Consider this the new era of painless teeth whitening and the end to soft tissue damage caused by hydrogen peroxide. Developments in the past five years have made a huge impact on the daily work of dentists, dental hygienists and well-trained dental nurses in the EU regarding the parameters for in-office teeth whitening and the purchase of teeth bleaching products containing hydrogen peroxide or carbamide peroxide.

**Impact of EU regulations for teeth whitening professionals**

In 2011, a new EU regulation called the EU directive 2011/84/EU brought about massive changes in teeth whitening across the blossoming industry in Europe. Following the new EU regulations, patients must be under constant dentist supervision and see the dentist before, during and after the teeth whitening process. Delegated, supervised and well-trained dental assistants are still allowed to perform teeth whitening procedures if supervised by a dentist on-site.

**Economic effect on dental hygienists and cosmetologists**

In the Netherlands and other EU countries, self-employed dental hygienists have been severely economically affected. Professional hygienists are no longer allowed to whiten teeth as they did for many years as independent business owners. To continue teeth whitening therapy and running their own local clinics, self-employed dental hygienists had to hire dentists for supervision purposes to fulfil the new EU regulations.

Cosmetologists and cosmetology studios were also required by the EU regulations to remove their teeth whitening practice. Even before the new EU regulations, some courts had already ruled that teeth whitening belonged in the dental field only and could only be performed by dentists and supervised by dental assistants and/or dental hygienists. In Germany specifically, teeth whitening in cosmetology studios where cosmecticians, dental students and dental assistants were employed, had to stop their non-regulated businesses or had to hire dentists for supervision.

**Professional products banned in EU countries**

Professional teeth whitening products above 6% hydrogen peroxide and 16% carbamide peroxide were banned from the market and are no longer available in all restricted EU countries. The only cosmetic products available to consumers for at-home teeth whitening contain less than 0.1% hydrogen peroxide and can only be purchased online.

Reactions have been varied in different EU countries. Most of the countries are following and monitoring EU regulations completely. Several EU countries are only allowing teeth whitening by the dentist or dentist supervised dental assistants. The same countries are no longer allowing teeth whitening products above 6% hydrogen peroxide or above 16% carbamide peroxide. The current countries following these regulations are: the Netherlands, Belgium, Luxembourg, United Kingdom, Ireland, Slovenia, Croatia, France, Romania, Sweden, Finland, Norway and Denmark.

**Different guidelines in Germany**

Missing from this list is Germany. Usually Germany is the first country to follow new restrictive guidelines, no matter where they come from. However, hydrogen peroxide is still being used in higher concentrations and is still available in Germany.

At the moment, the German government allows higher concentrations above 6% hydrogen peroxide.
But patients receiving the bleaching therapy should have medical purposes and not cosmetic reasons for such a special, highly concentrated teeth whitening treatment.

The state control system has not yet detected the use of higher concentrations of hydrogen peroxide in Germany and these products should also be banned from the market because of EU directive 2011/84/EU. But, we expect German regulations to follow the EU directive for this year.

Off the market in France

France had some special reactions on the EU directive and control mechanisms. All teeth whitening products—even the ones that should have only 6% hydrogen peroxide—were taken off the market for some months and went into a state control system. The Health Ministry of France wanted to be sure that all products contained the exact concentrations of the teeth whitening agents that were displayed on the packages. All teeth whitening products were analysed and double checked by a governmental state control.

After this analysis, some products failed the new restrictions; in reality they contained a higher concentration than what was printed on the packages. Of course these products were taken off the market, along with the products with officially higher concentrations of the teeth whitening agents.

Other reactions from EU countries

In countries like the Netherlands or the United Kingdom, the new rules have led to a massive change to teeth whitening treatments. Market shelves were completely empty because of all the banned products and the dentists were sending patients away from in-office teeth whitening to home teeth whitening. Products containing only 16% carbamide peroxide for home teeth whitening had a massive increase in sales.

The UK market also had an increase in home teeth whitening products. For in-office teeth whitening, UK dentists no longer saw a safe and effective alternative therapy. In general, the market appeared confused and nervous based on a lack of alternative new teeth whitening products and lack of information.

The UK’s Commonwealth States had similar reactions to the regulations and availability of products. India and Australia adapted the EU regulations to the local market and made plans to reduce hydrogen peroxide concentration down to 3% instead of 6%. By following the EU regulations like the UK, the market opportunities in these countries are growing more in the home teeth whitening business.
Studies and new product compliant with EU regulations

To put professional teeth whitening therapy back into the hands of qualified dentists, new technology had to be developed to deliver great and safe results and still comply with the EU regulations. This applied not only to whitening agents with just 6% hydrogen peroxide, but also finding new additives to increase the value and results of teeth whitening treatment, and on challenging cases with hypersensitive teeth and gums.

The regulations made it necessary to go back to studies carried out in 2010 by a Japanese University (Kawamata et al.) as well as the University of Indianapolis to find a new product. All over the world, teeth whitening scientists were waiting for the discovery—or rather, rediscovery—of the additive nHAp: nanohydroxyapatite.

