

Health Insurance Programs and Drug Pricing in Japan

1. HISTORY OF HEALTH INSURANCE PROGRAMS

Health insurance programs in Japan began in 1922 with enactment of the Health Insurance Law which was aimed only at workers for the purpose of ensuring sound development of national industries through increases in labor efficiency and close cooperation between workers and employers by eliminating workers' anxiety about their daily life. This law was implemented in 1927. The National Health Insurance Law (NHI) enacted in 1938, and the Employees' Health Insurance Law and the Seamen's Health Insurance Law both enacted in 1939 were subsequently enforced. In 1961, it was ruled that every citizen was required to join either one of industry-managed employees' health insurance programs or locally-based health insurance programs. At this point, "health insurance covering the entire population" was established.

Increasing efforts were made thereafter to improve the structure/scope of medical benefits given under various health insurance programs. In addition, under the Welfare Law for the Elderly, all medical costs for the elderly have been provided free of charge since 1973, and additional health care services became available for patients with intractable diseases to alleviate their economic burden. These, special health insurance programs have been implemented to reduce high medical costs for special populations.

On the other hand, because of the long-term deficit in the health insurance system, not only temporary financial measures but also radical measures have been successively introduced to counteract the deficit.

As medical services for the elderly had been concentrated on financial support and provided free, the cost of their medical treatment sharply increased every year, seriously affecting the financial status of the NHI program.

In addition, the financial support for the elderly created an imbalance in the amount of medical costs of the elderly and hence burden of insured persons between the different industry-managed and locally-based health insurance programs due to differences in the proportion of elderly persons covered under each program. This made it necessary to radically review the health insurance system in Japan, and as a result, the Health and Medical Services Law for the Aged was enacted and enforced in 1983.

This law encourages general health related projects for the elderly, including the prevention and treatment of diseases and rehabilitation training. The law also introduced a new system in which medical costs for the elderly are shared by public expenditure and by contributions from individual health insurance programs in order to distribute the costs more fairly.

Thereafter, anxiety increased among the people concerning home care of elderly people because of the

aging of society and changes in family function, and the excessive burden of home care on families has become a social problem. Another problem is stringency on health insurance finances by social hospitalization, i.e., long-term hospitalization of the elderly for nursing care. There are limits on solving the home care problem under the current health insurance system, and a reform of the health-care insurance system together with the introduction of a new social security system was debated. The Long-Term Care Insurance Law was passed together with the third revision of the Medical Care Law on December 19, 1997 and it was enforced from April 1998. It is amended every 5 years.

The health-care insurance reform concurrently studied in 1997 brought a change in the coverage on benefits by employee's health insurance to 80% and to introduce a partial cost-sharing for medication. Thereafter, in 2002 the revision of the Health Insurance Law containing the 30% copayment for the insured was passed by the Diet. The 30% burden for the insured was enforced from April 2003.

The law to reform the health insurance system was discussed from 2005 and was enacted in June 2006. From October 2006, persons aged 70 years or older with similar regular income as during their working years were subject to a copayment of 30% and limits on copayments and food/housing costs for inpatients of nursing home increased. From April 2008, a healthcare system for very old people was initiated.

2. MEDICAL BENEFITS OFFERED UNDER HEALTH INSURANCE PROGRAMS

As mentioned above, there are various types of health insurance programs in Japan and medical benefits available vary from one program to another. Medical benefits available for the insured person can also differ depending on the type of insurer, type of insurance program, and presence of family members (non-working dependents). Under industry-managed health insurance programs, 90% of medical costs of insured persons is covered by health insurance programs according to the revision of the Health Insurance Law in 1984 (the original coverage was stipulated to be 80% in the law but it was 90% until a notification of the Minister of Health and Welfare issued on a day after April 1986 after approval by the Diet). From September 1997, the coverage was changed to 80% of medical costs to medical institutions where patients are treated under health insurance programs. A copayment by patients for outpatient medication fees was also introduced with children less than 6 years of age and low-income elderly patients excluded.

Thereafter, problems related to the burden on the elderly were pointed out and the government adopted a policy of exemption of the elderly from outpatient partial cost sharing for medication as an extraordinary measure in July 1999. In December 2000, the Health Insurance Law was promulgated and from January 1, 2001, it became possible to select a copayment system with 10% of the medical expenses as the upper limit or a fixed copayment for the elderly. From October 2002, the burden on elderly patients aged 70 years or older was set at 10% and at 20% for those with a certain level of income, latter of which was revised to 30% from October 2006.

For family members of insured persons, regardless of type of health insurance program, at least 70% of actual costs are covered by the programs. Furthermore, when a patient's medical payment reaches a certain limit, the patient is refunded the excess. Supplementary programs are also available to cover the costs of special treatments including highly advanced medical treatments and to support specified medical care coverage system that permits selection of treatment by patients. These all contribute to overall improvement in medical care.

