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peroxide (present or released) will be prohibited from use and are considered illegal cosmetic products and will be withdrawn from the marketplace.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 between 0.1% and up to 6% hydrogen peroxide (present or released) must be labelled with the following information:

- ❒ Contains hydrogen peroxide
- ❒ Concentration of hydrogen peroxide present or released must be 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.

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
- ❒ Responsibilities in terms of product recall and withdrawal and investigation of complaints.
- ❒ The level of hydrogen peroxide present or released in the product and that it is not in excess of 6%.
  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 wholesalers should carryout periodic goods-in checks to ensure that on an on-going basis products received continue to comply with the above. In this regard it is recommended that a sample pack from each in-coming batch is checked to ensure on-going compliance.

What other factors should I consider in terms of the distribution of tooth whitening products?

It is important to ensure that the onward supply of tooth whitening products is compliant with the new legislative requirements. In this regard wholesale distributors need to ensure that the supply of products containing between 0.1% and up to 6% hydrogen peroxide is confined to dental practitioners only. In this regard wholesalers should ensure that all such products are appropriately identified and the necessary picking controls put in place to ensure that these higher strength products are not supplied to any other customers.

Wholesalers will also need to consider how they may establish that the customer is a dental practitioner. The registration of dentists to professionally practice can be checked with the Irish Dental Council www.dentalcouncil.ie.

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 distributors, including retailers, to report serious undesirable effects to the Irish Medicines Board at the contact details provided.