

GMP implementation in China: A double-edged sword for the pharmaceutical industry

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ABSTRACT: China's Good Manufacturing Practice (GMP) standards that mainly parallel WHO standards were made compulsory in 2004. However, GMP implementation had both positive as well as negative impacts on the pharmaceutical industry, with negatives including pharmaceutical companies suffering economic hardships, poor execution of GMP standards, and sequent health scares. This report briefly describes the problems with GMP implementation in China.

Key Words: GMP, pharmaceutical sector reform, policymaking, China

Zheng Xiaoyu, the former director of China's State Food and Drug Administration (SFDA), had promoted Good Manufacturing Practice (GMP) certification in China but was convicted of taking bribes and dereliction of duty and sentenced to death this year (2007). Many high-ranking officials were involved in the scandal. Problems with many aspects of GMP implementation were one of the key points in the accusations against Zheng. The scandal, together with many recent health scares, spotlights the paradoxical nature of GMP implementation and serious flaws with drug administration in China.

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(WHO), GMP is a system to ensure that products are consistently produced and controlled according to quality standards (1). Starting in the 1960s, GMP standards were established and revised in most developed countries. Today, GMP are internationally recognized as an effective system for safety and quality assurance. China's GMP standards, basically paralleling WHO standards in developing countries, were introduced in the early 1980s and established in the form of present legislative and compulsory standards in 2004 (2). However, GMP implementation has created a great deal of confusion and problems for China's pharmaceutical industry.

The background of GMP implementation involves reforms in drug legislation and regulation as well as reforms in administrative systems for drug administration as accompany economic restructuring. With its opening up to the outside world, China has, as a global strategy for its domestic pharmaceutical industry, inaugurated many reforms paralleling international practices in an attempt to devise drug regulation and administration suited to a market economy. Stimulated by high profits and government deregulation, the number of pharmaceutical companies increased substantially to approximately 6,000 before GMP implementation (3). However, most were small-scale companies with minimal efficiency and outdated manufacturing technology that competed viciously in the market. Amidst this chaos, the pharmaceutical market suffers from inadequate drug safety and quality and is even plagued by fake drugs. Thus, the SFDA's original intent was to improve the safety and quality of drugs, to upgrade drug manufacturing, and to optimize the composition of the pharmaceutical industry by eliminating a number of small and medium companies in poor condition.

GMP implementation was expected to strengthen

China's pharmaceutical industry. However, results have differed from what the SFDA intended. Obvious problems for which SFDA has been criticized were that more than 3,700 small and medium companies still account for the majority of firms in China's pharmaceutical industry and that many face economic hardships with a heavy debt burden and an even more severe lack of funds. The huge cost of GMP implementation has led to a worsening of their financial situation. Meanwhile, poorly planned projects to adapt the GMP guidelines led to unnecessarily excessive production capacity. A number of qualified plants with expensive GMP product lines lay idle and do little to recoup the funds invested in GMP implementation (4).

In addition, there were differences between GMP standards and what was actually implemented and certified at several pharmaceutical companies. One factor causing this poor state of GMP implementation is believed to be a lack of transparency in the drug administration system that has allowed financial relationships between local governments and pharmaceutical companies and regional protectionism by these forces (5). A typical case was the bribery scandal mentioned at the beginning. Thus, many health scares have arisen from shoddy products manufactured by companies with perfunctory GMP certification (6), severely hurting the credibility of GMP.

Given the issues discussed above, GMP implementation has been a double-edged sword wielded by governments supervising drug administration. All of the processes involved should serve as a good lesson for other developing countries promoting pharmaceutical sector reform. As a part of China's global strategy for its domestic pharmaceutical industry, its endeavors to enhance these regulatory and legislative standards

put drug regulation on the right path early on. In this regard, the SFDA took the right tack. However, the issue of rationalization of the government structure of drug administration should be resolved incrementally in the near future; this resolution may be facilitated by interdisciplinary studies incorporating diverse views from policymakers, corporate executives, and researchers.

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