Under these health insurance programs, medical benefits are almost always provided to insured persons in the form of actual treatment rather than as a cash reimbursement. In exceptional cases where this rule is difficult to apply, money is provided to cover treatment costs.

3. REIMBURSEMENT OF MEDICAL FEES

Medical institutions where patients are treated under health insurance programs apply to respective health insurance associations, after treatment has been rendered, for reimbursement of actual treatment costs after subtracting the amount paid directly by patients. Medical fees listed in the NHI system are set by the MHLW, which consults with the Central Social Insurance Medical Council ("Chuikyo"). The fees are calculated based on the Rules to Calculate Treatment Fees According to the Health Insurance Law (MHW Notification No. 177 issued in June 1958). Under these rules, a point value is assigned for each of the thousands of medical procedures listed. Fees (in Yen) are then calculated by multiplying the number of points by 10. This system, in which medical fees are paid to medical institutions for the procedures performed, is called the "payment for services system" as the basis of the medical cost reimbursement system in Japan. There are many types of points set for "lump sum" payment for hospitalized treatment, etc. of patients with chronic disease. From April 2003, the Diagnosis Procedure Combination (DPC) system was introduced by university and other large hospitals (university hospitals, National Cancer center, and National Cardiovascular Center: 82 hospitals in total) for diagnosis-based assessment of lump sum payments for emergency admissions and treatments. With this system, medical bills per day per patient are determined using 1,860 DPC classifications. The medical bill includes basic admission fees, laboratory test fees, imaging diagnosis fees, drug dispensing fees, injection fees, and treatment fees of less than 1,000 points. The medical bill is calculated by the following formula.

Number of points per day for each DPC x coefficient by medical institution x number (days) of admissions x ¥10

The coefficient by medical institution is set by the function and past performance records of the hospital. No. of points per day is set higher for cases of earlier discharge than the mean number of hospitalization days of the DPC.

The number of DPC classifications was increased to 2,873 as of April 2014 and the application of this billing system has been extended to 1,585 hospitals (about 490,000 beds) as of April 2014.

Medical procedures, such as medication and injection,

require the use of drugs, and the list of reimbursement prices of drugs permitted under health insurance programs is called the National Health Insurance (NHI) Price List.

4. NATIONAL HEALTH INSURANCE PRICE LIST

The National Health Insurance (NHI) Price List is a list of drugs for which medical providers can be reimbursed under the health insurance programs as specified in the regulations for hospitals and nursing homes covered by health insurance. The rules used to calculate healthcare fees in accordance with the Health Insurance Law state that the reimbursement price of drugs for medical institutions is to be determined separately by the Minister of the MHLW. Thereby, the prices to be invoiced for drugs used in hospitals are set by the Minister and shown in the NHI Price List.

5. PRICING FORMULA FOR REIMBURSEMENT PRICE REVISIONS OF DRUGS LISTED IN THE NHI PRICE LIST

The difference in the purchase price by medical institutions and the NHI reimbursement price (price discrepancy), which provides extra income for medical institutions, has been a problem since the latter half of the 1980s, and various pricing formulas have been used to reduce this price discrepancy and correct the fluctuations in purchase prices, but improvements have not been adequate.

Under these conditions, taking an opportunity of an attempt to improve the distribution of drugs from April 1, 1991, the former bulk line method was abolished and a pricing formula based on the weighted average market price was adopted in anticipation that the NHI Price List would more accurately reflect market prices, unnatural fluctuations in prices would be corrected, and pricing would be simplified. Based on a recommendation submitted by Chuikyo to the MHLW on May 31, 1991, the pricing formula used for drugs listed in the NHI Price List at the time of reimbursement price revisions was revised, and the first overall price revision using the new formula was conducted in 1992.

In brief, the revised reimbursement prices are determined by calculating weighted means of sales prices of all existing package sizes by brand and adding a certain percentage of the current reimbursement prices (within a "specified price range") to the weighted mean prices obtained (however, the new reimbursement prices must never be higher than the current prices).

Chuikyo believes that the "specified price range", which was intended to take into account the differences in market prices according to differences in terms of sales conditions, should be 10%. However, since stable supply of all necessary drug products could not be ensured if the price range was set at 10% from the beginning, Chuikyo recommended that it be set at 15% initially so as not to have too strong an effect on business conditions at the time, and that it be reduced to 13%, 11%, and finally 10% on a step-by-step basis each time the reimbursement prices were revised in the future.

Thereafter, price increases of some products presented problems, and a Chuikyo recommendation was issued to deal with the problems on November 22, 1995. In addition to the usual price revision in April 1996, repricing was undertaken for products that showed a much greater market scale (at least double) than originally expected at the time of listing and for which annual sales (converted to reimbursement prices) exceeded 15 billion yen. Repricing was also undertaken for drugs for which indications were added after the original listing.

