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A paradigm shift in drug regulations in Taiwan

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Across Asia, a convergence of economic trends, government policies and greater awareness among the general public of healthcare issues has created an environment that is poised for dramatic growth and change. Taiwan, for instance, can be taken as an example. Taiwan has one of Asia's most highly-praised healthcare systems with excellent provision of healthcare and key health outcomes. Nevertheless, the government is facing new pressures for public healthcare reforms as a result of rapidly ageing population and rising healthcare costs. This paper provides an introductory overview of Taiwan's sudden changes in its drug regulations due to TFDA (The Taiwan Food and Drug Administration) establishment in 2010, TFDA of the Department of Health (DOH) made an advance announcement about the "amendment draft of the Provisions Governing the Registration and Market Approval of Drugs", which amends a total of 40 articles. Without impeding the quality, safety and therapeutic effect of drugs, most of the amended articles are about simplification of application procedures and loosening of regulations for drug registration and market approval. Regulations loosened are imposed on new drugs, radioactive drugs, allergenic drugs and drugs for export that is intended to accelerate the process to sell new drugs in market and promote the export of domestically manufactured drugs. As a result of these changes in regulations many pharmaceutical MNCs and local manufacturers explored their business in Taiwan due to quick approval of their NDAs and gained more flexibility in the local market. To support Taiwan's generic drug industry, DOH has also decided to take measures to simplify and reduce the ANDA application time.

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