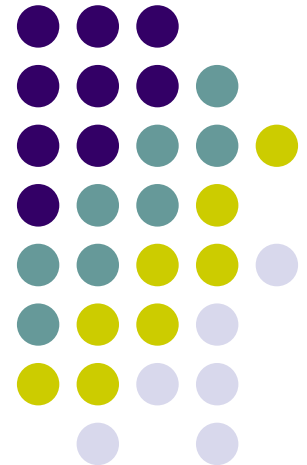


A worldwide regulatory and payer perspective
The Asian Perspective

The 5th IPECAD
New Jersey
March 27 - 29, 2008

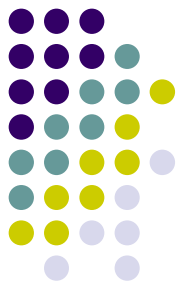
Guk-Hee Suh, MD, PhD
Professor of psychiatry , Hallym University &
Chair, Mental Health Economics Task Force of IPA



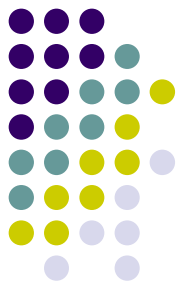
Contents



- Asia
- Comparison across Asian countries
 - Price of antimentia drugs and their affordability
 - Availability and subsidization of antimentia drugs
 - Clinical indication and reimbursement criteria
 - Barriers
- Health policy reform in Korea
 - Long-term care insurance system
 - From Negative to Positive list system policy (PLSP)



Asia



- The world's largest and most populous continent.
 - 29.4% of land area of the earth
 - About 4 billion people : > 60% of world population
 - China : 1,322 million
 - India : 1,130 million
 - Indonesia : 235 million
 - Japan: 127 million
- The largest increase in the prevalence of AD will occur in Asia.
 - 12.65 million in 2006 (48% of the world's AD cases)
 - 62.85 million in 2050 (59% of the world's AD cases)

Population



Country	Population , 2007	Age Structure (%)			Life expectancy at birth		
		0 ~ 14	15 ~ 64	65 +	Male	Female	Total
India	1,129,866,154	31.8	63.1	5.1	66.28	71.17	68.59
Japan	127,433,494	13.8	65.2	21.0	78.67	85.56	82.02
Korea	49,044,790	18.3	72.1	9.6	73.81	80.93	77.23
Philippine	91,077,287	34.5	61.3	4.1	67.61	73.55	70.51
Taiwan	22,858,872	17.8	72.0	10.2	74.65	80.74	77.56
Thailand	65,068,149	21.6	70.1	8.2	70.24	74.98	72.55
USA	301,139,947	20.2	67.2	12.6	75.15	80.97	78.00

Price of donepezil & its affordability



Country	Price in the country, 2007		exchange rate to US\$, 2007 average	Converted Price, US\$		Affordability index = number of pills purchasable with one's daily income	
	5 mg	10 mg		5 mg	10 mg	5 mg	10 mg
India	10.80	15.80	41.3570	0.26	0.38	6.2	4.2
Japan	452.80		117.8145	3.84		25.9	
Korea	3853.00	4258.00	935.2698	4.12	4.55	13.3	12.0
Philippine	228.00	240.00	46.2140	4.93	5.19	0.5	0.5
Taiwan	114.00	117.00	32.8826	3.47	3.56	13.6	13.3
Thailand	150.00	155.00	32.5301	4.61	4.76	1.9	1.8
USA	6.64	6.64	1	6.64	6.64	19.0	19.0

Source: Suh GH. 2008. Medicine prices and affordability. International survey report of the Mental Health Economics Task Force of International Psychogeriatric Association

Availability of antidementia drugs across east Asia



Country	Donepezil	Rivastigmine	Galantamine	Memantine
Japan	+	-	-	-
Korea	+	+	+	+
Hong Kong	+	+	+	+
Taiwan	+	+	+	+
China	+	+	+	+

+ available / - not available

Subsidization of antidementia drugs by national health insurance



Country	Donepezil	Rivastigmine	Galantamine	Memantine
Japan	+	*	*	*
Korea	+	+	+	+
Hong Kong	+	+	+	-
Taiwan	+	+	+	+
China**	-	-	-	-

