



# Korean Government's Policy Direction for Promotion of Korea's Health Industry (Pharmaceutical & medical device)



보건복지부  
MINISTRY OF HEALTH & WELFARE

# 1. Importance of HT industry

## 1 New growth engine in Post-IT era

- Growing demand for HT is expected due to aging population, rising income, and strong interest in health.

## 2 Fundamental solution for tackling rising medical cost

- Korea ranks no.1 in medical cost growth rate (8.7%), and no.2 in drug expenditure growth rate (10%) among OECD members.

## 3 Far-reaching effects on economy

- The HT industry can lead related industries, including manufacturing, education, finance, and communications, and address the issue of economic growth without employment

# 1. Importance of HT industry

❖ Developed nations are fostering the HT industry as a strategic industry in the post-IT era.

U S

NIH Roadmap (\$31.2 billion in 2010, 50 thousand projects in 3 thousand institutions), commercialization of medical R&D

E U

7th Framework (FP-7 Health) investing €9.5 billion, IMI (€2 billion, pharmaceutical companies accounting for 50%)

Japan

New strategy for growth (medical tourism, development of medical institutions, etc.), supporting R&D in five major sectors in response to the aging population

❖ **US HT industry expected to create more jobs than any other sectors**



Source: CEA aggregations of Inforum LIFT Model Industry Projections.  
Note: Totals do not include jobs in agriculture, forestry, and fisheries.

## 2. Chronology of Korea's policies for promotion of HT industry

- ▶ In 2007, the “Strategy to enhance the competitiveness of pharmaceutical industry” was announced.
- ▶ In 2009, the bio pharmaceutical and medical device industries were designated as “New Growth Engines.”
- ▶ In 2010, the “plans to bolster the competitiveness of the medical device industry” were announced.
- ▶ In 2011, the “Columbus project” to advance into the North American health care markets was initiated.

## 2. Chronology of Korea's policies for promotion of HT industry

- ▶ In Jan. 2012, the “2012 plan to strengthen the competitiveness of the pharmaceutical industry” was established.
  - Implemented the 『Special Act on Pharmaceutical Industry Promotion and Support 』 (Mar.)
  - Established the “Vision and strategy for the pharmaceutical industry”(briefed President, Aug.)
- ▶ In 2013, launch of the new Park administration
  - ① Building 『creative economy』 is a policy direction of the new administration
  - ② 『Fostering HT industry as a new growth engine』 is a national agenda



### 3. Recent developments of policy for promotion of HT industry

1) **Comprehensive approach to create a health industry eco-system**

2) **Highlighting a role in leading 『creative economy』**

3) **Entering the global market**

※ **With focus on building technology collaboration with leading companies in a global trend of open innovation**

# 4. Policy for promotion of pharmaceutical industry: background

## Changing global pharmaceutical environment

### 1) Growth in mid- to long-term expected



- Biopharmaceutical
- Emerging markets
- Generics

2011

2016

16%

18%

20%

30%

25%

35%

### 2) Restructuring of global pharmaceutical companies and spreading open innovation

- o **Emergence of strategic cooperation** in response to patent expiration of blockbusters and shrinking productivity of R&D

\* e.g.) TEVA : established production lines of biopharmaceuticals : US Sicor ('04), Cephalon ('11)  
built a foothold for entering local generic markets : Spain Bentley ('08), Japan Taisho ('09),  
Germany Ratiopharm ('10)

**Discovering markets for quality generics and expanding opportunity to develop innovative drugs through partnership with multinational companies**

## 4. Policy for promotion of pharmaceutical industry: background

### Rapidly changing business environment in Korea

#### 1) Generic drug price adjustment, eliminating unfair distribution practices

- Price reduction of generics by 14% for drug price rationalization (Apr.1, 2012)
- Implementation of extensive measures to eradicate illegal rebates, which have been obstacles to innovation of the pharmaceutical industry

#### 2) Pushing ahead with a vision and strategies for promotion of the pharmaceutical industry as a new growth engine

- Designated biopharmaceuticals as a new growth engine (Jan. 2009), Implemented the 「Special Act on Pharmaceutical Industry Promotion & Support」 (Mar. 2012)

