BioSpectrum the business of Bio & Health Sciences ASIA EDITION

How to get your drug registered in Singapore?

September 28, 2012 | Regulatory | By BioSpectrum Bureau

How to get your drug registered in Singapore?



The sector of life sciences in the Asia Pacific (APAC) region offers massive opportunities for companies, which are looking for growth. These firms often face many regulatory challenges in the APAC region.

BioSpectrum speaks to industry individuals and regulatory professionals from Singapore, in order to compile a guide on the regulatory processes in the country. (Also read during this week: Regulatory requirements in China, Taiwan, Australia, Hong Kong, India, Indonesia and Korea)

In Singapore, pharmaceuticals, biologics, medical devices and health-related products are regulated by Health Products Regulation Group, a division of Health Sciences Authority.

How to register a new drug in Singapore
If the application is yet to be approved by any regulatory agency, a full dossier has to be submitted to the Health Sciences Authority (HSA) for regulatory decision. It takes around 270 working days.

If the application is approved by one drug regulatory agency, an abridged dossier has to be submitted for abridged evaluation and regulatory decision. It takes around 180 working days.

Ã?Â

If the application is approved by HSA's reference regulatory agencies, which include the US FDA, Health Canada, UK MHRA, Australian TGA and EMEA, a verification dossier has to be submitted for evaluation and regulatory decision based on assessment report by reference regulatory agency. This takes around 60 working days.

How to register a generic drug in Singapore

If the product is approved by one drug regulatory agency, an abridged dossier has to be submitted for abridged evaluation and regulatory decision. It takes 240 working days.

If a product is approved by reference regulatory agencies, verification dossier has to be submitted for evaluation based on assessment report by reference regulatory agency for regulatory decision. It takes around 120 working days.

(As shared by Dr Raymond Chua, group director, Health Products Regulation Group, Health Sciences Authority, Singapore. To know more about regulatory-related issues in Singapore, visit www.hsa.gov.sg)