



CED ANNUAL REPORT ON UNDESIRABLE EFFECTS OF TOOTH WHITENING PRODUCTS

THIRD REPORT
1 November 2014 to 31 October 2015

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.

I – Introduction

This is the third and final report 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)¹. The first report covered the period from 31 October 2012 to 31 October 2013 and is available [here](#)². The second report covered the period from 1 November 2013 to 31 October 2014 and is available [here](#)³.

The agreement was signed to support the ongoing availability of tooth whitening products on EU market, to ensure that these products are not directly available to the consumer and that, for each cycle of use, the first use is 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.

II – Methodology

This report is prepared based on the reporting incidents received from dentists between 1 November 2014 and 31 October 2015 who have themselves observed undesirable effects caused by tooth whitening products or from dentists whose patients have reported to them undesirable effects caused by tooth whitening products, 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 a third questionnaire for dentists to report undesirable effects (see Annex I – Third Survey on Undesirable Effects). Question 8 of the Third Survey was amended on 22 May 2015 as per suggestion of the European Commission (see Annex II).

The questionnaire was made available online in www.surveymshare.com between 1 November 2014 and 31 October 2015 through the link <http://www.surveymshare.com/s/AYAATKD>. The survey could only be answered online and the survey's link was solely 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 survey was advertised on the CED website (please see [here](#)⁴).

The CED informed its members about the survey encouraging them to distribute the questionnaire among their members and non-members through the CED mailing on 5 November 2014 and two oral reminders during the CED General Meetings on 21 November 2014 and on 29-30 May 2015.

The CED requested its members to:

- i. make the link available to dentists only in order to avoid false reporting. In case of replies on paper, to complete the form directly online or send the reply to the CED (ced@eudental.eu);
- ii. translate the questionnaire in their national language/s;

¹Tooth whitening or bleaching products are currently regulated by Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. This Regulation repealed 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. The latest consolidated version of Regulation (EC) No 1223/2009 is available at <http://eur-lex.europa.eu/legal-content/EN/AUTO/?uri=CELEX:02009R1223-20150416>.

² <http://www.eudental.eu/component/attachments/attachments.html?task=download&id=1582>

³ <http://www.eudental.eu/component/attachments/attachments.html?task=attachment&id=2179>

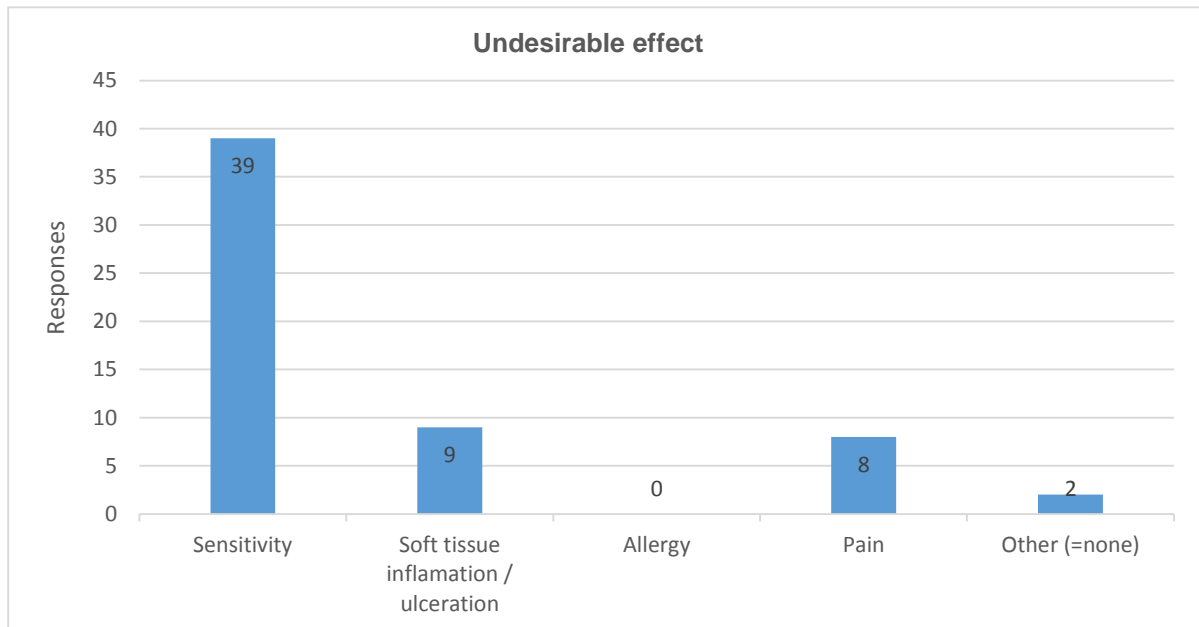
⁴ <http://www.eudental.eu/library/surveys.html>

