TOOTH BLEACHING PRODUCTS – MEDICAL DEVICES OR COSMETIC PRODUCTS?

The different classification in the European case law and a critical consideration of the arguments for the decision making

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vorgelegt von

Jutta Lange

aus Namborn

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Betreuer und 1. Referent: Herr Dr. Ehrhard Anhalt

Zweiter Referent: Frau Dr. Elke Lehmann

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List of Abbreviations

AGMP	Arbeitsgruppe Medizinprodukteüberwachung (Working Group for Medical Product Supervision)
AIMDD	Active Implantable Medical Devices Directive
BAG	Bundesamt für Gesundheit (Federal Office of Health) in Switzerland
BGH	Bundesgerichtshof (Federal Supreme Court) in Germany
BverwG	Bundesverwaltungsgericht (Federal Administrative Court) in Germany
CD	Cosmetics Directive
CEN	European Committee for Standardization
COLIPA	European Cosmetic Toiletry and Perfumery Association
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
DBA	Dental Bleaching Agent
DOH	Department of Health in UK
DTI	Department of Trade and Industry in UK
EC	European Community
EDI	das Eidgenössische Departement des Innern (Federal Department of the Interior) in Switzerland
EEA	European Economic Area
EFTA	European Free Trade Association
EU	European Union
ECJ	European Court of Justice
EuGH	Europäischer Gerichtshof
FG	Finanzgericht (Finance Court) in Germany
GebrV	Verordnung über Gebrauchsgegenstände (Ordinance on commodities) in Switzerland
HMG	Heilmittelgesetz (Law on Drugs) in Switzerland
IVDD	In Vitro Diagnostic Directive
LFGB	Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (Act on Reclassification of Food and Animal Feed Law)
LMBG	Lebensmittel- und Bedarfsgegenständegesetz (Law on Food and Commodities) in Germany
MDD	Medical Device Directive
MPG	Medizinproduktegesetz (Law on Medical Devices) in Germany
MPGÄndG	Medizinprodukte-Änderungsgesetz (Amendment Law of Law of Medical Devices) in Germany
MPV	Medizinprodukte-Verordnung (Ordinance on Medical Devices) in Germany
NRW	Nordrhein-Westfalen (North-Rhine Westphalia) in Germany
OVG	Oberverwaltungsgericht (Higher Administrative Court) in Germany
SCCNFP	Scientific Committee on Cosmetic Products and Non-Food Products
SCCP	Scientific Comitee on Consumer Products
UK	United Kingdom
VG	Verwaltungsgericht (Administrative Court) in Germany
WHO	World Health Organisation
ZLG	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten in Germany (Central Authority of the Laender for Health Protection Regarding Medicinal Products and Medical Devices) in Germany

1 Introduction

A spotless white smile is for many people the embodiment of beauty and is often synonymous with “health“, “youth“, “cleanliness“, “sympathy”, “prosperity” and “competence”.
Therefore the whitening of teeth has been enjoying an ever-growing popularity over the past few years. The industry reacts to the growing demand with more and more products for bleaching the teeth.
But the legislator and jurisdiction in the whole of Europe has problems to classify these products legally. Tooth whitening preparations have been the subject of much discussion in Europe as to whether they are properly classified as cosmetics according to the EU Cosmetics Directive (CD) 76/768/EEC or as medical devices according to the Medical Device Directive (MDD) 93/42/EEC. This classification is of vital importance for the marketability of the products.
Present tooth-bleaching techniques are based upon hydrogen peroxide as the active agent. Hydrogen peroxide may be applied directly or produced in a chemical reaction from carbamide peroxide or zinc peroxide for example. The Cosmetics Directive 76/768/EEC classifies whitening products as cosmetics with a maximum allowable concentration of hydrogen peroxide (present or released) of 0.1 %. Notwithstanding, a lot of whitening products with more than 0.1 % hydrogen peroxide are marketed. Several firms have classified these products as medical devices under Medical Device Directive 93/42/EEC. Thus, a discussion exists, whether tooth bleaching products with more than 0.1 % hydrogen peroxide have to be classified as cosmetics or as medical devices. If they are cosmetics these products would not be marketable under the actual Cosmetics Directive, if they are medical devices they have to be certified by a notified body and need the CE mark to be marketable.

2 Definitions and explanations

2.1 Types of tooth discoloration

Tooth discoloration varies in etiology, appearance, localisation, severity and adherence to tooth structure. It may be classified as intrinsic and extrinsic discolorations.

2.1.1 Intrinsic discoloration

Intrinsic discoloration is caused by incorporation of chromatogenic material into dentin and enamel during odontogenesis or after eruption. Exposure to high levels of fluoride, tetracycline administration, inherited developmental disorders and trauma to the developing tooth may result in pre-eruptive discoloration. After eruption of the tooth, aging, pulp necrosis and iatrogenesis are the main causes of intrinsic discoloration[1].

2.1.2 Extrinsic discoloration

Teeth can be stained on the surface (extrinsic) by food and drinks such as carrots, oranges, coffee, tea, red wine. Tobacco smoking can also stain teeth. Abrasion of the tooth structure, deposition of secondary dentine due to aging, or as a consequence of pulp inflammation, and dentine sclerosis affect the light-transmitting properties of teeth, resulting in a gradual darkening of the teeth[1].

2.2 Tooth whitening products (non-bleaching)

Non-bleaching tooth whitening products basically depend on physical principals like scaling and polishing with silica and remove many extrinsic stains. The effect of the abrasives can be

supported by additional substances like polyphosphate which dissolve calcium containing discolorations on the tooth surface by the building of chelates.

2.3 Tooth bleaching products

For more stubborn extrinsic discoloration and intrinsic staining, various bleaching techniques may be attempted. 3 categories of bleaching products can be classified[2]:

2.3.1 Products for In-office-Bleaching

These are products which are used by the dentist in his surgery ("in-office"). He uses products containing a high concentration of hydrogen peroxide (30-35 %[2, 13], 35-50 %[1]) or carbamide peroxide (35 %[13], 35-40 %[1]) for bleaching vital teeth or non-vital teeth.
For bleaching vital teeth, the dentist will apply a rubber dam or a gel to protect the soft tissues, and the bleaching agent is then applied onto the teeth. A light or laser is then shone on the teeth to activate the chemical so that it acts more quickly on the discolouring molecules within the tooth. The actual procedure will take about one hour.
Another possibility for bleaching vital teeth is a bleaching tray that is placed in the mouth for 30 minutes up to 2 hours while the person is in the dental office[1].
For bleaching non-vital teeth the dental bleaching agent (DBA) is placed intracoronally. The substance is placed in the pulp chamber, that is sealed, and is left for 3-7 days[1]. Several treatments are usually needed to reach an acceptable result.

2.3.2 Home-Bleaching-Products

Home-bleaching products are dispensed by the dentist and used by the patient at home. These products contain up to 10 % hydrogen peroxide[2, 13] or 16 %[13] resp. 5-22 %[1] carbamide peroxide. Impressions of the teeth are taken by the dentist and a custom made bleaching tray is constructed. The tray fits closely around the teeth to ensure that the bleaching gel can be applied to the teeth without touching the gums. The dentist shows how to put a small amount of the bleaching gel into the tray and demonstrates how to slide it over the teeth. Then the treatment is continued at home. The tray is worn for several hours, usually at night time. The treatment usually takes two weeks but may vary on the concentration of the bleaching agent or the grade of discoloration and is supervised by the dentist.

2.3.3 Mass-Market-Products

Mass-market-products can be bought over-the-counter in pharmacies, drugstores and in the retail trade. Their content of hydrogen peroxide is up to 6 %. They are marketed as pre-fabricated trays or textured strips to adhere directly to the surface of the teeth. The strips should be worn twice a day for 30 minutes over a period of 14 days[13]. Also peroxide containing paint-on gels have become available. The gel stays on the teeth overnight for a certain period of time.

2.4 Hydrogen peroxide and its mode of action

Tooth bleaching products contain either hydrogen peroxide (H_2O_2) or one of its precursors, notably carbamide peroxide ($CO(NH_2)_2 \bullet H_2O_2$). Carbamide peroxide breaks down into hydrogen peroxide and urea, with hydrogen peroxide being the active ingredient[1].

$$H_2NCONH_2 \bullet H_2O_2 \rightarrow H_2NCONH_2 + H_2O_2$$

Both hydrogen peroxide and carbamide peroxide are used for hair bleaching, oxidation of permanent waves, hair relaxer, ear drops, disinfection of eye contact lenses, disinfection of wounds, oral antiseptics, mouth washing, dentifrices and tooth bleaching.

Hydrogen peroxide acts as a strong oxidizing agent through the formation of free radicals like hydroxyl and perhydroxyl radicals and superoxide anions (A), reactive oxygen molecules that are unstable und transform to oxygen (B) and hydrogen peroxide anions (C):

(A) $H_2O_2 \rightarrow 2\ HO^{\bullet}$
$HO^{\bullet} + H_2O_2 \rightarrow H_2O + HO_2^{\bullet}$
$HO_2^{\bullet} \leftrightarrow H^+ + O_2^{\bullet -}$

(B) $2\ H_2O_2 \leftrightarrow 2\ H_2O + 2\ \{O\} \leftrightarrow 2\ H_2O + O_2$

(C) $H_2O_2 \leftrightarrow H^+ + HOO^-$

The reactive molecules attack the long-chained, complex organic chromophore molecules that are responsible for the colour of the stain and split them into smaller, less colored and more diffusible molecules. This results in a reduction or elimination of the discoloration.
Carbamide peroxide also yields urea that theoretically can be further decomposed to carbon dioxide and ammonia. It is unclear however, how much ammonia is formed during tooth bleaching with carbamide peroxide. The high pH of ammonia facilitates the bleaching procedure. This can be explained by the fact that, in a basic solution, lower activation energy is required for the formation of free radicals from hydrogen peroxide, and the reaction rate is higher, resulting in an improved yield compaed with an acidic environment.
The outcome of the bleaching procedure depends mainly on the concentration of the bleaching agent, the ability of the agent to reach the chromophore molecules, and the duration and number of times the agent is in contact with the teeth.

As can be seen by the mechanisms described above, the bleaching process achieves its principal action by chemical and not by pharmacological means. Thus, classification as a medicinal product is out of the question.

3 Legal position in the European Union

3.1 Legal basis

By Article 100 of the European Treaty[3] the Council of the European Community was required to issue directives for the approximation of the laws of the Member States as directly affect the establishment or functioning of the common market.

3.1.1 Cosmetic products

In the early 1970's, the Member States of the EU decided to harmonise their national cosmetic regulations in order to enable the free circulation of cosmetic products within the Community. As a result of numerous discussions between experts from all Member States, Council Directive 76/768/EEC ("Cosmetics Directive") was adopted on 27 July 1976[4].
The principles laid down in the Cosmetics Directive take into account the needs of the consumer while encouraging commercial exchange and eliminating barriers to trade. It is laid down in the third recital of the Cosmetics Directive that the main objective of the Community legislation is the safeguarding of public health, but this objective must be attained by means which also take account of economic and technological requirements.

The fifth recital recognises the problem of defining the scope of the application of the Directive. It states:

… whereas this Directive is not applicable to the products that fall under the definition of cosmetic products but are exclusively intended to protect from disease; whereas, moreover, it is advisable to specify that certain products come under this definition, whilst products containing substances or preparations intended to be ingested, inhaled, injected or implanted in the human body do not come under the field of cosmetics;

The definition of a “cosmetic product” is given in Article 1 (1) of the CD. The actual definition was given by the directive 93/35/EEC[5] as follows:

> *A "cosmetic product" shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.*

The directive has several annexes which often have been changed in the course of time to adapt them to the technical progress.
Annex I for example contains an “*illustrative list of products to be considered as cosmetic products within the meaning of this definition*”. “*Products for care of the teeth and the mouth*” are mentioned in this annex.

Annex III, first part, is a *“list of those substances which cosmetic products must not contain except subject to restrictions and conditions laid down”*. At the beginning, that list included hydrogen peroxide only for use in “Oxidation colouring agents for hair dyeing”. As time went on, the use of hydrogen peroxide came to be more controlled. With the fifteenth adaption of the CD 76/768/EEC by the directive 92/86/EEC[6], it was laid down that the maximum permitted concentration for hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide in oral hygiene products is 0.1 % (present or released) (Number 12 in the list).

3.1.2 Medical devices

As a legal basis for medical devices in the different member states, there are three main European directives: the directive for “Active Implantable Medical Devices” (AIMDD) (90/385/EEC)[7], the “Medical Devices Directive” (MDD) (93/42/EEC)[8] and the “In Vitro Diagnostic Directive” (IVDD) (98/79/EC)[9].
The tooth bleaching products – if they are medical devices - would be covered by the MDD 93/42/EEC. This directive was adopted on 14 June 1993, following the new approach laid down for harmonisation and standards in Council Resolution of 7 May 1985 (No C136/1). In the recitals it is pointed out that the national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices should be harmonised in order to guarantee the free movement of such devices within the internal market.

The definition of “Medical Device” is given in the Article 1 (2) (a)

> *'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:*
> *- diagnosis, prevention, monitoring, treatment or alleviation of disease,*
> *- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
> *- investigation, replacement or modification of the anatomy or of a physiological process,*
> *- control of conception,*
> *and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means*

By Article 1 (5) (d) it is provided that the directive “*does not apply to cosmetic products covered by Directive 76/768/EEC*”.

Article 4 (1) (“Free movement,…”) sets out that *“the Member States shall not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the*

CE marking provided for in Article 17 which indicate that they have been the subject of an assessment of their conformity in accordance with the provisions of Article 11".

Article 3 says that *"the devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned"*.

Article 17 ("CE mark") points out that devices considered to meet the essential requirements must bear the CE mark when they are placed on the market. The conformity assessment procedures laid down in Article 11 and annexes II to VII are to be carried out by a Notified Body designated by Member States and notified to the Commission.

Article 18 ("Wrongly affixed CE marking) lays down that *"where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to end the infringement under conditions imposed by the Member State"*.

3.2 Opinions of the SCCNFP

By the Commission Decision 97/579/EC[10] the Commission decided to set up Scientific Committees in the field of consumer health and food safety. The Scientific Committees shall be consulted in the cases laid down by Community legislation (for cosmetic products for example laid down in Article 4a, 4b, 8, 8a CD). The Commission may also decide to consult them on other questions of particular relevance to consumer health and food safety. At the Commission's request, the Scientific Committees shall provide scientific advice on matters relating to consumer health such as critically examine risk assessments made by scientists belonging to Member States' organisations or draft scientific opinions designed to enable the Commission to evaluate the scientific basis of the recommendations, standards and guidelines prepared in international forums.

For cosmetic products, the Scientific Committee on Cosmetic and Non-Food Products intended for Consumers (SCCNFP) was set up. The SCCNFP assists the European Commission in examining the scientific and technical questions associated with the safety evaluation of cosmetics and toiletries. The SCCNFP comprises scientific experts from several member states. It provides formal opinions on the safety of new and existing cosmetics ingredients as well as related advice, such as adapting to technical progress the testing methods used. The SCCNFP plays a key role in the safety evaluation of cosmetic ingredients (not finished products) thought to pose a significant risk to human health. These include ingredients contained in Annexes of the Cosmetics Directive 76/768/EEC.

3.2.1 Opinion concerning hydrogen peroxide 1999

As stated in chapter 3.1.1, the limit for hydrogen peroxide, including carbamide peroxide and zinc peroxide in oral hygiene products is 0.1 % (present or released). So tooth bleaching products with a higher amount of hydrogen peroxide would not be marketable. Therefore the cosmetics industry applied to the Commission to increase this limit concentration. So the SCCNFP was requested to answer the questions whether an increase of the limit concentration to 3.6 % in tooth-whitening products is permissible and whether the SCCNFP propose any restrictions or conditions for use of these cosmetic products.
The submission concerning the use of hydrogen peroxides (and equivalent) for tooth whitening products did mainly employ a technique where hydrogen peroxide or a hydrogen peroxide releasing substance was used in a custom made or prefabricated tray that covered the teeth.
A toxicological evaluation and characterisation was made and data on exposure and margin of safety (MOS) were deduced. In its "Opinion concerning Hydrogen (Carbamide) Peroxide in Tooth Whitening Products" of 17 February 1999[11], the SCCNFP comes to the opinion that the content of hydrogen peroxide in tooth whitening products should not exceed 3.6 % (10 % carbamide peroxide). Tooth whitening products with more than 0.1 % hydrogen peroxide (0.3 % carbamide

peroxide) should exclusively administered under supervision of a dentist. The products should contain a printed warning against overuse or reuse of tooth whitening products several times and that they should not be used during pregnancy or by habitual tobacco and alcohol users.

It was the opinion of the Commission services, responsible for the regulation of cosmetic products within the Community, that it would be inappropriate to provide for such an ingredient, with the restrictions mentioned above on cosmetic products. So the opinion was revised on 23 June 1999[12] and it was decided to remove the term “during pregnancy”.

