PERSPECTIVES IN COSMETIC-VIGILANCE

G. Salvatore
Comparative Toxicology and Ecotoxicology Laboratory - High Institute of Health, Rome - Italy

Received: *February, 2002*

Key words: Cosmetics, Cosmetic-vigilance; Safety

Summary

The national surveillance system, provided for by legislative decree n. 126 dated April 24th 1997 (modifying the law n. 713 dated October 11th 1986 and especially concerning safety of the cosmetic products) is not concretely and uniformly used in the national territory and is not subjected to central co-ordination by Public Administration. Actions carried out by more active Regions and others organisms of the Public Administration suggest a possible way to act at least during the initial experimental phase. Among them it is worth mentioning the basic professional training course on Cosmetic Surveillance organized by the High Institute of Health (Rome, September 27th-29th 2000) in which supervision operations carried out by some regions have been included.
Since the specifications of the above mentioned course have been recently published, we suggest referring to them in order to carefully examine the situation.
A first step is to understand the real meaning of Cosmetic Surveillance. Instead of monitoring the undesired effects only, it is important to undertake a more global action characterized by the prevention and safety criteria of cosmetic uses as specified in the above mentioned LD n. 126 and including the examination of conformity with the laws in force.
Moreover, on the basis of a previous pilot study carried out in the Regione Lazio, we suggest the following initiatives:
- census of cosmetic manufacturing, packaging and exporting industries in each region;
- drawing up of a notified ingredients form;
- drawing up of a product form;
- setting up of a method to report all undesired effects (family doctor, dermatologist, chemist, center for antidotes) through an adequate form for data collection;
- definition of an interregional pilot program of surveillance.

The most important and useful elements on this topic will be discussed.

Riassunto

Il sistema nazionale di sorveglianza, previsto dal decreto legislativo 24 aprile 1997, n. 126 (che modifica la legge 11 ottobre 1986, n. 713, soprattutto per la parte della sicurezza d'impiego dei cosmetici), non trova ancora modalità operative concrete e uniformi sul territorio nazionale e sfugge ad un coordinamento centrale assicurato dalla Amministrazione pubblica. Le azioni svolte al riguardo dalle Regioni più attive, insieme ad altre intraprese in ambienti dell'Amministrazione pubblica, suggeriscono una possibile traccia da seguire almeno in una fase sperimentale iniziale. Tra queste si cita il corso di formazione di base sulla Cosmeticosorveglianza organizzato dall'Istituto Superiore di Sa-

nità (Roma, 27 - 29 settembre 2000) in cui è stato dato spazio anche alle azioni di vigilanza effettuate da alcune regioni. Poichè di questo corso ne sono stati di recente pubblicati gli atti, a questi si rimanda per un esame attento della situazione, cogliendone qui solo quegli elementi di discussione più importanti e più utili ai fini di questa tavola rotonda.

Una prima riflessione riguarda il significato di cosmeticosorveglianza. Ad una azione rivolta al solo monitoraggio degli effetti indesiderati si è preferito puntare ad una azione più globale che, ispirata ai criteri di prevenzione e di sicurezza d'impiego dei cosmetici di cui è intessuta l'intera normativa citata, includesse la verifica di ogni conformità alle norme vigenti.

Inoltre, sulla base di una precedenza esperienza maturata nell'ambito di uno studio pilota effettuato presso la Regione Lazio si possono suggerire le seguenti iniziative:

- censimento per regione delle imprese produttrici, confezionatrici ed importatrici di cosmetici;
- elaborazione di una scheda per gli ingredienti notificati;
- elaborazione di una scheda per i prodotti;
- individuazione del possibile percorso per la notifica degli effetti indesiderati (medico di famiglia, dermatologo, farmacista, centri antiveleni) mediante l'uso di una idonea scheda di rilevamento dei dati;
- definizione di un programma interregionale pilota sulla sorveglianza.

Questi indirizzi già attuati in alcune regioni sono qui discussi.

INTRODUCTION

The national surveillance system, provided for cosmetics by legislative decree n. 126 dated April 24th 1997 (modifying the law n. 713 dated October 11th 1986 and especially concerning safety of cosmetic products) is not concretely and uniformly used in the national territory and is not subjected to central co-ordination by Public Administration. Actions carried out by more active Regions and other organisms of the Public Administration suggest a possible way to act at least during the initial experimental phase. Among them it is worth mentioning the basic professional training course on Cosmetic Surveillance organized by the High Institute of Health (Rome, September 27th-29th 2000) in which some operations of surveillance carried out by some regions have been included.

Since the specifications of the above mentioned course have been recently published, we suggest referring to them in order to carefully examine the situation. In this report we'll only discuss the most important and useful elements for our aims.

