



JANUARY 2013

// CED ANNUAL REPORT 2012



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// INTRODUCTION FROM CED PRESIDENT

As we enter 2013, I am pleased to take this opportunity and look back on the many activities and achievements of the CED over the last year.

In 2012, the CED General Meeting adopted policy on nitrogen sedation, Professional Qualifications Directive, eHealth and liberal professions. CED representatives worked hard to influence European legislation on standardisation, mutual recognition of qualifications, medical devices, data protection, dental amalgam, tooth whitening and entrepreneurship. The CED started contributing as an Associated Partner to the European Union Network on Patient Safety and Quality of Care (PaSQ) Joint Action in its aim to create a permanent platform for future cooperation between Member States in the area of patient safety and quality of care. CED liaisons attended meetings of European Committee for Standardization (CEN), European Skills, Competences and Occupations taxonomy reference group (ESCO), and eHealth Stakeholder Group. The CED was also represented in European Commission-chaired working groups on patient safety, health workforce and medical devices. Finally, the CED organised in June a policy debate in the European Parliament entitled Healthy Mouth, Healthy Living, Healthy Ageing, to raise awareness about links between general and oral health, of oral health prevention, particularly in older patients, and of cooperation between different health professions.

I would like to sincerely thank all CED members for excellent collaboration in 2012. I am particularly grateful to CED Directors and to chairs and members of CED Working Groups and Task Forces for their tireless work and to CED liaisons for representing European dentists in various EU stakeholder forums. Finally, special thanks go as always to the staff of the CED Brussels Office. I look forward to working with all of you and with our friends and partners to continue to make the voice of dentists heard in European politics and to promote good general and oral health of all Europeans also in 2013!

Sincerely,



Dr Wolfgang Doneus

CED President



MAY 2012

// CED RESOLUTION

THE USE OF NITROUS OXIDE INHALATION SEDATION IN DENTISTRY



// INTRODUCTION

The main objective of the Council of European Dentists (CED), which represents over 330,000 dental practitioners across Europe, is to promote high standards in dentistry and oral healthcare for European citizens. It is therefore committed to continually reviewing and updating its strategic plan in order to ensure that the profession meets oral healthcare needs in Europe both now and in the future. The CED guiding vision regarding the future of dentistry is that every European has access to quality of oral health care given by well-educated, skilled and fully competent dental practitioners, in a comfortable and cost-effective manner, using the latest and most appropriate technology.

Pain and anxiety management is of paramount importance in dentistry. As many as 10 to 30% of adults and children may have some form of fear or anxiety related to dental treatment. There is substantial evidence that these patients will benefit from sedation with nitrous oxide (N₂O) and that this form of sedation is extremely safe and efficient in the trained “dental practitioner’s hands.”

Based on the fact that the use of N₂O conscious sedation by dental practitioners in the dental office has encountered some legal problems on its use in some European Countries, the CED decided with the help of some experts in the field, to develop this resolution aimed to support the benefits, the safety and the usefulness of the use of N₂O in the dental office and that such a tool should be maintained in the dental practitioner’s armamentarium for use under certain conditions by trained and certified dental practitioners.

// DEFINITION AND USAGE

Conscious Sedation can be defined as: *“A technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drugs and techniques used to provide conscious sedation for dental treatment should carry a margin of safety wide enough to render loss of consciousness unlikely”¹*

Nitrous oxide gas is no stranger to either anaesthesia or dentistry and its use links both sciences in history. The technique in which low concentrations of nitrous oxide gas is titrated with oxygen has been used for years (as early as 1889) in many countries (USA, Great Britain, Australia, and Scandinavia) and is recognised as clinically successful and cost effective compared to General Anaesthesia.

// EFFICACY OF NITROUS OXIDE INHALATION SEDATION AS AN ADJUNCT TO BEHAVIOURAL MANAGEMENT

The European Academy of Paediatric Dentistry, the American Academy of Paediatric Dentistry and the British Society of Paediatric Dentistry all recommend a “titration” technique that involves increasing the dose of N₂O in oxygen by 5 to 10% increments in the oxygen mix every 1 minute or so and according to the patient’s response until the desired sedative effect is achieved.

Nitrous oxide inhalation sedation, when it is supported by behaviour management techniques is efficacious for children and adults. A 2008 Cochrane review reported favourable changes in behaviour or anxiety when N₂O was used. Furthermore, this has been described as the “standard technique” for paediatric dentistry (NICE 2010) and might be successful in up to 90% of cases provided the patients are carefully selected.

// GENERAL INDICATIONS FOR N₂O-OXYGEN SEDATION IN DENTISTRY

The patients in need of N₂O conscious sedation belong to the following groups: 1) Anxious or fearful patients; 2) those with low coping ability, (e.g. behaviour management problems, dental fear, anxiety and needle phobic patients, prominent gag reflex; 3) special needs patients that communicate; 4) those with special treatment needs, (e.g. emergency treatment, complicated and prolonged treatment, minor oral surgery in conjunction with local anaesthesia, special procedures, etc).

// MAIN CONTRA-INDICATIONS/CAUTIONS FOR N₂O SEDATION IN PATIENTS WITH:

1) Inability to communicate; 2) inability to nose breath; 3) severe psychiatric or Behavioural/personality disorders; 4) B12 or folate deficiency/disorders; 5) chronic obstructive pulmonary disease (COPD); 6) neuromuscular disorders, e.g. multiple sclerosis; 7) cancer undergoing chemotherapy with Bleomycin drugs; and 8) in patients during the first trimester of pregnancy.

// NITROUS OXIDE INHALATION SEDATION SAFETY

Nitrous oxide is non-irritant to the respiratory tract, has rapid onset and a fast recovery (both within minutes). The gas has low tissue solubility and the minimum alveolar concentration (MAC) is so high that it is a poor anaesthetic at normal atmospheric air pressure.

Dedicated, purpose-designed machines for the administration of inhalation sedation for dentistry must be used, capable of delivering N₂O to an upper limit of 70% and never less than 30% oxygen by volume, although in most cases adequate relative analgesia is achieved with concentrations of nitrous oxide that do not exceed the 50% by volume. Such machines must conform to current European Standards and be maintained according to manufacturers' guidance with regular, documented servicing and must contain a fail-safe device (i.e. if the oxygen pressure falls, the supply of nitrous oxide automatically stops); flow-meter for individual set of gas flow and nitrous oxide concentration; emergency air-valve; non re-breathing tubes with low breathing resistance, and an effective scavenging system for exhaled and excess gas.

// EDUCATIONAL & TRAINING STANDARDS

Nitrous oxide inhalation sedation should only be administered by accredited dental practitioners and assisted by other dental personnel who have been appropriately trained in theoretical, practical and clinical skills, and competent to meet any complication. Provided that these requirements are fulfilled, there is no contraindication for administration in the dental practice setting (Dental Sedation Teachers Group, 2000).

// THEORY

A theoretical 2 days course (10-14 hours) must include: anxiety and behaviour management strategies, technical aspects of different sedation units, chemical, physiological and biological aspects of nitrous-oxide, emergency and basic life support. It is strongly recommended that anaesthesiologists or sedationists are involved in the teaching. A reading list is provided and an assessment (on the essential requested knowledge) must be taken.

// PRACTICAL AND CLINICAL SKILLS

In addition to the theory, practical skills must be trained using “role-playing” as the educational model. After training, the trainee should be mentored and provide evidence of five assessments; five observations; and five treated cases.

// AREAS FOR THE PROVISION OF EDUCATION AND TRAINING

Education and training must be given by accredited people in the best setting and depending on the Country, University or Hospital clinics may be ideal for this training.

Of key importance is that the students become certified at the end of the whole programme (theory-exam-practical skills-clinical skills) and understand the need to maintain and develop the skills through regular usage.

// SUMMARY

- Inhalation sedation utilising nitrous oxide-oxygen has been a primary technique in the management of dental fears and anxieties for more than 150 years and remains so today.
- The technique is safe, valuable and effective for dental procedures and will allow the majority of apprehensive dental patients to be successfully sedated and treated in a much more comfortable and stress-free environment.
- Administered properly, by accredited dental practitioners with well-maintained equipment and appropriately trained assistants, the technique has an extremely high success rate and must be maintained in the armamentarium of dentistry as a fundamental tool for the pain and anxiety management of patients undergoing dental treatment in the Dental operatory.
- The usage of inhalation sedation utilising nitrous oxide-oxygen has to comply with relevant national legislation.

Prepared by a CED Task Force:

Constantine J. Oulis (GR), Coordinator, **Marie Therese Hosey** (UK), **Luc Martens** (BE), **Doniphan Hammer** (FR), **Juan Ángel Martínez** (ES), **Angel Alcaide Raya** (ES).

Document reviewed and initiative supported by:

The European Federation for the Advancement of Anaesthesia in Dentistry (EFAAD), and The Society for the Advancement of Anaesthesia in Dentistry (SAAD).

Supporting references:

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Adopted unanimously by the CED General Meeting on 11 May 2012



Transparency register: 4885579968-84

Brussels, 28 March 2012

CED POSITION PAPER

The Council of European Dentists (CED) is the representative organisation of the dental profession in the European Union, representing over 330,000 practicing dentists from 32 national dental associations in 30 European countries. Established in 1961 to advise the European Commission on matters relating to the dental profession, the CED promotes high standards of oral healthcare and effective patient-safety centred professional practice across Europe and contributes to safeguarding the protection of public health.

The CED welcomes the opportunity to comment on the Commission's *Proposal for a Directive of the European Parliament and the Council amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation [...] on administrative cooperation through the Internal Market Information System, COM(2011)883* (hereinafter "**proposal**").

Directive 2005/36/EC on the recognition of professional qualifications (hereinafter "**PQD**") is currently one of the main concerns of the dental profession, since the evaluation process of the PQD has shown that the automatic recognition system does not work perfectly. In order to enhance confidence and to facilitate the principle of automatic recognition, the dental profession strongly recommends that the revision of the PQD takes into account the following:

- a) Minimum duration of training for dental practitioners [Article 34(2)]** – the minimum duration of training for dental practitioners should be expressed not only in years (5 years) but also (in a cumulative sense) in training hours (5000 hours), in order to safeguard against part-time training and the proliferation of "weekend diplomas" by private Universities, as well as to maintain an acceptable standard of dental education without jeopardizing patient safety and the delivery of healthcare.

Therefore, the CED would recommend that Article 34(2) be amended as follows: "*Basic dental training shall comprise a total of at least five years, which may also be expressed with the equivalent of 300 ECTS credits, and shall consist of at least 5000 hours of full-time theoretical and practical study, comprising at least the programme described in Annex V, point 5.3.1 and given in a university, in a higher institute providing training recognised as being of an equivalent level or under the supervision of a university.*"

- b) European Credit Transfer and Accumulation System (ECTS)** – the CED can only support the introduction of ECTS if the minimum duration of training is expressed both in years (5 years) and in training hours (5000 hours). Furthermore, Article 34(2) would have to mention 300 ECTS. The reasons for this are:
- ECTS is not defined in the proposal providing a degree of uncertainty which is not desirable in a legislative document;
 - The reference to 60 credits per one academic year (where 60x5years=300 ECTS) under recital 13 is non-binding; and,

iii. The reference to 25-30 hours of “study” also under recital 13 does not specify which types of hours it includes – theoretical, practical or study at home. An interpreter which is not familiar with ECTS, would multiply (30hoursx60ECTS)x5years = 9000 hours. So the range would be between 7500-9000 hours, colliding with the desired 5000 hours under Article 34(2).

c) **Knowledge of languages (Article 53(2) second subparagraph)** – the wording proposed in the case of professions with patient safety implications needs to be simplified in order to avoid confusion. Indeed, the provision introduces new concepts, such as “affiliated” and “national health care system”, involves new actors, particularly the “representative national patient organisations”, and creates a request mechanism with different requirements. These elements do not bring a real added value to this process. For example, it is not clear what should be understood by “affiliated” – its meaning may vary across the EU. Moreover, in some Member States health professionals have a contract with social security systems rather than “health care systems”, so this part would not be applicable in all Member States. Furthermore, patient organisations do not exist in all Member States. Some countries simply have organisations representing patients suffering from a specific disease. In these cases, the provision would increase the uncertainty as to which organisation would be the most representative. Finally, it is not clear how the language checking is triggered, if the request is on a case-by-case basis or by profession or a general request for all professions with patient safety implications.

Therefore, the CED would recommend that this provision be amended as follows: *“In case of professions with patient safety implications, Member States may confer to the competent authorities the right to carry out language checking covering all professionals concerned ~~if it is expressly requested by the national health care system, or in case of self-employed professionals not affiliated to the national health care system, by representative national patient organisations.~~”* This amendment simplifies the procedure and safeguards the correct result – the knowledge of the language.

The CED would further recommend that competent authorities use the Common European Framework of Reference for Languages (CEFR)¹ to control the knowledge of a language of a professional. This tool is widely used across the EU to self-assess language knowledge. The degree of knowledge could be decided by the competent authority of each Member State. The CED recommends that a high level of knowledge is required for professions with patient safety implications, such as C1.

d) **Dental practitioners’ activities [Articles 34(3) second subparagraph and 36(3)]** - the dental practitioners’ activities should be better described under this provision. The objective is to improve the wording so that the dentist skills/activities are in line with the currently acceptable scientific terminology and factually accurate (these are the activities already performed by dentists). This amendment serves the purpose of injecting more confidence into the system.

Hence, Article 34(3) second subparagraph should be amended as follows: *“This training shall provide him with the skills necessary for carrying out all activities involving **health promotion and specific prevention at individual and community level, diagnosis and treatment including anatomical and functional rehabilitation of all pathologies and anomalies of the hard and soft tissues of the mouth, its appendages and the stomatognathic system**”.*

This amendment implies also an amendment to Article 36(3) as follows: *“Member States shall ensure that dental practitioners are generally able to gain access to and pursue the activities of **health promotion and specific prevention at individual and community level, diagnosis and treatment including anatomical and functional rehabilitation of all pathologies and anomalies of the hard and soft tissues of the mouth, its appendages and the stomatognathic sys-***

¹ The CEFR was put together by the Council of Europe: basic user - A1 and A2; independent user - B1 and B2; and proficient user - C1 and C2. For the grid see <http://www.linguanet-europa.org/pdfs/self-assessment-grid-en.pdf>.

tem, having due regard to the regulatory provisions and rules of professional ethics on the reference dates referred to in Annex V, point 5.3.2.”;

- e) **Principle of partial access** – this principle should be generally excluded from Directive 2005/36/EC since it compromises the high standards of education and standardises the professions across the EU. It should particularly not be applied to health professions. According to Article 168 of the TFEU, it is up to Member States to regulate their healthcare services. The principle of partial access would require legislative changes in national healthcare services, forcing Member States to recognise new professions. This would mean that a health professional wishing to work in another Member State where his activities are performed by more qualified health professionals and where that health profession does not exist as such, but it is in fact part of the qualification of another profession, would be able to gain access to the profession in the host Member State (e.g. denturists). The logic of the internal market and the idea of standardising professions across the EU cannot be applied to the health sector where patient safety and public health considerations are at stake.
- f) **Delegated acts (recital 24)** - Professional organisations should be consulted on a regular and official basis as they are the experts in their own field; a specific mechanism for the European Commission to consult with relevant stakeholders should be introduced in the PQD. Furthermore, the definition of “expert level” is required under the delegated acts regime.
- g) **Remunerated traineeship (Article 55a)** – this provision obliges the recognition of a remunerated traineeship carried out in another Member State. For Article 55a to comply with Articles 165 and 166 of the TFEU² it must be amended in a way that the professional does not become a fully qualified professional after the recognition of the vocational training, particularly if the vocational training is different in terms of content and duration. The CED suggests the following amendment: *“With a view to grant access to a regulated profession, the home Member State shall **take proportionate account of** recognise the remunerated traineeship pursued in another Member State and certified by a competent authority of that Member State.”*
- h) **European Professional Card** – the CED welcomes the concept of the electronic certificate obtained via the IMI system but it is concerned about the newly created short deadlines established therein, especially taking into consideration that a professional will be allowed to practise if the competent authority fails to meet these deadlines. According to the proposal, the home Member State must take a decision within two-weeks and the host Member State within one-month after receiving a complete application, after which, in the absence of a reply, the card is automatically validated and the professional qualification recognised [Article 4d(5)]. These deadlines should be extended due to the substantial increase of the home Member State responsibilities under the recognition procedure and the full trust that it will require from the host Member States. Failure to do so would risk jeopardising patient safety.
- i) **Procedures by electronic means [Article 57a (4)]** – this provision needs to be amended in a way that the time limits related to procedures and formalities only commence when the citizen has introduced a complete application [following the reasoning of Article 4c(1)]. Furthermore, it is necessary to demonstrate that the points of single contact are only intermediary actors that do not have direct access to the IMI system, which is reserved to the competent authorities. This provision should therefore be amended as follows: *“All procedures shall be carried out in accordance with the provisions of Directive 2006/123/EC relating to the points of single contact. Any time limits for Member States to be complied with procedures or formalities set out in this Directive shall commence at the point when a complete application has been received via submitted by a citizen to a point of single contact by the competent authority..”*

² Articles 165 and 166 of the TFEU, exclude any harmonisation of the laws and regulations of the Member States concerning the content of subjects taught and the organisation of education systems and their cultural and linguistic diversity, as well as the content and organisation of vocational training.

In this sense, a similar provision of Article 6(2) of Directive 2006/123/EC should be introduced in the PQD: **“The functioning of points of single contact shall be without prejudice to the allocation of functions and powers among the authorities within national systems.”**

- j) **Alert mechanism [Article 56a(1) final subparagraph]** – the CED is in favour of establishing an alert mechanism. However, the three-day deadline to notify the decision prohibiting the professional from exercising the profession does not take into account the possibility of appeals with suspensory effect and the negative impact that such an alert could have on the career of a professional if the decision is revoked. Thus, the decision should only be notified to other competent authorities when it becomes legally binding. The CED suggests therefore the following amendment: *“The information referred to in the first subparagraph shall be sent at the latest within three days from the date ~~of adoption of~~ **when** the decision prohibiting the professional concerned from **permanently** exercising a professional activity **is legally binding**”.*

Adopted by the CED General Meeting on 11 May 2012



NOVEMBER 2012

// CED RESOLUTION

eHEALTH



// INTRODUCTION

The Council of European Dentists (CED) is a European not-for-profit association which represents over 340,000 dental practitioners across Europe through 32 national dental associations and chambers in 30 European countries. Established in 1961 to advise the European Commission on matters relating to the dental profession, the CED key objectives are to promote high standards of oral healthcare and dentistry and effective patient-safety centred professional practice.