+ subsidized / - not subsidized / * not available

** In some China areas, e.g., Zhejiang Province, Jiangsu Province, the use of Cholinesterase inhibitors may be covered by medical insurance



Use of other medicine

Country	Ginko	Vit. E	Fish oils	Herbal medicine
Japan	+	+	+	+
Korea	+	+	+	+
Hong Kong	+	+	+	Red seed extract
Taiwan	+	+	+	+
China*	+	+	+	Huperzine A, Lei Gon Teng

*In China, most patients are receiving Huperzine A, a ChEI extracted from Chinese herb, since Huperzine A has been covered by National Drug Catalog (China) and is inexpensive.



Clinical indications for ChEIs

Country	Alzheimer's disease	Vascular dementia	Mixed dementia	Lewy body dementia
Japan	+	-	-	-
Korea	+	+	+	?
Hong Kong	+	+	+	+
Taiwan	+	-	+	?
China	?	?	?	?

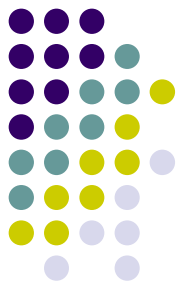
+ approved / - not approved/ ? not defined yet

Reimbursement criteria for ChEIs



Country	Reimbursement criteria
Japan	No criteria
Korea	MMSE 10 - 26 AND (CDR 1 - 2 OR GDS 3 - 5)
Hong Kong	MMSE \geq 10, mild to moderate dementia
Taiwan	MMSE 10 - 26 AND CDR 1 - 2
China	No criteria

Specialists authorised for ChEIs



Country	Psychiatrist	Neurologist	Geriatrician	Any doctor
Japan	+	+	+	+
Korea	+	+	(+)	(+)
Hong Kong	+	+	+	-
Taiwan	+	+	-	-
China	+	+	+	+

(+) : officially allowed to prescribe antideementia drugs, but reimbursement is limited by national health insurance.

Barriers



- Stigma attached to AD makes pts avoid to get help or treatment
- Ignorance about dementia makes lose opportunity for early diagnosis and treatment
- *Korea* : Long-term care insurance will not subsidize medical treatment. Drug treatment should be subsidized by national health insurance instead.
- *Hong Kong*: Long waiting list for psychogeriatric assessment and treatment
- *Taiwan* : There is no government policy related to long-term care of dementia
- *Japan* : In rural area, access to specialized dementia service is still limited
- *China* : Financial support for dementia care (i.e., antidementia drugs) is greatly limited in most area. Further, there is no national health insurance covering all Chinese people.

Long-term care insurance in Korea



- Pilot project to implement the LTC insurance to care for elderly with dementia, stroke, and frailty are on-going in 8 cities
- LTC insurance system will launch in July, 2008.

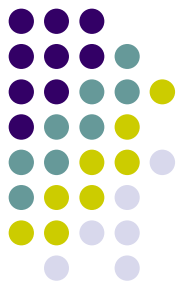


Introduction of Economic Evaluation into Pharmaceutical Reimbursement Decisions: Recent Reform

Previous Pharmaceutical Reimbursement under NHI



- All the approved drugs were automatically enlisted in the reimbursement list of Korean medical insurance
- Cost and cost-effectiveness of drugs were not counted in the reimbursement decision
- Drug expenditure accounted for more than one quarter of total NHI outlay (28% in 2004, 29% in 2005).



Trend of Pharmaceutical Expenditure

Proportion of drug expenditure out of total KNHI expenditure
(2001~2006)

(unit : 1trillion KRW, %)

	2001	2002	2003	2004	2005	2006
Total exp.	17,820	19,061 (7.0%↑)	20,534 (7.7%↑)	22,356 (8.9%↑)	24,797 (10.9%↑)	28,558 (15.2%↑)
Drug exp.	4,180	4,801 (14.9%↑)	5,583 (16.3%↑)	6,353 (13.8%↑)	7,229 (13.8%↑)	8,404 (16.3%↑)
Drug share	23.5	25.2	27.2	28.4	29.2	29.4

Note 1: Proportion of drug expenditure out of total KNHI expenditure has been increasing from 23.5% (2001) to 29.4% (2006)