A first step is to understand the real meaning of Cosmetic Surveillance. Instead of monitoring the undesired effects only, it is important to undertake a more global action characterized by the prevention and safety criteria of cosmetic uses as specified in the above mentioned LD n. 126/1997 and including the examination of conformity with the laws in force.

THEREFORE CONSIDERED THE INVOLVED SUBJECTS:

- the Public Administration (Ministry of Health, Ministry of Industry and Commerce and artisanship, Ministry of Labour and Social Security and High Institute of Health);
- regional and independent and local provinces authorities;
- cosmetic manufacturing and importing industries;
- raw materials manufacturing and distributing industries;
- the technical manager, security appraiser and imported products expert;

It is necessary to analyze the single points that are fundamental for cosmetic surveillance and the related verifications of conformity with the law in force. Here follow some of these points: - the prohibition of the use of specific substances; – the use of precisely authorized or freely useable ingredients in any case according to methods assuring they are harmless under the responsibility of cosmetic manufacturing or exporting industries considering that raw material manufacturing and distributing industries must supply the required information; - raw materials and cosmetic preparations chemical and microbiological purity criteria; - analysis methods for products composition determination; – labeling including information about the product function and the list of ingredients; - the dossier of the information regarding the commercial product that must include safety evaluation elements and data of possible undesired effects caused by the application of the product itself (this record must be at the disposal of the Ministry of Health); - the use of good practices for laboratory (GLP) and manufacturing process (GMP) and quality assurance; - products of dubious appurtenance to the cosmetic category and deceptive advertising; - hygiene and health risks in industrial manufacturing; - inspection checks in manufacturing and storage facilities and customs checks; - possible computerized management of data regarding raw materials and undesired effects complaints.

As for the last point, it is necessary provide for adequate methods for:

- the notification to the Ministry of Health of undesired effects connected to cosmetic use

given by:

a) regional and local health authorities through notices within January and July each year;
b) citizens themselves according to the procedures that will be stated by the Ministry of Health;

- a six-month-diffusion of data regarding undesired effects of cosmetics provided by the Ministry of Health;
- the issue in the Official Gazette of notices regarding cosmetic preparations withdrawal from the market;
- consultation of the High Institute of Health and the High Health Council for the evaluation of information regarding both undesired effects and the dossier of information.

The reason why cosmetic surveillance is carried out only in some regions is that law lends itself to interpretation and has got gaps which we must discuss about.

The global process for the evaluation of cosmetic compliance with the law is based on three fundamental concepts that must be coherently considered according to the nature and application of the product itself:

1. Effectiveness.
2. Safety (application of good laboratory practice requirements, GLP, provided for in the decree law 120/1992).
3. Quality (application of good manufacturing practice requirements, GMP, and quality assurance system).

Indications of conformance specifically provided for in the LD 126/1997 have been specified in brackets.

The described approach is considered the most correct and should guarantee public health to a greater extent. Since some issues of the LD 126/1997 are still pending, the evaluation process of the three parameters on effectiveness, quality and safety remain incomplete, ambiguous or variable.

We must ensure that quality is achieved by correct procedures in manufacturing and packaging operations in compliance with GMP applications. The technical manager and the entrepreneur are responsible for this. On the contrary, if products are not imported from countries belonging to the European Union, an expert must guarantee the standard of the manufacturing method used. With regard to the afore mentioned, there are two important issues that need further consideration in the LD 126/1997.

That is:

a) The Ministry of Health together with the Ministry of Industry and Commerce and Artisanship and the Ministry of Labour and Social Security will be issuing an act regarding GMP concepts in compliance with community requirements. Until that moment, the regulations of the MD 328/1987 regarding the general suitability standards of premises and equipments of cosmetic manufacturing factories will remain valid. The European Union is still examining a basic policy.
b) Inspection checks carried out by regions in all manufacturing factories and importers' warehouses within their territorial competence are aimed at verifying the compliance with the law 713/1986 and their quality certification system, if adopted. The time spent on inspections is decided by the regions themselves. They must report all negative outcomes collected to the Ministry of Health. If things remain as described, inspection checks will still be carried out without co-ordination on the national territory.

Even if the LD 126/1997 provides for a product effectiveness proof, it does not specify the cosmetic functions to be proved nor the criteria to be used. Obviously, in order to assure the coexistence of other safety and quality characteristics during the different phases of cosmetic preparation planning, producing and manufacturing, it

would be useful to study the effectiveness of the cosmetic. Unfortunately this is a gap in the LD 126/1997 that must be filled especially in regard to regulations on clinical examinations carried out in order to determine the effectiveness and tolerability of the cosmetic products. Moreover, it will be necessary to specify the institutes that can be considered suitable for this research and the evaluation criteria.

