



HTA of Medical Devices in Asia Pacific

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Agenda

- Background
- Pharmaceuticals vs Medical Devices
- HTA scenario in a few Asia-Pacific countries for Medical Devices

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Background

- In Asia-Pacific, Medical device expenditures account for only a small proportion (between 3% and 6%) of total healthcare spending per capita.
- Definition of medical devices: varies in complexity under different health systems
- Reimbursement and healthcare spending issues also a barrier.

Skinner B.J. Medical Devices and Healthcare Costs in Canada and 65 Other Countries, 2006 to 2011. Canadian Health Policy, May 9, 2013. Toronto, Canada: Canadian Health Policy Institute, 2013.

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HTA for Pharma vs Med Devices

- Evidence base (RCTs vs Observational studies)
- No general consensus
- Efficacy- For Medical Devices depends on the user ("Learning curve")
- Often diagnostics: difficult to measure health outcomes
- Wide economic implications for the organisation
- Pricing depends on procurement orders

Drummond et al. 2009. Economic Evaluation for Devices and Same or Different? Value in Health

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Japan

- National health insurance (multiple payer)
- Decision maker is MLHW and *Chuikyo*
- Medical device prices are determined similar to drugs.
- Price applies to category (not product) of medical devices (“similar function category”)
- Depending on the innovation, medical devices can be in existing category or if innovative, creation of a new reimbursement category is allowed
- Price of Innovative devices are calculated by :“Similar category comparison method” or “Cost calculation method”

Shiroiwa et al. 2017. New decision-making processes for the pricing of health technologies in Japan: The FY 2016/2017 pilot phase for the introduction of economic evaluations. Health policy

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South Korea

- HTA has a key role: The revised Medical service act 2006 paved the way for new Health Technology Assessment (nHTA) from April 2007.
- Unlike drugs, the medical devices HTA is less well understood.
- Assessment tool for nHTA is systematic review of the safety and efficacy
- Formal economic evaluation is not required
- Revision of the nHTA for medical devices due to conflict between stakeholders

Lee and Salole. Market Access for New Medical Technology in South Korea: A case study in HTA Policy Development and Implementation 2016.

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Singapore

- The Agency for Care Effectiveness (ACE) published the first HTA for medical device in March 2018.
- Structure of the guidance was similar to that of drugs
- An additional section of “organisational feasibility” was added
- It is unclear which devices will undergo HTA in Singapore
- HTA for medical devices is still evolving

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China, Thailand and India



- Thailand has Universal Health Coverage and has a well established HTA process
- Health Intervention and Technology Assessment Program (HITAP)- non-profit autonomous organization under MOH since 2007
- Follows rigorous HTA assessments. No particular difference between pharmaceuticals and medical devices.
- China and India both have HTA guidelines being framed by the respective government stakeholders in association with iDSI and HITAP.
- For China, the China National Health Development Resource Centre (CNHDRC) and for India, the Department of Health Research (DHR), Govt of India are the main national bodies.
- India has Kalam Institute of Health Technology as a dedicated organization for medical devices HTA and policy analysis.

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New Zealand

- For Medical Devices, the Pharmaceutical management agency (PHARMAC) is the nodal body.
- Conceptually, the HTA framework remains similar for drugs and devices.
- PTAC, the Pharmacology and Therapeutics Advisory Committee, advises PHARMAC on priority setting and methodological aspects.
- The information to support an assessment against the criteria comes from pharmaceutical companies, clinicians, the public and their own HTA analysts.

<https://www.otago.ac.nz/wellington/otago070001.pdf>

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Conclusion

- Medical Devices are an important component of the health care system.
- But the HTA scenario is geared towards pharmaceuticals.
- The question remains:

What is the way forward for Health Technology Assessment in Medical Devices?

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