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Ministry of Food and Drug Safety

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MFDS improves regulations for the quality improvement and clinical testing of pharmaceuticals

"Rules on the Safety of Pharmaceuticals, etc." revised and promulgated

☐ The Ministry of Food and Drug Safety (MFDS, Minister Eui-kyung Lee) revised and promulgated the "Rules on the Safety of Pharmaceuticals, etc." (Ordinance of the Prime Minister) on Oct. 14 focused on raising the standards for the quality and safety management of pharmaceuticals and easing the process for changing clinical trial plans.

☐ The highlights of the recently revised Ordinance of the Prime Minister are as follows:

○ The revision was intended to strengthen the quality and safety management of prescription drugs by improving review and evaluation system applicable to standards and test methods, bioequivalence tests, GMPs, among others, to the international level, paralleling those of the U.S. and the EU.

- Regarding applications for marketing authorizations of all prescription drugs, the MFDS will require applicants to submit documents related to "the standards and evaluation methods," and "bioequivalence test," among others, to strengthen the quality management.

- Until now, the submission of GMP documents has been exempted for prescription drugs produced on an OEM basis at the establishment and through the manufacturing process same as those of previously approved products. Following the revision, documents on 3 batches will be required for submission.

* The documents for one batch may suffice when not only the manufacturing process but also manufacturing equipment, batch, packaging and container are equivalent.

○ Furthermore, the MFDS has improved and complemented the regulations for procedures to address the challenges faced by the industry.

- Matters that were subjected to obtain "approval for changes" in clinical trial plans, such as the ▲addition of treatment and control groups, ▲change in the termination criteria for clinical trials, and ▲changes in the administration route will now be required to "report for changes" to facilitate and accelerate clinical trials.

- The MFDS revised the regulation to exclude narcotic and psychotropic drugs from the list of drugs whose import and export records are required under the "Rules on the Safety of Pharmaceuticals, etc." as their manufacturing, export and import status are reported through the "Integrated Narcotics Management System."

- When only safety documents need to be reviewed for the marketing authorization and notification of pharmaceuticals, the processing period will be shortened to allow rapid authorization.

* Example: (approval) 70 days → 45 days, (reporting) 55 days → 30 days, (approval for changes) 65 days → 40 days

☐ The MFDS anticipates that the revision will help enhance the quality of overall pharmaceuticals by improving the quality pharmaceutical development and approval process through reasonable harmonization. Also, the MFDS expects that the revised law will contribute to creating an environment for rapid roll-outs of pharmaceuticals.