CHAPTER 6

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 on the basis of Article 76, Item 2 of the Health Insurance Act (Act No. 70, 1918) and Article 71, Item 1 of the Act on Assurance of Medical Care for Elderly People (Act No. 80, 1982), and according to the Calculation Method of Medical Fees (Public Notice No. 59 of the Ministry of Health, Labour and Welfare in 2008) (partially revised on August 19, 2019 by Public Notice No. 85 of the Ministry of Health, Labour and Welfare).

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 changed to 4,955 (number of payment classification: 2,462) in April 2018 and forecast of the application of this billing system has been extended to 1,730 hospitals (approximately 490,000 beds) in April 2018.

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).

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.

At the same time, 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. Later in 2014, a new rule for an additional indication of an orphan drug was added to ensure that repricing shall be considered when the sales of the orphan drug increases at least 10 times than originally expected and exceeds 10 billion yen. In 2016, while conflicting topics of evaluation of innovative drugs and maintenance of nationwide comprehensive health insurance system were being discussed, repricing for market growth was applied in an exceptional manner as a measure of reconciliation when the annual sales exceeded 100 billion yen but not 150 billion yen and reached at least 1.5 times of the originally expected sales, and when the annual sales exceeded 150 billion yen and reached at least 1.3 times of the originally expected sales. Thus, special repricing of drugs was implemented.

Reflecting the issues of unapproved drugs and the time-lag in new drug approval, a new "premium system for the promotion of innovative drug discovery and resolution of off-label use" was applied to the new drugs without generic drugs as of 15 years after listing (discrepancy shown in the drug price survery is smaller than the mean discrepancy for all products) after discussion at the Central Chuikyo, and the pilot operation was continued until 2016. In April 2018, a rule was established to strictly select the target products in view of innovativeness and usefulness, and to gradually set the premium according to the status of research and development by companies. On the other hand, the evaluation of cost-effectiveness of drugs and medical devices was introduced on a trial basis in April 2016 and was implemented on a full scale in April 2019.

In addition, the rule of special lowering (Z2) adopted from 2014 was reconsidered for long-listed products (branded products with generic products), and a new rule was introduced to classify the products with the generic product replacement rate of 80% or more (G1 product) and those with the rate of less than 80% (G2 product) as of 10 years after the first listing of a generic product and to gradually lower each drug price to the level of the drug price of generic products.

Furthermore, to ensure stable supply of drugs with high medical needs covered by health insurance, the drug price maintenance system for basic drugs was

to be implemented as a pilot operation. This system may be applied to drugs meeting all of the following requirements (except for sufficiently profitable drugs):

[1] The drug has an established position in clinical settings and is clearly known to be widely used in clinical practices.

[2] Of the concerned already listed drug as well as all similar drugs with the same composition and dosage form category as those of the former, at least one drug has been on a NHI Price List for 25 years or longer.

[3] If there are similar drugs with the same composition and dosage form category as those of the concerned already listed drug, the mean discrepancy of the similar drugs including the concerned already listed drug between the NHI price and current market price does not exceed that of all the listed drugs.

[4] The discrepancy of the concerned already listed drug between the NHI price and current market price does not exceed the mean discrepancy of all the already listed drugs.

The products previously subjected to repricing due to unprofitable sales and the drugs against pathogens serving the medical platform for years and medical narcotics were added to the target products in the revision of the NHI price list in 2016, and the drug efficacy classifications, etc. which showed discrepancy of 2% or less 3 times in the past were added in the revision in 2018. The pilot operation is still continued.

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. 0819-2 of the Health Insurance Bureau dated August 19, 2019, “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 as described above 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 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 was institutionalized in 2018.

Drug prices listed in the NHI Price List were revised to include consumption tax because the consumption tax rate was raised to 8% in April 2014 and 10% in October 2019.