A guiding vision of CED regarding the future of dentistry is that every European has access to quality oral health care provided by well-educated, skilled and fully competent dental practitioners, in a comfortable and cost-effective manner, using the most appropriate technology. In this context, the CED welcomes the European Commission's initiative included in the eHealth Action Plan 2012-2020 to develop eHealth systems with the aim to achieving better information exchange and efficient data usage in healthcare.

// PATIENT DATA

To ensure patient safety and effective interoperability of eHealth systems, the CED:

1. Considers that dental practitioners must have access to patients' relevant medical data;
2. Supports the definition of a minimum common set of patient data for the exchange of core information, consisting of:
 - a) General information: name, date of birth and gender;
 - b) Medical information: allergies, including allergies to dental materials, medical devices and implants, list of current health problems, major surgical procedures and medication summary;
 - c) Dental information: oral status, diagnosis (namely on periodontal, caries, occlusion and erosion indices) and performed treatments;
3. Stresses that dental practitioners should not be allowed to change any data about procedures that they have not carried out themselves;
4. Argues that dental practitioners can only be liable for the information included in the dental record by them;
5. Supports the EPSOS pilot-project³ in coordination with CED Members.

// CODIFICATION IN ORAL HEALTHCARE

A uniform codification is required to communicate electronically. It gives the possibility to transfer and to consult information from different kinds of software and different nations across Europe. The CED:

1. Considers that oral status should be complete and supported with the use of uniform codification for diagnosis (particularly on periodontal, caries, occlusion and erosion indices), localisation (charting) and performed treatment;

³ EPSOS is the main European electronic health interoperability project co-funded by the European Commission which aims at improving medical treatment for European citizens abroad by providing the health professional with the necessary patient data in a secure electronic format. This is based on the patient's consent to the health professional. Two services will be developed during the course of the EPSOS project and tested in practice: *Patient Summary* – access to important medical data for further treatment of patients, and *ePrescription* – cross-border use of electronic prescription services. A list of all participating points of care (hospitals/health professional's offices) can be found on www.epsos.eu.

2. Recognises that it is very difficult to develop a uniform codification system for diagnosis and treatments to achieve interoperability of e-Health systems in dentistry.
3. The CED has studied the existing codes for treatment and diagnosis and will continue to monitor these developments (particularly ICD-10, ICD-11, SNOMED CT / SNODENT and ISO 3950:2009⁴);
4. Supports the expansion of ISO 3950:2009 standard to include areas not covered like tooth surfaces, supernumerary teeth and so on;
5. Supports preferably the development of common codes or, as an alternative, correspondence tables in Member States with regard to treatment codes, in order to develop the interoperability of services in cross-border healthcare;
6. Recommends that the DMFT/S index for the measurement of caries (decayed, missing, filled teeth) is generated by the software used;
7. Supports the development of common codification for oral status, localisation (charting) and treatment to achieve the interoperability of eHealth systems.

// DENTAL SOFTWARE

The CED:

1. Highlights that software standards currently in use, such as XML-HL7 V2 and V3, ISO 13606 for electronic health record communication and DICOM (Digital Imaging and Communications in Medicine standards) for x-rays, are often not specific enough to assure interoperability. Furthermore, they may not be complementary, or even contradictory. The same conclusion was reached on the basis of the final European progress report on *“European countries on their journey towards national eHealth infrastructures”*, point 5.3.3 *“Standards in use”*, January 2011;
2. Recommends the implementation of national certification procedures for dental software in the context of use, reimbursement, communications and in order to ensure compliance with national legislation;
3. Stresses that it should be possible for all patient data to be exported into an open and standardised format to ensure competition and to avoid loss of patient data (e.g. in case of closure of a dental practice, necessity to move data to another dental practice or software provider, etc.).

// DATA PROTECTION AND SAFETY OF DENTAL RECORDS

The CED wishes to recommend guidelines to protect patient data in-office and to safely exchange information between health professionals. In this context, the CED carried out a survey among its Members to investigate who has access to dental records, what should be seen and stored, if patient data should be linked to the internet, etc. The CED:

1. Notes that patients must have access to their medical data;
2. Notes that patient data is highly sensitive and must be secured appropriately;
3. Notes that access to patient data must be limited to healthcare professionals with appropriate and traceable permission;

⁴ ISO 3950:2009 is currently most commonly used for localisation (charting) purposes.

4. Recommends that, in case of exchange of information, an appropriate level of security must be ensured (e.g., secure encryption process, sender and recipient identification and authentication)
5. Recommends the back-up of dental records outside of the dental practice. This is to avoid unexpected circumstances such as fire, break-in, flooding, etc. Any back-up needs to be subject to stringent security regulations in accordance with EU data protection legislation;
6. Notes that if patient data are used for statistical purposes relevant EU data protection legislation and anonymity for both patients and healthcare providers have to be ensured.

// INITIATIVES TO BOOST EHEALTH

The CED:

1. Notes that practice costs for implementation of ICT tools are likely to impact on patient fees, and the financial burden should be kept at a reasonable level for dental practitioners. The financial impact on all dental practices, specially related to clinic size, needs to be recognised appropriately;
2. Notes that ICT costs connected to reimbursable treatment must themselves be reimbursed;
3. Supports the provision of financial incentives to dental practitioners to implement ICT tools;
4. Supports measures to stimulate competition among companies providing eHealth solutions as a way of reducing prices over time;
5. Recommends that, if a secure healthcare network is established in a Member State, oral healthcare providers should be given the opportunity to be included whereas both patients and dental practitioners must be guaranteed a voluntary participation.

Unanimously adopted by the CED General Meeting on 23 November 2012



NOVEMBER 2012

// DRAFT CHARTER FOR LIBERAL PROFESSIONS

// INTRODUCTION

Liberal professions are a key social and economic factor in all Member States of the European Union. Europe is developing into a knowledge-based service society in which liberal professions are becoming more and more important for the state and citizens due to the increasing complexity of society. The European Commission has acknowledged that services are one of the main drivers of the EU economy: they account for over two-thirds of EU GDP and employment and have been the source of all net job-creation in recent years. Approximately one third of this can be attributed to liberal professions.

Despite their growing importance and the fact that liberal professions often provide public services in core areas of general interest, the social significance of liberal professions is still not sufficiently acknowledged at Community level. The specific situation of liberal professions particularly is often not properly taken into account by the European legislator when Community law is newly adopted or when existing provisions are changed.

The Charter for Liberal Professions aims therefore to establish binding guidelines which will ensure that the European Institutions consider possible implications for liberal professions of any new or amended legislation. The Charter will also provide a definition of the term liberal professions based on the existing case law of the European Court of Justice and outline the distinguishing characteristics of liberal professions.

// HISTORICAL BACKGROUND

The European Institutions have emphasised the importance of liberal professions, also for European society, in various ways over the past decade. The following documents either directly or indirectly refer to liberal professions:

- Commission Communication on the 'Report on Competition in Professional Services' (COM(2004)0083),
- Commission Communication on 'Professional Services - Scope for more Reform - Follow-up to the Report on Competition in Professional Services' (COM(2005)0405),
- Commission Communication on the European semester (COM(2011)0400),
- Commission Communication on a Growth Initiative of the Internal Market (COM (2012)0299),
- Commission Communication on country specific recommendations (COM (2012)0305),
- Resolution of the European Parliament of 5 April 2001 on scale fees and compulsory tariffs for certain liberal professions, in particular lawyers, and on the particular role and position of the liberal professions in modern society,
- Resolution of the European Parliament of 16 December 2003 on market regulations and competition rules for the liberal professions,
- Resolution of the European Parliament of 23 March 2006 on the legal professions and the general interest in the functioning of legal systems,
- Resolution of the European Parliament of 12 October 2006 on the follow-up to the Report on Competition in Professional Services,
- Council Directive 77/249/EEC of 22 March 1977 to facilitate the effective exercise by lawyers of freedom to provide services,
- Directive 98/5/EC of the European Parliament and of the Council of 16 February 1998 to facilitate practice of the profession of lawyer on a permanent basis in a Member State other than that in which the qualification was obtained,

- Council Directive 2002/8/EC of 27 January 2003 to improve access to justice in cross-border disputes by establishing minimum common rules relating to legal aid for such disputes,
- Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications – Recital 43,
- Jurisdiction of the European Court of Justice on competition law and freedom of services in the Community, with particular regard to national provisions on minimum fees, especially case „C-267/99, Adam./Administration de l'enregistrement et des domaines de Luxembourg“,
- Report Study of the Institute for Advanced Studies (IHS) on behalf of the Commission, 'Economic Impact of Regulation in the field of Liberal Professions in Different Member States' of January 2003,
- New edition of the Report Study of the Institute for Advanced Studies, commissioned by the Directorate General for Research of the European Commission in March 2012.

// DEFINITION OF THE TERM LIBERAL PROFESSIONS

Since the term liberal professions is understood differently in different Member States, a common definition of this term is crucial. In 2001, the European Court of Justice issued a judgment in the case „C-267/99, Adam./Administration de l'enregistrement et des domaines de Luxembourg“ according to which liberal professions are characterized by the features hereafter:

- they have a highly intellectual character,
- they require a high level of qualification,
- and are usually subject to specific and strict professional regulations.
- Furthermore, a personal element is very important when exercising such a profession.
- Finally, exercising such a profession requires a great deal of independence in professional practice.

// CHALLENGES LIBERAL PROFESSIONS HAVE TO FACE

The consequences of the financial and economic crisis have put liberal professions and their professional self-government lately in the focus of the European legislator.

The European Commission plays in this regard a key role by strongly pushing for more economic growth in the interest of open markets for services. Liberalization and deregulation of the liberal professions seems so be the solution to generate more economic growth. In May 2012, the European Commission presented for example country specific recommendations and pleaded for a stronger competition in services, including the regulated professions. It is the task of liberal professions to show that a short term gain in economic growth could have on the long run disastrous consequences for the society.

On the contrary the European Commission is also pushing for more regulation when it comes to liberal professions. The proposal on the revision of the Directive on statutory audit from December 2011 includes a provision which foresees that the registration and admission of auditors shall be completely transferred to the state in the form of a public authority, thus breaking with the tradition of self-government of the auditors in many EU Member States.

In general, European law does not differentiate enough between liberal professions and regular enterprises. Such a “one-size-fits-all” approach has enormous consequences when it comes to, for example, reporting duties or other bureaucratic requirements.

// PRINCIPLES

The following ten principles distinguish liberal professions. They are values shared by all liberal professions.

- Liberal professions accept responsibility and serve the common good: Liberal professions are responsible for important public goods in areas such as health, justice, security, language and art. By offering their services in these areas liberal professions fulfill an important role in society and create value for society as a whole.
- Liberal professions are part of a free society: Liberal professions are an expression of a free, democratic constitutional order. The freedom to carry out a profession is limited to the extent that the professionals, of their own volition, subject themselves to ethical and public responsibilities. These considerations primarily ensure the fulfillment of the special duty of the liberal professions to the common good.
- Liberal professions protect trust: For the liberal professions the protection of their relationship of trust with their clients has the highest priority. This includes absolute confidentiality by maintaining professional secrecy, acting in the interest of the client and avoiding any possible conflict of interest.
- Liberal professions provide high quality services: Liberal professions provide a high standard of knowledge-based services. Quality is assured through demanding requirements concerning training and further education and a system of self-regulation by colleagues. An effective system of further education, independent of the interests of third parties, should provide the foundation to enable the liberal professions to rise to future challenges and remain internationally competitive.
- Liberal professionals are independent: Liberal professions are independent in their area of expertise and from the interests of third parties and carry out their professions autonomously. They are independent in arriving at their judgment and in performing their individualized service and bear full responsibility for their actions.
- Liberal professions perform their services personally: Liberal professions always provide their services for their clients personally. They are only able to delegate a small part of these services to less qualified persons. This is because liberal professional services are very closely related to the liberal professionals themselves, with their knowledge, expertise and creativity.
- Liberal professions are reliable partners: Liberal professions have a professional ethos. It includes moral standards for the proper carrying out of liberal professional services. In carrying out their services the liberal professionals are not primarily motivated by commercial considerations, instead they are guided by their professional ethos. This distinguishes them considerably from purely commercial service providers.
- Liberal professions support transparent self-regulation: Liberal professions and self-regulation as a principle of liberal professional organization belong together. Self-regulation should be protected and optimized in the interest of clients. It should be efficient and transparent and aimed at benefitting the society.
- Liberal professions invest in training: Liberal professions fulfill an important responsibility towards society in that they offer young people training places in professions with above-average prospects in the labor market. In this way they contribute to skill enhancement and job creation in Europe.
- Liberal professions support an innovative Europe: Liberal professions form a key sector of the European economy. As a driving force behind competition and innovation they are making an important contribution to the realization of the Europe 2020 goals. The medium-sized structure of the liberal professions enables them to ensure the future of competition in services in Europe. Due to their closeness to their clients, the liberal professions can react flexibly to changing needs.

// GUIDELINES FOR THE EUROPEAN INSTITUTIONS

The following seven guidelines have to be respected by the European Institutions before adopting new or changing existing Community law or taking Community action:

- The European Union shall strengthen the role of Liberal Professions and support these professions within its competences.
- The European Union shall respect the added value of the liberal professions to European society and shall make sure that the liberal professions are not assessed solely on the basis of market-economy criteria.
- The European Union shall respect the self-governing structures of the Liberal Professions as they exist in many Member States. Following the fundamental principle of subsidiarity Member States shall have the freedom to choose their way of organising the professional structures of liberal professions.
- The European Union shall acknowledge that a decision to deregulate liberal professions, without considering all possible consequences, could lead to a decline in quality and in the full coverage of supply, as for example with health services.
- European Institutions shall guarantee that specific impact assessment on the consequences of legislative proposals on liberal professions is carried out before and after European legislation is adopted. In this regard the European Legislator shall especially take into account the negative effects of bureaucratic burden on liberal professions.
- The European Union shall guarantee that services provided by liberal professions, which are individual solutions on a highly creative basis, shall not be subject of standardisation on European level.
- The European Union shall guarantee that the special trust relationship between members of the liberal professions and their clients / customers / patients is fully protected.

Unanimously adopted by the CED General Meeting on 23 November 2012



CED PRESS RELEASE OF 14 MAY 2012

EUROPEAN DENTISTS DISCUSS PROPOSED CHANGES TO PROFESSIONAL QUALIFICATIONS DIRECTIVE AND MEDICAL DEVICES LEGISLATION, ADOPT POLICY ON NITROGEN SEDATION

Representatives of CED member and observer organisations met in Copenhagen, Denmark on 11 and 12 May 2012 for a regular six-monthly General Meeting, under the chairmanship of CED President Dr. Wolfgang Doneus. The meeting was hosted by the Danish Dental Association, in the context of the Danish EU Presidency.

The Council of European Dentists (CED) is a European not-for-profit association which represents over 330,000 practising dentists through 32 national dental associations and chambers from 30 European countries. Its key objectives are to promote high standards of oral healthcare and effective patient-safety centred professional practice across Europe, including through regular contacts with other European organisations and EU institutions.

PROFESSIONAL QUALIFICATIONS DIRECTIVE

CED members reaffirmed their views on the possible changes to the Directive on the recognition of professional qualifications (Directive 2005/36/EC), which is currently being considered by the European Parliament.

The CED has called for defining the minimum duration of training for dental practitioners not only in years (5 years) but also in training hours (5000 hours), to maintain a high standard of dental education in the interest of patient safety. CED members support language checks for dentists practising in another Member State, but believe that the wording proposed by the European Commission should be simplified in order to avoid confusion and different procedures depending on the status of the healthcare provider. The CED supports the increased use of electronic means in recognition of professional qualifications through the IMI system but calls for extension of the newly introduced short deadlines imposed on competent authorities, particularly in view of the suggested tacit approval of recognition if the deadline is not met. Finally, CED members are strongly opposed to the application of the principle of partial access and ask for a clear exemption for healthcare professions and professions related to public health in the Directive.

CED Position Paper: [CED Position Paper on the Professional Qualifications Directive](#)

MEDICAL DEVICES LEGISLATION

In view of the proposal for the recast of the medical devices legislation, which the European Commission is expected to present before the summer break, European dentists called for increased traceability and transparency of the system.

The PIP breast implant scandal clearly showed the need to strengthen medical device regulation and its implementation, to reduce the risk of similar incidents in connection to other medical devices in the future. Specifically, the CED has suggested enhancing reporting obligations of manufacturers, requiring them to report all sites of manufacturing and subcontracting of custom-made devices, to ensure transparency and free choice for end users.

NITROUS OXIDE SEDATION IN DENTISTRY

In a resolution reviewed by the European Federation for the Advancement of Anaesthesia in Dentistry (EFAAD) and the Society for the Advancement of Anaesthesia in Dentistry (SAAD), CED members unanimously supported the use of inhalation sedation using nitrous oxide in dentistry. Administered properly and in line with relevant national legislation, by accredited dental practitioners using well-maintained equipment, and appropriately trained assistants, the technique is safe and effective, with an extremely high success rate and should be maintained in the armamentarium of dentistry as a fundamental tool for pain and anxiety management.

As many as 10 to 30% of adults and children may have some form of fear or anxiety related to dental treatment. While there is substantial evidence that these patients can benefit from this safe form of sedation, its use has been challenged in some European countries.

CED Resolution: [The use of nitrous oxide inhalation sedation in dentistry](#)

For more information contact:

Nina Brandelet-Bernot

Head of CED Brussels Office

Tel: + 32 2 736 34 29

ced@eudental.eu

<http://www.eudental.eu>



CED PRESS RELEASE OF 12 SEPTEMBER 2012

COUNCIL OF EUROPEAN DENTISTS CELEBRATES WORLD ORAL HEALTH DAY

The Council of European Dentists (CED) is pleased to celebrate 12 September, the World Oral Health Day.

