Regulation (EC) No. 1223/2009 on cosmetic products ('Cosmetics Regulation'): the European Cosmetovigilance System. Serious Undesirable Effects Reporting Guidelines and notification Forms

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Currently, cosmetics are very popular and their use continues to increase because consumers consider physical appearance important and, at the same time, these products are considered to be safe. However, in spite of their safety and tolerability, during recent decades, we have become aware that undesirable effects can occur (Lindberg et al, 2004; Sportiello et al, 2009). The number of undesirable effects known so far is very low indeed, partly because of the absence of an European cosmetovigilance system (Sautebin, 2008) that has been suggested years ago by the Council of Europe (ResAP(2006)1E). Cosmetovigilance is defined by the collection, evaluation and monitoring of spontaneous reports of undesirable events observed during or after normal or reasonably foreseeable use of a cosmetic product. Together with other tools, cosmetovigilance contributes to post market surveillance.
More recently Regulation (EC) No 1223/2009 on cosmetic products ('Cosmetic Regulation') created the basis for a uniform approach to the management of serious undesirable effects (SUEs) attributable to the use of cosmetics (Article 23). Undesirable effects (UEs) are defined as 'adverse reactions for human health attributable to the normal or reasonably foreseeable use of a cosmetic product' [article 21 (o)], whereas SUEs are defined as 'undesirable effects which result in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death' [Article 21 (p)]. Cosmetic Regulation provides for notification of SUEs without delay to the Competent Authorities (CA) of the Member State where the effect in question occurred, as well as the notification of any corrective measures taken by the Responsible Person (RP) or Distributor (D). Data on SUEs become part of the Cosmetics Product Safety Report (CPSR) (Annex 1) and have to be made available to the public (Article 21).
In order to facilitate the implementation of Article 23 of the Cosmetics Regulation, and to establish a management and communication system on SUEs throughout the European Union (EU), in conjunction with Member States and industry, the European Commission established guidelines describing the system, by a series of meetings of the Members of the group 'Serious Undesirable Effects' of the Platform of European Market Surveillance Authorities for Cosmetics (PEMSAC). The Italian Ministry of Health was represented by a member of high expertise in cosmetovigilance. The aim was to ensure harmonized notification of SUE by the RP or D and follow-up on SUE notifications by CA, RP or D. Three different notification forms were drawn up, enabling a structured submission of all important factors related to the SUE, as well as relevant ancillary information (report reference number, outcome of causality assessment, status of notification: initial vs. follow-up, etc.). SUE Form A has to be filled in by RP or D notifying SUEs to the CA; SUE Form B has to be completed by the CA and attached to SUE Form A to provide a brief summary and perspective of the case when the CA transmits Form A to other CA and to the RP. SUE Form C has to be filled in by CA transmitting SUE reported by health professionals or end users to other CA and the RP.
The Italian Ministry of Health has developed an informatics platform to manage both SUE and UE notifications, to record all type of UEs and to collect new information on quality and safety of cosmetic products on the market in order to adopt both corrective and preventive actions to guarantee the safeguard of public health.

Lindberg et al. (2004). *Acta Derm Venereol* 84: 291–295.
Sautebin (2008). *Drug Safety* 31: 433-436.
Sportiello et al. (2009). *Pharmacol Res* 59: 101-106
ResAP(2006)1E (online: http://www.coe.int).
Cosmetic Regulation, OJ L 342, 22.12.2009, p.59