

The need and development of HTA in Japan

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Background

Public health insurance covers approximately 15,000 prescribed drugs.

In 2005,

Annual health expenditure : JPY 33,000 billion
(US\$300 bill., NT\$ 9500 bill.)

Pharmaceutical expenditure: JPY 7000 billion
(US\$64 bill., NT\$2000 bill.)

Proportion of pharmaceutical expenditure is decreasing.

Drug Price Decision Makers

Ministry of Health, Labour and Welfare

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

7 representatives from health care insurers

7 representatives from health care providers

6 representatives from public

Drug Price Assessment Organization

6 medical doctors, 2 dentists, 2 pharmacists,

1 economist

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%)

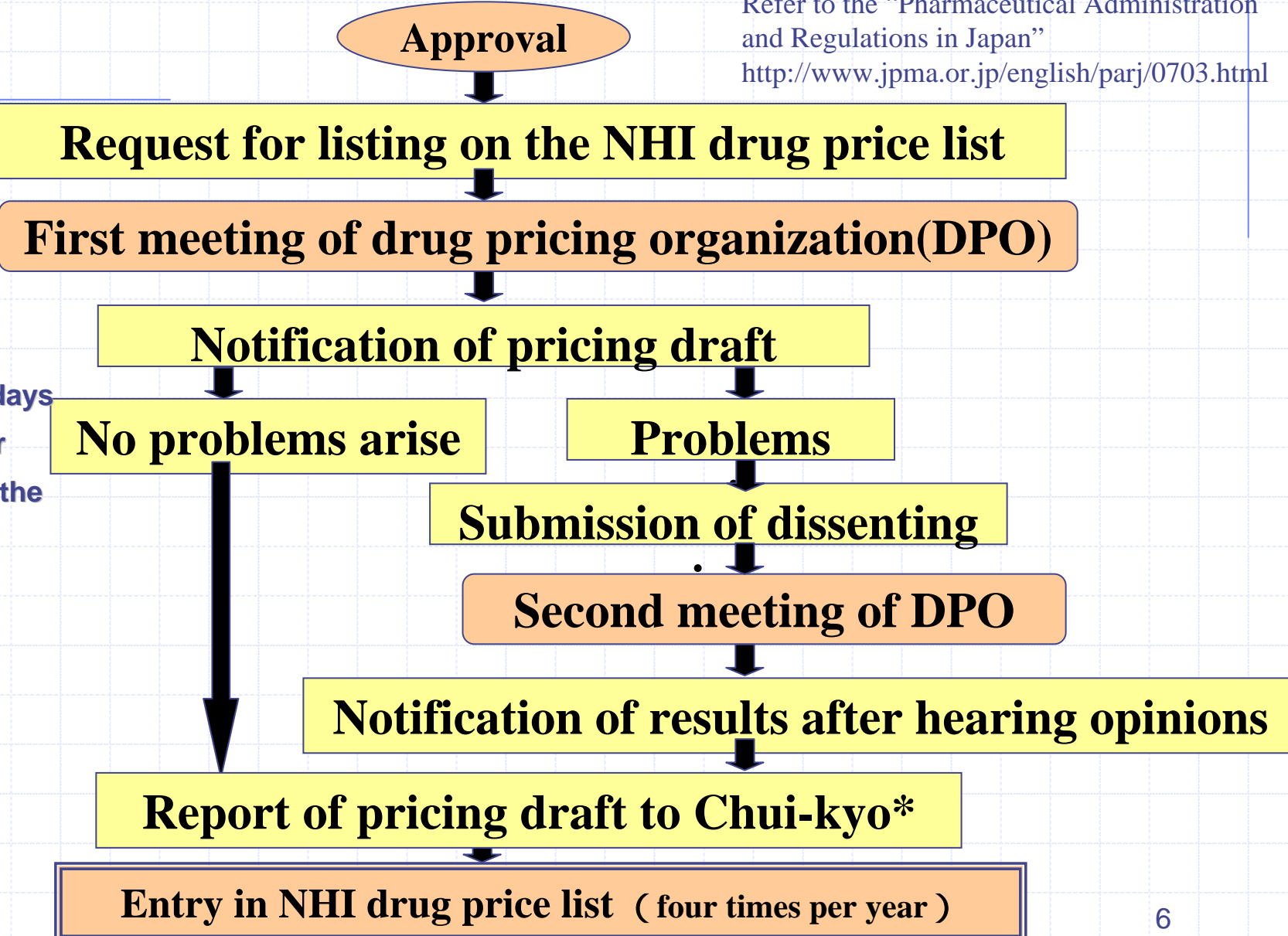
Drug Price Revision Rate



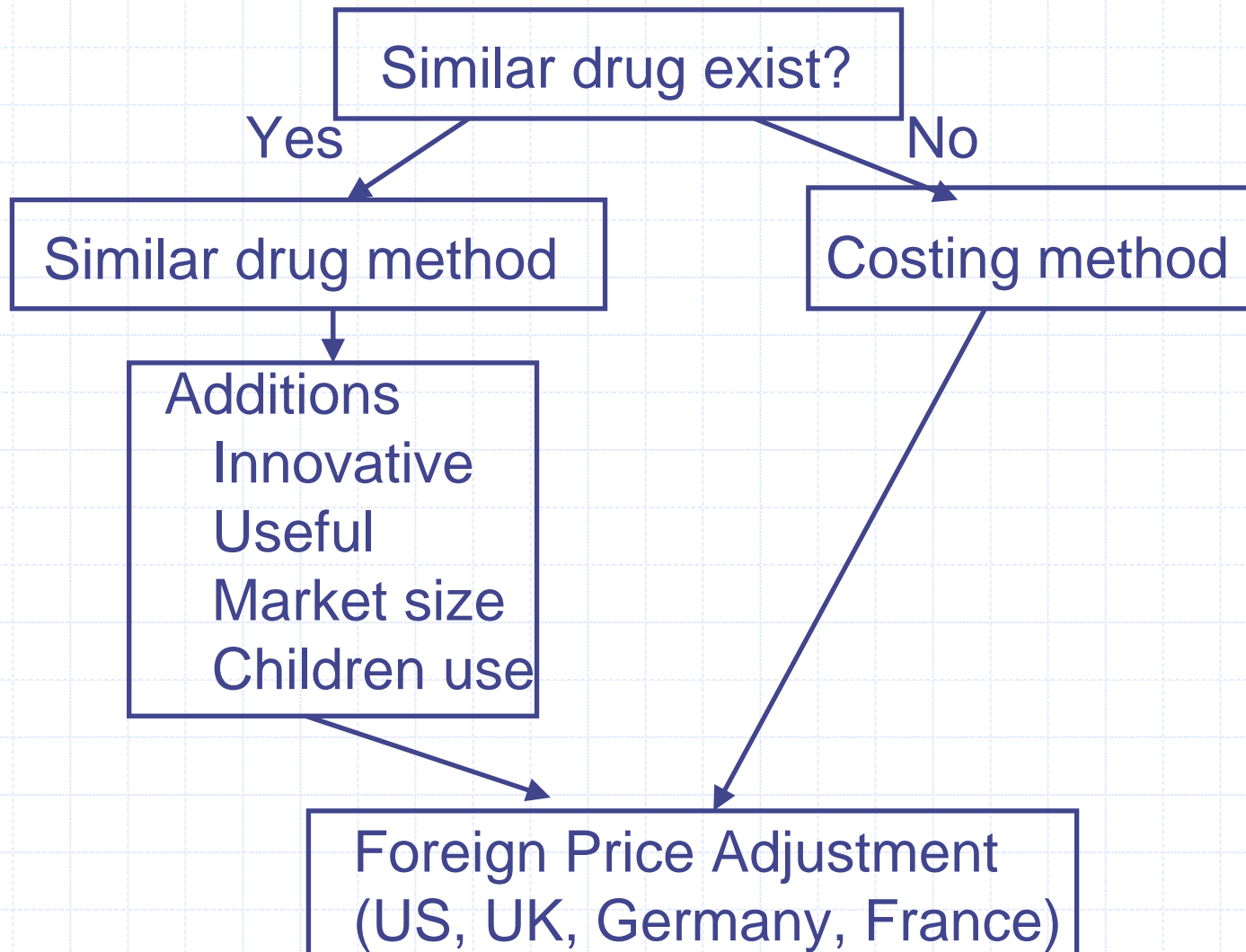
Reimbursement Pricing Process for New Drugs

