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Current Issues of Pharmaceutical Equivalence

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Recent changes such as the globalization of the ICH regulatory harmonization, innovation of pharmaceutical sciences, and advances in pharmaco-medical technologies in pharmaceutical industry have significantly affected and necessitated a revision in the way we regulate pharmaceutical products.

In additions to these global changes, our local practice system also underwent a significant changes in the year 2000, namely, separation of prescription and dispensing of drugs, and permission of generic substitutions, which are 2 of the most highly debated health topics in our society today. Another current issues in pharmaceutical surroundings are pharmacovigilence, clinical safety, bridging study, generics of modified release drugs and bioequivalence, combination drugs and new concept drugs which have same active ingredient with different salts.

KFDA has also changed and renovated in the field of drug evaluation and approval system, especially. The drug evaluation and approval had been made by three different organizations; drug evaluation department, pharmaceutical safety bureau and National Institute of Toxicological Research (NITR). Since February 2004, the review body, the department of drug evaluation, for the drug evaluation of quality, safety and efficacy has combined in order to establish streamlined review system and quality regulation. Such changes have significantly affected our regulations that have revised more clearly, consistently and comprehensively.

In this time I would like to introduce "what are or what will be changed in our regulation for the drug evaluation centering around current issues, generic drugs and pharmaceutical equivalence."