

Drug pricing system in Japan and the Environment surrounding generic drugs

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National Health Insurance (NHI) in Japan

- Health Insurance Law enacted in 1922 and enforced in 1927 for the first time in Japan.
- The National Health Insurance Law enacted in 1938. Subsequently the universal NHI established in 1961.
- It covers various society-managed insurance funds and regional funds made after the German model.
- It provides a comprehensive set of uniform benefits in kind.
- It is financed by employer-employee contributions to either private employer-based or government insurance funds but also by government subsidies for certain groups for regional funds which include self-employed, farmers and others.
- Now co-pay for the majority of the patients is 30% for medical and pharmaceutical benefits after various changes.
- With a health insurance certificate, any NHI registered institute or practitioner will accept the patient all over the country.

National Health Insurance (NHI) Scheme

This scheme basically consists of 2 Groups.

- Work Place Basis (Employees) ⇒ Employee's Insurance
- Community Basis (who are not insured by the Employee's Insurance –
Example : Self-employed persons , Farmers,) ⇒ Community Insurance

The reimbursable fees include 2 categories:

- The fee for each practice and procedure such as consultation, examination, medication, dispensing, treatment, surgery, nursing, hospitalization, etc.
- The fee for reimbursement price of drugs and medical devices.

However, Diagnosis Procedures Combination (DPC) System has been introduced since 2003 and subsequently adopted by major hospitals. It is a fixed amount payment plan based on each pre-designated diagnosis, of which the fee is standardized for medical procedures and drugs. DPC adopted medical institutions are permitted to appropriate the earned difference between the fixed DPC prices and actual expenses.

The NHI budget is supported by the public funds (about 37%), the insurance premiums (about 49%) and the co-payment by the patient (about 14%). The current co-payment of majority of the insured is 30% of the total medical fee including drug expenses.

Key Profile of NHI scheme



Compulsory Enrollment of Nationals

All persons have the obligation to enroll in the NHI scheme.



Freedom of Access

Patients are free to choose any medical institutions.



Equitable Medical Benefits

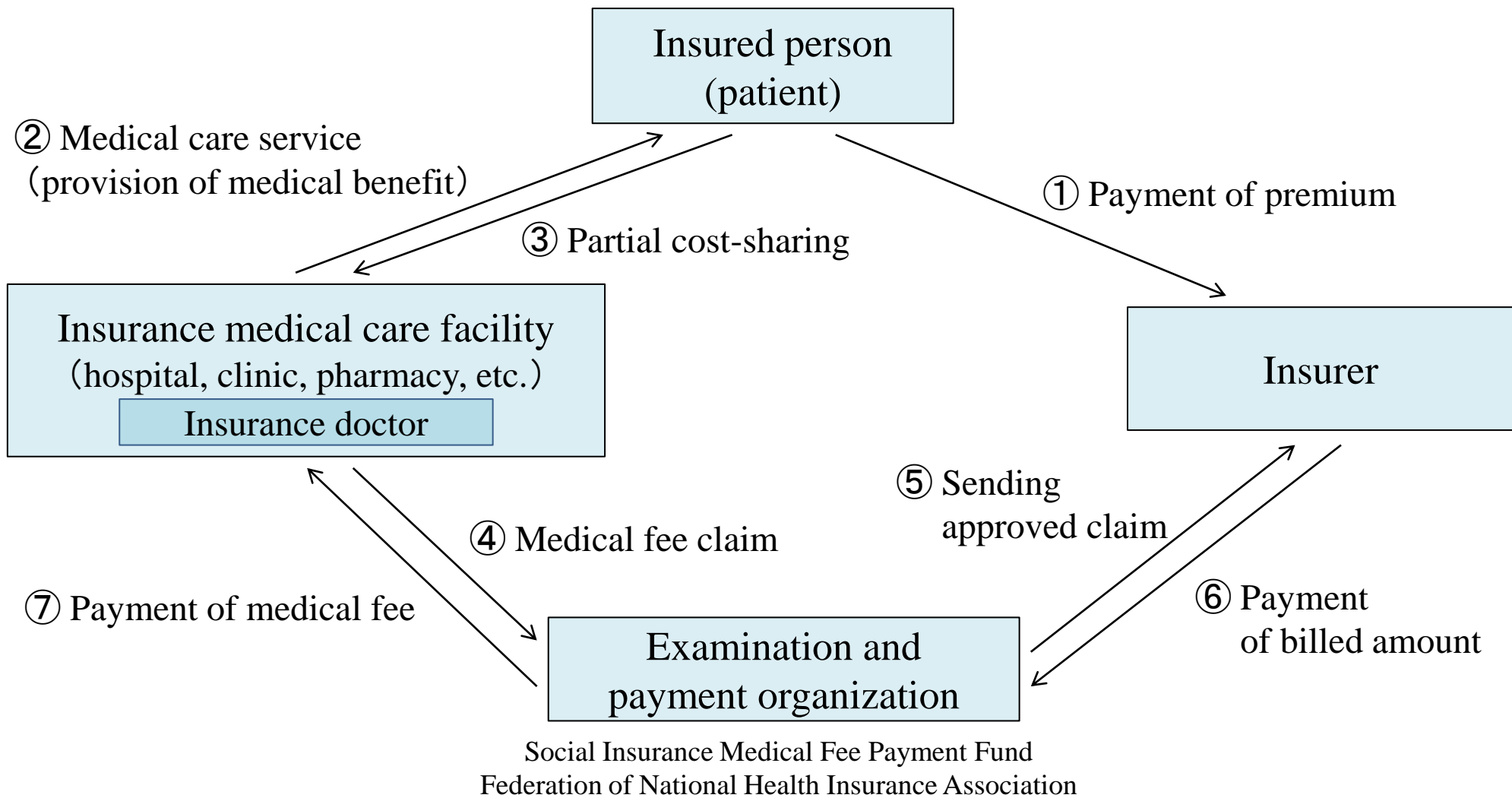
The equitable medical benefits are delivered and the fees for medical services are universal for same medical practice and medication.



