Botanicals and vigilance

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Botanical is “a plant or plant part valued for its medicinal or therapeutic properties, flavor, and/or scent” (NIH, 2011). Products made from botanicals (sold as herbal dietary supplements, nutraceuticals, cosmetics, etc.) are promoted as "natural products" and several claims are made on their possible health benefit. They are generally considered as safe, even if are not usually subjected to the same testing and regulations as conventional drugs (preclinical and clinical safety and efficacy). As reported by the Scientific Committee of European Food Safety Authority (EFSA, 2009), botanicals for which an adequate body of knowledge exists could benefit from a “presumption of safety”: if this assumption is not possible, a more extensive safety assessment is required.

The evaluation of botanicals’ safety is a very complex multistep process that requires a multidisciplinary approach, which should take into account product-related (e.g., taxonomic identity, quality of source material, markers, bioavailability) and patient-related factors (susceptible populations, improper use or abuse, interactions). Consequently, vigilance on botanicals should start from characterization of plant material and end to post-marketing surveillance, but the reality is quite different.

Botanicals are widely available in pharmacies, supermarkets, catalogs, internet, etc. and, as their use continues to increase worldwide, concerns regarding their safety have been raised. Principal concerns include the composition of the preparation (e.g., isolated compounds instead of phyto-complex, use of enriched extracts compared to the genuine composition of the starting herbal material), in which the need to ensure that concentrations of bioactive agents are within safe limits is often forgotten (EFSA, 2009; NIH, 2011). In this context, particular attention is devoted to products containing lycopene, alpha-lipoic acid, monacoline, isoflavones, etc., substances for which a maximum daily intake and/or special warnings have been established (Ministry of Health, 2017).

The safety assessment of botanicals used in food supplements and their vigilance are not subject to EU regulation, but are managed by national food authorities in each member state.

In Italy, in order to improve consumer safety and considering that suspected adverse reactions (ARs) to herbal products not registered as drugs cannot be collected in the National Pharmacovigilance Network, a phytosurveillance system was set-up by the National Centre for Epidemiology, Surveillance and Promotion of Health of the Italian Institute of Health (CNESPS, ISS). This system, based on spontaneous reporting, allows a careful monitoring of ARs, useful to identify possible risks and/or to highlight any early alarm signal. Taking into account the peculiarities of botanical products, a Scientific Committee (consisting of experts in pharmacology, pharmacognosy, herbal medicine, toxicology, etc.) supported by a Coordination Committee (composed of experts from ISS, AIFA and the Ministry of Health), is involved for the evaluation of severe cases.

Nowadays, many regulatory agencies (including the National Institute of Health - NIH, the Federal Institute for Risk Assessment - BfR, the French Agency for Food, Environmental and Occupational Health & Safety - ANSES) seek to strengthen knowledge of the safe use of botanicals, (BfR, 2015). Therefore, a good functioning of the various phytosurveillance systems and the spread of the acquired knowledge could ameliorate the awareness on the safety profile of botanicals.

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