# 食药监总局：将对含马兜铃酸产品进行专项检查

2017-10-31 17:50 来源： 新华社
【字体：大 中 小】打印

新华社北京10月31日电（记者　陈聪）业界近日对马兜铃酸与肝癌相关性的热议引发民众关注，国家食品药品监督管理总局新闻发言人就此回应称，马兜铃酸安全性问题直接关系公众健康，关系中医药事业发展。食品药品监管部门将进一步加强监管，对上市的含马兜铃酸产品进行专项检查，加强检验检测，严厉打击违法生产、经营行为。

食药监总局新闻发言人日前对媒体说，马兜铃酸与肝癌的直接相关性尚无直接有力数据支撑，但马兜铃酸具有明显肾毒性，可造成肾小管功能受损，甚至存在引发肾癌的风险。鉴于此，我国自2003年以来采取一系列风险控制措施，马兜铃酸肾损害病例数量已大幅下降，未收到直接引发肾癌报告。

据了解，不是所有马兜铃科植物都含马兜铃酸，而马兜铃酸药材的根和根茎部位几乎不含马兜铃酸。我国早前已调整药材使用部位，将马兜铃科植物细辛的药用部位由全草改为根和根茎。此外，我国已禁止使用马兜铃酸含量高的关木通、广防己和青木香，同时明确对含马兜铃属药材的口服中成药品种严格按处方药管理。

食药监总局提醒患者，药品要严格按照医生处方和医嘱使用，注意含马兜铃属药品的肾毒性、致癌性风险。任何药品都不能大剂量、长时间服用。

该发言人强调，确保药品安全是企业的主体责任。所有把含马兜铃酸药材作为原料生产制剂的企业，都要对其产品进行安全性评价，限期提供评估结论，逾期未能提供评估结论，要停止生产，注销药品批准文号；有评估结论的，要提出风险控制措施，经药品审评中心审评后，对获益大于风险的修改完善说明书，对风险大于获益的予以淘汰。

据介绍，食药监总局将进一步加强中成药基础性研究，开展相关药材和中成药使用的流行病学调查，有针对性地对国家药品不良反应监测数据中肝损伤病例进行系统分析，并组织技术机构和专家对含马兜铃酸药材和中成药进行风险评估，研究采取慎用、限用、停用等风险控制措施。

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

**2017-10-31 17:50 Source: Xinhua News Agency**

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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