Cosmetic regulatory writing

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Abstract

On 11 July 2013, a new regulation for cosmetics was applied in Europe, Regulation (EC) 1223/2009, replacing Directive 76/768/CEE. This new regulation clarifies the roles and responsibilities of all stakeholders and introduces new notions such as cosmetovigilance and online notification. Compliance and safety of cosmetic products must now be clearly documented for them to be placed on the EU market. Professional medical writers are well positioned to help prepare the documentation needed for cosmetic approval according to this new directive.

Keywords: Regulation, Cosmetic, Safety, Compliance, EU market

Prior to 2013, cosmetics were approved in the EU according to Cosmetics Directive 76/768/EEC, which set forth the main requirements for their composition and labelling. Previously, each EU member state was allowed to apply the guidelines according to their needs. Owing to growth of the cosmetics market and differences in the interpretations of existing regulations in Europe, in 2008 the European Commission decided to harmonise its numerous cosmetics directive amendments. The goal, according to the European Commission, was to have 'a robust, internationally recognised regime, which reinforces product safety taking into consideration the latest technological developments, including the possible use of nanomaterials'.[1] New regulations, described in Regulation (EC) No 1223/2009,[2] went into force on 11 July 2013.

Regulation (EC) No 1223/2009

The new regulation made the following important changes to the previous directive:

- Strengthened safety requirements for cosmetic products
- Required manufacturers to follow specific requirements in the preparation of a product safety report prior to placing a product on the market
- Introduced the concept of a Responsible Person
- Centralised notification of all cosmetic products placed on the EU market
- Stipulated that the manufacturer needs to notify about its product only once, via the EU Cosmetic Products Notification Portal (CPNP)
- Introduced reporting of serious undesirable effects
- Described new rules for the use of nanomaterials in cosmetic products

Importantly, one requirement that was not changed in the new regulation is that animal testing of cosmetic products is not permitted in the EU.

Definition of a cosmetic product

The new guidelines also provided a definition of what a cosmetic product is:

> Cosmetic products are substances or mixtures of substances intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, etc.) or with the teeth and the 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 odours.

To classify a product as a cosmetic, the product must meet the definition according to function, presentation, mode of application, and composition. With the exception of composition, the other criteria are evaluated according to the claims made on the label. To be a cosmetic, the manufacturer cannot refer to treating, preventing, or alleviating a disease. A product that deviates from the definition for any of these criteria can be considered as a non-compliant cosmetic product and may be assigned another category (e.g. medical device, room fragrance, or general consumer product) covered by other regulations. Products that do not fit into an alternative category become 'non-classified' or

'borderline products', and in these cases, interpretation of which category they fit into may differ between member states.

The Responsible Person and the Distributor

The guidelines defined two new clearly defined individuals that must participate in the approval of cosmetic products: the Responsible Person and the Distributor.

- The *Responsible Person* is someone dedicated to ensuring compliance of the products with the rules in the Regulation, notably, requirements for human health, safety, and consumer information. The Responsible Person has the following responsibilities:
    - Ensuring that the labelling is compliant with Article 19 of Regulation (EC) 1223/2009, language requirements are fulfilled, and the date of minimal durability has not expired;
    - Ensuring that the storage or transport conditions are compliant with the regulation;
    - Maintaining a product information file accessible to the public authorities;
    - In the case where a product is non-compliant, taking steps to make it compliant, withdraw it from the market, or recall it to the manufacturing company wherever the product is available;
    - Informing the competent authorities when the product presents a risk to human health.

For a product manufactured in the US, the manufacturer must mandate a designated third party based in the EU as the Responsible Person; when the product is imported, it can be the importer or a designated third party; and for a product where the Distributor places its name on or modifies a product, the Distributor must be the Responsible Person.

- The *Distributor* is the person to whom the cosmetic product is supplied. They must be listed for 3 years following the date on which the batch of the cosmetic product was made available to the Distributor. The same applies to all other persons involved in the supply chain. The Distributor is responsible for:
    - When a product is suspected to be non-compliant, stopping making the product available and ensuring that necessary measures are taken;
    - If there is a risk to human health, providing the information to the Responsible Person and to the competent authorities.

The CPNP

The European Commission also created the CPNP (http://ec.europa.eu/consumers/sectors/cosmetics/cpnp/index_en.htm), an Internet site for notification with the ambitious challenge of creating an online database for all cosmetic products marketed in the EU. Responsible Persons must register each product placed on the EU market in the CPNP. Once the product has been registered, a CPNP number of notification is allocated, which serves as proof of registration. The website is also used for notification about substances that might be defined as nanomaterials.

The new regulation also clarified the concepts of 'undesirable effects', 'serious undesirable effects', and the specific responsibilities for each individual. It also describes the so-called 'cosmetovigilance' system for recording all undesirable health-related effects of cosmetic products. The cosmetovigilance records are regularly evaluated and are to be used for eventual product safety re-assessment and determination if further steps are needed, such as withdrawal of the product from the market.

