

Legal status of certain preparations with herbal extracts in the European Community

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Abstract. This study focuses on the legislative regulation of cosmetic products containing plant extracts in Romania and Europe. The classification of such products as medicinal products, cosmetics, or food supplements is explored within the context of European and Romanian laws. Cosmetic products with herbal extracts must meet the safety, quality, and efficacy requirements outlined in Regulation (EC) No 1223/2009 of the European Parliament and the Council. The distinction between cosmetic products and other categories like medicinal products, medical devices, or biocidal products is emphasized, with clear definitions provided to differentiate them.

A “cosmetic product” is defined as any substance or mixture intended for external application on specific body parts or oral cavity areas, serving purposes like cleaning, perfuming, appearance alteration, protection, maintenance, or odor correction.

The study finds that there are numerous cosmetic preparations with herbal extracts available in the Romanian and European markets, all registered as cosmetic products in the Cosmetics Notification Portal. The assessment of whether a product falls under the cosmetic category depends on an evaluation of its characteristics on case-by-case basis. The paper also explores the diverse range of cosmetic products with herbal extracts, including skin creams, gels, make-up, hygiene, hair care, and sunbathing products among others.

The study concludes that clear legislative regulations play a crucial role in ensuring the safety and quality of cosmetic products containing herbal extracts within the European and Romanian markets.

Keywords. herbal extracts, pharmaceutical product, national legislation.

1. Introduction

The growing interest in cosmetic products containing plant extracts has prompted the need for a comprehensive examination on their regulatory framework in both Romania and Europe. The aim of the present study is to delve into the legislative aspects governing these products and shed light on their classification, safety, and quality requirements.

The term “pharmaceutical product” encompasses a wide range of substances, including allopathic and homeopathic medicinal products designed for human use. These substances, whether chemically synthesized or derived from plant or animal sources, are intended to combat diseases, enhance overall health, and restore disrupted bodily functions. Additionally,

the category includes phytopharmaceutical products, which consist of simple medicinal plants, herbal teas, and plant-based tablets, and para-pharmaceutical products like woven and non-woven articles, biomedical devices, and glass containers.

However, this study primarily focuses on cosmetic products containing plant extracts and their compliance with Regulation (EC) No 1223/2009 of the European Parliament and the Council. It is essential to distinguish cosmetic products from medicinal products, medical devices, and biocidal products to ensure appropriate regulation. A cosmetic product, as per human body's external parts or oral cavity.

Their purpose may encompass cleansing, perfuming, appearance alteration, protection, maintenance, or odor correction.

The Romanian and European markets offer a wide range of cosmetic preparations containing herbal extracts, which undergo notifications through the Cosmetic Notification Portal. The assessment of whether a product qualifies as a cosmetic product is a case-by-case process, considering all product characteristics.

Various cosmetic products with herbal extracts are available, such as skin creams, lotions, makeup, hair care, and sunbathing products. To ensure consumer safety, the presentation of cosmetic products, including packaging, labeling, and other aspects, should not impose any harmonized standards, is imperative for manufacturing these products.

The qualitative analysis of herbal products should align with the European Pharmacopoeia standards, ensuring uniformity and adherence to safety and quality guidelines.

Moreover, the Cosmetic Product Safety Report, guided by Commission Implementing Decision 2013/674/UE, plays a crucial role in monitoring consumer exposure to potentially harmful substances.

The study will offer valuable insights into the Romanian and European regulatory landscape for cosmetic products containing plant extracts. The clear understanding of these legislative regulations is vital to ensure the safety, quality, and efficacy of cosmetic products circulating freely in the Single Market, promoting consumer confidence and well-being.

2. Material and methods

The present study aimed to address the Romanian and European legislative regulation of cosmetic products containing plant extracts in their composition.

The term "pharmaceutical product" includes the following: allopathic and homeopathic medicinal products for human use – meaning any substance or mixture of chemicals, plant-based, or animal-based products intended for treating diseases, strengthening health, and restoring disrupted bodily functions; phytopharmaceutical products: simple medicinal plants and combinations thereof, single-dose herbal teas, tablets made from plant powders; para-pharmaceutical products: woven and/or non-woven articles made from natural and/or synthetic fibers (cotton, gauze, bandages, compresses), biomedical devices made from plastic and/or elastomers (infusion sets, catgut, syringes, laminaria, probes), glass containers for medicines; dental products; radiopharmaceutical products; dietetic products registered by the Ministry of Health through the Drug Commission; cosmetic products registered by the Ministry of Health through the Drug Commission [1].

Cosmetic products with herbal extracts must comply with the safety, quality and efficacy requirements of Regulation (EC) No 1223/2009 of the European Parliament and of The Council of 30 November 2009 on cosmetic products, Official Journal of the European Union [2].