Coverage over the Almost Medical Services

Medical services are basically delivered under the NHI scheme.

Conceptual Chart of Insured Medical Treatment



- Medical fees are classified into three types; medical, dental, and dispensing fees.
- The medical fee is calculated by adding stipulated numbers of points for the individual medical activities provided (so-called “fee-for-service system”) The unit price for one point is ¥10.

Drug Price Standard

NHI Drug Price list (so-called “Yakka-kijun”)

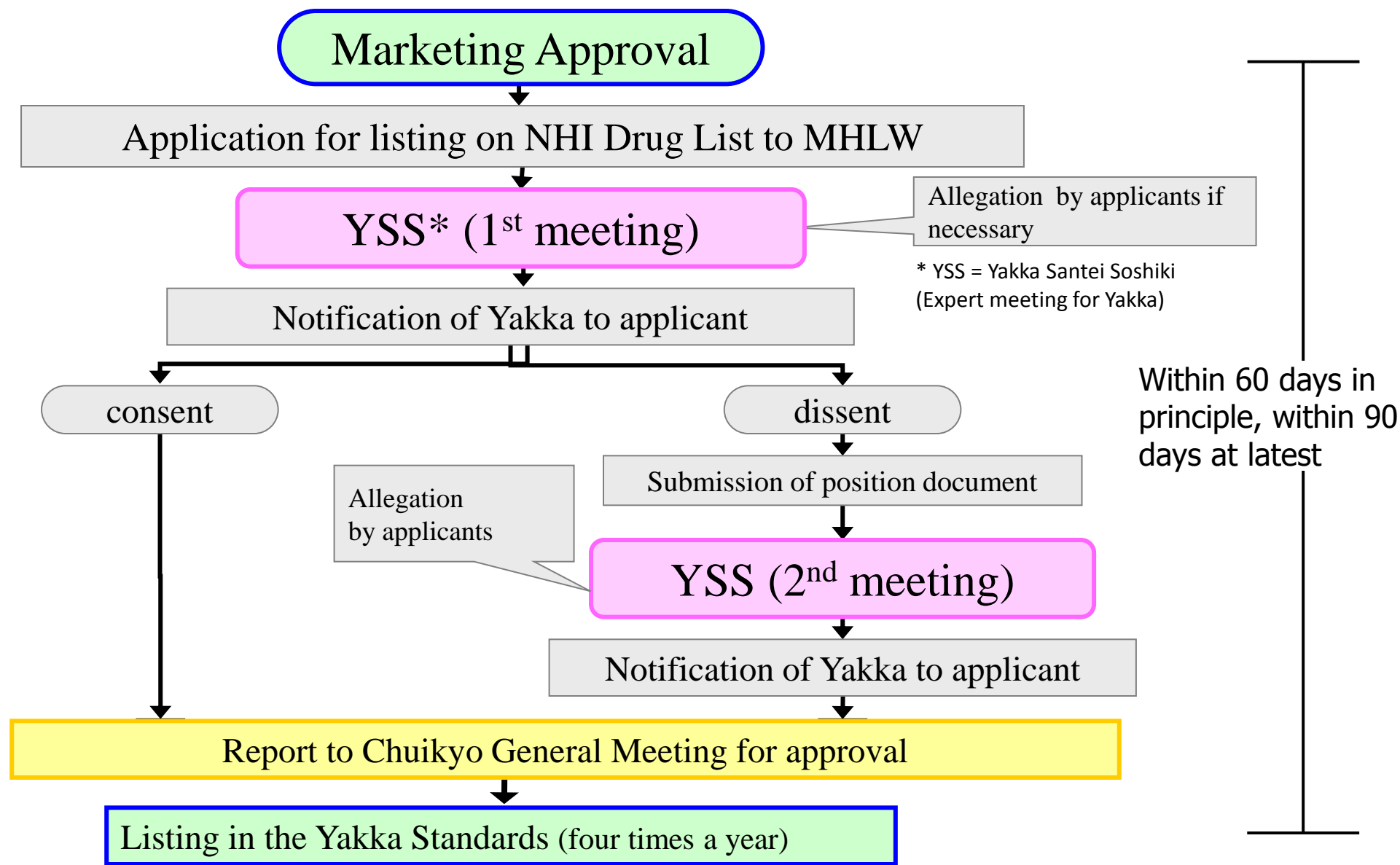
- Products registered on the NHI Drug Price List are only reimbursable for their therapeutic use under NHI scheme.
- ➡ Drugs approved by Pharmaceutical Affairs Law for medical use are listed in NHI drug price list in principle .
- Drugs NOT listed in NHI drug price list are;
 - OTC drugs
 - Drugs for medical use as follows:
 - In vitro diagnostics (reimbursed as medical materials)
 - Not suitable for NHI scheme, such as Viagra

