Cosmetic Products
Cosmetic products

The cosmetic products have a large importance and an essential role in the lives of each of us. In their category, besides „traditional” cosmetics, such as make-up products and perfumes, are included also personal hygiene products, such as teeth care products, shampoos and soaps.

How can a cosmetic product be separated from other product categories? Can the cosmetic product be regarded as a medicine?

The separation of cosmetic products from other categories requires an analysis of both the cosmetic product definition and the legal provisions regarding other product categories which, by their nature can be confounded with the cosmetics.

According Law 178/2000 on cosmetic products, republished and harmonized with the provisions of Directive 76/768/CEE, a product is considered cosmetic if it is put in contact with different external parts of the human body, such as skin, hair, lips, external genital organs or with the teeth and the mouth, with the exclusive or main goal to clean, perfume them, modify their aspect and/or correct the body scents and/or protect or maintain them in good shape. Also, in order to be considered as cosmetic a product must be delivered as substance or mixture of substances.

In spite there are certain products that, although are not cosmetic by their nature, are considered as cosmetic, due to the fact the organism liberates or absorbs the substances in their content. It is the case of napkins for make-up removal, perfumed napkins or temporary tattoos. The permanent tattoos cannot be considered cosmetic products as they come in contact with the internal body organs.
The products indicated or recommended as having therapeutic or prophylactic properties have also the same regime. Even though these correspond to the definition of cosmetic products, they cannot be considered as cosmetic products, due to their destination to ensure protection against sickness.

Be careful! The European Court of Justice has decided that “a product indicated or recommended as having therapeutic or prophylactic properties must be considered as a medicine product, due to its presentation, even if it is known that it has no therapeutic effect.”

Instead, are cosmetic products antidandruff shampoos, antibacterial shampoos etc. because their main function corresponds to the cosmetic product definition, “to protect and maintain in god shape”. But, for these products the declared effect must be proved.

As for the delimitation of cosmetics from medicines, this is done according to the provisions of art. 2 from Directive 2004/27/CE for the establishment of a community code regarding human use medicines showing that in case of doubt, where a product, taking into consideration all its characteristics, can fit both in the definition of “medicine” and in the definition of a product regulated by other community laws, the dispositions of the directive will apply. This means that, if a product, in the virtue of its “presentation” and “function” corresponds both to the definition of medicine and of cosmetic product, his placement on the market must be done following the rules on human use medicines. So, these products cannot be regarded as cosmetic products.

For a series of other products, which cannot be defined as cosmetic products and which are not found in the Annex 1 “List of categories of cosmetic products” from the Law no. 178/2000 on cosmetic products, republished, the provisions of Law 245/2005 on general safety of products will apply (Directive 2001/95/CE). The norms apply for all products that have no specific regulations
and are delivered to consumers. For example, **aromatherapy products** (with the exception of the case when are not placed in contact with the external body parts and have a cosmetic function) **are not considered cosmetic products**.

In consequence, the evaluation of each product is done in each case, taking into consideration objective criteria, such as the presentation of the product and the usual application method.

**Cosmetic product labeling**

Cosmetic products can be put on market only if on the container and on the package the following information **are written visibly, easy to read and with characters that cannot be easily wiped:**

1. **The identification data for the producer or the person responsible with the placement on the market:**
   - Name of the producer or the person responsible with placement on the market if are established in the European Union or abbreviation, if this allows for an identification of the persons;
   - Headquarters or the address from the EU Member State of the producer or the person responsible for the placement of an imported product on the market, in the European Union, or its abbreviation, while this is possible to be identified;
   - Country of origin for products made outside the European Union.

Be careful! The address can be shown through the abbreviation of a city, district, county or country, like those used by the post. A full postal code can be considered as sufficient information. In case of products made in EU Member States and placed on the Romanian market the legislation does not ask for an address in Romania.
2. The nominal content at the moment of the packaging, indicated in weight or in volume, except packages with less than 5 grams or less than 5 milliliters, free samples and single doses.

Regarding the package of products that are sold in an ensemble and for which the indication of weight or of volume is not of significance, the content may not be indicated, but the number of pieces will be mentioned on the package.

Be careful! The mention regarding the nominal content is not necessary when the number of pieces can easily be determined from the outside or if the product is usually sold as a unit.

3. Minimum durability date

The minimum durability date must be indicated through “To be used best before ...” followed by the date or the indication of the place on the package where this date is written. The date must be clearly mentioned, by indicating in order and with Arab numbers the month and the year, or the day, month and the year. If it is necessary, this information will be supplemented by an indication of the conditions that must be fulfilled in order to guarantee the declared durability.

Regarding the information on the minimum durability date it is important to mention that this is different if the product has a minimum durability higher or lower than 30 months.

