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Executed Chinese drug czar corrupted by system, observers say

On 10 July, six weeks after sentencing Zheng Xiaoyu, the former chief of its food and drug regulatory agency, for taking bribes, China executed him.

The shocking move was a symbol of China's efforts to get past scandals surrounding the agency's approval of counterfeit medicines that have killed dozens. Coming a day ahead of the announcement of new drug approval policies, it was also intended to signal a new era in drug safety that the government envisions.

But observers in the pharmaceutical industry and elsewhere are waiting to see if the events that follow match the government's ambitious plans.

"The execution was a catharsis. Now they can look forward," says Drew Thompson, director of China Studies at the Washington, DC–based Nixon Center.

Zheng took over the helm of the newly formed State Food and Drug Administration (SFDA) in 1998, after having headed the State Pharmaceutical Administration for the previous five years. The post gave him wide authority to streamline the chaotic system he had inherited. Zheng played the role of reformer, in part by enforcing national standards for traditional Chinese medicines and requiring 'Good Manufacturing Practice' at all drug companies.

But the requirement that drug makers comply with the new standards also proved useful for those looking to extract bribes.

Scapegoat?

STR/AFP/Getty Images

Zheng himself was accused of taking 6.49 million yuan (US$832,000) in exchange for pushing through the approvals of questionable drugs. His wife and son were also investigated and reportedly arrested for running 'consulting agencies' to which the SFDA referred applicants.

In November, one of Zheng's former secretaries, Hao Heping, who headed the SFDA's medical equipment department, received a 15-year prison term for accepting bribes. On 6 July, another former secretary, Cao Wenzhuang, was convicted of taking 2.4 million yuan ($315,700) to approve drugs and medical equipment. Cao was also given the death sentence, although his punishment may be reduced to life in prison.

Despite his missteps, however, Zheng "was trying to create a system out of chaos," says Thompson, who until earlier this year served as national director of the China–MSD HIV/AIDS Partnership in Beijing, a $30 million program established in 2005 by Merck and the Chinese Ministry of Health.

"Zheng came in with good intentions, but he was corrupted by a bad system," Thompson says.

The 63-year-old Zheng appealed for leniency, noting that he had confessed to the crime and cooperated with investigators—which, by Chinese law, could merit a lighter sentence—but to no avail.

Chinese authorities say the harsh sentence was fitting. Zheng approved six types of medicines during his tenure. One antibiotic alone was reportedly to blame for ten deaths.

The court found that Zheng "greatly undermined the uprightness of an official post and the efficiency of China's drug monitoring and supervision, endangered public life and health, and had a very negative social impact."

The day after Zheng's execution, the SFDA announced plans for a new system that is expected to go into effect 1 October. Under the new rules, drugs will be approved by a special panel, rather than by any single person. Agency officials will carry out spot checks on manufacturers. New chemical entities—as opposed to the copycat drugs that have dominated the list of SFDA approvals thus far—will be given fast-track status in the approval process.

The SFDA also plans to crack down harder on those who violate the rules. Companies that give false information about their drugs could be barred for three years from applying for new drugs. Access to information on drug approvals will be open, rather than dependent on personal connections within the agency. "Transparency is the enemy of corruption," SFDA deputy director Zhen Wu told reporters on 11 July.

In an attempt to make the agency's decisions more open, the SFDA also plans to hold press conferences on a fixed date every month, in contrast with the previous custom of holding them only when there were notable announcements.

That approach is truly unique in China, notes Wang Ming-Wei, director of the National Center for Drug Screening in Shanghai. "They are going to be communicating with the public about what really is going on," Wang says.

Wang says his greatest concern is the "slow-motion" pace of the drug approval system in the wake of the execution. Getting approval to start a new drug trial takes between 12 and 18 months, compared with 30 days in the US, he says.

"People are panicking. [The SFDA investigators] are very strict—they'll either do nothing or they'll reject [the drug]," he says.

The government will also find it challenging to come through on its promise to give more enforcing power to local offices, which Zheng limited during his tenure. "But local governments don't always have the same commitment to transparency that central government has," says Thompson. "The SFDA is trying to centralize and standardize approval, but decentralize enforcement. It's a tough formula to get right."

Still, most observers say the proposed regulations are a step in the right direction.

"[The new system] has transparency, accountability, checks and balances," says Thompson. "This is new for China."

David Cyranoski, Tokyo