

## Full-scale Support for Swift Development of COVID-19 Treatments

The world is at war with the coronavirus. Thanks to scientific advancements, things in Sci-Fi, such as AI, self-driving cars, and gene editing, are becoming a reality, and yet we're still struggling in the battle against newly emerging viruses like Ebola and the coronavirus. The war between humanity and microorganisms has a long history.

In the "Annals of the Joseon Dynasty," containing 500 years history of the Joseon Dynasty, terms related to infectious diseases have been used 745 times. There is also a record that during the reign of Seonjo in the mid-16th century, the entire nation suffered from malaria in summer, and scarlet fever and influenza in winter. To contribute to treating the infectious diseases, a physician named Heo Jun (1539-1615) listed some 190 types of effective domestic herbal ingredients in his book "Donguibogam." Four-hundred years have passed since then, and the ways we deal with the infectious diseases now have changed, but our firm will to prevent and treat them remains the same.

To expand treatment opportunities for citizens suffering from COVID-19 and help the country to lead the global development of the drugs and vaccines, the Ministry of Food and Drug Safety has begun to run "Intensive and Quick Commercialization Support Program" (Go Expedited Review Program, GERP) in earnest since Apr. 13.

GERP is a comprehensive and specialized support system that can shorten the development period by minimizing potential trial-and-error in each stage from R&D to the commercialization of the COVID-19 treatments and vaccines, focusing on the following three items.

First, the program serves as a "compass" that gives an accurate direction for commercialization. In deserts where there are no roads like cities, it is crucial that you know the right direction. For this, it is providing scientific advice from the stage of exploring candidate substances for treatments, and professional consulting customized for the characteristics of each stage throughout the whole process of approval and evaluation by opening an exclusive "consultation window." Also, the program will designate project managers from within the MFDS for items that are highly likely to be used for treatment to



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commercialize them quickly without trial-and-error.

Second, the program will serve as a "stepping stone" to help developers with commercialization and smoothly address any regulatory barriers they face during the commercialization stage. Since drugs are administered directly to humans, the process of evaluating not only the efficacy but also toxicity, side effects and other safety issues is absolutely necessary, and a high level of

regulation is required as well. The Ministry of Food and Drug Safety(MFDS) is developing and sharing animal models infected with COVID-19 for the developers to utilize in product efficacy evaluation, and also supporting the development of clinical protocols for treatments and vaccines. It has also established and operated a "hotline connected to the head of the commercialization team" to provide quick tips on what to consider when developing treatments, and the users can submit complaints and get instant replies to questions that arise during the product development stage.

Third, GERP serves as a "catalyst" for quick commercialization. The program includes organizing and operating an evaluation team for COVID-19 treatments and vaccines comprised of highly-experienced examiners, and granting exemption of toxicity testing for vaccines developed through platforms already proven to be safe. With regards to clinical testing approvals, the evaluation period will be shortened to no more than 7 days for drugs that have already been used on humans, and no more than 15 days even when a drug contains new substances. They will be prioritized in approval and examination over other products to minimize the bottlenecks.

In "Jungyong" (Doctrine of the Mean), one of the "Four Books and Three Classics," you can find the phrase "go jiseongmusik bulsikjeukgu gujeukjing," meaning "if you continue to make effort with all your heart, you will win good results."

The MFDS promises to do its best to help the people working in the healthcare and medical fields, business industries, academia, and research centers, dedicating themselves to overcome COVID-19 to swiftly develop safe and effective treatments and vaccines.

A happy country can be made only when its people are

healthy. It is my dearest wish for our people to be able to return to their normal lives soon and fully enjoy the warm spring sun by developing treatment drugs and vaccines.