

Post-Marketing Surveillance Guidelines

These guidelines are intended only to aid manufacturers and distributors in developing programs that meet their individual needs, and they are not intended to constitute either minimum or maximum requirements of effective programs. Alternative ways to reach the goals of the Guidelines may well exist and may be equally useful. Guidelines on any topic must, of course, be adapted to the particular operation of the user.

The Guidelines are dynamic documents and comments are welcome at any time. CTFAS assumes no responsibility for the adequacy of the Guidelines, nor does it purport to advise as to the necessity for their use in any particular situation. Decisions on when a report must be filed and what information must be included in it can be made only by those individuals for making such submissions. With regards to all of the area covered by CTFAS guidelines, each company must independently assume responsibility to assure that their conduct is consistent with all current, applicable state and local laws and regulations.

Introduction

The ASEAN consultative committee for standard and quality, Cosmetic Product Working Group in its 4th meeting held in Ho Chi Minh City, Vietnam on 8 -9 February 2001 agreed for the need to have a "Safety Evaluation/ Post market Surveillance" Guidelines and asked Singapore to lead the establishment of such.

The Guidelines have been prepared by a sub-committee of the Cosmetic Toiletries and Fragrance Association of Singapore (CTFAS). Their main purpose is to show how finished products can be assessed for their safety in market.

General Approach

A cosmetic product put on the market within ASEAN, must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use. One must take into account, in particular, product presentations, its labeling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for putting the product on the market (herewith referred to as "distributor").

Hence cosmetic products have to be safe both for consumers and, if relevant, for involved professionals (e.g. hairdressers, beauticians, etc).

Manufacturer Responsibility

Ensuring safety of the product is manufacturer's prime responsibility. This required a global approach throughout the life of the product from the choice of the raw materials to the marketing follow up. A number of issues have to be taken into account, including:

- careful selection of cosmetic ingredients, making sure that they will be safe at a given concentration in a given finished product;

- checking local tolerance of the finished product;
- selection of adequate packaging to maintain the quality of the product and to avoid, as far as possible, risks of misuse or accident;
- applying Cosmetic Good Manufacturing practices;
- quality control, mainly microbiological and chemical contaminants;
- appropriate labelling - presentation of the product, instruction for use and disposal, warnings (if relevant) and appropriate action to take in case of accidents;
- adequate procedures in case of side effects with the marketed product; case by case treatment, appropriate medical, dermatological, ophthalmological, etc; advise as necessary, follow up of the product on the market and consumer comments, etc.
- ensures corrective action, follow-up if any visible product change or adulteration is advised from the market place.

Although it is not possible to attain zero risk or to obtain absolute safety in any kind of human activity, including cosmetology, reasonable efforts have to be made to reduce the risk from cosmetic products to a minimum, according to the state of the art at the time.

As far as skin is concerned, the two main untoward reactions to be avoided are skin irritation and skin sensitization. Products applied to the scalp or the face may come in contact with the eye. Consequently, eye tolerance has to be addressed with optimal attention as a major component of the safety assessment for a cosmetic product.

The person in charge of assessing the safety of the product is called the safety assessor. It is in the interest of the company to select a person knowledgeable in the field who is responsible and ethical. That person must hold a diploma in the field of pharmacy, toxicology, dermatology, medicine, biology or a similar discipline and/or experience in cosmetology. Data show qualification should be on record.

Extensive marketing of a product over a long period of time without a significant occurrence of adverse product experience is excellent presumption of safety. The manufacturer should have the data, review it and determine whether additional safety substantiation is necessary, based on new scientific developments.

In the event of significant adverse reaction, the manufacturer must collaborate with the relevant authorities to determine the course of action based on proper evaluation of the data. This could include:

- additional warnings;
- modification to the product formulation, use conditions, labeling, etc; as deemed relevant to increase product safety;
- total or partial recall of the product from the market.

Distributor Responsibility

The distributor is responsible for putting products on the market. As such, it is highly recommended that distributors make sure the manufacturer have the adequate systems to ensure product safety. Distributors should have, on record, proper documentation of such.

The distributor, to collect the information in the event a consumer has an adverse experience with a product, should put a system in place. This could be done, through toll free number, training of the sales person at the point of sale, e-mail, etc. All this information must be collated and transferred to the manufacturer on a timely basis, trends determined and records kept.

In the event of a critical case, the distributor must report immediately to the relevant authorities and to the manufacturer.

Ministry of Health (or other relevant authority) Responsibility

In each country, the Ministry of Health or any other relevant authority, has responsibility for ensuring public health and safety. As such, audits may be conducted at the distributor to ensure adequate measures are taken to this end, compliance to regulations are met and records kept.

In case of an adverse event or product testing showing a potential risk for human safety, the relevant authorities must contact the distributor to determine the appropriate course of action.