COUNCIL OF EUROPEAN DENTISTS

CED ANNUAL REPORT

ON UNDESIRABLE EFFECTS OF TOOTH WHITENING PRODUCTS

First report:

Period from 31 October 2012 to 31 October 2013

The content of this report represents the views of the CED and is its sole responsibility; it can in no way be taken to reflect the views of the European Commission or any other body of the EU.

Please note that the Annexes to this report reflect the legal state of play of when the survey was launched making reference to entry 12 of Part 1 of Annex III of the Cosmetic Products Directive (76/768/EEC) as amended by the Council Directive 2011/84/EU. This Directive has been repealed by Regulation (EC) No 1223/2009 of 30 November on cosmetic products and entry 12 of Annex III has currently been amended by Regulation 1197/2013 of 25 November.

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ANNEXES

I – Introduction

This report was prepared under an agreement signed between the CED and the European Commission on 31 March 2010 in the framework of the future regulation on the use of tooth whitening or bleaching products (TWPs).

The agreement was signed to support the ongoing availability of tooth whitening products on EU market, to ensure that patients can only access appropriate treatment via trained and qualified dental professionals (i.e. dentists) and to reassure Member States that the occurrence of undesirable effects is followed by appropriate actions (e.g. the possibility of checking the products).

Under this agreement, the CED agreed to prepare an annual report to the European Commission of the undesirable effects reported by patients themselves or observed by dentists on a voluntary basis. The report should contain information gathered in all EU Member States, in particular the following:

1. the undesirable effects
    a. full description of reaction(s)/types of undesirable effects,
    b. duration and gravity of the undesirable effects, and
    c. whether a medical or dental follow up/treatment was necessary
2. the relative concentration in peroxide hydrogen of the product, indicated as appropriate,
3. If relevant, the form of the product (e.g. stripes, tray, etc.),
4. Whether a dental practitioner was involved, i.e. whether the product was delivered and/or used by a dental practitioner or under its direct supervision if an equivalent level of safety is ensured
5. The ratio between the number of cases leading to undesirable effects reported to the dentists and the estimate of the total number of uses of tooth whitening products (an estimate will be provided in order to take into account the fact that finally the consumer may choose not to continue to use or may improperly use the product at home).

The report should be made public.

II - Methodology

The report was prepared based on the replies received from dentists between 31 October 2012 and 31 October 2013 who have themselves observed undesirable effects caused by TWPs or from dentists whose patients have reported to them undesirable effects caused by TWPs, with concentrations of hydrogen peroxide between 0.1% and 6% and of carbamide peroxide between 0.3% and 16.62%.

In order to implement the annual reporting activity, the CED prepared the following documents:

a) a questionnaire for dentists to report undesirable effects (see Annex I – Survey on undesirable effects);

b) fact sheet containing information on tooth whitening, to provide information on relevant legislation and on CED reporting (see Annex II);

c) draft template letter to relevant national ministries, to be adapted to CED members' specific national circumstances and to be sent to their ministry/ministries if they so wished in order to inform them why they were assisting the CED in collecting this information (see Annex III);

d) the CED Guidelines to interpret and implement Council Directive 2011/84/EU on Tooth Whitening Products (see Annex IV).

The questionnaire was made available online in www.surveyshare.com between 31 October 2012 and 31 October 2013 through the link http://www.surveyshare.com/s/AQAQ5HC. The survey could only be

answered online and the survey's link was only provided to CED Members in order to avoid false reporting. As the answers are anonymous there was no possibility to check the authenticity of the replies.

The CED created a page in its website to help advertise the survey and to concentrate all information in one place (see CED website).

The CED informed its members about the survey encouraging them to distribute the questionnaire among their members and non-members through CED mailing on 19 October 2012, sending reminders on 24 January, 13 March, 15 May, 29 July and on 30 October 2013; and during the CED General Meeting on 12 May and 23 November 2012, and 24 May and 22 November 2013.

The CED requested that its members:

i. make the link to the online questionnaire available to their members (disseminating the link to their members as they judged appropriate), and to encourage them to reply. The CED recommended not making the link available in the public part of their website to avoid false reporting;

ii. to advertise the questionnaire to other dentists who were not their members as appropriate;

iii. to translate the questionnaire in their national language/s to assist dentists in replying;

iv. to use the fact sheet, the CED Guidelines and the template letter addressed to relevant national ministries.

