
Workshop: Pyrrolizidine alkaloids – a problem?



WSL 1: Assessment of potential contamination of herbal medicinal products with PA: Activities of the German industry

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Abstract

Since July 2013 it has become evident that medicinal plant material may be contaminated by pyrrolizidine alkaloid (PA)-containing weeds e.g. *Senecio* species (BfR, 2013; MULDER et al. 2015). This is a big challenge for growers and manufacturers with regard to the precise qualitative and quantitative determination of the contaminants as well as to their reduction. Already at an early stage, the German herbal medicinal products industry has taken measures in order to avoid and/or reduce PA contamination as far as possible. These measures consist e.g. in the collection of data, participation in research projects and the adoption of a „Code of Practice“ (BAH AND BPI, 2015) that was elaborated together with herb growers. This document provides a framework for the implementation of individual measures in pharmaceutical companies along the entire process chain from cultivation up to control and release of the finished product.

The EMA Herbal Medicinal Products Committee (HMPC) had published its final „Public Statement“ on the assessment of PA-containing herbal medicinal products in December 2014 (EMA/HMPC, 2014). It concludes that the exposure to PA should be kept as low as possible and sets a daily limit of 0.35 µg PA. E.g. in Germany, the health authority (BfArM, 2016) implemented a transitional limit of 1.0 µg PA daily, considering the fact that implementation of a lower limit for all medicinal plants did not seem realistic. Industry had argued that due to worldwide cultivation and season-dependent production processes, a short-term reduction of PA contamination at all sites is impossible.

The complexity of the problems requires an intensive co-operation of agriculture, industry, health authorities and scientific societies. In this respect, ongoing and new research projects on the occurrence and reduction of PA-containing weeds as well as the toxicological assessment of PA play an important role. The target is a continuous and sustainable further reduction of PA contamination and to guarantee further production of products which are safe and of high and consistent quality.

References

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