Tooth Whitening/Dental Bleaching Products Containing Hydrogen Peroxide in the European Union

Proposals to Modify Current Regulations - Submitted to the European Union Scientific Committee on Consumer Products (SCCP)

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Prepared by:
Steven L. Ziemba, M. Sc.
Fullerton Regulatory & Clinical
Fullerton, California, 92835 USA
909.437.1630
714.990.2254 – fax
steve@fullertonreg.net

NOTE: Mr. Ziemba is a professional regulatory consultant and has drafted these comments in the interest of furthering public policy and appropriate regulation of dental whitening products in the European Union.

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Overview

Tooth whitening preparations, commonly known as dental bleaching gels, have been the subject of much discussion in Europe as to whether they are properly classified as cosmetics and where limits should be placed regarding the maximum acceptable concentrations of hydrogen peroxide. The Cosmetics Directive 76/768/EEC classifies whitening products as cosmetics with a maximum allowable concentration for hydrogen peroxide of 0.1%. The Directive is not clear on what the status should be for whitening products with a higher peroxide concentration. In the U.K., a series of legislative acts ultimately resulted in a stance wherein the supply of any cosmetic whitening product that contains more than 0.1% hydrogen peroxide is classified as a punishable offense but insofar as it is known, no firms have been restricted from selling such products in the other Member States.

Notwithstanding, several firms who market whitening products with more than 0.1% hydrogen peroxide, have classified their products as medical devices under the Medical Device Directive 93/42/EEC[1]. Since there are few, if any, published clinical safety issues associated with whitening products, these firms have been able to achieve the "CE Mark" from various Notified Bodies required for marketing medical devices. Thus, these firms are not bound by the Cosmetic Directive's concentration restriction and they therefore legally market their products within the EU with a hydrogen peroxide content as high as 35% or as high as they are able to substantiate as being clinically safe with their Notified Body.

Thus, a conundrum exists as EU Medical Device Directive 93/42/EEC makes it clear that products with a CE Mark may be legally marketed *anywhere* in the EU. In Germany, the courts have affirmed this, yet in Spain, the government requires they be marketed with some restrictions as dental devices. In Great Britain, the case of *Optident Limited and Ultradent Productions Inc –v- Secretary of State for Trade and Industry and Secretary of State for Health* confirmed that a whitening gel with a hydrogen peroxide content of 3.4% is nonetheless a cosmetic product and the marketing of that gel as a medical device in Great Britain, despite its CE Mark, was not allowed as it was necessarily a violative cosmetic due to its peroxide content. Further, since the

[1] The rationale for this is based upon the definition in Annex IX of 93/42/EEC that an "invasive device" is anything which, in whole or in part, penetrates inside the body, either through a body orifice, or through the surface of the body. As peroxide-based whitening products are used intra-orally and are widely believed to penetrate the teeth, they are defined to have penetrated the body and are thus classified as Class IIa invasive devices for transient use.

European Cosmetics Directive limits the hydrogen peroxide content of cosmetics to less 1%, the gels in the aforementioned case do not qualify as legally marketed cosmetics in the U.K. The case for marketing whitening gels with more than 0.1% hydrogen peroxide therefore appears muddled defined in the E.U.: Spain classifies them as dental devices, Germany classifies them as medical devices and there is no legal provision for their marketing in the U.K. because the hydrogen peroxide content exceeds that allowed for cosmetic devices.

The ambiguity exists because "grandfathered" provincial regulations define bleaching of vital teeth as a cosmetic procedure but, as mentioned, the Cosmetic Directive excludes virtually all teeth bleaching agents. Despite this, many firms openly market such products throughout the European Union, including the U.K.; for example:

The Teethwhite Laboratory System (approx. 5% hydrogen peroxide)
Nu Radiance Whitening System (approx. 22% carbamide peroxide)
BrtiteSmile Professional Teeth Whitening Treatment (approx. 28% hydrogen peroxide)
Pola Advanced Tooth Whitening System (approx. 35% hydrogen peroxide)

The Optident/Ultradent case makes it clear that, in some cases, the law could actually be enforced in the U.K., but in the E.U. (and perhaps even in the U.K.) one must assume a *de minimus* concept as the governments clearly have not chosen to restrict other firms from marketing high-peroxide content whitening gels. Further, since there are no documented enforcement cases regarding actions against violative dental whitening gels in the U.K. one may conclude that the U.K. government appears unwilling to enforce its own regulation of low-peroxide content whitening products. As a result, there are many dental whitening products (with as much as 35% hydrogen peroxide) that are readily available in the E.U. and even within the U.K.

Although products with high concentrations of hydrogen peroxide (i.e., greater than 6%) generally produce excellent results with few complications, they are usually administered under the supervision of a dental professional. However, their peroxide concentration does have the potential to cause dentinal hypersensitivity, irreversible pulpitis and irritation to the mucous membranes if used inappropriately or even if used properly on the wrong patient (e.g., patients with deep fissures or frank cracks in their teeth are extremely susceptible to irreversible pulpitis if the peroxide gel penetrates the tooth to the pulp/nerve). But even the "over-the-counter" whitening products, used without professional supervision, should not be construed as being completely safe as side-effects associated with their over-use have been documented[2].

