Tooth Whitening Advocacy Document: Focus on national level

Overview

This advocacy document focuses on reversing the European ban on using tooth whitening products in patients under 18 years of age. It contains the following sections:

1. Objective
2. Context
3. Use of the document
4. Previous CED activities
5. Required action from national dental associations
6. Speaking points
7. Annex

1. Objective

The goal is to withdraw the current prohibition of EU legislation on the use of tooth whitening products on patients under 18 years of age (*for more detailed background see Annex)*. Such a change will provide the best possible and least invasive treatment for this age subgroup and is therefore in the interest of patients, and contributes to improving the public health of EU citizens (as outlined in Articles 169 and 168 of TFEU).

The CED believes that this change could be brought about with a review of the topic by the Standing Committee on Cosmetics Products. Participants of this Committee come from the Member States' authorities, including the health ministries or medical products agencies, environment, business and consumer protection ministries, depending on the country[1].

The use of tooth whitening products in patients under 18 is not intended for aesthetic improvement but for patients with a clinical indication, such as molar incisor hypomineralisation (MIH), traumatised/non-vital discoloured anterior teeth, fluorosis, genetic conditions like amelogenesis imperfecta and dentinogenesis imperfecta, discolouration of non-vital teeth, etc.

2. Context

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. For tooth whitening products (TWPs) containing > 0.1% and ≤ 6% hydrogen peroxide, the SCCP opinion concluded that: "In the absence of specific

[1] See full list of participants in Annex.

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As a precautionary measure, Directive 2011/84/EU aimed to implement the opinion of the SCCP of 2007 (later repealed by Regulation (EC) N° 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, hereinafter Regulation), **forbidding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.

3. Use of the document

This document is based on the safety dossier on tooth whitening in persons under 18 that the CED sent to the European Commission in April 2017. The present document can **be used to approach relevant stakeholders like health ministries, chief dental officers, regulators, paediatric dental associations and others** in different countries in order to gather bottom-up support for **a reversal on the ban of tooth whitening** in persons under 18. As the already mentioned CED safety dossier was not accepted by the European Commission, the CED aims to still tackle the tooth whitening issue by leveraging the topic through national level stakeholders, such as the CDOs, paediatric dental associations and health ministries.

4. Previous activities

The CED previously worked with different organisations to reverse the ban, in particular the European Academy of Paediatric Dentistry (EAPD).[2] In a letter of support, the EAPD President, Professor Dr Paddy Fleming, advised 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).

Between 2012 and 2016, the CED conducted several inquiries about the safety of use of concentrations > 0.1% and ≤ 6% hydrogen peroxide on patients under 18, mobilising a network of experts across the EU with the support of its members.[3]

5. Required Action from national dental associations

- Get in touch with relevant and influential stakeholders like CDOs, paediatric dental associations, children's commissioners, national ministries, etc. in order to identify their

[2] 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.
[3] To be accessed via the CED website: https://cedentists.eu/library/surveys.html

thinking on tooth whitening in patients under 18, as well as on the significance this ban has had on your specific country.

- Highlight that the prohibition of using tooth whitening materials for a patient under 18 years of age is unnecessary; changing it is in the interest of patients, and contributes to improving the public health of EU citizens, providing that the treatment is being done by a registered dentist for the purpose of treatment or disease prevention[4]. Remind that the dentist takes full professional responsibility for the safety of the treatment provided.
- Identify whether any other national stakeholders have worked on this issue and outlined their position on the matter (e.g. paediatric dentistry organisations).
- Work together with stakeholders, for example CDOs, to reach a common support statement on the need to reverse the ban as well as to increase awareness on the issue among relevant national stakeholders.
- Identify the position of your national Ministry of Health and try to obtain their support in raising the issue at the Standing Committee on Cosmetics Products as well as in other relevant supranational meetings.

6. Speaking Points

Tooth Whitening and Safety

- **Where deemed appropriate by a dentist, tooth whitening is the most conservative measure, leading to the least amount of future damage in relation to maintenance of the results**: options such as porcelain veneers lead to greater complications as the young patient reaches adulthood: for example, if 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, meaning that more extensive restorations such as crowns are likely to be necessary.
- **It is a world-wide, common practice:** Tooth whitening in children continues to be provided in the rest of the world up to the present day, and has not been accompanied by any reports of harm.
- **While other options for treatment exist, tooth whitening remains the best possibility in the long-term:** for example, direct composite veneers may involve minimal or in some cases no tooth preparation, however such direct restorations change the contour of the tooth, are prone to discolouring and fracturing, and thus require repeated repair or replacement.
    - **Why not other procedures – what is the problem with repeated repair?** No restoration is 100% successful, i.e. will not last forever. Therefore, 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

[4] General Dental Council, UK, *Position Statement on Tooth Whitening*, https://www.gdc-uk.org/api/files/Tooth-Whitening-Position-Statement.pdf

(2005) noted 15.6% of teeth restored with full crowns became non-vital requiring endodontic treatment after 10 years.