- iii. advertise the link in their newsletter, journal, website (members only part), via other relevant national stakeholders (e.g. ministries, patients' organisations, dental schools), etc., encouraging dentists to reply;
- iv. use the CED logo in their national campaign for this specific survey if appropriate; and
- v. reassure their members that the survey is anonymous and that any undesirable effects result from the product itself and not from the dentists' professional conduct.

The survey was anonymous and the reporting of incidents voluntary. The CED only considered complete replies.

III – Survey results - general findings

1. **Number of incidents reported:** 43
2. **Countries:** 3 [Ireland (31 responses), Greece (11 responses) and the United Kingdom (1 response)]
3. **Undesirable effect:**



39 replies reported that the undesirable effect was sensitivity, of which 7 also reported soft tissues inflammation/ ulceration, of which 2 also reported pain.

9 replies reported that the undesirable effect was soft tissue inflammation/ ulceration, of which 7 also reported sensitivity, of which 2 also reported pain.

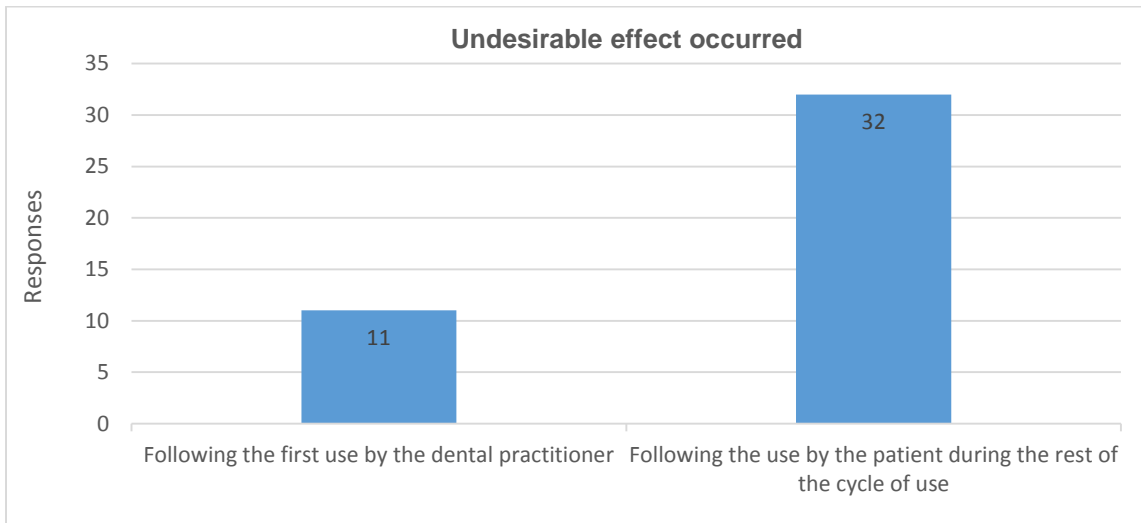
8 replies reported that the undesirable effect was pain, of which 7 also reported sensitivity, of which 2 also reported soft tissue inflammation / ulceration.

2 replies reported *other*, mentioning however that the undesirable effect was “*none*”.

No allergic reactions were reported as undesirable effect.

Conclusion: the main undesirable effect is sensitivity. This is a usual side effect and corresponds to scientific literature findings.

