China overhauls drug regulation agency

After years of complaints over the slow pace of drug review in China, in March the National People's Congress ratified the revamping of the State Food and Drug Administration (SFDA), which will now operate as the China Food and Drug Administration (CFDA). The changes are touted to strengthen the agency's regulatory muscle, although how much the overhaul will be translated into improved oversight and more rapid decision-making remains uncertain. "I hope the CFDA can really boost innovative drug review," says Zailin Yu, president of Tianjin-based SinoBiotech.

The restructuring was set in motion on February 22 when the SFDA outlined a series of proposals designed to boost confidence in the drug review and approval process as well as help promote regulatory oversight. If implemented, this will be the first major reform since former SFDA head Zheng Xiaoyu was executed for taking bribes in 2007 (*Nat. Biotechnol.* **25**, 835–837, 2007).

Key messages in the proposals include redefining 'innovative' drugs from a narrow focus on scientific originality to one that emphasizes their therapeutic impact. "[The new measures] encourage drug innovation as defined by clinical values…It is important to have an original compound, but more attention should be given to the appraisal of clinical values," says the SFDA reform document.

A proposed flexible reviewing process would allow new drug sponsors to amend applications and add new documents. It would also introduce the concept of priority generics and a simplified approval pathway for ordinary generics. In China, there is no distinction between copies of small molecules and biologic drugs—they are all called generics. Biologics, if modified from the original, are treated not as generics but as new drugs.

The CFDA's approach has the potential to benefit the me-too and me-betters, comments Yu, whose company is developing modified versions of granulocyte colony-stimulating factor (GCSF) and interferon alpha. Like Yu, most Chinese drug developers have had to cope with long waiting times before receiving SFDA approval for clinical testing. "The slow review is caused by SFDA's overcautious attitude and understaffing, because a great effort is being spent on thousands of generics applications each year, which are reviewed under an [unnecessarily] strict process," says Tuo Jin, a professor of pharmacology and innovative drug developer at Shanghai Jiaotong University.

Meanwhile, SFDA officials are constantly worried about being blamed for approving a trial for a drug with no precedents elsewhere in the world if it causes problems, resulting in a cautious and exceedingly slow process, adds Yu.

Two years after Zheng's execution, a group of SFDA officials, including deputy head Zhang Jingli, were arrested again for corruption. This prompted an internal reshuffling in which the approval process for drugs and medical devices was divided, compounding the delays. The SFDA had no dedicated pathway for approving generic drugs. The proposed priority generic pathway, considered an urgent need for China, will run as a simplified version of the ordinary generics pathway. It will apply to both small molecules and copies of biologics. Under the new CFDA, the ordinary generics review focuses on similarity with the original patented drug, instead of requiring new data on safety and efficiency.

"This could liberate new drug reviewers from spending huge amounts of time studying individual clinical trials of ordinary generics. As a result, resources can be shifted to enable quicker and better quality reviews for innovative drugs," Jin says. It is unclear when the proposed reform will be implemented; no one at CFDA could be reached for comment.

In addition to its renaming, CFDA was also upgraded in March to become a ministry-level agency. The reshuffle is aimed mainly at boosting its food jurisdictions to cope with widespread public outcries over food safety.

One key new development is that for the first time since the agency was established in 1998, it is headed by a person without a pharmaceutical background. Zhang Yong was previously the director of the State Council's Food Safety Office, which also merged with CFDA in March. As *Nature Biotechnology* went to press, however, none of the deputy commissioners had been appointed. Zhang Yong was also deputy secretary general of the State Council, China's cabinet.

"There could be some impacts (on proposed drug review reform) in the short term, mainly due to personnel adjustment," says Hong Song, a senior research fellow at Beijing-based Chinese Academy of Social Sciences. "But a stronger food regulation branch and a more powerful agency should benefit CFDA's drug review and regulation."

Jin agrees. "With a senior 'outsider' leading the agency, CFDA and its technocrats may shake off their historical corruption images and become more confident in their new drug review."

Hepeng Jia *Columbus, Ohio*

IN their words

"When I first started going around and giving talks… routinely I would hear: 'You are seven years into this. Where are the wins? Where are the successes?' I don't hear that as much anymore." Eric Green, director of NHGRI, on the 10th anniversary of the publication of the first human genome. (*The New York Times*, 15 April 2013)

"Why shouldn't we worry that Myriad or companies like it will just say, 'Well, you know, we're not going to do this work anymore'?" Justice Elena Kagan ponders the Myriad gene patents during oral arguments. (*Washington Post*, 15 April 2013)

"Where [genes] start and stop, what they do, what they are made of, and what happens when they go wrong are all decisions that were made by nature, not by Myriad. … Myriad does not deserve a patent for it." Christopher A. Hansen, representing the American Civil Liberties Union before the US Supreme Court in the case of *The Association for Molecular Pathology v. Myriad Genetics, Inc.* (*Washington Post*, 16 April 2013)

"They want to make clearer arguments as to why this is helping people in the relatively short run, rather than helping pointy-headed scientists." Economist Adam Jaffe, Brandeis University in Waltham, Massachusetts, explains the emphasis on applied research in the Obama budget. (*Nature News*, 16 April 2013)