contrast EUROPEAN & BUSINESS LAW

ADDE Serving dental Europe

Overview of EU initiatives and other developments at EU level in 2015

Dear President,
Dear Board members,
Dear ADDE members,

Below we provide you with a practical overview of the initiatives and developments that were relevant for the business of dental dealers at EU level in 2015. With this overview, we intend to inform you on the status of these topics.

For each topic a short summary is given. You can find more information and the relevant Commission documents via the hyperlink.

- MEDICAL DEVICE REGULATION

The European Commission ("Commission"), the European Parliament and the Council continued their trialogue negotiations on the new Medical Device Regulation in the course of 2015. The Luxembourg Presidency reported on 4 December 2015 on the current status of the negotiations. The Presidency concluded that, "*now that discussions on all blocks have been opened,[*it is*] convinced that the ground has been laid for an agreement between the Institutions*."

You can read here the Report of the Luxembourg Presidency of 4 December 2015.

- SCENIHR OPINIONS

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks) provides opinions on emerging or newly-identified health and environmental risks and on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health. SCENIHR adopted in the course of 2015 two final opinions relating to dental medical devices:

- Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users.

  SCENIHR concluded that current evidence does not preclude the use of either amalgam or alternative materials in dental restorative treatment. The choice of material should be based on patient characteristics such as primary or permanent teeth, pregnancy, the presence of allergies to mercury or other components of restorative materials, and the presence of impaired renal clearance.

  You can read here the Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users.

- Final Opinion on the safety of the use of bisphenol A in medical devices.

  Medical devices using bisphenol A include implants, catheters, and dental devices. SCENIHR concluded that the risk for adverse effects of BPA may exist when the BPA is directly available for systemic exposure after non-oral exposure routes, especially for neonates in intensive care units, infants undergoing prolonged medical procedures and for dialysis patients.

You can read here the Final opinion on the safety of the use of bisphenol A in medical devices.

- BETTER REGULATION PACKAGE

On 19 May 2015 the Commission adopted a package of documents focused on Better Regulation, including an EU Agenda for Better Regulation, Better Regulation Guidelines, a Decision to establish a REFIT Platform in order to ensure an ongoing dialogue with stakeholders and a proposal for an Interinstitutional Agreement on Better Regulation.

You can read here the EU agenda - Better regulation for better results.

On 16 December 2015, the Commission published the provisional text of the proposed interinstitutional agreement on better regulation and appointed the members of the Stakeholder group of the REFIT Platform. Members of the REFIT Platform have the mandate to (i) invite and collect suggestions on regulatory and administrative burden reduction; (ii) assess the merits of the collected suggestions; (iii) forward for comments those suggestions considered to merit most attention and (iv) respond to each person making a suggestion and render public the suggestions it receives.

You can consult here the Interinstitutional agreement on better law-making and verify the Appointment of the Members of the Stakeholder group of the REFIT Platform.

- EUROPEAN PROFESSIONAL CARD

On 24 June 2015, the Commission adopted its Implementing Regulation (EU) 2015/983 on the procedure for issuance of the European Professional Card (EPC) and the application of the Alert Mechanism pursuant to the Professional Qualifications Directive. The EPC shall be available for nurses responsible for general care, pharmacists, physiotherapists, mountain guides and real estate agents. It will be extended to other professions in the future.

The EPC is an electronic certificate issued via the first EU-wide fully online procedure for the recognition of qualifications. The digital procedure is based on an Internal Market Information System (IMI) that allows professionals to communicate with the relevant authorities inside a secure network.

The Commission also introduced an Alert Mechanism, in order to quickly warn the Competent Authorities through the IMI of professionals in the health and education of minors sectors who have been prohibited or restricted from practicing the profession in a country or have used falsified diplomas for their application.

You can read here more about the New European Professional Card.

- CROSS-BORDER HEALTHCARE

On 4 September 2015, the Commission published a report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. The Commission concluded that patient mobility for planned healthcare is still low and that patients have to be better informed about their options and the procedures they need to follow to benefit from cross-border healthcare.

You can read here the Report on cross-border healthcare.

- TRANSATLANTIC TRADE and INVESTMENT PARTNERSHIP (TTIP)

Between 19 and 23 October 2015, the eleventh round of negotiations on a bilateral trade agreement between the EU and the US took place. The goal of the trade agreement is to slash trade taxes and facilitate trade between the EU and the US.

The eleventh round resulted in substantial progress on market access for EU and US companies in three areas: tariffs, services and public procurement. Both the EU and US exchanged proposals on product-specific rules of origin, discussed public procurement and regulatory cooperation. The EU also brought forward its proposal for sustainable development.

The negotiations will continue in February 2016.

You can read here the Report on the eleventh round of negotiations for the TTIP.

- SINGLE MARKET STRATEGY

On 28 October 2015, the Commission presented a new Single Market Strategy. The strategy aims to deliver a deeper and fairer Single Market. The Commission intends to take several measures in 2016 to modernize the standards system, strengthen the single market for goods, reduce barriers in key sectors, … Its main objectives are to provide a regulatory framework that fosters the free movement of goods and services and enhances competitiveness; to remove existing barriers to intra-EU trade and prevent the creation of new ones and to promote a business and consumer-friendly environment based on transparent, simple and consistent rules offering legal certainty and clarity.

You can read here more about the Single Market Strategy.

- DATA PROTECTION LEGISLATION

On 15 December 2015, the Commission, the European Parliament and the Council concluded their negotiations on the reform of the EU data protection legislation, which started in 2012. According to the Commission the reform will allow citizens to regain control of their personal data. Furthermore, the reform is intended to stimulate economic growth by cutting costs and red tape for European business, especially for small and medium enterprises (SMEs).

You can read here the Commission press release and the Questions & Answers.

We hope this information provides a useful overview of the activities and developments at EU level in 2015.

We will continue assisting ADDE in 2016 by monitoring the initiatives and developments at EU level and will inform you through our regular ADDE Flashes.

Please do not hesitate to contact us should you have any further questions.

Best regards,

Sarah