



## Introduction

Welcome to the 1st issue of CED EU Info of 2014. 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 15 November 2013, the [Council of the EU adopted the review of the Professional Qualifications Directive \(PQD\)](#).

The main features concerning the dental profession include i) 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, ii) possibility for Member States to refuse partial access to the profession on the grounds of public health concerns, iii) obligation for Member States' competent authorities to alert, through a specific alert mechanism, the authorities of other Member States about professionals who are no longer entitled to practice as a result of a disciplinary action or criminal conviction, and iv) possibility for Member States' competent authorities to conduct language controls in order to verify that professionals are in possession of necessary language skills.

The PQD entered into force 20 days after [its publication in the Official Journal of the EU](#). Member States have 2 years to adapt their national laws to the modernised PQD.

### GENERAL DATA PROTECTION REGULATION (GDPR)

[On 6 December 2013, the EU Council discussed the proposed General Data Protection Regulation](#) with a focus on the one-stop-shop mechanism and related questions on judicial review and judicial redress.

The vote in the European Parliament plenary has been postponed until 12 March 2014. The data protection framework is currently not expected to be adopted before the end of 2014.

### MEDICAL DEVICES REGULATION

During the meeting of the Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council on 10 – 11 December 2013, the [proposed Medical Devices Regulation](#) was discussed. Several delegations expressed their opposition towards the reprocessing of medical devices classified by the manufacturer as 'single-use' and assessed that if reprocessing was allowed at the EU level, reprocessors should be subject to the same requirements as manufacturers. Some delegations, referring to reprocessing as a possible cost-saving measure, wanted to make sure that only medical devices which could not be reprocessed to be labelled as 'single-use'. Other delegations had preference to allow Member States to decide if medical devices could be reprocessed, provided that patient safety was ensured.

### TOBACCO PRODUCTS DIRECTIVE

On 26 February 2014, the European Parliament approved in plenary the [draft legislation updating the Tobacco Products Directive](#). The new legislation would require all packs to carry health warnings covering 65% of their surface, front and back; e-cigarettes would be regulated either as medicinal products, if marketed as a quit aid, or as tobacco products. Furthermore, flavourings in cigarettes would be banned, as well as certain additives particularly damaging for health but those essential for tobacco production such as sugar would be authorised; other additives would be listed.

The text is expected to be approved by the EU Council on 14 March. After the approval and its publication in the Official Journal of the EU, Member States will have 2 years to adapt their national laws.

Tobacco remains the largest health threat in the EU; every year it kills around 700,000 people.

### GUIDELINES ON MINIMUM PATIENT SUMMARY DATASET

On 19 November 2013, during the 4<sup>th</sup> meeting of the eHealth Network<sup>1</sup>, Member States adopted [guidelines on patient summary dataset for electronic exchange](#). The guidelines

<sup>1</sup> eHealth Network, established according to Art. 14 of the Directive 2011/24/EU (Cross-border Healthcare Directive), brings together all 28 Member States and is co-chaired by the European Commission and Austria.

were adopted to enable sharing of basic health information of a patient across borders. The guidelines are targeted at ensuring safe and high quality healthcare and at enhancing continuity of care as laid down in the Cross-border Healthcare Directive. The basic information for a patient includes, according to the guidelines, both administrative and clinical data.

These guidelines are non-binding and should be interpreted as a set of recommendations. It is up to the Member States whether they adopt the guidelines or not.

### **EESC'S OPINION ON THE ROLE AND THE FUTURE OF THE LIBERAL PROFESSIONS**

On 10 February 2014, the European Economic and Social Committee's (EESC) Section for the Single Market, Production and Consumption adopted its [opinion on 'The role and the future of the liberal professions in the European civil society 2020'](#). The opinion highlights that liberal professions are an important component of any democratic society and offer significant potential for growth in terms of employment. Furthermore, the opinion calls for development of a common EU definition of the term 'liberal professions' which would lay down the general characteristics of liberal professions. The opinion will be voted in the EESC's plenary on 25 – 26 March 2014.

### **PUBLIC CONSULTATION ON PATIENT SAFETY AND QUALITY OF CARE**

On 4 December 2013, the European Commission launched a [public consultation on patient safety and quality of care](#). The aim of the consultation is to seek opinion of civil society on i) whether patient safety measures included in the [Council Recommendation 2009/C151/01](#) have been implemented by Member States and contribute to improving

patient safety in the EU, ii) which areas of patient safety are not covered by the Recommendation and should be, iii) what should be done on patient safety at EU level beyond the Recommendation and iv) whether quality of healthcare should be given more importance in future EU activities.