The survey was anonymous and the replies voluntary. Only a summary of reporting incidents was to be made public.

III - Survey results - general findings

1.	**Number of reporting incidents**	13 (all date from 2013)		
2.	**Countries**	6 (Lithuania, France, Germany, Malta, Slovakia and Iceland)		
3.	**Undesirable effect**	11 replies the undesirable effect was sensitivity, of which 1 also reported pain.	2 replies the undesirable effect was soft tissues inflammation/ ulceration	
4.	**Undesirable effect occurred**	5 replies the effect occurred following the first use by the dentist	8 replies the effect occurred following the use by the patient during the rest of the cycle of use	
5.	**Duration of undesirable effect**	9 replies the undesirable effect lasted 1-5 days	2 replies the undesirable effect lasted 6-10 days	2 replies the undesirable effect lasted more than 10 days
6.	**Material used**	12 replies the material used was carbamide peroxide	1 reply the material used was hydrogen peroxide	
7.	**Concentration**	3 replies concentrations between 0.3-10% carbamide peroxide	9 replies concentrations between 11-16.62% carbamide peroxide,	1 reply did not reported the concentration

8.	**Form of procedure**	11 replies the form of procedure was tray based with gel		2 replies the procedure was in surgery/office only	
9.	**How many cases of tooth whitening do you carry out a year**	7 replies between 0-10 cases a year	4 replies between 11-20 cases a year	1 reply between 31-40 cases a year	1 reply more than 50 cases a year
10.	**Were dental or medical follow up/treatment necessary**	11 negative replies		2 positive replies	
11.	**Any other observations**	1 reply clarified that sensitivity after first use was observed only in cases of concentrations higher than 6% used in surgery/office.			

IV – Discussion of survey results

Only few reporting incidents were received. There are no reliable and verifiable statistics on how many tooth whitening cases are carried out in Europe annually. It is difficult to estimate reasons for the small number of responses (lack of interest of dentists, lack of information about the survey or, indeed, no undesirable effects to report).

Nevertheless, based upon the number of reporting incidents received, we can tentatively conclude the following:

- the use of small concentrations of hydrogen peroxide or carbamide peroxide, in accordance with Directive 2011/84/EU, only has few undesirable effects;
- most of the replies underline sensitivity as an undesirable effect;
- this undesirable effect only lasts for a few days.

The CED decided to carry out an internal survey to find out, to the extent possible, why there were so few reporting incidents (see results under point V below).

V – Follow-up actions:

a) Results of the feed-back questionnaire

Due to the lack of reporting incidents and in order to address this issue, the CED carried out a feed-back questionnaire among its members (see Annex V) which was distributed on 30 October 2013.

By 20 November 2013, the CED received 18 replies (16 CED Members of out 29 and 2 CED Observers out of 3). Most members advertised the survey on their website, newsletter or at national dental associations/chambers meetings/workshops. Two members replied that they did not advertise the survey and one of the reasons mentioned was that TWPs was not an issue in their country.

The barriers identified by CED Members were the following:

- internet access and language (only some members had the possibility to translate the survey into their language);
- dentists may fear that self-reporting could become a basis for assumption that undesirable effects were caused by dentists' professional conduct (even though it is specified that the survey is anonymous);

- lack of dentists' interest for this kind of cooperation, not being able to identify the benefits to respond to the survey;
- management of undesirable effects is understood by the profession. Dentists may not see the added value in the reporting as the undesirable effects are detailed in peer reviewed dental scientific literature.
- dentists still offering higher concentrations than 6% of H2O2 are not able to reply to the questionnaire;
- dentists who are not members of a CED Member Association being unaware of the survey.

The solutions proposed by CED Members:

- associate CED logo to the campaign and/or develop logo to promote the survey;
- CED Members should communicate with other national relevant stakeholders in order to increase replies (e.g ministries, patients' organisations, dental schools);
- develop a detailed CED resolution on tooth whitening with accurate guidelines, including possible exceptions for using higher concentrations (e.g. specific medical conditions which required the use of higher concentrations);
- CED members to create their dedicated website page;
- Repeat messages in professional journals, websites, newsletters, mailings.

b) Conclusions

The CED identified three potential risks associated to the survey and suggests certain actions to prevent and mitigate those risks in the future.