#### 3) Companies actively engaging in strategic partnerships with other companies to enhance competitiveness

- In 2012, domestic companies agreed on M&A or strategic partnership with overseas companies.
  - : Kunwha-US Alvogen M&A (Sep.2012)
  - Handok-Israel Teva formed a joint venture (Dec.2012)

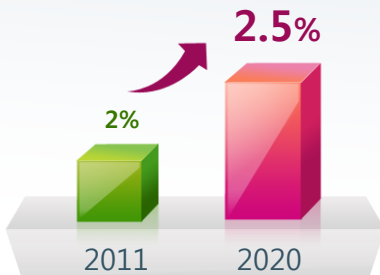


# 4. Policy for promotion of pharmaceutical industry: vision and goal

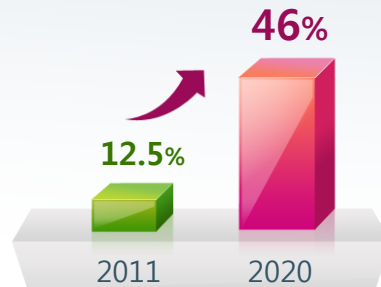
Goal : joining **top 7 pharmaceutical powerhouses** by 2020

## Market scale & export

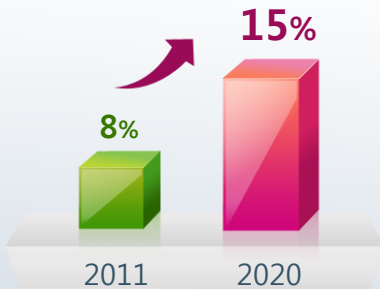
### Global market share



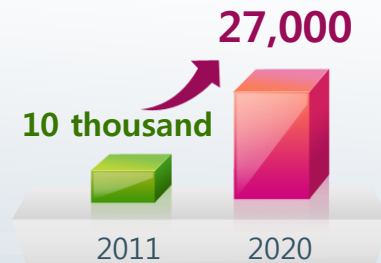
### Export



### R&D investment



### Professionals



## Major company and product

### Major 50 companies



### Blockbuster



## **4. Policy for promotion of pharmaceutical industry: major strategies**

### **1) Active and open technology innovation**

**① Increasing the nation's R&D investment in the pharmaceutical sector:  
investment of ₩249.3 billion in 2013 (₩14.9 billion increase year on year)**

**- With particular emphasis on the development of high-tech products, such as global innovative drugs and stem cell treatment**

**② Expanding incentives to encourage companies to set first priority on R&D investment**

**- Tax credit: expansion of the scope of corporate tax on R&D investment in new drug development in 2013 (vaccines, phase 1 and 2 clinical trials, innovative IMDs)**

**- Finance of clinical trial costs: extension of the tariff exemption period on imported drugs for clinical trials (from 2012 to 2015)**

## 4. Policy for promotion of pharmaceutical industry: major strategies

### 2) Bolstering global competitiveness of companies

- ① Providing funds to help companies engage in M&As with overseas companies, developing technology partnership, and securing local marketing networks and production facilities
- ② Financing overseas technology development funds
  - Providing loans for phase 3 clinical trials conducted overseas for innovative drugs and biosimilar (Korea Eximbank)

### 3) Improving institutional predictability

- ① Reforming the pricing mechanism for innovative drugs
  - Streamlining the listing process of innovative drugs
  - Enhancing consistency of evaluation standards and improving the guidelines for negotiating with the NHIC (Mar. 2013)
- ② Making the product approval process more efficient by taking into account specific attributes of drugs
  - Expansion of fast-track approval

