

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 cost/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

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

Source: Bae EY, Hong JM, Kwon HY, Jang S, Lee HJ, Bae S, Yang BM. Eight-year experience of using HTA in drug reimbursement: South Korea. [Health Policy](#) 2016;120(6): 612-620.

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

Source: Bae SJ et al., Sourcing Quality-of-Life Weights Obtained from Previous Studies: Theory and Reality in Korea, [The Patient](#) 2014;7(2):141-50.

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