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Understanding the Adverse Effects of Cosmetics

A Pilot Project in Cosmetovigilance

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Abstract

Currently, cosmetics and toiletries are very popular and their use continues to increase because consumers consider physical appearance important and, at the same time, these products are considered to be safe. However, in spite of their safety and tolerability, during recent decades, we have become aware that adverse effects can occur. The number of adverse effects known so far is very low indeed. This is partly because such adverse effects are underestimated as a result of self-diagnosis and self-medication, which are common behaviours in the presence of mild-to-moderate reactions, as in the case of cosmetics. Moreover, such effects are underestimated because of the absence of formal and reliable monitoring systems ('cosmetovigilance'). This requires the creation of a standard reporting form, as well as resolution concerning professional categories authorized to report and the subsequent validation/evaluation of the collected forms. All these items are of great importance, not only to investigate but also to prevent risks caused by cosmetic use.

A pilot project was undertaken to test the effectiveness of a notification system by the validation of either a reporting form or the role of dermatologists and community pharmacists as reporting categories. Collection of reporting forms began in July 2006 and it is still in progress; the preliminary data reported here refer to the period July 2006–June 2007 and mainly concern the recording and validation of the collected reporting forms. During this period, we have received 40 reporting forms (32 by dermatologists and 8 by pharmacists).

The validation process of the recorded forms revealed several drawbacks, such as incompleteness (19 forms), inadequacy of the description of the suspected undesirable effect and its location (2), illegible handwriting (6) and mistaken statements (3). Six forms reported a misuse of a cosmetic product: four of these were related to the site of application while two were related to time. In one case, instructions for use were not followed.

In conclusion, our experience regarding the notification of adverse effects of cosmetics, although limited to a restricted geographical area, suggests that for an efficient and reliable monitoring system to be in place, which includes all the necessary measures to protect public health, an education and training programme for all stakeholders (health professionals, consumers and appropriate authorities) is required.

To the average consumer, 'cosmetics' are preparations used for beautifying the skin, hair and nails. Currently, cosmetics and toiletries are very popular and their use continues to increase because physical appearance is important in many cultures.[1]

The European Union Cosmetic Directive, in addition to defining a 'cosmetic product',[2] has underlined the need for a cosmetic not to cause damage to human health when applied in normal or reasonably foreseeable conditions of use.[3] Generally, consumers consider cosmetics safe since they are submitted to several tests to assess their safety and tolerability before they are launched into the market. In spite of this, during recent decades, we have become aware that they can cause adverse effects.[4,5] The number of adverse effects of cosmetics that are known so far is very low. This is probably because these adverse effects are underestimated as a result of self-diagnosis and self-medication, which are common behaviours in the presence of mild-to-moderate reactions, as in the case of cosmetics. However, it must be underlined that severe reactions have also been reported.[6-9] In a survey published in 2006,[10] >50% of the people who had experienced an adverse effect to a cosmetic did not take medical advice, nor did they consult a pharmacist. A total of 3474 cosmetic users were interviewed, of whom 848 had experienced adverse effects to cosmetics.

The absence of formal and reliable monitoring systems, as we have recently reported,[11] has certainly played a great part in the underestimation of adverse effects to cosmetics. Moreover, as a consequence of the different handling of such adverse effects in Europe their severity on a population level it is really not known, although valuable information is provided by independent organizations, mainly represented by dermatologists.[12,13]

Because there are potential risks to consumers as a result of the use of cosmetics and also because of the lack of a harmonized cosmetovigilance system in Europe, the Council of Europe, Committee of Ministers, has recently adopted a resolution on a vigilance system for adverse effects of cosmetic products ('cosmetovigilance') in Europe to protect public health.[14]

The notification of adverse effects, which includes the creation of a standard reporting form as well as resolution concerning professional categories authorized to report and the subsequent validation/evaluation of the collected forms, is vital for the investigation and prevention of risks caused by cosmetic use.[5,14] Taking these points into consideration, we have carried out a pilot project to test the effectiveness of a notification system by the validation of either a reporting form or the role of dermatologists and community pharmacists as reporting categories.

The first step of our project was to set up a reporting form and the second step was to get in touch with dermatologists and community pharmacists in our regional territory (Regione Campania, Italy). To this aim, we have contacted dermatologists directly and community pharmacists through their territorial associations.