The price range decreased gradually from 15% in 1992 to 13% in 1994, 11% in 1996, 10% (8% for products listed for a long time) in 1997, and 5% (2% for high price products with relatively large margin) in 1998. In 2000, the range was set at 2% to secure stable drug supply involved over the need of reimbursement system reform. The pricing formula was changed to the weighted average market price and range adjustment method.

The pricing formulas for drugs included in the list were specified in March 2000 to assure transparency of drug pricing. The most recent revision is given in Notification No. 0212-(7) of the Health Insurance Bureau dated February 12, 2014, "Drug Pricing Standards."

6. RECENT REVISIONS OF THE NHI PRICE LIST

Based on the 1991 Chuikyo recommendation, the MHW undertook a complete revision of the reimbursement prices of all products already in the NHI Price List using the weighted average pricing formula from 1992.

The actual reimbursement price revisions covers the drugs sold in the month of September of a previous year. A survey of all products in the NHI Price List is conducted on about 4,000 sellers, all first-class wholesalers, and about 3,400 purchasers consisting of hospitals, clinics and pharmacies selected at random using specified sampling fractions in each case. Supplemental price surveys including those on changes with time are performed six times. The new reimbursement price is calculated by adding a reasonable adjustment zone (R) to the weighted average marketing price obtained from these surveys in consideration of the consumption tax (refer to the calculation formula).

Formula

New drug price = weighted average value of market price in survey x (1 + consumption tax rate) + current reimbursement price x R/100 (however, the new price shall not exceed the current reimbursement price).

This pricing formula is applied to products that are sold in large quantities, and the prices for drugs sold in lower quantities are adjusted using the revision rate for drugs of the same class and same indication.

From 1992, prices were revised at about every 2 years, but an adjustment was made for the increase of the consumption tax rate in 1997, and as a result, reimbursement prices were reduced for 3 consecutive years: 1996, 1997, and 1998. The reimbursement prices were reduced 2% further by the range-adjustment method in 2000. In 2002, the adjustment range was kept at 2%, and an additional reduction of an average of 5% was made

for original drugs of generic drugs (excluding those in the JP) in the case of drugs entered in the NHI Price List for a long time. In 2004, a price range of 2% and exceptions for long-listed products were applied. Among JP products entered by brand name, original products for which generic products are available on the market were subjected to an additional price reduction of one half of the rate for non-JP products. In 2006, a further reduction of 2% was applied as an exception for long-listed products.

In order to deal with of the pending "drug lag" issue (unavailability for use or longer approval time of new drugs), the Central Chuikyo discussed the issue and proposed a new "premium for promoting new drug research and resolving problems of treatment not covered by insurance. In 2010, the premium was applied for prescription drugs that have been in the reimbursement list within 15 years and not followed by generic drugs (for negative price divergence from average price of all drugs in class confirmed by price surveys). This premium pricing system on trial still continues to be implemented in 2014.

Drug prices listed in the NHI Price List were revised to include additional 3% consumption tax in April 2014 as the tax rate was raised from 5% to 8% in the month.

The results of reimbursement price revisions from 1992 through 2014 are shown in [Table 7. Methods of Previous Reimbursement Price Revisions](#) and [Table 8. Revision Rates of Reimbursement Prices](#).

7. DETERMINATION OF REIMBURSEMENT PRICES FOR NEW DRUGS

In view of trends in the new drug development environment in recent years, Chuikyo stated in their May 1991 recommendation concerning the reimbursement price of new drugs that a more appropriate premium system should be introduced with a new premium for innovation that would be applicable to only truly innovative new drugs. Specifically, it was recommended that the reimbursement price of new drugs should be determined on the basis of comparison with existing drugs from the same category as before but marked up using premiums for innovation, usefulness, and market size; and that requirements for each premium be clearly defined. The price of a daily dose of a new but non-innovative drug approved on or after April 1, 1996, for which several drugs with similar pharmacological action and indications are already listed and for which the efficacy and safety are objectively evaluated to be about the same as these drugs (excluding drugs within 3 years from the launch of the first drug or within three drugs with the same pharmacological action) was set at a lower price for a daily dose. The rule for coordinating prices with foreign reimbursement prices was also clarified (maximally twice the foreign price).

The seven premium rates as of February 2014 were set at 70-120%, 35-60%, 5-30%, 5-20%, 10-20%, 5%, and 10% for innovation, usefulness I and II, pediatric use, market size I and II, and world's first registration in Japan, respectively. Requirements for applying premiums are listed in [Table 9. Requirements for Applying Premiums](#).

A special calculation formula was introduced for new combination drugs (oral preparations): as a rule, the price is

set at 80% of the total of prices of individual drugs.

