식품의약품안전처	Press Release	국민 안심이 기준입니다	
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우리 백신

MFDS Approves Korea's First Homegrown COVID-19 Vaccine

☐ On June 29th, the Minister of Food and Drug Safety (OH Yu-Kyoung) decided to grant marketing authorization for Korea's multidose Covid-19 vaccine, "SKYCovione™ Multi inj." on the condition of receiving the final clinical trial report from SK Bioscience. The company had submitted a license application for manufacturing and marketing authorization after its development.

○ This vaccine is a recombinant protein-based vaccine which induces immunological response against the novel coronavirus.

- The authorized vaccine, a 0.5mL mixture consisting of both antigen vial and adjuvant vial, is given two injections four weeks apart in individuals 18 years of age and older to prevent COVID-19.

○ With the authorization of SKYCovione™ Multi inj., the Republic of Korea has now become a country with homegrown COVID-19 treatment (Regkirona Inj., authorized on February 5, 2021) and vaccine (SKYCovione™ Multi inj.), establishing a health security system that can preemptively respond to future pandemics.

1 The First Homegrown COVID-19 Vaccine

☐ MFDS granted marketing authorization for Korea's homegrown vaccine for the first time in the world which has been developed and manufactured by SK Bioscience.

☐ Even amidst the pandemic, MFDS strategically and persistently supported the facilitated development of homegrown domestic vaccines by operating the "Woori Vaccine Project."

○ In September 2020, the Ministry launched the COVID-19 Vaccines and Treatment Review Team, which consists of experienced reviewers, to support the development and commercialization of COVID-19 vaccines and treatments. The team provided customized consultations for each non-clinical, clinical, and quality assessment stage and conducted preliminary reviews.

* COVID-19 Vaccines and Treatment Review Team: A team comprised of four to nine reviewers from multidisciplinary areas of non-clinical, clinical, and quality assessment to support accelerated authorization of COVID-19 vaccines and treatments.

○ In the phase 3 of the clinical trials – which is the main stage of product development and requires a large number of clinical trial participants – the Ministry preemptively introduced the comparative immunogenicity clinical trial method* to facilitate the process of developing clinical trial designs.

* Comparative immunogenicity clinical trial: A clinical trial method that compares immunological markers between developed vaccine and authorized vaccine, reducing the time needed in clinical trials by having fewer participants than placebo-controlled efficacy clinical trials.

○ Also, MFDS led discussions in international meetings and workshops between regulatory authorities for the comparative immunogenicity clinical trial method to gain international recognition. This method was reflected in the WHO guidelines published in March, 2022.

2 Review and Authorization Process for SKYCovione™ Multi inj.

□ SK Bioscience submitted its application for SKYCovione™ Multi inj. on April 29, 2022. MFDS has been conducting a rigorous review of the submitted data based on scientific evidence while prioritizing safety.

○ The COVID-19 Vaccines and Treatment Review Team reviewed data required in `authorizing non-clinical, clinical, and quality assessments.

- Non-clinical trial reviews were based on proof of concept studies (virus antibody titer, immune response, etc.), safety pharmacology and bio-distribution study, and toxicity studies (repeated dose toxicity study, developmental and reproductive toxicity study, etc.)

- The Ministry evaluated two clinical trial data during the clinical trial review to assess the safety and effectiveness of the vaccine: (1) a clinical trial conducted in Korea (Phase 1 & 2) and (2) a multi-regional clinical trials conducted in six countries such as Korea and the Philippines (Phase 3).

- For the quality review, data such as the manufacturing method, standard, and testing method were evaluated to assess the quality of the vaccine. Also, the Ministry conducted a GMP inspection of the manufacturing site, examining the facility and management system to ensure quality consistency.

3 MFDS' Internationally Renowned Review Capacity

□ MFDS authorized and reviewed the COVID-19 vaccine based on the authorization requirement and review standard under laws and regulations* including the Pharmaceutical Affairs Act.

* Regulation on Safety of Medicinal Products etc., Regulation on Approval and Review of Biological Products, Standard for Toxicity Study of Pharmaceuticals, Regulation on Stability Test of Pharmaceuticals, etc.

