

Bird & Bird

China Regulatory Update: Life Sciences



China Issues New GMP

China's new drug GMP, entitled Drug Manufacturing Quality Management Standards (2010 revision) (the "New GMP") was issued as an order by the Minister of Health on 17 January 2011. It was posted on the website of the State Food and Drug Administration (SFDA) on 12 February 2011 and will become effective on 1 March 2011. Implementation of the New GMP is expected to be a crucial aspect of China's Twelfth Five Year Plan.

The Drug Manufacturing Quality Management Standards was first published in 1988, and since then, two revised versions have been issued, in 1992 and 1998. Revisions leading up to the New GMP started in 2005, with two draft forms published for public comments before the final issuance.

As with similar guidelines imposed in other jurisdictions, China's GMP forms part of a quality management system which sets out the basic requirements for the manufacture and quality management of pharmaceutical products with the goal of ensuring continuous and stable manufacture of pharmaceuticals that comply with the designated purpose and registration requirements. China's GMP aims to reduce to the greatest extent possible the likelihood of any contamination or cross contamination in the manufacturing process, as well as other risks resulting from errors.

Key Changes in the New GMP

Generally speaking, the New GMP significantly elevates the GMP standards in China. Compared to the pre-existing GMP, the New GMP places more emphasis on the operation of a comprehensive quality control system by drug companies. Key changes in the New GMP include the following: (i) strengthens the establishment of a drug manufacturing quality management system; (ii) bolsters the overall employee quality requirements; (iii) refines document management rules such as operating procedures, manufacturing records, etc., in order to enhance guidance and operating capabilities; and (iv) further improves the measures to be taken in order to ensure drug safety.

Potential Impact on the Industry

China's drug industry remains highly fragmented, with close to 5000 drug companies, many of which are small to medium-sized companies. As elevated standards under the New GMP mean higher manufacturing costs for drug companies, the New GMP potentially benefits big drug companies with resources, particularly those who have already adopted higher GMP standards, whereas many smaller companies will likely be eliminated. We would expect to see greater market consolidation in this industry. These developments will significantly boost the overall quality of China's pharmaceutical industry which will improve the competitiveness of Chinese pharmaceutical companies on the global market. The New GMP demonstrates China's continuing determination to push its domestic drug enterprises to become true world-class players in the global pharmaceutical industry.

Compliance Schedule

The impact of the New GMP on the industry is expected to be gradual. Although newly established drug manufacturing enterprises, and the new establishment (renovations or expansions) of manufacturing facilities by existing drug manufacturing enterprises will have to comply with the New GMP immediately, starting from 1 March 2011, existing drug manufacturing enterprises will be given a transition period to comply – those manufacturing sterile drug products such as blood products, vaccines and other injectable drug products will be required to comply by 31 December 2013, and all others will be required to comply by 31 December 2015. Companies that fail to comply by the above deadlines will no longer be allowed to continue manufacturing their drug products in such non-compliant manufacturing facilities.

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