

〈教育セミナー〉

化粧品・医薬部外品の安全性～よりよい製品開発のために～

化粧品・医薬部外品の安全性とその評価

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Safety Assessment of Cosmetics/Quasi-Drugs

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Abstract

The cosmetics may be used by vast numbers of individuals, extensively over a large part of their lifespan. Therefore, great care should be taken with them and well designed investigations should be conducted to obtain greater guarantees so that they can be used safely. It is essential that attention be paid to potential toxicological hazards to consumers at an early stage when developing new products. Safety can be defined as freedom from danger or risk, but absolute safety does not exist. The concept of risk/benefit balance has been developed. As there is no way to guarantee total absence of risk, some kind of pragmatic approach to reaching decisions on risk acceptability is certainly needed for cosmetics. This risk/benefit balance varies with the categories of products. The “non-essential” products like cosmetics must not give rise to any risk. “To what extent we should assure the safety of cosmetics” when we actually make the assessment of them. We should guarantee the safety-in-use of the products. The practical safety assessment process starts with the review of the existing information. The actual safety assessment procedures for ingredients and finished products will vary according to the product and its intended use. Then we determine from all of this information, what we need to focus on or what may be a question or problem to be solved. It must be stressed that there is no textbook formula procedure which can be followed and that the sequence can vary considerably with different ingredients and products. However, adequate series of toxicity studies should be performed especially with newly developed components in order to enable reliable conclusions to be made on potential harmful effects. The post-marketing safety re-evaluation may be necessary. Toxicological and safety evaluation techniques are ever-advancing. Questions may arise about the safety of products, on the market for a long time and previously regarded as safe, as a reflection of new scientific developments. The investigators in charge of the safety assessment should be very sensitive to the related information with wide knowledge and experiment, to make the above-mentioned pre- and post-marketing assessment more precise.

Key words: cosmetics/quasi-drugs, safety assessment, safety-in-use, risk/benefit balance.