Press Release

Ministry of Health and Welfare,
Republic of Korea

Date: March 10, 2023
Contact: Chi, Younsuh / Foreign Media Spokesperson(+82-44-202-2048 / cys12@korea.kr)

Announcement of 「New Bio-Health Industry Regulation Innovation Plan」

☐ On Thursday, March 2, the Ministry of Health and Welfare, led by Minister Cho KyooHong, announced the New Bio-Health Industry Regulation Innovation Plan at the Third Regulatory Innovation Strategy Meeting (presided over by the prime minister).

○ The Plan comes on the heels of the strategies for creating new bio-health markets announced at the interdepartmental meeting held on February 28. The government is seeking innovation of bio-health regulation to create the foundation needed for S. Korea to grow into a global digital and bio healthcare leader.

☐ The bio-health industry is a promising new industry owing to its potential for rapid growth*, given the aging population trend worldwide and a rising global need for good healthcare. Its importance also prioritizes the health security domain which involves vaccines and other treatments needed to protect people's lives, health, and safety.

* The Korea Health Industry Development Institute predicts the global bio-health market will grow at an annual average of 5.4% until 2027

○ Korea's bio-health industry has made significant achievements over the years, including developing the world's second-largest capacity to produce bio-pharmaceuticals, but the global bio-health market* is so vast that there is still massive room for growth of the domestic bio-health industry.

* In 2021, the Korean pharmaceutical market and medical device market tallied a mere 1.7% and 1.8%, respectively, of the sizes of their global counterparts (Korea Health Industry Development Institute)

○ Through interdepartmental cooperation, the Ministry of Health and Welfare will pursue regulatory innovation in the following seven core areas* of bio-health emphasized for their importance in protecting public health and promotion of innovation by the private sector.

* ① Innovative medical devices, ② Innovative and essential pharmaceuticals, ③ Digital health care, ④ Advanced regenerative medicine and advanced bio-pharmaceuticals, ⑤ DNA tests ⑥ Brain-machine interface, ⑦ Infrastructure

○ The key details of the New Bio-Health Industry Regulation Innovation Plan are as follows.

1 Innovative Medical Devices

○ Background: Framework updates have been made as necessary to allow innovative medical device's fast commercialization, including the suspension of new medical technology evaluation* and the standardized and integrated review of innovative medical devices**.

* Once a new medical technology obtains the Ministry of Food and Drug Safety's approval after a clinical trial, the mandatory new medical technology evaluation is deferred by two years to allow the technology's pre-commercialization (field use in non-benefit status). A system which allows new medical technologies to find a footing for validation (Sept. 2015).

** If an innovative AI or digital medical device becomes approved after a standard integrated review by the authorities, it can be used in the field in non-benefit status by completing the minimum required administrative procedure (30-day notice) (Oct. 2022).

- There is still high demand* for fast commercialization of and due compensation for all the innovative medical devices becoming developed on the heels of advances in convergence technology.

  * For example: AI software-based medical devices have jumped in number from 4 in 2018 to 149 in 2022, as records of the Ministry of Food and Drug Safety's approvals indicate, but most of them are seen as derivatives of existing technologies which health facilities are not willing to pay for.

○ Key details: A framework for pre-commercialization of innovative medical devices will be established to accommodate such needs surrounding medical devices in the healthcare field.

- Short-term measures include standardized and integrated reviews of innovative medical devices and suspension of a greater range of candidate devices from the new medical technology evaluation. These measures are pending a review.

- Longer-term measures pending a review include pre-use of innovative medical devices on a tentative basis of non-benefit status for a period of one to three years*, and subjecting such devices to the new medical technology evaluation at the stage of health insurance registration**.

  * To be executed in stages, starting with innovative medical devices of a high need for validation and low safety concerns (to be used in non-benefit status on a tentative basis).

** The new medical technology evaluation will be substituted with a health insurance registration application. The new medical technology evaluation will be

performed after undergoing tentative pre-use in non-benefit status, and depending on the evaluation findings, the device in question will be decided if it is covered by health insurance or imposed with certain restrictions on use in the field.

※ The National Health Insurance Service will add a new account ("Innovation Account"; preliminary name) to its health insurance funding scheme to allow for recognition of innovative medical devices that have become commercialized without the due recognition.

< Example: Short-Term Plan for Pre-Commercialization of Innovative Medical Devices (Provisional basis) >

Classification	Pre-improvement		Post-improvement
Standardized & integrated review	Non-invasive AI, big data, & digital wearable technologies	➔	Existing & non-invasive convergence image diagnosis & next-gen in vitro diagnosis technologies, etc.
New medical technology evaluation	- Subjects: Non-invasive testing & diagnostic technologies; - Suspension: Up to 2 years		- Subjects: All non-invasive medical technologies; - Suspension: Up to 2 years with a possible extension on a single occasion

- In view of the expectations that the digital treatment device market* will undergo a global boom, measures will be formed to apply health insurance to digital treatment devices to stimulate their use in S. Korea and the development of the Korean digital treatment device market.