On the occasion of the World Oral Health Day, European dentists stress that oral health strongly impacts and is impacted by our general health. Oral health messages should be therefore routinely integrated in general health promotion and prevention initiatives at national and EU level. Interdisciplinary and integrative approaches to healthcare, with enhanced education, communication and cooperation between dentists and other healthcare professions should be implemented to ensure that patients receive consistent information and the best care possible. Dental care should be recognised as an integral part of healthcare and good oral health of all Europeans should not be sacrificed in these times of fiscal austerity and budget cuts.

For more on these issues, please see

- [Report: "Healthy mouth, healthy living, healthy ageing: Investing in prevention is the most cost-effective approach to healthcare"](#)
- [CED Resolution: "For better oral health of all EU citizens: Mutual integration of oral and general health"](#)

Background information:

The Council of European Dentists is a European not-for-profit association which represents over 340,000 practising dentists through 32 national dental associations and chambers from 30 European countries. Its key objectives are to promote high standards of oral healthcare and effective patient-safety centred professional practice across Europe, including through regular contacts with other European organisations and EU institutions

For more information contact:

CED Brussels Office

Tel: + 32 2 736 34 29

ced@eudental.eu

<http://www.eudental.eu>



CED PRESS RELEASE OF 27 NOVEMBER 2012

EUROPEAN DENTISTS ADOPT POLICY ON E-HEALTH, CALL FOR RESPONSIBLE DECISIONS ON DENTAL AMALGAM, AND SUPPORT CHANGES TO PROFESSIONAL QUALIFICATIONS DIRECTIVE

Representatives of CED member and observer organisations met in Brussels, Belgium on 23 November 2012 for a regular six-monthly General Meeting, under the chairmanship of CED President Dr. Wolfgang Doneus.

The Council of European Dentists (CED) is a European not-for-profit association which represents over 340,000 practising dentists through 32 national dental associations and chambers from 30 European countries. Its key objectives are to promote high standards of oral healthcare and effective patient-safety centred professional practice across Europe, including through regular contacts with other European organisations and EU institutions.

CED BOARD ELECTIONS

Dr. Wolfgang Doneus (Austria) was re-elected to the position of CED President for another three-year term. Dr. Marco Landi (Italy) and Dr. Nikolai Sharkov (Bulgaria) were re-elected as Directors. Dr. Alexander Tolmeijer (the Netherlands) was also elected to the position of a CED Director. They join current Directors Dr. Susie Sanderson (Treasurer, United Kingdom), Dr. Peter Engel (Germany), Dr. Pirkko Grönroos (Finland) and Dr. Roland L'Herron (France). The Board met briefly after the General Meeting and appointed Dr. Marco Landi as the new CED Vice-President.

CED Board of Directors is composed of eight members who must be dental practitioners and share the powers of administration of the organisation, including communication and representation of the CED towards third parties, in particular the European Institutions, as well as implementation of CED policy and financial management.

E-HEALTH

During the plenary session, Members of the CED unanimously adopted a Resolution on eHealth. CED Members stressed that dentists must have access to patients' relevant medical data, and while they should not be allowed to change any data about procedures they have not carried out themselves they can only be liable for the information included in the records by them. The CED supports a minimum common set of patient data which should also include dental information to have a clear and effective system for functioning of eHealth. Patients must have access to their medical data which is highly sensitive and must be secured appropriately in line with relevant EU data protection legislation.

European dentists recognise the difficulties inherent in trying to develop a uniform codification system for diagnosis and treatments to achieve semantic interoperability of eHealth systems in dentistry and support preferably the development of common codes or, as an alternative, correspondence tables in EU Member States with regard to treatment codes.

Dentists recommend the implementation of national certification procedures for dental software and stress that it should be possible for all patient data to be exported into an open and standardised format to ensure competition and avoid loss of data.

CED Resolution: [eHealth](#)

DRAFT CHARTER FOR LIBERAL PROFESSIONS

Liberal professions are growing in importance as one of the main drivers of the EU economy and often provide public services in core areas of general interest. Nevertheless, their social significance and specific situation are still not properly taken into account when adopting or amending EU legislation.

Through this draft for a Charter for Liberal Professions, European dentists support establishing guidelines which will ensure that European Institutions consider possible implications for liberal professions of any new or amended legislation. The CED looks forward to discussing the draft with other organisations representing liberal professions at European level.

CED Draft Charter for Liberal Professions

DENTAL AMALGAM

CED Members noted the preparations for the January INC5 meeting which is expected to lead to a legally binding global treaty on mercury. They called on the EU to take an evidence based position in relation to dental amalgam and pointed to the risks of a phase out or over-swift phase down of dental amalgam on health economies and on the stability of the health of European populations.

The CED supports the World Health Organisation's recommendation for a phase down of dental amalgam, coupled with a flexibility to allow national governments to manage the change in the balance of the use of the range of dental materials at a pace which is appropriate to their own domestic circumstances. In addition, national governments should be challenged to commit to programmes to improve the oral health of their communities so that the overall need for restorative interventions is reduced, an element which is currently not mentioned in the draft UNEP treaty.

PROFESSIONAL QUALIFICATIONS DIRECTIVE

CED Members confirmed their positions on the Directive on the recognition of professional qualifications which is currently being considered by the European Parliament and the Council.

Minimum duration of training for dentists should be expressed not only in years (5 years) but also in the number of training hours (5000 hours of fulltime theoretical and practical training) to prevent the proliferation of weekend diplomas and content-light academic programmes and to maintain an acceptable standard of dental education without jeopardizing patient safety. In addition, the principle of partial access should not be applied to health professions and for health professions language checks should be carried out prior to the admission to the profession.

EUROPEAN ORAL HEALTH DAY

CED Board recommended to CED Member Associations to maintain 12 September as the European Oral Health Day. The Board noted that this date was well-established in European countries and linked to existing national initiatives and that it would therefore not be appropriate to move it to another date.

For more information contact:

CED Brussels Office

Tel: + 32 2 736 34 29

ced@eudental.eu

<http://www.eudental.eu>

CED ACTIVITIES INFO

COUNCIL OF
EUROPEAN DENTISTS



Issue 1 – March 2012

Introduction

Welcome to the 1st issue of CED Activities Info of 2012. CED Activities Info reports on the political activities of the President and Board members, as well as on the work of CED Working Groups, Board Task Forces and the Brussels Office.

CED BOARD

MEETING ON 2 MARCH

On 2 March, the CED Board of Directors met in Brussels for its regular quarterly meeting. During the meeting, hosted by the Permanent Representation of Austria, CED Board members reviewed CED political activities since their November meeting and discussed current political developments which are most likely to significantly impact the dental profession.

The Board approved a number of initiatives by CED working bodies in preparation to the May CED General Meeting in Copenhagen. They reviewed CED finances and discussed the possible financial, operational and reputational risks to the CED, agreeing that these should be reflected upon and appropriate mitigating actions taken at regular intervals. In connection to the November elections for the CED Board, they agreed that an information sheet, summarising obligations of CED Directors under Belgian law and CED Statutes will be sent to CED Members together with the call for candidacies.

Board members also raised concerns in connections to recent attempts in several EU countries to deregulate liberal professions in response to the economic crisis. They supported continued self-regulation of liberal professions and maintenance of high standards in their performance.

OBE FOR A CED DIRECTOR

CED Treasurer and Board member Susie Sanderson was awarded the

title of an Officer of the Order of the British Empire (OBE) as part of the 2012 New Year Honours List recognising her services to dentistry.

CED PRESIDENT

LETTER TO PRIME MINISTER OF POLAND

On 12 January, CED President Wolfgang Doneus wrote, at the initiative of the CED's Polish member, to Prime Minister Tusk of Poland in connection to the **Polish law on the reimbursement of medicines and medical devices**. The law which entered into force on 1 January 2012 instituted new responsibilities of doctors and dentists prescribing products subject to reimbursement. CED President expressed concerns that requiring the prescribers to be liable for verifying the level of patient entitlement would be excessively burdensome and unfair, especially in view of the absence of a regularly updated and reliable list of the insured.

CED WORKING GROUPS (WG)

WG AMALGAM

The European Commission is currently reviewing the issue of mercury pollution with the aim of determining if there is a need for further legislative action and has commissioned BIO Intelligence Service to carry out a **study on the life cycle of dental amalgam**. CED WG Amalgam prepared a communication package on responsible practice to help CED members to initiate contacts with the relevant national ministries on this issue. The package was released by the CED on 27

February and includes the [CED resolution on responsible practice](#), which signposts actions that dentists should take in order to reduce the environmental impact of the use of dental amalgam, as well as the [WHO report on the future use of materials for dental restoration](#), suggesting a phase-down, rather than a phase-out of the use of dental amalgam.

The CED has been invited to attend a **stakeholders' workshop on 26 March** organised by the Commission where [BIOIS](#) will present its "Study on the potential for reducing mercury pollution from dental amalgam and batteries". WG Chair Susie Sanderson, CED member Stuart Johnston and CED Policy Officer Sara Roda will attend. BIOIS preliminary report will be released in early March and the final report is expected by May 2012. The WG is planning to meet shortly after the workshop to discuss and prepare the CED comments on the study which will then be forwarded to BIOIS and the Commission for consideration. During the meeting the WG will also discuss the use of alternative materials for dental restorations.

WG EDUCATION & PROFESSIONAL QUALIFICATIONS (WG EPQ)

On 25 November 2011, **WG member Barbara Bergmann-Krauss was confirmed as a member of the Reference Group "Human health and Social work activities"** in the [ESCO project](#), acknowledging her professional profile and expertise. She was nominated by the



COUNCIL OF EUROPEAN DENTISTS (formerly EU Dental Liaison Committee)

President Dr Wolfgang Doneus

T +32 (0)2 736 34 29

F +32 (0)2 740 20 26

ced@eudental.eu

www.eudental.eu

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CED as an expert which will represent the dental profession in this Group.

On 31 January, **the sectoral professions under the Professional Qualifications Directive (PQD) met with the European Commission** to discuss and address specific questions related to the [Commission's proposal on the PQD](#). The CED, represented by Head of Office Nina Bernot and Policy Officer Sara Roda, raised the issues of minimum training requirements in dentistry, the new provision on remunerated traineeship and the modalities of the decision to introduce the European Professional Card (which now adopts the format of an electronic certificate) for a given profession. Other questions were addressed, such as partial access, language regime, delegated acts and the alert mechanism. The meeting marked another step in the ongoing dialogue between the Commission and the sectoral professions on the PQD.

On 2 February, CED Board member Peter Engel, Nina Bernot and Sara Roda attended **a meeting organised by the Commission on the modernisation of the PQD**. In the meeting, the Commission explained its proposal to amend the PQD and once again the CED took the opportunity to stress the need to define the minimum duration of dental training in both years and hours.

On 9 February, the **WG EPQ met in Brussels**. Besides preparing the CED's position to the Commission's Proposal on the PQD, they finalised the draft resolution on the use of nitrous oxide inhalation sedation in dentistry, discussed the CED's recommendations for continuing professional development (CPD), and analysed the replies to the CED questionnaires on the implementation of the Bologna system and on vocational training for dental training. WG members also noted that the CED would start scheduling

meetings with the relevant MEPs to discuss the PQD; a meeting between shadow rapporteur MEP Constance Le Grip and CED Board member Roland L'Herron took place on 27 February.

On 10 February, the **CED-ADEE task force met in Brussels**. [ADEE](#) represents European dental schools. The interlocutors discussed the minimum training requirements established in the PQD, the ECTS system and a possible joint proposal on these issues. The task force agreed on proposing a joint amendment to the PQD, asking for the **minimum duration of training for dental practitioners to be expressed in years (5 years), hours (5000 hours) and ECTS credits (300 ECTS)**, to ensure continued high quality of dental education in the interest of patient safety. The task force further agreed to prepare a new draft Annex for the PQD which will combine, in this order, competences, learning outcomes (which will include students' assessment and grading as a separate section) and subjects. The task force will meet again on 6 July.

WG EHEALTH

On 20 January, the **WG met online** to discuss to discuss Dr Jørn Jorgensen's memo on codes and classification. The WG agreed to investigate in further detail at the next WG meeting, scheduled for 12 March in Brussels, the [SNOMED classification](#). Each member would report their preliminary findings about the use of this classification at national level. The WG will also prepare the **CED draft resolution on eHealth** which will be submitted for adoption to the CED General Meeting in Copenhagen.

The **CED has been accepted to participate in the [eHealth Stakeholders Group of users and industry representatives](#)**. The Group, led by the Commission, will provide a platform for stakeholders to contribute to the development of legislation or

policy related to eHealth, e.g. by providing reports, opinions and relevant data. The CED will be represented by WG chair Dr Piret Väli (member) and WG member Dr Jørn Jørgensen (substitute).

WG MEDICAL DEVICES

WG Medical Devices met on 10 January to discuss CED position on the **upcoming Commission's proposal for a new regulation on medical devices**. In a letter to the Commission on 19 January, the CED called for clarification of definitions, strengthening the reporting obligations of manufacturers of custom-made devices and introduction of exemptions from the Unique Device Identification (UDI) system for custom-made devices and small healthcare providers. CED Board member Marco Landi and CED Head of Office Nina Bernot discussed the proposal with DG SANCO's Director Jacqueline Minor during a meeting on 9 February. The Commission's proposal is expected to be published by summer.

On 22 February, Nina Bernot attended on behalf of the CED the meeting of the Ad hoc working group on UDI during which the Commission presented its intentions in connection to a **future European UDI system**. The Commission intends to include the main principles about the UDI system in the upcoming regulation on medical devices and to publish a Recommendation to Member States by the end of 2012. Details of the European UDI system are proposed to be clarified through delegated or implementing acts, expected in 2014. Concerns about this suggested way forward were expressed.

On 23 January, WG chair Edoardo Cavallé and Board member Marco Landi met with the rapporteur on the [proposed regulation on European standardisation](#), MEP Lara Comi. They called for **excluding healthcare services from the scope of the regulation on stan-**

standardisation, recalling the special character of healthcare and raising concerns that standardisation might infringe on the rights of Member States to independently organise and deliver medical care, exclude some dentists and negatively impact the overall quality of dental care. The CED joins European doctors and pharmacists in asking for this exclusion.

The CED sent a template letter to its members on 14 February, asking them to contact their national governments to ensure agreement in the Council on exclusion of healthcare from the scope of the standardisation regulation.

WG ORAL HEALTH

WG Oral Health met online on 16 January to discuss the **CED public event on oral health** to be organised in 2012. The event will be based on the [CED resolution For better oral health of all EU citizens: mutual integration of oral and general health](#) and will stress the links between general and oral health, common risk factors and the need for cooperation between different health professionals, as well as engagement of patients. MEPs, health attachés and stakeholders will be invited to participate.

In January, the CED contributed to the EU Health Policy Forum's response to **DG SANCO's consultation on chronic diseases**. The CED stressed that oral diseases remain a major health burden in Europe, affecting majority of the population, and that oral diseases both share and are in themselves risk factors for other major chronic diseases.

WG PATIENT SAFETY

On 21 November 2011, CED Head of Office Nina Bernot attended on behalf of the CED the meeting of the **Patient Safety and Quality of Care Working Group**. The Group is currently discussing its future role. Ideas such as focusing on gaps to be revealed by the Com-

mission's report on the implementation of the 2009 Council Recommendation on patient safety are being discussed.

Joint Action on patient safety (PaSQ) in which the CED will participate as an associated partner, is expected to formally start with a kick-off meeting in Roskilde, Denmark, on 24 and 25 May in which Nina Bernot will take part.

WG TOOTH WHITENING

CED WG Tooth Whitening met on 1 March in Brussels to finalise the CED Guidelines on [Directive 2011/84/EU](#). The Directive, which introduces a new **EU regulatory regime for tooth whitening products** containing hydrogen peroxide and will have to be implemented by Member States from 31 October 2012, has created a fair amount of confusion among individual dentists and the general public. The CED Guidelines are meant to help CED Members guide their national authorities in correct transposition and provide accurate information to the public. They will be sent to CED Members by the end of March.

WG Tooth Whitening also discussed the CED commitment to report on the undesirable effects of tooth whitening to the European Commission and the need to raise with the Commission the dangers of the use of chlorine dioxide in tooth whitening.

CED BOARD TASK FORCES (BTF)

BTF INTERNAL MARKET

In January, the CED replied to the Commission's [public consultation on measures for improving the recognition of medical prescriptions issued in another Member State](#). The CED suggested ways of **improving safety and accuracy of cross-border prescriptions, while calling for continued respect for patient privacy**, in line with applicable legislation and ethical norms of prescribing health professionals.

In February, the CED was nominated by the European Commission to become an **associated partner within the future Joint Action on health workforce planning and forecasting**. BTF Internal Market will coordinate CED contributions and hopes to inject into the Joint Action the perspective of practising dentists. On 11 January, CED Head of Office Nina Bernot attended the preparatory meeting for the Joint Action where the content of individual work packages was discussed.

On 20 February, the **BTF IM met in Brussels** to discuss the CED's position to the Commission's Proposal on the PQD. The Task Force also discussed the results of the CED questionnaire on dentist workforce trends and planning (which will be reported to the CED Members shortly), the [Commission's communication on the future of VAT](#) and the [Data Protection Reform](#). The CED will monitor and prepare positions on these two issues.

CED OFFICE

CED ON TWITTER

Since mid-December 2011, the CED Office provides short and timely updates on CED work and political developments in Brussels affecting European dentists. If you are on Twitter, please feel free to follow us. If you are not familiar with Twitter but curious to see what we are tweeting, simply use the following link: www.twitter.com/CEDentists.

If CED Members wish to receive further information about any of the items mentioned in the newsletter, please contact: ced@eudental.eu.



Introduction

Welcome to the 2nd issue of CED EU Info of 2012. This issue is divided in two sections: the first section provides updates on EU topics relevant to the dental profession and the second section contains more general information regarding EU policy.

