Overview
about the scope of duties and main activities of FIDE

Years under review: 2005-2014

I. Introduction

FIDE represents around 550 large, medium-size and small companies in 12 European countries. These companies cover the complete range of industrial products for use by dentists and dental technicians. In light of the increasing international complexity and the global competition, FIDE undertakes its role as a "global player" on behalf of its members in the area of European interests. FIDE remains focused on cooperation and teamwork with relevant European and international associations. Moreover, opportunities for the advancement of the European dental market are deliberated and researched.

II. Aims and missions of FIDE

FIDE is the voice of the European dental manufacturing industry. The aims of FIDE are to represent the common interests of the European dental manufacturers associations and to promote their co-operation. FIDE represents the dental manufacturers in the area of medical legislation and standardisation and promotes and improves the availability of dental market data.

Main aims of FIDE are:

- Liaison with the Institutions of the European Communities
- Representation of the dental industry at international bodies
- Representation of the dental industry at governments
- Relationship with the European associations of dealers, dentists and dental technicians
- Technical harmonisation and standards
- Common trade policy
- International exhibitions and congresses
- Annual European dental market survey

III. Communication and collaboration with partner organisations

FIDE maintains relations to all international associations of the dental field. In detail, these organisations are:

a.) ADDE

ADDE is the Association of Dental Dealers in Europe. The European Dental Business Committee (EDBC) is a joint body composed of the executive boards of FIDE and ADDE. This body meets annually. The meetings serve as an exchange of experiences and opinions on topics which are relevant to both manufacturers and trade. Discussions and debates focus on potential joint measures in reaching common goals. Recurring themes were the

revision of the European medical device legislation, requirements of the unique device identifier (UDI), Minamata Convention on mercury, working group “Radiology”, water quality, waste disposal, questions of technical law and regulation and the international exhibition schedule.

b.) IDM

FIDE is a member of the International Dental Manufacturers (IDM). IDM represents as an association the global interests of the manufacturing industry before governments and professional dental organisations and coordinates the joint international interests and benefits of the regional member industry associations. The IDM General Assembly meets two times a year, generally on occasion of the annual FDI-congress or the International Dental Show (IDS).

c.) FDI

FIDE and IDM cultivate a good relationship to the international dentist organisation FDI (World Dental Federation). Main topics in the regular meetings are the exchange of information and the exchange of views about the venue of the annual FDI congress.
Because some of the FDI congresses in the past were not very successful for the industry, IDM members installed the Congress Committee Task Team (CCTT). This group discussed in several telephone conferences on the future of FDI Congresses. IDM and FIDE are in the opinion that FDI needs a professional experienced business partner with business ideas for the organization of congresses. The success of FDI congresses primarily depends on the attendance of regional dentists.
The venues for the next FDI Congresses are: 2014 in New Delhi and 2015 in Bangkok.

d.) FEPPD

FEPPD is the European and International Federation of Dental Technician Laboratory Owners. FIDE supports current projects of FEPPD, such as “Leonardo da Vinci” or “DOSAM”.

e.) ISO TC 106

The "ISO / TC 106 - Dentistry is the Technical Committee on Dentistry, of the International Organization for Standardization. FIDE works in liaison with ISO TC 106. The annual meeting of ISO TC 106 and its subcommittees took place in Paris in September 2013. Main goal of the Committee is to develop standardization of terminology, test methods and specifications for materials, instruments, dental equipment and other devices used in all segments of Dentistry. To date, more than 160 standards were developed by the TC-106 and the subcommittees and have been published by ISO. About 350 experts and delegates (6 representatives from FIDE) attended the meeting of ISO/TC-106.

IV. Regulatory Affairs

The importance of regular and sustained coordination at the European and international level is demonstrated by the various themes and of challenging topics that were under discussion in the business meetings. The impact of the decisions taken by these bodies – whether fundamentally political or material and operational - may not always be immediately noticeable to firms which are members of the national associations within FIDE. As opposed to individual firms, the associations that make up this federation are authorized as participants or dialog partners.
In many areas, owing to the participation, input and influence of the associations in Brussels, as a counterpart to their associates in Europe or abroad, to organisations such as

IDM, FDI or institutions outside of the dental branch, – agreements are concluded. The end results facilitate individual firms' activities in the market, or actually open new markets.

Main topics in the last years were:

a.) Dental Amalgam

The strategy of the EU-Commission and the United Nations Environment Programme (UNEP) was to reduce the emissions of mercury in the environment. Also the question of a ban of amalgam was discussed. FIDE was asked by the Commission to collect information about the state of the art of restorative materials and evaluate the cost-benefit implications for patients of substituting dental amalgam with other alternative materials, such as composite resins, glass ionomers, other metals (alloys) and ceramics.

