Drug Pricing System in Japan

Ministry of Health, Labour, and welfare Insurance Bureau

(Underlined phrases in red in this text: New features and modifications to the current pricing system adopted by the 2016 system reform)
Outline of the current pricing system

1. The National Health Insurance (NHI) Drug Price List ("NHI Price List") is a list of drug prices to be reimbursed to hospitals and pharmacies ("health-insurance medical service providers") under the national health insurance programs.

2. The latest NHI Price List was publicly notified by the Minister of the MHLW on Feb 10, 2016 based on the “Drug Price Calculation Criteria” proposed by Chuikyo*.

3. Drug prices listed in the NHI Price List are periodically reviewed and revised to reflect actual trade prices (“market prices”) based on market survey results (“drug price survey”).

* Chuikyo: the Central Social Insurance Medical Council
Price Calculation of New Drugs
New drug pricing process

Marketing Approval

Request for entry into the NHI Price List

1st DPO (Drug Price Organization)

Notice of calculated drug price

Objection, No

Objection, Yes

Appeal of dissatisfaction

2nd DPO

Notice of decision

Reporting of the NHI price to and consent from Chuikyo

Price listing (4 times/yr)

≤60 days, as a rule

≤ 90 days at the latest

Hearing on marketing authorization holder’s opinion, if requested

Hearing on applicant’s opinion on dissatisfaction
Price calculation method for new drugs

**Overview**

- **Similar drug(s), Yes**
  - (1) Comparative Method (I)
  - (2) Comparative Method (II)
  - (3) Cost Calculation Method

- **Similar drug(s), No**
  - (1) Comparative Method (I)
  - (2) Comparative Method (II)
  - (3) Cost Calculation Method

**New drugs**

**Similar drug(s), Yes**

**(1) Comparative Method (I)**

<table>
<thead>
<tr>
<th>(1) Premiums</th>
<th>Innovation</th>
<th>70 – 120%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value (I)</td>
<td>35 – 60%</td>
<td></td>
</tr>
<tr>
<td>Value (II)</td>
<td>5 – 30%</td>
<td></td>
</tr>
<tr>
<td>Marketability (I)</td>
<td>10 – 20%</td>
<td></td>
</tr>
<tr>
<td>Marketability (II)</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Pediatric</td>
<td>5 – 20%</td>
<td></td>
</tr>
<tr>
<td>SAKIGAKE</td>
<td><strong>10-20%</strong></td>
<td></td>
</tr>
</tbody>
</table>

**(2) Comparative Method (II)**

<table>
<thead>
<tr>
<th>(4) Adjustment w/ foreign prices</th>
<th>(Drugs with less novelty)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reduce price if ( \geq 1.25 ) fold the foreign price</td>
</tr>
<tr>
<td></td>
<td>Reduce price if ( \geq 0.75 ) fold the foreign price</td>
</tr>
</tbody>
</table>

**(3) Cost Calculation Method**

- Costs:
  - Manufacturing (import)
  - Sales & general administration
  - Operating profit
  - Distribution & marketing
  - Consumption tax, etc

**New drugs**

**Similar drug(s), No**

**(1) Comparative Method**

(1) Premiums

| Innovation | 70 – 120% |
| Value (I) | 35 – 60% |
| Value (II) | 5 – 30% |
| Marketability (I) | 10 – 20% |
| Marketability (II) | 5% |
| Pediatric | 5 – 20% |

**(2) Comparative Method**

<table>
<thead>
<tr>
<th>(4) Adjustment w/ foreign prices</th>
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<tr>
<td></td>
<td>Reduce price if ( \geq 0.75 ) fold the foreign price</td>
</tr>
</tbody>
</table>

**(3) Cost Calculation Method**

- Costs:
  - Manufacturing (import)
  - Sales & general administration
  - Operating profit
  - Distribution & marketing
  - Consumption tax, etc

**Note** Kit products with high utility: Add 5% premium to costs of kit parts as well as Premium (5) above.
Calculation method for new drugs (1)

Basic rules

- When a comparable drug is available, the daily price of the new drug is set the same to ensure fair market competition [Comparative Method (I)].

![Image: Calculation method for new drugs (1)]

- Premiums (e.g., innovation, value, marketability, pediatrics, and SAKIGAKE) are added to the above price when the new drug has higher benefits than the reference drug.

