

First domestically developed COVID-19 vaccine under the leadership of the Pan-government Support

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On June 29 (Wed.), Korea's **first domestically developed COVID-19 vaccine, "SKYCovione™ Multi inj."**, was granted marketing authorization from the Ministry of Food and Drug Safety (MFDS).

Regarding the vaccine's authorization, the government stated that it had provided **whole-of-government support for the vaccine development under the leadership of the Pan-government Support Committee for COVID-19 Treatment and Vaccine Development** (launched in Apr. 2020) in a bid **to achieve the goal within the first half of this year.**

The development of Korea's multi-dose COVID-19 vaccine is even more significant as it is the outcome of a **public-private partnership** between the vaccine developer, the government, research institutes, and private experts.

The Ministry of Science and ICT (MSIT) worked with governmental think tanks and private research institutes **to support the required procedures leading up to the clinical trial on vaccine candidates, such as efficacy studies, preclinical in vivo tests in animal models, and toxicity research.**

The Ministry of Health and Welfare (MOHW) focused its efforts on the **expedited establishment of related regulations and infrastructure**, working in collaboration with the Korea Disease Control and Prevention Agency (KDCA) and Korea National Enterprise for Clinical Trials (KoNECT). These endeavors included the **operation of the National Infectious Disease Clinical Trial Center** (5 locations), recruitment and priority referrals of clinical trial volunteers, **introduction of certification** for vaccine trial participants and provision of various incentives, and **issuance of vaccination certificates** to phase 3 clinical trial participants.

In addition, **to facilitate expedited clinical trials**, which remains the most challenging step in drug development, **the Pan-government COVID-19 Vaccine and Treatment Clinical Trial Support Task Force was launched (Jul. 2020) to promptly address any issues concerning the trials by ensuring across-the-board collaboration from government authorities.**

MFDS prepared guidelines for phase 3 comparative trial designs trial designs, provided customized technical support for each company, and operated the pilot institutional review board (IRB) to speed up the start of clinical trials.

In particular, the government **focused its all-out efforts on supporting expedited phase 3 clinical trials**, the final gateway to success in vaccine development.

The government sat down at the negotiation table with international organizations such as the World Health Organization (WHO) and Coalition for Epidemic Preparedness Innovations (CEPI) and global pharmaceutical companies to **help Korean vaccine developers secure a comparator vaccine**, while also supporting the developers with **priority referrals of vaccine trial volunteers in Korea** and **one-on-one matching with diplomatic missions overseas** for clinical trials in foreign countries.

The National Institute of Infectious Diseases (NIID) of the KDCA and International Vaccine Institute (IVI) utilized the infrastructure of the Korean Vaccine R&D Center for Public Vaccines to enable the expedited analysis and reporting of samples collected through clinical trials, thus offering a government-led analysis of samples. The KDCA also signed an **advance purchase agreement** (10 million doses, Jan. 2022) with SK bioscience, the drugmaker of SKYCovione™, to help expand the platform for vaccine manufacturing.

Even after the authorization of the homegrown vaccine, research is still in progress **to ensure its safe and reliable use.**

The NIID is currently **conducting an immunogenicity study on the homologous and heterologous booster trials of SKYCovione™**, while also **supporting its efficacy tests on SARS-CoV-2 variants such as Delta and Omicron.**

Currently, in Korea, six drugmakers beyond SK bioscience are developing COVID-19 vaccines, and 18 drugmakers are developing related therapeutics. The

government is committed **to continuing its support for the development of COVID-19 vaccines and treatments.**

Leveraging its experience in pan-government support for the development of Korea's first domestic vaccine, **the government will continue to mobilize all of its capabilities to ensure the rollout of more homegrown vaccines** and various types of treatments going forward.

In addition, the government plans to lay out the **Ultra-fast Therapeutics/Vaccine Development Strategy** (unofficial) to safeguard the health and safety of citizens in a timely manner against future pandemics.

MSIT Minister Lee Jong-ho stated, "The first-ever shared experience of success in developing Korea's domestic vaccine drawing on a pan-government approach will serve as an important asset not only for overcoming COVID-19 but also for responding to future infectious diseases." He continued, **"Given that the interval between pandemics is getting shorter, new infectious diseases can occur at any time.** Therefore, we will **continuously support R&D from a mid- to long-term perspective, such as securing source technologies and scaling research infrastructure,** in order to enhance our capability to promptly respond to future pandemics."

MOHW Second Vice Minister Lee Ki-il stated, "Although there still remain additional studies to be conducted, such as the homologous and heterologous booster trials of the vaccine and verification of its efficacy against the Omicron variant, **the development of Korea's first domestic COVID-19 vaccine is meaningful** in that **it represents a major step for Korea toward vaccine sovereignty."** He added, **"The vaccine developed by a Korean drugmaker will be used not only in domestic vaccination campaigns but also in the global market, helping enhance global health security."**

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