Discovery of nHAp—nanohydroxyapatite

Multiple studies had previously shown several positive effects of nHAp on solid tooth structures as enamel, dentine and on gingival soft tissues leading to reduction of tooth decay and periodontitis or gum disease.

The application of nHAp provides a remineralisation of the tooth surface and seals sensitive dentine tubules. The nHAp remineralisation is an active agent against white spots and early enamel lesions. Nanohydroxyapatite helps to effectively remineralise the erosions on teeth caused by soft drinks, for example. With a new smoother tooth surface, bacterial adhesion is decreased and fewer periodontal infections occur.

As result of the studies, the World Health Organization (WHO) announced that nHAp could become the effective and economical prevention therapy for third world countries. Thanks to the University of Indianapolis for discovering that teeth whitening with 6% hydrogen peroxide simultaneously with nHAp reduces all the well-known painful and negative side effects of teeth whitening. Currently, their studies are leading to brilliant teeth whitening results without sensitivities during and after the teeth whitening process. This is a massive breakthrough in teeth whitening over the past few decades.

Results of nHAp

From these results, the Dutch company PrevDent created patents for teeth whitening combined with nHAp, the first EU-legal teeth whitening product with an intensive simultaneous remineralisation. The new developments and changes by this technology for the sensitive patient are visible, detectable and remarkable.

In the past, hypersensitive patients with exposed dentine structures had severe challenges with teeth whitening products. To make these conditions possible to treat, patients visited the clinic several times for desensitisation therapy before the teeth whitening appointment. Multiple fluoridations of the tooth surface and multiple use of amorphous calcium phosphate (ACP) started weeks in advance of the treatment and were standard procedure.

Before, during and after the teeth whitening procedure, the patient had to consume painkillers and anti-inflammatories as a recommended therapy. Without any kind of preventive desensitisation programme, teeth whitening therapy was not possible.

Now even patients with sensitive teeth and exposed dentine can have painless teeth whitening without other side effects. The combined teeth whitening therapy is called ‘In-Office Repair Whitening’ by PrevDent.

How to achieve excellent results with only 6% hydrogen peroxide

PrevDent did their homework, used scientific research, and patented a device to arrive at the best and safest results while at the same time meeting EU regulations. The active ingredients in in-office repair whitening create an interactive reaction between 6% hydrogen peroxide combined with a
special stabilising molecule, which bonds with the surface of the teeth and is applied with a special mixing device and container that seals and preserves both liquids—nHAp and hydrogen peroxide.

**Technical evolution**

For each patient, the solution is mixed to freshly activate the ingredients into a foam with a solid structure that physically adheres to the tooth surface. This foam mixture is another technical evolution. Because of the way it bonds with the tooth surface, the teeth whitening process works immediately and actively.

**Time and sequence of results**

PrevDent’s standard application is six times every ten minutes. In each sequence, the foam is always mixed and freshly applied and fully concentrated. Applying the fresh foam mixture with those extremely active ingredients each time is key in reaching the predictable perfect results within the estimated time of one hour. When necessary, a few extra applications are possible.

**Therapy for sensitivities and remineralisation**

Using results based on scientific research, PrevDent also developed DeSensiDent—a tooth serum of highly concentrated nHAp. DeSensiDent has become the universal desensitising tool and is used for all kinds of treatments against dental sensitivities and for tooth surface remineralisation.

In the field of orthodontic treatment, PrevDent has opened doors for intensive preventive therapy, which is being studied and discussed by the World Health Organization (WHO). Before, during and after the orthodontist performs corrective treatments with braces, the tooth surface is treated with the highly concentrated nHAp. PrevDent’s OrthoCare products help prevent tooth decay and remineralises enamel erosion occurring at the contact points between teeth and braces.

**Medical treatment**

Preventive therapy with nHAp is a focused medical treatment and not an aesthetic, cosmetic treatment. This therapy is not based on aesthetical indications or patients’ wishes, and is therefore considered a medical treatment without additional taxes for the dental and orthodontist businesses.

In some countries like Germany, similar surface sealant therapy is paid by insurance as a preventive therapy for every single tooth before, during and after orthodontic treatment with braces (GOZ No. 2000a).

Mineral restoration and surface sealant therapy follows the GOZ No. 2000a, which is the fissure sealant and surface sealant therapy of healthy tooth surfaces. The general office of the German private insurances declares that such a treatment is medically necessary and will be covered by all German private insurance companies.

**Availability for professional treatments facilities**

The DeSensiDent product line is currently available on the market, meets EU regulations, and is the number one professional product developed by PrevDent for mineral restoration and surface sealants. PrevDent has opened a big and important scientific door for dental professionals performing orthodontic procedures and who want to include remineralising and desensitising treatments into their preventive and restorative therapy portfolios.

To summarise, based upon scientific results PrevDent’s in-office repair whitening is a combined teeth whitening and remineralisation product that is fulfilling all national and international restrictive parameters that occurred out of the EU directive 2011/84/EU. As additional complementary products, they developed new desensitising and remineralisation tools based on the usage of nHAp for intermediate short-term applications and intensive long-term applications as sealant products.

As another future perspective, this nHAp technology of PrevDent can become a successful partner for surface sealant technology in the perioprevention concept.

_images courtesy of Dr Skander Ellouze._

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