"Slimming" food supplements adulterated with sibutramine and phenolphthalein

In August last year, the Montpellier regional pharmacovigilance centre reported two cases of poisoning to ANSES's Nutrivigilance Unit, following consumption of the food supplement Chewell® manufactured by Irem Naturel®. Claimed by the manufacturer to be a slimming and appetite-suppressant product, according to the label it contains guarana, tragacanth gum, green tea, red pepper, ginseng and starch extracts.

The two women concerned obtained the product on the internet after being "recruited" through social media via a Facebook group.

The first presented with polydipsia (severe thirst), followed by insomnia and significant weight loss (5 kg in one month). The second woman experienced episodes of discomfort from the first few days of taking the food supplement, as well as chest pains, palpitations and huge weight loss, of around 300 to 500 g/d.

The excessive weight loss, the adverse effects experienced by these two patients and the manufacturer's previous judicial offences raised suspicions that these food supplements had been adulterated with an anorectic substance. In 2015, a similar alert had revealed the presence of sibutramine and fluoxetine in Irem Naturel® from the same manufacturer, following reports from two people who had experienced cardiovascular adverse effects related to consumption of the product. A health enforcement decision was taken at the time by the French Health Products Safety Agency (ANSM).

Analysis of the remaining Chewell® capsules by the ANSM's Control Department revealed the presence of sibutramine and phenolphthalein. The estimated content in the analysed samples corresponded to pharmacologically active levels i.e. likely to have an effect on health.

As a reminder, sibutramine is an anorectic that was banned in Europe in 2010 due to the cardiovascular risk previously revealed by several cases of serious adverse effects. Phenolphthalein has been prohibited in France since 1988 because of its potential carcinogenicity.

As a result of these reports, a health enforcement decision against the manufacturer is under way at the ANSM. Information was also sent to the Rapid Alert System for Food and Feed (RASFF), the European network.

Such cases of adulteration of food supplements with unauthorised active substances have been on the increase for several years [1-5].

The substances usually encountered include benzodiazepines (estazolam, clonazepam) in food supplements promoting sleep, anorectic substances such as sibutramine or fenfluramine in food supplements for weight loss, sildenafil or equivalent substances (tadalafil, vardenafil) in food supplements for erectile dysfunction, and steroids in products for muscle development.

These adulterated food supplements represent a real threat to consumer health. Indeed, consumers think the products they are using are safe because of their seemingly harmless composition, but are in fact exposed to hazardous substances.

Healthcare professionals are invited to report to ANSES's Nutrivigilance Unit any adverse effects of food supplements observed in their patients (https://pro.anses.fr/nutrivigilance/) and to keep the suspect tablets or capsules for possible analysis. Consumers can contact a poison control centre or report the adverse event on the Ministry of Health's adverse effect reporting portal (opened in January 2017). Websites selling fraudulent products can be reported on the Ministry of the Interior's portal (https://www.internet-signalement.gouv.fr/PortailWeb/).

In view of the increase in these reports in France and Europe, it seems important to improve communication to consumers about these products.

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