Pharmaceutical and Food Safety Bureau

Toward the safety of drugs, medical devices, etc.

The Pharmaceutical and Food Safety Bureau collects and provides information on the regulations of manufacturing/sales of drugs, quasi-drugs, cosmetics, and medical devices and on adverse reactions in order to secure the efficacy and safety of the products.

The Bureau is working on blood projects such as blood donation, etc., measures to control abuse of drugs (narcotics and stimulants), and other various issues that are directly linked to people's lives and health.

Protecting people's lives and health

The technological advance of drugs and medical devices has dramatically improved people's health and hygiene. In recent years, however, although rapid advances of high technology have invented many products with powerful effects, there are increasing numbers of products that may be difficult to use properly or may cause strong adverse reactions in some cases.

. Under such circumstances, people's concerns about the safety of pharmaceutical and related products have increased to the greatest level ever.

In response to this situation, the Pharmaceutical and Food Safety Bureau aims to protect people's lives and health through comprehensive efforts including clinical experiments, technical examinations for product registration, and post-market follow-ups in order to secure the safety and efficacy of pharmaceutical and related products.

Prompt provision of effective and safe drugs and medical devices

It has been pointed out that drugs and medical devices used in Western countries have not been made available promptly in Japan. In other words, there is a delay of the time to market for new pharmaceutical and related products in Japan compared to that in Western countries. On the contrary, people's concerns about the safety of pharmaceutical and related products are very high and it is required to secure the safety when releasing new drugs with stronger effects.

With this situation in mind, on the basis of the Five-Year Strategy for Creation of Innovative Drugs/Medical Devices (created in April 2007), the Bureau set an objective for drugs: accelerating the time to market for new drugs by 2.5 years (1.5 years for development and 1 year for examination) during the 5 years between fiscal 2007 and 2011. This will be the world's quickest on a par with that of the United States. In order to realize this, the Bureau is making the following efforts: sharply increasing the number of examiners in the Pharmaceuticals and Medical Devices Agency, clarifying examination procedures and the criteria for approval, improving the operation of Good Clinical Practice (GCP), creating an environment for the promotion of Global Clinical Trials, and strengthening cooperation with Asian countries. The Bureau also works to decrease the number of unapproved or unadapted drugs.

Based on the Action Program for the Acceleration of Medical Device Reviews (created in December 2008), the Bureau aims to accelerate the time to market for new medical devices by 19 months (12 months for development and 7 months for examination) until fiscal 2013. It also works to promote the provision of clinically useful medical devices in a safe and prompt way by ensuring to introduce devices with high medical needs into medical practice.

Pursuing the safety of pharmaceutical and related products

- **Promotion of the separation of dispensing from medical practice and appropriate use of drugs**

Today, people's awareness and concerns about health are increasing and the idea of self-medication is spreading. Under such circumstances, it is becoming increasingly necessary to promote better understanding of people toward pharmaceutical products, by informing people across Japan of the necessity of knowing the property and appropriate usage of drugs in an easy-to-understand way. As the separation of dispensing from medical practice

is rapidly developing, each community is required to promote the idea in an effective manner.

Under these circumstances, the Pharmaceutical and Food Safety Bureau works to conduct educational activities and promote the appropriate use of pharmaceutical products nationwide. It aims to improve the quality of medical care by promoting the correct understanding of drug use, so that more people can know the advantages of the separation of dispensing from medical practice.

- **Post-market safety measures**

The quality, safety, and efficacy of pharmaceutical and related products are thoroughly examined and approved by the Minister of Health, Labour and Welfare. Pharmaceutical and related products are used in medical practice for patients in various age groups and health conditions, or with complications, etc. Therefore, information on new efficacy, safety, etc., of some products, which could not be identified during the examination for approval, can be found after the products are released in the market. For this reason, as safety measures, it is extremely important to collect and evaluate the post-marketing information concerning adverse drug reactions and promptly provide feedback about the information to the medical facilities.

It was, therefore, made mandatory for pharmaceutical companies to report collected information concerning important adverse drug reactions, etc. to the government, and also for doctors, pharmacists, and related experts to report newly-discovered adverse reactions. The Bureau participates in the WHO International Drug Monitoring Programme and aims to share information concerning adverse drug reactions, etc., with other countries.

Reported information, etc., on adverse drug reactions is promptly and accurately evaluated, and revised precautions, etc., are published for medical and pharmaceutical experts on monthly Pharmaceuticals and Medical Devices Safety Information. Urgent and important information is provided promptly and accurately to medical and pharmaceutical experts through the emergency safety information (known as the “Doctor’s Letter”) published by the Ministry or the positive publicity in the media.

Providing safe blood products through blood donations from citizens

Blood products for transfusion produced from donated blood are precious pharmaceuticals that are essential for medical treatment. However, even with today’s advanced science, no method has yet been found to produce artificial blood. Furthermore, in recent years, blood donation by young people, in particular, is seeing a decline and securing donated blood needed for transfusion has become a major issue. The Bureau is recruiting blood donors from the public in cooperation with local governments and the Japanese Red Cross Society. People who wish to donate their blood are asked to show some form of identification, have an interview with the doctor, and have a nucleic acid amplification test (NAT) for virus checks. Thus, the Bureau aims to provide blood products with a higher level of safety and stability.

Creating a society without drug abuse

In recent years, the incidence of drug abuse (mainly stimulants) in Japan has been at a high level. In particular, Cannabis and synthetic drugs such as MDMA, etc., are being abused among young people and the drugs being abused have become diverse, which remains a serious situation.

In order to address this problem, in August 2008, the Promotion Council for Countermeasures to Drug Abuse (Minister of State for Special Missions assigned to the chairman) formulated the 3rd Five-Year Strategy to Prevent Drug Abuses. Based on the strategy, the Bureau takes various measures including the tightening of regulations, upgrading of public education, promotion of measures to prevent relapse of drug abuse, and promotion of international cooperation, etc.