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Health Technology Assessment of Medical Devices in Korea

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NECA

Medical devices

- Less mature industry
  - Less experience preparing submission
  - Lower quality evidence (historically, and ethically)
- Less obvious patent protection
  - Short life cycle
  - Frequent functional, minor improvements
- Insufficient evidence fundamental
  - Pharmaceutical oriented researchers, expers
  - Data insufficiency (weaker surveillance system..)

NECA

Strong regulatory HTA

- nHTA introduced in 2006
  - Influenced by evidence-based medicine
  - Focusing on safety and effectiveness of newly introduced medical procedures
  - Systematic review for safety and effectiveness
  - Most of procedures are related to medical devices
  - After market approval, before NHI coverage
  - Delayed market access

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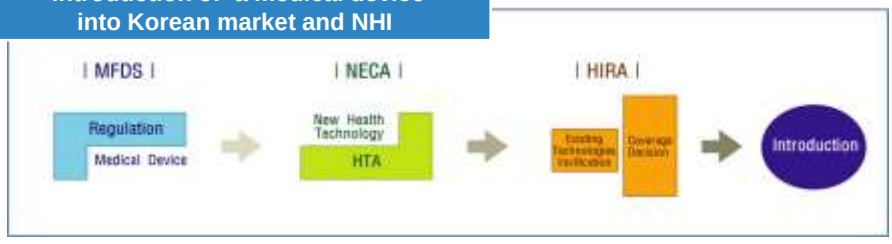
Strong regulatory HTA

- nHTA take almost 1 year after market approval

Introduction of a medical device into Korean market and NHI



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

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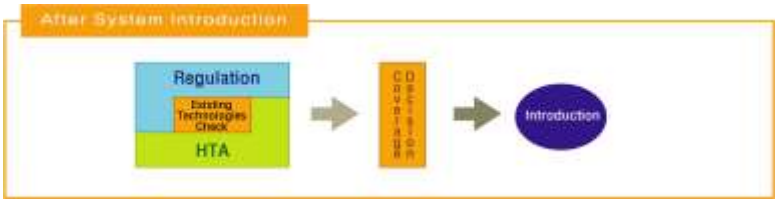
One-stop system

- Parallel process of approval, nHTA, NHI coverage introduced in 2014
  - Improve patient accessibility by shorten process



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Conditional use for evidence generation

- Introduced in 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
  - RWE generation
- Early dialogues from development to NHI coverage
  - Each stage with MFDS, NECA, and HIRA
- One-stop service system
  - Unified service team
  - Parallel process of regulatory review and nHTA
- R&D support for evidence generation

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Challenges

- Scientific evidence for invasive medical devices
  - In debate
  - RWE generation and use system with strong research infrastructure and patient protection
  - Who will pay for RWE?
- International cooperation
  - Harmonization of regulatory affairs
  - HTA and research capacity building

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Thank You!!