



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 presented by the European Commis-

sion 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 workforce](#)

[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, GlaxoSmithKline 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 ac-

companied 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:
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