

 보건복지부	<h1>Press Release</h1> <p>Release on the morning of Wednesday, May 22</p>		
	Released on May 22, 2019 (9 pages total)		
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Bio-health Industry to Achieve People-centered Innovative Growth

- The Korean government announced “Innovative Strategy on the Bio-health Industry” -

- Increase the global market share three times, hit USD 50 billion of export, and create 300K jobs
- Establish five big data platforms, raise government’s R&D investment to KRW 4 trillion, and improve regulations on review and approval
- Develop innovative new drugs to address rare diseases and protect health and life of the people

□ The Korean government announced “Innovative Strategy on the Bio-health Industry” on May 22, 2019. The announcement was jointly made by relevant ministries including the Ministry of Health and Welfare (MOHW), the Ministry of Economy and Finance (MOEF), the Ministry of Science and ICT (MSIT) and the Ministry of Trade, Industry and Energy (MOTIE).

* Time & Date: 10:50~11:35, May 22, 2019

** Participants: 300 attendees from relevant Ministries (Ministers of the MOHW, the MOEF, the MSIT, the Ministry of SMEs and Startups, Minister of the MFDS, and the Commissioner of the Korean Intellectual Property Office) and involved industries

□ The bio-health industry has **enormous growth** and **employment potential**, serving as a **future key industry** which contributes to **public health**. Major content of the Strategy is as follows;

○ Utilize **big data**, **expand investment in policy financing and R&D**, and improve regulations to **match global standards** under a strategy to create an **innovative eco-system** ranging from technology development, approval, production, market launch of the bio-health industry which is biopharma-based,

- Establish **“National Bio Big Data”** on up to **a million people** to be utilized in R&D on personalized new drugs and medical technology by **2029**. Raise government investment in R&D to **over KRW four trillion** to develop innovative new drugs and medical devices by **2025**.

- **Reform regulations** which do not match global standards including the approval period for medicines and medical devices to **expand the global reach** of the industry, while **fully protecting the safety and life of the people**.

- Develop a **master plan on nurturing professionals** in the bio-health field in line with the industry demand, create a cooperation mechanism for **open innovation** between leading companies and startups and venture firms, and encourage the use of **domestic raw and subsidiary materials** to seek joint growth of relevant industries, and

- Support joint export of advanced hospital systems and hospital information systems, medicines, medical devices, and stem cell plants.
- The government plans to intensively nurture the bio-health industry into one of the next key industries of Korea along with non-memory semiconductors and future automobiles. This plan sets goals of increasing the global market share of the bio-health industry three times, hitting the export of USD 50 billion, and creating 300,000 jobs.
 - * “The bio-health industry” comprises manufacturing industries including medicines and medical devices and a service industry of health management.
- “The development of the bio-health industry will lead to people-centered innovative growth by protecting the health and life of the public, promoting national economic growth, and creating jobs,” and
 - “As Korea boasts world-class IT infrastructure, hospital systems, medical data, and skilled personnel, Korea will be able to fulfill its potential to the fullest and grow into a global bio-health powerhouse,” said Neunghoo Park, Minister of Health and Welfare.

<Reference> Main Tasks under the Innovative Strategy on the Bio-health Industry

Reference

Main Tasks under the Innovative Strategy on the Bio-health Industry

① (Technology Development Stage) Create an innovative ecosystem of bio-health technology development

① Establish five big data platforms for technological innovation

- (Bio big data) Create "National Bio Big data" on over a million people and develop new drugs by utilizing data such as genome information to combat diseases and advance the bio-health industry
- (Data-centered hospitals) Build a big data platform on medical information per hospital in accordance with the existing laws and support the utilization of the data in new technology development
- (Platform for new drug development) Support discovering of new drug candidates on an AI platform to reduce the period and cost of new drug development
- (Big data on bio patents) Analyze and open big data on patents in the field of bio-health
- (Public big data on public health) Devise a system to open and utilize big data from public agencies including the National Health Insurance Service

- (Innovation hub) Establish an Office of Medical Technology Cooperation and a technology holding company at research-centered hospitals, introduce an accreditation scheme for research-centered hospitals to gradually increase the number of the hospitals
- (Hospital-corporation joint research) Build open labs and encourage joint research by the industry, academia, researchers, and hospitals