The CED Working Group Patient Safety has prepared and submitted a CED reply to the consultation in February 2014.

### **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 2013. These questions are available [here](#).

### **PUBLIC CONSULTATION ON PRELIMINARY OPINION ON USE OF BISPHENOL A IN MEDICAL DEVICES**

On 29 January 2014, the European Commission and the Scientific Committee on Emerging Newly Identified Health Risks launched a [public consultation](#) on the [preliminary opinion on 'The safety of the use of bisphenol A in medical devices'](#). The objective of the consultation is to assess whether the use of bisphenol A in medical devices could give reasons for concern from the health point of view and, if possible, to provide indications on limit values for BPA release from medical devices.

The consultation is open until 26 March 2014.

## **SECTION II – GENERAL EU POLICY**

### **EUROPEAN ELECTIONS 2014**

Every five years the EU citizens choose, through direct elections, their representatives in the European Parliament. This year the elections will take place on 22 – 25 May. Each EU Member State has the

right to elect a fixed number of Members of the European Parliament (MEPs). The allocation of seats is distributed on the basis of the principle of degressive proportionality as laid down in the Treaties: countries with a larger population have more seats than smaller countries, but the latter have more seats than strict proportionality would imply. For the 2014 election, the number of MEPs ranges from 6 for Malta, Luxembourg, Cyprus and Estonia to 96 for Germany.

Since the entry into force of the Treaty of Lisbon, the Parliament has become a powerful co-legislator and plays an important role in shaping European policies. By voting in the EU elections every citizen can influence the composition of the Parliament and the decisions it takes during its mandate.

More information on the 2014 EU elections can be found on the [European Parliament's website](#).

The CED has issued its own call on voters to vote and is preparing a manifesto for the elections which is currently being discussed by CED members.



This year also, a new team of 28 Commissioners (one from each EU Member State) will be appointed for a 5-year period. The candidate for the post of the President of the Commission is nominated by the European Council; if approved by a majority of the MEPs, the President-elect chooses the Commissioners from the candidates put forward by Member States. The list of Commissioners is forwarded to the EU Council, then to the Parliament. If the Parliament approves, the new

Commission is officially appointed by the Council.

More information is available on the [Commission's website](#).

### **EPSCO COUNCIL MEETING**

[The Employment, Social Policy, Health and Consumer Affairs \(EPSCO\) Council met on 10 – 11 December 2013](#). The Council agreed on a general approach on the enforcement directive on the posting of workers. It looked at initiatives encouraging youth employment. The Council exchanged views on the European Semester 2014 in the area of employment and social policy as well as on the proposed legislation on medical devices (see page 1 of this newsletter). The Council also adopted [conclusions on the ongoing reflection process on modern, responsive and sustainable health systems](#). The conclusions reflect the progress made since the launch of the reflection process in June 2011, examine the challenges currently faced by national health systems and invite the Commission and Member States to take further steps to identify effective ways of investing in health.

### **REPORT ON HEALTH INEQUALITIES IN THE EU**

On 11 December 2013, the European Commission published the [report 'Health inequalities in the EU'](#). The report outlines new evidence of health inequalities in the EU and the policy response at both EU and national levels since 2009.

### **PRIORITIES OF THE GREEK PRESIDENCY OF THE EU COUNCIL**

On 10 December 2013, the Greek Health Minister Spyridon Adonis Georgiadis presented the [priorities of the Greek Presidency in the area of health](#). During the first six months of 2014, the Greek Presidency is focusing on the progress of a number of legislative files and specifically tobacco products, clinical trials,

pharmacovigilance fees and transparency directive; however, the top priority will be a significant progress on medical devices legislation. In terms of non-legislative work, the Presidency will concentrate on promoting successfully implemented initiatives towards more efficient healthcare systems and better public health.

### **COUNCIL CONCLUSIONS ON EFFICIENT AND INNOVATIVE EDUCATION AND TRAINING TO INVEST IN SKILLS**

On 24 February 2014, the EU Council adopted [conclusions on 'Efficient and Innovative Education and Training to Invest in Skills – Supporting the 2014 European Semester'](#). The conclusions focus mainly on the need for education and training systems across the EU to improve skills performance to make sure that young people and low-skilled adults acquire skills and competences relevant to today's labour market. The conclusions also urge for a more innovative approach to education and training by incorporating digital forms of learning into mainstream education, as well as calling Member States to make full use of the new generation of financial instruments, particularly the Erasmus+ Programme and the European Structural and Investment Funds.

**Comments, questions and contributions please contact:**  
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