3.2.2 Opinion concerning hydrogen peroxide 2002

On the basis of new data, the SCCNFP was asked whether the safety profile supports that hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide are safe for use in tooth bleaching products at concentrations up to 6.0 % (present or released) with a limitation of a maximum of 50 mg per day and whether the SCCNFP propose any restrictions or conditions for use of these cosmetic products.
The opinion of the SCCNFP was given on 17 September 2002[13].
The submission is primarily based on the use of textured strips containing 6 % hydrogen peroxide and designed to fit the front teeth. The strips should be worn twice a day for 30 minutes over a period of 14 days. After using all of the upper strips, the process is repeated with the lower teeth.
Toxicological data such as acute toxicity, mucous membrane irritation, skin irritation, eye irritation, sensitisation, repeated dose oral toxicity, genotoxicity, carcinogenicity, toxicity to reproduction, toxicity after dermal exposure and clinical side effects of treatment with tooth whiteners have been taken into account for the safety evaluation.
The most commonly observed clinical side effects of treatments with tooth whiteners include tooth hypersensitivity to temperature changes and irritation of oral mucosa. Tooth hypersensitivity often occurs during the early stage of bleaching treatment and is usually transient. Some patients have also reported burning palate, throat and gingiva.
All bleaching materials demonstrate diffusion of hydrogen peroxide through dentin. Few investigators have addressed the possible pathophysiological effects on oral and pulpal tissues from long-term treatment. Most scanning electron microscopy showed little or no morphological changes in enamel surfaces treated with carbamide peroxide tooth whitening agents. Some authors however, reported alterations of enamel surfaces, including shallow depression, and increased porosity and slight erosion, associated with whitening treatments.
It has been noted that prolonged treatment with bleaching agents might cause microstructural changes in amalgam surfaces and possibly increasing exposure of patients to mercury.
Studies to detect adverse effects of low frequency, long-term studies and studies concerning reusing tooth bleaching agents several times were lacking.
Conditions such as pre-existing tissue injury or the concurrent use of alcohol and/or tobacco while using tooth whiteners may also exacerbate their toxic effects. Hydrogen peroxide even at concentrations as low as 3 % may be especially harmful to oral tissues if they have been previously injured. Therefore, particular care should be taken in administering bleaching agents to patients with gingivitis, periodontal disease, or pre-existing gingival lesions, and to those using alcohol and tobacco.

The SCCNFP stated the following final opinion:

The content of hydrogen peroxide in tooth whitening products should not exceed 6 % (present or released) with a limitation of maximum 50 mg hydrogen peroxide per day. The use of tooth whitening products is not recommended prior of immediately after dental restoration. Conditions such as pre-existing tissue injury or concurrent use of tobacco and/or alcohol may exacerbate the toxic effects of hydrogen peroxide.

Overall evidence indicates that the proper use of tooth bleaching agents containing 0.1 % - 6.0 % hydrogen peroxide (or equivalent for hydrogen peroxide releasing substances) is safe if used under supervision of a dentist (“take home” (=Home Bleaching, see chapter 2.3.2)).

3.2.3 Opinion concerning hydrogen peroxide 2003

In October 2003 the SCCNFP was asked to clarify its opinion. On the basis of the dossiers already submitted, the SCCNFP adopted opinion SCCNFP/0752/03 of 20 October 2003 on "The Use of Hydrogen Peroxide in Tooth Whitening Products, Clarification concerning its opinion of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers", concluding following:

"It is known that the use of tobacco, and alcohol abuse, cause an increased risk of oral cancer. Hydrogen peroxide may enhance this risk. This effect cannot be quantified. It is not anticipated that the tooth whitening products of the type being discussed will represent a risk of oral cancer in people neither using tobacco nor abusing alcohol.

The tooth whitening products of the type being discussed should only be used under the surveillance of a dentist. These tooth whitening product should not be freely available to consumers."

3.3 Commission recommendation 2004

In the framework of Council Regulation 793/93/EEC[14] hydrogen peroxide has been identified as a priority substance for evaluation of risks. Finland as the rapporteur Member State had carried out the risk analysis and suggested a strategy for limiting the risks. The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) had been consulted and issued an opinion with respect to the risk evaluation. The results of the risk evaluation and the risk reduction strategy was laid down in the Commission Recommendation 2004/394/EC of 29 April 2004[15].

The conclusion of the risk evaluation to consumers of hydrogen peroxide is reached because of *"…concerns for specific adverse effects on tooth pulp and teeth as a consequence of exposure arising from tooth bleaching with 35 % hydrogen peroxide by a dentist"*.

As strategy for limiting the risks for consumers it is recommended that:

"in the framework of Commission Directive 2003/83/EC[16] regarding the maximum acceptable percentage of hydrogen peroxide for tooth bleaching products used under supervision of a dentist, a concentration limit of up to 6 % hydrogen peroxide should be considered, provided appropriate conditions of use and warning are printed on the label".

3.4 Opinion of SCCP 2005

The Commission Decision 97/579/EC which had set up the SCCNFP was repealed by the Commission Decision 2004/210/EC[17] of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment.

By this Commission Decision, the Scientific Committee on Consumer Products (SCCP) was set up. Annex I of the Commission Decision states the field of competence. "The SCCP shall provide opinions on questions concerning the safety of consumer products (non-food products intended for the consumer). In particular, it shall address questions in relation to the safety and allergenic properties of *cosmetic products* and ingredients with respect to their impact on consumer health, toys, textiles, clothing, personal care products, domestic products such as detergents and consumer services such as tattooing".

The SCCP now discussed the use of hydrogen peroxide in tooth whitening products. 2003 and 2004, new data on hydrogen peroxide have been submitted by COLIPA (European Cosmetic Toiletry and Perfumery Association), the French Committee on Cosmetology and PHD Pharmaceuticals NV. During the 2nd plenary, the SCCP has decided to undertake a public consultation. Interested parties were invited to submit comments or pertinent scientific information by 31 January 2005.

During the 3rd plenary meeting of 15 March 2005, the SCCP adopted the Opinion on Hydrogen Peroxide in Tooth Whitening Products[18].

The SCCP was requested to answer the following questions:

1. *Does the SCCP agree that the new additional data provide the necessary reassurance to support the safety of up to 6% hydrogen peroxide in tooth whitening products freely and directly available to consumer in various application forms (strips, trays, etc.)?*
2. *Considering the new additional data provided, does the SCCP recommend that any specific information should be provided to consumers related to the safe use of these tooth whitening products?*
3. *If the answer to the question on free and direct availability to consumer is negative, would the SCCP identify and quantify any remaining risks that need to be addressed taking into account in particular the overall data on pharmacokinetics and exposure?*

By the new data, bleaching effects on enamel and dentin, effects on restorative materials and the uptake of bleach and transport to dental pulp have been described. The safety evaluation of SCCNFP could be updated and the SCCP came to the following conclusion:

tooth whitening products containing up to 0.1% hydrogen peroxide

- *The use of tooth whitening products up to 0.1% hydrogen peroxide is safe.*

tooth whitening products containing > 0.1% to 6.0 % hydrogen peroxide

- *The proper use of tooth whitening products containing > 0.1 to 6.0 % hydrogen peroxide (or equivalent for hydrogen peroxide releasing substances) is considered safe after consultation with and approval of the consumer's dentist.*
  - *The use of tooth whitening products is not recommended prior to or immediately after dental restoration.*
  - *Particular care should be taken in using tooth whitening products by persons with gingivitis and other periodontal diseases or defective restorations. Conditions such as pre-existing oral tissue injury or concurrent use of tobacco and/or alcohol may exacerbate the toxic effects of hydrogen peroxide.*
- *There is an absence of good clinical data and long-term epidemiological studies that assess the possible adverse effects within the oral cavity.*
- *The new additional data supplied does not provide the necessary reassurance in terms of risk assessment to support the safety of hydrogen peroxide up to 6 % in tooth whitening products freely and directly available to the consumer in various application forms (strips, trays, etc…). SCCP cannot quantify the risk of potential serious adverse effects in relation to the use of tooth whitening products.*

Thus, as can be seen from the above mentioned depictions, the risk assessment concerning hydrogen peroxide did not change principally over the last years since 1999.

4 Legal position in Germany

4.1 Legal basis

In contrast to EU regulations which are directly valid and legally binding, an EU directive has first to be implemented in national law. This means that the Member States are obliged to transfer the objectives and requirements of the directive into national law.

4.1.1 Cosmetic products

For cosmetic products, this occurred through the “Lebensmittel- und Bedarfsgegenständegesetz”, LMBG (Law on Food and Commodities) [19].
The German wording of the definition of cosmetic product in Article 1 para 1 of CD 76/768/EEC:

Kosmetische Mittel sind Stoffe oder Zubereitungen, die dazu bestimmt sind, äußerlich mit den verschiedenen Teilen des menschlichen Körpers (Haut, Behaarungssystem, Nägel, Lippen und

intime Regionen) oder mit den Zähnen und den Schleimhäuten der Mundhöhle in Berührung zu kommen, und zwar zu dem ausschließlichen oder überwiegenden Zweck, diese zu reinigen, zu parfümieren, ihr Aussehen zu verändern und/oder den Körpergeruch zu beeinflussen und/oder um sie zu schützen oder in gutem Zustand zu halten

has been transferred to the definition as is given in § 4 (1) LMBG:

Kosmetische Mittel im Sinne dieses Gesetzes sind Stoffe oder Zubereitungen aus Stoffen, die dazu bestimmt sind, äußerlich am Menschen oder in seiner Mundhöhle zur Reinigung, Pflege oder zur Beeinflussung des Aussehens oder des Körpergeruchs oder zur Vermittlung von Geruchseindrücken angewendet zu werden, es sei denn, daß sie überwiegend dazu bestimmt sind, Krankheiten, Leiden, Körperschäden oder krankhafte Beschwerden zu lindern oder zu beseitigen.

It can be realised, that this is not identical in all aspects with the European definition.

The annexes of the CD 76/768/EEC have been transferred to the "Verordnung über kosmetische Mittel" (Ordinance on cosmetic products) [20]. The use of hydrogen peroxide as it is described in Annex III of the EU directive can be found in Annex 2, Part A, No. 12 of the "Kosmetikverordnung" (Ordinance on cosmetic products) – the maximum permitted concentration for hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide in oral hygiene products is 0.1 % (present or released). This means that products with an amount of hydrogen peroxide higher than 0.1 % are not marketable in Germany.

4.1.2 Medical devices

For medical devices, the implementation of the three EU directives **90/385/EEC** , 93/42/EEC and **98/79/EC** resulted in the "Medizinproduktegesetz", MPG, (Law on Medical Devices)[21]. The definition of a medical device is given in § 3 (1) MPG:

Medizinprodukte sind alle einzeln oder miteinander verbunden verwendeten Instrumente, Apparate, Vorrichtungen, Stoffe und Zubereitungen aus Stoffen oder andere Gegenstände einschließlich der für ein einwandfreies Funktionieren des Medizinproduktes eingesetzten Software, die vom Hersteller zur Anwendung für Menschen mittels ihrer Funktionen zum Zwecke

a) der Erkennung, Verhütung, Überwachung, Behandlung oder Linderung von Krankheiten,
b) der Erkennung, Überwachung, Behandlung, Linderung oder Kompensierung von Verletzungen oder Behinderungen
c) der Untersuchung, der Ersetzung oder der Veränderung des anatomischen Aufbaus oder eines physiologischen Vorgangs oder
d) der Empfängnisregelung

zu dienen bestimmt sind und deren bestimmungsgemäße Hauptwirkung im oder am menschlichen Körper weder durch pharmakologisch oder immunologisch wirkende Mittel noch durch Metabolismus erreicht wird, deren Wirkungsweise aber durch solche Mittel unterstützt werden kann.

As a consequence of the MDD and MPG, medical devices can only be put in the market if they bear the CE mark (§ 6 MPG). The CE mark can only be fixed if the products fulfil the essential requirements (§ 7 MPG) and if they have performed the suitable conformity assessment procedure under involvement of a state accredited Notified Body (§ 3 (20.) MPG and "Medizinprodukte-Verordnung", MPV[22] ("Ordinance on Medical Devices")). In this case the products are allowed to be circulated freely throughout the EU and the EFTA (Iceland, Norway, Switzerland, and Liechtenstein) without the need for any national registration. § 27 MPG (Article 18 MDD) deals the case where the CE marking was affixed unduly. In this case, the withdrawal of the product from the market is possible.

4.2 German case-law

The legal position in Germany will be described in the following by the case of the company Ultradent Products Inc., sited in the USA[23, 24].
Ultradent is manufacturer of the tooth bleaching products of a series called “Opalescence”. Four products of the Opalescence family - O. Regular, O. Mint, O. Quick and O. Xtra - are marketed by their European distributor (probably the company Optident Ltd. – see case-law in UK), who acts as their Responsible Person (according to Article 14 MDD, § 5 MPG) as well as their safety officer (according to § 30 MPG). The products are tooth bleaching gels for In-Office-bleaching (see chapter 2.3.1) or Home-bleaching (see chapter 2.3.2) to remove intrinsic discoloration. The products differ in their concentration of carbamide peroxide, which is the active substance in the gels (O. Regular and O. Mint contain 10 % carbamide peroxide – they only differ by their taste; O. Quick and O. Xtra contain 35 %), and their kind and time of application.
The above mentioned products have been certified as medical devices of class IIa in November 1997 (O. Regular, O. Mint and O. Quick) and September 1998 (O. Xtra) respectively by the TÜV RW Anlagentechnik GmbH who acts as Notified Body.
In the amendment of the MPG by the 1. MPGÄndG of 6 August 1998, § 2 MPG was supplemented by clause 5 (in the actual version of MPG this is § 2, clause 4). Here it was laid down that the MPG is not valid for products within the meaning of § 4 LMBG. Therefore the local authority investigated whether the afore-said products would be cosmetic products.

4.2.1 Prohibition Order of the Local Authority

On 26 November 1998, the local authority prohibited the distribution of Opalescence by an interdiction order on the basis of § 27 MPG. According to § 27 (2) MPG (in the actual version § 27 (1)) the responsible authority is able to ensure that the product is withdrawn from the market if the authority establishes that the CE marking has been affixed unduly.
The authority substantiates its decision by stating that the disputed products are cosmetic products within the meaning of § 4 (1) LMBG and Article 1 CD 76/768/EEC. Thus, the Law on Medical Devices is not applicable and the CE certification is illegal. On the basis of the definition of cosmetics (see Chapter 4.1.1), the authority categorises the products as cosmetic products for the following reasons:

- bei den Produkten der Opalescence-Reihe handelt es sich um Zubereitungen, die in der Mundhöhle zur Anwendung kommen bzw. mit den Zähnen in Berührung kommen.
- auf die Wirkungsweise der Zahnbleichmittel kommt es nicht an, nur auf den Verwendungszweck, der in der Zahnaufhellung und somit in der Beeinflussung des Aussehens liegt.
- eine überwiegend medizinische Zweckbestimmung gem. Definition (*Krankheiten, Leiden, Körperschäden oder krankhafte Beschwerden zu lindern oder zu beseitigen*) treffe nicht zu, da Zahnverfärbungen keine Erkrankung per se darstellen, da die Funktionen des Zahns (Kau-, Abbiss-, Sprechfunktion) nicht beeinträchtigt würden. Außerdem seien Zahnverfärbungen überwiegend die Folge einer Erkrankung und nicht die Erkrankung selbst. Dass sich für einzelne Patienten ästhetische oder psychische Probleme aufgrund der Verfärbungen ergeben, kann nicht als Entscheidungsgrundlage für die Abgrenzung herangezogen werden, da diese Probleme auch bei kosmetischen Erzeugnissen wie Zahnpasten oder Mundspüllösungen auftreten könnten.

The manufacturer filed an opposition against this prohibition order, which was dismissed by the authority through the opposition decision of 20 August 1999.

4.2.2 Judgement of the Administrative Court of Düsseldorf

The manufacturer appealed against the prohibition order and the opposition decision based on it at the Administrative Court of Düsseldorf, which pronounced its judgement on 30 August 2000[23].
Firstly, the Court decided that the responsible authority had applied the basis for the prohibition, namely § 27 (2) MPG (Prohibition of Placing on the Market) legitimately. To be specific, this

regulation does not only come into consideration for medical products in a real sense, but also for such products that were placed on the market with the CE mark, without being medical devices.

It therefore now had to be decided whether the products in question were medical devices or cosmetics. The Court reached the decision that the products are to be categorised as medical devices. The following grounds were cited:

- aufgrund der Begriffsbestimmungen für Kosmetika und Medizinprodukte (siehe Kap. 4.1.1 und 4.1.2,) treffe eine überwiegend medizinische Zweckbestimmung (*Krankheiten, Leiden, Körperschäden oder krankhafte Beschwerden zu lindern oder zu beseitigen*) auf die umstrittenen Produkte zu, da die Produkte dazu bestimmt seien, intrinsische Zahnverfärbungen (s. Kap. 2.1.1) aufzuhellen.

