

## **Suspected adverse reactions to herbal dietary supplements for weight loss collected by the Italian surveillance system on natural products**

1)A. Vitalone 2)F. Menniti-Ippolito 3)R. Da Cas 4)G. Mazzanti

*SAPIENZA - University of Rome*

Overweight/obesity is a serious public health problem all over the world with a continuous increase in its prevalence<sup>1,2</sup>. Many people use herbal dietary supplements (HDS) for weight loss, even though their efficacy and safety is doubtful<sup>3</sup>. Being HDS used as automedication it is important to monitor their safety through spontaneous reports of suspected adverse reactions (ARs). In Italy ARs to HDS cannot be collected by the National Pharmacovigilance System, for this reason, since 2002, a specific phytosurveillance system was set up. The project started as a pilot study but in 2012 was enhanced and officially adopted from the Ministry of Health as an alert system. The surveillance is based on the collection and evaluation of spontaneous reports of suspected ARs to: 1) food supplements; 2) herbal preparations and galenic formulations; 3) other preparations of natural origin (e.g. propolis); 4) homeopathic medicines. A Scientific Committee, including experts in different disciplines (pharmacology, pharmacognosy, phytotherapy, toxicology, etc.), evaluates severe reactions. A Steering Committee comprising experts of the National Institute of Health, Italian Medicines Agency and Ministry of Health, supports the Scientific Committee. Up to March 2017, 1549 reports of ARs to natural products have been collected; here we describe those associated with herbal products used for weight control, received from July 2010 to December 2016. Data up to June 2010 have been previously published<sup>4</sup>. The ARs were analyzed and causality assessment was performed using the WHO-UMC algorithm<sup>5</sup>.

Forty seven ARs to weight loss products were collected. Women were involved in 83% of reports. The herbal products involved in the reactions were multicomponent (2-14 components) in more than 80% of cases; three galenic preparations and one homeopathic medicine were also included. The reactions affected mainly the cardiovascular system, the liver, the skin, the digestive system and the central nervous system. In about 28% of cases other medications were reported, while concomitant conditions were present in 23% of the reports. Most of ARs were serious and required hospitalization. Outcome was complete recovering in more than 50% of cases, improvement or recovering with sequelae in 15% of cases and unknown in the others. Dechallenge was positive in 70% of cases, information on rechallenge was not always present but was positive in one case.

Present results confirm the safety issues in the use of herbal products for weight loss. Obesity and overweight are growing public health problems and their treatment is becoming of great clinical importance also considering the limited number of available drugs. Herbal dietary supplements are easily available on the market and consumers use them as self medication, unaware of the risk associated to their use and of lack of evidence of their efficacy. Encouraging spontaneous reporting can contribute to improve awareness among health personnel and patients, about the risk profile of these remedies.

## References

- 1 Flegal et al. (2016). JAMA. 315:2284-91.
- 2 NCD Risk Factor Collaboration (NCD-RisC) (2016). Lancet. 387:1377-96.
- 3 Gabay et al. (2017). Pharmacotherapy. 37:e1-e15.
- 4 Vitalone et al. (2011) Eur J Clin Pharmacol. 67:215-24.
- 5 WHO-UMC available from: <https://www.who-umc.org/media/2768/standardised-case-causality-assessment.pdf>