What are the obligations for dentists importing cosmetic products?

If you are importing a cosmetic product from a country outside the European Union (including internet supplies) for sale or supply in the form of a service, you may be considered to be the Responsible Person (RP) for the product. If this is applicable, you are advised to contact your supplier to determine if a designated European RP has been appointed for the cosmetic product which you are importing.

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

What are the obligations for dentists in terms of product recalls?

Dentists are expected to co-operate with actions taken by the RP, distributors and/or the Competent Authority to ensure no unsafe product is made available for sale or supply to consumers. In the event of a product withdrawal/recall it may be necessary to determine which customers received a particular batch of a product which was defective. In such cases, records of the batch number received and supplied are most valuable and should be maintained by dentists. Dentists should ensure that their records are maintained in a sufficient detail to meet these obligations.

What Market Surveillance activities will be carried out in relation to tooth whitening products?

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.

What happens if a dentist breaches these regulations?

Dentists who breach these regulations may be subject to Fitness to Practice proceedings under the Dentists Act, 1985 in addition to any action taken by the IMB or authorised officers of the HSE.

Dental Council
An Comhairle Fiaclóireachta

57 Merrion Square, Dublin 2.
Tel: (01) 676 2226. Email: info@dentalcouncil.ie
www.dentalcouncil.ie

IRISH MEDICINES BOARD

Kevin O'Malley House, Earlsfort Centre,
Earlsfort Terrace, Dublin 2
Tel: (01) 676 4971. Email: cosmetics@imb.ie.
www.imb.ie

Notice to Dental Practitioners

Hydrogen Peroxide in Tooth Whitening Products

SEPTEMBER 2012

IRISH MEDICINES BOARD

Dental Council
An Comhairle Fiaclóireachta

Notice to Dental Practitioners

Hydrogen Peroxide in Tooth Whitening Products

Introduction

This is a joint communication to dental practitioners from the Dental Council and the Irish Medicines Board (competent authority in Ireland for cosmetic products) in relation to impending changes in the legislation covering the use of tooth whitening products containing hydrogen peroxide.

Background

The safety of Hydrogen Peroxide (H_2O_2) in tooth whitening products has been under discussion at EU level for some time. The Cosmetics Directive 76/768/EEC (as amended), transposed into Irish law by S.I. 870 of 2004 (as amended), restricts the level of hydrogen peroxide to 0.1% present or released in oral hygiene products.

An assessment by the European Commission's Scientific Committee on Consumer Safety (SCCS) was carried out to determine a safe level of hydrogen peroxide in oral hygiene and tooth whitening products with a report being published in 2007 (SCCP/1129/07). The assessment notes that particular care in using tooth whitening 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, Council Directive 2011/84/EU was adopted in September 2011 and will be in force from October 2012.

What does this new legislation mean for dentists?

European Council Directive 2011/84/EU 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.

What are the general labelling requirements for cosmetic products and what are those specific to tooth whitening products?

The following information should appear on the labelling of a cosmetic product:

1. Name and address of the Responsible Person (EU address)
2. Nominal weight / volume
3. Best before date or open jar symbol (where applicable)
4. Precautions for use*
5. Professional use only (where applicable)
6. Batch number for traceability
7. Product function
8. List of ingredients
9. A suitable language

*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 it can be provided to the consumer to complete the cycle of use.

What should I do if an undesirable effect or complaint is reported to me?

All Serious Undesirable Effects (SUEs) occurring on the Irish market should be reported without delay to the IMB as Competent Authority for cosmetics. The IMB can be contacted by e-mail at cosmetics@imb.ie. In addition, any SUEs should be reported to the Responsible Person for that tooth whitening or bleaching product in order to allow the effect to be investigated.