  * The KoreaBIO valued the global digital treatment device market at KRW 5 tril in 2021 and expects it to grow to KRW 30 tril by 2030.

- Where a product classification cannot be assigned to a new digital treatment device under a review for approval, a temporary classification will be assigned. Regulatory improvements are being implemented to optimize and shorten the medical device approval process.

○ Anticipated effects: Faster commercialization of innovative medical devices enabled by improving the approval process is expected to

trigger the innovation from private developers and manufacturers of medical devices.

2 Innovative and Essential Pharmaceuticals

○ Background: A number of systems are in operation, with new ones being instituted to support development and fast commercialization of innovative and essential pharmaceuticals, for example the Innovative Pharmaceutical Company Certification* and the Review-Approval Integration System**.

* Instituted to support and certify companies making significant contributions to R&D required to create an industrial ecosystem centered on new drug development (47 companies certified as of Jan. 2023).

** Health insurance applications for pharmaceuticals can be made before the Ministry of Food and Drug Safety's approval as long as a safety and validity review is completed.

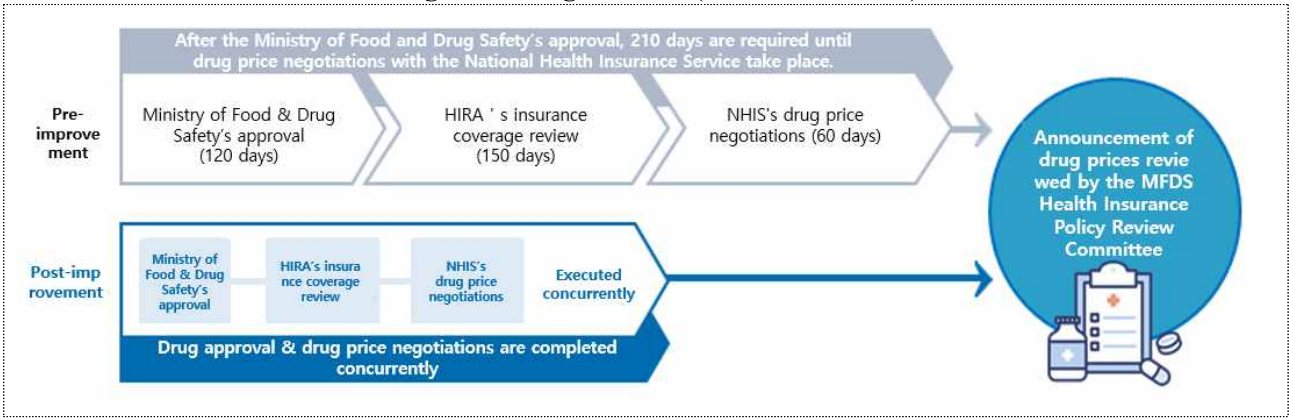
- Demand for creation of a support system that can drive improvement of essential medicine such as treatments for cancer and rare diseases and development of innovative new drugs has been persistent.

○ Key details: A scheduled pilot project will see product approvals (Ministry of Food and Drug Safety, MFDS), insurance coverage reviews (Health Insurance Review and Assessment Service, HIRA), and drug price negotiations (National Health Insurance Service, NHIS) concerning treatments for cancer and rare diseases* taking place concurrently. Manufacturers of essential pharmaceuticals will be able to file requests for manufacturing cost preservation at any time, a measure allowing the authorities to increase caps on drug prices swiftly when necessary**.

* Limited to drugs of proven effectiveness and without substitutes.

** To date, requests for essential drug manufacturing cost preservation can only be filed two times a year. Documents to be submitted with an application for a modification of drug coverage will also be simplified.

< Pilot Project for Integration of Product Approval, Insurance coverage review & Drug Price Negotiations (Provisional basis) >



- A public-private consultative body will be formed for establishing guidelines on contactless clinical trials* and plans for appropriate compensation for innovative new drugs**. Certification of innovative pharmaceutical companies will be diversified*** to actively facilitate pharmaceutical companies' development of innovative new drugs.

* Research company Medi-Tech Insights predicts the contactless clinical trial market will grow in value from USD 8.8 bil in 2021 to 14.2 bil in 2026, at a rate of over 10% every year.

** Examples: Expansion of the risk allocation system, promotion of domestic ingredient use for health security purposes, etc.

*** Certification of innovative pharmaceutical companies is currently without segments. The improvement will see creation of the general, venture, and foreign segments.

○ Anticipated effects: Systems for on-time supply of the public with the necessary drugs will be installed. An environment for development of new blockbuster drugs will be created.

