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Regulatory Harmonization Takes Center Stage At IFPMA Asia Event

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KUALA LUMPUR, Malaysia - Industry and regulators in Asia are mapping out strategies for regulatory harmonization, mostly borrowed from the U.S. and European Union experiences, in an effort to help the rapidly growing Asian pharmaceutical markets.

"One of the things that needs to be fixed is the relative lack of transparency, and accountability of governments in regulatory affairs globally," Lembit Rago, coordinator, Quality Assurance and Safety: Department of Medicines Policy and Standards, World Health Organization, told attendees March 11 during the Fifth Asian Regulatory Conference, sponsored by the International Federation of Pharmaceutical Manufacturers & Associations in Kuala Lumpur, Malaysia.

He said the second pressing issue is developing public confidence about drug quality, which makes the need for collaboration among stakeholders more pressing given the global shortage of human resources.

In response to that shortage, industry appears more willing to move beyond sharing minimal requirements, as evidenced by increased transparency via clinical trial registries and increased stakeholder meetings.

Need For Asian Regional Solutions

The need for Asian regional solutions was also stressed at the meeting. For example, Northern and Southeast Asia have split into two groups with different approaches to harmonization.

China, Japan and Korea have formed the Regional Harmonization Initiative to address clinical data sharing to achieve harmonization and reduce duplication. Part of the initiative is the study of pharmacogenomic factors that single out Chinese, Korean and Japanese genetic variances from Caucasians.

Such studies could allow countries such as Japan to accept data from other countries in lieu of data from Japanese clinical research participants.

The 10 member countries that make up the Association of Southeast Asian Nations, or ASEAN, also have formed an initiative to eliminate technical barriers to trade and promote cooperation to achieve harmonized products in Southeast Asia. Those countries are Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam.

Health is one area of ASEAN focus, with a goal, similar to the European Medicines Agency, of harmonized solutions that could include variances within each country. ASEAN set a target date of Dec. 31, 2008 for full implementation of ICH standards.

Similar to the EU experience with its Clinical Directive deadline, not all ASEAN countries are expected to meet that deadline. But some will, and the effort to move toward that goal has been applauded by industry and regulators as a welcomed step in the right direction.

"Asia is now firmly at the core of most companies R&D efforts, mostly for Phase III studies, but we are beginning to see more early phase research there as well," GlaxoSmithKline VP - International Affairs Alistair Davidson told conference attendees. "The way we do our business is just as important as what we deliver," he said, noting that agencies and companies must look at internal ethical barometers to pass regulatory and public scrutiny and move the industry forward in the region.

Is Asia Ready For More R&D?

With more insight into the causes of diseases and the ability to tailor treatments based on genetic differences, solutions must be global, Malaysia's Ministry of Health Director General Ismael Merican said.

Asia is readying itself by ramping up training in good clinical practices and good regulatory practices, as R&D resources begin to shift away from the U.S. and EU toward Asia, he said. "Malaysia is trying to put requisites [in place] so that our country is able to compete in the global arena," Merican said, adding that "all doctors in Malaysia who undertake clinical research are trained in GCP practices. We will not allow those without GCP training to conduct any clinical trials."

To that end, Malaysia and other Southeast Asian countries aim to establish a network of R&D facilities in partnership with other countries and cooperative research groups to enable more multi-center clinical trials.

"We are cognizant that this is not easy to obtain global acceptance," Merican said, adding that Malaysia has taken steps so that data will be recognized and will be accepted in all ICH countries.

"Investors in the field of R&D do not look for the cheapest locations, but for the country where their intellectual property enjoys the best protection and where the environment is most conducive to the creation of new IP," Merican said. He noted that the relationship between intellectual property and protection of public health has been a major issue of public debate in several international forums, but stressed that "IP issues can be addressed in such a manner without stifling innovation."

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[Editor's note: Look for more in-depth coverage of the Fifth Asian Regulatory Conference from Kuala Lumpur in an upcoming issue of PharmAsia News.]

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