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Review Article

A review of quality surveillance projects on cosmetics in Taiwan

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ABSTRACT

The Food and Drug Administration in Taiwan is responsible for the quality regulation and control of cosmetics. In order to have a clear understanding of the trends in the product quality monitoring outcomes and the regulatory control measures over the past years, this study has put together the reports of nine cosmetic surveillance projects conducted between 1982 and 2012. The findings can be used as a reference in developing a more solid quality monitoring plan and management system for cosmetic products. Results show that permanent wave products, hair dye products, and phthalate esters in cosmetic products have the highest average noncompliance rates at 39.2%, 14.2%, and 11.2%, respectively. These are followed by the average noncompliance rates of mercury in products, sunscreen products, and microorganisms in products, at 8.5%, 7.1%, and 5.5%, respectively, and the remaining three projects averaging below 4.1%. Since 1997, when new standards were announced and assistance to manufacturers was reinforced, the noncompliance rates of permanent wave products decreased annually, until 2007, when it was fully qualified for the standards. Overall, the study showed that the noncompliance rates of permanent wave products and for levels of phthalate esters, mercury, and hydroquinone in cosmetic products have all decreased in the previous years. The results of surveillance projects conducted after 2005 revealed only one noncompliance sample with lead, arsenic, and cadmium, whereas the surveillance projects on permanent wave products and chloroform- and 1,4-dioxane-containing products revealed full compliance with regulation standards. However, the noncompliance rates for microorganisms in cosmetics and the ingredients in hair dye products and sunscreen products were still high. These high-risk products must be monitored. These surveillance projects are conducted to ensure the safety of cosmetics in the market.

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1. Introduction

According to The Law for the Control of Cosmetic Hygiene, cosmetics are defined as products designed for topical use, such as moisturizers, deodorants, and makeup [1]. Cosmetic products in the market frequently contain diverse and complex ingredients, and if they have been contaminated by hazardous substances, the products may harm consumers. Therefore, monitoring the quality of and the risk involved in the usage of cosmetic products is of utmost importance to accomplish the important goal of protecting consumers' health.

The postmarketing surveillance of cosmetics is an important public service offered by the government, which serves to prevent and control cosmetics-related security incidents. In order to reach the expected effectiveness of quality surveillance, it is necessary to have an overall plan and to conduct risk assessments. The Taiwanese government has been surveying the quality of general and medicated cosmetics since 1982. In 2004, the government combined the resources of local health bureaus, making this a nationwide project called "Quality Surveillance of Drugs, Medical Devices and Cosmetics", which aimed to continue the monitoring of cosmetic products.

In Taiwan, cosmetics are classified as general cosmetics and medicated cosmetics. All medicated cosmetics, whether imported or domestic, have to be registered with the Taiwan Food and Drug Administration (TFDA), before they are manufactured or introduced into the market [1]. Because the ingredients in general cosmetics are much safer for human use, with reference to the management model of the European Commission and U.S. Food and Drug Administration, we have adopted the practice of postmarketing health and safety monitoring, with a focus on "product labeling" and "hazardous ingredients". The findings of the present study, constructed from compiled results and trend analysis, can be used as a reference for developing a more solid quality monitoring plan and management system for cosmetic products.

2. Methods

2.1. Source

This study summarizes and discusses the results of cosmetics quality research and surveillance reports from the Annual Scientific Report of the National Laboratories of the Food and Drug Administration, the Annual Scientific Report of the Bureau of Food and Drug Administration, and the Annual Report of Food and Drug Research.

2.2. Principles of the monitoring plan

The postmarketing product surveillance plan is based on the following: (1) high potential hazard and risk of product usage; (2) likelihood of causing health effects in specific groups of users; (3) domestic (consumer groups, congress, and other related units) and international concerns; (4) large supply, broad circulation, and high consumption; (5) results of previous monitoring reports; and (6) response to emergencies and administration needs.

2.3. Details of the monitoring projects and their sampling

The present monitoring survey reviewed nine projects, including projects monitoring permanent wave products, hair dye products, products containing phthalate esters or heavy metals, microorganisms in cosmetic products, sunscreen products, and products containing chemicals such as hydroquinone (HQ), salicylic acid, methanol, chloroform, and 1,4-dioxane. These products were tested either by the TFDA or were outsourced to external agencies. The sampling was primarily done by the local health bureaus, although the background surveillance for part of the samples was conducted by the TFDA. All tests were conducted according to the methods published by the TFDA or by following internationally recognized or validated methods.

3. Results

The reports of nine surveillance projects on cosmetics, conducted between 1982 and 2012, were reviewed in the present study (Tables 1 and 2).

3.1. Quality surveillance of permanent wave products

In order to monitor permanent wave products in a simple and effective manner, the Department of Health (DOH) specified limits for the contents of such products with thioglycolic acid and bromate salts in 1990, 1997, and 1998, to ensure that these products met health and safety requirements [2]. These criteria for evaluating the permanent wave products were in accordance with The Law for the Control of Cosmetics Hygiene. However, it is important to mention that prior to 1997, the contents of permanent wave products were only required to match the specifications as per their registration. Yet, after 1997, safety limits were set by specifying that the proportion of thioglycolic acid must be between 2.0% and 11.0%, depending on different categories, and the proportion of bromate salts should be less than 11.5%. The surveillance of postmarketing permanent wave products was conducted nine times between 1984 and 2007. The results demonstrated that before the permitted limits of the contents of these products were announced in 1997, the incidence of noncompliance in these products was high, with a noncompliance rate greater than 40%. The main reason for noncompliance was that the composition of the product did not match the original specifications. Another major reason for noncompliance was that the products failed to meet the pH recommendations. After the specification of permitted limits of the contents of these products, noncompliance rates improved significantly, decreasing to 5.7% in 1998, 3.6% in 2004, and 0% in 2007 [3].

3.2. Quality surveillance of hair dye products

Hair coloring is a modern fashion trend. For safer use and prevention of adverse effects, the DOH has established standards for the ingredients of hair dye products. According to these standards, all products must be registered through the TFDA for inspection prior to import or manufacture. In 1998,