

## **Tooth Whitening – Guidance to the Dental Profession**

### **Introduction**

The Regulations regarding Tooth Whitening changed on 31 October 2012 and dentists have received the joint statement issued by the Dental Council and the Irish Medicines Board regarding the implementation of the new Regulations. The Regulations increase the percentage of hydrogen peroxide allowed in tooth whitening or bleaching products to 6%, subject to conditions which include first use by a dental practitioner.

The new Regulations allow the use, for tooth whitening, of hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide. The maximum concentration that may be used for tooth whitening under the Regulations is 6% present or released. This is the equivalent of 16.62% carbamide peroxide, which, in Ireland, has been rounded up to 17%. If using a compound or mixture other than hydrogen peroxide the dentist should check the levels of hydrogen peroxide released from the product with the supplier.

The Regulations stipulate that products containing or releasing up to 6% hydrogen peroxide can be used, subject to conditions:

- To only be sold to dental practitioners
- For each cycle of use, first use by a dental practitioner
- Afterwards to be provided to the consumer to complete the cycle of use
- Not to be used on a person under 18 years of age.

### **Responsibility of the dentist**

The dentist must examine the patient to determine whether tooth whitening is a suitable treatment option and as a result products should only be supplied to patients under the dentist's care. As with any treatment, the dentist must ensure that tooth whitening is an appropriate treatment and that the oral examination and the consent process is thorough and carefully documented.

The requirement that the first use of each cycle is by the dentist means that tooth whitening products containing or releasing more than 0.1% hydrogen peroxide cannot be sold to patients at reception or by post. It is important that, during this first use appointment every effort is made by the dentist to ensure that the use by the patient of the bleaching agent is as efficient and effective as possible and that the risk of swallowing of the bleaching agent by the patient has been minimised.

The dentist should therefore check to ensure:

- the proper size and fit of the tray in the patient's mouth,
- the ability of the patient to seat the tray properly in the mouth,
- proper loading of bleaching agent, in the correct amount, by the patient, into the tray,
- the patient is avoiding swallowing of any bleaching material.

The dentist should also ensure that a note of all instructions given to the patient at this first appointment is included in the patient record.

After the first in-surgery application, the patient can be provided with the product for home use. If any additional product is required to complete that course of treatment the product should be dispensed by the dentist only.

The Dental Council believes that some manufacturers in Europe are marketing tooth whitening products containing or releasing more than 6% hydrogen peroxide as medical devices. It should be noted that even if a tooth whitening product is marketed as a medical device it falls within the Regulations. This means that it is not possible to circumvent the Regulations by using a product that has a CE mark. Concentrations of greater than 6% of hydrogen peroxide present or released in oral products, including tooth whitening or bleaching products, will continue to be prohibited.

The EU as part of the agreement to change the Directive requires that there should be reporting of adverse effects. All serious undesirable events must be reported to the Irish Medicines Board.

Dentists can advertise tooth whitening procedures using products containing or releasing up to 6% hydrogen peroxide. However, dentists who advertise bleaching techniques using products containing or releasing greater than 6% hydrogen peroxide (or its equivalent) leave themselves exposed to possible IMB / Dental Council proceedings.

In Ireland tooth whitening can only be carried out by a registered dentist. As the regulatory framework currently stands, dental hygienists or orthodontic therapists are not allowed to perform tooth whitening.

If you are importing or manufacturing tooth whitening products you should check with the Irish Medicines Board to ensure that you are in compliance with the relevant Regulations.

#### **Guidance regarding treating patients under 18 years of age**

In the case of a child presenting with a specific condition or trauma and a clinical assessment concludes the most appropriate course of treatment is to use a tooth whitening product containing hydrogen peroxide up to 6%, consideration should be given firstly to appropriately licensed alternatives. Other than this, providing tooth whitening treatments to patients under 18 should only be considered where there is no appropriately licensed alternative available or you are satisfied, on the basis of authoritative clinical guidance, that a tooth whitening product is as safe and effective as an appropriately licensed alternative.

The treatment of a patient is the dentist's direct personal responsibility and it must accord with the principles of good clinical governance and the Dental Council's Code of Practice regarding Professional Behaviour and Ethical Conduct.

The dentist may be responsible for any liability associated with any adverse effect experienced by the patient due to the off-label use of such products as the product is not being used in accordance with the intended use. A dentist should in such cases record a justification for using the tooth whitening product as well as obtaining written consent from the parent prior to use. A limitation on the amount to be used should also be recorded and communicated to the patient and parent.

**Assistance**

The proposed relaxation in the Regulations to permit the use of higher strength products containing or releasing hydrogen peroxide will significantly improve the ethical and legal dilemmas that have been faced by dental practitioners in recent years. However dentists are advised to seek advice from the Dental Council or your indemnity provider if necessary.