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ASIA EDITION

How to get your drug registered in S Korea?

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How to get your drug registered in Korea?

The bioscience sector in the Asia Pacific (APAC) region offers ample opportunities for firms that are seeking to grow in the region. However, regulatory approvals often emerge as a bottle-neck for these companies in the APAC region. BioSpectrum speaks to individuals from the industry and professionals belonging to the regulatory domain from Korea, to compile a guide on the regulatory processes. (Also read during this week: Regulatory requirements in China, Taiwan, Australia, Hong Kong, India, Indonesia and Singapore)

The Food Drug Application (KFDA) is the main body regulating pharmaceutical products in Korea. Its Pharmaceutical Safety Bureau is responsible for Pharmaceutical and Narcotic Safety Management Acts and Institution and establishment of comprehensive plan, pharmaceutical quality management, instruction and inspection and post market management; approval and evaluation of pharmaceutical manufacture and imports.

How to get a drug approved in Korea
In order to get a drug approval in Korea, the applicant has to prepare a dossier for drug approval and submit it to drug approval and review management division of the KFDA. The regulatory management would then write a preliminary report on application outline and examination of the application for the preliminary evaluation.

At the evaluation stage, the Drug Evaluation Department reviews the result of the preliminary report, technology dossier by therapeutic area, safety, efficacy, quality, bioequivalence and clinical trials and social impact. Once the drug is approved, the applicant gets a certificate of approval and he can release the result of the drug approval and disclose review reports on the website.

(As shared by Ms Chong-Hui Hong at the 'Pharmaceutical Regulatory Summit' in Singapore during August 2012. To know more about regulatory-related issues in Korea, visit www.kfda.go.kr)