Risk	Preventive action	Potential action
Lack of response to the survey	Send reminders to CED members every two months; raise awareness for the survey at internal events; create a page in the CED website to disseminate the information; use online survey tools; CED members requested to translate the questionnaire in their national language/s; carry out a feedback questionnaire among CED members.	Continue to disseminate as before; associate CED logo to the online questionnaire; translate the survey into the 3 CED official languages; CED members should dialogue with other national relevant stakeholders (e.g ministries, patients' organisations, dental schools);
False reporting by non-dentists	Survey's link only provided to CED Members, members' membership and members' non-members.	
Estimating total number of uses of tooth whitening products in the EU	-	Identify an organisation in possession of this information to request the relevant information.

ANNEXES[1]

Annex I: Survey on undesirable effects

Welcome to the CED survey!

Please complete this questionnaire in relation to problems that have occurred in any tooth whitening case, reported by the patient himself or observed by you, for each patient. Tick in the appropriate box or write your comments when asked.

This information is being collected to support the ongoing availability of tooth whitening through dentists. This questionnaire is anonymous. Only summary results will be shared with the European Commission through a report on an annual basis. The report shall be made public.

Please note that under paragraph 4 of Article 23 of the Cosmetics Regulation 1223/2009, when end users or health professionals report serious undesirable effects to the competent authority of the Member State where the effect occurred, that competent authority shall immediately transmit the information on the cosmetic product concerned to the competent authorities of the other Member States and to the responsible person.

Thank you for your time!

Undesirable effects/adverse reactions report by the dentist:

1) Country:

2) Date of the report:

3) Undesirable effect:

- ☐ Sensitivity
- ☐ Soft tissue inflammation/ulceration
- ☐ Allergy
- ☐ Pain
- ☐ Other:

4) Undesirable effect occurred:

- ☐ Following the first use by the dental practitioner
- ☐ Following the use by the patient during the rest of the cycle of use

5) Duration of undesirable effect:

- ☐ 1-5 days
- ☐ 6-10 days
- ☐ 10+ days

6) Material used:

- ☐ Hydrogen peroxide
- ☐ Carbamide peroxide
- ☐ Sodium perborate

[1] Please note that the Annexes reflect the legal state of play of when the survey was launched.

7) Concentration:

- ☐ 0.1-3.6% hydrogen peroxide (0.3-10% carbamide peroxide)
- ☐ 3.7-6.0% hydrogen Peroxide (11-16.62% carbamide peroxide)

8) Form of procedure:

- ☐ Tray based with gel
- ☐ Whitening strips
- ☐ Internal bleaching
- ☐ In surgery/office

9) How many cases of tooth whitening do you carry out a year?

- ☐ 0-10
- ☐ 11-20
- ☐ 21-30
- ☐ 31-40
- ☐ 41-50
- ☐ 51+

10) Were dental or medical follow up/ treatment necessary?

- ☐ Yes. Please specify:
- ☐ No

11) Any other observations, please specify:

Annex II: Fact sheet information on tooth whitening

Brussels, 31 August 2012

Fact sheet

Tooth Whitening or Bleaching Products – Council Directive 2011/84/EU

1. The use of tooth whitening and bleaching products is regulated under Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, as amended by Council Directive 2011/84/EU of 20 September 2011 (hereinafter "the Directive") as well as partially regulated by Regulation (EC) n° 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (which will enter into complete force on 11 July 2013). They are classified as cosmetic products and not as medical devices.

2. The substances affected concern **hydrogen peroxide** and other compounds or mixtures that release hydrogen peroxide in tooth whitening or bleaching products, including **carbamide peroxide** (where 16.62% of carbamide peroxide corresponds to 6% of hydrogen peroxide) and **zinc peroxide**and **sodium perborate and perboric acid** (as they are considered to be hydrogen peroxide releasing substances, pursuant to the opinion of the Scientific Committee on Consumer Safety (SCCS) on sodium perborate and perboric acid, published on 22 June 2010).[2]

3. The Directive prohibits the marketing of products containing over 6 % of hydrogen peroxide and establishes new conditions for using products between 0.1% and 6% of hydrogen peroxide, regardless the place where their use occurs – in the dental office or at home.

4. According to the Directive, products between 0.1% and 6% of hydrogen peroxide:

   4.1. can only be sold to dental practitioners[3]. Distributers need to ensure that these products cannot be supplied directly to retail;

   4.2. must have their first use within the dental office i.e., by dental practitioners (or under their direct supervision if an equivalent level of safety is ensured), in order to ensure that a clinical examination takes place and the exposure to these products is limited;

   4.3. cannot be used on a person under 18 years of age;

   4.4. for the rest of cycle of use, can be performed by consumers themselves as long as the access to the product is provided by dental practitioners, or by other qualified dental professionals who are under the dental practitioner's direct supervision and responsibility.

