Cosmetics Safety in the EU: Key Safety Reporting Requirements of EC No. 1223/2009

Is your organization in compliance?

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Recent regulatory changes in the EU have created new safety reporting requirements for the distributors of cosmetics within this region.

The requirements of EC Regulation 1223/2009, which took effect 11 July 2013, are quite substantial, with mandatory reporting of certain types of events to competent authorities as well as the establishment of a "responsible person" to oversee this reporting. Although these requirements have helped to streamline and harmonize reporting requirements across the EU, they have greatly increased reporting requirements for distributors of cosmetic products in this region.

Consequently, distribution companies must thoroughly understand these requirements and take appropriate action to ensure compliance. If distributors fail to comply with the requirements of this Regulation, the agency has the authority to force withdrawal of the product from the market.

WHAT IS A "COSMETIC?"

In order to fully understand the scope of these regulations, one must first grasp the definition of "cosmetic" in this Regulation. This definition is broad, made on a case-by-case assessment, and may include products for the skin and face, soaps, perfumes, deodorants, hair and shaving products, products applied to the lips and for care of the teeth, mouth, and nails along with sunbathing products. For example, a medicated OTC shampoo used to treat dandruff would be considered a drug, while an everyday shampoo used for general cleansing of hair would qualify as a cosmetic.

WHO ARE THE DISTRIBUTORS AND THE "RESPONSIBLE PERSON?" WHAT ARE HIS OR HER RESPONSIBILITIES?

Distributors are defined as the entity which makes the product available to consumers in the EU. These entities must now report all serious, undesirable events (SUEs) to the competent authority in the country of incidence within 20 calendar days. This regulatory definition of 'serious' is somewhat different from what is typically encountered in pharmacovigilance, but these differences have significant implications.

According to these regulations, serious undesirable effects are defined as "undesirable effects which result in temporary or permanent functional incapacity, disability, hospitalization, congenital abnormalities, or an immediate vital risk of death."

Furthermore, undesirable effects are clarified as "adverse reactions for human health attributable to the normal or reasonably foreseeable use of a cosmetic product." This broad definition necessitates that events such as temporary taste loss due to use of a mouthwash or missing work due to a severe sunburn where sunscreen was applied, must be reported.

These cosmetics regulations also require that distributors have in place a "responsible person," and that each marketed product be "linked" to such a person. In many instances, the distributor will be the manufacturer or importer of the product. The "responsible person" should be someone with an "appropriate" professional background who has experience in complaint handling. This individual is responsible for reviewing the information gathered by the distributor, HCPs, or end users on a particular case, making a causality assessment and notifying the competent authorities of the SUEs using Form A. Also, this person must ensure that existing data on undesirable effects are made accessible to the public on request.

One of the key roles of the responsible person is making a causality assessment of individual cases, on a case-by-case basis. The purpose of this assessment is to evaluate the probability that an SUE is attributable to the product utilized by the end user and to have a consistent and reproducible analysis of reported cases.

In Annex 1 of the regulations, the method used to estimate causality is explained, taking into account three components of the case: chronology, the nature of the undesirable effect, and specific medical investigations and/or rechallenge. Based on these factors and investigations, a level of causality is calculated: very likely, likely, not clearly attributable, unlikely, and excluded. This assessment of causality is then placed on Form A, which is used to report the event to the competent authority in the country of incidence.

In addition to the causality assessment, other information is required to be reported on Form A. Reporter and patient information, product use, and the nature of the event much also be documented. The responsible person must report corrective actions taken (if any). At present, the form must be completed manually. Once completed, Form A is sent to the competent authority in the country of incidence. This competent authority is then required to notify other competent authorities in other EU countries where the product is distributed. Competent authorities may evaluate reports in aggregate to look for any signals or trends and may then make a specific enquiry to the responsible person for further evaluation of the signal or trend.

WHAT ABOUT THE US?

In the US, new cosmetics safety regulations are not yet in place. The FDA has been working with cosmetics industry groups on implementing a new regulatory regime for cosmetics. Even though a consensus has not yet been reached, the FDA remains committed to implementing new safety reporting requirements for cosmetics to promote safe use and mitigate risk for the public.

As reporting requirements for cosmetics continue to evolve in the EU and US, it is imperative that distributors and other stakeholders in the cosmetics industry maintain an awareness of their responsibilities.

Although these regulations may seem overwhelming, they are an important first step in improving cosmetics safety and advancing public health. Prior to the implementation of these reporting requirements, there was no consensus on how to best achieve cosmetics

safety. These regulations should serve to harmonize reporting requirements, and over time, regulators, distributors, and the public will all benefit.

NOTES

1. Regulation EC No. 1223/2009: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF (info on notification and transmissions forms can be found within this link)

2. Example Form A (from Irish Medicines Board): http://www.imb.ie/EN/Publications/Publications/Cosmetic-product-undesirable-effect-report.aspx?page=1&year=0&categoryid=&letter=&q=cosmetic

ABOUT THE AUTHOR

Thomas Winkler, *PharmD*, joined Drug Safety Alliance, Inc. in 2012 providing a range of pharmacovigilance activities related to case management. He recently was promoted to Associate Drug Safety Scientist in the Safety Sciences and Risk Management division where he is involved in Safety Data Exchange Agreement (SDEA) review, aggregate reporting, and signaling. He also serves as a preceptor to 4th year students in the UNC Eshelman School of Pharmacy during their rotations at DSA.

ABOUT US

Founded in 2000 and acquired by UDG Healthcare plc in 2012, as part of its Ashfield Division, Drug Safety Alliance, Inc. (DSA) is a global leader in safety and risk management services supporting pharmaceutical, biotech, medical device, consumer health and animal health organizations. Exclusively focused on pharmacovigilance, DSA provides comprehensive outsourced solutions as well as customized services to augment existing safety departments. DSA is headquartered in Research Triangle Park, North Carolina. For more information, please visit www.DrugSafetyAlliance.com.

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