<table>
<thead>
<tr>
<th>Premium Type</th>
<th>Percentage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovation Premium</td>
<td>70–120%</td>
<td>Novel mechanism, improved efficacy / safety / therapeutic method</td>
</tr>
<tr>
<td>Value Premium</td>
<td>5–60%</td>
<td>Improved efficacy / safety / therapeutic method, etc.</td>
</tr>
<tr>
<td>Marketability Premium</td>
<td>5%, 10–20%</td>
<td>Orphan indications, etc.</td>
</tr>
<tr>
<td>Pediatrics Premium</td>
<td>5–20%</td>
<td><em>Ex.</em> Dosage / administration clearly implies potential use in children.</td>
</tr>
<tr>
<td>SAKIGAKE Premium</td>
<td>10–20%</td>
<td>Newly entered drugs that have been designated as the target drugs for the SAKIGAKE</td>
</tr>
</tbody>
</table>

The “reference drug” should be similar to the new drug in any one of the following features:
A Indications / efficacy
B Pharmacological actions
C Composition and chem structure
D Application route, formulation category, dosage form, and way of administration
### Premiums

#### Innovation Premium (70–120%)
- New drugs (entered in the NHI Price List) that meet all of the following requirements:
  - A The drug has a new clinically useful mechanism.
  - B The drug efficacy & safety have been demonstrated to be greater than the reference drug with evidences.
  - C The drug has been objectively confirmed to improve therapy of indicated diseases and injuries.

#### Value Premium (I) (35–60%)
- New drugs that meet two of the following three requirements for utility premium:
  - A The drug has a new clinically useful mechanism.
  - B The drug efficacy & safety have been demonstrated to be greater than the reference drug with evidences.
  - C The drug has been objectively confirmed to improve therapy of indicated diseases and injuries.

#### Value Premium (II) (5–30%)
- New drugs that meet any one of the following requirements:
  - A The drug has a new clinically useful mechanism.
  - B The drug efficacy & safety have been demonstrated to be greater than the reference drug with evidences.
  - C The drug has been objectively confirmed to improve therapy of indicated diseases and injuries.
  - D The drug has been objectively shown to offer greater therapeutic utility than the reference drug as a result of formulation improvement.

#### Marketability Premium (I) (10–20%)
- New drugs that meet both the following requirements:
  - A The drug is an orphan drug defined in the PAL* and an orphan indication is its main indication.
  - B The reference drug has not been given marketability premium (I).

#### Marketability Premium (II) (5%)
- New drugs that meet both the following requirements:
  - A Main indications of the drug correspond to separately defined indications for drugs with small markets.
  - B The reference drug has not been given marketability premium (I) or (II).

#### Pediatric Premium (5–20%)
- New drugs that meet both the following requirements (except for drugs not studied in Japanese children):
  - A Main indications or dosages for the indications of the drug explicitly imply the potential for use in children (including infants, suckling babies, newborns, and low-birth-weight babies).
  - B The reference drug has not been given pediatric-use premium.
  - Note) If the drug also meets requirements for marketability II, only the pediatric-use premium is given.

#### SAKIGAKE Premium (10-20%)
- Drugs that have been designated as the target drugs for the SAKIGAKE based on the “Notification of Trial Run of SAKIGAKE (Notification No.0401-(6) of the Evaluation and Licensing Division PFSB dated April 1, 2014).”

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* PAL: Pharmaceutical Affairs Law

When multiple premiums are applicable, the total premium is calculated as:

\[ \text{Total premium} = \text{Calculated price} \times (\alpha_1 + \alpha_2 + \ldots) \]
The SAKIGAKE was created to facilitate early introduction, as the world’s first approval, of innovative drugs/medical devices/regenerative medicine products in Japan. SAKIGAGE designations are given to pioneering pharmaceuticals/medical devices that have been developed uniquely in Japan, and that are expected to have outstanding efficacy in the early phase of clinical trials. SAKIGAKE-designated pharmaceuticals/medical devices are entitled to receive various support (e.g., approval of drugs/medical devices within 6 months, and half of the usual approval review period) that facilitates their early utilization.

### Designation Criteria

1. **Innovativeness of the therapeutic drug**: As a rule, the action mechanism should be different from that of previously approved drugs. (This includes a drug with the same action mechanism as that of a previously approved drug, but used in the target disease for the first time.)