- Alternative procedures lead to more interventions and greater damage in the long-term, directly affecting quality of life: in a study (Krisdapong et al. 2014) 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. Such associations increased incrementally by the intensity of oral impacts (e.g., on eating, emotional stability and smiling), especially in relation to dental caries, periodontal diseases, malocclusion and tooth discolouration, as reported by the children in the sample.

Tooth Whitening and the Patient

- **Denying an existing solution is against the best interests of the patient, causing more harm than good:** 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.
- **It is against the rights of a child (***see relevant points from the UN Convention on the Rights of the Child and the Constitution of the World Health Organisation in Annex***) for a dentist to refuse to treat discoloured permanent tooth/teeth in a patient under 18 years of age**, leading to many complications related to the child's health and wellbeing.
- **What kind of complications would those be?**
  - **Denying this treatment can have long term implications for a child's psychological and social wellbeing:** not using the opportunity to provide such treatment means that children, being aware of discoloured permanent teeth, may make negative psychosocial judgements on the basis of enamel appearance (Craig et al. 2015).
  - **Delaying a treatment is not an option, as it also has implications on the child's mental wellbeing**: a recent publication highlighted the emotional vulnerability of a child in relation to delayed management of a discoloured traumatised permanent incisor (Marty 2016).
  - **The younger children are in a more vulnerable situation,** as they may be more critical of their discoloured anterior teeth than older children (Shulman et al. 2004), leading to permanent problems with self-perception and confidence.

ANNEX: Additional Resources

List of Participants to Standing Committee on Cosmetic Products

Bundesministerium für Gesundheit AGES	AT
SPF Santé Publique	BE
Ministry of Health	BG
Permanent Representation of Cyprus to the EU	CY
National Institute of Public Health	CZ
Bundesministerium für Ernährung und Landwirtschaft (BMEL)	DE

Chemisches und Veterinäruntersuchungsamt (CVUA) Karlsruhe	
Danish Env. Protection Agency	DK
Agencia esp. de Med. y Prod. Sanitarios	ES
Health Board	EE
Ministry of Social Affairs and Health	FI
ANSM DGCCRF Ministère de la Santé	FR
	EL
Ministry of Health	HR
National Institute of Pharmacy and Nutrition	HU
	IT
IMB – Dpt of Health	IE
Public Health Laboratory Center	LT
Ministère de la Santé	LU
Dpt of Public Health	LV
	MT
Ministry of Health, Welfare and Sport	NL
Chief sanitary Inspectorate Ministry of Economic Development	PL
Infarmed	PT
Ministry of Health	RO
Swedish Medical Products Agency	SE
Ministry of Health	SI
Public Health Authority of the Slovak Republic	SK
Dpt for Business, Energy & Industrial Strategy LGC	UK
Norwegian Food Safety Authority	NO

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.*

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)

1. Attal J-P, Atlan A, Denis M, Vennat E, Tirlet G, *White spots on enamel: treatment protocol by superficial or deep infiltration (part 2),* Int Orthod Collège Eur Orthod. March 2014;12(1):1-31;
2. Bannister R., Harley K., *Vital bleaching for the management of hypomineralised enamel defects*, Faculty Dental Journal, July 2012, Volume 3, Issue 3, DOI 10.1308/204268512X13376834221550;
3. Castro KS, de Araújo Ferreira AC, Duarte RM, Sampaio FC, Meireles SS, *Acceptability, efficacy and safety of two treatment protocols for dental fluorosis: A randomized clinical trial*, J Dent. août 2014;42(8):938-44;
4. Cheung GSP, Lai SCN, Ng RPY, *Fate of vital pulps beneath a metal-ceramic crown or a bridge* retainer, Int Endod J. 2005; 38:521-30;
5. Cheung GSP., *A preliminary investigation into the longevity and causes of failure of single-unit extracoronal restorations*, J Dent. (1991); 19:160-3;
6. Cheung GSP., *Survival of first-time nonsurgical root canal treatment performed in a dental teaching hospital*, Oral Surg Oral Med Oral Pathol Oral Radiol Endod (2002); 93: 596-604;
7. Council on Clinical Affairs of the American Academy of Paediatric Dentistry, *Policy on the Use of Dental Bleaching for Child and Adolescent Patients*, review from 2014;
8. Craig SA, Baker SR, Rodd HD., *How do children view other children who have visible enamel defects?*, Int J Paediatr Dent 2015; 25: 399-408;
9. Croll TP, Donly KJ, *Tooth bleaching in children and teens*, J Esthet Restor Dent Off Publ Am Acad Esthet Dent Al. juin 2014;26(3):147-50;
10. Croll TP, Sasa IS, *Carbamide peroxide bleaching of teeth with dentinogenesis imperfecta discoloration: report of a case*, Quintessence Int Berl Ger 1985. oct 1995;26(10):683-6;
11. Donly KJ, *The adolescent patient: special whitening challenges*; Compend Contin Educ Dent Jamesburg NJ 1995. avr 2003;24(4A):390-6;