  Die Begriffe *Krankheiten, Leiden, Körperschäden oder krankhafte Beschwerden* sind jedoch weder im LMBG noch im MPG oder im Arzneimittelgesetz definiert. Nach ständiger Rechtsprechung gelte:
  unter Krankheit ist jede Störung der normalen Beschaffenheit oder der normalen Tätigkeit des Körpers zu verstehen, die geheilt, d.h. beseitigt oder gelindert werden kann.[25]
  Dieser Krankheitsbegriff sei denkbar weit gefaßt. Er schließe alle Beschwerden, die von der gesundheitlichen Norm abweichen, ein, ohne Rücksicht darauf, ob die Normabweichungen nur vorübergehend oder nicht erheblich seien. Es müsse jedoch berücksichtigt werden, dass die Norm, an der die Begriffe Krankheit und Gesundheit zu messen seien, eine gewisse Schwankungsbreite aufweise. Normal verlaufende Erscheinungen oder Schwankungen der Funktionen, denen jeder Körper ausgesetzt sei, die seiner Natur oder dem natürlichen Auf und Ab seiner Leistungsfähigkeit entsprechen, würden vom Krankheitsbegriff nicht erfaßt, solange solche Erscheinungen und Schwankungen nicht über das allgemeine und übliche Maß hinausgingen[25].
  Das Gericht zieht für den vorliegenden Fall auch den Krankheitsbegriff aus dem Gesetz über die Ausübung der Zahnheilkunde[26] heran:
  Als Krankheit ist jede von der Norm abweichende Erscheinung im Bereich der Zähne, des Mundes und der Kiefer anzusehen, einschließlich der Anomalien der Zahnstellung und des Fehlens von Zähnen.
  Aufgrund dieser Definition stelle sich eine deutlich wahrnehmbare Zahnverfärbung als Krankheit dar. Im Gegensatz zu extrinsischen Zahnverfärbungen, die im wesentliche eine Folge der Nahrungs- und Genußmittelaufnahme seien und durch gründliche Zahnpflege (regelmäßiges Zähneputzen, professionelle Zahnreinigung) beseitigt werden könnten, träten interne Zahnverfärbungen nicht generell auf, sondern würden nur durch bestimmte Ursachen ausgelöst, die nicht durch gewöhnliche Zahnreinigung entfernt werden könnten. Es handele sich bei internen Zahnverfärbungen daher nicht um normal verlaufende Erscheinungen oder Funktionsschwankungen, denen jeder Körper ausgesetzt sei. Mangels Entfernbarkeit mit einfachen Mitteln gingen solche Verfärbungen auch über das allgemeine und übliche Maß hinaus. Verfärbte Zähne, deren Farbe nicht beeinflußt werden könne, würden von weiten Bevölkerungskreisen in Mitteleuropa als Normabweichung angesehen. Aufgrund des zu Grunde gelegten Krankheitsbegriffs würde nicht das Vorliegen einer unmittelbaren Funktionsstörung verlangt, sondern gelte auch für Folgeerscheinungen.
  Eine einheitliche und damit allein normgebende Zahnfarbe gebe es jedoch nicht, es bestehe eine deutliche Schwankungsbreite innerhalb der Bevölkerung. Eine Normabweichung sei daher erst ab einem gewissen Verfärbungsgrad anzunehmen. Liege die Zahnfarbe unterhalb dieser Erheblichkeitsschwelle, die bei einer mit bloßem Auge deutlichen Sichtbarkeit anzunehmen sei, könne nicht von einer Krankheit ausgegangen werden, sondern nur von einer Abweichung vom Idealbild.
- Da die streitigen Produkte bei allen internen Zahnverfärbungen angewendet werden könnten, komme es bei der Abgrenzung kosmetisches Mittel / Medizinprodukt auf die überwiegende Zweckbestimmung dieser Produkte an.
  Maßgeblich sei die überwiegende Zweckbestimmung im Sinne von § 4 LMBG. Zwar enthalte § 3 Nr. 9 MPG (Anmerkung des Autors: in der aktuellen Fassung § 3 Nr. 10 MPG) eine Legaldefinition der Zweckbestimmung, diese könne als Abgrenzungskriterium aber nicht herangezogen werden, da diese die Einordnung als Medizinprodukt bereits

voraussetze, § 2 Abs. 5 Nr. 2. MPG (Anmerkung des Autors: in der aktuellen Fassung § 2 (4) Nr. 2. MPG).
Die überwiegende Zweckbestimmung nach § 4 LMBG sei nach objektiven Maßstäben festzustellen. Dabei komme der allgemeinen Verkehrsauffassung über die Verwendung der streitigen Produkte das entscheidende Gewicht zu. Die allgemeine Verkehrsauffassung, d.h. die Auffassung aller am Verkehr mit den betreffenden Produkten beteiligten Kreise, entwickele sich in der Regel anhand konkreter Anhaltspunkte, insbesondere daran, wie die jeweiligen Produkte nach der Konzeption des Herstellers dem Verbraucher gegenüber in Verscheinung träten. Hierbei komme unter anderem der Zusammensetzung der Produkte, den Verwendungsangaben und auch der Art des Vertriebs besondere Bedeutung zu.
Hiervon ausgehend sei die überwiegende Zweckbestimmung der genannten Produkte die Linderung oder Beseitigung von Krankheiten, denn sie sollen überwiegend zur Behandlung krankhaft verfärbter Zähne eingesetzt werden.
Durch die Zusammensetzung der streitigen Produkte, die alle einen hohen Carbamid-Peroxid-Anteil enthalten, werde deutlich, dass die bestimmungsgemäße und vorrangige Eignung darin läge, krankhafte Zahnverfärbungen zu mindern oder zu entfernen. Denn nur bei den hier enthaltenen Konzentrationen des Wirkstoffes könne nach Stand der Technik eine Reduzierung oder Beseitigung solcher interner Zahnverfärbungen erzielt werden. Geringer dosierte Mittel seien offenbar ungeeignet. Die Produkte des Herstellers zielten gerade auf diesen Behandlungseinsatz (lt. Gebrauchsanweisung sind unter Indikationen aufgeführt: Verfärbungen, die auf congenitale, systemische, metabolische, pharmakologische traumatische und iatrogene Faktoren zurückzuführen sind, wie z.B. Dental-Fluorose, Tetrazyklin, Trauma, fetale Erythroblastose, Gelbsucht, Porphyrie).
Wegen der mit der Verwendung derart konzentrierter Mittel verbundenen Risiken sei eine Befunderhebung, Entscheidung über das Therapieangebot und Auswahl der anzuwendenden Mittel sowie die Durchführung der Behandlung durch den Zahnarzt erforderlich. Die Produkte würden daher ausschließlich an Zahnärzte verkauft. Damit komme aber auch der Auffassung der Zahnärzte über diese Produkte als deren maßgebliche Anwender entscheidendes Gewicht zu. Im Hinblick auf deren ärztliche Pflichten und Verantwortung sei davon auszugehen, dass diese die streitigen Produkte den Angaben in der Gebrauchsanweisung entsprechend verwenden würden und dementsprechende Vorstellung von den bestimmungsgemäßen Einsatzmöglichkeiten entwickelt hätten.
Durch die Nennung der die Verfärbung auslösenden Faktoren in der Gebrauchsanweisung werde deutlich, dass diese Produkte nicht generell, sondern nur für bestimmte Zahnverfärbungen zum Einsatz kommen sollen. Der Hinweis auf die Behandlungsalternative zu Kronen oder Verblendschalen in der Gebrauchsanweisung rücke die Produkte in genau diesen Behandlungsbereich, der nur deutlich sichtbare Zahnverfärbungen betreffe.
Diese überwiegende Zweckbestimmung werde nicht durch eine Verwendung zu rein kosmetischen Zwecken verändert, da es sich dann um eine nicht bestimmungsgemäße Verwendung handele.

4.2.3 Judgement of the Higher Administrative Court of North-Rhine Westphalia

The responsible authority filed an appeal against this judgement, which was heard at the Higher Administrative Court of North-Rhine Westphalia. On 14 August 2003 the judgement was pronounced[24].
The Court decided that the appeal was in fact admissible, but unfounded, and dismissed the appeal.
The central question of the dispute, whether the Plaintiff's tooth bleaching products are cosmetics and therefore illegally bear the CE mark as a medical device, was denied by the Court. The Court substantiates its decision that the disputed products are medical devices as follows:

- Es wäre zwar denkbar, dass Produkte sowohl unter die Definition des MPG als auch die des LMBG fallen. Rechtlich könne es sich aber nur um ein Medizinprodukt *oder* um ein Kosmetikum handeln. Für die rechtliche Abgrenzung, ob es sich um ein Medizinprodukt

oder ein Kosmetikum handelt, müsse zunächst § 2 Abs. 5 Nr. 2 MPG (Anmerkung des Autors: in der aktuellen Fassung § 2 Abs. 4 Nr. 2 MPG) herangezogen werden, wonach das Medizinprodukt nicht für kosmetische Mittel im Sinne des § 4 LMBG gilt. Hieraus hat das Verwaltungsgericht zutreffend gefolgert, dass die eigentliche Abgrenzungsnorm § 4 LMBG ist.

Der Vorrang von § 4 LMBG vor § 3 MPG habe insbesondere zur Folge, dass es nicht – wie nach der Begriffsbestimmung des § 3 Nr. 1 MPG – auf die Zweckbestimmung durch den Hersteller ankomme.

Bei der Auslegung von § 4, Abs. 1 LMBG (siehe Kap. 4.1.1) sei zu berücksichtigen, dass dieser auf der Umsetzung des Art. 1 Abs. 1 der Richtlinie 76/768/EEC (siehe Kap. 3.1.1) beruhe und daher das Gemeinschaftsrecht zu berücksichtigen sei.

Aufgrund der unterschiedlichen Wortwahl der Definitionen könne es im Fall der Gleichgewichtigkeit von kosmetischer und sonstiger Bestimmung (d.h. wenn die Bestimmung des Produktes zu 50 % kosmetisch und zu 50 % medizinisch wäre) zu unterschiedlichen Ergebnissen kommen: nach § 4 Abs. 1 LMBG liege ein Kosmetikum dann nicht vor, wenn das in Rede stehende Mittel überwiegend zu einem anderen Zweck, z.B. Krankheiten, Leiden, Körperschäden oder krankhafte Beschwerden zu lindern oder zu beseitigen, verwendet werde, während nach Art. 1 Abs.1 CD der kosmetische Zweck überwiegen müsse. Nach deutschem Recht bliebe das Mittel ein Kosmetikum (da die medizinische Bestimmung überwiegen muß, um ein Medizinprodukt oder Arzneimittel zu sein), nach der Richtlinie wäre es ein Medizinprodukt oder Arzneimittel (da die kosmetische Bestimmung überwiegen muß um ein Kosmetikum zu sein). Für die Auslegung sei ein Auslegungsspielraum erforderlich. Angesichts des klaren Wortlauts des § 4 Abs. 1 LMBG würde im Fall der Gleichgewichtigkeit ein solcher Auslegungsspielraum fehlen.

Nach der Rechtsprechung des Europäischen Gerichtshofs müsse dem Vorrang des Gemeinschaftsrechts Geltung verschafft werden, wenn die nicht ordnungsgemäß umgesetzte europäische Regelung für den Bürger günstiger sei („effet utile“).

- Bei den streitbefangenen Zahnbleichmitteln handele es sich schon nicht um Zubereitungen aus Stoffen, die dazu bestimmt seien „äußerlich am Menschen oder in seiner Mundhöhle“ zur Beeinflussung des Aussehens angewendet zu werden, so dass sie bereits den ersten Teil der Definition in § 4 Abs. 1 LMBG nicht erfüllten.

  Hierbei sei davon auszugehen, dass das Wort „äußerlich“ sich nicht nur auf die nachfolgenden Wörter „am Menschen“ beziehe, sondern auch auf die Mundhöhle. Es wäre auch denkbar, den Begriff „äußerlich“ als nicht zur Mundhöhle passend zu beurteilen. Unter Heranziehung von Art. 1 Abs. 1 der Richtlinie 76/768/EEC , wo es heißt „äußerlich...mit den Zähnen und Schleimhäuten der Mundhöhle“, ergebe sich auch für den deutschen Begriff „äußerlich“ eine eindeutige Auslegung in Bezug auf „Mundhöhle“.

  - Unzutreffend sei eine Auslegung der Kosmetik-Richtlinie dahingehend, dass zwischen den Wörtern „Zähne“ sowie „Schleimhäuten“ das Wort „*und*“ steht, so dass ein Produkt kein Kosmetikum sein könne, das nur mit den Zähnen *oder* den Schleimhäuten in Verbindung kommen soll. Es sei nämlich nicht zu erkennen, warum ein Ausschluß von nur aud die Zähne oder nur auf die Schleimhäute bezogenen Produkten hätte gewollt sein sollen. Außerdem sei bei dem Klammerzusatz der Gebrauch von „und“ nicht additiv sondern trennend gemeint.

    Im Richtlinien-Text werde der Begriff „äußerlich“ ergänzt um die Worte „in Berührung zu kommen“, was deutlich auf Äußerlichkeit hinweise und zwar entsprechend der Satzstellung auch bei Zähnen und Schleimhäuten. Hätten die Zähne von dem Erfordernis „äußerlich“ ausgenommen werden sollen, wäre die Richtlinie anders zu formulieren gewesen.
- Ob es sich bei den streitigen Zahnbleichmitteln um kosmetische Mittel im Sinne von § 4 Abs. 1 LMBG handele, sei weiter danach zu beurteilen, ob sie „dazu bestimmt“ seien, in der Mundhöhle des Menschen „*äußerlich*“ zur Beeinflussung des Aussehens *angewendet zu werden*.

  Nach ständiger Rechtsprechung in Abgrenzungsfragen habe die Einordnung eines Produktes hinsichtlich der Zweckbestimmung nach objektiven Merkmalen zu erfolgen.[27, 28, 29]

Diese objektiven Merkmale bestimmten die Verkehrsauffassung und im Rahmen dieser, wie sich die fraglichen Produkte für einen durchschnittlich informierten, aufmerksamen und verständigen Durchschnittsverbraucher darstellten.[27, 28, 29]
Die Verbrauchererwartung als Teil der Verkehrsauffassung knüpfe regelmäßig an eine schon bestehende Auffassung über den Zweck vergleichbarer Mittel und ihrer Anwendung an, die wiederum davon abhänge, welche Verwendungsmöglichkeiten solche Mittel ihrer Art nach haben.
Die Vorstellung der Verbraucher von der Zweckbestimmung könne durch die Auffassung der pharmazeutischen oder medizinischen Wissenschaft, dem Produkt beigefügte oder in Werbeprospekten enthaltene Indikationshinweise und Gebrauchsanweisungen sowie der Aufmachung des Produkts beeinflusst werden.[29]
Da die Vorstellung der Verbraucher auch von der medizinischen Wissenschaft beeinflusst werde, könne es sich bei dem Durchschnittsverbraucher nicht um den vom Zahnarzt noch nicht aufgeklärten Verbraucher handeln. Der unaufgeklärte Verbraucher möchte nämlich nur sein Zähne aufgehellt wissen, habe aber noch keine Vorstellung von der Vorgehensweise, insbesondere nicht, ob die Produkte „äußerlich“ oder nicht „äußerlich“ wirken würden.
Im Gegensatz zum angefochtenen Urteil, das als Durchschnittsverbraucher die Zahnärzte selbst sehe, neigt der Senat dazu, den vom Zahnarzt aufgeklärten Verbraucher als Durchschnittsverbraucher anzusehen.
Dass dies der potentielle Patient sei, werde auch dadurch klar, dass er und nicht der Zahnarzt die Initiative ergreife und die letztendliche Entscheidung, ob die Maßnahme erfolgt oder nicht, bei ihm liege.

- Für die Prägung der Verbrauchererwartung sei wesentlich, dass die Wirkung der Anwendung der Gattung der Bleichmittel, zu denen auch die streitigen Produkte gehören, nicht äußerlich, sondern im Zahn selbst erfolge. In der Literatur werde zwar vertreten, dass es zur Erfüllung des Begriffs „äußerlich“ nicht auf die „äußerliche Wirkung“, sondern nur auf die „äußerliche Anwendung“ ankomme[30]. Der Senat, der sich aus diversen Stellungnahmen über Bleichmittel informiert habe und daher die Verbrauchererwartung beurteilen könne, gehe aber von einer anderen, mehr von den Umständen des Einzelfalls geprägten Sichtweise des angesprochenen Verbrauchers aus. Dabei gelte zunächst, dass bei der Vorgehensweise im Falle von nicht-vitalen und vitalen Zähnen der innerliche Wirkmechanismus gleich sei – wenn auch in umgekehrter Richtung, da bei nicht-vitalen Zähnen das Öffnen der Pulpahöhle prägend hinzukomme. Die innere Wirkungsweise sei für den Verbraucher gerade deshalb bedeutsam und nicht etwa eine technische Detailfrage, weil er durch die Wirkung im Inneren – anders als bei nur äußerlicher, mechanischer Vorgehensweise wie bei Zahnweißern – Hoffnung auf ein dauerhaftes Ergebnis setzen könne, andererseits Fragen nach Schmerzen, Funktionsbeschränkungen und Nebenfolgen nahe gelegt würden. Angesichts des möglichen Eingriffs in seinen Körper und angesichts seiner Unkenntnis über Zeitaufwand, Kosten und Erstattungsmöglichkeiten, aber auch über Schmerzen, Funktionsstörungen und Nebenwirkungen, gehöre zum „interessierten und informierten“ Durchschnittsverbraucher die Information durch den Zahnarzt. Dieser Durchschnittsverbraucher werde dann auch verstehen, dass es äußerliche Ablagerungen auf den Zähnen gebe, die durch andere Aufhellungsmittel, nämlich Zahnweißer – im Gegensatz zu den Zahnbleichmitteln, beseitigt werden könnten. Nach Einholung des zahnärztlichen Rates erwarte der Durchschnittsverbraucher auch bei vitalen Zähnen keine nur äußere Aussehensveränderung mehr.
- Die Verbrauchererwartung an die Zweckbestimmung werde auch dadurch zu einer medizinischen geführt, weil der Zahnarzt an dem Behandlungsvorgang wesentlich beteiligt sei, nicht nur bei nicht-vitalen Zähnen, bei denen die Zähne aufgebohrt werden, sondern auch bei vitalen Zähnen durch die Notwendigkeit der Anpassung einer individuellen Schiene.
- Die Anwendungsmöglichkeit – hier die Wirkung im Innern der Zähne, Anwendung und Aufsicht durch den Zahnarzt – sei einer der Gesichtspunkte, die auch der EuGH bei Abgrenzungsentscheidungen heranziehe.[31]

