5 April 2017

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DG Internal Market, Industry,
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European Commission

Brussels, 5 April 2017

Subject: Use of tooth whitening products on persons under 18 years of age in the EU

Dear Mr D'Acunto,

I - Background information

In 2007, the Scientific Committee on Consumer Products (currently replaced by the SCCS) issued an opinion on hydrogen peroxide, in its free form or when released, in oral hygiene products and tooth whitening products. This opinion provided a safety evaluation of hydrogen peroxide in oral hygiene products incorporating relevant publicly available scientific data that had become available since the previous opinion of the SCCP on "Hydrogen Peroxide in Tooth Whitening Products" (SCCP/0844/04) on 15 March 2005.

For tooth whitening products (TWPs) containing > 0.1% and ≤ 6% hydrogen peroxide, the SCCP opinion concluded that: *"In the absence of specific data on the safety of tooth whitening products in children/adolescents, the SCCP is not in a position to assess the potential health risks associated with their use in this population subgroup."*

As a precautionary measure, Directive 2011/84/EU aimed to implement the opinion of the SCCP of 2007 (later repealed by Regulation (EC) N° 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, hereinafter Regulation), **forbidding the use of TWPs** containing > 0.1% and ≤ 6% hydrogen peroxide, present or released by other compounds or mixtures such as carbamide peroxide and zinc peroxide, **on persons under 18 years of age.** This prohibition is currently regulated by entry 12 of Annex III of Regulation 1223/2009 as amended by Regulation 1197/2013.

II – Questions to the Scientific Committee

1. *Does the SCCS agree that the data in Annex I provide the necessary reassurance to support the safety of use of tooth whitening products containing > 0.1% and ≤ 6% hydrogen peroxide, present or released, in children and adolescents, when clinically indicated?*

2. *Considering the data provided in Annex I, does the SCCS recommend that the use of tooth whitening products containing > 0.1% and ≤ 6% hydrogen peroxide, present or released, in children and adolescents is performed only by a dental practitioner?*

III – CED request to the European Commission

Considering the arguments detailed below, the CED would like the European Commission to request a review of the 2007 SCCP scientific opinion in order to withdraw the current prohibition of EU legislation on the use of tooth whitening products on under 18 years of age.

It is also requested that the following changes are made to the current Regulation on Cosmetic Products concerning tooth whitening products:

- In entry 12, column h) "Restrictions", "Other" of Annex III of Regulation 1223/2009 as amended by Regulation 1197/2013, delete the statement *"Not to be used on a person under 18 years of age"*;

- In entry 12, column i) *"Wording of conditions of use and warnings"* of Annex III of the Regulation, replace the statement *"Not to be used on a person under 18 years of age"* with the following sentences:

  "The use in a person under 18 years of age to be restricted to therapeutic treatment of a discoloured tooth or of discoloured permanent teeth. For each cycle of use, the first use to be only done by dental practitioners or under their direct supervision if an equivalent level of safety is ensured. Afterwards to be provided to the parent/guardian to complete the cycle for their child under 18 years of age."

IV – Tooth whitening

The withdrawal of tooth whitening as a means of managing discoloured teeth in children has had a huge impact on the dental treatment options of children in Europe. Tooth whitening is the most conservative mean of managing teeth which are discoloured as a consequence of trauma or due to developmental or genetic causes, such as Molar Incisor Hypomineralisation (see images 5 and 6).

The photographs below are some examples of the effectiveness of tooth whitening for some of the conditions listed in section IIV

Images 1 and 2: Discolouration due to trauma following with an aesthetic result following bleaching

Images 3 and 4: Developmental opacities with aesthetic appearance following bleaching

Image 5 and 6: Discolouration due to Molar Incisor Hypoplasia- Hypo mineralisation and defects of the enamel on a 14 year old boy with an aesthetic result following bleaching

Images 7, 8 and 9: Discolouration due to fluorosis mottling and aesthetic result following bleaching

Tooth whitening in children continues to be provided in children in the rest of the world up to the present day, and has not been accompanied by any reports of harm. Long recognised as an extremely conservative means of effectively managing tooth discolouration, tooth whitening is considered the method of choice for young patients in order to avoid the more destructive forms of treatment such as veneer or full coverage restorations for immature teeth.