4. Undesirable effect occurred:

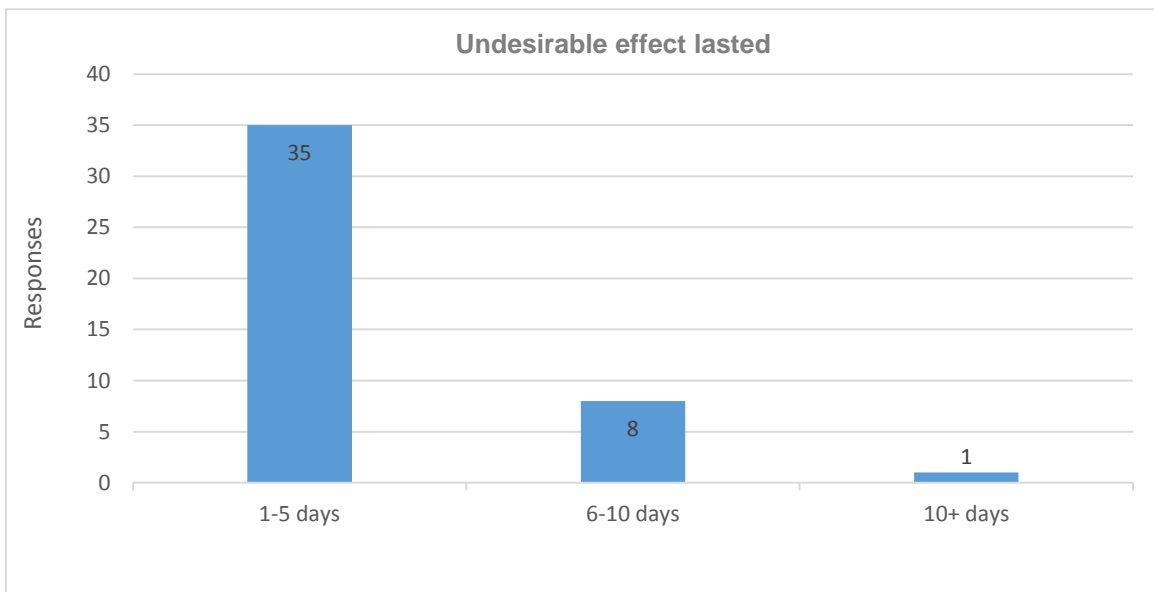


11 replies reported that the undesirable effect occurred following the first use by the dental practitioner.

32 replies reported that the undesirable effect occurred following the use by the patient during the rest of the cycle of use.

Conclusion: the responses are as expected and according to the scientific literature.

5. Duration of undesirable effect:



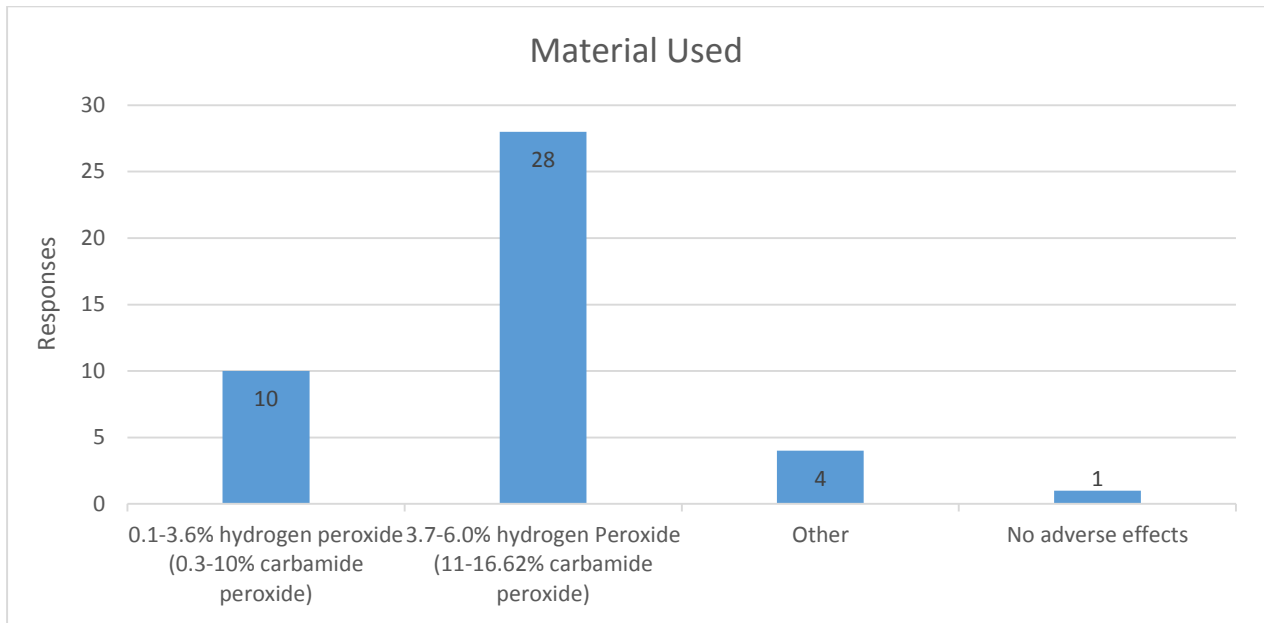
35 replies reported that the undesirable effect lasted 1-5 days.

