

CHINA'S DANGEROUS DRUG EXPORTS

Roger Bate

The recent furore over contaminated heparin, a blood-thinning drug, that killed at least 81 Americans, was just the latest in a string of medical problems traced back to Chinese food and pharmaceutical exports. Heparin was exported from Scientific Protein Laboratories LLC, based in Changzhou, China. Raw heparin is normally sourced from the intestines of pigs, but the US Food and Drug Administration found a contaminant that comes from pig cartilage. The contaminant – oversulphated-chondroitin sulphate – is much cheaper, but isn't approved for medical use because it can cause severe allergic reactions in humans. Prior cases of melamine-contaminated products follow a similar pattern. Cheaper contaminants are added, with Chinese authorities unable or unwilling to stop it. Why did Beijing not stop them?

Because Beijing can't – at least not yet. China is a vast country with 31 provinces and 333 districts. Harmonising – not to mention enforcing – drug quality control across them is therefore difficult, especially since there are over 6,000 manufacturers of Western drugs and more than 2,000 traditional Chinese drug-makers.

Chinese officials are fully aware of this situation. According to Jin Shaohong, director of China's National Institute for the Control of Pharmaceutical and Biological Products, '14% of the many thousands of drug samples tested in 1998 were of low quality'.

Since 1998, post-marketing quality surveillance has improved and poor-quality producers are being shut down. Of the more than 40,000 lots tested in Anhui and Guangxi provinces in the past 18 months, between 3% and 10% were sub-standard. This would be intolerable in the EU or USA, where far less than 1% of drugs are considered sub-standard. Many of the poor-quality products enter the market through internet sales, not through the traditional supply chain.

Beijing has also established mobile labs, which rely on simple testing to establish sub-standard drugs in the marketplace. The Chinese government spent \$70 million on 400 mobile labs between March 2006 and September 2007. As of March, 374 labs have been allocated to 29 provinces, covering 80%

of China's rural areas. In addition, 760 technicians have been trained to use the labs.

But the testing regime can be only part of the solution. Beijing also needs to make drug-makers 'internalise' quality-management best practices. Efforts to do this are also under way. Article 9 of the 1984 Drug Administration Law already mandates that manufacturers adhere to 'good manufacturing practice', or GMP, a set of quality-control principles that form the basis of Western drug-manufacturing practice. As always, though, enforcement is the problem. There are too few inspectors to examine all suspicious manufacturing sites and those inspectors are rarely exacting when they find poor performance.

To help remedy this, Zheng Qiang of Peking University has started a new programme to improve understanding of, and adherence to, best practices on the part of manufacturers themselves. His inaugural class of 25 students (21 on sabbatical from Chinese pharmaceutical companies) started their master's degree programme in best practices in March 2007 at Peking University's new Institute for Pharmaceutical Excellence. But that is a drop in the ocean compared with China's drug manufacturing sector, which employs tens of thousands of workers. And this kind of training takes time. Quality-control experts note that it has taken decades for such 'habits of excellence' to become second nature to Western drug manufacturers. Until a similar transformation takes place in China, quality-control problems like the melamine and heparin cases are inevitable.

Nonetheless, there are many quality drug-makers in China even today, and EU consumers benefit from those manufacturers' products. The key to ensuring that all Chinese products are of high quality is more governmental and private-sector engagement, not less. Rather than demonise China's insufficient oversight, as many protectionists do, Europe and the USA must continue regulatory co-operation with China. If the heparin episode teaches anything, it is that neither country can afford to do otherwise.

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