# 4. Policy for promotion of pharmaceutical industry: major strategies

## 4) Establishing a large and transparent market

- ① Building a one-stop service system for global market entry
  - Providing support tailored to each phase of the drug development and commercialization process, including R&D of innovative drugs, information collecting and consultancy for global market entrance, patent and approval, and overseas marketing
- ② Expanding G2G cooperation
  - Holding Pharm-Fair on a frequent basis targeting major strategic nations (inviting persons in charge of approval and influential buyers)
  - Establishing bilateral cooperation with nations that Korean companies are likely to enter (Poland, Columbia, Russia, Brazil, UAE, etc.)
- ③ Helping domestically developed medicines advance into pharmaceutical procurement markets of international organizations, including UN, UNITAID, and WHO PQ (provision of information)
- ④ Ensuring transparent distribution order in the nation
  - Continuing efforts to eliminate illegal rebates, such as disclosure of rebate-offering company list, suspension of law-breaking hospitals and pharmacies (e.g., by revising the Medical Service Act and Pharmaceutical Affairs Act)
  - Reducing the accounts payable payment period for medicines to three months (e.g., by revising the Pharmaceutical Affairs Act)

## **4. Policy for promotion of pharmaceutical industry: major strategies**

### **5) Establishing infrastructure for industrial support**

#### **① Training**

- Short-term: 「PB 300 Project」 to attract overseas experts
- Mid- to long-term: 「PB 8,000 Project」 to train key experts

#### **② Creating infrastructure organizations to support new drug development**

- Fostering contract research organizations
- Developing TLO (Technology Licensing Office) to facilitate commercialization of R&D outcomes

#### **③ Establishing research-based hospitals**

- \* Building an open research system linking industry, academy, and institution within a hospital,  
1<sup>st</sup> designated research-based hospitals (10 hospitals in Mar. 2013)

#### **④ Building medical complexes and inviting companies to participate in the complexes**

- \* Construction of core R&D facilities will be completed by the end of this year (₩194.3 billion in 2013)



# 5. Policy for promotion of medical device industry: background – situation in Korea

## 1) Incompetent eco-system of medical device industry

### Market scale (2013)



### Company size (2013)

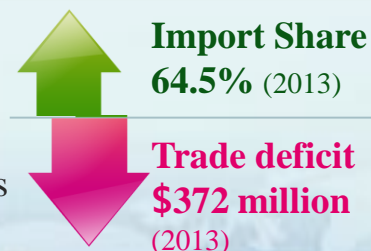


### Technology trend (2011)



Mainly manufacturing cheap and simple products for general use

- Weak business governance, lack of global competitiveness



- **Generally** manufacturing household products rather than cutting-edge products
- **Lack** of an ecosystem where companies can develop into high-tech companies
  - \* closed environment lacking linkage with other industries

# 5. Policy for promotion of medical device industry: background – situation in Korea

## 2) Recent positive developments under unfavorable environment

### Growth potential in IT convergence products

- Highly advanced Korea's IT-based products, such as ultrasound imaging device, dental equipment, and PACS
  - Ultrasound imaging device manufactured by domestic companies most ranking no. 1 market share in global obstetrical and gynecological markets
  - Dental equipment ranking top led by such as Vatech and Osstem Implant
  - PACS: one of the top 2 and highest penetration rates with domestically developed technology



### Improving R&D infrastructure and technology

- **Rising R&D investment in medical device industry made by public and private sectors**