8 replies reported that the undesirable effect lasted 6-10 days.

1 reply reported that the undesirable effect lasted more than 10 days.

Conclusion: all undesirable effects are transient, lasting on average just a few days. This is consistent with scientific literature.

6. Material used



10 replies reported concentrations between 0.1-3.6% of hydrogen peroxide (0.3-10% carbamide peroxide).

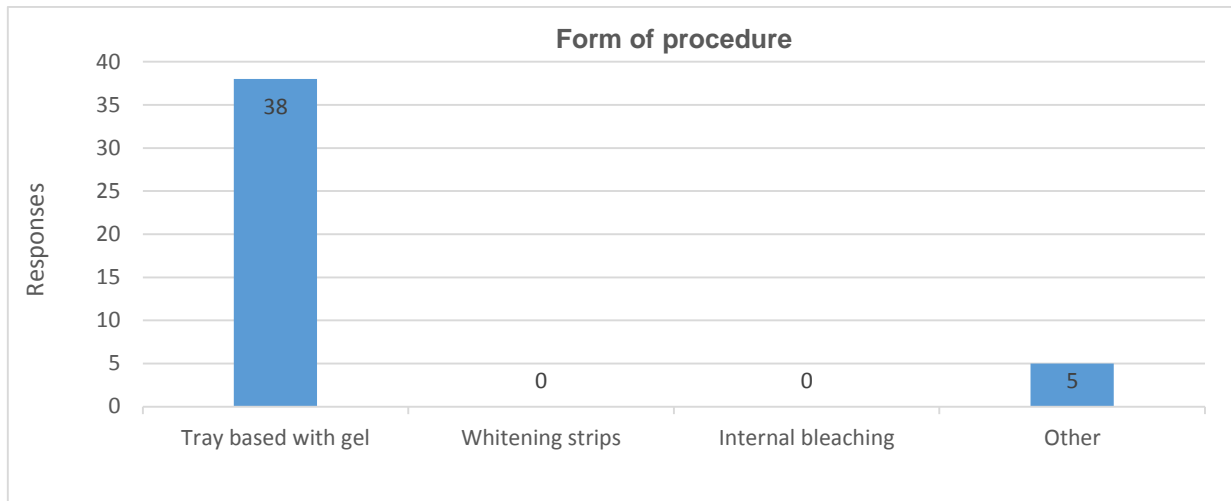
28 replies reported concentrations between 3.7-6% of hydrogen peroxide (11-16.62% carbamide peroxide).

4 replies reported *other*, out of which 1 reported both used; 1 reported 15% of hydrogen peroxide; 1 reported 25-35% of hydrogen peroxide; and 1 reported 30% of hydrogen peroxide.

1 reply “*not applicable, no adverse effects*”.

Conclusions: the regulation is not always enforced, products over 6% of hydrogen peroxide (H₂O₂) are available on the market.