The result of the FIDE survey was: Dental amalgam is very durable, it is easier to use and it is cheaper than alternatives.

At the beginning of 2013 the EU-Commission and UNE published their final decisions.

Based on the scientific opinions the EU-Commission informed that amalgam does not cause health risks for patients and users. Merely pregnant women and children as well as patients who are allergic should not be treated with amalgam. Therefore there are no reasons for a reduction of the use of amalgam. But amalgam should be used in future only in encapsulated form.

But the Commission is also in favour to promote the future use of alternative filling materials. In the moment the Commission has too little scientific expertise concerning the risks of alternatives. This is why the Commission asks all member states, stakeholders and manufacturers for support:

- to send any available data on safety of amalgam and on alternatives and
- to provide contribution on the necessity and level of use to assist the implementation of the International Instrument.

In a UNEP meeting in January 2013, Governments agreed to the text of a global legally binding instrument on mercury. This treaty was finalized and included important provisions to reduce and eliminate mercury pollution, one of them being a requirement for countries to phase down the use of dental amalgam (mercury fillings). The treaty, which has been under negotiation for four years, will require countries to undertake at least two of the prescribed steps to "phase down amalgam use." Among those measures listed are these:

- Setting national objectives aimed at minimizing (amalgam) use
- Promoting the use of cost-effective and clinically-effective mercury-free alternatives;
- Encouraging professional societies and dental schools to educate and train dental professionals in the use of mercury-free dental restoration; and
- Encouraging insurance policies and programs that favour the use of quality alternatives to amalgam.

FIDE welcomes the outcome of the treaty. In the past FIDE campaigned for a reduction of the use of dental amalgam -versus a ban- through a greater focus on dental prevention and health promotion, increased research and development on alternatives and best management techniques for amalgam waste.

b.) Revision of the European Medical Device Legislation

On 26th September 2012 the European Commission presented the draft revision of the European Medical Device Act. It provides for numerous changes in existing regulations,

which are also welcomed by the industry, to further increase patient safety. However, the draft also contains new rules that do not provide additional benefits for the safety of the products and patient protection but have massive negative effects on the entire medical technology industry, which consists predominantly of small and medium enterprises.

Most extensive impacts on the dental industry may have the content of the new classification rule 19. All medical devices containing nanomaterial are class III devices in future if nanoparticles can be released from the product. More than 80 % of all dental medical devices would be affected by this rule (e.g. impression materials, filling materials, artificial teeth).

Therefore the dental industry started several actions to avoid this rule 19. FIDE developed in 2012/2013 several detailed statements and proposed a change of the rule. In January-April 2013 FIDE also had personal discussions with Members of the European Parliament. Some of them were ready to support a change request.

The Parliament voted on the revision in a first reading on 02 April 2014. Relating to rule 19 parliamentarians decided on a modification. The text is as follows: “Medical devices consisting or incorporating of nanomaterials deliberately intended to be released into the human body are in class III”.

The position of the EU-Council is expected at the end of 2014. Afterwards conciliation proceedings are foreseen.

c.) Nanomaterial

The EU-Commission deals intensive with this topic since summer 2010. In July-August 2010 the Commission started a hearing with several questions about the use of nanomaterial in products. FIDE established a working group “Nano” and released a very comprehensive statement.
For preparing a definition of the term “nanomaterial” the Commission installed a working group “New and Emerging Technologies”. FIDE succeeded in becoming member of this working group and delegated two representatives of member companies to this group.
In October 2010 the working group published the first draft of a recommendation on the term “nanomaterial”. Afterwards the Commission started the second hearing which closed on 19th November 2010. FIDE released a statement again.
In October 2011 the EU-Commission published the recommendation on the definition of nanomaterial. This definition will be reviewed in the light of experience and of scientific and technological developments. JRC (Joint Research Centre of the Commission) installed a technical workshop and discussed the content of the definition with more than 70 participants in a meeting on 19 February 2014 in Brussels. FIDE is member of this working group and participated in the meeting.

d.) Tooth whitener and bleachings

EU-Commissions working group developed a paper relating to the classification of tooth whitener and bleaching as cosmetics or medical devices. In a “Manual on Borderline and classification in the community regulatory framework for medical devices” the working group proposed that these products should be considered as cosmetics. The reasons of the working group are that in some cases, in addition to other contributory factors, discoloration of teeth may be caused by a disease. But nevertheless discoloration of teeth is not considered to be a disease in itself. Besides, application of tooth-whitening products is not intended to treat the underlying disease; it only may mask a sign of an underlying disease.