○ Also, the Ministry applied the same level of requirements and review standards as advanced countries including the United States, Europe, and Japan during the SKYCovione™ Multi inj.'s review and authorization process as a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)*.

* International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH): An international consultative group in the pharmaceutical regulatory field that lays out the standards for pharmaceutical safety, effectiveness, and quality. Regulatory authorities of Korea, the United States, European Council, Japan, Canada, and Pharmaceutical Associations of the United States, Europe, and Japan are members of the Council.

□ Unlike the COVID-19 vaccines approved so far*, MFDS assessed the safety, effectiveness (immunogenicity), and quality of SKYCovione™ Multi inj. throughout the whole process, from its development to clinical trial to production management and final approval stage.

* Pfizer Korea, AstraZeneca Korea, Moderna Korea, Janssen Korea, Novavax

□ MFDS spared no efforts to conduct a scientific and thorough review to determine the safety and effectiveness of the vaccine.

○ Also, the Ministry utilized the three-tier advisory review procedure to ensure scientific expertise and transparency of the review results and authorization process. Concerning the three-tier advisory procedure, MFDS not only sought advice from the Central Pharmaceutical Advisory Committee, which is a mandatory procedure stipulated in the Pharmaceutical Affairs Act, but also from the newly launched Advisory Committee for the Safety and Efficacy Assessment of COVID-19 Vaccine and the Final Evaluation Committee.

○ In addition, the Ministry significantly shortened the regular processing period for authorization (180 days) through the priority review and rolling review process.

□ Moreover, while reviewing and determining authorization of SKYCovione™ Multi inj., the Ministry established test methods for a swift and thorough national lot release that would ensure timely supply of a safe and effective COVID-19 vaccine.

4 Korean Company Obtains COVID-19 Vaccine Development Technology

□ The approval of SKYCovione™ Multi inj., is expected to be a stepping stone for Korean companies to enter the global vaccine market in earnest.

○ SK Bioscience is seeking Emergency Use Listing (EUL) from the World Health Organization (WHO) and plans to supply vaccines through the COVAX Facility.

* COVAX Facility: A global vaccine procurement mechanism suggested by the Global Vaccine Alliance (GAVI) to guarantee sufficient and equitable access of COVID-19 vaccines

○ SK Bioscience's vaccine can be stored in the refrigerator between 2℃ to 8℃, which will be able to support countries without ultra-low temperature (ULT) freezers with their pandemic response.

5 Innovative Products Development Support Department to Further Support Industry

□ MFDS launched the Innovative Products Development Support Department* to support the rapid market entry of medical products for public health response and products using new concepts and technology.

* Innovative Products Development Support Department: Director General of the National Institute of Food and Drug Safety Evaluation is the leader and consists of 90 officials (35 public officials, 55 reviewers) from the ▲Products Development Team ▲Innovative Products Review Team ▲Clinical Review Team.

○ To expedite the development of medical products, the Innovative Products Development Support Department connected the development stage with the non-clinical stage, and the clinical trial stage with the review and authorization stage, and also further provided expertise on clinical trial design.

□ Moreover, MFDS invested 22.6 billion won to build infrastructure such as the Vaccine Center for Assisting Safety & Technology. If pre-consultation for vaccine development, consultation for product development such as quality and clinical consult, and fostering experts could be promoted through the Vaccine Center, a bigger synergy could be created when supporting product development of a pharmaceutical company.

6 Future Plans

□ Minister Oh announced that “when approving SKYCovione™ Multi inj., MFDS rigorously reviewed the vaccine’s safety and effectiveness through the three-tier advisory review procedure,” and “our Ministry will redouble efforts to proactively respond to future pandemics by further cooperating with various institutions.”

○ Furthermore, MFDS will cooperate with related government agencies to strengthen the adverse event monitoring system, and thoroughly monitor and rapidly respond to adverse events so that the public have confidence in vaccination.

<Attachment>

1. Contact point

Attachment 1	Contact Information per Division

◇ Please refer to the following contact information in case of enquiry.

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