A Measure to Ensure Transparency and Efficiency in Drug Pricing System

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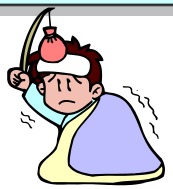
Shinichi TAKAE
Deputy Director
Economic Affairs Division
Health Policy Bureau
Ministry of Health, Labour and Welfare

Ministry of Health, Labour and Welfare

Conceptual diagram of health insurance treatment

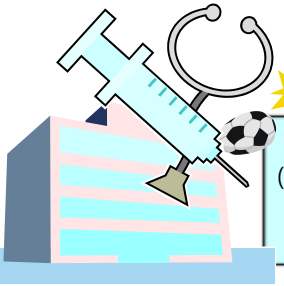


Insured person (patient)

(2) Medical care service (medical treatment benefits)

(3) Co-payment

(1) Payment of premium



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

Insurance doctors

Insurer

(5) Sending approved bill

(7) Payment of medical treatment fee

(4) Claim for medical treatment fee

(6) Payment of billed amount

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

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

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Outline of current drug price standard system

- **Drug price standard specifies the prices of drugs used for the payment by medical insurance to insurance medical institutions or insurance pharmacies (insurance medical institutions, etc.).**

  ⇒ **The prices should be appropriate.**

- **Drug price standard is based on "The Standard for Drug Pricing" developed by Central Social Insurance Medical Council on February 12, 2014 and announced by the Minister of Health, Labour and Welfare.**

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

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Roughly biennially, recently

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What is adequacy of drug reimbursement price?

Requirements for reimbursement price specified in drug price standard

(1) Compensation of actual expense for medical institutions including hospitals and pharmacies that purchased drugs

(2) Reimbursement price must be fair and adequate.

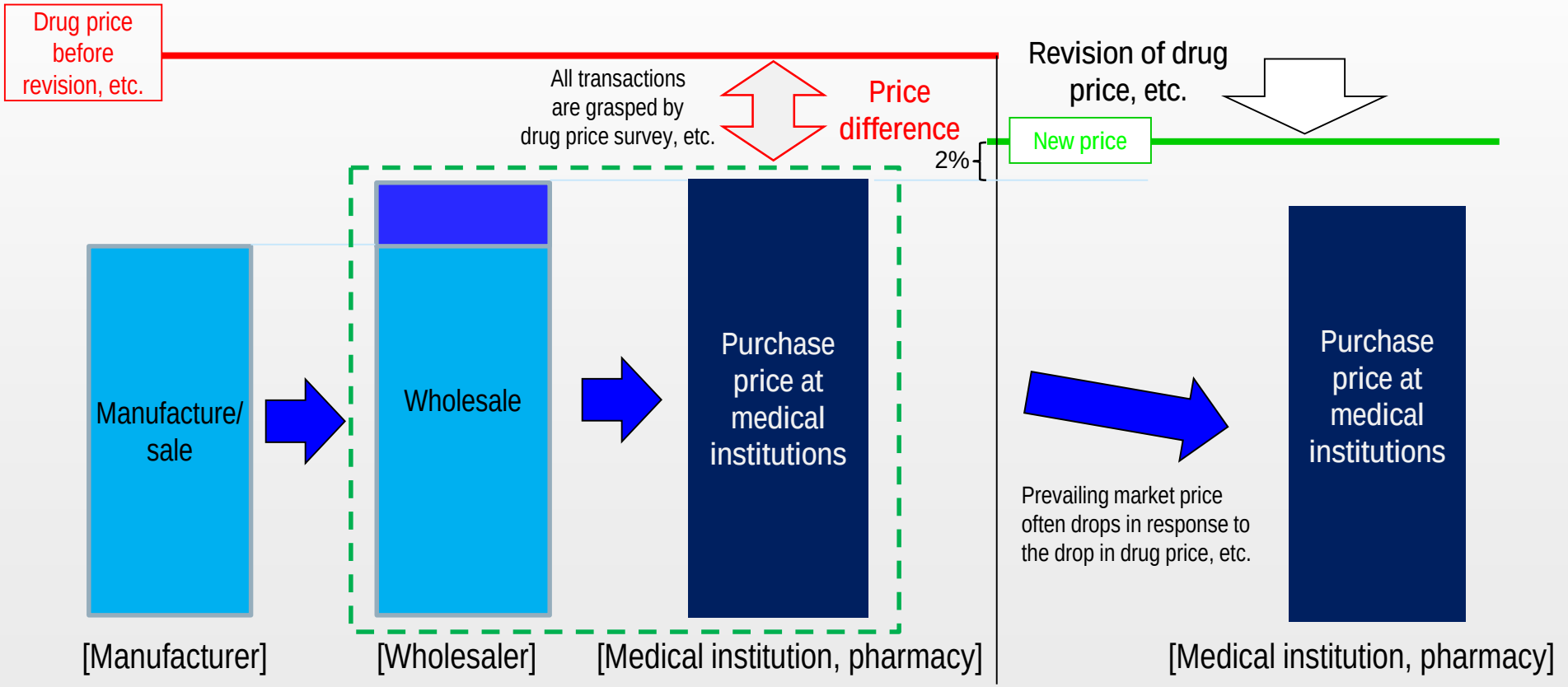
Revision of price for already listed drugs