SECTION I – EU TOPICS RELEVANT TO THE DENTAL PROFESSION

DIRECTIVE ON THE RECOGNITION OF PROFESSIONAL QUALIFICATIONS (PQD)

On 2 February, the Commission held a [conference \(conference web-cast\)](#) to explain the main changes introduced by the legislative proposal to amend the PQD. During this conference, the CED learnt the new [timeline for the legislative procedure](#):

- Consideration of draft report 17-19 September 2012;
- Deadline to table amendments 15 October 2012;
- IMCO vote on 28 November 2012;
- Plenary sitting vote scheduled for 14 January 2013.

On 28 February, the European Parliament's [IMCO committee held a first exchange of views](#) on this issue. The Committee is now planning a hearing entitled ["Growth & Mobility: Modernising the Professional Qualifications Directive"](#) on 25 April to continue to discuss the Commission's proposal on the PQD.

MEDICAL DEVICES

On 9 February, the European Commissioner for Health and Consumer Policy John Dalli called on Member States to ensure full and stringent implementation of the current EU legislation on medical devices. In a letter to the EU Health Ministers, the Commissioner set out

his proposals for a joint plan of immediate measures, including verifying the designation of notified bodies, ensuring that notified bodies fully use their powers under the current legislation, such as the power to conduct unannounced inspections, and reinforcing market surveillance. He also proposed improving the vigilance system for medical devices, for example by encouraging healthcare professionals to report adverse events, and supporting the development of traceability tools such as Unique Device Identification systems and implant registers. The proposal came as a result of the PIP breast implant scandal.

In addition to the immediate actions, the European Commission asked the Scientific Committee on Emerging and Newly Identified Health Risks to conduct an in-depth investigation of the potential health impact of the faulty PIP silicone breast implants. Commissioner Dalli also indicated that lessons learned from the PIP case will influence the upcoming revision of the medical devices legislation, particularly by strengthening the provisions on market surveillance, vigilance and functioning of notified bodies.

eLABELLING

On 9 March, the Commission adopted [a Regulation on Electronic Instructions for Use of Medical Devices](#). The regulation establishes the conditions under which manufacturers can provide instructions for use of medical devices in electronic form. One of the conditions is

that the medical device in question is intended for exclusive use by professional users (healthcare providers). In addition, the manufacturer has to undertake a risk assessment demonstrating that providing instructions in electronic form maintains or improves the level of safety compared to providing instructions in paper form; he is obligated to provide instructions in paper form to the user, if so requested by the user; and finally he has to keep instructions for use available to the users in electronic form for at least 2 years after the expiry date of the last produced device (for devices with a defined expiry date, except implantable devices) or for a period of 15 years after the last device has been manufactured (for devices without a defined expiry date and for implantable devices). This regulation will enter into force on 1 March 2013.

EUROPEAN STANDARDISATION

On 21 March, the European Parliament's IMCO committee approved the report on the draft Regulation on European Standardisation. The report was approved by 36 votes in favour and one abstention. During the discussions, S&D and Green MEPs stressed their concern to include services in the scope of the regulation, explaining that Member States should remain free to decide on the development of standards in areas such as social services and public health. The Committee now has to decide when to open formal negotiations with the Council; first informal meeting will take place on

11 April. The Council debate is planned for 30 May (Competitiveness Council) and the vote in the European Parliament plenary for 2 July. The approved version of the report has not yet been published.

DENTAL AMALGAM

On 26 March, the Commission organised a stakeholder meeting where BIOIS (consultancy firm contracted by the Commission) presented the [draft report on the potential for reducing mercury pollution from dental amalgam and batteries](#). Stakeholders are now invited to provide written feedback by 16 April. The final report is expected by May 2012 and the Commission will use it to assess for further action at EU level.

CED Working Group Amalgam and Working Group Infection Control and Waste Management will meet in London on 4 April to discuss and prepare the CED response on the draft report.

JOINT ACTION ON HEALTHCARE WORKFORCE

On 9 March, the future partners of the Joint Action for Health Workforce Planning submitted to the Executive Agency for Health and Consumers the proposal for the Joint Action (JA). The main purpose of this JA is to provide a common platform for Member States to work together on: 1) data for health workforce planning; 2) exchanging good practices with planning methodologies; 3) forecasting future health workforce needs; and 4) the sustainability of the results of the JA. The JA is structured in 7 Work Packages and is expected to start at the end of 2012 or in early 2013. The CED will contribute as an associated partner to Work Package 6 – horizon scanning. Specific objectives of this Work Package are to estimate future needs in terms of skills and competences of the health workforce, their distribution and to develop a user guide on how

to estimate future needs. The Work Package will be led by the UK-based Centre for Workforce Intelligence.

WRITTEN HEALTH WARNINGS FOR TOBACCO PRODUCTS

On 7 March, the Commission adopted 14 new health warnings to appear on tobacco packs through [Directive 2012/9/EU](#). The Directive amends the Annex of Directive 2001/37/EC on the manufacturing, presentation and sale of tobacco products. New health warnings include “*Smoking causes mouth and throat cancer*” and “*Smoking damages your teeth and gums*”. Member States will have to comply with the Directive by 28 March 2014 but may decide to allow continuation of marketing of products not complying with the Directive until 28 March 2016.

SAFETY OF BISPHENOL A IN MEDICAL DEVICES

The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has been [requested to provide a scientific opinion on the safety of the use of bisphenol A in medical devices](#). The deadline is July 2012 after which the opinion is to be submitted for a public consultation. The CED is planning to contribute at that time through one of its Working Groups.

eHEALTH

The Commission launched a [Public Consultation on the Access to Interoperability Information of Digital Products and Services](#) to obtain information on the needs, barriers and opportunities for measures leading significant market players to license interoperability information not covered by standards. Interoperability is defined as the ability of hardware or software products, or services to exchange information and mutually to use that information. The consultation is open until 20 June 2012.

Article 29 Data Protection Working

Party (independent advisory body on data protection composed by Member States’ data protection authorities, the European Data Protection Supervisor and the Commission) has recently published an [opinion on data protection issues related to epSOS](#) (European Patients Smart Open Services) project.

A home video about how epSOS work in a real-life situation is available [here](#). The video shows a Greek pharmacist dispensing medication to an Italian patient using epSOS services.

PUBLIC CONSULTATION ON ePRESCRIPTIONS

On 26 March, the Commission published the [results of the public consultation on measures for improving the recognition of prescriptions](#). The results of the consultation, to which the CED also contributed, will be used for the impact assessment on measures to improve the recognition of prescriptions issued in another Member State. This impact assessment will be published by the end of 2012.

EUROPEAN INNOVATION PARTNERSHIP ON ACTIVE AND HEALTHY AGEING

On 29 February, the Commission issued a [Communication](#) to take forward the Strategic Implementation Plan of the European Innovation Partnership on Active and Healthy Ageing. In this Communication the Commission:

- [invites stakeholders to commit](#) to specific actions on innovation in active and healthy ageing;
- puts in place, as of April 2012, a ["marketplace for innovative ideas"](#), helping stakeholders find partners, share good practices and disseminate evidence;
- intends to address regulatory and standardisation issues, e.g. by developing a new EU framework for interoperability testing, quality

labelling and certification on e-Health; and,

- intends to use EU funding instruments such as the Competitiveness and Innovation Framework Programme (CIP).

JURISPRUDENCE

The European Court of Justice recently ruled – [Case-135/10](#) – on whether producers of phonograms are entitled to obtain remuneration when private dental practices broadcast phonograms by way of background music in the waiting room to entertain – free of charge – their patients while waiting for the treatment. The Court ruled that these phonograms were not a “communication to the public” for the purposes of EU law (Article 8(2) of Directive 92/100/EEC currently repealed by [Directive 2006/115/EC on rental right and lending right and on certain rights related to copyright in the field of intellectual property](#)), and therefore, such broadcasting did not give rise to a right to a remuneration. The plaintiff (a royalties collecting agency for phonograms producers) had tried to conclude a collective agreement with CED Member ANDI (Associazione Nazionale Dentisti Italiani) to quantify an equitable remuneration. As those negotiations were unsuccessful, the plaintiff brought an action before the Turin district court.

SECTION II – GENERAL EU POLICY

FISCAL COMPACT TREATY

As CED EU INFO went to press on 30 January, EU leaders were meeting in Brussels to finalise the text of a [new treaty](#) to tighten fiscal discipline in the eurozone. The treaty, which was in principle agreed at the Summit on 9 December 2011, was vetoed by the UK and will as a result be concluded on an intergovernmental basis and outside of the EU legal framework. All EU Member States except the UK and Czech Republic have expressed

their interest in joining the new “fiscal compact”.

FIRST SINGLE MARKET GOVERNANCE REPORT

On 27 February, the Commission presented the [first single market governance report](#) to evaluate the state of the single market. This report will feed into a new report due in June on further means to enhance the implementation of the single market legislation, since 2012 is its 20th anniversary. These actions come as a response to the [Statement of the Informal European Council of 30th January 2012](#) towards growth-friendly consolidation and job-friendly growth. Before the end of 2012, the Commission will present its programme for the next stage. Its considerations will be fed by a large-scale economic study, the results of which will help to identify the areas still unexploited and pinpoint new drivers of growth.

Comments, questions and contributions please contact:
ced@eudental.eu

CED ACTIVITIES INFO

COUNCIL OF
EUROPEAN DENTISTS



Issue 2 – April 2012

Introduction

*This issue will be the first in a series of newsletters not only updating you on CED activities but also taking a closer look at CED Working Groups and Board Task Forces, their policy priorities for 2012-2013 and, most importantly, the experts that make their work possible. The first edition is dedicated to the **CED Working Group Education and Professional Qualifications**. Section I continues to report on the political activities of the CED President, Board members and to summarise the work of the other CED Working Groups, Board Task Forces and the Brussels Office. In Section III, CED member associations share their positions on current issues.*

HEALTHY MOUTH, HEALTHY LIVING, HEALTHY AGEING

CED EVENT IN THE EUROPEAN PARLIAMENT

On 26 June 2012, the CED will organise an event, hosted by MEP Cristian Silviu Buşoi and entitled **"Healthy mouth, healthy living, healthy ageing: Investing in prevention is the most cost-effective approach to healthcare"** in the European Parliament. Featuring health professionals' and patients' perspectives, the event will explore links between general and oral health, the need for prevention in the context of healthy ageing, and the importance of an interdisciplinary approach and cooperation between different health professionals in treatment of diseases. More information will be available and registration will open in May.

SECTION I – CED INTERNAL ACTIVITIES

CED PRESIDENT

LETTERS FROM DG SANCO

In April, the CED received the European Commission's (DG SANCO) comments to the CED Guidelines to interpret and implement the [Council Directive 2011/84/EU](#) concerning tooth whitening products as well as to the CED draft template to report undesirable effects. These documents were developed by the CED Work-

ing Group Tooth Whitening and will be presented by this WG at the May General Meeting.

CED WORKING GROUPS (WG)

WG AMALGAM

On 26 March, WG Chair Susie Sanderson, CED member Stuart Johnston and CED Policy Officer Sara Roda attended the Commission **stakeholders' workshop** where [BIOIS](#) presented its *"Study on the potential for reducing mercury pollution from dental amalgam and batteries"*. The CED has contributed vigorously to the discussions supporting option 1 of the study (which recommends an improvement in the enforcement of EU waste legislation regarding dental amalgam), and challenged option 3 (which recommends banning the use of mercury in dentistry).

On 4 April, the **WG met in London** to discuss and prepare the CED response to the BIOIS study. The WG concluded that the study is *"significantly flawed and unbalanced"* and that it *"attempts to suggest inappropriately that a highly complex situation can be solved with an overly simple solution"*. The WG criticised the fact that *"much of the data it relies on is based on a survey requesting information from 27 disparate countries which, as CED has previously discovered, is almost impossible to access with accuracy. (...) Regardless of the*

acknowledged estimations, assumptions and rough guesses, more worryingly the report contains dangerous speculation and inaccuracies of fact." In its response, the **CED urged the Commission to take a more balanced view than that which was represented in the BIOIS study.**

WG EHEALTH

On 12 March, the **WG met in Brussels** to prepare a draft CED resolution on eHealth, to discuss the CED membership in the Commission-led [eHealth Stakeholders Group of users and industry representatives](#), which will provide a platform for stakeholders to contribute to the development of legislation or policy related to eHealth, and to analyse the implementation of the [SNOMED CT classification](#) in the different EU countries.

On 23 March, the **WG met on-line** to conclude the draft resolution on eHealth which will be considered for adoption at the May General Meeting. The next WG meetings will take place in Brussels (11 June 2012) and on-line (10 September 2012).

On 29 March, **WG member Dr Jørn Jorgensen attended the eHealth Stakeholders Group** on behalf of the CED. The objective of this first meeting was to define the role of the Group and its members; discuss the policy context; and establish the work programme for 2012 and the modus operandi of the group.



COUNCIL OF EUROPEAN DENTISTS (formerly EU Dental Liaison Committee)

President Dr Wolfgang Doneus

T +32 (0)2 736 34 29

F +32 (0)2 740 20 26

ced@eudental.eu

www.eudental.eu

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WG INFECTION CONTROL

On 4 April, the WG met in London to discuss the issue of dental unit water samples testing positive for *Legionella pneumophila*. The WG intends to organise a seminar to debate pathogenic species contamination, but will request specific guidance from CED members on this matter at the May General Meeting.

CED BOARD TASK FORCES (BTF)

BTF COMMUNICATIONS

On 18 April, BTF Communications met in Brussels to review the progress on reaching the goals listed in the 2012 Annual Communications Work Plan. BTF noted the development of new communications tools available to CED members through the CED website and agreed that fact sheets on policy issues should be developed to support members in their contacts with policy makers. BTF members supported the plans for organising a meeting of national dental association communications officers in the second half of 2012 and agreed that changes to CED questionnaires should be envisaged to make the results more accurate and useful. They also suggested regularly organising discussion evenings with a small number of MEPs to present to them the positions of European dentists on current political issues.

CED OFFICE

HEALTH FIRST EUROPE ROUNDTABLE EVENT

On 24 April, CED Policy Officer Sara Roda attended an invitation-only roundtable event in the European Parliament on behalf of the CED President. This event was organised by [Health First Europe](#) (HFE) and sponsored by MEP Christofer Fjellner, (EPP, Sweden) to discuss the future of patient safety in Europe and HFE's recommendations on patient safety

and on healthcare associated infections.

SECTION II – CED WG EDUCATION AND PROFESSIONAL QUALIFICATIONS (WG EPQ)

HISTORY

WG EPQ was established in May 2003. Over the years, it has helped develop CED policy related to the minimum training requirements for dental practitioners, the profile of a future dental practitioner, the competences required to practice dentistry in the EU, continuous professional development, the impact of the Bologna process on dentistry and many other aspects related to dental training and professional qualifications.

HOW DOES IT WORK?

The current **WG mandate** was adopted by the CED General Meeting (GM) in May 2011. Every two years the GM (where all CED members are represented) has the possibility to renew, amend or end the mandate of the WG. On the basis of this mandate, the WG EPQ has developed several policy papers and resolutions to defend high quality of dental training in Europe and represent the interests of the dental profession during the review of the Professional Qualifications Directive (PQD).

WG members are appointed by CED members and CED observer associations at their discretion from experts with relevant experience and knowledge. At present, WG EPQ is composed of experts from 9 different countries, including the WG Chair (selected by the GM) and two Board liaisons (selected by the Board to supervise and report on the WG's progress to the Board).

Task forces can be created at the initiative of the WG Chair, with the approval of the CED Board and sometimes the CED General Meeting when it assumes high political importance. These task forces are

active for limited periods of time and for precise issues requiring specific expertise. Their members are selected on the basis of their expertise but they are no longer restricted to CED membership. At present, three task forces operate within WG EPQ:

- (i) **CED-ADEE taskforce**, in which both organisations – of dentists and of dental educators – are developing a joint proposal for a new Annex for the PQD which will combine competences, learning outcomes and subjects. CED and ADEE have already agreed on a joint amendment to Article 34/2 of the PQD;
- (ii) **the CPD task force** which is preparing a CED position on continuous professional development;
- (iii) **the nitrogen sedation task force** which has recently concluded drafting a resolution on nitrogen sedation that will be considered for adoption at the May General Meeting.

ROLE OF THE WG CHAIR

The WG Chair, **Prof Dr Kostantinos Oulis**, Professor in the Department of Paediatric Dentistry, University of Athens, dental practitioner and author of innumerable articles, has the responsibility to ensure that the WG's mandate is fulfilled and that the will of the CED members is correctly and timely translated in policy papers and resolutions. The WG Chair leads the WG's task forces and reports on the progress of the work of the WG to the GM twice a year. He attends all meetings of the WG and may represent the CED externally within the remit of the WG.

ROLE OF THE WG MEMBERS

The WG members attend the WG meetings and may attend the CED GM. They are at the heart of CED policy as they are responsible for drafting CED policy papers and resolutions. They represent the interests of the respective member or observer association within the WG. The current members of the WG

are:

- **Dr Peter Engel**, CED Board member and Board liaison, dental practitioner and President of the German Dental Association (Bundeszahnärztekammer), Germany;
- **Dr Marco Landi**, CED Board member and Board liaison, dental practitioner, ANDI - Associazione Nazionale Dentisti Italiani, Italy;
- **Mrs. Barbara Bergmann-Krauss**, Head of Agency for Quality in Dentistry, Institution of the German Dental Association, Germany;
- **Dr Edoardo Cavallé**, dental practitioner, ANDI - Associazione Nazionale Dentisti Italiani, Italy;
- **Dr Doniphan Hammer**, dental practitioner, CNSD - Confédération Nationale des Syndicats Dentaires, France;
- **Dr Stefaan Hanson**, dental practitioner and Executive Director of the Flemish Dental Association, Belgium;
- **Prof Dr Péter Hermann**, Professor in the Department of Prosthodontics, Faculty of Dentistry, Semmelweis University, and President of the Dental Section of the Hungarian Medical Chamber, Hungary;
- **Prof Dr Juan Seone Lestón**, Professor in the Departement of Stomatology, University of Santiago de Compostela, Spanish Dental Association, Spain;
- **Dr Roland Svensson**, dental practitioner, Swedish Dental Association, Sweden;
- **Dr Piret Väli**, dental practitioner and President of the Estonian Dental Association, Estonia; and,
- **Prof Dr Alfonso Villa Vigil**, Professor in the Department of Surgery and Medical-surgical Specialties, University of Oviedo, and President of the Spanish Dental Association, Spain.

