so that the two regulators can work together to safeguard quality.

Indeed, on March 14, FDA announced its intention to set up eight full-time permanent positions at the US embassy in China with the specific aim of ensuring the quality of APIs produced in China for US firms; it is now waiting for authorization from the Chinese government. A Chinese GMP expert, who declined to be identified, welcomes the move, saying FDA presence in China will not only bring more site inspections, but will encourage frequent information exchange between FDA and SFDA, help coordinate their activities and boost the SFDA's capacity building.

On the Chinese side, new measures to improve the quality of APIs or other pharmaceutical constituents have already been set in motion. A national-scale evaluation of heparin production and its supply chain was launched in March, just after the Baxter accident. Already in January, SFDA governor Shao Mingli had announced his intention to implement a management strategy for API exports centered around a catalog of APIs. The catalog will list ten types of medicine—which Shao did not identify—that will receive special monitoring and supervision by SFDA's local branches, in addition to regular drug licenses and GMP certification.

Shao told a news conference on March 15 that the SFDA has been investigating chemical firms making pharmaceutical contents without pharmaceutical GMP certificates. In future, these producers will need to be registered and approved by his agency, he said.

On the same day, the SFDA ceased to be an independent agency and came under the governance of the Ministry of Health. The change was mandated by China's highest legislature, the 11th National People's Congress. Shao confirms that SFDA's role in drug registration and quality control will not be changed.

Market watchers agree that a tightened quality control system and the full-time presence of the FDA in China will help the country move one step closer to this goal.

Although the government reshuffle may delay some of the SFDA's work, Ken Ren, president of a Beijing-based consulting firm Accelovance, speculates that a close link between SFDA and the health ministry will facilitate the creation of a network and database to monitor medicines for adverse effects. Zheng agrees: "A sound domestic database on adverse effects of drugs will help ensure the quality of exported pharmaceutical ingredients, because they are used in China as well."

China has yet to become a major supplier of biologic material. Market watchers agree that a tightened quality control system and the full-time presence of the FDA in China will help the country move one step closer to this goal. Hisun's Luo says most of China's biologics production has been shifted from extracting natural products to either recombinant expression in microorganisms or chemical synthesis. For this reason, he believes the contaminant detected in heparin is unlikely to be a recurring problem for other biologics.

Table 1 Number of deaths of patients receiving heparin reported to FDA[a]

Month	Number of reported deaths
October 2007	6
November 2007	9
December 2007	20
January 2008	24
February 2008	20
March 2008	0

[a]Includes heparin produced by any manufacturer.

Zailin Yu, president of Beijing-based Bioway-Fortune Research Center, also believes China's small, but steadily growing biologics exports will not be dented by the heparin case. However, he points out that "an improved quality control system on pharmaceutical materials will also benefit big molecule production," as human plasma is still heavily relied on to produce protein drugs like antihemorrhagic factor for hemophilia.

So far, more than 100 Chinese firms are producing biotech drugs ranging from erythropoietin and human interferons to interleukins. Although most of them are for domestic use, orders are increasing from the developing world and the World Health Organization (Geneva) for insulin and vaccines. Customers in the developed world also buy low-cost antibodies for research and diagnosis purposes and large quantities of serum proteins for further processing into therapeutic drugs.

Although the debate on whether biogenerics can be produced safely rages in the US, more than 30 Chinese drug makers produce copies of erythropoietin. Some have done so for nearly two decades. Most of their manufacturing techniques are based on technologies "copied" before 1993 when China began to protect foreign drug patents. "At that time, there were no GMP regulations and no requirements for bioequivalence," says Zheng. "So if the SFDA establishes a network and database to monitor adverse drug events, it will help evaluate the qualities of these biotech drugs."

Hepeng Jia *Beijing*

EU to monitor for Chinese GM rice

The European Commission has put in place emergency importation measures to flag any Chinese products that contain the genetically modified (GM) rice Bt 63. The rules mean that the EU will accept only consignments of rice products that have been indicated as acceptable, and even these must be tested by an official or accredited laboratory using a specific testing method accompanied by an analytical report. EU member states will ensure products already on the market do not contain Bt 63 through such methods as random sampling. The problems with Bt 63, an insect-resistant rice strain modified with the Cry1Ac toxin gene from *Bacillus thuringiensis,* which is not yet approved for food or feed anywhere in the world, began in September 2006, when the UK, France and Germany discovered the unregistered GM rice in certain foods. The countries notified the Rapid Alert System for Food and Feed, and China, in turn, tracked the originators of the products and suspended their exports. Despite this, unauthorized Bt 63 rice continued to resurface, most notably in February 2007 in a shipment of protein concentrate intended for feed; late last year, Bt 63 was still being reported in imports. The European authorities are set to reassess the matter in October to gauge the effects of the new measures. *—Brady Huggett*