When treating a child, as for any patient, the over-riding aim of the dentist must be to do no harm and enable the patient to maintain good oral health. As no restoration is 100% successful, i.e. will not last forever, once a restoration has been placed, the patient enters a cycle of restorative dentistry for the rest of their life. Each time a restorative procedure is repeated, there is an inevitable further loss of tooth structure accompanied by potential pulpal damage. A number of studies have attempted to quantify the harm that may be observed through tooth preparation. Saunders and Saunders (1998) found 19% of initially vital teeth developed periapical radiolucencies following crown placement whilst Cheung et al (2005) noted 15.6% of teeth restored with full crowns became non-vital requiring endodontic treatment after 10 years.

Images 10 and 11: Discoloured incisor tooth in an 8 year old child following trauma with an aesthetic result following bleaching

No study has looked at the loss of vitality following crown preparation in children where one can safely assume the incidence of pulpal necrosis is likely to be substantially higher than in adults due to the larger size of the pulps in immature teeth in children and the closer proximity of the pulp to the enamel surface. The need to avoid over-reduction, over-heating or dehydration of the tooth during tooth preparation (Cheung 1991) and the provision of adequate pulpal protection during fabrication of the final restoration (Cheung 2002) have been well documented.

Images 12, 13, 14: Discoloured and pitted incisor teeth in a 13 year old child that were treated with bleaching to whiten the tooth followed by veneers

Image 15:
Crown preparation. Invasive prosthetic solution which can be inflicted in a child due to current prohibition

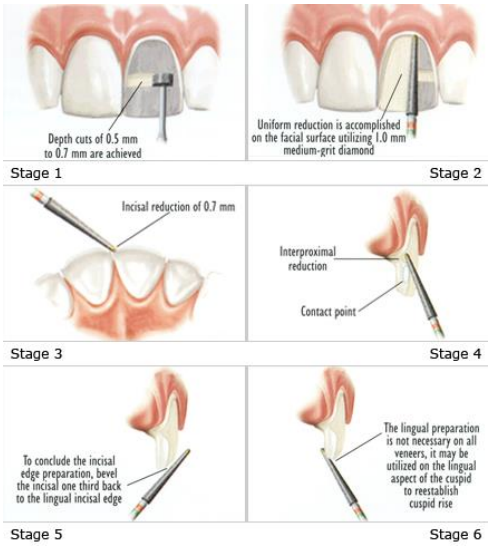

Image 16:
Veneer preparation. Invasive prosthetic solution which can be inflicted in a child due to current prohibition

Porcelain veneers are undoubtedly more conservative than full coverage crowns but they too have finite life spans and will eventually fail and require replacement. Petridis et al. (2012) in a systematic review of 9 studies where ceramic veneers were followed-up for 5-10 years noted the most frequent complication was marginal discolouration (9% at 5 years), followed by loss of marginal integrity (3.9-7.7% at 5 years). Such restorations also require the use of rotary instruments and the removal of enamel leaving the immature teeth of children even more vulnerable to loss of vitality following preparation.

The lack of literature on this subject would suggest that few children are treated in this way or more likely the poor outcomes associated with such treatment are not deemed suitable for reporting. In children the permanent teeth and associated gingival tissues are growing and maturing so that more of the crowns of the teeth become visible as the child grows – thus replacement of veneers would be required to compensate for this physiological process of growth and development. If porcelain veneers have been provided when the patient is a child, by the time the patient reaches middle age, several replacements will have been necessary. Each time more tooth tissue is lost, more extensive restorations such as crowns are likely to be necessary.