Overview of Current Drug Pricing System

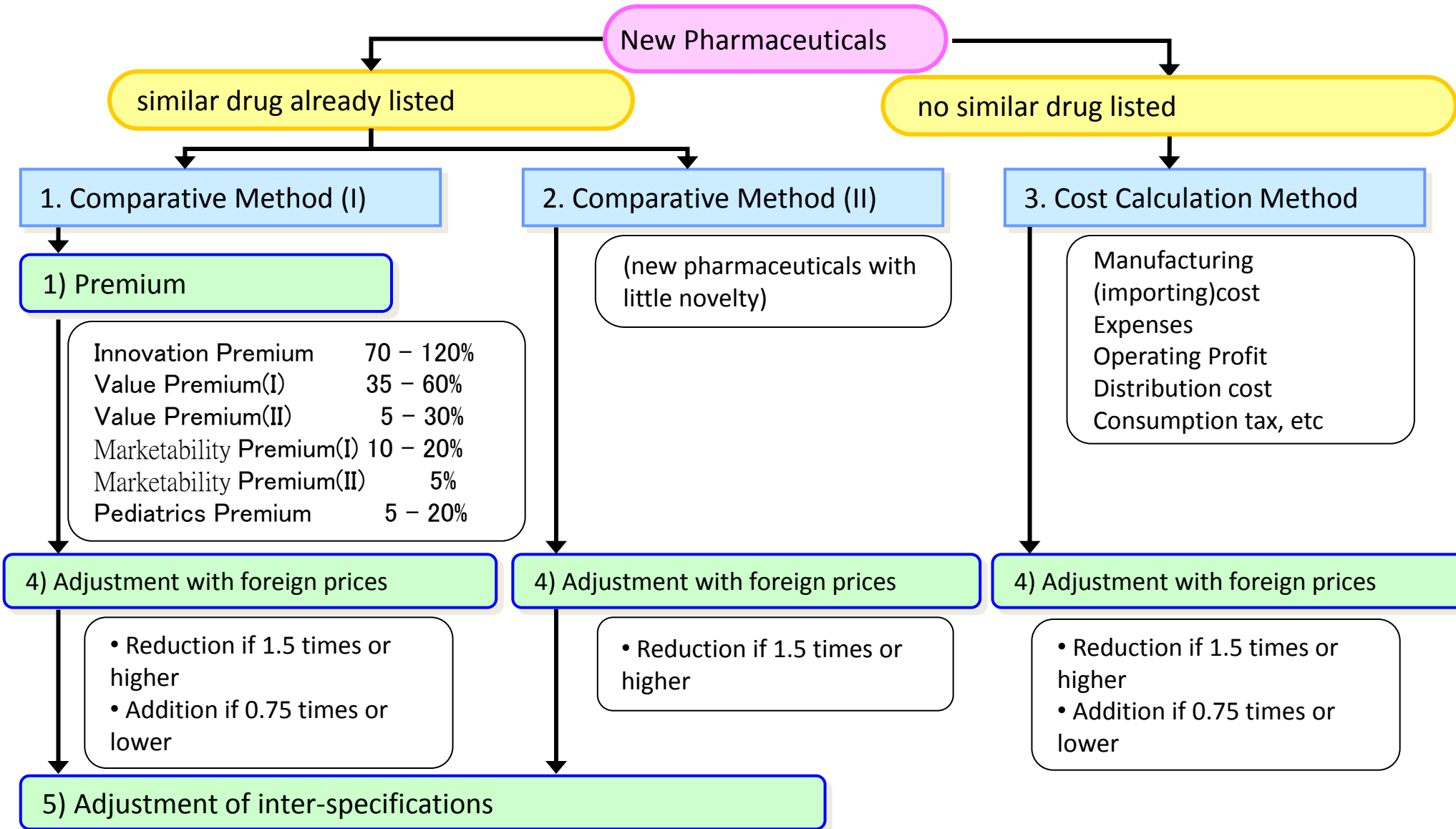
- 1 . Drug Pricing System (so-called "*Yakka-Kijun*") stipulates the price of the drugs, when medical institutions and pharmacies insurance (insurance medical care facility, etc.) are paid from the National Health Insurance (NHI).
- 2 . Current Drug Pricing System is based on the RUMinister of Health, Labour and Welfare announced "Rule of pricing medicines" on 10th February 2012 in accordance with Central Social Insurance Medical Council (so-called "*Chuikyo*").
- 3 . The price of drugs is periodically revised based on official survey of the actual sales price (market price) in medical institutions and pharmacies.