7. Form of procedure:



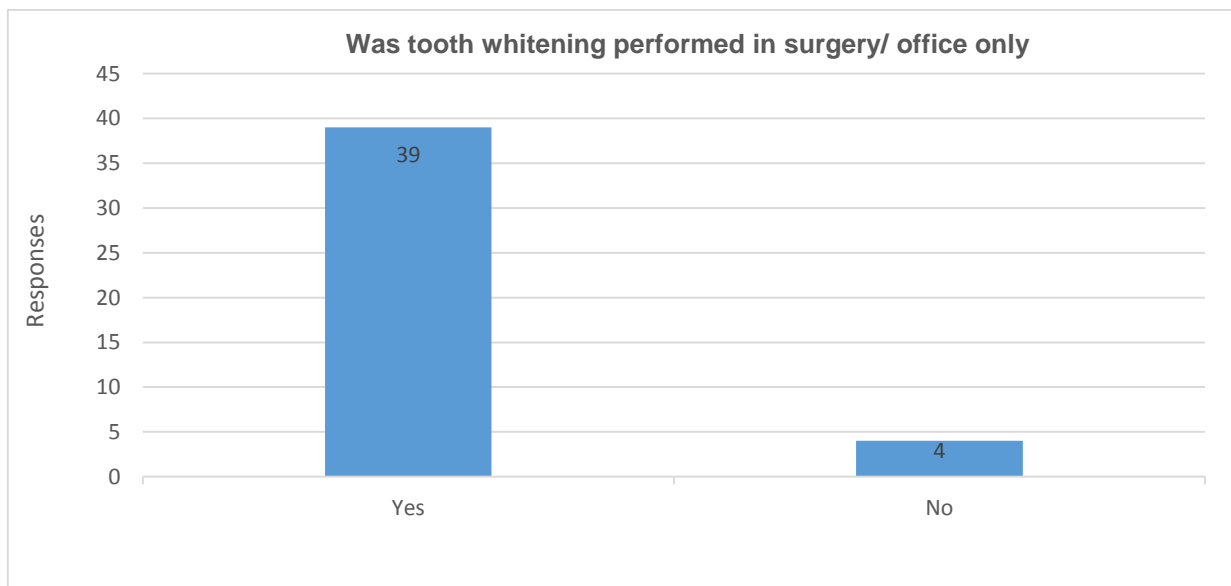
38 replies reported that the form of procedure was tray based with gel.

5 replies reported *other*, of which 1 reported laser; 1 reported “*in office whitening assisted with light*”; 1 reported “*whitening lamp and then use of tray with gel*”; and 1 reported “*directly on teeth in surgery with gum protection*”.

Conclusion: the majority of treatments which caused undesirable effects were performed with trays (however, this is also the most common form of procedure and it is in line with scientific literature).

8. Was tooth whitening performed in surgery/ office only?

[Note: this question was amended on 22 May 2015 as per suggestion of the European Commission (see Annex II). However, all the replies to this survey pre-date this change. For this reason, we maintained the question as responded by the respondents (see Annex I)].



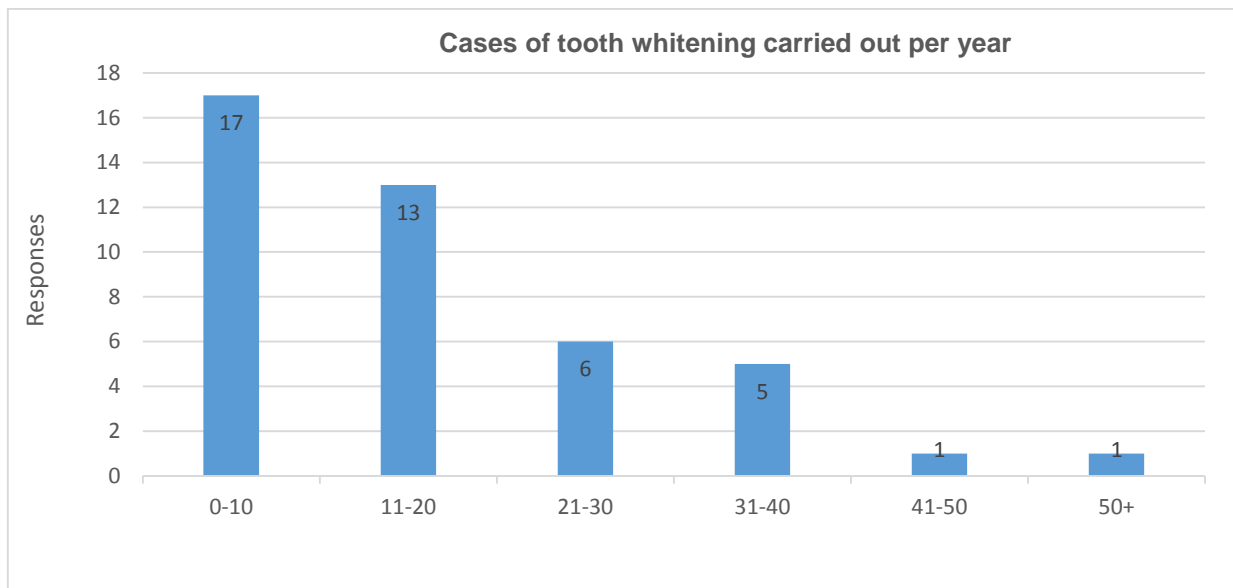
39 replies reported that tooth whitening was performed in the office/ surgery only.

