

CORRESPONDENCE

Chinese Slimming Capsules Containing Sibutramine Sold Over The Internet—A Case Series

by Dr. med. Dieter Müller, Prof. Dr. rer. nat. Dipl.-Chem. Wolfgang Weinmann, Dr. med. Maren Hermanns-Clausen in volume 13/2009

Crude Herbal Drugs May Be Safe

The dubious quality of Chinese drug preparations or food supplements is hardly news. However, this problem affects not only herbal preparations but is a general quality issue in some Asian countries, which also affects chemical preparations (heparin) and food preparations (melamine).

Generally, extreme caution is advised vis-à-vis Chinese drug preparations, although there are Chinese manufacturers that provide high-quality products and are audited, for example, by the Australian drug regulator. The quality cannot be guaranteed by the dispensing pharmacist. Our center keeps receiving queries from laypersons who have bought drug preparations while visiting China as tourists. We can only strongly advise against their consumption.

The situation is different for crude medicinal herbs, which can be tested and which have to be accompanied by valid certificates. Adherence to the threshold values has to be guaranteed and the identity of the substances confirmed. In Germany, it is therefore possible to purchase good-quality crude Chinese drugs without any problem—as long as the pharmacist has sufficient specialist knowledge. Specialized pharmacies have, for example, formed the German working group of TCM [traditional Chinese medicine] pharmacies. Purchases via the internet constitute a real problem, however. EU Directive 2004/24/EC for the licensing of traditional herbal medical products is interpreted in an inappropriately rigid way, and its criteria consequently cannot be met by drug preparations that are not protected by patents. Companies therefore go down the food supplement route or follow illegal routes. Internet trading can ultimately not be controlled. Instead of consumer safety, the opposite outcome is achieved. Pragmatic licensing conditions—such as in Switzerland or Australia—are a necessary step forward.

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REFERENCES

Mueller D, Weinmann W, Hermanns-Clausen M: Chinese slimming capsules containing sibutramine over the internet—A case series. *Dtsch Arztebl Int* 2009; 105(13): 218–22.

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In Reply:

We take it that Wiebrecht agrees with us, that drug preparations and food supplements of dubious quality are readily available and that internet trading is an obstacle to tighter controls. In this context I refer readers to the press release issued by Germany's Federal Institute for Drugs and Medical Devices that was published simultaneously with our article (1).

The preparation that we reported on was advertised as a "purely plant based (herbal)" product, to which a high dose of a synthetic substance had been added intentionally without being declared. The product thus met neither the criteria for a "traditional drug" (in terms of its ingredients) nor for a proprietary medicinal product (in terms of pharmaceutical law). It was falsely declared as a food supplement and was thus not subject to any licensing procedures. In my opinion, this practice is not the result of the EU Directive on the licensing of traditional drugs; improvement by means of "pragmatic" licensing conditions or laws is therefore impossible.

Poisons centers have registered a notable increase in patients presenting to emergency outpatient clinics with clinical signs of overdose and side effects of medical drugs after ingestion of seemingly harmless slimming capsules. In the samples in our article, the dose of sibutramine—which requires a license for distribution in Germany—in each capsule was nearly twice the recommended maximum daily dose that is licensed for use in the country. Further, the monitoring authorities were informed (toxicovigilance). Our article's objective was to highlight the possibility that such products have been consumed, in order to be able to identify these substances by means of a targeted medical history in patients with particular clinical symptoms, and in order to consult a poisons center and initiate toxicological analyses if required.

We do not by any means advocate the wholesale discreditation of phytotherapeutic drugs, neither do we intend wholesale condemnation of Chinese drug preparations; this was not the subject of our article. We agree with Wiebrecht's demand for valid certification with a complete declaration of ingredients (and thorough pharmacological/pharmaceutical testing). DOI: 10.3238/arztebl.2009.0584b

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Conflict of interest statement

The authors of both contributions declare that no conflict of interest exists according to the guidelines of the International Committee of Medical Journal Editors.