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Where are we now in the race for innovation?— A proposal of three laws for stronger Japan

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Abstract

The national policy announcement in 2006 of the Japanese new Prime Minister Shinzo Abe and the subsequent report entitled "Innovation 25" emphasizes the importance of innovative drug development. In order to promote innovations in drug development, the author proposes three legal frameworks as the prerequisites.

It should be emphasized that drug development is exclusively a patent business. Thereby, first, a law for the protection of intellectual property rights (IPR), which promotes strategic, business-minded management of IPR in the academie. Second, a law on protecting human research subjects, which covers the conduct of all the clinical trials under the supervision of Good Clinical Practice (GCP), using medical products manufactured under Good Manufacturing Practice (GMP), based on pre-clinical researches under Good Laboratory Practice (GLP), all of which fall under the Pharmaceutical Affaires Law. Third, a law for quality assurance of clinical practice, which defines standardizations of medical record formats; risk management and outcome evaluation systems; and medical audit, by which medical practice is standardized and state-of-the-arts could be established, and by which the bases of clinical research and development is to be constructed.

Without the appropriate legal framework such as mentioned above, uninformed and unprotected Japanese citizens could become victims of exploitation by others. The government and other authorities concerned must realize the importance of a strong legal framework in modern drug research and development.

Key words

innovation, clinical research, drug development, intellectual property right, protection of human subjects

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