2. **Seriousness of the target disease**: serious disease that is severely life-impacting or disease that continuously affects social life with no radical therapy

3. **Outstanding efficacy in the target disease**: No previously approved drugs are available, or considerable improvement in efficacy as compared to the previously approved drugs can be expected.

4. **Drugs intended to be developed from the early development phase in Japan in order to obtain new drug approval (NDA) for the first time in Japan** (including simultaneous NDA submission in other countries)

### Contents of the Designation System

1. **(1) Prioritized consultation**
   - **[Waiting time: 2 months → 1 month]**
   - Reducing the waiting time for clinical trial consultation after submission of materials by accelerating preliminary correspondence with the applicant

2. **(2) Substantive pre-application review**
   - **[Practical ahead-of-time approval review]**
   - Substantiating the pre-application review, and accepting submission of materials written in English

3. **(3) Prioritized review**
   - **[12 months → 6 months]**
   - Setting the goal of completing the approval review within 6 months
   - *Depending on the circumstances, the result of the phase III clinical study may be submitted after submission of the application for new drug approval, in order to reduce the time required from development to approval.

4. **(4) Review partner system**
   - **[Concierge assigned by PMDA]**
   - A managerial staff member who oversees the entire process required to obtain approval, including approval review, safety measures, quality control, and reliability assurance, is appointed as a concierge.

5. **(5) Substantive post-marketing safety measures**
   - **[Extension of the re-examination period]**
   - Although the conventional re-examination period is 8 years for a drug containing a new active ingredient, the re-examination period may be extended to a maximum of 10 years.
The price of a new but less novel drug shall be set at the lowest among the prices of drugs in its class entered to the NHI Price List during the past several years [Comparative Method [II]].

Less novel new drugs: that meet all of the following criteria

- The drug does not meet any requirements for premiums categories.
- More than 3 drugs in class are already available on the market.

As a rule, the drug is subject to the lower price of the following two options:

1. Lowest daily price of drugs in class listed during the past 6 years
2. Average daily price of drugs in class listed during the past 10 years

If the lowest price selected above is higher than the price calculated by the drug of similar efficacy comparison-based price setting (I) (→ price of most similar drug), this price is compared to the following two options to select the lowest price among (3), (4), and (5).

3. Lowest daily price of drugs in class listed during the past 10 years
4. Average daily price of drugs in class listed during the past 15 years
Calculation method for new drugs (3)

Special rules

- If no reference drug is available, the price of the new drug is set based on costs such as those of raw materials and manufacturing (Cost Calculation Method).

(Example)

1. Raw materials (API, additives, containers, packages, etc.)
2. Labor \( ( = 3,903 \times \text{labour time} ) \)
3. Manufacturing

4. Total manufacturing (importation) costs
5. Marketing, R&D, etc. \( (5 / (4 + 5 + 6) = 0.459 < \text{Note 2} > ) \)
6. Operating profit \( (6 / (4 + 5 + 6) = 0.146 < \text{Note 2} > ) \)
7. Distribution \( (7 / (4 + 5 + 6 + 7) = 0.070 < \text{Note 3} > ) \)
8. Consumption tax \( (8\% ) \)

Total: drug price

%Operating profit (currently 14.6\% ) is adjusted between -50\% and +100\%, depending on novelty, efficacy, and safety compared to existing drugs.

<Note 1> Unit labor cost: Average over 2012–2014: Monthly Labor Survey and the General Survey on Working Conditions (MHLW)
<Note 2> General operating expense rate, operating profit rate: Average over 2012–2014: Handbook of Industrial Financial Data (Development Bank of Japan)
<Note 3> Distribution expense rate: Average over 2012–2014: Statistics on the Pharmaceutical Industry (Economic Affairs Division, Health Policy Bureau, MHLW)
(The aforementioned values shall be average rates [mean value over the last 3 years in the pharmaceutical manufacturing industry], as a rule).
The price, whether calculated by the drug of similar efficacy comparison-based price setting (1) or by cost-based price setting, is compared with foreign prices and recalculated and adjusted accordingly if price differences are substantial [adjustment with average foreign price].

