Thieme

Consensus Statement on the Outcome of the European Herbal Health Products Summit – Which Way Forward?

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Keywords
herbal medicinal products, herbal medicines, botanicals, EU pharmaceutical legislation, health claims

received	July 2, 2024
accepted after revision	September 10, 2024
published online	October 10, 2024

Bibliography
Planta Med 2024; 90: 1052–1055
DOI 10.1055/a-2419-1602
ISSN 0032-0943

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ABSTRACT

Herbal medicinal products are a vital part of the healthcare system in Europe and beyond. Being predominantly sold as non-prescription medicines in pharmacies, they are very popular with patients, physicians, and pharmacists and are therefore an important part of self-medication. Interest in this sector has recently gained momentum, reflecting the ongoing revision of the general pharmaceutical legislation and the recent discussion on nutrition and health claims on foods based on the implementation report of Regulation (EC) No 1924/2006 by the European Parliament [1]. Therefore, on 20th February 2024, the Society for Medicinal Plant and Natural Product Research (GA), in collaboration with the German Pharmaceutical Industry Association (BPI) and the German Medicines Manufacturers' Association (BAH, now Pharma Deutschland), hosted an in-person summit in Brussels entitled 'European Herbal Health Products Summit – Which way forward?'. The summit featured a wide range of speakers, including policymakers, regulatory authorities, industry representatives, and academic experts. It was divided into several sessions covering topics such as the future and relevance of herbal medicinal products in the EU, the revision of the EU pharmaceutical legislation, and the resulting impact on herbal medicinal products. Furthermore, the discussions delved into the "Health Claims Regulation" – the European Parliament's implementation report and the related regulatory challenges of herbal medicinal products at an EU level. This consensus paper summarises the current status and provided recommendations to pave the way for future strategies to ascertain the continued use of herbal medicinal products as an important therapeutic option for patients.

Status Quo: Challenges for Herbal Medicinal Products

Herbal medicinal products play a crucial role in self-medication and are, therefore, an important part of our healthcare systems, as the pandemic has impressively shown. The authorisation approval or registration and the resulting medicinal product status of the herbal preparations ensures the high pharmaceutical quality of the product and thus its safety. This is carefully and regularly monitored by national competent authorities and the responsibility of pharmaceutical companies as Marketing Authorisation Holder (MAH) [2].

Pan-European market data from IQVIA was presented and shows increasing consumer interest in herbal (medicinal) products linked to increased and changing healthcare needs, sustainability concerns and demand for products with proven benefits [3]. Herbal products are an important product group in the self-medication market and include registered/authorised herbal medical products, as well as food supplements containing herbal materials, commonly called 'botanicals' [3]. As shown in IQVIA's presentation, one in four packages of OTC products (over-the-counter products, for self-medication) sold in Europe was a herbal product, with cough and cold being the main category of use [3]. (Traditional) herbal medicinal products ((T)HMP) and botanicals are competitors in an evolving market. According to IQVIA's data, a significant increase in sales value and volume can be observed in the EU's herbal market, especially in the area of botanicals with numerous new products entering the market [3]. In contrast, new herbal medicinal products have rarely been developed and cannot withstand the pressure of botanicals in terms of innovation rate and time to market, resulting in a declining number of marketing authorisations/registrations of herbal medicinal products across Europe [3].

Compared to botanicals/supplements, herbal medicinal products fall within the scope of the general pharmaceutical legislation [2]. Herbal medicinal products must meet all legal/regulatory requirements, including quality, safety, and efficacy. This is reviewed and approved by the national competent authority before obtaining a marketing authorisation [2]. Herbal medicinal products have a specific indication that describes a treatment or prevention of a disease through a pharmacological, metabolic, or immunological action. Adverse reactions occurring during therapy with herbal medicinal products are reported and monitored by the European pharmacovigilance system [2].

On the other hand, botanicals have a nutritional and/or physiological effect and must comply with food law [1,4,5]. This requires compliance with specified quality parameters and a manufacturing process set by the food company, as well as appropriate labelling in terms of claims and warnings under the responsibility of the food company, considering food legislation and general information on a product's composition [4,5]. Botanicals on the market are randomly checked by the supervisory authorities and generally require neither an assessment and approval by relevant national competent authorities nor monitoring for adverse reactions, as is the case with herbal medicinal products [4,5]. There was agreement that awareness about the importance of education on healthy and adequate nutrition, including a focus on the composition including herbal medicinal products and food supplements, should be integrated into school curricula.