[2]Please note that after this fact sheet had been released, we received clarifications from the Commission services that sodium perborate and perboric acid had been banned in cosmetic products pursuant to Article 15 (2) indent 1 of Regulation 1223/2009 on cosmetic products ('Cosmetics Regulation') as they are considered hazardous substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1B according to Part 3 of Annex VI of Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures,and no exception to the ban has been granted according to Article 15 (2) indent 2 of the Cosmetics Regulation.

[3] Dental practitioner (i.e. dentist) is the term used by Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (see Articles 34-37).

5. The conditions of use and warnings which must be printed on the label of tooth whitening and bleaching products containing more than 0.1% and up to 6% of hydrogen peroxide, present or released are specified on entry 12 of the first part of Annex III of the Directive.

6. The Directive aims at implementing the opinion of the Scientific Committee on Consumer Products (SCCP) of 18 December 2007 on hydrogen peroxide, in its free form or when released, in oral hygiene products and tooth whitening products (SCCP/1129/07). It intends to adapt to technical progress Directive 76/768/EEC while ensuring the protection of public health. SCCP was replaced by the new Scientific Committee on Consumer Safety (hereinafter "SCCS").

For further information please consult the CED website www.eudental.eu or contact CED Brussels Office by telephone +32 2 736 34 29 or by email ced@eudental.eu.

Annex III: Draft template letter to relevant national ministries

(place), (date)

Dear Minister [*National Health Ministry/Department*],

We are writing to you on behalf of *(CED Member organisation)*, representing …. dentists in …., in connection to the Council Directive 2011/84/EU of 20 September 2011 amending Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress (hereinafter "**the Directive**").

This Directive regulates the use of hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide in tooth whitening or bleaching products. It establishes a new legal framework for products between 0.1% and 6% of hydrogen peroxide and prohibited the marketing of products containing over 6 % of hydrogen peroxide, as is the case now.

On 31 March 2010, while the Directive was being discussed in the Standing Committee on Cosmetic Products, the Council of European Dentists (CED)[4], for which the *(CED Member organisation)* is a member, formalised an agreement with the European Commission (EC) to reassure Member States that the occurrence of undesirable effects would be followed by appropriate actions (e.g. the possibility of checking the products). It was also meant to ensure the ongoing availability of tooth whitening and bleaching products in the market and that patients could only access appropriate products via trained and qualified dental professionals (i.e. dentists).

In this agreement, the CED accepted to **annually report undesirable effects** observed by dentists or reported by patients themselves which result from the use of tooth whitening products. The report would gather the information collected in Member States. It would be submitted to the EC and should be made public.

In order to achieve this objective, the CED developed a questionnaire for dentists to report undesirable effects (see attached document 1). The questionnaire will be anonymous and only the summary results will be submitted to the EC. The questionnaire will be made available on our website, as well as on the CED's, and will be accompanied by an information package containing: i) a fact sheet on the European regulation of tooth whitening products (see attached document 2); and, ii) the CED Guidelines to interpret and implement Council Directive 2011/84/EU on tooth whitening products (see attached document 3).

We also intend to advertise this questionnaire in the newsletter of our association in order to inform and engage individual dental practitioners to cooperate in this activity.

We would be glad to provide further information on this issue if you so require.

Sincerely,

(CED Member organisation)
Annex: 3 documents.

[4] The CED is a European not-for-profit association which represents over 340,000 practising dentists through 32 national dental associations and chambers from 30 European countries. Its key objectives are to promote high standards of oral healthcare and effective patient-safety centred professional practice across Europe, including through regular contacts with other European organisations and EU institutions.

Annex IV

CED GUIDELINES TO INTERPRET AND IMPLEMENT COUNCIL DIRECTIVE 2011/84/EU ON TOOTH WHITENING PRODUCTS

I – INTRODUCTION

This document provides guidance for interpreting and implementing the Council Directive 2011/84/EU of 20 September 2011 amending Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress (hereinafter "the Directive"). It intends to support CED Members and CED Observers when they contact the Ministries responsible for transposing the Directive into national legislation and to advise individual dental practitioners. It is important to ensure that CED Members and CED Observers are heard by the relevant competent authorities in the beginning of the transposition procedure.