The results of reimbursement price revisions from 1967 through 2019 and the annual changes in the drug expenses in 1993 and afterwards and the estimated divergence rate are shown in **Table 14** (History of Reimbursement Price Revisions) and **Table 15** (Annual Changes in Drug Expenses and Estimated Divergence Rate).

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 10-20% 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 16** (Requirements for Applying Premiums).

Furthermore, it has been decided to apply premium to the drug price itself from the point of view of evaluation of innovation in drug pricing by cost calculation although some adjustment is made depending on the level of disclosure.

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. 0819-2 of the Health Insurance Bureau dated August 19, 2019, "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. 0329-5 of the Health Policy Bureau dated March 29, 2019, “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. 0207-(2) of the Economic Affairs Division, Health Policy Bureau dated February 7, 2018.

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. 21** (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. 0819-2 of the Health Insurance Bureau dated August 19, 2019, “Drug Pricing Standards.”) Procedures for calculation of reimbursement prices were specified in detail in September 2000 (most recent revisions: Notification No. 0329-5 of the Health Policy Bureau dated March 29, 2019, “Handling of Entries of Prescription Drugs in the NHI Price List” and Notification No. 0207-(2) of the Economic Affairs Division, Health Policy Bureau dated February 7, 2018 “Method for Submission of Requests for Entry in the NHI Price List for Prescription Drugs”).

- 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 0.5. The factor is 0.4 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.

  A special formula was introduced for biosimilar products. A premium (maximally 10/100 of the standard) is added to the standard price (the factors are 0.7 and 0.6, respectively) 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 “Special Committee 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 “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 Chuikyo also joined the support and 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 “Special Committee to investigate Unapproved Drugs and Off-Label Use of Drugs Urgently Required for Healthcare” 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, that committee has been evaluating individual drugs and indications to determine if they are worthy to be reimbursed by the National Health Insurance System before 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.

