IRISH MEDICINES BOARD

New Legislation on hydrogen peroxide content in tooth whitening or bleaching products

Introduction

The Irish Medicines Board is highlighting changes in EU legislation that are shortly to be introduced 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.

Irish distributors, retailers and dental professionals using products containing or releasing hydrogen peroxide, should familiarise themselves with this new legislation and ensure they are aware of the new requirements.

Background

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 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 only be administered 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 the new legislation mean for supply of tooth whitening products?

Council Directive 2011/84/EU allows the use of hydrogen peroxide, present or released, in products sold directly to consumers up to a maximum concentration of 0.1%. Products containing greater than 0.1% and up to 6% hydrogen peroxide (present or released) must be applied under the 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. Distributors must therefore ensure that such products are only supplied to dental practitioners and are not supplied directly to retail.

Products containing greater than 6% hydrogen peroxide (present or released) will be prohibited from use and are considered illegal cosmetic products and will be withdrawn from the marketplace.

Product labelling

Tooth whitening products containing up to **0.1% hydrogen peroxide** must be labelled with the following:

- ❒ Contact details for the European Responsible Person
- ❒ Weight/ volume of the product (nominal content)
- ❒ The expiry date of the product

The egg-timer symbol may be used followed by the date (*dd/mm/yyyy* or *mm/yyyy*). If the product has a shelf-life greater than 30 months then the expiry date is not mandatory; however the period after opening should be displayed in this case (see next requirement).

- ❒ An open jar symbol or Period After Opening (PAO) on the label

  

  This is represented by the open-jar symbol and should be present when the minimum durability or shelf-life is greater than 30 months.

- ❒ Precautions and conditions of use
- ❒ The ingredient list:

  

  If the product is too small to print ingredients, the information may be provided elsewhere and should be indicated by the open book symbol.

- ❒ The batch number: this is the unique product identifier allowing traceability of the cosmetic product.

Tooth whitening products are classified as cosmetic products and not as medical devices. Products bearing a CE mark and marketed as medical devices are incorrectly classified as such and should be brought to the attention of the IMB.

What precautions should I take in sourcing tooth whitening products?

Due diligence and care should be taken in sourcing such products from suppliers. When sourcing product, confirm with your supplier the strength of hydrogen peroxide present or released from the product.
Product safety updates, listing products that pose a risk to consumers, are available on the European Commission's website at: www.ec.europa.eu/consumers.

What information should I request from my supplier?

- ❒ Contact details of the European Responsible Person for each product supplied.
- ❒ Labelling information (see labelling checklist above) is present on the product packaging
- ❒ The level of hydrogen peroxide present or released in the product and that it is not in excess of 0.1%.
  Please note that care should be taken with any of the following ingredients: hydrogen peroxide, carbamide peroxide, calcium peroxide, magnesium peroxide, zinc peroxide, sodium carbonate peroxide, sodium perborate, strontium peroxide and urea peroxide. All of these ingredients can release hydrogen peroxide

It is important that the above factors are appropriately accounted for within the relevant supplier agreements. In addition it is recommended that retailers carryout periodic goods-in checks to ensure that on an on-going basis products received continue to comply with the above.

What should I do in the case of an undesirable effect?

If an undesirable effect is reported to you following use of the product, you should report this effect to the Responsible Person for the product for investigation and we would encourage all retailers to report serious undesirable effects to the Irish Medicines Board at the contact details provided.