FIDE members do not agree with this opinion. The amendment of the Cosmetic Directive 2011/84/EC did not change or amend the definition or the distinction line between the

product categories cosmetic product and medical device. It just extended the possible range of cosmetic products for whitening teeth for aesthetic purpose up to products with concentrations of max. 6 % hydrogen peroxide present or released. As the new directive did not change the underlying classification, the above referenced court decisions are still in place and acknowledge the situation that in cases where tooth bleaching is required as a medical treatment these products are medical devices.

Therefore FIDE requests in a detailed statement in March 2013 a clarification that medical devices which fulfil the definition of Art 1 (2.) a.) of Directive 93/42/EEC are not affected by the amended Cosmetic Directive 2011/84/EC. The general limit of hydrogen peroxide present or released in cosmetic products for oral use based on a special risk evaluation for cosmetic products as products given to consumers and used by consumers directly is not applicable to medical devices in general. Medical devices follow different risk evaluations.

e.) REACH

The new chemical legislation “REACH” came into force on 1 June 2007.
Medical devices are not excluded from the substantial requirements of REACH. This means that the dental industry is completely affected by the new regulation. The main requirement of REACH is that if any producer, importer (from outside of the EU) or downstream user of chemical substances brings such chemical substances in quantities of one ton or more per year into the market, they are under obligation register with the new chemical agency in Helsinki.
For implementation of the new REACH regulation, all Member States are required to establish national “helpdesks”, because specifically small and medium-sized companies need help in preparation for REACH.
In April 2007, FIDE informed all member associations as well as ADDE about the main content of the new regulation, highlighting the requirements and obligations under REACH.

New requirements relating to CLP (classification, labeling and packaging of substances and mixtures) will be set into force from 1 June 2015.

f.) Reprocessing

In August 2010 the European Commission published the report on the issue of reprocessing of medical devices in the European Union. The report is an assessment of the issue regarding public health, ethical, legal, economic and environmental aspects. The report does not contain any policy measures and the Commission confirms that such measures will be addressed within the context of the Recast of the Medical Devices Directives.
In the report, the EC recognises that the "reuse of single use medical devices may not be without risk from a public health point of view" and highlights the fact that "to date, no comprehensive study clearly demonstrates that reprocessing single use medical devices is globally a cost effectiveness and environmental friendly practice when done under high quality standards". The Commission also points out that in order to identify the potential risks associated with this practice the entire reprocessing cycle needs to be "evaluated and validated".

g.) Bisphenol A

The American Dental Organisation (ADA) published an article about Bisphenol-A (BPA) which received widespread media coverage.
Because dental materials (e.g. sealants, composites) may contain BPA, ADA informed about the safety and risks of BPA. ADA stated that the current evidence does not indicate a health risk related to the use of resin-based sealants and composites.

The Ministry of Health in Canada came to the result that BPA in baby bottles could be a risk and banned BPA in baby bottles. But the ministry also states that BPA in other products is without risks.

The European Commission and the Scientific Committee on Emerging Newly Identified Health Risks (SCENIHR) have launched at the beginning of 2014 a public consultation on the preliminary opinion “the safety of the use of bisphenol A in medical devices”.
The aim of this opinion is to assess whether the use of bisphenol A in medical devices could give reasons for concern from the health point of view and, if possible, to provide indications on limit values for BPA release from medical devices.
In line with the Stakeholder Dialogue Procedures SCENIHR is now seeking feedback from the scientific community and stakeholders on the risk assessment related to the safety of the use of bisphenol A in medical devices.
Dental manufacturers evaluated this preliminary opinion and sent their comments to FIDE.
FIDE collected all opinions and sent a common statement to SCENIHR.
SCENIHR will assess all comments from interested parties. All comments submitted may be published on the Scientific Committees' website.

h.) Dental Fillers

COEN (compliance and enforcement group) is a working group within the European Commission (DG Sanco) and consists of members of the Commission and national competent authorities.
COEN invited dental manufacturers to an open meeting in February 2014. COEN stated that relating to the outcome of joint market surveillance activities on dental fillers there are three loopholes such as:
- a lack of complaints reporting: no complaint reported on dental fillers, which may indicate an underreporting by users,
- a lack of clinical investigation data: few data collected over a long period of time, a high number of references to published studies, and
- a lack of data on the nanoparticles used in dental fillers.

Subsequent to the meeting and in collaboration with several dental manufacturers FIDE sent an answer to COEN. FIDE stated that users and not manufacturers are responsible for the reporting of incidents. FIDE does not see a lack of clinical investigation data because the reference to clinical studies is a practical way if the devices are comparable. Additional FIDE pointed out that dental manufacturers include the question of the risk of products containing nanomaterials in their risk management.