- Auch Inhaltsstoffe könnten die objektive Zweckbestimmung beeinflussen[27], ebenso die Gefahren bei der Verwendung[32]. Hierzu verweist das Gericht auf die Stellungnahme des Wissenschaftlichen Ausschusses für Kosmetik und Non-Food-Produkte für den Verbraucher (SCCNFP) bezüglich Wasserstoff- bzw. Carbamid-Peroxid,[11] (siehe auch Kap. 3, Diskussion um die Erhöhung des Grenzwertes auf 3.6 %) und beurteilt diese wie folgt: Wenn Zahnweißprodukte, die mehr als 0.1 % Wasserstoffperoxid (0.3 % Carbamid-Peroxid) enthalten, mit einem Hinweis versehen sein sollten, mit dem vor einer übermäßigen bzw. mehrmaligen Anwendung von Zahnweißmitteln sowie vor einer Anwendung während der Schwangerschaft oder durch gewohnheitsmäßigen Tabak- und Alkoholkonsum gewarnt werde, werde über 50 % der allgemeinen Bevölkerung von der Anwendung der Produkte ausgeschlossen, so dass die für die Regulierung kosmetischer Mittel innerhalb der Gemeinschaft zuständigen Dienststellen der Meinung waren, dass angesichts dieser Einschränkungen es nicht angebracht wäre, Bestimmungen in Bezug auf einen solchen Inhaltsstoff in die Richtlinie 76/768/EEC aufzunehmen. Auch wenn der SCCNFP seine Stellungnahme dahingehend revidiert habe, dass Wasserstoffperoxid den Fötus nicht erreiche und deshalb auf eine Warnung in Bezug auf eine Schwangerschaft verzichtet werden könne[12], ergebe sich, dass gesundheitliche Bedenken nicht nur in Bezug auf das Zahnfleisch bestünden, sondern wegen der Gefahr der Tumorbildung bei ganzen Bevölkerungsgruppen, nämlich bei anfälligen Personen mit Risikoverhalten.
- Diese Kriterien – Anwendungsmöglichkeit, Inhaltsstoffe, Gefahren – bewirkten, dass der informierte Verbraucher nicht nur von einer nicht äußerlichen Wirkung der Zahnbleichmittel ausgehe, sondern den beschriebenen Umständen auch wesentliches Gewicht beimesse, so dass der ursprünglich ästhetische Anlass zurücktrete.
- Nach Anhang III, Teil 1, lfd. Nr. 12 der Kosmetik-Richtlinie bzw. Anlage 2, Teil A, lfd. Nr. 12 der deutschen Kosmetik-Verordnung dürfe „Wasserstoffperoxid und andere Wasserstoffperoxid freisetzende Verbindungen oder Gemische, Carbamid-Peroxid und Zinkperoxid“ in „Mundpflegemitteln“ nur in einer Höchstmenge von 0.1 % anwesend oder freigesetzt sein. Dass die Konzentration in den streitigen Produkten höher sei, sage für die Einordnung nichts. Die zeitweilige Normergänzungsabsicht bestätige aber, dass die Produkte keine „Mundpflegemittel“ seien.
  Nach dem Regelungszusammenhang „Höchstkonzentration“ dürfe nicht auf einen Willen des Normgebers zu einer Begriffsfestlegung oder Produkteinordnung geschlossen werden. Das gelte umso mehr, als die 1999 in der Kommission diskutierte Ergänzung von Anhang III, Teil 1, lfd. Nr. 12 der Kosmetik-Richtlinie, wo die schon beschriebene Regelung für Zahnweißer angefügt werden sollte, nicht erfolgt sei. Dies zeige, dass die fraglichen Produkte keine „Mundpflegemittel“ seien.
  Dass die Einordnung der von Zahnärzten angewandten, hier strittigen Zahnbleichmittel über die Jahre virulent war, der Normgeber eine derartige Kategorie aber nicht in die Kosmetik-Richtlinie aufgenommen habe, zeige vielmehr, dass die strittigen Produkte keine Kosmetika sein sollen. Dies werde dadurch unterstützt, dass dem Normgeber bekannt sein müsste, dass eine CE-zertifizierte Anzahl von Zahnbleichmitteln in den Mitgliedstaaten auf dem Markt war. Dies bedeute zugleich, dass die fraglichen Inhaltstoffe in Verbindung mit den von ihnen ausgehenden Gefahren und Anwendungsmodalitäten eine Einordnung als Kosmetika nicht zulassen würden.
- Der Senat verkenne nicht, dass in dem vergleichbaren englischen Fall, von dem drei Urteile in den Akten seien, das erste Urteil vom 4.8.1998 ebenfalls auf die Wirkweise der strittigen Bleichmittel im Zahninneren abgestellt habe, dass diese Sichtweise jedoch in den nachfolgenden Urteilen vom 1.7.1999 und vom 28.6.2001 verworfen worden sei (siehe Kapitel 5.2). Soweit das Berufungsurteil vom 1.7.1999 ausführt, es sei nicht richtig gewesen, dass der Vorderrichter der Wirkung des Mittels so viel Gewicht beigemessen habe, weil es nicht auf die Wirkung, sondern auf den beabsichtigten Zweck ankomme, bedürfe es keiner vertieften Auseinandersetzung damit. Die englischen Urteile stellten – anders als nach der ständigen Rechtsprechung in Deutschland geboten – nicht auf die Verkehrsanschauung oder auch nur auf die von dieser umfassten Verbrauchererwartung ab. Beide würden jedoch – wie ausgeführt – sehr wohl von der Anwendungsmöglichkeit, den Inhaltstoffen und den Gefahren der Zahnbleichmittel geprägt.

Bereits danach sei das Kriterium „äußerlich“ im Sinne des § 4 Abs. 1 LMBG objektiv und nach der Verkehrsanschauung nicht gegeben.

- Aus der Stellungnahme eines Sachverständigen gehe hervor, dass er die äußere Anwendung mehrheitlich verneint. Nach Wiedergabe möglicher Begriffsbestimmungen für „kosmetische Mittel“ – auch von § 4 Abs. 1 LMBG – würde man Bleichmittel nicht zu der Gruppe der Kosmetika rechnen können, weil sie nicht auf die Haut, sondern in (und gelegentlich auf) die Zähne appliziert werden. Der Gebrauch des Wortes „Haut“ sei zwar eine gewisse begrifflich verkürzende Unschärfe, die aber für die eigentliche Gewichtung unerheblich sei. Allerdings stelle der Sachverständige nicht auf den Wirkungsort der Zahnbleichmittel allein ab, sondern darauf, dass nicht-vitale Zähne zunächst aufgebohrt werden müssten und die Wirkung des Bleichmittels von ihrem Innern ausgehe.
- Der Senat verkenne auch nicht, dass nicht alle Anwendungsgründe im Zahn krankheitsbezogener Art seien. Wie aus der Stellungnahme des Sachverständigen hervorgehe, gebe es degenerative Veränderungen der Zahnpulpa im Rahmen des natürlichen Alterungsprozesses. Ob wegen dieses Grundes Bleichmittel eingesetzt werden und in welchem Umfang, bedürfe keiner weiteren Aufklärung. Im Rahmen der Beurteilung des Erfordernisses „äußerlich“ komme es nämlich auf den nur die überwiegende objektive Zweckbestimmung prägenden Gegensatz „im weiten Sinne krankheitsbezogen“ – „altersbedingt“ nicht an.
- Nachdem sich im Rahmen der Ausführungen zum Fehlen des Erfordernisses „äußerlich“ gezeigt habe, dass die diesbezügliche Verbrauchererwartung und Verkehrsanschauung auch durch - die Modalitäten der Anwendung (Zahnarzt),
  - den hochdosierten Inhaltsstoff mit seiner Wirkung im Zahninneren
  - und die damit verbundenen Gefahren beeinflusst werde,

  begründet der Senat die Entscheidung zusätzlich auch damit, dass aus diesen Gesichtspunkten
  und den gescheiterten Bemühungen einer Ergänzung der Kosmetik-Richtlinie durch die Kommission

  folge, dass die kosmetische Zweckbestimmung – trotz des kosmetisch/ästhetischen Ausgangspunkts – nicht gegeben sei, jedenfalls nicht überwiege.
- Scheitern nach den vorstehenden Ausführungen schon die Feststellung des Tatbestandsmerkmals „äußerlich“ in § 4 Abs. 1 Halbsatz 1 LMBG und die Anerkennung einer kosmetischen Zweckbestimmung im Sinne der vorgenannten Vorschrift, brauche auf das Vorliegen einer anderen Zweckbestimmung nicht eingegangen zu werden. Letztlich habe der Senat keine Bedenken, die fraglichen Zahnbleichmittel mit dem angefochtenen Urteil als Medizinprodukt anzusehen, da sie die Kriterien der Begriffsbestimmung in § 3 MPG erfüllten.

5 Legal position in the United Kingdom

5.1 Legal basis

5.1.1 Cosmetic products

The Cosmetics Directive 76/768/EEC had been implemented in the United Kingdom by the Cosmetic Products (Safety) Regulations[33].

According to Art. 3 (1) of this regulation, "cosmetic product" means

any substance or preparation intended to be placed in contact with any part of the external surfaces of the human body (that is to say, the epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours except where such cleaning, perfuming, protecting, changing, keeping or correcting is wholly for the purpose of treating or preventing disease.

Similar to the German definition, products for the purpose of treating or preventing disease are excepted.

The use of hydrogen peroxide as it is described in Annex III of the EU directive can be found in Schedule 4, Part I of the Cosmetic Products (Safety) Regulations. The content of hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide including hydrogen peroxide-urea (hydrogen peroxide-carbamide) and zinc peroxide in oral hygiene products may not exceed 0.1 %.

5.1.2 Medical devices

The Medical Devices Directive 93/42/EEC, the *In Vitro* Diagnostic Medical Devices Directive 98/79/EC and the Active Implantable Medical Devices Directive 90/385/EEC have been implemented in the United Kingdom by the Medical Devices Regulations[34].
According to Part I, No. 2 of this regulation, "medical device" means

an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which –

a. is intended by the manufacturer to be used for human beings for the purpose of
   i. diagnosis, prevention, monitoring, treatment or alleviation of disease,
   ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
   iii. investigation, replacement or modification of the anatomy or of a physiological process, or
   iv. control of conception; and
b. does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means.

5.2 Case-law in UK

The same products that were the object of trials in Germany were also tried to come to terms in the UK. In April 1992, the company Optident Ltd. as the UK distributor of the company Ultradent Inc. placed the product "Opalescence" on the market. In October 1992 the Cosmetics Directive was amended by the Directive 92/86/EEC which proscribed the use of hydrogen peroxide in oral hygiene products in concentrations higher than 0.1 % (present or released). In November 1993 the Department of Trade and Industry (DTI) advised that the product was regulated by the EC Cosmetics Directive and not permitted for dental bleaching because it contained more than 0.1 % hydrogen peroxide (equivalent). Opalescence was withdrawn from the market. After the Medical Device Directive came into force in 1995, Opalescence had been certified as medical device by the German TÜV RW Anlagentechnik GmbH who acts as Notified Body. So it could be marketed in all Member States of the EU. Article 1 (5) (d) of MDD provides that the directive does not apply to cosmetic products covered by the CD 76/768/EEC. So the DTI and the Department of Health (DOH) considered that because Opalescence was a cosmetic product it did not come within the scope of the MDD and because of its content of carbamide peroxide its marketing in UK was prohibited by the CD. Optident Ltd. and Ultradent Inc. now sued the Crown Departments DTI and DOH in the High Court (Royal Court of Justice). They claim that the Crown Departments' statements amounted to an infringement of Article 4 MDD. Article 4 MDD prohibits EU Member States from creating any obstacle to the placing on the market within their territory of a device bearing the CE mark.

5.2.1 Judgement of the Royal Court of Justice

The issues were tried by judge J. Laws. He analysed the dispute into four questions:

A. Where a CE mark has been conferred in relation to a product in one Member State and has not been revoked, must the relevant authorities in the other Member States respect

it and so allow the product's free movement within their jurisdictions, even though on the facts the products falls within the Cosmetics Directive, unless and until the CE-mark is cancelled or withdrawn?

B. Is Opalescence a cosmetic product within the CD?

C. Is Opalescence a medical device within the MDD?

D. Have the defendants placed unlawful obstacles against the marketing or putting into service of Opalescence?

On 19 October 1998 the judgement was pronounced. Judge J. Laws answered the questions A., C. and D. with *yes*, question B. with *no*.

The considerations which influenced him to decide that the tooth bleaching product is *not* a cosmetic product were:

1. Opalescence fell outside the definition because the word "and" in the phrase "the teeth *an*d the mucous membranes of the oral cavity" was used in a conjunctive sense but the intended application of Opalescence was to the teeth alone;
2. the illustrative list of cosmetic products set out in Annex I CD indicated that the effect of the use of a cosmetic was temporary, superficial and reversible, but the effect of Opalescence was not transient;
3. the nature and purpose of Opalescence is to ameliorate a troublesome condition which arises in specific circumstances and is different in kind from those of a "cosmetic device";
4. the reference to "changing appearance" in the context of cleaning, perfuming, correcting body odours or protecting was consistent with the underlying effect of a cosmetic being temporary, superficial and reversible;
5. a property of the mechanism of Opalescence is that it penetrates the tooth structure at least to the dentine, so that, at least in relation to non-vital teeth, it is intended to be "implanted" so as to be excluded by the reference to the fifth recital to the CD.

The questions A, C and D deal with the question whether the MDD applies to Opalescence.

In question A, J. Laws came to the conclusion that once the CE mark was attached, the only way to override the effect of the mark was by taking steps under the MDD so that even Opalescence would be a cosmetic product within the meaning of CD the authorities could do nothing about it as a matter of law. He thought that a product could as a matter of fact be both a cosmetic product and a medical device, but as a matter of law, it could only be subject to one regime at the same time. He thought that Article 1 (5) (d) MDD merely provides that the regimes are mutually exclusive.

Question D refers to the free movement of good as described in Article 4 (1) MDD: *"Member States shall not create any obstacles to the placing on the market …"*. J. Laws concluded that the fact that Opalescence bore the CE mark meant that in particular Article 4 MDD applies.

Concerning the question C, J. Laws decided that Opalescence was a medical device within the definition of MDD. He considered that it was intended by the manufacturer to alleviate a disease or a handicap or to modify the anatomy (Article 1 (2)(a)).

5.2.2 Judgement of the Supreme Court of Judicature

The Crown Departments DTI and DOH now appealed this judgement and the case was tried at the Supreme Court of Judicature[35]. On 1 July 1999 the judgement was announced. The court decided that Opalescence is a cosmetic product. The propositions of J. Laws for considering Opalescence not as cosmetic products have been discussed:

- proposition 1 (a cosmetic product must be intended for "tooth *and* mucous membranes"): First, the phrase "tooth and mucous membranes of the oral cavity" is used in contradistinction to the earlier phrase "the various external parts of the human body". Just as it is obviously unnecessary in order to qualify as a cosmetic product for the relevant substance to be intended to be placed in contact with all the external parts of the human body so it does not seem to be necessary that it should be intended to be placed in contact with both the teeth and the gums. Second, the phrase "the various external parts of the human body" is explained by the phrase ("epidermis, hair system, nail, lips, and external genital organs"). It is plain that in that context the word "and" is used in disjunctive sense. There are no good reason why it should be regarded as used in a different sense in the context of teeth and gums. Third, the illustrative list in Annex I refers to "products for care of

the teeth and the mouth". It cannot have been intended to exclude products for the care of the teeth *or* the mouth.

- proposition 2 (the effect of a cosmetic product must be temporary, superficial or reversible): this common factor was derived from the illustrative list in Annex I CD. So it can be considered together with
- proposition 4 (the common element in the processes of cleaning, perfuming, correcting body odours or protecting is likewise temporary, superficial or reversible): First, the products listed in Annex I CD are, as stated, illustrative only. Article 1 (2) does not indicate that the list is exhaustive so as to be capable of restricting the width of the definition itself. Second, it is by no means clear that the effect of all the products described in the list is temporary, superficial or reversible. For example it was not established by evidence and is not obvious that the effect of a hair bleach on the strands to which it is applied is temporary, or of a depilatory is reversible or of a deodorant superficial. And what of "products for tanning without sun" or "anti-wrinkle products"? The same considerations apply to the processes of cleaning, perfuming, correcting body odours or protecting. "Protecting" like "changing appearance" may well be permanent and neither superficial or reversible. These considerations lead naturally to the third – it is wrong to place such weight on the effect of the product. Not the effect, but the intended purpose matters. The words of the definition point to the purpose in the phrases *"intended to be placed in contact with"* and *"with a view exclusively or mainly to"* cleaning etc. Were it otherwise it would be productive of much uncertainty for the gradations of effect by the standards of what is temporary, superficial or reversible are too many. Moreover the concern of the CD is with the use of substances in the context of safeguarding public health. The seventh recital recognises the need to have regard to the possibility of danger to zones of the body contiguous with the areas of application of the substance. The question of whether the effect of the substance as a cosmetic is temporary, superficial or reversible would seem to be immaterial when compared with the intended use of the substance. In this connection it is referred to publicity material that shows that the purpose of the treatment is to whiten dark teeth. Such purpose is properly described as cosmetic even if some of the underlying reasons for it go beyond mere beautification of the body.
- proposition 3 (nature and purpose is to ameliorate a troublesome condition): The troublesome conditions to which J. Laws referred were analogous with disfiguring birthmarks for which the assumed treatment was the application of a substance under the supervision of a skin specialist. The court can not accept this proposition either. For example a face cream is specially included in the list of Annex I. There is nothing in the CD to suggest that such a substance is included if used for beautification but excluded if recommended by a skin specialist to a teenager suffering from acne.
- proposition 5 (in its application to non vital teeth Opalescence is implanted in the human body and therefore excluded from the definition of a cosmetic product): But J. Laws was mistaken in his understanding of how Opalescence gel is applied in the case of non-vital teeth. He appears that the gel was left in such a tooth and sealed in by the filling. If so he was mistaken because the evidence was clear that all traces of Opalescence gel were washed out before the filling was installed. So the aspect of implantation is eliminated.

In addition the court did not accept the argument of the counsel for the claimants who emphasised that the manufacturer's publicity material pointed out, that the use of Opalescence was an alternative to composite placement, veneers or crowns and this would be a recognised aspect of dentistry. The counsel for the claimants further underlined the consideration that Opalescence was only supplied to dentists and applied on their recommendation and subject to their supervision. The judge of the Supreme Court argued that the first and the third of these factors seemed to be merely different ways of adverting to proposition 3. The second factor cannot alter the plain meaning of the definition.

The court also investigated question C of J. Laws and decided that Opalescence is *not* a medical device: The Crown Departments DTI and DOH suggested that having teeth in need of bleaching is not a disease, though it may be the symptom of a disease nor is it either a physical or mental, though it may be a social handicap. It is contended that even if the Opalescence gel permeates into the dentine that cannot amount to a modification of the anatomy. Out to determine it would involve the court interpreting the words "disease" and "handicap" so as to exclude the symptoms of

the one and a social variant of the other. The court was also doubtful whether the intended purpose of Opalescence is the alleviation of any such disease or handicap or the modification of the anatomy. Article 1 (2)(g) specifies that the intended purpose is that of the manufacturer and is to be ascertained from the labelling, instructions and promotional materials supplied by him. The fair reading of such material indicates that the purpose of Opalescence is bleaching dark teeth, whatever their cause, rather than the alleviation of the condition which gave rise to them.
As a consequence of Opalescence being a cosmetic product, the court decided that it is excluded from the whole MDD by the terms of Article 1 (5)(d) (*"this directive does not apply to ..cosmetic products covered by Directive 76/768/EEC"*). The fact that it bears the CE mark does not change that because the CE mark is not "granted in any member state".

