

In 2013, the Cosmetic Products (Safety) (Amendment) Regulations 2012 (implementing Directive 2011/84 EU) were revoked and replaced with the Cosmetic Products Enforcement Regulations 2013 (and including amendments from Regulation 1223/2009, Regulation 344/2013 and Regulation 1197/2013) commonly known as the “EU Cosmetics Regulation”.

The law surrounding tooth whitening remains unchanged and it is illegal for tooth whitening products which contain more than 6% hydrogen peroxide or for any associated products which release greater than 6% hydrogen peroxide to be supplied or administered for cosmetic purposes.

In addition, the new regulations continue to state that tooth whitening products containing or releasing between 0.1%-6% hydrogen peroxide should not be made directly available to the consumer, other than through treatment by a registered dentist, dental hygienist, dental therapist or clinical dental technicians working to a dentist’s prescription. Breach of these regulations is a criminal offence. The GDC does not enforce the law around the Directive, as this is the responsibility of Trading Standards and the Health and Safety Executive. Should the GDC receive information concerning the supply or use of a product, we will refer this information on to Trading Standards.

The General Dental Council (GDC) would like to remind its registrants:

- Products containing or releasing between 0.1% and 6% hydrogen peroxide cannot be used on any person under 18 years of age, except where such use is intended wholly for the purpose of treating or preventing disease.
- Products containing or releasing less than 0.1% of hydrogen peroxide, including mouth rinse, tooth paste, tooth whitening or bleaching products are safe and will continue to be freely available on the market.
- Tooth whitening or bleaching products containing or releasing between 0.1%-6% of hydrogen peroxide should be used as follows:
 - an appropriate clinical examination is to be carried out in order to ensure that there are no risk factors or any other oral pathology concerns;
 - exposure to these products should be limited to ensure that the products are only used as intended in terms of frequency and duration of application;
 - the products should not be directly available to the consumer, only through a dentist, dental hygienist, dental therapist or clinical dental technician.

Tooth whitening products containing or releasing between 0.1% and 6% hydrogen peroxide can **ONLY** be sold to dental practitioners;

For each cycle of use, the first use can **ONLY** be carried out by dental practitioners or under their direct supervision, if an equivalent level of safety is ensured.

After the first cycle of use, the product may be provided by the dental practitioner to the consumer to complete the cycle of use.

- Concentrations exceeding 6% of hydrogen peroxide present or released in oral products, including tooth whitening or bleaching products, remain prohibited unless wholly for the purpose of the treatment or prevention of disease.
- It is a criminal offence to act in breach of the Regulations.
- GDC registrants need indemnity for any treatment which they provide.
- The GDC does not bring criminal prosecutions of breaches of the regulations as this role is undertaken by Trading Standards. However, the GDC is concerned with the fitness to practise of its members. It takes the view that if a practitioner has committed a criminal offence, that must be relevant to any assessment of that practitioner's fitness to practise irrespective of whether there has been a prosecution. Therefore, if we receive information or a complaint that a registrant is using a product for cosmetic purposes in excess of the 6% they may face fitness to practise proceedings and can expect to have the matter referred to the relevant Trading Standards department.
- The GDC's position remains unchanged in relation to non-registrants providing tooth whitening. Where an individual is not registered with the GDC, they are not entitled to provide tooth whitening, as tooth whitening falls within the definitions of practice of dentistry under sections 37 and 38 of the Dentists Act. The GDC will continue to prosecute individuals who carry out tooth whitening illegally under the Dentists Act 1984.

Dental professionals who need further advice interpreting the details of the Directive and how it affects them should contact their indemnity or insurance provider, or seek independent legal advice.

11 July 2016