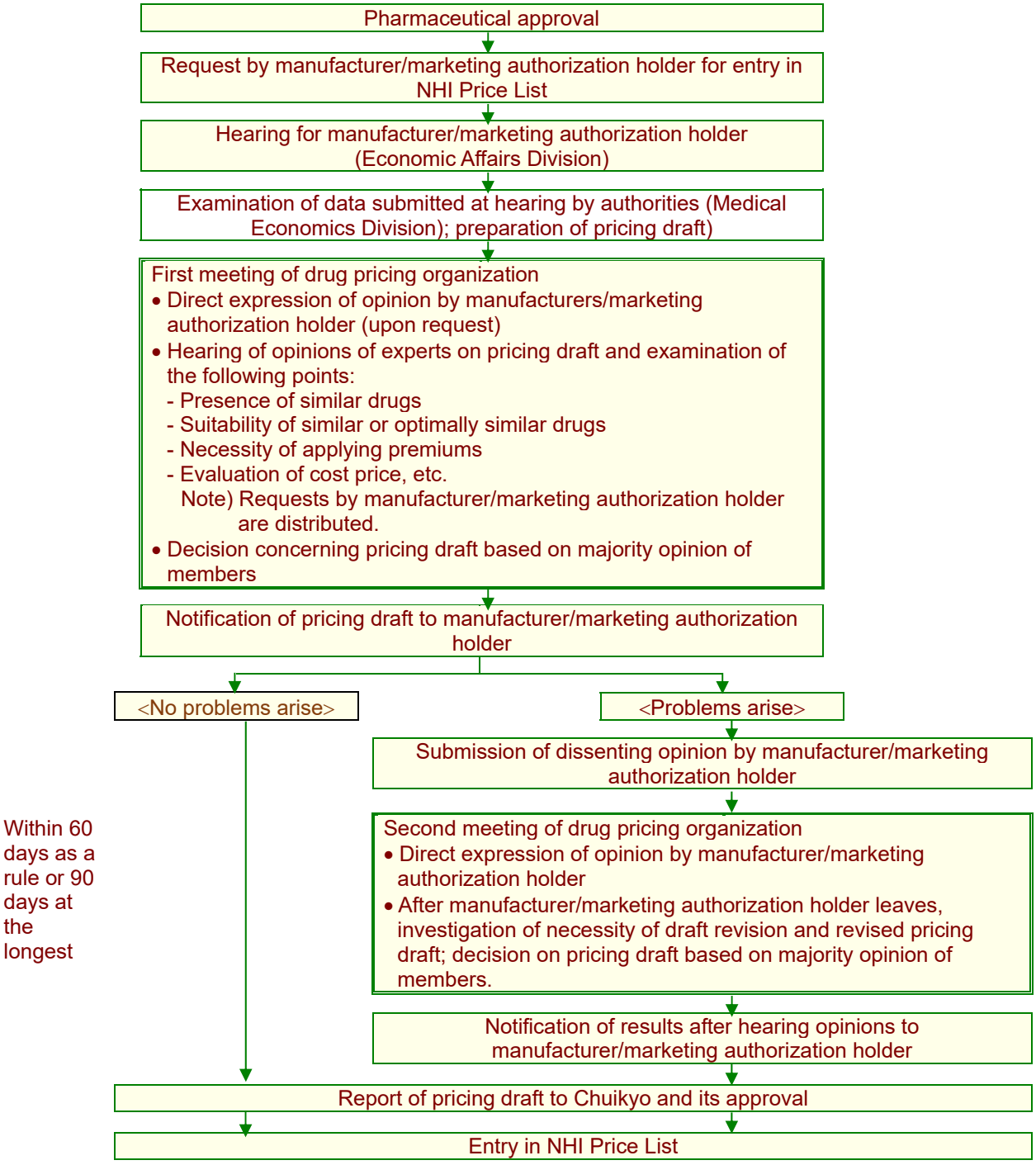
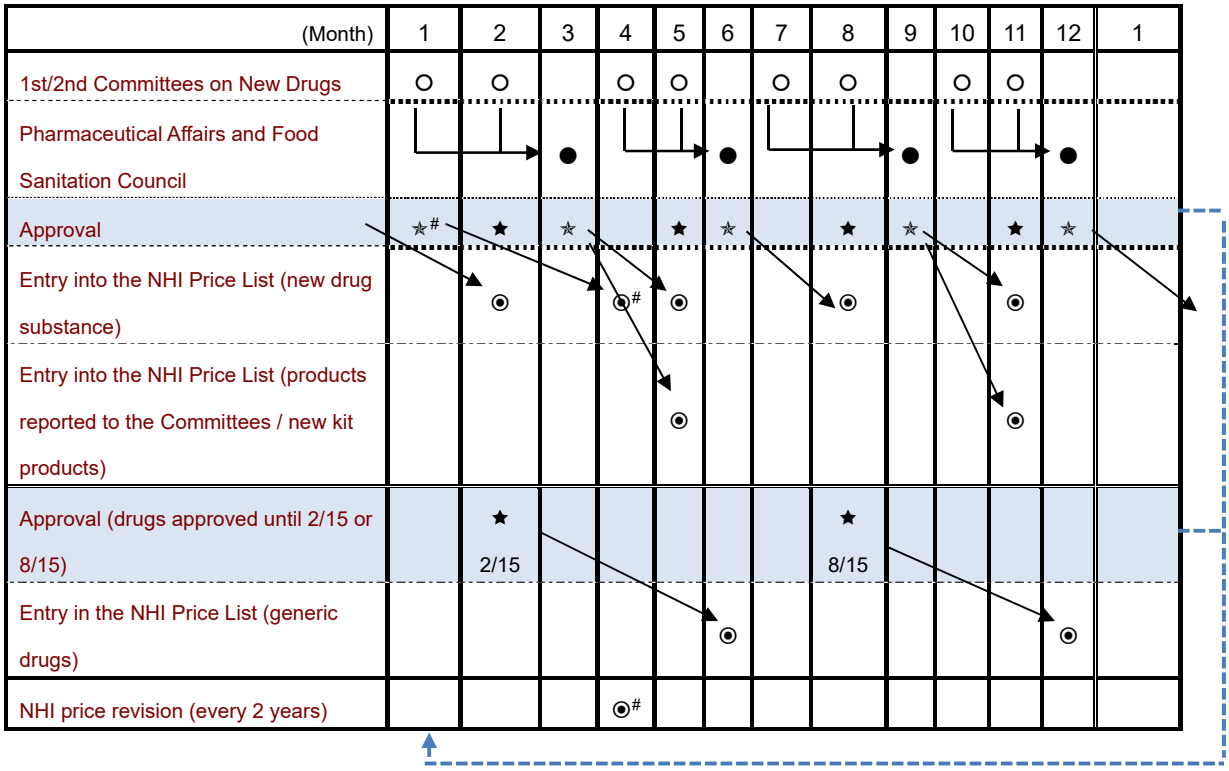


