

Accessibility of herbal substances containing toxic medicinal plants on the Bulgarian market

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Abstract

The aim of the presented study is to investigate whether raw herbal products containing herbal substances of poisonous medicinal plants are freely accessible on the Bulgarian digital market and, if so, to perform a brief analysis of the main flaws in the legislative framework that fails to prevent that. Twenty herbal substances enlisted as poisonous in Ordinance №5 (2004) on the requirements for the herbal procurement facilities and warehouses for herbal drugs were randomly selected, and the related herbal products that appear in a browser's top eight suggestions were analyzed. The study found that herbal products containing raw herbal drugs of poisonous plants, according to the mentioned Ordinance №5 (2004), are offered with varying frequency on Internet sites. These products have an unclear status because they violate specific legislative rules to be registered as food supplements or herbal medicinal products. Serious flaws regarding the consistency of the label information were also found. The results of our study indicate that a revision of the legislative framework related to the status, use, and control of these products is necessary.

Keywords

herbal substances, toxic plants, herbal products regulation

Introduction

In recent years, there has been an increased supply of raw herbal products on the global market. This mirrors a global policy for accessibility of natural products that enhance human health and promote well-being (Thakkar et al. 2020). There are many benefits of the simplified procedures for registration of traditional use (THMPs) and well-established use (WEU) herbal medicinal products (HMPs) as

well as herbal food supplements, such as high diversity, availability, and reasonable price (Qi et al. 2018; Peacock et al. 2019). On the other hand, herbal substances have a complex, multi-component chemical composition, and their combination with other products containing active ingredients with therapeutic properties may lead to undesirable health effects (Al-Worafi 2020). Herbal substances may also contain toxic compounds, which makes the problem even more complex (Farzaei et al. 2020, Zahariev 2022).

The aim of the presented study is to investigate whether herbal products containing herbal substances of poisonous medicinal plants are freely accessible on the Bulgarian internet market and, if so, to perform a brief analysis of the main flaws in the legislative framework that fails to prevent that.

Materials and methods

Twenty herbal substances enlisted as poisonous in Ordinance №5 (2004) on the requirements for the herbal procurement facilities and warehouses for herbal drugs were randomly selected, and the related raw herbal products were browsed by the Bulgarian name of the plants in the period June–September 2024. The browsing results represent the products that appear in the browser's top eight suggestions. The following binding legal acts at the EU and national levels were used for the analysis of the gathered information: Directive 2004/24/EC, Regulation (EU) No 1169/2011, Directive 2002/46/EC, Medicinal Products in Human Medicine Act (MPHMA) (2007), Ordinance №5 (2004), Ministerial decree № 434 of 10 December (2021).

Results and discussion

The study found that all 20 randomly selected substances included in Appendix 5 (Poisonous plants) of Ordinance №5 (2004) (Table 1) are offered with varying frequency on Internet sites. These herbal substances are affiliated with the same number of botanical species (20) and belong to 15 families. According to Manolov (2008), the level of toxicity of eighteen

of them should be classified as a serious threat to human health if not prescribed and taken under strict control by a physician specialized in phytotherapy. Only one substance—*Fummarie herba*—is permitted for use in traditional medicinal products according to Directive 2004/24/EC 2004.

In Fig. 1 the total number of products (73) containing the selected herbal substances is shown, as some of them are offered on more than one site. In 97% of the cases, traders provide information about the action and application of the herbal products, and in all of these cases, the herbal substances are presented as having properties for treatment or prevention of illnesses in humans. That specific information presents health claims that are regulated for medicinal products and not allowed in food supplements (Regulation (EU) No 1169/2011, Directive 2002/46/EC 2002, Ministerial decree № 434 (2021), MPHMA (2007)). Data on the application methods of the offered herbal drugs were provided in 85% of the cases, and safety warnings were provided in 75%. In 53% of the cases, instructions for the method of storage were given, with two of the traders not providing such data for any of the herbal products they offer. The least available information was about the shelf life of the products (5%). These results complement the findings of previous studies (Farzaei et al. 2020; Gavrilova and Gavrilov 2022).

For two of the web pages, information regarding the name of the legal entity, registration and/or management address, telephone number, and email address was missing. There have also been cases where traders use vicious practices and misleading messages that could be dangerous to health, such as suggestions that a certain toxic plant can be “part of your daily routine” or advertisements like “With this product, people also buy....”

Table 1. List of investigated herbal substances included in Regulation 5, their occurrence in 8 most common internet sites, and toxicity levels.

