CED EU INFO

Issue 4 - November 2013

COUNCIL OF EUROPEAN DENTISTS

Introduction

Welcome to the 4th 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 9 October 2013, the European Parliament (EP) voted in plenary on 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 Council is expected to approve the draft text in November.

On 18 October, the Commission launched a call for expression of interest inviting representative professional organisations and associations at national and EU level to express an interest in the introduction of the European Professional Card for their respective professions. The deadline to reply is 22 November. Further information can be found here.

GENERAL DATA PROTECTION REGULATION (GDPR)

On 21 October, the EP's **Civil Liberties Committee (LIBE)** adopted the report by Jan Phillip Albrecht MEP on the GDPR. Many aspects of the report are very positive as it strengthens individual rights and tackles the challenges of globalisation and new technologies. However some provisions do not take into due account SMEs. For them, this proposal brings more financial and administrative burdensome, in particular provisions on respect to risk, data protection impact assessment and data protection officer (Articles 32a, 33, 33a, 35-37). Furthermore, recital 122a on the processing of personal data concerning health can be very restrictive, bringing additional difficulties for one working in a team. The final report is not yet available (please see compromise amendments I and II).

The committee vote also included a Parliament's mandate to start negotiations with the Council. The trilogue will start once the Council agrees on its own negotiating position for both proposals (regulation and directive). **The data protection framework is not expected to be adopted before the end of 2014.**

MEDICAL DEVICES

On 25 September 2013, the EP's **Environment, Public Health and Food Safety (ENVI) Committee** adopted the draft report on the future Medical Devices Regulation which was voted in plenary on 22 October. The EP agreed that all medical devices shall be considered as suitable for reprocessing and reusable devices unless they are placed on the list of single-use devices; any natural or legal person who wishes to reprocess a single-use device to make it suitable for further use within the EU and who can provide scientific evidence that such a device could be safely reprocessed shall be considered as manufacturer of the reprocessed device and held liable for reprocessing activities; dental implants shall be exempted from the obligation of an implant card; before adopting implementing acts regarding the classification of medical devices, the Commission shall consult with relevant stakeholders and take into account their suggestions; the Commission shall establish a Medical Devices Advisory Committee (MDAC) composed of experts and representatives of relevant stakeholders in order to provide support, advice and expertise on technical, scientific, social and economic aspects of regulating medical devices; an Assessment Committee for Medical Devices (ACMD) shall be established to fulfil the tasks in connection to the assessment procedure defined in Article 44a;

ACMD shall be composed of at least one member representing each of the medical fields referred to in Article 78b, paragraph 3 (dentistry included); the specificities relating to the dental profession must be respected when applying requirements for medical devices arising from Directive 2010/32/EU on the prevention from sharp injuries in the hospital and healthcare sector; all devices incorporating or consisting of nanomaterial deliberately intended to be released into the human body are in class III (Annex VII, part III, point 6, point 6.7, paragraph 1).

The vote in the EP opened the way for trilogue negotiations with the Council. In the Council (Employment, Social Policy, Health and Consumer Affairs) several Working Party meetings have already been scheduled for this year. The legislation is expected to be adopted in 2014, to come into force between 2015 and 2019.

TOBACCO PRODUCTS DIRECTIVE

On 8 October 2013, the EP voted in plenary on the revised Tobacco Products Directive.

The EP agreed among other on the following issues: health warnings covering 65% of the packs' surface, ban on characterising flavours (additives essential to tobacco production such as sugar would be authorized, as would other explicitly listed substances), ban on packs of fewer than 20 cigarettes, e-cigarettes to be regulated but not as medicinal products unless they are presented as having curative or preventive properties and to be subject to the same advertising restrictions as tobacco products, Member States should guarantee that single packets and transport packaging are identified with a mark enabling them to be traced in order to reduce the number of illegal tobacco products on the market. The MEPs, unfortunately, rejected the proposed ban on slim cigarettes.

The vote opened the way to trilogue negotiations with the Council. Once the text is agreed by both the Parliament and the Council, it will be resubmitted to the Parliament's plenary vote planned on 14 April 2014.