Bulk-line system	1992 →	Prevailing market price system (weighted average, fixed price range)
Pricing focused on (1)	→	Pricing focused on (2)

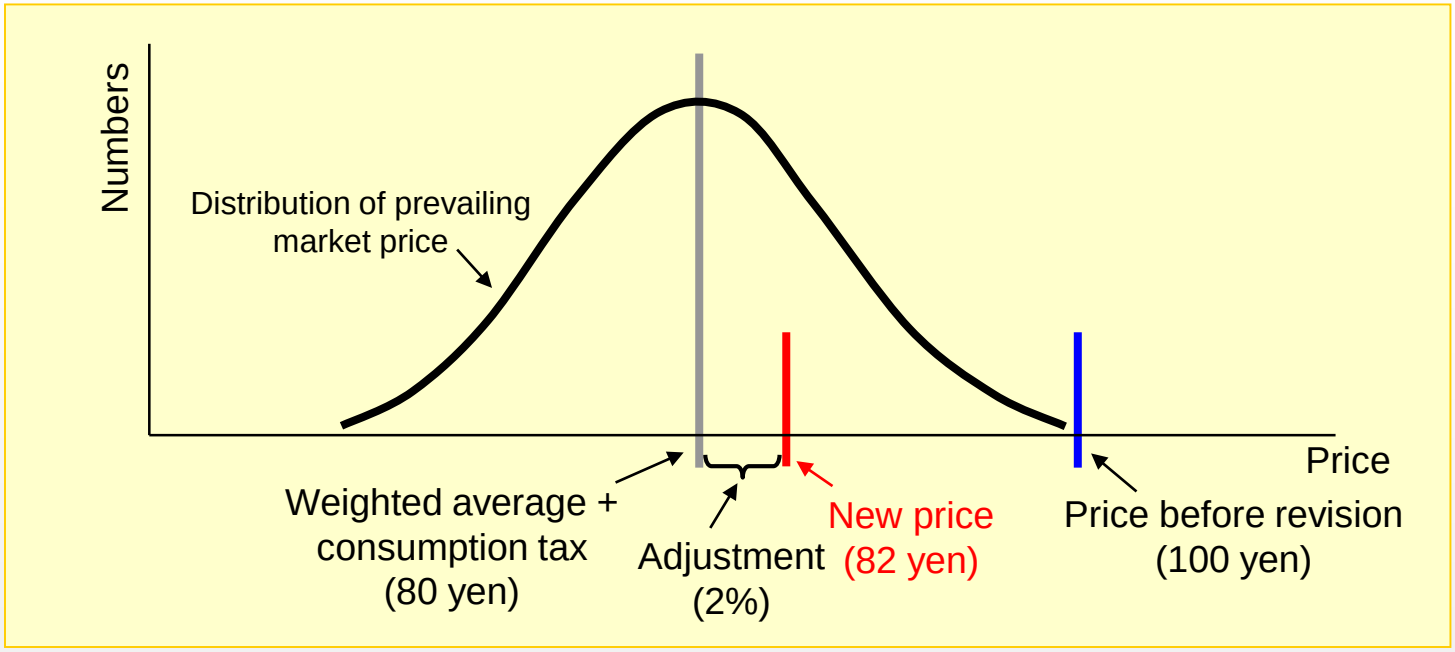
Assuming “market price = fair and adequate price”

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.



Pricing method of listed drugs



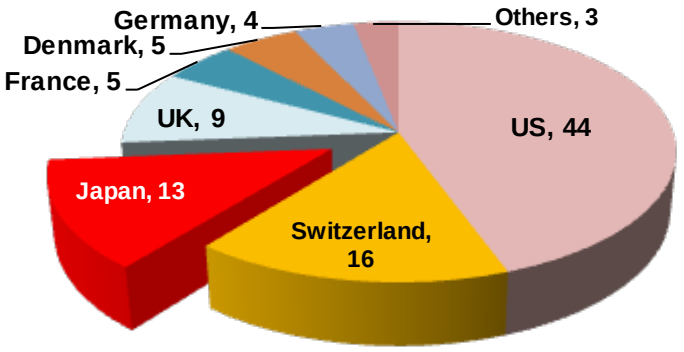
The new drug price is determined by adding consumption tax to the weighted average of sales price at which the drug was sold by wholesalers to medical institutions or pharmacies (prevailing market price before tax) and adjusting the resulting price (adding 2% of the price before revision) for stable distribution of drugs.

$$\text{New price} = \left[\begin{array}{c}\text{weighted average of sales price for}\\ \text{medical institutions/pharmacies}\\ \text{(prevailing market price before tax)}\end{array}\right] \times \begin{array}{c}\text{1 + consumption tax rate}\\ \text{(including local consumption tax)}\end{array} + \text{Adjustment}$$

Current status of pharmaceutical industry

■ While only a limited number of countries can continuously develop new drugs, Japan stands third in the world in drug development, contributing to the improvement of healthcare and public health in the world.