POLICY PRIORITIES 2012-2013

The WG has been contributing to the evaluation process of the PQD

since 2010 through the preparation of several position papers and resolutions which call on the EU Institutions to update the minimum training requirements for dental practitioners. The focus of the WG will continue to be the modernisation of the PQD (now in co-decision process), with emphasis on the dental curriculum changes which are linked to the challenges that dentistry faces today. The WG will also develop a position on continuous professional development as well as on vocational training, and will contribute to the ongoing projects related to healthcare workforce (e.g., [ESCO project](#) and other projects mentioned in the [Action Plan for the EU Healthcare Workforce](#)).

SECTION III – CONTRIBUTIONS BY CED MEMBER ASSOCIATIONS

DENTAL CARE FOR PEOPLE IN NEED OF NURSING ATTENTION AND FOR DISABLED PEOPLE IN GERMANY

In 2010, the German Dental Association (BZÄK), the Dental Authority (KZBV) and scientific organisations together developed a draft concept for the elderly and disabled people with the objective to improve the oral health for people in need of nursing attention and for disabled people by creating the necessary preconditions for better dental care. The need for nursing services for the elderly and disabled people impedes dental care, thus more time, and more dental staff is required for their treatment. Furthermore, general anaesthesia or sedation and sophisticated treatment plans must also be taken into consideration.

Prerequisite for the implementation of the “AuB-Konzept” would be indeed that the legislator creates a framework which fosters and promotes the initiative similar to the already existing dental prevention campaign for children and young adults. This prevention program is

being carried out with obvious success and has resulted in remarkably better oral health for the relevant age groups.

The politics reacted and created a regulation in the Social Code (SGBV) in the beginning of 2012 for dentists. Dentists treating disabled patients are now entitled to an additional fee for visits in nursing homes. This is a first step to compensate the practitioners for the extra effort, but unfortunately there is as yet no additional payment for preventive or therapeutic measures. Consequently, much work still remains to be done to improve oral health for people in need of nursing attention and for disabled people.

Contributed by BZÄK, Germany

If CED Members wish to receive further information about any of the items mentioned in the newsletter, please contact: ced@eudental.eu



Introduction

Welcome to the 3rd issue of CED EU Info of 2012. This issue is divided in two sections: the first section provides updates on EU topics relevant to the dental profession and the second section contains more general information regarding EU policy.

SECTION I – EU TOPICS RELEVANT TO THE DENTAL PROFESSION

DIRECTIVE ON THE RECOGNITION OF PROFESSIONAL QUALIFICATIONS (PQD)

On 25 April, the European Parliament (Internal Market and Consumer Protection committee - IMCO) held a hearing on *Growth & Mobility: Modernising the Professional Qualifications Directive* ([web stream](#), [presentations](#)). The debate, attended by the CED, focused on the modernisation of the minimum training requirements, the partial access for regulated professions, common training principles and the European professional card. The Rapporteur, MEP Bernadette Vergnaud (S&D, France) expressed her great fear of using the principle of partial access for the regulated professions. She supported the professional card but stressed that further clarification was required as to its standardisation, reliability, flexibility, exhaustiveness, personnel data and voluntary nature. She also favoured the assessment of language knowledge by competent authorities or language professionals /institutions rather than associations. Ms Vergnaud is expected to publish her draft report in July (see EP timetable [here](#)).

On 30 May, the Environment, Public Health and Food Safety Committee (ENVI) held a [first exchange of views on the PQD](#). The Rapporteur, MEP Anja Weisgerber (EPP, Germany), expressed during the meeting the need for high quality training

in medicine and dentistry, supporting the cumulative conditions of 5 years and 5000 hours for the minimum duration of basic dental training. Ms Weisgerber is expected to publish her opinion on the PQD before the end of this month.

On 30 May, the Competitiveness Council met to discuss the PQD ([web stream](#), [background note](#)). The debate focused on the European Professional Card and on a transparency exercise to reduce the number of regulated professions and/or remove unjustified regulatory barriers. Concerning the latter, the Commission mentioned that it intends to prepare a Communication to help Member States in their evaluation exercise on regulated professions. The goal is to develop a common methodology that Member States could use to decide if a profession needs to continue to be regulated or not.

On 7 June, the health professions covered by the sectoral regime of the PQD (doctors, dentists, nurses, midwives, pharmacists and veterinarians) [agreed on 7 joint amendments to the Commission's proposal on the PQD](#). These joint amendments relate to the principle of partial access, language knowledge, delegated acts, common training frameworks and the former recital 44 of the PQD.

MEDICAL DEVICES

In the aftermath of the PIP breast implant affair, the Commission has proposed a [Joint Plan of immediate actions](#), proposing a number of

measures to be taken by Member States under the existing legal framework for medical devices and mainly related to notified bodies. The Commission now intends to adopt by the end of the year an implementing regulation on the designation and supervision of notified bodies under Directives 90/385/EEC and 93/42/EEC and a recommendation on the audits performed by notified bodies in the field of medical devices on which consultation with stakeholders has already started. The Commission is also planning to send a questionnaire on market surveillance to the Member States and is mapping the vigilance systems and the situation on patient registers in Member States. Meanwhile, the European Parliament voted on 14 June in favour of [a resolution on PIP breast implants](#) (see pages 227-232) calling for a number of changes to the existing legislation on medical devices. The Commission is planning to adopt the legislative proposal for a new medical device regulation which will replace Directives 90/385/EEC and 93/42/EEC on 26 September.

EUROPEAN STANDARDISATION

On 31 May, the Danish EU Presidency announced that an agreement has been reached on the proposed regulation on European Standardisation. The Presidency stated that "the agreement will improve conditions for participation of business and stakeholders in the development of standards, ensure

that standards reach the market faster, which will shorten the time span from idea to production, and boost the development of European standards for services.” Danish Minister of Business and Growth further confirmed that “the regulation creates the foundation for the development of more European standards for services” which “can contribute to innovation and growth, which is much sought after in Europe.”

The regulation is expected to enter into force on 1 January 2013, following a vote in the European Parliament plenary sitting scheduled for 10 September and a formal approval by the Council.

While the regulation as agreed reportedly restricts the right of the Commission to request the development of European standards in the delivery and organisation of services in several sectors, including healthcare, this restriction will likely not affect further development of market-driven standards. European Committee for Standardisation (CEN) has already initiated or completed work on a number of standards in healthcare services, including on aesthetic surgery services, chiropractor services, quality management system of health services, hearing aid technicians services, osteopath services and quality criteria health checks.

DENTAL AMALGAM

On 11 June, the [Environmental Council adopted conclusions](#) to prepare two international negotiations on the management of chemicals, including the intergovernmental negotiating committee on mercury, Punta del Este, Uruguay, 27 June – 2 July 2012. The EU emphasized its commitment to protecting human health and the environment from releases of mercury and its compounds by minimising and, where feasible, ultimately eliminating

global anthropogenic mercury releases to air, water and land. It reiterated that it will continue their international efforts to reduce mercury emissions and exposure on a global scale, taking into account the availability of alternatives or reduction measures. Finally, it stressed the importance of continuing to participate actively in negotiations on all elements of the future global mercury convention, aiming at an ambitious overall outcome prior to the twenty-seventh regular session of the Governing Council/Global Ministerial Environmental Forum (UNEP) in 2013 (see points 10-12 of the conclusions).

VAT

On 15 May, [the Economic and Financial Affairs Council adopted conclusions on VAT](#) (see pages 16-19). The conclusions invite Member States to review their tax systems with the aim of making them more effective and efficient, and removing unjustified exemptions. The Commission’s position is to favour a restricted use of reduced rates of VAT. In this context will launch this year an assessment of the current VAT rates structure. The CED Board Task Force Internal Market will analyse the possible impacts of VAT in the dental profession at its next meeting on 25 June.

DATA PROTECTION REGULATION

On 29 May, the Civil Liberties, Justice and Home Affairs Committee (LIBE) held a [workshop](#) to discuss in detail the Data Protection Regulation ([programme and background documents](#)). The [LIBE first exchange of views](#) took place on 31 May and the timeline procedure is available [here](#). The Rapporteur, Jan Philipp Albrecht (Greens, Germany), is expected to publish his report by November 2012. The Industry, Research and Energy Committee (ITRE) and IMCO will provide opinion reports with Séan Kelly (EPP, Ireland) and Lara Comi

(EPP, Italy) as respective Rapporteurs. In the EU Council, the Regulation is being discussed in the Justice and Home Affairs Council, Working Party on Information Exchange and Data Protection. The CED Board Task force Internal Market will analyse this Regulation at its next meeting on 25 June.

eHEALTH

In May, an eHealth network of Member State representatives responsible for eHealth met in Copenhagen to begin to determine the minimum set of patient data required for interoperable Electronic Health Records (EHRs) across the EU. This network was created by Article 14(1) of the [Cross-border Directive](#) and the rules for its managements and functioning were laid down by the [Commission Implementing Decision 2011/890/EU of 22 December 2011](#). The Commission’s objective is to enable EU citizens to securely access their health information wherever they travel in the EU. In this sense, the [European Health Insurance card](#) is now being used in [epSOS pilot-project](#).

On 4 June, the Commission adopted a new [proposal for regulation on electronic identification and trusted services for electronic transactions in the internal market](#). This proposal intends to ensure mutual recognition of electronic identification across borders (eID) and to create an internal market for eSignatures and related online trust services across borders. In this context, it will provide a legal framework for electronic seals, time stamping, electronic document acceptability, electronic delivery and website authentication in order to ensure that these on-line trust services will work across borders and will have the same legal status as traditional paper based processes.

EU HEALTH POLICY FORUM

On 10 May, the [EU Health Policy Forum](#) met in Brussels to exchange

views on the implementation of the EU health policy, focusing on the [European Innovation Partnership on Active and Healthy Ageing](#), on chronic and communicable diseases, [on the European Health Technology Assessment network](#), [on health workforce issues](#) and [HEIDI \(wiki and data tool\)](#). This Forum brings together 52 umbrella organisations representing European stakeholders in the fields of public health and healthcare. The CED is a member.

EU HEALTH WORKFORCE

On 18 April, the Commission adopted a [Communication on “Towards a job-rich recovery”](#) which was accompanied by a number of staff working documents focusing on specific sectors with a high potential for job creation, including an [Action Plan on for the EU Health Workforce](#). Its goals are to:

- *improve health workforce planning and forecasting* by launching a Joint Action to share good practices, develop forecasting methodologies and improve EU-date on health workforce (the CED is already an associated partner and further information will be provided below);
- *better anticipate future skill needs and skills mixes in the healthcare sector* by fostering partnerships between education/vocational training providers and employers through a Sector Skills Alliance to be set up in 2013; by promoting exchange of good practice on continuous professional development (to update skills and competences and promote retention of healthcare personnel through lifelong learning) through a review and mapping of national systems and practices in 2013; by developing recommendations for the training requirements of healthcare assistants (including educational support for informal carers) through setting up a pilot health case as-

sistants expert network database by 21014;

- *stimulate exchange on recruitment and retention of health workers* by mapping recruitment and retention strategies with a view to exchange good practices; and,
- *support ethical recruitment of health workers* by supporting the implementation of the WHO Global Code of Practice on the international recruitment of health workers in the Member States.

JOINT ACTION ON PATIENT SAFETY AND QUALITY OF CARE (PaSQ)

PaSQ formally started on 1 April and a kick-off meeting was organised on 24-25 May in Roskilde, Denmark. The meeting brought together all partners of the Joint Action and allowed the work on individual Work Packages to start. Work Package 4, to which the CED will contribute as an associated partner, started discussing the definitions and the conceptual framework which will form the basis for identifying proven and innovative Safe Clinical Practices at clinical level, including in dental practices. In the next stage, practices will be shared among the Joint Action partners who might decide to adapt them to local circumstances and implement them at the local level.

2012 EURO HEALTH CONSUMER INDEX (EHCI)

On 15 May, MEP Christofer Fjellner (EPP, Sweden) hosted a seminar of the [Health Consumer Powerhouse](#) to present the [2012 edition of the EHCI](#). The 2012 edition ranked 34 national European healthcare systems on 42 indicators, covering five key areas to the “health consumer”: i) patients’ rights and information; ii) accessibility of treatment (waiting times); iii) medical outcomes, range and reach of services provided; and v) pharmaceuticals. The Netherlands received the highest score for the third consecutive year. For a

quick and short overview see the [Index table](#).

WORLD NO TOBACCO DAY

On 31 May, on the occasion of the World No Tobacco Day, the Commission published a [Eurobarometer survey on attitudes towards tobacco](#). On average, 60% of citizens support measures to make tobacco less visible and attractive, such as keeping tobacco products out of sight in shops or curbing the use of attractive flavours and colours. At the same time, other figures gave cause for concern: 28% of EU citizens aged 15 over smoke, and 70% of the smokers and ex-smokers took up the habit before the age of 18. Tobacco is the single largest cause of avoidable death in the EU, accounting for around 700.000 premature deaths each year. In order to reduce tobacco consumption in the EU, the Commission launched the EU’s “Ex-Smokers are unstoppable” campaign in 2011 and intends to table its proposal to review the 2001 Directive on Tobacco Products in the second half of 2012.

EUROBAROMETER SURVEY ON PATIENT INVOLVEMENT

On 18 May, the Commission published a [Eurobarometer Qualitative Study on Patient Involvement](#) in healthcare. The study revealed that the term “*patient involvement*” is not understood by patients or practitioners in the same way. The main risks of patient involvement, mentioned by both patients and practitioners, are increased demands on practitioners’ time, and the possibility of patients disagreeing with doctors’ opinions. The internet has helped patients to have greater access to information about their symptoms and healthcare as well as about healthcare options. Patients in Eastern European countries were identified as most likely to be dissatisfied with their current level of involvement in healthcare and wanting to be more involved.

PARLIAMENTARY QUESTIONS RELATED TO DENTISTRY

The CED Brussels office compiled a series of questions related to dentistry brought forward by Members of the European Parliament to the Commission in 2012. These questions are available [here](#).

JURISPRUDENCE – EFTA COURT

The EFTA Court ruled last year – [Case E-1/11](#) – on the necessary language knowledge for practicing a profession in another country. The Norwegian Appeal Board for Health Personnel requested an Advisory Opinion of the EFTA Court to an appeal proceeding brought before them which concerned a refusal of the Norwegian Registration Authority for Health Personnel to grant the complainant (a medical doctor from Bulgaria) license to practice as a medical doctor in Norway. The Court concluded that Directive 2005/36/EC (PQD) precludes the authorities of EEA States from denying an authorisation as a medical doctor to a migrant applicant from another EEA State who fulfils the requirements under the PQD. However, an EEA State may make an authorisation conditional upon the applicant having knowledge of languages necessary for practising the profession on its territory. Moreover, an EEA State may suspend or withdraw an authorisation to pursue the profession of medical doctor based on information concerning the personal aptitude of a migrant doctor relating to the professional qualification other than language skills, only if such requirements are objectively justified and proportionate to achieve the objective of protecting public health and if the same information would also entail a suspension or withdrawal of authorisation for a national doctor. If such grounds for suspension or withdrawal are available to the competent authorities at the time of assessment, the authorisation may be

denied.

SECTION II – GENERAL EU POLICY

TRANSPARENCY WEBSITE

On 7 June, the Commission launched a [new website](#) for EU citizens to better follow and participate in the EU decision-making processes. It provides quick access to information on legislation, impact assessments, experts groups and advisory committees, consultations, interest representation and lobbying, access to documents, and recipients of EU funds.

DG INFSO BECOMES DG CONNECT

As of 1st July 2012, the Directorate General for Information Society & Media (DG INFSO) will be renamed as Directorate General for Communications Networks, Content and Technology (DG CONNECT) to better represent the range of topics it works on (namely Digital Agenda for Europe).

ENLARGEMENT

On 24 April, the Commission adopted its [Monitoring Report on Croatia's accession preparations](#). This is a part of the regular 6-monthly monitoring as foreseen by the Accession Treaty. The Report assesses the progress made by Croatia and highlights the areas where further efforts are necessary before it becomes a Member on 1 July 2013. In the field of consumer and health protection, the Commission recommended continued efforts to upgrade, restructure and licence facilities for handling blood, tissues and cells in accordance with the EU technical requirements.

On 17 May, the Commissioner for Enlargement and European Neighbourhood Policy Štefan Füle and the Turkish Minister for European Affairs and Chief EU negotiator Egemen Bağış launched in Ankara the new Positive EU-Turkey agenda

to bring fresh dynamics into the EU-Turkey relations. The agenda intends to enhance cooperation and to promote reforms in Turkey in areas of joint interest such as alignment with the EU legislation, political reforms and fundamental rights, visa, mobility and migration, trade, energy, counter-terrorism and dialogue on foreign policy.

On 22 May, the Commission adopted a [Report on Montenegro's progress in the implementation of reforms](#). The Report concludes that Montenegro has made further progress in the areas of rule of law and fundamental rights, including in the fight against corruption and organised crime and recommends that accession negotiations with Montenegro are opened in June 2012.

Comments, questions and contributions please contact:
ced@eudental.eu

CED ACTIVITIES INFO

COUNCIL OF
EUROPEAN DENTISTS



Issue 3 – July 2012

Introduction

Section I of our newsletter reports on the political activities of the CED President and Board members and summarises the work of CED Working Groups, Board Task Forces and the Brussels Office. In Section II, we take a closer look at individual CED Working Groups and Board Task Forces, their policy priorities for 2012-2013 and, most importantly, the experts that make their work possible. In Section III, CED member associations share their news and positions on current issues.

HEALTHY MOUTH, HEALTHY LIVING, HEALTHY AGEING

CED EVENT IN THE EUROPEAN PARLIAMENT

On 26 June 2012, MEP Cristian Silviu Buşoi hosted the CED event **"Healthy mouth, healthy living, healthy ageing: Investing in prevention is the most cost-effective approach to healthcare"** in the European Parliament in Brussels. More than 50 participants attended the event, including delegates of 14 national dental associations and dental chambers from across Europe, as well as representatives of Association for Dental Education in Europe (ADEE), French Union for Oral Health, European Heart Network (EHN), AGE Platform Europe, European Region of the World Confederation for Physical Therapy (ER-WCPT), industry and MEP assistants.

