



## **Medical Equipment, Devices and Healthcare**

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### **Introduction:**

The Chinese government recently announced a long-term plan for healthcare reform. The announced plans include 20 specific laws and regulations that address several acknowledged weaknesses in the Chinese healthcare system. The new regulations will include; universal access to basic health insurance, introduction of an essential drug supply system, improved primary health facilities, access to public health services and reform of state-run hospitals. Improvements in infrastructure, growing demand for medical supplies and equipment and higher demand for drugs will encourage private investment into the medical field. Healthcare reform will provide much needed medical care to a large segment of the population and provide upper-income Chinese with the highest levels of care. However, many remaining issues prevent China's healthcare system from reaching its full potential.

### **Issues:**

One major function of the State Food and Drug Administration is to approve access to medical devices. SFDA resources are inadequate to handle the workload presented. Lehman, Lee & Xu recommends standardizing and streamlining the application requirements in an effort to eliminate redundant testing. Furthermore, increasing the resources available to the SFDA would improve efficiency.

In 2009, the SFDA announced new regulations that allowed a bypass of re-registration for products which have not undergone any changes. This policy helps reduce unnecessary duplication of testing. However, very few products actually qualify for the exemption. Considering the nature of the medical industry, minor tweaks and changes are inevitable for a large majority of products. Therefore, Lehman, Lee & Xu suggests the SFDA allow use of the original product registration and simply test the altered part.

An additional issue facing the Chinese medical industry is overlapping governmental supervision. Many areas of the medical field are supervised by two or more agencies. This inevitably leads to confusion regarding registration and difficulties meeting each agencies requirements. For example, products such as pacemakers, dialysis equipment, ultrasound and X-ray equipment must gain approval by the SFDA, the China Compulsory Certification and the General Administration of Quality

Supervision, Inspection and Quarantine. Lehman, Lee & Xu suggests a simplification of the process and only one supervising agency for each medical field. Ending this redundancy would surely improve efficiency.

One improvement that is critical to improving coverage and quality of care is China's capacity to provide access to new and high-tech medical devices and treatments. Every purchase of select classes of medical equipment must gain approval by the Ministry of Health, even if it has previously acquired marketing approval. Lehman, Lee & Xu suggests this policy be lightened in an effort to make it more affordable and easier for hospitals to acquire high-tech medical equipment.

China's import/export regulations also prove to be an impediment to an improved Chinese healthcare system. The requirement that items produced outside of China receive prior approval in the country of export drastically increases the cost of imports and lengthens the approval timeline. Many medical equipment manufacturers place manufacturing plants within countries where they do not plan on selling the product. Type testing is also required prior to importation of a medical device. Many medical devices are manufactured within countries that lack the laboratory resources to conduct such testing, further impeding importation of high-tech medical equipment. Lehman, Lee & Xu advocates a removal of these regulations and urges the SFDA to accredit foreign laboratories and allow test reports from those locations. This change in policy would alleviate redundancies and streamline the importation of medical equipment into China.

In an effort to increase insurance coverage, the Chinese government is now encouraging private investment to supplement the public system. However, the insurance industry remains a restricted investment category and many regulations inhibit private investment. Additionally, patients who seek care at premium hospitals are not eligible for reimbursement from the Urban Employed Worker Health Insurance. Lehman, Lee & Xu recommends a removal of the regulations restricting private investment into the insurance industry, and a policy allowing patients to receive the same level of reimbursement regardless of which hospital they choose. These policies would be consistent with allowing for choice in healthcare and encouraging private investment.

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