CED EU INFO

Issue 2 - April 2013

COUNCIL OF EUROPEAN DENTISTS

Introduction

Welcome to the 2nd issue of CED EU Info of 2013. 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)

The European Parliament's Internal Market and Consumer Protection (IMCO) Committee approved the mandate to enter trilogue negotiations with the Council on 21 February 2013. The vote in plenary on the Directive is foreseen in September 2013.

In the Council, the file was submitted to the Permanent Representatives Committee (COREPER I) on 1 March 2013 with a view to agreeing a mandate for a first trilogue with the European Parliament.

There have been four technical meetings with the Parliament and the Commission (7, 18, 27 March and 9 April 2013) during which the following issues were discussed: European Professional Card (EPC), partial access, language tests and the alert mechanism, temporary provision of services, recognition for purposes of establishment and sectoral professions (doctors, nurses and dentists). The first trilogue was held on 20 March 2013 and the issues related to EPC, partial access and the alert mechanism were discussed.

The second trilogue was scheduled for 24 April 2013 and was intended to focus on the sectoral professions and any remaining horizontal issues which cannot be resolved at technical level; the discussion of the sectoral professions would include the delegated and implementing acts associated with those provisions.

JUDGMENT OF THE COURT OF JUSTICE ON COMPULSORY TRAINING

In its judgement delivered on 28 February 2013, the Court of Justice of the European Union (CJEU) declared that a regulation adopted by a professional association must be regarded as a decision adopted by an association of undertakings within the meaning of the EU competition law. The fact that a professional association is required by law to put into place a system of compulsory training for its members cannot remove the rules adopted by that association from the scope of the EU competition law. Furthermore, the CJEU stated that a regulation adopted by a professional association putting into place a system of compulsory training constitutes a restriction on competition which is prohibited by EU law to the extent which it eliminates competition within a substantial portion of the relevant market, to the benefit of that professional association, and in so far as it imposes, on the remaining portion of that market, discriminatory conditions to the detriment of competitors of the association.

GENERAL DATA PROTECTION REGULATION

The amendments to the European Parliament's Civil Liberties, Justice and Home Affairs (LIBE) Committee's draft report were tabled on 27 February 2013.

On 20 March 2013, LIBE Committee held a consideration of amendments. MEPs highlighted that the data protection legal framework should be transparent, comprehensive and feasible. The debate focused mainly on the notion of explicit consent, the lawfulness of processing, the need for data protection impact assessment and data protection officers.

On 2 April 2013, Jacob Kohnstamm, chair of the Article 29 Working Party, expressed his support for the draft report. The Article 29 Working Party which is an advisory body to the European Commission representing Data Protection Authorities in the Member States delivers opinions and recommendations in regard to the protection of personal data in the EU.

Due to the high number of amendments tabled (more than 3,000) the vote in LIBE has been postponed to the end of May. The vote in plenary is planned in autumn 2013.

In the Council, the Working Party on Information Exchange and Data Protection met on 13 and 14 March 2013.

MEDICAL DEVICES

On 26 February and 19 March 2013, the European Parliament's Environment, Public Health and Food Safety (ENVI) Committee and the Group of the Progressive Alliance of Socialists and Democrats (S&D) organised workshops on medical devices. During these workshops, the Rapporteur, MEP

Dagmar Roth-Behrendt (S&D, Germany) indicated her positions on some of the issues in connection to the future Regulation, for instance: centralized pre-market authorization, classification of medical devices, reprocessing of single-use devices, assessment of clinical data, vigilance and reporting of incidents.

On 20 March 2013, there was a first exchange of views on the Regulation in ENVI Committee. The MEPs agreed with the need to reinforce patient safety with better checks and notified bodies with reinforced roles. MEPs' views differed on whether certain medical devices should be subject to an EU pre-market authorisation requirement as suggested by the Rapporteur. The Rapporteur highlighted again her proposal for a centralised approval system and explained that definition of single-use devices should be clarified as well as the conditions and liabilities for reprocessing them. She suggested to set up a more transparent fee system and to ensure that the notified bodies have their own in-house expertise.

On 12 April 2013, the Rapporteur published the draft report in which she suggests tightening up provisions to ensure higher level of public health and safety. She introduces a streamlined centralised (via European Medicines Agency (EMA)) and decentralised marketing authorisation procedure (via national authorities) for specific types of high risk devices. Furthermore, she clearly distinguishes between single use and reusable devices and seeks to ensure that labelling of class III devices as single-use or re-labelling of single-use devices as reusable is only allowed if validated by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). She also suggests that anyone reprocessing a reusable device should take on the responsibilities of the original manufacturer (labelling, etc.). Alignment to the provisions on clinical investigations to the Clinical Trials Regulation is also proposed; hence ethics committees should be consulted before investigation is allowed. The Rapporteur also proposes to improve transparency, tighten the requirements for notified bodies in terms of qualifications of permanent personnel and fees; and establish a multidisciplinary advisory committee of experts and representatives of stakeholders and civil society organisations to provide specialist expertise.

