

Legal regime of mouthwashes with plant extracts in the european community

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Abstract. The mouthwashes in the Romanian legislation are not clearly included in the category of cosmetics, alimentary supplements or medicines.

According to European legislation, the mouthwashes fall under Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 in the category of cosmetic products. Thus, on the Romanian and European market there are many cosmetic preparations in the form of mouthwashes that are notified as cosmetic products in the Cosmetics Notification Portal.

Other products in the form of mouthwashes in general containing plant and animal extracts are approved and regulated as dietary supplements by the Institute of Food Bio resources, according to Order no. 244/2005, Order No. 1228/2005, Order No. 1946/2014, Law 491/2003, Annex to Order no. 244/2005 and Order 1069/2007 [1].

The ANMDMR (National Agency for Medicines and Medical Devices of Romania) has not approved on the Romanian market any medicine to be formulated in the form of a mouthwash to the EMA (European Medical Agency) which has regulated mouthwashes with active medicinal substances in the pharmaceutical form of mouthwashes.

Keywords. Mouthwash, European Medicines Agency, cosmetic, plant, ingredient

1. Introduction

Mouthwashes are pharmaceutical preparations, cosmetics or food supplements that come in the form of solutions, emulsions or suspensions [2].

The objectives of this work were:

1. approaching the Romanian and European legislative regulation of preparations in the form of mouthwashes;
2. Approach to legislative regulation of mouthwashes containing plant active substances.

Mouthwashes may contain pharmaceuticals and are examples on the European market approved by EMA.

Also, some mouthwashes are put for consumption on the Romanian and European market in the form of cosmetic products, being notified through the European Cosmetics Portal, which puts into practice Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009.

Some mouthwashes existing on the European and Romanian market are considered and regulated as dietary supplements, especially those containing herbal ingredients.

2. Legal regime of mouthwashes in the European Community

According to Article 2 (a) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 [3] on cosmetics, mouthwashes fall within the category of cosmetic products.

Thus, Article 2 (a) defines a cosmetic product as 'any substance or mixture intended to be brought into contact with the external parts of the human body (epidermis, hair, nails, lips and external genital organs) or with the teeth and mucous membranes of the oral cavity for the sole or main purpose of cleaning, perfuming or changing their appearance, to protect them, keep them in good condition or correct body odors.

Mouthwashes come into contact with the teeth and mucous membranes of the oral cavity for the sole or main purpose of cleaning, perfuming, changing their appearance, protecting them, keeping them in good condition or correcting oral odours, which explains their belonging to cosmetic products.

By extrapolation, therefore, mouthwashes must comply with all the requirements of Regulation (EC) No 1223/2009 of the European Parliament and of the Council.

Thus, Romania transposed the European legislation on cosmetics into national legislation through specific laws, along with other adjacent regulations, aiming to clearly regulate the requirements for a safe cosmetic product to circulate freely within the Single Market.

In accordance with EEC legislative regulations, cosmetic products must comply with provisions concerning:

- their circulation on the market of member countries;
- substances prohibited for use in formulation;
- permitted substances and indication of their scope, maximum concentrations and conditions of use;
- use of colouring agents, antimicrobial preservatives and UV filters;
- packaging and labelling conditions;
- methods of analysis for checking composition;
- criteria of chemical and microbiological purity and methods of verification in accordance with these criteria.

The realization of these preparations requires compliance with certain conditions: not to be absorbed and not to exert a harmful effect in the body, to be stable, and their use to be simple and convenient.

The Cosmetic Products Notification Portal (CPNP) [4] is the on-line notification system set up for the implementation of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products.

Thus, any placing on the market of a cosmetic product, mouthwash, must be notified in advance in the Cosmetics Notification Portal, by a natural or legal person (article 4 (1) of the same Regulation) who becomes the person responsible for the presentation, quality and all aspects of that cosmetic product.

Thus, the ingredients that are part of the mouthwash composition become involved substances and must comply with the requirements of a cosmetic ingredient according to Regulation (EC) No 1223/2009 of the European Parliament and of the Council.

Thus, the substance contained in a cosmetic product complies with Regulation (EC) No 1223/2009 of the European Parliament and of the Council, Article 1 (b): 'substance' means a

chemical element and its compounds, in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition'.

Thus, all cosmetic ingredients should be listed in the annex to cosmetic ingredients published periodically in the Official Journal of the European Union. The cosmetic product must also comply with the provisions relating to the quality of cosmetic products and their safety.

