A three year Cosmetovigilance experience in Italy

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Regulation (EC) No 1223/2009 on cosmetics ('Cosmetics Regulation') created the basis for a uniform approach to the management in the European Union of serious undesirable effects (SUEs) attributable to the use of cosmetics (Article 23). To evaluate the Cosmetovigilance system 3 years after entry into force of Cosmetics Regulation, the notification forms received by the Ministry of Health, the Italian Competent Authority (CA), during July 2013-May 2016, either by Responsible Person (RP)/Distributor (D) or end users/health professionals have been analyzed. The Ministry of Health received 64 reports of them 7 (10.9%) were notified by industry (3 by RP; 1 by D and 3 from either RP or D); 40 (62.5%) by health professionals and 17 (26.6%) by end users (14 by consumers and 3 by others). Among the 40 reports notified by health professionals, hospital pharmacists represented the main reporting category (n=15; 37.5%) followed by dermatologists (n=10; 25.0%); hospital doctors (n=7; 17.5%); general practitioners and community pharmacists (n=3; 7.5% for each), pharmaceutical representative and paediatrician (n=1; 2.5% for each). All the events notified by industry (n=7), according to the Cosmetics Regulation, were SUEs, the other SUEs (n=10) were notified by 7 health professionals and 3 consumers for a total number of 17 SUEs (26.6% vs total reports). The seriousness criteria of either the 7 SUEs notified by industry or the 7 SUEs notified by health professionals were 6 'temporary functional incapacity' and 1 "hospitalization" whereas 2 'temporary functional incapacity' and 1"hospitalization" were reported by consumers. Among the 3 SUEs notified by RP the causality assessment level reported was "very likely", "likely", "not reported" whereas the evaluation of the CA was "likely", "unassessable", "unassessable", respectively. In the remaining 3 SUEs from either RP or D the causality assessment level reported was "unlikely" whereas the evaluation of the CA was "not clearly attributable". There was only 1 case whose causality assessment level by the D and CA was the same ('likely'). Among the 7 SUEs notified by health professionals the causality assessment level evaluated by CA was 4 "likely" and 3 "very likely" whereas for the 3 SUEs notified by consumers was 2 "likely" and 1 "very likely". The remaining 47 reports (73.4% vs total reports) comprise 23 UEs, 18 events not classified and 6 events whose classification UE/SUE was uncertain. The causality assessment level established by the CA was 31 "likely" ; 6 "not clearly attributable"; 5 "unassessable"; 3 "very likely"; 1 "unlikely"; 1 "excluded". The people who have claimed an UE/SUE were mainly females (n=47, 73.4%), mean age 36.63 ± 18.65 years (range 6m-76y), whereas male (n=17, 26.6%) mean age was 25.59 ± 20.14 years (range 3y-61y). The main categories suspected to give rise to an UE/SUE were body care (n=16); face care other than face mask (n=9); oxidative hair colour (n=7). The products involved in the 17 SUEs notified were body care (n=7) followed by make-up remover (n=2); chemical depilatories; chemical exfoliation; face care other than face mask; mascara; oxidative hair colour; shampoo; sun protection; toothpaste (n=1 for each). The main location of UE/SUE was skin (n=73) followed by lips (n=9); eyes (n=8); scalp (n=6); vaginal mucosa (n=1). Only 3 (4.7%) events (nausea, vomiting, dyspnea) were systemic. The evaluation of the 'Cosmetovigilance' system is positive considering that the notified reports was 8 in the last 6 months of 2013, 22 in 2014, 20 in 2015 and 14 in the first 5 months of 2016. An appropriate education and training program will contribute to the establishment of a more and more efficient reporting system.