- **Narrowing the technology gap over the last three years (2008-2010)**

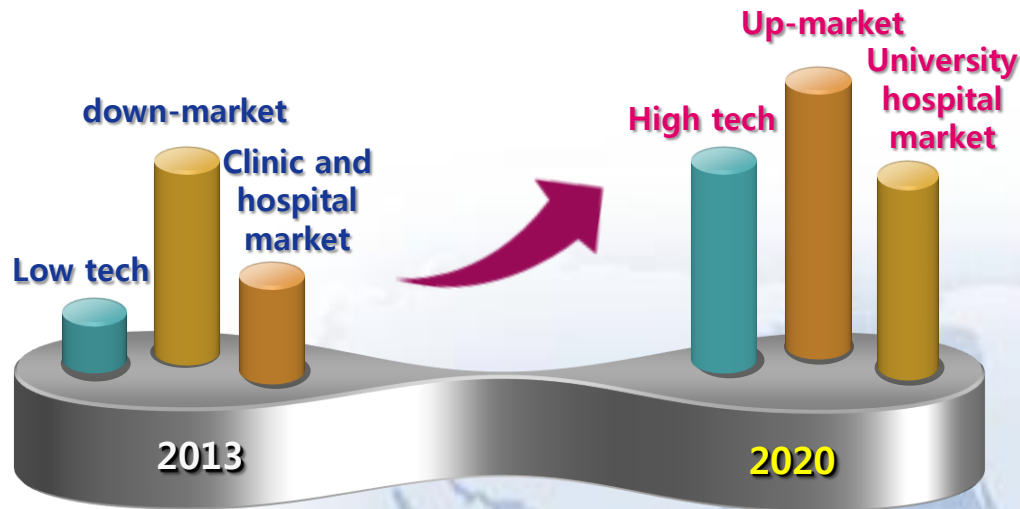
- Medical sector (1.9 yrs),
- Bio sector (1.7yrs)
- Medical device development technology (3.5%),
- Biochip sensor technology (4.7%)



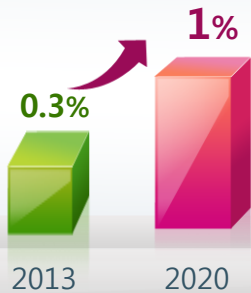
# 5. Policy for promotion of medical device industry: vision and goal



Global competitiveness: 11<sup>th</sup> (2013) → 7<sup>th</sup> (2020)



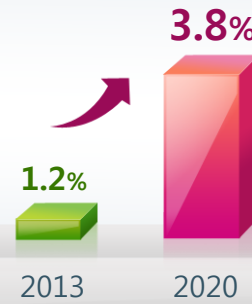
Production (percent of GDP)



Employment



Global market share



Top 100 companies



# 5. Policy for promotion of medical device industry: strategy

## 1) Active and open technology innovation

### ▶ Increasing national R&D

- Doubling the current R&D investment of the government by 2017

- Proactive investments aiming to dominate the global market

\* Mid- to long-term projects on a large scale for development of high-end medical devices and medical devices specialized in niche markets, support for assessment and convergence products to dominate new markets

## 2) Bolstering global competitiveness of companies

### ▶ Encouraging specialization of companies: designating and supporting leading and promising companies

\* R&D/tax credit/finance under the “Medical Device Industry Promotion Act”

## 5. Policy for promotion of medical device industry: strategy

### 3) Improving institutional infrastructure reasonable and efficient

#### ① The “Medical Device Industry Promotion Act”

\* Foundation for introduction of the accreditation system for leading and promising products, and a five-year-master plan to foster the industry

#### ② Supporting early introduction of new products to markets: streamlining the pre-marketing process, such as approval and HTA

\* Tentatively assessing and designating new health technology which is proven safe but lacks evidence of effectiveness, thereby allowing hospitals to review the early adoption of the technology

### 4) Establishing a large and transparent market

#### ① Growing confidence in domestically manufactured medical devices: supporting tests of new products

#### ② Supporting global marketing: participation in establishing new hospitals in Middle East, Southeast Asia, Africa, etc.

\* G2G cooperation to facilitate export of hospitals and to streamline the approval and customs process  
\* Inviting MDs from Southeast Asia and training for adoption of outstanding domestically produced medical devices

