Explanation of Terms

- **Appropriate use of pharmaceuticals**

Prescribing and preparing pharmaceuticals in their optimum form in regards to ingredient selection, formulation, and appropriate administration and dosage, based on a precise diagnosis. Also, encouraging patients to understand the prescribed drug, evaluating the efficacy and negative side effects, and reflecting the results in subsequent prescriptions. Appropriate use refers to this entire cycle.

- **Clinical trials**

Tests in which pharmaceuticals believed to have medical value are administered to patients as well as healthy subjects in order to determine their efficacy and side effects.

- **Pharmaceuticals and Medical Devices Law**

This is an abbreviated name for the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices. On November 25, 2014, the name was changed from the Pharmaceutical Affairs Law to the current name.

- **E-learning**

A learning system conducted by means of electronic media including the PC and Internet.

- **Good Clinical Practice (GCP)**

Standards for conducting clinical trials of pharmaceuticals.

- **General Data Protection Regulation (GDPR)**

A new personal information protection framework instituted by the European Parliament, European Council and European Commission.

- **Good Laboratory Practice (GLP)**

Standards for conducting preclinical trials on pharmaceutical safety.

- **Good Manufacturing Practice (GMP)**

Standards for manufacturing and quality control of pharmaceutical and quasi-pharmaceuticals.

- **Good Post-marketing Study Practice (GPSP)**

Standards for conducting post-marketing surveillance and studies of pharmaceuticals.

- **Good Quality Practice (GQP)**

Standards for quality control of pharmaceuticals, quasi-pharmaceuticals, cosmetics, and medical devices.

- **Good Vigilance Practice (GVP)**

Standards for post-manufacturing and marketing safety management of pharmaceuticals, quasi-pharmaceuticals, cosmetics, medical devices, and regenerative medical products.

- **Good X Practice (GXP)**

A generic term meaning various good practice standards, where "X" is a variable and could be replaced by C for GCP (good clinical practice), L for GLP (good laboratory practice), M for GMP (good manufacturing practice), etc. These standards are set by the government or other public agencies to guarantee product safety and reliability during manufacturing, maintenance, storage, and distribution of any product, but most often used for products in the pharmaceutical industry.

- **ICH-GCP**

International good clinical practice (GCP) guidelines for pharmaceuticals related to tests and clinical trials, agreed to at the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

- **Informed consent**

A process in which the doctor provides the patient with adequate information on medical care and obtains agreement from said patient.

- **Medical representative (MR)**

A pharmaceutical company's employee in charge of sales and providing medical information. An MR visits medical institutions, sells pharmaceuticals, and exchanges information regarding the quality, efficacy, safety, etc., of pharmaceuticals so as to ensure their proper use.

- **Modality**

Treatment methods, such as small molecule compounds, protein drugs, including peptide drugs and therapeutic antibodies, and nucleic acid drugs.

- **Proof of Concept (POC)**

Confirmation of efficacy and safety of a candidate substance for a new drug based on trials made on humans during the research stage.

- **Quality of Life (QOL)**

Criteria used to evaluate medical treatment to consider, in addition to simply judging the cure of a disease, whether a person is living his or her daily life with a sense of fulfillment and contentment, without a decline in either following the patient's treatment.

- **Self-medication**

Medicating oneself without the supervision of trained health professionals in order to mitigate health problems. This is done at one's own risk using products, information, and knowledge related to health and medical care available in one's own surroundings. This includes the use of over-the-counter (OTC) drugs to prevent or alleviate mild symptoms.

- **Unmet medical needs**

Medical needs that are not addressed adequately by existing therapies. The lack of effective therapies for these needs urgently requires the development of pharmaceuticals since little or no progress is being made.