The enrolled dermatologists and community pharmacists were then asked to notify (by fax) suspected adverse effects of cosmetics, through the standard reporting form. Collection of the reporting forms began in July 2006 and it is still in progress. The preliminary data reported here, mainly concerning reporting/recording and validation of the collected forms, refers to the period July 2006–June 2007.

Upon receiving the reporting form, we immediately notified the reporter and each form was subsequently subjected to a validation and evaluation process. If something was not clear or was missing, we contacted the reporter (pharmacist or dermatologist). Finally, the relevant and correct information from each form was inserted in the database for the subsequent analysis.

During the period July 2006–June 2007, we collected 40 reporting forms: 32 from dermatologists and 8 from pharmacists. The reporting dermatologists were 8 of the 21 enrolled; among them, one filled in 11 forms and 2 filled in 6 forms each. There were three reporting pharmacists. However, it must be underlined that, since, as reported above, we contacted pharmacists through their territorial associations, we do not know the number of pharmacists originallly involved in our project.

Regarding notification, dermatologists have sometimes pointed out a certain difficulty in finding practical accessibility to the fax machine; this, of course, has made the notification step time consuming.

The validation process of the recorded forms, which involves verifying the presence on each recorded form of minimum relevant information, revealed several drawbacks. Incompleteness was one of the most frequent problems we encountered: in about half of the recorded forms (n = 19), the manufacturer was not reported. In fact, most of the reporters had problems in the identification of the precise product giving rise to the event. This was probably a result of lack of information provided by the consumer/patient. However, in some cases, incorrect comprehension of the question in our form regarding the specifications of the product could be responsible for this.

In two forms, the description of the suspected adverse effect and its location was not adequate. Illegible handwriting was another drawback of the recorded forms as was the case in six of the 40 collected. In three cases, mistaken statements were present. The use of a perfume was incorrectly considered as a misuse with respect to the site of application, as was the use of a sunscreen product with respect to the time of application. The third case was related to an anti-seborroheic shampoo that clearly could not be responsible for the reported suspected event.

In the standard reporting form, one of the items was the presence, among the cosmetic ingredients, of substances of natural origin. Six reporters did not consider this item, whilst four of them reported a mistaken statement considering synthetic substances as natural ingredients.

Frequently, the improper use of cosmetics and toiletries can result in problems, mainly related to the skin.[15] Six of the recorded forms reported a misuse of the cosmetic product, in four episodes the misuse was correlated to the site of application, while in two the misuse was correlated to the time of application. In one episode, the manufacturer's instructions were not followed: a colouring shampoo was utilized without wearing gloves. Misuse related to the site of application concerned two body sunscreens smeared on the face, a hand cream utilized for the legs and a perfume put on the axillas. Misuse related to the time of application concerned an anti-seborrhoeic shampoo and a depilatory cream. However, the reporters were too generic: they did not specify the time of application of the two products, which were supposedly used for too long. Obviously, these two reports were also included in the 21 incomplete reporting forms.

The validation and evaluation process are important steps in a cosmetovigilance system, since they are prerequisites for a correct assessment of causality, which is the main purpose of the system. The validation of a reporting form is to verify the presence of minimum relevant information.[14] So far, we have run into many problems during the validation process. In fact, some of the data requested turned out to be unnecessary or not clearly defined, while some important data were not requested. Moreover, in some cases, reporters could have misunderstood the meaning of the requested data because of the incorrect formulation of the question in the form. Nevertheless, all these findings helped us to improve our reporting form, which was one of the purposes of our project.

The other aim of the project was to validate the role of dermatologists and community pharmacists as reporting categories. This includes the awareness of health professionals of the occurrence of adverse effects of cosmetics and the acquirement of a reporting culture. In view of this, our experience suggests that both health professionals and consumers need to accustom themselves to reporting. Moreover, it has been reported that adverse effects of cosmetics and toiletries are underestimated, even when the consumer/patient asks for a medical consultation.[4]

In conclusion, our experience regarding the notification of adverse effects of cosmetics, although limited to a restricted geographical area, suggests that for an efficient and reliable monitoring system to be in place, which includes all the necessary measures to protect public health, an education and training programme for all stakeholders (health pro-

fessionals, consumers and appropriate authorities) is required.

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