Contents of the Product Information File for registration of a cosmetic product

Before a product can be registered in the CPNP database, the following safety and stability information must be provided in a Product Information File (PIF), also known as a Product Information Pack:

- All active substances and subcomponents including antioxidants, preservatives, and additives
- The toxicological profile of its ingredients; the formulation with the exact percentages of raw materials
- The physico-chemical and microbiological characteristics of the substances and the finished product
- Compilation of all analysis certificates and Material Safety Data Sheets for each raw material
- All technical data that can be obtained from toxicological databases
- Data from preservative challenge and stability tests, although as of 7 November 2013,[1] finished products may not require preservative challenge testing as long as it can be shown that the product's environment will not support microbiological growth.

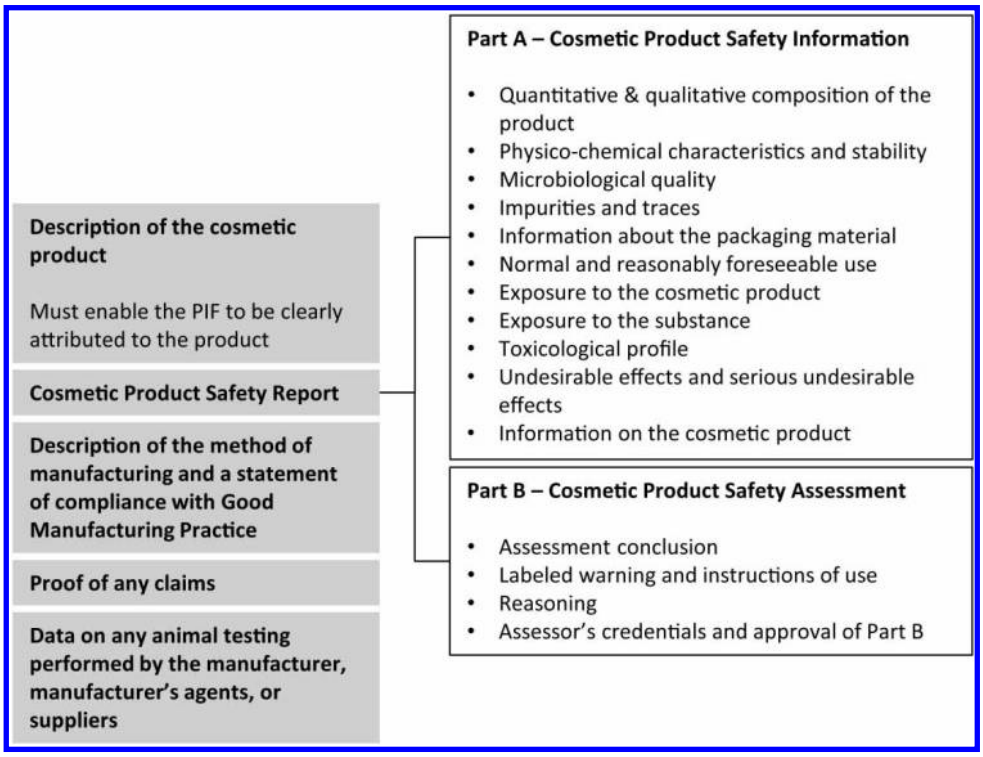

Figure 1: Makeup of a PIF. Adapted from *COLIPA Guidelines on the Product Information File (P.I.F.) requirement.*[3]

EU Regulation (EC) 1223/2009 also stipulates that the PIF contains:

- A statement of water quality
- A Good Manufacturing Practice certificate
- A description of the filling and packaging process
- The manufacturing method
- The batch number
- The Material Safety Data Sheet of the finished product
- The materials used for the packaging
- A non-animal testing statement for the finished product
- The tests performed on the finished product, such as tests performed in human subjects and other efficacy tests.

The makeup of the PIF is summarised in Figure 1.

Safety assessment

The above information is examined by a Safety Assessor on behalf of the Responsible Person. The Safety Assessor must have a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine, or a similar discipline, or a course recognised as equivalent by a member state. Vrije Universiteit in Brussels, for example, organises a yearly training course on how to perform safety assessments of cosmetics in the EU.

For specific questions related to the safety of cosmetic substances, the Safety Assessor consults the Scientific Committee on Consumer Safety, an independent committee of scientific experts. Based on this opinion and toxicological data, the European Commission delivers an opinion.

Medical writing for the cosmetic industry

Medical writers with experience in clinical and regulatory writing for the pharmaceutical industry are familiar with presenting necessary information, formulating key messages, and telling a product story with a clear, complete, and consistent approach. Such medical writers are therefore well placed to assist cosmetic companies in compiling a PIF; the advantage of an experienced medial writer is to reduce the amount of time needed to produce the documents and to minimise questions and delays during registration. Although some international cosmetic companies have well-established regulatory and pharmacovigilance departments, many smaller companies may have to rely on outsourcing. Thus, cosmetic regulatory writing is an opportunity for both medical writing agencies and freelance medical writers.

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Conflicts of interest

The interpretation of Regulation (EC) 1223/2009 requirements is according to Biorius experts and is not binding in any way. Biorius is not related to competent authorities and shall not be considered as part of Belgian governmental bodies.

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