1. Average foreign price: Mean of US, UK, German, and French prices
2. Criteria for adjustment: (1) ≥ 1.25 fold higher than the average → Lower the price
   (2) ≤ 0.75 fold lower than the average → Increase the price

(Note: Maximum price increase: 2 fold)
Calculation method for new drugs (4)-2

Adjustment with Average Foreign Price

Special provisions in calculating price based on foreign average price

- Price increase adjustment with foreign price is not permitted in the following instances
  - Price calculation is based on the drug of similar efficacy comparison-based price setting (II) (low-novelty drugs).
  - There are multiple drug specifications (i.e., strengths) subject to premium considerations which are valued at both higher and lower foreign prices.
  - There are multiple drug specifications subject to premium considerations among which only non-general-purpose specification is subject to the price setting.
  - Only one foreign price is available for price adjustment.

- Price reduction is not permitted if all of the following criteria are met.
  - The drug is developed upon request or through public recruitment by the MHLW based on the result of discussions by the Special Committee on Unapproved Drugs and Drugs of Off-label Use Urgently Required for Healthcare.
  - A minimum of 10 years have passed since the time of approval in a foreign country.
  - The calculated price is greater than 3 times the average foreign price.
Calculation method for new drugs (5)

Adjustment of inter-specifications

- The price of a new drug product with the same dosage form containing a different amount of the same active ingredient is adjusted based on the relationship between the drug price and the content of a similar drug.
- However, the upper limit of the specification-based price adjustment ratio should be 0.5850 for the drug price calculation of a new product in which the content has been increased for the sole purpose of prolonging the dosing period without any improvement in the formulation.

[Adjustment of inter-specifications]

Ex. The calculated price of Tablet A for a general purpose specification (5 mg) is ¥ 174.60.

- NHI prices of a reference drug (Tablet B):
  - 10-mg tab: ¥ 158.30 (general purpose), 5-mg tab: ¥ 82.50 (non-general purpose)
- Price ratio between specifications of a reference drug (Tablet B):
  \[ \frac{\log \left( \frac{158.30}{82.50} \right)}{\log \left( \frac{10}{5} \right)} = ¥ \, 0.9402 \]
  Drug prices: non-general purpose vs. general purpose
  Drug prices: non-general purpose vs. general purpose

- Calculated prices of Table A for non-general-purpose specifications (2.5 & 10 mg)
  - 2.5-mg tab: ¥ 174.60 \times \left( \frac{2.5}{5} \right)^{0.9402} = ¥ 91.00
  - 10-mg tab: ¥ 174.60 \times \left( \frac{10}{5} \right)^{0.9402} = ¥ 335.00

Because of the specification-based adjustment ratio, the content ratio (2-fold or 0.5-fold) will not be the same as the ratio of calculated drug prices.
Kit products: Products composed of “APIs” and delivering systems (eg, prefilled syringes)

Price calculation method:

Price of APIs contained in the kit calculated by routine procedures for listing in the NHI Price List + Costs of materials (other than APIs) to feature kit parts which are necessary for the manufacture & distribution of the kit

Premiums for kits having high clinical utility:

A premium (A = 5%) is given to the new kit (other than kits already listed in the NHI Price List), provided that the new kit meets any one of the following requirements (its structure and functions must be novel compared to existing kits).

(a) Capable of reducing a risk of infection
(b) Capable of reducing a risk of erroneous dispensing
(c) Capable of patient treatment in emergency setting
(d) Capable of improving quality of care
Calculation method for new drugs (7)

Combination products

- With regard to a new combination product of existing drugs or a new combination product containing a new API (a new but non-innovative drug) that is not listed in the NHI price list, the drug price is calculated as follows. The rule does not apply to anti-HIV drugs or to injectable or topical combination products with evident supportive clinical data or clinical merit.

- Calculation method
  1) When all APIs contained in a new combination product are original products of the manufacturer:
     ⇒ With regard to the APIs of a new combination product, 0.8 x total of “drug prices of own originals”

  2) When APIs of a new combination product are a combination of original product(s) and non-original product(s) of the manufacturer:
     ⇒ Either of the following prices, whichever is the smaller.
       - “0.8 x price of the own original” + “0.8 x price of supplier’s original drug”
       - “0.8 x price of the own original” + “lowest price of generic drug”

  3) When all APIs contained in a new combination product are non-original products of the manufacturer:
     ⇒ Total of “the lowest drug prices of non-original products of the manufacturer”

  4) When a new combination product contains an API (a new but non-innovative drug) that is not listed in the NHI price list:
     ⇒ Treat such product as a new combination product that does not contain an API that is not listed in the NHI price list, and calculate the drug price.

