MS03-2 **Scientific drug safety information for patients consent**

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One of the important roles of pharmacists is to continue their contributions to new drug discovery and development. However, it seems to be very difficult to obtain patient satisfaction with new drugs. Because new medicines have both benefit and risk, there should be many systems to maximize the safety and efficacy of the drugs. In clinical trials, the rights, safety and welfare of human subjects under the investigator's care must be protected. Good Clinical Practice is a harmonized ICH-guideline, and the safety information of an investigational product is explained to patients who voluntarily enter the clinical trials. Since safety information about investigational products is still limited, subjects are informed about the results of animal experiments and those of finished clinical trials. The sponsor of clinical trials should be responsible for the on-going safety evaluation of the investigational products. When additional safety information is collected in the clinical trials, the written informed consent form should be appropriately revised. During the review process, quality, safety and efficacy of new drugs are evaluated and judged based on the scientific risk-benefit balance. The safety information collected in clinical trials is reflected in the decision-making process written in the review reports. All-case investigation should be also performed until data from a certain number of patients has been accumulated in order to collect early safety and efficacy data. Important messages written in review reports for drug safety and patient consent are explained. Risk communication will improve the application of patients consent for new drugs.