4 replies reported that tooth whitening was **not** performed in the office/ surgery only, it was partly in the office/ surgery and partly by the patient in his home.

No replies reported only by a patient in his home.

Conclusion: the majority of treatments are initiated in surgery. Possible confusions in the replies, as the first application for a home kit is in office.

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



17 replies reported between 0-10 cases a year

13 replies reported between 11-20 cases a year

6 replies reported between 21-30 cases a year

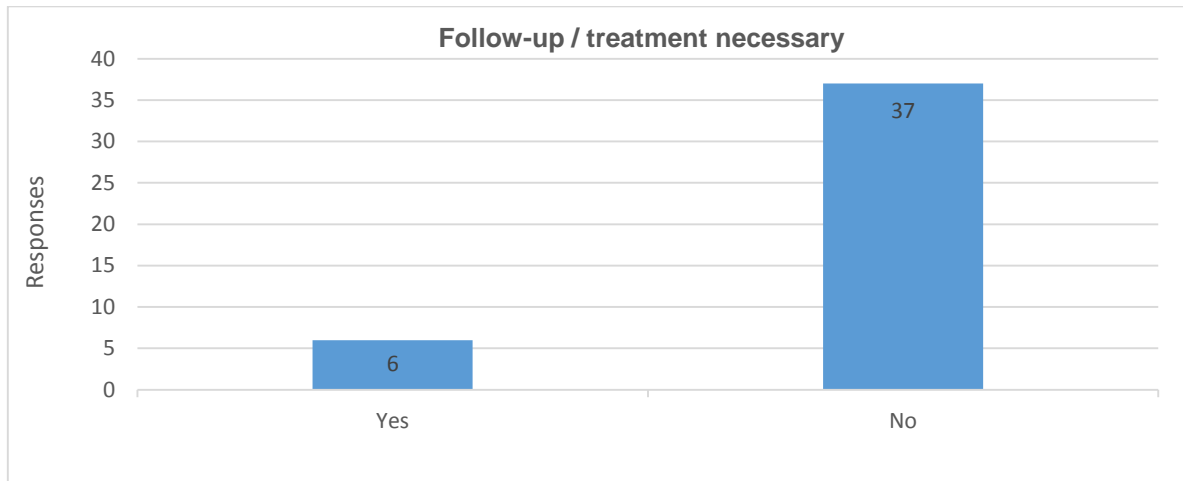
5 replies reported between 31-40 cases a year

1 replies reported between 41-50 cases a year

1 reply reported more than 50 cases a year

Conclusion: this is the normal variation of treatment prescription of tooth whitening in dental practice.

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



37 negative replies

6 positive replies. 1 reply specified that the *“it had to be explained twice to the patient that any excess of the material had to be removed from the gums”*; 1 reply specified that *“only to change colour of fillings”*; 1 reply specified *“ozone sensitive teeth”*; 1 reply specified *“application of fluoride dressing”*; 1 reply specified *“desensitisation of affected teeth and reducing number of days exposure to bleaching”*; and 1 reply specified *“review and desensitisation only”*.

Conclusion: the vast majority of undesirable effects do not require follow-up treatment.

11. Any observations?

Specific individual comments from respondents:	
	If trays are not very accurate fabricated the results are very poor.
	Treatment with sensitive toothpaste sufficient
	Available materials do not whiten teeth!
	Only mild sensitivity and it was transient
	10% Carbamide Peroxide is very safe for vital teeth.
	Some patients over bleach leaving teeth very transparent. They can become over conscious of appearance
	These events were rare

IV – Conclusions

These conclusions are a summary of what has been reported by individual dentists:

- the regulation is not always enforced, products over 6% of hydrogen peroxide are available on the market.
- in all cases, the use of tooth whitening is safe. The most common undesirable effect is sensitivity, followed by gingival irritation. Both side effects are transient.
- the findings are in line with the general scientific literature on undesirable effects caused by tooth whitening products.⁵