Number of top 100 drugs in global sales developed in each country (2010)



Source: prepared based on the data of Office of Pharmaceutical Industry Research

Number of drugs listed in drug price standard and market share by category

		No. of products	Share in No.	Share in amount
Brand name drugs	No generics	2,074	18.2%	49.3%
	With generics	1,562	31.2%	31.7%
Generics		8,038	27.6%	11.1%
Other products		3,629	23.0%	8.0%

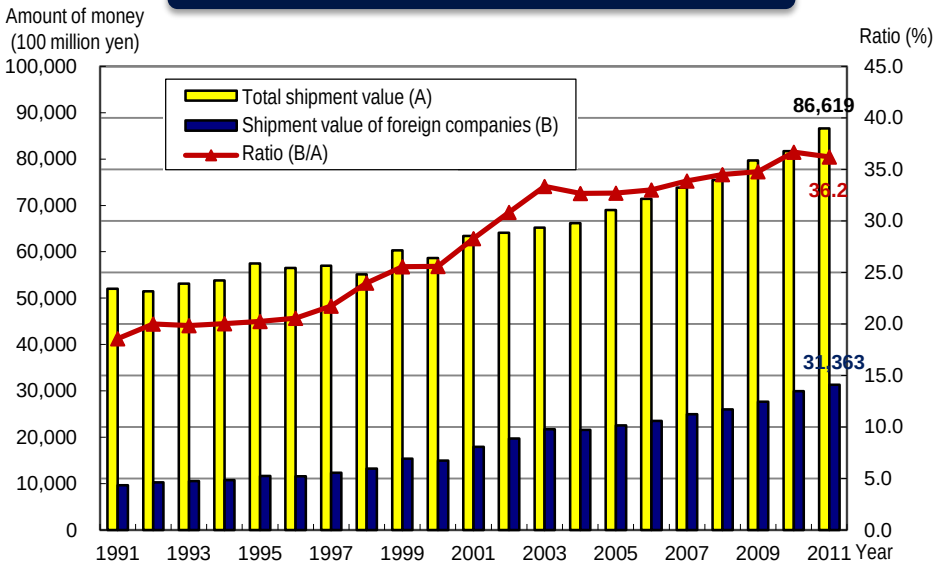
- Only the numbers of products are the data as of April, 2014.
- Share in number and share in amount are based on the numbers and drug prices at the time of the survey in September 2013.
- "Other products" include drugs, etc. (blood products, etc.) approved in 1967 or earlier that cannot be categorized into brand name drugs and generics in terms of Pharmaceutical Affairs Law.

Innovative drugs developed in Japan among top 100 drugs in global sales (2011)

Product	Company	Indication	Product	Company	Indication
Crestor	Shionogi	Hyperlipidemia	Leuplin	Takeda	Prostate cancer
Abilify	Otsuka	Schizophrenia	Aricept	Eisai	Alzheimer-type dementia
Blopress	Takeda	Hypertension	Prograf	Astellas	Immune suppression
Actos	Takeda	Type II diabetes	Takepron	Takeda	Peptic ulcer
Olmetec	Daiichi Sankyo	Hypertension	Cravit	Daiichi Sankyo	Infection
Pariet	Eisai	Peptic ulcer	Vesicare	Astellas	Pollakiuria, urinary incontinence