This document can also serve to support CED Members and CED Observers in providing complete information about the regulation of tooth whitening and bleaching products to the dentists and the general public in their countries.

The European Commission (Directorate General for Health & Consumers) has been informed and commented this document.

The Directive has entered into force on 18 November 2011. **Member States will have to apply the Directive provisions from 31 October 2012**.

II – WHAT HAS CHANGED IN THE DIRECTIVE?

The Directive regulates the use of hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide in tooth whitening or bleaching products.

Until now, according to entry 12 of the first part of Annex III of the Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (hereinafter "Directive 76/768/EEC"), the use of hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide was limited to 0.1% of hydrogen peroxide present in oral hygiene products or released. Concentrations above this limit were prohibited. Indeed, under Article 4 paragraph 1 (b) of Directive 76/768/EEC, marketing of cosmetic products which contained the substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down therein, was prohibited in all Member States. Hence, only concentrations of 0.1 % of hydrogen peroxide were considered safe and were allowed to be freely available to the consumers on the market.

The current Directive establishes a **new legal framework**: products between 0.1% and 6% of hydrogen peroxide present in tooth whitening or bleaching products or released can now be sold to dental practitioners and must have their first use within the dental office i.e., by dental practitioners (or under their direct supervision if an equivalent level of safety is ensured). The rest of cycle of use can be performed by consumers themselves as long as the access to the product is provided by dental practitioners, or by other qualified dental professionals who are under the dental practitioner's direct supervision and responsibility, as explained under point III a) below. These concentrations cannot be used on a person under 18 years of age.

The Directive aims at implementing the opinion of the Scientific Committee on Consumer Products of 18 December 2007 on hydrogen peroxide, in its free form or when released, in oral hygiene products and tooth whitening products (see attached for your information). It intends to adapt to technical progress Directive 76/768/EEC while ensuring the protection of public health.The Scientific Committee on Consumer Products was replaced by the new Scientific Committee on Consumer Safety (hereinafter "SCCS").

III – GUIDELINES

a) The meaning of the term "dental practitioners" in the Directive

Recital 4 of the Directive establishes that: *"Those products* [products containing more than 0.1% and up to 6% of hydrogen peroxide present or released] *should therefore be regulated in a way that ensures that they are not directly available to the consumer. For each cycle of use of those products, the first use should be limited to* ***dental practitioners, as defined under Directive 2005/36/EC*** *of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications or under their direct supervision if an equivalent level of safety is ensured.* ***Dental practitioners*** *should then provide access to those products for the rest of the cycle of use."*

The new Directive does not provide a definition of "dental practitioners". It refers to the definition established under Directive 2005/36/EC on the recognition of professional qualifications (hereinafter PQD). The PQD however does not provide a definition *stricto sensu* of a dental practitioner. In fact, under Article 36, the PQD describes the professional activities of dental practitioners and the conditions under which a dental practitioner can pursue his/her activities.

In this sense, Article 36 of the PQD establishes the following:

> *"1. For the purposes of this Directive, the professional activities of dental practitioners are the activities defined in paragraph 3 and pursued under the professional qualifications listed in Annex V, point 5.3.2.*
>
> *2. The profession of dental practitioner shall be based on dental training referred to in Article 34 and shall constitute a specific profession which is distinct from other general or specialised medical professions. Pursuit of the activities of a dental practitioner requires the possession of evidence of formal qualifications referred to in Annex V, point 5.3.2. Holders of such evidence of formal qualifications shall be treated in the same way as those to whom Articles 23 or 37 apply.*
>
> *3. The Member States shall ensure that dental practitioners are generally able to gain access to and pursue the activities of prevention, diagnosis and treatment of anomalies and diseases affecting the teeth, mouth, jaws and adjoining tissue, having due regard to the regulatory provisions and rules of professional ethics on the reference dates referred to in Annex V, point 5.3.2."*.

As a result, by limiting the fist use within a cycle of use to "dental practitioners", **the new Directive intends to ensure that only dental practitioners, and no other professionals, have direct access to tooth whitening and bleaching products containing more than 0.1% and up to 6% of hydrogen peroxide present or released**. Those products cannot be directly available to the consumer or other professionals.