However, in all cases, the price is not lower than the total individual API prices (individual drugs). Moreover, with regard to a new combination product (excluding anti-HIV drugs) for which a combination of individual drugs that are not concomitantly used clinically is used as a reference drug, the upper limit of the drug price should be the total daily prices of individual drugs.
Calculation method for new drugs (8)

Other new rules

New drugs with racemates or precedent drugs

With regard to a new drug that meets any of the following criteria, either already listed in the NHI Price List or a precedent drug of the same kind is calculated by multiplying 80/100 by the value obtained by the drug of similar efficacy comparison-based price setting (I) using the racemate(s). (Premiums are added to the calculated price if the new drug has greater benefits than the reference drug.)

- A new drug created by optical which are similar in dosing route, indications, etc. to racemate(s) already listed in the NHI price list.
- A new drug for which an equivalent or similar drug (precedent drug) having equivalency or similarity in its marketing authorization holder, main indications, pharmacological actions, dosage form, and role in clinical use exists, and whose listing in the NHI price list is planned after 5 years from the date of listing of the precedent in the NHI price list.

However, these rules are not applicable to new drugs for which excellent efficacy or safety has been objectively demonstrated and new drugs for which clinical significance has been recognized.
Price Calculation of Generic Drugs
Calculation method for new generic products

- When a generic drug is entered in the price list for the first time:
  - The price is calculated by multiplying the price of a brand drug that has been entered in the price list as a new drug by a factor of 0.5.
  - With regard to oral preparations, however, when the number of brands exceeds 10, the price should be calculated using a multiplying factor of 0.4.
  - With regard to biosimilar products, the price is calculated by multiplying the price of a brand drug by a factor of 0.7. (With regard to oral preparations, however, when the number of brands exceeds 10, the price should be calculated using a multiplying factor of 0.6.)

- When generic drugs have already been entered in the price list:
  - The price of newly entered generic drugs should be the same as the lowest price of the generic drugs.

*The multiplying factor for oral preparations whose number of brands exceeds 10.
Revision of Prices Listed in the NHI Price List
The new price is calculated by adding consumption tax and price adjustment rate (2% of market price – for securing drug supply to the market) to the weighted average wholesale price to hospitals / pharmacies.

\[
\text{New price} = \left( \frac{\text{weighted average wholesale price (market price before tax to hospitals / pharmacies)}}{1 + \text{Consumption tax rate (including local consumption tax)}} \right) + \text{Adjustment}
\]
Change over time in generic share in sales quantity and targets of generic share in sales quantity

**Targets of generic share in sales quantity**

1. **70% or above by mid-year 2017**
2. **80% or above as early as possible between FY2018 and the end of FY2020**

Note: Generic share (%) in sales quantity = [Generic drugs] / [(Original drugs for which generic drugs are available) + (Generic drugs)]

Source: MHLW
Special rules

- Price reduction for original products for which the entry of generic products is slow (Reduction as an exception (Z2))

If the replacement rate of an original product with generic products calculated at each NHI price revision after 5 years from the entry of the first generic product in the NHI price list does not exceed 70%, the special price reduction is applied in accordance with the replacement rate after the revision of the drug price based on the current market price.

**<Reductions>**

Replacement rate with generic products
- <30%: -2.0%
- 30%–<50%: -1.75%
- 50%–<70%: -1.5%

**<Replacement rate>**

\[
\text{Replacement rate} = \frac{\text{Quantity of generic products}}{\text{Quantity of original drugs for which generic drugs are available} + \text{Quantity of generic products}}
\]
Calculation method for listed drugs (3)

Special rules (1)

- Price revision of combination products
  If an ingredient of the combination product is subject to the consideration for Reduction as an exception (Z2), the price of the combination product is calculated by taking into account the revision rate of the ingredient.

- If pediatric, orphan or SAKIGAKE indications are approved or if true clinical utility has been verified after launch, premiums are added to the price revised in accordance with the basic rules.