Fig. 21 Reimbursement Pricing Flow-sheet for New Drugs

(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 longest provided that there are no further problems with the pricing draft.



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

Table 14 History of Reimbursement Price Revisions

Revision date	Revision category	Number of products listed	Revision rate		Remarks
			Based on drug cost	Based on medical expenses	
1967.10.1	Complete	6,831	▲10.2%	–	
1969.1.1	Complete	6,874	▲5.6%	▲2.4%	
1970.8.1	Complete	7,176	▲3.0%	▲1.3%	
1972.2.1	Complete	7,236	▲3.9%	▲1.7%	
1974.2.1	Complete	7,119	▲3.4%	▲1.5%	
1975.1.1	Complete	6,891	▲1.55%	▲0.4%	
1978.2.1	Complete	13,654	▲5.8%	▲2.0%	Listing by brand
1981.6.1	Complete	12,881	▲18.6%	▲6.1%	
1983.1.1	Partial	16,100 (3,076)	▲4.9%	▲1.5%	81% bulk line system
1984.3.1	Complete	13,471	▲16.6%	▲5.1%	
1985.3.1	Partial	14,946 (5,385)	▲6.0%	▲1.9%	
1986.4.1	Partial	15,166 (6,587)	▲5.1%	▲1.5%	
1988.4.1	Complete	13,636	▲10.2%	▲2.9%	Revised bulk line system
1989.4.1	Complete	13,713	+2.4%	+0.65%	Increase by the amount equivalent to consumption tax
1990.4.1	Complete	13,352	▲9.2%	▲2.7%	
1992.4.1	Complete	13,573	▲8.1%	▲2.4%	Weighted average fixed price range system R15
1994.4.1	Complete	13,375	▲6.6%	▲2.0%	R13
1996.4.1	Complete	12,869	▲6.8%	▲2.6% (Including partial change of the drug price calculation system and material costs, etc.)	R11
1997.4.1	Complete	11,974	▲4.4% In addition, the amount equivalent to consumption tax +1.4%	▲1.27% In addition, the amount equivalent to consumption tax +0.4%	R10 (Long-listed product R8)
1998.4.1	Complete	11,692	▲9.7%	▲2.7%	R5 (Long-listed product R2)
2000.4.1	Complete	11,287	▲7.0%	▲1.6%	Adjustable range 2%
2002.4.1	Complete	11,191	▲6.3%	▲1.3%	Adjustable range 2% (lowering for branded product by a fixed rate)
2004.4.1	Complete	11,993	▲4.2%	▲0.9%	Adjustable range 2% (lowering for branded product by a fixed rate)