To assure transparency of the pricing system, drug pricing formulas were made public in March 2000 (the most recent revision is given in Notification No. 0212-(7) of the Health Insurance Bureau dated February 12, 2014, "Drug Pricing Standards"). Procedures for calculation of drug prices were issued in detail in September 2000 (the most recent revision is given in Notification No. 0212-(8) of the Health Policy Bureau dated February 12, 2014, "Handling of Entries of Prescription Drugs in the NHI Price List"). Methods for submission of requests for inclusion of new drugs in the price list were most recently revised in Notification No. 0212-(4) of the Health Policy Bureau dated February 12, 2014.

A drug pricing organization was established to undertake scientific surveys concerning selection of products for price comparison and the applicability of premiums by experts in the medical and pharmaceutical fields. This organization deals especially with pricing and repricing of new drugs in the NHI Price List.

With the establishment of the pricing organization, flowcharts of the process from new drug approval until entry in the NHI Price List are shown in **Fig. 20** (Reimbursement Pricing Flow-sheet for New Drugs).

(Entries of new drugs in the NHI Price List are made as a rule four times a year.)

8. ENTRY OF GENERIC DRUGS IN THE NHI PRICE LIST

In the past, generic drugs have been entered in the NHI Price List once every 2 years, but the entry has been made once a year from 1994 and twice a year since 2008 (entries in May and November from 2009). The reimbursement prices for the drugs listed since 1996 are calculated as follows in principle.

As in the case of new drugs, the drug pricing formulas were issued in March 2000 with the aim of assuring transparency of the generic drug pricing system. (The most recent revision is given in Notification No. 0212-(7) of the Health Insurance Bureau dated February 12, 2014, "Drug Pricing Standards.") Procedures for calculation of reimbursement prices were specified in detail in September 2000 (most recent revisions: Notification No. 0212-(8) of the Health Policy Bureau dated February 12, 2014, "Handling of Entries of Prescription Drugs in the NHI Price List" and Notification No. 0212-(4) of the Health Policy Bureau dated February 12, 2014 "Method for Submission of Requests for Entry in the NHI Price List for Prescription Drugs").

- 1) When a generic drug identical to the brand drug is entered in the price list for the first time, the price of the generic drug is obtained by multiplying the brand drug price by a factor of 0.6. The factor is 0.5 for "oral" preparations, in

the case that more than 10 brands are already on the market. When both the brand and generic drugs are already entered, the price of a newly entered generic drug is the same as the lowest of the generic prices.

- 2) When there are many brands with the same standard, i.e., when the number of products already entered and to be entered exceeds 20, the price of the generic drug to be entered is obtained by multiplying the lowest among all products entered by a factor of 0.9. A special formula was introduced for biosimilar products. A premium (maximally 10/100 of the standard) is added to the standard price depending on qualitative and quantitative data obtained from clinical trials.

9. ISSUES RELATED TO THE USE OF DETERMINATION OF UNAPPROVED DRUGS AND OFF-LABEL USE

There have been major issues related to the use of unapproved drugs and the "time-lag" in new drug approval. The Ministry of Health, Labour and Welfare formed the Review Conference on Unapproved Drugs in 2005 to address these issues. In view of an increasing need for regulatory and industry measures to lend greater support to the use of unapproved drugs and new indications, the Ministry and member companies of the JPMA worked together and established the Pharmaceutical Development Support Center in May 2009 to improve regulatory systems and structures to support the development of such drugs and new indications by pharmaceutical companies. The Chuiyko also joined the support: they discussed potential approaches and introduced the New Premium System for the Promotion of Innovative Drug Discovery and Resolution of Off-Label Use in April 2010 on a trial basis.

In addition, the Ministry established the Review Conference on Unapproved Drugs and Off-label Use of Drugs of High Therapeutic Need in February 2010 and, since that time, it has been working to realize the early approval of unapproved drugs and new indications of high medical need that are available in foreign countries, by requesting pharmaceutical companies to develop such drugs and indications. Since August 2010, the Conference has been evaluating individual drugs and indications to determine if they are worthy to be reimbursed by the National Health Insurance System without license approval, provided that the Social Insurance Council, Pharmaceutical Affairs and Food Sanitation Council (PAFSC) accept the use of unapproved indications (off-label use) without domestic clinical trial data.