Speakers included the CED President Dr. Wolfgang Doneus and the chair of CED Working Group Oral Health Dr. Paula Vassalo, as well as Prof. Frauke Müller, Secretary of the European College of Gerodontology, Dr. Katrín Fjeldsted, President elect of the Standing Committee of European Doctors (CPME), Paul De Raeve, Secretary General of the European Federation of Nurses Associations (EFN), Mervi Jokinen, President of the European Midwives Association (EMA), Jurate Svarcaite of the Pharmaceutical Group of the European Union (PGEU) and

Elizabeth Manero, Director of Health Link, an independent patient interest group. The main messages that emerged from the event included a reminder that oral health is an integral part of general health and well-being; that tackling oral diseases separately from general diseases is neither medically effective nor cost-efficient; and that oral health must be integrated in general prevention and health promotion at national and EU level. Participants also noted that oral health of the elderly presents specific challenges, requiring systemic changes and sufficient funding, and encouraged interdisciplinary and integrative approaches to health-care, with enhanced education, cooperation and exchange of information between different health-care professions and patients.

A full report will be available on the CED website in early September.

SECTION I – CED INTERNAL ACTIVITIES

CED PRESIDENT

BRUSSELS EVENTS

In June, CED President Wolfgang Doneus travelled to Brussels twice: on 5 June, to attend the conference on liberal professions and professional organisations co-organised by BZÄK (see article on page 5) and on 26 June, to speak at the CED event on oral health in the European Parliament. During the BZÄK event he met the IMCO rapporteur on the Professional Qualifications Directive MEP Bernadette

Vergnaud, while the CED event proved to be an opportunity to talk to the representatives of other health professions, including the newly elected CPME President elect Dr. Katrín Fjeldsted who will lead CPME between 2013 and 2015.

CED BOARD

DENTAL INDUSTRY EVENTS

On 31 May, **CED Director Marco Landi attended a dinner event** organised by ADDE (Association of Dental Dealers in Europe) and FIDE (Federation of the European Dental Industry) in the European Parliament. During the event, which was hosted by MEP Paul Rübig (Austria, EPP) and attended by MEP Matteo Salvini (Italy, EFD). Marco Landi addressed the participants and called on MEPs to keep oral health high on their agenda, despite the economic crisis. He underlined the importance of phasing down rather than phasing out dental amalgam and the dentists' commitment to environmentally responsible practices. Finally, he expressed concerns about the attempts to develop standards for delivery of dental treatment at EU level and the linked proposed [Regulation on European Standardisation](#).

CED WORKING GROUPS (WG)

WG EDUCATION AND PROFESSIONAL QUALIFICATIONS (WG EPQ)

On 8 June, CED Head of Office Nina Bernot represented the CED at the **meeting of health professions with MEP Emilie Turunen**, Greens'



COUNCIL OF EUROPEAN DENTISTS (formerly EU Dental Liaison Committee)

President Dr Wolfgang Doneus

T +32 (0)2 736 34 29

F +32 (0)2 740 20 26

ced@eudental.eu

www.eudental.eu

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shadow rapporteur for the Professional Qualification Directive in the Internal Market and Consumer Protection Committee (IMCO). Apart from discussing the [joint health professions' position](#), Ms. Turunen was also interested in hearing about the specific suggestions of the dentists for the Directive.

On 13 June, **CED Policy Officer Sara Roda met with the assistant of MEP Anja Weisgerber** to present and discuss the [CED position on the Professional Qualifications Directive \(PQD\)](#). Ms. Weisgerber is responsible for preparing the draft opinion on the PQD of the Environment, Public Health and Food Safety Committee (ENVI). Her [draft opinion](#) was published on 20 July (for the moment only available in German). Ms. Weisgerber supported the CED amendment to include the 5000 hours of theoretical and practical training under article 34 paragraph 2 of the PQD. She also suggests the deletion of the new paragraph 4 of Article 34, proposed by the Commission, in connection to delegated acts.

On 3-4 July, **former WG member Ms. Barbara Bergmann-Krauss attended the introductory meeting of the ESCO reference groups** as an expert and on behalf of the CED. ESCO, the multilingual taxonomy of skills, competences, qualifications and occupations, shall be developed as an instrument which intends to stimulate the mobility in the EU. It is an advanced development of the EURES platform for job placement and for international CVs.

On 11 July, **the CED-ADEE Task Force met to discuss the new draft Annex 5.3.1 of the PQD**. The Task Force's first draft was prepared by ADEE and it mainly focused on competences. The second draft will now include learning outcomes in modules and the measurement of these modules in ECTS (European Credit Transfer System). This second draft will be drafted by 3 September and the Task Force will meet

again on 24 October to finalise the draft annex and to start preparing an accompanying working document which will explain some of the new concepts introduced therein.

On 16 July, MEP Bernadette Vergnaud published her [draft report on the PQD](#) (for the moment only available in French). Ms. Vergnaud also supported the CED amendment to include 5000 hours of theoretical and practical training (amendment 57 of the draft report). The report did not however include the intended reference to 300 ECTS. Rather, Ms. Vergnaud brought forward a definition for ECTS (amendment 19), which the CED pointed out should be included in the Directive. Certain MEPs are reticent to accept the introduction of the ECTS in the PQD since this system is not standardised at EU level. Each Member State can define the number of ECTS it can give to a dental subject as well as the hours that each subject will take. Ms. Vergnaud's draft report also includes an amendment on language knowledge similar to the one proposed by the health professions (Article 53 of the PQD), as well as amendments on the provisions for delegated acts for which she proposes the consultation of national competent authorities and professional associations (amendments 10 and 86). Concerning the principle of partial access, Ms. Vergnaud suggests conferring to the Member States the power to exclude a profession from this regime (amendment 1).

WG EHEALTH

On 11 June, the WG met in Brussels and on 27 June on-line, to discuss and conclude the draft CED Resolution on eHealth. The draft resolution has been amended and will be considered for adoption at the November General Meeting. The WG also discussed the General Data Protection Regulation, followed up on the CED's participation in the e-Health Stakeholders Group and decided on the next WG's steps.

WG MEDICAL DEVICES

On 15 June, CED Head of Office Nina Bernot attended a **stakeholder consultation on the European Commission's actions following the PIP breast implant affair**. The Commission is moving forward with measures aiming at more consistent and uniform application of existing medical devices legislation, particularly as they relate to the functioning of notified bodies and unannounced audits, at national level. The Commission is also planning to adopt by the end of the year an implementing regulation on notified bodies and a recommendation on the audits. The proposal for a new Regulation on Medical Devices (to replace the existing directives) is in the Commission's interservice consultation and will be probably adopted on 26 September 2012. The proposal is likely to include some strengthened language on incident reporting by healthcare providers, as well as provisions on registers/databases for implants.

On 5 July, CED Policy Officer Sara Roda attended the **meeting of the UDI Ad-Hoc Working Group**. The Commission explained in general lines the provisions related to UDI (Unique Device Identification) in the future Regulation on Medical Devices, presented the draft recommendation establishing an EU UDI system which will include obligations for professional users (dentists), and updated on the activity of the International Medical Device Regulator's Forum (IMDRF) and UDI Work Team. CED requested the inclusion of an exemption for custom-made devices in the draft recommendation, which was accepted by the Commission.

WG Medical Devices member and CED liaison to the European Committee for Standardisation (CEN) Jens Nagaba submitted **a report from the CED to the CEN/TC 55** (Technical Committee 55) meeting which took place in Brussels on 10 July. The report stressed the CED's

opposition to development of European standards for the delivery of dental treatment. The CED had no proposals for new standardisation projects in TC 55.

WG ORAL HEALTH

WG Oral Health met on 26 June to evaluate the CED event on oral health which was organised in the European Parliament earlier on the same day. They underlined the importance of follow-up with European decision-makers and of continued cooperation with other health professions. They felt that similar events should be organised also by national dental associations, to raise at national level the awareness of correlation between oral and general health. They also discussed the future work of the WG and decided to propose to the CED General Meeting in November the adoption of a new mandate.

On 17 July, **CED Policy Officer Sara Roda participated in a teleconference of the I2-FRESCO project**. The CED has been invited to participate in this project in cooperation with CPME following the CED event on oral health in the European Parliament. This project aims at developing an integrated approach for preventing physical frailty. CPME will be the leader of the Work Stream on Health Literacy and Education which will focus on early identification of physical frailty and raising awareness among the population, though a dedicated website and other campaign tools. This will include advice on nutrition, physical activity and, with cooperation of the CED, on oral health.

CED BOARD TASK FORCES (BTF)

BTF ANTIBIOTICS IN DENTISTRY

In May, and following contact with the European Centre for Disease Prevention and Control (ECDC), **CED Board agreed to establish a new Task Force on antibiotics**.

Named Board Task Force Antibiotics in Dentistry, the group will be chaired by CED Director Susie Sanderson, with Director Nikolai Sharkov also participating. Membership in the Task Force is open to other CED Members who have particular experience and interest in the issue.

BTF Antibiotics in Dentistry will meet with representatives of ECDC on 24 September in Brussels to discuss possible participation of the CED in the European Antibiotic Awareness Day (16 November) and other ways of collaboration.

BTF COMMUNICATIONS

As part of the CED Annual Communications Work Plan, **the first meeting of CED Communications Officers** will be organised in Brussels on 21 September. This will be an opportunity for those responsible for communications in national dental associations to acquaint themselves with CED work, exchange experiences from their daily work and comment on current and planned CED communications activities. The meeting will also include a briefing about the Professional Qualifications Directive from a Commission official and a guided visit to the European Parliament.

BTF INTERNAL MARKET

On 25 June, the **BTF Internal Market met** to discuss and prepare the CED position on the [General Data Protection Regulation](#); to discuss the impact on the delivery of oral healthcare of a possible introduction of VAT in dental care following the [Commission's Communication on VAT](#); and to follow up on the [2012 Euro health Consumer Index report](#), prepared by Health Consumer Powerhouse. This report ranks 34 national healthcare systems based on different groups of indicators of quality. This year winner was the Netherlands and the index table is available [here](#).

The BTF decided to write to Vice-President of the European Commis-

sion in charge of Justice, Fundamental Rights and Citizenship Viviane Reding, requesting clarification on certain provisions of the Regulation that introduce new legal obligations which can have severe impact on micro, small and medium-sized enterprises. The BTF intends to clarify i) if and what kind of specific measures are going to be introduced to micro, small and medium-sized enterprises through delegated acts; ii) the right to retain patient data (i.e., dental records) for purposes such as outside inspections, complaint procedures, identification of remains; iii) the investigative powers of the supervisory authorities to access a dental clinic premises, including to any processing equipment as well as to all personal data and information necessary for the performance of their duties; iv) the controller's (dentist) obligation to document in writing the controller's instructions; and to alert v) to the financial consequences of being brought to justice in another Member State. According to the Regulation, the data subject (i.e. patient) has the right to file a lawsuit against the controller (dentist) or the processor (e.g. receptionist, secretary, etc.) in the Member State of the data subject residence if the latter considers that the processing of his/her data was not in compliance with the Regulation.

BTF LIBERAL PROFESSIONS

On 25 June, **a joint meeting of BTF Liberal Professions and BTF Internal Market** took place in Brussels, to allow BTF Liberal Professions to provide input for CED positions on VAT and data protection. Among other issues, BTF Liberal Professions also discussed the IHS study on liberal professions, the upcoming Green Paper on European entrepreneurship, and CED activities connected to the future of liberal professions in Europe.

On 19 July, BTF Chair Nikolai Sharkov, BTF member Wolfgang

Sprekels and CED Policy Officer Sara Roda attended the “**EU Day of the Liberal Professions**” organised by the European Economic and Social Committee. The aim of the meeting was to take stock of the current state of regulation and de-regulation in the different Member States, exchange information in this regard, and to elaborate some conclusions to be transmitted to different European institutions.

SECTION II – CED WORKING GROUP

AMALGAM & OTHER RESTORATIVE MATERIALS (WG A&ORM)

HISTORY

WG A&ORM was established in May 2006 as WG Amalgam to explain the position of the CED on the safety of dental amalgam, particularly in light of the European Parliament's call for restrictions on its use. Over the years, this WG has helped developing CED policy related to the use of dental amalgam and responsible practice. It has i) pointed out that research over many decades had failed to show any significant health risk posed by dental amalgam; ii) called on Member States to ensure the full implementation and enforcement of EU waste laws; iii) supported the use amalgam separators which respect ISO standards; iv) highlighted that dental amalgam continues to be the most appropriate filling material for many restorations due to its ease of use, durability and cost-effectiveness; iv) alerted on the fact that restrictions on the use of amalgam will impact on patients' ability to afford dental care as well as damage the financial stability of health systems; v) stressed that dentists are best placed to identify patients' oral health needs; vi) underlined that amalgam should remain part of the dentist's armoury in order to best meet patients' needs; and vii) stressed that preventive disease management and oral health promotion should be actively fos-

tered by national governments in order to reduce the use of restorative materials, including dental amalgam.

CURRENT ACTIVITY

Since 2010, the WG follows the review of the [Community Strategy Concerning Mercury](#) and, indirectly, the discussions under the auspices of the United Nations Environment Programme (UNEP) to develop a global treaty on mercury. For this purpose, the WG has prepared the [CED Resolution on Amalgam](#) (November 2010) and the [CED Resolution on Responsible Practice](#) (November 2011). Most recently, the WG developed the CED's response to the [BIOIS](#) draft report entitled “*Study on the potential for reducing mercury pollution from dental amalgam and batteries*”. The WG has criticised the draft report (further information can be found in [Issue 2/2012 of the CED Activities Info](#)). In brief, the CED supported option 1 of the BIOIS draft report which recommends an improvement in the enforcement of EU waste legislation regarding dental amalgam, and challenged option 3 which recommends banning the use of mercury in dentistry.

On 12 July, the [BIOIS final report](#) was released and, as this article went to press, the WG was updating its position on the issue.

At present, the dental profession intends to contribute to a phase-down scenario in 20-30 years, emphasising however that this goal can only be achieved if supported by strong prevention programmes at national level. Otherwise, an immediate ban will only contribute to create an unintended consequence of increased untreated disease levels, or, indeed, the unintended consequence of the choice by the patient of extraction rather than restoration. EU countries need to have the flexibility to introduce restrictions on the use of amalgam at a pace which supports their own health economies.

On 19 July, the Scientific Committee

on Emerging and Newly Identified Health Risks (SCENIHR) has been requested to issue two scientific opinions with interest for the WG:

1. Request for a scientific opinion on [The safety of dental amalgam and alternative dental restoration materials for patients and users](#);
2. Request for a scientific opinion: [Health effects of nanomaterials used in Medical Devices](#).

NEW NAME, NEW MANDATE

In May 2012, the WG Amalgam became WG Amalgam & Other Restorative Materials (WG A&ORM) in order to cover the entire range of dental restorative materials. The new WG remit includes developing an evidence-based summary of alternative materials, starting with those containing bisphenol A, and preparing a CED position on the use of Atraumatic Restorative Treatment (ART).

POLICY PRIORITIES 2012-2013

The WG intends to assess the impact of possible proposals emerging from the final report of the BIOIS study as well as the EU's reaction to the report, and to review reports emerging from countries that have had amalgam bans in place for some years. The WG will carefully consider the proposals emerging from several Member States' governments to change their approach to the use of dental amalgam in the light of environmental groups' pressure and will encourage and support CED Members in communicating regularly with their health and environment government departments in this regard. The WG will continue to actively put the profession's views to influential stakeholders, liaise with the FDI Dental Amalgam Task Team, develop the CED's position on significant constituents of other restorative materials, and develop the CED's position on Atraumatic Restorative Treatment and minimal intervention concepts.

WHO MAKES THIS POSSIBLE

WG members are at the heart of CED policy. The current members of the WG are:

- **Dr. Susie Sanderson**, WG Chair and Board liaison, CED Treasurer, Director of the British Dental Association Principle Executive Committee, awarded an OBE in the New Year Honours list 2012, dental practitioner and author of innumerable articles, British Dental Association, United Kingdom;
- **Dr. Audrey Camilleri**, dental practitioner, Dental Association of Malta, Malta;
- **Dr. Francisco Rodriguez Lozano**, CED Vice-President, President of the Spanish Committee on Tobacco Prevention (CNPT), member of the CGOE – Consejo General de Colegios de Odontólogos y Estomatólogos de España, dental practitioner, Spanish Dental Association, Spain;
- **Prof. Dr. h.c. Georg Meyer**, Managing Director of the Centre for Oral and Maxillofacial Surgery of the Ernst-Moritz-Arndt University of Greifswald, German Dental Chamber, Germany;
- **Prof. Dr. Gottfried Schmalz**, Director of the Department of Operative Dentistry and Periodontology, University of Regensburg, author of "[Biocompatibility of Dental Materials](#)" 2009, Distinguished Scientist Award of the IADR, German Dental Chamber, Germany;
- **Prof. Dr. John Tzoutzas**, Associate Professor in Operative Dentistry, School of Dentistry, University of Athens, Hellenic Dental Association, Greece;
- **Dr. Klaas-Jan Bakker**, lawyer, Dutch Dental Association – NMT, Netherlands;
- **Prof. Dr. Péter Hermann**, Professor in the Department of Prosthodontics, Faculty of Dentistry, Semmelweis University, and President of the Dental Section of the Hungarian Medical Chamber, Hungary;
- **Prof. Dr. Matjaž Rode**, MDD, PhD, Professor in the Department of Clin-

ical Oral Pathology, Medical Centre, Ljubljana, Slovenia, Vice-President of the Medical Chamber of Slovenia;

- **Dr. Serge Deschaux**, dental practitioner, CNSD - Confédération Nationale des Syndicats Dentaires, France.