It is recognised that treatment with direct composite veneers may involve minimal or in some cases no tooth preparation. However such direct restorations change the contour of the tooth and exposed to the oral cavity composites are prone to discolour and fracture requiring repeated repair or replacement. **For this reason dentists have for many years selected to use tooth whitening as the treatment of choice to improve the aesthetics of discoloured teeth in children. Children presenting with discoloured teeth should not be denied treatment and should not be provided with inferior restorative management.** Indeed no adult presenting with teeth discoloured in a similar way to those illustrated would be provided with veneers or crowns. Why then would any parent wish such substandard treatment for their child or why should a dentist be mandated to do so?

Images 17, 18 and 19: Discoloured canine tooth in a 12 year old child with aesthetic appearance following bleaching and subsequent placement of a composite resin white veneer restoration

Children are of course aware of discoloured permanent teeth, may make negative psychosocial judgements on the basis of enamel appearance (Craig et al. 2015) and younger children may be more critical of their discoloured anterior teeth than older children (Shulman et al. 2004).

In a study that was undertaken to assess perceived needs for dental treatment (PNDT), oral health-related quality of life (OHRQoL) and oral diseases in a national representative sample of Thai school aged children, PNDT were highly associated with OHRQoL with significant odds ratios that increased incrementally by the intensity of oral impacts. Oral impacts on eating, emotional stability and smiling and

those attributed specifically to dental caries, periodontal diseases, malocclusion and tooth discolouration were associated with PNDT that were reported by children (Krisdapong et al. 2014). A recent publication highlighted the emotional vulnerability of a child in relation to delayed management of a discoloured traumatised permanent incisor (Marty 2016).

Images 20, 21:
Same case as 17,18 and 19,
after complete restoration

V – United Nations Convention on the Rights of the Child

The UN Convention on the Rights of the Child may be interpreted to support the right of the child to the most appropriate management of a discoloured permanent tooth/teeth including the use of tooth whitening agents.
The following excerpts from the UN Convention on the Rights of the Child seem relevant in this case:

- Preamble: *Recalling that, in the Universal Declaration of Human Rights, the United Nations has proclaimed that childhood is entitled to special care and assistance,*

- Preamble: *Bearing in mind that the need to extend particular care to the child has been stated in the Geneva Declaration of the Rights of the Child of 1924 and in the Declaration of the Rights of the Child adopted by the General Assembly on 20 November 1959 and recognized in the Universal Declaration of Human Rights, in the International Covenant on Civil and Political Rights (in particular in articles 23 and 24), in the International Covenant on Economic, Social and Cultural Rights (in particular in article 10) and in the statutes and relevant instruments of specialized agencies and international organizations concerned with the welfare of children,*

- **Article 3. 1**. *In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration.*

- **Article 12. 1.** *States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child.*

The following excerpt from the principles of the Constitution of the **World Health Organization** also seem to be relevant:

- *Healthy development of the child is of basic importance; the ability to live harmoniously in a changing total environment is essential to such development.*

The appropriate dental management of a discoloured permanent tooth/teeth in a child may require the use of a tooth whitening product containing hydrogen peroxide up to 6%. Tooth whitening treatment using a tooth whitening product containing hydrogen peroxide up to 6% should not be denied to a child, who on best clinical judgement requires bleaching of a discoloured permanent tooth/teeth. Inadequate treatment including prosthetic solutions or removal of sound tooth substance or even non-treatment of a discoloured tooth/teeth in a child who requires treatment of his/her discoloured tooth/teeth, with a tooth whitening product containing hydrogen peroxide up to 6%, may inflict severe and prolonged psychological distress in a child and be detrimental to the child's health and wellbeing.

VI – Relevance to EU policy and objectives

A change of the EU legislation is required to allow the use of TWPs on persons under 18 years of age. This is to provide the best possible and least invasive treatment for this age subgroup. This change is in the interest of consumers and contributes to improving the public health of EU citizens (Articles 169 and 168 of TFEU).

Furthermore, new scientific data is currently available which directly relate to the safety of use of TWPs in permanent teeth of children and adolescents [please see Annex I, references 2, 3, 4, 5, 11, 13, 14, 15, 16, 18, 20, 25, 26, 28, 29, 30, 31, 32 and 33].