Refer to the “Pharmaceutical Administration and Regulations in Japan”
<http://www.jpma.or.jp/english/parj/0703.html>

Within 60 days
as a rule or
90 days at the
latest



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: 50 - 100%
developed with innovative idea
high efficacy or safety
much improvement in treatment of disease
- Useful addition I: 25 - 40%
two of above criteria achieved
- Useful addition II: 5 - 20%
high efficacy or safety OR
much improvement in treatment of disease

Additions to Base Price

- Market-size addition: 1.5 - 15%
drugs for rare diseases
- Children use addition: 3 - 10%
application and dosage for children are
clearly mentioned

Methods of New Drug Base Price Setting

	1998	1999	2000	2001	2002	2003	Total
New drugs approved	26	38	59	34	42	38	237
Similar drug method	25	32	51	24	34	37	203
Costing method	1	6	8	10	8	1	34

Additions to Base Price for New Drugs

	1998	1999	2000	2001	2002	2003	Total
Innovative addition				1	2		3
Useful addition	9	5	6	5	11	17	53
Market-size addition	3	7	4	2	1		17
Foreign price adjustr	3	6	12	8	14	14	57

Should be Reconsidered

Drug price revision

Does wholesale price reflect true market value?

New drug pricing

Drug category: selection of similar drug

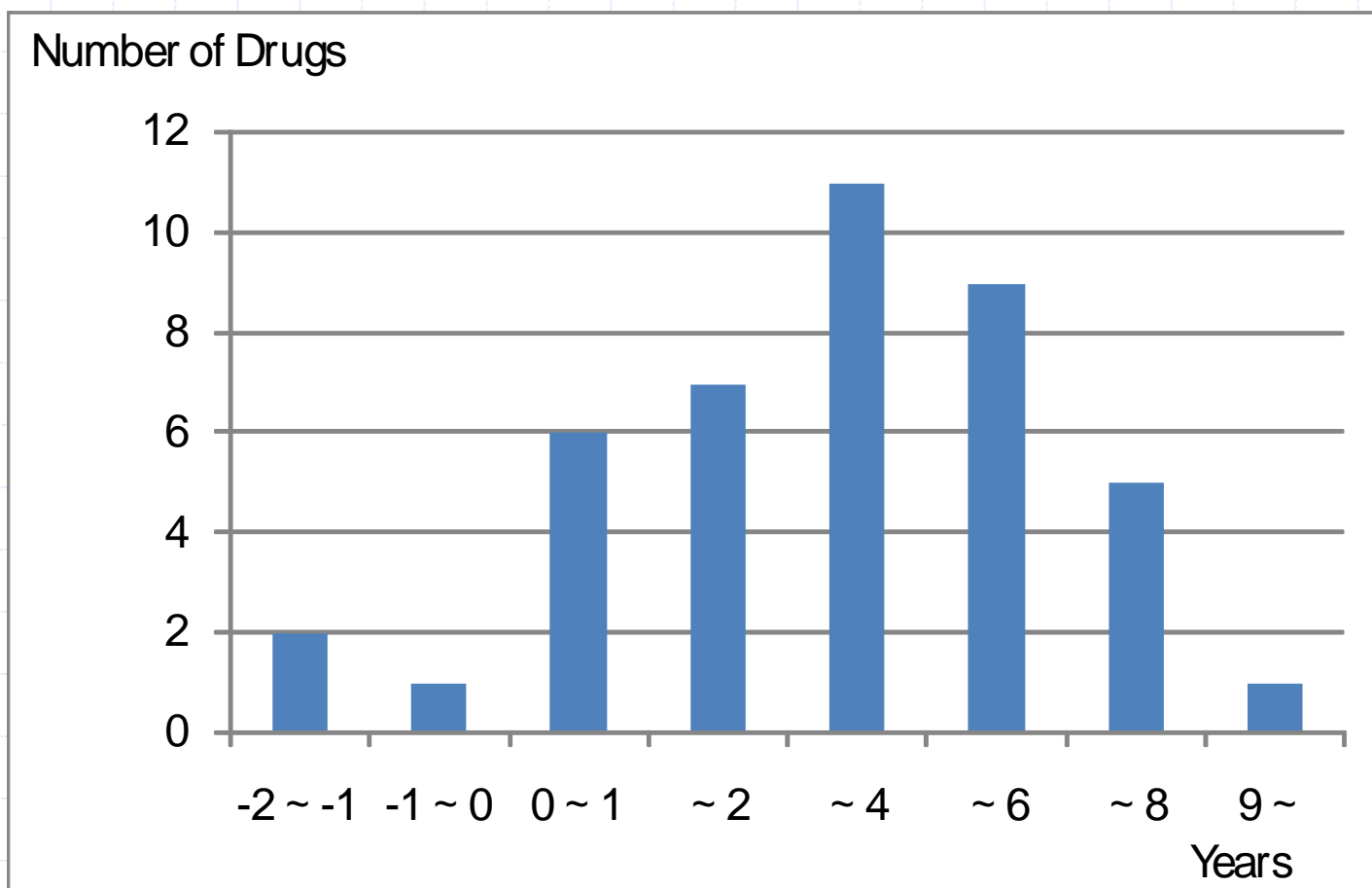
Criteria for additions

-> have to consider value for money

application of economic evaluation

Problems of Drug Lags

Number of years from the drug was approved in US or Europe till it was applied in Japan in 2003-2005.



Pharmacoeconomic Studies of New Drugs

From 1992, pharmaceutical companies are allowed to attach the results of pharmacoeconomic studies to the new drug application dossier.

