BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Challenge No 6: Regulatory hurdles

17 May 2012 | Analysis | By BioSpectrum Bureau

Compliance with different regulations a challenge for life sciences companies in APAC

The regulatory environment for life sciences companies is known for its challenging nature. The framework is confusing and at times overshoots the understandable need to protect patients with regulation making life-saving tests often unaffordable. Also, the Asia pacific region, which has many countries with their own rules and regulations, lacks regulatory harmonization, resulting in longer time for clinical validation of products (Read about all 10 challenges for businesses in APAC).

"With newer set of regulations and guidelines each year, compliance can be a painful and costly affair. Creating forums where government policy makers and company regulatory personnel meet to discuss general issues in the regulatory environment and ways to improve and expedite could be a positive step forward, as is common in many other countries, " says Dr Bhuwnesh Agrawal of Roche Diagnostics India.

One of the greatest challenges before any medical technology company is not the required regulatory approval to sell in a particular jurisdiction, but the clinical market size for the product that justifies the costly regulatory approval process. "The last thing any company would want is to spend huge amount of resources to obtain regulatory approval only to realize that the approved product has a limited and diminishing market to operate in," says Dr Noel Moore of HistoIndex, Singapore.

He further adds, "For our medical related products, data from clinical validation is essential for many aspects, including product development and marketing. However, as a young start-up company based in Singapore, it is difficult to achieve this in a cost- and time-effective manner. Conducting these tasks in Singapore is more expensive than doing them in other Asian cities, and the patient pool is also smaller here."

Commenting on regulatory issues Mr Rahul Dev of Tech Corp Legal LLP India says a major challenge in India is to have an effective mechanism for dealing with the government, given its active responsibility in taking funding decisions, regulating healthcare services, and deciding policy issues, including the most crucial ones regarding intellectual property rights. "In China, companies need to pass many hurdles such as complicated regulatory framework and a lengthy process for getting a product registered and then getting it added to the national reimbursement list," he adds. In Australia, he says, the challenge for pharmaceutical companies "is the upcoming patent expiration for drugs developed in the 1980s and replicating those profit streams".

"There certainly are issues in terms of speed and a lot still requires to be done to minimize the time line for approvals. We don't believe in criticizing the government because it doesn't help. We are all part of the same process and I believe we must have frequent interactions to resolve issues, " says Dr Rajesh Jain, joint managing director, Panacea Biotec, India.

Dr Amar Kureishi, head- Strategic Drug Development Asia, Quintiles, Singapore, says the challenge for Quintiles would vary from country to country. "But generally, it would be to get the clinical trial application process done as soon as possible, because in drug discovery timelines are everything. So, from a regulatory standpoint, it is difficult when the process is not clear. Setting up the framework for quality is another issue. It would be nice if there were some expectations set by a regulatory body for the investigators to follow which would help enforcement of quality," he adds.

As Mr Kamal Joshi from Venus Remedies, India, says, "There is need for implementation of harmonized regulatory framework in Asia Pacific."

Previous challenge
Next challenge