

VIGILANCE SYSTEM FOR UNDESIRABLE EFFECTS OF COSMETIC PRODUCTS (COSMETOVIGILANCE) IN EUROPE

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Post-marketing vigilance is of primary importance for the safeguard of public health and consumer protection. Due to the diffused use of cosmetics within the population and an increase of allergy-induced diseases, undesirable effects (UEs) of cosmetics, although generally not so serious, might be a problem for the safeguard of public health, especially because they are underestimated for different reasons. The lack of information concerning the type, number and severity of UEs could be, at least in part, responsible for the absence of a reporting culture and favourable reporting environment. The aim of this study was to collect, among the countries belonging to the European Union and to the Common European Economic Space, information concerning cosmetovigilance, particularly with respect to notification of UEs. To this aim a questionnaire was sent, by e-mail, to the competent authorities. At the end of the survey, we could get information from 50% of the countries to whom the survey was addressed. The results of the research show that cosmetovigilance is different from country to country, with particular regard to notification of UEs. So in few countries there is a formal system to collect reports, in others the rules are not yet established and UEs are collected by different authorities or there is no obligation to report or no need to collect them. Another difference concerns the procedure for reporting UEs. In fact among the fourteen countries who have supplied information, only two collect UEs through a reporting form. Moreover it is interesting to note that the professional categories authorized to report, as well as state bodies who take charge of vigilance of cosmetic products, vary from country to country. In fact it is up to agencies for food safety, for environment or consumer protection or for public health. Besides, it must be underlined that in some countries private initiatives are undertaken, mainly by dermatologists, either in the presence or absence of a formal cosmetovigilance system. In conclusions this survey shows that cosmetovigilance is differently handled in the European countries, although in some countries attempts are underway to set up a formal system. Moreover the general impression is that an European cosmetovigilance system would be really appreciated by many countries. Concerning this at the beginning of November 2006 the Council of Europe's Committee of Ministers has adopted a resolution on a vigilance system for undesirable effects of cosmetic products ("cosmetovigilance") in Europe to protect public health.