Cosmetic Regulation

From July 11th, 2013 the new European Regulation No. 1223/2009 on Cosmetic Products replaces the "Cosmetic Directive" 76/768/EEC

Important changes in the regulation of Cometic Products

The new Cosmetic Regulation brings important changes to how Cosmetic Products are regulated in the European Community. While the old directive required the manufacturer, his agent or the person responsible for placing the product in the EU market to keep a list of information about the cosmetic products, the new regulation introduces the term "Responsible Person" who has to keep an – also newly defined – Product Information File. The latter must include a safety report, whose content and structure is described in detail in the annex of the regulation.

Responsible Person (RP)

A key issue of the new regulation is the designation of a RP for each cosmetic product by a written mandate. The RP must be established within the European Community (EC). A manufacturer of cosmetic products, established in the EC, **may** designate a RP whereas a manufacturer established outside the EC **must** designate a RP.
The RP shall ensure compliance of the products with the rules set out in the Regulation. They shall maintain a Product Information File accessible to the public authorities. The RP performs the Pre-marketing registration of the products into a central European database.

Product Information File (PIF) and Safety Report

The PIF consists of a description of the product and its production method as well as the safety report, proof of any claims, data of animal testing and a statement on compliance with GMP.

The Safety Report has to be issued by an experienced and qualified safety assessor. It discusses, among others, the toxicological profile of each chemical component of the product, the microbiological quality, the exposure of the finished product and undesirable effects.

MedNet helps with offering the service as Responsible Person

The first step would be to sign a contract with MedNet that defines MedNet´s service as well as the manufacturer´s duties.

If necessary, MedNet can help in arranging safety assessments and necessary tests at selected safety assessors and test laboratories.

After receipt of the complete documents of the PIF, MedNet performs the mandatory registration of the products into the Cosmetic Product Notification Portal CPNP, an online database established by the European Commission.

In short, with the new regulation coming into force, manufacturers and importers will face a major challenge to comply with the regulation. MedNet provides professional help to cope with this challenge.

For more detailed information, please do not hesitate to contact us!

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