Revision date	Revision category	Number of products listed	Revision rate		Remarks
			Based on drug cost	Based on medical expenses	
2006.4.1	Complete	13,311	▲6.7%	▲1.6%	Adjustable range 2% (lowering for branded product by a fixed rate)
2008.4.1	Complete	14,359	▲5.2%	▲1.1%	Adjustable range 2% (lowering for branded product by a fixed rate)
2010.4.1	Complete	15,455	▲5.75%	▲1.23%	Adjustable range 2% (lowering for branded product by a fixed rate)
2012.4.1	Complete	14,902	▲6.00%	▲1.26%	Adjustable range 2% (lowering for branded product by a fixed rate)
2014.4.1	Complete	15,303	▲5.64% In addition, the amount equivalent to consumption tax +2.99%	▲1.22% In addition, the amount equivalent to consumption tax +0.64%	Adjustable range 2% (lowering by a fixed rate for branded products for which replacement by generic products is slow)
2016.4.1	Complete	15,925	▲5.57%	▲1.22%	Adjustable range 2% (lowering by a fixed rate for branded products for which replacement by generic products is slow) In addition, ▲0.19% for repricing for market growth, and ▲0.28% for special repricing for market growth (based on medical expenses)
2018.4.1	Complete	16,434	▲7.48%	▲1.65%	Adjustable range 2% (lowering by a fixed rate for branded products for which replacement by generic products is slow) Out of the revision rate, ▲1.36% is for revision of actual price, etc. and ▲0.29% is for drastic reformation of the drug price system (based on medical expenses)
2019.10.1	Complete	16,510	▲4.35% In addition, the amount equivalent to consumption tax +1.95%	▲0.93% In addition, the amount equivalent to consumption tax +0.42%	

(Note) The number in parenses in the space for the “number of products listed” in partial revision indicates the number of products to be revised.

Table 15 Annual Changes in Drug Expenses and Estimated Divergence Rate

Year	National medical expenditures (A) (trillion yen)	Drug expenses (B) (trillion yen)	Drug expense ratio (B/A) (%)	Estimated divergence rate (C) (%)
FY1993	24.363	6.94	28.5	19.6
FY1994	25.791	6.73	26.1	–
FY1995	26.958	7.28	27.0	17.8
FY1996	28.454	6.97	24.5	14.5
FY1997	28.915	6.74	23.3	13.1
FY1998	29.582	5.95	20.1	–
FY1999	30.702	6.02	19.6	9.5
FY2000	30.142	6.08	20.2	–
FY2001	31.100	6.40	20.6	7.1
FY2002	30.951	6.39	20.7	–
FY2003	31.538	6.92	21.9	6.3
FY2004	32.111	6.90	21.5	–
FY2005	33.129	7.31	22.1	8.0
FY2006	33.128	7.10	21.4	–
FY2007	34.136	7.40	21.7	6.9
FY2008	34.808	7.38	21.2	–
FY2009	36.007	8.01	22.3	8.4
FY2010	37.420	7.88	21.1	–
FY2011	38.585	8.44	21.9	8.4
FY2012	39.212	8.49	21.7	–
FY2013	40.061	8.85	22.1	8.2
FY2014	40.807	8.95	21.9	–
FY2015	42.364	9.56	22.6	8.8
FY2016	42.138	9.22	21.9	–
FY2017	43.071	9.46	22.0	9.1

* The estimated divergence rate for FY2018 is 7.2%.

(Note)

- National medical expenditures (surveyed by Health Statistics Office for Counselor for Director-General for Statistics and Information Policy, Ministry of Health, Labour and Welfare) are the estimated expenditures required for treatment of injuries and diseases at medical institutions, etc. in the fiscal year concerned. It is obtained by adding the expenditures for industrial accidents, polluter pays principle (for pollution-related health damage, etc.), self pay for all expenses, acupuncture and moxibustion, etc. to the total medical expenditures covered by medical insurance.

- Drug expenses are estimated by assuming that drugs are used for industrial accidents, etc. in the same percentage as in the cases covered by health insurances, and multiplying the national medical expenditures with the drug expense ratio for medical insurance. Drug expenses for the cases in which the drug expenses such as DPC are calculated together with the hospitalization fee are not included.
- The hyphen (-) in the space for the estimated divergence rate indicates that the data is not available because the drug price survey was not conducted.
- After introduction of the long-term care insurance in FY2000, a part of the national medical expenditures was shifted to long-term care insurance.