This Regulation concerns only cosmetic products and not medicinal products, medical devices or biocidal products. The delimitation results in particular from the detailed definition

of cosmetic products, which covers both the area of application and the purpose for which these products are used.

3. Discussions

A "cosmetic product" is defined as any substance or mixture intended to be put in contact with the external parts of the human body (epidermis, areas with hair, nails, lips and external genital organs) or with the teeth and mucous membranes of the oral cavity, for the exclusive or principal purpose of cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odor's [2].

Thus on the Romanian and European market there are many cosmetic preparations with herbal extracts that are notified as cosmetic products in the Cosmetics Notification Portal.

The assessment of whether a product is a cosmetic product must be carried out on a case-by-case basis, taking into account all product characteristics [3].

The category of cosmetics with herbal extracts includes: skin creams, emulsions, lotions, gels and oils; face masks, foundations (liquids, pastes, powders), make-up powders, after-bath powders, hygiene powders, toilet soaps, deodorant soaps, perfumes, toilet waters and colognes; bath and shower preparations (salts, foams, oils, gels), depilatories, deodorants and antiperspirants, hair dyes, products for curling, straightening and fixing hair, hair styling products, hair cleaning products (lotions, powders, shampoos); hair conditioning products/hair conditioners (lotions, creams, oils), styling products (lotions, lacquers, breezes), shaving products (creams, foams, lotions); make-up and make-up removal products, lip products; products for oral hygiene, products for nails care and painting, products for external intimate hygiene, products for sunbathing; artificial tanning products, skin whitening products and anti-wrinkle products [4,5].

The presentation of a cosmetic product - in particular its shape, smell, color, appearance, packaging, label, volume/size should not endanger the health and safety of consumers in accordance with Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, not being what they appear to be, may endanger the health or safety of consumers. In order to ensure the safety of cosmetic products with herbal extracts placed on the market, they should be manufactured in accordance with good manufacturing practice.

Compliance with good manufacturing practice implies that manufacturing is in accordance with the relevant harmonised standards, the references of which are published in the Official Journal of the European Union [6,7].

For the purposes of effective market surveillance, a product information file should be easily accessible at a single address in the Community for the competent authority of the Member State where the file is kept [6].

In order to be comparable and of high quality, the results of non-clinical safety studies conducted to assess the safety of a cosmetic product with herbal extracts should comply with the relevant Community legislation. The specified information should be made available to the competent authorities and should include all necessary details on the identification, quality, safety for human health and claimed effects of the cosmetic product with herbal extracts. This product information should include in particular a safety report on the herbal cosmetic product demonstrating that a safety assessment has been carried out.

In order to ensure uniform enforcement and control of restrictions on substances, sampling and analysis should be carried out in a reproducible and standardised manner.

Cosmetic products with herbal extracts should be safe under normal or reasonably foreseeable conditions of use. In particular, a risk/benefit rationale should not be used to

justify a risk to human health. Herbal products in cosmetic products must otherwise comply with certain rules, internal regulations or officinal regulations, monographs in pharmacopoeias in force. The qualitative analysis of herbal products should also be regulated and carried out according to the European Pharmacopoeia in force (10.0) [8].

According to the European Pharmacopoeia for Herbal Products the following requirements according to Chapter 5.23, Monographs on herbal extracts and the monograph “Herbal drug preparations, *Plantae medicinales praeparatae*” must be complied with, as follows: identification of herbal products carried out by macro and microscopic examinations; determination of foreign substances; loss on drying; determination of heavy metals; determination of pesticides; determination of total ash insoluble in HCl; determination of soaking factor, for plant products containing polyuronides; determination of aflatoxin B1; determination of ochratoxin A; determination of bitterness index for plant products containing bitter substances; microbiological control of plant products; determination of the radioactive load of the plant product [8].

All these requirements are addressed by pharmaceutical, pharmacognostic, analytical methods, physical and chemical detection methods are used - MS, GS, HPLC [9-12].

The Cosmetic Product Safety Report must comply with Commission Implementing Decision 2013/674/EU on guidelines concerning Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products published in the Cosmetic Product Control Guidelines developed by the National Institute of Public Health of the Ministry of Health [4].

The objectives of this guide are to monitor cosmetic products placed on the market in relation to consumer exposure to contaminants and substances posing a risk to health in the composition of cosmetic products and to harmonise with the procedures operating in the European Union internal market for the control of cosmetic products in accordance with the requirements of Regulation No 1223/2009.

The characteristics of the raw materials of plant origin must first be specified. The botanical name, popular name, family to which the plant belongs; the plant's use - root, bark, resin, fruit, leaves, flowers, inflorescences, whole plant, aerial part of the plant, seeds, thallus, buds; the geographical origin of the plant - place of harvesting; time of harvesting and stage of development of the plant; whether there has been pesticide treatment during development (pesticide residues, radioactivity, contamination with toxic metals); processing dates: processing during drying, extraction, distillation; commercial form of presentation: powder, solution, solvent; characteristics of components: active ingredients, impurities [13].

