Generic Drugs at Medical Institutions

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In the clinical setting, there is a conflict between “management efficiency” based on corporate policy and “safety and security” from the medical perspective. The rate of using generic drugs is gradually increasing, but this is not attributable to the increased reliability of such drugs. Instead, it can be said that changing the reimbursement system for medical fees from an actual cost basis to an all-inclusive payment basis has played a large role in determining the adoption rate.

Since it is considered that the factors related to drug manufacturer include the substances used, the information provided, and company ethics, high-quality generic drugs should be defined as nothing other than drugs with a high reliability that show confirmed efficacy, safety, and usability based on additional data/information. Generic drugs are not limited to those in which the shortcomings of the original drugs are improved and additional convenience is added. Since drugs can directly cause harm to patients, obtaining data based on clinical studies is a high priority. The reliability of generic drugs will not be improved without data obtained in vivo, at the very least. For example, would you administer an injectable drug intravascularly if it was approved only on the basis of specifications and stability tests?

The government approves generic drugs, but it is the responsibility of pharmaceutical manufacturers to ensure the quality of these drugs. There is a large gap between the approval criteria for drugs used by the government and the criteria for the adoption by medical institutions. It is necessary for drug manufacturers to close this gap and the self-help efforts of manufacturers are required. In the future, generic drugs will not be adopted by medical institutions if they are manufactured with a passive and old-fashioned attitude, merely complying with the government’s approval criteria. Medical institutions want generic drugs that not only meet the government’s approval criteria, but also have the manufacturer’s own quality assurance data.