V. Market Data Survey

The annual survey European Dental Trade Survey (Market Trends) is in 2014 in its 19th consecutive year of publication. Simon Gambold, Chairman of the FIDE Working Group Market Statistics, together with Dominique Deschietere, President of ADDE, have undertaken the supervision and completion of this valuable industry publication. In this joint effort, data submitted by the member associations of both ADDE and FIDE have been synthesized.
The survey continues to be the most authoritative publication on the European dental industry. On occasion of the 50th anniversary of ADDE this years survey was published in a special edition.

The cost of production has remained steady, allowing the 2014 version to be offered at the same price as in the previous years. More information, with a preview, is available on the ADDE website (www.adde.info).

VI. EDI-Dent

Member companies of the Association of Dental Dealers in Europe (ADDE) and of the European Dental Industry (FIDE) developed since March 2006 a common project called EDI-Dent.

EDI means “Electronic Data Interchange”. EDI is a collective term for all electronic procedures for the automatic transmission of structured messages between the electronic systems of the dental dealer and the dental manufacturer. With this system all partner companies can exchange several documents such as order, order entry, order confirmation, shipment information or invoice on an electronic way.

The main advantage of EDI is that this data interchange is significantly faster than before due to a highly increased rate of transmission. In addition, the improved data integrity reduces the number of mistakes**;** this also avoids discrepancies and misinterpretations, which can occur with manual entry of data. Other positive side-effects are cost reductions for placing orders, shipment information or invoices; shorter lead times and execute cycles; reduced inventories; optimised business processes; accelerated processing (transmission in a matter of seconds); and elimination of postal charges. The partner company can respond quickly; the order confirmation and the dispatch notification allow you to give your customers a definite date of delivery. These are just some of this communication system's numerous advantages.

Every interested manufacturing dental company can obtain the software tool free of charge. After making the necessary IT adjustments, this module will allow to enter into the EDI-Dent system.

On the common website www.edident.info which was specifically set up for this purpose, interested companies can get more information about Edi-Dent. The mandatory password is available from the FIDE office.

VII. Fairs and Exhibitions

FIDE develops and publishes an overview about the worldwide most important dental fairs and exhibitions. This calendar will be continuous revised; it is available on the FIDE website.

VIII. International Representing of FIDE

As FIDE has no permanent establishment in Brussels, FIDE´s interests are represented by delegates, voluntarily placed at FIDE´s disposal from German member, VDDI, and Italian member association, UNIDI, ensuring continuity in the CEN TC 55 & ISO TC 106. In questions of standardisation and regulatory affairs, FIDE works successfully with other key European industry associations, notably through the long-standing cooperation with EUROM VI.

VDDI and UNIDI delegates are also permanent participants in the meetings of the MDEG (Medical Device Expert Group) at the EU-Commission in Brussels.

IX. FIDE Executive Committee

The executive board’s term of office has been under the leadership of FIDE President Dr. Jürgen Eberlein, who has held this position since 2005.

Election of the New Executive Committee

At the General Assembly in Cologne 2013, the slate of candidates was presented for election.
All candidates were unanimously elected for a two-year term of office. Dr. Jürgen Eberlein, a long-time FIDE board member, was re-elected to the office of President for the term 2013-2015.

The officers for 2013-2015 terms are:

President: Dr. Juergen Eberlein (VDDI, Germany)
Vice President: Dr. Alessandro Gamberini (UNIDI, Italy)
Vice President: Kim Soerensen (DBF, Denmark)
Members: Peter Malata (FMWI, Austria), Simon Gambold (BDTA, UK) and Nicolas Gehrig (ASDI, Switzerland).

X. FIDE MEMBERSHIP

FIDE represents the interests of more than 550 dental manufacturers affiliated to FIDE through their membership in national dental manufacturers associations in 11 European countries.
Current FIDE members include national manufacturers associations from the following countries:

Austria
Belgium
Denmark
France
Germany
Italy
The Netherlands
Spain
Switzerland
The United Kingdom

The next FIDE General Assembly will take place on Monday, March 09, 2015 in Cologne during the IDS. The Executive Committee will meet on the same day.

XI. FIDE-WEBSITE

More information about FIDE is available on our website

http://fide-online.org

XII. FIDE HEADQUARTERS

The General Secretariat of FIDE is located in the heart of Europe in Cologne, Germany through the auspices of its member association, VDDI. The FIDE headquarters team works in the interests of their member associations, carrying out the day-to-day business of FIDE and Executive Committee directives, in addition to the coordination and execution of liaison and logistical matters. The Secretariat maintains editorial responsibility for the Website and is also responsible for public relations.

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