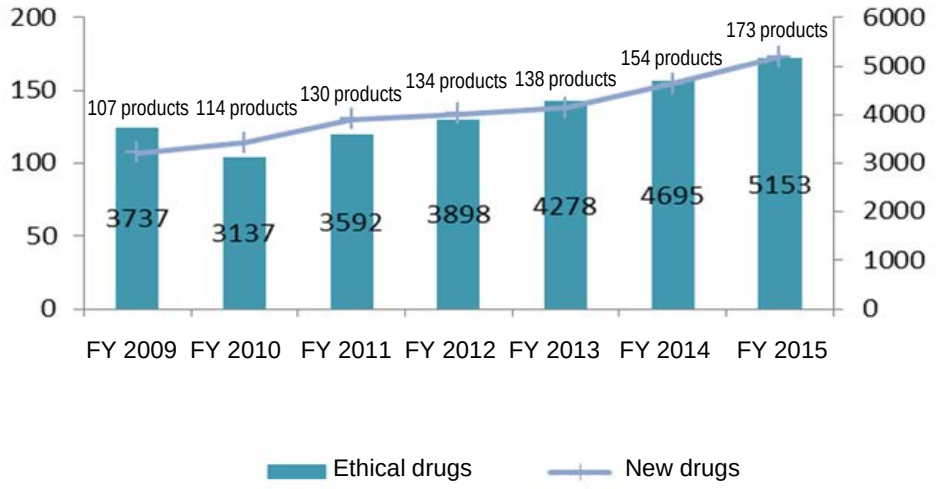
Source: Pharma Future, No. 265

Share of foreign companies in Japanese market

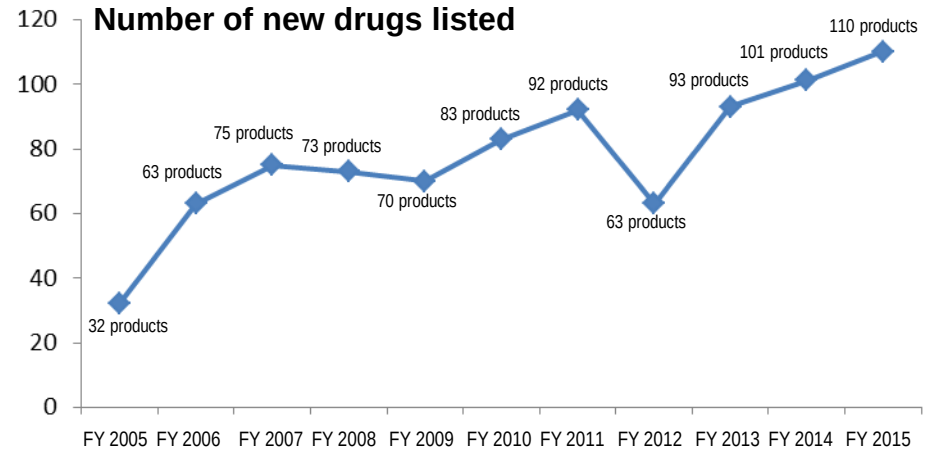


Recent trend in number of approval and listing of new drugs

Number of drugs approved



★ The figures for FY 2014 and FY 2015 were estimated based on the mean growth rate from FY 2005 to FY 2013.



★ The figures for FY 2013 to FY 2015 were estimated based on the mean growth rate from FY 2009 to FY 2012.

- ○ The number of listing tends to be increased as the number of approval is increased.
- ○ Products listed as new drugs was increased about 3.5-fold from 10 years ago.

⇩

- ○ Drugs are more actively developed.
- ○ Acceleration of approval review contributed.

