Drug Pricing in Japan

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IP1: Cost vs Value: What is the fair price of a drug?
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Health Insurance Coverage and Pricing

- Health insurance coverage decision and reimbursement prices are determined by the Ministry of Health, Labour and Welfare (MHLW), not depend on health insurance bodies.
- Prices are revised every two years.
- MHLW has to consult with Central Social Insurance Medical Council (Chu-I-Kyo.)

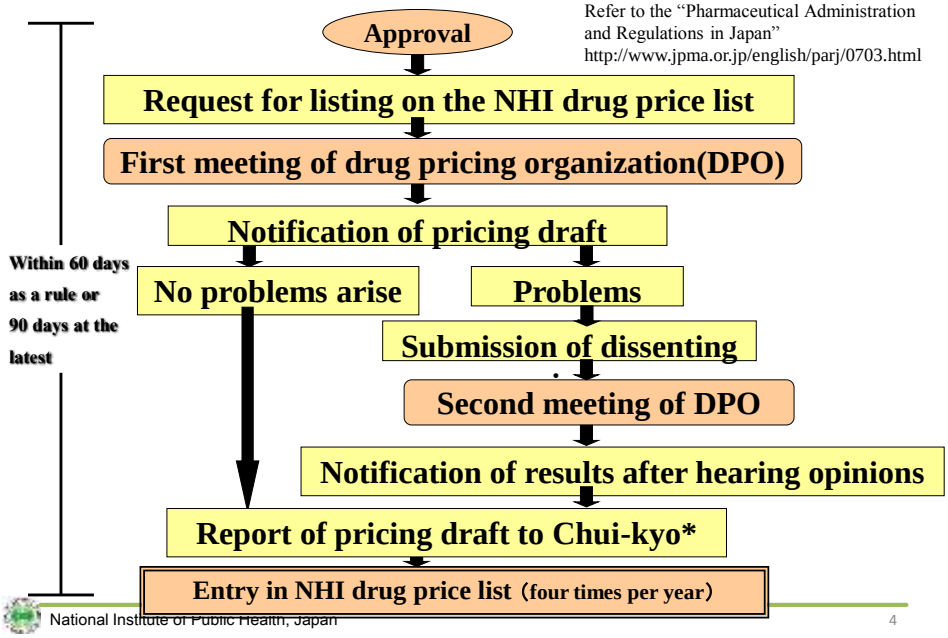
Central Social Insurance Medical Council (Chu-I-Kyo)

7 representatives from health care insurers
employees health insurance, community based health insurance

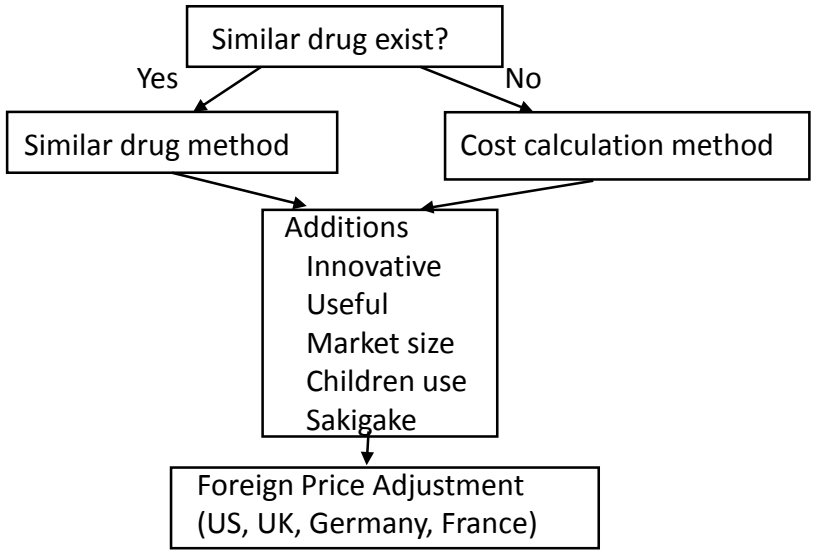
7 representatives from health care providers
physicians, dentists, pharmacists

6 representatives from public
academia

Reimbursement Pricing Process for New Drugs



Process of New Drug Pricing



Similar Drug Method

Price of a new drug is determined

as one day expenditure of the new drug

equivalent to

one day expenditure of the similar drug

Additions to Base Price

- Innovative addition: 70 - 120%
  developed with innovative idea
  high efficacy or safety
  much improvement in treatment of disease

- Useful addition I: 35 - 60%
  two of above criteria achieved

- Useful addition II: 5 - 30%
  high efficacy or safety OR
  much improvement in treatment of disease

Additions to Base Price

- Market size addition I: 10 - 20%
  rare diseases

- Market size addition II: 5%
  small market size

- Children use addition: 5 - 20%
  indication, dose, administration method are clearly described for children use

