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South Korea to cut new drug approval reviews to 240 days

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Approval and review innovation grants Korean citizens the fastest access to medical treatments in the world



The Ministry of Food and Drug Safety (MFDS) in South Korea has established the "Medical Product Approval and Review Innovation Plan" to expand medical treatment opportunities for citizens through the expedited approval and review of new drugs, biosimilars, and innovative medical devices, and will implement it immediately.

This innovation plan aims to expand patient treatment opportunities and support K-Bio's global leap by rapidly launching safe treatments within a target timeframe of 240 days.

Efforts will be made to shorten the approval period by shifting to a simultaneous and parallel review system through the hiring of 195 new approval and review personnel, and by conducting face-to-face meetings prior to filing application as well as deficiency resolution meetings during the review stage.

Previously, inquiries regarding upcoming new drug applications were addressed through one-time consultations, but no official written documentation was provided afterward.

To offer more substantial practical assistance to companies preparing approval and review dossiers, the MFDS will utilise its expanded personnel to strengthen communication by conducting two or more official "Pre-NDA Meetings."

Previously, due to a shortage of review personnel, a limited number of experts had to review massive amounts of data sequentially, resulting in extended review timelines.

Moving forward, the MFDS will deploy a larger pool of reviewers to form dedicated teams for each review category, executing a fast-paced "Simultaneous and Parallel Review."

Applications for "Pre-NDA Meetings" for new drugs, biosimilars and innovative medical devices has opened on June 1.