Timing of listing of new drugs

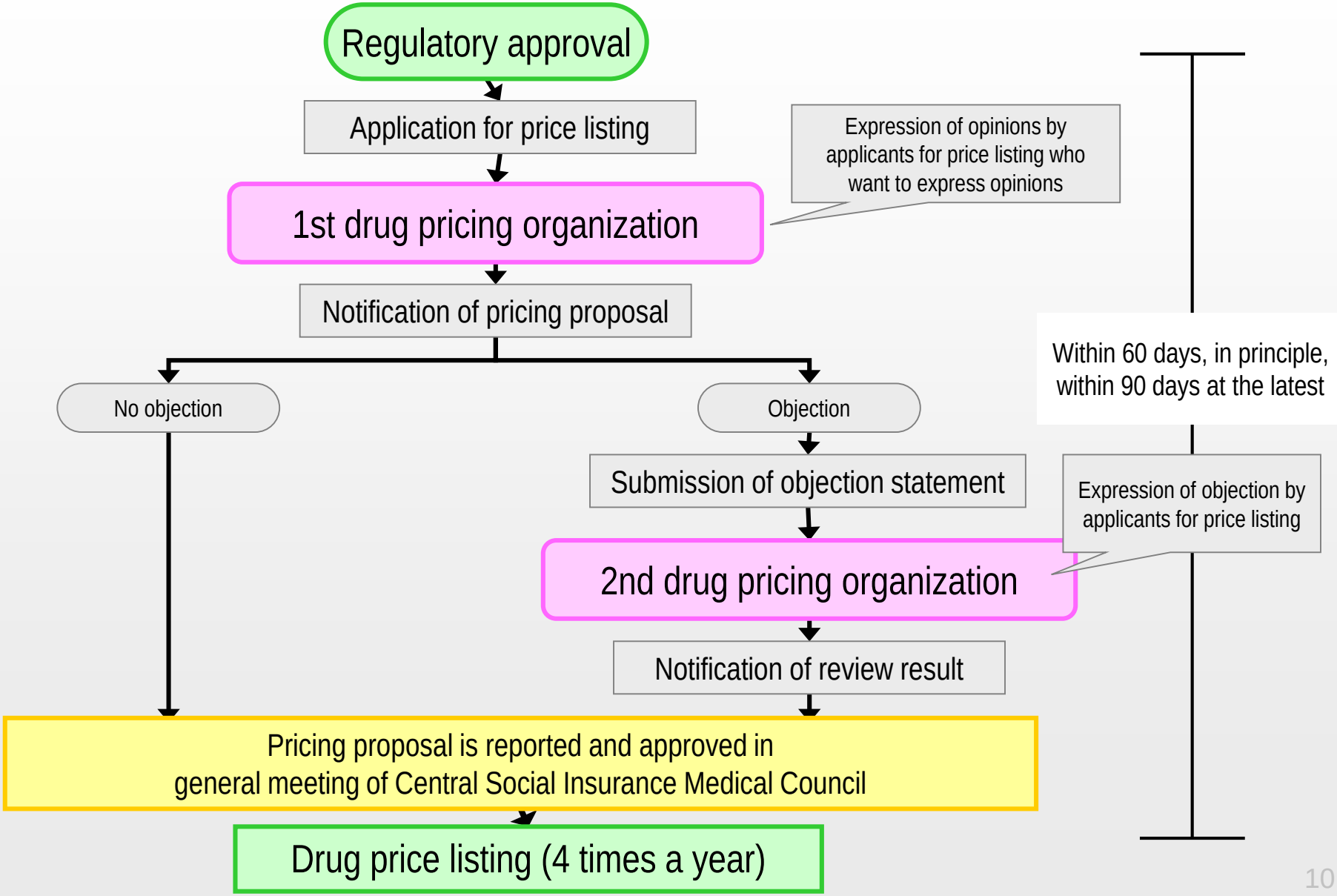
○ Basic rules

- 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

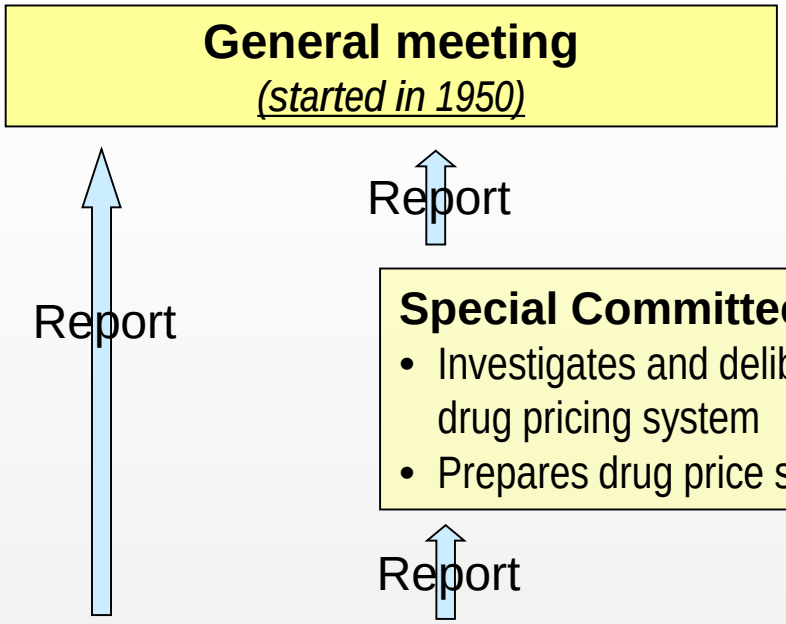
Pricing process of new drugs



Recent status of listing of generics

Listing date (announcement date)	Deadline of application for listing (deadline for approval)	Number of listed products
November 28, 2011	August 5, 2011 (July 15, 2011)	521
June 22, 2012	March 1, 2012 (February 15, 2012)	519
December 14, 2012	August 22, 2012 (August 15, 2012)	595
June 21, 2013	February 25, 2013 (February 15, 2013)	715
December 13, 2013	August 23, 2013 (August 15, 2013)	694
June 20, 2014	February 25, 2014 (February 17, 2014)	454

Organizations of Central Social Insurance Medical Council involved in drug pricing



Drug Pricing Organization *(formed in 2000)*

- Consists of experts of medicine, dentistry, pharmaceutical sciences and medical economics
- Examines the following for individual products in accordance with drug pricing rule and report to general meeting
  - Pricing of new drugs(listed 4 times a year)
  - Examination of premium rate for re-pricing following market expansion, etc.(every 2 years)
  - Others (examination of drug classification, etc.)(as needed)
- Summarizes opinions for reform of drug price system and report to Special Committee on Drug Prices (every 2 years)

Revision of medical treatment fee and drug price system in FY 2014 (summary)

(1) Price premium for promotion of new drug development and resolution of off-label use, etc. (exceptional price reduction, “Z” and “Z2”)

Opinion regarding institutionalization of price premium for promotion of new drug development and resolution of off-label use, etc.

(Special Committee on Drug Prices, December 18, 2013)

(Proposal):

As shown in the attachment, how about institutionalizing the price premium for the purposes of stabilizing the profit from new drugs during patent term and promoting development of new drugs and resolution of off-label use, etc., assuming the introduction of the rule (Z2) requiring price reduction of brand name products that are not appropriately replaced by generics within a certain period?

In applying this premium, how about having Central Social Insurance Medical Council confirm whether research and development of unapproved drugs or drugs used off label are appropriately promoted by this premium upon every revision?

In addition, how about applying this premium to products of companies that conduct research and development for "the drugs that truly contribute to the improvement of quality of medical care ((1) drugs for pediatric use or in orphan disease areas, (2) drugs for diseases insufficiently treated by existing therapeutics (drugs for intractable diseases, drugs meeting unmet needs, etc.)"?

"Opinion No. 1" (opinion from payer side):

Although efforts to resolve the issue of unapproved drugs and drugs used off label seems to be going well, some companies have premium prices but do not request for them or respond to open recruitment for certain products.