Drug pricing for new drugs

Reimbursement Price Decision Flow Chart for New Innovator Drugs



Drug pricing system for New Drugs




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

Pricing Rule for New drugs


Similar efficacy comparison method

Basic Rules

- 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.


1 tablet = 50 yen
3 tablets / day

=


1 tablet = X yen
2 tablets / day

<Daily price equivalence>
50 yen X 3 tablets
= X yen X 2 tablets
X = 75 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

Pricing Rule for New drugs

Similar efficacy comparison method

Basic Rules

Innovation Premium (70–120%)

Applicable to new pharmaceuticals that meet all conditions as below:

- a) New mechanism of action, which is proven to be clinically beneficial
- b) High efficacy or safety toward similar drugs
- c) Significant improvement in treatment

Value Premium (I) (35–60%)

Applicable to new pharmaceuticals that meet 2 conditions shown in innovation premium

Value Premium (II) (5–30%)

Applicable to new pharmaceuticals that meet either of following conditions:

- a) New mechanism of action, which is proven to be clinically beneficial
- b) High efficacy or safety towards similar drugs
- c) Significant improvement in treatment
- d) High clinical efficacy by improving drug formulation

+

Marketability Premium (I) (10–20%)

Applicable to new pharmaceuticals that meet all the following conditions:

- a) Orphan Drug designated by the Pharmaceutical Affairs Law and its primary indication as Orphan Drug
- b) Its comparable drug without applied Marketability Premium (I)

Marketability Premium (II) (5%)

Applicable to new pharmaceuticals that meet all the following criteria:

- a) Primary indication suiting for a certain pharmacological effect for small market
- b) Its comparable drug without applied Marketability Premium (I) or (II)

Pediatrics Premium (5–20%)

Applicable to new pharmaceuticals that meet all the following conditions: (not applied if clinical trials for pediatric indication is not implemented in Japan)

- a) Pediatric indication/dosage/administration is shown explicitly in the major indication (including small children, infants, newborns, and low-birth-weight infants)
- b) Its comparable drug is not applied with Pediatrics Premium.
(Note) Pediatrics Premium is prioritized than Marketability Premium(II).

Pricing Rule for New drugs

Similar efficacy comparison method

Exceptional Rules

- Price of new pharmaceuticals with little novelty is determined to be adjusted to the lowest price among similar drugs listed in the past few years.

【Comparative Method (II)】

- Definition of New pharmaceuticals with little novelty
 - premium not applied
 - more than 3 pharmacologically similar drugs already listed
 - oldest pharmacologically similar drug listed more than 3 years ago
- In principle, the lower **price** of the following a) or b) is applied:
 - a) lowest daily price among similar drugs listed in the past 6 years
 - b) average daily prices among similar drugs listed in the past 10 years
- When the price determined above, is higher than c) Yakka calculated by the Comparative Method (I), the lowest price of c), d), or e) is applied:
 - d) lowest daily price among similar drugs listed in the past 10 years
 - e) average daily prices among similar drugs listed in the past 15 years

