Pharmaceuticals and Medical Devices Agency (PMDA)

独立行政法人　医薬品医療機器総合機構

Towards “Drug and Health Week”
- Consideration with relief services for adverse health effects -

26 October, 2021

17 to 23 October was the “Drug and Health Week” in Japan. This is intended to enhance healthcare and hygiene of the Japanese people by widely spread correct knowledge of drugs and the role of health care professionals such as pharmacists. Related to the Week, here, I would like to introduce Japanese relief services for adverse health effects as one of significant health infrastructure today.

The Pharmaceuticals and Medical Devices Agency (PMDA) offers not only review and post-marketing safety measures to ensure quality, efficacy and safety of medical products but also relief services for adverse health effects as significant pillars. This relief services provide treatment and other fees to individuals who have suffered damage to their health from drugs and regenerative medical products. Very few countries incorporate such relief system: Japan may be the only country in which an organization that performs a series of operations, from drug development to review and safety measures, deals with this issue.

Drugs and regenerative medicines are known to cause unavoidable adverse reactions, even if used properly. The relief service was established in 1980 to provide fees for medical treatment and other fees to sufferers of health injury due to adverse drug reactions, as well as to offer prompt relief to them. It is a public service, based on the Act on the Pharmaceuticals and Medical Devices Agency.

Fees necessary for the payment of medical treatment and other expenses is being covered mainly by contributions from marketing authorization holders and so on. In this system, the PMDA investigates and organizes, from medical and pharmaceutical viewpoints, the facts of the content of the claims based on applications made by either the individuals suffered health damage or their bereaved families.

To make use of this system, individuals who have suffered damage to their health must file an application. The PMDA actively carries out publicity activities each year to make the system widely known among not only healthcare professionals but also the general public by advertising in major newspapers and on television as well as on web portals and social media.

As the regulatory authority for pharmaceuticals and medical devices, PMDA must steadfastly implement measures to reduce avoidable adverse drug reactions, and execute risk management to detect risks as soon as possible to promote proper drug use. Simultaneously, it is also our responsibility to build and operate a system to support individuals suffered from adverse reactions on its own.

The world of medicine is making rapid progress, including the emergence of innovative drugs and the realization of a cure for diseases that have hitherto been considered intractable. We should never forget the possibility, however, that risks humans had never experienced before are lurking in innovative technologies. As a drug regulatory authority, PMDA will continue carefully monitoring these risks, and, once identified, it will promptly establish countermeasures and support those who suffered drug-related health damage by providing meticulous and sympathetic care.

It is only after comprehensively deal with these issues that it can call itself a sophisticated pharmaceutical authority.

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