№	Herbal substance	Number of occurrences	Botanical species	Family	Herbal substance permitted in THMPs ¹ and WEU ² HP	Toxicity level (Manolov 2008)
1	Adonidis herba	4	<i>Adonis vernalis</i>	Ranunculaceae		**
2	Aristolochiae rhizome et radix	1	<i>Aristolochia clematitis</i>	Aristolochiaceae		***
3	Ari maculati tuber	5	<i>Arum maculatum</i>	Araceae		***
4	Belladonae folium, radix	1	<i>Atropa belladonna</i>	Solanaceae		***
5	Berberidis radix	7	<i>Berberis vulgaris</i>	Berberidaceae		***
6	Bryoniae radix	1	<i>Bryonia alba</i>	Cucurbitaceae		***
7	Chelidonii herba	8	<i>Chelidonium majus</i>	Papaveraceae		***
8	Conii herba	1	<i>Conium maculatum</i>	Apiaceae		***
9	Convallariae herba, folium	2	<i>Convallaria majalis</i>	Asparagaceae		***
10	Stramonii folium	1	<i>Datura stramonium</i>	Solanaceae		***
11	Digitalis lanatae folium	2	<i>Digitalis lanata</i>	Plantaginaceae		***
12	Digitalis purpureae folium	1	<i>Digitalis purpurea</i>	Plantaginaceae		***
13	Fumariae herba	6	<i>Fumaria officinalis</i>	Papaveraceae	+	***
14	Hellebori radix et rhizome	5	<i>Helleborus odoratus</i>	Ranunculaceae		***
15	Laburni semen	1	<i>Laburnum anagyroides</i>	Fabaceae		***
16	Tami rhizome	6	<i>Dioscorea communis</i>	Dioscoreaceae		**
17	Tanacetii herba	6	<i>Tanacetum vulgare</i>	Asteraceae		***
18	Veratri radix et rhizome	5	<i>Veratrum album</i>	Melantiaceae		***
19	Vincae minoris folium, herba	3	<i>Vinca minor</i>	Apocynaceae		***
20	Visci herba	7	<i>Viscum album</i>	Santalaceae		***

¹ THMPs—herbal medicinal products with traditional use under Directive 2004/24/EC.

² WEU HP—herbal medicinal products with well-established use under Directive 2004/24/EC.

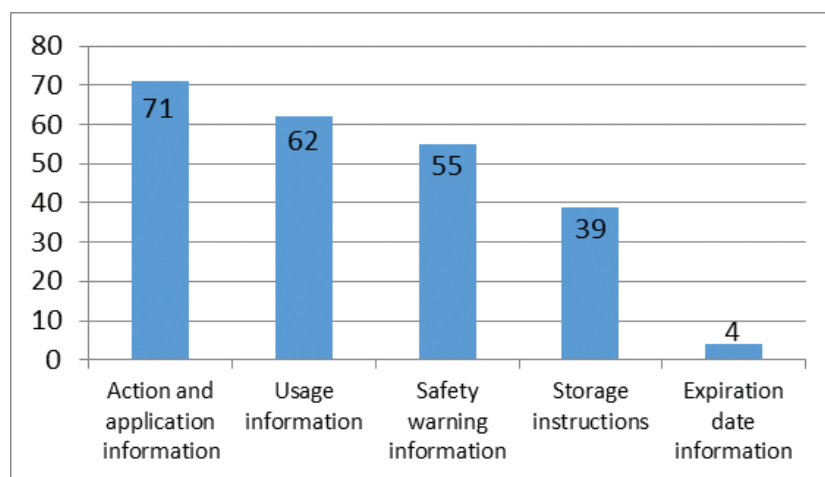


Figure 1. Total product counts (73) of important label information about the action, application, usage dose, safety, storage, and expiration date across the studied products.

Conclusion

A large number of raw herbal drugs containing toxic plant substances and having health claims are available in Bulgarian digital stores. These raw herbal products have an unclear status. With the exception of *Fumariae herba*, all other investigated substances are not supported by EU monographs, which could give ground for treating these products as THMPs or WEU HMPs. According to the current legislation, they cannot be classified as food supplements either, because they contain poisonous plants and have unauthorized health claims for this type of product. Serious flaws regarding the consistency of the label information were also found.

The results of our study indicate that a revision of the legislative framework related to the status, use, and control of these products is necessary.

Additional information

Conflict of interest

The authors have declared that no competing interests exist.

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Ethical statements

The authors declared that no clinical trials were used in the present study.

The authors declared that no experiments on humans or human tissues were performed for the present study.

The authors declared that no informed consent was obtained from the humans, donors or donors' representatives participating in the study.

The authors declared that no experiments on animals were performed for the present study.

The authors declared that no commercially available immortalised human and animal cell lines were used in the present study.

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Author contributions

All authors have contributed equally.

Data availability

All of the data that support the findings of this study are available in the main text.

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