Manufacturers subject to latest drug recall rules

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The State Food and Drug Administration (SFA) Wednesday announced a new provision that obliges all manufacturers of imported drugs to provide Chinese authorities with full details of product recalls in a bid to avoid potential health hazards.

The Provisions for Drug Recall, the country's first nationwide regulation on the issue, states that drug manufacturers at home and abroad should be the first to be held accountable for the safety and quality of the drugs they sell, SFDA spokeswoman Yan Jiangying said at its regular monthly press briefing.

The provision states that drugs found to be potentially hazardous should be recalled voluntarily by producers, while those that are found to be fake or of substandard quality will be dealt with under the terms of the Drug Administration Law.

The provision stipulates that recalls are divided into three categories based on different risk levels.

These range from 24 hours for drugs that may cause serious damage to human health, to 72 hours for those deemed non-life-threatening.

Once the hazardous products have been recalled, producers must immediately inform distributors and medical institutions to stop using or selling the drugs.

The manufacturers involved will also have to report the recalls to the drug administration.

"We hope governments and companies can cooperate to enhance and refine the establishment of the recall system to safeguard drug safety and public health," Yan said.

The provision also states that penalties or liabilities for companies that voluntarily recall hazardous drugs will be eased or excused.

Conversely, manufacturers that fail, for whatever reason, to recall hazardous drugs will be subject to compulsory recalls by the authorities if deemed necessary. Such firms will also be fined three times the value of the recalled drugs.

To realize and facilitate adequate drug recalls, producers should also put in place surveillance systems to monitor and look out for potentially harmful products, the SFDA said.

"Drug manufacturers cannot merely rely on government information.

"They should, out of a sense of social responsibility, make efforts to monitor potential adverse reactions to their products," Yan said.

Distributors and medical institutions must also inform the authorities and producers of any safety risks associated with a particular drug, the provision says.

"The involvement of the general public, especially drug distributors and users, is extremely important given the fact that a pilot scheme of drug recalls in Wuhan, capital of Hubei Province,

showed that the recalls were imposed in most cases," Yan said.(China Daily)

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