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How to get your drug registered in China?

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The domain of biosciences in the Asia Pacific (APAC) region offers several opportunities for companies that are looking for growth in the region. Regulatory approvals are, however, a challenge for these firms in the APAC region. *BioSpectrum* speaks to industry insiders and regulatory professionals from China, in order to compile a guide on the regulatory processes in the dragon nation. (Also read throughout this week: Regulatory requirements in **Taiwan**, **Australia**, **Hong Kong**, India, Indonesia, Singapore and Korea)

In China, drug and biological products are regulated by the SFDA, which is a counterpart of the US FDA. The Center for Drug Evaluation regulates both drug and biological products in the country.

Marketing authorization of a new drug in China mandates clinical trials with Chinese patients as prerequisite. The applicant has to conduct phase I pharmacokinetic studies together with randomized clinical trial with at least 100 pairs of subjects. Clinical trial application review and approval takes approximately 12 months.

Drug import approval requires availability of marketing authorization outside China, such as certificate of pharmaceutical product from a reference country. Multi-region clinical trials can be started only after the new chemical entity has been tested in phase II outside of China. This prevents China from participating in simultaneous global drug development.

Drug approval in China follows first international new drug application approval. There are two drug registration pathways in China which include new drug application and import drug license. Similarly, there are two clinical development strategies. They are sequential development and parallel development.

Under sequential development, phase I to phase III followed by the stage of new drug application and Certificate of Pharmaceutical Product takes place in the reference country. The stages from China clinical trial application to getting China import drug license can take up to five-to-eight years. Under parallel development, the approval process is shortened by

three-to-five years.

Clinical trial requirements in China
For new or imported drug applications, the sample size should meet the statistical requirement. For category I and II (new drugs), the minimum number of cases required (trial group exposure) are 20-30 for phase I, 100 for phase II, 300 for phase III, 2,000 for phase IV. For category III and IV (imported drugs), trials should have at least 100 pairs. In the event of more than one indication, cases for each main indication shall be at least 60 pairs.

Challenges before China
China needs to expedite the review and approval of new chemical entities (NCEs) or new biologics. Also, China needs to adopt better guidelines, such as adoption of International Conference on Harmonization eCTD guidelines are needed for acceptance, review and management of regulatory submissions.

Moreover, drug safety surveillance system for in-development or post marketing drugs needs to be enhanced by China. Drug registration in China should be prioritized based on patient need at evaluation. Furthermore, the Chinese government should investment on local talents in clinical development, and regulatory affairs should be boosted.

(Shared by Mr Dong Zhao, director, regional submissions head for Asia, Pfizer Worldwide Safety and Regulatory, at the 'Pharmaceutical Regulatory Summit' in Singapore during August 2012)
To know more about regulatory-related issues in China, visit http://eng.sfda.gov.cn