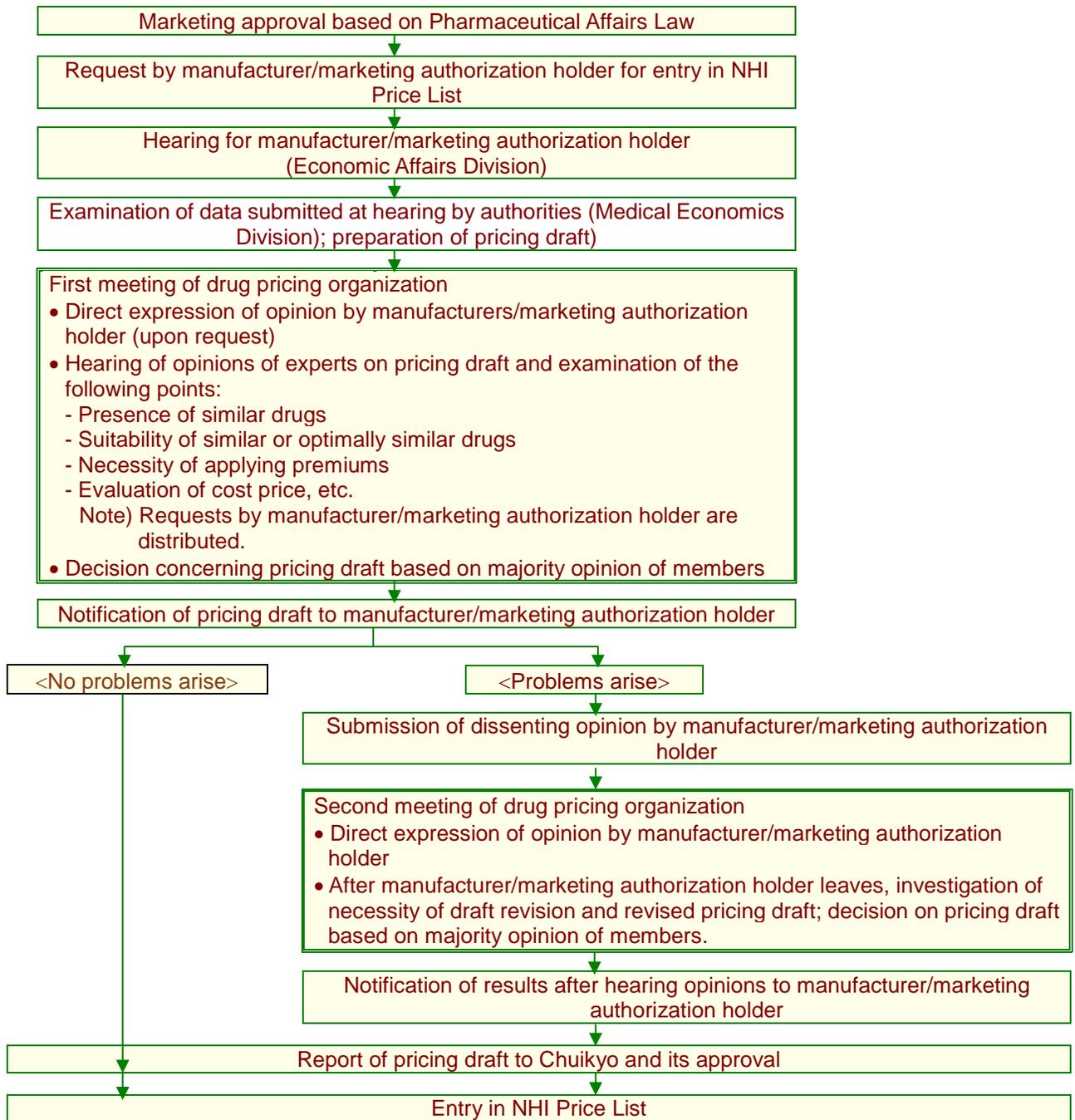
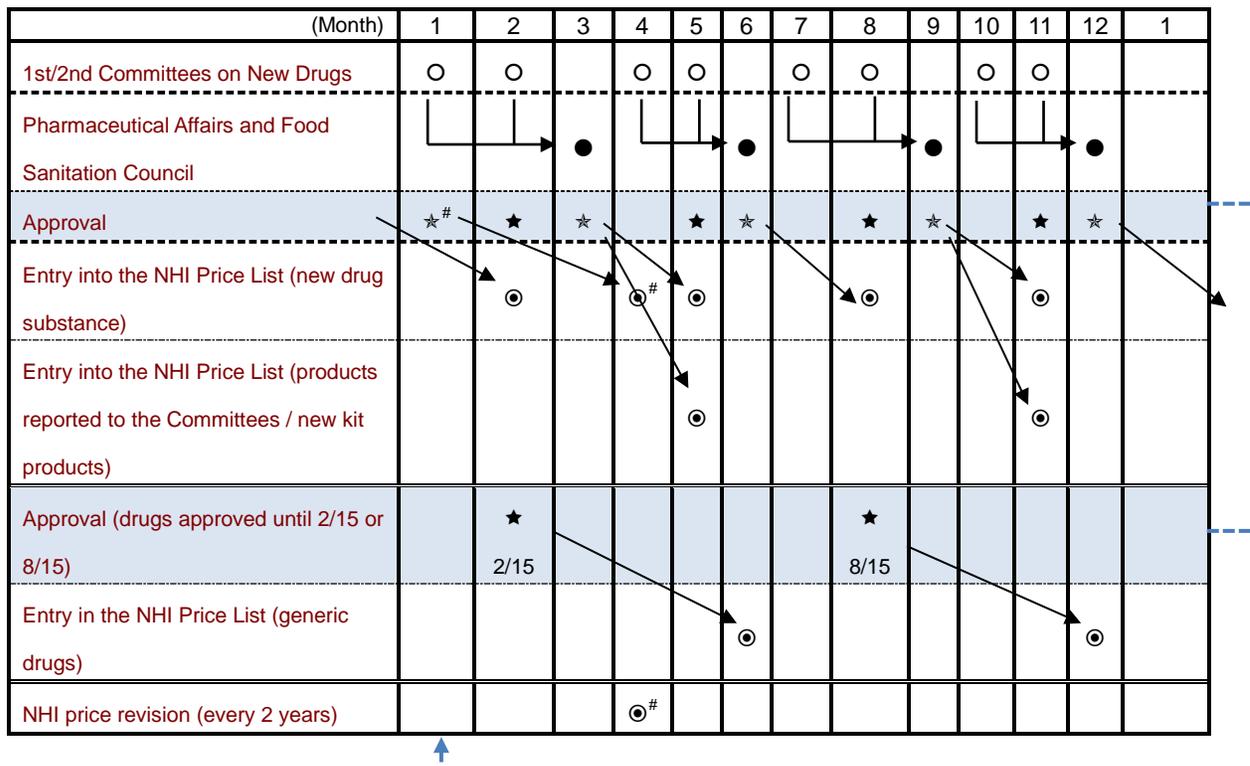