In accordance with Article 12(2) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council, 'in the absence of applicable Community legislation, reliability and reproducibility shall be presumed to be fulfilled if the method used complies with the relevant harmonised standards, the references of which have been published in the Official Journal of the European Union'.

Cosmetic ingredients as defined in 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.

As there are approaches to oromucosal preparations in the European Pharmacopoeia, mouthwashes may be regulated and registered as oromucosal preparations when they contain official pharmaceuticals.

According to the European Pharmacopoeia, oromucosal preparations are solid, semi-solid or liquid preparations containing one or more active substances intended to be administered into the oral cavity and or throat to obtain a local or systemic effect.

Oromucosal preparations may contain suitable antimicrobial preservatives and other excipients, such as dispersants, suspending, thickening, emulsifying, buffering, wetting, solubilizing, stabilizing, flavouring and sweetening.

Several categories of preparations for oromucosal use can be distinguished: gargles; mouthwashes; gingival solutions; oromucosal solutions and oromucosal suspensions; semi-solid oromucosal preparations (including, for example, gingival gel, gingival paste, oromucosal gel, oromucosal paste); oromucosal drops, oromucosal sprays and sublingual sprays (including oropharyngeal sprays); tablets; sublingual tablets and buccal tablets; oromucosal capsules; mucoadesive preparations; orodispersible films.

There is no mouthwash preparation in the NAMMD Nomenclature of Medicinal Products for Human Use [5] and all mouthwash preparations on the Romanian market are registered as cosmetics or food supplements.

The European Medicines Agency (EMA), but has mouthwashes approved as medicines, for example, mouthwashes containing octenidine dihydrochloride. It is approved by EMA [6] by decision number P/0240/2018, with pharmaceutical form, mouthwashes.

Some of the mouthwashes are products that contain exclusively active herbal principles, for this reason they may fit into medicines or herbal dietary supplements.

The marketing of a food supplement on the Romanian market can only be done based on the agreement of the relevant authorities, namely the National Service for Medicinal Plants, Aromatics and Hive Products within the National Institute for Research and Development for Food Bioresources (IBA Bucharest). In order to put the food supplement on the Romanian market, it must comply with the provisions of the laws in force: Order nr. 244/2005, Order no. 1228/2005, Order no. 1946/2014, Law 491/2003, Annex to Order no. 244/2005 and Order 1069/2007.

On the Romanian and European market there are many preparations, mouthwashes that are classified as food supplements and contain vegetable products.

3. Legislative regulation of mouthwashes containing plant and animal products

Plant products [7] must otherwise comply with some norms, internal regulations or officinal regulations, presenting monographs in the pharmacopoeias in force.

The qualitative analysis of plant products should also be regulated and followed according to the European Pharmacopoeia (10.0).

According to the European Pharmacopoeia for plant products, the following requirements must be complied with according to Chapter 5.23, Monographs on herbal extracts and monograph Herbal drug preparations [8], *Plantae medicinales praeparatae* [8], as follows:

- identification of plant products carried out by macro- and microscopic examinations;
- determination of foreign substances;
- loss on drying [9];
- determination of heavy metals;
- determination of pesticides;
- determination of total ash insoluble in HCl;
- determination of the soaking factor, for plant products containing polyuronides;
- determination of aflatoxins B1;
- determination of Ochratoxin A;
- determination of the bitterness index for plant products containing bitter substances;
- microbiological control of plant products;
- determination of the radioactive charge of the plant product.

All these requirements are addressed by pharmaceutical, pharmacognostic, analytical methods. Thus, physical and chemical determination methods such as mass spectrometry (MS), gas chromatography (GS) and high-performance liquid chromatography (HPLC) are used.

4. Conclusions

Mouthwashes in European and Romanian legislation can fall into the category, medicines, cosmetics or food supplements.

In the Romanian pharmaceutical approach, mouthwash is not defined as a pharmaceutical form, more being presented in the form of a cosmetic product for oral hygiene. Indeed, mouthwashes according to European cosmetic product legislation, according to the definition of cosmetic product, fall into the category of cosmetics.

Also, on the Romanian and European market there are many mouthwashes that are regulated and placed on the market in the form of food supplements.

Mouthwashes containing plant and animal products must comply with European plant product regulations, in particular monographs on plant products existing in the European Pharmacopoeia.

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