

Market Surveillance Study on Tooth Whitening Products Summary Report

Introduction

Tooth whitening for cosmetic purposes has become more common in Europe and cosmetics regulation has evolved in recent years to better regulate these products. The European Network of Official Cosmetics Control Laboratories (OCCLs) decided to survey cosmetic products for tooth whitening in order to ascertain their compliance with European or national regulations and to gather information on their active ingredients.

Samples

In total, 261 samples were checked by thirteen OCCLs between 2013 and 2017. Almost 50% of the samples collected were toothpastes for bleaching purposes; whitening gels represented 23% of the samples tested in this study. The remaining 30% were tray-based tooth whiteners, whitening strips, paint-on whiteners, mouthwashes and cosmetics (general). The majority of the products (68%) were manufactured in European countries. Several products were found not to be registered in the Cosmetic Products Notification Portal (CPNP) and the labels of some products wrongly reported CE marking.

Testing

Laboratories involved in the study defined the testing parameters for each sample according to their own expertise and resources. Laboratories tested ingredients with tooth whitening purposes (hydrogen peroxide, carbamine peroxide, sodium hypochlorite, sodium perborate), preservatives (triclosan, isothiazolinones, brominated preservatives), fluorides and colourants. Microbiological testing was also performed (aerobic mesophilic bacteria, yeasts and moulds, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Candida albicans*, *Escherichia coli*).

Results

The overall compliance of tooth whitening products tested in this market surveillance study was 71%. Non-compliance issues identified concerned the hydrogen peroxide content (higher than permitted), the presence of a CMR substance – those which are carcinogenic, mutagenic or toxic for reproduction – (sodium perborate) and labelling issues. Product safety may be compromised in these cases. There were no issues of non-compliance related to microbiological contamination. For the “mouthwashes/whitening rinses” no non-compliant samples were identified. The cosmetic category that showed the largest percentage of non-compliances was “paint-on (brush-on) whiteners” (78%), followed by “tray-based tooth whiteners” (59%), “whitening strips” (53%), and “whitening gel” (45%). The percentage of non-compliant samples of toothpaste was very low compared to other cosmetics categories (3%).

None of the results obtained in this study led to product recalls. For some products, the result obtained led to voluntary withdrawal from the market, demands for corrective measures or sales bans. The data reviewed in this study demonstrate that incorrect labelling of cosmetic products as medical devices is amongst the issues that should be closely monitored by national competent authorities and OCCLs. The overall compliance found in this study (71%) shows that tooth whitening products should remain under close surveillance.

The activities were coordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM). For further information, please contact the national authorities.