Yakka Determination Methods for New Pharmaceuticals

Exceptional Rules

- Yakka 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>4,026 yen</u> ^(*1) X labor hours)
	c) Manufacturing expenses	(= b X <u>3.418</u> ^(*2))
	<hr/>	
	d) Manufacturing cost	
	e) Marketing, R&D cost	(= (d + e + f)) * <u>0.464</u> ^(*2))
	f) Operating profit	(= (d + e + f)) * <u>0.191</u> ^(*2))
	g) Distribution cost	(= (d + e + f) + g)) * <u>0.079</u> ^(*3))
	h) Consumption tax	(<u>5%</u>)

Total= Yakka of a new pharmaceutical

(figures underlined: average coefficients of pharmaceutical industry (average of latest 3 years) is generally used)

Increase of up to 50% (150%) 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 2008-2010

*2: Ratio of expenses/labor, marketing/administration cost, operating profit:
"Handbook of Industrial Financial Data" (Development Bank of Japan), average of 2008-2010

*3: Ratio of distribution cost: "Current Report of Pharmaceutical Industry" (MHLW), average of 2007-2009

Pricing Rule for New drugs

Adjustment with Average Foreign Price

- Yakka 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) 1.5 times or higher than average foreign price Reduction $\overrightarrow{\text{Addition}}$ *
- b) 0.75 times or lower than average foreign price Addition $\overrightarrow{\text{Reduction}}$

(1) 1.5 times or higher:
$$\left(\frac{1}{3} \times \frac{\text{Temporally calculated Yakka}}{\text{average foreign price}} + 1 \right) \times \text{average foreign price}$$

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

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

Pricing Rule for New drugs

Adjustment with Average Foreign Price

- Exceptional Rules for Average Foreign Price Adjustments

- When there are more than 2 foreign prices listed and the highest price is more than 5 times the lowest price, the highest price is excluded from the average foreign price.
- When there are more than 3 foreign prices listed and the highest price is more than 2 times the average of other countries, the highest price is regarded as equivalent to twice the average price of other countries.

Downward/upward adjustment is calculated by these adjusted average foreign price.



- The adjustment is not applied in the following cases:
 - In case of Comparative Method (II) (new pharmaceutical with little novelty)
 - Multiple specifications, some of which are both higher and lower than the average foreign price
 - Multiple specifications, and only minor specifications are adjusted
 - Average foreign price calculated from one country only

Pricing Rule for New drugs

Inter-Specification Adjustments

- In case of Comparative Method I and II, Yakka of minor specification is calculated from its major specification and the inter-specification ratio of a comparable drug. **【Inter-Specification Adjustment】**

Example: Determined Yakka of “tablet A” 5mg (major spec) is 174.60 yen

1) Yakka of comparable drug “tablet B”

- 10mg tablet = 158.30 yen (major specification)
- 5mg tablet = 82.50 yen (minor specification)

2) Inter-specification ratio of “tablet B”

$$\log \left(\frac{\text{Yakka of major spec}}{\text{Yakka of minor spec}} \right) / \log \left(\frac{\text{Content of major spec}}{\text{Content of minor spec}} \right) = 0.9402$$

3) Calculation of “tablet A” 2.5mg and 10mg (minor spec)

- 2.5mg tablet: $174.60 \text{ yen} * \left(\frac{\text{Yakka of major spec}}{\text{Content of minor spec}} \right)^{0.9402} = 91.00 \text{ yen}$
- 10mg tablet: $174.60 \text{ yen} * \left(\frac{\text{Content of major spec}}{\text{Content of minor spec}} \right)^{0.9402} = 335.00 \text{ yen}$

Pricing Rule for New drugs

Kit Products

- Kit Product: a pharmaceutical with an administration system
(e.g. an injector with a prefilled syringe)
- Calculation Formula

Yakka calculated by "Rule of medicines"

+

Cost of raw materials that shows typical feature of kit

- Premium for highly useful kit products

Premium (5%) is applied to Yakka of kit products when kit meets one of the following conditions in consideration of existing drugs (kit products excluded) (provided that novelty of mechanism or function comparing to **existing kit products** be proved).

- to reduce of risk of infection,
- to reduce of risk of error in dispensing medicine,
- to enable prompt treatment in emergency, or
- to enhance quality of medication

Drug Pricing for Generic Drugs

NHI Drug Price System for Generic Drugs

1. Initial entry Generics

→ The NHI drug price shall be 70% of original drug, when the drugs is first launched as Generic Drugs. However the NHI price shall be 60% of brand drug, if the product's category is "medicines for internal use" and the number of Generic Drug entries exceeds 10.

2. Late entry Generics

→ The NHI drug price shall be the same as the lowest of generics. However the NHI drug price of the product shall be 9/10 of the minimum NHI drug price (90% of the lowest generics), if the number of the same category of generics exceeds 10 for internal use products, or 20 for injection and external use products.

