The BIO Convention in China
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Building Your China Strategy

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China's SFDA Planning Biosimilar Regulations and Speedier Innovative Drug Approvals

This Week's Buzz is Courtesy of L.E.K. Consulting

China's SFDA recently revealed that it has begun to draft guidelines for biosimilar drugs, calling upon scientists and entrepreneurs to actively participate in the process. Weihong Chang, SFDA biological products division Vice Director, said that four working teams are being established to encompass policy, quality control, pre-clinical research, and clinical research. An additional consultation team comprised of scientists, researchers, and entrepreneurs from overseas and domestic companies is also in formation (Click here for current SFDA registration guidelines).

L.E.K.'s interviews with both Western and Chinese pharmas indicate that they expect SFDA to follow the progress of FDA's biosimilar registration discussions, and that is unlikely SFDA will publish its views until the US's biosilimar policy becomes clearer. While biosimilar regulations are being discussed, the two dozen Chinese companies working on mAb biosimilars and their international counterparts planning for China market entry are moving through the process via the standard biologics registration pathways.

In contrast to biosimilars, SFDA has already implemented regulations supporting speedier regulatory review of "new drugs for special approval" since January 2009. This special approval status streamlines the communications and review with SFDA during the application process and may also reduce the data submission requirements. Often called the "green channel," this pathway covers:

- New treatments for AIDS, cancers and rare diseases with superior efficacy vs. existing treatments
- New drugs targeting diseases without effective treatment
- Drugs, APIs or biological products that have not been approved worldwide
- Biological extracts new to the Chinese market (expected to be mostly Chinese medicine)

Since the green channel's implementation in 2009, L.E.K. has tracked nearly 30 products sped up by SFDA. More than one-third of these products are in oncology. Hutchison MediPharma, Simcere, Jiangsu Henrui, Zhengjiang Beta Pharm, and FibroGen all have products with green channel status.

Other healthcare policies under evaluation by the Chinese government include chronic disease prevention plans, a study on the relationship between drug patents and drug registration systems, and encouragement of private health insurance.

To hear more from L.E.K. Consulting and other China biopharma policy experts, attend the Globalizing Traditional Chinese Medicines and Regulatory Review Process of New Medicines in China panels at The BIO Convention in China.

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