Fig. 20 Reimbursement Pricing Flow-sheet for New Drugs

- (Note 1) The parts in the double box show parts involving the drug pricing organization
- (Note 2) Time clock (agreed on at MOSS conferences)
Entry in price list 4 times per year. Listing within 60 days as a rule or 90 days at the



- Rule on the entry into the NHI Price List: Generally, within 60 days (or within 90 days at the latest) after approval
- New formulations of drugs approved after the reexamination period: Classified as generic drugs (time of entry: twice a year)
- Drugs reported to but not reviewed by the Committee (PAFSC) are handled by the principle of "change on late notice." Approvals indicated with ★ means those that do not require price listing (Approval indicated with ★ means 4 times/year of approval of drugs that requires price listing procedures).

★[#]/⊙[#]: Special entry in the year of NHI price revision (every 2 years)

⊙[#]: The entry in February in the year of NHI price revision (year of "special entry") is actually made in April (based on the 90-day rule).

Fig. 21 Correlation between the Time of Marketing Approval Based on Pharmaceutical Affairs Law and the Time of Entry in the NHI Price List

Table 7 Methods of Previous Reimbursement Price Revisions

Year	Survey	R zone	Special items
1992	June 1991	15%	
1994	June 1993	13%	Repricing
1996	June 1995	11%	Repricing
1997	Sept. 1996	10% 8% (Long listed products)	Repricing Long listed products
1998	Sept. 1997	5% 2% (Long listed products)	Repricing Long listed products
2000	Sept. 1999	Range adjusted, 2%	Repricing Range adjusted: 2%
2002	Sept. 2001	Range adjusted, 2%	Repricing Long listed products (Special adjustment: 4, 5, 6%)
2004	Sept. 2003	Range adjusted, 2%	Repricing Long listed products (Special adjustment: 4, 5, 6%) 1/2: JP products entered by brand name
2006	Sept. 2005	Range adjusted, 2%	Repricing Long listed products (Special adjustment: additional 2%, new 8%) 5%: JP products entered by brand name
2008	Sept. 2007	Range adjusted, 2%	Repricing Long listed products (Special adjustment: 4, 5, 6%) 1/2: JP products entered by brand name
2010	Sept. 2009	Range adjusted, 2%	Repricing Long listed products (Special adjustment: additional 2.2%, new 6%) 1/2: JP products entered by brand name
2012	Sept. 2011	Range adjusted, 2%	Repricing Long listed products (Special adjustment: additional 0.86%, new 6%) 1/2: JP products entered by brand name Long listed generic products: 0.33%
2014	Sept. 2013	Range adjusted, 2%	Repricing Long listed products (Special adjustment for original product which replacement rate with generic products is less than 60% at 5 years after their entry is permitted: 2% to 1.5%) 1/2: JP products entered by brand name

Table 8 Revision Rates of Reimbursement Prices

Year	Number of products with price decrease	Number of products with price increase	Number of products with price unchanged	Total	Revision rate
1992	7,681	2,121	3,771	13,573	-8.1%
	-8.5%	0.4%	-		
1994	8,613	2,083	2,679	13,375	-6.6%
	-6.8%	0.2%	-		
1996	9,568	1,697	1,604	12,869	-6.8%
	-7.0%	0.2%	-		
1997	7,718	3,394	862	11,974	*-3.0%
1998	9,921	6	1,765	11,692	-9.7%
	-9.7%	0.0%	-		
2000	8,935	61	2,291	11,287	-7.0%
	-7.5%	0.5%	-		

2002	9,096	98	1,997	11,191	-6.3%
2004	9,645	39	2,309	11,993	-4.2%
2006	10,113	75	3,123	13,311	-6.7%
2008	12,740	77	1,542	14,359	-5.2%

*In 1997, the overall drug price revision was -3.0% when a 1.4% rise based on the increased consumption tax rate is included.