It is not mandatory and there are no guidelines for the methods of study.

Pharmacoeconomic Studies attached to New Drug Application

1997-2000	w/ study	(proportion)	w/o study	Total
Total	37	32.5%	77	114
Similar drug method	33	32.0%	70	103
Costing method	4	36.4%	7	11
Useful addition	8	40.0%	12	20
Market-size addition	3	17.6%	14	17

Sakamaki et al.(2001)

Pharmacoeconomic Study Type for New Drug Application

1997-2000	Number of studies	(proportion)
Total application	37	
Cost-minimization analysis	6	16.2%
Cost-effectiveness analysis	14	37.8%
Cost-utility analysis	0	0.0%
Cost-benefit analysis	7	18.9%
Cost comparison	7	18.9%
Cost description	2	5.4%
other	1	2.7%

* some applications include more than one study

Reason for NOT attached Pharmacoeconomic Studies

Reason	Proportion
No merit to attach PE studies	70%
Lack of data for PE studies	43%
No expert personnel in company	11%
Other	9%

multiple answer

Recent Movement in Academia

Education periods for Pharmacists:

4 years -> 6 years from 2006

Pharmacoeconomics is becoming popular in Pharmacy schools

ISPOR (International Society for Pharmacoeconomics and Outcomes Research)

Japan Chapter established in 2005

annual meeting, training sessions

Economic Evaluation Study Guidelines proposed under Government funded grants

Pharmacoeconomic Study Guideline proposed by Shiragami et al. (2004)

1. Purpose
2. Perspective
3. Comparators
4. Costs and data sources
5. Outcomes and data sources
6. Time horizon
7. Discounting
8. Modeling
9. Type of analysis
10. Uncertainty
11. Budget impact
12. Reporting

Recent Example in Government

Smoking cessation therapy was one of the issues for price revision for 2006.

