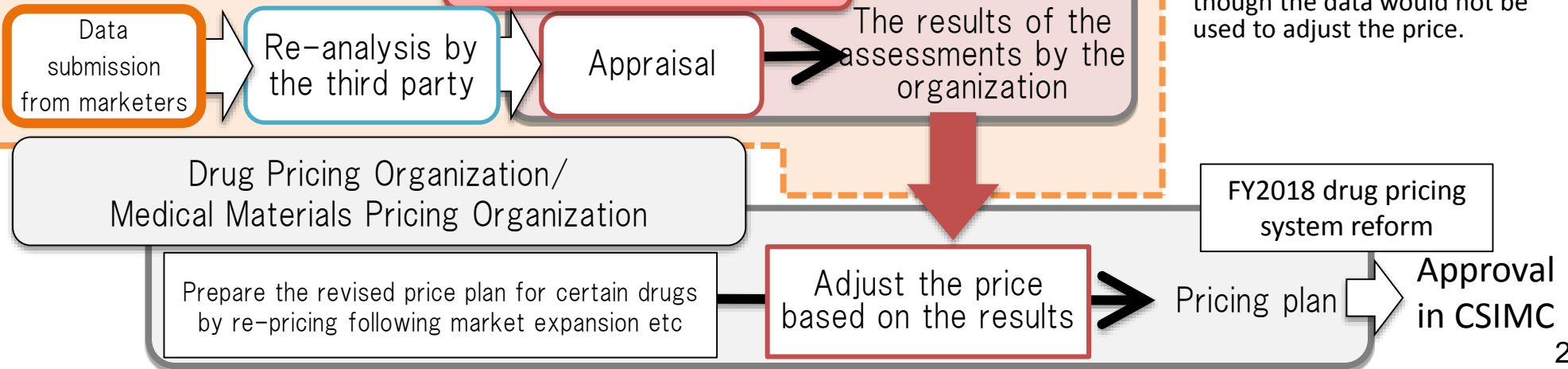
## <Discussion at Central Social Insurance Medical Council(CSIMC) >

- 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)>

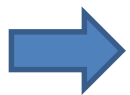
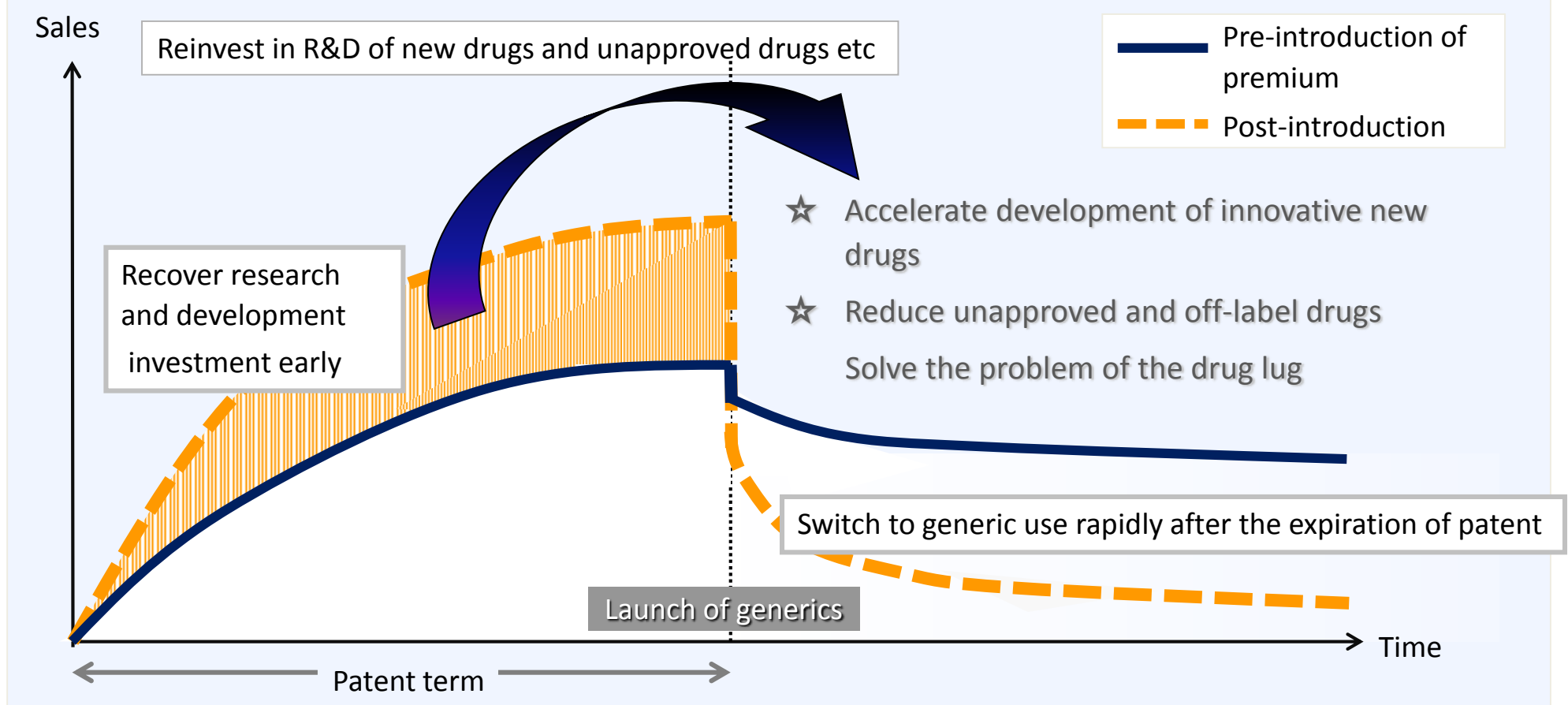
### Rules of the cost-effectiveness assessment

※specify the subjects at the beginning of FY2016



# How the drug industry should be

- It is important to assure virtuous cycle in which we gain a sizable profits that corresponds to the risk and the innovation of new drug development before steadily switching to generic use through market mechanisms following the expiration of patent, and reinvest the profits in another development of innovative new drugs.



To assure virtuous cycle mentioned above, support for development of new drugs and acceleration of generic use should be promoted simultaneously.