IRISH MEDICINES BOARD

Hydrogen peroxide in tooth whitening products – new legislation from October 2012

The Irish Medicines Board (IMB) is highlighting changes in EU legislation that will come into effect in October 2012 under Council Directive 2011/84/EU, the 'Tooth Whitening Directive', for the purpose of assuring a greater degree of protection of consumer health in this area.

An assessment by the European Commission's Scientific Committee on Consumer Safety published in 2007 (SCCP/1129/07) notes that particular care in using tooth whitening/bleaching products should be taken by persons with gingivitis and other periodontal diseases or defective restorations. A clinical examination by a dentist prior to using such tooth whitening products will ensure the absence of any conditions, such as, pre-existing oral tissue injury or pathology or concurrent use of tobacco and/or alcohol, which may exacerbate the possible toxic effects of hydrogen peroxide.

The assessment concludes that a limit of 0.1% hydrogen peroxide, present or released, is safe for products sold directly to consumers. Products containing more than 0.1% and up to 6% hydrogen peroxide, present or released, should be administered only by a dental practitioner. Because of the increasing risks of acute and long-term effects, tooth whitening products containing more than 6% hydrogen peroxide are not considered safe for use by the consumer. In light of this opinion, the Tooth Whitening Directive was adopted in September 2011 and will be in force from October 2012.

What does this new legislation mean for dentists?

The Tooth Whitening Directive will allow use of hydrogen peroxide in oral hygiene products above 0.1% and up to 6% under the professional supervision of a dental practitioner. A restriction on the sale of such products means that tooth whitening or bleaching products, containing greater than 0.1% hydrogen peroxide, can only be sold to dental practitioners. In addition, such products should not be used on persons under 18 years of age.

For each cycle of use, the first application is performed by a dental practitioner, as defined under Directive 2005/36/EC, or under his/her direct supervision if an equivalent level of safety is ensured. Dental practitioners may then provide the product to the consumer to complete the cycle of use.

Complaints and undesirable effects (adverse reactions)

It is recommended that all serious undesirable effects (SUEs) occurring on the Irish market be reported to the IMB as Competent Authority for cosmetics and to the Responsible Person for that tooth whitening or bleaching product in order to allow the effect to be investigated. The IMB can be contacted by e-mail at cosmetics@imb.ie.

Importing tooth whitening products

If a dentist imports a tooth whitening product from a country outside the European Union (including internet supplies) for sale or supply in the form of a service, the dentist may be considered the Responsible Person (RP) for the product. In such cases, dentists are advised to contact their supplier to determine if a designated European RP has been appointed for the specific product.

The RP is legally accountable for ensuring that the cosmetic product is in compliance with the cosmetics legislation. As such, the RP is required to maintain a product information file, which includes a safety assessment, and to submit a cosmetic product notification to the IMB or the EU Commission. For further information on product information file requirements and the responsibilities of the RP, refer to the IMB's Guide to Cosmetics at www.imb.ie.

Market surveillance

A risk-based approach to market surveillance will be adopted by the IMB and its market surveillance partners in the Health Service Executive (HSE). Environmental Health Officers within the HSE are also authorised to inspect, seize and detain cosmetic products. The IMB and HSE will coordinate activities in this area with initial focus on products sold directly to consumers and illegal products that contain in excess of 6% hydrogen peroxide.

LABELLING REQUIREMENTS FOR TOOTH WHITENING PRODUCTS

The following information should appear in English on the packaging of tooth whitening products:

- Name and address of the Responsible Person (EU address)
- Nominal weight/volume
- Best before date or open jar symbol (where applicable)
- Precautions for use*
- Professional use only (where applicable)
- Batch number for traceability
- Product function
- List of ingredients

**Specific precautions for use to appear on tooth whitening products containing between 0.1% and 6% hydrogen peroxide include:*

'Contains hydrogen peroxide'

Concentration of hydrogen peroxide present or released indicated in percentage terms.

'Avoid contact with eyes, rinse immediately if product comes into contact with them'.

'Not to be used on a person under 18 years of age'

'To be only sold to dental practitioners'.

For each cycle of use, the first use to be carried out only by dental practitioners, or under their direct supervision if an equivalent level of safety is ensured. Afterwards to be provided to the consumer to complete the cycle of use.

Note: Tooth whitening products that are CE marked as medical devices are incorrectly classified as such and should be brought to the attention of the IMB.

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