Astellas has established a committee inside the Company that evaluates and monitors the ethical propriety and scientific validity of clinical studies from their planning phases. In addition, we implement education and training for employees and other staff members who are involved in clinical trials, and conduct monitoring of medical institutions that perform trials to ensure that clinical trials are performed properly according to GCP. In the course of performing clinical trials, Astellas confirms that trial subjects have provided their informed consent to participating in clinical trials, i.e., they have given their consent based on a full explanation of the substance of the trials and other details. Moreover, we properly administer the trial data so as to protect the privacy and confidentiality of personal information of the trial subjects.

* Helsinki Declaration: A statement of ethical principles for medical research involving human subjects, addressed to physicians and others who are involved in medical research on human subjects.

Ensuring Transparency in Relationships With Medical Institutions in Clinical Trials

Astellas provides disclosure of information on conflicts of interest* to ensure transparency in its relationships with medical institutions performing clinical trials.

In Japan, Astellas discloses research expenses and other fees/charges paid to medical institutions in line with the Transparency Guidelines of the Japan Pharmaceutical Manufacturers Association on our website (http://www.astellas.com/jp/transparency/index.html (Japanese only)). These efforts are directed at improving transparent relationships with these medical institutions.

* Conflicts of Interest: When companies entrust clinical trials to medical institutions, a variety of potential conflicts of interest arise between the two parties, including those concerning the payment and receipt of research fees. For the purpose of making the relationship between the two parties transparent, the potential conflicts of interests that arise between the two parties as a result of performing clinical trials must be disclosed.

Disclosure of Study Information and Publication of Study Results

Astellas believes that significant benefits of public health are acquired from disclosure of study information and results widely, not only to medical professionals and patients, but also to researchers and the general public. Besides providing information to patients who are eagerly awaiting the development of new drugs, we also believe that the disclosure contributes to medical progress by inducing the effective use of trial results obtained through the cooperation of trial subjects. We also believe that disclosure of this information is crucial to the advancement of medicine.

Astellas has formulated a global policy on the disclosure of clinical trial information and results. At the same time, we are working to disclose information on clinical trials by publishing academic papers on the trial results.

QUALITY AND RELIABILITY ASSURANCE (REGULATORY AFFAIRS (RA), QUALITY ASSURANCE (QA), CLINICAL AND RESEARCH QUALITY ASSURANCE (CRQA), PHARMACOVIGILANCE (PV))

Anti-Counterfeiting Activities

The World Health Organization (WHO) defines a counterfeit medicine as “one which is deliberately and fraudulently mislabeled with respect to contents and/or source.” Counterfeit medicines in commercial distribution not only prevent patients from receiving medical treatment, but could also impair people’s health. Counterfeit medicines have therefore become a serious problem worldwide.

Under these conditions, Astellas has established the Anti-Counterfeit Committee to help prevent and respond to counterfeit medicines globally. It has also appointed members to investigate and take action against counterfeit medicines. When selling products, Astellas systematically introduces effective anti-counterfeit technologies based on risks in each market where products are sold and product characteristics.

Additionally, Astellas carries out educational activities to prevent the spread of counterfeit medicines, in collaboration with members of the pharmaceutical industry and international organizations, such as the WHO, as well as the Pharmaceutical Security Institute and the Transported Asset Protection Association. We also support and cooperate with law enforcement agencies, such as INTERPOL, as well as national governments, judicial authorities and others to crack down on counterfeit medicines.

Product Recalls

Astellas has a recall system that is activated when the safety, efficacy or quality of a product is brought into question. The system ensures that the relevant information is promptly passed on to medical institutions and other affected parties, and a recall of the product in question.

If an event affecting safety, efficacy or quality occurs, an internal committee is convened to assess the risk posed to patients. A process is in place whereby a decision on a product recall is made based on the judgment of the committee.

In fiscal 2013, Astellas voluntarily recalled six products on a global basis. As of June 2014, we have not received any reports of health impairment related to these recalls.