The drug price revision implemented in 2018 is outlined below:

The revision rate is -7.48% on the drug price basis and -1.65% on the medical care expenditure basis.

Among them, the portion for revision of actual price, etc. accounted for 6.17% on the drug price basis and 1.36% on the medical care expenditure basis. The proportion attributable to the drug price system reform accounted for 1.31% on the drug price basis and 0.29% on the medical care expenditure basis.

The numbers of products listed on the price list as of April 2018 are shown in the following table.

	Oral	Injection	Topical	Dental	Total
Announced number	10,253	3,827	2,324	28	16,432

1. Drug price revision for long-listed drugs

(1) Drug price lowering for original drugs with slow replacement with generic drugs

1) For original drugs (except for orphan drugs, etc.) between 5 years and 10 years after listing of the first generic drug for which the rate of replacement with generic drugs is <80%, the drug price is lowered by the following percentage from the value calcualted based on the actual market price.

i. Replacement rate <40%, 2.00%

ii. Replacement rate ≥40% and < 60%, 1.75%

iii. Listed drugs with replacement rate ≥60% and < 80%, 1.50%

(2) Lowering of drug price to the price of generic drugs for long-listed drugs 10 years or more after listing of generic drugs

1) Among the original drugs (except for orphan drugs, etc.) 10 years or more after listing of the first generic drug, the price of the drugs for which the rate of replacement with generic drugs reached 80% or more (except for the cases in which the indications of the original drug and the generic drug are not identical; hereinafter referred to as G1 product) is lowered to the following amount.

i. Drugs subjected to drug price revision for the first time after falling under G1 product
2.5 times of the weighted mean of the price of generic drugs

ii. Drugs subjected to drug price revision for the first time after passage of 2 years after falling under G1 product
2 times of the weighted mean of the price of generic drugs

iii. Drugs subjected to drug price revision for the first time after passage of 4 years after falling under G1 product
1.5 times of the weighted mean of the price of generic drugs

iv. Drugs subjected to drug price revision for the first time after passage of 6 years after falling under G1 product
Weighted mean of the price of generic drugs

2) Among the original drugs (except for orphan drugs, etc.) 10 years or more after listing of the first generic drug, the price of the drugs other than G1 products (hereinafter referred to as G2 product) will be lowered to the following price. The rules in 3) will be applied to biological products.
   i. Drugs subjected to drug price revision for the first time after falling under G2 product
      2.5 times of the weighted mean of the price of generic drugs
   ii. Drugs subjected to drug price revision for the first time after passage of 2 years after falling under G2 product
      2.3 times of the weighted mean of the price of generic drugs
   iii. Drugs subjected to drug price revision for the first time after passage of 4 years after falling under G2 product
      2.1 times of the weighted mean of the price of generic drugs
   iv. Drugs subjected to drug price revision for the first time after passage of 6 years after falling under G2 product
      1.9 times of the weighted mean of the price of generic drugs
   v. Drugs subjected to drug price revision for the first time after passage of 8 years after falling under G2 product
      1.7 times of the weighted mean of the price of generic drugs
   vi. Drugs subjected to drug price revision for the first time after passage of 10 years after falling under G2 product
      1.5 times of the weighted mean of the price of generic drugs

3) For the products the amount calculated by the rules in 2) is higher than the amount lowered according to the following classification, the price will be revised to the amount lowered according to the following classification, regardless of the rules in 2) (C).
   i. Replacement rate is <40%, 2.00%
   ii. Replacement rate is ≥40% and < 60%, 1.75%
   iii. Listed drugs with replacement rate ≥60% and < 80%, 1.50%

4) Number of ingredients and number of products of target drugs
   i. Drug price lowering for original drugs with slow replacement with generic drugs (Z2)

