CED EU INFO

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COUNCIL OF EUROPEAN DENTISTS

Introduction

Welcome to the 3rd 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)

On 26 June 2013, the Committee of Permanent Representatives (COREPER) in the Council of the European Union endorsed the agreement reached on 12 June 2013 between the Irish Presidency of the Council and the European Parliament's representatives on the review of the Professional Qualifications Directive.

The aim of the review of the Directive is to make the current system of mutual recognition of professional qualifications more efficient in order to obtain greater mobility of skilled workers across the European Union.

The main features of the agreement with regard to the dental profession include the basic dental training comprising at least five years of study, which may in addition be expressed with the equivalent ECTS credits and consisting of at least 5 000 hours of full-time theoretical and practical training, a possibility for a Member State to refuse partial access to the profession on the grounds of public health concerns, an obligation for competent authorities of Member States to alert, through a specific alert mechanism, the authorities of other Member States about professionals who are no longer entitled to practice the profession as a result of a disciplinary action or criminal conviction and a possibility for competent authorities of Member States to conduct language controls in order to verify that the professionals are in possession of necessary language skills.

The plenary vote in the European Parliament is scheduled on 7 October 2013.

GENERAL DATA PROTECTION REGULATION

During the meeting of the European Parliament's Civil Liberties, Justice and Home Affairs (LIBE) Committee on 9 July 2013, the rapporteur for the General Data Protection Regulation, MEP Jan-Philipp Albrecht (Greens, Germany), informed that the vote on his draft report was postponed to autumn due to the very high number of amendments tabled and tough negotiations. He also informed that there has been progress in finding compromise and that the trialogue negotiations with the Council might start in autumn after the vote in LIBE Committee.

The vote in plenary is scheduled on 15 January 2014.

MEDICAL DEVICES

The vote on the future Medical Devices Regulation which was initially planned to take place in the European Parliament's Environment, Public Health and Food Safety (ENVI) Committee on 10 July 2013 has been postponed to 18 September 2013. The MEPs remain divided over the pre-market approval procedure proposed by the rapporteur, MEP Dagmar Roth-Behrendt (S&D, Germany), reprocessing of single-use medical devices and notified bodies.

In the meantime, the European Parliament's Internal Market and Consumers (IMCO) and Employment and Social Affairs (EMPL) Committees adopted their final opinions on the future Regulation.

The indicative vote in plenary will take place on 22 October 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.

TOBACCO PRODUCTS DIRECTIVE

On 21 July 2013, the Council of the European Union agreed a general approach on the draft EU Tobacco Products Directive which aims at making tobacco products less attractive by strengthening the rules on how they can be manufactured, presented and sold. The agreement includes a ban on the use of cigarettes and roll-your-own tobacco with characterising flavours, an obligation for combined picture and text health warnings to cover 65% of the front and the back of packages of tobacco products for smoking, a ban of any misleading labelling, the extension of the scope of the directive to novel tobacco products, nicotine containing products and herbal products for smoking, and a possibility for Member States

to decide to ban cross-border distance sale of tobacco products and to introduce more stringent rules on additives or on packaging of tobacco products.

On 10 July 2013, the European Parliament's Environment, Public Health and Food Safety (ENVI) Committee adopted the draft report on the Tobacco Products Directive. The Committee voted in favour of stronger EU tobacco rules: a prohibition of the use in tobacco products of additives and flavours that make them more attractive, a ban of any misleading labelling, an obligation for health warnings to cover 75% of external area of packets and packaging of tobacco products for smoking, a ban of slim cigarettes, an obligation for e-cigarettes to be placed on the market under existing rules on medicinal products.

The vote in plenary is scheduled on 10 September 2013.

DEADLINE FOR IMPLEMENTATION OF SHARPS DIRECTIVE

Directive 2010/32/EU implements the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector signed by the European social partners HOSPEEM and EPSU on 17 July 2009, which is an annex to this Directive.

The aim of the Directive is to implement the Framework Agreement in order to prevent workers' injuries caused by all medical sharps (including needlesticks), protect workers at risk and set up an integrated approach establishing policies in risk assessment, risk prevention, training, information, awareness raising and monitoring.

The deadline for implementation of the Directive into national laws of Member States was on 11 May 2013 at the latest.

COSMETICS REGULATION

On 11 July 2013, the new EU Regulation 1223/2009 ('Cosmetics Regulation') came into force. It strengthens the safety of cosmetic products and streamlines the framework for all operators in the sector. The Cosmetics Regulation replaces Directive 76/768/EC which was adopted in 1976 and has been substantially revised on several occasions.

The new Regulation provides a strong regime aimed at strengthening product safety by taking into consideration the latest technological developments, including the possible use of nanomaterials.

The most significant changes introduced by the Cosmetics Regulation include strengthened safety requirements for cosmetic products, introduction of the notion of 'responsible person', centralized notification of all cosmetic products placed on the EU market, introduction of reporting of serious undesirable effects and new rules for the use of nanomaterials in cosmetic products.

ENTREPRENEURSHIP 2020 ACTION PLAN DRAFT RESOLUTION

On 9 July 2013, the European Parliament's Industry, Research and Energy Committee (ITRE) adopted a motion for resolution on the Entrepreneurship 2020 Action Plan presented by the rapporteur MEP Paul Rübig (EPP, Austria). In his draft resolution the rapporteur calls for promotion of entrepreneurial spirit and entrepreneurial education and training, emphasises the necessary environment and framework conditions for entrepreneurship suggesting a European charter for the liberal professions, as well as calls for actions reaching specific target groups.

SECTION II – GENERAL EU POLICY

EPSCO COUNCIL MEETING

The Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council met on 20-21 June 2013. The Council agreed a general approach on a revised draft Tobacco Products Directive aimed at making tobacco products less attractive by strengthening the rules on how tobacco products can be manufactured, presented and sold. It took note of Presidency progress reports on a draft regulation on clinical trials of medicines and on two draft regulations on medical devices and *in vitro* medical devices.

The Council also adopted a directive on the minimum health and safety requirements regarding the exposure of workers to the risks arising from electromagnetic fields.

PRIORITIES OF LITHUANIAN PRESIDENCY

During the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) on 21 June 2013, the Lithuanian Minister of Health, Vytenis Povilas Andriukaitis, presented the priorities in health sector during the Lithuanian Presidency of the Council of the European Union. The Minister named the revision of the Tobacco Products Directive, concentration on sustainable heath systems, continuity of Ireland's efforts to reach general approach on clinical trials on medicinal products for human use and mediating the discussions on the Regulations on medical devices as well as on *in vitro* diagnostic medical devices as the priorities during the Lithuanian EU Council Presidency.

WELCOME CROATIA!

On 1 July 2013, Croatia became the 28th Member State of the European Union.

NEW EUROPEAN OMBUDSMAN

On 3 July 2013, the European Parliament elected a new European Ombudsman, Ms Emily O'Reilly. Ms O'Reilly is currently the Ombudsman in Ireland and will take up the duties of the European Ombudsman on 1 October 2013.

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