The draft report was presented and debated in ENVI Committee on 24 April 2013.

The Rapporteurs for opinion, MEPs Nora Berra (IMCO, EPP, France) and Edite Estrela (EMPL, S&D, Portugal) also published their draft opinions on the future Regulation. In her draft opinion, MEP Nora Berra (EPP, France), stresses that the overriding objective of the Regulation must be the safety of patients and users but that steps should also be taken to guarantee the free movement of products. She also proposes that only those nanomaterials which are intended to be intentionally released in the human body should be classified as class III; single use devices cannot be reprocessed and manufacturer has to prove that it is impossible or unsafe to reprocess them; intended single use devices (for which the manufacturer has not proven they cannot be reprocessed) can be reprocessed if the reprocessor assumes the obligations of the manufacturer. Finally, she suggests besides a scientific advisory board to the Medical Devices Coordination Group (MDCG) also a stakeholder dialogue group.

The draft opinion of MEP Edite Estrela (S&D, Portugal) takes a look at the Regulation from safe working conditions perspective. She specifically proposes that medical devices should fully comply with the requirements of Directive 2010/32/EU on prevention from sharp injuries.

The deadline for tabling amendments in ENVI Committee is on 13 May 2013. The indicative vote in plenary will take place in November 2013.

In the Council (Employment, Social Policy, Health and Consumer Affairs) four Working Party meetings have already been scheduled for this year.

The legislation is expected to be adopted in 2014 and would come into force between 2015 and 2019.

COMMISSION'S RECOMMENDATION ON UDI

On 5 April 2013, the European Commission adopted a Recommendation on a common framework for a unique device identification system of medical devices in the Union.

The Commission's Recommendation is non-binding (without legal force) and encourages Member States to structure their national UDI systems in a harmonised way, in preparation for what will eventually be a binding system on the basis of the Regulation on Medical Devices.

The Recommendation specifies that the UDI system does not apply to custom-made medical devices. Member States are recommended to apply a gradual approach (UDI system should be first applied to highest risk class devices). Although it should generally apply to every packaging level for all classes of medical devices, exceptions are possible. There are no obligations on professional users (distinct from health institutions) but where feasible, UDI information should be used by them when they report incidents.

TOBACCO PRODUCTS DIRECTIVE

The public hearing on tobacco products in the European Parliament's Environment, Public Health and Food Safety (ENVI) Committee took place on 25 February 2013. During the hearing of European Institutions representatives, main

stakeholders, health and other experts discussed the issues concerning the economic and health burden of tobacco products and issues related to their packaging.

On 10 April 2013, the Rapporteur, MEP Linda McAvan (S&D, UK) published her draft report in which she supports the proposal on tightened rules on ingredients. However, she would like the Commission to monitor carefully the use of waterpipes. The rapporteur is also in favour of all proposed measures on labelling and packaging, but suggests to go further in the case of cigarettes and so-called "roll your own" by proposing a form of standardisation which removes branding from packaging. Moreover, she supports to maintain restrictions on the sale of oral tobacco and calls for prior authorisation for all novel tobacco products.

The vote in ENVI Committee is scheduled on 10-11 July 2013 and the vote in plenary is planned in October 2013.

REPORT ON THE IMPLEMENTATION OF THE COUNCIL'S RECOMMENDATION ON SMOKE-FREE ENVIRONMENTS

On 22 February 2013, the European Commission published a report on the implementation of the Council Recommendation of 30 November 2009 on Smoke-free Environments (2009/C 296/02). According to the report, the protection from second hand smoke has improved. The report is based on self-reporting by the 27 Member States, following the Council Recommendation on Smoke-free Environments adopted in 2009, which called upon governments to adopt and implement laws to fully protect their citizens from exposure to tobacco smoke in enclosed public places, workplaces as well as public transport. The report dissipates concerns about smoking bans that impact negatively on the revenues of bars and restaurants. It shows that the economic impact has been limited, neutral and even positive over time. However, the report also illustrates that some Member States are lagging behind, in terms of comprehensive laws protecting public health, and enforcement.