Chu-I-Kyo finally decided to cover smoking cessation therapy by public health insurance from April 2006 and nicotine patch from June 2006.

Clinics where smoking cessation programs take place have to report success rate of the program.

Points of Discussion at Chu-I-Kyo for Coverage of Smoking Cessation Therapy

Representatives from health insurers insisted to consider not only short term budget impact of the coverage but also its cost-effectiveness.

Pharmacoeconomic studies in foreign countries were considered not enough for decision making because of the difference in health insurance systems and costs. Thus, domestic study results were requested.

Although positive ICER(Incremental Cost-Effectiveness Ratio) was presented, the therapy was covered.

Cost-Effectiveness of smoking cessation therapy : when future cost savings are considered

sex	d- rate*	cost (yen)			outcome (life years)		
		no teaching	teaching	teaching +NRT	no teaching	teaching	teaching +NRT
male	3%	1,328,048	1,174,475	1,065,454	21.339	21.453	21.537
female	3%	781,410	701,480	644,544	22.781	22.851	22.899
male	0%	2,840,988	2,440,683	2,158,950	36.151	36.489	36.728
female	0%	1,714,225	1,476,972	1,308,124	39.968	40.178	40.326

*discount rate

Cost-Effectiveness of smoking cessation therapy : when future cost savings are NOT considered

sex	d-rate*	Incremental cost (yen)	teaching		teaching+NRT		
			incremental outcome (year)	ICER** (yen/LYG)	Incremental cost (yen)	incremental outcome (year)	ICER** (yen/LYG)
male	3%	36,294	0.113	320,000 (\$2460)	59,674	0.193	308,000 (\$2370)
female	3%	36,294	0.068	530,000 (\$4080)	59,674	0.115	519,000 (\$3990)
male	0%	36,294	0.338	107,000 (\$820)	59,674	0.572	104,000 (\$800)
female	0%	36,294	0.209	173,000 (\$1330)	59,674	0.355	168,000 (\$1290)

* discount rate

** incremental cost effectiveness ratio

Future

- ✓ Transparent and reasonable method of drug pricing will be required under universal public health insurance system.
- ✓ Application of economic evaluation studies should be considered.
- ✓ Standard methods for economic evaluation studies must be developed
- ✓ Acceptable threshold for positive ICER should be investigated.

Willingness to Pay per QALY

We have conducted the survey of willingness to pay for an additional QALY in Japan, Republic of Korea, Taiwan, Australia and UK.

Respondents were randomly sampled from the internet survey panel in each country until the number of respondents reached 1000 in each country (500 in Taiwan).

WTP per QALY

country	unit	WTP _{sel} 95%CI		WTP _{5sel} 95%CI		WTP _{fam} 95%CI		WTP _{soc} 95%CI	
Japan	1 mil JPY	5.0		3.5		6.4		5.4	
		4.7	5.4	3.2	3.9	6.0	6.8	5.0	5.8
Korea	1 mil Won	68		56		79		69	
		64	73	52	60	75	83	65	73
Taiwan	1 mil NT\$	2.1		1.9		1.9		1.8	
		1.9	2.3	1.7	2.1	1.7	2.1	1.6	1.9
UK	1,000£	23		20		26		38	
		22	25	19	22	24	28	36	39
Australia	1,000 AU\$	64		58		78		89	
		60	68	54	62	73	82	85	93
US	1,000 US\$	62		52		69		96	
		57	66	48	56	65	74	92	101

WTP per QALY

