Limitations of pharmacopoeial herbal monographs as source of risk

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Herbal monographs in European Pharmacopoeias contain definition of drugs, which includes biological identification and chemical tests. Herbal material by meeting pharmacopeial criteria is considered as good quality and safe drug. However, quality control case reports point on limitations of Pharmacopoeia definitions and demonstrate how are these limitations leading to usage of low-quality drug material or adulterations.

In our work the herbal monographs of European Pharmacopoeia (10.5) were reviewed and assessed. During assessment the reliability, accuracy and safety of chemical procedures were estimated, and four-level scale was set up: 1–chemical investigation is missing or with major limitations; 2–chemical investigation does not include LC or GC analysis; 3–chemical investigation is based mainly on spectrophotometry or titration; 4–chemical investigation is satisfactory. According to our assessment out of 313 monographs are classified (level 1: 10 monographs, level 2: 30 monographs; level 3: 92 monographs; level 4: 181 monographs).

Assessment allowed us to create database in which the monographs and their limitations were organised. This database made possible the selection of several drugs for further chemical studies with limitations in order to elaborate safer chemical procedures, and by this, to eliminate possible safety risks.

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