In addition, certain references mentioned in Annex I have never been discussed or analysed by the Scientific Committee in its 2007 Opinion [please see Annex I, references 1, 6, 7, 8, 9, 10, 12, 17, 19, 21, 22, 23, 24 and 27]. This data needs to be scientifically assessed in order to re-evaluate the current Regulation on the use of TWPs on under 18's and to correctly reply to the oral health needs of this age subgroup.

VII - Importance of withdrawing prohibition for the health of this age subgroup

Between 2012 and 2016, the CED conducted several inquiries about the safety of use of concentrations > 0.1% and ≤ 6% hydrogen peroxide on under 18's, mobilising a network of experts across the EU with the support of its members.

It is against the rights of a child for a dentist to refuse to treat discoloured permanent tooth/teeth in a patient under 18 years of age, as this could cause psychological damage to the child associated with an unaesthetic discoloured permanent tooth/teeth. From a clinical and ethical point of view, to offer only the options of *"no treatment"* or *"treatment with significant drilling of tooth/teeth for crown preparation"* to improve the discoloured appearance of a tooth/teeth is unacceptable.

VIII - Letters of support

The CED contacted different organisations to know their opinion about this prohibition, in particular the European Academy of Paediatric Dentistry (EAPD).[1] In a letter of support, the EAPD President, Professor Dr Paddy Fleming, advises that: *"the current EU Cosmetic Directive that forbids the use of tooth whitening product containing Hydrogen Peroxide up to 6% in people under 18 years of age, should be changed so that the use of such tooth whitening products may be used in children when clinically indicated and that such treatment should be provided by a dentist"* (please see Annex II for integral letter from 16 February 2015).

[1] The EAPD is a not-for-profit organisation of individuals whose primary concern is in the area(s) of practice, education and/or research specifically related to the specialty of Paediatric Dentistry. It purpose shall be the advancement of the specialty of Paediatric Dentistry for the benefit of the oral health of children.

IX – Published scientific literature exists to withdraw current prohibition on under 18's

The CED analysed current scientific bibliography (please see Annex I) and is able to recommend the following:

a) The use of tooth whitening products with concentrations > 0.1% and ≤ 6% hydrogen peroxide is safe and needed to treat patients under 18 years of age; the use of tooth whitening products with concentrations > 0.1% and ≤ 6% hydrogen peroxide, present or released, should be allowed on under 18's when it is clinically indicated and should be performed only by a dental practitioner;

b) In particular, tooth whitening in children is frequently clinically indicated in the following conditions (non-exhaustive list):

i. discolouration of a non-vital tooth or non-vital teeth;
ii. developmental opaque white spots/ white marks/ white lesions on anterior teeth;
iii. developmental brown or yellow markings on anterior teeth;
iv. molar incisor hypomineralisation
v. fluorosis;
vi. intrinsic discolouration due to antibiotics;
vii. systemic diseases causing intrinsic discolouration, such as liver disease, kidney disease;
viii. genetic conditions - amelogenesis imperfecta and dentinogenesis imperfecta;
ix. post orthodontic white spots and hypomineralisation;
x. any other opacity or discoloration affecting the quality of life of the child.

The CED is ready to assist you in any way they can, and we look forward to hearing from you.

Yours sincerely,

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Document reviewed and initiative supported by:

- European Academy of Paediatric Dentistry, special gratitude to Prof Dr Paddy Fleming;
- Dr Katheryn Harley (UK), Specialist in paediatric dentistry;
- Prof Dr Michael Noack (DE), Director of the Department of Operative Dentistry and Periodontology, University Hospital of Cologne;
- Prof Dr Roeland De Moor (BE), Restorative Dentistry, Endodontics, Dental Traumatology, Lasers in dentistry of Ghent University

Annex I: Collection of scientific bibliography on the safety of use of tooth whitening products on persons under 18.
Annex II: Letter from the European Academy of Paediatric Dentistry

Annex I:

Collection of scientific bibliography on the safety of use of tooth whitening products on persons under 18 years of age not discussed by the Scientific Committee on Consumer Safety (previously known as SCCP)

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