





South Korea

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The pharmaceutical system in South Korea in the in- and out-patient sector

New Medicine

Korea Food and Drug Administration (KFDA)

Task: Decision on authorization

Criteria: Safety, efficacy (Pharmacy act. no. 31)

Central Pharmacy Review Committee

Task: Recommendation on classification of Rx / non-Rx / OTC

Criteria: Safety (Pharmacy act. no.18)

Pharmacovigilance

: Post-marketing Surveilance (PMS)

- Reporting system for drug adverse effect
- Review on new medicine
- Drug reassessment

Health Insurance Review and Assessment Service (HIRA)

Task: Decision on registration in positive list

Criteria: clinical effectiveness, cost-effectiveness

Review of listed medicines

- new criteria of pharmacoeconomics is introduced since Dec. 2006.
- To date, HIRA has completed 3 out of 48 therapeutic groups in the reimbursement system (treatment of migraine, lipid lowering agents, treatment for hypertension)
- 14,599 products on positive list (as of Jan. 1. 2009)

Sub-committee for pharmacoeconomics

(* National Health Insurance Act)

National Health Insurance Corporation (NHIC)

Task: Price negotiation original medicine with pharmaceutical company Criteria: clinical effectiveness, cost-effectiveness, budget impact, internal-/ external price comparison, etc.

Pharmaceutical Benefit Review Committee / Ministry of Health and

Task: The committee adjust and set listed price for essential drugs if price

(* National Health Insurance Act, Guide on price negotiation)

Pricing of generic medicines

- 1st 5th generic : 68% of original medicine from 6th generic : 90% of lowest generics

The price of original medicines fall by 20% after entry of $\mathbf{1}^{\mathrm{st}}$ generic

- From Jan 2012, the pricing will be changed:
- Original : fall by 30%
- Generic: 59.5% of original medicine at first entry, 53.55% of original medicine 1 year after

- Price Review & Adjustment Price adjustment with criteria of pharmacoeconomics
 - Price-volume agreement (in condition of price negotiation)
 - Price survey and adjustment

negotiation fails. The minister notify the listed price.

Price cut

Welfare (MOHW)

No regulation for wholesalers' margin or mark-up Zero margin (until Sep. 2010) for pharmacies, clinics, hospitals - Reimbursement by actual transaction price, but since October 2010 M-ATP (Market based Actual

* Margin is gap between purchasing price and listed price to trigger price competition

Hospitals may have their own formularies which include medicines reimbursed or not reimbursed by the National Health Insurance (NHI) scheme

* Hospital's P&T Committee Hospitals over 300-beds have to proceed bid process to procure medicines from wholesaler or manufacture by law

From October 2010, large sized hospitals (usually teaching hospital) could get more margin under M-ATP

Transaction Price) allows margin as an income of pharmacies, clinics, hospitals

Co-payment for adult (6-64 year old) under National Health Insurance (NHI)Scheme (covers 97% of total population)

- Inpatient : 20% of cost (dispensing fee + drug cost)
- Outpatient : 30% of cost (dispensing fee + drug cost)

(From October 2011, 50% for outpatient, prescription issued by general hospitals and tertiary care hospitals for not severe cases such as cold, hypertension, diabetes, osteoporosis etc.)

Safety mechanisms for vulnerable person or catastrophic cost under NHI Scheme

- Age: Elderly (65 and over): 1,200won if the cost less than 10,000won, else 30% of cost, Children (under 6): 70% of adult's cost
- Disease: Cancer 5% (Jan. 2010), Rare disease 10% (Jul. 2009)
- Ceiling of Co-payment: patients exempt if the amount of co-payment reaches over 2, 3. or 4 million won per annum, according to contribution level (respectively low 50 percentile, medium 30% percentile, high 20 percentile)

PRICING

AUTHORIZATION /CLASSIFICATION

REIMBURSEMENT

DISTRIBUTION/ COPAYMENT