J. Appl. Cosmetol. **29**, 129-133 (July/September 2011)

Overlapping Definitions of Drugs, Topical Medical Devices, Cosmetics.

The cosmetic efficacy: myth or reality?

Sonia Selletti
Lawyer, Studio Legale Astolfi e Associati, 20122 Milan - Italy

Received: *September 2011. Presented at The IX ISCD International Multidisciplinary Congress "Wellness and Beauty Outside In: East & West working together", Rome, 21-23 October 2009.*

Key words: *Medicinal products; Cosmetics; Medical devices; Overlapping definitions;*

Summary

The purpose of this paper is to outline the main issues arising out from the possible overlapping in the definitions provided for by the law for medicinal products, topical medical devices and cosmetics.
The Legislators carefully consider the need to clearly determine the demarcation between these different categories of products and recognizes that the determination of clear borderline among products is aimed at enhancing for the proper implementation of the European Directives and the correct interpretation and enforcement of transposing national laws. Nevertheless quite often happens that overlapping spaces objectively occur so to originate borderline cases where the parties involved (mainly companies and competent authorities) have to find fair solutions.
With the support of the European Court of Justice interpretation and of the Guidance Documents concerning borderline products issued by the European Commission (and agreed between the Commission services and the competent authorities of Member States) it is possible to identify a correct approach to the matter which caveat are figured in the following paper.

Riassunto

Questo lavoro si propone di delineare alcuni profili di interesse che emergono dalla possibile sovrapposizione ed interferenza nelle definizioni poste dalla legge con riguardo ai medicinali, dispositivi medici per uso topico e cosmetici.
Il legislatore considera attentamente l'esigenza di determinare con chiarezza la demarcazione tra queste differenti classi di prodotti e riconosce che la definizione di ambiti chiari tra prodotti è volta a

favorire un'appropriata trasposizione delle Direttive Europee ed una corretta interpretazione ed attuazione nelle norme nazionali. Ciò non di meno sovente si constatano ambiti di possibile interferenza capaci di determinare casi di frontiera (cd. borderline) che costringono le parti coinvolte (principalmente le imprese e le autorità competenti) a trovare una soluzione.
Con il supporto della interpretazione della Corte di Giustizia delle Comunità Europee e con i Manuali interpretativi e le Linee Guida emanate dalla Commissione Europea (concordati tra i servizi della Commissione e le Autorità competenti degli Stati membri) è possibile identificare un corretto approccio al problema i cui caveat sono prospettati in questo lavoro.

The rules governing the marketing of health and wellbeing products contain precise definitions meant by the Legislator to mark the identification of the various classes of products and correctly determine their implementation field.
It has in any case been proved that scientific and technical progress often confers the health products such original and innovative features as to make it more difficult their classing as to legal definition due to the overlapping that can occur among the different areas.
The cosmetic sector is an emblematic example of such a situation. Research and progress have favored the notion of functional cosmetics which can interact with physiological functions, without interfering, on the action level, with mechanisms typical of other classes of products (for instance, medications). The basic issue is therefore identifying which is actually the frame for functional cosmetics within our current legal classification.
In order to do so, we must first say that the definition of cosmetic (a cosmetic product means any substance or preparation intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours) comprises functional profiles that when effectively interpreting the development and the progress in the cosmetic field, broadens the interpretation limits. It becomes therefore necessary to proceed on a "case by case" basis as indicated also the Judges of the European Court of Justice, when asked to decide upon the interpretation of rules in borderline situations (1) in such a case supported by the "Manuals" drawn by the Work Groups and by the Guidelines on Borderline products issued by the European Commission (2), that, although not binding at a legal level, are certainly effective interpretation tools to correctly orient the enterprise and interpreters' performance.
Without claiming to give an exhaustive view on this issue, may we give some hints about the assessment frame.
Therefore, taking into account typical cosmetic functions, if no interpretation issue can be raised about the commonest functions such, for instance "perfuming", on the contrary, reference to "protection" and "keeping in good condition" the parts of the body which the cosmetic can be applied on, reminds of activities which, with much greater difficulty, can be classified and determined a *priori* to establish abstract classification schemes.
A cosmetic protective function can in fact occur in various areas, so as the keeping in good state, and the space for the correct classification of the products is precisely close to these limits.
It is apparent that the protective fnnction and the keeping in good state can not imply therapeutic functions, but this does not prevent the cosmetic from having protective adjuvant function together with the use of medication for skin care and such property from having action mechanisms not interfering with other product classes.
This principle is clearly stated: as regards the meaning of "restoring, correcting or modifying physiological functions" (3) it is clear from the aim of health protection pursued by the Community legislator that the phrase must be given a sufficiently broad interpretation to cover all substances capable of having an effect on the actual functioning of the body.
However, that criterion does not serve to include substances such as certain cosmetics which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions (4).
We might argue whether the above principle is