Thus, the public policy at work here appears to be ineffective at best and at worst, missing the point; which should be consumer protection. If one assumes that the restrictions on peroxide content are based on safety considerations, the *de minimus* approach is potentially dangerous in that essentially ***all*** whitening products currently marketed in the E.U., and in Great Britain as well, have peroxide contents that can cause harm to oral/gingival tissues if used improperly. To that end, revising this directive to limit cosmetic dental whitening products to a maximum

[2] See: Opinion of the Scientific Committee on Cosmetics Products and Non-Food Products intended for consumers concerning Hydrogen Peroxide (Carbamide, Zinc) Peroxide in Tooth Bleaching/Whitening Products, 17 September, 2002)

hydrogen peroxide content of 6% will have essentially zero effect on protecting consumers as even at that level, the products can cause harm. Many whitening strips will easily conform within this limit but they remain products with peroxide contents high enough to cause complications and they will be marketed in apothecaries without professional dispensing or any dental supervision. Thus, optimal protection of public cannot be ensured. To ensure that, the dispensing of all take-home whitening gel preparations should only be through professional channels and professional supervision of their use encouraged. The use of dental whitening strips or take-home dental whitening gels to be used with overnight or all-day trays can truly only be considered safe if the products are professionally fitted and their use monitored by dental professionals.

Higher peroxide-content gels ("chairside gels" with as much as 35% peroxide) are the fastest growing segment of professional bleaching but because of their formulations, their use is, and must continue to be, professionally administered and monitored. The peroxide concentration in these gels is quite effective at whitening but it can quickly and easily cause significant damage to mucosal membranes, the dentinal pulp or tissues surrounding the mouth if used improperly. Significant dentinal hypersensitivity is a common sequelae to this procedure that can be mitigated by professional application of fluorides or other preparations. Most parties would agree that these products carry much more risk than products with lower peroxide contents, but these products continue to defy E.U. and U.K. regulations and are openly marketed without valid CE Marks in the E.U. and without any legal approval in the U.K. If the Cosmetics Directive is modified to limit dental whitening strips and gels to a 6% hydrogen peroxide content, the very popular chairside whitening products will still remain easily available and patients will be exposed to considerable risk. We therefore recommend they be properly classified as Class IIa medical devices requiring professional supervision, even in the U.K. Great Britain, and the proper distribution of them monitored and managed as medical devices.

Classification of chairside whitening gels as medical devices also affords better protection of the public as the manufacture of such devices would therefore be required to conform with stringent "good manufacturing practices" specified under current ISO 13485 guidelines as well as preclinical in vivo safety testing specified in ISO 10993. Cosmetics are not required to conform with such guidelines and are therefore produced with little or no oversight.

Recommendations:

The SCCP should move to protect consumers as much as possible but make its regulation comprehensive and clear. The confused situation exists today because all commercially sold dental bleaching agents do not conform with the Cosmetic Directive and because some of the Member States have decided to restrict access to the bleaching agents by requiring they be classified as Class IIa medical devices. The SCCP should move to clarify this as follows:

1. Dental whitening/bleaching products with low (<6%) peroxide content, such as whitening strips and all-day or overnight trays, should be continue to be allowed to be marketed as cosmetics, but should be required to be dispensed only through dental practices. Appropriate package inserts explaining the risks of the products and precautions to be followed to ensure

their safe use should be required. This will require professional supervision and should reduce potential health risks.

2. Dental whitening products with higher (>6%) peroxide contents, such as chairside whitening gels, should continue to be allowed to be marketed throughout the E.U., *including Spain and Great Britain*, as Class IIa medical devices. As Class IIa medical devices under 93/42/EEC, they would be required to conform with ISO 13485 manufacturing standards, pass ISO 10993 pre-clinical safety testing requirements and be dispensed only by dental professionals, which would ensure appropriate professional supervision and greater protection of the public.

3. The Cosmetics Directive should be modified to state that bleaching agents with 6% or less peroxide qualify as cosmetics but are required to be dispensed only through dental professionals and that bleaching agents with more than 6% peroxide are medical devices, requiring CE Marking with dispensing allowed only through dental professionals.

When properly used, bleaching of vital teeth has been extremely safe, but risks to teeth and adjacent tissues are present along with varying degrees of dentinal hypersensitivity which can occur in the patient population. Thus, significant health risks exist for these products and their use can result in significant discomfort for some patients. The only way to minimize these risks and eliminate sensitivity reactions is to require dental professionals to properly screen inappropriate patient candidates and maintain appropriate professional dental supervision before, during and after treatment. Treatment performed or monitored by a dental professional ensures maximum patient safety. The only way to ensure that professional supervision will occur is to require that low-peroxide (<6%) whitening products be dispensed by a dental professional and to require that high peroxide dental whitening products ($\geq$6%) be treated as Class IIa medical devices requiring dispensing and supervision of a dental professional.

S. Ziemba
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