Since a new premium formula was introduced for the promotion of new drug research and resolution of problems of treatment not covered by insurance on a trial basis in 2010, above data for 2010 are not available.

The drug price revision implemented in 2014 is outlined below:

The revision rate is -2.65% (+2.99%) on the drug price basis and -0.58% (+0.64%) on the medical care expenditure basis.

Figures in parenthesis are costs for 3% consumption tax raised on April 1, 2014.

1. "Premiums for the promotion of innovative drug discovery and resolution of off-label use issue, etc."

(1) Products covered

1) Premium is added to the price of a new drug calculated based on current market prices of drugs in class if the new drug meets all of the following conditions:

- i. **The drug was listed in the NHI Price List less than 15 years ago and no generic drug has not been available on the market yet.**
- ii. **The discrepancy between the NHI price and current market price of the drug is not larger than that averaged for all drugs available in the NHI Price List.**
- iii. **The drug is manufactured and marketed by a company engaged in the development of a new drug(s) upon request by the MHLW or application for public recruitment or a company conducting R&D activities for the development of "new drugs that could truly contribute to the improvement of medical care quality."**
- iv. **The drug is not subject to repricing.**

2) Number of active ingredients and products that met requirements for premiums (a drug reformulated (old and new formulations) was counted once)

	Oral	Injection	Topical	Total
Number of active ingredients	185	149	63	397
Number of products	346	292	120	758

Of these, 4 ingredients and 10 products were given premium for pediatric indication, etc. and 3 ingredients and 5 products for orphan indication, etc. (additionally to the premium for the promotion of innovative drug discovery and resolution of off-label use issue, etc.).

3) Premium rate

0 – 4.94%

4) The proportion of products which NHI price was maintained the same by obtaining premium (revised price = price before revision × 108/105)

83.1% (630 out of 758 products)

5) The proportion of original products that received premiums whereby generic products are not available
Approximately 37%

(2) Number of products which premiums were abolished

1) The price of a new drug that has become not compliant with Requirements i) or iii) above is reduced by a premium(s) given in a preceding price revision from the price calculated by referring to current market price.

2) Number of active ingredients and products which premiums were abolished

	Oral	Injection	Topical	Total

Number of active ingredients	27	17	13	57
Number of products	50	29	26	105

2. Special price reduction for original products for which the entry of generic products is slow

1) The price of an original drug which replacement rate with generic products does not exceed 60% over 5 years after the entry of the first generic product in the NHI Price List is lowered by the following rate from the price calculated by referring to current market price.

- i. Replacement rate of < 20%: 2.00%
- ii. Replacement rate of ≥ 20% - < 40%: 1.75%
- iii. Replacement rate of ≥ 40% - < 60%: 1.50%

2) Number of active ingredients and products that were subject to special price reduction

	Price reduction (%)	Oral	Injection	Topical	Total
Number of active ingredients	2.00	52	25	38	115
	1.75	116	16	25	157
	1.50	64	26	17	107
	Total	232	67	80	379
Number of products	2.00	126	106	129	361
	1.75	323	39	70	432
	1.50	210	87	28	325
	Total	659	232	227	1118

3. Price recalculation based on expanded market size and revised dosage/administration

1) Number of active ingredients and products that were subject to the price recalculation

	Repricing based on expanded market size				Repricing based on revised dosage and administration			
	Oral	Injection	Topical	Total	Oral	Injection	Topical	Total
Number of active ingredients	7	4	0	11	0	1	0	1
Number of products	17	5	0	22	0	2	0	2

4. Premiums for pediatric indication, orphan indication, and innovative clinical usefulness (therapeutic benefits)

1) Number of active ingredients and products that received premiums for additional pediatric indication

	Oral	Injection	Topical	Total
Number of active ingredients	2	3	2	7
Number of products	5	13	3	21

2) Number of active ingredients and products that received premiums for additional orphan indication

	Oral	Injection	Topical	Total
Number of active ingredients	2	2	0	4
Number of products	3	3	0	6

3) Number of active ingredients and products that received premiums for innovative clinical usefulness (therapeutic benefits)
None

5. Price recalculation based on unprofitable trade of products

1) Number of active ingredients and products that were repriced due to unprofitable trade

Number of active ingredients: 34

Number of products: 196

2) Main active ingredients repriced

Active ingredient	Unit	Current price	Revised price	Remarks
Atractylodes lancea rhizome	10g	12.60-14.30	25.20	Crude drug
Uncaria hook	10g	14.10-14.40	25.00	Crude drug
Glucose inj	5%	103	113	Saccharide prep
Isotonic Na-Cl sol	100mL/botl	145	149	Blood substitute
Cataplasms	500 mL/bag	8.30-9.10	9.60	Nonsteroidal anti-inflammatory drug
	10g			Disinfectant
Saponated cresol sol		9.20-9.40	12.90	Ointment base
Purified lanolin	10mL	21.30	32.00	
	10g			

6. Other

Number and market share of products by the category of drugs in the NHI Price List (source: Drug price survey conducted in September 2013) (The number of products was obtained by the survey conducted in April 2014 and the market share in sales quantity and amount in September 2013.)