Note 2: Nominal drug expenditure increased from 4.2 trillion KRW to 8.4 trillion KRW in 5 years

Note 3: Annual increasing rate of drug expenditure is 15.0%, compared to 10.6% of other medical expenditure in KNHI

Fast Introduction of New Drugs into KNHI Reimbursement List: 2003-2005



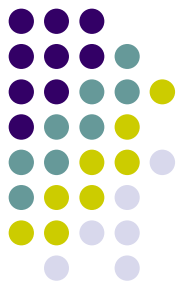
No. of Countries Adopted		0	1	2	3	4	5	6
164 New Drugs to Korea	Number	7	67	32	20	17	12	9
	%	4.3	40.8	19.5	12.2	10.4	7.3	5.5

Note 1: Annually, about 50 new drugs are introduced into Korean NHI

Note 2: 7 new drugs are first launched in Korea across the world

Note 3: Korean NHI introduced 67 (out of 164, 40.8%) new drugs as 2nd country in the world; 32 products (19.5%) 3rd in the world

Source: MOH, Korea



Issue with Fast Introduction

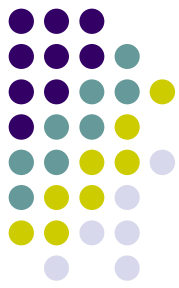
- Drug pricing had been done based on average of A7-country prices as a reference
 - A7 countries: US, UK, Switzerland, Japan, France, Germany, Italy
- When few countries adopted a new drug, price and clinical data enough to guarantee reasonable pricing were not available
 - There were 25 new drugs in 2003, for which Korea reviews as the 2nd country in the world,
 - These 25 drug prices were determined based on only one price from A7-countries as a reference

Policy makers' Concerns



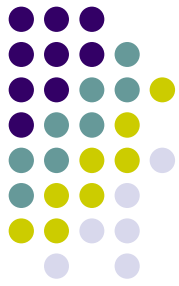
- New drugs are entering into the Korean market very quickly
- Drugs have been enlisted in the reimbursement list with little consideration of budget impacts and cost-effectiveness
- Drug expenditure is increasing rapidly, compared to other portions, resulting in occupying steadily higher proportion of NHI expenditures
- Recently policy makers examined appropriateness of drug expenditure systemically

Use of Economic Data in Decision Making



- NHI Reform Committee recommended to use economic data in decision making of drug reimbursement and pricing (Oct. 2004)
- Related law was introduced in December 2006
- Canadian, Australian, and UK models have been closely studied

Positive List System Policy (PLSP)



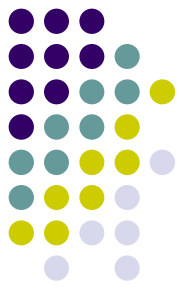
- The new system stipulates enhanced use of economic evaluation data for reimbursement decisions
- The new policy is aimed boosting appropriateness in drug expenditures.

Stages to Translate Economic Data into Decision Making

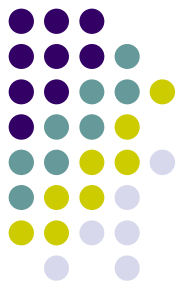


- Three stages
 - Registration & approval for new drug – by KFDA
 - Decision to enlist new drug in the formulary (when clinical effective + cost effective) – by HIRA (a body of KNHI)
 - Price negotiation – by NHIC (a body of KNHI)

Anticipated Impact of PLSP



- Consumers
 - Better-off with improved access to cost-effective pharmaceuticals
- Insurance authority
 - Purchase health outcomes, not products
 - i.e., pay more only if gain more
 - More efficient allocation of scarce financial resources
 - Rationality of drug expenditure would be enhanced



- Pharmaceutical companies
 - Financial burden for preparation of economic data
 - Price negotiation would not be easy to bear
 - Prolonged period of approval/reimbursement decision
 - Competition on the ground of price and outcomes (cost-effectiveness)
- Impact on domestic firms would be varied
 - Domestic firms conducting R&D have better chances to grow and enlarge market share internally and globally

Comment



- PLSP is a new initiative for Korea
 - PLSP and use of economic data is becoming a global trend
- It is desirable to implement PLSP gradually
 - To build further capacity required for new policy
- Impact on other Asian markets? May be some, forthcoming

Thank you !