Nevertheless, **other qualified dental professionals can perform** tooth whitening and bleaching under the supervision of dental practitioners where an equivalent level of safety is ensured. Who can perform tooth whitening and bleaching under the abovementioned circumstances and how the equivalent level of safety is ensured needs to be further developed by Member States when transposing Directive 2011/84/EC. Indeed, in order to ensure consistency of what one should understand by *"an equivalent level of safety"*, Member States should specify the minimum conditions under which the equivalent level of safety is ensured. For example, Member States should specify the minimum professional qualifications required (i.e., in the area of dentistry and by qualified dental care professionals) and/or, if appropriate, the need to be registered in a professional organisation or to be authorised by a competent authority.

Furthermore, the purpose of the new Directive is to enhance patient safety and to ensure that patients can only access appropriate products via trained and qualified dental professionals. Recital 3 of the Directive explains the conditions under which these products can be safely used. It mentions that an **appropriate clinical examination** needs to be carried out in order to ensure that there are no risk factors or any other oral pathology of concern, and that the **exposure to these products is limited** so

as to ensure that the products are used only as intended in terms of frequency and duration of application.

A clinical examination implies therefore an examination by a clinician (the dental practitioner) in a clinical setting. Moreover, the clinical examination must be carried out **before the first use** of tooth whitening products, and the **ongoing exposure** to these products (the rest of the cycle of use), which shall be limited in terms of frequency and duration of application, must be **monitored** by the dental practitioner.

b) The substances regulated

The Directive regulates the use of **hydrogen peroxide** and other compounds or mixtures that release hydrogen peroxide, **including carbamide peroxide and zinc peroxide**. Note that the active ingredient of carbamide peroxide is hydrogen peroxide where **16.62% of carbamide peroxide corresponds to 6% of hydrogen peroxide**.

Sodium perborate and perboric acid[5] are also regulated as they are considered to be hydrogen peroxide releasing substances, pursuant to the opinion of the Scientific Committee on Consumer Safety (SCCS) on sodium perborate and perboric acid, published on 22 June 2010 (see attached).

The conclusion of the SCCS opinion (pages 22 and 23) states the following:

> *"**4. CONCLUSION***
> ***(1)** Based on the current knowledge on the chemistry, biology and toxicology of sodium perborate and perboric acid, does the SCCS consider that sodium perborate and perboric acid can be considered as "hydrogen peroxide" releasing substances in the sense as the already regulated substances in Annex III, entry 12 of the Cosmetics Directive 76/768/EEC?*
>
> *The SCCS is of the opinion that **sodium perborate and perboric acid can be considered as "hydrogen peroxide" releasing substances** and thus are covered by the entries 12 of Annex III, of the Cosmetics Directive 76/768/EEC,*
>
> ***(2)** If the answer to question 1 is yes, does the SCCS consider that the general restrictions applicable to hydrogen peroxide releasing substances should apply to sodium perborate and perboric acid?*
>
> *The SCCS considers that **the general restrictions applicable to hydrogen peroxide releasing substances should apply to sodium perborate and perboric acid**. As laid out in opinion SCCS/1249/09, the substances listed in the Annex I of this mandate are, in addition to entry 12 of Annex III, also covered by entry 1a of Annex III of the Cosmetics Directive 76/768/EEC. The more restrictive of the two entries should apply."*The European Commission is currently discussing with Member States the legal regime for sodium perborate and perboric acid. In the future, it is possible that these substances are banned from cosmetic products.

c) Is there a difference between in-office and at-home concentrations?

The Directive regulates the use of hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide **regardless the place where their use occurs – in the dental office or at home**:

- **Concentrations of ≤ 0.1 % of hydrogen peroxide** present or released in oral products, including mouth rinse, tooth paste and tooth whitening or bleaching products are safe and will continue to be freely available on the market.
- **Concentrations of >0.1% - ≤ 6% of hydrogen peroxide** present or released in tooth whitening or bleaching products can only be sold to dental practitioners and, for each cycle of use, the first

[5] Please see footnote 2.

use can only be carried out by dental practitioners or under their direct supervision if an equivalent level of safety is ensured, as explained under point III a) above. Afterwards the product may be provided by the dental practitioner, to the consumer to complete the cycle of use.

- **Concentrations of >6 % of hydrogen peroxide** present or released in oral products, including tooth whitening or bleaching products, **will continue to be prohibited, as before**. However, in several Member States, concentrations higher than 6% of hydrogen peroxide are currently being used due to the fact that the relevant national legislations regulating the use of tooth whitening or bleaching products containing more than 0.1% of hydrogen peroxide are based on the Medical Devices Directive (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices).

