Food and Drug Administration: Special inspection will be carried out on products containing aristolochic acid

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Xinhua News Agency, Beijing, October 31 (Reporter Chen Cong) The recent heated discussion in the industry about the correlation between aristolochic acid and liver cancer has aroused public attention.

The bureau spokesman responded that the safety of aristolochic acid is directly related to public health and the development of traditional Chinese medicine. Food and Drug Administration will further strengthen supervision

To manage, conduct special inspections on listed products containing aristolochic acid, strengthen inspection and testing, and severely crack down on illegal production and business activities.

The spokesperson of the State Food and Drug Administration told the media a few days ago that there is no direct and strong data to support the direct correlation between aristolochic acid and liver cancer, but aristolochic acid has obvious renal toxicity.

Sex, can cause damage to renal tubular function, and even lead to the risk of kidney cancer. In view of this, my country has adopted a series of risk control measures since 2003.

The number of harmed cases has dropped significantly, and no direct cause of kidney cancer has been reported.

It is understood that not all Aristolochiaceae plants contain aristolochic acid, and the roots and rhizomes of aristolochic acid medicinal materials hardly contain aristolochic acid. my country has already adjusted the medicinal materials

Using parts, the medicinal parts of Aristolochiaceae Asarum were changed from whole grass to roots and rhizomes. In addition, my country has banned the use of Guanmutong, Guangfangji and Guangfangji, which are high in aristolochic acid.

At the same time, it is clear that the oral Chinese patent medicine varieties containing Aristolochia genus are strictly managed according to prescription drugs.

The Food and Drug Administration reminds patients that drugs should be used strictly in accordance with doctors' prescriptions and orders, and pay attention to the nephrotoxicity and carcinogenic risks of drugs containing aristolochia. no medicine

Can be taken in large doses for a long time.

The spokesperson emphasized that ensuring drug safety is the main responsibility of enterprises. All enterprises that use medicinal materials containing aristolochic acid as raw materials to produce preparations must conduct safety inspections on their products.

Comprehensive evaluation, provide evaluation conclusions within a time limit, if the evaluation conclusions are not provided within the time limit, production should be stopped and the drug approval number should be cancelled; if there are evaluation conclusions, risk control measures should be proposed

After review by the Center for Drug Evaluation, the instructions for those whose benefits outweigh the risks will be revised and improved, and those whose risks outweigh the benefits will be eliminated.

According to reports, the CFDA will further strengthen basic research on Chinese patent medicines, carry out epidemiological investigations on the use of related medicinal materials and Chinese patent medicines, and conduct targeted research on national medicines.

Systematic analysis of liver injury cases in adverse product reaction monitoring data, and organized technical institutions and experts to conduct risk assessment of aristolochic acid-containing medicinal materials and Chinese patent medicines.

Risk control measures such as prudent use, restricted use, and deactivation.

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