5.2.3 Judgement of the House of Lords

Now Ultradent Inc. and Optident Ltd. appealed this judgement. The case was retried by the House of Lords[36]. The judgement was pronounced on 28 June 2001. The House of Lord dismissed the appeal and constituted that Opalescence is a cosmetic product within the meaning of the Cosmetics Directive and is excluded from the application of the Medical Devices Directive.
Lord Slynn of Hadley, the main speecher of the House of Lords, explained the reasons for the decision.
In his speech, he first explained the regimes of the CD and MDD and he pointed out that the two regimes were not only different but were intended to be separate and distinct. So it is not surprising that Article 1 (5) (d) MDD excludes cosmetic products. He did not accept the approach of J. Laws who took the view that if a CE mark was "granted" in one Member State it must be respected in other Member States, that the CE mark excludes the competence of the national authorities and the courts of a Member State in order to achieve uniform application of the Community-wide regime throughout the Member States. He pointed out that to benefit from the protection of Article 4 (1) MDD the product has to be a medical device and not a cosmetic product. The fixing of the CE mark does not mean that it is not a cosmetic product.
Then he considered whether Opalescence is a cosmetic product within the meaning of CD:

- The CD expressly excludes, as it is said in the recitals, that a product, even if otherwise within the definition of CD, is not within the directive if it is "exclusively intended to protect from disease". There is no suggestion here that Opalescence is "exclusively intended to protect from disease" even if in some cases the darkening of teeth may result from disease. Since one of the purposes of Opalescence use is to lighten teeth darkened by the ageing process it obviously cannot be said that it is exclusively intended to protect from disease.
- Next it is said in the recitals that substances "injected or implanted in the human body" do not come under the field of cosmetics. Because of the use of Opalescence in non-vital teeth, J. Laws thought it is excluded from the field of cosmetics. According to the description of the process of dealing with non-vital teeth, it is plain that the Opalescence put into the canal is removed before the canal is finally sealed.
- At first instance, J. Laws rejected Opalescence as a cosmetic product because the definition of cosmetic product said "contact…with the teeth ***and*** the mucous membranes" but it was clearly not intended to be in contact with both teeth and mucous membranes (see chap. 5.2.1, proposition 1.). But the words are to be read disjunctively. It is enough if the product is to be intended to be in contact with teeth ***or*** membranes. In a similar way the words defining the "various external parts of the human body" are to be read disjunctively. It would be ludicrous to reject lipstick because it was not intended for use on the hair system or the external genital organs.
- The 1993 Directive (remark of the author: the definition in CD was changed in 1993 by directive 93/35/EEC) provides that they must be so placed *"with a view exclusively or mainly to cleaning them … changing their appearance…and/or protecting them or keeping them in good condition"*. It seems that it is arguable that what is done here is to clean the teeth in some cases or to contribute to keeping them in good condition. But it is clear that Opalescence is put in contact with the teeth exclusively or mainly to "change their appearance" whatever other effects the Opalescence may have on the inner layers of the teeth.

- It is suggested that Opalescence is used “to ameliorate a troublesome condition which arises in specific circumstances” (proposition 3.). It is difficult to understand that it cannot therefore be a cosmetic product. Many cosmetic products such as face creams can be said to deal with troublesome conditions.
- It has also been said that, based on the illustrative list of cosmetic products in Annex I CD, to be a cosmetic the effect of the substance must be temporary, superficial or reversible (proposition 2 and 4). But in the first place the list is merely illustrative and it is not clear that all the products listed have merely temporary, superficial or reversible effects. What should be regarded as temporary, superficial or reversible may in any event be a subject of debate. The important consideration however is not the effect but the intended purpose which is of relevance. It seems to be clear that the purpose here was to change or restore the appearance.

So the decision of the Court of Appeal was accepted – Opalescence is within the Cosmetics Directive. Therefore it was not necessary to decide whether it is also alternatively within the Medical Devices Directive. The House of Lords only inclined that it would be a medical device. It does not seem to them that it is a product used for the treatment or alleviation of disease. In some cases it is simply dealing with the effect of disease by changing the appearance. The suggestion that Opalescence is used to treat or alleviate or to compensate for a “handicap” within the meaning of Art. 1. 2 is questionable. Darker teeth may be less attractive than sparkling white teeth but it does not seem that they constitute a “handicap” within the meaning of MDD.

6 Legal position in Switzerland

6.1 Legal basis

Switzerland is a Member State of the EFTA (European Free Trade Association). On 1 January 1994 the Agreement on the European Economic Area (EEA Agreement) between the EFTA states Iceland, Liechtenstein and Norway on the one hand and the Member States of the European Union on the other entered into force. The aim of the EEA Agreement is to guarantee the free movement of goods, persons, services and capital.
The EEA States must continuously live up to their obligations in the EEA Agreement. In particular, they must transpose and apply the Internal Market rules (the *“acquis communautaire”*) timely and correctly. The main legal instrument of the Internal Market is that of directives, which must be transposed into national legislation in the EEA States.

6.1.1 Cosmetic products

The CD 76/768/EEC was transposed into the "Verordnung über Gebrauchsgegenstände“ (GebrV)(Ordinance on commodities)[37]. The definition of “Cosmetic Product” is given in Art. 21:

> *Kosmetische Mittel sind Stoffe oder Zubereitungen, die bestimmungsgemäss äusserlich mit den verschiedenen Teilen des menschlichen Körpers (Haut, Behaarungssystem, Nägel, Lippen und äussere Genitalregionen) oder mit den Zähnen oder den Schleimhäuten der Mundhöhle in Berührung kommen. Sie dienen ausschliesslich oder überwiegend ihrem Schutz, der Erhaltung ihres guten Zustandes, ihrer Reinigung, Parfumierung oder Desodorierung oder der Veränderung des Aussehens.*
>
> *Sie wirken lokal auf die gesunde Haut und ihre Organe, auf die Schleimhäute des Mundes oder der äusseren Genitalregionen oder auf die Zähne. Die darin enthaltenen Stoffe dürfen bei der Resorption keine inneren Wirkungen entfalten.*
>
> *Als kosmetische Mittel gelten namentlich die in Anhang 2 dieser Verordnung aufgeführten Erzeugnisse.*

Similar to Germany, in Switzerland also exists an Ordinance on cosmetic products[38], which also includes a list of substances that are only allowed to use having regard to the restrictions and conditions laid down (Annex 2). It is laid down too that the maximum permitted concentration for

hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide in oral hygiene products is 0.1 %.

6.1.2 Medical devices and drugs

The terms „Arzneimittel“ („Drugs“) and „Medizinprodukte“ („Medical Devices“) are defined in Art. 4 of the Heilmittelgesetz (HMG)(Law on drugs)[39] of 15 December 2000 as follows:

Im Sinne dieses Gesetzes gelten als:

a. *Arzneimittel: Produkte chemischen oder biologischen Ursprungs, die zur medizinischen Einwirkung auf den menschlichen oder tierischen Organismus bestimmt sind oder angepriesen werden, insbesondere zur Erkennung, Verhütung oder Behandlung von Krankheiten, Verletzungen und Behinderungen; zu den Arzneimitteln gehören auch Blut und Blutprodukte;*
b. *Medizinprodukte: Produkte, einschliesslich Instrumente, Apparate, In-vitro-Diagnostika, Software und andere Gegenstände oder Stoffe, die für die medizinische Verwendung bestimmt sind oder angepriesen werden und deren Hauptwirkung nicht durch ein Arzneimittel erreicht wird.*

The term „Medizinprodukt“ („Medical Device“) is defined again more precisely with nearly the same wording as the MDD 93/42/EEC by the Medizinprodukte-Verordnung (Ordinance on medical devices)[40]:

> *Medizinprodukte sind einzeln oder miteinander verbunden verwendete Instrumente, Apparate, Vorrichtungen, Stoffe oder andere medizinisch-technische Gegenstände, einschliesslich der eingesetzten Software sowie des Zubehörs, welche zur Anwendung beim Menschen bestimmt sind und deren bestimmungsgemässe Hauptwirkung im oder am menschlichen Körper nicht durch pharmakologische, immunologische oder metabolische Mittel erreicht wird, deren Wirkungsweise durch solche Mittel aber unterstützt werden kann und die dazu dienen, beim Menschen*
>
> a. *Krankheiten zu erkennen, zu verhüten, zu überwachen, zu behandeln oder zu lindern;*
> b. *Verletzungen oder Behinderungen zu erkennen, zu überwachen, zu behandeln oder zu lindern oder Behinderungen zu kompensieren;*
> c. *den anatomischen Aufbau zu untersuchen oder zu verändern, Teile des anatomischen Aufbaus zu ersetzen oder einen physiologischen Vorgang zu untersuchen, zu verändern oder zu ersetzen;*
> d. *die Empfängnis zu regeln oder Diagnosen im Zusammenhang mit der Empfängnis zu stellen.*

The Medizinprodukte-Verordnung (Ordinance on medical devices) also regulates the conformity assessment procedures, the placing on the market, the information on incidents etc. and thus represents the real implementation of the AIMDD, the MDD and the IVDD.

6.2 Case-law in Switzerland

Also in Switzerland there have repeatedly been discussions in the past regarding the correct classification of tooth-bleaching agents containing peroxide, whether it be as a cosmetic agent, medical device or drug. According to Bulletin 21/05 of the Federal Health Authority, Bundesamt für Gesundheit (BAG)[41], tooth-bleaching agents are exclusively aimed at the bleaching of teeth and, in consequence of a lack of definition of medical purpose, do not fall under the definition of drugs in accordance with Art. 4 HMG (see 6.1.2). However, the BAG and its forerunner, Swissmedic (Schweizerisches Heilmittelinstitut (Swiss Institute for Drugs)), had decided some years ago to categorise tooth-bleaching agents as *drugs*. The reason for this was the fact that the limit value prescribed in the Cosmetics Ordinance was always exceeded by 0.1 %, so that tooth-bleaching agents could achieve the desired effect at all. In spite of this regulation, in Switzerland still not a single tooth-bleaching product containing peroxide was applied for to be approved as a drug. The market offer for such products, imported from the EU or the USA, has, however, steadily increased

in recent months, as is proven by advertisements in magazines. Partially, the packets for Europe bear the CE mark as a medical device.

The classification of these products containing peroxide is currently under heavy discussion at the European level and should find its way into a revised version of the EU directive regarding cosmetic products in two to four years.

Until the introduction of a definitive regulation in Switzerland, the BAG and Swissmedic have agreed not to categorise tooth-bleaching agents as a drug any more, but as a *cosmetic product*, because it could take some years until the revised EU directive is adopted and because tooth-bleaching agents are currently encountered in commerce, in the case of which ambiguity exists regarding their legal status.

Until the definitive regulation in the Cosmetics Ordinance comes into force, the BAG can permit a higher peroxide content than is permissible in the Cosmetics Ordinance for oral hygiene products.

For products which are intended to be delivered to the end user, a maximum of 6 % hydrogen peroxide or equivalent amount of other oxygen-supplying substances is temporarily permitted. Products with higher peroxide contents are not approved by the BAG. They are exclusively intended for professional use (dentist).

For tooth-bleaching agents from the European region marked with the CE mark, marketed up to now as medical devices, there is a transition phase of 2 years up to 23 May 2007. Anyone who has been marketing tooth-bleaching products which are marked with the CE mark up to now must be in possession of a certificate of conformity and exhibit this to the controlling bodies upon request.

Since 23 May 2005 no *new* tooth-bleaching products marked with the CE mark may be placed on the market in Switzerland.

As the following disadvantageous effects can occur in connection with the use of tooth-bleaching agents:

- temporary increased sensitivity of the teeth
- gingivitis or gum irritations
- possible influence upon the release of mercury and the hardness of amalgam fillings

the BAG therefore recommends only using tooth-bleaching agents after consultation with a dentist, and not too often. Persons with existing or untreated caries lesions should avoid tooth-bleaching agents containing peroxide. The same applies in the case of high alcohol and/or tobacco consumption, as peroxides can reinforce the already increased predisposition to cancer of the oral cavity.
If used as prescribed, however, no toxic side effects are to be expected, according to the authorities.

7 Results and discussion

7.1 Position of the EU

As already stated in 1996 by commissioner Bonino on behalf of the Commission, addressed to the issue of the written question of the delegate Newens[42], "tooth whitening products, either used by consumers or by professionals, are cosmetic products according to the definition of a cosmetic product of the Council Directive 76/768/EEC".
This position was confirmed again on 6 September 2004 by commissioner Rehn in his written answer E-1655/04EN[43]. The Commission confirms that "tooth whitening products placed on the market for the principal purpose of lightning discoloured teeth, whether or not they contain peroxide and regardless of concentration, cannot be considered as medical devices since they do not meet

the definition of 'medical device' contained in Council Directive 93/42/EEC concerning medical devices".

Since the fifteenth adaption of the CD 76/768/EEC by the directive 92/86/EEC[6] , the maximum concentration of hydrogen peroxide (present or released) in oral hygiene products is 0.1 %. The increase of this limit has been discussed many times by the commission respectively by the SCCNFP / SCCP as can be seen in the chapters 3.2 to 3.4. But till now, a consensus on the limit was not reached.

7.2 German Case-Law

The arguments of the local authority in their prohibition order appear, to the average observer, to be entirely plausible, at first glance. The classification must, however, be viewed more closely in accordance with the legal basis or the definitions, as the Decisions of the Administrative Court of Düsseldorf and the Higher Administrative Court of North-Rhine Westphalia show.

The Courts are, first of all, in agreement that the actual delimitation norm is § 4 LMBG, as, in accordance with § 2 (4) No. 2 MPG, the Law on Medical Devices cannot be applied to cosmetic products within the meaning of § 4 LMBG.

The precedence of § 4 LMBG over § 3 MPG in particular leads to the consequence that it is not, as stated in the definition of § 3 No. 1 MPG, the intended purpose by the manufacturer that matters („*die vom Hersteller zur Anwendung für Menschen ... zum Zwecke* ...", "subjective intended purpose"), but that the intended purpose is to be determined in accordance with objective standards ("objective intended purpose").
This means that, for the classification of a product as a cosmetic or medical product (drug, medical device), its intended purpose, largely connected to objective characteristics, as it is constituted for an averagely informed, observant and judicious average consumer, is relevant.[27, 28, 29, 44]
The consumer opinion is coined by

- an already existing opinion about the purpose of comparable products and their application. This is, for its part, dependent upon what possibilities for use such products of its kind have.
- the opinion of pharmaceutical or medical science;
- the notes on indications enclosed with the product or contained in advertising brochures and instructions for use;
- the packaging in which the product generally confronts the consumer.

In determining the objective intended purpose or interpretation of § 4 (1) LMBG, the definition of a cosmetic product in accordance with Article 1 (1) CD 76/768/EEC is also to be taken into account, as § 4 (1) LMBG concerns the implementation of Community Law.

§ 4 (1) LMBG	Article 1 para 1 CD 76/768/EEC
Kosmetische Mittel im Sinne dieses Gesetzes sind *Stoffe oder Zubereitungen aus Stoffen,* *die dazu bestimmt sind,* *äußerlich* *am Menschen* *oder in seiner Mundhöhle* *zur Reinigung, Pflege oder zur Beeinflussung*	*Kosmetische Mittel* *sind* *Stoffe oder Zubereitungen,* *die dazu bestimmt sind,* *äußerlich* *mit den verschiedenen Teilen des menschlichen Körpers* *(Haut, Behaarungssystem, Nägel, Lippen und intime Regionen)* *oder mit den Zähnen und den Schleimhäuten der Mundhöhle* *in Berührung zu kommen,* *und zwar zu dem ausschließlichen oder überwiegenden Zweck,* *diese zu reinigen, zu parfümieren, ihr Aussehen*

des Aussehens oder des Körpergeruchs oder zur Vermittlung von Geruchseindrücken angewendet zu werden, *es sei denn, daß sie überwiegend dazu bestimmt sind, Krankheiten, Leiden, Körperschäden oder krankhafte Beschwerden zu lindern oder zu beseitigen.*	*zu verändern und/oder den Körpergeruch zu beeinflussen und/oder um sie zu schützen oder in gutem Zustand zu halten*

In that regard, the application of Community Law is to be enforced priority, according to the prevailing case-law of the ECJ in the interpretation of national norms which are based on provisions of Community Law ("effet utile", Art. 10 EC Treaty).

7.2.1 Intended Purpose "Äußerliche Anwendung"

In order to find the classification of the disputed products, the intended purpose, in accordance with objective characteristics, as they arise for an averagely informed, observant and judicious average consumer, must be assessed.
Here the question firstly arises, who the standard-forming average consumer is:

- the consumer who only wishes to see the discoloured teeth, which disturb him, whitened, without being advised by the dentist on the matter,
- the consumer who is interested in having his teeth whitened, and who has been informed by the dentist about the procedure, effect, risks, pains, disfunctions, side effects, time involved, costs and possibilities for reimbursement,
- the dentist himself.

While the Administrative Court of Düsseldorf sees the dentist as the average consumer, the Higher Administrative Court of NRW substantiates the fact that the informed potential patient is the average consumer, as he has to take the initiative and is responsible for making the final decision.