- Recalculation of price
  (1) Drugs sold far more than expected due to massive changes in therapeutic practices induced by eg, changes in usage, target populations
     [Repricing based on expanded market size* Special rules for repricing based on expanded market size]
  (2) Drugs whose main indications have been changed : [new indications-based price resetting]
  (3) Drugs whose dosage & administration for main indications have been changed
     [new dosage/administration-based price resetting]
Repricing based on expanded market size

If the annual sales exceed the expected annual sales by a certain factor, the price will be further reduced at the time of price revision.

Special rules for repricing based on expanded market size
In addition to the current rules, special rules were added for products creating very large annual sales.

- E.g., new drug* for which the price was calculated using the cost-based calculation rules
- * When no first price revision has been made after 10 years from the time of listing in the NHI price list

<table>
<thead>
<tr>
<th></th>
<th>1st year</th>
<th>2nd year</th>
<th>3rd year</th>
<th>4th year</th>
<th>5th year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual sales (x 10 million yen)</td>
<td>30</td>
<td>40</td>
<td>60</td>
<td>65</td>
<td>70</td>
</tr>
<tr>
<td>Drug price (yen)</td>
<td>100 yen</td>
<td>98 yen</td>
<td>98 yen</td>
<td>95 yen</td>
<td>95 yen</td>
</tr>
</tbody>
</table>

**Recalculation of market expansion**

- A maximum of 25% reduction
- >=2 times expected annual sales
- and annual sales of >=15 billion yen
- or >=10 times expected annual sales
- and annual sales of >=10 billion yen

**Annual sales of 100–150 billion yen**
- >=1.5 times expected annual sales

**Annual sales of ≥150 billion yen**
- >=1.3 times expected annual sales

**A maximum price reduction of 25%**

**A maximum price reduction of 50%**
Special rules for low-priced drug products

(1) Basic drugs

With regard to existing drug products that have been listed in the price list and meet all of the following criteria (excluding drugs for which adequate profitability is expected), the drug price before price revision (if there is a similar drug having the same composition, dosage form, and specifications, the price of the brand with the largest annual sales) should be the drug price of such drug product listed in the price list.

- At least 25 years have passed since the time of listing in the NHI price list, and the deviation rate of the entire ingredients and the brand does not exceed the average deviation rate of all NHI-listed drugs.
- Versatile drug products, including drugs that are recommended in general guidelines or widely used in medical institutions, etc.
- Drug products that have previously been subjected to price recalculation based on unprofitable trade of the product, drug products that have been used against pathogenic organisms for a very long time as a basis of medical care, and narcotics for medical use.

(2) Unprofitable trade-based price resetting

With regard to drugs for which there are high health & medical needs but that are priced too low to continue supply, the drug price calculated using the cost-based rules should be the drug price of such drugs.

(3) Lowest price

When the calculated price of a listed drug is lower than the lowest formulation-based price, the lowest price is selected for the listed drug.
Overview of individual items included in the special rules, such as low-priced drugs

| (1) Basic drugs | (Role of this category)  
|-----------------|----------------------------------------------------------------------  
|                 | This category has been implemented to support price recalculation based on unprofitable trade of the product, and the drug price before falling to the minimum drug price.  
|                 | (Eligibility criteria)                                                 
|                 | • A drug for which there is high medical need                          
|                 | • A drug whose efficacy and safety have been substantiated based on a long history of extensive clinical use  
|                 | • A drug for which a stable continuous flow of supply to the market needs to be secured (including repair of manufacturing facilities)  
| (2) Recalculation for unprofitable products | • A drug for which there is high medical need  
|                                              | • A drug for which a minimum drug price has not been determined, or whose minimum drug price is not high enough to make any profit  
|                                              | • A drug that cannot be continuously manufactured and sold by the manufacturer/distributor because the drug is significantly low-priced  
| (3) Minimum statutory NHI price | • The minimum drug price is selected for each dosage form in order to secure the minimum profit that covers the supply cost. The minimum drug price is selected for each dosage form, irrespective of ingredients.  