The physico-chemical characteristics of the finished cosmetic product should be discussed. The dossier shall contain the specifications of the finished product drawn up by the manufacturer.

Each specification must be accompanied by the relevant limits. For each physico-chemical property described in the finished product specification, the reference method shall be specified.

The stability of the cosmetic product must be indicated in the dossier. The dossier includes notes on the stability of the cosmetic product, namely: the methodology used to determine the minimum validity of the product, specific precautionary measures relating to preservation, all available data used to justify the minimum shelf life indicated on the label.

In addition, the following shall also be stated: evidence that the composition of the product used for stability testing corresponds to the product actually placed on the market; the results of the shelf-life effectiveness study, challenge test, if applicable; if applicable, the period of use after opening (POU) and its justification.

As the requirement is to assess the stability of the cosmetic product under reasonably foreseeable storage conditions, where stability depends on storage conditions, information about these conditions shall be communicated throughout the supply chain and, where relevant to the end user, indicated on the product label.

The SCCS Scientific Committee on Consumer Safety has recommended: "relevant stability tests should be carried out, adapted to the type of cosmetic product and its intended use.

In order to ensure that the type of container and packaging used does not give rise to stability concerns, physical stability tests are currently carried out with inert containers and those intended for use on the market."

Microbiological quality data include information is essential to justify the efficacy of the preservation system and to justify the indicated minimum shelf life of the cosmetic product with herbal extracts and the period of use after opening (POU) of the finished product.

Special attention shall be paid to the microbiological specifications of cosmetic products intended for use on sensitive parts of the body and in specific populations (in children <3years, the elderly or people with compromised immune systems) and of cosmetic products intended for use around the eyes, on mucous membranes in general, on skin showing lesions (e.g. skin care products for use on atopic or irritated skin) [14].

Any statement (claim) on the label must comply with the provisions: REGULATION (EU) No 655/2013 establishing common criteria for the substantiation of claims used in relation to cosmetic products [14].

The Cosmetic Products National Portal is the online notification system created for the implementation of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products.

Any placing on the market of a cosmetic product with herbal extracts must be notified in advance in the Cosmetic Products Notification Portal by a natural or legal person (art.4 of the same Regulation) who becomes the person responsible for the presentation, quality and all aspects related to that cosmetic product.

The substance contained in a cosmetic product with herbal extracts is according to Regulation (EC) No 1223/2009 of the European Parliament and of the Council, Article 1 (b): "a chemical element and its compounds, in the natural state or obtained by any manufacturing process, including any additive necessary to preserve stability and any impurity deriving from the process used, with the exception of any solvent which may be separated without affecting the stability of the substance or changing its composition".

All cosmetic ingredients must be included in the Annex of cosmetic ingredients published periodically in the Official Journal of the European Union. The cosmetic product with herbal extracts must also comply with the provisions on the quality and safety of cosmetic products.

According to Article 12(2) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council, "in the absence of applicable Community legislation, the conditions of reliability and reproducibility shall be presumed to be fulfilled if the method used conforms to the relevant harmonised standards, the references of which have been published in the Official Journal of the European Union" [15].

Cosmetic ingredients according to Regulation (EC) No 1223/2009 of the European Parliament and of the Council must comply with the requirements of Chapter IV, Restrictions for certain substances [2].

Preservatives are one of the ingredients that make the difference in the quality and safety of cosmetic products. Parabens have an antimicrobial effect, being also economically efficient, but repetitive and long-term use has been associated with unwanted side effects (the most serious being breast cancer) [16]. To avoid the controversies associated with parabens,

formulators try to use organic acids and their salts, such as sodium benzoate. Sodium benzoate is a preservative allowed in acidic foods, soft drinks, cosmetic products. Although the admissible concentrations are limited, by the corresponding regulations, a great concern regarding the use of sodium benzoate is its ability to transform into benzene (especially if there is also vitamin C in the composition of the product), a known carcinogen. Moreover, the unwanted adverse effects of benzoate are recognized, such as: it can increase the risk of inflammation, oxidative stress, obesity, ADHD and allergies [17, 18].

4. Conclusions

In European and Romanian legislation, products with herbal extracts can be classified as medicinal products, cosmetics or food supplements.

On the Romanian and European market cosmetic preparations with herbal extracts are notified as cosmetic products in the Cosmetics Notification Portal.

Romania has transposed the European legislation on cosmetic products with herbal extracts into national legislation through specific laws, together with other related regulations, aiming at clearly regulating the requirements for a safe herbal cosmetic product to circulate freely within the Single Market.

For herbal products or extracts in cosmetic products, adherence to specific regulations, internal guidelines, or official regulations is required. These products should also present monographs in the applicable pharmacopoeias to ensure their compliance with safety and quality standards.

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