Frequency and Period of Listing

○ Basic Rule

- 4 Times per year for new innovated drugs (Within 60 days after the approval, in principle, at the latest within 90 days)
- 2 Times per year for new drugs and new kit products
- 2 Times per year for Generic drugs

● Listing Period

New innovative drugs	4 times per year	Basically in February, May, August and November (Time in conjunction with approval in accordance with the Pharmaceutical Affairs Law) (2011, in April, September and November)
New drugs and new kit products	2 times per year	Basically in May and November (2011, in April and September)
Generic drugs	2 times per year	Basically in June and December (2011, in June and November)

Drug Pricing for registered drugs

Drug Price Survey

○ Significance of drug price survey

- The item registered in NHI drug price list are conducted once every two years the revision based on actual market prices.
- Referred to as "drug price survey" the market price survey conducted for this price revision.

○ Types of drug price survey

● Main drug price survey

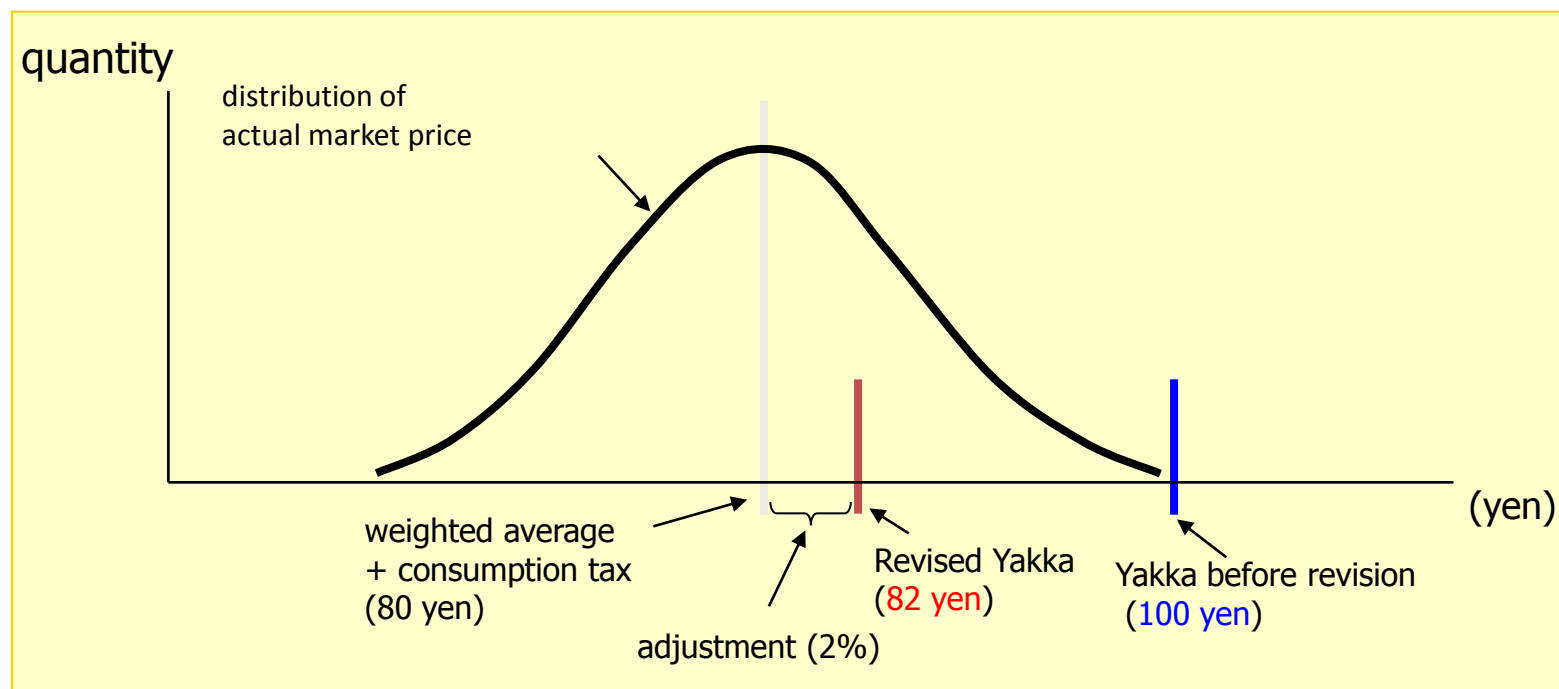
In order to obtain basic data for price revision, for all items in the listing criteria drug prices, subject to dealer drug to supply prescription drugs to medical institutions directly (pharmacies, distributors general, distributors general wholesale), and nationwide survey. In addition, the purchase price of the survey in a medical institution that is extracted at a constant rate.

