



PHARMACEUTICALS EXPORT PROMOTION COUNCIL
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China's new approvals system brings outsourcing opportunity

By Michael Stones in New York, 31-Mar-2011

A new, tougher approvals policy for pharmaceutical products in China will bring opportunities for Western contract companies able to help domestic firms meet the strict new rules, according to a seminar at InterPhex in New York.

John Choate, CEO Advanced Pharmaceuticals, told the seminar, entitled Development of the Chinese Pharmaceutical Industry, that many Chinese companies would rely on western outsourcing companies to help them meet the new regulations or face closure.

"The Chinese regulatory body, the SFA is working in co-operation with the US Food and Drug Administration (FDA) to introduce a US-style approvals system in China," said Choate. The new standards *"...will force some Chinese companies out of business because they cannot provide large-scale process development...unless US contract companies assist them."*

Higher quality products

The new Chinese regulations emulate the FDA approvals system including: Large-scale process development, large clinical trials, GMP (good management practice) and testing. Their aim is to provide a more transparent system which results in more consistent, higher-quality products, said Choate.

Of the 7,467 pharmaceutical companies operating in China, 5,989 are domestic firms and 1475 are international companies, acting either alone or in joint venture agreements with Chinese companies, according to Yu Xiong, vice president of China State Institute of Pharmaceutical Industry.

Domestic firms earn \$89.6bn year or 68.9 per cent of total revenues, he said.

The Chinese authorities' approval system borrows so heavily on the FDA system that Choate said: *"Yu Xiong had joked that he hoped the FDA had not patented its approval system because the SFDA is emulating it."* All drugs in China must receive SFDA approval before production and sale.

Much of the domestic pharmaceutical industry is characterised by small to medium-scale businesses which lack innovation and research and development expertise. *"Domestic drugs are low to medium quality compared with imported drugs,"* said Choate. *"The government is pushing*

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to advance the Chinese pharmaceutical industry."

Yu Xiong admitted: "*Pharmaceutical products (produced in China) are mostly generic, low-tech with low standardisation. Chinese companies find it hard to compete in the world market.*"

Massive opportunities

Meanwhile, the Chinese government's pledge to invest \$125 bn in health care services to extend basic health care to 90 per cent of the population offered massive opportunities not just for contract service providers but drug manufacturers too, said Choate.

He listed the largest drug markets in China, in order to sales, as: First, Antibiotics, followed by, cardio-vascular, diabetes, neurological conditions including depression, GI diseases and finally cancers. "*The Chinese population is becoming increasingly westernised and is picking up our diseases,*" said Choate.

China is already the world's third-largest pharmaceutical market. Growth is expected to climb to between 25 to 27 per cent this year compared with a global growth rate of 5 to 7 per cent last year, according to IMS Health.

Source: Interphex 2011