So, the “To be used best before...” followed by the date or the indication of the place on the package where it is written, it is specific for products with a durability date lower than 30 months, if it is possible that the product deteriorate in the course of 30 months from the production date, so it cannot satisfy anymore the general safety requirements and also cannot realize its function.
Be careful! For cosmetic products with a minimum durability date higher than 30 months the indication of the minimum durability date is not compulsory. For these products the phrase “Period after opening” it is used, representing the period starting from which a cosmetic products stops being safe and which is materialized through the symbol of the box with the lid opened, followed by the period in moths or years specified through a number inside or near the symbol.

In the case of cosmetic products used by professionals in specialized units, it imposed that after the product was opened, an inscription on it to be made, in order that the minimum durability date to be verified.

Important! The minimum durability date must be specified in Romanian, on the main package and on the secondary package.

4. Special use precautions, mainly those regarding ingredients that must be mentioned on the label

The European Commission and the Member States have agreed to use the letter “M” to show the months, but for the short version for the representation of the years no agreement exists. At the EU level it is agreed that the number of months will be used to illustrate the period after opening.

So, when the period after opening is half a year, one year, 2 years, etc., the symbol will be presented like this: 6 M, 12 M or 18 M etc.

The special use precautions and the special warning information must be written on the package or the container. In case this is not possible for practical reasons, a prospect, a label, a band or a flyer will be put aside which will contain the necessary information, abbreviated or by using the following symbol that must figure on both the package and the container.
5. **The cosmetic product function**, except the case when this results from the presentation of the product

The function will be mentioned both on the secondary exterior package's label (box) and on the primary package (container), with the exception of the case when the function of a cosmetic product results from presentation.

For example, the function of a lipstick or of toilet soap is obvious, but a hair fixative (spray) must be differentiated from a deodorant spray, case in which the functions must be mentioned.

6. **Number of fabrication lot or an indication to permit the identification of the product**

The number of fabrication lot must be marked on both the primary package (container) and the secondary package (box) **in the form of a code** that must allow the producer or the provider to identify the lot in which the product was made. If the product is not fabricated in lots, a code is applied through which the place and date of fabrication can be identified. In the case of a product ensemble (a products including in a secondary package several products I primary packages – as it is the case for hair dyes) the product lot numbers can be different, under the condition the producer has an exact identification system, for each product in the ensemble and for the package itself.

A good practice that allows the identification of the lot or a series in a very precise way, has the advantage that in the case where a problem appears, the product quantities the authorities or the producer have decided to retire or “to retain the stock for a later investigation”, would be as limited as possible.

**Be careful!** Where the reduced product dimensions do not allow for the specification of the code on both the packages, primary and secondary, the code marking is accepted only on the exterior package (secondary).
7. **The list of ingredients** that are part of the cosmetic product's composition, in descending order of their weight at the moment of the incorporation; this list is preceded by the word “ingredients”.

In the case where, from practical reasons, the enumeration of ingredients is not possible, the prospect, label, band or flyer attached must contain all the necessary information, in the abbreviated form that must be written on the package.

Are not regarded as ingredients the impurities from the prime materials, auxiliary technical materials used in the mixture, that are not found in the finished product, materials used in strictly necessary quantities like solvents or perfumes carriers or aromatic compositions.

But, ingredients as colorants, perfume or aromatic compositions and their prime materials must be mentioned on the label, with the mention that any ingredient in a concentration lower than 1% can be mentioned without a specific order, but only after those whose concentration is higher than 1%. Also the colorants can be mentioned after the other ingredients, no matter in which order, according an index color number. For decorative cosmetic products sold in several colors/nuances all used coloring agents are mentioned, preceded by the phrase “can contain” or by the symbol “+/−”. The perfume and aromatic compositions and their prime materials will be mentioned by the words “perfume”, “aroma”.

**Responsibility for cosmetic products safety**

The cosmetic products can be put on market only if they are safe, so that their use will not harm the human health. The responsibility for the safety of cosmetic products regarding composition, package and information on the cosmetic product belongs entirely to the producer or importer.
Be careful! A product must be safe not only in normal conditions of use, but also in reasonable foreseeable use conditions.

In order to determine the “reasonable foreseeable use” conditions one must take into consideration all circumstances, including the product’s presentation (that include the warning), instructions of use and removal and any other indication.

The safety requirements do not include the wrong use of product (with the exception of the case where this wrong use is foreseeable). For example, a hair dye of general use (non professional) contains clear instructions, along with warnings for a safe use of the product, such as “Do not use for coloring of the eyelashes and eyebrows”, “Rinse immediately the eyes in case the product comes into contact with the eyes”. Through these warnings the producer has recognized the fact that the product could irritate the eyes and has warned the consumer on the possibility to apply the product near the eyes. If the consumer ignores this warning, the producer cannot be held responsible. But if the product is so irritating that affects invariable the eyes, without entering into contact with these and the consumer has used the product according the instructions of use, it is possible that the producer can be held responsible for the damage on the consumer’s health.
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