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Advanced biopharmaceuticals expected to open up new treatment opportunities based on safety and quality assurance

"Advanced Regenerative Bio Act" will be implemented at full-scale with subordinate statutes in place

☐ The Ministry of Food and Drug Safety (MFDS, Minister Lee Eui-Kyung) announced its plans to legislate and implement the subordinate statutes of the "Advanced Regenerative Medicine and Advanced Biopharmaceuticals Safety and Support Act" at full-scale in order to strengthen the management of the quality and safety of bio-pharmaceuticals and provide support to accerlerate their commercialization.

○ Accordingly, the Ministry will complete the legislation of the Enforcement Decree, Enforcement Rules and Administrative Rules with the details of the matters delegated by the law and secure a necessary budget so that the law can be implemented smoothly.

1 Strengthened management of the quality and safety of bio-pharmaceuticals

- Provide detailed requirements for approvals, quality and safety standards applicable to “management businesses for human cells, etc.,” among others.

  * “Regulations on the safety and approval of ‘human cells, etc.’ and advanced biopharmaceuticals”

- Enhancing investigations for more thorough long-term follow-ups on advanced bio-pharmaceuticals and safety management of “human cells, etc.”

  * “Management standards for long-term follow-up investigations on advanced bio-pharmaceuticals”

    “Regulations on Orders for the Recall and Disposal of Harmful ‘Human Cells, etc"

2 Support for the commercialization of bio-pharmaceuticals and the enhancement of qualitative competitiveness

- Provide support to accelerate the commercialization of bio-pharmaceuticals and devise standards for the product approvals and reviews in consideration of the characteristics of advanced bio-pharmaceuticals

  * “Regulations on the Bio-pharmaceutical Product Approvals and Reviews”

1 Strengthened management of the quality and safety of bio-pharmaceuticals

□ The MFDS created a new business type which specialize in dealing with “human cells, etc.”* used as the ingredients of advanced bio-pharmaceuticals. The Ministry also devised processes for the approval of such businesses and established detailed standards to ensure the quality and safety of “human cells, etc.”

* Human cells, etc.: organs, tissues or cells such as stem cells, hematopoietic stem cells, somatic cells, immune cells and other cells from humans or animals

○ Securing adequate facilities, human resources, and equipment, among others, is required before applying for the approval to operate a “cell processing facility” or a “management businesses for human cells, etc.” Approvals are granted after the business is proven to be conforming through document reviews and inspections.

- "Managers of 'human cells, etc.'" must conduct periodic inspections on equipment and facilities and the quality of "human cells, etc." When harmful human cells, etc. are detected, they must be reported immediately to the MFDS.

□ Serious adverse events that occur following the use of advanced bio-pharmaceuticals will be investigated thoroughly. The MFDS will take swift measures to including the discontinuation of use.

○ If an advanced bio-pharmaceuticals is designated as a subject of a long-term follow-up study, its manufacturer must submit study plans before the products are on the market.

* Components of long-term follow-up investigation plans: test subjects, scope, items, procedures, and methods of investigation; and matters related to the reporting and assessment of the results

○ Also, doctors who administer advanced bio-pharmaceuticals subjected to a long-term follow-up investigation must report participating patients' personal information to the "Center for regulatory science of advanced bio-pharmaceuticals" after obtaining their consent. The businesses must report the progress of the study to the MFDS.

- When a serious adverse event occurs, the business must notify the investigation plan to the MFDS within 15 days and report the cause, the correlation between the adverse event and the substance, and countermeasures within 6 months.

□ The Ministry will give an approval after repeating the test on the safety and quality standards of Cell Therapy Products that are currently on sale.

○ In accordance with the Act, the existing products should be newly approved within 1 year after the enactment of the Act. Thus, the MFDS

will assess the documents submitted at the time, and receive the Risk Management Plan (RMP) for reviews.

- To this end, the Ministry will support the products to get an approval within the time frame by providing instructions on how to fill the documents.

2 Supporting the commercialization of Bio-pharmaceuticals

□ The Ministry will designate the advanced bio-pharmaceuticals as products for fast track since they should be developed swiftly. The commercialization of the products will be supported by customized and priority reviews from the early stage of development.

○ The products for fast track includes the advanced bio-pharmaceuticals which aim to prevent and treat serious illnesses that don’t have any alternative treatment, rare diseases which are included in the Rare Disease Managment Act, and contagious diseases.

- When the safety and efficacy of the designated pharmaceuticals are proved are proved in the results of clinical trials in the early stages or in the process of clinical trials, the products can get the approval bt submitting relevant documents of the clinical trials.

* Documents to be submitted : Development background, substances, manufacturing method, clinical trial results, etc.

* The approval process of the products for fast track is shortened from 115 days to 90 days

○ Furthermore, the Ministry will support developers to enhance the potential in research and development by checking whether the products made through a cutting-edge bio-technology which can be considered advanced biopharmaceuticals.

* Documents to be submitted : plan of development, efficacy and efficiency, major substances, manufacturing method, etc.

□ The Ministry will designate "Korea Institute of Drug Safety & Risk Management (KIDS)" as an institute supporting comprehensive information and technology for the bio-pharmaceuticals, and will establish "Center of Supporting Safe Vaccine Technology" to support the development of vaccines.

○ By designating "Korea Institute of Drug Safety & Risk Management (KIDS)" as a Regulatory Science Center for the Advanced Bio-pharmaceuticals, it will conduct the research and investigations on policies related with home and abroad bio-pharmaceuticals, and will nurture the experts needed for manufacturing and managing the quality of the products.

- To do so, we allocated 3.8 billion won of 2021 national budget for advancing the regulation and managing the safety of the advanced biopharmaceuticals at Regulatory Science Center.

* The establishment/operation cost of long-term tracking system 2.9 billion won, labor costs 900 million won, etc.

○ "Center of Supporting Safe Vaccine Technology" not only provides consulting for vaccine development but also carries out clinical trials, quality inspections, and expert nurturing program to support the commercialization of essential domestic vaccine products.

- To this end, we allocated 5.8 billion won of 2021 national budget for establishing and operating the Center of Supporting Safe Vaccine Technology.

☐ The Ministry will provide online education about the ADVANCED REGENERATIVE BIO ACT on September 8 related to the businesses of the advanced bio-pharmaceuticals and the advanced regenerative medical service.

○ The education includes ▲the main information about the ADVANCED REGENERATIVE BIO ACT, ▲the management activities of human cells and the approval, and ▲the long-term tracking inspection. To find out more information, visit the webpage of Korea Institute of Drug Safety & Risk Management.

☐ The Minister Lee stated “the Ministry will run the customized approval policies to support the customization of safe biopharmaceuticals with high quality.”

○ She also added “the implementation of the ADVANCED REGENERATIVE BIO ACT is expected to contribute on enhancing the competitiveness of the products by increasing the quality and safety management of the advanced bio-pharmaceuticals. Also, it will provide new opportunities to receive new treatment for patients suffering from rare/incurable diseases.”