ENDOCRINE DISRUPTORS

On 15 November 2012, a Draft report on the protection of public health from endocrine disruptors was presented by the Rapporteur, MEP Åsa Westlund (S&D, Sweden) in the European Parliament's Environment, Public Health and Food Safety (ENVI) Committee. In her report, the Rapporteur underlines that there are measures which can be adopted quickly to increase protection for the most vulnerable groups and to restrict the use of endocrine disruptors in products aimed at specific target groups. The draft report asks for more stringent safety requirements, implementation of appropriate tests for identifying endocrine disruptors, definition of criteria need for the interpretation of tests and introduction in all relevant EU legislation appropriate testing requirements for the identification of substances with endocrine-disrupting properties. A comprehensive set of compromise and consolidated amendments have been negotiated by the Rapporteur and the Shadows.

On 14 March 2013, the European Parliament approved a resolution on protection of public health from endocrine disruptors. The resolution says that current rules should be closely examined with a view to updating or proposing new legislation by June 2015 at the latest.

Upon a request in 2012 from the European Commission, European Food Safety Authority's (EFSA) Scientific Committee has published on 20 March 2013 an opinion which clarifies the scientific criteria for identifying an endocrine disruptor. EFSA endorses the World Health Organization's (WHO) definition of an endocrine disruptor and emphasizes that not all endocrine substances are endocrine disruptors. The Committee's opinion brings recommendations for future activities, including testing methods and testing strategies.

IONISING RADIATION DIRECTIVE

On 30 May 2012 the European Commission adopted the proposal for a Directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. The proposal sets out the basic safety standards (BSS) to protect the health of the public, patients and workers against the dangers of ionising radiation. It builds on the recently updated recommendations of the International Commission for Radiological Protection, including also natural radiation sources.

The Rapporteur, MEP Thomas Ulmer (EPP, Germany) presented his draft report on 20 December 2012. In his report, the Rapporteur welcomes the proposal as a further step towards improving protection against exposure to ionising radiation. Among others, he seeks to avoid possible conflicts in the disposal of different radioactive materials and reduce administrative burden related to requirements for certain medical devices.

The vote on the draft report in ENVI Committee is scheduled on 19 June 2013 and the vote in plenary is expected on 2 July 2013.

ELECTROMAGNETIC FIELDS DIRECTIVE

On 10 April 2013, the EU Council's Committee of Permanent Representatives approved the compromise reached between the European Parliament and the Council on the proposal to amend Directive 2004/40/EC on electromagnetic fields. This Directive sets minimum requirements regarding the protection of workers that are for instance operating or installing broadcasting equipment, operate MRI scanners, or are engaged in magnetic testing.

On 22 April 2012, an exchange of views on the outcome of negotiations took place in the European Parliament's Committee on Em-

ployment and Social Affairs (EMPL).

The vote in plenary is scheduled on 10 June 2013, and the Council is expected to approve the final version before summer.

SECTION II – GENERAL EU POLICY

EPSCO COUNCIL MEETING

The Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council met on 28 February 2013. The Council reached political agreement on a recommendation addressed to the member states on establishing "youth guarantee" schemes aiming to ensure that all young people under the age of 25 who lose their job or do not find work after leaving education quickly receive a good-quality offer of employment, continued education, an apprenticeship or a traineeship.

The Council also debated on the employment and social policy aspects of the 2013 European Semester exercise, with a view to contributing to the broader discussions in the European Council.

INFORMAL MEETING OF HEALTH MINISTERS IN DUBLIN

The EU Health Ministers held an informal meeting on 4-5 March 2013 in Dublin. They discussed a range of important issues in the area of health and specifically the impact of the economic crisis on health systems across the EU, progress to achieving a smoke-free environment and childhood obesity.

During the meeting, the European Commission presented a report on the implementation of the Council Recommendations on Patient Safety, including healthcare associated infections. Although considerable progress had been achieved, much work was still to be done and the Ministers discussed priority action areas across all health policies. They also shared examples of good practice.

CROATIA'S ACCESSION TO THE EU

On 27 March 2013, the European Commission adopted a first report evaluating the administrative preparations for the accession of Croatia to the EU. Except some manageable delays in five areas, the state of preparation in a large majority of fields is advanced. The Commission declared that Croatia is ready to join the EU on 1 July 2013. 23 Member States, including Slovenia, have already ratified Croatia's EU accession.

On 25 April 2012, the Commission announced the appointment of the senior minister in Croatian government, Neven Mimica, as Commissioner. He has been offered the Consumer Protection portfolio, meaning that the portfolio of the current Commissioner for Health and Consumer Protection, Tonio Borg, will be split in two.

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