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MFDS Establishes Evaluation Methods for Cardiovascular Safety Pharmacology

“Guidance on Cardiovascular Safety Pharmacology Evaluation Method” Published

□ The Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) has published a “Guidance on Cardiovascular Safety Pharmacology Evaluation Method”, which aims to help pharmaceutical companies better develop and market drugs.

* Evaluation of potential undesirable pharmacodynamic effects on physiological function when a drug is administered in the therapeutic dose range or above

○ Details of the guidance include ▲ Introduction of Cardiovascular Safety Pharmacology Test ▲ Explanation of Evaluation Test Method for Multi-cardiac Ion Channels, and ▲ Explanation of Evaluation Test Method for Cardiomyocyte Cell Action Potential Derived from Human Induced Pluripotent Stem Cells (hiPSCs).

- Specifically, considering that the “*hERG channel assay*”, an assay used in the existing safety pharmacology evaluation, has limitations in accurately predicting clinical arrhythmia, the “multi-cardiac ion channel evaluation test method” using sodium (Na^+) and calcium (Ca^{2+}) channels and the “action potential evaluation method” using cardiomyocytes derived from hiPSCs have been newly established.

* hERG channel evaluation: as a potassium (K^+) ion channel formed in the cell membrane by the expression of human EAG-related gene, it is closely related to the prediction of arrhythmia in cardiomyocytes.

□ The MFDS will continue to proactively support the development of new drugs in Korea by providing guidelines for drug safety evaluation and aligning evaluation methods with the international standards.