③ Increase government investment in R&D on innovative drugs and medical devices

- (Expand R&D investment) Raise government R&D investment in bio-health to over KRW 4 trillion per year by 2025
 - * From KRW 2.6 trillion in 2017 to KRW 4 trillion in 2025
 - (New drugs & medical devices) Develop promising medical technologies that will lead the global market such as targeted cancer drugs, stem cell drugs, and medical devices with technological convergence
 - (Future medical technology) Establish and support an Office of Future Medicine R&D at hospitals with advanced research infrastructure to conduct research on future medical technologies including precision medicine
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- (Financial support) Utilize a scale-up fund for the industry which will raise KRW 15 trillion from 2018 to 2022 and policy financing of KRW 2 trillion over the next five years to promote private investment in the bio-health industry
 - (Tax benefits) Expand customized tax benefits to bio-health companies including providing tax cuts for R&D on new growth engines to biobetters
 - (Accounting & Listing) Come up with customized standards on accounting, disclosure, and listing including assessment standards on unlisted bio-companies

② (Review and Approval Stage) Improve regulations to match global standards

① Strengthen the expertise of the Ministry of Food and Drug Safety and advance the pace of review and approval processes

- (Improve expertise) Hire dedicated personnel through raising commission fees of review and approval to a reasonable level and strengthen the expertise of those in charge of review
- (A report system on changes in clinical trials) Change the approval on changes in clinical trials to a report system for a fast implementation of clinical trials and introduce a pre-consultation scheme
- (Introduce a fast track) Adopt a priority and fast track for new drugs developed by innovative pharmaceutical firms and provide fast classification and pre-consultations on innovative products with technological convergence from a development stage

- (Regenerative medicine) Introduce safety measures including an institutionalization of clinical research on regenerative medicine which is differentiated from clinical trials on medicines and long-term follow-ups by the Korean Center for Disease Control & Prevention
- (Biomedicines) Strengthen safety management of cutting-edge biomedicines at all stages by establishing a new institution on "management business on human cells, etc." and introducing mandatory short tandem repeats (STR)

③ Advance regulations to match global standards

- (Discover & Improve regulations) Operate a consultative body on bio-health industry development and regulatory reform which consists of relevant ministries and the private sector and develop a roadmap for improving regulations per sector in 2019
- (Regulatory exemption for empirical evidence) Utilize a regulatory sandbox in cases including an expansion of items of Direct-to-Customer (DTC) genetic testing and improve laws and regulations once the effectiveness is proven
- (Regulation-free zone) Designate specific areas as a regulation-free zone and provide opportunities to carry out large-scale empirical studies on products of which commercialization is difficult because of regulations
- (Assessment on new medical technology) Organize a consultative body for regulatory reform on medical devices, examine the implementation progress of the "Regulatory Reform Plan" announced in July 2018 and discover additional tasks

- (Joint IR) Support joint IR for foreign investors by leading companies and startups and venture firms
- (Support startups) Strengthen support for commercialization at all stages through the Korea Biohealth Innovation Startup Center (KBIC) and favor the bio sector when selecting an operating company of TIPS (Tech Incubator Program for Startups)

② Nurture professionals in the bio-pharma field

- (Production professionals) Establish a bio-pharma education system that role models that of advanced nations, open a center to foster professionals in bio-processing, and develop a master plan for nurturing professionals
 - (Research personnel) Nurture medical scientists with creative convergence and increase the number of personnel who support lab research
 - (Competent professionals in the 4th Industrial Revolution) Nurture biomedical global talent by increasing the number of graduate schools of AI, fostering data experts, and AI-based new drug development
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- (Use domestic raw materials) Use domestic raw and subsidiary materials and equipment necessary to operate the world's 2nd largest biopharma production facility to reduce costs and lead joint growth of industries in the value chain
 - (Regenerative medicine-based technology) Develop key technology on raw and subsidiary materials such as cell culture media to develop cell treatments

① Support a market launch

- (Adopt new technology) Encourage the use of new technologies including digital healthcare devices in medical institutions to improve the quality of medical services provided by doctors in person and the satisfaction level of patients
 - (Wider use of bio-health products) Encourage the use of bio-health products in public medical institutions by designating large hospitals as assessment centers for domestic devices, raising the market confidence and improving the performance of the devices, and providing additional credits in government R&D investment
 - (Support innovative devices) Come up with a comprehensive support system and build infrastructure in line with the Act on Promoting Medical Devices and In-Vitro Diagnostics (will be in force in May 2020)

- (Plant export) Support plant export (a turn key method) of stem cell drugs which require direct extractions of a patent's cells and of which expiration date is short
- (Package export) Encourage package export of hospital system, hospital informatization, medicines and medical devices and dental training and dental devices

- (Expand mutual recognition) Expand mutual recognition agreements of GMP with major countries to reduce the time and cost for review and approval when Korean companies make inroads in overseas markets
- (Local infrastructure) Deploy personnel and establish in foreign countries for G2G cooperation, administrative support on review and approval, and information gathering
- (G2G cooperation) Promote the export of medicines and medical devices combined with Korean medical systems