Notification of Undesirable Effects and Serious Undesirable Effects to the Italian Ministry of Health according to the Regulation (EC) No. 1223/2009 on cosmetic products ('Cosmetics Regulation'): a two year survey

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Recently Regulation (EC) No 1223/2009 on cosmetic products ('Cosmetics Regulation') created the basis for a uniform approach to the management in the European Union (EU) of serious undesirable effects (SUEs) attributable to the use of cosmetics (Article 23). In order to facilitate the implementation of Article 23, notification forms and guidelines were established to enable a structured submission of all important factors related to the SUEs. In particular, SUE Form A was designed to be filled in by Responsible person (RP) or Distributor (D) notifying an SUE to the Competent Authority of the Member State where the SUE occurred. End users (consumers and cosmetic professionals) as well as health professionals may notify SUEs to the Competent Authority of the Member State where the SUE occurred through a National form set up by every single Member State. In order to evaluate the cosmetovigilance system the notification forms received by the Ministry of Health, the Italian Competent Authority for cosmetics, during the period July 2013-May 2015, either by RP/D (Form A) or End users/Health professionals (National form) have been analyzed. In this period the Italian Ministry of Health received 34 reports (UEs/SUEs), of them 3 (8.8%) were from RP and 1 (2.9%) from D; 23 (67.7%) from health professionals, 6 (17.7%) from consumers and 1(2.9%) from other (the aunt of a 14 years old girl). No reports were sent by cosmetic professionals. Among the reports notified by health professionals, hospital pharmacists represented the main reporting category (n=11; 47.8%) followed by community pharmacists (n=5; 21.7%), hospital doctors (n=3; 13%), general practitioners (n=2; 8.7%), dermatologists (n=1; 4.4%) and medical sales representatives (n=1; 4.4%). Among the total events notified (n=34), 10 (29.4%) were defined as UE, 11 (32.4%) as SUE whereas 13 events (38.2%) were not classified. According to the Cosmetic Regulation, all the events notified by RP (n=3)/D (n=1) were SUEs, the seriousness criteria indicated was 'temporary functional incapacity'. The causality assessment level indicated in 2 out of 3 reports notified by RP was 'unlikely' and 'likely' in the remaining; the level was defined as 'unlikely' in the report from D. Among the 23 events notified by health professionals, 5 were SUEs with seriousness criteria 'hospitalization' (n=4) and 'temporary functional incapacity' (n=1). Two of the 6 events notified by consumers were classified as SUEs, only in 1 of them the seriousness criteria was reported ('temporary functional incapacity'). The people who have claimed an UE/SUE were mainly females (n=27, 79.41%), mean age 37.95 ± 19.12 years (range 6m-72y), whereas male (n=7, 20.59%) mean age was 15.5 ± 12.44 years (range 4y-39y). Face care products other than face mask, sun protection, body care, eye contour, make-up remover products were the cosmetics more suspected to give rise to an UE/SUE (n=3) followed by oxidative hair colour products, face masks, skin cleansing products, chemical depilatories, products for temporary hair styling, chemical exfoliation, hand care, skin lightening and anti-hair loss products (n=1). Unfortunately in the remaining 10 notification forms, the category as well as the full name of the suspected cosmetic product was not specified not allowing the validation and evaluation of these reports. Moreover, a different terminology was often utilized for the description of the same type of event which means that a highly specific standardized medical terminology must be adopted. In conclusion, a careful settlement of these aspects and an education and training program could substantially contribute to the establishment of an efficient reporting system, although the bias due to underreporting could be difficult to eliminate.