In addition, the ratio between "development of drugs used off label, etc." and "development of drugs that truly contribute to improvement of quality of medical care" has been changing. Because there are problems including the criterion of average divergence rate or lower that does not represent the resolution of drug lag, further discussion is necessary.

"Opinion No. 2" (opinion from care provider side):

Drugs that truly contribute to improvement of quality of medical care include unapproved drugs/drugs used off label for which requests were filed or public recruitment was implemented and drugs the development of which was requested by academic associations or other parties. Other than these, drugs that meet unmet medical needs, drugs for pediatric use and orphan drugs are acceptable. For drugs with new mechanism of action, there is room for discussion because they may improve the efficiency of treatment. Other drugs should not be accepted. Is institutionalization different from making it permanent?

Special Committee on Drug Prices,
Central Social Insurance Medical Council
FPMAJ material (11/06/2013)

Survey results

- **The number of the drugs developed in response to requests or the developed drugs that truly contribute to improvement of quality of medical care exceeds 800 and many were developed simultaneously worldwide.**
- **For the development of the above drugs in Japan, approximately 290 billion yen is invested per year.**

1 . Status of drugs developed in Japan and drugs developed simultaneously worldwide

The figures are number of products, some products are counted more than once in [A], [B] and [C].

Total number of developed products	Products developed in response to request [A]		Drugs that truly contribute to improvement of quality of medical care[B] (with duplication)					Prevention of drug lag[C]
	Public recruitment, unapproved, off-label	Others, developed at request of academic societies, etc.	Pediatric	Orphan	Meeting unmet needs (※2)	New mechanism of action	Others (new dosage form, etc.)	Drugs developed simultaneously worldwide
804	146	60	103	165	231	341	189	260

* Drug developed in Japan at the end of the most recent accounting period for each company (including drugs in PI to III, drugs in preparation for application, drugs being applied and approved drugs)

*2 Drugs for the diseases for which drugs contribute only to a minor extent to the treatment or similar diseases and drugs for the diseases that cannot be effectively treated by existing therapeutics, for example, intractable diseases shown in Slide 8 used for the statement of opinion of FPMAJ at the meeting of Special Committee for Drug Prices of Central Social Insurance Medical Council on September 25, 2013

2 . Status of cost of development of the above drugs in Japan

Total development cost	Development cost related to drugs corresponding to products developed in response to request [A] (including products classified into[B])	Development cost for products classified only into drugs that truly contribute to improvement of quality of medical care [B]
2,906.2	387.9	2,518.3

Unit: 100 million yen

* Approximate estimates of the following cost related to the development of concerned developed products in Japan for 1 year up to the end of the most recent accounting period of each company
Actual cost of studies/application (including all the cost related to studies including cost for outsourcing), labor cost (research and development division and regulatory affairs division), etc.

“Framework for the next reform of drug pricing system”

(approved in the general meeting of Central Social Insurance Medical Council on December 25, 2013)

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

(Pharmaceutical companies shall accept the optimization of healthcare cost through replacement of brand name drugs with generics after the termination of patent term.)

- The rule (Z2) that requires price reduction of brand name drugs that are not appropriately replaced by generics within a certain period is introduced and the trial implementation of the price premium that stabilizes the profit from new drugs during patent term and promotes new drug development and resolution of off-label use, etc. is continued.
- The price premium is applied to the products of the companies that conduct research and development of “drugs that truly contribute to the improvement of quality of medical care” ((1) drugs for pediatric use or in orphan disease areas, (2) drugs for diseases insufficiently treated by existing therapeutics (drugs for intractable diseases or drugs meeting unmet needs))
- Confirmation and verification of the status of research and development in Japan of drugs that truly contribute to the improvement of quality of medical care shall be continued and the revision of the current system including the range of products to which this price premium is applied shall be discussed.