		Number of products	Share in sales quantity	Share in sales amount
Original drugs	Generic drugs not available	2,074	18.2%	49.3%
	Generic drugs available (A)	1,562	31.2%	31.7%
Generic drugs (B)		8,038	27.6%	11.1%
Other drugs (JP standard drugs, crude drugs, etc.)		3,629	23.0%	8.0%

Share in sales quantity* (new index) = (B) / [(A) + (B)] = 46.9%

*Source: "Roadmap for Further Promoting the Use of Generic Drugs" (MHLW April 2013)

Note 1) Generic drugs are defined as any drugs other than those approved as new drugs by the Pharmaceutical Affairs Law (excluding "drugs in other classes")

Note 2) "Drugs in other classes" are defined as JP standard drugs, crude drugs, biologicals (including vaccines, blood products), and drugs approved in or before 1967.

Note 3) Figures are rounded to one decimal place: the total does not add up to 100%.

Number of products included in the NHI Price List as of April 2014.

	Oral	Injection	Topical	Dental	Total
Number	9,092	3,721	2,465	25	15,303

Table 9 Requirements for Applying Premiums

<Types, requirements and rates of premiums>

(1)	Premium for innovativeness (rate: 70-120%) Applied to new drug products in the NHI Price List meeting all of the following requirements:
	1) The newly entered drug has a clinically useful new mechanism of action.
	2) The newly entered drug has been shown objectively to have greater efficacy and safety than existing (comparator) drugs in the same class.
	3) The newly entered drug has been shown objectively to improve treatment of the indicated disease or trauma.
(2)	Premium for usefulness I (35-60%) Applied to new drug products in the NHI Price List that meet two of the three requirements listed above

(3)	<p>Premium for usefulness II (5-30%) Applied to new drug products in the NHI Price List that meet one of the following requirements (excluding products to which the innovativeness premium or usefulness premium (I) is applied):</p>
	1) The newly entered drug has a clinically useful new mechanism of action.
	2) The newly entered drug has been shown objectively to be more effective and safe than existing (comparator) drugs in the same class.
	3) The newly entered drug has been shown objectively to offer, as a result of formulation improvement, greater therapeutic usefulness than other drugs in the same class.
(4)	<p>Premium for pediatric use (5-20%) Applied to new drug products in the NHI Price List meeting all of the following requirements:</p>
	<p>1) The newly entered drug is explicitly shown in the Indications section or Dosage and Administration section to be indicated for children (including infants, suckling infants, newborns, and low-birthweight infants).</p> <p>2) The premiums for pediatric use must not have been given to comparator drugs available in the NHI Price List.</p>
(5)	<p>Premium for marketability (I) (10-20%) Applied to new drug products in the NHI Price List meeting all of the following requirements:</p>
	<p>1) Orphan drugs pursuant to the provisions of Article 77-2 of the Pharmaceutical Affairs Law in the NHI Price List for which the orphan indications for the disease or trauma are the main indications of the drugs concerned.</p> <p>2) The premium for marketability (I) must not have been given to comparator drugs available in the NHI Price List.</p>
(6)	<p>Premium for marketability (II) (5%) Applied to new drug products in the NHI Price List meeting all of the following requirements (excluding products to which marketability premium (I) is applied):</p>
	<p>1) New drugs in the NHI Price List for which the main indications correspond to separately specified indication categories with a small market scale among drug indication classifications specified in the Standard Commodity Classification of Japan.</p> <p>2) The premium for marketability (I) or (II) must not have been given to comparator drugs available in the NHI Price List.</p>
(7)	<p>Premium for the world's first registration in Japan (10%) Applied to new drug products in the NHI Price List meeting all of the following requirements (the price of a comparator drug should be free of the premium for the world's first registration in Japan, when the price of a new drug is calculated by the Similar Efficacy Comparison-Based Price Setting Method I or II comparing with the price of the comparator to which the premium for the world's first registration in Japan was applied):</p>
	1) A new drug with novel action mechanism different from that of any drugs already approved in foreign countries (specifically in the US, UK, Germany, and France) and Japan
	2) A new drug first approved in Japan
	3) A new drug ascertained not to be marketed solely in Japan based on foreign clinical development status (including R&D plan), clinical trial notification, etc.
	4) A new drug for which premium for innovativeness or usefulness I is applicable