● Study time-varying

At all times, as well as insight into the current market price, in order to reinforce the implementation of the study drug price data.

Re-calculation scheme for NHI drug price already listed

Basic Rule



Weight average Yakka is tentatively calculated in consideration for market price and volumes of sales in medical institutions and pharmacies, and then consumption tax (5%) and adjustment (2%) for stabilizing distribution is added as revised Yakka.

$$\text{Revised Yakka} = \left[\text{weighted average of the actual market price to medical facilities and pharmacies} \right] \times 1.05 \text{ consumption tax (5\%)} + \text{adjustment (2\%)}$$

Re-calculation of drugs already listed

Special Rule 1

- 1) NHI drug price of an original drug is lowered after its first generic drug is listed.

(so called “*Tokurei Hikisage*” (special reduction))

In the first grand revision (every two years) after one's first generic drug is listed, the brand medicine (except orphan drugs) receive additional 4-6% price reduction from tentatively revised NHI drug price based on rule of pricing medicines.

- 2) For pharmaceuticals that acquired expanded indications for pediatrics or rare diseases, or that verify clinical effectiveness after the launch, they can obtain premiums from tentatively revised NHI drug price based on rule of pricing medicines.

- 3) Re-pricing of pharmaceuticals when:

- a) Its sales considerably exceeds their initial estimations through significant change of drug utilization due to change of mode of administration or expanded indications, etc. [Repricing by Market Expansion]

Note: Repricing by market expansion exempts those drugs that are listed long before and does not compete in the same market with the repricing drugs; and drugs calculated by cost calculation method receive repricing when their market expands ten times larger than initial estimations and when the market exceeds ten billion yen.

- b) its main indication changes. [Repricing by Indication Change]
- c) dosage or administration of its main indication changes. [Repricing by Dosage Change]
- d) negative earnings by low-priced NHI drug price despite of clinical necessity [Repricing by negative earnings]

Re-calculation of drugs already listed

Special Rule 2

4) The lowest NHI drug price adjustment

When a calculated NHI drug price becomes lower than the lowest NHI drug price defined in each form category, the price is adjusted upwardly to the defined lowest NHI drug price.

5) Revision of new medicines within patent or re-examination term

“Premium to promote creation of new pharmaceuticals and development of approvals of off-label use” introduced in FY2010 as a trial continues in FY2012.

6) Revision of NHI drug price of combination drugs

When a drug composing a combination drug receives special reduction (so-called “*Tokurei Hikisage*”), the price of combination drug is also revised accordingly.

7) Revision of drug price of generic drugs with the same indication

- Present unified pricing drugs (less than 20% of the highest price) and, in addition, those drugs whose prices are as 20-30% of the highest price are grouped into the same price based on weighed average method.
- For those drugs (more than 30% of the highest price), when their prices are within 3% of the highest price, they are grouped into the same price by weighed average method.

Outline of market survey of drug price in 2011

1) Main drug price survey

To conduct research with the aim to obtain the basic data for the price revision. Usually carried out once every two years.

Survey :	Wholesale dealer	all objects	about 6,000
	Hospital	1/10	about 900
	Clinic	1/100	about 1,000
	Insurance pharmacy	1/30	about 1,600

Mon survey: September 2011 minute deal

2) Study time-varying

The purpose of such a survey carried out by increasing the reliability of the data of this study. Self-study as well as a total system.

Survey:	Wholesale dealer	Extraction	about 1,500
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Mon survey : June, July, August and January

Result of market survey of drug price in 2011

○ The average deviation rate : about 8.4%

Note 1) Although the aggregate results for the September 2011 trading minutes, there was a report by October 26, from the sales side of the business.

Note 2) The average deviation rate is calculated below

$$\frac{\text{sum of (Current drug prices } \times \text{ Sales volume)} - \text{sum of (Actual sales prices } \times \text{ Sales volume)}}{\text{sum of (Current drug prices } \times \text{ Sales volume)}}$$

Note 3) Different dosage forms

Classification	Average deviation rate (%)	Occupancy in drug price (%)
Oral medicine	8 . 9	6 7 . 7
Injection	7 . 4	2 2 . 4
External medicine	7 . 6	9 . 9
Dental Pharmaceutical preparation	1 . 3	0 . 0
Total	8 . 4	1 0 0 . 0

○ Share of generic drugs : about 22.8% (volume basis)

