By Darshan Bhatt

Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 1999 on cosmetic products\(^1\) (the Cosmetics Regulation), governing cosmetic products in the EU, came into force on 11 July 2013. A new and important aspect of the regulation concerns postmarketing surveillance to be carried out by manufacturers, importers and distributors. This article highlights the industry’s responsibilities for designating a single point of contact, collecting and reporting serious undesirable effects (SUEs), maintaining records and submitting Cosmetics Product Safety Reports (CPSRs). Recommendations on how organizations can implement programs successfully to meet these regulations also are provided.

History

The Cosmetics Directive (76/768/EEC) was introduced on 27 July 1976 to regulate composition and ingredients, testing in animals, labeling and market surveillance for cosmetic products. The directive was amended several times over the years. Market surveillance requirements for Member States of the European Community (EC) included:

- checking the safety of products manufactured in or imported into the EC
- ensuring that characteristics attributed to cosmetic products were not deceptive

Importantly, there was no requirement to report adverse reactions to cosmetic products. Since the European cosmetics sector is an attractive market, there have been concerns about counterfeit products entering the market. The regulation provides for effective market surveillance of adverse effects of cosmetic products on human health.

On 30 November 2009, the Cosmetics Directive was replaced by the Cosmetics Regulation, which became applicable in the 47 EC Member States on 11 July 2013.
Definitions

The regulation defines a cosmetic product as “any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips, and external genital organs) or with the teeth and mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition, or correcting body odors.” It also defines an undesirable effect (UE) and serious undesirable effect of cosmetic products.

A UE is defined as “an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product.” A UE has an implicit causal association with the cosmetic product.

An SUE is defined as an undesirable effect that results in one of the following: temporary or permanent functional incapacity, disability, hospitalization, congenital anomalies, an immediate vital risk or death. The initial SUE report should, at minimum, include an identifiable reporter, the nature and onset of the alleged SUE and the suspected cosmetic product with identifying details.

In August 2005, the European Cosmetics, Toiletries and Perfumery Association (COLIPA) drafted a guideline on the Management of Undesirable Events Reports² and circulated it to member companies. The draft guideline was adopted by the industry on 15 May 2008.³ The SUE Reporting Guideline was finally issued by the European Commission in August 2012.⁴ This guideline recommends that all SUEs be monitored by manufacturers or importers of cosmetic products and be reported to the regulatory authorities. The guideline also proposes an algoriathm to determine the probability of a causal association between a UE and the suspect cosmetic product.

Implications of the New Regulation

As of 11 July 2013, all manufacturers, importers and distributors of cosmetic products within the EU are required to:

- Appoint a Responsible Person (RP) for a cosmetic product to be marketed; the RP is the single point of contact for regulatory authorities and the public regarding any issue related to a cosmetic product.
- Report all SUEs to the Competent Authority of the country where the event takes place.
- Carry out statistical analysis of both serious and non-serious UE data including trends, and submit an updated CPSR to the National Competent Authorities.

Responsible Person for Cosmetic Products

The regulations have specified that the RP should be one of the following:

- The manufacturer established within the EC, or a legal or natural person designated by the manufacturer by written mandate who shall accept the mandate in writing.
- The distributor, in cases where the cosmetic product is placed in the market under their name or trademark or modifies a product already placed on the market.
- For an imported cosmetic product, each importer shall be the responsible person. The importer may by written mandate, designate a person established within the EC as the responsible person who shall accept the mandate in writing.

The RP is responsible for:

- ensuring product conformity and taking immediate corrective action regarding nonconformity (i.e., bringing the product back into conformity, withdrawing it or recalling it)
- communicating information about an SUE to the Competent Authority in the Member State where it occurs
- immediately informing Competent Authorities regarding any risk to human health and corrective actions taken
• cooperating with Competent Authorities to eliminate risk and, if asked, providing them with information and documentation in a language easily understood by them; this may require provision of translated documents
• ensuring compliance with the regulations for cosmetic products
• undertaking trend analysis of all UE reports and updating the CPSR as required
• validating or refuting potential signals and, where possible, providing the scientific basis of the mechanism of action regarding the UE

Reporting Requirements

The Cosmetics Regulation requires all SUEs that are known or reasonably expected to be known, to be reported to the Competent Authority of the Member State where the event takes place.

• The report should be prepared using the format of SUE Reporting Form A and sent immediately but no later than 20 calendar days from the date on which any employee of the company, whatever their role or function, becomes aware of the SUE.
• Due diligence should be carried out to follow up on missing information, and a follow-up report should be sent within 20 calendar days of receiving new and significant information.
• Confidentiality of personal information must be maintained.
• Only SUEs where causality is not excluded are required to be reported.

The act of notifying the National Competent Authority does not imply admission of liability for the SUE and its consequences and there is no requirement to send the report to any other authority.

Guide to Causality Assessment

The assessment of causality in spontaneous reports of events associated with cosmetic products is different from that for pharmaceutical products in two respects. One, causality is not implied and two, a report must be sent to the Competent Authority unless causality can be positively excluded. For spontaneous reports, by “implied causality,” it is assumed the product caused the event. The SUE Reporting Guidelines require the SUE to be assessed for causal association at five levels using chronological and semiological scores. “Positive exclusion” means there is sufficient evidence to rule out the association between the UE and the product.

Challenges and Recommendations

Lack of understanding of the new Cosmetics Regulation and inadequate preparation potentially could lead to compliance issues for products already on the market and delay the launch of new products. The increased burden of specialized resources required for call centers, database management, data analysis and tracking tools, along with medical and regulatory expertise, is a significant challenge all organizations face. Appropriate interpretation, efficient planning and training, in particular regarding the stringent cosmetovigilance requirements of the new regulation, will help companies anticipate and resolve issues. Since this is a new area for industry and regulators, safety experts should be considered an integral part of a company’s strategy to interpret the regulation and define processes to implement it. Experienced safety personnel can help sponsor organizations formulate processes and develop and execute the implementation plans for cosmetovigilance.

Summary

The new EU Cosmetics Regulation has extended the scope of cosmetic product requirements to include postmarketing surveillance and reporting of SUEs. The regulations require an RP to be designated prior to marketing a cosmetic product and throughout its lifecycle. Companies must be aware of differences in minimum information, causality
assessment and reporting requirements from those of medicinal products. Efficient planning and training for the new regulation cannot only facilitate product launches but also prevent compliance issues and help to keep cosmetics on the market.

References


5. Ibid.

About the Author

Darshan Bhatt advises the medical safety organization at Sciformix Corp., providing medical review of Individual Case Safety Reports (ICSRs), aggregate safety reports, benefit-risk assessments and risk management plans to clients. He is a postgraduate in medicine and holds an MPhil degree in hospitals and health systems management. He has more than 20 years of clinical experience and 15 years of experience in applied biomedical research. Bhatt can be reached at darshan.bhatt@sciformix.com.

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