SECTION III – CONTRIBUTIONS BY CED MEMBER ASSOCIATIONS

"EUROPE 2020 – THE FUTURE OF LIBERAL PROFESSIONS – PROFESSIONAL QUALIFICATIONS" CONFERENCE IN BRUSSELS

Together with the German Association of Liberal Professions (BFB) and the German Medical Association (BÄK), the German Dental Association (BZÄK) organised a conference in Brussels at the beginning of June on the role of liberal professions in Europe attended by almost 200 guests from the European institutions and from national and international professional associations.

In his speech, the BZÄK President, Dr Peter Engel, outlined the tensions between European regulation and deregulation that have been dogging the liberal professions for years. He appealed for EU policy to better meet the particular concerns of the liberal professions. The conference concluded that, while the system of chambers is a tried and tested model of self-management, chambers must review their role and reinvent themselves for the future.

The programme and other information on the conference can be found [here](#).

Contributed by BZÄK, Germany

INVITATION TO PRAGUE DENTAL DAYS

The 15th international congress Prague Dental Days will take place on October 3 - 5, 2012 at the Prague Congress Centre under the auspices of the Mayor of Prague.

The scientific programme of the congress will be traditionally focused

on all members of the dental team as well as on students of those professions. The topics of sixty-four lectures will cover all disciplines of dentistry. We expect about 1300 participants from the Czech Republic and abroad.

After last year's success and great interest, the congress will be extended again by Days of Children's Prevention, a program for lay public. The event is intended for pupils of nursery and elementary schools and for children from mother-child centres.

This year's traditional international workshop for CED members and for invited guests will be held on the topic "To what extent should the dental care be covered by health insurance? "

Detailed programme and on-line registration form for the congress can be found [here](#).

Contributed by the Czech Dental Chamber

If CED Members wish to receive further information about any of the items mentioned in the newsletter, please contact: ced@eudental.eu



Introduction

Welcome to the 4th issue of CED EU Info of 2012. This issue is divided in two sections: the first section provides updates on EU topics relevant to the dental profession and the second section contains more general information regarding EU policy.

SECTION I – EU TOPICS RELEVANT TO THE DENTAL PROFESSION

DIRECTIVE ON THE RECOGNITION OF PROFESSIONAL QUALIFICATIONS (PQD)

On 17 September, the European Parliament's Employment and Social Affairs Committee (EMPL) held a first exchange of views ([web stream](#)) on the [182 amendments](#) which were tabled by members of the Committee to the [draft opinion](#) prepared by the Rapporteur, MEP Licia Ronzulli (EPP, Italy), on the PQD. The opinion, once adopted, will be submitted to the European Parliament's Internal Market and Consumer Protection Committee (IMCO) for consideration. EMPL MEPs have tabled amendments similar to the [CED's position on the PQD](#), particularly on partial access, delegated acts and knowledge of languages (in favour of the employer's right to carry out language checks). The Committee will deliberate and vote on the compromise amendments on 8 and 9 October respectively.

On 18 September, IMCO met to discuss [Ms Vergnaud's draft report on the PQD](#). The debate focused on partial access (certain MEPs expressed their intention to restrict the scope of the principle so that it is not applicable to healthcare professionals), professional card (the majority favoured extending the deadlines and emphasizing the voluntary nature of the card), remunerated traineeships (the intention to cover all traineeships, whether remuner-

ated or not), knowledge of languages (competent authorities should verify the language knowledge of healthcare professionals), and the minimum training requirements of certain professions (particular emphasis on nurses). MEPs may table amendments to Ms Vergnaud's draft report until 15 October. These amendments will be discussed by the Committee on 5-6 November and will be put to vote on 28 November.

On 20 September, the European Parliament's Environment, Public Health and Food Safety Committee (ENVI) met to discuss [Ms Weisgerber's draft opinion on the PQD](#). MEPs may table amendments until 8 October; they will be voted on 6 November.

MEDICAL DEVICES

On 26 September, the European Commission presented a [proposal for a Regulation on medical devices](#). Once in place, the Regulation will replace the Directive 90/385/EEC regarding active implantable medical devices and Directive 93/42/EEC regarding medical devices. The Commission's [package](#) also contains a proposal for a Regulation on in-vitro medical devices and a Communication.

When presenting the proposal, the Commission stated that the purpose of the new legislation is to adapt to the technological and scientific progress, avoid different ways of implementation of rules across the EU, increase traceability and transparency, and assure sustainable, effective and credible management of the

medical devices system. The revision did not result from the PIP scandal, but the Commission tested the new proposal to ensure that it is robust enough to avoid such problems happening again.

The Commission's proposal will now be discussed in the European Parliament and in the Council where four Working Party meetings are already scheduled for this year. The legislation is expected to be adopted in 2014 and would come into force between 2015 and 2019. CED Working Group Medical Devices will analyze the proposal and if necessary propose changes.

EUROPEAN STANDARDISATION

On 11 September, the European Parliament voted overwhelmingly in favour of the proposal for a [Regulation on European Standardization](#) (639 votes in favour, 18 against and 17 abstentions). The Parliament reached a political agreement on the Regulation, which opens doors to further development of standards in the delivery of healthcare with the Council on the proposal in May.

The new regulation will be formally approved by the Competitiveness Council which will meet on 10-11 October in Luxembourg. The Regulation will enter into force 20 days after its publication in the EU Official Journal and will apply directly in all Member States from 1 January 2013.

The Regulation on European Standardization will be the first legislation adopted in the framework of the Single Market Act, which was pre-

sented by the European Commission in April 2011. MEP Lara Comi, the rapporteur on the Regulation in the European Parliament, was awarded the MEP Award 2012 in the category Internal Market and Consumer Protection on 25 September for her role in the adoption of the Regulation.

Meanwhile, the European Committee for Standardisation (CEN) started a reflection process on its relations with European level stakeholders. In a letter sent to the CED in July, CEN recommended that in the future liaison organisations such as the CED would have to contribute actively to the development of standards within technical committees and pay an annual fee if they wanted to maintain their status. CED President responded with a letter, suggesting that if liaison organisations are required to pay a fee, they should also be given a vote, which is currently not the case.

DENTAL AMALGAM

In August, the Commission requested the Scientific Committee for Emerging and Newly Identified Health Risks (SCENIHR), as well as the Scientific Committee for Health and Environmental Risks (SCHER) to update their opinions on dental amalgam issued in 2008 on the basis of new information made available:

- i) Opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users ([SCENIHR's mandate](#));
- ii) Opinion on the environmental risks and indirect health effects of mercury in dental amalgam ([SCHER's mandate](#)).

Two associated calls for experts to join the scientific committees ([SCENIHR](#), [SCHER](#)) and two calls for information ([SCENIHR](#), [SCHER](#)) were launched. The deadline for submission is 10 October.

The Commission has also requested SCENIHR for a scientific opinion on the safety of medical de-

vices containing nanomaterials ([mandate](#)) and launched a [call for experts](#) and a [call for information](#). The deadline for submissions is also 10 October.

CED Working Group Amalgam & Other Restorative Materials is following these issues and is gathering material to reply to the calls for information.

DATA PROTECTION REGULATION

On 19 September, the Civil Liberties, Justice and Home Affairs Committee (LIBE) had a [second exchange of views](#) on the Rapporteurs' Jan Philipp Albrecht's (Greens, Germany) and Dimitrios Droutsas's (S&D, Greece) [working document on the data protection reform](#). The draft report is expected to be published on 17-18 December ([new timeline](#)).

On 9-10 October, LIBE will organise an Interparliamentary Committee Meeting on the reform of the EU Data Protection framework. Registrations are open until 1 October ([agenda](#), [background documents](#)).

JOINT ACTION ON HEALTH WORKFORCE PLANNING

In July, the Joint Action on European Health Workforce Planning and Forecasting was selected for funding by the European Commission at the level of €3 million. During July and August, meetings between different Work Packages were organised to prepare the contents of the Joint Action and on 28 September a meeting with stakeholders was organised in Brussels.

The Joint Action is expected to formally start in December 2012. The CED expects to participate as an associated partner and to contribute specifically in the area of future workforce needs in terms of skills and competences.

To prepare the Joint Action, the Commission has contracted a [feasibility study on EU level collaboration on forecasting future work-](#)

[force needs, workforce planning and health workforce needs](#), the results of which are now available online.

TOBACCO HEARING

On 20 September, the [ENVI Political Coordinators decided to hold a hearing](#) in early 2013 on the revision of the Tobacco Products Directive, when the Commission's proposal will have been presented and a Rapporteur has been appointed. The indicative date is 25-26 February 2013.

PLATFORM FOR BETTER ORAL HEALTH IN EUROPE EVENT

On 5 September, the Platform for Better Oral Health in Europe organised an event in the European Parliament, hosted by MEPs Karin Kadenbach (S&D, Austria) and Cristian Buşoi (ALDE, Romania). The Platform presented a report on the [State of Oral Health in Europe](#) which i) examines the prevalence and trends of oral diseases in Europe; ii) assesses the economic impact of oral diseases in Europe; iii) identifies best practice initiatives in oral health promotion across Europe; and iv) develops a set of key recommendations for decision-makers to improve oral health in Europe. The Platform is a joint initiative of the European Association of Dental Public Health (EADPH), the Association for Dental Education in Europe (ADEE), the Wrigley Oral Healthcare Program, GlaxoSmith-Kline Consumer Healthcare and the Council of European Chief Dental Officers (CECDO), which was created to promote oral health and cost-effective prevention of oral diseases in Europe.

EUROPEAN ANTIBIOTIC AWARENESS DAY

On 18 November, the European Centre for Disease Prevention and Control (ECDC) will be organising for the fifth time the [European Antibiotic Awareness Day](#). The campaign aims at promoting prudent use of antibiotics by raising aware-

ness of everyone's role in keeping antibiotics effective for future generations. Dentists and other health professionals have a key role to play by ensuring the correct prescribing, dosage, duration and selection of antibiotics and by ensuring that patients are well informed about when and how to take antibiotics. This year, the European Antibiotic Awareness Day will be commemorated by a press event in Brussels on 16 November which the CED will attend and by a Twitter discussion on 20 November (follow @ECDC-EU). In addition, ECDC has prepared a media toolkit which can be used to communicate with the public and is available on their [website](#).

CLOUD COMPUTING STRATEGY

On 27 September, the Commission adopted a [Communication "Unleashing the Potential of Cloud Computing in Europe"](#). Cloud computing allows users to rent services and data storage, making significant savings compared to buying new equipment and software themselves. Using a webmail, a social network or an online music service is de facto using the cloud. The Commission's objective is to promote cloud innovation by providing a friendly legal environment. Key actions of the strategy include: i) cutting technical standards so that cloud users get interoperability, data portability and reversibility; necessary standards should be identified by 2013; ii) support for EU-wide certification schemes for trustworthy cloud providers; iii) development of model 'safe and fair' contract terms for cloud computing contracts including Service Level Agreements; iv) a European Cloud Partnership with Member States and industry to shape the European cloud market, boost the chances for European cloud providers to grow to achieve a competitive scale, and deliver cheaper and better eGovernment.

WORKING TIME DIRECTIVE

In August, the Commission has agreed to extend the negotiating period of the EU social partners (employers and workers' representatives at EU level) on reviewing the [Working Time Directive](#) to 31 December 2012. This Directive lays down the minimum safety and health requirements to organise the working time (i.e. limits the weekly working time, establishes the minimum periods of daily rest, weekly rest and annual and regulates certain aspects of night work, shift work and patterns of work), applying to both private and public sector.

SECTION II – GENERAL EU POLICY

STATE OF THE UNION

On 12 September, José Manuel Barroso, President of the European Commission, delivered the [2012 State of the Union Speech](#) to the European Parliament. He called for more European unity, more integration and more democracy, proposing that the EU moves towards becoming a federation of nation states. He called for a new direction and a new thinking for Europe, presenting a *"decisive deal for Europe"* that *"requires the completion of a deep and genuine economic union, based on a political union."* President Barroso confirmed that the proposed reforms would require changes to the EU treaty and added that a broad debate should start in Europe on treaty change, before a convention or an intergovernmental conference is called.

COMMISSION'S PROPOSAL FOR A BANKING UNION

On 12 September, the Commission adopted a set of legislative proposals to establish a single supervisory mechanism for banks in the euro area led by the European Central Bank to strengthen the Economic and Monetary Union ([Regulation I](#) and [Regulation II](#)). The set was accompanied by a Communication on

a [roadmap for completing the banking union](#) over the coming years.

SINGLE MARKET ACT II

On 3 October, the Commission will present the "Single Market Act II: Together for new growth" outlining new steps to deepen the Single Market in the service of growth, employment and cohesion. The Commission has identified 12 priorities to boost growth, employment and social cohesion in the Single Market, under four main drivers: i) developing fully integrated networks in the Single Market; ii) Fostering mobility of citizens and businesses across borders; iii) supporting the digital economy across Europe; and iv) strengthening social entrepreneurship, social cohesion, and consumer confidence/non-discrimination.

EUROPEAN SMALL CLAIMS PROCEDURE

This legal procedure was established by [Regulation \(EC\) n° 861/2007](#) to resolve cross-border disputes in cases involving €2,000 or less. It has entered into force in 2009 but it is not very well known by consumers or judges. It provides fast judgements which are recognised and enforced in another Member State without the need for a declaration of enforceability and without any possibility of opposing its recognition. It applies to cross-border shopping, on-line or not. Dentists are able to use it in case of cross-border purchases (ex: an Austrian dentist orders equipment from a German website, paying in advance the €784 via bank transfer. The German trader never delivered the equipment nor reimbursed the purchase price. The Austrian dentist may start a European Small Claims Procedure).

Comments, questions and contributions please contact:
ced@eudental.eu

CED ACTIVITIES INFO

Issue 4 – October 2012

COUNCIL OF
EUROPEAN DENTISTS



Introduction

*This issue is the third in a series of newsletters which take a closer look at CED Working Groups and Board Task Forces, their policy priorities for 2012-2013 and, most importantly, the experts that make their work possible. This edition is dedicated to the **CED Working Group Tooth Whitening**. Section I continues to report on the political activities of the CED President, Board members and to summarise the work of the other CED Working Groups, Board Task Forces and the Brussels Office. In Section III, CED member associations share their positions on current issues.*

SECTION I – CED

INTERNAL ACTIVITIES

CED PRESIDENT

LETTER TO COMMISSION VICE-PRESIDENT VIVIANE REDING

On 1 August, **CED President Wolfgang Doneus** wrote to the **Commission Vice-President responsible for justice, fundamental rights and citizenship Viviane Redding** requesting clarification on certain provisions of the [Commission's proposal for a General Data Protection Regulation](#), in particular, on the impact that this Regulation will have on micro, small and medium sized enterprises. The CED is still waiting for a response which was promised to be delivered soon.

On 5 September, **the CED President travelled to Brussels** to meet with MEP Emma McClarkin, ECR's shadow rapporteur for the Professional Qualification Directive (PQD) in the Internal Market and Consumer Protection Committee (IMCO) to present the CED position on the PQD. Several points were discussed, including the risks of having tacit recognition in the Directive (Article 4d/5 of the Commission's proposal on the PQD) and the minimum duration of training for dental practitioners, where the CED favours the introduction of the dual criteria in the PQD (5 years and 5000 hours of full-time theoretical and practical training) and a reference to 300 ECTS. The President

also attended the event of the Platform for Better Oral Health in Europe organised in the European Parliament, hosted by MEPs Karin Kadenbach (S&D, Austria) and Cristian Buşoi (ALDE, Romania), where the report on the [State of Oral Health in Europe](#) was presented.

CED BOARD

MEETING ON 14 SEPTEMBER

On 14 March, **the CED Board of Directors met in Brussels** for its regular quarterly meeting. During the meeting, CED Board members reviewed CED political activities since their May meeting and discussed current political developments related to the PQD, the Review of the Community Strategy concerning Mercury, tooth whitening products, the Medical Devices Regulation, the UDI System and the General Data Protection Regulation.

The Board approved a number of initiatives by CED working bodies in preparation of the November CED General Meeting in Brussels, such as the draft CED Resolution on eHealth and the CED participation in the I2-FRESCO Project (Integrated intervention against physical frailty) - Work Stream 1 on Health Literacy led by CPME. They reviewed CED finances, discussed the draft CED budget for 2013, the update of the CED Manual of Dental Practice and the CED communications activities.

CED WORKING GROUPS (WG)

WG AMALGAM AND OTHER RESTORATIVE MATERIALS

On 10 October, **the CED replied to calls for information** of the Scientific Committee for Emerging and Newly Identified Health Risks ([SCENIHR](#)) on the safety of the use of dental amalgam and its substitutes and of the Scientific Committee for Health and Environmental Risks ([SCHER](#)) on the environmental risks and indirect health effects of mercury in dental amalgam. These calls were launched to assist both Scientific Committees in the update of their opinions on dental amalgam issued in 2008 (see [SCENIHR](#) and [SCHER](#) mandates). Further information will be provided during the CED General Meeting in November.

On 22 October, **WG chair Susie Sanderson, CED member Stuart Johnston and CED policy officer Sara Roda met two EU officials from the European Commission's DG Health and Consumers (DG SANCO)** to discuss and understand, among other issues, the future EU position on dental amalgam in the [Community Strategy Concerning Mercury](#) and for the United Nations Environment Programme (UNEP) currently developing a global treaty on mercury. The CED was able to explain that prevention is the way forward to reduce the use of dental amalgam in Member States. The gap identified by the CED (and also by the FDI) was that



COUNCIL OF EUROPEAN DENTISTS (formerly EU Dental Liaison Committee)

President Dr Wolfgang Doneus

T +32 (0)2 736 34 29

F +32 (0)2 740 20 26

ced@eudental.eu

www.eudental.eu

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Member States are only focusing on the disease (caries), instead of working on how to reduce the disease. The CED also stressed that dental amalgam should remain part of the dentist's armoury in order to best meet the needs of patients. Dental amalgam continues to be the most appropriate filling material for many restorations and the quality of alternatives needs to be further improved for use in public dental care.

WG EDUCATION AND PROFESSIONAL QUALIFICATIONS

On 18-19 September, **former WG member Ms. Barbara Bergmann-Krauss attended the second meeting of the ESCO Reference Group (RG) "Healthcare and social work activities"** as an expert and on behalf of the CED. The aim of this project is a job-matching web application for competences. The RG will have to prepare a 1st draft sectorial breakdown (typical organisation of the healthcare sector as a kind of navigator in order to search for vacant jobs) by 15 November. RG members will have to provide, among others, the definition of each occupation, the entry-level education / qualifications for each occupation / profession, and a list of core skills and competences.