	Replacement rate of generic drugs			Total
	<40%	≥40% <60%	≥60% <80%	
Number of ingredients	30	34	21	85
Number of products	60	79	68	207

   ii. Lowering of drug price to the price of generic drugs for long-listed drugs 10 years or more after listing of generic drugs

Classification			Number of ingredients	Number of products
G1			38	85
G2			137	293
C	Replacement rate of generic drugs	<40%	111	275
		≥40% and <60%	98	189
		≥60% and <80%	59	108
	Total for C		268	572
Total			443	950

2. Premium for addition, etc. of indication of pediatric indication or rare disease and verification of true clinical usefulness

Number of ingredients/ products subject to premium for addition, etc. of pediatric indication

	Pediatric indication	Rare disease	Verification of true clinical usefulness	Total
Number of ingredients	7	11	1	19
Number of products	27	19	3	49

3. Repricing for market growth and repricing for change of dosage and administration

Number of ingredients/ of products of target drugs

	Repricing for market growth	Special repricing for growth	Repricing for change of dosage and administration
Number of ingredients	9	2	3
Number of products	19	4	5

4. Price zone of generic drugs

Number of price zones	Number of ingredient specifications	Number of ingredient specifications at each price as compared with maximum price		
		<30%	30%-50%	≥50%
1	1,440	23	332	1,085
2	364	95	348	285
3	83	83	83	83

5. Basic drugs

(1) For the drugs satisfying the following requirements, integrate the price to the brand with the largest sales volume, and maintain the price.

i. It should be clear that the medical positioning has been established, and the drug is widely used in clinical settings.

ii. Among all similar drugs for which the listed product, component, and dosage form are same, identical, the time after the date of drug price listing is more than 25 years for some of the products.

iii. If there is any similar drug for which the listed product, component, and dosage form are same, the mean discrepancy rate for the similar drugs including the listed product is not larger than the mean discrepancy rate for all listed drugs.

iv. The discrepancy rate of the listed drug from the actual market price is not larger than the mean discrepancy rate for all listed drugs.

Classification	Number of ingredients	Number of products
Unprofitable	119	370
Pathogenic organisms	81	205
Narcotics	9	24
Crude drugs	48	55
Ointment base	3	3
Dental topical analgesics	1	3
Total	261	660

* Any drugs falling under multiple classifications should be included in the classification listed higher.

6. Repricing for unprofitable products

The drug price was increased from the current drug price because of being unprofitable.

Target ingredient: 87

Number of products: 184

7. Premium for promotion of innovative drug discovery and resolution of off-label use

(1) Target of premium

1) Target products

New drugs meeting all of the following requirements

I) 15 years or less after drug price listing without entry of generic drugs

II) Falling under any of the following requirments

i. Drugs approved for indications designated for orphan drugs

ii. Drugs for which development is requested publicly based on the results of examination by the Unapproved Drug, etc. Review Committee

iii. Drugs for which plus correction for premium for innovativeness, premium for usefulness (I), premium for usefulness (II) or operating margin was applied at the time of drug price listing, or drugs for which special repricing associated with drug price revision for a listed drug for which true clinical usefulness was verified after marketing at the time fo drug price revision (hereinafter referred to as the product subject to premium)

iv. Drugs with new mechanism of action falling under the criteria for innovativeness and usefulness

v. Drugs for which only one or two drug(s) with similar pharmacological action existed at the time of drug price listing, listed within 3 years after listing of the first drug with similar pharmacological action, and for which the drug with similar pharmacological action listed first is a product subject to premium or satisfies the criteria for innovativeness and usefulness

III) For any combination product for which drug price is calculated as an exceptional measure for new medical combination products, an active ingredient of any listed product more than15 years after the date of drug price listing, or an active ingredient of any listed product for which generic drugs have been listed on the drug price list must not be contained

IV) The drug is not subject to repricing

2) Target company

The target company for premium for new drug discovery must not be a company which showed inappropriate behaviors, such as refusal of development and unreasonable delay in develoment, for the products for which development is requested by the Ministry of Health, Labour and Welfare, based on the results of examination in the Unapproved Drug, etc. Review Committee.

