Transferability Issues: South Korea

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PEG (PE guideline) of South Korea

• PEG was developed in 2006 by HIRA, and revised in 2012
• In its PEG, HIRA takes an official position on transferability of data from other jurisdictions
Guideline for transferability
(source: EE Guideline for pharmaceuticals, HIRA, 2012)

• For services utilization and costs, local data should be used
• For clinical outcomes, application of results from foreign studies to domestic evaluation studies to be reviewed with considerations of
  – epidemiological environment,
  – treatment patterns, and
  – genetic backgrounds.
• A final report submitted should contain results from such reviews.

Guideline for transferability
(source: EE Guideline for pharmaceuticals, HIRA, 2011)

• If domestic incident rates or treatment patterns distinct from those of foreign countries’ and considered problematic
  – Sensitivity analysis (SA) required using local data.
  – Results from such SA to be presented along with base case analysis
• If data from multi-national trials used,
  – a base case analysis to be conducted using only domestic samples in the multi-national trials when sample size big enough
  – Otherwise, all the samples in multi-national trials are used for base case analysis, and a SA with only domestic samples should be added/submitted
In sum, transferability of foreign data

- Data on epidemiology of disease or baseline risk (occasionally transferable)
- Data of relative treatment effect (highly transferable)
- Data on resource use (not transferable)
- Unit costs/prices (not transferable)
- Health state preference values/utilities (occasionally transferable)

Use of foreign data in actual submissions

- PE studies submitted to HIRA often use data from other jurisdictions
- Categories of data used
  - Data on epidemiology of disease or baseline risk (often)
  - Data of relative treatment effect (often)
  - Data on resource use (not recommended, but occasionally used)
  - Unit costs/prices (never)
  - Health state preference values/utilities (often)
Use of DAM

- PE studies submitted to HIRA ever used decision-analytic models (DAM) developed in other jurisdictions
  - With no adjustment of model structure to reflect local circumstances (often)
  - With adaptation to reflect local circumstances (sometimes)
- HIRA accepts models developed in other jurisdictions, provided they are adapted to local circumstances

Use of international sources

- HIRA consults other international websites for information on EE results in case of new drug submissions
  - NICE
  - PBAC
  - CADTH(CDR, pCODR)
  - SMC
- HIRA sometimes consults PE studies from other jurisdictions
  - For general background information
  - To check validity of data or assumptions used in the local dossiers submitted by manufacturers
  - But, hardly refers to conclusions in other country PE studies
Survey response on availability of local data

<table>
<thead>
<tr>
<th></th>
<th>Non-industry respondents (n=67)</th>
<th>Industry respondents (n=37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shortage of local data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>100.0%</td>
<td>93.1%</td>
</tr>
<tr>
<td>No</td>
<td>0.0%</td>
<td>6.9%</td>
</tr>
<tr>
<td>The most insufficient local data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HRQoL</td>
<td>57.1%</td>
<td>35.7%</td>
</tr>
<tr>
<td>Clinical trial data from Koreans</td>
<td>7.1%</td>
<td>25.0%</td>
</tr>
<tr>
<td>Epidemiology</td>
<td>14.3%</td>
<td>21.4%</td>
</tr>
<tr>
<td>Cost of illness</td>
<td>14.3%</td>
<td>17.9%</td>
</tr>
<tr>
<td>Others</td>
<td>7.1%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>


Source of QoL weights used in submissions

- Among 19 dossiers with QALY as an outcome measure
- QoL weights predominantly obtained from previous studies (15 of 19 submissions, 79 %)
- Most of the studies (17 of 19 submissions, 89 %) conducted in foreign countries

Challenges

• Need public and private projects/investments to promote producing local data, especially on
  – QoL
  – Disease epidemiology
  – Cost of illness

• Regional cooperation could happen in limited scale?
  – For above data and possibly for even exchanging review results
  – Among Asian economies
  – With similar racial and cultural backgrounds
  – But, still some barriers (difference in level of HTA system, communication/language, practice patterns, among others) exist to overcome