Indeed, in several Member States tooth whitening or bleaching products are considered medical devices and not cosmetic products. For this reason, these products bear the CE marking provided for in Article 17 of the Medical Devices Directive (which is a declaration by the manufacturer that the products comply with the essential requirements of the relevant EU legislation). **For the European Commission, however, tooth whitening or bleaching products have always been considered cosmetic products and therefore regulated under Directive 76/768/ECC concerning cosmetic products. Thus, the CE marking is unduly affixed; under EU legislation they remain to be treated as cosmetic products.**

The European Commission can decide to launch infringement procedures against those Member States which fail to comply with Directive 76/768/EEC. It is the opinion of the CED that the European Commission may be stricter with regards the enforcement of the new Directive 2011/84/EU.

d) Labelling

Entry 12 of the first part of Annex III of the Directive specifies the conditions of use and warnings which must be printed on the label of tooth whitening and bleaching products containing more than 0.1% and up to 6% of hydrogen peroxide, present or released. It requires the following:

i. The indication in percentage of the concentration of hydrogen peroxide present or released;
ii. The warning that it cannot be used on a person under 18 years-old;
iii. The warning that it can only be sold to dental practitioners, specifying that for each cycle of use the first use can only be done by dental practitioners or under their direct supervision if an equivalent level of safety is ensured, as explained under point III a) above. Afterwards the product may be provided to the consumer [by the dental practitioner] to complete the cycle of use.

e) How to deal with illegal practice of tooth whitening

In 2011, the CED carried out a survey among its Members and Observers to investigate if tooth whitening by non-dentists was a problem and, if so, what was the attitude of national competent authorities, and what kind of actions had they taken against non-dentists performing tooth whitening. The survey also included questions about the materials being used and if CED Members and Observers were aware of any complaints about damage done by non-dentists. 11 countries out of 27 reported having problems with tooth whitening being carried out by non-dentists; 2 countries reported not having problems, but expected they would appear in the future.

For those countries where tooth whitening by non-dentists is a problem or a developing problem, please find below some suggestions which might help you to deal with the illegal practice of tooth whitening in your country, considering the new legal framework of the Directive:

- Discuss the present guidelines with national competent authorities that enforce the Cosmetics Directive 76/768/EEC and regulate the dental profession;
- Specify in national legislation that tooth whitening is a medical act reserved to dental practitioners, as explained under point III a) above;

- Trace on the internet the entities which are currently offering training courses and/or qualifications on tooth whitening, and promote awareness campaigns aimed at informing students that only dental practitioners and individuals under their direct supervision if an equivalent level of safety is ensured are legally authorised to carry out tooth whitening or bleaching activities (Note: in some countries, teaching an illegal activity is by itself illegal, while in others it is not. This suggestion should be adapted taking into consideration national legislation);
- Trace on the internet companies franchising tooth whitening and promote awareness campaigns about their illegal activities and the risks of having tooth whitening or bleaching performed by unqualified persons;
- Trace companies selling or supplying any tooth whitening products and remind them of their legal obligations that these can only be supplied to a dental practitioner;
- Encourage national governments to reach informal agreements with tooth whitening or bleaching suppliers establishing that they will not sell/supply to beauticians or hairdressers.

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Annex V: Feed-back questionnaire on the CED survey on undesirable effects

Introduction

The CED WG Tooth Whitening is carrying out **an annual survey** to report to the European Commission the undesirable effects caused by tooth whitening products (TWPs) with concentrations between 0,1 and 6% of hydrogen peroxide or equivalent observed by dentists or reported by patients themselves. **At present, the CED has only received few replies.**

In order to demonstrate to the European Commission that the CED has done its best to receive as many replies as possible, and to find out, to the extent possible, why there were so few replies, the CED WG Tooth Whitening kindly requests CED members to reply to the following:

1. How did you advertise and ask dentists to respond to the CED survey on undesirable effects caused by tooth whitening or bleaching products?

   ☐ Association/chamber's website
   ☐ Newsletter/ letter to members
   ☐ Other (please give details) ……..
   ☐ Did not advertise

2. Do you have any suggestions to encourage dentists to reply to the survey?

3. Are there any national barriers preventing this information to be collected?

4. Any other comments?

Please reply by Monday, 18 November 2013 to ced@eudental.eu

The WG much appreciates your assistance in gathering this information. The preliminary results will be presented to the CED General Meeting in November.