3) Procedure of drug price revision

For the products falling under 1), the amount obtained by multiplying the amount with the premium coefficient for the value calculated based on the actual market price, etc., with the drug price before revision set as the upper limit, will be added, only if the products are produced by the companies listed in 2).

4) Number of ingredients/products satisfying the conditions for premium

	Number of ingredients	Number of products
i. Orphan drugs	147	229
ii. Products for which development is publicly requested	8	17
iii. Products subject to premium	91	184
iv. Drugs with new mechanism of action satisfying the criteria	51	92
v. Drug 3 years or less after the drug with new mechanism of action, which is ranked third or less, and for which the first product is a product subject to premium or a product meeting the criteria	17	38
Total	314	560

* Any drugs falling under multiple classifications should be included in the classification listed higher.

* In addition, one ingredient, 2 products were additionally listed on 3/14 as a product subject to premium.

5) Number of companies in each company category

	Categry I	Categry II	Categry III	Total
Number of companies	23	54	6	83

6) Total amount for innovative drug discovery premium: 81 billion yen

(2) Products for which the amount equivalent to premium was returned

1) For new drugs who no longer satisfy the requirements in 1) i) or iii) or 2) in the previous section, the total amount equivalent to the premium in the past drug price revision will be deducted from the value calculated from the actual market price.

2) Number of ingredients/products returning the premium amount

Number of ingredients: 57

Number of products: 143

3) Total amount of innovative drug discovery premium, etc. deducted: 65 billion yen

8. Others

Drug price investigation result for 2017

(1) Mean discrepancy rate: 9.1%

* Mean discrepancy rate is calculated as {Total of (current drug price×sales volume)－ total of (actual sales unit price×sales volume) } / Total of (current drug price×sales volume).

(2) Percentage of generic drugs in volume: 65.8%

* Percentage of generic drugs in volume is calculated as (Volume of generic drug) / {(volume of original drug with generic drugs) ＋ (volume of generic drugs)}.

(3) Settlement rate (on the drug price basis) = 97.7%

* Settlement rate (on the drug price basis) is based on the results of the survey on the status of price settment (for September 2017).

(4) Percentage for each classification

Classification		Number of products	Percentage against total on the drug price basis	Percentage of volume against total
Original drugs	Without generic drugs	2,276	55.8%	16.9%
	With generic drugs	1,667	22.5%	21.5%
Generic drugs		9,254	15.0%	40.2%
Other products		3,241	6.7%	21.4%

*1 "Other products" include products of Japanese Pharmacopoeia, herbal extracts, crude drugs, biological products (vaccines and blood products, etc.) and drugs approved in 1967 or before.

*2 Number of products is the figure as of April 2018, and discrepancy rate, percentage against total on the drug price basis, percentage of volume against total, and percentage of volume of generic drugs are based on the volume and drug price as of investigation in September 2017.

*3 Since figures are rounded to the first decimal place, the total of the percentages may not be equal to 100.0%.

Table 16 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)	**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):**
	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) The newly entered drug has been shown objectively to improve treatment of the indicated disease or trauma.
(4)	**Premium for pediatric use (5-20%)** **Applied to new drug products in the NHI Price List meeting all of the following requirements:**
	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).
	2) The premiums for pediatric use must not have been given to comparator drugs available in the NHI Price List.
(5)	**Premium for marketability (I) (10-20%)** **Applied to new drug products in the NHI Price List meeting all of the following requirements:**
	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.
	2) The premium for marketability (I) must not have been given to comparator drugs available in the NHI Price List.
(6)	**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):**
	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.
	2) The premium for marketability (I) or (II) must not have been given to comparator drugs available in the NHI Price List.
(7)	**Premium for the world's first registration in Japan (10%-20%)** **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):**
	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