대한민국 대전환 한국판뉴딜

Ministry of Food and Drug Safety

Press Release for Reference

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MFDS Publishes Q&A Guidance on Development of COVID-19 Therapeutics & Vaccines

Consultation Cases Provided as Q&As for Rapid Product Commercialization

☐ The Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) has published a "Q&A Guidance on the Development of COVID-19 Therapeutics and Vaccines" based on pre-submission consultations on R&D and clinical trials to support and facilitate rapid commercialization of COVID-19 therapeutics and vaccines.

○ The published Q&A guidance is divided into quality, non-clinical study and clinical trial, respectively for chemical drugs, biopharmaceuticals and vaccines. The Q&As are based on the analysis of consultations across 98 products, submitted either through "GO, Expedited Pathway" of the rapid review process or the "Pre-submission Consultation" process.

☐ The guidance will help the industry minimize trials and errors and expedite product commercialization. MFDS will further strive to successfully overcome the COVID-19 pandemic by providing domestic manufacturers with full support for the development of therapeutics and vaccines.

< Main Components of the Guidance >

No.	Category	Main Components
1	**COVID-19 Chemical Drugs**	○ (New Drugs) Required data for chemical manufacturing & controls and for safety and efficacy ○ (Repurposed Drugs) Scope of required data in case of any changes in dosage forms
2	**COVID-19 Biopharmaceuticals**	○ Considerations in developing manufacturing processes, determination of standards and test methods, types of toxicological tests
3	**COVID-19 Vaccines**	○ Requirements for clinical trial initiation, animal species subject to efficacy tests