History of recent price revision

	Number of the listed products	Rate of Price Revision (%)		Remarks
		Based on Drug Price	Based on NHI	
1990	13,573	▲8. 1%	▲2. 4%	Reasonable Zone 15%
1992	13,375	▲6. 6%	▲2. 0%	Reasonable Zone 13%
1994	12,869	▲6. 8%	▲2. 6%	Reasonable Zone 11%
1996	11,974	▲4. 4%	▲1. 3%	Reasonable Zone 10% (A long-term listed item 8%)
1998	11,692	▲9. 7%	▲2. 7%	Reasonable Zone 5% (A long-term listed item 2%)
2000	11,287	▲7. 0%	▲1. 6%	Width adjustment 2%
2002	11,191	▲6. 3%	▲1. 3%	Width adjustment 2%
2004	11,993	▲4. 2%	▲0. 9%	Width adjustment 2%
2006	13,311	▲6. 7%	▲1. 6%	Width adjustment 2%
2008	14,359	▲5. 2%	▲1. 1%	Width adjustment 2%
2010	15,455	▲5. 75%	▲1. 23%	Width adjustment 2%
2012	14,902	▲6. 00%	▲1. 26%	Width adjustment 2%

Overview of FY 2012 medical fee revision

- Anticipation of an image while in 2025 shown in the "Outline of integrated social security and tax reform", the revision of the first step towards the realization of health care should be.
- Priority allocation in the field needed to create an environment which will receive a safe, secure, high-quality medical care to patients and the public want

Overall revision rate **+0. 004%**

Medical fee **+1. 38%**

(about 550 billion yen)

{	medical	+1. 55%	(about 470 billion yen)
	dentistry	+1. 70%	(about 50 billion yen)
	dispensing	+0. 46%	(about 30 billion yen)

Drug price etc. **▲1. 38%** (about 550 billion yen)

the rate of price revision **▲1. 26%**

(NHI price basis **▲6. 00%**)

Overview of FY2012 NHI price revision

1. Timing of implementation

Register notice : March 05th, 2012 (Mon)

Implementation : April 1st, 2012 (Sun)

2. Key issues of the revision

(1) Based on the survey results drug prices, drug prices completely revised standards

(2) Method for drug pricing, the calculation is based on the understanding in the Central Social Insurance Medical Council of February 10, Heisei 24 standard "Drug Pricing"

(3) Adjust the width, the amount obtained by multiplying the previous 2% to drug price revision

(4) Revision rate is 6.00% in the base drug prices, 1.26% in terms of health care costs

It should be noted that, as minute replacement effect reimbursement of generic products, the implementation of generic drug price cuts and the original drugs with generic

(5) Notice listing the number of standard pharmaceutical drug prices are as follows:

	Oral medicine	injection	External medicine	Dental Pharmaceutical preparation	total
Notice number	8, 629	3, 820	2, 426	27	14, 902



Dissemination of generic drugs



○ Consciousness of healthcare professionals

- (1) Healthcare professionals are generally uneasy about the quality and stable supply and do not feel sufficient necessity of using generic drugs in place of familiar forerunner drugs.
- (2) Burden of assortment of many products at pharmacy, difficulty in selection of generic drugs (for a certain antihypertensive drug, 34 companies are supplying generic drugs)

○ Consciousness of patients

- (1) Awareness of generic drugs has been improved to some extent .
- (2) There is a merit of lower drug expenses for patients. But, on the other hand, a sufficient feeling of security that familiar forerunner drugs can be safely switched to generic drugs has not been obtained from healthcare professionals.



Major countermeasures



Goal: Achievement of **30%** amount share of generic drugs by fiscal 2012 (**22.8%** as of September 2011)

- | | |
|--|---|
| <p>(1) Measures mainly targeting medical institutions and pharmacies</p> | <p>⇒</p> <ul style="list-style-type: none">▪ “Action program for promotion of easy-mind use of generic drugs”
(Specific efforts related to environment arrangements for securement of stable supply , quality and information provision system and use promotion)▪ Environmental arrangement related to medical fee (Gradual appreciation of pharmacies depending on the amount rate of prescribed generic drugs and environment arrangement for prescription switching, appreciation of medical institutions using generic drugs proactively, insurance physicians’ obligation to check patient’s intention to select generic drugs, etc.▪ Disclosure of list of generic drugs adopted at National Hospital Organizations |
| <p>(2) Measures mainly targeting patients</p> | <p>⇒</p> <ul style="list-style-type: none">▪ Holding of “generic drug easy-mind use promotion seminar”▪ Delivery of generic drug-wishing card▪ Notification of cost difference on switching to generic drugs▪ Publicity activities by preparation and delivery of posters and leaflets, etc. |