NECA National Evidence-based Healthcare Collaborating Agency

ISPOR Asia Pacific 2018, 8-11 September, Tokyo, Japan

Medical Devices HTA in Korea

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HTA system overview

Flow of benefit decision in NHI

Approval in use
↓
Reimbursement assessment
↓
Pricing
↓
Final decision

	New health technology categories		
	Medical procedure	Medical device	Drug
Safety & efficacy	NECA	MFDS	MFDS
Cost-effectiveness	HIRA	HIRA	HIRA
Affordability	HIRA	HIRA	NHIS
Final decision		MOHW	

MOHW (Ministry of Health and Welfare), MFDS (Ministry of Food and Drug Safety), HIRA (Health Insurance Review & Assessment Service), NHIS (National Health Insurance Service), NECA (National Evidence-based Healthcare Collaborating Agency)

Jang J. HTA in Korea – focused on Drug and Reimbursement system, 2013. 10. 4

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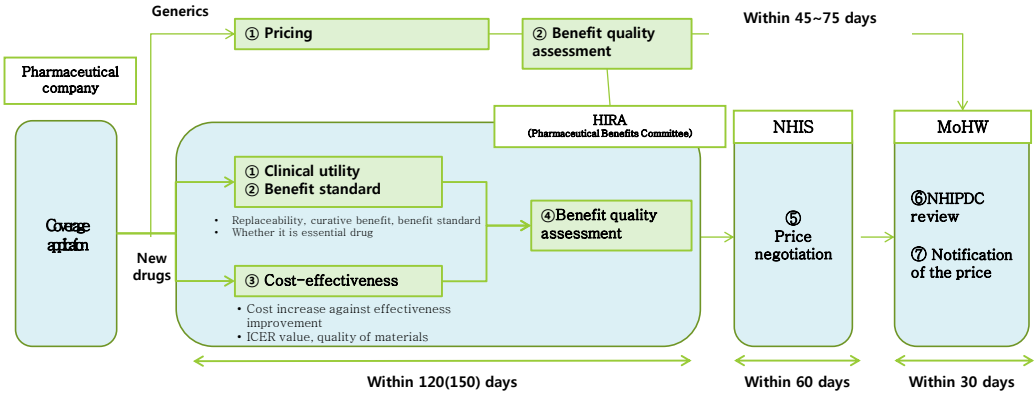
Pharmaceuticals HTA 2006

- **NHI introduced positive list system for the new drugs based on cost-effectiveness**



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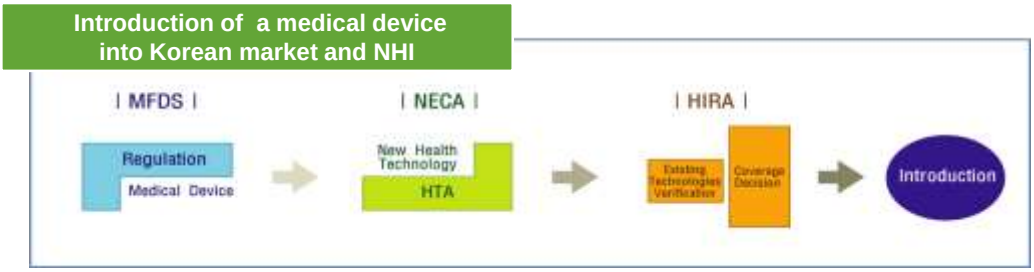
Medical devices HTA

- **Health Technology Assessment for new procedures with medical devices (2006)**
  - Systematic review for safety and effectiveness of procedures (nHTA)



- MFDS : Ministry of Food and Drug Safety
- NECA : National Evidence-based Healthcare Collaborating Agency
- HIRA : Health Insurance Review & Assessment Service

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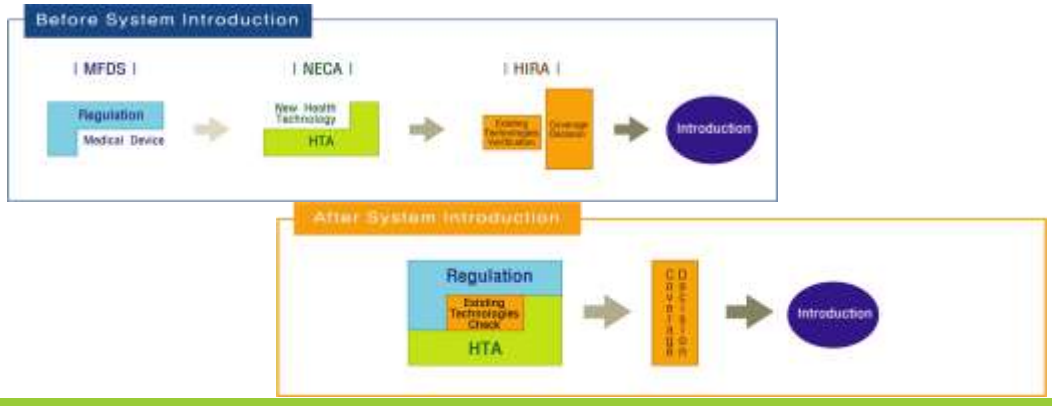
Medical devices HTA improvement

- **Parallel process of approval, nHTA, and review for NHI coverage introduced in 2014**
  - Improve patient accessibility to shorten the process



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Medical devices HTA improvement 2

- **Conditional use of health technologies (2013)**
  - Government supports health interventions for safety and effectiveness evidence generation
  - Urgent need for rare and severe diseases without alternative treatments
  - Only in designated hospitals during prescribed time period

Technology	Period
Autologous Platelet Rich Plasma Application	2014.10~2017.09
Therapeutic Use of Autologous Peripheral Blood Stem Cell in MI	2014.10~2017.09
Pancreatic Cancer Irreversible electroporation	2015.09~2018.08
PET-CT for C-11-Methionine	2016.08~2019.07
Autologous Platelet Rich Fluid to Vitreous body	2016. 11~2019.10
Smart PrePZ BMAC to Diabetic Critical Limb Ischemia	2018.01~2020.12
Autologous Adipose-Derived Stem Cell Therapy	2018.05~2021.04

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New policy for medical devices

- **Fast tract for In Vitro Diagnostics**
  - nHTA exemption, and RWE
  - **Early dialogues from development stage with related agencies**
  - development stage: MFDS
  - nHTA: NECA
  - NHI coverage: HIRA
- **Real One-stop service system**
  - Unified service team: MFDS, NECA, and HIRA
  - Parallel process of regulatory review and nHTA
- **R&D support for evidence generation**

Differences with Pharmaceutical HTA

- Less mature industry
  - less experience preparing submission
  - lower quality evidence (historically, and ethically difficult)
- Less obvious patent protection
  - short life-cycle
  - frequent functional, minor improvements
- Evidence fundamental
  - pharmaceutical oriented researchers, experts
  - data insufficiency (weaker surveillance system)

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Challenges

- New policies are focusing on non-invasive leading edge medical devices
- Guidelines for early dialogues need to be developed
- RWE generation supported by government and industry
- RWE generation needs stronger multidisciplinary approaches and experts of research methodology and data
- International cooperation for improving HTA capacity is important

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Thank You!!