On 19 September, **WG member Alfred Büttner and CED policy officer Sara Roda met with MEP Andreas Schwab** (EPP, Germany) to present and discuss the CED position on the PQD. Mr Schwab was interested in hearing, among other issues, the CED views on rendering the delegated acts regime more transparent and on bringing speed and efficiency to the European Professional Card procedure without jeopardising patient safety (tacit recognition regime).

The CED has afterwards called for the creation of an Expert Group composed of experts from national authorities, professional organisations at both European and national level, representatives of

academia and social partners to provide advice and expertise to the Commission in the preparation of delegated acts. In connection with the tacit recognition regime, the CED has suggested the exemption of the healthcare sector as tacit recognition can endanger the lives of patients or the suspension of the deadline in case of justified doubts.

On 17 October **Alfred Büttner and Sara Roda met with MEP Birgit Collin-Langen** (EPP, Germany), to present the CED position on the PQD, highlighting certain aspects that could be improved in the Commission's proposal on the PQD. **Sara Roda also met with the assistant to MEP Sirpa Pietikäinen** (EPP, IMCO's Vice-Chair, Finland), on 4 October, also to present the CED position on the PQD.

On 24 October, **the CED-ADEE Task Force met again to discuss the new draft Annex 5.3.1 of the PQD**. The Task Force introduced several amendments in the document with the objective to shorten it and better adapt it to a future legislative document. The Task Force will meet again in March 2013 to conclude the draft Annex, which is expected to be submitted to the CED General meeting in May 2013. The Task Force also discussed and decided on the general structure of the document which will accompany the draft Annex. The purpose of this accompanying document is to explain certain concepts as well as to justify the shift from subjects to competences in the draft Annex. The Task Force further agreed to prepare a joint letter or statement requesting MEPs' support to vote favourably certain amendments to the Commission's proposal to amend the PQD, in particular on the minimum duration of training for dental practitioners to be expressed in years (5 years), hours (5000 hours) and ECTS credits (300 ECTS).

WG EHEALTH

On 18 September, **WG chair Piret Väli attended the third meeting of the eHealth Stakeholders Group** as an expert and on behalf of the CED. This Group discussed the ongoing actions of the eHealth Action Plan (the CED is part of the interoperability subgroup), as well as on the agreed actions for 2013 (the CED intends to participate on Workforce/skills issues). At the moment, three more meetings are foreseen, two of which would take place in Brussels, and one at eHealth Week in Dublin during the period 13-15 May 2013

On 20 September, **the WG met online** to discuss the current activities of the WG and decide on the WG's next priorities. Among other issues, the WG agreed that the CED should participate at the Dental SIG meeting in Stockholm (see below) and to focus on common strategy information to patients in relation to the initiatives on the Use of Technology for Remote Consultation (eConsultation) and Patient Monitoring in the Home (eHome).

On 24 October, **WG members Eric Delaeter and Jørn Jorgensen attended the Dental SIG meeting** during the [IHSTDO](#) Conference in Stockholm. This SIG intends to meet regularly to develop the dental part of SNOMED-CT. SNOMED-CT is a standardised health terminology that represents clinical concepts in a consistent and comprehensive way in health records. The focus is on enabling the implementation of semantically accurate health records that are interoperable.

WG INFECTION CONTROL

On 28 September, **WG Infection Control met in Gdansk, Poland**, to discuss, among other issues, the information collected on legionella incidents and recommended techniques to deal with this issue, the results of the CED questionnaire on legionella pneumophila in dental settings, the current Member

States' developments on infection control trends and policies, and the WG's mandate which will be submitted to the November CED General Meeting for approval.

WG ORAL HEALTH

On 26 June, **WG Oral Health met in Brussels**, immediately after the [CED's "Healthy mouth, healthy living, healthy ageing" event](#) in the European Parliament. They regretted that the event was not attended by more MEPs but were satisfied that it launched important discussions about the correlation between general and oral health in the context of ageing and the need for co-operation between different health professions. They agreed that it would be important to encourage national dental associations to organise similar events at national level.

On 15 October 2012, **WG Oral Health met online** to prepare the draft mandate for its future work, to be adopted by the CED General Meeting in November.

CED BOARD TASK FORCES (BTF)

BTF ANTIBIOTICS IN DENTISTRY

On 24 September 2012, **BTF chair Susie Sanderson and CED head of office Nina Bernot met with Head of Disease Programme, Antimicrobial Resistance and Healthcare-associated infections (ARHAI) Dominique Monnet and Group Leader in Public Health Capacity & Communication Unit Giovanni Mancarella from the [European Centre for Disease Prevention and Control](#) (ECDC)**. The meeting was organised at the request of the ECDC and focused on the activities planned in support of the [European Antibiotic Awareness Day 2012](#) and the opportunities for cooperation with the CED. In 2012, the European Antibiotic Awareness Day will be highlighted with a press event in Brussels on 16 No-

vember and a Twitter chat with an ECDC expert on 20 November; the CED encourages its members to participate and promote both activities.

BTF COMMUNICATIONS

On 22 October, **BTF Communications met in Brussels** to discuss CED communications activities. BTF Communications reviewed the activities carried out under the current Communications Annual Work Plan and decided to recommend to the General Meeting that the final report for the year should be submitted during the November meeting to inform the adoption of next year's Work Plan. They also finalised the draft Annual Work Plan for 2013 and discussed the next update of the EU Manual of Dental Practice.

BTF LIBERAL PROFESSIONS

On 14 September, **BTF Liberal Professions met in Brussels** to prepare the CED's response to the European Commission's [consultation on entrepreneurship](#). The CED's response, sent to CED members on 24 September, stressed the importance of liberal professions such as dentists and suggested that the provisions supporting entrepreneurs should also take into account the specific situation of liberal professions. The consultation will feed into the Commission's Entrepreneurship 2020 Action Plan.

CED COMMUNICATIONS OFFICERS

On 21 September 2012, the **CED Brussels Office hosted the first meeting of CED Communications Officers** – persons responsible for communications in national dental associations. Fifteen participants from ten different countries attended the meeting which included a visit to the European Parliament, a presentation of CED policy and structures and a discussion with a guest speaker from the European

Commission's DG Internal Market, Ms Nevena Mateeva, on the PQD. Communications Officers advised the CED Office on CED communications issues and exchanged national experience with communicating dentistry-related messages. The meeting was seen as very useful by the participants and another such meeting is planned next year.

CED BRUSSELS OFFICE

JOINT ACTION ON HEALTH WORKFORCE

On 28 September 2012, **Nina Bernot and Sara Roda attended a preparatory meeting of the Joint Action on Health Workforce Forecasting and Planning in Brussels**. The Joint Action is expected to officially start in December 2012 and will focus on quantitative and qualitative planning of health workforce. The CED will contribute to the Joint Action particularly in the work package on qualitative planning and horizon scanning which will discuss future health needs and consequently skills and competences of health workforce. Within the CED, BTF Internal Market, WG Education and WG Oral Health will be asked to provide advice for CED input into the Joint Action.

JOINT ACTION ON PATIENT SAFETY AND QUALITY OF CARE

On 3 October 2012, **Nina Bernot and Sara Roda participated on behalf of CED WG Patient Safety in a meeting of the Joint Action on Patient Safety and Quality of Care in Madrid**. The CED participates in the Joint Action as an associated partner in the work package on identifying, assessing and sharing best clinical practices on the local clinical level where patient and health professionals interact. Practices are expected to be collected through an online questionnaire which will be active from November 2012 and CED members will be informed about the possibili-

ties for contribution.

MEETING DG JUSTICE AND DG SANCO ON DATA PROTECTION

On 29 October, Sara Roda represented the CED at a joint meeting between the health professions (CED, CPME and PGEU) and two EU officials of the European Commission's DG Justice and DG SANCO. The purpose of this meeting was to discuss the effects of the [Commission's proposal for a General Data Protection Regulation](#) on micro, small and medium-size (SMEs) health practices and to have some clarification on the provisions related to the following points: 1) explicit consent applied to health services; 2) right to be forgotten and the scope of derogations related to the retention of data and the possibility to restrict processing; 3) certain requirements applied to controllers and processors, such as the need to undertake an impact assessment and to designate a data protection officer; 4) amount of the administrative fines; and 5) costs' estimation to implement the new Regulation on SMEs dealing with sensitive data.

EU HEALTH POLICY FORUM

On 25 October 2012, Nina Bernot and Sara Roda attended a meeting of the EU Health Policy Forum, a group through which health stakeholders receive updates and provide input to the European Commission on health policy. The meeting featured presentations by the Commission and the Cypriot and Irish Presidencies on health related issues and on the proposed data protection regulation. The Forum members agreed on a position paper on the importance of health research and decided that the Forum should lobby the European Parliament and the Council to ensure that the EU recognises health as a value in itself and does not neglect it in the time of general economic crisis.

SECTION II – CED WORKING GROUPS

TOOTH WHITENING (WG TW)

HISTORY

WG TW was established in May 1998 as WG Bleaching Agents, changing its name to Tooth Whitening in May 2006. Over the years, this WG has helped developing CED policy related to the use of hydrogen peroxide (H₂O₂) in dentistry, providing expertise on the proper classification of tooth whitening products (TWPs). To this end, the WG examined if TWPs treat the consequences of a disease or the disease itself; investigated how TWPs were classified by Member States, looking at the criteria to apply a CE mark, and how the concentrations of H₂O₂ influenced the way they were classified. The WG analysed who should be permitted to apply concentrations over 6% of H₂O₂; reviewed the scientific literature on TWPs, in particular to find evidence about the safety (or non-safety) of use of different concentrations of H₂O₂; and monitored the availability of concentrations of over 6% of TWPs in the market.

CURRENT ACTIVITY

Between 2010 and 2011, the WG followed the Commission's proposal to regulate tooth whitening products containing H₂O₂ under the [Cosmetic Products Directive \(76/768/EEC\)](#). Annex III of this Directive was amended by [Council Directive 2011/84/EU](#) which prohibits the marketing of products containing over 6 % of H₂O₂ and establishes new conditions for using products between 0.1% and 6% of H₂O₂. These are explained in the [CED Guidelines on the interpretation and implementation of Directive 2011/84/EU](#) which were developed by the WG in 2012 as well as on the [tooth whitening fact sheet](#). Directive 2011/84/EU aims to implement the opinion of the [Scientific Committee on Consumer Products \(currently](#)

[replaced by the SCCS\)](#), of 18 December 2007 on hydrogen peroxide, in its free form or when released, in oral hygiene products and tooth whitening products.

The WG investigated the use of alternative TWPs, including chlorine dioxide, and their effect in teeth. The WG also monitored and provided support to member associations in countries where tooth whitening products was (and still is) used illegally by non-dentists, placing the public at risk.

TW POLICY

Tooth whitening constitutes the practice of dentistry and should only be carried out by dentists or other dental care professionals who are registered to provide dental care. Non-dental professionals are not trained to consider a patient's wider health and detect problems (such as gum disease) that impact on the suitability of an individual to have their teeth whitened, and sometimes they use inappropriate and potentially dangerous chemicals.

TWPs are regulated under Directive 76/768/EEC being classified at EU level as cosmetic products, and not medical devices (see [version 1.13 of the Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices](#), pages 35-36). Therefore, the CE mark is unduly affixed in these products.

POLICY PRIORITIES 2012-2013

The WG will continue to monitor the implementation of Directive 2011/84/EU, answering to any questions arising from it. The WG intends to encourage the use of [the reporting mechanism for undesirable effects](#) caused by TWPs and it will prepare and review the "annual report summary" to present to the Commission on the undesirable effects caused by TWPs of concentrations between 0,1% and 6% of H₂O₂ or equivalent observed by dentists or reported by patients themselves. The first report

will cover the period from 31/10/2012 to 31/10/2013. The WG also intends to encourage further research by the industry as well as search for scientific evidence, in order to allow an approach to the Commission in relation to concentrations over 6% of H2O2 and the use of TWP's on the under 18 years old.

WHO MAKES THIS POSSIBLE

WG members are at the heart of CED policy. The WG has 6 members from 6 Member States. Among these are:

- **Dr Stuart Johnston** – CED WG Chair, Principal Executive Committee member of the British Dental Association, Chair Dental Practice Committee of the World Dental Federation (FDI) and dental practitioner, United Kingdom;
- **Prof Dr Nicolai Sharkov**, CED Board member and Board liaison, Vice-President of the Bulgarian Dental Association, President-Elect of the Balkan Stomatological Society, dental practitioner, Bulgaria;
- **Prof Dr Alessandro Pala**, senior Professor in the University of Rome, running a couple of research projects on magnetic nanoparticles and on structure-activity relationships of proteins, ex-Professor of Clinical Chemistry in the same University (until 1 November 2011), Ph.D. in Chemistry, member of SC7 "Oral Care" of ISO TC 106 (dentistry), consultant in ANDI - Associazione Nazionale Dentisti Italiani, Italy;
- **Dr Roland L'Herron**, CED Board member, dental practitioner and author of many articles, CNSD - Confédération Nationale des Syndicats Dentaires, France; and,
- **Dr Stefaan Hanson**, dental practitioner and Executive Director of the Flemish Dental Association, Chief Dental Officer, Belgium.

SECTION III – CONTRIBUTIONS BY CED MEMBER ASSOCIATIONS

HUGE INTEREST IN IRELAND'S NEW DENTAL COMPLAINTS SCHEME

A new dental complaints resolution service launched by the Irish Dental Association in May 2012 is already proving an outstanding success.

The Dental Complaints Resolution Service aims to assist dental patients and participating dentists resolve complaints about dental services. The complaints scheme is the latest initiative from the Association designed to promote confidence in the high standards of dental care provided in Ireland.

The complaints scheme's mediator Mr Michael Kilcoyne, formerly a Ministerial nominee to the Dental Council and currently Chairman of the Consumer Association of Ireland, says the number of enquiries received is already well ahead of expectations.

Michael sees this as a really positive indication of support for the scheme from both the dental profession and the general public.

He says most complaints relate to patient concerns regarding pricing, allegations of poor service, poor communications or unsatisfactory after-care service. Already a handful of complaints have been fully resolved to the mutual satisfaction of the parties which represents a very timely and successful outcome in such a short space of time. Dentists have been pleased to see cases resolved in a timely fashion and without recourse to lengthy and expensive legal correspondence.

The availability of the scheme can also reassure patients, provide a useful way to review engagement with patients and help to nurture long-lasting relations with patients who see the commitment of the practice to handling complaints in a professional manner.

More information on the scheme is available to dentists and members of the public at www.dentalcomplaints.ie.

Contributed by the Irish Dental Association

"STOMATOLOGY 2012 – THE WORLD NO TOBACCO DAY" CONFERENCE IN WARSAW

The Polish Chamber of Physicians and Dentists, in particular its Dental Practitioners' Committee, is since years committed to raising public awareness of the significance of oral health as part of overall human health. The Chamber is engaged in various activities in this field. One of such an event is the annual conference held in Warsaw that gathers leading dental and medical practitioners of various specialties, academics, researchers, representatives of mass media and health administration. In previous years the main topics included epidemiology of dental disease, role of dentists in the delivery of general healthcare (dentist as a GP).

This year the Conference took place on 31 May - the WHO World No Tobacco Day. It was a perfect occasion to present the health risks related to smoking and to discuss prevention and diagnosis issues in the context of oral health. The presentations were focused on different aspects of this matter – not only the responsibilities and cooperation between dental and medical practitioners was discussed, but also important legal and financial considerations were mentioned. The invited speakers included representatives of the WHO and the Ministry of Health.

As in previous years, special attention was paid to proper dissemination of the information presented at the Conference, as we know that it is of utmost importance that the message is received not only by the dental and medical professionals, but also the general public. To this end many representatives of mass media were invited and the Conference was followed by a number of interesting publications in the press, radio and TV.

Contributed by the Polish Chamber of Physicians and Dentists.

THE EUROPEAN SINGLE MARKET FOR FREELANCE HEALTH CARE PROFESSIONALS: PUTTING THE QUALITY OF CARE AT RISK? – 7TH EUROPEAN CONFERENCE OF THE GERMAN DENTAL ASSOCIATION

The impact of the shortage of qualified healthcare professionals on the quality of patient care and the growing mobility of healthcare employees within Europe was the main focus of the 7th European Conference of the German Dental Association (BZÄK), held in Berlin on 5th September 2012.

Around 70 delegates from various authorities, associations and other organisations accepted the invitation to attend the conference, which was held in the preserved ruins of the former lecture hall at the Berlin Museum of Medical History. This year, the main topics for discussion were the Action Plan for the EU Health Workforce published in April 2012 and the ongoing consultations on a revision of the Directive on the Recognition of Professional Qualifications. Annette Widmann-Mauz (CDU), MP, Parliamentary State Secretary at the Federal Ministry of Health, got the debate underway with her keynote speech. Caroline Hager of the European Commission's Directorate General for Health and Consumers explained how the EU is looking to use the Action Plan to combat the lack of qualified healthcare professionals, which has now become a problem in all EU member states.

Journalist Dr Ursula Weidenfeld moderated the panel discussion on ways of dealing with the shortage of qualified professionals and the important role to be played by professional bodies in terms of self-regulation. The panel comprised Dr Rolf Koschorrek, MP, Chairman of the CDU/CSU German Bundestag Par-

liamentary Committee on Health and President of the Federal Association of Liberal Professions, Gertrud Stöcker, Vice President of the German Nursing Association, Undersecretary Dr Volker Grigutsch, Head of the Department of Disease Control and General Healthcare at the Federal Ministry of Health, Prof. Winfried Kluth, Chair of Public Law at the Martin Luther University of Halle-Wittenberg, Caroline Hager and BZÄK President Dr Peter Engel.

For the conference programme and further information on the event, please visit the BZÄK homepage at: www.bzaek.de/wir-ueber-uns/europa.html

Contributed by BZÄK, Germany.

If CED Members wish to receive further information about any of the items mentioned in the newsletter, please contact:
ced@eudental.eu