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Briefing Paper

Pharmaceuticals

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Introduction:

In 2009, the Chinese government announced an RMB 850 billion investment into the healthcare system over the next three years. This announcement was the latest reforming measure in China's continual effort to overhaul the healthcare system. Along with monetary investment, China announced its four pillars of healthcare reform; enhancing the medical insurance system, improving the basic drug delivery system, upgrading local healthcare facilities and revamping public hospitals.

Clearly these announcements are a step towards an improved healthcare system, however, many challenges remain. Relevant challenges include; appropriate healthcare funding, prescribing and dispensing practices, hospital bidding procedures, government pricing and reimbursement policies, and the protection of intellectual property. Unless these areas are addressed, China's healthcare system will fall behind the global standard for modern countries.

Costs:

Despite the large investment announced in 2009, the percentage of China's GDP invested into the healthcare system remains relatively small compared to other modern nations. Additionally, a majority of Chinese patients pay their healthcare costs out of pocket. For these reasons, Lehman, Lee & Xu supports the Chinese government's expansion of public health insurance and increased regulation of private healthcare.

Issues:

Chinese medical regulations allow physicians to both prescribe and distribute medicine. Due to inadequate funding to hospitals and poor compensation for doctors, this practice may result in physicians prescribing medicine based on financial motives, rather than what is best for the patient. China has announced plans to restructure hospital financing in hopes to eliminate hospital mark-ups.

China's plans for a comprehensive drug policy that aims to make pharmaceuticals available to the undeserved populations is a commendable goal. However, implementation details are still under consideration. Lehman, Lee & Xu advocates the implementation procedures be transparent and consistent. Policies should include; the ability to appeal, patient choice, access to innovative medicines and that medical care

be based on quality of care, rather than purely on costs. It is also critical that both provincial and local governments consistently and uniformly implement the policies and that a mechanism exists to monitor proper implementation.

China's clinical trial application is highly burdensome when compared to other modern nations. When applying for a clinical trial, applicants are unable to supplement their applications with new information. Therefore, if new information becomes available, they must resubmit their application for every clinical protocol. Furthermore, China's pre-clinical and clinical requirements are much more stringent than other countries. These issues make regional or global trials, which would make new therapies available, much more difficult. Lehman, Lee & Xu suggests the Chinese government allow China's medical community to participate in both global and clinical trials.

Like many other industries within China, the pharmaceutical industry is burdened by limited IP protection. Chinese medical patent regulations require sales in the marketplace prior to an infringement suit being filed. As a result, many companies are unable to enforce their patent rights until damage has already occurred. Lehman, Lee & Xu suggests that patent holders be allowed to file infringement suits prior to market sales. Furthermore, drug registration approval should be postponed until resolution of the patent dispute.

Counterfeit pharmaceuticals also present IP issues, as well as general health issues. Lehman, Lee & Xu advocates implementation of drug safety regulations and multilateral cooperation. Currently, China lacks adequate enforcement of laws addressing pharmaceutical counterfeiting. One major burden for adequate enforcement is the requirement of proof of actual harm prior to criminal liability. Removal of this requirement would drastically increase a patent holder's ability to protect their innovation.

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