MINAMATA CONVENTION ON MERCURY

On 10 October 2013, the European Union signed the Minamata Convention, the first global legally binding instrument on mercury. The objective of the treaty is to protect the human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds. Dental amalgam is a compound containing mercury and therefore is among the products regulated in the treaty. Part II of Annex A lists the measures that governments may take to phase down the use of dental amalgam. The measures are to take into account countries' domestic circumstances and relevant international guidance. **Governments will need to adopt at least two measures to implement the treaty. This is now an opportunity to discuss with Member States' competent authorities the most appropriate measures which suit national needs, improve oral health and communities' life, and bring oral health in the political agenda**.

The Commission is assessing the changes to existing EU policy and legislation in order to achieve full compliance with the treaty. It will be assisted by a consultant and a stakeholder consultation is expected for spring 2014.

The treaty will be open for signature until 9 October 2014.

COMMISSION'S COMMUNICATION ON EVALUATING NATIONAL REGULATION ON ACCESS TO PROFESSIONS

On 2 October 2013, the Commission published a communication on evaluating national regulations on access to professions. It announces the start of an evaluation of national regulations on access to professions foreseen in Article 59 of the revised PQD. The process should start in November 2013. As a **first step there will be a transparency exercise** during which each Member State will have to report the list of professions it regulates. The list will be published by the Commission in the form of a map of regulated professions that will demonstrate which professions are regulated and in which countries. Member States will also have to provide a description of reserved activities. The European Map of Regulated Professions will be published in March 2014. **The second step will consist of a detailed screening and mutual evaluation** of the respective barriers Member States have in place and which limit the access to certain profession. This exercise will be grouped in **two clusters** taking account of the economic context. The **first cluster** (starting between November 2013 and April 2015) will comprise regulated professions where modernisation of the regulations could contribute to employment and growth, i.e. business services, construction, manufacturing, real estate, transport, wholesale and retail. The **second cluster** (starting between June 2014 and January 2016) will cover the remaining sectors such as education, entertainment, **health** and social services. At the end of each screening and mutual evaluation exercises, Member States will have to prepare a report/action plan indicating the measures that they have taken or intend to take to modernise national frameworks which limit access to professions. The Commission will propose follow up actions based on Member States' action plans which may include the launch of infringement procedures in cases where discriminatory or disproportionate national requirements are

maintained. **The results of this exercise should encourage the mobility of professionals in the Single Market, create new jobs in the professional sectors concerned, improve competitiveness and increase growth opportunities.**

In order to provide a more complete picture of the barriers which affect the access and exercise of regulated professions, the Commission published on the same day in parallel a report on the findings of the peer review on legal form, shareholding and tariff requirements conducted under the Services Directive.

CROSS-BORDER DIRECTIVE

On 25 October, Directive 2011/24/EU on patients' rights in cross-border healthcare has entered into force. By this date, all Member States should have implemented this Directive into national legislation. Further information can be found here.

REPORT ON PATIENT SAFETY

On 22 October, the EP plenary adopted the report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare- associated infections. The EP recommended that the issue of patient safety, and particularly the prevention and control of healthcare associated infections (HAIs), should be given a high priority in the political agenda, both at national level in the Member States and at regional and local level. MEPs welcomed the measures put in place by Member States with the principal aim of improving general patient safety and preventing the incidence of HAIs. They also welcomed the fact that some of the actions recommended by the Council have been implemented by only a few Member States, and that there is room for improvement. The EP also urged Member States to continue their efforts to improve patient safety by taking, if they have not already done so, additional measures, including setting up action plans for combating HAIs. The Parliament also recommended Member States to conduct specific awareness-raising and training measures concerning HAIs which are aimed not only at healthcare professionals but also, for example, formal and informal carers and hospital volunteers who have contact with patients and to introduce national guidelines for health professionals on how to train patients in the use of antibiotics.