⁵ The CED believes that it is important to put in perspective the few undesirable effects reported in the survey by quoting scientific literature on the side effects of tooth whitening in general. The literature shows that:

- a) side effects of sensitivity are transient; once the whitening treatment is completed sensitivity stops; the main sensitivity is at day three, when there is maximum saturation of oxygen inside the tooth;
- b) allergy is extremely rare;
- c) gingival ulceration is not common and the area heals; and
- d) blotchy teeth is not common and is due to the anatomy and internal structure of the tooth. The tooth whitening process will even out the blotchy appearance. The effect is transient.

Literature:

- Home-based chemically-induced whitening of teeth in adults, Hasson H, et al. Cochrane Database Syst Rev, <http://www.ncbi.nlm.nih.gov/m/pubmed/17054282/?i=5&from=/25998351/related>
- Assessment of efficacy and post-bleaching sensitivity of home bleaching using 10% carbamide peroxide in extended and non-extended bleaching trays, Morgan S, et al. Br Dent J. 2015, <http://www.nature.com/bdj/journal/v218/n10/full/sj.bdj.2015.391.html>;
- Clinical performance of topical sodium fluoride when supplementing carbamide peroxide at-home bleaching gel, Barcellos DC, et al. Gen Dent. 2015 May-Jun, <http://www.ncbi.nlm.nih.gov/m/pubmed/25945764/?i=2&from=sensitivity%20tooth%20whitening>.

ANNEX I

THIRD CED SURVEY: DENTIST REPORT ON UNDESIRABLE EFFECTS/ ADVERSE REACTIONS 2014-2015

Welcome to the Third 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!

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:

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

7) Form of procedure:

- Tray based with gel
- Whitening strips
- Internal bleaching
- Other

8) Was tooth whitening performed in surgery/office only?

- Yes
- No

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 (Amendment to question 8 on 22 May 2015)

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Thank you for your time!

- | | |
|---|---|
| <p>1) Country:</p> | <p>7) Form of procedure:</p> <p><input type="checkbox"/> Tray based with gel</p> <p><input type="checkbox"/> Whitening strips</p> <p><input type="checkbox"/> Internal bleaching</p> <p><input type="checkbox"/> Other</p> |
| <p>2) Date of the report:</p> | <p>8) Was tooth whitening performed:</p> <p><input type="checkbox"/> in surgery/office?</p> <p><input type="checkbox"/> partly in the office/surgery and partly by a patient in his home?</p> <p><input type="checkbox"/> only by a patient in his home?</p> |
| <p>3) Undesirable effect:</p> <p><input type="checkbox"/> Sensitivity</p> <p><input type="checkbox"/> Soft tissue inflammation/ulceration</p> <p><input type="checkbox"/> Allergy</p> <p><input type="checkbox"/> Pain</p> <p><input type="checkbox"/> Other:</p> | <p>9) How many cases of tooth whitening do you carry out a year?</p> <p><input type="checkbox"/> 0-10</p> <p><input type="checkbox"/> 11-20</p> <p><input type="checkbox"/> 21-30</p> <p><input type="checkbox"/> 31-40</p> <p><input type="checkbox"/> 41-50</p> <p><input type="checkbox"/> 51+</p> |
| <p>4) Undesirable effect occurred:</p> <p><input type="checkbox"/> Following the first use by the dental practitioner</p> <p><input type="checkbox"/> Following the use by the patient during the rest of the cycle of use</p> | <p>10) Were dental or medical follow up/ treatment necessary?</p> <p><input type="checkbox"/> Yes. Please specify:</p> <p><input type="checkbox"/> No</p> |
| <p>5) Duration of undesirable effect:</p> <p><input type="checkbox"/> 1-5 days</p> <p><input type="checkbox"/> 6-10 days</p> <p><input type="checkbox"/> 10+ days</p> | <p>11) Any other observations, please specify:</p> |
| <p>6) Material used:</p> <p><input type="checkbox"/> 0.1-3.6% hydrogen peroxide (0.3-10% carbamide peroxide)</p> <p><input type="checkbox"/> 3.7-6.0% hydrogen Peroxide (11-16.62% carbamide peroxide)</p> <p><input type="checkbox"/> Other:</p> | |