In her review of the Decision of the Higher Administrative Court, C. Granich[45] explains, that the intended purpose would have to be individualised, according to the consumer circles concerned, who would be responsible for determining the objective intended purpose. Labelling, instructions for use and also the consumer route contribute towards deciding who determines the objective intended purpose of the product. Should an initial consultation with a doctor result, on the grounds of the manufacturer's specifications, the purpose will be defined on the basis of the position which an average consumer holds following consultation. Should it be sold by pharmacies, the advice of the pharmacists is to be included. Should the product be freely sold in drugstores, etc., the picture formed by that average consumer who only confronts the product as it appears outwardly, without further information, would be decisive. In the opinion of the author, the latter, however, does not mean that such a consumer must come to a different conclusion regarding the intended purpose, as an "observant", "judicious" consumer would, by means of the packaging and use of tooth-bleaching agents (e.g. by means of strips or trays), try for further information from sources of information such as, for example, the Internet.

In its grounds for its Decision, the Higher Administrative Court of NRW explains that a cosmetic purpose is therefore not given, because the characteristic fact „äußerliche Anwendung" (1st part of the definition in § 4 (1) LMBG (*„äußerlich ... angewendet zu werden"*)) does already not apply.

In its analysis, the Higher Administrative Court of NRW initially establishes that, on the basis of the comparison with the wording of the European Cosmetics Directive, the word "äußerlich" also refers to the teeth. This fact is to be absolutely agreed with.

In its grounds, the Court links the term "äußerlich" with the intended purpose and argues very dubiously.

As already mentioned, the opinion of the consumer or the expectations of the consumer as part of the opinion of the consumer, is characterised by the opinion regarding the purpose of comparable products, their application and the possibilities of use for such agents. The consumer opinion is equally characterised by notes on indications and instructions for use.

In the opinion of the Court, the average consumer will, following an explanation by the dentist, understand that the category of bleaching products to which the disputed products belong, would develop its *effect* inside the teeth when it is used (for the mode of action of the bleaching agent, see Chapter 2.4). This would apply to both vital and non-vital teeth, in the case of which the opening of the dental pulp cavity would be of significance in addition. In view of the possible operation on his body, questions regarding pain, functional limitations and side effects would also be implied.
The consumer would also understand that, due to the internal mode of action, there is a difference between tooth-bleaching products and tooth-whiteners, which remove deposits in a purely mechanical way.
The Court comes to the conclusion, so to speak, that, due to the **internal mode of action**, the tooth-bleaching agent **does not have any external application**.

The author cannot accept this argumentation. In the literature (Zipfel/Rathke[30]), by the term “äußerlich“ it is not the “external effect“ that is to be understood, but the “external application“. The word „Anwendung“ is usually understood in the sense of “use“, “application“, “handling“, whereas, by “effect“, rather “result“ is meant. An average consumer (not only the consumer informed by the dentist, but also a user who has not been informed, who only, for example, takes his information from the leaflet accompanying the packet, as well as the advertising) knows the term „äußerliche Anwendung“ / "external application" from the fields of medicine and cosmetics (ointments, creams, gels, lotions, oils, etc) and understands, by that, "application to the surface of the skin", not however the result of the application or the effect of the application.
Thus the conclusion of the Court, that the non-external effect of the tooth-bleaching agent leads to the denial of the intended purpose „äußerliche Anwendung“ / “external application”, is more than questionable. What would the Court’s logic be like if applied to other products in the field of cosmetics?
This should be explained, taking the example of an anti-ageing cream[46]. According to the Internet presentation, the cream, which is described as a breakthrough in cosmetics, works as follows (highlighting by the author):

Patentierte Microbione **durchdringen die oberen Hautschichten** und transportieren als Pflegeboten Anti-Age Substanzen zu den Zellen, den Schaltstellen biologisch junger Haut. Natürliche Defizite an Vitalstoffen werden **tiefenwirksam** ausgeglichen, die Haut wird **von innen heraus** geglättet: 74% bestätigen: weniger Falten, 80% bestätigen: straffere Haut* Die Anti-Age Substanzen der patentierten MicroCell-Formel: • Duboisia-Extrakt: regeneriert die Collagenstruktur und strafft die Haut spürbar. • Körpereigenes Co-Enzym Q10: spendet den Hautzellen wichtige Lebensenergie und stärkt die Schutzfunktion der Haut vor freien Radikalen. • Hyaluron S: wirkt biorevitalisierend und bildet Feuchtigkeitsspeicher zur nachhaltigen Versorgung der Haut. * Von 523 Frauen über einen Zeitraum von 4 Wochen getestet. Zustimmungsquote in Prozent.	Patented microbions **penetrate the upper layers of the dermis** and, as care agents, transport anti-ageing substances to the cells, the centres for biologically younger skin. Natural deficits in vital substances are compensated for **at a deep level**, the skin is smoothened **from the inside out**: 74% confirm: less creases, 80% confirm: firmer skin* The anti-age substances of the patented MicroCell Formula: • Duboisia extract: regenerates the collagen structure and noticeably firms the skin. • The body’s own Co-Enzyme Q10: gives the skin cells important life energy and strengthens the protective function of the skin against free radicals. • Hyaluron S: works in a bio-revitalizing manner and forms stores of moisture for sustained supply of the skin. * Tested by 523 women over a period of 4 weeks. Agreement quota in per cent.

As also in the case of tooth-bleaching agents, also here the effective substances penetrate into the interior and bring about a change. The fact that a substance can penetrate from the outside to the inside, and works internally, has therefore not made this product to a medical device (or possibly a drug). Granich also sees it similarly when asking, from which layer of the dermis an internal reaction is to be assumed, and when, according to consumer expectations, in spite of external application, no further "external application“ exists.

Also the placement of a substance into the inside (as occurs in the bleaching of non-vital teeth through the opening up of the dental pulp cavity) still does not make a product a medical device, as the case-law shows in the case of pigmentation equipment[47]. In this case, pigmentation equipment is concerned, which serves to store dyes in the skin to produce a permanent make-up. The Courts decided that in this case there was no purely "external" application, but that the products, without doubt, exclusively served to bring about a positive change in the external appearance, within the meaning of a beautification, and thus did not serve any medical purposes whatsoever.

After its argumentation on the internal mode of action, the Higher Administrative Court goes further and argues, on the topic of ingredients and risks of use, that the *supplementation* of Annex III, Part 1, No. 12 of the Cosmetics Directive 1999 discussed in the Commission[11, 12], where the regulation of the upper limit for tooth-whitening products is supposed to be *annexed*, is not effected, which is demonstrating that the products in question are not “oral hygiene products”. The Court even goes further and argues that, through the prohibition of the supplement regarding the category “tooth-bleaching products", these products do not concern cosmetics. As can be seen from chapter 3, the SCCNFP and the Commission discussed increasing the limiting value for tooth-whitening products by 0.1 % to 3.6 %. That this plan was not realised does not mean, in the author’s opinion, that tooth-whiteners are not “oral hygiene products” and thus are not cosmetics. Alone the fact that the limiting value of “0.1 %“ for tooth whitening products was discussed indicates that the Commission assumes tooth-bleaching agents to be cosmetics.

Every consumer knows that there are also dangers and health risks, e.g. allergic reactions, intolerances or toxicities, from cosmetic products, due to their ingredients, regardless of whether they have been informed by a doctor or not. That is to say, the dangers of a product do not hinder its categorisation as a cosmetic agent.

The Court draws the conclusion that the criteria “external application“, “ingredients” and “risks” have the effect that the informed average consumer assumes a “non-external” effect of the tooth-bleaching agent and thus no, or no predominant, cosmetic intended purpose exists.

Granich[45] in addition, puts forward the following considerations: Should the Court’s method of argumentation be transferred to the tooth-bleaching agents freely available on the market, which are identical with the disputed products in regard to their composition, application and thus also mode of action, and the viewpoint of the consumer be established, firstly a well informed consumer, informed about the mode of action, could no longer automatically be assumed. It stands to reason here that the consumer would conclude „äußerlichen Anwendung“ / “external application". Should this criterion be the sole valid one for categorisation, these products would not be excluded from the category “cosmetics”. Consequently, another criterion – namely the medical intended purpose - would have to be given.

All tooth-bleaching products, regardless of whether they are mass market products (see chapter 2.3.3), home bleaching products (see chapter 2.3.2) or in-office bleaching products (see chapter 2.3.1) are not differentiated in their mode of action (penetration of hydrogen peroxide into the tooth, oxidation reaction ... see chapter 2.4), their active substance (only the concentration varies) and their risks. Should solely the argument of the Court regarding “inner mode of action” or “non-external application” be drawn upon, all these products would have to be medical devices.

In the opinion of the author, the argumentation of the Higher Administrative Court regarding the cosmetic intended purpose „äußere Anwendung“ / "external application" is quite superfluous if the choice of wording in the German version of Article 1 para 1 CD 76/768/EEC is looked at. There it is stated that “*äußerlich ... mit den Zähnen ... in Berührung zu kommen und zwar zu dem ausschließlichen oder überwiegenden Zweck, ...ihr Aussehen zu verändern“*. Here it becomes clear that the criterion for categorisation is not the „äußerliche Anwendung“ / “external application“ – there is no intended purpose “external application“, but the choice of words “*äußerlich ... in Berührung kommen*“ rather indicates the fact that the product in question must only come into contact with the teeth from the outside. The criterion for establishing the intednded purpose of a cosmetic is the alteration of the appearance. Now it could be argued that, in bleaching a non-vital

tooth, the latter is drilled into, and the agent then no longer comes into contact with the tooth from the outside, but from the inside. If, however, we take a look at the wording in the English version („*intended to be placed in contact with the various external parts of the human body … or with the teeth … with a view exclusively or mainly to … changing their appearance"*), then we recognise that "*external*" only refers to "*body*". In this case, it does not, for example, say "externally in contact with the various parts…", but "external parts…". Therefore a differentiation must be made between

- the place of application
  - outer parts of the human body (skin, hair, nails, lips…)
  - in the oral cavity (teeth, oral mucosa)
- and the purpose or the effect of application
  - cleaning
  - influence upon the appearance
  - influence upon the odour
  - maintenance of the condition

For tooth-bleaching agents, the following thus applies: Place of application – teeth, effect of application – influence upon appearance.

Contrary to the opinion of the Court, it may be more correct, due to the above-mentioned considerations, to accept the purpose „äußerliche Anwendung" / "external application" as given, and, instead, to consider the medical intended purpose.

7.2.2 Intended purpose of alleviation/treatment of diseases

After the Higher Administrative Court of NRW established that the cosmetic purpose is not given, due to the lack of the requirement "external", the Court, so to speak, in order to substantiate the results previously obtained, approves yet an existing medical purpose, as the criteria of the definition in § 3 MPG („...*Behandlung oder Linderung von Krankheiten*" - "...*treatment or alleviation of diseases*") are fulfilled. No arguments are put forward, however, in this regard, as, after all the first part of the definition in § 4 (1) LMBG (*„äußerliche Anwendung" - "external application"*) is not fulfilled.
As we have seen in the previous chapter, the argumentation of the Higher Administrative Court is, however, more than dubious. Rather, the Court would have had to investigate whether a medical intended purpose (2nd part of the definition in § 4 (1) LMBG [„...*überwiegend dazu bestimmt sind, Krankheiten, Leiden, Körperschäden oder krankhafte Beschwerden zu lindern oder zu beseitigen.*"] is predominant. Also here, the opinion of the consumer, as it is constituted in the case of an averagely informed, observant and judicious average consumer, is to be investigated.

The Administrative Court of Düsseldorf is preoccupied with investigating the medical intended purpose and, in this respect, initially with the disease term.

What is to be understood by the terms "*Krankheiten, Leiden, Körperschäden oder krankhafte Beschwerden"* is, that is to say, not defined either in the LMBG, in the MPG or in the Law on Drugs. According to prevailing case-law the following would apply[25]:

unter Krankheit ist jede Störung der normalen Beschaffenheit oder der normalen Tätigkeit des Körpers zu verstehen, die geheilt, d.h. beseitigt oder gelindert werden kann.

The Court recognises that this disease term is conceivably broadly construed. It includes all affliction which deviate from the health norm, without taking into consideration whether the deviations from the norm are only temporary or insignificant. Normally functioning symptoms or fluctuations in functions, to which every body is subject, which correspond to its nature or to the natural flow and ebb of its efficiency, would not be covered by the definition of disease, as long as such symptoms and fluctuations do not extend beyond the general and usual standard. It must, however, be taken into account that the norm, by which the terms disease and health are to be measured, demonstrates a certain range of variation.
The Court arrives at this definition of disease in consequence of its analogy in the Law regarding the Practice of Dentistry[26], which the Court draws upon in the case at hand.

Als Krankheit ist jede von der Norm abweichende Erscheinung im Bereich der Zähne, des Mundes und der Kiefer anzusehen, einschließlich der Anomalien der Zahnstellung und des Fehlens von Zähnen.

Here the question is now raised what the normal appearance of a tooth is. What is the norm tooth colouring?

The Court recognises that there is no unified, and thus sole standard tooth colouring, but that, within the population, a range of variation exists, so that, only above a “significance threshold”, namely what is clearly visible to the naked eye, an disease could be assumed. Teeth with such discolouration would, in the opinion of the Court, be viewed by large parts of the population in Central Europe as a deviation from the norm. Due to this definition of “disease“, the discolouration itself constitutes the disease, however it is not assumed that the discolouration is the result of a disfunction.

In any event, the Court does assume only intrinsic discolouration (see Chapter 2.1.1) as a disease, as this, contrary to extrinsic discolouration (see Chapter 2.1.2), does not generally occur, but is only triggered by certain factors and could not be removed by normal tooth cleaning. Intrinsic discolouration precisely does not concern normal symptoms or functional fluctuations, to which every body is subjected, while extrinsic discolouration is a normal consequence of nutritional intake and the consumption of stimulants. This opinion of the Court can, to this extent, not be shared by the author. Intrinsic discolouration is, for example, also evoked through the aging process, which naturally constitutes a normally occurring symptom and consequently does not fall under the definition of disease. Furthermore, intrinsic discolouration arises through tooth root treatments or nerve degeneration following accidents. In the author’s opinion, it constitutes a thoroughly normal occurrence that teeth take on another colour without a live tooth nerve.

Another definition of "disease" is that of general medicine[48]:

Unter dem Krankheitsbegriff wird in der allgemeinen Medizin die Störung der Lebensvorgänge in Organen oder dem gesamten Organismus mit der Folge von subjektiv empfundenen oder objektiv feststellbaren körperlichen, geistigen bzw. seelischen Veränderungen verstanden

Applied to tooth discolouration, firstly the question now arises whether the discolouration itself constitutes a disturbance to life processes in the tooth (as an organ in the broadest sense). In the case of intrinsic discolouration, chromatogenic materials are stored in dentine and enamel. The physiology of the tooth is, however, not influenced. Rather, the causes of the discolouration, such as, for example, erythroblastosis, jaundice, porphyria (according to the leaflet in the packet of the disputed tooth-bleaching agent), constitute a disease. The tooth discolouration itself is the consequence of this, in the form of subjectively felt or – according to the degree of discolouration – objectively discernible physical changes.

A further definition of disease is applied by the Federal Statistical Office (Statistisches Bundesamt) on investigation of disease costs[49]:

The Federal Statistical Office defines "disease" as *"Störung der körperlichen, geistigen oder seelischen Funktionen, die ein Ausmaß erreicht hat, bei dem eine medizinische Behandlung erforderlich wird."*

Tooth discolouration itself would not, in this regard, fall under the heading of „physical disfunction“, as the functions (chewing, biting) are not disturbed. It looks, however, quite different if a person suffers from their discoloured teeth to such an extent that it leads to mental disturbances. This, in turn, then constitutes a disease. It is, however, generally the case that products which treat a mental disturbance therefore do not become a medical device (or drug) (such as make-up which covers up the aesthetically disturbing birthmarks remains a cosmetic product).

To strengthen the Decision pronounced by the Court, that intrinsic discolourations constitute a deviation from the norm and thus would fall under the definition of disease of the prevalent case-law, Köhler/Lenz[2] argue in their essay that also the World Health Organisation WHO defines the term dental health as

lebenslangen Erhalt einer funktionellen, ästhetischen und natürlichen Dentition von nicht weniger als 20 Zähnen (ohne Berücksichtigung von Prothesen).

Therefore, intrinsic discolouration would also correspond with this definition of disease. The author cannot go along with this generalised statement. In the case of intrinsic discolouration, which

occurs, for example, through the dying off of the nerve following an accident or through earlier dental treatments, normally only a few teeth are affected, often only one or two teeth. According to this definition, up to 12 teeth could be affected (the permanent dentition has 32 teeth). Also in the case of other intrinsic discolouration, for example through fluorosis, also mostly only a few teeth are affected[50].

Significant tooth discolouration would, according to Köhler/Lenz[2], also be considered as a disease in the opinion of the consumer. The mouth region plays a lifelong prominent role for people. Conspicuous characteristics, such as, for example, tooth or jaw displacements, would trigger social conflicts among children in the puberty phase. Children with an attractive dento-facial appearance would be favoured as friends. When pathological changes occur, such as, for example, tooth discolouration, these often culminate in a fear of loss of attractiveness. The external appearance would be viewed, among consumers, as an outstanding social and psychological component. The sight of discoloured teeth would be assessed as "bedraggled" or also "diseased". White teeth would be considered by consumers to be a normal physical state, significant deviations as being a disease. The author can only partially go along with these arguments. The particular significance of the oral region, in particular the teeth, is, in the opinion of the author, thoroughly relevant, along with the fear of loss of attractiveness. However, the sign of discoloured teeth is not necessarily assessed as a disease, but rather as “unaesthetic”, which, in the author’s opinion, constitutes a great difference.

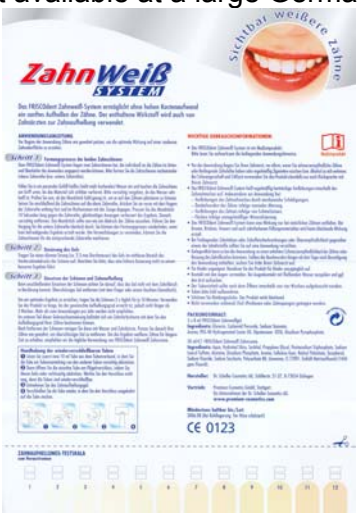
After the Court established that intrinsically discoloured teeth with a certain degree of discolouration could concern a disease, the disputed products could, however, be used with all internal discolouration, the classification problem, however, concerns the *predominant* intended purpose.