still relevant to the present in the light of article 1(2) of Directive 2001/83 according to which "medicinal product" means "(a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis" and also in the light of article 2(2) of the mentioned Directive according to which "in case of doubt, where, taking into account all its characteristics, a product may fall within the definition of a "medicinal product" and within the definition of a product covered by other Community legislation the provisions of medicinal directive shall apply" (id est: non cumulation principle).

The possible solution derives from a recent ECJ interpretation assessing that: Directive 2001/83 does not apply to a product in respect of which it has not been established that it is a medicinal product within the meaning of art. 1(2) (b) of that directive, that is to say, a product in respect of which it has not been scientifically established that it is capable of restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or that it may be used to make a medical diagnosis.

It follows that products containing a substance having a physiological effect cannot automatically be classified as medicinal products by function unless the competent administration has made an assessment, with due diligence, of each product individually, taking account, in particular, of that product's specific pharmacological, immunological or metabolic properties, to the extent to which they can be established in the present state of scientific knowledge.

It should be borne in mind that the capacity to restore, correct of modify physiological functions should not lead to the classification as medicinal products by function of products which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions (5).

Still, the cosmetic definition, with regard to the product aim, involves the issue of the "exclusive or prevailing" use, thus granting access to the representation of primary and ancillary functions. In such cases the legal limit is of course the former prevailing on the latter, in order to respect the cosmetic functionality domination with regard to secondary areas.

Some indications ruling the possible overlapping issue between cosmetics and medical devices arise out for the mentioned European Commission Guidance Documents according to which Medical devices are defined as articles which are intended to be used for a medical purpose.

The medical purpose is assigned to a product by the manufacturer who determines through the label, the instruction for use and the promotional material related to a given device its specific medical purpose. Medical purpose relates to finished products (supplied to the final user).

The definition of medical device should be understood to include products intended to be used principally for a medicinal use. Therefore products intended to have a toiletry or cosmetic purpose are not medical devices even though they may be used for prevention of a disease.

This precious indications make it efficient the work of interpreters' and companies engaged in the proper classification of their products.

In any case we may conclude that the frame for the assessment of cosmetic effectiveness "between myth and reality" is still wide, but also thanks to this fact, there remains a wide margin for progress, science and the interpreters' work.

References

1) ECJ, HLH Warenvertriebs GmbH, para 51; also ECJ, C-290/90 of May 1992 "Eye lotions, ECR 1992 I-3317, para 17.
2) http://ec.europa.eu/enterprise/sectors/cosmetics/cosmetic-products/borderline-products/index_en.htm
3) Directive 65/65, art. 1-2.
4) ECJ, Upjohn, C-112/89, 16 April 1991.
5) ECJ, Hecht –Pharma, C-140/07, 15 January 2009.

Author Address:

Sonia Selletti, Lawyer
Studio Legale Astolfi e Associati
Via Larga n. 8
20122 Milano
E-mail: avvocati@studiolegaleastolfi.it