It is clear that volunteers request should suggest ethical reasons requiring particular consideration and regulation by Health Authorities.

Finally, safety must be assured by qualified responsible professionals (the so called safety evaluator and the manufacturer who focus attention on the general toxicological outline of the ingredients, the chemical structure and the exposure level) in addition to that mentioned above (no more animals experimentation and alternative methods inadequacy) it is necessary to consider that:

a) a future decree will define, on a community requirement basis, the guide-lines regarding the information obligations that manufacturing industries and those distributing raw materials for cosmetic preparations have towards buyers in order to draw up the dossier;

b) it is therefore compulsory: - to have at the disposal of the Ministry of Health all possible information contained in the dossier; - to carry out the safety evaluation for human health in compliance with GLP requirements as provided for in the LD 120/1992.

The above described obligations are applied to national manufactures (of complete products and raw materials) and importers. With regard to the other requirements provided for in the LD 126/1997, it is fundamental to activate an adequate sourveillance system to monitor all undesired effects connected to the use of cosmetic products. The operative approach to be used has yet to be defined but it must provide for data collecting form. Moreover, as for imported products (art. 10-bis), an adequate decree must assure to know the importer in each product distribution and selling phase.

In order to put a cosmetic preparation onto the market, we still need to define and co-ordinate all aspects of the law for a global evaluation of the product conformance. All this must be carried out on the basis of rationally applied criteria of effectiveness, safety and quality, thus avoiding situations in which the products are considered effective but unsafe or, vice versa, safe but ineffective.

Unfortunately, the various delays and subsequent ministerial acts, currently foreseen in defining all pending issues of the law on cosmetics, the complexity of tasks assigned by law and the inadequacy of public structures and the required resources to carry out supervision operations, represent a huge limit that, in the long run, could play down the importance of each health prevention act in cosmetics.

In conclusion, in order to avoid or minimize all risks related to cosmetic use, it is fundamental to comply with all laws in force.

Attention should be focused especially on the following issues:

- adequate selection of raw materials that must be chemically and microbiologically acceptable with regard to their purity;
- GLP adoption in the study of raw materials;
- GMP, and adequate quality assurance system adoption;
- verification of topical effects of the complete product (good tolerability on skin);
- appropriate packaging in order to preserve the qualitative characteristics of the products;
- correct labeling of complete products regarding their composition and specific warnings; intervention advice in case of undesired effects;
- correct information about the real effectiveness of products by avoiding any advertise-

ment that could mislead the consumer or put him in danger;
- correct instructions for use and exposure.

As for public administration, it should:
- implement the still pending points of the law ;
- start surveillance activities in the whole territory both for national and imported products; verify the adequacy of the resources of these activities;
- create a database accessible to all Regions both to receive basic information and send their data;
- encourage professional training for different health workers;
- adequate public structures for the development of all these tasks.

Moreover, on the basis of a previous pilot study carried out in the Regione Lazio, we suggest the following initiatives:
- census of cosmetic manufacturing, packaging and exporting industries in each region;
- drawing up of a notified ingredients form;
- drawing up of a product form;
- setting up of a method to report all undesired effects (family doctor, dermatologist, chemist, center for antidotes) through an adequate form for data collection;
- definition of an interregional pilot program of surveillance.

The above mentioned initiatives have been considered by different regions; the results obtained will be discussed during a second specialization course on Cosmetic supervision to be held at the High Institute of Health next autumn.

References

1) **Legislative decree n. 328, 9th July 1987 -** Italian G.U. n. 180, August 4th 1987
2) **Legislative decree n. 126, April 24th 1997 -** Italian G.U. n. 112, May 16th 1997
3) **Legislative decree n. 120, 27th January 1992 -** Italian G.U. n. 40, February 18th 1992
4) **Legislative decree 5 August 1999 -** Italian G.U. n. 241, October 13th 1999
5) **R. Centore, G. Salvatore, D. Trucchi, G. Spagnoli, G. Mancini (1994)** Prevenzione igienico-sanitaria e vigilanza nel settore della cosmesi della regione Lazio. Rapporti ISTISAN 94/16.
6) **O. Cozzoli, G. Salvatore (2000)** Proccedings "Cosmeticosorveglianza - Corso di Formazione di base" - Istituto Superiore di Sanità, Ministero della Sanità - Roma 27-29 settembre 2000. Editors Oreste Cozzoli e Giuseppe Salvatore

Author Address:

Giuseppe Salvatore
Comparative Toxicology and Ecotoxicology Laboratory
High Institute of Health, Rome - Italy
V.le Regina Elena 299
00161 ROMA - Italy