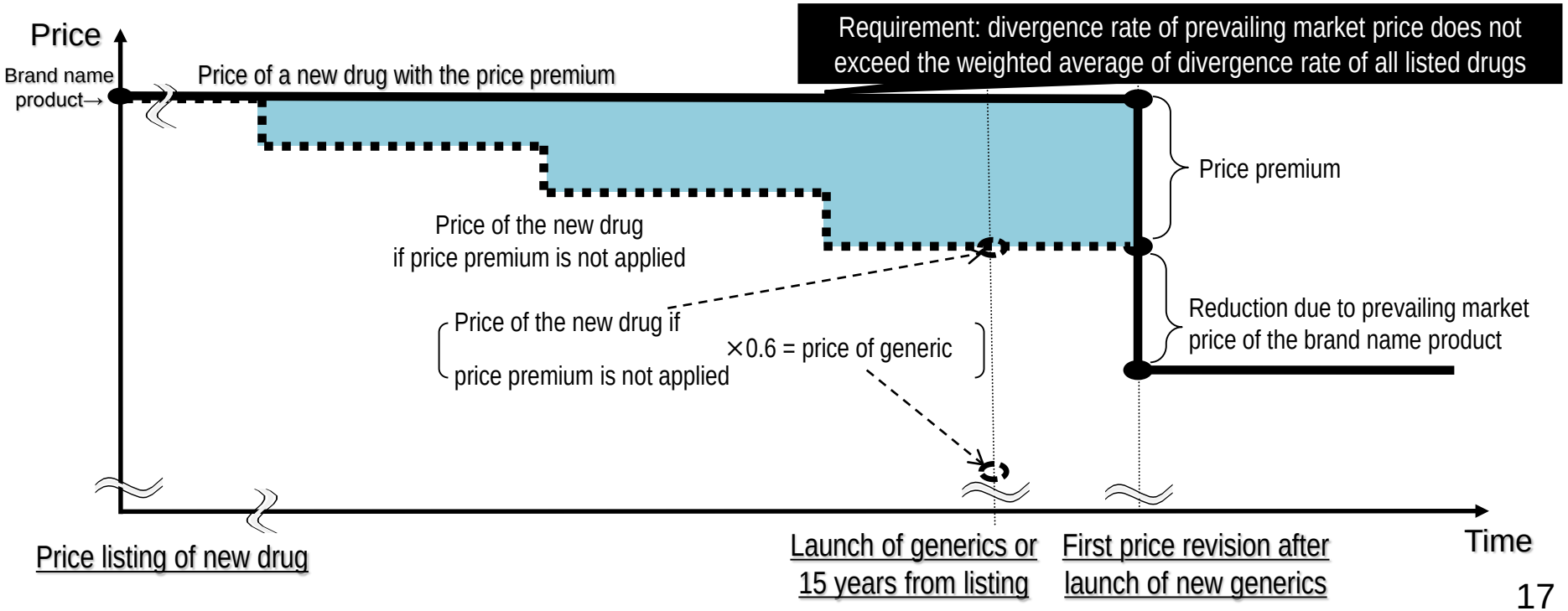
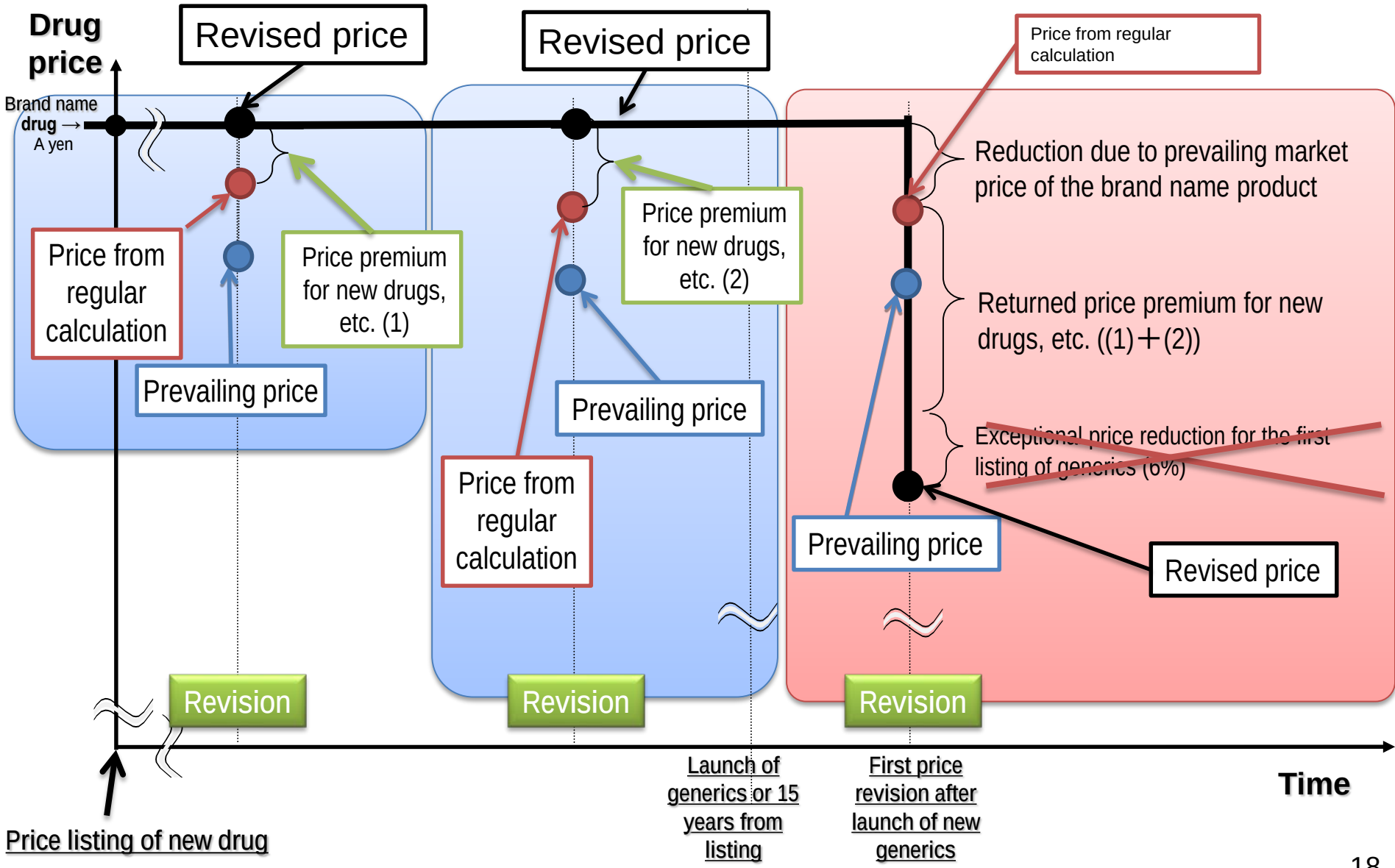
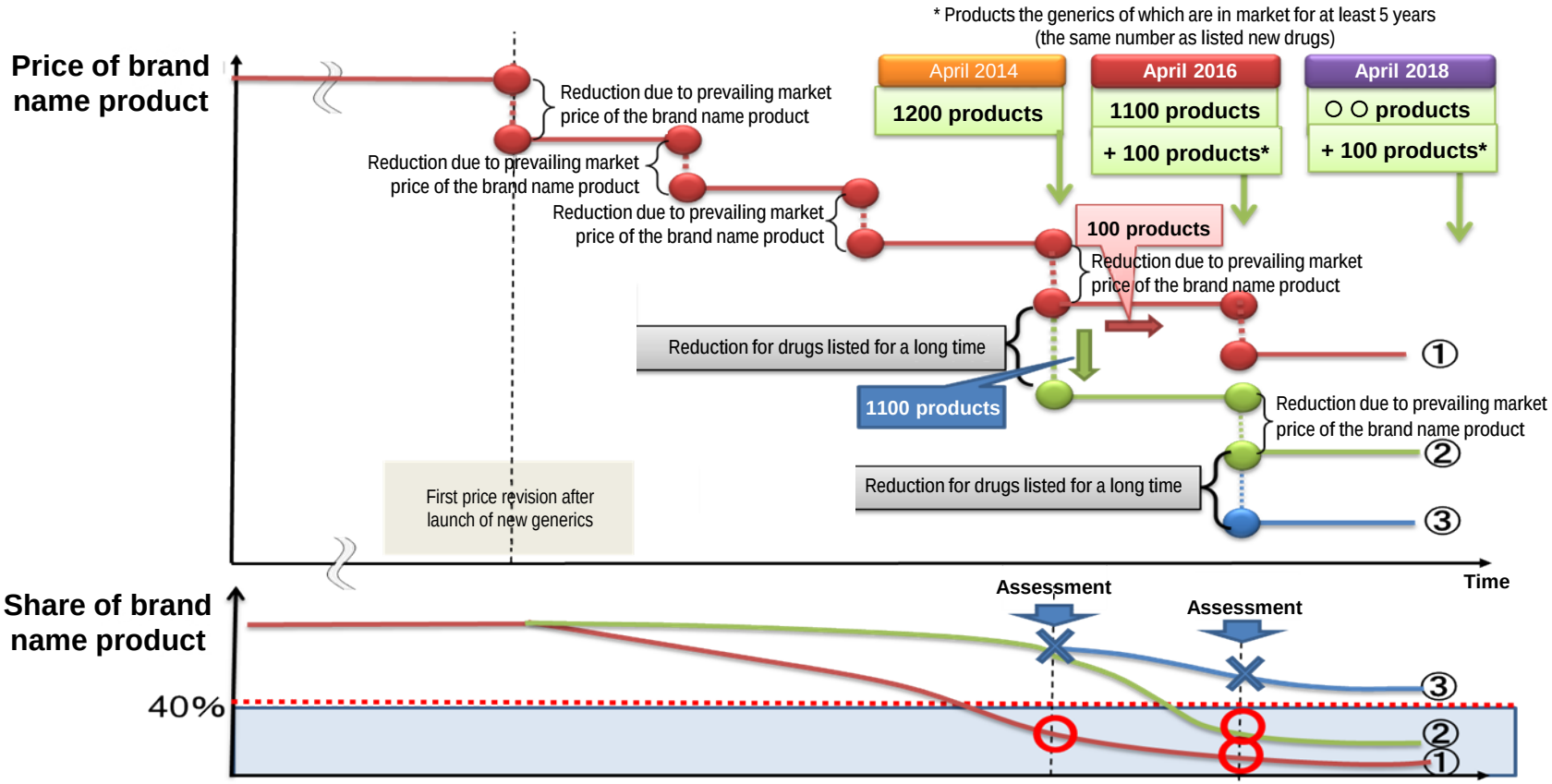


Image of price change of new drugs to which "price premium for promotion of new drug development and resolution of off-label use, etc." is applied at drug pricing



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 20% of replacement rate by generics : 2.0%
  - Price reduction of brand name products with less than 40% of replacement rate by generics : 1.75%
  - Price reduction of brand name products with less than 60% of replacement rate by generics : 1.5%
- "Special provision for price revision of listed drugs the generics of which are listed for the first time" is abolished.



Thank you for your attention!