3 Digital Healthcare

○ Background: Since the bio-health industry shares roots with traditional health manufacturing industries like the pharmaceutical and medical device industries as well as the digital healthcare industry where IT plays an integral role, it is expected to grow rapidly*.

* Market research company Global Industry Analysts predicts the global digital healthcare market will grow in value from USD 152 bil in 2020 to 509 bil in 2027 at an annual average of 18.8%.

○ Key details: Legislation* will be formed to allow health facilities to directly supply** patients' healthcare data to safety-verified third parties with patients' consent.

* To date, Article 21 of the Medical Service Act prohibits health facilities from directly sharing patients' healthcare data with third parties even with patients' consent.

** The revised Personal Information Protection Act grants legal status of third-party information request rights across all industries. The Digital Healthcare Act, once enacted, will accommodate the special characteristics of healthcare data.

- The Health and Medical Data Utilization Guidelines stipulate the procedures for pseudonymization and data review committee operations. The IRB* Guidelines** will be established specifically for application to bio-health data for creating a system for safe use of health and medical data.

* The Institutional Review Board performs voluntary reviews of ethical and scientific validity of researches pursuant to the Bioethics and Safety Act for protection of research subjects.

** Key details (provisional): Standards and methods of IRB reviews of researches using pseudonymized data, eligibility for IRB review, steps in selections, and cost allocation in group reviews by the IRB, etc.

- Frameworks for contactless treatment will be installed for improved access to healthcare services and promoting the public's health and wellness. contactless treatment will be limited to return patients and health facilities having the status of clinic or higher. Patients from the medically vulnerable segments, including patients in isolated regions, Koreans living abroad, and infectious disease patients, will be prioritized for contactless treatment provision.

- Frameworks for contactless treatment of foreign national patients will be created to attract medical tourists to S. Korea.

○ Anticipated effects: Such regulatory innovations derived on the principle of improved health of the people and protection of personal information are expected to help create new markets in the digital healthcare sector.

4 Advanced Regenerative Medicine and Advanced Bio-Pharmaceuticals

○ Background: Demand for treatment for cancer and intractable diseases is increasing. Advances in regenerative medicine technology will likely multiply* the share of advanced bio-pharmaceuticals in the bio-pharmaceuticals market over the coming years.

* The Regenerative Medicine Acceleration Foundation predicts the share of advanced bio-pharmaceuticals in the bio-pharmaceuticals market to increase from 10% in 2022 to 30% by 2030.

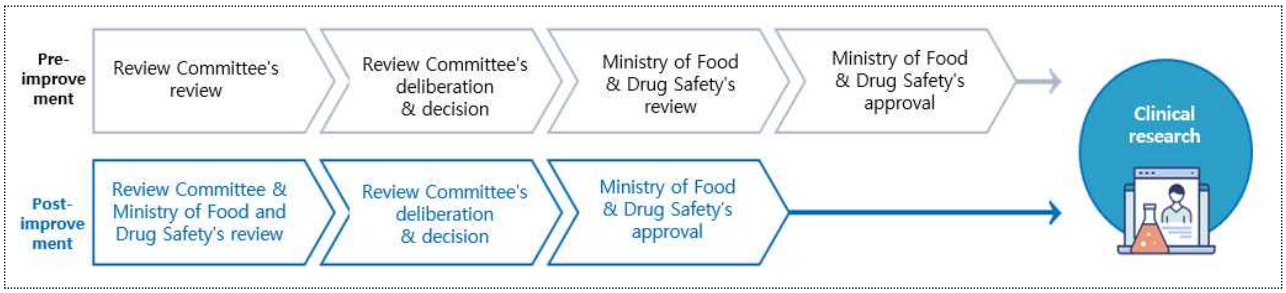
○ Key details: Advanced regenerative medicine will be activated to increase opportunity for treatment for rare and intractable diseases and treatments in general, as well as support development of the necessary technologies.

- As a short-term measure, the high-risk clinical research review process will be improved* to shorten the review time frame. As a longer-term measure, introduction of regenerative medicine technologies and expansion of the range of diseases to undergo clinical research** will be reviewed.

  * To date, a review and decision by the Advanced Regenerative Medicine and Advanced Bio-Pharmaceuticals Review Committee are followed by the Ministry of Food and Drug Safety's review and approval. After the improvement, both sets of said procedures will take place concurrently with the research party's consent.

  ** To date, the range is limited to severe diseases that are life-threatening without available treatment, rare diseases as defined in Sub-Paragraph 1, Article 2 of the Rare Disease Management Act, and other intractable diseases (as defined in Sub-Paragraph 4, Article 2 of the Act on the Safety of and Support for Advanced Regenerative Medicine and Advanced Biological Products).