As already elucidated, the predominant intended purpose is established in accordance with objective characteristics, as they are constituted for an averagely informed, observant and judicious average consumer.
The Court sees the dentist as the average consumer, as he is accorded a decisive weight, being the significant user of the tooth-bleaching agent. To view the patient informed by the dentist as the average consumer, as the Higher Administrative Court of NRW does, necessarily leads, in the opinion of the author, to the same result regarding classification, as the dentist, in the end, passes on his knowledge to the potential user.

As a criterion for assessment, the Court firstly takes into consideration the high concentration of the active substance. The disputed products (introduced in Chapter 4.2) all have a very high amount of carbamide peroxide, and would therefore principally be suited to removing pathological discolouration. The author, however, doubts that the tooth-bleaching agent with a high proportion of carbamide peroxide is **principally** used to remove **pathological** discolouration. Should the indications of Opalescence mentioned in the leaflet[51] be fully considered, then in the first sentence it is mentioned that the product is also effective in the case of discolouration due to age. Discolouration due to age, does not, however, fall under the definition of disease applied by the Court. In addition, tooth-bleaching products with high concentrations of carbamide peroxide ($\geq$ 10 %) are also used by dentists to remove extrinsic discolourations. This is clearly derived from various advertising presences of dentists (see further below[55, 56, 57]).

The opinion of the consumer is further influenced by the notes on indications enclosed with the product or contained in advertising brochures and instructions for use. In the instructions for use, under indications, a series of trigger factors is specified (see Chapter 4.2.2). Through the specifying of these factors and the hint to the treatment alternative to crowns or veneers, the disease-dependent indication comes to the fore for the consumer, according to the Court.
The Court is therefore convinced that the disputed products would possess a predominantly medical intended purpose. A use of the products for purely cosmetical purposes would constitute use not in accordance with the intended use. The author cannot go along with this opinion. That certain medical indications are mentioned on the leaflet does not mean that tooth-bleaching agents serve medical purposes. The opinion of the author on intrinsic discolouration as a disease has

already been explained. Rather, the purpose of tooth-bleaching products lies in the brightening of the teeth, thus in an alteration in the appearance. This is also apparent from the leaflets of tooth-bleaching agents which are freely available and which are authorised as medical devices (in this case a product available at a large German discounter[52]):



For the opinion of the consumer, the advertising also plays a great role.
The tooth-bleaching agents to be found on the market and freely available as medical devices are promoted with statements such as “the simple way to a visibly whiter smile“[53]. From the advertising text of a cosmetic retail chain:

> Der einfache Weg zu strahlend weißen Zähnen - das transparente Gel hellt die Zähne innerhalb von 14 Tagen um bis zu 4 Nuancen auf. Benutzen Sie Simply White hierfür zweimal täglich 14 Tage lang und die Zähne bleiben bis zu sechs Monate weißer. Colgate Simply White entfernt äußere und innere Verfärbungen mit dem sicheren und klinisch erprobten Inhaltsstoff Wasserstoffperoxid, der auch von Zahnärzten für die Aufhellung der Zähne seit Jahren erfolgreich eingesetzt wird. Es ist so absolut sicher für den Zahnschmelz. Simply White ist ein zertifiziertes Medizinprodukt, bitte die Gebrauchsanweisung beachten.
>
> The simple way to radiant white teeth – the transparent gel brightens the teeth within 14 days by up to 4 nuances. For this, use Simply White twice per day for 14 days and the teeth will remain whiter for up to 6 months. Colgate Simply White removes external and internal discolouration with the secure and clinically tested ingredient hydrogen peroxide, which has also successfully been used by dentists to brighten the teeth for years. It is so absolutely secure for the enamel. Simply White is a certified medical product. Please heed the instructions for use.

Alone through the fact that the product is marketed by a cosmetic retail chain points to the fact that it is rather used for cosmetic purposes. The removal of internal and external discolouration is, so to speak, named in the same breath. The use of the product for medical purposes is not mentioned. One would also have been able to write, along the lines of the instructions for use, “for treatment of pathological or traumatically caused internal discolouration” – the Drugs Promotion Act (Heilmittelwerbegesetz) also permits areas of application to be specified in the advertising[54]. Instead of that, it is only mentioned that it concerns the same active substance that a dentist also uses. That the product is a certified medical device is actually mentioned, however, it is placed in the background, behind the other promises (brightening of up to 4 nuances, teeth remain whiter). The question arises, however, if the product is a medical device, why is the brightening of external discolouration, which actually, in the Court's opinion, does not constitute a disease, promoted?

Dentists also promote tooth-bleaching agents, which are marketed through them or used by them, as the following example shows[55]:

> Gesunde Zähne und ein makeloses Gebiss verleihen Selbstbewusstsein und Anerkennung. Durch eine Zahnaufhellung (Bleaching) steigert sich Ihr ästhetisches Selbstwertgefühl. Ein strahlendes Lachen bringt Ihnen mehr Lebensfreude und Jugendlichkeit. Profitieren Sie von unserer effektiven und schonenden Behandlung.
>
> Healthy teeth and a flawless dentition impart self-confidence and recognition. Through bleaching the teeth, your aesthetic self-esteem is increased. A radiant smile brings you more zest for life and youth. Profit from our effective and gentle treatment.
> **What is bleaching?**

Was ist Bleaching?
Bei der Zahnaufhellung in unserer Praxis vertrauen wir einer wissenschaftlich anerkannten Methode. Unsere Zahnärzte sind speziell für dieses Verfahren ausgebildet worden.
Einfach ausgedrückt wird ein mildes Bleichmittel auf die Zähne aufgetragen und mit Wärme bestrahlt. Vorher bedeckt der Arzt das Zahnfleisch mit einer lichtresistenten Maske. Die Zähne werden dann mit einer Wärmelampe bestrahlt, um den Bleichungsprozess in Gang zu setzen. Der Wirkstoff durchdringt den Zahn und hellt ihn auf. Verfärbungen im Schmelz werden gleichzeitig rückgängig gemacht.
Wann ist Zahnbleichen (Bleaching) sinnvoll?
Erwachsene Patienten jeden Alters mit Zähnen, die eine gute Gesamtstruktur aufweisen, können von dieser Bleaching-Methode profitieren. Stark abgenutzte oder kariöse Zähne können nicht behandelt werden. Auch Zähne mit tiefen Schmelzrissen oder undichten Füllungen und Kronen sind von der Behandlung ausgeschlossen. Schwangere und Kinder sollten vom Bleichen absehen.
Wie lange hält das Ergebnis an?
Die Veränderungen der Zahnfarbe durch das schonende Bleaching-Verfahren halten über einen Zeitraum von bis zu zwei Jahren.
Was verursacht Zahnverfärbungen?
Auch gesunde Zähne können sich verfärben. Gerade ab dem 35. Lebensjahr nimmt die Zahnverfärbung zu. Durch den Genuss von Tabak, Kaffee, Tee oder Rotwein lassen sich diese Verfärbungen durch normales Zähneputzen nicht mehr vollständig entfernen. Aber auch Verletzungen, Antibiotika, starke Fluoride, Nervenrückbildungen und frühere Zahnbehandlungen können Verfärbungen verursachen.
Gibt es Nebenwirkungen?
Aufgrund der Wirkungsweise des Verfahrens wird den Zähnen Wasser entzogen. Die Erfahrung hat gezeigt, dass dies während und kurz nach der Behandlung zu einer Kälteempfindlichkeit führen kann. Allerdings verschwindet diese Überempfindlichkeit bereits nach etwa drei Tagen. In seltenen Fällen können vorübergehend weitere Nebenwirkungen auftreten.
Ihre Vorteile
Für das problemlose, sichere und langzeitige Aufhellen Ihrer Zähne:
Ein schonendes Verfahren ohne mechanische Schleifarbeit
Kompetente Behandlung durch ausgebildete Spezialisten
Keine Beschädigungen des gesunden Zahnschmelzes
Vorhandene Füllungen werden nicht beschädigt
Zugelassene Behandlungsprodukte
Bezahlt die Krankenkasse die Zahnaufhellung?
Das Bleaching ist eine kosmetische Behandlung, die von den Krankenkassen nicht bezahlt wird. Von den in der Werbung angepriesenen frei verkäuflichen Bleichmitteln ist aus Sicherheitsgründen abzuraten. Denn beim Bleaching müssen medizinische und gesundheitliche Aspekte unbedingt beachtet werden. Dies kann nur der Zahnarzt.

When bleaching teeth, in our practice, we rely upon a scientifically recognised method. Our dentists are specially trained for this procedure. Simply expressed, a mild bleaching agent, applied to the teeth and irradiated with warmth. In advance, the dentist covers up the gums with a light-resistant mask. The teeth are then irradiated with a thermal lamp, in order to start the bleaching process. The active substance penetrates the tooth and bleaches it. Discolouration in the enamel is simultaneously reversed.
When is bleaching a good idea?
Adult patients of all ages with teeth which show a good overall structure can profit from this bleaching method. Extremely worn down teeth, or teeth with caries, cannot be treated. Also teeth with deep cuts into the enamel or leaky fillings and crowns are excluded from treatment. Pregnant women and children should avoid bleaching.
How long does the result last?
The alterations in the tooth colour through the gentle bleaching process last for a period of one to two years.
What causes tooth discolouration?
Even healthy teeth can become discoloured. From around the 35th year of life, tooth discolouration increases. Through the enjoyment of tobacco, coffee, tea or red wine this discolouration can no longer be completely removed through normal cleaning of the teeth. However, also injuries, antibiotics, strong fluorides, nerve deterioration and earlier dentral treatment can cause discolouration.
Are there side effects?
Due to the method of working of the process, water is drawn out of the teeth. Experience has shown that this can lead to a sensitivity to cold during and shortly after the treatment. However, this extreme sensitivity already disappears after around three days. In rare cases, further side effects can temporarily occur.
Your advantages
For problem-free, secure and long-term bleaching of your teeth.
A gentle process without mechanical grinding.
Competent treatment by trained specialists.
No damage to healthy enamel.
Existing fillings are not damaged.
Authorised treatment products.
Is bleaching of the teeth paid for by the health insurance?
Bleaching is a cosmetic treatment, which is not paid for by the health insurance. For security reasons, we advise that you keep away from the freely available bleaching agents promoted in advertising. For, when bleaching, medical and healthcare aspects must, in all cases, be heeded. Only the dentist can do this.

Many further examples of advertising by dentists[56] or special cosmetic dentistry studios[57] show that the advertising addresses the motivation to carry out a bleaching treatment: beauty, an increase in self-confidence or aesthetic self-esteem and the imparting of greater recognition or success. Furthermore, it is pointed out that bleaching is a cosmetic treatment, which is not paid for by the health insurance. In listing causes, firstly discolouration through age is specified, then both the causes of external discolouration and also internal discolouration are specified (consequence of injuries, antibiotics, strong fluoride, nerve deterioration and earlier dental treatment). The medical intended purpose thus does not come to the fore - rather a cosmetic intended purpose becomes clear.

To reinforce classification as a medical device, Köhler/Lenz[2] make additionally reference to the Decision of the District Court of Hanover[58]. In the case of the products which are the subject of the dispute in this case, two tooth-bleaching agents with carbamide peroxide gel in 10-25 % concentration for the removal of internal tooth discoloration with pathological causes are concerned. Neither product was certified by a Notified Body as a medical device of Class IIa, but they were categorised by the manufacturer as medical devices in Class I. The Plaintiff now demands of the Defendant, the European Authorised Representative of both products, to prohibit the placing on the market as medical device of Class I, as the medical devices are Class IIa products. The Court admitted the Action and decided that it concerned medical devices in Class IIa, on the basis of Annex IX, III 2.3 Rule 7 of MDD 93/42/EEC (surgically invasive products intended for short-term use). That it concerns medical devices at all is not doubted by the Court. In the grounds for the Decision it is stated that *the disputed products concern medical devices and not, for example, mere cosmetics. To be viewed as medical device are products in accordance with Art. 1 IIa of the Medical Device Regulation (author's note: it ought to be called Medical Device Directive), which are determined by the manufacturer for the treatment and alleviation of diseases. The tooth-bleaching products serve to treat pathological or traumatically caused internal tooth discolouration and not merely to remove disturbing external discolouration. The parties unanimously assume that medical devices are concerned.* Far-reaching reactions to classification as a medical device were, however, not made, so that this Decision, in the opinion of the author, is not relevant to the classification problem.

In addition, Köhler/Lenz[2] mention that tooth-bleaching products for **intra**dental bleaching (thus bleaching of non-vital teeth through drilling of the dental pulp cavity) were recommended as medical devices of Class IIa by the Arbeitskreis Europäische Normung (Working Party for the Regulation of European Standards)[59]. The Working Party is the National Coordination Committee for the German position in that working group within the European Committee for Standardization, the CEN, which is compiling the European dental classification document CEN/TR 12401 "Guidance on the classification of dental devices and accessories", the last revision of which was published in June 2003. The corresponding German version was printed in September 2003 as Pre-Standard DIN V 13974, "Zahnheilkunde – Anleitung zur Klassifizierung von Dentalprodukten und Zubehör".

On the occasion of the Decision of the Higher Administrative Court of NRW, the „Arbeitsgruppe Medizinprodukteüberwachung"(AGMP) ("Working Group for Medical Product Supervision") of the German supervisory authority ZLG at its meeting of 15/16.12.2003, concerned itself with the problem of tooth bleaching products and published a recommendation to the local authorities. As a result, tooth-bleaching products which are intended for application or supervision by a dentist, thus in-office bleaching products, as well as home bleaching products supervised by a dentist, should only be classified as medical devices of Class IIa in accordance with MDD 93/42/EEC Annex IX, III. 2.3 Rule 7. Intended purpose ought to be tooth-bleaching of non-vital or discoloured vital teeth. Tooth-bleaching products which are not anticipated for use or supervision by the dentist should be classified as cosmetic products. Intended purpose is the bleaching of teeth for aesthetic or cosmetic reasons.
That the Working Group has mentioned the intended purpose of tooth-bleaching of non-vital or discoloured vital teeth in the case of the tooth-bleaching products to be categorised as medical devices contradicts, in the opinion of the author, the medical intended purpose, which is supposed

to prevail for medical devices. The intended purpose of tooth-bleaching - thus an alteration in the appearance - is clearly a cosmetic purpose.
In addition, the composition of tooth-bleaching products for supervision by the dentist (home bleaching) and the tooth-bleaching agents freely available (mass market) is often not to be distinguished at all. It is therefore difficult to appreciate why one tooth-bleaching product, in one case, should be a medical device, and in the other case should be a cosmetic product.
According to Granich[45] the Decision must be made, in each case, with reference to the product and not with reference to the product category. This is, however, also not entirely plausible, for the products possess a similar composition, and consequently also the same mode of action and the same intended purpose. Only the risk of side effects in the event of improper use of tooth-bleaching agents is reduced if used by the dentist.

7.3 Case-Law in the United Kingdom

What is first of all striking is that all instances of English case-law refer to the EC Directives 76/768/EEC and 93/42/EEC, whereas, in German case-law, primary the implementation of these directives, the LMBG and the MPG, serves as a legal basis.

The Courts of the Supreme Court of Judicature and House of Lords, similarly to the German Courts, come to the conclusion that the Medical Device Directive is, due to Article 1 (5) (d) MDD, not applicable to cosmetic products (in Germany, § 2 (4) No. 2 MPG). The term “delimitation norm” is actually not used, but, in the end, it is initially checked whether the product is a cosmetic product in accordance with CD.

The analysis of the definition or the recitals of the CD are partially addressed very scantily. The First Instance decides, on the basis of 5 points, why the product is not a cosmetic. That the product is a medical device is decided on the basis of the manufacturer’s intended purpose (“intended by the manufacturer to alleviate a disease or a handicap or to modify the anatomy“). In addition, the product is already certified as a medical device by a Notified Body in another Member State (in Germany by the TÜV RW Anlagentechnik GmbH as Notified Body).

Both of the following instances of the Supreme Court of Judicature and House of Lords correspondingly examine the five points of the first instance.
The definition of a cosmetic product indicates that it is determined for the purpose of „placing in contact ... with the teeth **and** the mucous membranes“. A product cannot be a cosmetic if it only comes into contact with the teeth, but not with the mucous membranes, as is the case here with the use of the tooth-bleaching agent (application to the mucous membranes is avoided). As both Courts establish, the word “and“ is not intended to be indicative of an addition here, but is meant disjunctively. In the end, the listing behind “human body” – “*epidermis, hair system, nails, lips and external genital organs”* is also meant disjunctively. It would, in any case, be absurb not to view a lipstick as a cosmetic, just because it is not meant for use on the hair. The meaning of the word “and” was also recently seen in the Decision of the Higher Administrative Court of North-Rhine Westphalia. The Court came to the same conclusion. The author can only agree with it.

Furthermore, it is argued that the list of examples of cosmetic products in Annex I leads to the conclusion that the effect is “temporary, superficial and reversible”. The effect of the tooth-bleaching product is, however, not transient, so that the product could not be a cosmetic. The Appeal Courts both emphasise that the list in Annex I firstly only concerns a list of examples, and it is also not clear whether all products in the list have a temporary, superficial and reversible effect. Should the effect of a depilatory agent be reversible or the effect of an anti-wrinkle cream (see also Chapter 7.2.1) superficial? What, for example, should the definition for transient, superficial or reversible look like? In addition, it is not the effect with which we are concerned, but the intended purpose. The author can only go along with the arguments of the Appeal Courts. It should still be added that the effect of tooth-bleaching agents is certainly longer than in the case of most “normal“ cosmetics, but also does not last for ever (for details on duration, see also[1, 13]).

