



FEDCAR STATEMENT

TOOTH WHITENING CLINICS & TOOTH WHITENING IN BEAUTICIANS CENTERS

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INTRODUCTION

FEDCAR is the European federation of competent authorities and dental regulators. We bring together councils and organisations that are responsible for the regulation, registration and supervision of dental practitioners. Our objectives are to :

- Ensure a high level of oral health care in Europe,
- Promote patient safety across Europe,
- Contribute to a safe mobility of dental professionals in the EU.

SITUATION

What is the applicable law?

1. The Cosmetics Regulation, in its Annex III, entry 12, regulates the use of hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide, in several categories of cosmetic products including tooth whitening or bleaching products. It foresees that the maximum authorised concentration of hydrogen peroxide in tooth whitening or bleaching products is 6%, present or released.
2. Given the risks that products containing more than 0.1% and up to 6% of hydrogen peroxide, present or released, may pose in certain situations the EU Legislator aims to ensure a safe use of these products by requiring an appropriate examination, prior to use, by the dental practitioner who would also advise on the frequency and duration of application. Patients could have access to these products only after a first use, within each cycle of use, by the dental practitioner, or under their direct supervision if an equivalent level of safety was ensured.
3. In the case of products with 0.1% or less of hydrogen peroxide, present or released, **the Cosmetics Regulation does not impose any restrictions as regards the use of those products.**
4. The European Commission underlines that the above-mentioned rules only apply to tooth whitening or bleaching products containing hydrogen peroxide, or other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide. **They do not cover those tooth whitening or bleaching products that do not contain hydrogen peroxide or do not contain compounds or mixtures that release hydrogen peroxide.**

What is at stake for high standards on oral healthcare and dentistry?

5. The tooth whitening treatment cannot be marketed as a mere and safe cosmetic service, given the health precautions it requires to ensure a successful and a secure application. Prior to any tooth-whitening a dental practitioner has the duty, for example, to screen for oral disease including oral cancer, to complete needed tooth-fillings to exclude any

bleach entering into a decayed cavity and to protect the surfaces of the roots in cases of periodontal disease given the extreme sensitivity caused by peroxide.

What is the problem faced by regulators?

6. The practice of tooth whitening is taught in dental schools as part of the curriculum, and as such, it is regarded as part of the practice of dentistry, and should be carried out by a qualified and registered or licensed dental practitioner.
7. Tooth whitening treatment carries the risk of post-operative pain and sensitivity and for this reason it is appropriate that this treatment is provided under the supervision of a dental practitioner.

STATEMENT

In this statement, the FEDCAR would like to address the risks associated with the use of tooth whitening without dental supervision. We state that in the interest of high standards of oral healthcare, and irrespective of the chemical products used, tooth whitening should only be provided under the supervision of a dental practitioner. Tooth whitening should only be provided in a safe environment where appropriate aftercare can be provided. This cannot be provided for in, for example, a beautician's studio or tooth whitening clinic.

Adopted by the General Assembly of FEDCAR on 25 November 2016.

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