## Drug products selected as essential drugs in the FY2016 Drug Pricing System Reform

Selected items: 134 ingredients, 439 products

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of Ingredients (Number of products)</th>
<th>Product (examples)</th>
<th>Main Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathogenic organisms</td>
<td>51 (160)</td>
<td>AMOLIN FINE GRANULES EButol Retrovir Capsules ARASENA-A for I.V. Infusion</td>
<td>Various infections Pulmonary tuberculosis, etc. HIV infection Herpes simplex encephalitis, etc.</td>
</tr>
<tr>
<td>Narcotics</td>
<td>6 (15)</td>
<td>MS Contin MORPHINE HYDROCHLORIDE INJECTION</td>
<td>Analgesia in various cancers with severe pain Analgesia/sedation for severe pain, etc.</td>
</tr>
<tr>
<td>Unprofitable drugs</td>
<td>77 (264)</td>
<td>Phenytoin Powder THYRADIN-S POWDER Endoxan PAM SOLDEM 3 (maintenance solution)</td>
<td>Convulsive seizure in epilepsy Hypothyroidism in infants Multiple myeloma, etc. Intoxication with organic phosphorus compounds Hydration in patients who are incapable of ingestion</td>
</tr>
</tbody>
</table>

* If multiple categories are applicable for a drug, the drug is grouped into the unprofitable drugs category.
Calculation method for listed drugs (5)

Special rules

- Price revision of generic drugs

With regard to all similar drugs having the same composition, dosage form, and specifications, the drug price is calculated as follows.

1. One drug price (weighted average) is selected for all generic drugs having a calculated drug price that is <30% of the maximum drug price (listed as an uniform name).

2. One drug price (weighted average) is selected for all generic drugs having a calculated drug price that is ≥30% and <50% of the maximum drug price.

3. One drug price (weighted average) is selected for all generic drugs having a calculated drug price that is ≥50% of the maximum drug price.

For example:

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Unit (yen)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original A</td>
<td>221.80</td>
</tr>
<tr>
<td>B</td>
<td>144.70</td>
</tr>
<tr>
<td>C</td>
<td>121.40</td>
</tr>
<tr>
<td>D</td>
<td>95.80</td>
</tr>
<tr>
<td>E</td>
<td>84.50</td>
</tr>
<tr>
<td>F</td>
<td>84.30</td>
</tr>
<tr>
<td>G</td>
<td>76.20</td>
</tr>
<tr>
<td>H</td>
<td>64.90</td>
</tr>
<tr>
<td>I</td>
<td>59.90</td>
</tr>
</tbody>
</table>

Maximum price: 221.80 yen

- 50% of maximum price
  - Other generic drugs
    - Weighted average
  - Semi-low-priced drugs
    - Weighted average
  - Low-priced drugs
    - Weighted average

Note: In the FY2016 Drug Pricing System Reform, the currently used three price ranges will be maintained; however, in consideration of the price ranges after revision, additional consideration will be given to further integration of price ranges.
## Calculation method for listed drugs (6)

### Special rules
- **Price revision of new drugs protected under patent or in the reexamination period**

  The Premium System for the Promotion of Innovative Drug Discovery and Resolution of Off-Label Use introduced on a trial basis in Fiscal 2010 **has been continued in Fiscal 2016.**

### Eligible drugs

- New drug that meets all of the following criteria
  1. The drug has been listed in the NHI price list as a new drug, and no generic drug related to this drug has been listed in the NHI price list. (*Limited to drugs for which no first price revision has been made after 15 years have passed since the date of listing in the NHI price list)*
  2. 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.
  3. The drug is not subject to repricing.

### Premiums

- Drug price calculated based on current market prices of drugs in class x (average deviation rate of all drugs available in the NHI price list) x 0.8
  (* However, the newly calculated price of the drug should not exceed the drug price before recalculation.*)
- After the market launch of generic drugs, the accumulated total premiums applied prior to the price recalculation should be deducted at once.

### Company Requirements

- 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
Premium to Promote the Development of New Drugs and Eliminate Off-Label Use, and Change over Time in Drug Price in Pricing of New Drugs Covered by This Premium

Requirement: The deviation rate of the actual market price does not exceed the weighted average deviation of all listed drugs.

Drug price of new drugs that are covered by this premium

Drug price of new drugs that are not covered by this premium (Drug price of new drugs in the current system)

Listing of new drugs in the NHI price list

Market launch of generic drugs or 15 years from the time of listing in NHI price list

First drug price revision after launch of new generic drugs