HEALTH CARE NEWS

Study: Drugs from Emerging Markets Have High Failure Rates

Kenneth Artz
03/01/2011
The Heartland Institute

A new study assessing the quality of drugs made in emerging markets found the danger of variability remains high for several areas.

Roger Bate, Legatum Fellow in Global Prosperity at the American Enterprise Institute, studied drug samples in African and Asian countries, assessing their variability by spectrometer. Significant variability in drugs is typically an indicator of production failures which undermine drug quality.

Bate examined 1,838 samples, sorting them by apparent country of origin and manufacturing class and, where appropriate, by the size of the company. His study found the most variability occurred in products made in Africa, followed by products made in China, Vietnam, and the smaller producers in India.

Assessing Failure Rates

According to Bate's research, the brands procured from the European Union, Switzerland, and the United States all passed spectrometry testing. But the failure rates of drugs from African companies was 9.3 percent, of Chinese companies was 7.7 percent, and of Indian companies was 4.4 percent.

Bate said he undertook this research because he spent a considerable amount of time studying markets in developing countries and saw a significant number of substandard drugs and counterfeit drugs being produced. In some countries, generic drugs are advertised as interchangeable with drugs from other countries, but Bate says that isn't the case.

"In some instances, the regulatory regime is just not there, and criminals are involved in the manufacture and distribution of drugs," Bate said. "In some instances, drugs cut with chalk, road paint, and talcum powder are being sold as legitimate drugs in developing countries and even in some mid-level countries."

Drug Safety Uneven in China

According to Bate, drug quality in China and India is improving.

"One of the biggest assumptions we in Western countries—America, Canada, or Western Europe—have is that we make the best and safest drugs in the world. Our study largely bore this out. However, in places like China and India, where the competition to ship to Western markets is high, the quality of drugs is generally very good," says Bate.

One key problem, Bate maintains, is an uneven regulatory regime depending on the company designation.

"China is an unusual country—they have some good producers and some shoddy producers. Some of those problem suppliers have to do with the fact that in China you don't have to be registered as a drug producer in order to sell your chemicals or compounds—instead, you can register as raw chemical producer and the regulations are less strict," explains Bate.

India Improving Dramatically

The most interesting finding of his study, Bate says, was how good the generic drug producers are in India, despite a disparity in consistency between large and small companies.

"The best Indian producers make good drugs. What determines if they are a good producer has to do with the size of the company, who they sell to, and how long they've been selling drugs. They have very good products, and in many cases their generic drugs are interchangeable. It's a warning sign to Western industry and a good sign for globalization. Their regulatory regime is not as strong as in the West, but it's getting there," says Bate.

Bate's study found larger generic producers performed virtually the same (a 1.3 percent failure rate) as smaller Western generic producers, who failed at a 1.2 percent rate.

Risk Involved in Emerging Market Drugs

According to Mark Grayson, deputy vice president of communications and public affairs for the Pharmaceutical Research and Manufacturers of America, the Bate study indicates the problem with drugs from emerging markets is the consumer's lack of certainty about the origin and ancestry of the products.

"What the study shows is you have to be careful with drugs from emerging markets. When you're talking about importation and you don't know the pedigree, then you have no idea where the drugs are manufactured, how they're made, and under what conditions," explains Grayson.

Although drugs are made in many parts of the world, their background is not necessarily exclusive to that company or producer, Grayson notes.

"Saying something is made somewhere is no guarantee that it is made there. For instance, a country produces some raw chemicals for a compound, then ships it to Ireland, and they might combine five more ingredients there and stamp it 'Made in Ireland.' Then it could be shipped

somewhere else," Grayson said. "The end result is that even though [the label on] a drug says it was made somewhere, the component parts are made all over the world."

Devon Herrick, a senior fellow with the National Center for Policy Analysis, says Bate's study confirms preexisting suspicions regarding drug quality.

"The Bate study confirms what we already know: Drugs from emerging markets can be very dangerous," says Herrick. "A lot of foreign companies are cranking out pills that are still under patent. Although this helps the local population, they're probably not suitable for Western consumption. However, the companies that can meet our standards are probably already selling them here, and those that can't meet our standards won't be allowed to do so."