< Improvement of High-Risk Clinical Research Review Process in Regenerative Medicine Field >



- Fast commercialization of advanced bio-pharmaceuticals will be supported by making it possible to apply clinical research results concerning advanced regenerative medicine to advanced bio-pharmaceuticals approval reviews*.

  * The Pharmaceutical Affairs Act places clinical trials under different classifications based on research purpose, research subjects, submitted materials, and other factors, and precludes a substitution of clinical trials with clinical research results.

- Further reviews will be performed to enable use of human body cells and other materials collected prior to the enforcement (August 2020) of the Act on the Safety of and Support for Advanced Regenerative Medicine and Advanced Biological Products as advanced bio-pharmaceutical ingredients being still unusable due to conflict between the quality and safety standards involved.

○ Anticipated effects: By improving accessibility of innovative treatments and quickly commercializing safety-verified treatments, the framework for defeating rare and intractable diseases can be created.

5 DNA Tests, Brain-Machine Interface, Infrastructure

○ DNA tests: With the enforcement (July 2022) of a direct-to-consumer (DTC) DNA test certification framework*, a large number of DTC DNA tests is expected to take in place in S. Korea.

* DNA testing institutions validated in testing accuracy, proficiency in test results analysis and communication, personal information protection, follow-up management, and other factors are allowed to carry out DTC DNA tests (as stipulated in Paragraph 2-2, Article 49 of the Bioethics and Safety Act).

- The DTC DNA Testing Guidelines in place, largely elaborations on terminology, systems and activities, will be revised into information of practical utility to consumers and testing institutions in the field to promote correct use of test results.

< Key Details of Revision of DTC DNA Testing Guidelines (Tentative) >

- Lmits on test results accuracy (provisional basis): Test results indicating concentrations of specific nutirents in the body do not quantify concentrations of actual nutrients, but suggest that nutrient concentration can be out of normal ranges. Test recipients should be cautious not to over-consume nutritional supplements depending on the results.
- Precautions in communication of test results: A scientific basis is required where goods and services, free of charge or subject to a fee, are recommended or provided on communication of test results.

- DTC DNA testing information platforms will become functionally improved to provide advice concerning instances of damage or loss related to DTC DNA tests as well as consumer education content.

○ BMI: Brain-machine interface technology allows machine control by brain signals, and is a future technology of massive potential for application to numerous areas, including rehabilitative medicine (assistance or substitution of body functions), transport, leisure, and national defense.

* Market research company Grand View Research predicted in 2022 that the BMI market would grow in value from USD 1.74 bil in 2022 to USD 6.18 bil by 2030.

- Interdepartmental consultative bodies, civilian advisory groups, IRB* guidelines, and other solutions will be employed to drive full-cycle development of BMI technologies.

* The Institutional Review Board performs voluntary reviews of ethical and scientific validity of researches pursuant to the Bioethics and Safety Act for protection of research subjects.

○ Infrastructure: The Korean bio-health industry will be developed by providing support to resolve challenges in the field from early R&D to production.

- A framework for support for development of pharmaceuticals featuring

new technologies such as nano-pharmaceuticals* will be installed to actively support companies enduring challenges in early R&D.

* (To date) Pharmaceutical companies developing drugs featuring new technologies face challenges to reach the clinical trial stage with such products due to lacking experience or personnel.
(Improvement) Such companies will have at their disposal expert regulatory support in the form of R&D coordination, custom consultations prior to product development, access to evaluation guidelines, etc.

- A virtuous cycle which includes installation of industrial-academic cooperation groups for medical and health technology R&D* will be created to enable research hospitals** to re-invest commercialization revenue in greater R&D to pursue more commercialization of new technologies.

* (To date) R&D → Commercialization revenue → Business-university cooperation groups
(Improvement) R&D ⇄ Commercialization revenue

** According to a 2021 report by the Korea Health Industry Development Institute, research hospitals achieved an increase in technology transfer earnings at an annual average rate of 34.6% between 2013 and 2019, surpassing those of public research entities (2.4%) and universities (16.4%) by 14.4 and 2.1 times, respectively.

- Restrictions on medical innovation clusters' product ranges* and leases to resident companies** will be relaxed to provide better support to startups already or slated to be in medical innovation clusters.

* (To date) Products developed within the cluster → (Improvement) Products can be developed outside the cluster if a manufacturer's head office is located in one.

** (To date) Restrictions on resident companies' transactions and leases
→ (Improvement) After improvement: Leases granted with joint R&D required and in other similar instances.

□ Health and Welfare Minister Cho, KyooHong said, "Bio-health is a future lucrative industry in the low secular growth era, and plays a pivotal role in public health and national security."

○ He concluded, "The Ministry of Health and Welfare will continue to pursue bio-health-geared regulatory innovation to create new markets for the bio-health industry and provide the people with improved health and medical services."