RECENT ECJ RULINGS

On 12 September, the European Court of Justice (ECJ) pronounced a judgement in which it was decided that Article 5(3) of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications must be interpreted as meaning that national rules such as, first, paragraph 12(1) of the Code of professional conduct for doctors in Hesse, under which **fees must be reasonable and, unless provided otherwise by law, calculated on the basis of the official Regulation on doctors' fees**, and, secondly, paragraph 27(3) of that **code, which prohibits doctors from engaging in unprofessional advertising, do not fall within its material scope**. It is, however, for the referring court to ascertain, taking into account the indications given by the ECJ, whether those rules constitute a restriction within the meaning of Article 56 TFEU, and, if so, whether they pursue an objective in the public interest, are appropriate to ensuring that it is attained, and do not go beyond what is necessary for attaining it. Furthermore, the Court declared that Article 6(a) of Directive 2005/36 must be interpreted as not laying down the rules of conduct or disciplinary procedures to which a service provider who travels to the territory of the host Member State to pursue his profession on a temporary and occasional basis may be subject, but as merely stating that Member States may provide either for automatic temporary registration with or for pro forma membership of a professional organisation or body, in order to facilitate the application of disciplinary provisions in accordance with Article 5(3) of that directive.

On the same day, the Court issued another judgement on the interpretation of Article 1(9), second subparagraph, point (c) of Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts. The Court ruled that a body such as a professional association governed by public law satisfies neither the criterion relating to financing for the most part by the public authorities when that body is financed for the most part by contributions paid by its members, in respect of which it is authorised by law to fix and collect the amount, if that law does not determine the scope of, and procedures for, the actions undertaken by that body in the performance of its statutory tasks, which those contributions are intended to finance, nor the criterion relating to management supervision by the public authorities simply because the decision by which that body sets the amount of those contributions must be approved by a supervisory authority.

On 19 September, the Court delivered a judgement on the interpretation of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications. The Court decided that Directive 2005/36/EC on the recognition of professional qualifications

must be interpreted as not precluding the creation, by a Member State, of a specialised training course, either in the field of medicine or that of **dentistry**, the title of which does not correspond to those listed, in respect of that Member State, in Annex V to that directive. Such a specialised course may be open both to persons who have completed only a basic medical training course and to those who have completed and validated only studies in the context of a basic dental training course. It is for the national court to verify:

– whether that specialised training course, in so far as it does not fulfil the requirements laid down by Articles 23 and 24 of the directive regarding basic medical and dental training, does not lead to the issuing of evidence of basic medical training or evidence of basic dental training, and

– whether the qualification awarded following the completion of that specialised training course does not authorise the practice of the core medical or dental profession by persons who do not possess evidence of formal qualifications in basic medical training or evidence of formal qualifications in basic dental training. Finally, Directive 2005/36 must be interpreted as not precluding medical subjects from forming part of a specialised training course in dentistry.

SECTION II – GENERAL EU POLICY

EPSCO COUNCIL MEETING

The Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council met on 15 October 2013 in Luxembourg. The Council debated on posting of workers but was not in a position to reach a general approach on the Directive. The Ministers also discussed youth unemployment, the social dimension of economic and monetary union (EMU), the evaluation of the 2013 European Semester and the report of the European Court of Auditors on the European globalization adjustment fund (EGF). 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.

COMMISSION'S REPORT ON HEALTH INEQUALITIES

On 9 September 2013, the European Commission published its report on health inequalities. According to the report the wide variation in life expectancy and infant mortality between EU countries is narrowing. The report points to some positive developments in implementing the EU strategy on health inequalities, 'Solidarity in Health' adopted in 2009 but concludes that more action is needed at local, national and EU levels. The report examines various factors causing health inequalities and finds that social inequalities in health are due to a disparity in the conditions of daily life and drivers such as income, unemployment and education levels. The report also looks at the progress made on the main challenges laid down in the strategy on health inequalities.

COMMISSION'S WORK PROGRAMME 2014

On 22 October, the Commission adopted its work programme for 2014. Promoting growth and jobs remain are the priorities that will drive the Commission's analysis of the reforms required at national level and the initiatives proposed at European level. Among others, the Commission states that *"It is essential to invest in education and skills and increase labour mobility, including by means of reinforced cooperation between public employment services and* ***by removing unjustified or disproportionate obstacles to access to and free movement of regulated and professional services****. Tapping into the potential of key growth sectors, such as the green economy, ICT and health and social care, should be a particular priority".*

EU HEALTH PROGRAMME 2014-2020

On 13 November 2013, the Permanent Representatives Committee (Coreper) endorsed an agreement reached with the European Parliament on a draft regulation establishing the EU health programme for the period 2014 – 2020. The new EU health programme encourages innovation in healthcare, increasing sustainability of health systems, improving health of EU citizens and protecting them from cross-border health threats.

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