In 2012, the EU Commission established an 'on-hold' list of 2078 health claims of botanicals related to herbal substances in food supplements, mainly due to the lack of human intervention studies [1]. 'On-hold' health claims of botanicals – both negatively assessed or not yet reviewed – are still used on the EU market in accordance with the transitional measures set out in the Nutrition and Health Claims Regulation (NHCR) until a decision is made on the 'on-hold' list [1]. In many cases 'on-hold' claims refer to the use of the herbal active substance as a medicinal plant and provide a claim describing the prevention of a disease for which the medicinal plant is used. This practice lacks a sound, science-based process. To date, 530 claims have been assessed as negatively providing consumers with false and misleading information and 1548 botanical-related claims are still on the on-hold list waiting for the Commission's and Member States' final consideration. [6,7].

Health claims influence consumers' choices, along with other characteristics such as price or brand. Therefore, there is an urgent need for health claims to be assessed by a competent authority, providing a scientific basis consumers can rely on. Additionally, panellists agreed that ensuring appropriate safety labelling is crucial to protect consumer health.

In addition, it is very important to ensure fair competition between herbal and chemically defined medicinal products. Comparing the requirements for chemically defined medicinal products and herbal medicinal products in case of changes in manufacturing and sourcing, the requirements for herbal medicinal products are higher than for medicinal products with chemically defined active ingredients [8]. There is no scientific basis for this as the manufacturing and control processes for herbal medicinal products are robust and validated. In order to restore equal treatment for both groups, the revision of the Variation Classification Guideline [6] should be taken as an opportunity to simplify the change processes for herbal medicinal products. For example, if a supplier of herbal raw materials changes, a simplified procedure in the Variation Classification Guideline is essential, as such changes are required more frequently due to the effects of climate change. The focus should be on minimising bureaucratic burden to ensure security of supply.

Conclusion and Outlook

The revision of the general pharmaceutical legislation and of the Variation Classification Guideline should be seen as an opportunity to secure the future of herbal medicinal products. In general, (traditional) herbal medicinal products are already well regulated by law. Efforts are being made to strengthen supply chains, manage shortages and adapt to changes. For market access, it is essential to maintain well-established use as a legal basis and application type for herbal medicinal products. Well-established use is successfully used as the legal basis for the EU monographs established by the Committee on Herbal Medicinal Products (HMPC), via a harmonised review and assessment process across the 27 member states. Therefore, the HMPC monographs form the

harmonised basis for the marketing authorisations of herbal medicinal products in Europe.

With respect to the revision of the general pharmaceutical legislation, panellists recommend focussing not only on harmonisation. This carries the risk of the lowest common denominator in indications and patient groups. The numerous opportunities, such as new strategies to use real-world data to enable safe access to vulnerable populations, including children, and to promote innovation, need to be explored. Better regulatory support for herbal medicinal products containing combinations of herbal drugs and their preparations was also highlighted.

Botanicals should also be regulated in a more harmonised way in the EU, for example, in terms of labelling and nutrivigilance. This will enhance product transparency and protect consumer safety. In the interest of transparency for informed patients and consumers, it should be immediately clear whether it is a medicinal product or a food supplement/botanical, requiring clear labelling on the front of the package. Due to the different regulations governing medicinal products and food supplements/botanicals, understanding of potential health risks associated with botanicals is limited. To ensure and protect consumer safety in Europe, stricter compliance with harmonised quality standards, an assessment of pending health claims on botanicals, and appropriate safety information in the product information of botanicals are required. A harmonised legal food system would be an important step in the right direction.

There was consensus that the market for herbal medicinal products is largely harmonised through the successful work of the HMPC, which guarantees that effective and safe herbal medicinal products of a high level of quality are available according to the same standards across Europe. The HMPC monographs provide a solid basis for the evaluation and enable market access of herbal medicinal products. Since the revision of the general pharmaceutical legislation foresees a change in the structure of the European Medicines Agency (EMA), it is vital that the quality of work and resources of the HMPC remain at the same standards.

In addition, the value of herbal medicinal products needs to be given greater consideration in both education and training of staff of the national competent authorities, healthcare professionals, and the general public. Herbal medicinal products' value in terms of assessed and approved quality, efficacy, and safety, as well as their potential, needs to be recognised and clearly visible to the patient.

Increased support for research and development on all aspects of herbal medical products and botanicals to foster innovation is essential. Strategically, this contributes to overcoming the societal challenges with the growing demand and financial burden on the healthcare system. Here, herbal medicinal products, like all other self-medications, can play an important role in saving millions in the healthcare system.

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Funding Information

The authors are grateful to the contributors of the European Herbal Health Products Summit on 20 February 2024.

Conflict of Interest

Michael Heinrich is working as a professor for pharmacognosy and phytotherapy at an independent university. Babette Reiken, Bernd Roether, Angela Müller are working for pharmaceutical companies producing and selling herbal medicinal products. Furthermore, Babette Reiken is vice-chairwoman of Pharma Deutschland. Julia Rumsch is working for BPI and Nico Symma is working for Pharma Deutschland, both are German pharmaceutical industry associations.

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