- Sakigake designation scheme addition: 10 - 20%
  applied first in Japan

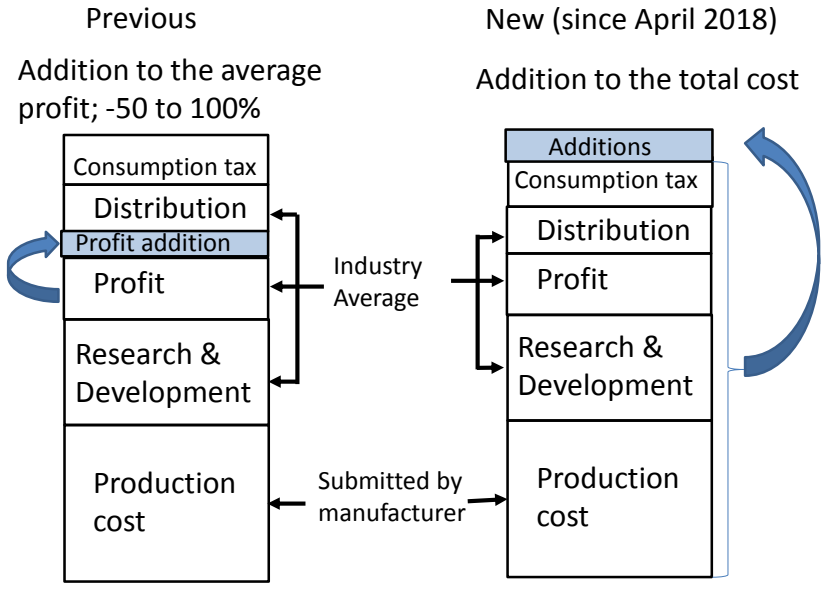
Cost Calculation Method

No similar drug exist.

Based on costing data submitted by manufacturers.

Fixed proportion is used for cost of R&D, marginal profit and distribution, based on average of pharmaceutical industry.

Cost Calculation Method



Additions to Base Price

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- Useful addition I: 35 - 60%
- Useful addition II: 5 - 30%
- Market size addition I: 10 - 20%
- Market size addition II: 5%
- Children use addition: 5 - 20%
- Sakigake designation scheme addition: 10 - 20%

Additions in case of Cost Calculation Method

Addition = Total Cost × Additional Rate × Additional Factor

Transparency Index	>80%	50 -80%	<50%
Additional Factor	1.0	0.6	0.2

Transparency Index : Proportion of detailed structure of total production cost reported to the drug pricing organization

Foreign Price Adjustment

To make the difference between price in Japan and prices in other countries smaller

Average Foreign Price(AFP):
France, Germany, USA and UK

When the base price is 1.25 or higher
(1/3 x base price / AFP + 5/6) x AFP

When the base price is 0.75 or lower
(1/3 x base price / AFP + 1/2) x AFP

(Example) Obnituzumab 1000mg40mL

Average Foreign Price: JPY603,490
JPY (1/3 * 446,136/603,490 + 1/2)* 603,490
= JPY450,457

Useful addition II: 20%, Additional Factor: 0.2
JPY 428,977 * (1+ 0.2*0.2) = JPY446,136

Additions

Total Cost : JPY 428,977

Consumption tax — (4) JPY 31,776 = ((1)+(2)+(3))*8%

Distribution — (3) JPY 29,393 = ((1)+(2)+(3))*7.4%

Profit — (2) JPY 52,597 = ((1)+(2))*14.3%

Total production cost — (1) JPY 315,211 submitted by manufacturer

Issues on Cost Calculation Method

- Actual cost for production is important for manufacturers.
- Some costs such as R&D are difficult to attribute to one product.
- Detailed cost information should be disclosed?
- All the cost should be reimbursed regardless of the efficacy?
- Role of foreign price adjustment?

Drug Price Revision

Every two years

Wholesale price survey
- all wholesalers(approx. 4000)
- sampled hospitals(900), clinics(1000) and Pharmacies(1600)
- all insurance-covered drugs: approx. 15,000 drugs

Revised price
=(average wholesale price) x (1+consumption tax)
+R-zone

Reasonable zone (R-zone) : 2% of the previous price
(~1998: 15%, ~2000: 5%)

Drug Price Revision Rate

Date	Number of Drugs	Drug Price Revison Rate (%)
1975.1.1	6,891	−1.55
1978.2.1	13,654	−5.8
1981.6.1	12,881	−18.6
1983.1.1	16,100	−4.9
1984.3.1	13,471	−16.6
1985.3.1	14,946	−6
1986.4.1	15,166	−5.1
1988.4.1	13,636	−10.2
1989.4.1	13,713	−2.4
1990.4.1	13,352	−9.2
1992.4.1	13,573	−8.1
1994.4.1	13,375	−6.6
1996.4.1	12,869	−6.8
1997.4.1	11,974	−4.4
1998.4.1	11,692	−9.7
2000.4.1	11,287	−7
2002.4.1	11,191	−6.3
2004.4.1	11,993	−4.2
2006.4.1	13,311	−6.7
2008.4.1	15,405	−5.2
2010.4.1	15,455	−5.75
2012.4.1	14,902	−6
2014.4.1	15,303	−2.65
2016.4.1	15,925	−5.57

Repricing for Market Expansion

If actual annual sales of the drug exceeds the double of originally estimated sales and the annual sales over 15 billion yen

↓

Price of the drug may be reduced up to 25%.