12. FDI policy statement on dental bleaching materials, adopted by the FDI General Assembly:17 September 2011, Mexico City, Mexico, http://fr.slideshare.net/AxexDental/fdi-policy-statement-on-dental-bleaching-materials-adopted-by-the-fdi-general-assembly-17-september-2011-mexico-city-mexicoid-j12013

13. Greenwall, L., *Therapeutic aesthetics*, May 2014;

14. Greenwall-Cohen, J., Greenwall, L., Haywood, V., Harley, K. *Tooth whitening for the under-18-year-old patient*. British Dental Journal 2018 225(1): 19-25;

15. Haywood VB, *Bleaching children's teeth: questions and answers*, Ga Acad Gen Dent Newsl. 2006;4-7;

16. Haywood VB, *Treating sensitivity during tooth whitening*, Compend Contin Educ Dent Jamesburg NJ 1995. sept 2005;26(9 Suppl 3):11-20;

17. Kelleher M., *The law is an ass: legal and ethical issues surrounding the bleaching of young patients' discoloured teeth*, Faculty Dental Journal, April 2014, Volume 5, Issue 2;

18. Krisdapong S, Prasertsom P, Rattanarangsima K, Sheiham A., *Associations between perceived needs for dental treatment, oral health-related quality of life and oral diseases in school-aged Thai children*, Community Dent Oral Epidemiol 2014; 42:323-32;

19. Kugel G, Gerlach RW, Aboushala A, Ferreira S, Magnuson B, *Long-term use of 6.5% hydrogen peroxide bleaching strips on tetracycline stain: a clinical study*. Compend Contin Educ Dent Jamesburg NJ 1995. Oct 2011;32(8):50-6;

20. Lee SS, Zhang W, Lee DH, Li Y, *Tooth whitening in children and adolescents: a literature review*, Pediatr Dent. Oct 2005;27(5):362-8;

21. Leith R1, Moore A, O'Connell AC., *An effective bleaching technique for non-vital, discoloured teeth in children and adolescents*, J Ir Dent Assoc. 2009 Aug-Sep;55(4):184-9;

22. M.J. Noack, Ö. Padrok, K. Höfer, *Zahnaufhellung – medizinisch indiziert*, DOI http//dx.doi.org 10.1055/s-0035-1545301 ZWR – Das Deutsche Zahnärzteblatt 2015; 124: 96-100;

23. Marty M., *Time Loss*, JDR Clinical & Translational Research 2016; 20(10); 1-2;

24. Parinitha M. S., Annapoorna B. M., Sunil Tejaswi, Suneeth Shetty, Sowmya H. K., *Effect of power bleaching on the fluorosis stained anterior teeth case series*, J Clin Diagn Res JCDR. août 2014;8(8):ZJ01-3;

25. Petridis HP, Zekeridou A, Malliari M, Tortopidis D, Koidis P, *Survival of ceramic veneers made of different materials after a minimum follow-up period of five years: a systematic review and meta-analysis*, Eur J Esthet Dent. 2012; 7(2): 138-52;

26. Saunders WP, Saunders EM, *Prevalence of periradicular periodontitis associated with crowned teeth in an adult Scottish subpopulation*, Br. Dent J. Aug.1998; 185(3): 137-40;

27. Shulman JD, Maupomé G, Clark DC and Levy SM., *Perceptions of desirable tooth color among parents, dentists and children*, J Am Dent Assoc 2004; 135: 595-604;

28. Sujak SL, Abdul Kadir R, Dom TNM, *Esthetic perception and psychosocial impact of developmental enamel defects among Malaysian adolescents*, J Oral Sci. December 2004;46(4):221-6;

29. Sundfeld RH, Rahal V, Croll TP, De Alexandre RS, Briso ALF, *Enamel microabrasion followed by dental bleaching for patients after orthodontic treatment--case reports*, J Esthet Restor Dent Off Publ Am Acad Esthet Dent Al. 2007;19(2):71-7; discussion 78;

30. Tom L. Beauchamp and James F. Childress, *Principles of biomedical ethics*, 10 January 2013, seventh edition, Oxford University Press;

31. Van B. Haywood, *Orthodontic caries control and bleaching*, Inside Dentistry, April 2010;

32. Van B. Haywood, *Pre-bleaching Exam Vital for Optimum Whitening*, www.dentalaegis.com/cced, Compedium, January 2012;

33. Wolff A, Stark H, Sarnat H, Binderman I, Eisenstein B, Drukker A., *The dental status of children with chronic renal failure*, Int J Pediatr Nephrol. 1985 Apr-Jun;6(2):127-32;

34. Yiming Li, *Toxicological considerations of tooth bleaching using peroxide-containing agents*, The Journal of the American Dental Association, April 1997,Volume 128, Supplement, Pages 31S–36S;

35. United Nations (www.un.org), Convention on the Rights of the Child http://www.ohchr.org/en/professionalinterest/pages/crc.aspx.

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