Drug Pricing and Reimbursement in South Korea

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Recent Pharmaceutical Policy Reform in South Korea: three P&R schemes and one legislation
OECD Health Financing Data

<table>
<thead>
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<th>OECD Ave.</th>
<th>Korea</th>
<th>US</th>
<th>France</th>
<th>Japan</th>
<th>Germany</th>
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<tbody>
<tr>
<td>Drug exp. annual growth rate ('98~'06, %)</td>
<td>5.9</td>
<td>12.3</td>
<td>8.5</td>
<td>5.7</td>
<td>3.6</td>
<td>5.5</td>
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<tr>
<td>Drug/NHE ('08, %)</td>
<td>17.44</td>
<td>23.9</td>
<td>11.9</td>
<td>16.4</td>
<td>20.1</td>
<td>15.1</td>
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</tbody>
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Source: OECD Health Data, 2009/2010

-NHE: including all health related expenditure
-Drug exp.: including insurance, OOP, OTC(vitamin, etc) expenses
-Within NHI, Drug exp/NHI exp. is about 29% throughout 2005-2010
-Japan: up to 2007

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Drug Reimbursement and Pricing

• Three schemes in place
  
(i) New drugs - HTA (economic evaluation, i.e., PE data): *value for money* sought for

(ii) Drugs in the formulary
  • Actual Transaction Pricing (ATP): list price downward adjusted toward actually transacted prices when ATPs are detected somehow
  • Price cuts, when illegal rebates are detected, by the amount of rebates: as a *penalty for rebate giving-taking*
  • Volume-price Agreement: for *controlling drug expenditure*

(iii) Off-patent generics: Equal Maximum Price (EMP): *controlling drug expenditure*
DPL (Dual Punishment Legislation)

- A recent legislation to oust illegal rebate giving-taking
- Amount of illegal rebates estimated to be around 20% of total drug expenditure (Korea Fair Trade Commission, 2010)
- Before the DPL, only the giving end (manufacturer/wholesaler) was punished, leaving the receiving end un-touched. Potential expectation of kick-back by receiving end (prescribers, hospitals, dispensers) remained unchanged, so illegal rebates persisted
- From 2011 on, however, a new legislation, DPL, mandates both rebate givers and takers are being punished (financially, imprisoned, license temporarily ceased/revoked)
Overview of EMP (Equal Maximum Price), started April 2012

100 Original

70 Original

59.5 Generic

53.5 5 Original

53.5 5 Generic

53.5 5 Generic

53.5 5 Generic

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Impact: Industry

- Generic market shifting likely to global companies
- Domestic industry will be withering
- For price competition, further policy option feasible, such as reference pricing
- Polarization of domestic firms: larger (R&D and improved/branded generics) vs. disappearing
- Surviving domestic firms could be, hopefully, more competitive in international markets
HTA for New Drugs

• HTA system introduced:
  • NHI now selects the drugs to be in the reimbursement list
  • Based on cost-effectiveness evidence
  • First HTA system in Asia (benchmarking UK, Canada, Australia)

• Technology developers submit a dossier based on the Korean Pharmaco-economic Guideline (KPEG)

• The new policy became effective from January 2008, after one year (2007) of grace period

• HIRA (HTA agency within NHI) in charge of review and reimbursement decision
Impact

• Policy aims to boost efficiency (cost-effectiveness) in drug expenditures
  • Improved patient access to cost-effective drugs
  • NHI budget to be used more efficiently
  • Value for money pursued
• Costly to drug industry with delayed (and sometimes negative) reimbursement decisions
• Nonetheless, pharma industry has been adjusting to this new environment
Procedure for Reimbursement Decision for New Drugs

1. Production or import of a new drug
2. K-FDA approval of marketing
3. HIRA: Decision on listing
4. NHIC: Negotiation on drug pricing
5. Inclusion of the drug in the formulary
How much is PE data (CEA) weighed in actual reimbursement decisions?

- PE data is one of many factors involved in value decisions
- However, it may well function as an entry point
- Which seems the case in many other countries of early HTA adopters
- This is why the pharma industry is so sensitive to PE regulation
Factors Considered in Reimbursement Decisions

- Available alternatives
- Budget impact
- Distributional impact
- Necessity/Severity of disease
- Reimbursement status in other countries
- HTA (Economic evaluation)
- Therapeutic benefit

Source: edited from Bae (2009)
Listing New Drugs with the HTA System

• Decisions to reimburse new drugs decreased while decisions not to reimburse increased
  • Between Jan 2007 and June 2010, a total of 248 drugs applied for reimbursement in the NHI
  • About 27% (66/248) were denied reimbursement, previously none denied
  • About 61% (40/66) of those denied drugs were due to lack of evidence or unacceptable cost-effectiveness (source: HIRA & Kim(2010))
Future of Korean HTA: refinement of policy and procedure continues by considering local health care context
Refinements

• Methodology
  • Use CUA when using QALY is proper
  • Use CEA when estimating QALY poses difficulty or improving QoL is not important

• QALY
  • Generic utility index preferred
  • Results from using patient specific index can be added
  • Justify use of a certain generic utility index
  • Do SA using an alternative index
  • In case of direct utility measurement, using SG or TTO recommended
Refinements (2)

• **Cost estimates**
  - Social perspective confirmed
  - But costs may not be too broad (i.e., issue of productivity loss)
  - In case of including payer perspective, costs of non-insured services could be mentioned as additional data

• **Experts opinion**
  - Must specify who are consulted, how they are chosen, why they are selected

• **Economic model of PM (personalized medicine) is expected**
Thank you!!