CED EU INFO

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COUNCIL OF EUROPEAN DENTISTS

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 webcast) 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 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 feed-

back 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 HEALTH-CARE 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 Join 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:
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