The purpose of “changing appearance“ is connected by the first instance with being “temporary, superficial and reversible“. Also here, the arguments apply as described in the previous paragraph. Rather, it is necessary to view “changing appearance“ in connection with “intended to be...“ and “exclusively or mainly“ and, so to speak, establish the predominant intended purpose. This is established by the Appeal Courts on the basis of the manufacturer’s advertising material as bleaching of discoloured teeth. Such a purpose is of a purely cosmetic nature, even if the underlying grounds extend beyond merely beautification.
The determination of the predominant, cosmetic intended purpose is not made so precisely as in German case-law. It is not gone into that the intended purpose is determined on the basis of objective characteristics, as they are constituted for an averagely informed, observant and judicious average consumer. The English case-law in particular draws upon the manufacturer’s advertising material, which, in any case, constitutes an aspect of the objective characteristics. In the second instance Supreme Court of Judicature, it is once again emphasised by the Plaintiff’s attorney that, in the manufacturer’s advertising material, the tooth-bleaching agent constitutes an “alternative to composite placement, veneers or crowns”. This evokes certain medical associations with the reader of the advertising material. Viewed as a whole, however, the bleaching of teeth stands in the foreground.

Furthermore, a possible medical intended purpose is gone into, as the tooth-bleaching product is supposed to be used “to ameliorate a troublesome condition which arises in specific circumstances and is different in kind from those of a cosmetic device”. The “troublesome conditions” are compared with disfiguring birthmarks, in the case of which a special substance is used under the supervision of a skin specialist. Many cosmetic products are used with “troublesome conditions”, however they are not medical devices. Another example would be the use of make-up: if the make-up is used by a person who, for example, suffers from white spot disease, in order to cover up the white spots, the make-up has thereby not become a medical product.

Lastly, the use of tooth-bleaching agents is gone into in the case of non-vital teeth. The drilling and insertion into the dental pulp cavity is viewed by the first instance as an implant, which, however, is excluded from the CD in accordance with the 5th recital. As, however, emphasised in the further instances, the product is removed before the filling is put in. This does not constitute an implant.

A possible medical intended purpose, and thereby the exclusion of the CD, is only given if the product is exclusively used to protect from diseases (5. recital of CD). As the House of Lords has, however, unanimously established, in this case the definition “exclusively intended to protect from disease” is not present here at all. It can, actually, not be denied that discolouration could be both the consequence and cause of diseases (of a mental nature), but tooth-bleaching agents certainly do not protect against diseases.

As it was hereby established that the definition of a cosmetic is correct for a tooth-bleaching product, i.e. that the product falls under the CD, the medical intended purpose or the definition of a medical device in accordance with MDD was no longer investigated further. It was only recently noted by both Courts that the product is used to treat the effect of a disease, and also the alleviation of a "handicap“ does not appear to be the case – dark teeth would in fact be less attractive than radiant white teeth, but that would not be a “handicap” within the meaning of Article 1.2 MDD. As is striking here, the Courts interpret the term "disease" in such a way that the discolouration could be a consequence of a disease, however the discolouration itself is not the disease. This would probably be viewed in this way by every average citizen. This is, however, interpreted differently in German case-law, where the term "disease“ constitutes every deviation from the norm and thus even discoloured teeth constitute a disease.

8 Conclusion and outlook

8.1 Conclusion (author´s opinion)

As tooth-bleaching products, as described in Chapter 2.4, do not have either a pharmacological, immunological or metabolic action, but react chemically with chromatogenic molecules in the interior of the tooth, classification of the tooth-bleaching agent as a drug is eliminated right from the start.
Consequently, tooth-bleaching agents are either medical devices or cosmetic products. As the legal basis within the EU, the directives 93/42/EEC (MDD) and 76/768/EEC (CD) must be taken into account in this regard. From Article 1 (5) (d) MDD it emerges that the MDD does not apply in regard to cosmetic products within the meaning of CD 76/768/EEC; it constitutes, so to speak, the delimitation norm. Consequently, it must first of all be checked whether tooth-bleaching agents fall under the definition of a cosmetic products within the meaning of the CD. The definition of a cosmetic products is laid down in Article 1 (1) CD:

> *A "cosmetic product" shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.*

In this definition, teeth and oral mucosa are expressly mentioned, whereby the word *"and"* between "*teeth and the mucous membranes"* is meant in the disjunctive sense – just as the word "and" in the list after "*human body*".

According to the wording of this definition, a cosmetic product is intended for the purpose of **coming into contact with** the various **external parts** of the human body (...) **or with the teeth** (...)**.** This holds true for a tooth-bleaching product – it comes into contact with the teeth! In this English version of the CD it is not demanded that it must come into contact with the teeth **externally**, as is the case in the German version of the CD 76/768/EEC („*äußerlich ... mit den Zähnen in Berührung zu kommen*" - "*externally ... come into contact with the teeth*"). However, even if this definition is taken as a basis, the condition "externally come into contact with" is fulfilled by all tooth-bleaching agents which are used in the form of gels or strips to bleach vital teeth. Only the substances which are applied to the bleaching of non-vital teeth, by being injected into the drilled dental pulp cavity, do not come into contact with the teeth merely externally. However, as can be seen from the example of pigmentation devices[47] also such products, in the case of which there is no merely external use, are categorised as cosmetics if they are used for a positive alteration in the appearance within the meaning of a beautification.

In the second part of the definition, now the possible intended purpose is listed: "…*cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition".* The intended purpose must be "*exclusively or mainly"* fulfilled. This **predominant** intended purpose now has to be decided.

The intended purpose is defined in German case-law by the opinion of the consumer, which is characterised by objective characteristics, such as, for example, the name of the product, the ingredients, the instructions for use, the product packaging, the advertising, features of use (e.g. use by the dentist), the discussion and formation of opinion in the scientific world, and consumer expectations.

Already the name of the products to be found on the market, such as, for example, "Zahnweiss-System" (Odol), "Simply White" (Colgate), "White strips" (blend-a-med), etc. implies to the consumer the idea of white teeth. This also applies to product packaging and advertising which visibly promise the consumer whiter teeth and address his desire for an improved appearance. Consumer expectation is also in accordance with this. Characterised by the social and cultural

environment, in which white teeth are associated with “beauty”, “success”, “sympathy” and “competence”, the consumer expects from a tooth-bleaching product a brightening of the tooth colour and thus a beautification of his teeth.
That in both the instructions for use and the advertising, factors are also mentioned which lead to internal discolouration and which can be ascribed to diseases, such as, for example, dental fluorosis or porphyria, is not ostensibly noticed by the consumer, especially the discolouration of teeth due to age or often also persistent extrinsic discolouration are mentioned at the same time. The reference to a medical intended purpose does not in any way predominate as a result. Rather, it emerges from the instructions for use that the purpose of the treatment is the bleaching of the teeth, thus changing the appearance.
Should the consumer inform himself about the ingredients, in particular the active substance, it becomes clear, due to the mode of action, that a tooth-bleaching agent alters the appearance - the tooth becomes "whiter" or brighter. This applies to both intrinsically discoloured teeth and extrinsically discoloured teeth.
That many tooth-bleaching agents are used by the dentist gives the user a feeling of security through competent treatment, as the bleaching of the teeth is also associated with side effects, such as, for example, making the teeth sensitive or irritation of the gums. But also the intended purpose when used by the dentist is the change of the appearance within the meaning of a beautification.

For these reasons, the predominant (or actually the exclusive) intended purpose is of a cosmetic nature, whereby the defintion of CD 76/768/EEC is fulfilled.

8.2 Outlook

8.2.1 EU

On 20. October 2004, at a joint meeting in Brussels of the national and EU Commission experts from the authorities for medical devices and those for cosmetics, it was decided that tooth-bleaching products are exclusively intended for the bleaching of teeth and do not possess any medical intended purpose, and therefore are cosmetic products[41]. The EU and national entities decided to initiate harmonisation efforts for tooth-bleaching products within the EU, with the aim of being able to classify such upon the revised EC Directive 76/768/EEC coming into force. This process could still last another two to four years. The reason for this is the lack of consensus regarding the maximum permitted concentration of peroxides and placing warnings on the products (e.g. “only use following consultation with a dentist"). The reason was comprehensively described under Section 3.2 of this work.
In order to obtain marketability, the manufacturers of tooth-bleaching agents, must, after the revised directive comes into force, adhere to the (probably new) limiting value for hydrogen peroxide, as well as to the restrictions or conditions of use.

8.2.2 Germany

On 28. January 2002 Regulation (EC) No. 178/2002 of the European Parliament and the Council, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, was enacted[60]. With the new “Gesetz zur Neuordnung des Lebensmittel- und des Futtermittelrechts” (LFGB) (Act on Reclassification of Food and Animal Feed Law), which came into force on 1 September 2005[61], in regard to this regulation in particular the necessary adaptations of national law should be undertaken. At the same time, further adaptations of national law, arising from Community Law, should result. This largely concerns the adaptation of the food additives term and the definition of cosmetic products.

The new definition for cosmetic products is laid down in § 2 (5) LFGB (here in comparison with the old definition and the definition of the CD 76/768/EEC:

§ 4 (1) LMBG	§ 2 (5) LFGB	Article 1 (1) CD 76/768/EEC
Kosmetische Mittel im Sinne dieses Gesetzes sind *Stoffe oder Zubereitungen aus Stoffen,* *die dazu bestimmt sind,* *äußerlich* *am Menschen* *oder in seiner Mundhöhle* *zur Reinigung, Pflege oder zur Beeinflussung des Aussehens oder des Körpergeruchs oder zur Vermittlung von Geruchseindrücken angewendet zu werden,* *es sei denn, daß sie überwiegend dazu bestimmt sind, Krankheiten, Leiden, Körperschäden oder krankhafte Beschwerden zu lindern oder zu beseitigen.*	*Kosmetische Mittel* *sind* *Stoffe oder Zubereitungen aus Stoffen,* *die ausschließlich oder überwiegend dazu bestimmt sind,* *äußerlich* *am Körper des Menschen* *oder in seiner Mundhöhle* *zur Reinigung, zum Schutz, zur Erhaltung eines guten Zustandes, zur Parfümierung, zur Veränderung des Aussehens oder dazu angewendet zu werden, den Körpergeruch zu beeinflussen.* *Als kosmetische Mittel gelten nicht Stoffe oder Zubereitungen aus Stoffen, die zur Beeinflussung der Körperformen bestimmt sind.*	*Kosmetische Mittel* *sind* *Stoffe oder Zubereitungen,* *die dazu bestimmt sind,* *äußerlich* *mit den verschiedenen Teilen des menschlichen Körpers (Haut, Behaarungssystem, Nägel, Lippen und intime Regionen)* *oder mit den Zähnen und den Schleimhäuten der Mundhöhle* *in Berührung zu kommen,* *und zwar zu dem ausschließlichen oder überwiegenden Zweck,* *diese zu reinigen, zu parfümieren, ihr Aussehen zu verändern und/oder den Körpergeruch zu beeinflussen und/oder um sie zu schützen oder in gutem Zustand zu halten*

As can be clearly recognised, the choice of wording strongly approaches that of the CD 76/768/EEC. Only the second sentence „*als kosmetische Mittel gelten nicht... Beeinflussung der Körperformen..*“ is newly added, the second half-sentence in the old law text (*„..überwiegend bestimmt sind, Krankheiten, Leiden, Körperschäden oder krankhafte Beschwerden zu lindern oder zu beseitigen“*) has instead been removed.

By the altered choice of wording, the problem in the event of equal weighting (if a product has both a cosmetic and a medical intended purpose and these have a 50:50 distribution), which the Higher Administrative Court of NRW addressed in its grounds for judgement, is dispensed with (see Chapter 4.2.3, first sub-item). Should it thus now be accepted that a tooth-bleaching agent has a 50 % cosmetic purposes and a 50 % medical purpose, then the cosmetic purpose does *not* predominate, thus the product is *not a cosmetic*, because it does not pursue the cosmetic purpose either exclusively or predominantly.

Also in the new definition, the teeth are not explicitly mentioned, however, as a part of the oral cavity or through drawing upon the formulation in the directive, it becomes clear that also the teeth must be taken into consideration.

Should one not be subject to a misinterpretation of “external application”, like the Higher Administrative Court of NRW, the question must now be posed, whether the tooth-bleaching products are used “*exclusively or mainly*“ to “*change the appearance*”. In the author’s opinion, this question would have to be answered with a clear “yes”, because, also in the case of pathologically discoloured teeth, the appearance is changed by the tooth-bleaching products, and in fact for aesthetic purposes. This also corresponds to the classification of the European Commission, which, at a joint meeting on 20. October 2004, decided that tooth-bleaching agents are cosmetic products (see Chapter 8.2.1).
Until the new Cosmetics Directive comes into force, it is left to the Member States whether they interfere, and, if so, what measures they take. It would therefore be conceivable that there will shortly be renewed judicial disputes on the grounds of the new LFGB.

9 Summary

The tooth-bleaching agents currently to be found on the market are based on hydrogen peroxide as their active substance, which is either used directly or results during use from a chemical reaction from sodium perborate or carbamide peroxide. The hydrogen peroxide penetrates into the tooth and there is a chemical reaction with chromatogenic molecules there. There is no pharmacological, immunologicial or metabolic effect. For this reason, the classification of the tooth-bleaching agent as a drug is eliminated right from the beginning and is also not discussed by the Courts. Consequently, tooth-bleaching agents are either medical devices or cosmetic products.
This classification was handled by various Courts, which came to different decisions, as the following table shows.

Authority/Court	Date	Cosmetic Product	Medical Device	Drug
Local Authority	26.11.1998	Yes	No	
VG Düsseldorf	30.8.2000	No	Yes	
OVG North-Rhine Westphalia	14.8.2003	No	Yes	
DTI, DOH in UK		Yes	No	
Royal Court of Justice	19.10.1998	No	Yes	
Supreme Court of Judicature	1.7.1999	Yes	No	
House of Lords	28.6.2001	Yes	No	
BAG Switzerland	Prior to 23.5.2005	Yes (according to definition)		Yes (regulatory)
	Since 23.5.2005	Yes	No	No

As the legal basis within the EU, the directives 93/42/EEC (MDD) and 76/768/EEC (CD) must be taken into account in this regard. From Article 1 (5) (d) MDD it emerges that the MDD does not apply to cosmetic products within the meaning of CD 76/768/EEC. Consequently, it must first of all be checked whether tooth-bleaching products fulfil the definition of a cosmetic product within the meaning of the CD. This is recognised and also checked by all Courts.
The basis used by the German Courts in coming to a judgement is, in any case, the LMBG, which constitutes the implementation of the EC Cosmetics Directive to German Law. However, the wording of the definition here is not exactly identical with that of the CD 76/768/EEC.

The Administrative Court of Düsseldorf firstly deal with the disease term and comes to the decision that intrinsic discolouration, which is clearly visible to the naked eye, constitutes a disease. In establishing the predominant intended purpose, the Court comes to the conclusion, on the basis of the assessment criteria of concentrations of active substances and indications for use in the instructions for use, that there is a predominantly medical intended purpose and the products are therefore not cosmetics, but medical devices. The author cannot accept these arguments. Neither can the disease term that was taken as a basis be applied to all intrinsic discolouration, nor do the assessment criteria lead to a *predominantly* medical intended purpose.
The Higher Administrative Court of NRW, in coming to its decision, primarily deals with the cosmetic purpose on the basis of the criterion “external”. The Court comes to the conclusion that, based on the “internal mode of action” of the products, there is no “external application”, and therefore also no cosmetic intended use is present. Furthermore, the Court substantiates its judgement with the unsuccessful efforts at an alteration in the Cosmetics Directive. This would show that the products are not supposed to be cosmetics. In the author’s opinion, the wording of the German definition was falsely interpreted by the Court, and the wrong conclusion drawn from the arguments.

The English Courts, the Supreme Court of Judicature and the House of Lords, are revising the arguments of the Royal Court of Justice (1st instance). Firstly, it is emphasised that the word “and” in the definition “the teeth *and* the mucous membranes of the oral cavity“ is meant in a disjunctive sense, and not in a conjunctive sense. After all, the listing after “human body“ is also meant disjunctively. It is thus sufficient if the products are intended solely to be used on the teeth. The first instance argument, that the expression “changing appearance” in the context of “cleaning, perfurming,...”, as well as the list of examples of cosmetic products in Annex I CD would show that the effect of cosmetic products is “temporary, superficial and reversible”, is irrelevant, as it is not the effect that would be concerned, but the intended purpose. The argument that tooth-bleaching agents are supposed to be intended for “to ameliorate a troublesome condition...” does not contradict the use of cosmetics. Many cosmetic products, such as, for example, face creams, are intended for the purpose of dealing with troublesome conditions. That the product has been “implanted” when bleaching non-vital teeth (this is excepted in the 5th recital of the CD) can likewise not be accepted by the Courts, as the product has been washed out again prior to filling the teeth. Thus, the appeal Courts come to the conclusion that the definition of a cosmetic product is fulfilled. With regard to a medical purpose, the Courts also argue that the products would not be used to treat or alleviate a disease, but to treat the consequences of a disease. Tooth discolouration rather concerns a social handicap. In addition, it is evident from the labelling, the instructions for use and the advertising material that the purpose of the products is supposed to be the bleaching of dark teeth. Consequently, the tooth-bleaching agents are cosmetic products. The author can only go along with the argumentation of the Supreme Court of Judicature and the House of Lords.

Finally, the author comes to the conclusion that tooth-bleaching agents are cosmetic products. This opinion is also represented by the EU Commission. On 20. October 2004, at a joint meeting in Brussels of the national and EU Commission experts from the authorities for medical devices and those for cosmetics, it was decided that tooth-bleaching products are exclusively intended for the bleaching of teeth and do not possess any medical intended purpose, and therefore are cosmetic products. The EU and national entities decided to initiate harmonisation efforts for tooth-bleaching products within the EU, with the aim of being able to classify such upon the revised EC Directive 76/768/EEC coming into force. This process could still last another two to four years. The reason for this is the lack of consensus regarding the maximum permitted concentration of peroxides and placing warnings on the products.

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