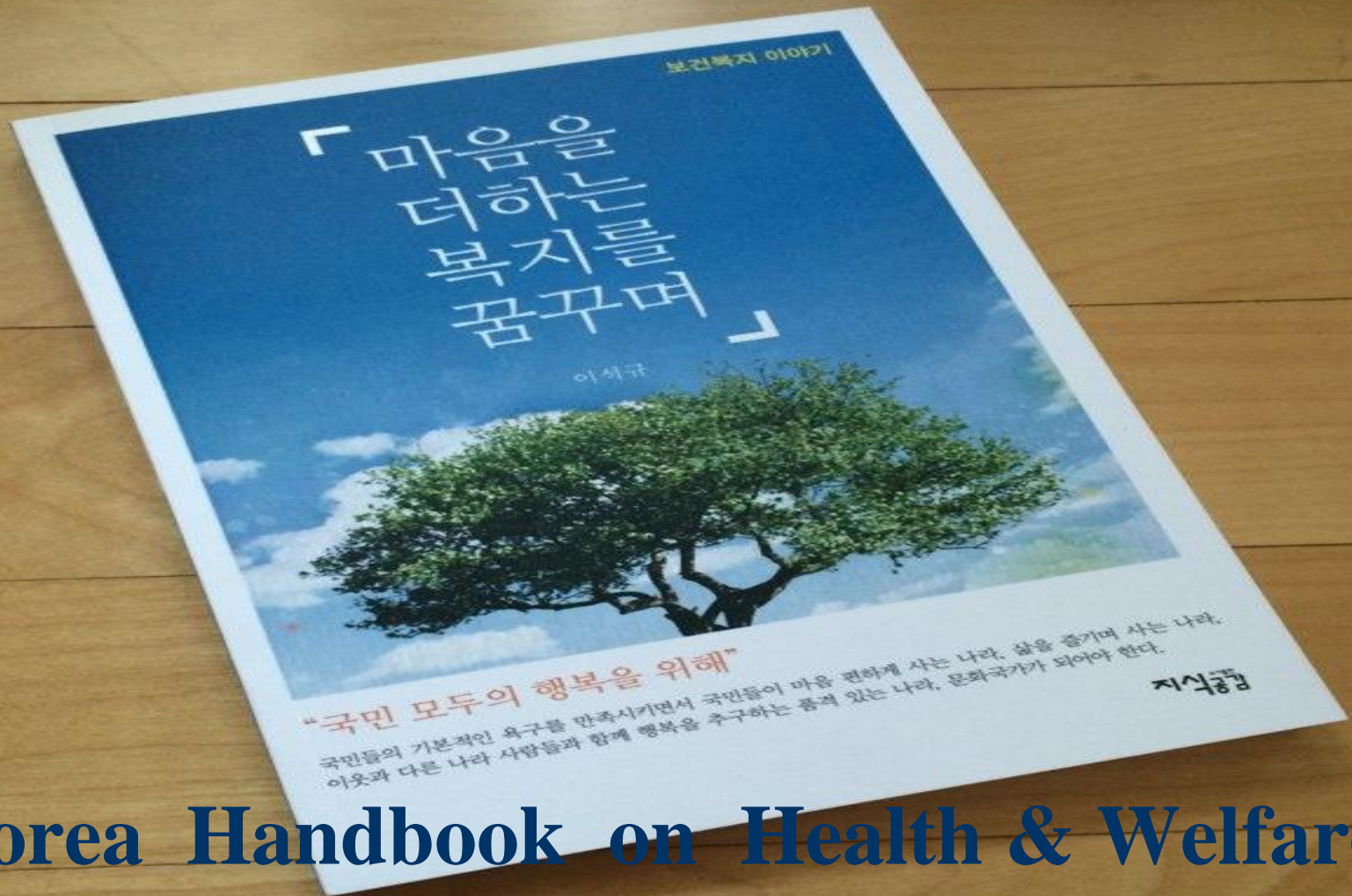
#### ③ Ensuring fair and transparent distribution order: eliminating illegal rebates and false claim of reimbursement



## **5. Policy for promotion of medical device industry: major strategy**

### **5) Building infrastructure for industrial support**

- ① Attracting and training promising professionals to develop and market medical devices**
  - Supporting establishment of graduate schools specialized in the medical device industry**
  - Encouraging small and mid companies to utilize MDs**
  
- ② Accelerating efforts to invite companies by creating medical complexes**
  - Completing construction of core facilities, including support center for high-tech medical device development (prototype development), animal lab (non-clinical support), and clinical trial center (clinical trial)**
  - Partnering with the “Wonju Medical Industry Techno Valley” and the “Gumi Medical Device Component Manufacture Complex”**



# Korea Handbook on Health & Welfare

- Dreaming of mindful Welfare Society -

Lee, Suk Kyu





*Thank you for your attention.*

